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**

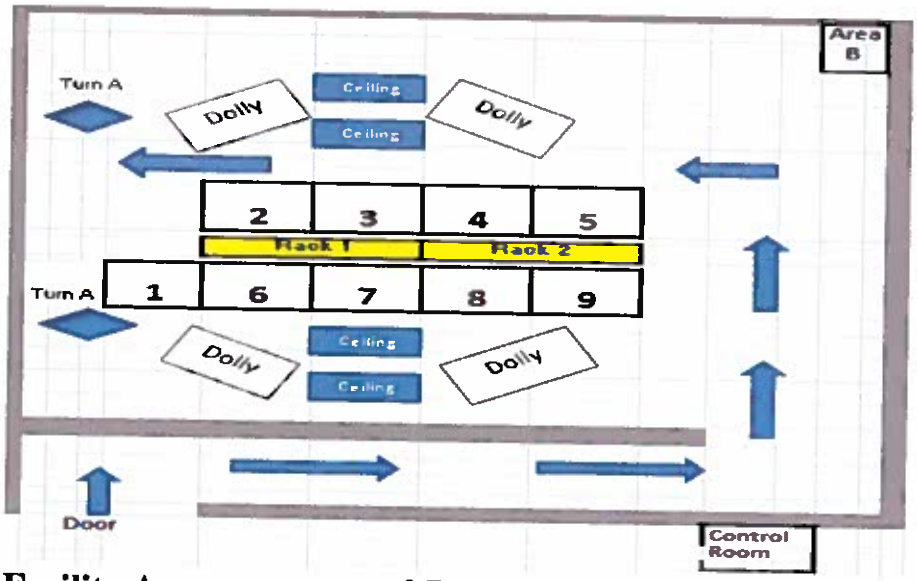
The Whippany irradiator is primarily utilized for the sterilization of single -use medical devices and supplies, and/or the processing of other materials, such as consumer goods and packaging materials. The Whippany facility utilizes Cobalt – 60 isotope as a source to provide this service. Cobalt -60 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. 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.
3. 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.

