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From the Blog

Monitoring EO in Ambient Air: Badge Testing & In-Package Safety Checks

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EO remains essential for sterilizing heat- and moisture-sensitive medical devices. But as regulatory expectations tighten, controlling EO in the workplace air and inside packaged product is now a critical part of safety and compliance.

Why This Matters More Than Ever

Across Europe, binding occupational exposure limits (BOELVs) for carcinogens are being strengthened, and national regulators are pushing for more rigorous indoor air control. In the U.S., the EPA has announced new measures to drastically reduce EO exposure for workers, with phased reductions in permissible levels down to 0.1 ppm over the coming decade.

These initiatives confirm a global trend: regulators expect documented, reliable monitoring strategies for EO in both production and handling environments.

For manufacturers, that means demonstrating not only that EO is removed from devices (ISO 10993-7) but also that the air around operators, warehouses, and packaged pallets remains safe.

EO Badge Testing

EO badges are small, passive samplers worn by operators or placed in critical areas. Over a defined exposure period, they absorb EO from the surrounding air. Once analyzed in our laboratory, they provide:

- · Quantitative measurement of EO exposure
- · Comparison against occupational limits
- · Clear documentation for regulatory submissions and safety files

This makes badge testing a simple yet powerful tool to verify compliance, protect staff, and satisfy inspectors.

In-Package / Headspace Checks

More and more clients also request EO headspace testing inside packaging — from pallets to cartons and boxes. These checks ensure that EO residues do not accumulate in confined spaces that staff open, handle, or transport. By combining device residual testing with real-world packaging checks, manufacturers provide stronger assurance that EO risks are under control throughout the supply chain.

Partner with Medistri

By combining EO badge testing, in-package headspace checks, and residual testing on devices, Medistri offers a complete solution for chemical safety monitoring. Our services are developed in line with international standards and regulatory expectations, providing manufacturers with reliable data and practical support for audits, risk assessments, and occupational safety strategies.

Contact us at <u>contact@medistri.com</u> to learn how we can support your EO monitoring and chemical safety programs.



Badge Testing Beyond EO

While EO is the most regulated in sterilization contexts, the same badge monitoring approach can be applied to other volatile compounds frequently present in healthcare and pharmaceutical environments. Passive diffusion badges can also measure solvents such as isopropanol (IPA), ethanol, acetone, toluene, or methyl ethyl ketone (MEK).

This makes badge testing a versatile solution: manufacturers can document workplace safety not only for EO, but also for a broader range of chemicals used in cleaning, disinfection, and production processes.