

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



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, 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.

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.



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 $\pm 3.5\%$ at Turntable A position up to $\pm 5.1\%$ 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.

STERIS®



ATTACHMENT 2

**Summary Report for
Off-Carrier Dose Rate Variability Study**

Whippany, NJ – IR 131

Protocol 14-001WH

Written by:  Date: 4/26/14
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

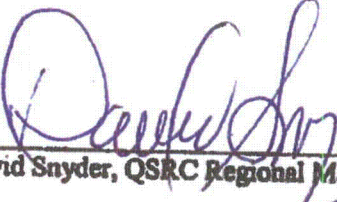
Approved by:  Date: 6/12/14
David Snyder, QSRC Regional Manager – East Zone

Table of Contents

| | | |
|---|-------------------------|--------|
| 1 | Objective | Page 3 |
| 2 | Equipment and Materials | Page 3 |
| 3 | Summary | Page 3 |
| 4 | Data Review | Page 3 |
| 5 | Addendum | Page 3 |
| 6 | Unexpected Results | Page 4 |
| 7 | Exhibits / Raw Data | Page 4 |

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”

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

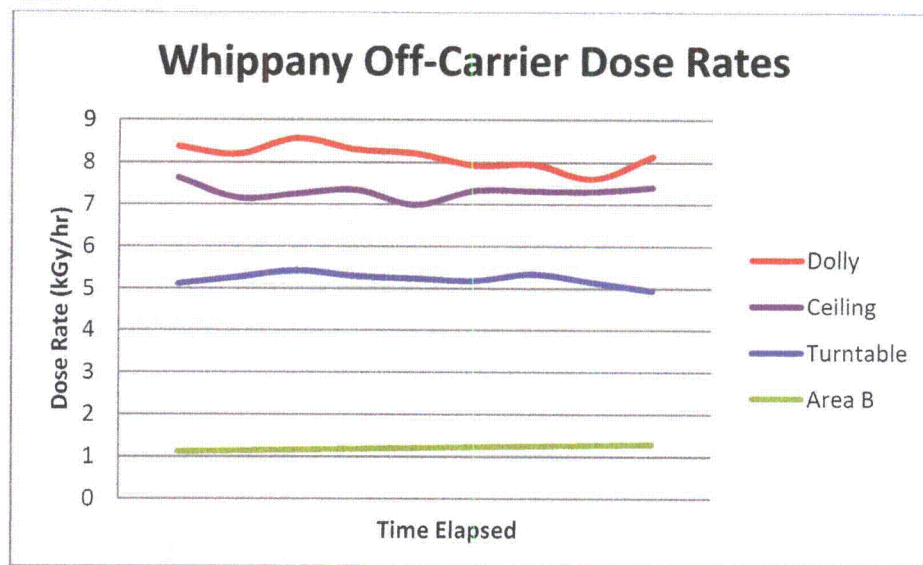
- 3.14 Form 1 calculated the total source uptime, total dose, and average dose rate for all values listed on the form.
- 3.15 The Whippany, NJ facility sent all Form 1's associated with the execution of this study to Radiation Physics for final analysis.

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:

