

Quality Management in Medical Physics: General Concepts

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Introduction

Quality management helps achieve the level of quality desired in any work. In clinical settings, it not only assists in delivering quality health care, but in preventing errors from injuring patients or compromising their health. Medical Physicists are very used to quality assurance (QA), and were on the forefront in verification of the correct operation of medical equipment through QA. Several major works highlighted quality assurance, such as the compendium of radiotherapy QA by Starkschall and Horton,¹ a manual by Constantinou,² and the Proceedings of the First International Symposium on Quality Assessment in Radiation Oncology.³ The American Association of Physicists in Medicine (AAPM) assembled a very comprehensive report on recommended QA in radiation oncology in 1994.⁴

However, as advanced as the field of medical physics has been in quality assurance, the vantage has been narrow and not particularly systematic. A rich literature and science of assuring quality exists as applied to other processes (mostly in industry) that provide great insight into delivering quality in medical settings. A handy reference on quality management, albeit targeted to wards brachytherapy can be found in *Achieving Quality in Brachytherapy*.⁵

The Concept of Quality Management

To understand what quality management (QM) means and how QA as practiced in medical physics fits into QM requires consideration of several concepts.

Quality

Discussions of QM center on *quality*, so this term must first be clear. Setting clear limits to what quality is becomes challenging at best. The protagonist in *Zen and the Art of Motorcycle Maintenance* suffers a nervous breakdown trying to pin down the concept of quality.⁶ Juran provides a definition of quality commonly used in industry that Quality consists of

- those product features which meet the needs of the customer.
- freedom from deficiencies.
- conformance to standards or specifications.⁷

In medical setting, “patient” replaces the word “customer,” but otherwise, the specifications hold well.

Quality Control and Quality Assurance

In radiotherapy we are very used to performing “Quality Assurance.” Yet, not all we do under that title actually qualifies QA. The terms quality assurance and quality control (QC) refer to quite different processes. QC encompasses those procedures that force a level of quality on what we do, for example, a dose calculation program that checks the collimator opening automatically with the setting used in the record and verify system. Quality assurance, on the other hand consists of sets of procedures we perform to convince ourselves that what we are doing, or about to do, is correct. The dosimetry measurements commonly performed on accelerators in the morning form an example of QA. Diagrammatically, Figure 1 shows the difference.

Each of these serves a difference function. They also have very difference characteristics. Because most processes use many inputs, QC requires a considerable expenditure in resources to cover all those inputs, making sure they are correct. QA, on the other hand evaluates the overall result of the process in a relatively efficient manner, thus taking much fewer resources. However, errors found by QC usually are relatively easy to fix and then allow the process to continue. Contrarily, an errors picked up on QA tend to require more investigation to find the source of the error, then to correct it, and run the process again. Thus, while QA requires fewer resources to find an error than QC, the remediation requires considerably more. The optimal situation is a balance between the two.

Figure 2 shows a fault tree for making an error in a dose calculation. A fault tree starts with a possible error on the left, and works backwards in time (moving right) to study what could possibly cause that error. This fault tree is extremely simplified just to be an example of the difference in the function of QC and QA. In the figure, an error

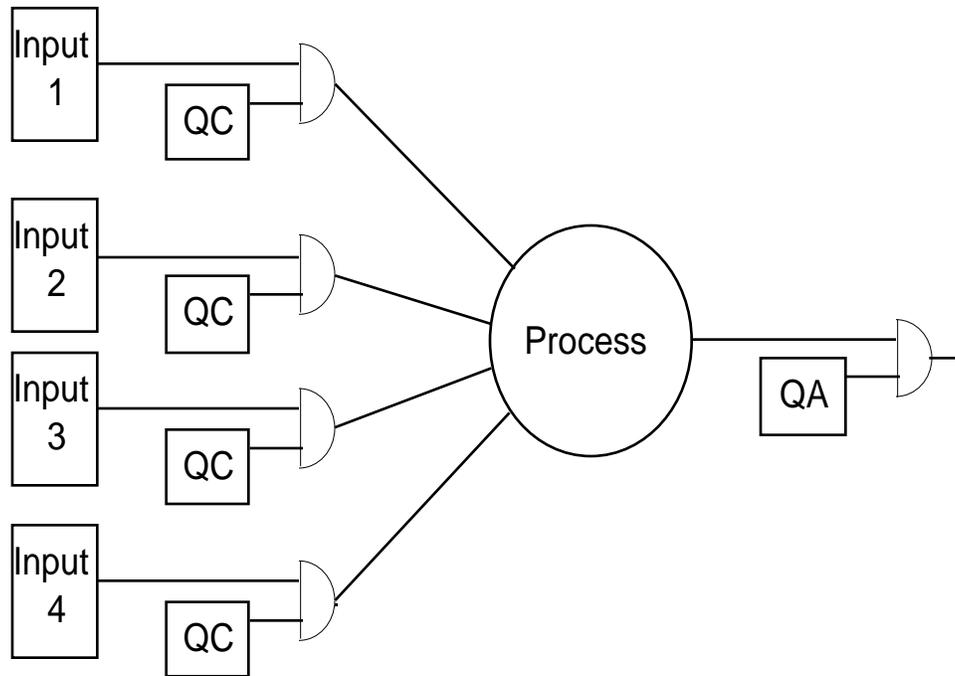


Figure 1. Quality control tries to insure the process works on good inputs while quality assurance examines the output to see if the results look correct.

