

Wavelength-Matched Process Control as a Prerequisite for the Post-TPO Photopolymer Transition

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Paper	Function	Main contribution
I	Framework	Material–Process–Workflow architecture for dental photopolymer biocompatibility
II	Industrial implementation	Production-scale case studies in hearing-device and dental photopolymer manufacturing
III	Audit methodology	Wavelength-matched post-cure audit for the post-TPO chemistry transition

Companion paper note

This article is the third paper in a three-part perspective trilogy on engineering-led photopolymer additive manufacturing biocompatibility. Paper I is “Biocompatibility in Dental Photopolymer Additive Manufacturing: A Material–Process–Workflow Perspective” (DOI 10.5281/zenodo.21969973). Paper II is “Industrial Implementation of a Material–Process–Workflow Framework in Dental and Hearing-Device Photopolymer Additive Manufacturing” (DOI 10.5281/zenodo.21973422).

Abstract

TPO was added to the REACH Candidate List on 14 June 2023 because of its reproductive-toxicity properties. Commission Delegated Regulation (EU) 2024/197, adopted on 19 October 2023 and published in 2024, introduced the corresponding harmonised classification under the CLP framework. These events have accelerated formulation review and substitution activities, but the legal consequences and applicable dates must be assessed for the specific product, use and regulatory framework. Changing from a TPO-containing formulation to a TPO-free formulation can alter spectral response and post-cure requirements. A nominal 365, 385 or 405 nm equipment label is insufficient to establish compatibility. The actual source spectrum, formulation response, delivered dose and cured-state endpoint should be evaluated for the specific chemistry–cabinet pairing. An unverified pairing can create a risk of insufficient cure, but insufficient cure cannot be inferred from the TPO-free designation alone.

This third perspective develops a four-step wavelength-matched audit methodology for the post-TPO chemistry transition: cabinet emission spectrum measurement, photoinitiator absorption verification, spectral overlap-based dose calibration, and FTIR or DSC degree-of-cure validation. A simplified spectral overlap integral (effective dose D_{eff}) is introduced as a laboratory-floor screening metric for gross wavelength mismatch; provisional engineering bands are proposed ($D_{eff,local} / D_{eff,reference} > 0.9$ higher relative spectral overlap; 0.7–0.9 intermediate relative spectral overlap; < 0.7 lower relative spectral overlap, with all three treated as author-proposed screening bands). The overlap metric and the engineering bands are intended for first-pass triage of cabinet-chemistry pairings prior to release-grade cure validation; they are not regulatory acceptance thresholds and do not replace full photochemical quantum-yield characterisation. The audit output is intended for integration into the ISO 13485 quality management documentation as a chemistry-cabinet pairing record.

Keywords: post-TPO photopolymer transition · wavelength matching · photoinitiator absorption · post-cure cabinet emission · Jacobs working curve · spectral overlap · audit methodology · ISO 13485 · REACH SVHC · Delegated Regulation 2024/197

Scope and methodology. This article develops an audit methodology for the post-TPO chemistry transition in dental and biomedical photopolymer additive manufacturing. The methodology is a laboratory-floor engineering protocol rather than a regulatory acceptance procedure; the audit output is intended for integration into the manufacturer's ISO 13485 quality

management documentation as a chemistry-cabinet pairing record, not as a substitute for the validation hierarchy developed in the first paper of this trilogy. The wavelength range of interest spans 340–420 nm, covering the legacy 365 nm Hg-lamp installed base and the current 385/405 nm LED installed base; sub-340 nm UVC sources and visible-light direct printing systems (e.g. 2PP at 600–1035 nm) are outside the scope. The proposed D_{eff} overlap metric and engineering bands are provisional and require calibration against formulation-specific degree-of-cure and extractables data; this scope limitation is restated in §7. The audit is intended to apply across the dental and biomedical photopolymer segment rather than to a single manufacturer's portfolio; the audit output for any specific chemistry-cabinet combination remains the responsibility of the device manufacturer.

1. Introduction

1.1 The post-TPO chemistry transition

TPO was added to the REACH Candidate List on 14 June 2023 because of its reproductive-toxicity properties. Commission Delegated Regulation (EU) 2024/197, adopted on 19 October 2023 and published in 2024, introduced the corresponding harmonised classification under the CLP framework. These events have accelerated formulation review and substitution activities, but the legal consequences and applicable dates must be assessed for the specific product, use and regulatory framework.

This third perspective addresses an operational constraint of the substitution that has received less attention than the chemistry-side substitution itself. Photoinitiator selection and post-cure source spectrum are coupled engineering variables, so a chemistry change requires verification of the actual chemistry–equipment pairing. An unverified pairing can create a risk of insufficient cure and a corresponding risk of increased residual reactive species or extractables, but those outcomes cannot be inferred from the TPO-free designation or nominal source wavelength alone.

