

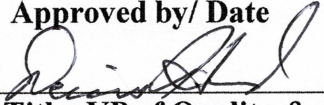
	Standard Operating Procedure	SOP Number D-121	Revision 0
	Management – Laboratory	Effective Date 11/29/21	Page 1 of 14
Written by/ Date  11/05/21	Reviewed by/ Date  11/05/21	Approved by/ Date  11-05-21	
Title: QC Laboratory Director	Title: Analytical Development Manager	Title: VP of Quality & Regulatory Affairs	

1.0 Objective and Purpose

The objective of the Management process is to ensure the continuing suitability, adequacy, and effectiveness of the laboratory management system (LMS) in meeting objectives and in meeting the requirements of ISO 17025, the assessment of opportunities for improvement, and to review and set new policies and objectives as appropriate. Another objective of the Management process is to ensure that actions are taken to correct problems, to avoid potential problems, and to improve efficiencies and service to the customer, LMS processes, and the LMS as a whole.

The purpose of this procedure is to describe how policies and objectives are established for LMS processes, and for the system of processes in place at Ion Labs. This procedure describes how performance against established objectives is measured or monitored, both as such information becomes available and on a periodic basis, and how management reviews and analyzes the outputs of such measuring and monitoring activities. This procedure describes how management reacts to analysis by making decisions and initiating actions to continually improve test services, LMS processes, as well as the LMS as a whole, including the policy and objectives themselves. This procedure also describes how any identified resource requirements are addressed, and how performance information is communicated internally.

2.0 Scope

This procedure is applicable to management of at Ion Labs, Inc laboratory activities.

3.0 Responsibility

- 3.1 This procedure applies to Management who are responsible for establishing and reviewing quality objectives and performance metrics, for analyzing performance against those metrics, and for making decisions and taking actions to correct problems, prevent potential problems, and to improve the LMS processes and resulting services under the ISO 17025 scope of accreditation. Responsibilities of Management are performed by the following members of Ion Labs staff: Lab Management.
- 3.2 This procedure also applies to personnel who are invitees to management review meetings, and those who are responsible for providing information and/or data for analysis.
- 3.3 Laboratory Management is responsible for being the point of contact for the accreditation

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agency and arranging activities such as internal audits and management reviews. Laboratory Management is responsible for reporting LMS performance information and the need to improve the LMS to other members of Management.

- 3.4 Laboratory Management is responsible for implementing, maintaining, and improving the LMS, and ensuring the effectiveness of laboratory activities.
- 3.5 All Ion Labs personnel are responsible for supporting procedures, for performing laboratory activities accurately, for identifying deviations from the LMS, and notifying management when deviations are detected so correction and corrective action may be initiated. All Ion Labs personnel are authorized to initiate actions to prevent or minimize such deviations.
- 3.6 Laboratory Management is responsible for ensuring that this procedure is accurate, understood and implemented effectively. This procedure may not be changed without the authorization of Laboratory Management.

4.0 Definitions

- 4.1 **Objective** – Result to be achieved
- 4.2 **Impartiality** – the presence of objectivity. This means that the outcome or result of an activity is not compromised by a situation or action of a person.
- 4.3 **Confidentiality**- the protection of information to ensure that data is accessible only to authorized personnel and is not made available or disclosed to unauthorized individuals, entities, or processes.

5.0 References

- 5.1 C-502, SOP, Record Storage, Retention, and Destruction
- 5.2 LMS Planning Tools, see Attachments for examples
- 5.3 D-121-F1, Form, Management Review Meeting Minutes
- 5.4 QS-108, SOP, Corrective and Preventative Action procedure
- 5.5 A-113, SOP, Training procedure

6.0 General

- 6.1 Evidence of Management’s commitment to the development and implementation of the management system and continually improving its effectiveness is demonstrated through

Management's involvement in decisions and actions related to the following:

- Establishing policies for the Lab's expectations and performance,
- Establishing objectives,
- Promoting the use of the processes described in LMS procedures,
- Providing resources (personnel, facilities, equipment, systems, and support services) to implement, manage, perform, and improve LMS processes and laboratory activities,
- Establishing methods of monitoring and measuring processes to achieve objectives,
- Participating in management review,
- Communicating the effectiveness of the LMS to staff members,
- Communicating the importance of meeting customer and other requirements to staff members, and the importance of conformance to ISO 17025 requirements,
- Taking steps to ensure impartiality and demonstrating commitment to impartiality by identifying and addressing risks to impartiality,
- Identifying opportunities to improve LMS processes and providing resources to implement improvements.

