INTRODUCTION

The following handbook provides a framework for the validation and routine operation of ethylene oxide (EO) sterilization processes. The guidance presented complies with ISO 11135-1:2006, *Sterilization of health care products – ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*, and ISO 11135-2:2006, *Sterilization of health care products – ethylene oxide – Part 2: Guidance on the application of ISO 11135-1* and EN 550 – *Sterilization of medical devices – validation and routine control of ethylene oxide sterilization*. These standards and guides provide a framework and should not be considered inflexible or static. This handbook defines methods to assist in the interpretation and understanding of the requirements provided in the standards and offers practical procedures for the validation and routine monitoring of individual, specific EO processes. Please note that medical devices should be manufactured according to a quality system that complies with ISO 9001 or ISO 9002, ISO 13485 and the Food and Drug Administration (FDA) Code of Federal Regulations (CFR) 21 Part 820. These quality standards recognize that some processes, such as sterilization, that may be used in the manufacture of products cannot be verified by inspection or testing. Therefore, the sterilization process must be validated and the routine process and equipment carefully monitored and maintained.