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| **Laboratory/CAP#**  |  |
| **Name, Date** |  |

**Background**

A laboratory’s quality management system (QMS) should continually improve and mature. CAP 15189 assessors look for improvements during surveillance and reaccreditation visits. This tool is designed to address the following objectives:

* Provide common benchmarks for QMS maturity
* Help your laboratory identify opportunities for improvements
* Facilitate discussion about the state of your QMS – both within your laboratory and with CAP assessors

**Contents**

This document addresses the following topics:

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**Instructions for using the QMS Maturity Assessment Tool for your organization:**

1. Consider the dimensions of your organization’s QMS in terms of the levels described below.
2. For each dimension, rate your QMS as Level 1, 2, or 3 by checking the appropriate box. For Levels 2 and 3, note evidence that supports your rating. (**Note:** A Level 3 rating incorporates the strengths of Level 2.)
3. You will have an opportunity to discuss your ratings with your assessor; after the conclusion of your CAP 15189 assessment, he or she will offer to set up a meeting to go over your report results.

Here are descriptions for the three levels of maturity:

|  | **Level 1 – Basic Level** | **Level 2 – Fully Functional** | **Level 3 – Best Practice** |
| --- | --- | --- | --- |
| **Applicable ISO 15189 Requirements** | Just meets ISO 15189 requirements. | Meets and in some cases exceeds ISO 15189 requirements. | Meets and consistently exceeds ISO 15189 requirements. |
| **QMS Implementation**  | All aspects of the QMS have been defined and are in the process of being implemented. Shows clear weaknesses in implementation.  | All aspects of the QMS have been implemented and effectiveness is being monitored. Few or minor weaknesses present. | ***Best in class*** – QMS exemplifies a quality level that other laboratories can aspire to and learn from, with no obvious weaknesses present. All aspects of the QMS have been implemented, effectiveness is monitored, and action is taken to improve processes and reduce risk, where appropriate. |
| **Benefits to Laboratory** | Some benefits to laboratory. | Substantial benefits to laboratory. | Maximal benefits to laboratory. |

**Note on Maturity versus Accreditation**:

This QMS Maturity Assessment Tool is designed to promote:

* Laboratory QMS improvement
* Discussion with your CAP 15189 assessor about your continual improvement progress

It is not a part of the formal accreditation process, which is governed by the CAP 15189 program policies and the ISO 15189 standard.

If a laboratory’s QMS is immature throughout all of these dimensions, showing all the weakness listed under Level 1, it most likely would not be ready for accreditation by the CAP 15189 program.

**Note on Relevant QM*Ed* Courses:**

For most of the QMS dimensions, the CAP has created a Quality Management Education (QM*Ed*) Resources course that provides guidelines and best practices.

QM*Ed* courses are online, self-paced courses that can be shared among laboratory staff and that provide continuing education (CE) credit. You will see references to these courses in this template.

For more information, go to cap.org and search QM*Ed*.