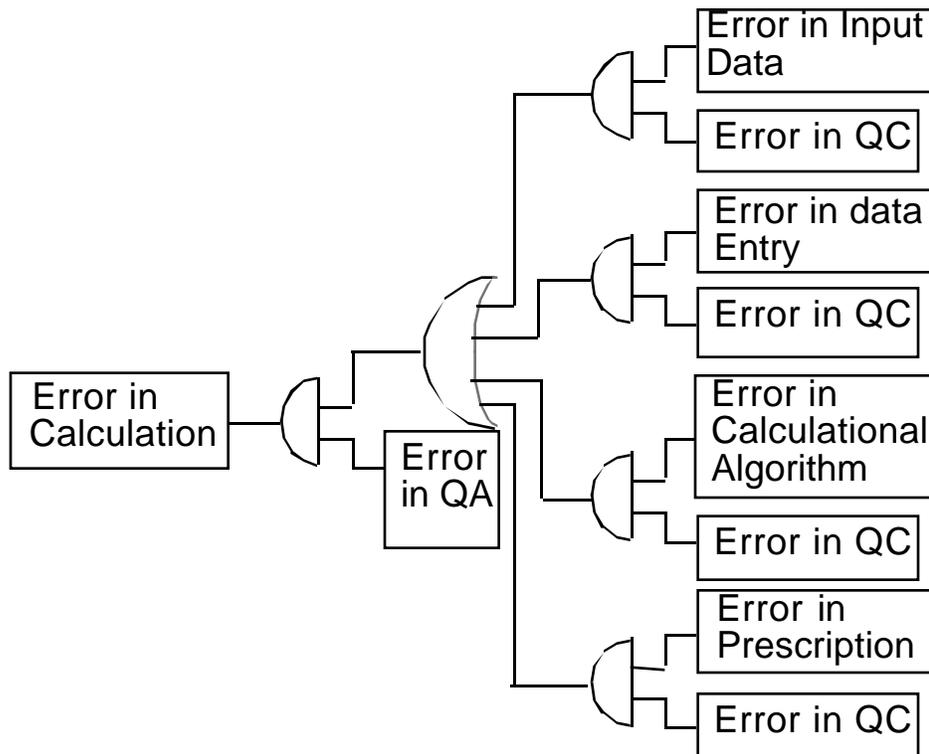


Figure 2. An extremely simplified fault tree to demonstrate the protective operation of QC and QA in the propagation of errors in a dose calculation.

in calculation could result from errors in the input data, the data entry, the calculational algorithm or the prescription. Because an error in *any* of these can propagate into an error in the calculation, they all enter into the process through an OR gate (here, the gate serves as the representation for the process). Parallel to each of the boxes indicating errors in the inputs are boxes indicating errors in QC associated with the process. Each of the “error in 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 calculational process, there must be a concomitant error in the QC that works on that input. The likelihood of simultaneous failures in both the processes becomes 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 error in QA.

Life becomes complicated, however, because the output of most procedures become the inputs to other procedures. Thus, the QA associated with the calculation in Figure 2 becomes QC as the dose calculation becomes the input in the treatment unit setting. As with many things, their identity depends on our vantage.

Quality Management

Quality Management is the overall program for achieving quality. QM includes several other facets in addition to QC and QA, such as quality audits and quality improvement.

Quality Audits

Most of us have had the experience of having someone else proofread something we wrote and find mistakes after we have gone through the document thinking all errors were fixed. The problem, of course, is that we read what we thought we wrote, not what we actually put on paper. The fact that someone else can see the mistakes we can't forms the basis for quality audits. A quality audit simply consists of having someone not associated with your facility, but who knows and understands what you do, review your work. Quality audits have two parts:

Process Audits. Process audits consider the methodologies used to perform tasks. For example, during a process audit the auditor might watch a physicist perform the required quality assurance measurements on a mammography unit.

Product Audits. During a product audit the reviewer looks over the results of your work. For example, a product audit might look through patient charts to check that dosimetry calculations have been performed correctly. Product audits often find that procedures in practice may be different than those described.

Internal Audits. Periodically, everyone should step back and assess how they are doing- whatever they are doing. Such a review becomes more productive if preceded by determining what aspects of the job may be most important for the review and establishing criteria for evaluation.

Quality Improvement

Variances found during audits, quality assurance or quality control may indicate the need to make some remedial actions (or not, which is a decision that also could be made). The review and plan for changes constitutes quality improvement.

Assessing the Need for Quality Management

Radiation physics has always been on the forefront of quality management in medicine. The reports from the AAPM usually attempt to be comprehensive in addressing QM for the respective procedure or field. However, the approach may not always achieve comprehensiveness, and comprehensiveness may not always be feasible. Few facilities have the resources to implement all the recommendations in the report of TG 40,⁴ not to mention TG 53 for treatment planning systems,⁸ or TG 56 and TG 59 in brachytherapy,^{9,10} and the myriad of diagnostic QA requirements. Effective and efficient QM requires a triage. Industrial engineers has long understood this dilemma and developed many tools to assist in the customizing of Q to a particular situation. Three techniques are discussed below. *They are not competitive!* That is, the analyst does not pick one; they work as a set.

