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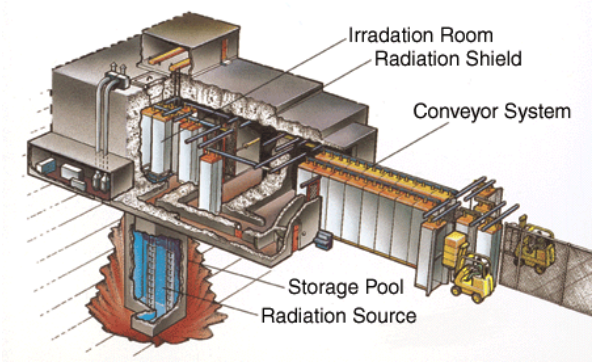
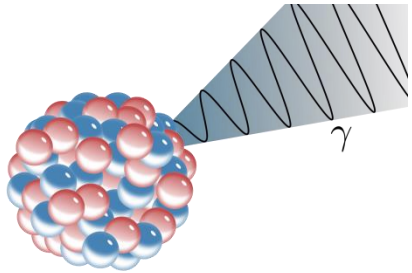
Steris Part 21 Impact on Qualification- Case Study Approach





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Bob Minadeo, ESG

Presentation Outline

- Problem Definition
- Areas for Evaluation
- Resolution Paths

Problem Definition and Implications

- Steris Part 21 impact on previous qualification: **M&TE Dosimetry Error & Variance Error**
- Part 21 driven by possible larger variability in non nuclear production carrier absorption than measured
  - Required radiation dose may not have been achieved
  - Dose effects on materials needed to support the larger qualification effort including accident simulations
- Could invalidate the EQ testing program results
- Clients must evaluate re-performing qualification program or demonstrating previous test results remain adequate via analysis per NUGEQ position paper and beyond, as discussed herein.

Margin Inherent in Most Applications

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- Radiation certs include standard statements of accuracy based on enveloping worst-case application of dosimetry and conditions of measurement.
  - Dosimeter Accuracy can be refined
  - Facility Variance can be refined
  - Refinements provide case-specific assessments of delivered dose for that project.
- In many applications sufficient margin exits to meet dose requirements

Typical Specimen and Multiple Dosimeters

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Dosimeters

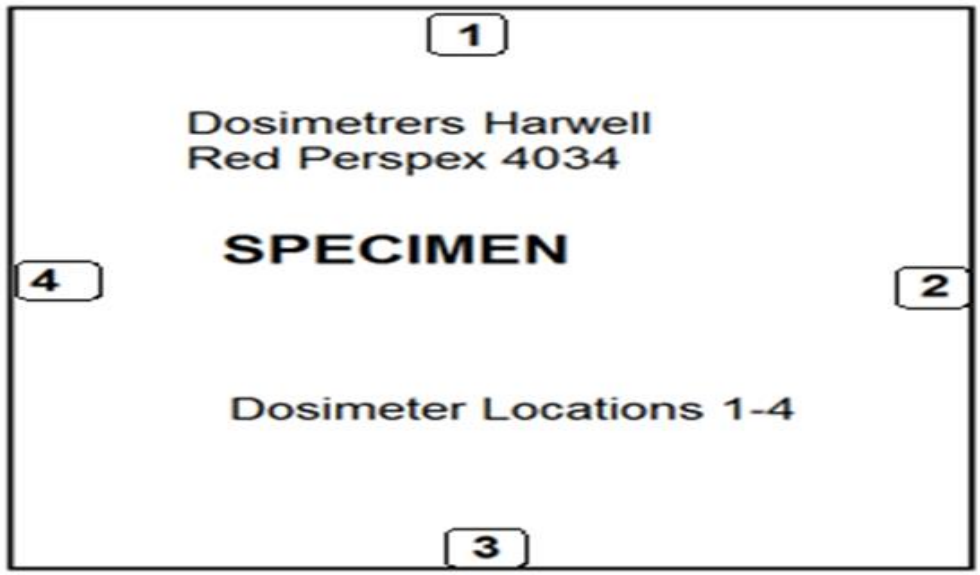

Figure 2: Dosimeter Placement

Dosimeters

Specimens may have multiple dosimeters. Bulk items are different than component specimen assemblies as far as how to address multiple dosimeters.

Multiple Dosimeters

- Depending on the type of specimen, multiple dosimeters may provide statistical basis for accuracy improvement.
- For bulk items, materials, cable, & items with identifiable weak links, SPECIFIC dosimeters or combination (SRSS) of dosimeters may be applied. Example: coil of cable
- For component with specific critical items, dosimeter(s) applicable to critical/most sensitive item may be applied. Example: valve assembly with critical soft seat
- Worst-case dosimeter may be applicable if entire specimen must be represented and no critical item can be identified. Example: MCC

NOTE: This worst-case method is the standard reporting method for radiation facilities per their 10CFR50 App. B QA requirements and M&TE controls.

Harwell Perspex 4034 Dosimeter

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- Fabricated from radiation sensitive polymethylmethacrylate (PMMA)
- Darkens when irradiated, so absorbed rad dose measured optically by Spectrophotometer
- Published error for each dosimeter is 6.5% (+/-).
- Published accuracy is applicable for use of dosimeter over the rated range of conditions which include numerous factors.