6.2 LMS Planning Tools are the control used to identify and monitor various aspects of our organization that are necessary to optimize the performance of the LMS and thereby ensuring optimal service to the customers. LMS Planning Tools consists of at least the following worksheets: Objectives, and Risks and Opportunities.

6.3 Any resource requirements relating to the operation or improvement of the LMS or its processes, are purchased per the Purchasing and Receiving procedure. Any human resource needs (including staffing level adjustments and/or training) are managed in accordance with SOP A-113 Training Procedure.

6.4 Laboratory Management, irrespective of other responsibilities, has the authority and resources needed to carry out duties including:

- a) implementation, maintenance, and improvement of the LMS,
 - i. This is done through planning the Lab's operations, ensuring the established processes are followed, maintaining the documentation that defines the processes, and identifying and implementing improvements to the infrastructure, processes, etc.
- b) identification of deviations from the LMS or from the procedures for performing laboratory activities,

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- i. This is done through recording the deviations, justifying the deviation, and authorizing the actions taken. This is documented in the Test reports.
 - c) initiation of actions to prevent or minimize such deviations,
 - i. This is done through taking corrective actions in accordance with the QS-108 Corrective and Preventative Action procedure.
 - d) reporting to laboratory management on the performance of the LMS and any need for improvement,
 - i. This is done as the need arises and actions are taken as necessary. This is also completed during the Management Review Meeting (see below).
 - e) ensuring the effectiveness of the Lab’s activities.
 - i. This done through monitoring daily activities and taking appropriate action as required when necessary.
- 6.5 Management designates a back-up to Laboratory Management to carry out his/her duties in case of his/her absence from the Laboratory.

7.0 Process Inputs

- 7.1 Inputs to the Management process include, but are not limited to:
 - Service and process performance information
 - Inputs for management review meetings and scheduled meetings
 - Resource needs

8.0 Process Activities

- 8.1 Policies, Objectives, Performance Analysis, and Improvement
 - 8.1.1 Management defines policies and objectives and ensures the objectives are measurable and are aligned with the established policies as appropriate. The policies and objectives address the competence, impartiality, and consistent operation of the laboratory. Performance against these objectives is monitored, measured, analyzed, and reacted to accordingly. Objectives are documented on the Metrics worksheet of the LMS Planning Tool.
 - 8.1.2 Management may also establish measurable objectives (e.g., goals or targets) for LMS processes (or functional levels) in support of the company objectives, where suitable and applicable. Suitable measurements are meaningful and add value to process effectiveness and

efficiency.

- 8.1.3 Data from quality assurance activities are included in objectives to measure competence and are analyzed and used to improve laboratory activities. If the results of this data analysis are found to not meet requirements, appropriate action is taken to prevent incorrect test results from being reported. Evidence of analysis and actions to improve laboratory activities will be documented in Management Review Meeting Minutes or corrective action records as appropriate.
- 8.1.4 Feedback from customers is received as described in the Sales procedure. The contents and nature of customer feedback will be as it is received for immediate response to the customer and will be analyzed during management review. The data analysis will be used as the basis for improving the LMS, laboratory activities, and customer service. Actions taken as a result of analyzing customer feedback will be documented in Management Review Meeting Minutes.
- 8.1.5 Opportunities to improve laboratory activities and the LMS are identified and selected based on the activities listed below. Depending on the source of the improvement opportunity and the actions required to implement improvements, records associated with specific improvements may be documented in corrective actions, Management Review Meeting Minutes, updated objectives, or changes to documented LMS procedures.
- Evaluation of performance data presented during management review,
 - Review of performance against objectives and the quality policy,
 - Feedback (both positive and negative) received from customers,
 - Determination and review of risks and opportunities,
 - Review of findings presented during internal audits or assessments from external bodies,
 - Evaluation of the results of corrective actions,
 - Suggestions from staff members who participate in the LMS,
 - Results of quality assurance activities,
 - Proficiency testing results.