| 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

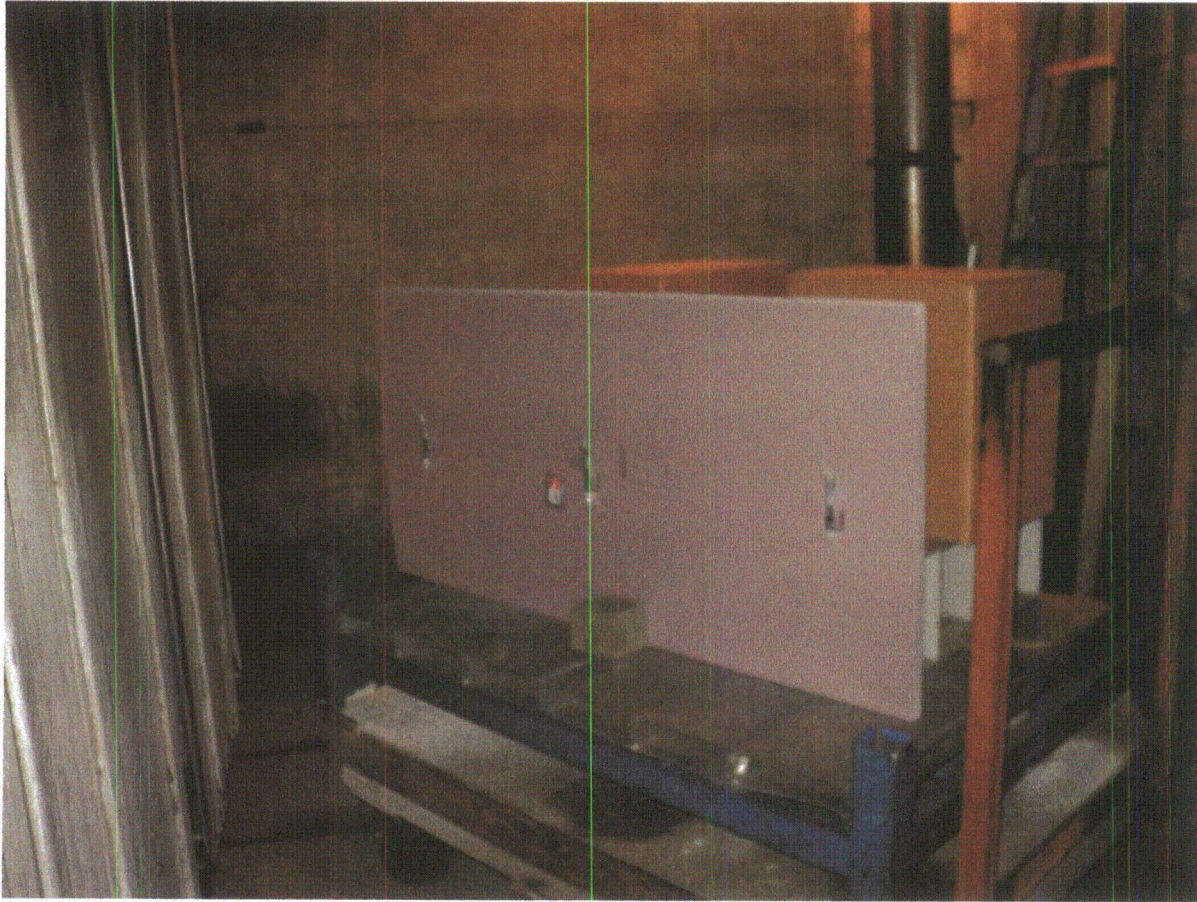
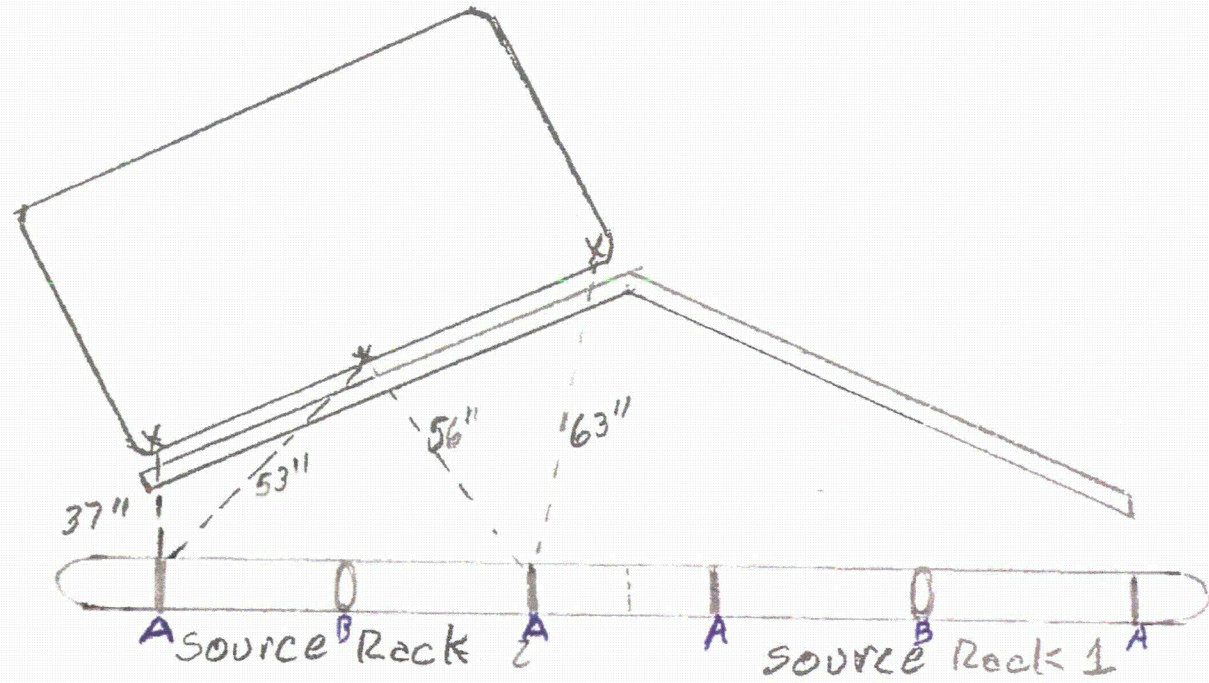


