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**Quality and Safety in Radiotherapy:
Learning the New Approaches
in Task Group 100 and Beyond**

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Editors

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Chapter 4

Risk Assessment Using the TG–100 Methodology

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4.1 Introduction

Risk assessment is the process of analyzing the hazards involved in a process. The purpose of risk assessment is to minimize the effects of failures in radiotherapy by being conscious of the risks associated with the system in which it operates.

The term risk is frequently defined as the set of answers to three related questions (American Society of Mechanical Engineers 2002/2003, U.S. Nuclear Regulatory Commission 1998):

1. What can go wrong?
2. How likely is it to go wrong?
3. What are the consequences if it goes wrong?

The first question is addressed by identifying all (or as many as possible) of the potential failure modes—or ways in which a process could fail—for a given process. The second question is answered by developing models that estimate the probability or frequency of occurrence of the failure modes resulting from various causes, such as human factors or errors. The third question is addressed by assessing the consequences of each failure mode on the outcome of the process, assuming that the causes for each failure mode are not detected and corrected. The goal of a quality management program is then to focus on risk assessment for the entire process involved in the treatment of a radiation therapy patient and put control measures in place which will inhibit failures and prevent degradation of treatment quality if there is a failure.

Risk assessments may be *a priori*, before much is known about the process and its potential failures, or *a posteriori*, considering data collected on events that have happened. An *a priori* analysis tends to weight the probability of all failures fairly equally, without reasons to differentiate. “Expert opinions” serve to give some guidance to the probabilities. An *a posteriori* analysis can be much more precise, with probabilities based on gathered data. For radiation therapy processes, the development of probabilistic risk assessment models is a challenging task because the equipment and therapy procedures are highly reliable, and there is a lack of measured data on occurrence and detection probabilities for undesired events. Most radiotherapy risk analyses studies are thus based on expert consensus opinion to subjectively estimate the required probability data.

New approaches are being developed to address the quality management (QM) needs of both existing and emerging technologies in radiation therapy. These are based on risk assessment that consists of analysis of the hazards involved in the entire radiation therapy process (critical or less critical) and accounts not only for the devices used for radiation treatment and the individual steps employed in each process (and their consequences, should they fail), but also for interactions between them. They reflect jointly the probability of a failure occurring and the severity should it occur. Thus, they allow a radiotherapy department to develop a systematic QM program that acknowledges its current level of technology and clinical practice. Task Group 100 (TG 100) of the Therapy Physics Committee of the American Association of Physicists in Medicine (AAPM) has adopted such an approach and developed a risk assessment-based framework for QM activities in radiation therapy [Huq et al. 2008, Huq et al. 2013]. This chapter will briefly present the methodology of this approach.

