

Using Failure Modes, Mechanisms, and Effects Analysis in Medical Device Adverse Event Investigations

Shunfeng Cheng¹, Diganta Das¹, and Michael Pecht¹

¹Center for Advanced Life Cycle Engineering (CALCE),
University of Maryland, College Park, MD, 20742.
{chengsf, digudas, pecht}@calce.umd.edu

Abstract. In the United States, when medical devices are associated with adverse events that result in death or serious injury, or have malfunctions that could lead to death/serious injury, these events must be reported to the Food and Drug Administration's Center for Devices and Radiologic Health by device manufacturers and user facilities. However, the defects in the medical device evaluation process (e.g., failing to identify the failure mechanisms), can result in assessment risks and reoccurrences of adverse events. This paper presents an approach for medical device evaluation by using failure modes, mechanisms, and effects analysis to identify the root causes and failure mechanisms, which can improve the designs and reliability of medical devices. This method can also help medical device manufacturers to generate an internal evaluation reports for medical device evaluation, which can improve the reporting process to Food and Drug Administration.

Keywords: Medical device; adverse event; failure modes, mechanisms, and effects analysis.

1 Introduction

A medical device is an instrument, implant, or in-vitro reagent which is intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, and which is not a drug or biologic product [1]. Manufacturers, user communities (e.g., hospitals or patients), and the Food and Drug Administration (FDA) all devote resources to ensure that medical devices are developed and used in a safe and effective manner throughout their lifetime. Even with this amount of oversight, devices still fail, resulting in adverse events, which are defined by FDA as "any undesirable experience associated with the use of a medical product."

In the United States, adverse events related to medical devices are collected by FDA in Medical Device Reports (MDRs). Manufacturers conduct evaluation on the adverse event related medical device and report the evaluation results to FDA by some evaluation codes [2][3], which are used to describe the methods, results, and conclusions following the evaluation of a device involved in an adverse event. Evaluation method codes are used to indicate how the adverse event or failure was analyzed by the manufacturer, such as electrical or mechanical tests or visual

examination. The outcome of this analysis is recorded using evaluation result codes, such as incomplete labeling. Finally, evaluation conclusion codes are used to summarize the manufacturer's findings of the analysis and focus on root causes to determine why the event occurred (for example, "device failure indirectly contributed to events"). Manufacturer evaluation codes are asked for in item H.6 in Form 3500A [4]; additional manufacturer narrative is asked for in item H10 to provide complementary information on the manufacturer evaluation.

Currently, there are no FDA guidance documents to guide manufacturers on the best practices for failure tracking and analysis. Device manufacturers might not use effective root cause analysis procedures leading to improper assignment of causes to the device failure. This may lead to the risk of reoccurrence of failures and inhibit the tracking of problems.

Center for Advanced Life Cycle Engineering (CALCE) at the University of Maryland have developed a failure modes, mechanisms, and effects analysis (FMMEA) based approach that helps manufacturers improve their medical device evaluation processes and the future products by providing a systematic evaluation method for potential failures and causes, making it more efficient to identify the root causes and mechanisms of the failure of devices.

2 Using FMMEA for Adverse Event Related Medical Device Evaluation

FMMEA (Figure 1) is a means to help manufacturers implement medical device evaluation in a systemic manner that allows for investigation of the failure mechanisms and generate manufactures' internal device-specific evaluation reports in a failure site-mode-cause-mechanism structure, which may aid in reporting adverse event related medical device evaluations to FDA.

No literature or reports have shown that medical device manufacturers are using FMMEA, although some similar abbreviations were reported. For example, failure modes and effects analysis (FMEA) or failure modes, effects, and criticality analysis (FMECA) are used to identify the possible failure modes and causes of medical devices [5]. FMEA or FMECA methodologies outline procedures to recognize and evaluate the potential failure of a product and its effects and to identify actions that could eliminate or reduce the likelihood of the potential failure to occur [6]. Many organizations within the electronics industry have employed or required the use of FMEA, but in general this methodology has not provided satisfaction, except for the purpose of safety analysis [7]. A limitation of the FMEA methodology is that it does not identify the product failure mechanisms in the analysis and reporting process. For example, when conducting FMEA on infusion pumps [5], the important failure mechanisms for catheter system leakage or breakage, such as fatigue, corrosion, kink, and chemical precipitation, were not identified, and as a result the design update process would not target those mechanisms.