| **Dimension** | **Level 1 – Basic Level** | **Level 2 – Fully Functional** | **Level 3 – Best Practice** |
| --- | --- | --- | --- |
| **Quality Culture*** **Innovation**
 | Management shows evidence of commitment to continual improvement. (ISO 15189:2012 Clause 4.1.2.1)Laboratory solicits improvement suggestions from staff. It evaluates and implements suggestions; it provides feedback. (Clause 4.14.4)Assessors may identify the following weaknesses:* Staff may complain that their suggestions are not always considered.
* Staff may experience criticism for suggesting innovations.
* Number of innovations is small and scope is limited.
 | Laboratory has a documented process for generating innovations or a process that the laboratory can describe.Laboratory provides training on continual improvement for employees at all staff levels. Laboratory maintains a record of suggestions for innovations that were submitted and implemented. | Laboratory has a strategy for sustaining and improving a culture of innovation, eg, through:* **Recruiting** – Seeks individuals who have a drive for innovating.
* **Communication** – Publicizes examples of successful change.
* **Training** – Provides training in improving processes.
* **Reward** – Recognizes individuals who suggest changes.
* **Rituals and Programs** – Initiates programs (eg, ISO 15189, Lean) that prompt improvements.
* **Visible Leader Actions** – Leader personally directs an improvement project.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Quality Culture*** **Speaking Up**
 | Laboratory establishes communication processes to support quality and continual improvement. (Clause 4.1.2.6)Laboratory solicits improvement suggestions from staff. It evaluates and implements suggestions; it provides feedback. (Clause 4.14.4)Assessors may identify the following weaknesses:* Instances where process and documentation do not match due to workarounds (eg, staff did not accept and follow the process, but did not speak up about it either).
* Evidence that those who speak up are punished or discouraged from doing so.
* Lack of adequate. mechanisms or forums for communicating problems.
 | Laboratory maintains evidence that processes have been standardized and that staff have come to consensus on the right process, with opportunity to disagree and discuss (eg, list project team members).Laboratory creates mechanisms and forums for communicating problems, eg: * Daily huddles.
* Program of “management by walking around,” where managers are encouraged/required to get out of their offices and spend time with staff.
 | Laboratory has a strategy for sustaining and improving a culture of speaking up, eg, through:* **Recruiting** – Seeks individuals who demonstrate willingness to speak up.
* **Communication** – Shares examples of the benefits of speaking up.
* **Training** – Provides training in risk awareness.
* **Reward** – Recognizes those who speak up about problems.
* **Rituals and Programs** – Initiates daily reporting strategies that encourage raising issues.
* **Visible Leader Actions** – Leader takes prompt action based on suggestions and concerns.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Quality Culture*** **Going Above and Beyond**
 | Management shows evidence of commitment to continual improvement. (Clause 4.1.2.1)Laboratory has overall strong performance on CAP accreditation inspection; it can show instances in which it goes beyond CLIA requirements.Assessors may identify the following weaknesses:* Few internally identified occurrences.
* Evidence that occurrences identified internally or externally are viewed as liabilities, or demerits.
* Internal audits are conducted inconsistently.
* Evidence that staff have an attitude of doing the minimum work required.
 | Laboratory coordinates internal audits, root cause analysis, corrective action, and management review to find and implement opportunities for improvement that go beyond requirements.Laboratory uses internal audits in ways that go beyond standard requirements – eg, focused audits to address a specific risk.Laboratory rewards and recognizes individuals and teams for going above and beyond.Laboratory communicates the importance of meeting and exceeding customer expectations. | Laboratory has a strategy for sustaining and improving a culture of going above and beyond, eg, through:* **Recruiting** – Seeks individuals who have ambition for going above and beyond.
* **Communication** – Provides information about stakeholder priorities and needs.
* **Training** – Provides training in topics such as mistake proofing.
* **Reward** – Gives awards for quality projects.
* **Rituals and Programs** – Initiates programs that prompt customer focus.
* **Visible Leader Actions** – Leader invests personal effort on an improvement project.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Quality Culture*** **Transparency**
 | Laboratory uses a communication mechanism for reporting errors and near misses to management. (Clause 4.1.2.6)Laboratory analyzes reports of errors/occurrences for their potential to prevent future failures of work processes; it uses error reports to improve processes. (Clauses 4.10, 4.11, 4.14.6)Assessors may identify the following weaknesses:* Staff tell external assessors and inspectors about quality issues that don’t appear in the laboratory’s occurrence management documents.
* Staff display a “hiding errors” mentality.
* Staff are punished (eg, on annual reviews) or reprimanded for identifying errors.
* Laboratory has practices that put people on the spot and make it difficult to admit problems.
 | Management demonstrates awareness of the need to drive fear out of the workplace and build trust between staff and supervisors/managers, eg, through:* Communications.
* Promoting the practice of Management by Walking Around to reduce the distance between staff and leadership.
* Training programs (eg, Just Culture).
 | Laboratory has a strategy for sustaining and improving a culture of transparency, eg, through:* **Recruiting** – Hires supervisors with a reputation for developing trust.
* **Communication** – Emphasizes the importance of driving out fear.
* **Training** – Teaches how to address defects and mistakes from a process-based and root cause perspective.
* **Reward** – Recognizes people who admit mistakes and speak up about problems.
* **Rituals and Programs** – Encourages processes such as daily status checks that create a supportive atmosphere for bringing up defects and mistakes.
* **Visible Leader Actions** – Leader addresses errors and mistakes with process investigation and process improvement.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Quality Culture*** **Process Orientation**
 | Laboratory has identified and documented key processes. (Clause 4.2.1)Laboratory has a documented root cause analysis and corrective action process. (Clause 4.10)Assessors may identify the following weaknesses:* Corrective action reports focus blame on individuals, rather than a system or process; they conclude that solution is to “retrain employee(s).”
* Many “quick fixes.”
* Daily activities are often responsive to immediate needs or problems – there is considerable “fire-fighting.”
* Once the fire has been put out, there is no awareness of further work that needs to be considered on the issue (eg, root cause analysis).
 | Processes are standardized and regularly evaluated for improvement.Laboratory staff are trained on, and employ, root cause analysis best practices (see Root Cause Analysis section of this document).Assessors notice at least some of the following best practices:* Daily operations and activities can be traced to processes.
* When fire-fighting occurs, it takes place in the context of an improvement process.