HDR Brachytherapy Process Tree

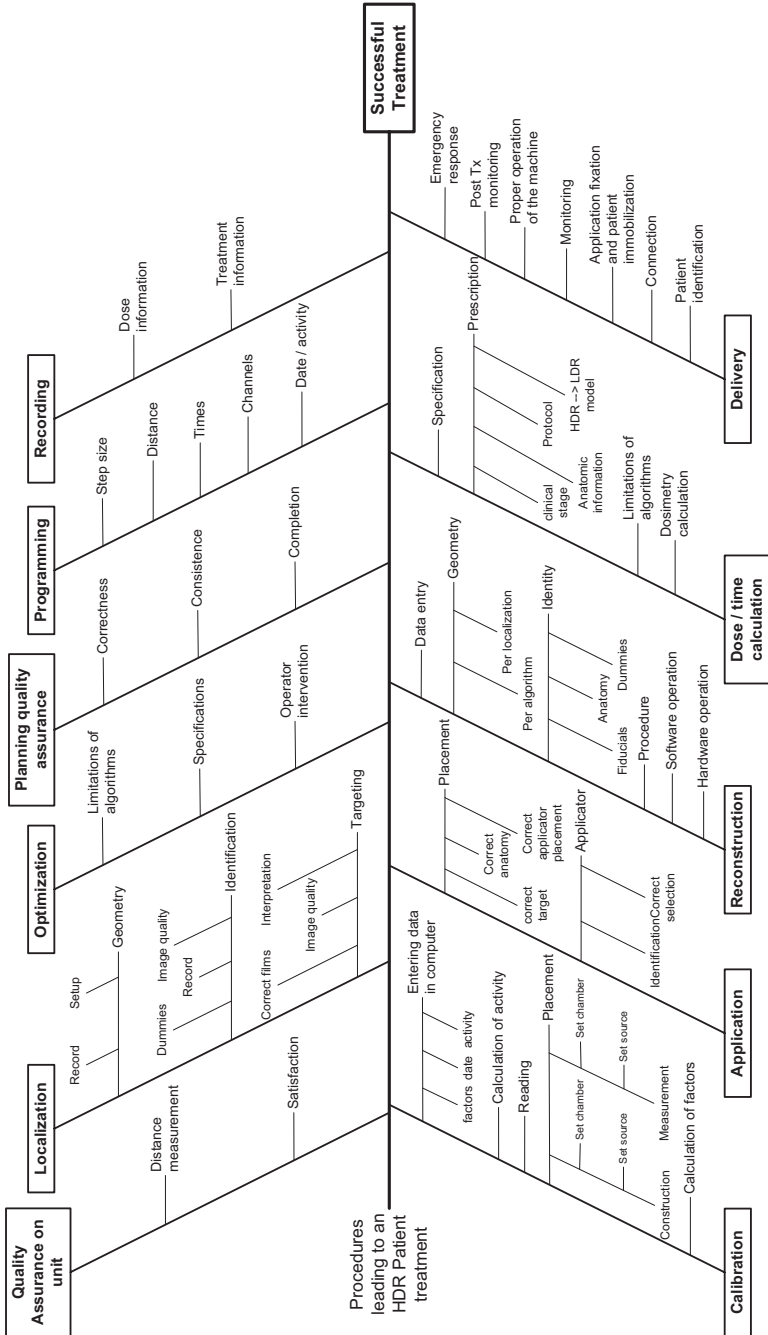


Figure 4–1. Example of one form of a process tree. Figure courtesy of Bruce Thomadsen.

4.2 Risk Assessment and the TG–100 Approach

Although many risk assessment and analysis techniques exist in industry, the framework for quality management in radiation therapy developed by TG 100 is based on the use of three industrial engineering-based tools. These are 1) process mapping, 2) failure modes and effects analysis (FMEA), and 3) fault tree analysis to create a quality management program that will mitigate the most important risks that are identified in the previous analyses. Successful implementation of this methodology will require the participation of a clinic's entire radiation therapy delivery team—consisting of radiation oncologists, medical physicists, dosimetrists, therapists, nurses, engineers, and IT personnel as appropriate—to develop an FMEA-based risk-aware QM program for all clinical processes by contributing to the analysis of process steps and failure modes that involve their work.

The following sub-sections briefly introduce the concepts of process mapping, FMEA, and fault-tree analysis.

4.3 Process mapping

4.3.1 Introduction

The purpose of this section is to 1) define “process map,” 2) discuss the reasons for creating and using process maps, 3) present an example map and case scenario, and 4) suggest techniques and tips for creating process maps.

We take the term “process map” (sometimes called a “process flow chart”) to mean any visual representation of the steps involved in a process. In doing so, we lump together terms like “process tree,” “fishbone diagram,” etc.—all different ways of presenting the same information, each with their own benefits and drawbacks. Technically, graphical approaches like fishbone diagrams or affinity diagrams are not really process maps since they are not temporally ordered and do not depict the connections between various steps in the workflow. However, we believe in a practical approach and leave it to the reader to use his or her preferred style of visual representation. An excellent example of a process tree is shown in Figure 4–1. The trunk of the tree describes the process, while the branches depict sub-processes that feed into the main process. There are also branches off of branches. This is a great way to handle detail in a process flow chart, as it is amenable to both high-level and detailed process descriptions.

Process maps offer an excellent starting point for those considering quality and safety improvement initiatives (The Victorian Quality Council 2007). They can be used to shape current clinical practice, as well as facilitate future quality and safety initiatives. Often, the simple act of sitting together to develop the process maps can produce immediate benefits in terms of communication and understanding between professional groups. Process maps also form the basis of other quality and safety tools, including Failure Modes and Effects Analysis (Fore et al. 2009) and Fault Tree Analysis (Ekaette et al. 2007), as well as Incident Learning Systems and Root