8.2 Monitoring and Measurement of Processes

- 8.2.1 All LMS processes (and the LMS as a whole), are monitored by internal audits to assess their continuing suitability and effectiveness in meeting their respective objectives, as well as their effectiveness in meeting the requirements of ISO 17025. See the H-101 Internal Audits procedure.
- 8.2.2 Management is responsible for establishing any suitable measurable objectives for processes as deemed necessary. Where such objectives exist, they will be reviewed during management reviews and monitored/measured, reported, analyzed, and acted upon accordingly (see below). Reported performance information from personnel will also be reviewed to determine process adequacy.

8.3 Impartiality

- 8.3.1 Management ensures actions are taken to safeguard impartiality. Actions include training activities, reviewing orders, reviewing reports and results as necessary, and reinforcing impartiality when deemed necessary. Training involves all Ion Labs personnel interfacing with the Laboratory and focuses on the need to ensure test results are not swayed in any way. The structure and management of laboratory activities are established and implemented in LMS procedures to ensure impartiality is always practiced. Potential compromises to impartiality may include commercial, financial, relationships to other organizations, relationships of Ion Labs staff, or other pressures. Management will be responsible for taking action to prevent pressures from compromising impartiality.
- 8.3.2 Risks to impartiality will be identified and documented on the Risks and Opportunities worksheet of the LMS Planning Tool. Risks to impartiality will be reviewed during management review. If changes to known risks or additional risks are identified prior to planned management review activities, Management will add to or revise the identified risks.
- 8.3.3 Complaint investigations will determine if impartiality contributed to the Lab's performance that instigated the complaint. Management will take appropriate action immediately if it is determined that impartiality caused a complaint or an inaccurate test result. Feedback information will also be reviewed during the management review to assess incidents that occurred during the review period.
- 8.3.4 Actions to eliminate or minimize risks to impartiality will be documented on the Risks and Opportunities worksheet of the LMS Planning Tool. As necessary, a corrective action will be completed per the QS-108 Corrective and Preventative Action procedure.

8.4 Risks and Opportunities

- 8.4.1 Management determines risks and opportunities associated with laboratory

activities that need to be addressed in order to give assurance that the LMS can achieve its intended results, enhance opportunities to achieve the purpose and objectives of Ion Labs, prevent or reduce undesired impacts and potential failures in laboratory activities, and achieve improvement.

- 8.4.2 Opportunities (situations favorable for achieving an intended result) may arise through various means including, but not limited to, requests for new services, ideas for new services generated during research activities, new technologies, new practices, new partnerships, changes to infrastructure, an effect of addressing risks, LMS changes, etc.
- 8.4.3 Risks and Opportunities are documented on the Risks and Opportunities worksheet in the LMS Planning Tool.
- 8.4.4 Management determines and plans actions to reduce or mitigate risks and works toward pursuing opportunities proportional to the potential impact on the validity of laboratory results. Actions to address risks and opportunities, including plans for integrating and implementing actions into the LMS are documented on the Risks and Opportunities worksheet of the LMS Planning Tool.
- 8.4.5 The risks that have been determined and the actions taken to address the risks are evaluated during management reviews. A record of the review is documented in the Management Review Meeting Minutes. The Risk and Opportunities worksheet of the LMS Planning Tool is updated as necessary when new risks and opportunities are identified or when changes are made to existing actions that address current risks.
- 8.4.6 The Risk and Opportunities worksheet is updated as necessary when new opportunities are identified, as opportunities are fulfilled or deemed no longer active, or when other existing information is no longer current.

