

# **The Pathologist and Patient Safety. An Introduction.**

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This handout provides an overview about how to manage quality and patient safety in clinical laboratories. The handout has been written for managers of clinical laboratories. The term “manager” includes laboratory directors – who have specific legal responsibilities when directing clinical laboratories in the United States – and also managing staff pathologists and non-physician supervisors who oversee laboratory operations. These other managers usually work under the authority of a laboratory director or an executive officer of an organization that administers a clinical laboratory.

## **What is Quality?**

“Quality” in laboratory medicine is all the features of the laboratory product that meet the requirements of laboratory customers or the requirements of society (as society expresses itself through law and regulation). Quality, then, is about meeting customer’s needs and society’s expectations. Quality should not be defined by the producer (the clinical laboratory or its leadership), no matter how experienced and authoritative a laboratory director may be. When we manage quality, we bring our service in conformance with the customer’s specifications and society’s requirements, not our own.

This customer-centered definition of quality, while used in many industries, does not fit easily within the traditional paternalistic medical model, in which a professional practitioner determines what is best for his patients much as a father determines what is best for his child. There are many vestiges of paternalism within pathology and laboratory medicine. For example, the director of a surgical pathology section may prescribe how surgical pathology reports are to be formatted without experiencing any inclination to consult with surgeons about the types of information they seek or the form of presentation they prefer. This sort of attitude does not promote quality.

It is certainly the case that the seasoned laboratory professional possesses a great deal of knowledge about pathology and testing operations that the typical laboratory customer lacks. When some of this information is shared with a customer, the customer may form a different opinion about what she wants or needs. Uninformed consumers may be no more reliable guideposts to quality than inward-looking producers. For this reason, clinical laboratory leaders and the caregivers who order tests and interpret results have a mutual obligation to interact with one another before specifying service levels that a laboratory should provide. But the final determination of what constitutes quality lies with the consumer, and the laboratory manager who acts on untested assumptions about what customers want or need does so at his peril.

Most of the quality issues that are discussed in this handout have been validated by customers as issues they consider important. But customers are a varied lot and some will have uncommon concerns that are not described in this handout, or place particularly heavy emphasis on aspects of laboratory service that we do not emphasize. Therefore, laboratory quality must be defined in relation to a laboratory’s particular customers, rather than to customers in general.

## **What is Patient Safety?**

“Patient safety” has been defined as freedom from accident or injury that results from the delivery of health care. This handout addresses patient safety as an essential and inseparable component of laboratory quality. Quality and safety are intertwined in clinical laboratories because of the way medicine is practiced. Laboratory results influence clinical care, and clinical care is fraught with risk. For example, improperly calculated international normalized ratios (INR) have led to over-prescribing of anticoagulants at several institutions, resulting in well-documented fatalities from the hemorrhagic complications of anticoagulant overdose.

Patient safety is threatened by more than inaccurate laboratory analyses. When specimens are mixed up, results are not communicated in a timely manner, or reports are misdirected, patients may also be denied needed care. A case study in chapter 2 concerns a patient whose care was adversely impacted by an important laboratory result that did not reach the physician who most needed the information. The patient safety movement has identified these “handoffs” – transfer of information between parties – as an important vulnerability in the care process that has not been the subject of traditional laboratory quality control.

In many industries there is no particular connection between quality and safety. A poorly written novel may waste readers’ money and time, but does not pose a safety risk. A poorly manufactured garden sprinkler may cause the death of a whole bed of tulips, but not their owner.

In clinical medicine – including laboratory medicine – the consequences of quality failures are often much more grave. For this reason, the management of quality in laboratory medicine necessarily includes a consideration of patient safety.

## **The Laboratory Manager’s Perspective**

The management of clinical quality and patient safety takes place at many different organizational levels. This handout is written from the perspective of the clinical laboratory manager, and describes what the laboratory manager can do to promote excellent clinical laboratory service. Managers exert a great deal of influence over the quality of laboratory operations, since managers specify laboratory policies, processes, and procedures, select analytic test systems and reagent manufacturers, have authority over the individuals who perform testing in the laboratory, and interact regularly with physicians and other laboratory customers. Depending on the particulars of how a laboratory is organized, the laboratory manager may have varying degrees of influence over clinical information systems, the selection of reference laboratories, budgets, and even over the organization of the laboratory itself. When we talk about managing laboratory quality in this handout, we are talking about making the types of changes that fall within the purview of laboratory management – modifying procedures, selecting and evaluating staff, etc.

