

Radiation Equipment Qualification Information Exchange

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STERIS Isomedix Services

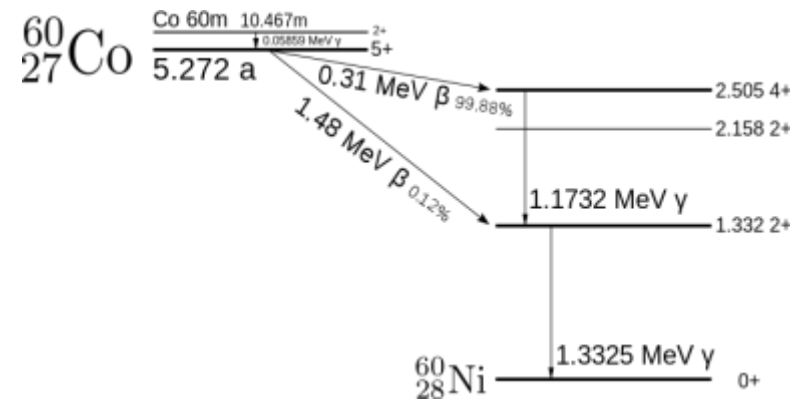
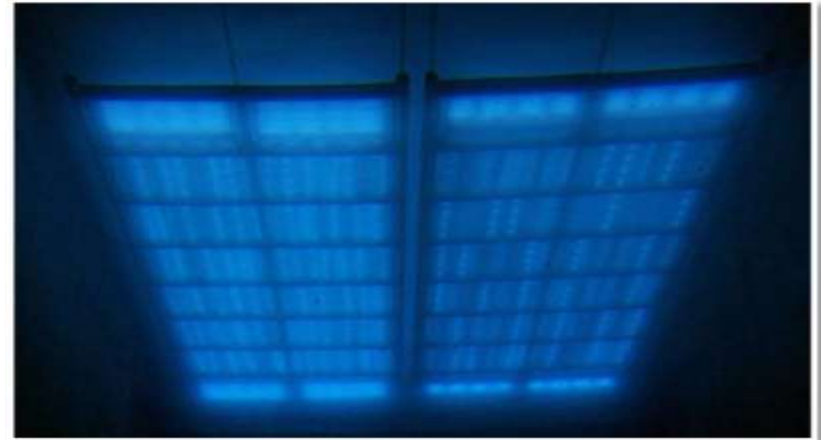
STERIS Isomedix Services

- Contract Sterilization of Single-use Medical Devices
 - (9) Ethylene Oxide Gas locations
 - (12) Cobalt-60 Irradiator locations
- Radiation sterilization provides a cost effective means to reduce microbial loads on pre-packaged goods



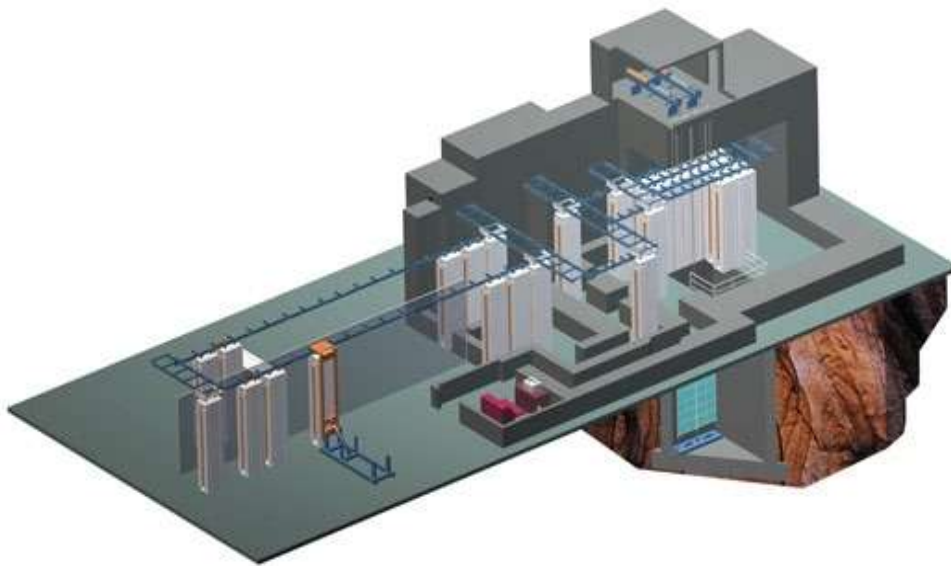
Cobalt-60 Isotope

- Medium life Isotope
 - 5.2714 year half-life
- Effective penetrating energies
- Induced radiation cannot occur through the use of Cobalt-60