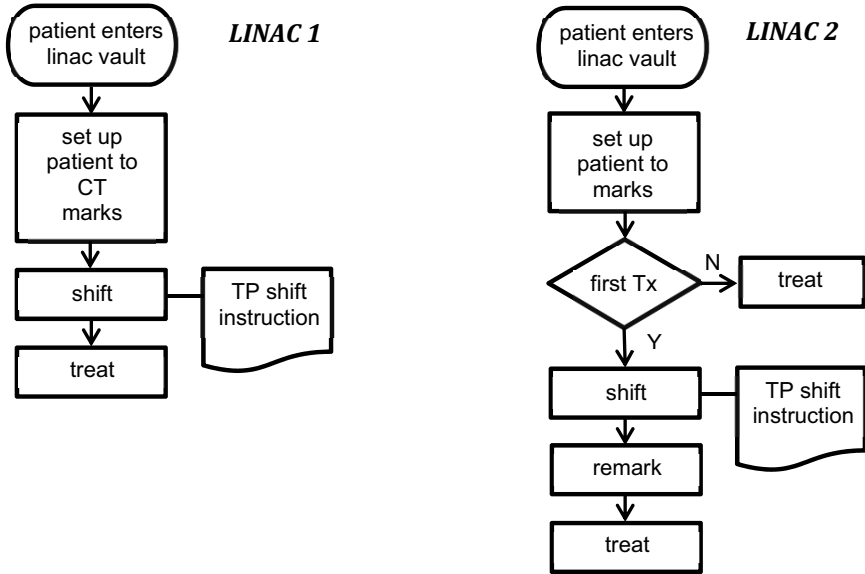


Figure 4-2. General process describing steps taken from the time the patient enters the treatment room until the time the beam is turned on. Different workflow processes are employed on linac #1 (left) vs. linac #2 (right). Figure 4-3 gives explanations for the symbols used in this type of process map.

Cause Analysis (Cooke et al. 2006). All of these often use process descriptions as a starting point.

4.3.2 Example Process Map Scenario

The many benefits of creating and using process maps can be illustrated using a simple, realistic clinical example. Consider the process of patient setup and treatment in an external beam radiation therapy clinic. The workflow is illustrated in Figure 4-2 in a simplified process map. Such a map might be created, for example, as part of a root-cause analysis in the wake of a patient mistreatment incident. The example in Figure 4-2 shows a clinic that has two treatment units (linac #1, left, and linac #2, right) each employing slightly different workflow processes.

To make the example more concrete, we consider two radiation therapists working in a medium-sized, 4-linac clinic: Greg (lead therapist on linac #1) and Marsha (lead therapist on linac #2). Greg on linac #2 follows the process on the right in Figure 4-2: he re-marks patients on the linac table after the first treatment setup. On subsequent treatment setups, he simply sets the patient up to the new marks. On linac #1, Marsha sets up the patient to CT marks and then shifts the patient according the treatment planning instructions for every fraction. The existing documentation on this process at the clinic is poorly written and confusing.

It's a busy day, and Marsha's teammate has called in sick, so Greg is asked to join Marsha on linac #2. Greg and Marsha are in the process of setting the patient up when Marsha is called away to deal with urgent questions from the spouse of another patient. Greg finishes the patient setup using the workflow that he is accustomed to (right panel of Figure 4–2). He sets the patient up to her marks and does not make a further shift. When Marsha returns, Greg has completed the setup and is at the treatment console. Marsha knows that Greg has significant experience, and she assumes he has made the correct patient shifts, but as a courtesy, asks him if everything is ready to go. Greg, always happy to help out, asserts that everything is ready to go. They beam on and treat, not realizing that Greg has not made the shifts that were required.

There is a clear divergence in this process. Two employees working in the same clinic, treating the same types of patients, are following two different processes. A root-cause analysis would reveal the multifactorial causal factors behind this incident, including communication, distraction, and deficiencies in policy and procedure. However, even before an incident occurs, creating process maps like those in Figure 4–2 would demonstrate a hazardous situation: the clinic is operating with diverging workflows.

In summary, process maps are valuable for several reasons:

- Improving communication—different professional groups, and different individuals within those groups, now have the same understanding of the process and how it fits together (providing a clear picture of where hand-offs occur).
- Harmonizing clinical practice and ensuring that everyone operates with a shared model.
- Improving efficiency. Workflow inefficiencies can become obvious when mapped out visually.
- Process maps also allow one to codify where along the workflow incidents are occurring, which is potentially powerful information for incident learning.

The section below suggests a recipe for process mapping and highlights some of the potential pitfalls that occur when creating a process map. In the workshop,

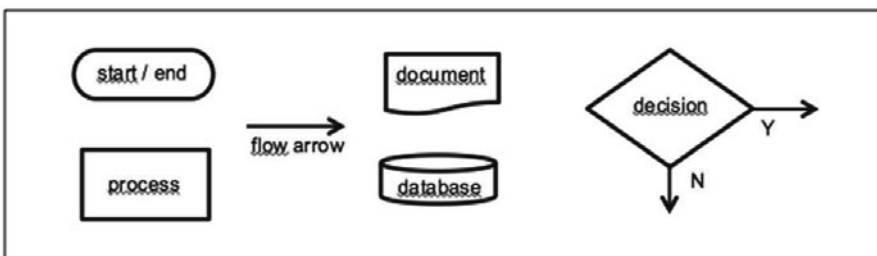


Figure 4–3. A dictionary of process map symbols.

the IMRT treatment planning process will be mapped as an exercise, selected because studies have shown that many errors originate in the treatment planning process (Clark et al. 2010). Here, the various steps involved are discussed.

