

Isotron Thorne Mixed EtO Cycle Validation Policy Summary

INTRODUCTION

In order for low volume, low frequency customers to have access to EtO sterilisation at an Isotron facility in the UK, Isotron Thorne has developed the Mixed Cycle Validation (MCV). Much of the upfront cost and work has already been completed allowing the customer to 'adopt into' the MCV with minimal product, minimal cost and minimal time whilst ensuring that their product is validated to meet the requirements of ISO11135. Although this validation approach is available at Isotron Thorne, it may not be available at other Isotron facilities where smaller chambers have already been installed to meet this customer requirement.

The MCV involves the validation of an Isotron reference load by the conservative Half Cycle approach as defined in ISO11135-1 Annex B.1.2. Data has been generated which may be used as a reference point to allow the adoption of new product into the MCV and consequently allow routine sterilisation to begin in a shorter timescale. Each customer taking advantage of the mixed cycle must have completed a Customer Adoption Validation (CAV) before inclusion with another customer. Once validated as comparable or 'easier to kill' than the Isotron reference load, different customers can make up the composition of routine loads by independent substitution, on a pallet-by-pallet basis, of the Isotron reference load.

MIXED CYCLE DATA

To allow adoption into the MCV, data for the new product must be compared against a reference set of data. The reference data is generated by performing an ISO11135 compliant Half Cycle Validation on the Isotron reference load which consists of 12 pallets of scrap medical device material. In total seven separate cycles are run to generate the necessary data consisting of: 3 x Physical Product Profiles, 1 x Sub Lethal Cycle & 3 x Half Cycles.

ADOPTION PREREQUISITES

In order for a new product/customer to be able to adopt into the MCV and use the Mixed Cycle Validation data as a reference point, the new product must meet the following specification:

- Product to be loaded onto 1.0 x 1.2m pallet(s) or 0.8 x 1.2m pallet(s). If 0.8 x 1.2m pallets are used they will be exchanged one to one for 1.0 x 1.2m pallets in the sterilisation load.
- Pallet height (including the pallet) limited to 2.00m (maximum chamber door height).
- Total product mass per pallet not to exceed 308kg (excluding the pallet).
- Total product density not to exceed 145 kg/m³.
- Customers must formally agree up front to be included in mixed customer cycles, including as yet, unknown future customers.
- Customers would be informed of the potential general composition of mixed load cycles.

CUSTOMER ADOPTION VALIDATION

Given that the above prerequisites have been met, the CAV will consist of one physical product profiling cycle, one sub lethal cycle and one confirmatory half cycle. The physical profile may be combined with the half cycle if intrinsically safe data loggers are employed. A full cycle, which may be the first routine cycle for the customer undergoing the CAV, may be required for the processing of samples for functionality and residuals testing.

For each pallet of customer product, one pallet from the Isotron reference load will be substituted ensuring a full 12 pallet load for each cycle. The total number of customer pallets used in the CAV will be half the maximum allowed for that customer in all routine processing. This is to allow for growth in production volume but sets a ceiling at which revalidation will be required as the difference from the 'as validated' state becomes significant. It is acceptable for fewer customer pallets to be used during routine processing.