Understanding the Process: Process Trees

The first step is to understand the process or the procedure. A process tree often helps understand the relationships, physical and temporal between the steps involved in a procedure. Figure 3 shows such a tree. The main stream of the process runs down the middle of the tree, forming the trunk (sometimes from top to bottom, or as in the figure,

as a tree blown over by the wind, from left to right). From the trunk stem the boughs that represent the major categories of the steps. Each bough in turn sprouts branches for the smaller steps that make the major steps. The subdividing of the steps can continue into as small of units as is useful in analyzing the process. For the treatment to successfully execute the intension, every step in the process tree must be performed correctly. As the tree fills out, the investigator develops a better feel for the demands of each of the steps, and which are more developed and which likely need more work. Understanding the process becomes a prerequisite for the next tool.

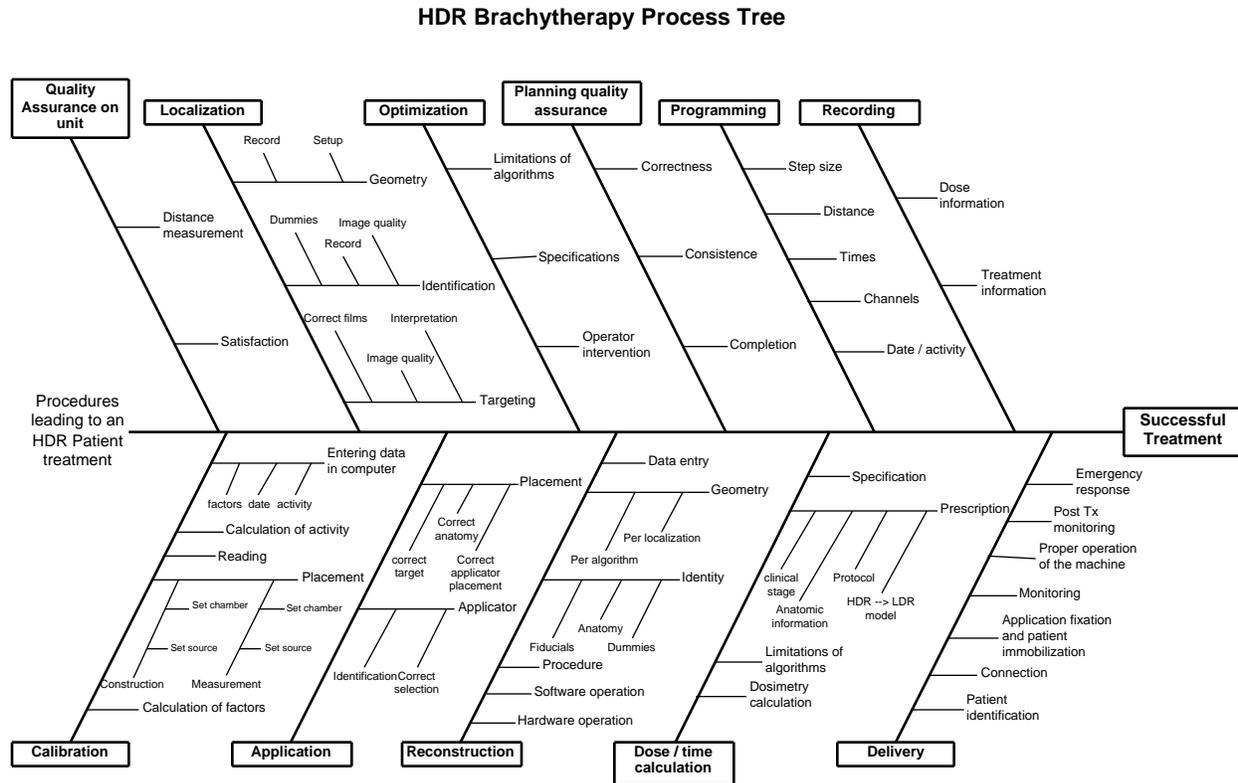


Figure 3. Example process tree.¹¹

Table 1. Simplified example of a failure mode and effects analysis table.

| Step | Function | Potential Failure | Potential Cause of Failure | Potential Effects of Failure | Current Controls | O | S | D | RPN |
|------|----------|-------------------|----------------------------|------------------------------|------------------|---|---|---|-----|
| | | | | Local | | | | | |
| | | | | Intermediate | | | | | |
| | | | | End (Patient) | | | | | |
| | | | | Local | | | | | |
| | | | | Intermediate | | | | | |
| | | | | End (Patient) | | | | | |
| | | | | Local | | | | | |
| | | | | Intermediate | | | | | |
| | | | | End (Patient) | | | | | |

Failure Mode and Effects Analysis (FMEA)

