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# How to Evaluate a New Product Against an Existing Product in a Validated Ethylene Oxide Process

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## Abstract

As defined in Section 12 of ISO 11135:2014, a new or modified ("candidate") product can be added to a validated Ethylene Oxide (EO) sterilization process if an evaluation shows that the candidate product is either equivalent to or a lesser challenge than an "existing" product or Internal Process Challenge Device (IPCD). Such an outcome could save considerable time and money. By reading this White Paper, Quality Assurance, Project Management, Sterility Assurance and Validation personnel within the medical device, pharmaceutical, commercial and food industries learn the necessary steps to evaluate a candidate product.

## Introduction

As defined in Section 12 of ISO 11135:2014, a new or modified product may be added to an existing validated process with reduced performance qualification if it is deemed an equivalent or a lesser challenge to sterilization than an existing qualified product or Internal Process Challenge Device (IPCD).

AAMI TIR 28 provides guidance for product adoption into an Ethylene Oxide (EO) cycle and contains a Product Evaluation Checklist in Annex A that encompasses all the areas that must be examined during technical review.

In the first instance, it should be determined whether the candidate product and package will remain functional and effective, ideally following double exposure to the full-cycle sterilization parameters. Secondly, a technical review for product equivalence should be performed comparing the candidate product with the product or IPCD that was used to validate the existing sterilization process. The outcome of the technical review, including the rationale for decisions reached, should be documented.

If the outcome of the review shows that:

- the candidate product and existing products (or IPCD) are similar, and the differences between them are insignificant
- the candidate product can be adopted into the product family without further study
- the candidate product has the potential to be a greater challenge to the sterilization process than the currently validated product (or IPCD)

Then further studies are required. If the review indicates that the candidate product presents a greater challenge than the currently validated product (or IPCD), then it does not meet the requirement for adoption and a full Performance Qualification (PQ) is needed.

## Technical Review for Product Equivalence

The candidate product must be compared to the existing worst-case product(s) or validated IPCD to evaluate the possibility to include it in the same product family or processing category.

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A **product family** is defined as a collection of products determined to be similar or equivalent for validation purposes based on their similarity (e.g., catheters of different sizes) or based on similar materials or similar production environment. The use of product families can make the validation process simpler, as the entire product family can be represented by a single worst-case product (called the 'master product') and the entire family is considered an equivalent challenge to the sterilization process. The product family may also be represented by a simulated product or product Process Challenge Device (PCD).

A **processing category** is defined as a collection of EO product families that can be dissimilar in detail but are qualified in a common sterilization process with the same worst-case PCD.

For example, a collection of products (e.g., intravenous sets) might constitute a product family and might be placed in a processing category that includes a separate collection of products (e.g., family of syringes). The commonality within the processing category might be, but is not limited to, that the PCD represents the microbial challenge for those products in that group.

The following elements must be reviewed:

- **Determination of adverse effects to product:** Consideration should be given to product functionality, integrity, stability, biocompatibility and residuals. If drugs are included as part of the product, ensure that the safety and efficacy of the drug will not be negatively impacted.
- **Determination of product design effects:** The design should be reviewed for any changes or differences that could present greater obstacles to EO, heat or humidity penetration than the existing product or PCD.
- **Determination of product material and characteristic effects:** The candidate product should be carefully examined for any differences that could potentially affect the product bioburden, such as manufacturing production methods, facilities, location and raw material types and sources. Materials should be reviewed to ensure that the product will not retain higher EO and/or Ethylene Chlorohydrin (ECH) residual levels.
- **Determination of sterile barrier system effects:** The sterile barrier system should be examined for any factors that could present obstacles to EO, heat or humidity penetration; for example, a decrease in the porosity of the venting material, smaller venting surface area or occlusion of the venting area. In addition, effects of changes to the sterile barrier system on the bioburden of the product and any effects on EO residual levels should be evaluated.
- **Determination of load configuration effects:** The load configuration of the candidate product should be examined for any changes that effect the uptake of heat, moisture or EO; for example, additional layers of stretch wrap, reconfiguration of the pallet or change in load size, density or any other change that could make the candidate product a greater challenge to the sterilization process.

## Outcome of the Technical Review for Product Equivalency

It is important to document the decisions taken, as well as the rationale for those decisions.

The candidate product may be adopted into the product family or processing category without further study if the changes are deemed to be insignificant or present a lesser challenge to the sterilization process than the existing validated product or IPCD. This decision is supported by virtually all 'No' answers to the checklist contained in Annex A of the AAMI TIR28 document.

