Background

What is management review?

Management review is a structured, periodic meeting intended to help management assess the effectiveness of the quality system.

The practice ensures that management takes a periodic "snapshot" of its processes, reviews relevant data and projects, makes plans to improve the system, and follows up to make sure plans are implemented.

Management review is a requirement in the ISO 15189 standard.

Who performs management review?

Position	Role in Management Review
Quality Manager	• Organize the meeting • Collect the information to be presented • Present information • Lead discussions / Facilitate decisions about next steps
Administrative Director Medical Director	• Help in making decisions about next steps • Implement the decisions made at the management review meeting
Laboratory staff	• Attend the meeting and present information as subject matter experts
Supervisors Managers	• Attend the meeting • Participate in decision making
Administrative staff	• Pull together data and create presentations of data and trends that are easily interpreted

What is the essence of a management review meeting?

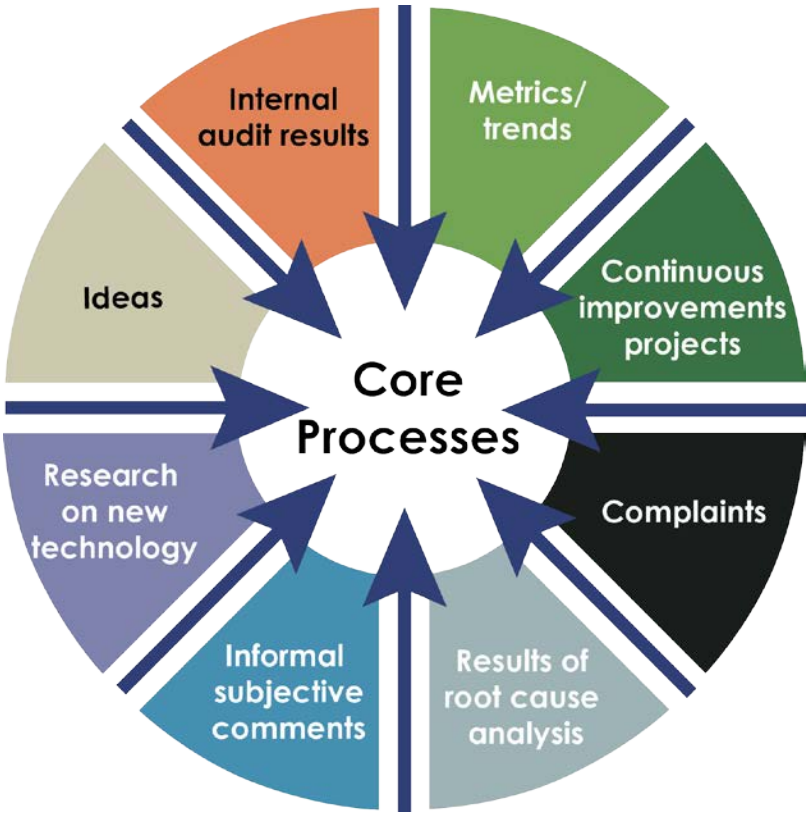
Management review is about "connecting the dots." It is taking all the information and ideas from the monitoring system that are relevant to the core processes, and asking what they are telling you.

> Note: Core processes are those that bear directly on the product (preanalytic, analytic, and postanalytic) as opposed to support processes, such as document control, training, and resolution of complaints.

Management review incorporates:

- Objective information coming from sources like metrics, internal audits, and complaints
- Subjective ideas, impressions, and concerns

In management review, the quality team reviews all trends and patterns that may indicate process problems or that may suggest ways to improve.



Management review inputs

Management review should emphasize core processes. When issues are found with core processes, these need to be investigated. Sometimes the investigation will reveal that there are problems with support processes, such as document control or training.

What are the inputs to management review?

The 15189 standard outlines a number of specific items that management should take into account in management review meetings. The following table lists these items and provides a brief description.