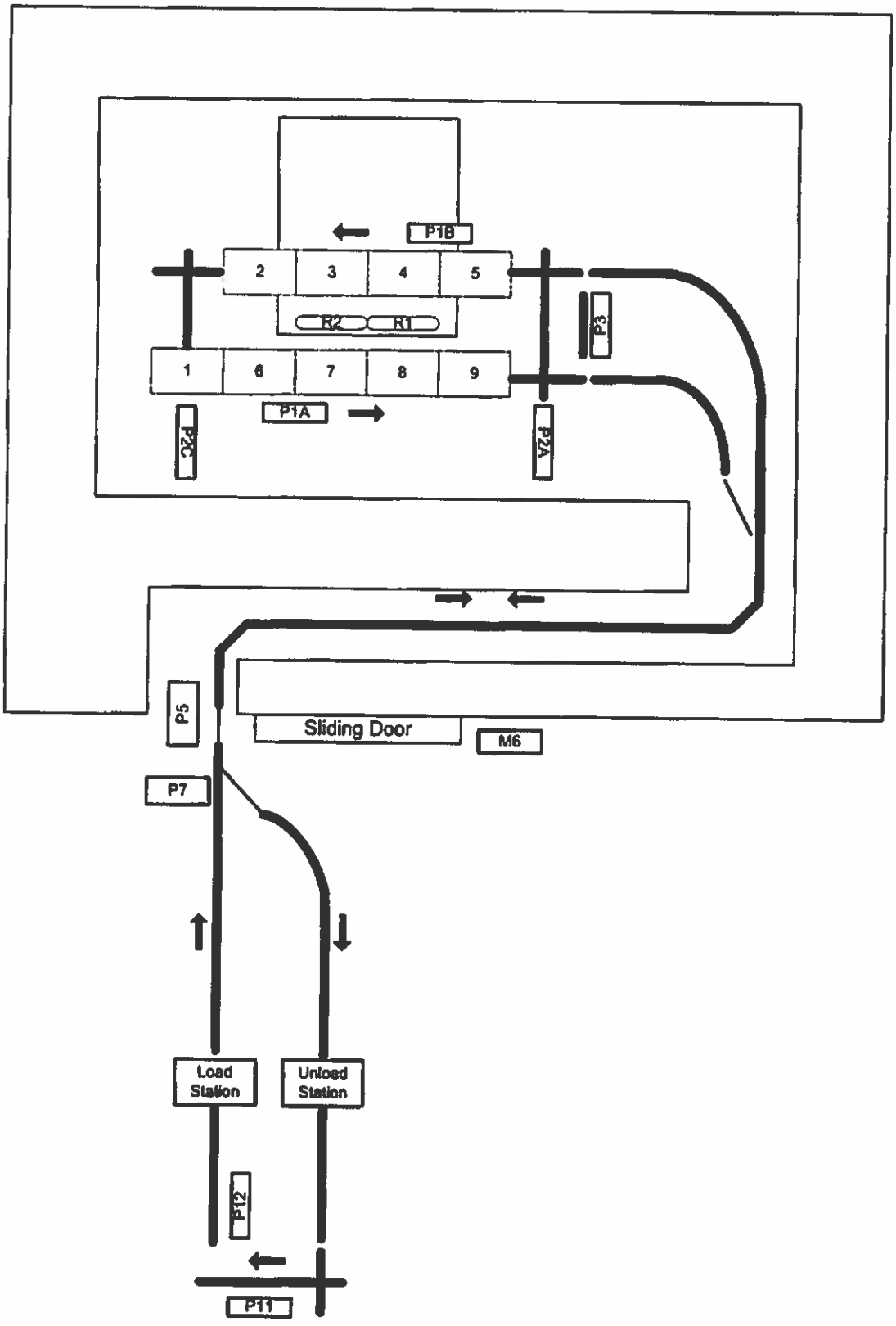
- **Isomedix Contact Information**

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

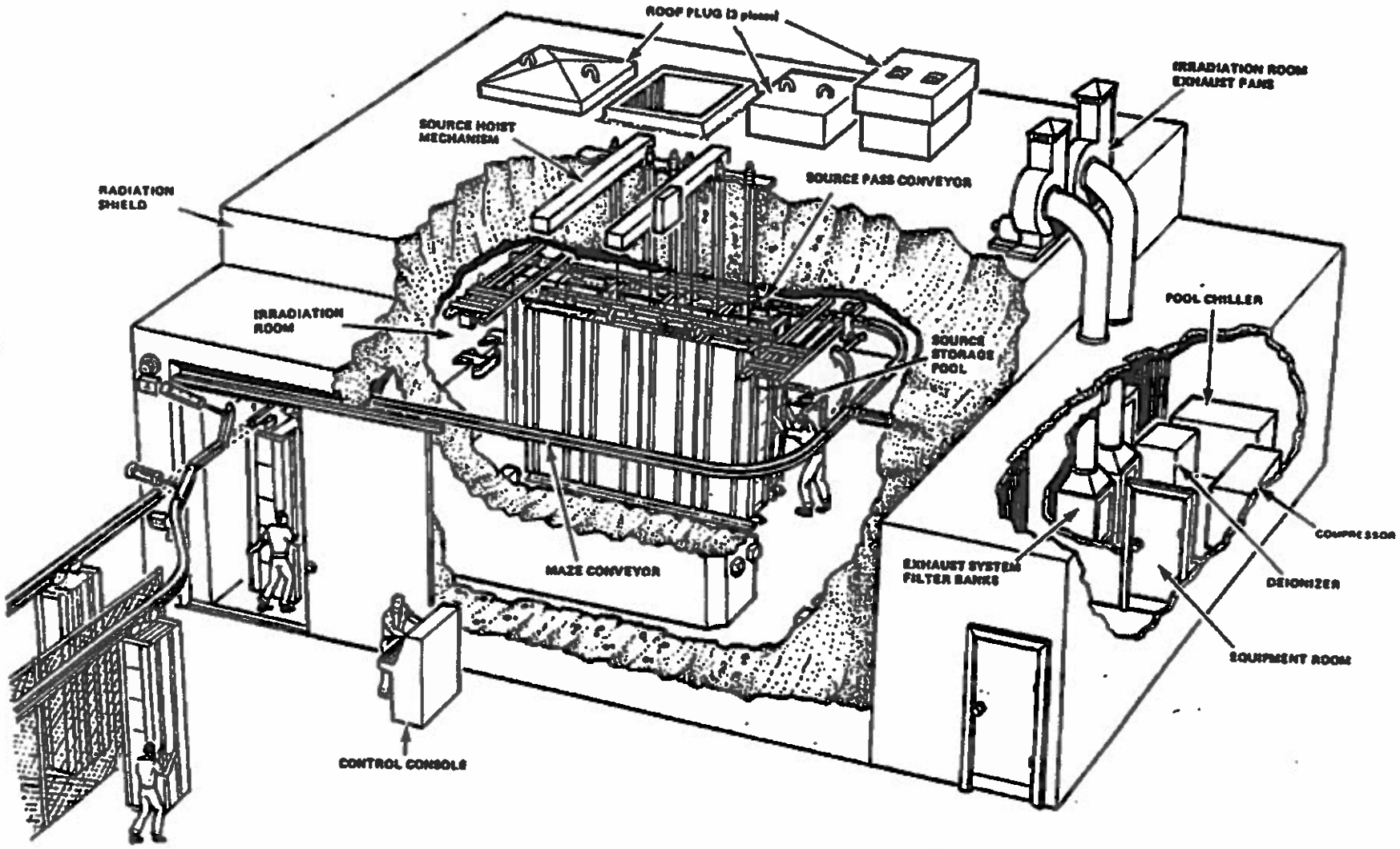
- **Referenced Attachments**

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



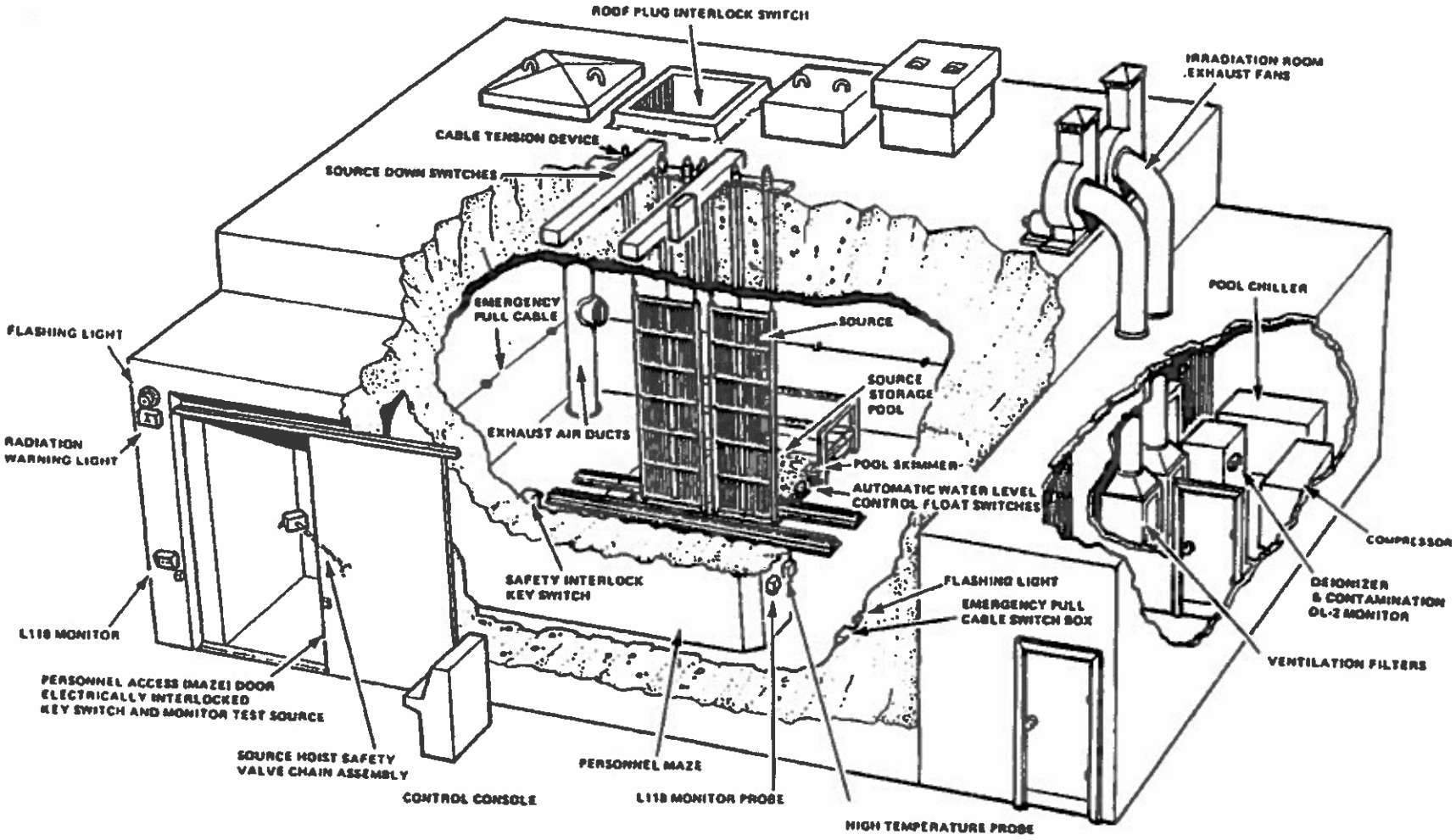