Factors Affecting Harwell Perspex Accuracy

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- Total dose applied (0.5 to 5 Mrads)
- Dose rate of radiation (any)
- Temperature of irradiation environment (-20 to 60°C)
- Temperature difference between irradiation and readout
- Time between irradiation and readout (0 to 6 months)
- Humidity level at readout (0 to 100% RH)
- Thickness of specific dosimeter chip (3mm, +/- 0.55mm)
- Visible light intensity/duration before readout
- Sensitivity variation within any given batch (Coefficient of variation of specific absorbance measurements on dosimeters for the batch, simultaneously irradiated together, in a gamma radiation field uniform within +/- 1%, is 2%)
- Shelf Life Time (0 to 10 years) and Temperature (ideally, 20°C +/- 5°C)

Facility Layout: Steris Whippany

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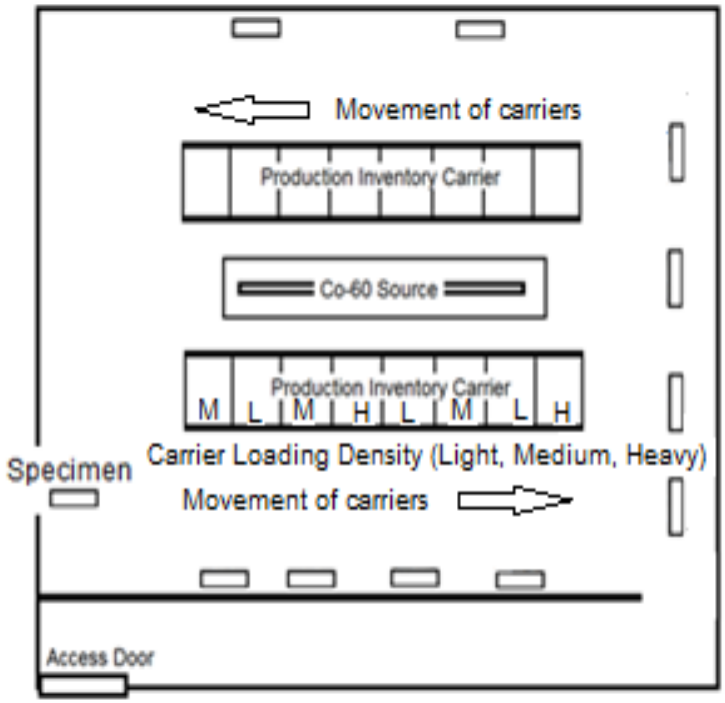
- Specimen locations are typically outside of production carrier path or in overhead.
- Carrier loading varies in loading density and absorption of rad dose (+/-5.1%)*.
- Initial dose rate run is a snapshot of the configuration at that time. Typically, first 1-3 Mrads for 1-2 hours.
- Total dose is applied in several increments with carriers repositioned. Variance applies to each subsequent increment dose rate.
- Initial dose rate from dose rate run reflects zero variance in carrier absorption of gamma radiation, as actual dose is measured.
- Subsequent dose rates may vary due to movement of carriers affecting radiation absorption.
- Total dose is calculated based on initial dose rate run.

***per Steris official calculations**



Steris Radiation Hot Cell

Possible Approaches

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- Assess dosimeter accuracy
  - SRSS statistical analysis error reduction for use of multiple dosimeters
  - SRSS applicable to evaluate dosimeter uncertainty effects (time accuracy, RH, temperature, total dose, dose rate, shelf life, batch uniformity, thickness verification, etc.)
- Assess impact of variance
  - Number of rad segments
  - Variance of carrier (+/- 5.1%) for each time segment after dose rate run
  - Zero variance baseline for dose rate run
  - SRSS for combined error for cumulative runs after dose rate run
- Relate to plant application and/or applicable IEEE standard for qualification

Calculations

- For Dosimeter Error (DE) effects:
  - E_{total} = SRSS (individual RANDOM errors, where $DE_{total} = ([\Sigma DEn]^{1/2}) / n$ where DEn represents the error associated with each of the various error terms shown on the earlier slide.
- For Variance effects:
  - Dose rate run is represented by actual measured dose with zero variance
  - Subsequent dose runs are represented by application of +/- 5.1% for each run.
  - If the elapsed time of each subsequent run is considered a random variable then the dose rate for each run can be calculated based on delivered dose = dose rate x time. With time random, then the subsequent dose delivered for subsequent runs is: $V_{total} = [\Sigma Vn]^{1/2} / n$ where Vn is the variance of each run (+/- 5.1%). So, $V_{total} = \{[n * (5.1\%)^2]^{1/2}\} / n$.
  - As a rough approximation, for Steris, a production segment might typically average 1-3 hours. Qualification specimens usually receive between 0.5 and 1.0 Mrads/hour, so each radiation segment is approximately 2MRads. These assumptions can be verified per the rad cell operator log on request. For an exposure requiring 10 subsequent segments, variance is reduced to +/-1.6%. 1.1% total variance for 20 runs, etc.
- For $E_{total} + V_{total}$, use SRSS again: $E_{total} = [DE_{total}^2 + V_{total}^2]^{1/2}$

Resolution

- Radiation requirement (RD) for rad facility typically includes dosimetry error allowance (DEA), or rad facility calculated allowance and added it to requirement for their target dose (TD).
- Based on calculations, total dosimeter error DE was X%.
- Total variance (V) was Y%.
- Therefore, the nominal reported radiation dose must be reduced by $(X^2 + Y^2)^{1/2} = Z\%$
- If TD - RD > Z, then specimens met the required radiation dose.
- Document calculations as technical reference.

Additional Statistical Investigation?

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- If this methodology presented supports existing qualification, requirement is satisfied.
- Further statistical approaches may identify other margins inherent in the application
  - Define a shape function of the random distribution
  - Application of Monte Carlo simulations to fine tune error and uncertainty
  - Methods may better quantify the Perspex 4034 dosimeter error for the Steris application

Questions

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