Industry Guidance Position Paper

Responding to the 2014 Steris 10 CFR Part 21

Revision 0

June 2015

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Industry Guidance on Responding to the 2014 Steris 10 CFR Part 21

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1.0 Purpose

This paper[1] is intended to provide guidance and methods to evaluate the 2014 Steris 10 CFR 21 notification that was issued on June 18, 2014 [2]. The purpose of this guidance document is to supplement information and analysis performed by Steris-Isomedix to assist Steris customers and nuclear utilities that need to evaluate the fact that Isomedix Certificates of Processing did not account for all uncertainties involved such that the actual radiation dose applied to nuclear components could be less than requested and as reported on the Certificate of Processing. This guidance is intended to be used in combination with the information provided in the Steris correspondence on Dose Rate Variability for the Whippany, NJ Facility [7].

This paper is also intended to provide guidance on how to evaluate the combined effects of the 2014 Steris Part 21 on dose rate variability with the earlier 1987 Isomedix Part 21 notification on dosimetry uncertainty [6].

[1] This paper was prepared by the Nuclear Utility Group on Equipment Qualification (NUGEQ), in collaboration with IEEE, for use by its members (operators of over 100 nuclear power reactors in North America), and for non-member utilities, manufacturers, or other parties who are responding to the Steris Part 21 issued in June, 2014, and related issues. This document is publically available. Any questions related to this document may be directed to Bill Horin (Counsel to NUGEQ, whorin@winston.com), Ron Wise (technical consultant to the NUGEQ, ronwise@aol.com), or John White (IEEE, johnlwhite@me.com)

2.0 Background

As part of the effort to review the Steris Part 21 on behalf of customers and Steris, and to provide support for and assistance related to the Steris Position Paper and the supporting technical analysis of the uncertainty evaluations, a working group of more than two dozen representatives from utilities, IEEE, manufacturers, test facilities, NUGEQ, and vendors was formed and regularly met and interfaced with Steris to provide input on the topics presented. A special thanks to all involved in that process, with particular acknowledgement to Eric Rasmussen, of R-SCC, who provided significant and critical support, guidance and direction for the industry input to the detailed technical evaluations, and David Bockstanz of Talen Energy (formerly Pennsylvania Power and Light) who provided valuable perspectives on behalf of operating reactors and the potential impacts on their qualification programs.

3.0 Scope

The equipment affected by the June 18th, 2014 10 CFR Part 21 notification by Steris has the potential to affect electrical or mechanical equipment that is classified as important to safety. As a result, this guidance document is intended to apply to safety related electric and mechanical equipment whose qualification is dependent upon irradiation services performed by Steris Isomedix at both the Whippany and Parsippany New Jersey facilities.

The 2014 Part 21 is applicable to all nuclear product irradiations performed since 1984 when the Whippany, NJ facility was first placed in service. Steris has also indicated that the Parsippany, NJ facility (which was the predecessor to the Whippany facility) would be bounded by the results for the Whippany, NJ facility. Due to the layout and design of the Parsippany, NJ plant, Steris has concluded that it would have a lower variability compared to the Whippany facility due to its static carrier placement and single source geometry. As such, the dose rate variability studies performed by Steris can also be conservatively applied to estimate the variability of irradiation exposures at the Parsippany, NJ facility.

Since both electrical as well as active and passive mechanical components are potentially affected, this issue is not limited to equipment subject to environmental qualification under 10 CFR 50.49 or covered by Mechanical EQ programs that address qualification of active mechanical equipment. Environmental equipment qualification packages, purchase specifications, or procurement documents may need to be reviewed in order to identify affected equipment. Equipment qualification summary packages and vendor test reports should contain radiation certificates necessary to identify affected components. If equipment qualification packages do not exist, or if vendor test reports were not provided, procurement documents may need to be reviewed to determine affected components. It must be noted that in the history of STERIS Isomedix, radiation doses reported have never been adjusted for uncertainties. Even if uncertainty values or minimum and maximum doses were provided, these reported dose values have not been adjusted.

4.0 Introduction

In June 2014, STERIS notified customers of a potential Part 21 Notice arising from a 10 CFR part 50 inspections by the NRC of the radiation processing performed by STERIS Isomedix at the Whippany, NJ facility [2]. In response to the notice, STERIS performed an analysis to determine the effect of Density Variability[2], Source Decay[3], and Intercomparison[4] variability on previously irradiated samples [7]. The analysis was presented in a paper titled Dose Rate Variability for the Whippany, NJ Facility (Off-Carrier Processing). This study introduced three new factors that need to be considered when assessing the minimum dose that an irradiated component may have been exposed to. These correction factors should be applied to all specimens processed at the facility since 1984.

Customers and Licensees may be required to assess the 2014 Part 21 Notice and its impact on work that was previously performed for the 1987 Part 21 Notice [6]. Since the 1987 Part 21 Notice was issued, there has been a significant change in 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.

Since the opening of the Whippany facility in 1984, the tolerance for the dosimetry system was estimated at +/- 8% based on 4% for dosimetry precision and 4% for bias at the 2σ confidence level. Dosimetry precision was a measure of the extent to which replicate measurements made under specified conditions are in agreement and bias was a systematic error. The precision and bias were

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2 **Density Variability** is the result of changes in shielding effects from on-carrier products that pass between the source and the nuclear component being irradiated. This variability can result in the effective dose rate being higher or lower over the duration of the exposure compared to the dose rated that was established during the dose rate study.

3 **Source Decay** is the reduction in the source strength over time due to radioactive decay.

4 **Intercomparison Variability** is the result of the nonperformance of dosimeter calibration for the Ceiling area combined with the incorrect use of Area A adjustment factors occurring between the dates of October 19, 2007 and April 28, 2014. The variability is based on a comparison between historic adjustment factors between the Ceiling and Area A for the time periods when dosimeter calibration was performed for the Ceiling.

thus specifically discussed and evaluated within the 1987 Part 21 Notice as being +/- 8.0% (2σ level) and remained in place until September 8, 2000.

The current dosimeter uncertainty of +/- 6.5% (2σ level) was established on September 8, 2000 as a result of ASTM 51707 being adopted by Steris. The ASTM standard adopted the methodology of the International Organization for Standardizations (ISO) for estimating uncertainty in dosimetry for radiation processing. Based on a review of STERIS's paper, Dose Rate Variability for the Whippany, NJ Facility (Off-Carrier Processing) [7], it can be seen that dosimeter uncertainty is based on this newer methodology. Since there has been no change in the dosimeters used by STERIS (since the Whippany, NJ facility opened in 1984), then the dosimeter uncertainty established using the current ASTM methodology can be applied to the Harwell Red 4034 Perspex dosimeter for all irradiations performed by Steris Isomedix since 1984 at the Whippany, NJ facility.

This change in the standard used to calibrate the dosimeters also has a potentially significant impact on the 1987 Part 21 Notice and how it should be applied in conjunction with the 2014 Part 21 Notice. It is recommended that the dosimeter uncertainty that is based on the current ISO/ASTM methodology be applied to dosimeter uncertainty calculations associated with the 1987 10 CFR Part 21 notification (e.g. prior to September 8, 2000).

A review of the 2014 and 1987 Part 21 notices identifies five potential correction factors that may exist. The 1987 notice identifies a dosimeter error and timer error. The 2014 notice introduces the addition of density variability, intercomparison and source decay. Depending on when irradiation testing was performed, the parameters will vary slightly. The timer variability will only be applicable to certifications issued between 1984 and April 1, 2000. With the exception of the addition of the timer uncertainty, all other parameters are the same and have been calculated and applied in the same manner. Examples will be provided for the two time periods (before and after April 1, 2000).

In April 2000, the Whippany facility upgraded the control system for the irradiator that provided improvements in the way source uptime was measured. Prior to April 1, 2000 the timer uncertainty for measuring source uptime was +/-

2% and needs to be considered in addition to the dosimeter uncertainty. From April 1, 2000 to present, there is no need to consider timer uncertainty separately since it is accounted for in the determination of dosimeter uncertainty (described later).

5.0 Evaluation Methods

The methodology used in this section to determine the total variability is the same as used by STERIS in their paper Dose Rate Variability for the Whippany, NJ Facility (Off-Carrier Processing) [7].

When processing a product utilizing their off-carrier system, Steris Isomedix utilized the Harwell Red 4034 Perspex dosimeters to establish a dose rate at the product's location within the irradiator. Due to a maximum dose limitation of approximately 6 Mrads, the Harwell Red 4034 dosimeters are not left in the irradiator for the entire exposure. As a result, these dosimeters are not used to directly measure the applied dose.

The dose rate is established based on the measured dose during the dose rate study divided by the duration of the source uptime. Once the dose rate is determined at the product's location, this value is then used to establish the necessary duration of exposure (e.g. source uptime) that is necessary to achieve the specified dose. These types of dose rate determination irradiations are referred to as "dose rate studies" and are used to report a final minimum and maximum dose based on the rates determined in the study. The minimum and maximum dose rates are based on differences in readings of multiple dosimeters that are used during the dose rate study. In establishing these dose rates, there are several factors that must be taken into account such as:

a) Dosimeter Variability (3.25% at the 1σ level / 6.5% at the 2σ level).

b) Timer Accuracy (measuring total source uptime prior to April 1, 2000)

As identified in the NRC Notice of Nonconformance and the June 18, 2014 Part 21, other factors also need to be considered:

a) Changes in effective shielding due to variation in density from On-Carrier products which move around the source racks (e.g. Density Variability). These density changes result in variations in the dose rate established using the Red 4034 Perspex dosimeters.

b) Source term decay. The half-life of Cobalt-60 is 5.27 years (1925 days)

c) Intercomparison variability for irradiations at the ceiling location.

Guidance regarding these additional factors are provided in the following sections.

5.1 Variability Calculations for 2σ Accuracy Reports dated prior to April 1, 2000

For these test reports, the four parameters of concern are the: Dosimeter Variability, Timer Variability, Density Variability and Source Decay. The Total Variability should be calculated in the following manner:

$$Total_{Variability} = \sqrt{Dosimeter^2 + Density^2 + Timer^2} + Decay$$

Given:

$\text{Dosimeter} = 0.0650\ (6.5\%)$
$\text{Density} = 0.0602\ (6.02\%)$
$\text{Timer} = 0.02\ (2\%)$
$\text{Decay} = 0.00538\ (0.538\%)$

$$Total_{Variability} = 0.096$$

Therefore, the total variability for this time period is 9.6% and represents the amount that the minimum reported dose on the Steris Isomedix Certificate of Processing should be reduced for products irradiated prior to April 1, 2000 to assure the minimum possible dose is determined.

5.2 Variability Calculations for 2σ Accuracy Reports dated April 1, 2000 to present
(All areas except ceiling from October 19, 2007 to April 28, 2014)

For these test reports, the parameters of concern are the:

Dosimeter Variability, Density Variability and Source Decay. STERIS has stated that on April 1, 2000, the Timer system was changed and the variability associated with the new timing system no longer needs to be considered as a separate variable since the effect of timer accuracy is accounted for when establishing the dosimeter uncertainty using the methodology from ASTM 51707. The Total Variability should be calculated in the following manner:

$$Total_{Variability} = \sqrt{Dosimeter^2 + Density^2} + Decay$$

Given:

$\text{Dosimeter} = 0.0650\ (6.5\%)$
$\text{Density} = 0.0602\ (6.02\%)$
$\text{Decay} = 0.00538\ (0.538\%)$

$$Total_{Variability} = 0.094$$

Therefore, the total variability for this time period is 9.4% and represents the amount that the minimum reported dose on the Steris Isomedix Certificate of Processing should be reduced for products irradiated since April 1, 2000 to assure the minimum possible dose is determined.

5.3 Variability Calculations for 2σ Accuracy Ceiling location from October 19, 2007 to April 28, 2014

From October 19, 2007 to April 28, 2014, there was a subset of products that were processed in the ceiling area in which dosimeter readings were made on curves specific to Area A of the irradiator rather than curves for the ceiling area. As such there is an additional source of error for products that have been identified as having been irradiated in the ceiling location. An additional bias of 0.0232 has been added to the post April 1, 2000 total variability equation to reflect the variability contribution from ceiling processing. The Total Variability should be calculated in the following manner:

$$Total_{Variability} = \sqrt{Dosimeter^2 + Density^2} + Decay + Intercomparison$$

Given:

$\text{Dosimeter} = 0.0650\ (6.5\%)$
$\text{Density} = 0.0602\ (6.02\%)$
$\text{Decay} = 0.00538\ (0.538\%)$
$\text{Intercomparison} = 0.0232\ (2.32\%)$

$$Total_{Variability} = 0.118$$

Therefore, the total variability for the ceiling in this time period is 11.8% and represents the amount that the minimum reported dose on the Steris Isomedix Certificate of Processing should be reduced for products that were irradiated at the ceiling location from October 19, 2007 to April 28, 2014 to assure the minimum possible dose is determined. Steris has indicated that they have notified customers who had products irradiated at the ceiling location in this time period.

5.4 Dosimeter Uncertainty

Currently, the uncertainty for a single Harwell Red 4034 Perspex dosimeter is 3.25% (1σ) or 6.5% (2σ) using the methodology in ASTM 51707. The 6.5% value should be used as this represents a 2σ confidence level. Prior to September 8, 2000 and as reflected in the 1987 Steris Part 21 [6], the tolerance for the Harwell Red 4034 dosimetry system was identified as +/-8% (4% precision & 4% bias) at the 2σ confidence level. The difference between the current 6.5% uncertainty value and the historic 8.0% uncertainty value is the result in a change in calibration methodology and not a change in the dosimetry or how it is being used. Therefore, it is reasonable to conclude that the uncertainty for a single Harwell Red 4034 Perspex dosimeter (+/- 6.5%) may be used independent of when the irradiation was performed. In other words, the uncertainty for the Harwell Red 4034 Perspex dosimeter can be considered unchanged for all irradiations at the Whippany, New Jersey facility.

However, it is possible to credit improved accuracy of the Harwell Red 4034 Perspex dosimeters when the dose rate study utilized multiple dosimeters using the following relationship:

$$Dosimetry\ Uncertainty_N = {Dosimetry\ Uncertainty_{Single}}\Big/{\sqrt{N}}$$

Where N = number of dosimeters

This relationship should only be used to refine the dosimetry uncertainty when all of the following conditions are met:

1) Multiple dosimeters were used during the dose rate study[5], and
2) The dosimeters were in close proximity of one another, and
3) Each dosimeter was within the bounds of the calibrated zone where the samples were irradiated (which are relatively small areas).

[5] Steris would need to identify the number of dosimeters used in the dose rate study if that information is not provided on the Certificate of Processing.

The above discussion on dosimeter uncertainty is consistent with the uncertainty values for the Harwell Red 4034 Perspex dosimeter in Reference 7 and are representative of a 2σ confidence level.

5.5 Source Term Decay

Since the source term decay is a negative bias, the effect should be numerically added to the combined effect of other uncertainty parameters which may be combined using the Square Root of the Sum of Squares (SRSS) method.

The duration of exposure for a majority of nuclear products are typically completed within one 24 hour period. However, some products are placed in the irradiator for longer periods (e.g. a week or a month). Since Steris uses a dose rate that is typically established within the first few hours of processing, it becomes necessary to consider the effect of Cobalt-60 decay on the actual dose rate over time. Based on Reference 7, the reduction in dose due to source term decay over a 30 day exposure period is 0.538%. This value is based on the following equation:

$$\text{Reduction in dose due to Source Decay} = \frac{\left(\frac{1925}{\ln(2)}\right)*\left(\frac{1}{2}^{\left(\frac{t}{1925}\right)}-1\right)}{t}+1$$

Where:

t = duration of radiation exposure (days)

1925 = half-life of Cobalt-60 in days (5.27 years * 365.25)

For applications where the actual exposure time is known, it is possible to refine the effect of source term decay for time periods less than 30 days. Table 1 presents the reduction in dose due to the decay of Cobalt-60.

Table 1 –Reduction in Dose from *Co-60* decay

Duration of Irradiation (days)	% reduction in Dose
30	0.538
25	0.449
20	0.359
15	0.270
10	0.180
7	0.126
5	0.090

The source term decay values used in Reference 7 and Sections 5.1, 5.2, and 5.3 of this paper are based on the source term decay that would occur for an irradiation exposure of up to 30 days. If any irradiation exposures were longer than 30 days, then the source term decay bias should be recalculated using the equation provided above and the resulting uncertainty incorporated into the appropriate variability calculations.