Assessors notice decreased frequency of repeat problems. | Laboratory has a strategy for sustaining and improving a culture of process orientation, eg, through:* **Recruiting** – Seeks people with problem-solving skills.
* **Communication** – Stresses the importance of asking “Why did it happen?” instead of “Who did it?”
* **Training** – Provides training in root cause analysis and mistake proofing.
* **Reward** – Recognizes teams who have analyzed and solved complex problems.
* **Rituals and Programs** – Initiates occurrence management tools and programs.
* **Visible Leader Actions** – Leader initiates and directs an investigation.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Quality Culture*** **Teamwork and Involvement**
 | Laboratory management: * Solicits and uses staff suggestions (Clause 4.14.4)
* Recognizes interrelationships within the organization (Clause 4.1.2.5)
* Communicates with all staff (Clause 4.1.2.6)

Assessors may identify the following weaknesses:* Staff have a low sense of ownership.
* Staff have a “cog in the machine” attitude, and take the attitude “I just do what I’m told.”
* Staff look to supervisors and managers for answers and solutions.
* Managers rarely involve staff in decisions, such as what quality metrics to use.
 | Management regularly involves staff in decisions that affect quality. For example, staff chooses the metrics that show whether their work group is doing a good job. Laboratory leadership provides a combination of training, communication, and management such that laboratory staff work effectively as a team.Laboratory staff understand the goals that the medical staff seek to achieve.Laboratory staff take initiative and act assertively to promote quality. | Laboratory has a strategy for sustaining and improving a culture of teamwork and involvement, eg, through:* **Recruiting** – Seeks people (eg, medical director) with facilitation and leadership skills.
* **Communication** – Stresses the importance of treating everyone in the organization with respect and appreciation.
* **Training** – Provides cross training and job rotation.
* **Reward** – Recognizes individuals who initiate team-based/collaborative projects.
* **Rituals and Programs** – Lets staff lead huddles and other meetings, giving them leadership roles.
* **Visible Leader Actions** – Leader explains how management is advancing the common purpose; leader delegates when appropriate.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Quality Culture*** **Risk Awareness**
 | Laboratory management:* Provides training to all personnel on the QMS, including risk management. (Clause 5.1.5)
* Applies root cause analysis and corrective action concepts to nonconformities, including issues such as QC failures and PT anomalies. (Clause 4.10)

Assessors may identify the following weaknesses:* Staff attribute events to “random error.”
* Managers tell staff to repeat a QC test that failed, and proceed with testing if it is acceptable.
* Delay in addressing known risks.
* Safety issues (eg, cluttered work areas, wet floor).
* Disorder (eg, work flow interrupted by clutter).
* Lack of attention to detail (eg, signoffs missing, data in wrong units).
 | All staff proactively look for, and report, risks in the environment.Staff celebrate finding errors.Laboratory shows strong record of compliance with policies, processes, and procedures.Leadership uses mistake proofing to take risks into account when revising processes or developing new processes. | Laboratory has a strategy for sustaining and improving a culture of risk awareness, eg, through:* **Recruiting** – Asks interview questions about scenarios involving risks.
* **Communication** – Makes discussions of risk and safety a part of regular meetings.
* **Training** – Trains individuals on how to resolve QC and/or PT failures.
* **Reward** – Recognizes individuals who identify risk in the environment.
* **Rituals and Programs** – Integrates risk management into your core processes, eg, validation process; use 5S principles.
* **Visible Leader Actions** – Leader directs staff to stop testing when QC or PT anomalies arise.
 |
| *See CAP QMEd course Quality Culture* | [ ]  | [ ]  | [ ]  |
| **Document Control** | Laboratory has developed and implemented a procedure to control documents. (Clause 4.3) Assessors may identify the following deployment issues/weaknesses:* Cheat sheets that are not controlled are posted in the laboratory.
* Staff are not able to locate controlled documents quickly.
* Outdated documents found in circulation.
* Document control system is difficult or time consuming to use.
 | Laboratory has deployed a user-friendly document control system.* Staff are able to locate documents quickly.
* Software is user friendly, or paper system is well designed.
* There are terminals near work areas, or binders near work areas.
* Work aids/job aids are controlled (eg, through secondary document log).
 | Assessors do not encounter any document control problems.The document control system uses current technology to create efficiencies and prevent errors or oversights. For example, the system sends review notifications and escalates action items.  |
| *See CAP QMEd course Document Control* | [ ]  | [ ]  | [ ]  |
| **Occurrence Management**  | Laboratory has a system for collecting and storing information about errors and incidents. (Clauses 4.8-4.11)Laboratory has deployed an occurrence management system, has collected data, and has taken actions based on collected data.Assessors may identify the following weaknesses:* The system is organized to gather data, not to analyze it.
* There are many locations for storage of data; the locations are not integrated, making it difficult to compare data and find trends.
* The system tends to be used for one-off fixes, rather than development of proactive plans to address multiple issues, or issue trends.
* Laboratory sometimes reacts slowly to issues; long closure times.
 | Laboratory uses occurrence management data to identify trends and anticipate problems.Occurrence management system enables laboratory to take appropriate preventive measures. | Occurrence management system facilitates laboratory’s ability to * Explore data.
* Detect trends.
* Compare past and present.
* Compare different kinds of occurrences (eg, internally-identified versus externally-identified).

Laboratory has occurrence management tools that enable easy comparison of trends from different sources (eg, one database that contains occurrence information on suppliers, customer complaints, instrument generated data, PT failures, etc).  |
| *See CAP QMEd courses:** *Root Cause Analysis*
* *Mistake Proofing*
 | [ ]  | [ ]  | [ ]  |
| **Root Cause Analysis and Corrective Action** | Laboratory has a documented process for corrective action, including conducting root cause analyses. (Clause 4.10)Laboratory has completed and documented multiple root cause analyses.Assessors may identify the following weaknesses:* No structured process is used for root cause analysis.
* One tool, such as Five Whys, or Fishbone diagram, tends to be used repeatedly, even when another tool such as process mapping may be more appropriate.
* Detail of analysis is out of sync with complexity of problem – usually too simple.
* Analysis tends to blame individual(s).
* Analysis yields simple solutions, such as “operator error” or “need for retraining.”
* Analysis concludes with need to “continue monitoring.”
 | Laboratory uses a structured process for root cause analysis.The root cause analysis and corrective action process incorporates at least some recognized best practices, eg:* Define problem first.
* Use a team.
* Understand *as is/current* state using process mapping.
* Drill down to root cause using a tool such as Five Whys, Fault Tree, or Flowcharting.
* Choose “stronger” solutions such as process redesign over “weaker” solutions such as training.
* Plan out implementation (including change management).
* Check for effectiveness of implemented corrective action(s).
* Generalize the root cause analysis results – use them to find and solve similar problems, with similar causes.
 | Laboratory can show evidence that problems have been solved permanently as a result of investigation and root cause analysis.Laboratory demonstrates that it understands and uses a variety of root cause analysis tools (eg, Five Whys) and selects those that best fit the situation.Laboratory consistently integrates change management tools (eg, Stakeholder Analysis) into implementation plans.Corrective actions employ mistake proofing tactics, such as eliminating mistake-prone steps, constraining the process to prevent slips, Lean and visibility principles, checks, and alerts. |
| *See CAP QMEd courses:** *Root Cause Analysis*
* *Mistake Proofing*
 | [ ]  | [ ]  | [ ]  |
| **Internal Auditing** | Laboratory has a structure in place for internal auditing (schedules, training, methodology, documentation, and mechanism for following up on audit findings). (Clause 4.14.1, 4.14.5)Laboratory has completed and followed up on at least its first round of audits.Assessors may identify the following weaknesses:* Lack of concrete results from internal audit program.
* Lack of adequate follow-up.
* Shallow, superficial, overly-detailed/picky audit findings.
* Use of the same audit schedule, and same frequency of audits, regardless of previous audit findings.
* Audits structured based on ISO standard clauses rather than the laboratory’s processes.
* Audits focused on detailed procedures rather than processes.
* Lack of focus on customer and patient care.
 | Laboratory has maintained structure of program through multiple audit cycles. The structure has become institutionalized.Laboratory has demonstrated consistency in following up on audit findings.Findings from core process audits consistently address support processes and systemic issues, rather than just the specific core process.**Note**: The distinction between core and support processes is as follows:* *Core processes* bear directly on the product or service that the customer purchases (eg, preanalytic, analytic, postanalytic).
* *Support processes* support a core process (eg, document control, complaint handling, corrective action).

*(continued on next page)* | Internal audits have become part of the culture. Laboratory can provide examples of small-scale audits that were conducted to address a specific issue, even though they were not part of the process audit schedule.Laboratory management provides auditors with training and credentials in areas such as Lean and Six Sigma. Auditors apply Lean/Six Sigma principles to their audit work to address process flow issues. Auditors play the role of consultants. Bench techs see auditors as partners and ask auditors how to improve processes and detect problems.*(continued on next page)* |
| *See CAP QMEd course Internal Auditing* | [ ]  | [ ]  | [ ]  |
| **Internal Auditing (continued)** |  | Laboratory has identified ways to improve efficiency of the internal audit process since first round.Laboratory analyzes findings and adjusts audit schedule as appropriate.Actions taken as a result of audit findings have improved efficiency and/or patient care. | Laboratory extends internal audits into hospital.Laboratory forms partnerships with Nursing, Radiology, etc. to conduct joint audits for issues where there is common responsibility.Laboratory is using tracer audits and laser audits to address process issues. |
| **Risk Management** | Laboratory has identified and addressed risks for any processes that may affect patient safety (eg, processes or software that have recently been installed or revised). (Clause 4.14.6)Laboratory demonstrates process mapping capability.Laboratory has an ongoing program for risk management, as demonstrated by examples of documented risk analyses and mitigation strategies.*(continued on next page)* | Laboratory has assigned process owners to core processes for risk assessment purposes.Assessors notice at least some of the following best practices:* Laboratory uses PT and QC activities to identify and address risks.
* Laboratory analyzes internal audit findings for risk level.

Once a risk is identified, investigated, and addressed, the laboratory applies corrective or preventive actions across other work areas where the same risk may occur. | Process owners have training in some/all of the following disciplines: * Root cause analysis
* Internal Auditing
* FMEA
* HACCP

Processes are routinely revisited and reassessed.After addressing problems and risks, laboratory monitors process variability and continues to address or reduce as much as possible until 1) only common cause variation remains, or 2) there are economic or technology constraints to lowering variability any further. Laboratory uses process variability to assess risk.*(continued on next page)* |
| *See CAP 15189 document*  *Risk Assessment Guide* | [ ]  | [ ]  | [ ]  |
| **Risk Management (continued)** | Assessors may identify the following weaknesses:* Lack of assessment of probability and severity for identified risks.
* Lack of root cause analysis for identified risks.
* Lack of follow-up on identified risks, such as not taking action to mitigate the risks or not tracking the effectiveness of mitigation strategies.
* Laboratory missed obvious risks (eg, dirty areas, poor testing habits, odors/fumes).
 |  | Risk management is incorporated into the organization’s culture, decision making, policies, and procedures. The QMS provides guidance that addresses:* Organizing risk assessment projects.
* Carrying out risk assessment (identification, analysis, and evaluation).
* Taking action to mitigate risk.
* Verifying effectiveness.
* Monitoring.
* Maintaining documentation.

