MesaLabs

NOTIFICATION OF CHANGE IN TESTING AND LABELING

Dear Customer,

This letter is to inform you that Mesa Laboratories, Bozeman Manufacturing Facility will cease reporting results of testing with Oxyfume blends on Certificates of Analysis for Mesa products intended for use in monitoring ethylene oxide sterilization cycles starting 23 Aug 2017. Certificates of Analysis for these products will continue to report testing with 100% ethylene oxide. This change impacts all EZTest Gas, MesaStrip Gas, and Releasat Gas Strips catalog, private label, and custom items.

The 2017 revision of ISO 11138-2 included revised performance requirements (Section 9.6) to reflect the use of 100% ethylene oxide sources in addition to Oxyfume blends. Manufacturing and availability of blends such as Oxyfume 2002 ended as of December 2015, though use was allowed until supply was exhausted. As detailed in the standard, the minimum required resistance (D-value) for 100% EtO sources shall not be less than 2.0 minutes. The requirement for Oxyfume was not less than 2.5 minutes.

This change in testing and labeling has no impact on performance of the biological indicators. For informational purposes, we include in this notification explanatory language from Annex B of ISO 11138-2:

> **Round robin *D* value testing at 54 °C completed by three U.S.-based biological indicator manufacturers on four different biological indicator products demonstrated that *D* values obtained using 100 % EO were consistently lower than *D* values obtained in the HCFC/EO mixture, even though the nominal EO concentration for both sets of tests was 600 mg/l. The reported differences between *D* values were as high as 40 %. This study has now been published in *Pharmaceutical Technology* (2014)[4].**
>
> **ISO 11138-2:2006 has been amended by changing the 54 °C *D* value requirement to add an option of a 2,0 min *D* value specification for tests performed in 100 % EO, based on data reported in the peer reviewed publication. Providing an option for BI manufacturers to maintain compliance with the standard without changing the actual BI resistance was preferred over driving manufacturers to increase BI resistance to meet the standard. This scenario would create more risk of positive BIs for end users whose sterilization processes were validated against the lower resistance BIs.**

We appreciate your business and are providing this change notification in advance to limit any inconvenience this change may cause. If you have any questions, please contact your Mesa Laboratories representative.

Sincerely,

Janis E Smoke 23 May 2017 Beth Ridgeway 23 May 2017

Janis E. Smoke
Director of Quality Assurance and Regulatory Affairs
(303) 987-8000 x 10352
jsmoke@mesalabs.com

Beth Ridgeway
Director of Production
(303) 987-8000 x 10352
bridgeway@mesalabs.com