But the quality of clinical laboratories is also influenced by forces outside the direct control of laboratory management. While not the main focus of this handout, it is useful to acknowledge these other influences and the role they play in promoting quality and patient safety. Some of these other influences are illustrated in Figure 1.

**Figure 1. Forces that Impact Laboratory Quality and Patient Safety**



Clinical caregivers and other departments within a health care system exert significant control over the sorts of tests that are ordered, the quality of specimens that are collected, and the fidelity of specimen labeling and transportation. Physicians and other caregivers are also the recipients of laboratory reports, and their availability to receive information from the laboratory and their ability to interpret and apply this information has a profound impact on quality and patient safety. Some of the most important and vexing frontiers in laboratory quality management concern the interface between the laboratory and caregivers in other departments and health care practices. When key computer systems are managed by other departments, such as a hospital information system being managed by a central hospital information systems department, then the process for ordering and viewing laboratory results may be under the direction of the information systems department.

Instrument and information system manufacturers are responsible for designing test systems and computer systems that function reliably, interface with other systems, and interact constructively with human operators, buffering the errors that humans will occasionally (but invariably) make. Reagent manufacturers and organizations that acquire and distribute blood products also impact laboratory quality by ensuring (or failing to ensure) the quality of their product. There are many examples of laboratory quality problems that have resulted from poor product design and from manufacturing inconsistency. These examples sometimes spur manufacturers to develop innovative products and services that address quality problems more effectively than anything a laboratory manager might do within an individual facility.

Professional organizations such as the College of American Pathologists (CAP) have an important role to play in the management of laboratory quality and patient safety. Enlightened professional societies bring members of the profession together with key customers to develop standards for

performance that ensure customer's needs are being met. A professional society is also in a position to detect infrequent, but recurring quality problems that may not be apparent to managers of individual laboratories, and to bring solutions to the attention of managers and manufacturers, as appropriate. The best example of a professional society taking the lead in promoting patient safety is the work that the American Society of Anesthesiologists (ASA) undertook in the late 1970s and 1980s. The ASA reviewed closed claim insurance files, developed practice guidelines, started a non-profit anesthesiology safety organization, and worked with manufacturers to improve the monitoring of patients and delivery of anesthetic agents, resulting in a significant decrease in anesthesia-related mortality. Although the work of the CAP has not been as overarching as that of the ASA, performance data acquired by the College during the administration of CAP quality improvement and accreditation programs should guide quality management efforts.

Governmental entities have established a number of mandatory standards for quality in clinical laboratories. Two particularly important sets of standards related to clinical laboratory quality are contained in the CLIA and HIPAA regulations. Government regulation is most useful in areas where quality can not be measured directly by the laboratory customer and the customer has no ability to "vote with his feet." Governmental standards for controlling analytic accuracy – which is very difficult for clinicians to assess on their own – has been particularly helpful in promoting laboratory quality.

Government regulation of laboratory suppliers also promotes laboratory quality. Laboratory managers can not look inside of manufacturers' factories and form their own assessment of manufacturing quality; government action helps keep the market from becoming dominated by shoddy or inattentive suppliers. Yet as with all governmental directives, excess regulation may stifle innovation, increase costs, and reduce competition by introducing unnecessary barriers to entry. For these reasons, the role of the government in promoting laboratory quality, while important, is also necessarily limited.

Executive leadership within an organization that owns or operates laboratories will influence quality by making decisions about operating and capital budgets. Less directly, but no less importantly, executive leadership will influence the quality of operations by the "tone" it sets within the organization, emphasizing (or failing to emphasize) the importance of quality and patient safety in the face of competing demands.

Finally, laboratory professionals who examine specimens and perform tests within the laboratory – such as pathologists, medical technologists, and cytotechnologists – contribute importantly to the quality of operations. These individuals have a personal responsibility to acquire and maintain up-to-date knowledge and skills through education, training, and practice, and also have a duty to maintain mental discipline on the job and to not work when impaired by illness, substances, or undue distress. Laboratory professionals have a responsibility to be honest, communicate effectively, work harmoniously with colleagues, to point out quality or safety issues they observe in the course of their work, and to know their own limitations.