6.0 Suggested Guidance

6.1 Extent of Condition

The evaluation provided by Steris in Reference 7 is specific to irradiations that were performed at the Whippany, New Jersey facility since it began operation in 1984. Steris has indicated that they do not possess the ability to review processing methodology or reconstruct any setup at the Parsippany, New Jersey facility. Even though the uncertainty correction factors that were derived based on a Whippany specific evaluation may be extremely conservative when applied to irradiations performed at Parsippany (or other Steris-Isomedix facilities)[6] it should be recognized that some of the contributors to the overall uncertainty, such as dosimetry and source term decay, may still be applicable to exposures performed at other facilities.

6.2 Application or Use of Required Qualification Margin

Section (e)(8) of 10 CFR 50.49 requires that "Margins must be applied to account for unquantified uncertainty, such as the effects of production variations and inaccuracies in test instruments. These margins are in addition to any conservatisms applied during the derivation of local environmental conditions of the equipment unless these conservatisms can be quantified and shown to contain appropriate margins."

The 10% margin on radiation that is recommended for compliance with IEEE 323-1974 and endorsed by Regulatory Guide 1.89 may be used to initially address operability or functionality of electrical equipment subject to the requirements of 10CFR50.49. The recommended margins in IEEE 323-1974 are intended to address normal variations in commercial manufacturing and reasonable errors in defining satisfactory performance. Qualification margin is

[6] Other Steris – Isomedix facilities that have performed irradiation of nuclear components besides the Whippany, New Jersey facility include; Parsippany, New Jersey, Northboro Massachusetts, and Morton Grove, Illinois.

not intended to provide a permanent resolution to known deficiencies or quantified uncertainties.

The 2014 Part 21 notification resulted in the identification of several additional parameters that had previously not been considered in quantifying the uncertainty associated with the minimum applied dose: density variability; source decay; and intercomparison variability. When the Part 21 notice was first reviewed, it was originally assumed that the additional parameters identified would result in total uncertainties in the range of 15%. This had the potential to be a significant concern since this level of uncertainty exceeded the IEEE 323 recommended margin. This perception was based on the newly identified density variability and source decay bias and that this uncertainty would be in addition to the existing dosimetry uncertainty.

The 1987 Part 21 Notice provided a dosimetry uncertainty of 8% and a separate Timer uncertainty of 2%. The combination of these two uncertainties results in a Dosimetry System uncertainty of 8.6%. The adoption of ASTM 51707 in 2000, resulted in a revised methodology for calculating the dosimetry uncertainty for the Harwell Red 4034 Perspex dosimeters. The new method provided an uncertainty of 6.5%. Since there was no change in the dosimeters, the 6.5% could be applied to calculations performed prior to the adoption of the standard. In Section 5, the calculations reflect that prior to April 1, 2000 the Dosimetry System uncertainty was 6.8%. On April 1, 2000 in addition to the adoption of ASTM 51707 the timer system was replaced. The net effect was that these changes eliminated the need to consider the Timer uncertainty separately. Accordingly after April 1, 2000, the Dosimetry System and the Dosimeter uncertainties are the same (e.g. 6.5 %). As shown in Section 5, the combined effect of the 2014 Part 21 along with the contribution of the dosimetry system (e.g. dosimeter and timer uncertainty) remains within the IEEE 323 recommended margin of 10% with the exception of certain exposures in the Ceiling area as discussed in Section 5.3.

6.3 Adjusting the Minimum Reported Dose

Adjusting the minimum reported dose to account for known uncertainties is considered appropriate in this instance for the following reasons:

a) The June 18, 2014 Part 21 identified new contributors to the overall uncertainty associated with the radiation processing at the Steris Whippany, NJ facility that had not been recognized at the time the qualification test program was conducted or used to support the conclusion that equipment is environmentally qualified. Thus, more extensive evaluation was considered appropriate to define past practice and its applicability to current assumptions.
b) The overall uncertainty in this instance is derived from a number of different factors, not all derived from direct measurement or single pieces of equipment. Further, the level of potential uncertainty predicted is of the same order of magnitude as the recommended 10% qualification margin in IEEE 323. Thus, a comprehensive assessment of all such factors and their interrelationship is appropriate given their magnitude and that some of these factors are biases, which differs from other typical LOCA test chamber parameters that are directly measured by thermocouples or pressure transducers which have an uncertainty that follows a normal Gaussian distribution.
c) Compared to other test instrumentation, the uncertainty associated with the minimum applied dose is a large percentage of the IEEE 323 recommended qualification margin.

Accordingly, the Steris Part 21 issue is considered to be a unique situation that should not be interpreted as setting a precedent for how test instrument uncertainty should be addressed for other environmental parameters or test service conditions.

6.4 Nuclear Utilities

If Customers or Licensees performed evaluations and reduced the qualified dose by 9.6% as provided within the 1987 notice, then the 2014 notices result in no adverse impact on the qualification of equipment (with the exception of items tested on the ceiling between October 19, 2007 to April 28, 2014). As part of the evaluation process equipment qualification summary packages, test reports, certificates of conformance or procurement documents may require review. Regardless of how the radiation dose data is presented, STERIS Isomedix has historically never adjusted their reported doses for uncertainties. It is the responsibility of the utility to ensure that uncertainties are reflected within the doses used for qualification.

Utilizing the examples and information provided within this paper, the minimum qualification dose can be determined.

From a qualification perspective, evaluation of the issue associated with the 2014 Steris Part 21 should focus on the minimum radiation exposure that was delivered to the test specimens. The approach used by Steris in Reference 7, as well as evaluation in Section 5.0 of this paper, is predicated on the use of a 95% confidence level assuming a normal (two tailed) distribution. This approach is conservative and consistent with the ASTM methodology used to calibrate dosimetry as well as the approach used in the 1987 Isomedix Part 21 [6].

Steris customers or end users may elect to use additional or alternate methods of addressing or refining the uncertainty associated with the radiation exposure of nuclear products. For these cases, the technical approach used should be documented and appropriately justified.

6.5 OTHER CONSIDERATIONS

1) Keep in mind that the issue described in the June 18, 2014 Steris Part 21 notification is not limited to equipment subject to 10 CFR 50.49 and can also impact the basis for qualification of mechanical equipment or electrical equipment located in mild environment areas.

2) Vendors and Test Laboratories may update or revise their qualification test reports to reflect any changes in the minimum reported dose or incorporate updated Certificates of Processing (COPs) due to this Part 21.

3) Steris / Isomedix Certificates of Processing may be provided on letterhead stationary that includes the location of the irradiation facility. It has been noted that some COPs have locations in the letterhead that doesn't correspond to the location where the irradiation took place. Steris should be contacted if there are any questions regarding which facility was used to perform the irradiation service.

4) Caution should be used regarding the use of any revised Certificates of Processing (COPs) that were updated, in response to the June 18, 2014 Part 21, to reflect the results of the initial dose study that was conducted using Protocol 14-001WH. Any COPs that were revised to reflect the range of process variability clarified in Steris – Isomedix memo dated June 23, 2014 [3] (+/- 3.5 to 5.1%) should be verified as being based on a 2σ confidence level and consistent with Attachment 5 to Reference 7.

5) There may be some affected customers[7] or end users that may no longer be in business or currently supporting the nuclear power industry such that they may not be in position to communicate the applicability of the June 18, 2014 Steris Part 21 to their customers.

[7] Steris has identified the affected customers is provided in Attachment 4 to Reference 4.

7.0 References[8]

1) *NRC Inspection Report of Steris Isomedix, Docket 99901445, Report No 2014-201, dated May 15, 2014 (contains Notice of Nonconformance 99901445/2014-201-01).

2) Steris Customer Notification under 10 CFR Part 21, dated June 18, 2014.

3) *Steris Correspondence from Scott Comstock (Plant Manager), Clarification Memo – Nuclear Regulatory Commission (NRC), dated June 23, 2014.

4) Steris Response to NRC Inspection Report Notice of Nonconformance 99901445/2014-201-01, dated July 14, 2014.

5) *Steris Customer Notification Update, dated December 19, 2014.

6) Isomedix 10 CFR Part 21 87098, Measurement Tolerance Concerns Associated with Dose and Dose Rate Certified by Vendor on Qualification Tests, dated March 30, 1987.

7) Steris Isomedix Services Position Paper, Isomedix Dosimetry Measurement – Nuclear Components, Whippany, NJ Facility, Revision Dated 4/27/2015.

8) *NRC Receipt Acknowledgement of Steris Response to Nuclear Regulatory Commission Inspection Report No. 99901445/2014-201, dated August 7, 2014.

[8] The reference citations with * in this section were used as developmental references and are included as attachments for convenience even though they are not specifically cited in the body of this position paper.

REFERENCE 1

NRC Inspection Report of Steris Isomedix, Docket 99901445, Report No 2014-201, dated May 15, 2014 (contains Notice of Nonconformance 99901445/2014-201-01).

(15 Pages)

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

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

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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

Enclosure 2

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

REFERENCE 2

Steris Customer Notification under 10 CFR Part 21, dated June 18, 2014.

(1 Page)

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

REFERENCE 3

Steris Correspondence from Scott Comstock (Plant Manager), Clarification Memo – Nuclear Regulatory Commission (NRC), dated June 23, 2014.

(1 Page)

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

REFERENCE 4

Steris Response to NRC Inspection Report Notice of Nonconformance 99901445/2014-201-01, dated July 14, 2014.

(26 Pages)

STERIS

STERIS Isomedix Services
9 Apollo Drive
Whippany, NJ 07981

Tel: 973-887-2754
Fax: 973-887-6591
Email: Yais_Geissler@steris.com
Web: www.isomedix.com

July 14, 2014

Jeffrey Jacobson
Office of New Reactors
U.S. Nuclear Regulatory Commission
(301) 415-2977
Jeffrey.Jacobson@NRC.gov

RE: NRC Docket #99901145/2014-201-01
STERIS Isomedix Services, Inc. Whippany, NJ

Dear Mr. Jacobson:

Attached is our corrective action plan in response to NRC Nonconformance # 99901145/2014-201-01 issued to the STERIS Isomedix Services, Inc. Whippany, NJ facility on May 15, 2014 as a result of the NRC inspection performed on April 1-3, 2014.

If you have any questions, please contact me at 973-887-2754.

Regards,

Mrs. Yais Geissler
QS/RC Manager, Whippany, NJ
STERIS Isomedix Services, Inc.

Attachments

Attachment 1 – Corrective Action Plan
Attachment 2 – Protocol 14-001 WH
Attachment 3 – Example Customer letter issued 06/18/2014
Attachment 4 – List of Customers Notified

IE09

STERIS®

Cc: Scott Comstock
Plant Manager, Whippany, NJ

Mark Thomas
Director Plant Operations & Technology
East Plant Operations, Chester, NY

Dave Snyder
QS/RC Regional Manager, Chester, NY

Michael Ezzo
Zone Director, Quality Systems, Mentor, OH

Ryan Tracy
Radiation Physicist, Libertyville, IL

STERIS

ATTACHMENT 1

Reference: Corrective Action Response
STERIS Isomedix Services, Inc. Whippany, NJ
NRC NC #99901145/2014-201-01

Nonconformance 99901145/2014-201-01:

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, impart, 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.

Corrective and Preventive Actions to Nonconformance 99901145/2014-201-01:

Following conclusion of the April 1-3, 2014 inspection, the STERIS Isomedix Whippany, NJ facility performed an assessment of process variability associated with processing of nuclear components in order to quantify the variation in dose rates at the different off-carrier processing locations used for processing nuclear components. This process variability results from the typical mix of product densities processed in carriers that pass through the irradiator while the nuclear components are resident. These products are mainly medical devices and pharmaceutical containers processed for health care manufacturers.

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Protocol 14-001WH was performed to estimate the potential dose rate variation experienced at the off-carrier locations where nuclear components are processed. Nuclear components are processed at several off-carrier locations within the irradiator including the Dolly, Turntable (Turn-A), Ceiling and Back Corner (Area B). This study concluded that there is range of process variability in dose rate depending on location from ±3.5% at Turntable A position up to ± 5.1% for the Ceiling position (Attachment 2). The calculation of process variability included the impact of product density variations, Co60 source decay and the in-situ dosimeter response function for each location within the irradiator.

In addition, the doses applied to all nuclear components processed at Whippany since the completion of Protocol 14-001WH have been adjusted to account for the estimated process variability depending on the applicable off-carrier processing location and Customers notified of this change and the rationale why this change was implemented.

As reviewed with you in June, all Customers who processed nuclear components at the Whippany facility were notified by letter on June 18, 2014 of the variability in reported dose readings and that they were being notified under the requirements of 10 CFR Part 21 because Isomedix is unable to evaluate the affect this variation may have on the components processed. An example Customer letter and list of Customers notified are included as Attachments 3 and 4, respectively.

The following additional changes are being implemented to ensure that all processing of nuclear components conforms to the requirements of 10 CFR Part 50, Appendix B:

1. Isomedix Procedure PROC-00830: Whippany Reactor Component Processing is being revised to include the following new requirements -

    - The 'Nuclear Component Qualification Request' will include the statement of dosimeter measurement uncertainty

    - The 'Component Irradiation Certification' provided to Customers will include the following:
        - Minimum and maximum delivered dose
        - Minimum and maximum dose rate per hour
        - A statement that details the following, "Total dose delivered includes dose rate variability"
        - Total exposure hours
        - Processing location within the irradiator

2. The dose rate variation will be re-evaluated after changes in source rack configuration (addition, removal, re-distribution). The procedure for performing this re-evaluation will be defined in the revision of procedure PROC-00830.

The planned revisions to PROC-00830 will be implemented by 09/01/2014.

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ATTACHMENT 2

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Isomedix Services

Summary Report for Off-Carrier Dose Rate Variability Study

Whippany, NJ – IR 131

Protocol 14-001WH

Written by: _____ Date: 4 Jun 14
Ryan Tracy, Radiation Physicist III

Approved by: _____ Date: 04 June 2014
Deepak Patil, Manager, Radiation Physics

Approved by: _____ Date: 6/12/14
Scott Comstock, Plant Manager - Whippany

Approved by: _____ Date: 06/12/14
Yais Geissler, QSRC Manager – Whippany

Approved by: _____ Date: 6/12/14
David Snyder, QSRC Regional Manager – East Zone

Table of Contents

1.0 OBJECTIVE

1.1 The objective of this test was to quantify the dose rates in the off-carrier areas of the IR-131 irradiator in the Whippany, NJ facility (WH) during normal on-carrier processing.

2.0 EQUIPMENT AND MATERIALS

2.1 All equipment used in execution of this protocol was calibrated and initialized prior to use. Equipment includes, but is not limited to:

2.1.1 Bruker e-scan

2.1.2 TV (Tapetab Very High) Holder

2.1.3 Alanine Dosimeters

3.0 SUMMARY

3.1 The following areas were tested during the execution of this protocol:

3.1.1 Dolly
3.1.2 Turntable
3.1.3 Ceiling
3.1.4 Back Corner (Area B)

3.2 A total of 72 alanine dosimeters were used in the execution of this study.

3.3 The study took place over the course of seven days to get an accurate representation of the variability in dose rate resulting from variation in on-carrier density products processed of the seven day timeframe as well as a representation of the upper end of typical processing times of nuclear components.

3.4 Foam boards were placed in the Dolly area as well as the Ceiling area. Cardboard boxes were used for the Turntable and Back Corner areas.

3.5 Dosimeters were placed on foam board / cardboard at min and max dose locations.

3.6 The serial number of each dosimeter as well as a description of the processing area was documented on Form 1.

3.7 Form 1 was completed for each processing area.

3.7.1 Pictures of dosimeter placements and measurements of distance from the source rack are included as Attachment A.

3.8 Dosimeters were left in their positions until approximately 100kGy was delivered to the dosimeter.

3.8.1 The facility used Red 4034 dosimeters to monitor the progress of the dose received to the alanine dosimeters, however the Red 4034 data will not be used in the final calculation of dose rates due to its dependence on dose rate.