1.2 The wavelength mismatch problem

The dental laboratory installed base of post-cure cabinets is heterogeneous and can include 365 nm mercury-lamp systems and 385 or 405 nm LED systems. Some TPO-containing systems may exhibit broader spectral response than some substituted systems, but adequate cure cannot be inferred from photoinitiator family or nominal source wavelength alone [P13]. Figure 1 therefore presents illustrative source and response curves only. The actual source spectrum, formulation absorption and reactivity, delivered dose, specimen geometry and cured-state endpoint must be evaluated for the specific pairing.

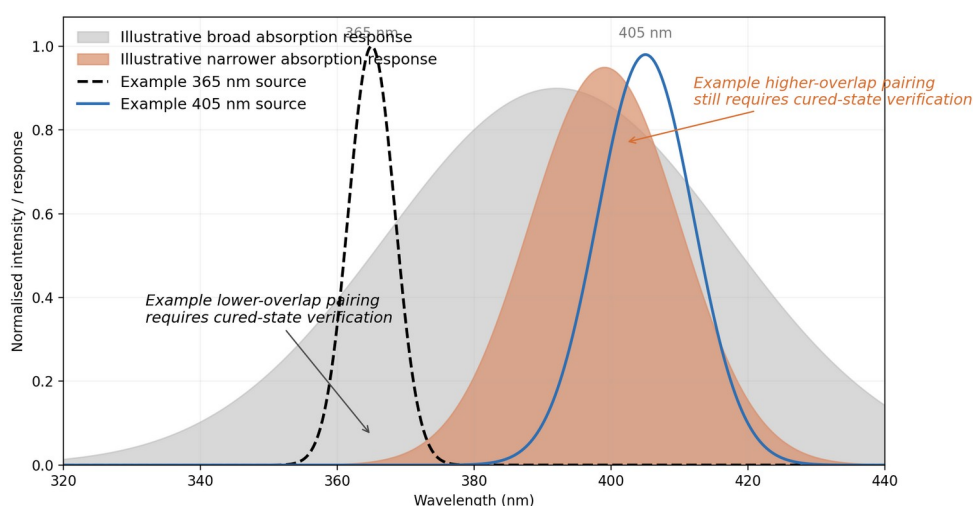


Figure 1. Illustrative spectral-response and source-emission curves for two chemistry–equipment pairings. The curves are schematic and do not represent universal TPO-containing or TPO-free behaviour. Higher or lower spectral overlap is a screening observation only; application-relevant cured-state verification remains necessary.

2. The four-step audit methodology

The proposed audit consists of four sequential steps (Figure 2). Each step has a defined input, a defined output and a documented pass criterion. The audit is intended for integration into the manufacturer's ISO 13485 quality management documentation as a chemistry-cabinet pairing record.

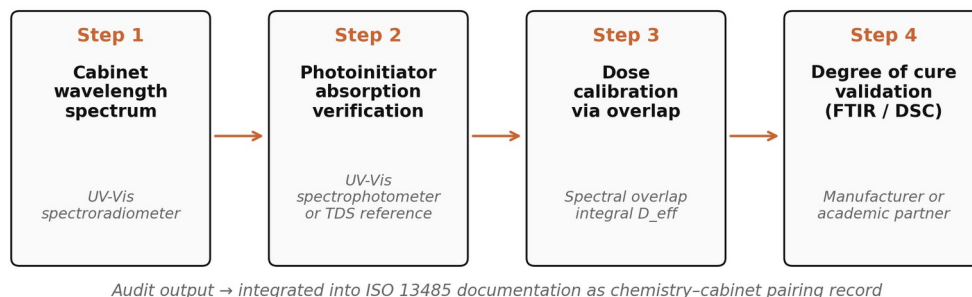


Figure 2. Four-step audit methodology for post-TPO chemistry-cabinet pairing. Step 1: cabinet emission spectrum measurement using a UV-Vis spectroradiometer. Step 2: photoinitiator absorption verification using a UV-Vis spectrophotometer or TDS-level reference. Step 3: dose calibration via the spectral overlap integral D_{eff} . Step 4: degree of cure validation via FTIR or DSC, conducted at the manufacturer or at an academic partner laboratory. The audit output is integrated into the ISO 13485 documentation as a chemistry-cabinet pairing record.

2.1 Step 1 — Cabinet emission spectrum measurement

The first step measures the cabinet emission spectrum $E(\lambda)$ across 340–420 nm using a UV-Vis spectroradiometer. The measurement is performed with the cabinet door closed and the resin platform empty, with the spectroradiometer placed at the platform centre, the cabinet operating at nominal duty cycle, and integration time set to capture the steady-state emission. The output is a digital file of intensity versus wavelength. Pass criterion: the measured spectrum is within manufacturer specification for the cabinet and is stable across replicate measurements (manufacturer-specific tolerance, typically $\leq 5\%$ emission drift between replicate measurements). The spectroradiometer is calibrated against a NIST-traceable reference standard at frequency defined by the manufacturer's ISO 13485 quality management procedure.