This handout is not designed to help laboratory professionals acquire the knowledge and skills necessary to care for individual patients, or to help individuals maintain the proper attitude about their work or their colleagues. A pathologist straight out of residency training or fellowship – with

no managerial responsibilities – will not find this handout especially useful, although she may read it to acquire a better appreciation for the quality systems that will be applied to her work. The same could be said for a recently graduated medical technologist. As the newly minted professional matures, however, she will begin to appreciate that some of her own fallibilities can be addressed only by the application of quality management practices within the laboratory. She will find herself unable, no matter how much she learns and how hard she tries, to perform without defect or deficiency. At this stage in her professional development the pathologist or technologist may become interested in improving the effectiveness of the quality management systems that protect patients from her own errors as well as from those of her colleagues. She may find herself helping to design new work processes to improve reliability of existing operations, or may formally assume a managerial role in which the oversight of quality is part of her responsibilities. Suddenly, the information presented within this handout becomes much more pertinent.

### **Case Studies**

This workshop will make use of some case studies. Case studies can help promote patient safety for several reasons. They underscore that quality problems in clinical laboratories may have real, and sometimes tragic, consequences for patients. Well told stories of clinical misadventures contain emotional energy that can drive organizational transformation. Case studies also remind us that quality problems develop and unfold over time. In the beginning, it may not be clear where the cause of a quality problem lies. In fact, it may not be clear that something is amiss at all. Finally, case studies call attention to the manifold origins of quality failures – they have no single cause and no single procedure can be applied to prevent every type of quality failure from occurring.

### **Approaches to Managing Quality and Patient Safety**

The general approach to managing patient safety and quality promoted in this workshop is straightforward. It consists of four elements:

1. Identify risks (threats) worth managing
2. Develop a control program for these risks
3. Use monitoring appropriately – for quality control and quality planning. But don't confuse the two.
4. Reasonably document your quality management plan, your monitoring efforts, and your reporting.

### **Widely Recognized Quality and Patient Safety Risks**

The central thrust of this presentation about patient safety and quality management is grounded in a simple overriding principle: All clinical laboratories are subject to certain quality and patient safety risks. These risks should be etched in every laboratory manager's mind, control measures should be instituted to mitigate each risk, and where required a monitoring system should be put in place to assure that risks are being adequately addressed.

We mention here sixteen widely recognized risks to clinical laboratory quality and patient safety. Four risks concern what has been called the “preanalytic” phase of laboratory testing: patient and

specimen identification, order communication, specimen collection and handling, and appropriate use of laboratory services. Four risks deal with the “analytic” phase of testing: problems that occur when introducing new tests, ongoing quality management of tests, establishment of reference ranges, and quality management of tests that contain a significant judgmental component, such as anatomic pathology testing performed by pathologists. Four risks concern the “postanalytic” phase of testing: risks involved in reporting results, administration of blood products, interpretation of results, and correcting reporting errors. The final four risks concern what have been called “general laboratory systems,” which is simply a catch-all phrase for risks that don’t fit neatly into the preanalytic, analytic, or postanalytic categories. These risks relate to personnel, information management, turnaround time, and organization of the laboratory.

For each major vulnerability, we can describe control measure that have proven useful in reducing the frequency of quality failures or patient safety events related to each of the sixteen risks, and provide practical advice about how to monitor each risk to assess the effectiveness of control measures. Managers who address the risks described in this handout will be well on their way to effectively managing laboratory quality and promoting patient safety.

### **Quality and Safety Risks in Individual Laboratories**

If every clinical laboratory was identical, and served identical patients and physicians, there would be no need for further discussion. Managers in every clinical laboratory would set about to address the same set of risks, mostly those described previously. Errors everywhere would be less frequent, communication more certain, results more accurate, and care safer for patients.

But every laboratory is different. Each serves a particular set of patients and caregivers, uses different suppliers, and has staked out its own strategic position in relation to its customers and competitors. Experience has taught us a great deal about what can go wrong in a clinical laboratory, but the constellation of risks and vulnerabilities that each laboratory faces is unique. Some customers have special requirements that will go unmet by a laboratory that addresses only common risks. Some groups of patients present particular testing needs that others do not. Clinical laboratories face different economic challenges that may impact the quality of their operations: some have more access to capital than others; some are located in tight labor markets and have difficulty recruiting qualified staff.