Highly Efficient Use of Isotope

Carrier or Tote systems used to present large volumes of finished goods around cobalt-60 source

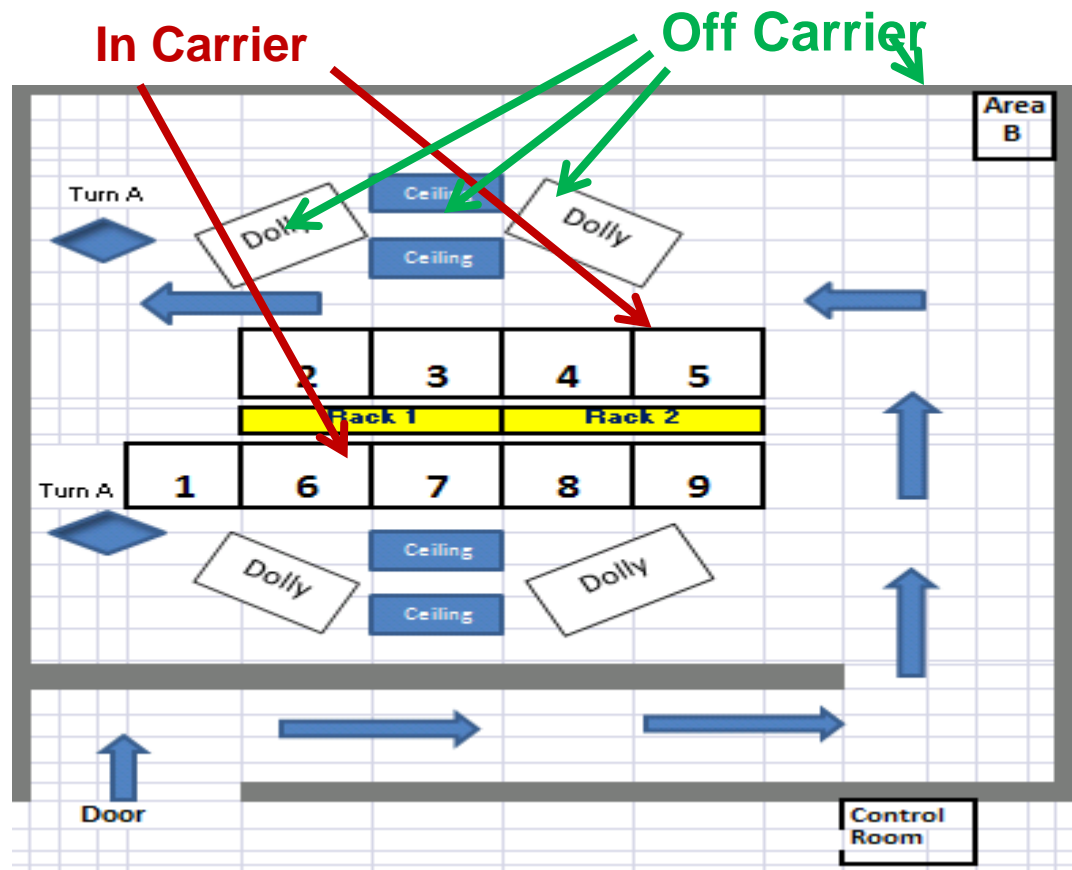


Source of Photons for Radiation EQ's

- Increased requests for STERIS Isomedix to provide gamma photons for component EQ testing
- Decreasing suppliers for EQ radiation exposures
 - Homeland Security Compensatory Challenges
 - Academic institutes closing programs
- “Off-Carrier” opportunities
 - Long exposure times/dose-rates prohibit use of carrier/tote systems



Whippany, NJ Off-Carrier Locations



Measuring Total Ionization Dose

- Dosimeters
 - Pro: allow for direct measurement
 - Cons:
 - 500 kRad (5 kGy) to 5000 kRad (50 kGy)
 - Dose-rate dependency
- Time (dose-rate x time)
 - Pro: allows for wider dose-ranges
 - Cons:
 - Dose-rate variability
 - Long exposures influenced by isotope decay



