Chapter XII
PACS Failure Mode and Effects

BACKGROUND

There are some medical errors for which preventability is rarely questioned. These include medical errors such as wrong site surgery, wrong procedure, wrong patient operations (Seiden & Barach, 2006; Michaels et al., 2007; Lee et al., 2007), wrong drug/dose/duration (Pugh et al., 2005) or incompatible organ transplantation (Cook et al., 2007). Less preventable medical errors include judgment type errors such as case studies reported in journals, where one or more experts review the treatment decisions of a clinician and conclude that the clinician’s judgment was incorrect (Lukela et al., 2005).

Many healthcare managers first heard about Failure Mode and Effects Analysis FMEA when Joint Commission on Accreditation of Healthcare Organizations (JCAHO) released its Leadership Standards and Elements of Performance Guidelines in July 2002 (JCAHO, 2002). The purpose of performing an FMEA for JCAHO was to identify where and when possible system failures could occur and to prevent those problems before they happen. If a particular, failure could not be prevented, then the goal would be to prevent the issue from affecting healthcare organizations in the accreditation process.

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FMEA is a tool that when performed adequately, can reduce the risk of preventable medical errors. Hospitals in the United States that are accredited by JCAHO are required to perform at least one FMEA each year. The main output of FMEA is a series of mitigations, each of which is some process change implemented to reduce the risk of error. Because resources are limited, implementing all mitigations is not possible so the challenge is to find the set of mitigations that provides the highest reduction in risk for the least cost. Hence, preventability may be viewed in terms of the cost and effectiveness of mitigation. A low-cost and effective mitigation is associated with a highly preventable medical error, whereas a high-cost and or less effective mitigation is associated with a less preventable medical error.

Currently AAPM TG 100 (2007) is reviewing reports from previous task groups and from several professional organizations. This group is also reviewing ISO guidelines in an effort develop a suitable general QA approach that “balances patient safety and quality versus resources commonly available and strikes a good balance between prescriptiveness and flexibility.” The TG 100 initiative identifies three industrial engineering–based tools as potential components of a QA management system in radiation therapy and FMEA is one of them.

There are a few potential problems with these recommendations, however. The first is that the general radiation therapy community is concerned that the use of these tools to reduce the risks or hazards associated with radiation therapy will require a considerable amount of additional resources. Although this should be a concern, process mapping, flowcharting tools, and FMEA (Stamatis, 1995; Fletcher, 1997; Thomadsen et al, 2003; Latino, 2004; JACHO, 2005; Hansen, 2007; Huq, 2007) have been used for decades by the medical device and pharmaceutical industries, among others, to reduce the level or risks or hazards in products and processes with many positive results. Also if the organizations are trained in the use of these tools and if these tools are applied with the assistance of experienced facilitators, there are few if any additional resources required, and the resulting process improvements will increase the effectiveness and productivity of the organization. A second potential problem is TG 100’s recommendation that these tools be used for risk and hazard analysis versus overall process improvement. This might prevent the realization of significant improvements in processes and the resulting increase in quality and productivity.

Although FMEA has been applied in the medical community, its use appears to have the highest potential for assisting the radiation therapy community in improving overall process quality and in reducing and controlling the risk of injury without overtaxing resources. In the modern environment the number and sophistication of possible tests and measurements have increased dramatically. There is a need to prioritize quality management activities in a way that will strike a balance between
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