PANEL ON GAMMA & ELECTRON IRRADIATION

www.irradiationpanel.org

Guidance on the Sterility Dose Audit Failure Risk Assessment as per the requirements of ISO11137 standard.

Date: November 2020

Foreword

ISO11137-2:2013 section 10.4 states ; '*Following failure of a sterilisation dose audit requiring the re-establishment of the sterilisation dose, the cause of the failure shall be investigated and correction and /or corrective action undertaken (see 4.4 of ISO 11137-1:2006). As part of the investigation, the effect of processing product at the sterilisation dose that has failed the sterilisation dose audit on the achievement of the specified SAL for previously processed batches of product shall be considered and a risk assessment undertaken on their suitability for use. The investigation and subsequent actions shall be recorded.'*

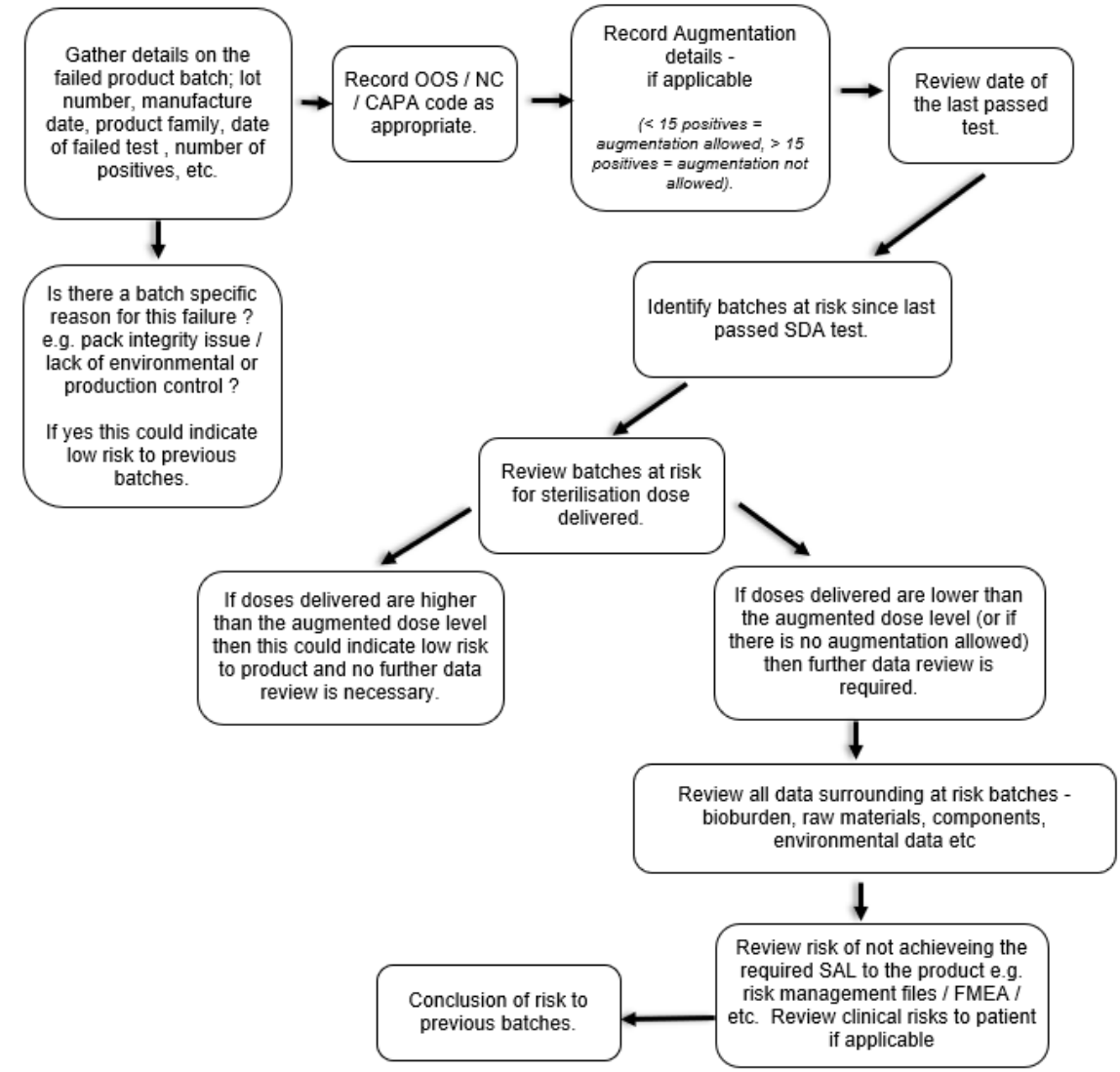
The aim for this guidance document is to assist both manufacturers and contract laboratories with the potential activities that can be employed in order to fulfil section 10.4 requirements on reviewing previously processed product.

The following should be considered a guide of the recommended risk assessment actions to be taken following an SDA failure resulting in a re-establishment as required by section 10.4 of ISO11137-2 – it is not an exhaustive list.

A flow chart of activities and an example record form follow to assist manufacturers in their approach.

> Note : Some manufacturers may also choose to utilise this guidance when a dose audit failure leads only to augmentation and not immediately re-establishment.

Risk Assessment following SDA failure - flow chart



Example record form to record the investigation :

Product Family Group affected: _____ Date of Failure: _____

Number of positives: _____ Investigation/NC / OOS/CAPA number: _____

What isolates were recovered from the failed SDA? _____

Follow the actions as detailed below:

If dose has been augmented follow from step 1: If no augmentation is allowed follow from step 2:

1. What is the new minimum augmented dose? _____

   What is the dose plus correction factor? _____

2. When was the last passed SDA result? _____

3. How many positives was last SDA result? _____

   If positives – what isolates were recovered from this SDA? _____

4. Since last pass SDA result – have all products in this product family group received higher or equal to the dose calculated in step 1? _____ (or N/A of no augmentation has been allowed)

   Please list product batches and minimum doses received below:

Cat No	Lot No	Min Dose

If all batches received higher of equal to dose in step 1 – skip to step 6,
If batch(es) did not receive higher or equal to dose in step 1 OR there has been no augmentation of this family allowed – go to step 5

5. For the product batches that have not received higher or equal to the dose in step 1 – please complete table below:

Product description	Cat number /Lot Number	Are there any lot specific bioburden testing results available?	What component results are there used in this batch?	What were the environmental / particulate results showing at the time of manufacture?	Time lag between manufacture and sterilisation for this specific batch?	Time lag between verification dosing and sterility test for this batch?	SDA isolates – are they the same as last passed SDA?
e.g. Product family	*xxxxxx, xxxxxx*	*Yes – passed bioburden – date xx/xx/xx*	*Yes – additive – batch xxxx – result 0 cfu, component testing 0 cfu etc.*	*Manufacturing area viable testing – MM/YY – all passed. Particulates first quarter – passed ISO class xx.*	*15 days – within the set 28 days steriliser dwell*	*1 day*	*2 x staph spp last passed SDA, this failure – 4 pseudo.*

6. Is there a batch specific reason for this failure?(*E.g. lack of environmental / production control, package integrity failure etc)*_____

_____

7. Review of risks to the specific product if there was a lack of sterility / lack of achievement of the required SAL. *(e.g. risk management files / product FMEA's etc)*

_____

8. Review of clinical risks of the specific product to the patient – *if applicable*

_____

9. Conclusion of risk to previously manufactured products

_____

10. Signatures: *(as required by business procedures)*

Responsibility	Print Name	Signature	Date
Microbiology/Sterilisation Leader			
Quality Manager			
Global Sterilization			