4.3.3 Techniques and Tips for Creating Process Maps

Step 1: Decide what process to map. The scale of the process is an important concern here. Mapping the entire external beam radiation oncology process, for example, is a large project that could take many weeks. It is beneficial to focus on smaller sub-sections. Often the needs of the analysis dictate the scope of the mapping project.

Step 2: Form a group and identify a team leader. It is vital that all professional groups are represented in this process. This may include administrators and managers, as well as clinical staff.

Step 3: Create an initial process map. It is often useful to make a first draft that does not attempt to capture the entire process in detail, but rather the workflow at a more general level. The standard symbol dictionary outline in Figure 4–3 may be useful. Programs such as Microsoft Office[®] (Microsoft Corp, Redmond, Washington) or OpenOffice[®] (The Apache Software Foundation, Forest Hill, Maryland) have these tools built-in. Dedicated software platforms for process mapping are also available, such as Microsoft Visio[®] and Lucidchart[®] (Lucid Software, Chennai, Tamil Nadu, India). However, hand drawing is often easier and sufficient.

Step 4: Iterative mapping. The process map is refined with the input of all staff involved.

Step 5: Check with external resources to make sure that no steps have been missed. Examples here include the incident reporting white paper from the AAPM Work Group on Prevention of Errors, which has a general list of process steps for external beam radiotherapy as well as brachytherapy (Ford et al. 2012). Process mapping is further discussed in TG 100 when it becomes available (Huq et al. 2013).

Step 6: Use the process map. Examples of this use can be found later in this chapter on FMEA analysis.

4.3.4 Tips for Creating Useful Process Maps

1. It is often useful to look at processes from the patient's perspective.
2. For clinical processes, a *multi-professional team* is necessary for the development of a valid map.
3. The number of subprocesses identified should be the *smallest number needed* to meet the objective.
4. The users of the map should have the *same understanding* of the meaning of the subprocesses.
5. Choose the right level of detail. A map that is too general loses its utility, while one that is too detailed becomes unmanageable and staff can lose the big picture.

6. Don't get hung up on fancy graphics. There is value in the *process of creating the map*.

4.3.5 Process-mapping Conclusions

It is important to note that process mapping is less about coming up with “the right” map and more about the process of creating the map—getting different groups to communicate and producing a map that accurately reflects the nuances of a particular clinic. We believe that process maps may find a future utility as a means for clinics to compare themselves to each other. To our knowledge, this has not yet been attempted in any significant way, but it may be a very effective way of communicating and quantifying differences in standard practices.

4.4 Failure Modes and Effects Analysis

4.4.1 Introduction

After outlining a process, the next step is to assess the potential risks involved in that process. FMEA is a technique that is used to perform a quantitative assessment of risks. A good FMEA defines, identifies, and helps to eliminate or intercept known and potential failures (failure modes) and errors from a process before they reach a patient. FMEA assesses the likelihood of failures in each step of a process, identifies the causes and effects of each failure mode, determines the likelihood that these failure modes will not be detected, and assesses how severe a failure's consequences might be on the patient. The overall risk of each identified failure mode is then scored according to a risk priority number (RPN) so these failures can be prioritized. A good FMEA thus facilitates problem follow-up and corrective actions required to prevent failures from reaching the patient, thereby assuring the highest quality and reliability in rendering service to the patient.

For quantitative FMEA analysis, numerical values are assigned to three components for each cause of failure:

- O, for the likelihood of occurrence
- S, for the severity of the effect of failure
- D, for the likelihood that the failure considered would go undetected

TG 100 used numbers between 1 and 10 for each of these indices, with 1 assigned to no appreciable danger and 10 to the most severe. The product of these three indices form the risk priority number, or RPN. The higher the RPN, the more likely the failure mode is to occur, the less likely the failure mode will be detected, and the more severe the results of a failure mode will be.

Each of the significant hazards requires the addition of controls or a quality management step to eliminate the dangers, i.e., bring the hazard rating to an acceptably low value. Fault tree analysis is a useful tool in determining the placement of these controls.

FMEA is a proactive methodology used to systematically evaluate and identify risks or weaknesses in product design or other process and to identify process con-

trols that address them. The origin of FMEA can be traced to the late 1940s to U.S. Military Standard MIL-P-1629 (Department of Defense 1980). During the 1960s, FMEA methodology was used in several NASA programs, including Apollo, to ensure robust designs and processes. In the 1970s, FMEA was adopted by the automotive industry (Automotive Industry Action Group) to better manage quality in product designs and throughout the supply chain. More recently, the use of FMEA in health care appears to have grown significantly, based on my own observations. For further reading on FMEA, see Stamatis and the Veterans Administration guide (Stamatis 1995, U.S. Veterans Administration).