8.5 Management Review

- 8.5.1 Management reviews the performance of the LMS on an annual basis at minimum to ensure its continuing suitability, adequacy, and effectiveness in meeting the requirements of Ion Labs stated policies, objectives, and conformity with ISO 17025. Management review meetings will be conducted according to the agenda in the Management Review Meeting Minutes form D-121-F1, which identifies the inputs for review and analysis and serves as a record of the results. Additional personnel may be invited to attend and provide input as deemed appropriate by Management. Attendees will be recorded on the agenda/minutes. The meeting may be held in one session or may occur over several meetings at the Management's discretion.
- 8.5.2 In preparation for the meeting, responsible personnel generate any reports and collect and/or summarize information required by the agenda in the Management

Review Meeting Minutes form.

8.5.3 During management review meetings, management reviews each agenda item. For each item, consideration will be given to events occurring since the previous review, any changes in the organization or in the market, as well as current performance levels relative to any established objectives. Notes regarding information presented and issues considered/discussed will be recorded in the minutes. Though items may be added to or removed from the agenda at the discretion of management, the agenda items will include at least the following:

- Status of actions from previous management reviews,
- Fulfillment of objectives,
- Suitability of policies and procedures,
- Changes in internal and external issues that are relevant to the Lab,
- Customer communications and feedback including complaints,
- Ion Labs personnel feedback regarding the LMS and performance in their areas,
- Results of quality assurance activities (validity of results) including proficiency testing,
- Results of monitoring activities and training,
- Performance of external providers (suppliers, vendors),
- Results of recent audits including internal audits and assessments by external bodies,
- Status of corrective actions,
- Effectiveness of implemented improvements,
- Changes in the volume and type of work or in the range of laboratory activities,
- Results of risk identification (including risks to impartiality),
- Adequacy of resources (human, infrastructure, facilities),
- Resource needs,
- Recommendations for improvement,
- LMS performance, adequacy, suitability, and effectiveness,
- Any need for change,

- Date of next meeting.
- 8.5.4 Outputs of management review will be recorded and will include decisions and actions to improve processes and services relative to customer and Ion Labs' requirements. Management review outputs will include the following decisions and actions at a minimum:
- Improvements to the effectiveness of the management systems and its processes,
 - Improvement of laboratory activities related to the fulfilment of the requirements of ISO 17025,
 - Changes or additions to resources required to perform laboratory activities,
 - Any other changes necessary to support the LMS.
- 8.5.5 Decided action items will be recorded in the Management Review Meeting Minutes form. Persons responsible for completing such actions will be recorded, and target dates for completion will be determined and recorded. Where appropriate, a corrective action will be initiated to implement actions and to track completion and effectiveness in accordance with the QS-108 Corrective and Preventative Action procedure.
- 8.5.6 Where changes to the LMS will be implemented as an output of management review, management will ensure that such changes occur in a controlled manner to maintain the integrity of the LMS, and that process effectiveness and test services will not be compromised during or after the change. Such planning will include considerations appearing in the Changes to the LMS and Planning section of the Management Review Meeting Minutes form.
- 8.5.7 New objectives and changes to the laboratory policies may result as performance levels and/or service quality improves. Management will ensure changes to the policy and/or objectives will be documented and implemented under controlled conditions.
- 8.5.8 The agenda, when complete, serves as the record of management review and is retained according to the SOP C-502 Record Storage, Retention, and Destruction.
- 8.5.9 Upon completion of management review activities, resulting performance information is summarized and reported to employees, as appropriate. Such information may be presented in meetings, on an individual basis, and/or it may be posted in conspicuous locations in the facility.

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8.6 Resources

8.6.1 Management ensures the personnel, facilities, equipment, systems, and support services necessary to manage the LMS and the test services provided are available. Resources are identified and allocated as described in LMS procedures and monitored through the management review process.

8.6.2 Management ensures personnel with responsibilities for managing the LMS have the authority and resources necessary to carry out their duties. Formal identification of authority is described in the process procedures where the decision-making and responsibilities occur. Training requirements for authorities and responsibilities is described in the A-113 Training procedure.

8.6.3 Any resource requirements which will be provided by external sources relating to the operation or improvement of the LMS or its processes, including those needed to meet customer requirements for the test services provided, will be arranged by Management according to the Purchasing and Receiving procedure. Any identified staff training needs will be provided as described in the A-113 Training procedure.