Laboratory associates risks with costs, using Cost of Quality concepts, and develops business case for prevention projects based on projected internal and external failure costs.Laboratory demonstrates thorough risk analysis in Section 1 of IQCP plans for its tests. |

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|  | **Level 1 – Basic Level** | **Level 2 – Fully Functional** | **Level 3 – Best Practice** |
| **Continual Improvement** | Laboratory has a process for investigating alternative methods in order to improve quality measures. (Clause 4.12)Assessors may identify the following weaknesses:* Many procedures are outdated, as evidenced by approval dates, indicating that the laboratory has not explored and implemented alternatives.
* Laboratory equipment is in need of replacement.
* Laboratory makes incremental improvements, but nothing that transforms the way work is done.
* Improvement records may list Human Resources projects (eg, new lunch room) rather than laboratory process improvements.
 | Laboratory looks for improvements in all areas, including: * Equipment.
* Work methods that may impact patient safety and/or testing personnel.
* Test methods.
 | Laboratory works in partnership with equipment vendors to transform both process flow and hardware.Laboratory uses mistake-proofing as part of continual improvement.Laboratory uses methodologies like Lean to discover more effective work processes.Laboratory uses Cost of Quality methodology to justify improvement projects (eg, by projecting internal and external failure costs).Laboratory assigns people to keep aware of new/changing technologies to stay current with industry practices (eg, attend AACC meetings).In developing process documents, laboratory uses structured writing techniques such as outlined in CLSI guideline QMS02-A6: *Development and Management of Laboratory Documents*. Documents are easy to read, navigate, and scan. |
|  | [ ]  | [ ]  | [ ]  |

|  | **Level 1 – Basic Level** | **Level 2 – Fully Functional** | **Level 3 – Best Practice** |
| --- | --- | --- | --- |
| **Competency and Personnel Development** | Laboratory has a documented procedure for personnel management and maintains records to ensure compliance with regulations. (Clause 5.1.5)Laboratory ensures that tests are performed by competent personnel. (Clause 5.1.2)*Continued on next page* | Laboratory identifies key departments and functions outside of the laboratory that are critical to performance (eg, ER specimen collection), and ensures that laboratory personnel understand how they work. Laboratory provides training in “the big picture.” Laboratory seeks to identify best practices and sources of specialized knowledge, and to provide access to them for everyone who can benefit.Laboratory seeks out and incorporates best practices and specialized knowledge from outside the laboratory. | Laboratory initiates “shadowing” programs with other key departments that laboratory interacts with. For example, laboratory technologists shadow ER nurses collecting specimens. Floor nurses shadow accessioners sorting specimens. Laboratory ensures mutual understanding of key processes among members of interacting departments. |
|  | [ ]  | [ ]  | [ ]  |
| **Competency and Personnel Development (continued)** | Assessors may find the following weaknesses:* Laboratory personnel have tunnel vision; they do not have adequate knowledge of what happens outside the laboratory.
* “Silos” or pockets of knowledge and skill exist within the laboratories that are not shared with the rest of the laboratory.
* The laboratory rarely goes outside its walls to identify new ideas and best practices that are worth incorporating.
* Laboratory only collects negative data (eg, complaints). It does not use surveys or other sources that provide both positive and negative feedback.
 |  |  |

|  | **Level 1 – Basic Level** | **Level 2 – Fully Functional** | **Level 3 – Best Practice** |
| --- | --- | --- | --- |
| **Customer Satisfaction/ Alignment with Customers** | Laboratory collects customer satisfaction (both internal and external) data using a survey. Customer survey data is discussed in management review meetings and generates action items. (Clauses 4.14.3 and 4.15.2)Assessors may identify the following weaknesses:* Little or no follow up on customer complaints.
* Survey is high-level and not specific in terms of who was surveyed, and where they are located.
* Laboratory glosses over problems because percentages are low, even though absolute numbers show a potential problem.
 | 1. Laboratory has effective system for organizing, analyzing, and acting on customer satisfaction data.
* System incorporates complaints, comments received by sales team, and operational metrics.
* Laboratory demonstrates clear alignment between customer satisfaction surveys/metrics and operational metrics.