Input	Description
a) Follow-up of previous management reviews	This refers to action items from previous meetings, such as a project to review alternative vendors for a reagent.
b) Status of corrective actions taken and required preventive action	A corrective action is an action taken to eliminate the cause of a **detected** problem. A preventive action is an action taken to eliminate the cause of a **potential** problem – to make sure a problem or event does not happen.
c) Reports from managerial and supervisory personnel	This refers to reports by department supervisors (eg, supervisor of Chemistry or Hematology) discussing issues facing their department and needs such as staffing, training, supplies, and capital budget.
d) The outcome of recent internal audits	An internal audit, sometimes called a first-party audit, is a careful, independent look at a work process, or set of work processes, to see: • Whether they are operating as planned and defined by the Quality Management System (QMS) • Whether they meet a chosen standard or regulation • Whether they are effective • How they can be improved An internal audit is conducted by someone within the organization but outside the discipline being audited.
e) Assessment by external bodies	This refers to evaluations of the laboratory's compliance to standards and requirements by external organizations (eg, CAP 15189, CAP/LAP, CMS).
f) The outcome of external quality assessment and other forms of interlaboratory comparison	This refers to the laboratory's performance in proficiency testing and other interlaboratory comparison programs.

g) Any changes in the volume and type of work undertaken	This refers to changes in volume and scope of work, personnel, and premises that could affect the quality management system.
h) Feedback, including complaints and other relevant factors, from clinicians, patients, and other parties	This refers to users' perception of the laboratory's ability to meet their needs and requirements.
i) Quality indicators for monitoring the laboratory's contribution to patient care	This refers to metrics used to evaluate the laboratory's performance throughout all aspects of preanalytical, analytical, and post-analytical processes.
j) Nonconformities	A nonconformity is an instance where the quality management system does not meet a requirement. Nonconformities are identified through complaints, QC requirements, and external/internal audits. As an input to management review, this includes • Trending of unfulfilled requirements • Follow-up actions and trending of unfulfilled requirements
k) Monitoring of turn-around time	Monitoring of turn-around time (TAT) is one of the primary quality indicators among those referred to in (i).
l) Results of continuous improvement processes	Continuous improvement refers to efforts to make actual performance correspond with intentions as outlined in the laboratory's quality policy and quality objectives. There are many processes that help generate improvements, for example: • Corrective Action • Preventive Action • Internal Audit • Management Review Continuous improvement processes also include projects to transform how the laboratory operates. This may involve adding new services, adding new instrumentation, or applying lean principles to existing workflows.
m) Evaluation of suppliers	This refers to suppliers' ability to meet the needs and requirements of the laboratory.

As the ISO 15189 standard points out, this list is not exhaustive but provides a starting point. Other items that a quality team may want to discuss include:

- Recommendations for improvement based on the evaluation of all quality activities (satisfaction surveys, complaints, audits, quality indicators, etc.), and ideas from research on new technology
- Methods used for testing, sample volumes, collection devices, and sample preservatives

How often should laboratories have management review meetings?

The ISO standard states the review meetings should be held at "planned intervals," but it is up to the lab to decide the intervals.

There is a potential for error each way. If the meetings occur too frequently, there is a risk of managing with excessive control, and getting into detail that should be left to lower-level managers and supervisors. If meetings are too infrequent, the team may miss important issues or opportunities.

A good middle option is quarterly meetings.

When is quality team ready to begin management review?

As soon your team has built portions of the quality management system, it is okay to start reviewing. The laboratory does not need to have everything built and in place. If you only have six things, then just review those six things. Get practice with the elements you have.

For example, let's say the organization has these elements:

- TAT metrics
- Customer complaint handling process
- External organization audits

It is completely appropriate to start conducting management review meetings that focus on just these things.

How many metrics should management review look at?

Look at six-to-eight key high level metrics for the organization. An example of a key metric is TAT.

If one of the high level metrics shows a problem, look at the lower level metrics that will give you more information. For example, if TAT is not adequate, look at instrument downtime or missed specimen pick-ups.

What do ISO 15189 assessors look for in an organization's management review process?

Assessors look at the structure of management review as it is reflected in scheduled meetings, attendees, minutes, action steps, and follow-up on action steps from meeting to meeting.

Assessors want to see that the organization is doing something with the information it collects. Are there specific action items? What happens to Corrective Action/Preventive Action (CAPA) reports? Assessors may sample CAPA reports (perhaps reviewing one of every six), and find out what specific results were achieved.

Case Example

Background on Laboratory

Becker-Maurer Laboratory is a community hospital-based laboratory that provides the following services:

- Centralized Phlebotomy
- Blood Gases
- Body Fluid Analysis
- Chemistry
- Special Chemistry
- Toxicology
- Coagulation
- Hematology
- Urinalysis
- POC Testing
- Transfusion Services

Becker-Maurer Laboratory serves as a reference laboratory for physician offices, and provides outpatient services.