FMMEA is a tool to support physics-of-failure based design for reliability [7]-[10]. It can identify potential failure mechanisms for all potential failures modes and prioritize the failure mechanisms. FMMEA can aid medical device manufacturers in

the development of reliable designs, planning tests, and screens to validate nominal design and manufacturing specifications and determine the limits on the level of defects introduced by the variability in manufacturing and materials. FMMEA enhances the value of traditional FMEA methodologies by identifying the high-priority failure mechanisms in order to create an action plan to mitigate their effects.

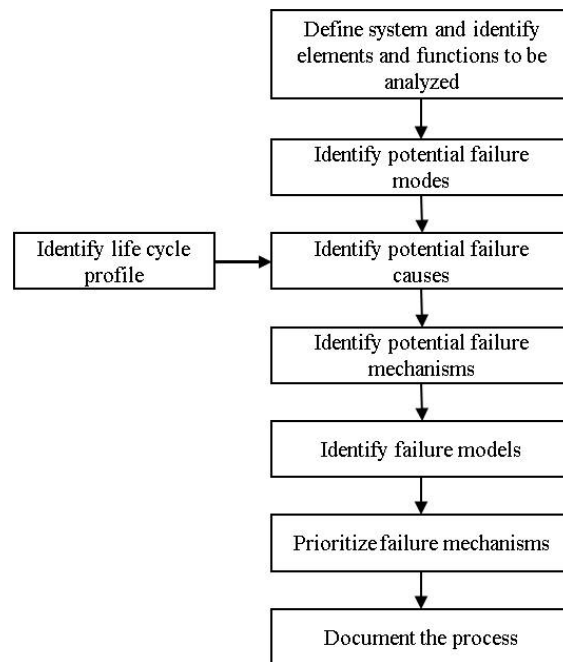


Figure 1: FMMEA Methodology [8]-[10]

FMMEA uses the life cycle profile (LCP) of a product along with the design information to identify the critical failure mechanisms affecting a product. An LCP is a forecast of the events and the associated environmental and usage conditions a product may experience from manufacture to end of life. The device is divided into its lower level subassemblies for investigation. For medical devices, FMMEA can be conducted down to the lowest level at which the device manufacturer still has design control; FMMEA at lower levels should be performed by subsystem or component vendors. These subassemblies are potential sites of failure. In FMMEA the potential failure modes for each failure site are listed. A failure mode is the manner in which a failure is observed by methods such as visual inspection, electrical measurement, or other tests and measurements. For each failure mode, the potential failure causes are analyzed. A failure cause is the specific process, design, and/or environmental condition that initiate a failure and whose removal will eliminate the failure. Possible failure causes are investigated in the entire life cycle of the device, including design, manufacture, operation, and maintenance. For example, in a multilayer ceramic capacitor (MLCC), a component used in medical devices [11], the failure modes may be short, open, or parameter shift, such as a decrease in insulation resistance or an

increase in dissipation factor. The potential causes of these failures may be operational temperature and humidity conditions during storage or transportation.

Next, potential failure mechanisms are identified. Failure mechanisms are the processes by which a specific combination of physical, electrical, chemical, biological, and mechanical stresses induces failures. Using MLCCs under temperature-humidity-bias conditions as an example, the dominant failure mechanisms include metal migration between the electrodes, dielectric degradation caused by moisture penetrating the voids, and creation of oxygen vacancies in the dielectric of the capacitor.

During the life cycle of a product, several failure mechanisms may be activated by different environmental and operational parameters acting at various stress levels, though, in general, only a few operational and environmental parameters and failure mechanisms are responsible for the majority of failures. In the process of conducting FMMEA, we assess the combinations of occurrence and severity of each failure mechanism, where the probability of occurrence is taken into consideration from the distributions of the loads and the geometric/material features, while the severity is obtained from the seriousness of the effects of the failure caused by a particular mechanism.

Medical device manufacturers can conduct FMMEA internally to identify the potential failure sites, modes, causes, and mechanisms of a medical device. The use of FMMEA will enable manufacturers to create an internal evaluation report organized in the failure site-mode-cause-mechanism structure, as shown in Figure 2. Another benefit of conducting FMMEA is that it would help manufacturers monitor and improve the reliability of their products and provide manufacturers with useful information to investigate and correct the adverse events.