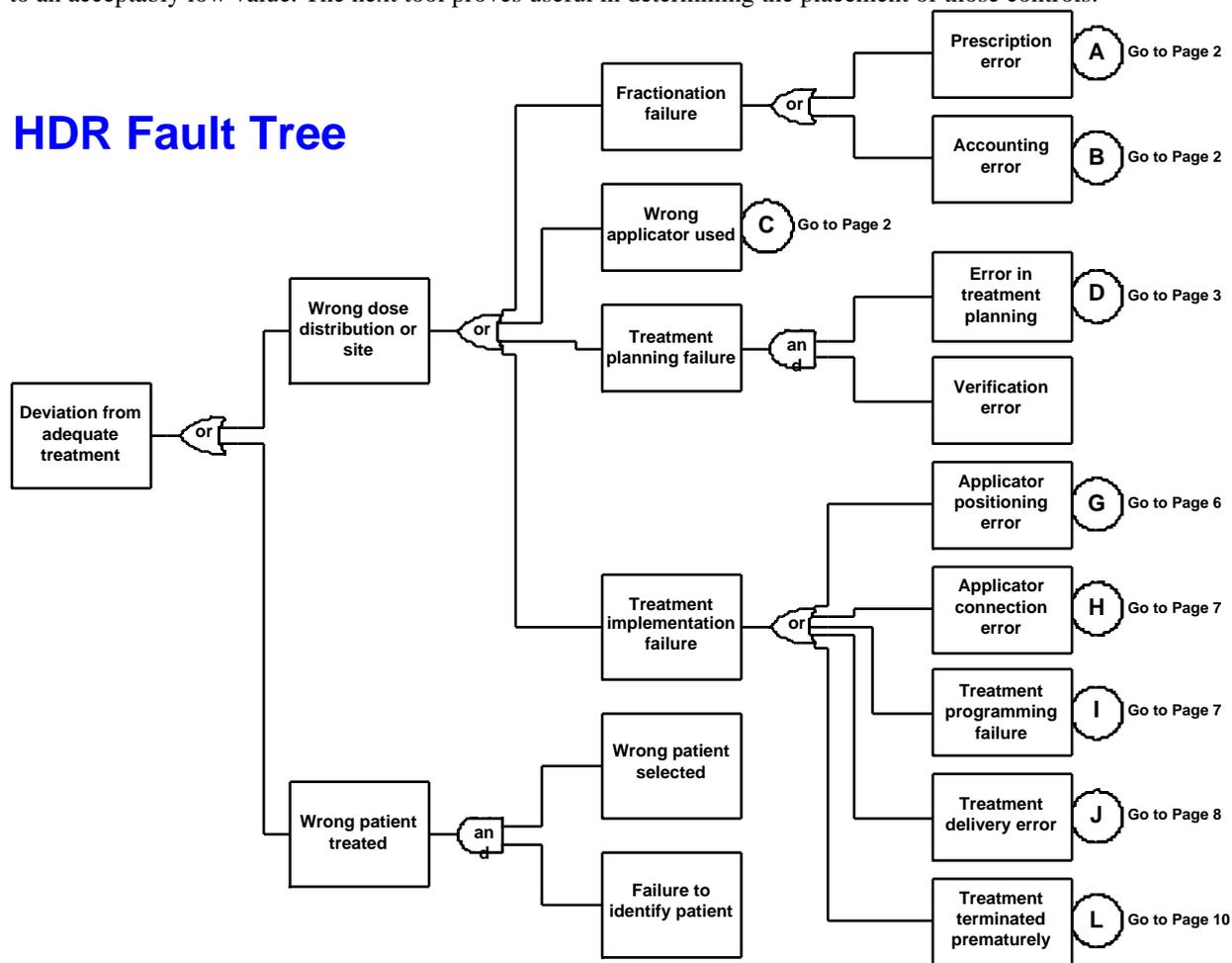
FMEA looks at the process, and at each step considers what could possibly go wrong, how could that happen (the failure mode) and what effects would such a failure produce. The analysis often uses a table, such as the simplified

version in Table 1. For each step there may be many potential failure modes, and each failure mode may have several potential causes of the failure. For each failure mode (and possibly for each potential cause, the effects must be considered. The failure may affect the operator or person or things nearby (local effects), down stream (intermediate) or cause in untoward results in the patient (end). Most likely any procedure has in place some control measures to prevent failures, and those would also be entered in the table.

For each line, values are assigned in three categories: O, for the likelihood of occurrence; S, for the severity of the effects of the failure; and D, for the likelihood that the failure considered would go undetected. Convention uses numbers between 1 and 10, with 1 assigned to now appreciable danger and 10 to the most severe. The product of these three indices forms the risk probability number (RPN). In industry RPN values below 125 carry little concern, however, in medicine, numbers about 20 might warrant some consideration.

Each of the significant hazards requires the addition of controls to eliminate the dangers (i.e., bring the hazard rating to an acceptably low value. The next tool proves useful in determining the placement of those controls.

HDR Fault Tree



Page 1

Figure 4a. Example of a fault tree for HDR brachytherapy. The entire tree covers 10 pages, so only a sample of the tree is shown. From reference 11.

Fault Trees

Fault trees compliment process trees. Fault tree, as shown in Figures 4a through 4c, begin on the left with something that could go wrong (one of the failure modes). In the tree shown in Figure 4a, the failure mode is an erroneous treatment. The analyst asks, what actions or events could cause the error directly? In this case, the