More fundamentally, each clinical laboratory has developed a unique strategic position to differentiate itself from rivals and defend its operations from competition. Commercial laboratories with national scope have organized themselves primarily to serve the testing needs of physicians practicing in offices. A handful of laboratories provide only reference testing that hospital-based laboratories can not economically perform on their own. Many laboratories have staked out strategic positions serving a hospital’s core patient population – inpatients, ambulatory surgery patients, and emergency department patients. Some specialized clinical laboratories have evolved to meet the particular needs of physicians within one medical specialty or the needs of one type of commercial concern, such as dermatopathology laboratories, forensic drug testing laboratories, pharmaceutical trial testing facilities, and urologic pathology laboratories. Finally, a

number of hospital-based testing operations have expanded into the community outpatient market, serving a defined medical staff that sees patients in both the hospital and outpatient setting. There are three techniques that laboratory managers may use to individualize their quality management programs – to adapt their efforts to the unique circumstances that face each clinical laboratory. The first approach involves surveying and learning from customers. Managers should be familiar with methods to assess their customer’s satisfaction with laboratory service and to identify gaps that require extra attention.

The second approach to individualizing a quality management program involves analysis of “incidents.” Incidents are events that did not transpire as expected or desired. They have variously been called “occurrences,” “exceptions,” “non-conformances,” “deviations,” and go by other names as well. The most serious, which involve patient injury or significant risk thereof, are called “sentinel events.” Managers should construct an occurrence management program that collects and organizes information about incidents, so that new or underappreciated vulnerabilities can be brought forward and addressed.

Finally, an organization’s mission and strategy impacts its laboratory’s quality management and patient safety program. The particular mission of the organization that owns a clinical laboratory, and its particular market position, will inevitably require that special emphasis be placed on certain aspects of laboratory quality. Some institutions will have a special, driving need for rapid turnaround time, others for high-quality, highly functional interfaces with the information systems of its customers. The unique strategic position of an individual laboratory presents a creative opportunity to design a quality program that reinforces the business interests of the organization that owns the laboratory.

### **The Laboratory Quality Management Plan**

United States clinical laboratories are required to have a written quality plan that describes the laboratory’s approach to ensuring the quality of operations – the accuracy of results as well as the integrity of pre-analytic and post-analytic processes. Unless a separate patient safety plan is prepared, the quality management plan also typically addresses major patient safety issues.

The CAP Laboratory Accreditation Program requires laboratories to maintain a written plan that describes the overall quality management program of the laboratory. In 2005, 1.3% of laboratories inspected by the CAP were cited for not having an adequate quality management plan.

A quality management plan spells out the steps that a laboratory will take to ensure that quality is being maintained. A well-constructed plan will be informed by material in the previous sections of this handout—case studies of quality failure, approaches to quality management, regulatory and accreditation requirements, particular laboratory risks and control measures, and feedback from customers and incidents.

Throughout this handout we have emphasized that laboratory quality and safety failures may result from diverse causes, ranging from poor communication to human error and from instrument failure to fraud. The laboratory director must ultimately choose which particular quality and safety hazards a laboratory will address, and the controls that will be used to mitigate each hazard. The laboratory’s quality management plan brings these decisions together in a

document that spells out the approach to managing quality and patient safety that will be used in a particular organization.

## **Purpose**

The purpose of the quality management plan is to describe the laboratory's approach to the management of quality and patient safety. A properly documented and implemented plan will provide reasonable assurance that the laboratory (1) meets defined standards of quality practice, (2) is in compliance with applicable laws and regulations related to quality and patient safety, and (3) is engaged in credible quality improvement activities. A clinical laboratory's quality management plan will be of interest to laboratory owners, laboratory users, external inspectors, and, potentially, to patients.

Some people have unrealistic expectations of what a quality management plan can accomplish. They believe a plan can absolutely ensure the quality of every laboratory operation, guarantee the accuracy of every laboratory report, and ensure complete and continuous compliance with laws and regulations. However, the quality management plan is primarily a system of controls, and all control systems have inherent limitations. Control systems rely on judgments that may be faulty. Controls may be upset by breakdowns that occur despite the existence of protective systems. Controls can be circumvented by collusion between several individuals or by managers who choose to override control systems. Finally, the design of any internal control system reflects resource constraints; controls will only be implemented when their benefits are likely to exceed their costs. Therefore, a quality management plan can provide only reasonable assurance that the laboratory substantially conforms to standards. It is not a guarantee.

## **Authority**

A quality management plan must be formally approved by the laboratory director on an annual basis. This approval is normally evidenced by a signature. By approving a quality plan, the laboratory director signifies that the activities described in the plan—if faithfully executed—should reasonably ensure that the laboratory meets applicable quality and patient safety standards and is committed to a program of quality improvement. If the director knows of substantial quality deviations in laboratory operations that will not be detected or addressed by a quality plan, the director should not approve the plan.

