In *Ethylene Oxide Sterilization: Validation and Routine Operations Handbook*, Anne F. Booth provides a comprehensive overview of the steps involved to successfully develop, validate, and maintain an ethylene oxide (EO) sterilization process. The book is well written and easy to read—no small feat for a technical book. Booth takes a step-by-step approach in explaining the overall framework to accomplish the task of tying together the science, the regulations, and the standards involved in EO sterilization.

**Audience:** This book is targeted at individuals with a wide range of knowledge of and experience with EO sterilization. For the experienced person, it is a valuable reference with current standards compiled in one table and exact code of federal regulation (CFR) imbedded in chapters as needed. This would be an excellent text book for a training course. Managers, quality assurance personnel, and medical device companies will all find invaluable, well-presented information. Because of the clear, concise manner in which universal sterilization considerations are addressed, such as microbial considerations and biocompatibility testing, this book is great reference material for any type of sterilization.

**Features:** This book contains 11 chapters, with detailed descriptions and critical insights regarding the validation and operation of EO sterilization. It begins with a rationale for the validation process; a description of issues to be addressed regarding the use of contract labs is presented. Issues such as interstate shipping when using contract labs reflect the thorough manner in which each subject is treated. Subsequent chapters lead the reader in a clear, logical manner through the process of establishing, validating, and maintaining an EO sterilization facility. Finer points of EO sterilization, like selection of process challenge devices, are well presented. Figures and tables are used effectively to illustrate and document important points.

Of universal value are the chapters applicable to any sterilization process. Starting with the basics of microbial considerations, discussions on biological indicator (BI) placement, bioburden limits, and process challenge devices are applicable to any means of sterilization. There is an extensive exhibit and annex section containing details such as minimum number of temperature and humidity sensors and conversion tables. There is a good set of references and a glossary. Although one could argue with some of the definitions, e.g., implying carcinogenic and mutagenic are the same, and one could suggest that Exhibits 2 (load configuration) and 6 (BI location) should be next to each other, one is hard pressed to find fault with the annexes and exhibits.

**Assessment:** Overall, this book provides excellent step-by-step details of how to perform EO validation and operation. The coherent manner in which Booth has tied the regulations, standards, and science of EO sterilization in each chapter makes this particular book a template other technical writers should strive to emulate. This book is now slightly outdated as ISO 10993 part 7 is undergoing revision, which will lower limits on certain devices, and AAMI TIR 17, which covered only material biocompatibility following radiation sterilization, is undergoing revision to include material biocompatibility following EO as well as other means of sterilization. In addition, the 1978 proposed rule for ethylene oxide residuals was officially withdrawn in 2003. The table regarding EO limits is still valid, but mentioning those devices with exception to the limits might be a valuable addition to the table. Still, one would be hard pressed to think of any detail or aspect of EO validation and sterilization not included in this book. This is an excellent reference book and a valuable practical guide for anyone in the field.

Reviewed by
Anne D. Lucas, PhD
Research Chemist
U.S. Food and Drug Administration
Silver Spring, MD