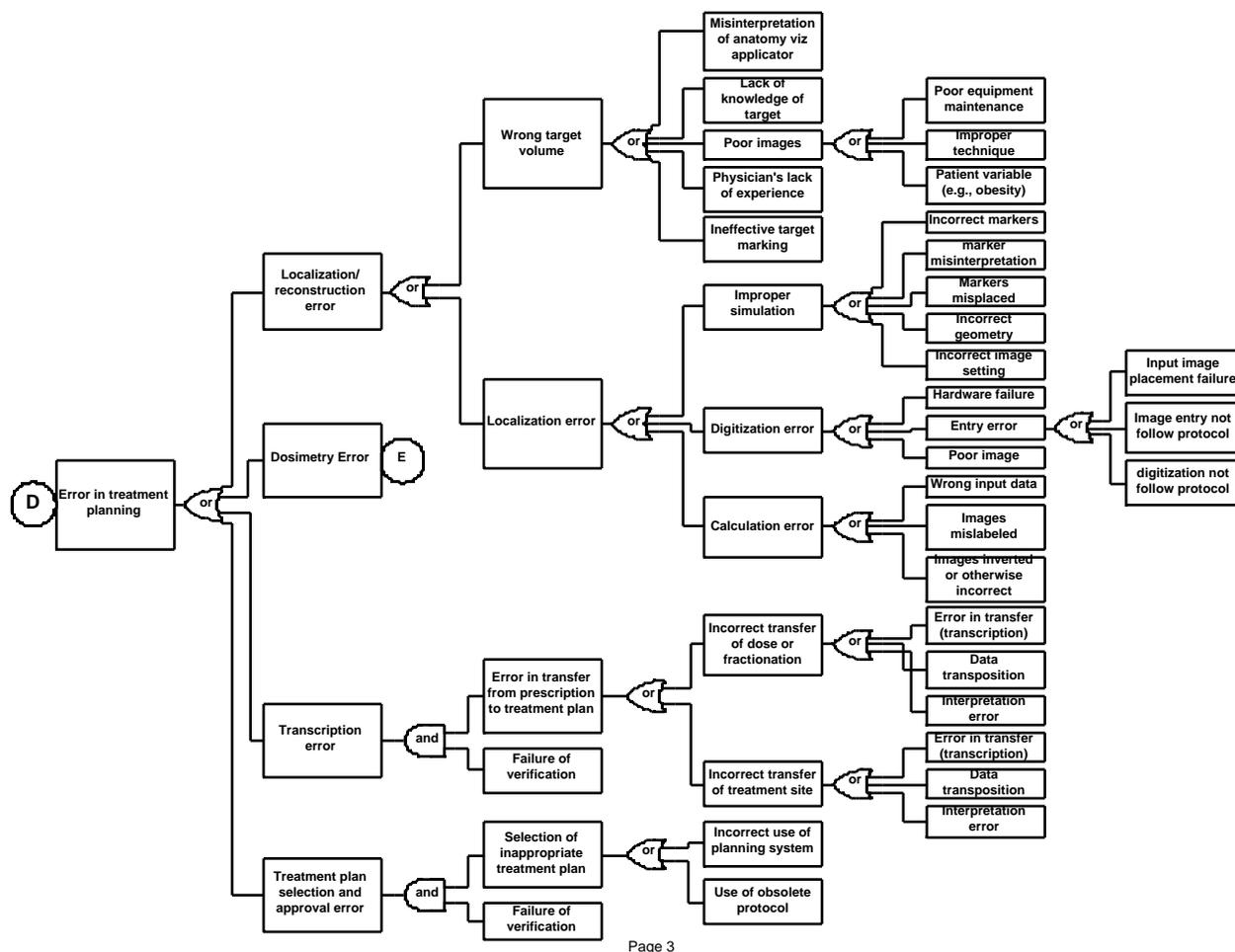
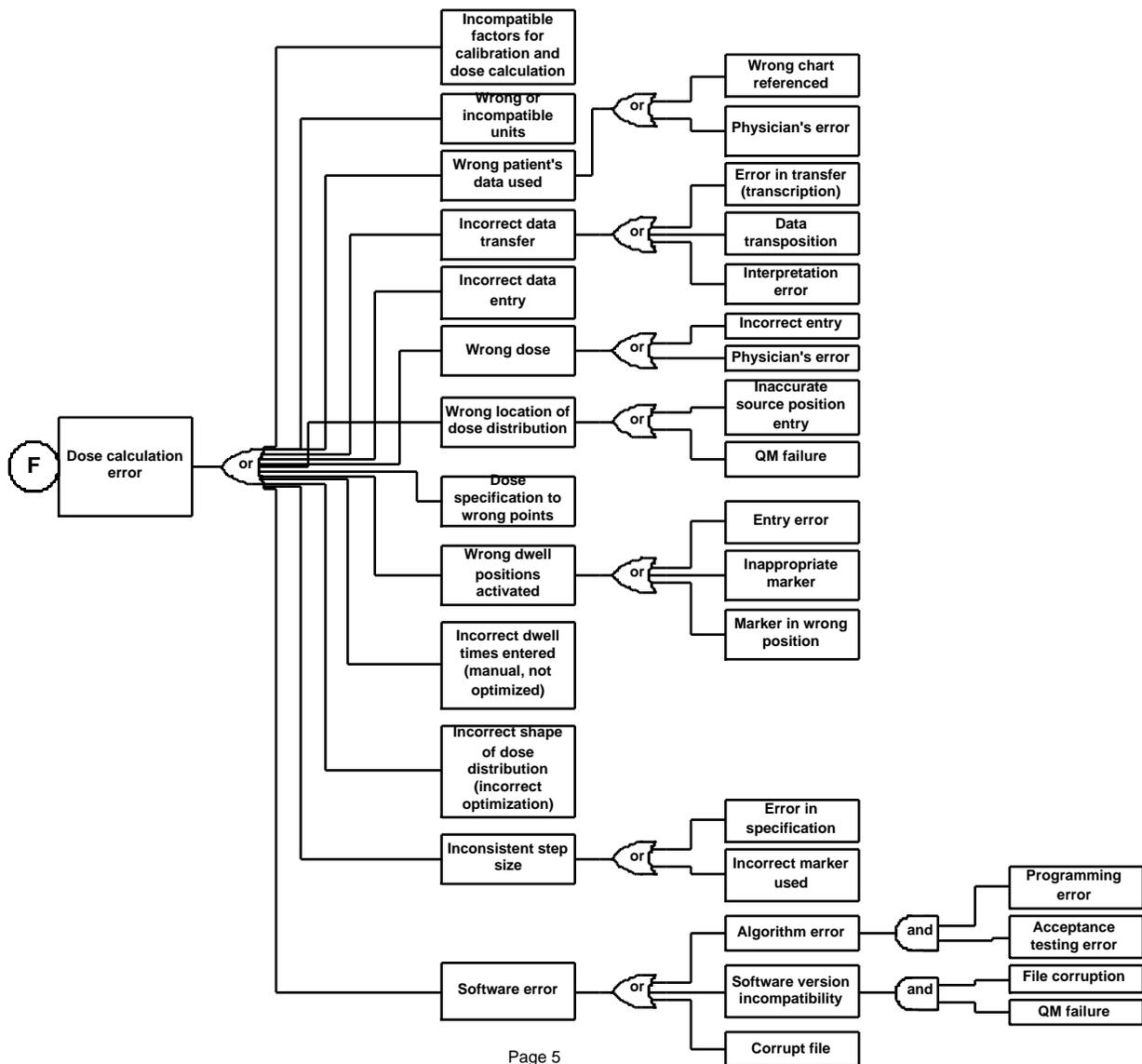