Click the link below to see the quality manual.

Quality Manual

Note: In this manual, for presentation purposes, analytical processes are limited to hematology, and sub-processes are limited to a single stage. Two support process examples are included.

Here is their quality policy poster (click to launch graphic file).

Pre-Meeting Materials

Here is the email the quality manager sent out to invitees.

To:	Management Review Team, Monique T, Ray B
Subject:	April 15 Meeting
Attachments:	Meeting packet

Hello all,

You are invited to the first quarter 20XX, Becker-Maurer management review meeting to be held on April 15, from 8:00 am to 12:00 pm.

Please review the attached meeting packet prior to the meeting. Also, please bring your laptop or a hard copy of the documents from the meeting packet to the meeting.

Let me know if you have any questions.

Monique and Ray,
You will not need to attend the entire meeting. Monique, please join us at the beginning of the meeting. Ray, you can join us after the second break.

Thank you,
Georgene M, Quality Manager
Becker-Maurer Laboratory

Click the link below to see the meeting packet folder and its contents.

Meeting Packet

Meeting Opening

In attendance:

Management review group:

Georgene M, Quality Manager
Christine S, Medical Director
Tim C, Administrative Director
Frank L, Director of Laboratory Operations
Joanne N, Support Services Manager

Other invitees:

Monique T, Chemistry Section Supervisor
Ray B, Purchasing Manager

 **Quality Manager, Georgene**	Welcome to the first quarter management review meeting. I've invited two guests. Monique, our Chemistry Section Supervisor, is here for the first half of the meeting. Ray, our Purchasing Manager, will join us for the second half. Thank you for taking time for us. You should all have had a chance to review the meeting packet that I sent out to you last week. The first document was the agenda. Agenda As is our custom here, we have clustered the inputs listed in the ISO 15189 standard into six categories: • Quality metrics • Internal audits • Supplier performance • Continuous improvement • External assessments and inspections • Customer satisfaction In your meeting packet, I included a document that shows how we cluster the inputs. **15189 Input Categories** There are a few management review items that we will not cover today. We'll have a chance to address those in future meetings. In order to review the rest of the items, we must keep on schedule as much as possible, so I've asked Frank, Director of Laboratory Operations, to be the timekeeper.

	The purpose of management review is for us to take periodic "snapshots" of Becker-Maurer's core processes and to review data from our quality activities. As a result of our review, we'll need to decide what is working effectively and what is not. From that we need to determine what needs to be improved, make plans for those improvements, and then implement those plans. I'd like us to start by reviewing Becker-Maurer's quality policy and quality objectives. Quality Policy (Georgene projects the contents of the meeting packet on a screen in the board room, starting with the quality policy.) You can see the quality indicators we've established to measure our performance to our quality objectives, so let's look at our metrics.

Quality Metrics

Overview and Action Items

Quality Manager, Georgene

We can easily see which metrics have met the target for the first quarter of 20XX and those that have not.

Quality Metrics

The asterisks indicate new monitors that we added as a result of our fourth quarter management review meeting. We'll discuss our problem with lost specimens and Point-of-Care Testing (POCT) policy compliance in a little while, but first I want us to look at areas in which we've made improvements.

Please take a look at the Action Item list from the fourth quarter of last year.