Some organizations require that individuals besides the laboratory director approve the quality plan. Other individuals may approve quality plans, but the laboratory director must also approve the plan to satisfy regulatory requirements. In 2004, 2.2% of laboratories inspected by the CAP were cited because the quality management program had not been reviewed for effectiveness during the previous year.

## **Relation to Other Institutional Quality Programs**

In small stand-alone clinical laboratories, the laboratory quality plan usually exists on its own. In hospital-based laboratories, the laboratory quality plan may include a section that specifies information that is to be reported to a higher-level authority, such as an institution-wide quality

committee. In very large operations, each section of the laboratory (e.g., chemistry, anatomic pathology) may have its own quality plan, and the implementation of the plan will generate reports to a laboratory-wide quality officer or committee. In multi-site operations, each testing site may have its own quality plan. The organizational level at which quality plans are developed depends on the size and complexity of the laboratory and the nature of its corporate ownership.

### **Format of the Plan**

There is no required format for a quality management plan. The plan may be of the laboratory's own design, or it may follow a reference resource, such as CLSI guideline GP-22, Continuous Quality Improvement: Integrating Five Key Quality System Components, or GP-26, Application of a Quality Management System Model for Laboratory Services; the ISO 9000 series; JCAHO's model for improving organizational performance; or the AABB quality program. The document need not be detailed, but it should itemize the essential aspects of the program. For a small office-based laboratory, the quality management plan may be as short as two typed pages in length; for a large laboratory, it may be several dozen pages long.

Ideally, the quality management plan should contain all of the required elements listed in next section of this handout or should reference the procedures that contain the required elements. For example, the plan should either spell out the approach that will be used to investigate and address complaints that could affect patient care or should reference a separate procedure that contains this information.

The plan can exist as a separate document, or it can be a single procedure within a larger laboratory procedure handout. One advantage of making the quality management plan a procedure within a larger handout is that the plan will be reviewed automatically as part of the annual review of the laboratory procedure handout.

Some organizations maintain a separate patient safety plan. We recommend incorporating patient safety considerations into our sample quality management plans because combining the two reduces paperwork and is consistent with our general philosophy that assuring patient safety is part of quality management. Some organizations may prefer to address patient safety in a separate document.

### **Plan Elements**

What should be included in a quality plan? Certain elements are required by major accrediting agencies, and we believe every plan ought to include several additional elements that have been identified by the accounting profession as important components of management control systems. We recommend the following elements be considered for inclusion in every quality management plan.

*A Commitment to Quality and Patient Safety.* Quality and patient safety flourish in laboratories with the proper "tone." This tone includes an acceptance of standards, controls, discipline, structure, and responsibility. Management should demonstrate that quality control and patient safety are taken seriously and create a work environment in which employees are encouraged to

discuss quality and safety concerns without fear of retribution. A statement to this effect within the laboratory quality plan helps set the proper tone, although words alone are never enough.

*Risk Assessment.* The quality management plan should identify significant risks to quality and patient safety that could impact laboratory operations. To some extent, CLIA regulations and the CAP Laboratory Accreditation Program have already done 90% of the work required to identify risks. The CAP LAP checklists (which incorporate relevant CLIA regulations) spell out hundreds of problems that can interfere with the quality of laboratory operations, particularly in the analytic phase of testing. These risks have been identified by experts in laboratory medicine who are also familiar with the practical challenges of running a clinical laboratory. The laboratory director participating in the CAP accreditation program need only be concerned with the remaining 10%—risks that are unique to the director’s organization or which local circumstances suggest require greater attention. In spelling out special local risks to quality and safety, we suggest that authors of quality management plans focus on (1) institutional priorities (perhaps the director’s institution has identified cancer care or heart disease as a priority), (2) known problems with laboratory operations, (3) customer feedback, and (4) recurring incidents or sentinel events. We believe the risk of fraud and malfeasance, while small, needs to be addressed in a plan, and we suggest examples of how this risk can be mitigated in one of our sample plans. There is a regulatory requirement that the quality management plan must cover all aspects of a laboratory’s scope of care, such as inpatient and outpatient services, reference laboratory services, satellite and point-of-care testing, and consultative services. Therefore, risks should be identified for each area of service. There is also a regulatory requirement that the quality management plan include all sections of the laboratory and all shifts of operation.

In some institutions, a quality management plan contains a section called “Quality Planning,” which includes the risk assessment activities discussed above as well as organized research into customers needs and the development of products and services that meet those needs.