8.7 Record Management

8.7.1 Records are maintained per SOP C-502 Record Storage, Retention, and Destruction.

8.8 Process Outputs

8.8.1 Outputs from the Management process include, but are not limited to:

- completed, and updated as needed, LMS Planning Tool,
- decisions and actions to improve LMS processes and the LMS as a whole,
- improvements to service,
- identification of resource needs,
- records of completed management reviews

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	11/04/21	New.	N/A	J. Sassman

9.0 Attachments

- 9.1 Attachment 1 – LMS Planning Tool
- 9.2 Attachment 2 – LMS Planning Tool Objectives
- 9.3 Attachment 3 – LMS Risks and Opportunities

Attachment 1 – LMS Planning Tool

Process / Objectives	Measurement	Data Source	Unit of Measure	Reporting Frequency	Person Responsible	Goal / Target	Notes
Overall QMS Objectives On-Time Delivery	# of orders delivered on time# of orders		%	Monthly		> 98% On Time	
Customer Satisfaction							
Repeat Sales (Returning Customers) Complaints	Repeat orders from customer # of Complaints/# of Orders	QuickBooks Customer Feedback Log	% %	Monthly Monthly		60% of customers < 8%	
Testing Services							
Number of Tests completed	# of tests performed		Quantity	Monthly		300 tests	
Calibration and Equipment Control							
Personnel, Training, and Competence							
Quality Performance	Performance Evaluations	Human Resources	Performance Rating	Annually			
Purchasing							
Sample Receiving							
Completion of Test Request Accurately	# of Correct forms# of Forms completed	Test Requests	%	Monthly		> 95%	
Quality Control Activities							
QC Forms: Confirm calculations are correct, sample names match with Test Requests	# of forms correct# of forms reviewed	Test Forms	%	Monthly		> 98%	
Impartiality							
Customer names/sample names are unknown until final reviews of Test Reports	# of customers known prior to Test Reports		#	Monthly		< 1%	

Attachment 2 – LMS Planning Tool Objectives

A	B	C	D	E	F	G	H
Process / Objectives	Measurement	Data Source	Unit of Measure	Reporting Frequency	Person Responsible	Goal / Target	Notes
1 Overall QMS Objectives							
2 On-Time Delivery	# of orders delivered on time/# of orders		%	Monthly		>98% On Time	
3							
4							
5							
6 Customer Satisfaction							
7 Repeat Sales (Returning Customers)	Repeat orders from customer	QuickBooks	%	Monthly		80% of customers	
8 Complaints	# of Complaints/# of Orders	Customer Feedback Log	%	Monthly		< 8%	
9							
10							
11 Testing Services							
12 Number of Tests completed	# of tests performed		Quantity	Monthly		300 tests	
13							
14							
15							
16							
17							
18							
19 Calibration and Equipment Control							
20							
21							
22 Personnel, Training, and Competence							
23 Quality Performance	Performance Evaluations	Human Resources	Performance Rating	Annually			
24							
25 Purchasing							
26							
27							
28							
29							
30 Sample Receiving	Completion of Test Request Accurately						
31	# of Correct forms/# of Forms completed	Test Requests	%	Monthly		>95%	
32							
33 Quality Control Activities							
34 QC Forms: Confirm calculations are correct, sample names match with Test Requests	# of forms correct/# of forms reviewed	Test Forms	%	Monthly		>98%	
35							
36							
37 Impartiality	Customer names/sample names are unknown until final reviews of Test Reports		#	Monthly		<1%	
38							

Attachment 2 – LMS Risks and Opportunities

	A	B	C	D	E	F
	Process and Risk/Opportunity	Risk or Opportunity?	Additional Description (if necessary)	Actions to Address	Method of Evaluating Effectiveness	Status
1	Overall QMS Risks/Opportunities					
2	Achieving ISO 17025 registration	Opportunity		Implement processes and controls	Receiving certification and accreditation of tests	In Progress
3						
4						
5						
6						
7	Impartiality					
8	Customers/sample names are unknown to lab analysts or technicians	Risk		Meeting with all employees on importance of impartiality	Verifying that no customer names are known in lab. Three Spot Checks- once per month for 3 months	Effective
9						
10						
11						
12	Customer Relationships					
13						
14						
15						
16						
17	Calibration and Equipment Control					
18						
19						
20						
21	Personnel, Training, and Competence					
22						
23						
24						
25						
26	Purchasing and Receiving					
27	Sole Source Providers					
28						
29						
30						
31	Testing					
32						
33						
34						
35	Test Method Development and Validation					
36						
37						
38						
39	Measurement Uncertainty					
40						
41						
42						
43	Quality Control Activities					
44						
45						
46						
47	Nonconformity and Corrective Action					
48						
49						
50						