3.9 Form 1 was completed until seven days had elapsed.

3.10 Once irradiations were complete, dosimeters were sent to the Chester, NY facility to be read.

3.11 The Chester, NY facility read the dosimeters and sent the data (both signed dosimetry records and exported Excel files) to the Whippany, NJ facility for data population.

3.12 The Whippany, NJ facility populated all forms with dosimeter ID's, source up hour clock reading information, and dose received.

3.13 Form 1 calculated the dose rate for the three dosimeters as follows:

$$r_{avg} = \frac{d_1 + d_2 + d_3}{3t}$$

Where d_n is the dose delivered, and t is the total source uptime during irradiation

3.14 Form 1 calculated the total source uptime, total dose, and average dose rate for all values listed on the form.

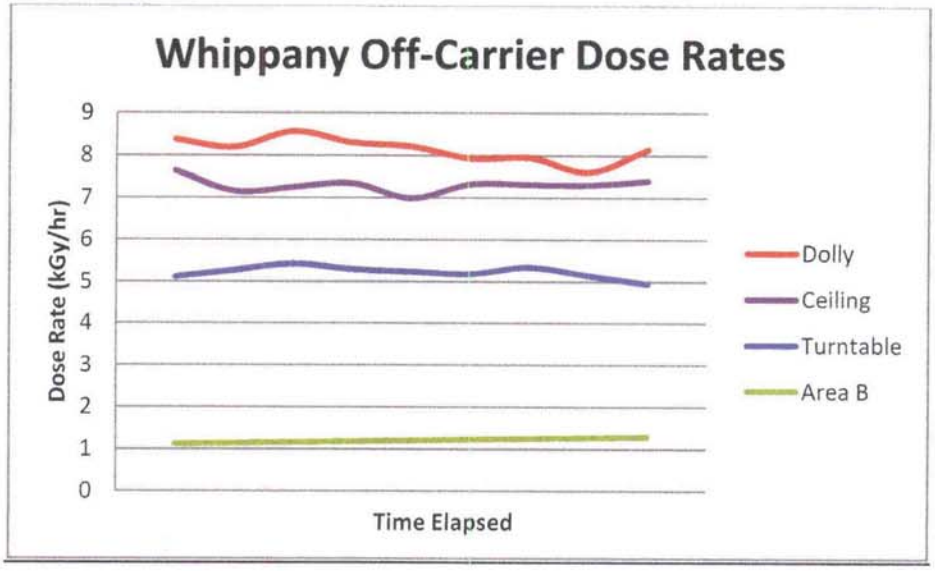
3.15 The Whippany, NJ facility sent all Form 1's associated with the execution of this study to Radiation Physics for final analysis.

4.0 DATA REVIEW

4.1 The following table and graph summarize the results of the dose rates. Each point represents an average dose rate of the 3 dosimeters once they reached 100kGy:

Whippany Off-Carrier Dose Rates (kGy/hr)			
Dolly	Ceiling	Turntable	Area B
8.37	7.64	5.12	1.22
8.19	7.16	5.43	1.29
8.56	7.35	5.30	
8.30	6.99	5.19	
8.21	7.33	5.35	
7.93	7.31	4.95	
7.95	7.41		
7.61			
8.14			

Average	8.14	7.31	5.22	1.26
STDEV	0.279	0.202	0.174	0.049
CV%	3.4%	2.8%	3.3%	3.9%



4.2 The data shows that the variation (defined as the coefficient of variance, CV%) as a result of source decay and density variability is approximately 2.8 – 3.7% (see Attachment A).

4.3 The maximum variation as a result of source decay, density variability and intercomparison variability for products processed in the ceiling area and read on Turntable / Dolly calibration curves is approximately 5.1%.

4.4 Attachment C provides a summary of the data produced from this study as a function of each individual area.

5.0 ADDENDUM

5.1 There were no addendums added during the execution of this study.

6.0 UNEXPECTED RESULTS

6.1 There were no unexpected results during the execution of this study.

7.0 EXHIBITS / RAW DATA

Attachment A – "Diagram of Off-Carrier Areas and Dosimeter Placements"
Attachment B – "Form 1 for Off-Carrier Dose Rate Variability Data"
Attachment C – "Data Summary for Off-Carrier Areas"

END OF SUMMARY REPORT

ATTACHMENT A - Diagram of Off-Carrier Areas and Dosimeter Placements

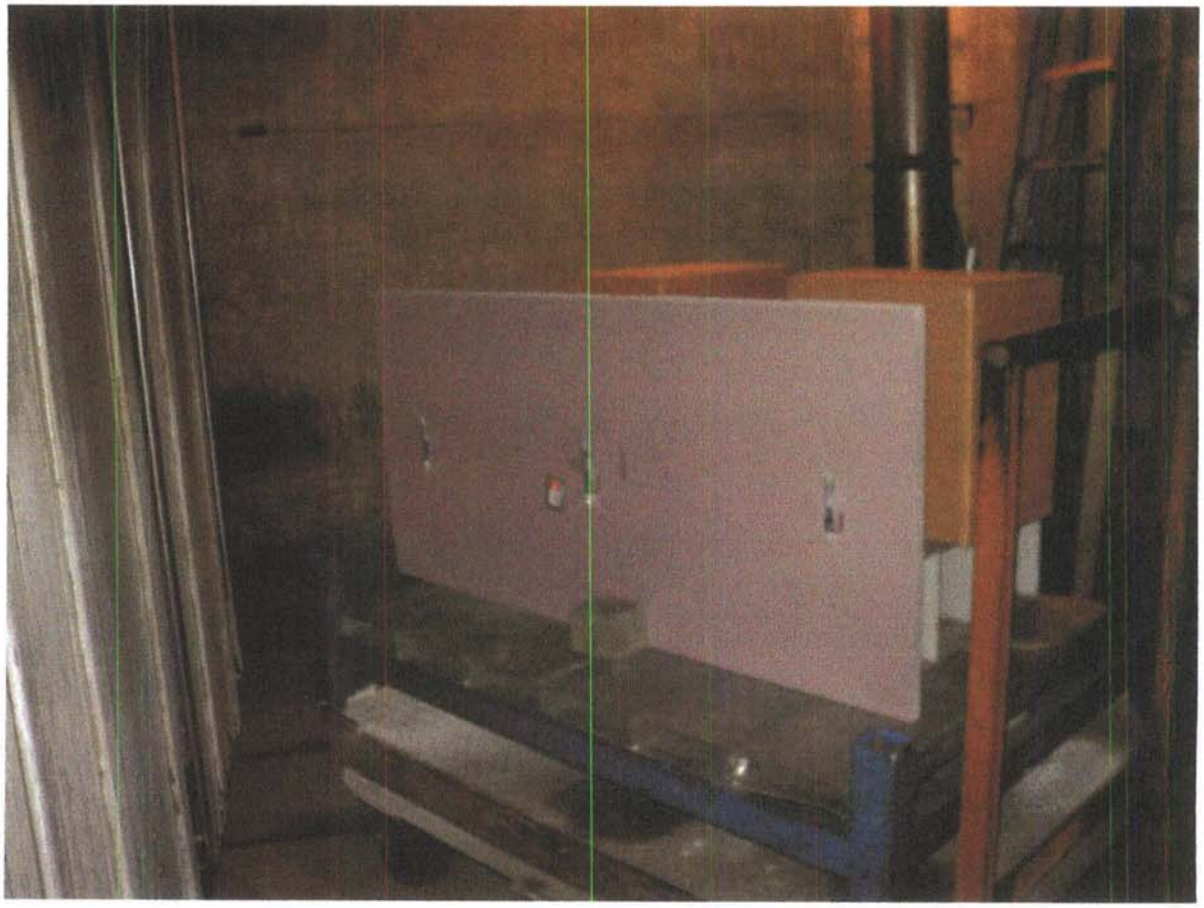
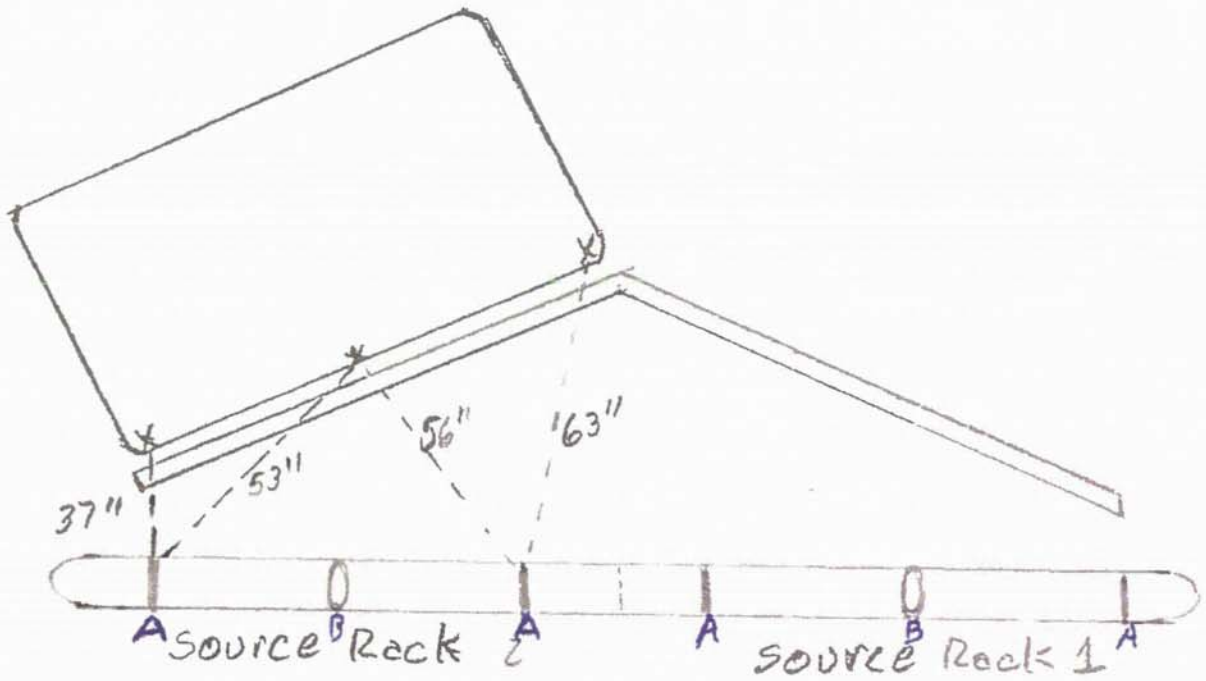


Figure 1 - DOLLY AREA WITH DOSIMETER PLACEMENTS

Pool side



Distance between
dolly and source rack

A- Source Rack guide
B- Middle of source rack

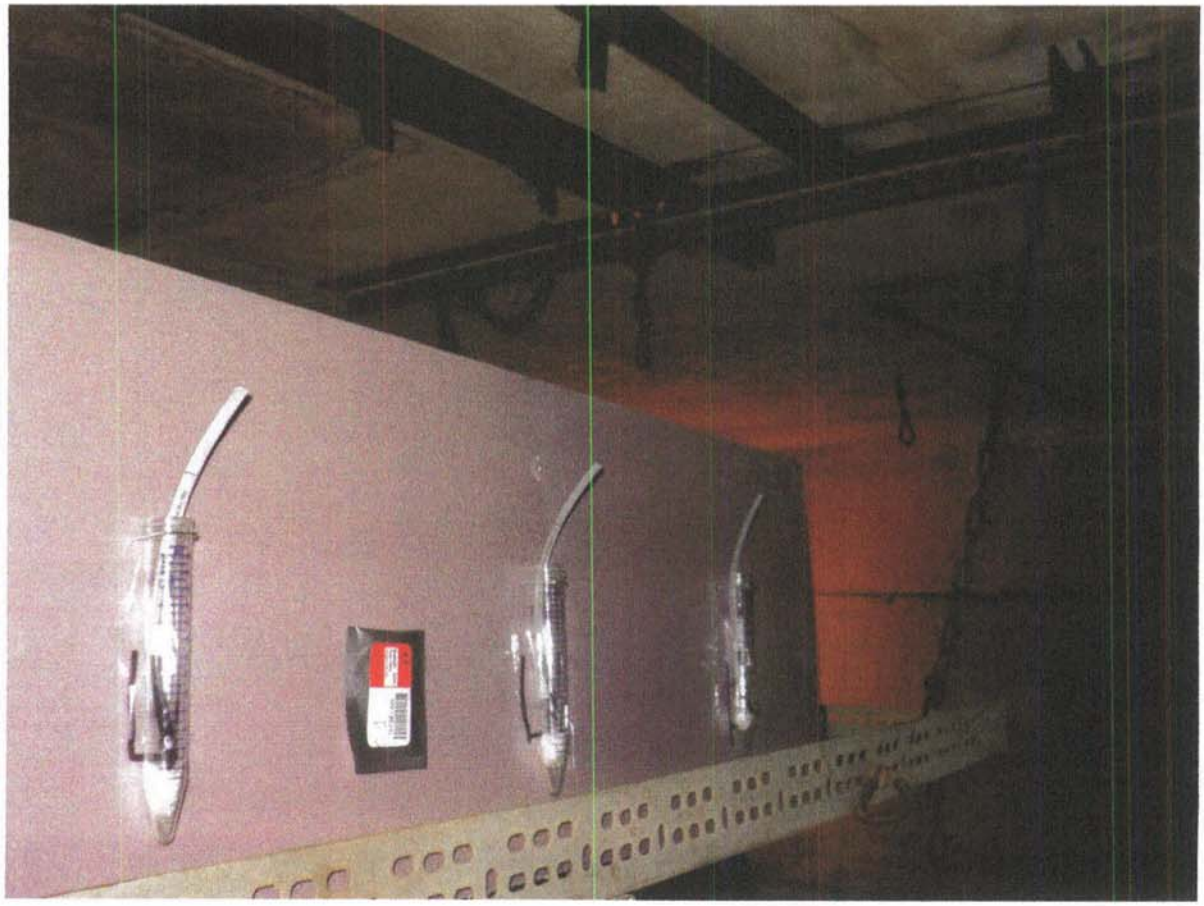
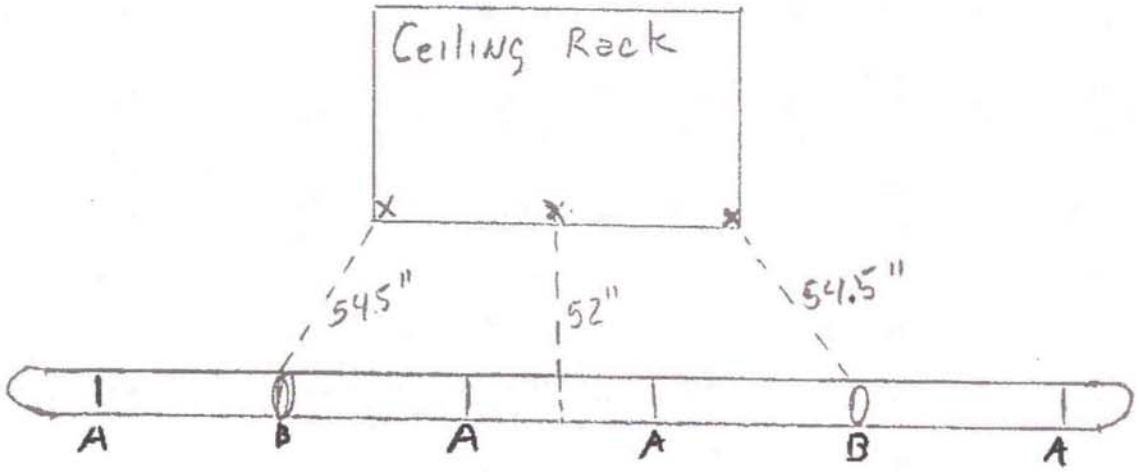