In industry, there are four distinct types of FMEA:

1. *Design FMEA*—used to evaluate a product design process
2. *Process FMEA*—used to evaluate a manufacturing or other type of process
3. *Application FMEA*—used to evaluate the use of a product design in a customer’s process
4. *Service FMEA*—used to evaluate the serviceability or maintainability of a product design

Each type of FMEA is independent, focusing only on the design, manufacture, use, or service/maintenance of a specific product. Companies designing equipment or devices should:

- Use Design FMEA to identify design risks that could result in suboptimal performance or hazardous results and take steps to eliminate those risks or mitigate the effects of those risks.
- Use Application FMEA to evaluate the use of their designs by their customers and identify potential problems their customers might experience.
- Use Service FMEA to make sure that their designs can be easily and adequately serviced or maintained.

Manufacturers of equipment or devices should:

- Use Process FMEA to evaluate their production processes to ensure that they are capable of meeting the specified requirements of an equipment or device design.
- Request that suppliers who produce parts, components, sub-systems, and systems use Process FMEA to ensure that their production processes are capable of meeting design requirements/specifications.

Healthcare organizations or hospitals should:

- Use Process FMEA to evaluate treatments, procedures, and processes and to identify specific process steps that are likely to or could produce suboptimal or hazardous outcomes.

FMEA is considered to be a living or continuous process and should be updated whenever any changes occur affecting designs or processes.

4.4.2 Overview of Process FMEA in Health Care

Process FMEA provides a “picture” of a process at the time it was performed, showing the weakest or riskiest areas of the overall process. Those areas are then addressed and more effective quality controls are developed and implemented to improve process performance and overall process quality.

4.4.3 Steps in Completing a Process FMEA in Health Care

A process FMEA should begin with a thorough and complete description of the process being evaluated in the form of a flow chart, process map, or process tree. It should be developed by a team of process experts who actually participate in the process, and it should be led by an experienced facilitator. All opinions of what actually happens during the process should be considered and valued. A visual representation or picture showing the entire process can be very useful. People involved in the analysis (and the process) can see how what they do fits into the process and gain an understanding of what is done upstream and downstream from their part of the process. Sometimes that knowledge and insight can lead to ideas on how to improve a process.

The typical or standard process FMEA form used to guide an analysis is shown in Table 4–1. The form normally has a general information header for identifying who participated in the analysis, when it was done, the revision number of the process FMEA, etc. The style and design of the general information header varies, and it is up to the healthcare organization to decide what information should be included. The analysis begins at the left of the form and progresses to the right until the risk priority number is calculated for each process step/failure mode/cause combination.

Step 1. Identify the major subprocesses. The process being analyzed is broken into major subprocesses. These major subprocesses correspond to steps in the process flow chart or map. The process can be broken into highly detailed subprocesses or larger or more macro subprocesses. Breaking the process into larger, or macro-level subprocesses, reduces the work required to perform the process FMEA and directs the team to the subprocesses that have the highest risk of sub-optimal performance or hazardous results. A more detailed process FMEA can then be performed on those areas with the highest risk.

Step 2. Identify each failure mode for each subprocess step. A failure mode is defined as the way in which a failure occurs or is observed, or the way in which a sub process step can fail to meet its intended purpose. Typical failure modes in radiotherapy are wrong dose (too high or too low) delivered, dose delivered to the incorrect location, etc. The failure mode should be defined in terms of the impact it could have on the patient.

Step 3. Identify the effects that could result from the failure mode. Effects are paired with failure modes—the failure mode occurs and produces the effect. Effects should be defined in terms of the patient. For the failure mode “dose delivered to the wrong location,” the effects could be damage to tissue or organs (unintended). Effects should be listed if they could occur, even if the likelihood is

Table 4–1. Standard or typical FMEA form

Resulting Risk Priority Number	Severity of Effects Resulting From Failure Mode	Resulting Detection of Failure Mode	Resulting Occurrence of Cause	Corrective Actions	Risk Priority Number	Severity of Effects From Failure Modes	Detection of Failure Modes	Occurrence of Causes	Current Process Controls	Potential Causes of Failure Modes	Potential Effects of Failure Modes	Potential Failure Modes	Process Step	Treatment or Major Subprocess

minimal. Multiple effects can be listed for a single failure mode, but only the most severe effect will be used in the analysis.

