

High-Dose Sterilisation Effects on Photopolymer Materials: Gamma, Electron Beam, Chemistry and Requalification

Separating sterilisation process validation from material compatibility and requalification of the printed device state

Juan Segurola

3Dresyns by Resyner Technologies S.L.

© 2026 Juan Segurola. All Rights Reserved.

Correspondence: info@3Dresyns.com · www.3Dresyns.com

ER-388 · Engineering Review · Version 0.1 · 5 October 2026

Abstract

Radiation sterilisation is controlled by absorbed dose, dose distribution and process validation, but product qualification adds a separate question: whether the printed polymer and assembled device retain required performance after the intended sterilisation history. Gamma, electron beam and X-ray can produce similar bulk dose while differing in penetration and dose-rate characteristics. Polymer response can include chain scission, crosslinking, oxidation, colour change, modulus drift or loss of elongation, and those responses may depend on package atmosphere and ageing after irradiation. ER-388 therefore does not select a sterilisation route; that comparative decision remains outside its scope. Instead it defines how to requalify a photopolymer material or device after a declared radiation process using pre/post chemistry, thermal and mechanical evidence tied to functional requirements. [1-4]

Keywords: radiation sterilisation; gamma; electron beam; X-ray; photopolymer; material compatibility; requalification

1. Two independent qualifications are required

A validated sterilisation process establishes delivery and control of the required radiation dose. Material compatibility establishes that the device remains fit for use after that process. ISO 11137 governs the first problem; material-compatibility guidance such as AAMI TIR17 addresses the second. [1-3] ER-388 is concerned with the second while preserving the sterilisation-process context.

2. Dose distribution and product geometry

Sterilisation equivalence must distinguish microbial lethality from material equivalence. Gamma and electron beam can deliver the same absorbed dose while imposing very different dose rates, oxygen histories and temperature profiles. A 2024 polypropylene study compared e-beam dose rates on the order of 10^4 kGy/h with gamma irradiation at 8 and 0.08 kGy/h, and showed that changes in properties depended strongly on dose rate; high-dose-rate gamma and e-beam responses were more similar than low-dose-rate gamma under the tested conditions. The material is not a photopolymer, but the result is direct evidence that modality cannot be compared by total kGy alone. [1-5]

For printed parts, manufacturing route adds another sensitivity. Chen et al. found 3D-printed polymers less stable than injection-moulded counterparts under the evaluated terminal sterilisation processes, with e-beam producing stronger oxidation/crosslinking signatures than vapour hydrogen peroxide. Their materials were HDPE and PA6 rather than VPP networks, so the numerical result is not transferable; the mechanistic lesson is that processing history can alter sterilisation response. [6]

Gamma, electron beam and X-ray differ in penetration and dose-rate characteristics. The material assessment therefore uses the product or a justified representative geometry and records the absorbed-dose range, not only a nominal target dose. Local dose extremes can control degradation in thick or shielded assemblies.

Table 1. Material requalification after radiation sterilisation.

Checkpoint	Before irradiation	After declared process
appearance/optical state	baseline colour, clarity or surface state	yellowing, haze, cracking or other visible change
network/thermal state	baseline chemistry and transition behaviour	evidence of scission, crosslinking or oxidation
mechanical function	property tied to device use	retained strength, strain, stiffness or seal function
dimensional/assembly state	critical dimensions and interface condition	warpage, fit or bond change

3. Source substitution is a comparability exercise

A qualification protocol should bracket the minimum and maximum delivered dose, not test only the nominal target. Dose mapping is needed for complex geometry because density and thickness can create spatial gradients. The worst-case location for sterility assurance may differ from the worst-case location for material damage, so both maps must be considered. [1-5]

Repeated sterilisation should be treated as cumulative ageing unless the device is explicitly single-use. Crosslinking, oxidation and chain scission can accumulate differently across cycles because the network and oxygen diffusivity have already changed. A second or third cycle therefore cannot automatically be represented by multiplying the first-cycle property loss. [1-6]

Recent studies comparing gamma, X-ray and electron beam show that many polymers can respond similarly at equal dose, but source-dependent differences occur for some materials and properties. [4] ER-388 therefore allows source substitution only after the property set relevant to the device has been compared; equal dose is not by itself proof of equivalence.

4. Package atmosphere and post-irradiation ageing

Oxidative reactions can continue after irradiation while trapped radicals decay. The time between sterilisation and test is controlled, and packaged atmosphere is documented when oxygen access can affect chemistry. Accelerated shelf-ageing is kept separate from the immediate sterilisation effect.