2.2 Step 2 — Photoinitiator absorption verification

The second step measures or verifies the photoinitiator absorption spectrum $A(\lambda)$ across the same 340–420 nm range. A primary measurement is conducted using a UV-Vis spectrophotometer on a liquid resin sample diluted to a calibrated concentration in a non-reactive solvent (typically ethyl acetate or methanol, selected against the formulation chemistry to avoid solvolysis); a secondary verification draws on the TDS-level absorption spectrum provided by the resin manufacturer. The output is a digital file of normalised absorbance versus wavelength. Pass criterion: the measured spectrum is consistent with the TDS-level reference within absorbance measurement uncertainty (typically $\leq 10\%$ peak intensity deviation). For TPO-free formulations, the absorption peak is expected in the 380–410 nm window.

2.3 Step 3 — Spectral overlap and effective dose

The third step computes the spectral overlap between the cabinet emission and the photoinitiator absorption. The effective dose delivered to the photoinitiator under cabinet exposure is approximated by the spectral overlap integral:

$$D_{\text{eff}} \approx t \cdot \int E(\lambda) \cdot A(\lambda) \, d\lambda$$

where $E(\lambda)$ is the cabinet emission spectrum ($\text{mW}/\text{cm}^2/\text{nm}$), $A(\lambda)$ is the normalised photoinitiator absorbance, t is the post-cure cycle time (s), and the integral is taken across the wavelength range of interest (340–420 nm). The metric is conceptually simple and can be computed on a spreadsheet from the two digital files generated in Steps 1–2. The output is a single numerical value (mJ/cm^2) representing the effective dose delivered to the photoinitiator under the audited cabinet. The D_{eff} formulation should therefore be interpreted as an engineering heuristic for first-pass process auditing rather than as a rigorous photochemical kinetic model; the rigorous

photochemical characterisation involves quantum-yield measurement, oxygen-inhibition modelling and explicit radical-propagation kinetics, all of which are outside the scope of the laboratory-floor audit developed here. Spectral overlap is therefore **necessary but not sufficient** for release-grade cure prediction: D_{eff} captures the photoinitiator-cabinet wavelength match but does not capture molar absorptivity, quantum yield, oxygen inhibition, scattering from pigments and fillers, formulation-specific viscosity and diffusion effects, part geometry, or post-cure thermal regime. The Step 4 FTIR or DSC degree-of-cure measurement is therefore mandatory at the release stage; D_{eff} serves only to triage chemistry-cabinet pairings before Step 4 is performed, not to substitute for it.