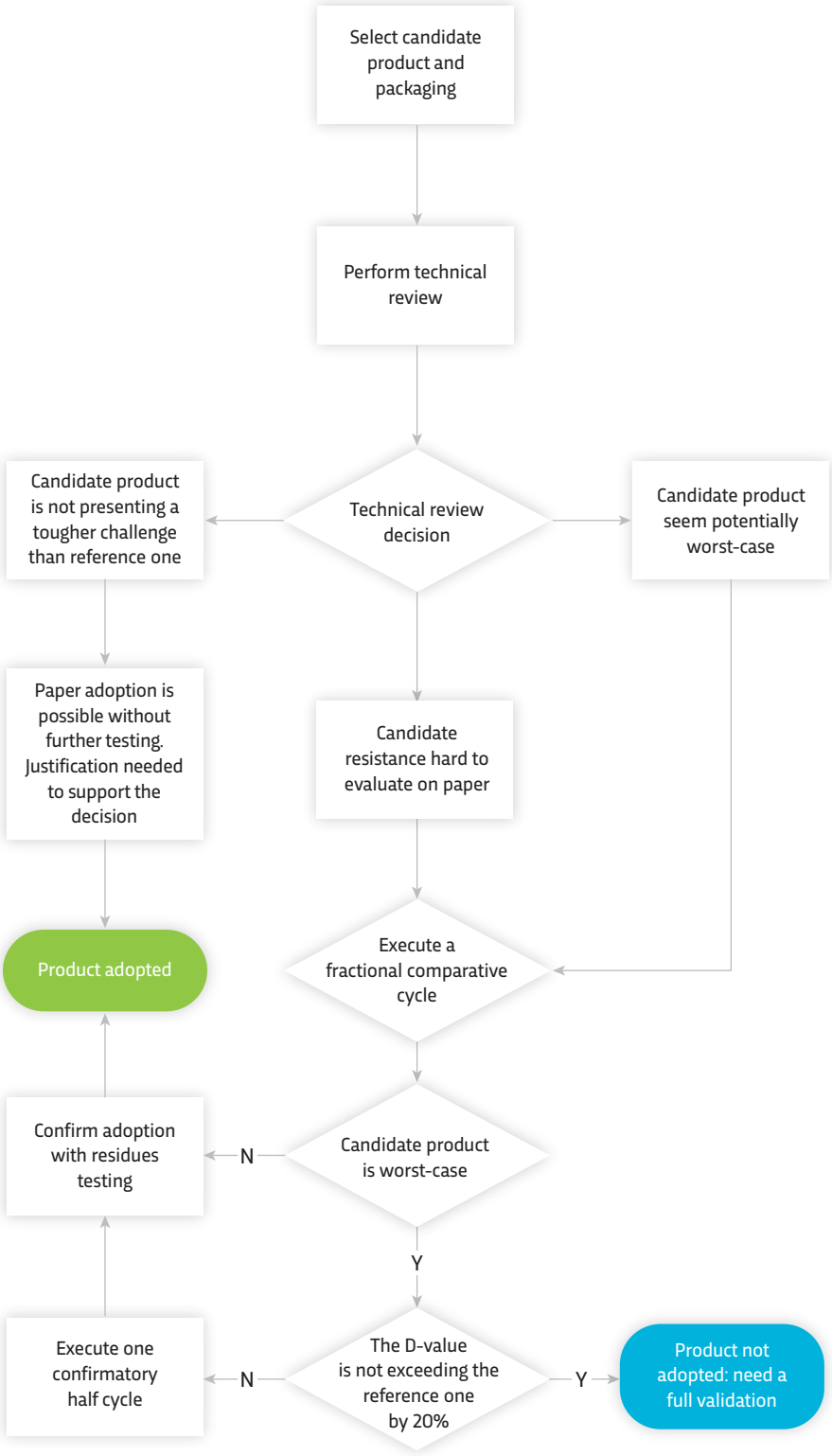
If the technical review indicates that the new product has the potential to be a greater challenge to the sterilization process than the existing validated product or IPCD, then further studies are required to:

a) Establish the candidate product is equivalent to the currently validated master product or IPCD, or

b) Establish a new product family / processing category or IPCD for the sterilization process, or

c) Establish a new sterilization process for the candidate product.

Chart 1: Product Adoption Decision Tree



## Conclusion

Product adoption consists of evaluation of a candidate product against an existing qualified product or IPCD to determine if it can be added to the currently validated sterilization process. A review for product equivalency must be performed on the candidate product. All evaluations performed, actions taken and decisions made during the review must be documented.

The output of the review for product equivalency can result in one of three scenarios:

1. Paper adoption of a lesser challenging or equivalent product
2. Comparative study and if needed, confirmatory study for an equivalent or slightly more resistant candidate product
3. Full validation for a candidate that would show significant higher resistance (more than 20% difference in D-value, based on guidance of ISO 11125:2014 section D8.6)

## References

ISO (International Standards Organization) 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

AAMI TIR (Technical Information Report) 28 2016: Product adoption and process equivalency for ethylene oxide sterilization

## About Sotera Health

Sotera Health Company is a leading global provider of mission-critical end-to-end sterilization solutions and lab testing and advisory services for the healthcare industry. Sotera Health goes to market through three businesses – Sterigenics®, Nordion® and Nelson Labs®. Sotera Health is committed to its mission, Safeguarding Global Health.

## About Sterigenics

Sterigenics is a leading global provider of outsourced terminal sterilization services for the medical device, pharmaceutical, food safety and advanced applications markets. With our industry recognized expertise we help to ensure the safety of millions of patients around the world every year. Across our 48 global facilities, we offer our customers a complete range of sterilization services, primarily using the three major technologies: Gamma irradiation, Ethylene Oxide processing and Electron Beam irradiation. We are committed to addressing the growing need for sterilization across the world and partnering with our customers to eliminate threats to human health.

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