Figure 1 - DOLLY AREA WITH DOSIMETER PLACEMENTS

Pool side



Distance between
dolly and source rack

A - Source Rack guide
B - Middle of source rack

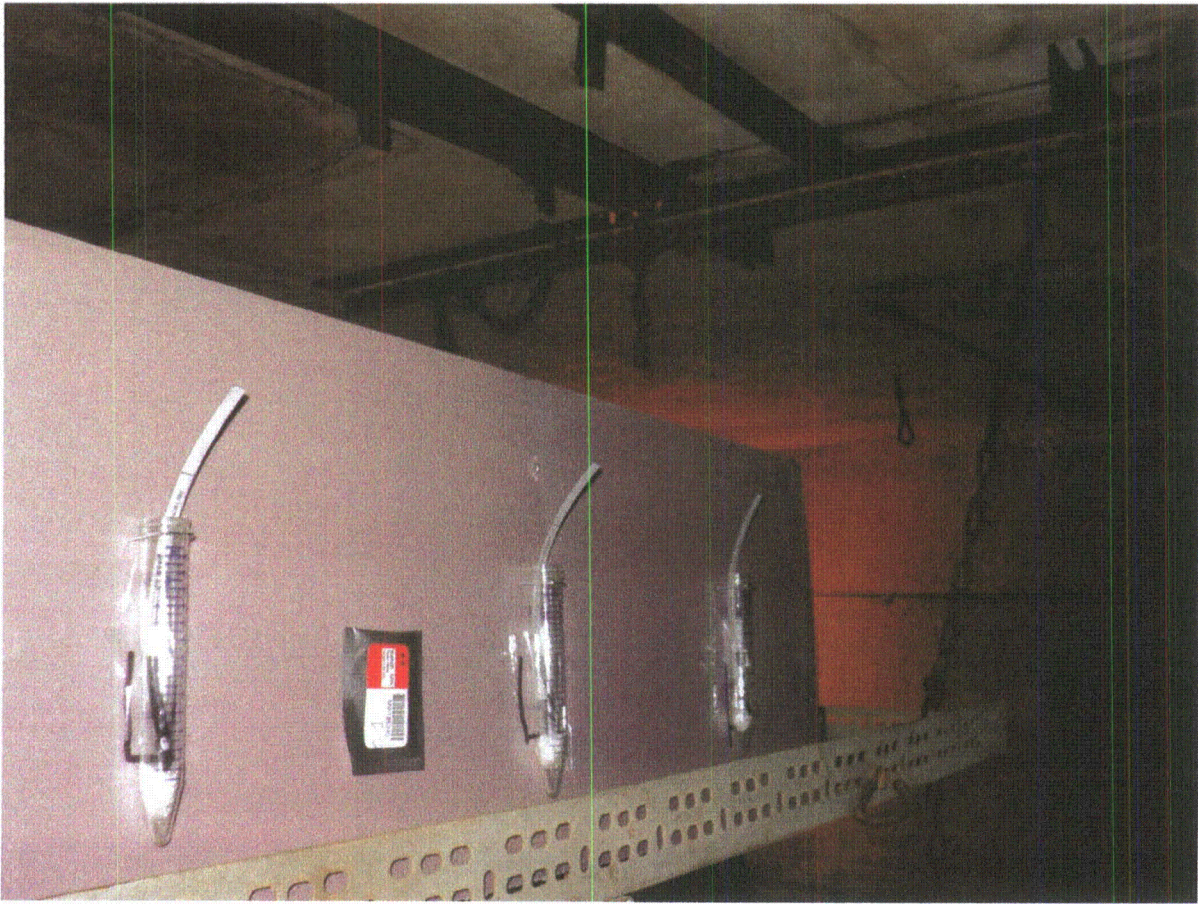
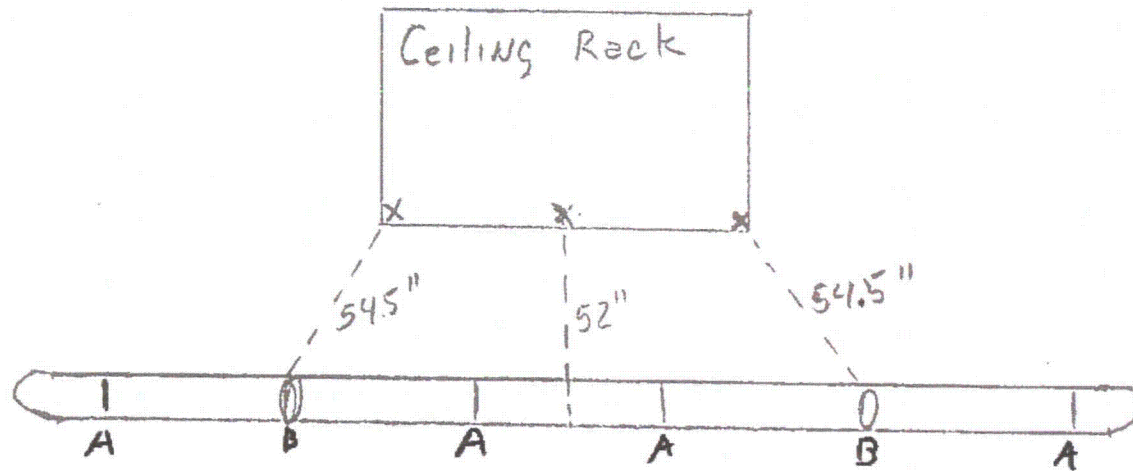