Figure 4b. A continuation of the sample fault tree begun in Figure 4a.

treatment could be given to the wrong patient, or the right patient could receive the wrong dose or the right dose to the wrong location. A logical OR gate joins the boxes representing these possibilities (called nodes) since any of these situations result in an erroneous treatment. From each of these boxes, the tree proceeds to the right asking what could cause the errors at the node. The questions keep probing to more fundamental actions until at some point the causes for a node fall outside of the control of the department or facility (defining the universe for the analysis). Some boxes could be joined by a logical AND gate, indicating that the actions in all the input boxes to the gate must fail to result in the failure at the gate’s output. Quality management produces such AND gate connections. If an action is checked for correctness, then in order for an error in the action to propagate to the left, there must also be a concomitant failure in the associated check. Thus, AND gates provide protection, while OR gates open opportunities for error propagation. Studying the fault tree for a procedure illustrates the paths that could lead to errors. *At some point along each path there should be some quality management to prevent propagation of errors.*

The FMEA helps lay out the fault tree, and the fault tree helps see steps that are not covered by QM. Looking at the trees it becomes clear that every line need not have QM in parallel, but every line needs some QM blocking the propagation of an error before the end. In general, it is not a good idea to rely on a singly box to interrupt the follow of failures. Although tempting to through a good QA step at the end as an efficiency measure, failure of that one step would leave the procedure completely unprotected.

At this step, the distinction between QC and QA becomes useful to keep in mind. Considering a step with a potential failure mode, there may be a simple and quick protective QC measure, or the step may be part of a group of steps that would better be evaluated as a whole with QA. From the FMEA, some steps may present a very low



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Figure 4c. A further continuation of the fault tree beginning in Figure 4a.

RPN because the effects would not be serious (possibly a bit irritating) or the failure would be obvious (such as a blown circuit breaker preventing use of an x-ray unit). For these steps, expending resources on QM seldom pays back the investment. On the other hand, counting on a very low value for the “occurrence” index can place the patient in jeopardy. Even systems with low O values can and do fail. Counting on the occurrence not happening leaves that pathway unprotected. The pattern of the indices in a failure with a low RPN can be important. For example, a failure with a RPN rating of 10 (a low value) that resulted from O=1, S=10, D=1 represents a situation that is unlikely to occur and is likely to be detected if it does, but is potentially very serious. Even with the low RPN, against such a failure protection should be placed.

Error Reduction Techniques and Tools

The selection of a QC or QA tool to interrupt the propagation of an error at a given step, of course, depends on the nature of the procedure and the error. And, there are numerous types of procedures that could be put in place. That being said, some tools find quite general application. The general, preventing injury to the patient falls into three main approaches: error prevention, error interception and error mitigation. As most of us learned in high school, errors come in two types, systematic and random. Systematic errors are biases in our procedures — mistakes in what we do that we don’t realize. They affect all, or at least a large number of patients, usually in the same way.

Most often, we cannot see our own biases. Audits bring to light systematic errors and allow them to be removed. The error prevention techniques discussed below apply to random errors — those that happen on a per patient basis.

Error Prevention (QC)

Error prevention usually corresponds with quality control. Two useful tools include protocols and forms.

Protocols

A protocol simply provides a formalized, standard set of expectations and procedures. When all persons involved follow a protocol, deviation from the protocol stand out as possible mistakes and items calling for investigation before proceeding to execution of the treatment. Protocols also establish and clarify communication patterns, delineating what information who passes to whom and how. Procedures to follow in particular situations also are contained in a protocol.

Forms

Not only do the forms remind the person checking a plan of items to review, but help speed the evaluation procedure, and let the reviewers know when they are finished. To be useful, the forms must have blanks for appropriate information. The occurrence of marginal notes indicates that there is information that users of the form consider important, and should lead to modification of the form to include blanks for recording that information. Also, all information on the form should be used (or potentially used) without wasting effort recording unused data. Forms form an effect mode for information exchange between principals in a procedure.

Independent second person (Monitors)

A monitor is a second person watching the operator input data or perform functions to notice mistakes so they can be corrected immediately. Unfortunately, monitors frequently miss errors. When most of the process the monitor is watching goes correctly, there is a tendency for the monitor's attention to fade. Monitors do not form an effective QC tool.