Figure 2 -CEILING AREA WITH DOSIMETER PLACEMENTS

Pool side



Distance between
ceiling rack and racks

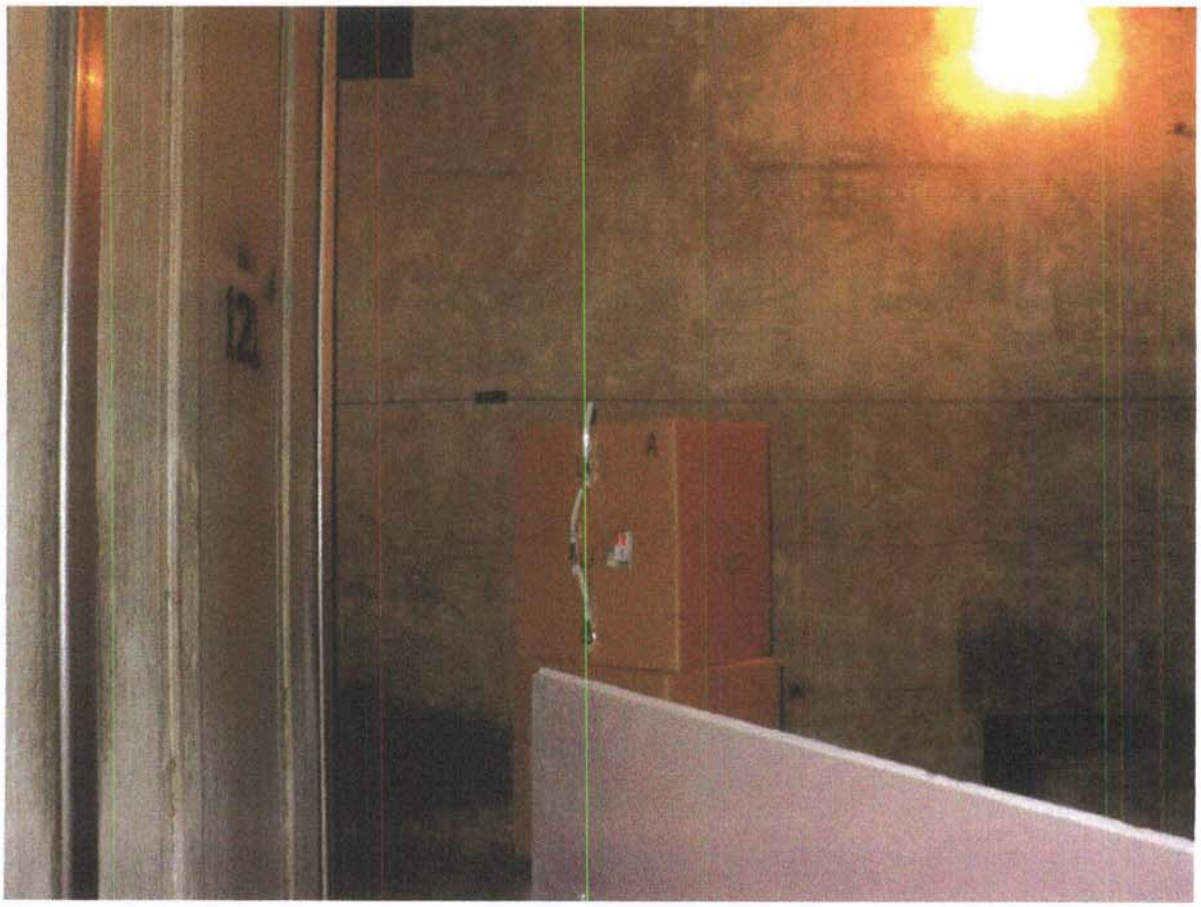


Figure 3 -TURNTABLE AREA WITH DOSIMETER PLACEMENTS

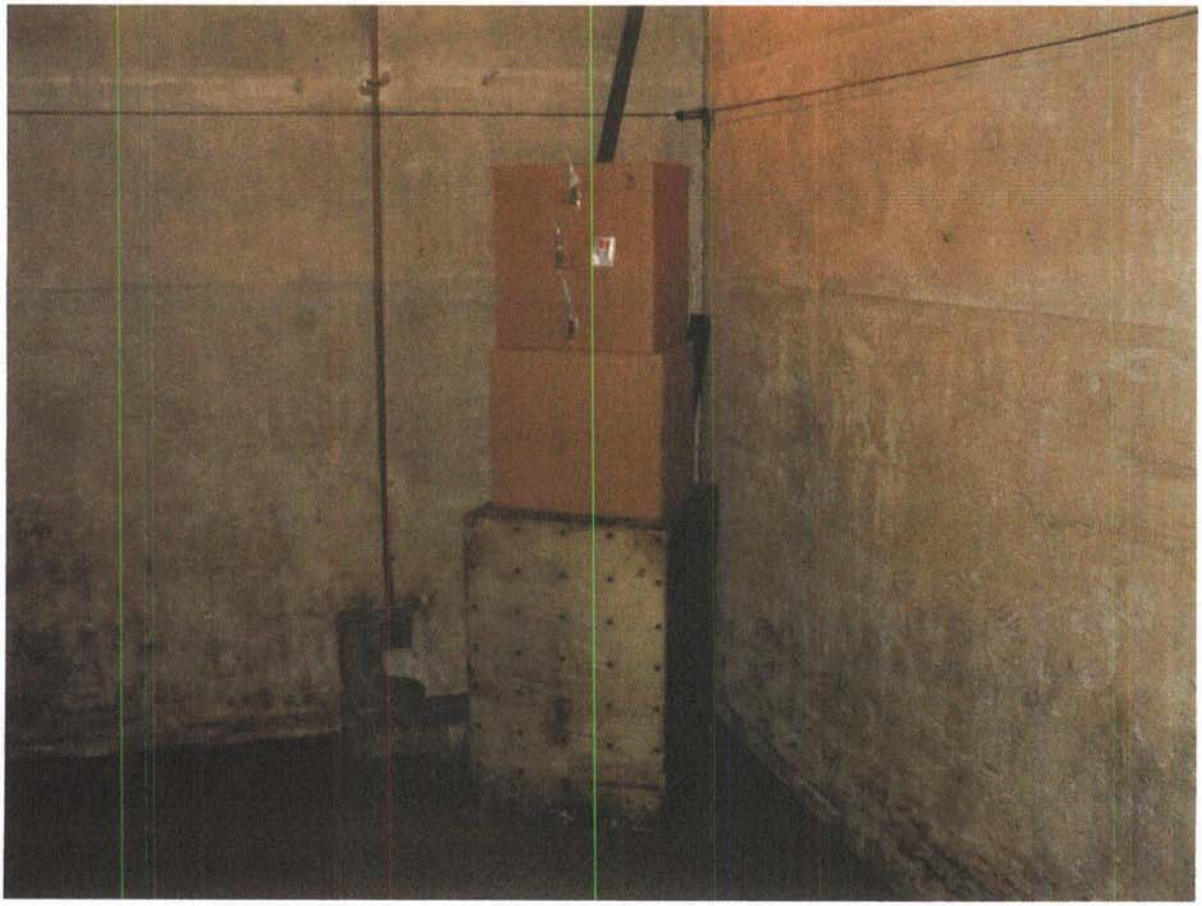
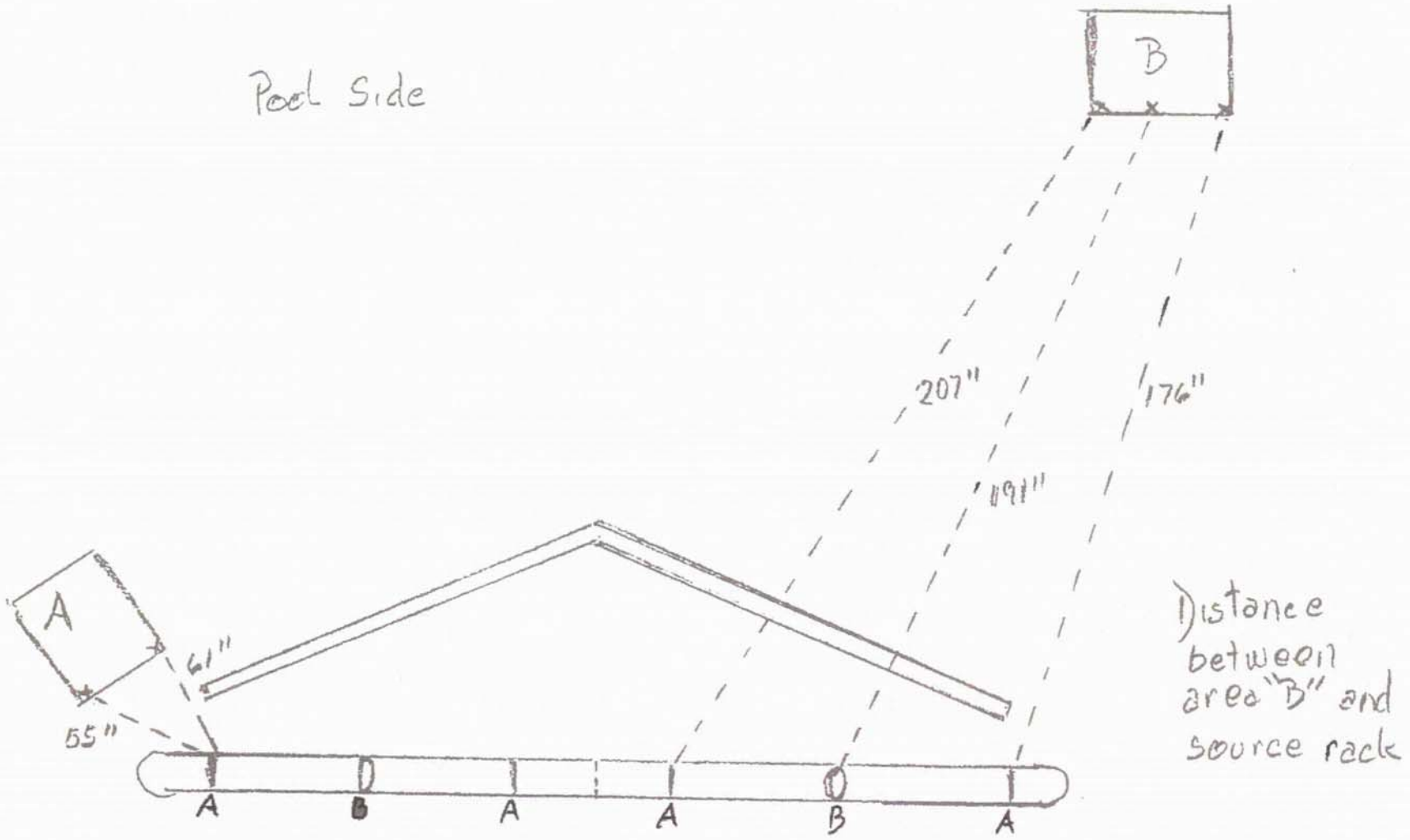


Figure 4 –AREA B WITH DOSIMETER PLACEMENTS



Distance between area "B" and source rack

Distance between area "A" and source rack

Form 1 - Off-Carrier Dose Rate Variability Data
14-001 WH

Off-Carrier Processing Area (e.g. Dolly, Ceiling etc.)	Dolly
Description of Dosimeter Placements (include pictures or physical description)	See Attachment A for pictures

	Dosimeter Serial Numbers	Total Source Uptime (hr)		Dose (kGy)		Dose Rate (kGy/hr)
1	082404	Start:	79929.15	1	101.00	8.37
2	081546	End:	79941.19	2	96.10	
3	082031	Total:	12.04	3	105.10	
1	082395	Start:	79941.19	1	106.60	8.19
2	082054	End:	79953.51	2	101.40	
3	081597	Total:	12.32	3	94.60	
1	081770	Start:	79953.51	1	105.50	8.56
2	082116	End:	79965.40	2	97.70	
3	081767	Total:	11.89	3	102.10	
1	081690	Start:	79965.40	1	101.30	8.30
2	082132	End:	79977.44	2	105.10	
3	081708	Total:	12.04	3	93.50	
1	082138	Start:	79977.44	1	106.90	8.21
2	082249	End:	79989.84	2	104.80	
3	081998	Total:	12.40	3	93.70	
1	081808	Start:	79989.84	1	91.00	7.93
2	082035	End:	80002.35	2	102.90	
3	082113	Total:	12.51	3	103.60	
1	082492	Start:	80002.35	1	102.50	7.95
2	081728	End:	80015.07	2	105.60	
3	082486	Total:	12.72	3	95.10	
1	082391	Start:	80015.07	1	101.80	7.61
2	081810	End:	80028.06	2	101.20	
3	082264	Total:	12.99	3	93.70	
1	081940	Start:	80028.06	1	37.66	8.14
2	081927	End:	80032.67	2	39.15	
3	082263	Total:	4.61	3	35.71	
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		

Page #:		Total:	103.52	Total:	841.77	Average:	8.13
						CV%:	3.42%

Form 1 - Off-Carrier Dose Rate Variability Data
14-001 WH

Off-Carrier Processing Area (e.g. Dolly, Ceiling etc.)	Ceiling
Description of Dosimeter Placements (include pictures or physical description)	See Attachment A for pictures

	Dosimeter Serial Numbers	Total Source Uptime (hr)		Dose (kGy)		Dose Rate (kGy/hr)
1	082221	Start:	79929.15	1	104.80	
2	081592	End:	79942.53	2	104.40	7.64
3	081761	Total:	13.38	3	97.50	
1	081825	Start:	79942.53	1	105.70	
2	081494	End:	79957.88	2	112.50	7.16
3	081556	Total:	15.35	3	111.40	
1	082163	Start:	79958.74	1	104.70	
2	082043	End:	79972.91	2	109.80	7.35
3	082154	Total:	14.17	3	97.90	
1	081784	Start:	79972.91	1	105.30	
2	082056	End:	79987.60	2	103.30	6.99
3	082146	Total:	14.69	3	99.40	
1	081809	Start:	79987.60	1	104.10	
2	081765	End:	80001.63	2	103.90	7.33
3	081618	Total:	14.03	3	100.40	
1	081915	Start:	80001.63	1	99.80	
2	082487	End:	80015.75	2	104.50	7.31
3	082474	Total:	14.12	3	105.40	
1	082412	Start:	80015.75	1	106.30	
2	081920	End:	80030.02	2	101.80	7.41
3	081826	Total:	14.27	3	109.10	
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		

Page #:		Total:	100.01	Total:	730.67	Average:	7.31
						CV%:	2.78%

Form 1 - Off-Carrier Dose Rate Variability Data
14-001 WH

Off-Carrier Processing Area (e.g. Dolly, Ceiling etc.)	Turntable
Description of Dosimeter Placements (include pictures or physical description)	See Attachment A for pictures

	Dosimeter Serial Numbers	Total Source Uptime (hr)		Dose (kGy)		Dose Rate (kGy/hr)
1	082491	Start:	79929.15	1	97.40	5.12
2	082041	End:	79948.16	2	96.10	
3	082419	Total:	19.01	3	98.50	
1	082044	Start:	79948.16	1	100.70	5.43
2	082134	End:	79966.72	2	101.00	
3	081818	Total:	18.56	3	100.70	
1	081688	Start:	79966.72	1	96.00	5.30
2	081696	End:	79984.51	2	93.10	
3	081762	Total:	17.79	3	93.90	
1	082245	Start:	79984.51	1	91.70	5.19
2	082194	End:	80002.35	2	94.70	
3	082406	Total:	17.84	3	91.50	
1	081812	Start:	80002.35	1	92.50	5.35
2	081737	End:	80019.73	2	94.30	
3	081820	Total:	17.38	3	91.90	
1	082444	Start:	80019.73	1	49.90	4.95
2	082158	End:	80030.02	2	50.80	
3	081664	Total:	10.29	3	52.00	
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
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Page #:		Total:	100.87	Total:	528.90	Average:	5.24
						CV%:	3.34%

Form 1 - Off-Carrier Dose Rate Variability Data
14-001 WH

Off-Carrier Processing Area (e.g. Dolly, Ceiling etc.)	Area B
Description of Dosimeter Placements (include pictures or physical description)	See Attachment A for pictures

	Dosimeter Serial Numbers	Total Source Uptime (hr)			Dose (kGy)	Dose Rate (kGy/hr)
1	081604	Start:	79929.15	1	89.50	
2	082402	End:	80002.35	2	89.80	1.22
3	082372	Total:	73.20	3	88.90	
1	082480	Start:	80002.35	1	38.97	
2	081555	End:	80032.67	2	39.17	1.29
3	082426	Total:	30.32	3	38.86	
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		
1		Start:		1		
2		End:		2		
3		Total:	0.00	3		

Page #:		Total:	103.52	Total:	128.40	Average:	1.24
						CV%:	3.66%

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

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

Dolly

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

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

Area B

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

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

Ceiling

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

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

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ATTACHMENT 3

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

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ATTACHMENT 4

1. AAF INTERNATIONAL
2. AECI
3. AMIDYNE
4. ARGO TURBOSERVE CORP.
5. ATC NUCLEAR
6. ATOMIC ENERGY OF CANADA LTD
7. AUTOMATIC SWITCH
8. AUTOMATIC VALVE CORPORATION
9. BALDOR DODGE RELIANCE
10. BECHTEL BETTIS ATOMIC POWER LABS
11. BETTIS ATOMIC POWER LABORATORY
12. CAMERON TECHNOLOGIES USA INC
13. CLARK DYNAMIC TESTING LABORATORY INC.
14. DAIKIN AMERICA INC
15. DRS CONSOLIDATED CONTROLS INC
16. FAUSKE & ASSOCIATES LLC
17. FIVE STAR PRODUCTS INC
18. FLOWSERVE US INC
19. GENERAL CABLE COMPANY
20. GLSEQ LLC
21. HERGUTH LABORATORIES INC
22. ITT ENIDINE INC
23. ITT INDUSTRIES
24. KINECTRICS INC
25. LIFE CYCLE ENGINEERING
26. LISLE METRIX
27. MIRION TECHNOLOGIES
28. MONROE CABLE COMPANY INC
29. NATIONAL TECHNICAL SYSTEMS
30. NUCLEAR LOGISTICS INC
31. NUCLEAR POWER SERVICES INC
32. NUTHERM INTERNATIONAL
33. OKONITE CO
34. PAWLING CORPORATION
35. PCI PROMATEC
36. PERMA FIX OF FLORIDA
37. PREFERRED METAL TECHNOLOGIES
38. QUALTECH NP
39. ROCKBESTOS COMPANY
40. SPACE SYSTEMS LORAL INC
41. SYNERGY QUALIFICATIONS LLC
42. TAYCO ENGINEERING INC
43. THOMAS & BETTS CORP
44. TRENTEC-DIV. OF CURTISS-WRIGHT FLOW - CONTROL
45. TOPWORX INC
46. ULTRA ELECTRONICS NSPI
47. UNDERWATER CONSTRUCTION CORP
48. WYLE LABORATORIES
49. WESTINGHOUSE

REFERENCE 5

Steris Customer Notification Update, dated December 19, 2014.

