

Statement from Brian DeBusk, President & CEO of DeRoyal Industries, Inc.:

“For nearly four decades, DeRoyal Industries, Inc. (“DeRoyal”) has engaged in the sterilization of medical devices using ethylene oxide. For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes a device without damaging it during the sterilization process. This effective, non-damaging sterilization is an important factor in preventing infections and ensuring patients have safe surgeries and medical treatments. For this reason, ethylene oxide is currently the most effective method for sterilizing medical devices, particularly those made from plastic polymers.

Throughout its history as a commercial medical device sterilizer, DeRoyal has met – or surpassed – the employee safety and environmental regulations for use of ethylene oxide. However, it has been indicated to commercial sterilizers, including DeRoyal, that the U.S. Environmental Protection Agency (EPA) plans to publish a proposed rule that is anticipated, if finalized, to expand the regulatory landscape to require commercial sterilizers to capture and control emissions that are currently unregulated, and potentially require the use of new emissions capture and control technologies. In its work to update this regulation, the EPA created computer models of emissions at existing commercial sterilizers, including DeRoyal’s facility.

DeRoyal acknowledges that the computer modeling prepared and released by EPA on August 3, 2022, is intended as background information in support of the agency’s proposed rulemaking. That said, it appears that the EPA’s modeling contains emissions estimates for both currently regulated and unregulated emissions that may be based upon conservative industry standards.

DeRoyal understands the importance that modeling plays in writing a new regulation, in addition to understanding - first and foremost - that the proposed rule will aim to benefit the health and safety of the employees of commercial sterilizers as well as the communities where these operations are located.

Therefore, DeRoyal has been in ongoing communication with both the EPA and the State of Tennessee Department of Environment and Conservation, Division of Air Pollution Control, regarding this modeling and upcoming proposed rule and looks forward to continuing its efforts with the EPA and the State of Tennessee to comply with any newly implemented regulations.”