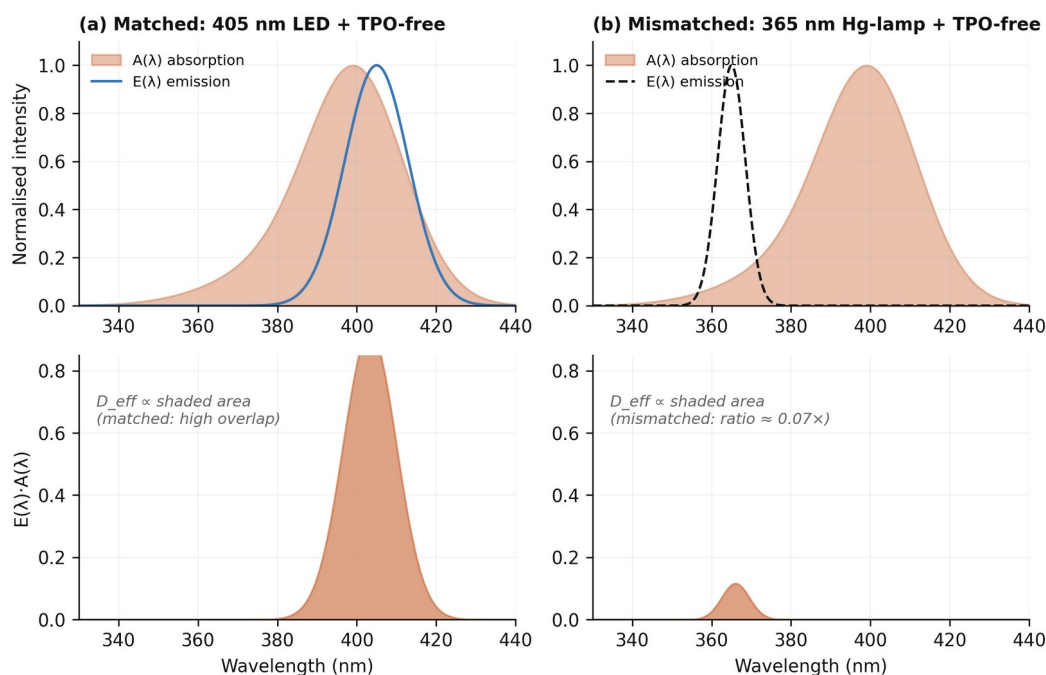


Figure 3. Effective dose D_{eff} visualization. **(a)** Matched case: 405 nm LED emission overlaps substantially with TPO-free absorption peak at 400 nm. **(b)** Mismatched case: 365 nm Hg-lamp emission falls in the low-absorbance tail of the TPO-free absorption spectrum. **(c)–(d)** Corresponding integrand $E(\lambda) \cdot A(\lambda)$; the shaded area is proportional to D_{eff} . The mismatched configuration delivers an effective dose that is a small fraction of the matched configuration despite identical nominal cabinet output. The D_{eff} metric is intended as a laboratory-floor screening metric for gross wavelength mismatch and does not replace full photochemical quantum-yield characterisation.

The D_{eff} metric protects against the practical engineering error of comparing nominal cabinet output (typically reported in mW/cm² at the peak wavelength) without reference to the photoinitiator absorption profile; two cabinets with identical nominal output can deliver materially different effective doses depending on the spectral match. The metric is intended as a laboratory-floor screening metric for gross wavelength mismatch prior to release-grade cure validation in Step 4; it is not intended to replace full photochemical quantum-yield characterisation, and it operates at the linear-dose regime of photopolymerisation kinetics. The non-linear regimes (near the gel-point and post-vitrification) require the FTIR or DSC validation of Step 4. This caveat is restated in §7.

2.4 Step 4 — Degree of cure validation by FTIR or DSC

The fourth step measures the degree of cure (DC) achieved on a test specimen cured under the audited cabinet at the nominal dose and cycle time. Two methods are recognised: FTIR monitoring of the methacrylate C=C absorbance band at 1635–1640 cm⁻¹ (quantitative gold-standard); DSC measurement of the residual cure exotherm (rapid screening, lower quantitative precision). The metrology requires equipment not typically present in dental laboratory environments and is therefore performed at the resin manufacturer (TDS-level characterisation) or at an academic partner laboratory. Pass criterion: the measured DC meets the operational release threshold specified for the chemistry-application combination; for monomer-free dental photopolymer chemistries operated for direct mucosal-contact applications, peer-reviewed evidence supports operational release at DC values in the >90% range under matched post-cure conditions [P10,P11,P12]. The pass criterion is specific to the chemistry-application combination and is documented in the resin manufacturer's TDS or in the

device manufacturer's product validation file under ISO 13485 quality management.

3. Provisional engineering bands for the D_{eff} overlap metric

The D_{eff} overlap metric is intended for first-pass triage of cabinet-chemistry pairings. To support that operational use, provisional engineering bands are proposed in Table 1 based on the ratio $D_{\text{eff,local}} / D_{\text{eff,reference}}$, where $D_{\text{eff,reference}}$ is the effective dose computed for the manufacturer-specified reference cabinet-chemistry pairing and $D_{\text{eff,local}}$ is the effective dose computed for the cabinet under audit. The provisional engineering bands are intended as laboratory-floor screening criteria prior to release-grade DC validation in Step 4. The bands are not regulatory acceptance thresholds and require calibration against formulation-specific DC% and extractables data; this caveat is established here before Table 1, not deferred to limitations.

$D_{\text{eff,local}} / D_{\text{eff,reference}}$	Provisional band	Recommended action
> 0.9	Higher relative spectral overlap (>0.9; author-proposed screening band)	These provisional ratios are first-pass comparison aids, not validated acceptance limits. Confirm the specific pairing with an appropriate cured-state endpoint before process release.
0.7–0.9	Intermediate relative spectral overlap (0.7–0.9; author-proposed screening band)	These provisional ratios are first-pass comparison aids, not validated acceptance limits. Confirm the specific pairing with an appropriate cured-state endpoint before process release.
< 0.7	Lower relative spectral overlap (<0.7; author-proposed screening band)	These provisional ratios are first-pass comparison aids, not validated acceptance limits. Confirm the specific pairing with an appropriate cured-state endpoint before process release.

Table 1. Provisional engineering bands for the D_{eff} overlap metric. The bands are intended as laboratory-floor screening criteria for gross wavelength mismatch and are not regulatory acceptance thresholds. The specific band boundaries (0.7, 0.9) are provisional and require calibration against formulation-specific DC% and extractables data; this calibration is the open external validation step for the methodology (§7).

