INSIDE STORY

Medical devices sterilized with ethylene oxide (EO) gas need to be tested to ensure they do not pose a toxicological risk to the end user. Many factors impact EO Residual levels following sterilization, which makes it difficult to determine when a device is safe for public use. To find out more about the expertise required to establish safe EO Residual levels for medical devices, Medical Design Briefs recently spoke with Leonard Harris, Manager, Chemistry and Container Testing for Eurofins Medical Device Testing (Lancaster, PA).

***MDB:* How does one determine residual solvents versus the limits listed in ISO 10993-7?**

Leonard Harris: The laboratory should get a concentration based on the completed testing. Using the extraction and testing process, the laboratory should be able to determine a number that can be reported in milligrams per device within a certain period of time. One can then compare the calculated value to the limits that are listed in ISO 10993-7, along with the flow chart in Annex C, to determine whether the residual levels are below the necessary limit.

***MDB:* How do you proceed with testing in a medical device that is too large to extract an entire piece of equipment?**

Harris: Per ISO 10993-7, you can select a representative portion of the medical device and then use that portion to extrapolate what the EO would be for the entire device. It is also important to make sure that you are testing the appropriate portion of a large device when conducting your tests. Typically, only the portion of the device that will be in contact with the patient is of concern, unless you have a fluid that flows through the device. In a case such as an IV Bag, or feeding tube, where the component may not contact the patient, only the EO residuals that would be extracted from the fluid pathway are of concern. In these cases, the device may be filled in such a way that only the fluid pathway is extracted and tested.

***MDB:* When calculating residual levels for an infusion-tubing device, should EO residuals be measured for the fluid path only? Would measuring the EO levels for the surface contact area be required for the Tolerable Contact Limit (TCL), also? If so, should this include the outer surface area of the tubing and the dressing for the device?**

Harris: TCL is only required for materials that make surface contact with the patient. If the outside of the tube makes contact with the patient, then knowledge of the EO residual levels would be necessary to determine irritation.

Each device contained within a kit needs its own considerations. A dressing would only need residual testing based on whether or not it would be in contact with the patient. The same could be said for the tubing. However, even if the tubing does not make contact with a patient, it will still need fluid pathway testing if a solution is introduced to a patient through the tube.

***MDB:* With EO residual testing, does every single test require that two medical devices be tested at the same time? For example, two devices will be tested on Day 0, then two devices will be tested again on Day 1, etc.?**

Harris: Due to the variability in EO affinity and the variability in the testing methods, multiple samples at each time point are critical to ensure that the results are accurate. Using multiple samples ensures that sample results are truly representative of the product. In most cases, the laboratory will request to test at least three samples at each time point. Discussing sample requirements with the testing facility is recommended.

***MDB:* If an EO residual test is required for a 2X EO cycle, must two continuous EO cycles be performed? Or does it not matter as long as the device undergoes the two EO cycles?**

Harris: This would depend upon the purpose of the testing. If you are trying to validate for 2X release, then the EO cycles should be performed as closely together as possible. Running the cycles closely together would represent the worst-case scenario for EO residual testing, as the samples would not have time to dissipate or break down. If you are performing lot release testing, then this would not matter as you would only need to show that the individual lot tested meets acceptable limits.

***MDB:* Once EO residuals are validated and hold times are set, does that mean you no longer need to think about EO residuals?**

Harris: No, you would still have to think about EO Residuals in case of a change that might affect the residual levels. A change to the sterilization cycle itself, a change to the packaging, or even a change to the materials within the device would lead you back to the point where you would need to reassess your ethylene oxide residuals.

To find out more about Eurofins Medical Device Testing, visit **www.eurofins.com/medical-device.**