5. Repeated sterilisation or reprocessing

The post-sterilisation measurement set should be function specific. Mechanical devices require modulus, strength, elongation and fracture or fatigue metrics; fluidic devices need dimensional and leak integrity; optical devices need transmission and colour; biological-contact devices may require extractables or surface chemistry. Tg and DMA can reveal network changes that are hidden by a single room-temperature tensile test. [1-6]

Conditioning time after irradiation should be controlled because trapped radicals and post-irradiation oxidation can continue after the beam stops. Testing immediately and after a defined ageing interval can separate instantaneous radiation effects from subsequent oxidative change. Packaging atmosphere and oxygen permeability belong in the test state for the same reason. [1-6]

If the use case includes more than one radiation cycle, cumulative dose and interval are tested explicitly. A single-cycle qualification is not extrapolated to repeated sterilisation because network changes can accumulate nonlinearly.

Table 2. Requalification triggers.

Change	Why it matters	Minimum action
radiation source	penetration and dose-rate distribution change	comparability study on critical properties
dose range	chemical and mechanical drift can be dose dependent	extend dose-response evidence
material formulation or post-cure	radical chemistry and network state change	repeat compatibility qualification
package atmosphere or geometry	oxygen access and dose distribution change	targeted chemistry/function assessment

6. Scope boundary with ER-042 and ER-387

ER-388 does not choose the preferred sterilisation technology. ER-042 addresses dimensional effects and qualification gaps for vat-printed photopolymers after defined sterilisation/disinfection workflows; it does not establish comparative route selection. Radiation ageing mechanisms and cumulative service exposure belong to ER-387. ER-388 closes the material/device compatibility question for a declared high-dose gamma or electron-beam sterilisation process.

7. Outcome

A sterilisation compatibility study should preserve traceability between each specimen and its dosimetry. Pooling specimens from different positions in a carrier can obscure dose-response relationships when the delivered dose varies spatially. Individual or position-resolved dose records make it possible to distinguish random material scatter from true radiation dependence. [1-6]

Where sterilisation is followed by washing, hydration or incubation, the complete post-sterilisation workflow should be included before final property testing. Radiation can change extractability and water uptake, so testing a dry sterilised coupon may not represent the state of a device used in aqueous conditions. [1-6]

Mechanical testing should include the property most sensitive to embrittlement. Tensile strength can remain acceptable while elongation or fracture energy falls sharply. For snap fits, flexible hinges or seals, cyclic and deformation-to-failure metrics may therefore be more relevant than static strength. [1-6]

Optical photopolymers require spectral rather than visual inspection. Small absorption bands or haze changes can compromise optical components without obvious discoloration. Paired pre/post spectra on the same geometry reduce specimen-to-specimen noise. [1-6]

If sterilisation is outsourced, process-change control should define which supplier changes require bridging. Source type, dose rate, carrier configuration and packaging can all alter the material exposure even when the nominal sterilisation standard remains the same. [1-6]

The qualification conclusion should state the tested number of cycles and shelf-life condition explicitly. A material that passes one irradiation and immediate testing should not be represented as validated for repeated reprocessing or long-term storage unless those states were included. [1-6]

Acceptance means that the tested printed and assembled state retains all declared critical functions across the validated dose window. Sterility assurance and material compatibility remain linked but separately evidenced decisions.

8. Functional equivalence is device-specific

Functional equivalence should be defined before choosing the sterilisation route. A dimensionally critical fluidic component may fail because of warpage while a flexible component fails because of embrittlement; the same radiation-induced chemistry can therefore have different acceptance consequences. [1-6]

Dose mapping should include dense or filled regions that can alter attenuation. A homogeneous coupon placed beside the device may not represent the absorbed-dose distribution in a thick, filled or metal-containing assembly. [1-6]

Sterilisation validation and material compatibility should share the same worst-case configuration where possible. The location receiving the minimum microbiocidal dose and the location receiving the maximum material dose can be different, so a single witness coupon cannot necessarily cover both. [1-6]

Post-sterilisation ageing should reflect shelf life. Radiation-generated species can continue to react during storage, and a device released immediately after sterilisation may not have the same properties at end of shelf life. Accelerated ageing can be useful only if it does not introduce a different degradation mechanism. [1-6]

Repeated sterilisation requires cumulative dose accounting and independent functional checks. If reprocessing is permitted, the maximum number of cycles should be qualified rather than extrapolated from one cycle by linear multiplication. [1-6]

Chemical indicators or dosimeters used for process validation should not be confused with material-state indicators. A correct delivered dose confirms the sterilisation process, not preservation of polymer properties. Both evidence streams are required. [1-6]

The final record should distinguish 'sterilisable under this validated process' from a generic material label. Compatibility is conditional on formulation, print state, geometry, packaging, modality and dose distribution. [1-6]