4. Failure-mode propagation from wavelength mismatch

An unaudited chemistry–source pairing can create a risk pathway that is not detectable by dimensional inspection alone. Figure 4 organises possible downstream effects of insufficient cure, including changes in residual reactive species, extractables, water sorption or solubility, and cell-response endpoints. The diagram is conditional: it does not assert that every lower-overlap pairing fails, and each endpoint must be evaluated under the applicable product-specific method and acceptance criterion.

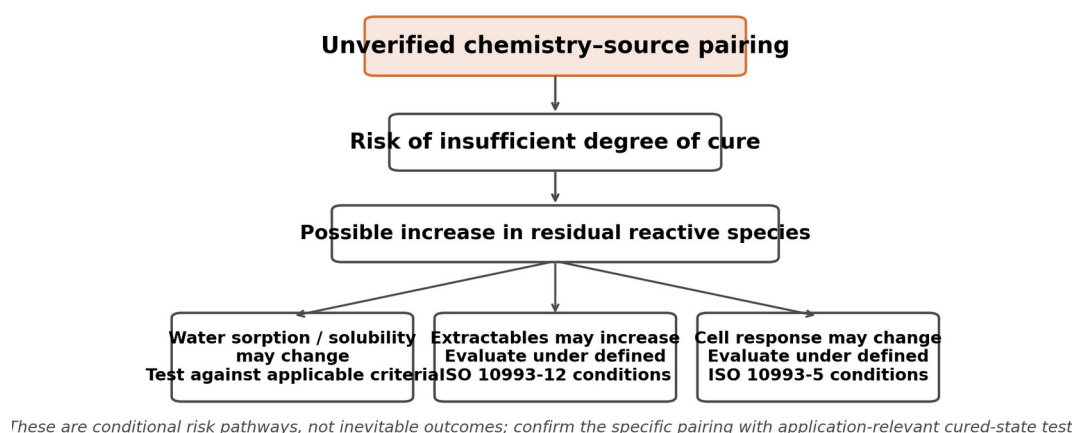


Figure 4. Conditional risk pathway for an unverified chemistry–source pairing. Insufficient cure may increase residual reactive species and may affect extractables, water sorption or solubility, or cell-response endpoints. These outcomes are not inevitable and require product-specific evaluation under defined methods and acceptance criteria.

5. Audit integration into ISO 13485 documentation

The audit output may be integrated into the manufacturer's ISO 13485:2016 quality-management documentation as a chemistry–equipment pairing record. The record should contain the measured source spectrum, formulation-response evidence, dose calculation, cured-state validation outcome, application-specific acceptance criteria, risk assessment and authorised sign-off. The provisional overlap band may inform investigation or mitigation, but it does not itself authorise process or device release.

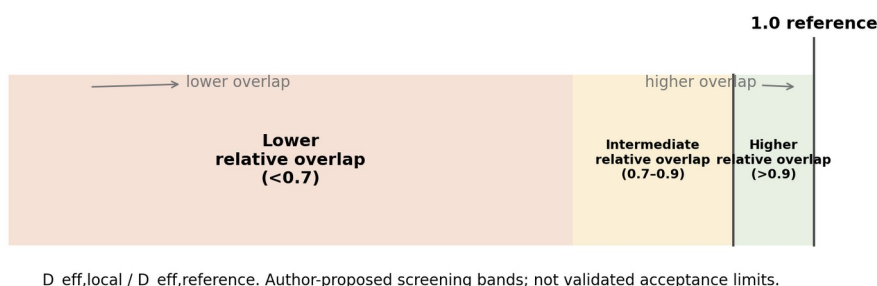


Figure 5. Visualisation of the provisional engineering bands for the D_{eff} overlap metric. Reference pairing at ratio 1.0. Higher (>0.9), intermediate ($0.7\text{--}0.9$) and lower (<0.7) relative spectral-overlap bands, each author-proposed for screening. The bands are laboratory-floor screening criteria and not regulatory acceptance thresholds.

6. Worked example — conceptual

A worked example illustrates the methodology under typical operating conditions. A dental laboratory operates a legacy 365 nm Hg-lamp cabinet on the previous TPO-containing aligner chemistry and intends to transition to a TPO-free aligner chemistry of the same manufacturer.

In this conceptual worked example, Step 1 measures the local cabinet emission spectrum and Step 2 measures or verifies the formulation response. Step 3 calculates an illustrative $D_{\text{eff,local}} / D_{\text{eff,reference}}$ ratio that places the pairing in the author-proposed lower relative spectral-overlap band.

That result identifies a candidate risk and supports investigation of alternative source conditions; it is not a release decision. Any retained or substituted pairing must proceed to Step 4 and meet a formulation- and application-specific cured-state acceptance criterion before release.