April 2014 NRC Inspection

Summary of Nonconformance 99901145/2014-201-01

On April 3, 2014, Steris was audited by the US NRC, Electrical Vendor Inspection Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors . From an outcome of the inspection:

(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.*



Density Challenges

- Finding #1:

*... failed to account for the **density** of other product placed into the irradiation chamber...*

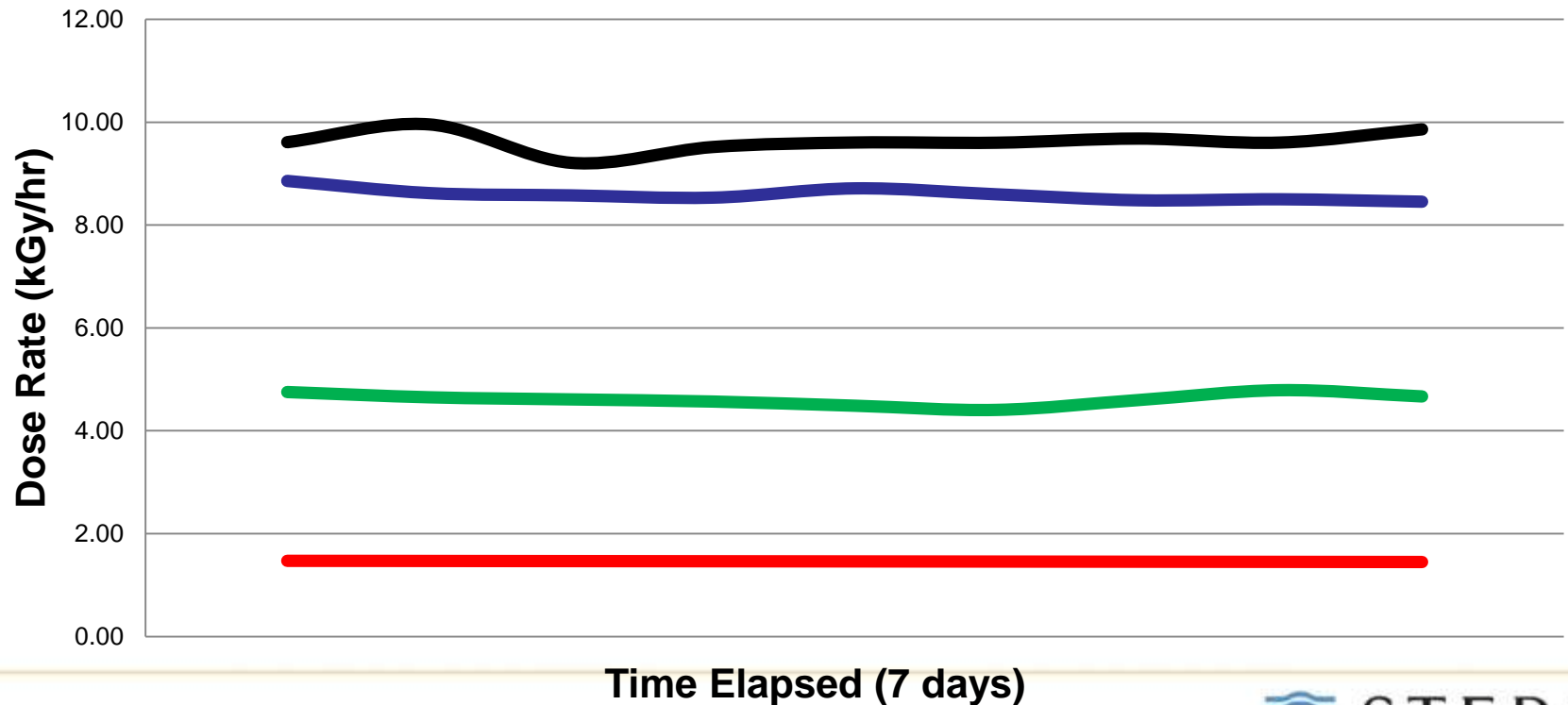
- Issue:

- Carrier densities influence dose-rates due to shielding in photon path

Action: Characterizing Carrier Densities

Based on the cyclical nature of the “On-Carrier” Customers; STERIS assessed density variations and the dose-rate impact on “off-carrier” locations by determining the dose rates over the course of 7 days:

Whippany Off-Carrier Dose Rates



— Dolly — Ceiling — Turntable — Area B

Density Challenge Result

- Based on study results, the worst-case on-carrier shielding effect on dose rate is -4.9% at a 95% confidence level.