Step 4. Identify each potential cause that could produce each failure mode.

Each failure mode will have several causes. Causes of failure modes include, but are not limited to, the following:

- Inadequate training
- Lack of procedures
- Lack of work instructions
- Stressful environment
- Lack of time to perform work properly
- Improperly calibrated or maintained equipment or devices
- Malfunctioning equipment or devices

Causes are linked to failure modes, not effects. In some instances, teams confuse failure modes and effects and attempt to link causes to effects.

Step 5. Identify and list all process controls.

Process controls are quality control measures put in place to control specific steps in the process. There are three categories of process controls:

- Controls that prevent the causes of failure modes from occurring.
- Controls that detect the failure mode of a process step (defined in terms of when the failure mode will be detected and how likely the failure mode will be detected).
- Steps taken to reduce the severity of effects resulting from a failure mode.

Process controls are listed for each failure mode and all causes of that failure mode. In some instances, teams confuse the detection of a failure mode with the detection of a cause of a failure mode. Detection is always associated with a failure

Table 4–2. FMEA ranking scales for occurrence, detection, and severity

Rank	Occurrence – Cause: Probability that the cause will occur and produce the failure mode	Detection – Failure Mode: Probability that the failure mode will be detected before resulting in the effect	Severity – Effect: Seriousness of the effect resulting from the failure mode
1	Remote probability	Always	No effect
2	Low probability	High likelihood	Minor effect
3			
4	Moderate probability	Moderate likelihood	Moderate effect
5			
6			
7	High probability	Low likelihood	Serious effect
8			
9	Very high probability	Very low likelihood	Injury
10	100% probable	Never	Death

mode, not the cause of a failure mode. Process controls include, but are not limited to the following:

- Formal technician or operator training
- Certification programs
- Standard work procedures, work instructions, or operating procedures
- Outcome metrics for the process or specific steps in the process
- Process audits (checks to ensure the work is being performed properly)
- In-process inspection (the least effective process control)
- Statistical-based monitoring of process parameters, such as monitoring the delivery of radiation via sensors during the radiotherapy process (statistical process control)
- Visual training aides

Step 6. Rank each combination of cause, failure mode, and effect, and develop recommended actions to improve quality control of the process. At this point in a process FMEA:

- Each potential failure mode has been identified
- The resulting effects have been defined
- The potential causes of each failure mode have been listed

The next step is judge how effective the process controls are at:

- Preventing the various causes of a failure mode
- Detecting the occurrence of a failure mode
- Minimizing the effects resulting from the occurrence of a failure mode

Three ranking scales are used to determine the effectiveness of the process controls: occurrence, detection, and severity. Each ranking scale runs from one to ten,

Table 4–3. Descriptions of the O, S, and D values used in the TG–100 FMEA

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	
					Estimated probability of failure going undetected
1	Failure unlikely	0.01%	No effect		0.01%
2		0.02%	Inconvenience	Inconvenience	0.2%
3	Relatively few failures	0.05%			
4		0.1%	Minor dosimetric error	Suboptimal plan or treatment	1.0%
5		<0.2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0%
6	Occasional failures	<0.5%			5.0%
7		<1%	Potentially serious toxicity or tumor underdose		10%
8	Repeated failures	<2%			15%
9		<5%	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20%
10	Failures inevitable	>5%	Catastrophic		>20%

with one being the best case and ten the worst. There are many versions of each ranking scale in use. The ranking scales shown in Table 4–2 are typical and are, in fact, often used in industry and health care. After judging the effectiveness of the controls, there will be an occurrence ranking, a detection ranking, and a severity ranking for each failure mode, effects, and cause combination. Next a risk priority number (RPN) is calculated for each combination by multiplying the occurrence, detection, and severity ranking. RPNs range from one to one thousand. High RPN values indicate the weakest areas of the process and should be addressed first. The team should hold a brainstorming session to identify process controls that will reduce the likelihood of a cause occurring, improve the detectability of a failure mode, or reduce the severity of an effect resulting from a failure mode. After addressing the items with the highest RPN values, teams should move on to the next highest and develop recommended actions to improve those process steps, continuing until arriving at those process steps that are adequately controlled, as indicated by their low RPN values. There are no firm guidelines that are used to determine what level of RPN indicates that corrective actions need to be taken. Instead, most organizations use PFMEA to guide continuous process improvement. Teams often have heated debates during the ranking and evaluation effort, and facilitators need to develop a way to defuse these debates and keep the analysis moving forward. For example, if one faction of a team believes that an occurrence ranking for a specific cause should be five, while a second faction believes the ranking should be a six, a facilitator could choose to always use the higher ranking.