Error Interception (QA)

Lucian Leape notes that the task in patient safety is not to prevent errors, but to keep the errors from injuring the patient.¹² The assumption in this statement isn't that error prevention is bad, just that no matter how good it is, errors will be made and slip through. It recognizes that comprehensive error prevention requires a lot of resources. Thus, Leape places a strong emphasis on quality assurance.

Some very useful tools in QA include the following:

Standards and Expectations

Because quality assurance evaluates the outcome of a process, it requires means for judging that outcome. Standards and expectations form these means. *Expectations* assume that the person performing the evaluation knows what the outcome should be, at least to within a range. The quantitative values for the limits on the range establish the *standard* for the evaluation. Without expectations and standards, a review of the outcome may be useful in some way, but does not serve as QA or error prevention. The expected values may come from previous cases, where a review has determined the normal limits, or from the experiences of others. An example of standards would be the use of the Manchester System tables to evaluate if the duration for an interstitial brachytherapy implant seemed reasonable.

Forms

As with error prevention, forms serve as a major tool in error interception. The guidelines for the forms presented in that section apply as well here, but with an additional rule. For quantities to be checked, whenever appropriate, there should be two blanks requiring entries: one for the value desired or expected and one for the value obtained. Forcing the entry of both values increases greatly the likelihood that the reviewer will notice discrepancies. Experience has shown that simply having a check box indicating that the values falls within limits provides a limited amount of protection. As the reviewer becomes rushed (often the case in the clinic), the mental processing of the values becomes less effective and the value may *seem* to fall within the limits when it really does not. The values for the standards must be readily available. If the reviewer needs to start looking for the values, the likelihood that the check may be skipped increases rapidly.

Having the forms in a computer can increase effectiveness if the computer has built in alarms that flag discrepancies. Otherwise, effectiveness can be lost as the reviewer expects the computer to participate in error detection.

Independent Review

As with an auditor, some one other than the person who performs a procedure can best review it for mistakes. Particularly if the procedure required decisions, choices or invention, some one looking at the results from a fresh perspective probably would question the decisions, making the operator defend their actions. Poor decisions may not hold up during such a review.

Error Mitigation

Error mitigation considers how to minimize injury or damage if an error slips past all the QM. This is a field just beginning development in the radiological sciences, and as of this writing, there is little to report. Each facility, however, should include in their planning, and this can be part of the FMEA, what to do when all error prevention fails.

The Hierarchy of Tools

Many other tools find applications in error reduction. Table 2 lists many in descending order of general effectiveness. In any given situation, the effectiveness of a particular tool depends on the situation.

Table 2. Ranking of QM tools based on the effectiveness, in part following the suggestions of ISMP.¹³

| | |
|--|---|
| <p>0. Environment problem correction (Not tool)</p> <ul style="list-style-type: none"> • Sound Control • Visual Control • Cleaning • Neatening • Isolation • Environmental Design <p>1. Forcing functions and constraints</p> <ul style="list-style-type: none"> • Interlock • Barriers • Computerized order entry with feedback <p>2. Automation and computerization</p> <ul style="list-style-type: none"> • Bar codes • Automate monitoring • Computerized verification • Computerized order entry <p>3. Protocols, standards, and information</p> <ul style="list-style-type: none"> • Check off forms • Establishing Protocol / Clarify Protocol • Alarms • Labels • Signs • Reduce similarity | <p>4. Independent double check systems and other redundancies</p> <ul style="list-style-type: none"> • Redundant measurement • Independent review • Operational Checks • Comparison with standards • Increase monitoring • Add status check • Acceptance test <p>5. Rules and policies</p> <ul style="list-style-type: none"> • External Audit • Internal Audit • Priority • Establishing / Clarify Communication Line • Staffing • Better Scheduling • Mandatory Pauses • Repair • PMI (Preventive Maintenance Inspection) • Establish and Perform QC and QA (Hardware and Software) <p>6. Education and Information</p> <ul style="list-style-type: none"> • Training • Experience • Instruction |
|--|---|

The first set of entries, environmental problem correction, are not really tools, but simply fixing problems in the workplace that might distract the staff, make it hard to communicate or interfere with tasks. The rest of the table does present tools. In general, the more automatic the tool, the more effectively it functions. Unfortunately, the more automatic tool also cost the most. One of the most effective improvements in reducing errors in medical care has been computerized medication delivery. With this system, physicians order medications through a computer with software that compares the patient’s diagnosis with the drug prescribed, as well as references other medications the patient takes. If the computer notices any problem with the prescription, it shows a warning and suggests corrections. Of course, the physician can override the suggestion. The nurse on the floor carries a handheld computer that communicates with the central computer through radio links. The computer reminds the nurse that it is time to

deliver the medication. The nurse must scan barcodes on: the nurse's own badge, the patient's wristband, the medication cart, and the medication pack or bottle. In one study, such a system reduced medication errors from 36% (a relatively normal rate of medication misadministration in a hospital – hard for us in medical physics to fathom that) to 0.2% — and all of those were late administration (more than 1 hour) because the nurse was too busy to keep up with the dispensing.)

None of the tools is a sure bet. Several of the computer order entry programs have been rejected by medical staffs at different hospitals because they interfered more than they facilitated. There is also the danger of unexpected consequences associated with any procedure, so careful observation must follow adding QM procedures.

Level, or Layers, of Quality Management

Quality management comes in various layers to cover a facility. Quality control associated with a procedure kicks in at every performance of that procedure. The frequency for quality assurance becomes a more complicated issue. Since the function of quality assurance is to provide the operator (and, yes, sometime the jury if things go awry) that things are functioning correctly, the frequency to perform those tests depends on how likely, and how quickly, the tested parameter may fall out of specifications. It also depends on the severity of the consequences of operating outside of acceptable limits. With this in mind, many of the procedures medical physics commonly do fall into layers of QA, as below.