Source Decay

- Finding #2:

... *failed to account for the ...*
source decay ...

- Issue:

- For long-term irradiations, dose-rates should account for the Cobalt-60 decay

Source Decay Result

Cobalt Half-Life (Days):
Original Cobalt Activity

1925
100

	Actual kGy/hr	Unadjusted kGy/hr	Actual kGy/day	Unadjusted kGy/hr	Dose Error
0	100.0000	100	2400	2400	0.000%
1	99.9640	100	2399.136	2400	0.018%
2	99.9280	100	2398.272	2400	0.036%
3	99.8920	100	2397.409	2400	0.054%
4	99.8561	100	2396.546	2400	0.072%
5	99.8201	100	2395.683	2400	0.090%
6	99.7842	100	2394.82	2400	0.108%
7	99.7483	100	2393.958	2400	0.126%
8	99.7124	100	2393.096	2400	0.144%
9	99.6765	100	2392.235	2400	0.162%
10	99.6406	100	2391.374	2400	0.180%
11	99.6047	100	2390.513	2400	0.198%
12	99.5688	100	2389.652	2400	0.216%
13	99.5330	100	2388.792	2400	0.234%
14	99.4972	100	2387.932	2400	0.252%
15	99.4613	100	2387.072	2400	0.270%
16	99.4255	100	2386.213	2400	0.287%
17	99.3897	100	2385.354	2400	0.305%
18	99.3540	100	2384.495	2400	0.323%
19	99.3182	100	2383.637	2400	0.341%
20	99.2824	100	2382.778	2400	0.359%
21	99.2467	100	2381.921	2400	0.377%
22	99.2110	100	2381.063	2400	0.395%
23	99.1752	100	2380.206	2400	0.413%
24	99.1395	100	2379.349	2400	0.431%
25	99.1038	100	2378.492	2400	0.449%
26	99.0682	100	2377.636	2400	0.467%
27	99.0325	100	2376.78	2400	0.485%
28	98.9969	100	2375.924	2400	0.502%
29	98.9612	100	2375.069	2400	0.520%
30	98.9256	100	2374.214	2400	0.538%

The source decay bias of 0.538% is calculated as the cumulative effects of using a single dose-rate on Day 0 throughout a 30-day irradiation in which the source is decaying at a rate equal to the half-life of Co-60

Location

- Finding #3:

... *failed to account for the ...*
location *within the irradiation chamber.*

- Issue:

- Dose-rate dependent *PMMA* dosimeters are influenced by dose-rate;
- i.e. location within the off-carrier areas will have differing dose-rates that may effect dosimeter response

Action: Location

- There are three groupings of off-carrier locations which require dose-rate corrections (intercomparisons) for the *PMMA* dosimeters within the irradiator
- Of the three locations, the *Ceiling* area was not corrected on a consistent basis
 - In use prior to 2007 with proper corrections
 - Began reuse in 2012 without proper corrections

Ceiling Location Challenge Result

- Based on historical intercomparison reference data, the intercomparison variability has a budget of $\pm 1.3\%$ for the Ceiling location.

Summarized Results

Turntable

- Variability from density variation: $\pm 4.9\%$
- Source Decay: -0.538%
- Intercomparison Variability: N/A
- Total Variation_{month} = $0.0491 + 0.00538 = 5.4\%$

Dolly

- Variability from density variation: $\pm 2.8\%$
- Source Decay: -0.538%
- Intercomparison Variability: N/A
- Total Variation_{month} = $0.0280 + 0.00538 = 3.3\%$

Area B

- Variability from density variation: $\pm 1.8\%$
- Source Decay: -0.538%
- Intercomparison Variability: N/A
- Total Variation_{month} = $0.0185 + 0.00538 = 2.4\%$

Ceiling

- Variability from density variation: $\pm 3.8\%$
- Source Decay: -0.538%
- Intercomparison Variability: $\pm 1.3\%$
- . *Total Variation*_{month} = $0.00538 + \sqrt{0.038^2 + 0.013^2} = 4.5\%$

Study Actions

- The most recent study (September 2014) indicates a worse-case variability 5.4% at 95% confidence level
- Corrected Certificates of Processing for past study efforts have been provided to those Customers who requested them as an outcome of the NRC findings
- Currently working with industry experts to further define and come to a reasonable best estimate

Study Actions

- A review of source rack activity shows a less than 3% difference in activity between the racks since 1984.
- Furthermore, each component has had its own independent dose rate study completed before it is processed.
- Therefore the recent dose rate variability study is expected to be worst-case representation of the variability for the lifetime of the Whippany facility.