(1 Page)

STERIS
Isomedix Services

December 19, 2014

Re: STERIS Isomedix Services Whippany NJ NRC Inspection Findings

Dear Valued Customer:

As a valued Customer of Isomedix gamma processing services, we are providing an update to you on the Part 21 notice issued on June 18, 2014 and further clarified on June 23, 2014 regarding variability factors applicable to irradiation services at the Whippany, NJ facility. This also updates the information included in our response to the NRC Inspection of STERIS Isomedix Services, dated July 14, 2014.

Isomedix with guidance and collaboration with a working group composed of component industry representatives including members of IEEE, NUGEQ, and nuclear component test facilities has conducted additional analyses on the information provided in the previous notification. The analyses represent our collaborative efforts to provide the most accurate information to our Customers. The analyses have indicated that the variability levels presented in the above notices will change.

Additional information will be provided to our customers on the variability applicable to components processed at the Whippany, NJ facility. The collaborative work is ongoing and progressing and additional work remains to be completed. Isomedix, in collaboration with the industry working group, will notify its customers once all additional work is complete.

Isomedix has committed to a partnership with the industry working group to provide our Customers with the most accurate information available. If you have any questions or require additional information, please contact me at (973) 887-2754.

Very truly yours,

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

REFERENCE 6

Isomedix 10 CFR Part 21 87098, Measurement Tolerance Concerns Associated with Dose and Dose Rate Certified by Vendor on Qualification Tests, dated March 30, 1987.

(3 Pages)

ISOMEDIX

March 30, 1987

Mr. Gary G. Zech, Chief
Vendor Program Branch
Office of Inspection and Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Zech:

As you may know, Isomedix provides gamma radiation services related to the qualification of nuclear reactor safety-related equipment. During the past few months, the nuclear equipment qualification program at Isomedix has been under close review by both our customers (equipment manufacturers and test labs) and utility end users. The scope of this review has included our past and present operating procedures and controls as well as current and historical test records. Based upon our review and the recommendations of our customers, we have instituted some changes to operating procedures and documentation methods.

One item which was noted concerns the measurement tolerance associated with the dose and dose rate values certified by Isomedix on our test reports. During a period of the late 1970's, a value of ± 3% was stated as the accuracy of the dose measurement. This value was based upon literature published regarding the Harwell Red 4034 Perspex dosimeter, the system primarily used to monitor these irradiations. However, the reporting of this tolerance value ceased by the early 1980's, and from that time until recently our test reports have not stated a value for the measurement tolerance associated with reported dose or dose rate values.

More recently, our Technical Department studied the Harwell Red 4034 dosimetry system and estimated the tolerance associated with this system to be ± 8% (4% precision, 4% bias) at the 95% confidence level. This value has been stated in our Standard Dosimetry Procedures since 1984, and is currently being quoted to customers when we are requested to bid on a job as well as listed on current test reports. However, the magnitude of this value has become a cause of concern to one of our customers and is the reason that this report is written.

Our survey of previous test records included the test files of the Automatic Switch Company of Florham Park, NJ. This customer has used our radiation services for three equipment qualification testing programs involving solenoid valves and three involving pressure/temperature switches. Our evaluation of test data for these programs was reported to ASCO, and they have requested that we report our findings to your agency under 10CFR21. Their concerns are as follows:

1) That the minimum doses stated in the test reports for ASCO tests cannot be assured due to the negative measurement tolerance associated with each dose measurement.

2) That the maximum dose rates stated in the test reports cannot be assured due to the positive measurement tolerance associated with each measurement.

Note: ASCO also voiced concerns regarding dose rate uniformity, test sample temperature, and test records. These subjects were listed by Mr. Steve Alexander of your staff during his April, 1985 inspection, and were addressed in our response dated June 26, 1985. The tests in question were performed between 1978 and 1984, and as such do not reflect the program revisions which were instituted in response to the 1985 E.Q. inspection.

With respect to the question of tolerance for dose and dose rate measurements, our report to ASCO listed a value of ± 2% for the associated time measurements, based strictly upon the test tolerance for calibration of timers. Following the issuance of this report, a review of calibration records for the past 5 years was performed for the timers in question. These records show that, in fact, the % error associated with these timer measurements has averaged less than 0.7%. Based upon this result, the total tolerance associated with Isomedix dose rate measurements (dose/time) is estimated to be ± 8.6%, while the tolerance associated with total dose measurements (dose rate x time) is estimated to be ± 9.6%.

During the time of the April 1985 E.Q. inspection, the subject of test tolerance was discussed with Mr. Alexander. Based upon our conversations at that time, it was our understanding that the 10% margins applied to test doses, as prescribed by IEEE 323, were designed to compensate for errors associated with the measurement process. As the inspection report shows, this subject was not listed as a deficiency or even a comment by the inspector. For this reason we had not taken action with regard to specifying measurement tolerances in our reports. Since our estimate of total dose tolerance is within ± 10%, it is our belief that the test requirements for minimum dose have been met.

In the case of the dose rate measurements, the tolerance must be considered in regard to dose rate limitations imposed by the purchase order. The ASCO tests were typically performed at dose rates well below the purchase order limitations, so that a potential increase of ≤ 10% will not cause a deviation. In one case, however, test records show a dose rate of 3.97 Mrads/hour, whereas the P.O. states the rate to be below 4 Mrads/hour. There most certainly have been other instances where the test dose rate was within 10% of the specified maximum value, and in these cases the potential exists for deviations from specifications. The degree of deviation would not exceed 10%, however, so the effect of this upon a qualification test is likely not significant. As stated above, this report is sent at the request of our customer, due to their concerns over the qualification status of their products. While we do not feel that the situation is critical, we wish to bring these facts to the attention of NRC in order to receive a determination from you regarding them.

Obviously, any effects upon the ASCO tests will also affect tests performed for other customers, since the same systems were used to perform the work. We would therefore appreciate hearing from you regarding this matter in order to guide our planning in this area and to assist our customers whose projects may be affected.

Sincerely yours,

ISOMEDIX INC.

Steven R. Thompson

Steven R. Thompson
Quality Assurance Manager

SRT:js

cc: G. Dietz
W. Owens
J. Young
L. Olsen, ASCO

REFERENCE 7

Steris Isomedix Services Position Paper, Isomedix Dosimetry Measurement – Nuclear Components, Whippany, NJ Facility, Revision Dated 4/27/2015.

(20 Pages)

STERIS
Isomedix Services

STERIS Isomedix Services Position Paper
Isomedix Dosimetry Measurement – Nuclear Components
Whippany, NJ Facility

• Purpose

This position paper provides supplemental information to STERIS Isomedix (hereafter "Isomedix") Customers that need to evaluate the Isomedix Part 21 notification of June 18, 2014 and to provide additional information obtained subsequent to the December 19, 2014 update letter.

• History and Background

An inspection was 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 (NRC Inspection Report 99901445/2014-201). The NRC issued a Notice of Nonconformance stating that the measuring and testing equipment used to determine the applied radiation dose reported 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. Additional details related to this observation are described in subsequent section titled "Description of Whippany Facility". A notification was issued on June 18, 2014 to Isomedix Customers in accordance with 10CFR Part 21. A response was provided to the NRC by Isomedix Services on July 14, 2014. The NRC reviewed the response and found it to be responsive to the Notice of Nonconformance.

Isomedix partnered with an industry working group composed of members of IEEE, NUGEQ, and nuclear component test facilities to collaborate in providing guidance to nuclear component manufacturers on the evaluation of components impacted by the notification. Through this partnership, Isomedix, with support of the industry group, has performed additional analysis and review of our Whippany, NJ irradiation processes and equipment. Based on this analysis Isomedix acknowledged that the variability information previously provided would change. In response, a follow up communication was sent to NRC component Customers on December 19, 2014 indicating that the variability levels presented in the previous notifications will change. This additional analysis was performed and additional information gathered to support this document. Through exhaustive review by Isomedix and the industry working group, this document represents a comprehensive approach and guidance for Customers to evaluate components impacted by the Part 21 notification.

• History of Whippany Facility – Overview

A. Irradiator

The irradiator type is an ANSI Category IV, panoramic wet source storage irradiator, designed and fabricated by MDS Nordion (Formally Nordion International and AECL), commissioned in September 1984 with the serial number designation of IR-131. The model type is designated as a model JS8900 Batch irradiator containing a carrier system with individual carriers measuring 84 inches in height.

It consists of a large concrete biological shield which houses the Cobalt-60 and a shuffle mechanism which transports product carriers past the source in a particular pattern for the purpose of irradiating the contents.

B. USE

The irradiator is primarily utilized for the sterilization of medical devices and supplies, and/or the processing of other materials, such as consumer goods and packaging materials, and other items not of an explosive or hazardous nature.

C. GENERAL OPERATION

The facility consists of three principle areas, the non- irradiated product area, the radiation hot cell and the irradiated product area. The general layout of the irradiator and product handling mechanism is shown in Attachments 1 thru 3.

Unprocessed product is loaded into 84" high aluminum carriers in the non-irradiated product storage area and staged in groups of nine on the monorail just outside the irradiator. With the source material safely positioned in the storage pool, the non-irradiated carriers are manually pushed into position within the source pass area of the irradiator room.

The Source Pass Mechanism holds nine (9) carriers in two rows, five (5) on one side of the source rack and four (4) carriers on the other side. After the source rack is raised, pneumatic cylinders index each product carrier progressively along the fixed monorail path around the source rack until each carrier has occupied each of the nine (9) positions for an equal amount of time. The length of the dwell period between movements is controlled by a Master Timer integrated in the SCADA control system. At the end of the batch process, the source rack lowers automatically to the fully safe position thus allowing the processed carriers to be manually pushed out of the irradiator. The carriers containing processed product are moved to the Unload Station where they are emptied and transferred back to the Non-irradiated Storage area to be reloaded with product.

Other products or materials can be processed manually on elevated platforms surrounding the carrier area. Exposure dose rates vary dependent upon the location within the room. Separate shutdown timers are incorporated within the control system to stop the process to place, rotate or remove these products.

D. LICENSED MATERIAL

The radioactive material is positioned within two planar racks, each approximately 3.5' wide by 9'high, normally located in the fully shielded (safe) position in the storage pool. Each rack is raised by a pneumatic source hoist mechanism consisting of a cylinder, lifting cable and sheaves. Upon completion of a specific list of preconditions, the Control System raises the source material out of the storage pool.
Gravity returns the source material to the fully shielded position upon loss of power or signal from the Control System to the source hoist solenoid. A number of other safety related fault conditions incorporated within the control system will immediately trigger a shutdown to the fully shielded position.

Attachment 4 shows a cutaway diagram of a typical Co60 source encapsulation.

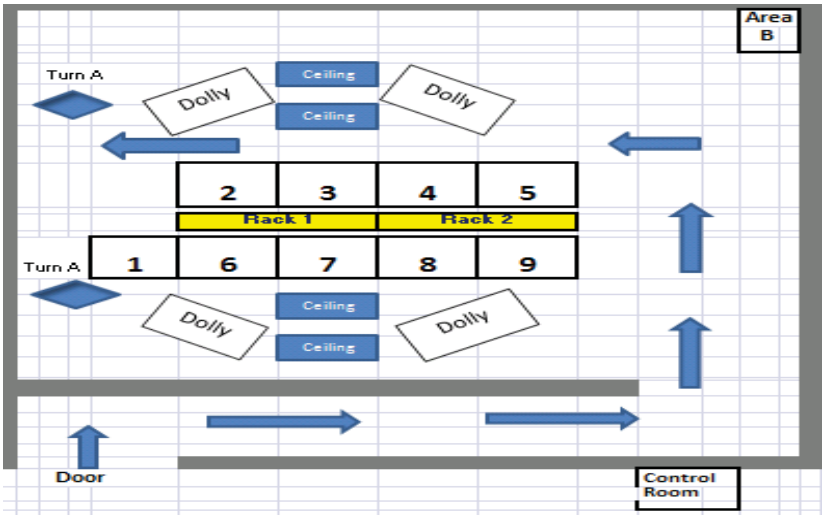
- **Description of Whippany Facility**

The Whippany irradiator is primarily utilized for the sterilization of single -use medical devices and supplies, and/or the processing of other materials, such as consumer goods and packaging materials. The Whippany facility utilizes Cobalt – 60 isotope as a source to provide this service. Cobalt -60 has effective penetrating energies and induced radiation cannot occur through the use of Cobalt -60.

GENERAL OPERATION

The facility can process products in two modalities – In-Carrier and Off-Carrier. In-Carrier work is utilized for processing high volume product and these carriers will cycle around the two Cobalt - 60 source racks within a preset timeframe. Below is example of a carrier with product loaded inside.

Off –Carrier processing is utilized for products that cannot be processed In - Carrier and/or have special requirements that can only be achieved in the off-carrier mode. Most of these products are consumer type products, R&D products, and component testing for the nuclear industry. These products are processed in designated locations outside the path of carrier work indexing around the source racks. These locations are defined as Dolly, Turntable A, Ceiling, and Area B. (See designated calibrated zones below).



- **History of Facility Arrangement and Dosimetry Measurement Protocols / Consolidated Uncertainty Conclusions**

The processing of nuclear components throughout the history of Whippany operations followed a uniform approach. This resulted in comparable analysis of potential variance from the first components processed to current processing. However, there are certain quantifiable factors that have been identified throughout Isomedix history of irradiation processing that may impact the overall variability in processing. A summary of the timelines associated with different contributing factors has been included in the variability study. See [Off-Carrier Study results] Attachment 5. Any past or future Part 21 notifications that apply to nuclear components processed should be evaluated independently of this analysis unless otherwise referenced within this document or the related attachments.