Requalification is required when formulation, pigment, filler, thickness or packaging changes alter dose deposition or oxygen transport. A validated sterilisation window should state modality, absorbed-dose distribution, dose rate, temperature, atmosphere, number of cycles and the property acceptance envelope. It should not be expressed as a generic claim that a resin is 'gamma compatible' or 'e-beam compatible'. [1-6]

Where gamma and e-beam are proposed as interchangeable routes, bridging evidence should compare the same printed material at matched absorbed-dose ranges and relevant dose rates. Equivalent sterility assurance does not establish equivalent polymer chemistry. [1-6]

A change in tensile strength may be irrelevant to a rigid optical housing yet critical to a snap fit or flexible seal. Requalification therefore starts from device critical-to-quality attributes and chooses chemistry, thermal and mechanical tests that can explain loss of those attributes. Generic material panels are supplementary, not definitive, when the device geometry changes dose distribution or stress state.

Where a source substitution is proposed, the comparison includes the most sensitive identified property rather than only properties that were stable in the baseline process. This turns equivalence into a conservative challenge of the material state.

9. Minimum radiation-sterilisation compatibility record

Sterilisation compatibility should be evaluated at both the minimum acceptable sterilising dose and the maximum dose a product location can receive after process mapping. The material qualification window must cover that distribution, including repeated exposures if reprocessing is permitted. [1-6]

Packaging can change radiation chemistry by limiting oxygen and can also be a source of extractables or condensates. Testing loose coupons in air is therefore not equivalent to an assembled, packaged device. The final-package state should be introduced before the definitive compatibility study whenever feasible. [1-6]

Dose-rate comparability should be supported by chemistry or property trajectories, not asserted from one end-point mechanical test. FTIR oxidation markers, DMA/Tg and tensile or fracture metrics together can reveal whether gamma and e-beam reach similar end states through different kinetics. [1-6]

Dimensional metrology is particularly important for printed fluidic or mating components. Sterilisation-induced shrinkage, warpage or residual-stress release can cause functional failure even when material strength remains acceptable. Critical dimensions and leak/fit should therefore be part of the device-specific acceptance set. [1-6]

Biocompatibility evidence may need reassessment when irradiation changes residual species or surface chemistry. Material compatibility with a radiation process is not by itself a biological-safety conclusion, and the required evaluation depends on the device contact category and regulatory framework. [1-6]

The remaining evidence gap is direct gamma-versus-e-beam equivalence testing on well-characterised VPP photopolymer networks at clinically relevant sterilisation doses. Current polymer and AM studies justify the variables that must be controlled, but they do not establish a universal modality substitution rule for printed resins. [1-6]

Table 3. ER-388 reporting set.

Record	Minimum content
sterilisation process	source type, minimum/maximum absorbed dose, dose map or product-relevant dosimetry
product state	printed formulation, cure, cleaning, assembly and packaging atmosphere
test timing	interval after irradiation and any ageing/conditioning step
critical functions	pre/post results for properties tied to intended use
change control	explicit triggers for source, dose, formulation, package or geometry requalification

The report concludes separately on process dose conformity and material compatibility so that a successful material test cannot be mistaken for sterilisation-process validation, and vice versa.

References

1. ISO 11137-1:2025. Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
2. ISO 11137-3:2017. Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control.
3. AAMI TIR17:2024. Compatibility of materials subject to sterilization. Recognized by the U.S. Food and Drug Administration, recognition number 14-609.
4. Hasan MK, Staack D, Pillai SD, Fifield LS, Pharr M. Connecting radiation-driven changes in structural, thermal, and mechanical properties in several medical device polymers. *Polymer Degradation and Stability*. 2024;221:110677. doi:10.1016/j.polymdegradstab.2024.110677.

5. Suljovrujic E, Milicevic D, Stolic A, Dudic D, Vasalic D, Dzunuzovic E, Stamboliev G. Thermal, mechanical, and dielectric properties of radiation sterilized mesomorphic PP: Comparison between gamma and electron beam irradiation modalities. *Polymer Degradation and Stability*. 2024;229:110940. doi:10.1016/j.polymdegradstab.2024.110940.
6. Chen Y, Neff M, McEvoy B, Cao Z, Pezzoli R, Murphy A, Gately N, Hopkins M Jr, Rowan NJ, Devine DM. 3D printed polymers are less stable than injection moulded counterparts when exposed to terminal sterilization processes using novel vaporized hydrogen peroxide and electron beam processes. *Polymer*. 2019;183:121870. doi:10.1016/j.polymer.2019.121870.

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L.; ER-388 contains no comparative recommendation between commercial products.

Data availability

ER-388 is a literature-based engineering review; no new experimental dataset was generated.