The conceptual worked example illustrates the operational use of the methodology in a strongly mismatched configuration. Intermediate mismatch configurations are expected in practice, particularly in ageing LED cabinets with measurable spectral drift over the cabinet service life, in mixed-spectrum cabinets combining multiple LED wavelengths or LED + Hg sources, and in chemistry-cabinet pairings where the photoinitiator absorption shoulder partially overlaps the cabinet emission. The D_{eff} metric is intended specifically for the triage of such intermediate cases, where the matched / mismatched binary is insufficient. Quantitative outcomes for specific chemistry-cabinet combinations are the responsibility of the device manufacturer and are calibrated against the specific TDS and ISO 13485 documentation of the resin and cabinet involved.

7. Limitations and calibration requirements

7.1 Methodology scope

The audit methodology is a laboratory-floor engineering protocol rather than a regulatory acceptance procedure. The audit output supports the manufacturer's ISO 13485 quality management documentation; it does not substitute for the device-level validation hierarchy developed in the first paper of this trilogy [P1], for the regulatory classification of the finished device under EU MDR or the applicable jurisdictional framework, or for the manufacturer's full ISO 10993 biological evaluation. The audit is intended to address one operational constraint of the post-TPO chemistry transition; other constraints — oligomer architecture compatibility, post-cure heat management, build-platform geometry effects — are outside the scope of the present perspective.

7.2 Simplification of the D_{eff} integrand

The D_{eff} integrand treats cycle time t as a linear multiplicative factor independent of dose, which is valid in the linear-dose regime of photopolymerisation kinetics. Near the gel-point and in the post-vitrification regime, the dose-conversion relation becomes markedly non-linear — diffusion control takes precedence over photochemistry, oxygen-inhibition effects vary with conversion, and radical termination becomes diffusion-limited. The D_{eff} metric over-estimates effective cure in these non-linear regimes. The audit accordingly operates D_{eff} at the linear-regime characterisation step (Step 3) prior to release-grade FTIR or DSC validation (Step 4); the non-linear regimes are addressed empirically at Step 4. A second simplification is that the integrand neglects intra-formulation optical effects — pigment absorption, filler scattering, and the wavelength-dependent penetration depth D_p of the Jacobs working curve [P4] — that modulate the actual delivered dose at depth. These effects are formulation-specific and require characterisation against the resin manufacturer's TDS-level optical documentation.

7.3 Provisional band calibration

The 0.7 and 0.9 band boundaries proposed in §3 are provisional engineering values. Their calibration against formulation-specific DC% and extractables data is the open external validation step for the methodology. The calibration would proceed by computing $D_{\text{eff,local}} / D_{\text{eff,reference}}$ for a defined set of chemistry-cabinet combinations and correlating the ratio with independently measured DC% (FTIR) and total extractables under a standardised ISO 10993-12 protocol. The peer-reviewed evidence base on cure kinetics × cytotoxicity coupling [P10,P11,P12] provides the underlying data on which a formal calibration study could draw.

7.4 Regulatory and validation boundaries

The methodology does not provide regulatory acceptance for any specific chemistry-cabinet pairing. Device-level regulatory classification of any finished medical device remains with the legal manufacturer of that device under the applicable jurisdictional framework (EU MDR 2017/745 for European market access; corresponding regulatory frameworks in other jurisdictions). The manufacturer's ISO 10993 biological evaluation, ISO 13485 quality management system and EU MDR conformity assessment are outside the scope of this engineering audit protocol.

8. Conclusions

The post-TPO photopolymer chemistry transition driven by the 2023 European Union regulatory framework is well established at the chemistry level. The corresponding operational constraint — the coupling between photoinitiator absorption and post-cure cabinet emission spectra — has received less attention than the chemistry substitution itself. This third perspective of the trilogy develops a four-step audit methodology for the chemistry-cabinet pairing, introduces a simplified spectral overlap integral (D_{eff}) as a laboratory-floor screening metric for gross wavelength mismatch, and proposes provisional engineering bands for first-pass triage of cabinet-chemistry pairings prior to release-grade FTIR or DSC validation. The audit output is intended for integration into the manufacturer's ISO 13485 quality management documentation as a chemistry-cabinet pairing record.

Three external research directions are identified for refinement of the methodology. First, calibration of the provisional 0.7 and 0.9 band boundaries against a defined set of chemistry-cabinet combinations with independently measured DC% and extractables data would consolidate the engineering bands into validated screening criteria. Second, cross-laboratory reproducibility of the Step 1–2 measurements under standardised spectroradiometer and UV-Vis spectrophotometer protocols would consolidate the audit as a transferable laboratory-floor methodology. Third, the methodology has been developed for the 340–420 nm range covering the legacy Hg-lamp and current LED installed base; extension to current visible-light direct printing systems (385–410 nm LCD, 405–420 nm DLP, and the 2PP visible-NIR regimes at 600–1035 nm) would extend the audit scope to advanced manufacturing platforms beyond the current dental and biomedical photopolymer transition.