The use of a carrier system and off-carrier processing was introduced at the Whippany facility leading to the density variability condition described in the Notice of Nonconformance. Isomedix facilities (Morton Grove and the Radiation Technology Center in Libertyville) that have processed nuclear components in the past that do not have a carrier system or perform off-carrier processing would not be impacted by the changing densities in on-carrier positions. These facilities were not designed to allow radiation pass-through as a routine method of processing products. As such, the variability of shielding as described in the Notice of Nonconformance does not apply to facilities that do not use an on-carrier and off-carrier processing configuration.

Any conclusions from studies presented in this paper are directed at the Whippany facility processing. They were not derived for the component processing performed at the Isomedix Parsippany location. We do not possess the ability to review processing methodology or reconstruct any run setup at Parsippany beyond what is described in documentation already in the Customer's possession.
Application of correction factors associated with processing at the Isomedix Whippany location may be unnecessarily conservative to work processed at Isomedix Parsippany and should be applied at the Customer's discretion.

- **Isomedix Programs**

The component irradiation process has maintained the dose rate study method since 1984. The Customer provides dose specifications, Isomedix performs a dos rate study to determine the min and max dose rates based on the min and max values derived from a set of dosimeters placed in min and max locations during the dose rate study. The min and max establishes a dose rate per hour, this is divided into the min and max established in the Customer specifications, the component is irradiated for the calculated time period and Isomedix issues a certificate of irradiation for the component reflecting the min and max dose rates per hour multiplied by the time the component was in the irradiator.

During the infancy stages of the component irradiation process there were limited work instructions. With guidance from component Customers and the Nuclear Industry Assessment Committee (NIAC) organized in 1994, the Whippany facility developed a site reactor component QA work instruction (SOP 1701NJ, Reactor Component QA Program) and a site reactor component processing work instruction (SOP 1702NJ, Reactor Component Processing). The documents were audited by the component Customers and NIAC on a routine basis.

The component irradiation process was consistently applied through-out the years with no changes to the basic steps of the process. Documentation practices did change and were applied in the revisions of the SOPs. The documents utilized have evolved over the years, but the foundation of the process (dose rate study) did not change.

In 2005 Isomedix implemented an electronic documentation system and migrated work instructions from the manual control system to the electronic system. In 2007, the component processing SOPs were migrated to the Isomedix electronic documentation system. Also, PROC-00829, Reactor Component Program, (previously identified as 1701NJ, Reactor Component QA Program) and PROC-00830, Reactor Component Processing, (previously identified as 1702NJ, Reactor Component Processing) were created in the electronic documentation system.

Document control practices at the Whippany facility did not require retention of documents more than five years from the origination date. As a result, some documents no longer exist as they were destroyed in compliance with the five year document retention requirement. However, Isomedix does have the revision history for the work instructions dating back to 2007.The Whippany facility has maintained all run folders for nuclear components going back to 1984 and can be retrieved by request.

- ## Isomedix Corrective Actions

Following the conclusion of the April 1-3, 2014 inspection, the Isomedix Whippany, NJ facility performed an assessment of process variability associated with processing of nuclear components in order to quantify the variation in dose rates at the different off-carrier processing locations used for processing nuclear components. This process variability results from the typical mix of product densities processed in carriers that pass through the irradiator while the nuclear components are resident. These products are mainly medical devices and pharmaceutical containers processed for health care manufacturers.

Protocol 14-001WH was performed to estimate the potential dose rate variation experienced at the off-carrier locations where nuclear components are processed. Nuclear components are processed at several off-carrier locations within the irradiator including the Dolly, Turntable (Turn-A), Ceiling and Back Corner (Area B). This study concluded that there is a range of process variability in dose rate depending on location from ±3.5% at Turntable A position up to ± 5.1% for the Ceiling position. A revised study was performed as a follow-up to 14-001WH that provided an updated calculation of process variability.

The calculation of process variability in both studies included the impact of product density variations, Co60 source decay and the in-situ dosimeter response function for each location within the irradiator. The doses applied to all nuclear components processed at Whippany since the completion of Protocol 14-001WH and the revised study have been adjusted to account for the estimated process variability depending on the applicable off-carrier processing location and Customers notified of this change and the rationale why this change was implemented.

Customers who processed nuclear components at the Whippany facility were notified by letter on June 18, 2014 of the variability in reported dose readings under the requirements of 10 CFR Part 21.

The following additional changes were implemented to ensure that all processing of nuclear components conforms to the requirements of 10 CFR Part 50, Appendix B:

1. Isomedix Procedure PROC-00830: Whippany Reactor Component Processing was revised to include the following new requirements -

    - The ‘Nuclear Component Qualification Request’ will include the statement of dosimeter measurement uncertainty

- The 'Component Irradiation Certification' provided to Customers will include the following:
  - Minimum and maximum delivered dose
  - Minimum and maximum dose rate per hour
  - A statement that details the following, "Total dose delivered includes dose rate variability"
  - Total exposure hours
  - Processing location within the irradiator

2. The dose rate variation will be re-evaluated after changes in source rack configuration (addition, removal, re-distribution). The procedure for performing this re-evaluation will be defined in the revision of procedure PROC-00830.

3. A revised study was performed as a follow up to 14-001WH protocol. This study was performed using a larger data population and a two sigma confidence level. The results of the study identified an overall process variability of approximately 10% which includes several variability factors as discussed within the Off-Carrier Study results (Attachment 5). The addition of 10% variability has now been added to the appropriate forms as an additional safety margin for processing components. This margin is specific to the Isomedix process and is viewed as independent of any other regulatory or industry requirements required by the Customer.

• Recommended Instructions for Customers

Isomedix Services has performed and provided a quantitative analysis in Attachment 5 of the overall variability associated with product processing throughout the history of the Whippany facility. This analysis provides applicable timelines and other important considerations to allow review of each component impacted by this notification.
Based on the analysis, an industry working group from members of IEEE, NUGEQ, nuclear component manufacturers and test facilities has developed a guidance document that incorporates this analysis into practical guidelines to evaluate the irradiation of past components and guidance on future processing.
A copy of that document may be obtained by contacting industry working group members Bill Horin (whorin@winston.com) (NUGEQ), Ron Wise (ronwise@aol.com) (NUGEQ) or John White (johnlwhite@me.com) (IEEE).

It is important to consider that the variability applied to the Whippany process will be independent of any regulatory or IEEE standard margin or other requirements for developing specifications for a component.

It is important to consider the following items when reviewing the information contained in this document and the Industry Working Group Guidance Document:

1. The study performed in June 2014 was enhanced to include a comprehensive variability number. This includes variability related to density, source decay, and dosimeter system. If any of these components have already been factored into your component evaluation prior to the Part 21 notification, the full 10% may not apply in your evaluation.
2. The analysis performed and guidance provided applies to the Whippany, NJ facility. Application of its results to other Isomedix facilities is at the customer's discretion, as it may be unnecessarily conservative for those other facilities.

3. Customers that have questions about the location where a component was processed should contact the Whippany Isomedix facility to confirm that the component is within the scope of the Part 21 notification.
4. Any past or future Part 21 notifications that apply to nuclear components processed should be evaluated independently of this analysis unless otherwise referenced within this document or the related attachments.

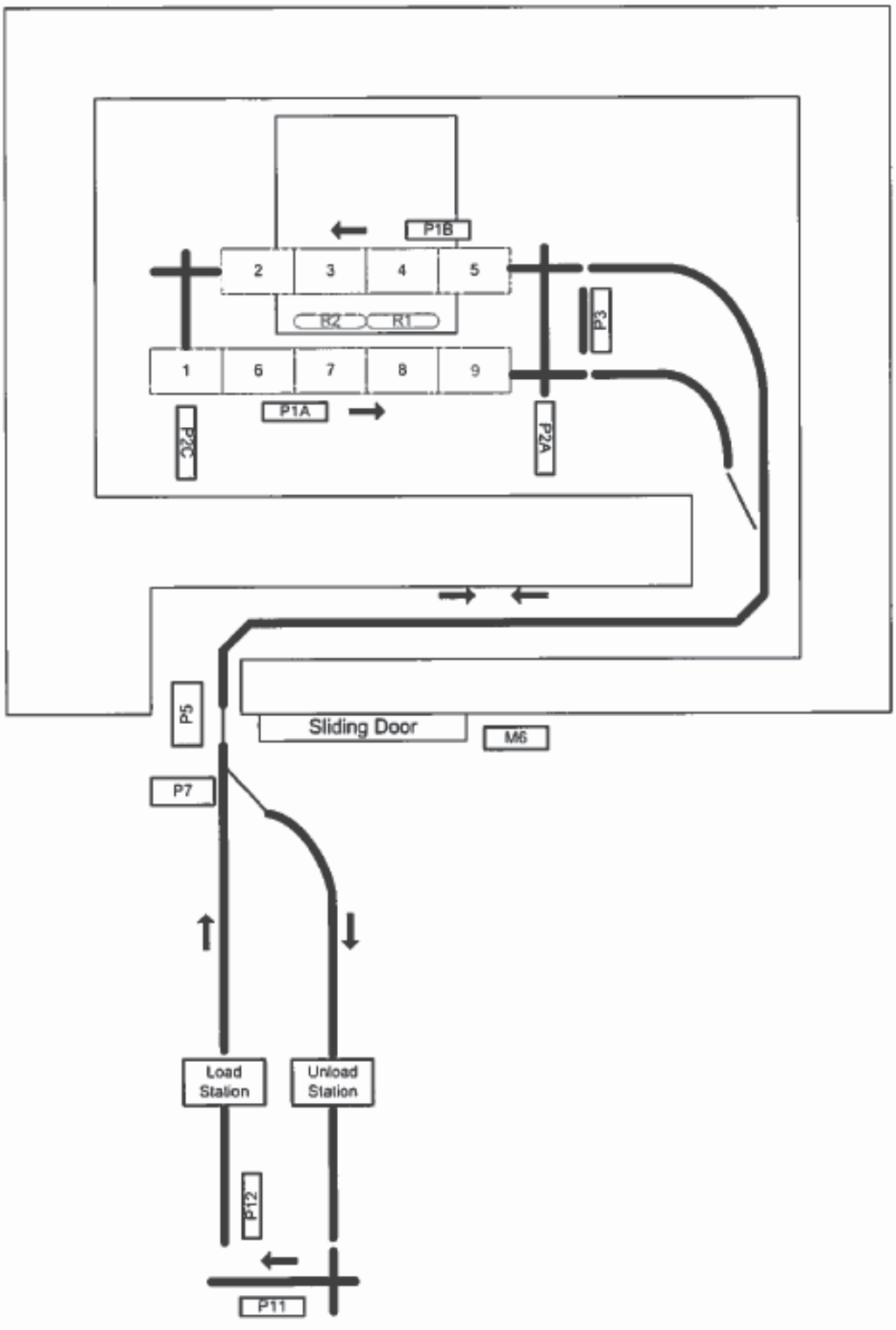
• Isomedix Contact Information

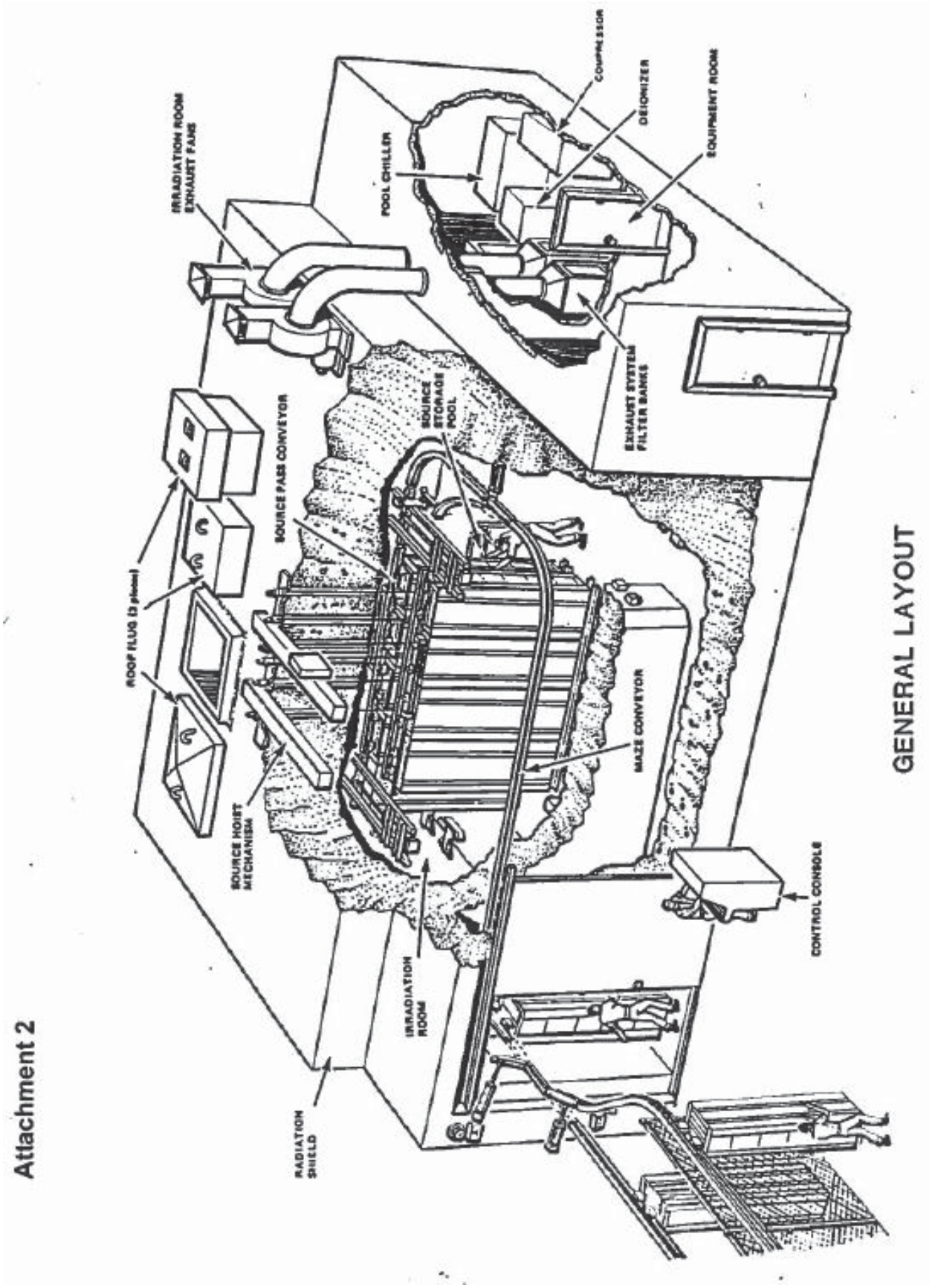
For additional information pertaining to this event, please contact Scott Comstock, Plant Manager, at scott_comstock@STERIS.com or 973-887-2754.