4.4.4 General Observations

How do you know if a PFMEA is a good one?

- Was it a team effort or done by one person?
- What is the level of detail—is there a lack of specific details for process definition?
- Is there a lot of uniformity—very few or a limited number of causes, etc.?
- Are there few, if any, serious effects?
- Low or very low cause occurrence or failure mode detection rankings?
- Does the PFMEA look like a “cut and paste” effort?
- Doesn’t pass the “reality” check? Are the overall results of the PFMEA what you would expect?

4.4.5 Alternative Ranking Scales

Occasionally teams will use occurrence, detection, and severity ranking scales that range from one to three or from one to five. The main problem with using ranking scales that do not go up to 10 is a reduced level of overall analysis sensitivity. Table 4–3 shows the ranking scale used by TG 100.

4.4.6 Using a Trained Facilitator to Lead a PFMEA

Although performing a PFMEA is not difficult, it is best to have a facilitator experienced in PFMEA to lead the effort. It is not unusual for teams to get confused during the process mapping, failure mode definition, effects definition, cause, definition, listing process controls, and ranking phases of a PFMEA. Having a trained facilitator will definitely streamline the process and increase the likelihood of a successful PFMEA.

4.5 Fault Tree Analysis (FTA)

The next step in the overall process is to evaluate the propagation of failures using fault tree analysis. A fault tree complements a process tree and gives a visual representation of the propagation of a failure in the procedure, and it also helps identify intervention strategies to mitigate the risks that have been identified. Fault tree analysis allows one to visualize potential locations in the process for effective and efficient quality management (QM) measures. Quality management is discussed in [Chapter 5](#). A fault tree starts with a potential error (i.e., a failure mode) on the left and works backwards in time (moving right) to study what could possibly have caused that error. Figure 4–4A shows an extremely simplified example of a fault tree illustrating the propagation of errors that result in an error in a calculated value for patient. For simplicity, only four potential failures are considered: error in data, error in data input, error in the calculational algorithm, or error in the prescription. Because an error in *any* of these can propagate into an error in the calculated value for the patient, they all enter into the process through an OR gate (here, the gate serves as the representation for the process). Figure 4–4B shows the same fault tree with added quality management protection. Parallel to each of the boxes indicating

errors in the inputs are boxes indicating failures of QC associated with the process. Each of the “failure of QC” boxes enter an AND gate with their respective error in