Acceptance testing and Commissioning

Acceptance testing, that is, initial evaluations to assure that a new piece of equipment or procedure works, and the associated commissioning, placing the equipment or procedure into use, has long been a staple in medical physics practice. Initial evaluations, definitely a form of QA, provide the basis for subsequent QA. While most of the discussion below takes as an example external beam radiotherapy, the principles and points apply equally to brachytherapy and imaging physics, as well as most medical procedures.

Periodic Testing

As TG 40 and the other TG reports referred to above note, *all* equipment used for patient care requires periodic testing. The reports, and those for imaging,¹⁴ specify periods between tests. The theory suggests that those parameters unlikely to change need be tested rarely, for example annually, while those with a higher probability of changing require testing more frequently. On the FMEA, this criterion corresponds to the O category, the probability of occurrence of a problem. Additionally, the period depends on the S, severity, and D, the likelihood of detection of a problem. For linear accelerators, the TG 40 suggests daily checking for several systems, including the dose monitors. The daily tests spot-check those systems that would most directly affect the patient treatment if they were to fail. More complete checks occur monthly, with a comprehensive review annually. Few systems on a linear accelerator have histories of large changes over short periods (or the units have interlocks that prevent operation if certain systems change too much), justifying the long interval between many of the tests, as long as the daily tests would catch the important ones. Many of the items checked in the annual review cannot change (unless they were measured incorrectly initially, but after a couple of annual reviews, these would be weeded out), and it is not clear the utility of repeated measurement. Deciding which items need testing and the period becomes the responsibility of the facility's medical physicist. Deviations from accepted recommendations, however, require justification, but should not be avoided if an analysis of the clinic's operation indicates different procedures would be adequate.

Are daily checks on the accelerator's dose rate enough? Should they be checked twice a day or before each patient? Changes in the dose rate on most accelerators either happen slowly with time or very quickly. The unit's interlocks usually (but not always) would detect large changes that happen very quickly. The slow changes will be followed over time and adjusted made when needed. More frequent checks would not be warranted (except during the first month of operation, but then that is part of acceptance testing).

The ability and mechanism for detection of changes between periodic tests needs to be quantitative. Many radiologists feel that they could see problems on their images if things change, but many changes in an imaging system can reduce the visualization quality of the images without being apparent.

As with any actions performed by humans, errors will happen. All of the results of the QA tests should be reviewed by a second person to guard against errors and omissions. If a second person is not available, the person performing the tests should review the results again at a different time, redoing as much as possible of any calculations.

Testing per Patient

Assuming that periodic testing assures that any equipment works correctly (or at least, significant deviations in the time between tests remain unlikely), for each patient QA consists of looking for blunders. Each patient requires checking because an error in that patient's calculation or treatment can cause great injury, and such errors could happen in any patient's case. The methods for checking a patient's dosimetry have become fairly routine in most facilities, and include having a different person check the calculations from the one who initially performs them, and the use of *in-vivo* dose measurements. What a medical physicist checks during a routine dosimetry review varies greatly among facilities, but obviously includes the monitor unit calculations. Medical physicists should not shy away from checking other aspects of the treatment. Most radiotherapy physicists have enough experience to detect a prescription that falls outside of the normal range, borders on a port film that don't math the plan, or inappropriate inhomogeneity in the isodose distribution. While verification of these features below to the physician, the physicist can often provide some measure of QA, calling attention to possibly inappropriate treatments. Many facilities have no other person who can serve as an independent reviewer for the radiation oncologist.

Routine chart check during the course of treatment, checking addition and the number of fractions, actual form quality control correcting values containing errors.

Failures of a test

If tests are worth doing it is because the item being tests can fail. Recognizing that failures *do* happen is important. If a test returns an indication that something is not correct, procedures should not continue until resolution of the discrepancy. Many of the medical events (formerly known as misadministrations) occurred even though quality assurance tests indicated that something was wrong and the results ignored by staff members. This may be the most important point in this handout.

Quality Improvement

Periodically, the quality management program requires some QM of its own. Reviewing how well the quality has been upheld and taking corrective actions forms quality improvement (QI). Generally the procedure involves:

1. Gathering data on which to assess quality. Deciding what data to gather and how often becomes the hardest part of QI. Image retake rate would be an example of a quantitative measure of some problem.
2. Analyzing the causes of the problem. (This step is a presentation all by itself.)
3. Proposing a solution for the problem.
4. Testing the solution on a small scale.
5. Evaluating the effects of the test solution.
6. Either implementing the solution as policy if the evaluation in step 5 indicated a success, or returning to step 3 to develop a new proposed solution if the test failed.

Failure of the solution may be because it did not solve the problem or because, while solving the problem, it resulted in creating new problems.

Summary

Keeping in mind the different functions of quality control and quality assurance helps in establishing an effective quality management program. Understanding the process, performing a failure mode and effects analysis, and charting a fault tree facilitate organizing the program. Published guidelines for quality assurance serve as starting points for each facility's program, but should be tailored to the needs and situation in that department based on the analysis. The quality of patient care and the quality management program itself require periodic review and evaluation. Quality audits can form an important part of this review. If quality test indicate a problem, take it seriously and stop procedures until the cause of the discrepancy is found.

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