CIRMS

Council on Ionizing Radiation Measurements and Standards

Scientific Exchange on Modeling and Simulation for Radiation Sterilization

Readout Report | NIST, Gaithersburg | September 16–17, 2025

47 Participants · 30 Organizations · Academia, Government, Industry & Regulatory

Executive Snapshot: The Exchange Baseline

Scientific Exchange on Modeling and Simulation for Radiation Sterilization — NIST, Sept 2025

47	30	2	5
Technical Participants	Represented Organizations	Days of Focused Exchange	Stakeholder Sectors

Key Exchange Parameters

- **The Event:** Scientific Exchange on Modeling and Simulation for Radiation Sterilization — NIST, Gaithersburg, Sept 16–17, 2025.
- **The Objective:** Determine engineering and regulatory requirements for ionizing radiation simulation to achieve clinical-grade credibility in industrial sterilization.
- **The Shift:** Moving the industry narrative from identifying theoretical benefits to executing concrete validation frameworks and benchmark test cases.
- **The Output:** Three convergent priorities: VVUQ frameworks, high-value demonstration use cases, and shared infrastructure (phantoms, credentialing, guidance).

The Metrological and Economic Bottleneck

Why the status quo is untenable for all stakeholders

The Constraints

- **Supply Chain:** Heavy reliance on physical dosimetry limits supply chain agility and device innovation as geometric complexity scales.
- **Spatial Limits:** Physical dosimeter placement resolution is becoming inadequate for mapping complex medical device geometries.
- **Stakeholder Bind:** Each sector faces distinct but interconnected barriers — all pointing toward the same conclusion: the current state is holding everyone back.

The Economic Reality

$5K – $10K

Per physical dose mapping run (status quo)

$50K – $100K

To benchmark a computational model — not externally validated and cannot replace physical dosimetry

The goal: establish the standards and regulatory pathways so a validated simulation can fully replace physical dosimetry in processing qualification — something neither current option delivers.

The Clinical Blueprint: Radiation Oncology

How a parallel field navigated the same trust barrier — and what sterilization can adapt

Radiation oncology integrated Monte Carlo and deterministic modeling into zero-margin clinical workflows decades ago. The mechanism is replicable.

Commissioning Protocols

Systematic, standardized procedures qualifying simulation tools before deployment — mandatory independent physical verification of all vendor beam and geometry specs.

QA Frameworks & Guidelines

Professional society guidelines (AAPM Task Group reports) provided consensus-backed, mandatory quality assurance requirements adopted industry-wide.

Personnel Credentialing

Defined operator qualifications codified in the Qualified Medical Physicist (QMP) role — mandatory, standardized training before anyone is authorized to use planning software.

Independent Verification

All vendor-provided beam and geometry specifications must be independently physically verified prior to operational use. No assumption of vendor accuracy.

Mitigating Critical Simulation Risks

Four non-negotiable failure modes — and their validated mitigations

Positioning Sensitivity

Predictions degrade with spatial variation in product placement within the radiation field.

Mitigation: Degrees-of-freedom sensitivity analysis to establish strict physical restraints and placement limits.

Parameter Degradation

Unmonitored drift in beam current, temperature, or process variables degrades model accuracy over time.

Mitigation: Continuous sensitivity analysis of observable parameters defines recalibration triggers and monitoring cadence.

Fundamental Accuracy Limits

Physics models or parameterizations may fail to capture all relevant secondary phenomena reliably.

Mitigation: Generate ground-truth data via independently engineered physical phantoms providing unambiguous validation points.

Out-of-Scope Application

Extending predictions beyond validated dose ranges, geometries, or material limits.

Mitigation: Publish hard, documented boundaries on a model's geometric and dosimetric applicability — and enforce them operationally.

Strategic Implementation Pathways

Complement physical dosimetry first — build iterative trust, then expand scope

Core principle: Build evidence incrementally. Each successful use case expands the trust envelope for the next application.

Strategic Dosimeter Placement

Mechanism:

Use simulation to mathematically optimize dosimeter positioning during PQ runs.

Value:

No absolute dose trust required — addresses a real pain point immediately. Low regulatory risk, high demonstrable ROI.

Product Change Management

Mechanism:

Prove dosimetric functional equivalence between legacy and updated product configurations.

Value:

Reduces dosimetry burden for product changes while maintaining sterility assurance. Defensible under ISO 11137.

Simulation-Based Qualification

Mechanism:

Replace physical dosimetry in processing qualification with a validated simulation model.

Value:

The end state the exchange was convened to enable — requires accepted standards, validation frameworks, and regulatory pathways that do not yet exist.

The Missing Infrastructure

Industrial sterilization lacks standard phantoms that made clinical metrology credible

> *The Gap: No well-characterized, universally adopted phantoms exist for radiation sterilization — unlike clinical metrology where reference phantoms are standard.*

Tier 1
Homogeneous

Purpose:

Baseline 3D dose verification and beam commissioning.

Rationale:

Simple, well-characterized geometry. Establishes beam model accuracy before any complex validation.

Tier 2
Layered

Purpose:

Testing heterogeneous geometries and material interfaces.

Rationale:

Validates model accuracy across material boundaries — critical for multi-component medical devices.

Tier 3
Semi-Realistic

Purpose:

Pallet-scale phantom mimicking operational product configurations.

Rationale:

Final validation step — confirms model performance under real-world processing conditions.

Defining Quantitative Acceptance Criteria

The field operates on inconsistent quality metrics — this must change before broad adoption is possible

The Problem & Analogue

Current Flaw: The meeting identified inconsistent quality metrics as a major barrier — no equivalent to oncology's gamma analysis or DVH criteria exists for sterilization

Clinical Analogue: Oncology relies on gamma analysis and Dose-Volume Histograms (DVH) — precise, application-specific, and universally adopted.

Core Question: What exact quantitative delta between prediction and physical measurement constitutes validation for sterilization?

Risk Scaling: A 5% deviation may be acceptable for routine QA — the same delta could be fatal at maximum-dose material limits.

The Required Action

Survey First

Canvass regulators, industry practitioners, and modeling experts to map existing thresholds and gaps.

Draft Criteria

Develop application-specific, risk-proportionate acceptance criteria — not a single universal threshold.

Pilot & Validate

Test proposed criteria against existing datasets from the mock Q-Submission and round-robin studies.

Publish & Adopt

Issue guidance through professional societies; submit for regulatory recognition

Operational Roadmap & Next Steps

Concrete commitments from the exchange — with owners and sequence

01 Working Group	CDRH leads a strategic working group to model a specific, open-source use case (standardized syringe geometry) and develop a roadmap including consortium funding mechanisms.
02 Phantom Fabrication	Immediate design and deployment of the three tiered reference phantoms — homogeneous, layered, and semi-realistic pallet — for commissioning and routine QA.
03 Proficiency Program	Draft architecture for an independent proficiency testing program to baseline modeling competency across participating laboratories.
04 Guidance Translation	Systematic review of existing AAPM Task Group reports to extract recommendations directly applicable to industrial sterilization, followed by a white paper and stakeholder webinar.

Key Insight: Regulators want more simulation. The barrier is community readiness — not regulatory resistance. Unified action starts now.

CIRMS 2026 — Need

Annual Meeting · April 13–15, 2026

Progress in **simulation-based qualification for radiation sterilization processing** is currently blocked because we lack **externally validated VVUQ frameworks and regulatory acceptance criteria**, which prevents **simulation from replacing physical dosimetry in processing qualification**.