Figure 2 -CEILING AREA WITH DOSIMETER PLACEMENTS

Pool side



Distance between
ceiling rack and racks



Figure 3 -TURNTABLE AREA WITH DOSIMETER PLACEMENTS

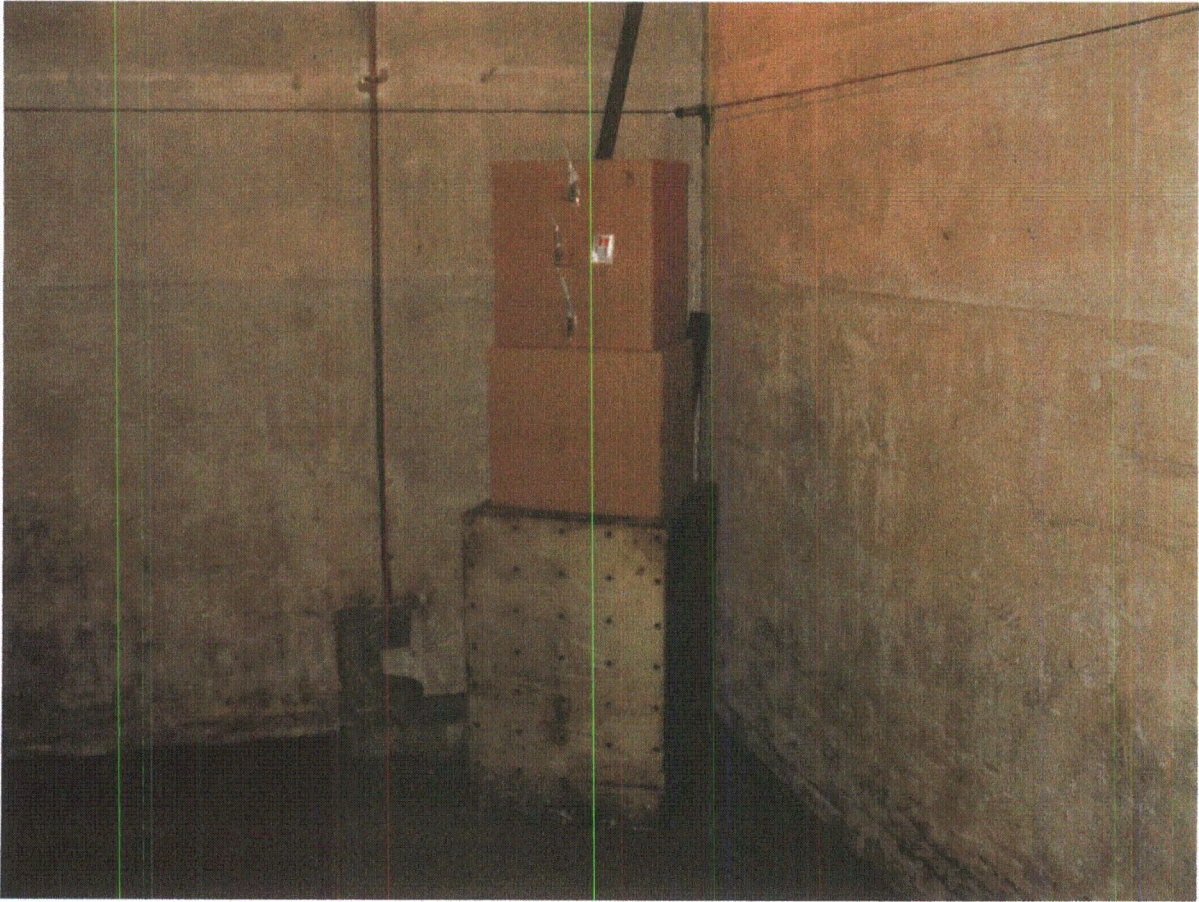
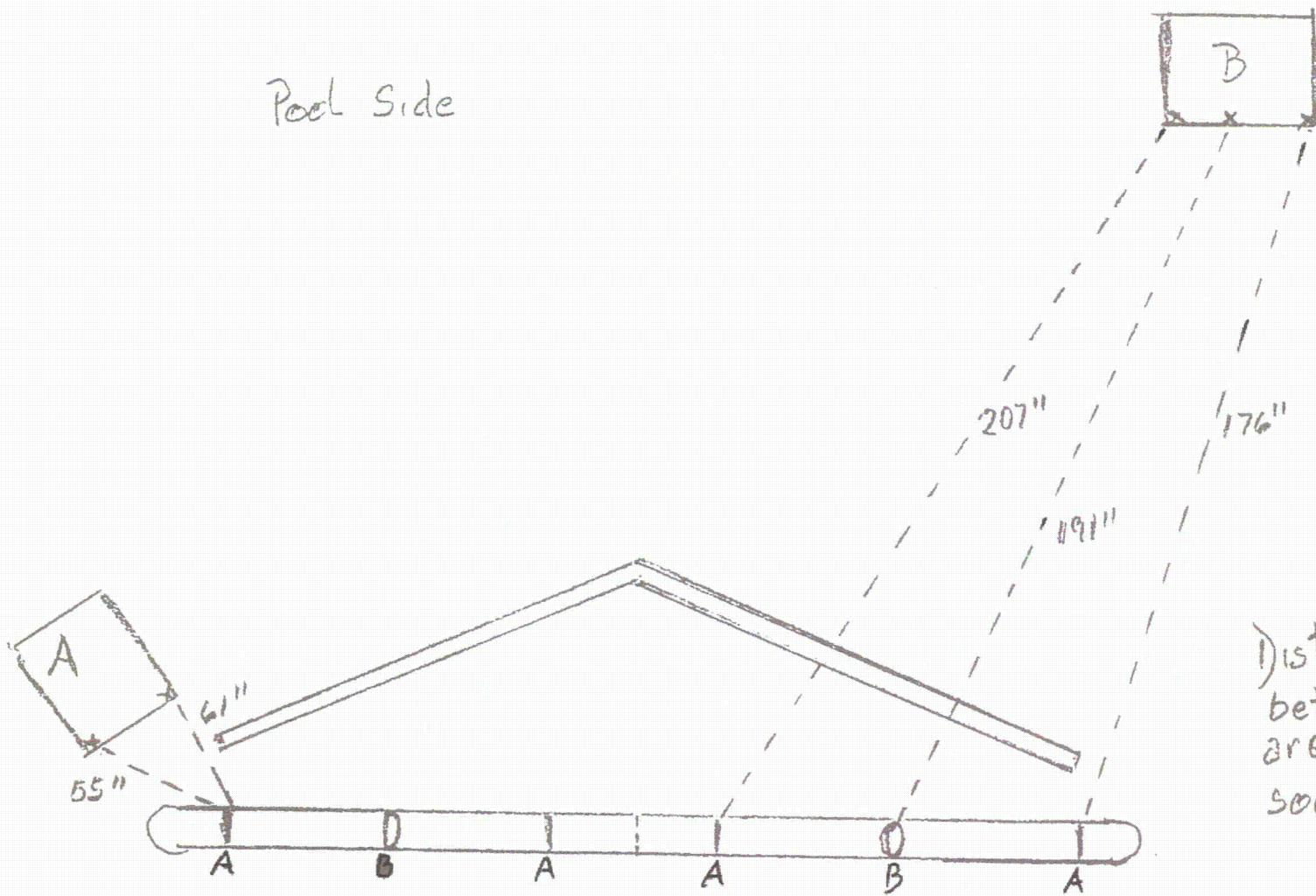