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Disclosure. The author is the founder and Scientific Director of 3Dresyns by Resyner Technologies S.L., a manufacturer of photopolymer resin systems for dental, orthodontic and biomedical additive manufacturing applications. This perspective is written from an industrial-academic perspective; the methodology is intended to apply across the dental and biomedical photopolymer segment rather than to a specific manufacturer's portfolio, and the audit output for any specific chemistry-cabinet combination remains the responsibility of the device manufacturer. All peer-reviewed citations are independently verifiable. Device-level regulatory classification of any finished medical device remains with the legal manufacturer of that device under the applicable jurisdictional framework.

Source-use map for the shared trilogy bibliography. [P2–P3] provide dental-resin cytotoxicity, stability and residual-TPO context; [P5–P9] support polymer-network, sustainability and photopolymerisation background; [P10–P17] support the cure, washing, biological-response and denture-property context; [P18–P21] provide adjacent dental-manufacturing and digital-workflow context; and [I1] identifies the disclosed manufacturer curing-rate-control framework. None of these contextual sources establishes the author-proposed spectral-overlap bands as release or regulatory thresholds.

References

Peer-reviewed literature

- [P1] Lee S.Y., Choi M.J., Park J.H., Lim Y.K., Chae H.S., Kim S.J. (2023) Comparison of mechanical properties of 3-dimensional printed and thermoformed orthodontic aligners. *American Journal of Orthodontics and Dentofacial Orthopedics* 164(2), 219–228. <https://doi.org/10.1016/j.ajodo.2023.01.012>
- [P2] Kim G.-T., Go H.-B., Yu J.-H., Yang S.-Y., Kim K.-M., Choi S.-H., Kwon J.-S. (2022) Cytotoxicity, Colour Stability and Dimensional Accuracy of 3D Printing Resin with Three Different Photoinitiators. *Polymers* 14(5), 979. <https://doi.org/10.3390/polym14050979>
- [P3] Messer-Hannemann P., Wienhold M., Esbak H., Brunner A., Schönebaum A., Schwendicke F., Effenberger S. (2024) Residual TPO Content of Photopolymerized Additively Manufactured Dental Occlusal Splint Materials. *Biomedicines* 13(1), 44. <https://doi.org/10.3390/biomedicines13010044>
- [P4] Jacobs P.F. (1992) *Rapid Prototyping & Manufacturing: Fundamentals of Stereolithography*. Society of Manufacturing Engineers, Dearborn, MI. ISBN 0-87263-425-6.
- [P5] Barszczewska-Rybarek I.M. (2019) A Guide through the Dental Dimethacrylate Polymer Network Structural Characterization and Interpretation of Physico-Mechanical Properties. *Materials* 12(24), 4057. <https://doi.org/10.3390/ma12244057>
- [P6] Stansbury J.W., Idacavage M.J. (2016) 3D printing with polymers: challenges among expanding options and opportunities. *Dental Materials* 32(1), 54–64. <https://doi.org/10.1016/j.dental.2015.09.018>