Meeting Date(s):

Meeting Attendees:

Agenda

- Status of Actions from Previous Meetings
 - Open action items
- Management
 - Suitability and monitoring of policies, objectives, and procedures, internal communications, internal and external issues, risks and opportunities, changes and LMS planning
- Sales
 - Process Effectiveness – customer and personnel feedback and complaints
- Purchasing and Receiving
 - Process Effectiveness - supplier performance
- Test Items
 - Test items, sample and retains preparation, and identification as well as environmental monitoring
- Laboratory Operations
 - Process Effectiveness –nonconforming work, quality control activities, measurement uncertainty, test method validations, software validations
- Calibration and Equipment Control
 - Equipment adequacy
- Resources and Training
 - Changes in the volume or type of work, infrastructure, environment, staffing levels, training needs
- Audits and Assessments
 - Internal audit results and plan, accreditation assessment results
- Corrective Actions
 - Status of open actions, timeliness
- Improvements
 - Improvements completed and effectiveness, improvements planned
- LMS Adequacy, Suitability and Effectiveness
 - Overall assessment of the LMS
- Date of Next Meeting



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MANAGEMENT

Inputs: policies and objectives, internal communications, suitability of policies and procedures, risks and opportunities and risk mitigation effectiveness, changes and LMS planning

Suitability of Policies and Procedures

Is the Lab's policy for competence of personnel suitable adequate and still appropriate?
If not, describe necessary changes.

Is the Lab's policy for confidentiality and impartiality suitable and adequate?
If not, describe changes.

Is the Lab's policy for consistent operation of the Lab suitable and adequate?
If not, describe necessary changes.

State how policies are known and followed.

Is it necessary to change any policies? If yes, describe plan.

State how procedures are known and followed.

Do procedures accurately describe current practices and conform to ISO 17025 requirements?

Is it necessary to change any procedures? If yes, describe plan.

Fulfillment of Objectives (review the Objectives worksheet in the LMS Planning Tool)

<i>Measurable Objective:</i>	<i>Current Level</i>	<i>Goal</i>	<i>Positive or Negative Trend?</i>

Other Objectives (non-measurable) ***Fulfillment Status***

Where objectives are not being achieved, describe necessary plans or corrective actions:

Internal Communications

Describe methods used for internal communications.

Are performance results communicated adequately? If not, describe necessary actions.

Are the current methods adequate? If not, describe necessary actions.

External and Internal Issues (review the Issues section of the LMS Overview worksheet in the LMS Planning Tool)

Are there any known external issues that could impact the company? (e.g., competition, technology, etc.)

Are there any internal issues that could impact the LMS? (e.g., changes in staffing levels, facility, equipment, layout moves, etc.)

Risks (review the Risks and Opportunities worksheet in the LMS Planning Tool)

Review the identified risks and determine if they are current. Indicate new risks or those that have changed since the last review.
Verify the worksheet is updated.

Review the actions taken to address risks. Have the actions been effective? If not, describe necessary changes.

Opportunities (review the Risks and Opportunities worksheet in the LMS Planning Tool)

Review the identified opportunities and determine if they are current. Indicate new opportunities or those that have changed since the last review. Verify the worksheet is updated.

If the opportunities have been pursued, were the actions taken effective at improving the LMS and/or the overall performance of the Lab? If not, describe necessary changes.

LMS changes and planning

List potential changes to the LMS and the necessary planning to implement them (include revisions to ISO 17025, internal issues, external issues, or other influences):

Determine how the integrity of the LMS will be maintained during such changing circumstances.

What roles, responsibilities and/or authorities will require changes?

What resources will need to be applied?