• Referenced Attachments

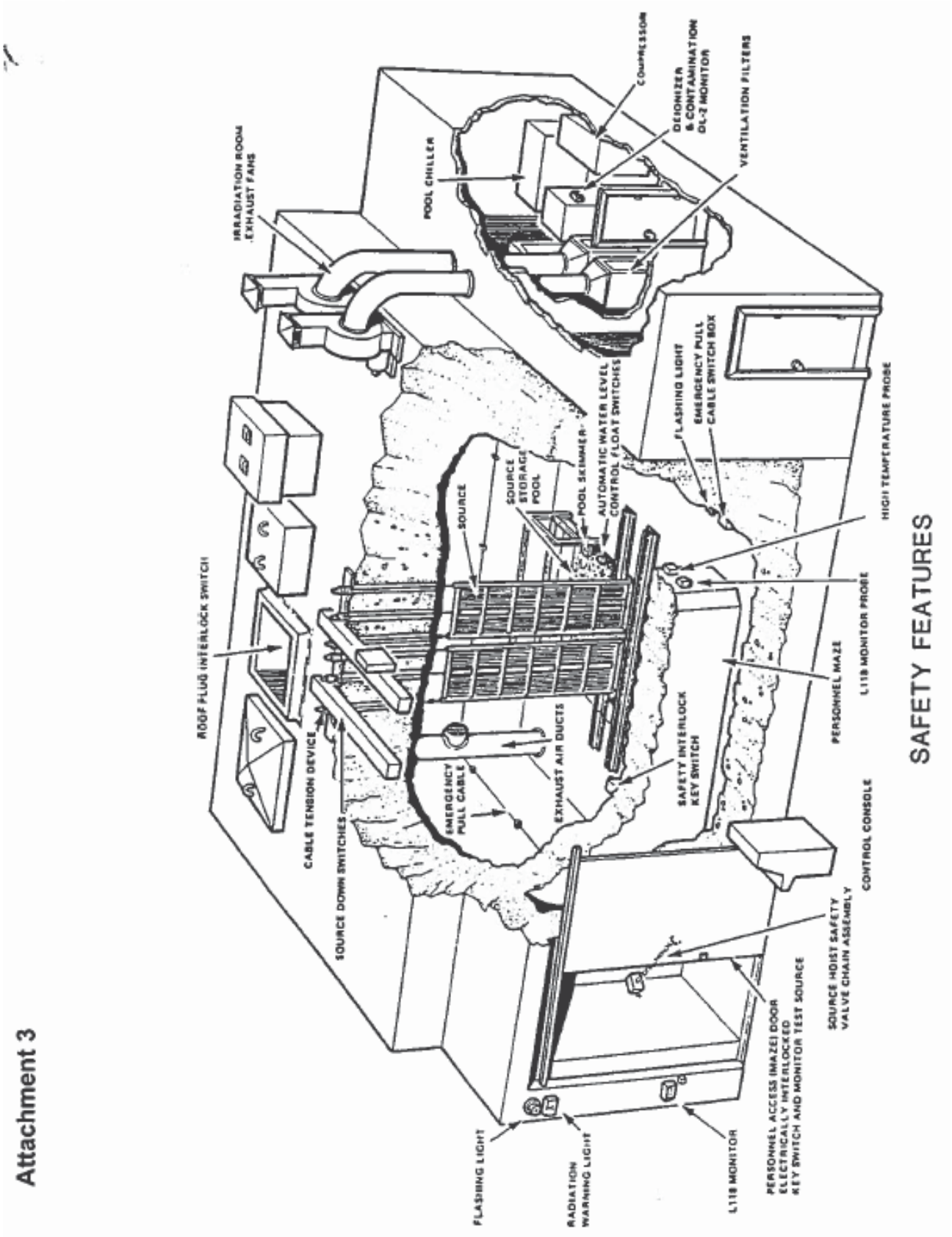
1. Attachment 1: Carrier Position Diagram of the Whippany, NJ Irradiator
2. Attachment 2: General Layout of the Whippany, NJ Irradiator
3. Attachment 3: Safety Features of the Whippany, NJ Irradiator
4. Attachment 4: Cobalt Sealed Source diagram for Cobalt-60
5. Attachment 5: Off-Carrier Processing Study: Dose Rate Variability for the Whippany, NJ Facility

Attachment 1
Carrier Position Diagram
Source Pass and Storage
IR131 – Whippany, NJ

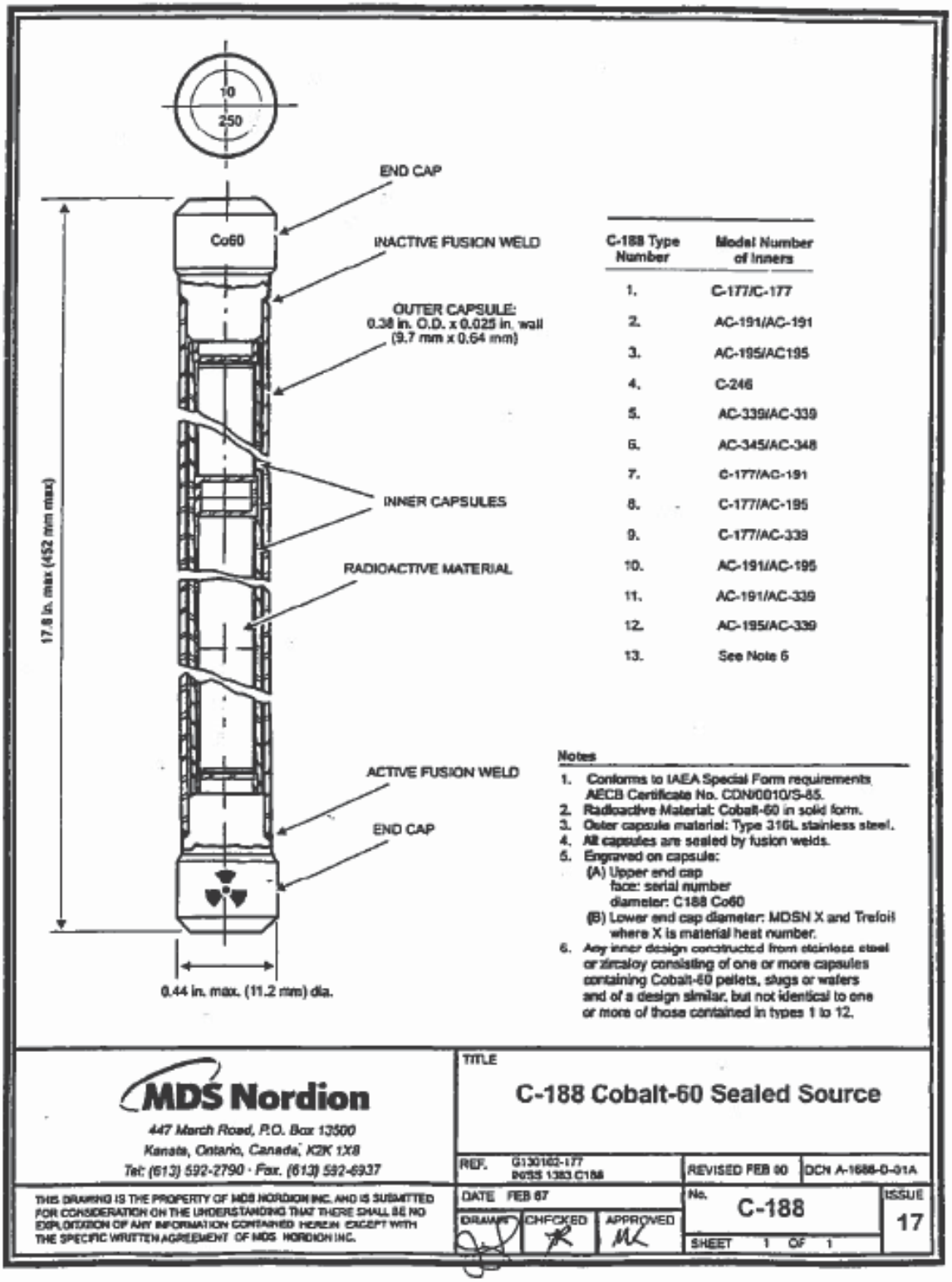



Attachment 2
GENERAL LAYOUT
IRRADIATION ROOM EXHAUST FANS
POOL CHILLER
COMPRESSOR
DEIONIZER
EQUIPMENT ROOM
EXHAUST SYSTEM FILTER BANKS
SOURCE STORAGE POOL
SOURCE PASS CONVEYOR
ROOF PLUG (3 places)
MAZE CONVEYOR
SOURCE HOIST MECHANISM
CONTROL CONSOLE
IRRADIATION ROOM
RADIATION SHIELD

Attachment 3



Attachment 4



C-188 Type Number	Model Number of Inners
1.	C-177/C-177
2.	AC-191/AC-191
3.	AC-195/AC195
4.	C-246
5.	AC-339/AC-339
6.	AC-345/AC-348
7.	C-177/AC-191
8.	C-177/AC-195
9.	C-177/AC-339
10.	AC-191/AC-195
11.	AC-191/AC-339
12.	AC-195/AC-339
13.	See Note 6

Notes

1. Conforms to IAEA Special Form requirements AECB Certificate No. CDN/0010/S-85.
2. Radioactive Material: Cobalt-60 in solid form.
3. Outer capsule material: Type 316L stainless steel.
4. All capsules are sealed by fusion welds.
5. Engraved on capsule:
   (A) Upper end cap
   face: serial number
   diameter: C188 Co60
   (B) Lower end cap diameter: MDSN X and Trefoil where X is material heat number.
6. Any inner design constructed from stainless steel or zircaloy consisting of one or more capsules containing Cobalt-60 pellets, slugs or wafers and of a design similar, but not identical to one or more of those contained in types 1 to 12.

MDS Nordion
447 March Road, P.O. Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel: (613) 592-2790 · Fax. (613) 592-6937

TITLE: C-188 Cobalt-60 Sealed Source

REF. G130162-177
B0SS 1383 C188
REVISED FEB 90 | DCN A-1686-0-01A
DATE FEB 67
No. C-188 | ISSUE 17
DRAWN | CHECKED | APPROVED
SHEET 1 OF 1

Attachment #5

DATE: March 2, 2015

TO: Internal File

FROM: Ryan Tracy (Radiation Physicist III)

SUBJECT: **Dose Rate Variability for the Whippany, NJ Facility (Off-Carrier Processing)**

History

Following an inspection performed by the Nuclear Regulatory Commission in April 2014, findings were presented to Steris Isomedix to review and address. These findings were presented to customers in June 2014 and further addressed in August 2014 when Steris completed an analysis which included an additional 7-day experimental study to estimate the dose rate variability within its irradiator for products processed on its off-carrier areas. These findings were built into the current processing methods of the Whippany, NJ facility to ensure proper dose reporting going forward. After meeting with the members of IEEE Subcommittee SC-2 in September 2014, further analysis that includes an empirical review of historic runs and a more rigorous statistical analysis of the data was recommended. In conjunction with these efforts, Steris has repeated the 7-day study, and presents the following results as a more robust analysis of the variabilities experienced associated with dose applications in the off-carrier areas of the Whippany facility.

Scope

When the facility opened in 1984, it was primarily running a product mix that was more homogeneous and more regular than its current product mix. It ran using the same dosimeter type currently in use (polymethylmethacrylate (PMMA) dosimetry). Now that there is a much more varied product mix, the results of the following empirical study and the 7-day experimental studies are judged to be a conservative representation of the entire history of the facility. This data only applies to product run at the Whippany, NJ facility; the application of correction factors associated with processing at the Isomedix Whippany location maybe unnecessarily conservative to work processed at Isomedix Parsippany (the predecessor to the Whippany facility) and should be applied at the Customer's discretion. Based upon interviews with previous and current staff, the layout and design of the Parsippany, NJ facility would have a lower variability due to its static carrier placement and single source geometry. The final result of this study includes the variability of the dosimetry system uncertainty calculated using the methodology outlined in ISO/ASTM 51707: *2005 Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing.*

Definitions

Covariance- measure of how much two random variables change together

Standard deviation (sample) – measures the amount of variation or dispersion from the average

Variance (sample) – measures the amount of variation or dispersion from the average expressed as the standard deviation squared

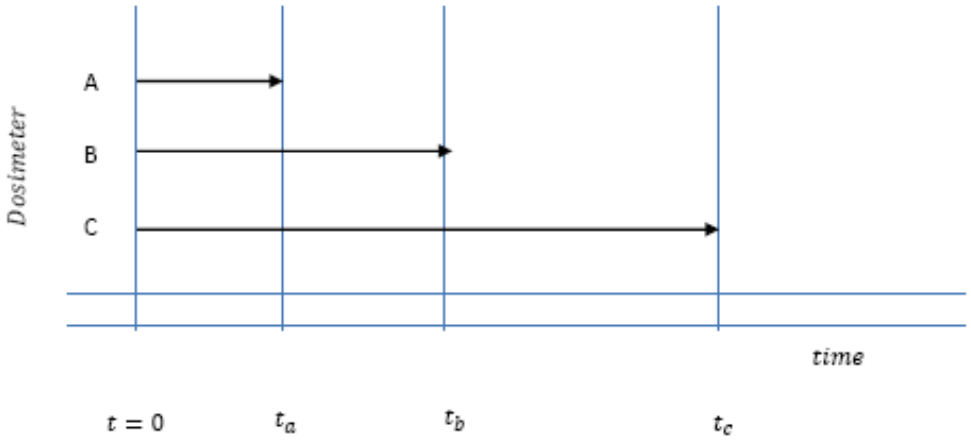
Uncertainty (of measurement) – parameter, associated with a measured or derived quantity, that characterizes the distribution of values that could reasonably be attributed to the measured or derived quantity.

Factors Influencing Variability

The following summary is an analysis of the factors that cause dose rate variability during off-carrier processing at the Whippany, NJ facility. When processing a product utilizing the off-carrier system, the facility uses Harwell Red 4034 (PMMA) dosimeters to establish a dose rate for the product in the irradiator. These types of dose rate determination irradiations are referred to as "dose rate studies" and are used to report a final minimum and maximum dose based on the rates determined in the study. There are two additional factors that must be taken into account to provide the most accurate dose rate that includes 1) the variability of density in on-carrier products that shield off-carrier areas during processing, and 2) the decay of cobalt.

Density Variability from Historical Intercomparison Studies

Determining the variability associated with the varying densities of on-carrier products was completed using five years of intercomparison data and confirmed through two separate experimental test protocols. Intercomparison studies are performed on a quarterly basis (at a minimum) and are representative of nuclear irradiation dose rate studies because they use Red 4034 dosimetry and the time periods for the irradiations are similar to the dose rate studies completed for customer products. For an intercomparison study, three sets of three dosimeters (A, B, and C) are placed on homogenous material in each of the respective processing areas. Dosimeters sets are then irradiated in unison for a given period of time as shown in graphical representation below:



Area A (characterized as the Dolly and Turntable areas) and Area B had the most sufficient data for a statistical analysis and given the symmetrical nature of these areas provide a good representation of typical processing within the irradiator. Area A is located closer to the source rack and has a higher dose rate than Area B which is in the back corner of the irradiator.

Dose rates for each set of the intercomparison studies are determined by the ratio of the mean of three dosimeter measurements within the time period. For example the dose rate for set A would be expressed as:

$$DR_A = \frac{\mu_{(3\ dosimeters)}}{t_a}$$

The variance of the three dose rates is equal to the sum of the variance and covariance of the dose rate studies A, B, and C. Since each dose rate study began in unison, there are periods of time where studies overlap. Therefore each study is not independent and covariance exists.

There are two known variabilities, the first of which is dosimeter variability ($\sigma_{dosimeter}$). The coefficient of variability for a dosimeter has been previously determined using ISO/ASTM 51707: *2005 Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing* and experimentally found to be 3.25% (at the 1σ level). Standard deviations, σ, from this point forward will be normalized with respect to the mean and will be referred to as standard deviations. The second variable is density variability ($\sigma_{density}$) which is not known and is the single unknown variable being solved for. Source decay is considered insignificant in this instance since studies do not typically exceed greater than 10 hours. Position variability is considered to be insignificant as well since each study was performed with the 3 dosimeters within very close proximity of one another. Both of these variabilities, though insignificant, and unknown variabilities are bounded within the density variability for simplicity and conservatism.