Attachment 2



GENERAL LAYOUT

FIGURE 2-1

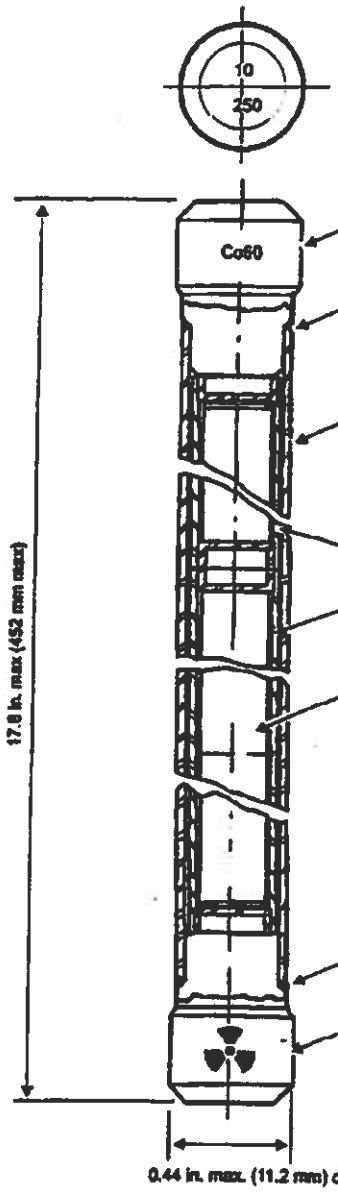
Attachment 3



SAFETY FEATURES

FIGURE 2-6

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-185
9.	C-177/AC-339
10.	AC-191/AC-195
11.	AC-191/AC-339
12.	AC-185/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. G130182-177
IN533 1393 C188

REVISED FEB 00 | DCN A-1688-0-01A

DATE FEB 87

DRAWN | CHECKED | APPROVED

No. C-188

ISSUE 17

SHEET 1 OF 1

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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

