Key Terms

Failure Mode and Effects Analysis (FMEA)—systematic method of proactive risk assessment used to improve the safety of complex processes by identifying ways in which failure can occur.

Cause—reason for the failure.

Detection—ranking number associated with recognition of a problem with a product or process.

Effect—consequence of the failure on the system or end user.

Failure mode—manner in which an item or process will potentially not meet or deliver the intended function.

Function—purpose of an item or process.

Item—specific steps in a process or product development assessed in the FMEA.

Probability—ranking number associated with the likelihood that the failure mode and its associated cause will occur.

Risk priority number (RPN)—numerical ranking of each potential failure mode that is the product of the severity of effect, likelihood of occurrence, and detection scores.

Severity—ranking number associated with the most serious effect for a given failure mode.

Healthcare FMEA (HFMEA)—adaptation of a FMEA tool for healthcare.

System FMEA model—analysis tool that focuses on the functions and relationships of the system as a whole including safety, integration, interfaces, and interactions of subsystems.
INTRODUCTION

FMEA is a systematic method of proactive risk assessment used to improve the safety of complex processes by identifying ways in which failure may occur. Identification of the potential risks or failures allows for process redesign to minimize the consequences of the failure or to prevent it entirely. After World War II, the U.S. Department of Defense developed the concept of FMEA; the National Aeronautics and Space Administration (NASA) then adapted it in the 1960s. Successful use of FMEA by the U.S. government led to adoption by many industries, and in the mid-1990s, the Institute for Safe Medication Practices (ISMP) supported this approach for medication error prevention. In 2001, the U.S. Veterans Administration National Center for Patient Safety developed the Healthcare FMEA (HFMEA) tool for risk assessment. In 2001, The Joint Commission adopted standards summarized in Table 14-1 that require healthcare organizations to select one high-risk process and conduct a proactive risk assessment every 18 months. HFMEA has now become the standard process for use with implementation of new medical technology and prevention of human errors in patient care.

HFMEA can be used prior to, during, and following the implementation of smart pump technology to identify and address potential failure. Initially, HFMEA may be used in the selection of smart pumps to identify desired attributes that enhance safety. Once the smart pump has been selected, the HFMEA may be expanded to reflect necessary changes to existing processes and the potential for errors that the use of the pump may introduce. HFMEA may also serve as a tool for continuous process improvement following implementation by tracking and addressing failure modes that have occurred. This chapter will highlight the process for developing a HFMEA for smart pump technology.

HEALTHCARE FMEA PLAN

HFMEA is a common human factors analytical method used to prospectively identify and eliminate potential failures or errors from the system, process, or technology design before reaching the end user. When conducting a HFMEA, a defined process is

| Table 14-1. The Joint Commission’s Suggested Steps in Assessing Proactive Risk Assessment |
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