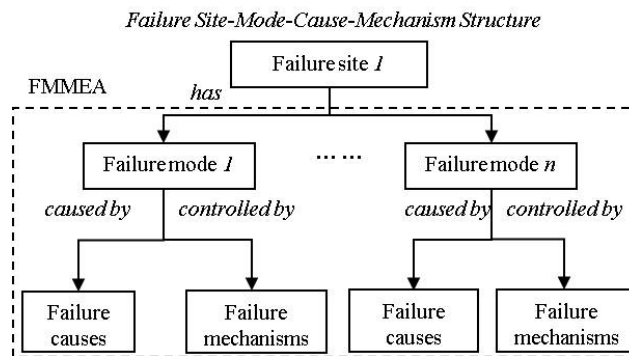


Figure 2: Failure Site-Mode-Cause-Mechanism Structure for Adverse Event Investigation

3 Example: FMMEA on Infusion Pump Failure

An external infusion pump is used to deliver fluids into a patient's body in a controlled manner. FDA has seen an increase in the number and severity of infusion

pump related adverse events [12]. An example of FMMEA of the flow generation and regulation system of an infusion pump is shown in Table 1.

Table 1: Examples of FMMEA on Infusion Pumps (Excluding biological or chemical hazards or failures)

Potential failure sites	Potential failure modes	Potential failure causes	Potential effects ¹	Potential failure mechanisms	
Flow generation and regulation system	Power (only battery is concerned)	Voltage error, unable to be charged, overheating	Battery depleted, overcharged, degraded	Underdose, overdose, therapy delay	Battery wear-out
	Pump	Pumps inaccurate size/rate of dose (including “fail to pump”), operating abnormally	Component defects; improper position of pump; failure to release inside air, lower inside air pressure; ambient temperature, humidity, air pressure too high or low; design error; labeling error; insufficient training; calibrating or programming error	Underdose, overdose, therapy delay, free flow, air in line, reverse flow	Wear-out, fatigue, corrosion
	Control module: software	Runtime error, incorrect messages, false alarms, failure to alarm, incorrect dose calculation	Buffer overflow or underflow; incorrect dynamic libraries; uninitialized variables; wrong algorithms or programming, threshold setting error; insufficient training	Underdose, overdose, or therapy delay	Design errors
	Control module: hardware (e.g., processor, memory)	Overheating, short or open circuit, high leakage current, high or low impedance, missed alarm, false alarm, fail to read/write data	Insufficient cooling, shielding or insulation; non-human interference; loose interconnection; corrosive fluid ingress; component failure, sensor contaminated, out of calibration; design error; labeling error; insufficient training.	Underdose or overdose, electric shock, therapy delay, contamination	Overstress or wear-out, fatigue, corrosion, radiation
	User interfaces (e.g., display)	Cracks in package or case, broken keypad, key stuck/depressed, speaker/audio unit failure	Incorrect operation, environmental effects, accidents (e.g., falling), fluid ingress, design defects, component defects, component degraded; design errors; labeling errors; insufficient training	Under-dose or over-dose, contamination, therapy delay	Wear-out, overstress, corrosion, fatigue, radiation, creep

¹ Information from this column is used just for determination of severity and prioritizing the critical mechanisms.

Generally, the infusion pump contains three main subsystems: the fluid reservoir, a catheter system for transferring fluids into the body, and a flow generation and regulation system that combines electronics (e.g., processor, memory, and power management module) with a flow control mechanism (e.g., pump and sensors) to generate and regulate flow [13].

When an adverse event related to an infusion pump is reported, the manufacturer can identify potential failure sites and modes based on the description of the adverse event. Manufacturers then refer back to FMMEA evaluation results to find the possible causes and mechanisms, and then conduct actual inspection to validate the failure sites, root causes, and mechanisms, and then have an internal report about the evaluation results. For example, if the device problem was reported as “failure to alarm”, which is failure mode, and patient problem code was “over-dose”, which is failure effect, the potential failure sites may include the software and related components. If the failure site was confirmed as “control module: hardware”, the potential failure causes and mechanisms could be determined. The final evaluation could be reported as shown in Figure 3.