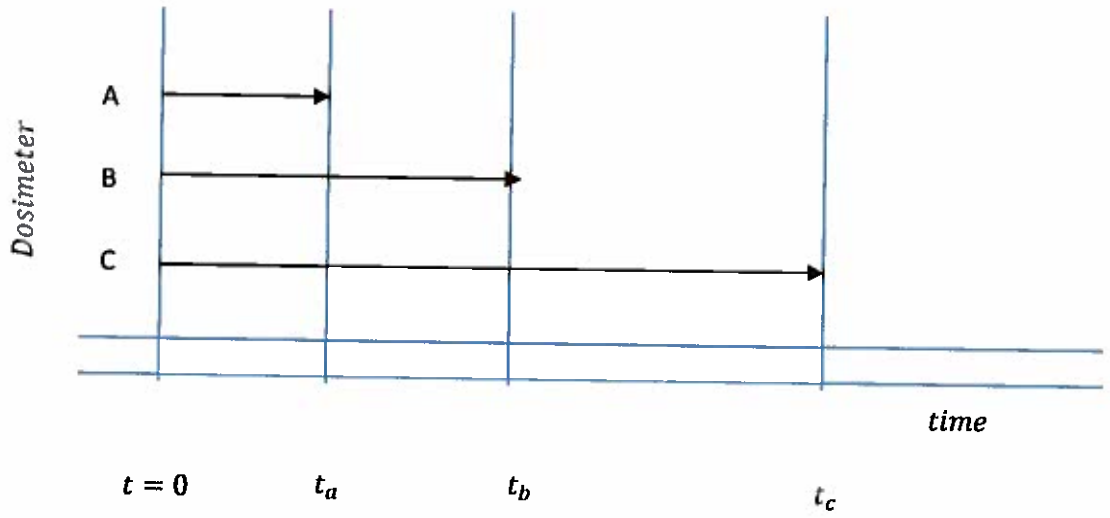
Uncertainty (of measurement) – parameter, associated with a measurand or derived quantity, that characterizes the distribution of values that could reasonably be attributed to the measurand or derived quantity.

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.

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

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:

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

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.

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

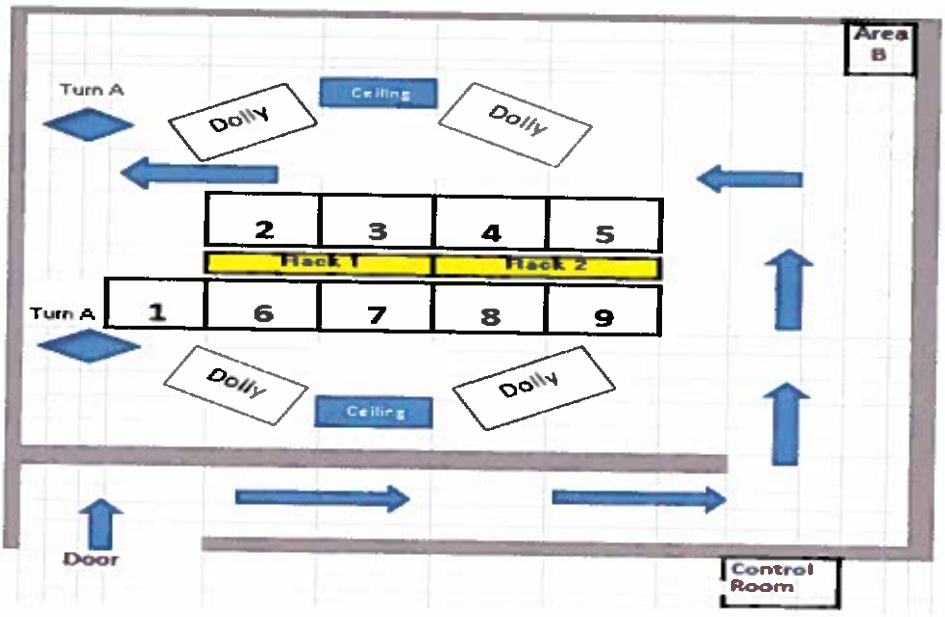
Conservatively, a value for the cumulative time ratio of 1.500 was chosen.

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:

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

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.

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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.

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: