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From the Blog

Beyond Aeration: Characterizing Residual EO Across the Post-Sterilization Supply Chain

June 15th 2026

A Technical Perspective For Medical Device Manufacturers
EO remains indispensable for terminally sterilizing medical devices that cannot tolerate moist heat or radiation, polymer assemblies, electronics, drug-device combinations, and complex geometries.

Control of EO and its reaction products on the finished device is mature and well-codified: ISO 10993-7 defines allowable residual limits, ISO 11135 governs the process, and most manufacturers demonstrate compliance routinely at product release.

What is far less characterized is what EO does after aeration — once a compliant device leaves the aeration cell and enters its packaging system, gets palletized, and moves through warehouses, vehicles, and distribution centers on its way to the hospital dock.

Residual EO does not vanish at the end of the validated aeration window. It can continue to desorb, and the gas that comes off has to go somewhere. For a manufacturer responsible for both product safety and worker safety across the full lifecycle, that post-aeration behavior is an increasingly relevant — and frequently under-documented — dimension of risk.

This article examines the physical chemistry behind post-aeration EO desorption, the two distinct regulatory frameworks it engages, and how a structured characterization programme can close the gap.

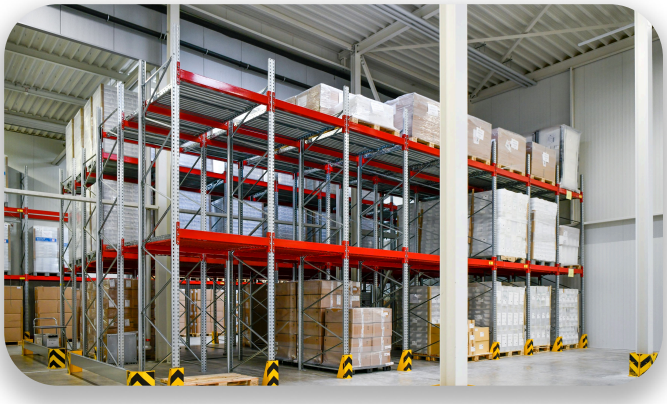
Why EO Does Not Stop at Aeration
EO sterilization works precisely because EO is a small, reactive, highly diffusible molecule. During the cycle it dissolves into and permeates the bulk of polymeric materials: primary packaging films and lids, device polymers, adhesives, and especially elastomers.

Aeration reverses the concentration gradient, using elevated temperature and forced, ventilated airflow to drive dissolved EO back out of the materials and away.

The point that matters for the supply chain is that this desorption is diffusion-limited, not instantaneous. The rate at which residual EO leaves a material is governed by:

- The diffusion coefficient of EO in that material, which varies widely — dense or highly crosslinked polymers release EO slowly.
- Diffusion path length — thicker walls and deeper assemblies hold EO longer.
- Temperature — diffusivity rises steeply with temperature, so desorption that is fast under aeration conditions slows markedly at ambient or cold-chain temperatures, and accelerates again during a hot transport leg.
- Material solubility and partitioning — silicones, plasticized PVC, polyurethanes, and many elastomers dissolve comparatively large amounts of EO and release it over extended periods.

Validated aeration removes the bulk of the residual and brings the device within ISO 10993-7 limits. But the long tail of the desorption curve — the slow release from high-retention materials — can continue



Two Regulatory Clocks Running in Opposite Directions
Post-aeration EO engages two distinct and independently binding regulatory frameworks. Manufacturers tend to manage the first thoroughly and the second incompletely.

Patient residual limits — ISO 10993-7
ISO 10993-7:2008, as amended by Amendment 1:2019, sets the maximum allowable doses of EO and ethylene chlorohydrin (ECH) that a device may deliver to a patient, scaled to the duration of contact: Limited exposure (≤ 24 h): no more than 4 mg EO in the first 24 hours. Prolonged exposure (> 24 h to 30 days): an average of 2 mg/day, not exceeding 4 mg in the first 24 hours or 60 mg over the first 30 days. Permanent contact (> 30 days): an average of 0.1 mg/day, not exceeding 4 mg in the first 24 hours, 60 mg over the first 30 days, or 2.5 g over a lifetime.

The 2019 amendment additionally introduced body-mass-adjusted limits for neonates and infants. ECH limits apply in parallel and are particularly relevant for chloride-containing materials such as PVC, where ECH forms when EO reacts with free chloride ions.

Compliance is demonstrated at the time of release, with EO and ECH quantified, by headspace gas chromatography (GC-FID or GC-MS) — following exhaustive or simulated-use extraction appropriate to the device's exposure category. The broader evaluation sits within ISO 10993-1 (biological evaluation planning) and, increasingly, ISO 10993-17:2023 (toxicological risk assessment), with the sterilization process itself controlled under ISO 11135:2014.

A Structured Approach to Post-Aeration EO Characterization
Closing the gap is fundamentally an empirical exercise: characterize how much EO is released, from what, under which conditions, and what concentrations result around people. Medistri's EO-Free Supply Chain Validation combines regulatory and toxicological consulting with accredited laboratory work across four complementary modules.

Packaging system desorption profiling. Time-resolved measurement of EO release from primary, secondary, and tertiary materials at defined post-aeration intervals, quantified by headspace GC-FID and

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beyond the aeration room, now into a very different environment: lower temperature, far less air exchange, and confined geometry.

This reframes the question. On the device itself, residual EO decreases with time, so a product released within limits only becomes safer for the patient as it ages. The post-aeration concern is therefore where the desorbing EO goes, and what concentrations build up around the people who handle the product.

Why Single-Package Data Does Not Represent a Pallet
Aeration validation and residual testing are commonly performed on individual units or on a limited set of worst-case configurations. Operationally, though, product moves as fully built, stretch-wrapped unit loads, and a pallet behaves nothing like a single carton.

In a built pallet, EO desorbing from inner cartons must diffuse through long, tortuous paths before reaching the surface, while stretch wrap and dense packing sharply reduce interstitial air exchange. The result is accumulation: EO concentrates in the headspace at the core of the load and establishes a radial gradient that is highest in the centre and lower at the periphery.

Storage duration and temperature modulate this further. Extended storage allows the residual tail to keep loading the interstitial space; warm, poorly ventilated warehousing or non-climate-controlled transport accelerates desorption, while cold-chain conditions slow it and lengthen the tail that arrives downstream. None of this is captured by single-package release data.

Environmental And Area Monitoring
Air-sampling campaigns in warehouses, transport vehicles, order-picking areas, and distribution centres, using sorbent-tube methods (charcoal collection with solvent desorption and GC-FID analysis, following OSHA/NIOSH methodology) and, where appropriate, real-time monitors. Results are mapped against applicable occupational limits to identify where engineering or ventilation controls add value.

Personnel Exposure Assessment
Passive time-weighted-average (TWA) dosimetry worn by warehouse operators, logistics and QC personnel, and transport operators over representative shifts, with short-term measurements during high-emission tasks such as pallet breakdown. Results are compared against the OSHA PEL and action level and the EU and Swiss occupational limits to support internal safety programmes and regulatory documentation.

Medistri supports manufacturers and healthcare organizations in characterizing EO behaviour beyond aeration, combining regulatory and toxicological expertise, risk-assessment methodology, and accredited laboratory capability to provide end-to-end visibility across the post-sterilization lifecycle.

To learn more about Medistri's Consulting services, contact our team via our website here or at contact@medistri.com.

— The Medistri Team

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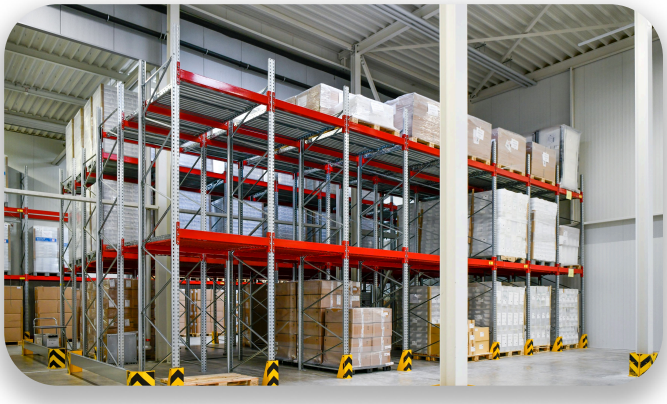

GC-MS.

This produces material-specific desorption curves, ranks the contribution of each packaging layer, and characterizes the residual tail — the basis for evidence-based aeration and quarantine decisions.

Who Benefits
The framework is built first for medical device manufacturers — supporting lifecycle risk management, regulatory submissions and post-market surveillance, and customer assurance with defensible, product-specific data. It also serves logistics providers and 3PLs needing warehouse and personnel exposure characterization, regulatory affairs teamsassembling chemical-safety and post-market documentation, and healthcare procurement teams seeking transparency on incoming sterilized goods.