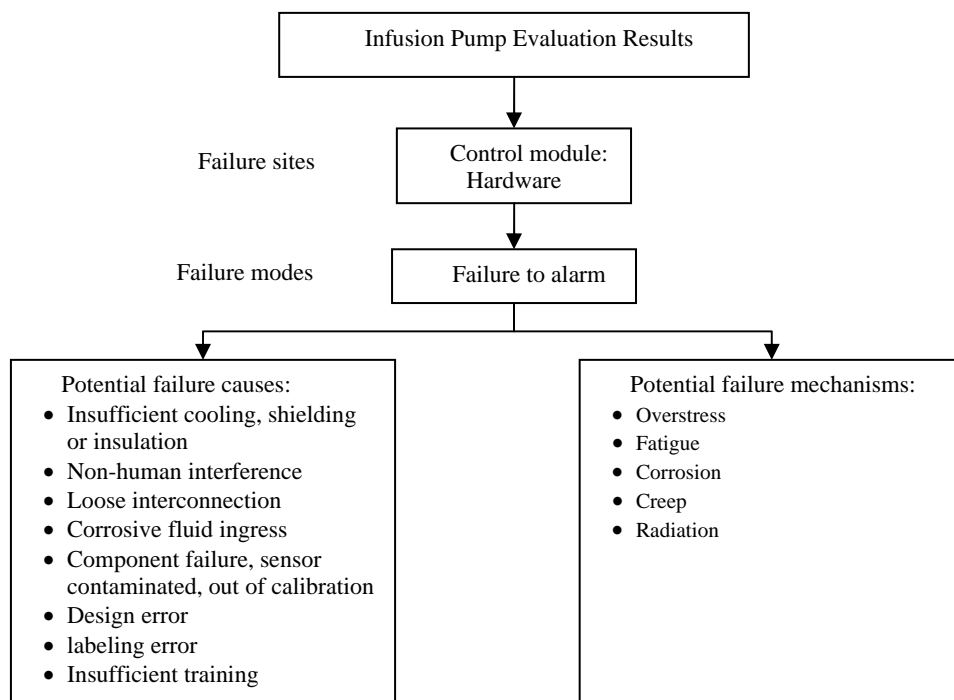


Figure 3: Example of Structured Medical Device Evaluation Results

5 Discussions and Conclusions

FMMEA enables manufacturers to narrow down device failures to a desired level of abstraction (system, subsystem, or component), identify the root causes and

mechanisms of the failures, take proper actions to reduce the recurrence of the failures, and improve device design, product realization, and sustainment. If the manufacturer has a family of similar medical devices that may be used in similar environmental and operational conditions, FMMEA evaluation results could be transferred to other devices in the family. With more root causes of device failure have been identified and controlled, medical devices can be expected to have better reliability. This can reduce the number of medical device-related adverse events. Manufacturer can utilize knowledge of a product's life cycle loading and failure mechanisms and models identified by FMMEA to assess reliability of medical devices. The possible failures of a medical device can be cataloged by FMMEA, and potential risks can continue to be updated by monitoring the device's life cycle environmental and usage conditions while taking into consideration the devices geometry and material properties. Adverse event possibilities can then be identified and averted based on that knowledge.

We are working with computer scientists within FDA to determine what the data structure might look like. However, we do not want prescribe for manufacturers the particular FMMEA data format that they will integrate into their design process. Manufacturers will store data in a format that is compatible with and accessible to their adverse event resolution process.

When reporting to FDA, manufacturers need not send the complete FMMEA evaluation to FDA, but share the parts related to a specific adverse event. When an adverse event is reported, the manufacturer could use existing FMMEA to narrow in on the potential failure modes and causes and report to FDA using the linked evaluation codes after actual validation. A failure site-mode-cause-mechanisms structure with explanations can provide content rich information in the text fields when reporting MDRs. One effect of FMMEA on adverse event ontology is that FMMEA can generate new medical device-specific codes. The device-specific codes used in failure-site-mode-mechanism structured reports can be used to extend current adverse event ontology beyond the current generic reporting terminology. However, the evolution of adverse event ontology in a general sense is beyond the scope of this paper.

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