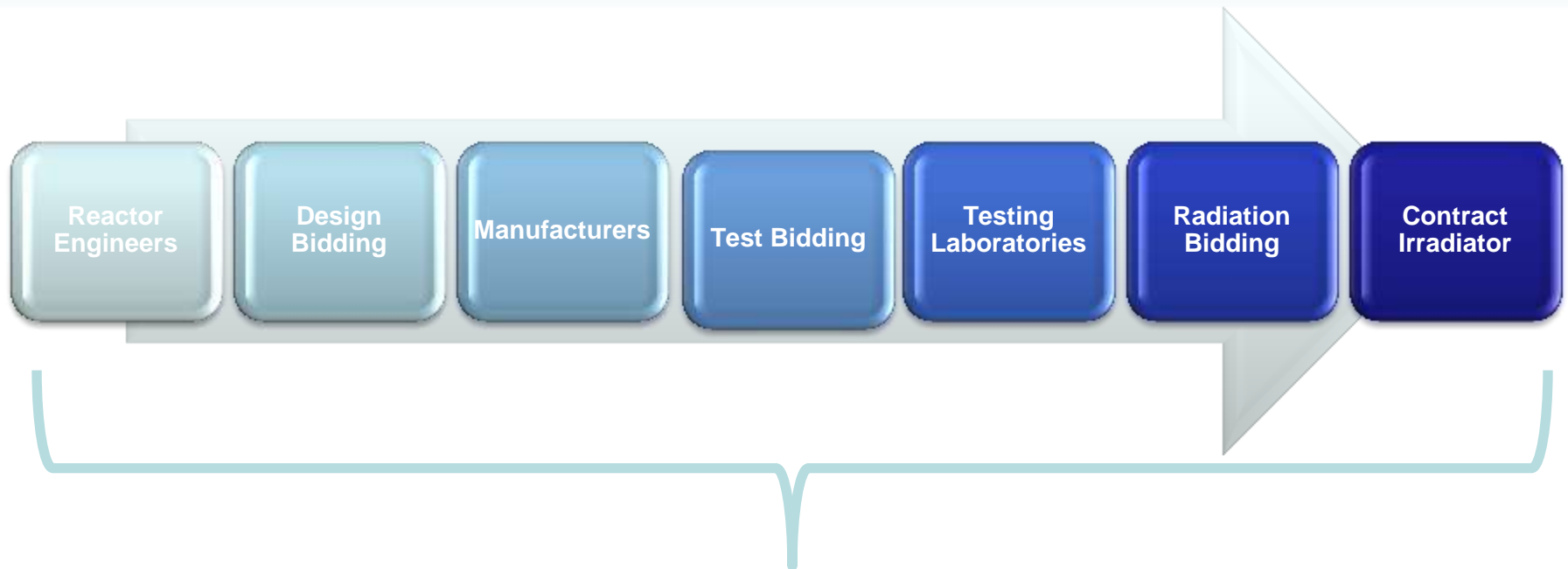
Other Continuous Improvement Actions

- Methodology Shifts: A historical review was performed on the procedural testing methods for EQ radiation applications. No shifts in the current methods have occurred from past efforts.
- Uncertainty statements have been added to the EQ submittal process to aid testing decision making requirements.
- Uncertainty statements have been added to the Certification documentation, as applicable.
- Exposure locations added to Certification documentation to aid in testing traceability.

Other Continuous Improvement Actions

- New validated forms determine dose rate and required processing times for operators
 - Forms account for source decay and dose rate shielding variability as a function of processing area
- Intercomparisons are now performed for the Ceiling area on a quarterly basis (May 2014 – present)
- Updated working procedures to reflect NRC findings

Design...to... Radiation Delivery



Opportunities for Standardization

Questions?