
The Laboratory Quality Management Plan

This final chapter provides guidance in preparing and implementing a quality management plan. Sample plans from three laboratories are included, and readers should feel free to excerpt from these examples when developing plans for their own operations.

The CAP Laboratory Accreditation Program requires laboratories to maintain a written plan that describes the overall quality management program of the laboratory.²⁷³ In 2004, 1.3% of laboratories inspected by the CAP were cited for not having an adequate quality management plan.⁹¹

A quality management plan spells out the specific 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 chapters of this manual—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 manual 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.²⁷⁴

Authority

A quality management plan must be formally approved by the laboratory director on an annual basis.²⁷⁵ 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—will 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.⁹¹

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 (eg, 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.

Plan Elements

What should be included in a quality plan? Certain elements are required by major accrediting agencies,²⁷⁶ and we believe every plan should include several additional elements that have been identified by the accounting profession as important components of management control systems.²⁵ 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 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 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

Internal control systems need to be monitored; that is, the performance of laboratory operations over time and the internal control system itself need to be periodically reviewed. At least three 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 trended over time. If performance is significantly worse than a laboratory’s past performance or industry norms, 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.

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.

The quality management plan should contain all of the required elements listed in preceding sections of this chapter 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 manual. One advantage of making the quality management plan a procedure within a larger manual is that the plan will be reviewed automatically as part of the annual review of the laboratory procedure manual.

Some organizations maintain a separate patient safety plan. We have incorporated 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.

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.²⁷⁷ In 2004, 1.6% of laboratories inspected by the CAP were cited for not implementing their quality management plans.⁹¹ The authors of this manual 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.

Sample Plans

Three sample quality management plans are provided. These samples are based on real plans in current use, but the names of the laboratories from which they have been borrowed and some laboratory-specific information have been changed. The samples included in this manual are significantly longer than many quality management plans. Shorter plans that are well constructed can meet regulatory requirements as well as these samples.

The first plan serves a fictitious 145-employee laboratory located within a Florida community hospital. The second plan serves a microbiology section of a large free-standing laboratory in Oklahoma, where each laboratory section maintains its own quality management plan. The third plan serves a fictitious academic medical center in California.

The three samples address all of the elements we believe should be included in a quality management plan. Yet each plan describes the laboratory's quality program in its own way. To conserve space, only the most significant portions of the sample plans are included in this manual. Readers should feel free to borrow sections from any of these examples.