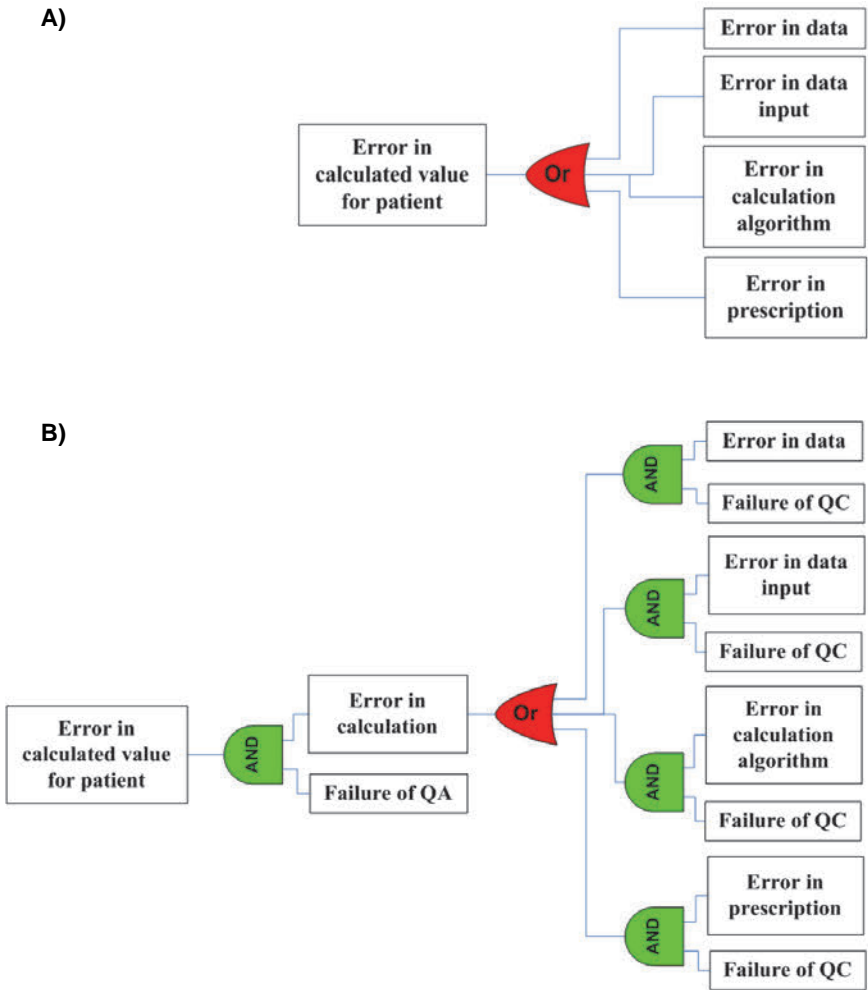


Figure 4–4. Example of a fault tree. A) A fault tree for a process with four inputs to calculate some quantity for a patient. Because an error in any of the four inputs can propagate into an error in the calculation, they all enter into the process through an OR gate. B) The same fault tree with quality management interventions. Parallel to each of the boxes indicating errors in the inputs are boxes indicating failures of QC associated with the process. Each of the “failure of QC” boxes enter an AND gate with their respective error in input box. This indicates that for the error in the input to pass into the calculation process, there must be a concomitant error in the QC that works on that input. The output of the process is interrogated with QA to provide confidence that the output of the process is correct. Again, propagation of any error requires a concomitant failure of the QA to pass the AND gate.

input box. This indicates that for the error in the input to pass into “Error in calculation,” there must be a concomitant error in the QC that works on that input. The likelihood of simultaneous failures in both the processes becomes considerably smaller than an error in either (if proper guidelines for the QC are followed), adding a great deal of protection from error. If an error were to pass into, and thus through, the OR gate, it should be caught by carefully conceived QA on the outbound side. In order for the error to propagate into an actual (realized) error in the calculation, the QA must also fail. The figure shows this as the error in output from the OR gate passing into an AND gate along with the failure of QA. In general, multiple potential failures connected to an OR gate signals hazards because any of the failures can lead to the failure to the left. The more potential failures leading to an OR gate, the greater the difficulty in controlling all the inputs.

The FMEA helps lay out the fault tree, and the fault tree helps see steps that are not covered by QM. In general, it is not a good idea to rely on a single box to interrupt the flow of failures. Although it is tempting to insert a QA step as an efficiency measure to block the propagation of errors from many steps combined, failure of that one QA step would leave the procedure completely unprotected. In addition, detection of the problem from that one QA step 1) may happen after many incorrect steps and much wasted effort, and 2) it may be hard to identify which of the upstream steps actually led to the problem, although this must be known in order to correct the problem. Thus, both QM program efficacy and overall process efficiency are enhanced by incorporating multiple QM measures along the way between a possible failure mode and the final process outcome. These redundant measures reduce the possibility of an error going undetected due to a failure in a single QM measure and, as described earlier, also provide an opportunity for detection of errors early in the process, thus avoiding wasted time and effort. Again, [Chapter 5](#) discusses the design of QM.

While making a fault tree, asking what could cause a given failure can almost always move another step farther to the right. At some point, the deeper cause may fall outside of the control of the facility. For example, a computer record may be disrupted by a power failure. In plotting the fault tree for this failure, among others causes for the disruption would be the power failure. However, if the power failure occurred because the power company had an outage, knowing what caused the outage would do the facility no good since they would not be in a position to do anything about it. The facility would need to address what to do in case of an outage, but not to prevent the outage. The point at which the facility no longer controls the situation defines the edge of that facility’s universe for this analysis. It makes no sense to probe beyond the universe.

During the analysis, particular attention should be paid to far-right causes that begin more than one propagation path. Such causes only become apparent after construction of the tree and searching for identical causes. An example could be that power failure which, in addition to disrupting a treatment record, could also result in a high dose-rate source retraction failure. Addressing causes that begin multiple paths provides some efficiency in quality management.

Often, a cause that appears to start several propagation paths may actually be different manifestations in each path. Obviously, a hardware failure in a linac and hardware failure in the scheduling computer are very different causes. Notwithstanding the independence of the different pieces of hardware, seeing multiple occurrences of this potential cause highlights the importance that the facility should place on preventative maintenance.

4.6 Summary

- Risk assessment is an analysis of a process to identify its more hazardous aspects.
- Many tools exist to assist in risk assessment. This chapter presents three recommended by AAPM Task Group 100 for applications in radiotherapy.
- Process mapping presents a visual representation of a process with the goal of understanding the procedure and the interactions between the people, equipment, facilities, and organization involved.
- Failure Modes and Effects Analysis facilitates identification and ranking of potential failures. It can suggest which potential failures to address first and what aspects of the failures to try to modify.
- Fault tree analysis graphically shows how failures propagate through a procedure, and it can help identify interventional strategies to reduce hazard and improve quality.

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