The variance of the three dose rate studies is represented as:

$$VAR(A,B,C) = VAR(A) + VAR(B) + VAR(C) - COV(A,B) - COV(B,C) - COV(A,C)$$

The variances of A, B, and C are equivalent and are the sum of density and dosimeter variabilities. Covariance does not exist for dosimeter variability since each dosimeter operates as an independent random variable. Since there is a time period of overlap between dose rate studies, then density variability between the two studies is zero during this time period, therefore, increasing its contribution and weight to the total variance.

$$\begin{aligned}
VAR(A) &= \sigma^2_{dosimeter} + \sigma^2_{density} \\
VAR(B) &= \sigma^2_{dosimeter} + \sigma^2_{density} \\
VAR(C) &= \sigma^2_{dosimeter} + \sigma^2_{density} \\
COV(A,B) &= \frac{t_a}{t_b}\,\sigma^2_{density} \\
COV(B,C) &= \frac{t_b}{t_c}\,\sigma^2_{density} \\
COV(A,B) &= \frac{t_a}{t_c}\,\sigma^2_{density} \\
\therefore VAR(A,B,C) &= 3\sigma^2_{dosimeter} + \sigma^2_{density}\left(3 - \frac{t_a}{t_b} - \frac{t_b}{t_c} - \frac{t_a}{t_c}\right)
\end{aligned}$$

Since all variables except for density variability within the above equation are known or can be empirically determined from historic data, then density variability can be solved for:

$$\sigma^2_{density} = \frac{(VAR(A,B,C) - 3\sigma^2_{dosimeter})}{\left(3 - \frac{t_a}{t_b} - \frac{t_b}{t_c} - \frac{t_a}{t_c}\right)}$$

The data for the Area A and Area B is derived from 14 and 13 intercomparison studies respectively spread over a 5 year period. The entire formula is summarized below:

The cumulative time ratio is the value under the denominator and is found to be 1.2547 for Area A and 1.4875 for Area B.

$$\frac{t_a}{t_b} + \frac{t_b}{t_c} + \frac{t_a}{t_c} = \begin{cases} 1.2547\ for\ Area\ A \\ 1.4875\ for\ Area\ B \end{cases} \approx 1.5\ (conservatively)$$

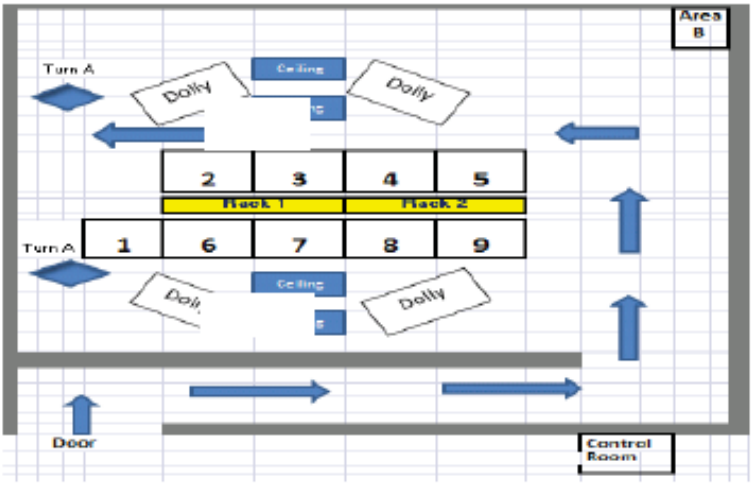
Conservatively, a value for the cumulative time ratio of 1.500 was chosen.

The central limit theorem allows for the standard deviation (σ) of a normal distribution of the sample mean to be calculated from the formula for the variance of the sum of independent random variables. It is equal to $\frac{\sigma}{\sqrt{n}}$, where n is the number of data points in the sample.

The central limit theorem may be applied to dosimeter variability if and only if all of the following conditions are met:

1. Multiple dosimeters were used during the dose rate study.
2. The dosimeters were within close proximity of one another.
3. Each dosimeter was within the bounds of the calibrated zone where the samples were irradiated.
4. Dosimetry distribution is normally distributed.
5. The dosimeters and samples were irradiated in air. (Applies to nuclear product irradiation.)

The calibrated zones are relatively small and are defined as Dolly, Turntable A, Ceiling, and Area B and are represented in the figure below:



Using the variability of 3.25% for a single dosimeter, the contribution of three dosimeters is calculated in the following equation:

$$\sigma^2_{dosimeter} = \frac{(0.0325)^2}{3}$$

Finally, the historical variance is computed by taking the geometric mean of each historical intercomparison study's normalized standard deviation.

$$VAR(A,B,C) = \begin{cases} 0.040455^2 \; for \; Area \; A \\ 0.040805^2 \; for \; Area \; B \end{cases}$$

Plugging each of these components into our final equation, we determine the $\sigma_{density}$ value to be:

$$\therefore \; \sigma_{density} = \begin{cases} 0.01967 \; for \; Area \; A \\ 0.02015 \; for \; Area \; B \end{cases} \approx 0.0203$$

For a 95% confidence interval and a double tailed distribution (2σ) the density variability is conservatively 4.1% derived from historical data.

Density Variability from Experimental Study

An experiment was designed in which alanine dosimeters (that are dose rate independent) were placed at fixed locations within each of the off-carrier areas and processed over the course of seven days. The seven day timeframe is a good unit of measure for a cyclical weekly processing cycle within the Whippany irradiator.

Dosimeters were placed on homogenous material, similar to the intercomparison dosimeters, and left in their positions until approximately 100kGy was delivered to the dosimeter. Dosimeters were then analysed and summarized in more depth as part of internal protocol *14-001WH Summary Report for Off-Carrier Dose Rate Variability Study (Whippany, NJ IR-131)* in May 2014 and once again as part of internal protocol *14-007WH Summary Report for Off-Carrier Dose Rate Variability Study (Whippany, NJ IR-131)* performed in September 2014 directly after a source loading activity.

The results of these studies are summarized below after removing the factors of dosimeter variability:

Area	Study 1 (May 2014)	Study 2 (Sep. 2014)	Average (σ)
Dolly	3.32%	1.49%	2.51%
Ceiling	2.63%	2.01%	2.28%
Turntable	3.21%	2.82%	3.01%
Area B	3.74%	0.43%	2.09%*

*It is important to note that each study from Area B was derived from 2 data points which is not an ideal sample size for determining the variability of this area and is included as information only.

Each of these areas shows results consistent with the empirical review of data (2.02% at the 1σ level) with variations on the order of 1% considered acceptable due to the variation from two different dosimetry systems and cobalt decay variability which would have been significantly lower in the historical analysis. The higher variabilities reported in the experimental study versus the historical study support the proposition that the current product variability is historically at its highest.

The results in the average column are the weighted average of the two week long studies. They can be used to give a more accurate representation of the variability that exists within each area since the sample size is doubled. The results for the Dolly area is based on 16 data points, the Ceiling area is based on 16 data points, the Turntable area is based on 12 data points, and the results of Area B are omitted due to the lack data. The average variability of the three areas that have sufficient data is 2.60% at the 1σ level.

The historical analysis supported the proposition that density variability is independent of location and a single variability can be applied across all areas. The 3.01% estimate was chosen as the contribution of variation as a result of on-carrier density processing for conservatism. Therefore, for a 95% confidence interval and a double tailed distribution (2σ) the density variability is 6.02%.

Cobalt Decay Time Variability

While most products and components are typically completed within one 24-hour period, some products are placed in the irradiator for a week or as long as a month. Since the facility uses a dose rate that is typically established in the first two hours of processing, then it is necessary to add a cobalt decay time variable to account for decreasing dose rates over time.

The decay of cobalt is a constant value expressed as the half-life of Cobalt-60 (Co^{60}):

$$A_E = A_0 * \left(\frac{1}{2}\right)^{t/t_{1/2}}$$

Where $t_{1/2}$ represents the half-life constant of Co^{60} of 5.2714 years (1925 days), A_0 represents the initial activity, and A_E represents the activity at some time in the future, t. Time decay at any point during processing is represented in the following equation:

$$1 - \int_0^t \frac{A_0 * \left(\frac{1}{2}\right)^{t/t_{1/2}}}{A_E}\, dt$$

Solving the equation the formula simplifies to the following where t represents the time in days:

$$\frac{\frac{1925}{\ln 2} * (\frac{1}{2}^{(\frac{t}{1925})} - 1)}{t} + 1$$

Using a conservative approach, we apply a bias of 0.00538 (0.538%) which is representative of 30 days and is considered the upper limit of products processed at the Whippany, NJ facility.

Conclusion

The results of the historical analysis and experimental study for density variability support the proposition that density variability is independent of location and a single representative variability can be applied. Based on the results from the dose rate variability from on-carrier density fluctuations, dosimeter variability, and time decay of cobalt bias, we can compute the total variability as follows:

$$2\sigma_{total} = \sqrt{(2\sigma)^2_{density} + (2\sigma)^2_{dosimeter}} + \sigma_{time}$$

$$2\sigma_{total} = \sqrt{0.0602^2 + 0.0650^2} + 0.00538$$

$$2\sigma_{total} = 0.09398 \approx 0.094$$

We round the value up to the nearest thousandths place and report the final value as 9.4% at the 95% confidence level.

Three appendices provide further analyses. Appendix A is an analysis of the ceiling area for a subset of products that were irradiated in the ceiling area without calibration curves. Appendix B is an analysis of historic dosimeter variability. Appendix C is a timeline that summarizes the overall variability based on the reported values in this analysis.

Acknowledgements

Steris Isomedix recognizes Eric Rasmussen, Director of Engineering for RSCC Wire and Cable LLC for his contribution and assistance with the statistical analysis and summary of empirical data.

Appendix A

Due the nature of temperature and dose rates throughout the Whippany, NJ irradiator, each area of the processing zones is characterized by performing an intercomparison study within that area per the requirements of ISO/ASTM 51276:2012 *Standard Practice for Use of a Polymethylmethacrylate Dosimetry System*. From October 19, 2007 to April 28, 2014, there was a subset of products that were processed in the ceiling area and dosimeter readings were incorrectly made on curves specific to Area A since intercomparison studies were not performed for the ceiling area. As such there is an additional source of error for products that have been processed in this way. Below is a historic analysis of the adjustment factors used for Off-Carrier A irradiations, k_A, and adjustment factors used for Off-Carrier Ceiling irradiations, k_C. These adjustment factors are multiplied by the final dose, as determined in the calibration process, and as with the cobalt decay, they represent a bias to the final dose.

Intercomparison studies were used to determine the ceiling's intercomparison variability from the adjustment factors, k, between Area A and the Ceiling, by applying the following formula:

$$\sigma_i = |k_A - k_C|$$

We again perform an empirical analysis of all ceiling and off-carrier A intercomparisons back to 2005 (including two intercomparisons performed in 2014) to determine a worst-case difference in adjustment factors. The largest difference was 2.15% in September 2006 while on average the difference was 0.98% with a standard deviation of 0.67%. Remaining consistent with previous methods, the 0.98% average and 2σ confidence interval is applied yielding 2.32%.

For products processed in the ceiling area from October 19, 2007 to April 28, 2014 the 2.32% factor is applied as a bias to the number established previously:

$$2\sigma_{total} = \sqrt{(2\sigma)^2_{density} + (2\sigma)^2_{dosimeter}} + \sigma_{time} + \sigma_{intercomparison}$$

After incorporating the value of 0.09398 from the previous analysis and our worst-case intercomparison bias yields:

$$2\sigma_{total} = 0.09398 + \sigma_{intercomparison}$$

$$2\sigma_{total} = 0.09398 + (0.0232)$$

$$2\sigma_{total} = 0.11718 \approx 0.118$$

We round the value up to the nearest thousandths place and report the final value as 11.8% for products run on the ceiling from October 19, 2007 to April 28, 2014 at the 95% confidence level.

Appendix B

Throughout the history of the Whippany facility, the dosimeter uncertainty had two distinct values. The current value of ±6.5% at the 2σ confidence level was established on September 8, 2000 as a result of ISO/ASTM 15572 *Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing* being published in 1998 (later changed to ISO/ASTM 051707 in 2002). With one exception the methodology, equipment, and analysis remained unchanged from the opening of the facility in 1984. In April 2000, the Whippany facility upgraded its irradiator control system which moved the timer setting with a precision measurement uncertainty of ±2.0% with a 95% confidence level to a timer precision equivalent to the current system. As a result, the variability previous to this change is calculated as follows and σ_{timer} represents the variability from the timer previous to the upgrade:

$$2\sigma_{dosimeter^*} = \sqrt{(2\sigma)^2_{dosimeter} + (2\sigma)^2_{timer}} = \sqrt{0.0650^2 + 0.02^2} = 0.0680$$

The two values are as follows:

Time Period	Dosimeter Uncertainty	Reason for change
1984 to 31-Mar-2000	±6.8% at 95% confidence level	N/A - Initial value
1-Apr-2000 to present	±6.5% at 95% confidence level	Updated based on installation of a new control system with a timer setting resolution equal to current resolution

Applying the previous values along with an additional 2% bias based on the precision measurement from the timer setting yields:

$$2\sigma_{total} = \sqrt{(2\sigma)^2_{density} + (2\sigma)^2_{dosimeter} + (2\sigma)^2_{timer}} + \sigma_{time}$$

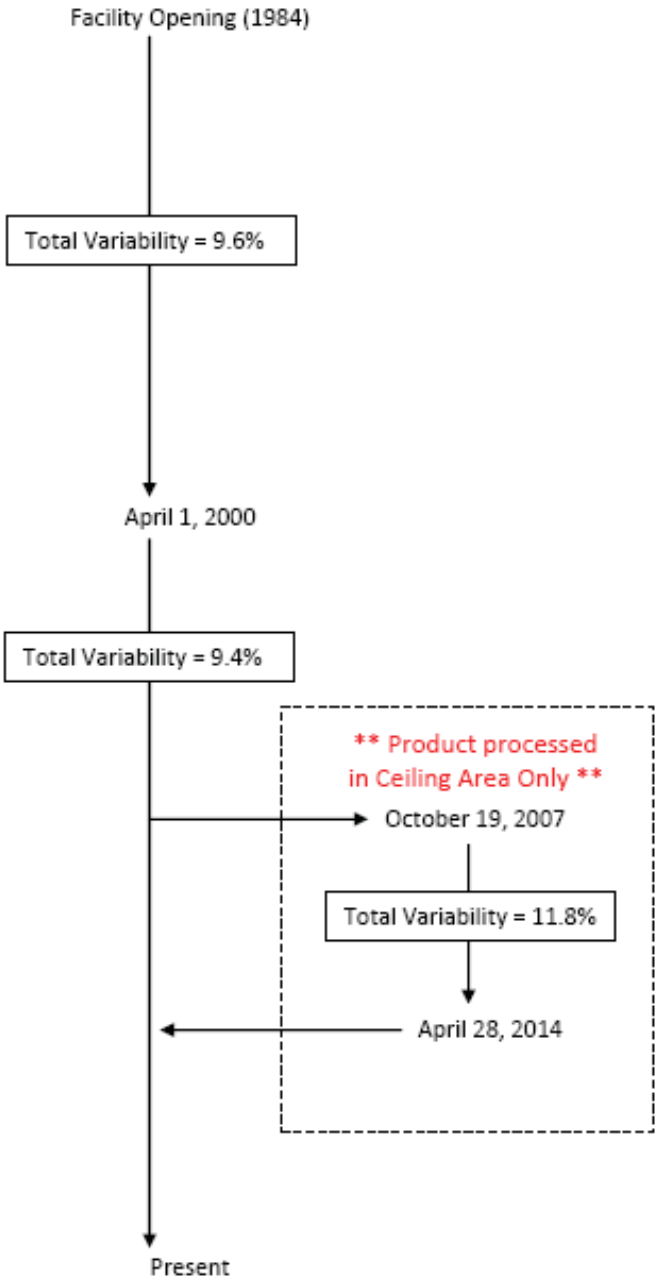
$$2\sigma_{total} = \sqrt{0.0602^2 + 0.0650^2 + 0.02^2} + 0.00538$$

$$2\sigma_{total} = 0.09619 \approx 0.096$$

The value is rounded up to the nearest thousandths place and reported as 9.6%. The 9.6% overall variability is considered effective for products run from the facility's opening in 1984 to April 1, 2000 at the 95% confidence level.

Appendix C

The following timeline indicates the overall variability of measurement based on the reported values in this analysis:



REFERENCE 8

NRC Receipt Acknowledgement of Steris Response to Nuclear Regulatory Commission Inspection Report No. 99901445/2014-201, dated August 7, 2014.

(2 Pages)

August 7, 2014

Ms. Yais Geissler, QS/RC Manager
STERIS Isomedix Services, Inc.
9 Apollo Drive
Whippany, NJ 07981

SUBJECT: STERIS RESPONSE TO NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 99901445/2014-201

Dear Mrs. Geissler:

Thank you for your July 14, 2014 letter in response to the Notice of Nonconformance (NON) that was discussed in the subject U.S. Nuclear Regulatory Commission (NRC) inspection report (IR). We have reviewed your correspondence and found that it was responsive to the NON documented in IR 99901445/2014-201. We have no further questions or comments at this time and may review the implementation of your corrective actions during a future NRC staff inspection to determine whether full compliance has been achieved and maintained.

Please contact Jeffrey Jacobson via electronic mail at Jeffrey.Jacobson@nrc.gov, if you have any questions or need assistance regarding this matter.

Sincerely,

/RA/

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

Docket No.: 99901445

August 7, 2014

Ms. Yais Geissler, QS/RC Manager
STERIS Isomedix Services, Inc.
9 Apollo Drive
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Office of New Reactors

Docket No.: 99901445

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