*Control Activities.* Control activities (sometimes called Quality Laboratory Practices) are the policies, processes, procedures, and inventions that mitigate risks. For every significant risk, one or more control activities should be in place. Control activities can take a variety of forms. For example, the risk of receiving a bad lot of reagents is mitigated by a procedure to test each new lot of reagents before placing the lot into service (as well as other controls). The risk of someone misappropriating private health information is mitigated by the requirement that passwords be used to access laboratory computer systems (as well as other controls). Most control measures are spelled out in individual laboratory technical procedures; there is no need to repeat in the plan every control activity that is already described elsewhere. When not specified in other documents, the quality management plan should include a description of the control activities that the laboratory will follow to address a particular hazard. Controls applied to broad laboratory issues, such as turnaround time or specimen collection, often are described in quality management plans.

*Information and Communication.* If not described in other procedures, the quality management plan should specify how quality and safety information is to be collected, stored, and disseminated. This is particularly important for quality monitors that bridge traditional organizational boundaries. The frequency of data collection, sources of information, and any calculations should be specified

in the plan or a separate procedure. If each section of a laboratory has its own quality plan, the information that will be sent “upstream” to the laboratory director or laboratory-wide quality committee should be specified. It may also be necessary to provide instructions for communicating with an institution-wide quality committee and with suppliers or customers who are to receive reports from the laboratory.

*Monitoring.* In addition to the monitoring that is part of regular quality control, the laboratory’s approach to quality must be monitored and reviewed. Generally, several types of monitoring are performed and should be spelled out in a quality management plan:

First, complaints, incidents, and sentinel events should be reviewed. There must be an organized program for documentation of external complaints and internal problems involving the laboratory. Any problem that could potentially interfere with patient care must be addressed, and the laboratory must document investigation and resolution of the problem. For JCAHO-accredited hospitals, there is a regulatory requirement that all sentinel events be investigated with a root cause analysis. The laboratory must be able to demonstrate that it has implemented any appropriate risk-reduction activities based on root cause analyses of sentinel events

Second, the results of ongoing measurement activities should be compared with internal or external benchmarks and, as appropriate, trended over time. If performance is significantly worse than a laboratory’s past performance, industry norms, or expected control limits, it is likely that processes or procedures will need to be changed.

Finally, the quality management plan itself requires regular (at least annual) review. The plan need not be changed every year but should be reviewed annually and kept current, as required. The annual review should be documented.

*Continuous Improvement.* A quality operation is committed to continuous improvement. At any point in time, some aspects of laboratory operations should be explicitly targeted for improvement. The actions that are planned to improve performance should be documented in the plan, and the effects of past quality improvement efforts (successful or unsuccessful) should be documented. In an organization committed to continuous improvement, small changes to operations are made daily, often without lengthy or formal planning, to make processes work better. There is no need to document these sorts of activities in an annual quality management plan. The plan should focus on major quality improvement activities that extend over longer periods of time and are more far-reaching.

## **Implementing the Plan**

A quality management plan that is not implemented has little value. Moreover, the CAP accreditation standards require that the plan be implemented as designed. In 2005, 1.6% of laboratories inspected by the CAP were cited for not implementing their quality management plans. The authors of this handout share deep concerns about laboratory managers who create beautiful paper documents that never come to life. Lest we lose site of our goal, it is worth reminding

ourselves that the purpose of quality management is to foster quality, not the creation of quality plans.

How do plans become practice? Often it is helpful to make specific individuals responsible for each task spelled out in the plan. Milestones and deadlines may be specified. Responsible individuals should also be given sufficient time to carry out assigned tasks. Insufficient time devoted to quality monitoring activities may result in incomplete or misleading information. Many laboratories create a quality committee that meets regularly to receive reports of ongoing measurements and to review complaints, problems, and any sentinel events. Social pressure from the quality committee helps motivate responsible individuals to complete required tasks. Evidence of plan implementation includes the minutes of the quality committee, the results of ongoing measurement, and any documentation related to complaint investigation, problems, and adverse events. These records, along with the plan itself, should be available to external inspectors. Quality management record-keeping need not be centralized, but on the day of a CAP inspection, summaries of all QM records should be grouped and provided to the inspector.

In our experience, plans are most easily implemented when a culture of safety and quality already exists within an organization. There are many authors and consultants ready to help managers cultivate a culture of safety and quality. Unfortunately, most approaches to promoting the right culture have not been scientifically tested, and we are reluctant to recommend specific techniques, even as we acknowledge the central importance of organizational culture to successful plan implementation.

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