- [P7] Tarancón S. et al. (2024) Stereolithographic 3D printing of dental products: current state and future perspectives. *Polymers* 16(3), 419. <https://doi.org/10.3390/polym16030419>
- [P8] Maturi M. et al. (2025) Sustainable approaches in vat photopolymerization. *Green Chemistry* 27, 8710–8754. <https://doi.org/10.1039/D5GC02299A>
- [P9] Bagheri A., Jin J. (2019) Photopolymerization in 3D printing. *ACS Applied Polymer Materials* 1(4), 593–611. <https://doi.org/10.1021/acsapm.8b00165>
- [P10] Iodice G., Ludwig B., Polishchuk E., Petruzzelli R., Di Cunto R., Husam S., Farella M. (2024) Effect of post-printing curing time on cytotoxicity of direct printed aligners: A pilot study. *Orthodontics & Craniofacial Research* 27(Suppl 2), 141–146. <https://doi.org/10.1111/ocr.12819>
- [P11] Kim J.-E., Mangal U., Yu J.-H., Kim G.-T., Kim H., Seo J.-Y., Cha J.-Y., Lee K.-J., Kwon J.-S., Choi S.-H. (2024) Evaluation of the effects of temperature and centrifugation time on elimination of uncured resin from 3D-printed dental aligners. *Scientific Reports* 14(1), 15206. <https://doi.org/10.1038/s41598-024-66150-6>
- [P12] Hwangbo N.-K., Nam N.-E., Choi J.-H., Kim J.-E. (2021) Effects of washing time and washing solution on biocompatibility and mechanical properties of 3D-printed dental resin materials. *Polymers* 13(24), 4410. <https://doi.org/10.3390/polym13244410>
- [P13] Goracci C., Mangal U., Cokic S.M., Mazzoni A., Vichi A., Josic U. (2025) Biocompatibility and Safety of 3D Printing Resins for Orthodontic Aligners: A Critical Review of Current Evidence. *Polymers* 17(22), 3060. <https://doi.org/10.3390/polym17223060>
- [P14] Bleilöb M., Welte-Jzyk C., Knöde V., Ludwig B., Erbe C. (2025) Biocompatibility of Variable Thicknesses of a Novel Directly Printed Aligner in Orthodontics. *Scientific Reports* 15, 3279. <https://doi.org/10.1038/s41598-025-85359-7>
- [P15] Bor S., Kaya Y., Demiral A., Gungormus M. (2025) Post-Process Cytotoxicity of Resins in Clear Aligner Fabrication. *Polymers* 17, 1776. <https://doi.org/10.3390/polym17131776>
- [P16] Lee H.-E., Alauddin M.S., Mohd Ghazali M.I., Said Z., Mohamad Zol S. (2023) Effect of Different Vat Polymerization Techniques on Mechanical and Biological Properties of 3D-Printed Denture Base. *Polymers* 15(6), 1463. <https://doi.org/10.3390/polym15061463>
- [P17] Greil V., Mayinger F., Reymus M., Stawarczyk B. (2023) Water sorption, water solubility, degree of conversion, elastic indentation modulus, edge chipping resistance and flexural strength of 3D-printed denture base resins. *Journal of the Mechanical Behavior of Biomedical Materials* 137, 105565. <https://doi.org/10.1016/j.jmbbm.2022.105565>
- [P18] Sabatini A. et al. (2024) Additive manufacturing trueness and internal fit of crowns in resin modified with a commercially available ceramic composite concentrate. *Journal of Prosthetic Dentistry* 132, 1323.e1–1323.e8. <https://doi.org/10.1016/j.prosdent.2024.08.014>
- [P19] Biun M., Dudhia R., Arora H. (2023) The in-vitro accuracy of fiducial marker-based versus markerless registration of an intraoral scan with a cone-beam computed tomography scan in the presence of restoration artifact. *Clinical Oral Implants Research* 34, 1257–1266.
- [P20] Biun M., Dudhia R., Arora H. (2024) The influence of metal artifact reduction on the trueness of registration of a cone-beam computed tomography scan with an intraoral scan in the presence of severe restoration artifact. *Journal of Prosthodontics*. <https://doi.org/10.1111/jopr.13767>
- [P21] Berretta D. et al. (2023) A Novel Digitized Method for the Design and Additive Manufacturing of Orthodontic Space Maintainers. *Applied Sciences* 13, 8320. <https://doi.org/10.3390/app13148320>

Standards and regulatory documents

- [S1] ISO 4049:2019. Dentistry — Polymer-based restorative materials. ISO, Geneva.
- [S2] ISO 20795-1:2013. Dentistry — Base polymers — Part 1: Denture base polymers. ISO, Geneva.
- [S3] ISO 10993-1:2025. Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process. ISO, Geneva.
- [S4] ISO 10993-5:2009. Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity. ISO, Geneva.
- [S5] ISO 10993-12:2021. Biological evaluation of medical devices — Part 12: Sample preparation and reference materials. ISO, Geneva.
- [S6] ISO 13485:2016. Medical devices — Quality management systems. ISO, Geneva.
- [S7] Regulation (EU) 2017/745 on medical devices (EU MDR). Official Journal of the European Union.
- [S8] European Chemicals Agency (ECHA) (2023) Support document for identification of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide as a substance of very high concern because of its toxic for reproduction (article 57c) properties. ECHA, Helsinki. 14 June 2023 (SVHC candidate list, 29th batch).
- [S9] Commission Delegated Regulation (EU) 2024/197 of 19 October 2023 amending Regulation (EC) No 1272/2008 on harmonised classification and labelling of certain substances. *Official Journal of the European Union* L 2024/197.
- [S10] ICH Q8(R2):2009. Pharmaceutical Development. International Council for Harmonisation, Geneva.
- [S11] ICH Q9(R1):2023. Quality Risk Management. International Council for Harmonisation, Geneva.
- [S12] ICH Q10:2008. Pharmaceutical Quality System. International Council for Harmonisation, Geneva.

Internal technical documentation (illustrative)

- [I1] 3Dresyns by Resyner Technologies S.L. (2026) Technical White Paper WP-04 — Curing Rate Control System (CRT). *3Dresyns Technical White Paper Series*. <https://www.3Dresyns.com/pages/3dresyns-technical-white-paper-series>