Management review meeting documents reflect prompt and thorough follow-through on action items.Laboratory seeks to understand reasons for dissatisfaction, even if the percentage is low; it pays attention to absolute numbers. | Laboratory encourages customers to provide feedback and suggestions that go beyond annual surveys.Laboratory actively solicits and encourages suggestions for improvements, new products, and training programs. Laboratory treats customers as business partners.Customer-centric metrics are used to manage organizational performance.Laboratory seeks to understand reasons for low customer satisfaction scores and makes appropriate adjustments. |
|  | [ ]  | [ ]  | [ ]  |
| **Management Review**  | Laboratory uses a structured process for reviewing its QMS to ensure its continuing suitability, effectiveness, and support of patient care. (Clause 4.15)Laboratory uses these meetings to integrate information and “connect the dots” regarding the core processes of its QMS.Laboratory has identified metrics that are consistent with quality policy and objectives. Laboratory is in the process of gathering and monitoring data. *(continued on next page)* | Management review records demonstrate the use of meetings to facilitate processes for: * Issue identification – from both internal and external sources.
* Investigation – with adequate root cause analysis.
* Action item tracking and follow-up.
* Achievement of positive results.

*(continued on next page)* | Laboratory management analyzes information for causes of issues that indicate core process problems.Problems with core processes lead the laboratory to investigate support processes.Laboratory management ties together trends and disparate elements, such as: * Customer satisfaction
* TAT
* Draw time

Laboratory uses these analyses to find leading indicators of quality issues.Management looks for unintended consequences of individual changes (eg, speeding up collection causes missed orders). Management uses line graphs to detect such patterns. |
| *See CAP QMEd course Management Review* | [ ]  | [ ]  | [ ]  |
| **Management Review (continued)** | Assessors may identify the following weaknesses:* Metrics are monitored but no action is taken when issues or trends are identified.
* Action items are inadequately addressed (eg, “Continue to monitor”).
* Root cause analysis is inadequate.
* Laboratory reaches no conclusion about overall QMS effectiveness and its contribution to quality patient care.
 | Management Review:* Focuses on QMS core processes, with high-risk aspects discussed/ reviewed during every meeting.
* Integrates information from multiple sources (eg, audit results, complaints, and research on new technology).
* Brings in the right people to participate in the meetings (eg, staff, admins, and vendors) to make decisions on a specific issue).
* Sorts and prioritizes issues – separates out those that require action.
 |  |

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|  | **Level 1 – Basic Level** | **Level 2 – Fully Functional** | **Level 3 – Best Practice** |
| **Quality Manual** | Manual contains necessary elements required by standard (eg, quality policy, scope of services management structure). (Clause 4.2.2.2)Assessors may identify the following weaknesses:* Manual is either not accessible by all staff members and/or is not used by anyone other than the quality manager for purposes of accreditation visits; it sits on the shelf.
* Manual is unnecessarily long, containing information that is of little or no benefit to defining the laboratory’s quality management system (eg, procedures that should be in SOPs, or that are also in SOPs; policy statements written to address each clause of the ISO 15189 standard).
 | Manual describes the quality management system in terms of processes, using process maps or stage tables of core and support processes.Manual is used for the following purposes:* To train and orient new people.
* To explain how the laboratory works; to point to key documents and procedures.
* To provide internal and external auditors with an overview of the laboratory’s quality management system that is useful for planning audits.
 | Manual shows link of quality policy, quality objectives, and metrics.In depicting processes, manual uses structured writing standards such as CLSI guideline QMS02-A6: *Development and Management of Laboratory Documents*.  |
| *See CAP QMEd course Quality Manual* | [ ]  | [ ]  | [ ]  |

**Summary of Maturity Ratings**

You can use the embedded Excel table to create a summary of your self-ratings. 

Here is an example of such a summary:



**Laboratory Comments on Key Areas of Improvement:**

|  |
| --- |
|  |