

Change Control and Requalification of Photopolymer Materials and Processes: Equivalence, Risk and Evidence Depth

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Abstract

Change Control and Requalification of Photopolymer Materials and Processes is evaluated as the bounded decision of how much requalification evidence is required when a material, machine, process, post-process, inspection or supplier state changes. The controlled state comprises baseline configuration, proposed change, affected characteristics, risk hypothesis, bridging evidence, residual uncertainty and authorised disposition. For ER-293, the three cited sources are used only for the evidence roles stated below and only within their demonstrated scope. ER-293 defines measurements, transfer logic, failure modes and release gates specific to this subject; no universal process window, product recipe or compliance conclusion is inferred.

Keywords: change control; requalification; equivalence; risk; photopolymer process; configuration

1. Significance, scope and ownership

ER-293 owns how much requalification evidence is required when a material, machine, process, post-process, inspection or supplier state changes. The review is organised around the decision-specific evidence chain and leaves neighbouring ownership intact.

1.1. Corpus boundary

ER-293 does not own supplier controls or the digital record system itself. ER-291 supplies configuration lineage, ER-292 requirement traceability, and ER-294 supplier-quality evidence. This paper owns the decision on whether a material or process change is equivalent, what could be affected, and how much new evidence is required.

2. Subject-specific state model and causal chain

For ER-293, causal interpretation begins by freezing baseline configuration, proposed change, affected characteristics, risk hypothesis, bridging evidence, residual uncertainty and authorised disposition. The qualification question is causal: the changed attribute must be linked to plausible affected characteristics before a bridge can be judged sufficient.

3. Direct evidence and point-of-use source map

ISO 10007 treats change control as part of configuration management, ISO 9001:2026 provides current quality-management requirements, and ISO/ASTM 52920:2023 frames industrial AM qualification. ER-293 turns those principles into a risk-based photopolymer requalification ladder. Reference [1] is used for configuration change control. Reference [2] is used for quality-management change/governance requirements. In ER-293, reference [3] supplies the industrial additive-manufacturing qualification context used at this point.

4. Measurement architecture

The measurement architecture for ER-293 is built around change classification, affected-state map, equivalence evidence, bridge-test sensitivity, worst-case selection, residual-risk rationale and updated controlled records. The bridge set is selected from the affected characteristics predicted by the change, with equivalence criteria declared before comparing old and new states.

5. Qualification and transfer

A change bridge is sized to the predicted consequence and the sensitivity of the retained tests. If the existing evidence cannot detect the plausible effect, the change requires new qualification rather than a paper equivalence statement.

6. Failure modes and interpretation traps

The central interpretation trap in ER-293 is that same trade name or nominal specification is called equivalent; no affected-characteristic analysis is performed; a bridge test lacks sensitivity to the proposed change. Baseline, change definition, affected characteristics, bridge sensitivity and equivalence criteria remain non-compensatory so a favourable final test cannot erase an unexamined causal path.

7. Non-compensatory release gates

Gate	Minimum evidence	Blocking failure
Baseline	Old configuration frozen	Moving baseline
Change definition	Material/machine/process change explicit	Nominally same label
Affected characteristics	Causal map of plausible effects	No impact hypothesis
Bridge sensitivity	Tests detect predicted differences	Insensitive bridge
Equivalence rule	Predeclared comparison/acceptance	Similarity by eye
Evidence depth	Risk-matched full/partial requalification	One fixed test set
Residual uncertainty	Unresolved effects recorded	Unknown treated as unchanged
Approval	Disposition and expiry/change triggers recorded	Informal acceptance

8. Minimum verification experiment

For a real or simulated change, freeze the old/new configurations, list plausible affected material/process/part states, select tests that can detect those effects, compare against a predeclared equivalence rule and document the rationale for full, partial or no additional requalification.

9. Knowledge boundary

No universal taxonomy maps every photopolymer change to a fixed requalification depth. The needed evidence depends on causal consequence, detectability and the previously qualified state.

10. Conclusions

ER-293 makes equivalence a measured consequence of a defined change, with evidence depth proportional to plausible impact and detectability rather than to the administrative size of the change.

References

1. International Organization for Standardization. ISO 10007:2017 Quality management — Guidelines for configuration management. Geneva: ISO; 2017.
2. International Organization for Standardization. ISO 9001:2026 Quality management systems — Requirements. Geneva: ISO; 2026.
3. International Organization for Standardization and ASTM International. ISO/ASTM 52920:2023 Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing processes and production sites. 2023.

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