Figure 4 –AREA B WITH DOSIMETER PLACEMENTS

Pool Side



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:

Total:

Average:

CV%:

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 | 7.64 |
| 2 | 081592 | End: 79942.53 | 2 | 104.40 | |
| 3 | 081761 | Total: 13.38 | 3 | 97.50 | |
| 1 | 081825 | Start: 79942.53 | 1 | 105.70 | 7.16 |
| 2 | 081494 | End: 79957.88 | 2 | 112.50 | |
| 3 | 081556 | Total: 15.35 | 3 | 111.40 | |
| 1 | 082163 | Start: 79958.74 | 1 | 104.70 | 7.35 |
| 2 | 082043 | End: 79972.91 | 2 | 109.80 | |
| 3 | 082154 | Total: 14.17 | 3 | 97.90 | |
| 1 | 081784 | Start: 79972.91 | 1 | 105.30 | 6.99 |
| 2 | 082056 | End: 79987.60 | 2 | 103.30 | |
| 3 | 082146 | Total: 14.69 | 3 | 99.40 | |
| 1 | 081809 | Start: 79987.60 | 1 | 104.10 | 7.33 |
| 2 | 081765 | End: 80001.63 | 2 | 103.90 | |
| 3 | 081618 | Total: 14.03 | 3 | 100.40 | |
| 1 | 081915 | Start: 80001.63 | 1 | 99.80 | 7.31 |
| 2 | 082487 | End: 80015.75 | 2 | 104.50 | |
| 3 | 082474 | Total: 14.12 | 3 | 105.40 | |
| 1 | 082412 | Start: 80015.75 | 1 | 106.30 | 7.41 |
| 2 | 081920 | End: 80030.02 | 2 | 101.80 | |
| 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:

Total:

Average:

CV%:

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 | | |
| 2 | | End: | 2 | | |
| 3 | | Total: 0.00 | 3 | | |

Page #:

Total:

Total:

Average:

CV%:

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 | 1.22 |
| 2 | 082402 | End: 80002.35 | 2 | 89.80 | |
| 3 | 082372 | Total: 73.20 | 3 | 88.90 | |
| 1 | 082480 | Start: 80002.35 | 1 | 38.97 | 1.29 |
| 2 | 081555 | End: 80032.67 | 2 | 39.17 | |
| 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 | | |

Page #:

Total:

Total:

Average:

CV%:

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: $\pm 3.34\%$

Source Decay: -0.25% (per week)

Intercomparison Variability: N/A

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

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

Dolly

Variability from density variation: $\pm 3.42\%$

Source Decay: -0.25% (per week)

Intercomparison Variability: N/A

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

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

Area B

Variability from density variation: $\pm 3.66\%$

Source Decay: -0.25% (per week)

Intercomparison Variability: N/A

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

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

Ceiling

Variability from density variation: $\pm 2.78\%$

Source Decay: -0.25% (per week)

Intercomparison Variability: $\pm 4.1\%$

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

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

STERIS®



ATTACHMENT 3



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 $\pm 5.1\%$ 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 $\pm 5.1\%$ 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 ($\pm 6.5\%$) 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,

A handwritten signature in blue ink, appearing to read "Scott Comstock".

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



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