Action Items 4th Quarter

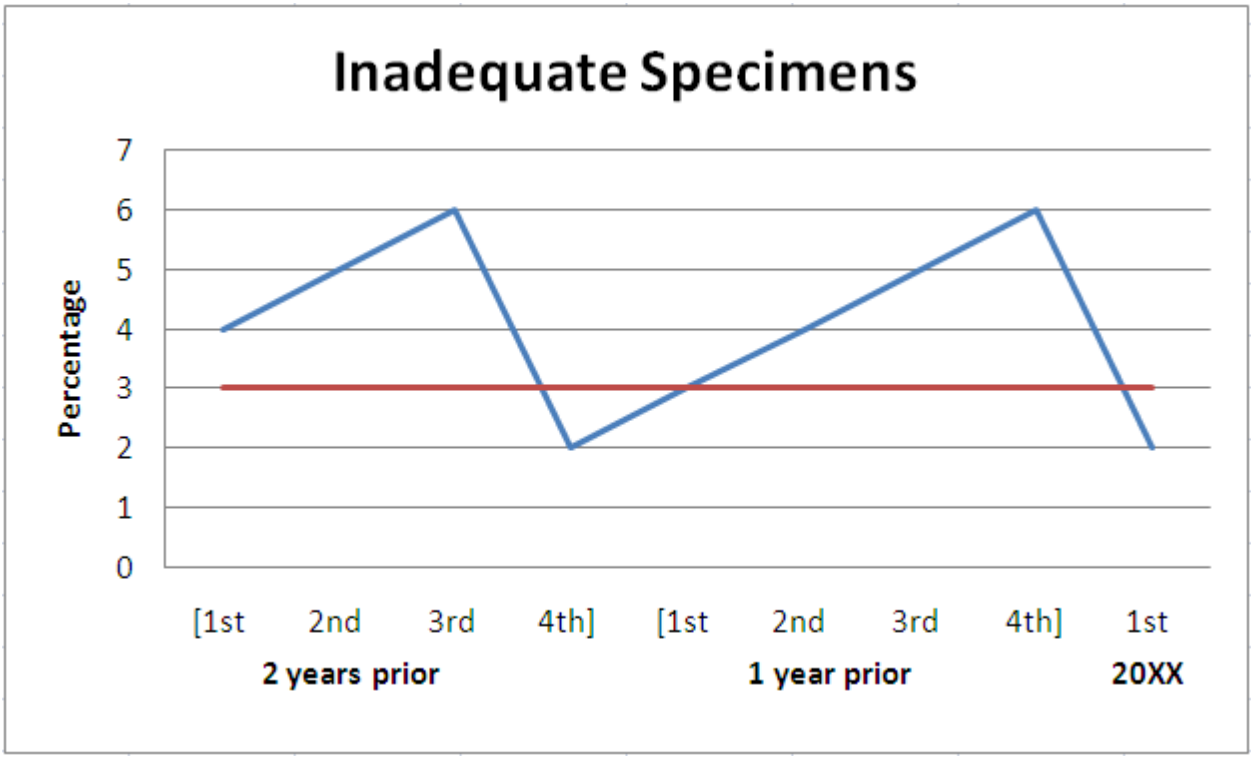
Last quarter we found that the percentage of inadequate specimens was continuing to rise, so one action item was to re-train some of our clients in the process of proper specimen collection. The other was to review our directory of services.

Inputs	Action Items	Responsibility	Due Date	Completion
Quality Indicators	Re-train clients identified in Rejected Specimen quality metric in specimen collection process	JN	March 4, 20XX	March 4, 20XX
	Review Becker-Maurer Directory of Services for proper instructions for specimen collection and for accurate specimen requirements		April 15, 20XX	Discuss next quarter

Quality Manager, Georgene

For this metric, any specimen that is clotted, grossly hemolyzed, quantity not sufficient (QNS), or collected in the wrong tube is counted as inadequate. We have two other categories for rejected specimens, mislabeled and misidentified. You can see that the effort paid off. The percentage of inadequate specimens has dropped from 6% in the fourth quarter last year to 2% this quarter.

Metric	Target*	2 years prior				1 year prior				20XX
Pre-analytical		**1st**	**2nd**	**3rd**	**4th**	**1st**	**2nd**	**3rd**	**4th**	**1st**
Rejected specimens										
Inadequate (clotted, QNS, wrong tube)	<3%	4	5	6	2	3	4	5	6	2
Mislabeled	<1%	3	3	2	3	3	2	1	0.9	0.8
Mis-identified	0%	1	1.5	1.3	1	0.5	0.4	0.2	0	0
*Frequency: Monthly										



 **Support Services Manager, Joanne**	The Client Support Reps were a huge help in re-educating the clients. I reviewed our directory of services and found some gaps in the instructions we provide to our customers as well as some incorrect volume requirements. Some of the specimen requirements have changed due to changes in methodology. Here's a copy of a revised draft. (Joanne hands out copies of the draft to the group. After everyone has had a chance to review the changes, they agree to adopt the revision. Tim, the Administrative Director, says that he will put the new instructions in when the directory comes up for review in July.) **Action Item!**