What additional training is required?

Other comments, suggestions:



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SALES PROCESS

Inputs: Process effectiveness, customer and personnel feedback including complaints

Sales process effectiveness

Describe the planned results for the Sales process.	
Describe whether or not the process is achieving planned results (reports from Managerial personnel)	
If not, what actions are being taken or are necessary?	
How has the process improved?	
Other comments, suggestions:	

Customer and personnel complaints and feedback (review Customer Feedback Log)

What complaints have been received? (summarize and list)	
Are corrective actions necessary or initiated?	
Have we received positive feedback? (summarize and list)	
What is the overall perception internal customers have of the Lab and its performance?	



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PURCHASING and RECEIVING PROCESS

Inputs: Process monitoring and measurements, outputs, supplier performance and incidents

Purchased Services and Supplies process effectiveness

Describe the planned results for the Purchasing process.

Describe whether or not the process is achieving planned results (reports from Managerial personnel).

If not, what actions are being taken or are necessary?

How has the process improved?

Other comments, suggestions:

Review information regarding supplier and vendor (external provider) performance

List suppliers (including service providers, subcontractors, technicians, laboratories) with inadequate performance and describe issue(s):

Should the status of any suppliers or vendors change as the result of their performance analysis?

Verify the accreditation status of any suppliers or service providers who are required to maintain their accreditation to ISO 17025 (or ISO 17034 if appropriate) is current. Identify those who are not current and the plan to ensure they are current or obtain an alternate source.

List any other actions that should be taken to ensure proper supplier and vendor performance.

Receiving process effectiveness

Describe the planned results for the Receiving process.

Describe whether or not the process is achieving planned results (reports from Managerial personnel).

If not, what actions are being taken or are necessary?

How has the process improved?



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Other comments, suggestions:

HANDLING OF TEST ITEMS

Inputs: test items, sample preparation and retains adequately identified and controlled

Samples process effectiveness

Are test items samples properly prepared and labeled?

Are storage and identification requirements for test items and retains adequate?

Are storage requirements for test items and retains properly monitored?

Other comments, suggestions:

LABORATORY OPERATIONS PROCESS

Inputs: Process monitoring and measurements, outputs, quality control activities, inter-laboratory comparisons or proficiency testing, measurement uncertainty budgets, test method validations, software validations

Laboratory Operations process effectiveness

Describe the planned results for the Laboratory Operations process.

Describe whether or not the process is achieving planned results (reports from Managerial personnel).

If not, what actions are being taken or are necessary?

How has the process improved?

Other comments, suggestions:

Nonconforming Work (review Lab Nonconformity Log)

Review Lab testing service nonconformities issued (trend data or specific incidents). Does the data indicate that competence or verification points and methods of verification/review are inadequate?

Is corrective action necessary? If not, why?

Is additional training or monitoring necessary? If yes, list.

Quality Control Activities (review Quality Control Activities Schedule and Results)

Describe the results of inter-laboratory comparisons or proficiency testing.

Review results and outcomes from other quality assurance activities. Describe whether or not the current activities are adequate to ensure valid results.

Does the data indicate that current methods or techniques are inadequate? If yes, describe necessary actions.

Does that data indicate that additional monitoring is necessary? If yes, describe plan.

Measurement Uncertainty

Are Measurement Uncertainty Budgets current for the tests performed and the measurement equipment used? If not, describe plan to update.

Test Method Validations

Have any changes occurred that would affect existing validations of test methods? If yes, describe plan.



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Have new lab-developed or non-standard test methods been introduced requiring test method validation? If yes, describe plan.

Software Validations

Have any changes occurred that would affect existing software validations? If yes, describe plan.

Has any new software been added that requires software validation? If yes, describe plan.

CALIBRATION AND EQUIPMENT CONTROL PROCESS

Inputs: equipment adequacy

Calibration process effectiveness

Is current calibration status of measurement and test equipment being maintained as required?

If not, what actions are being taken or are necessary?

Other comments, suggestions:

Equipment Maintenance process effectiveness

Is equipment being maintained in proper working order through required preventive maintenance activities?

If not, what actions are being taken or are necessary?



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RESOURCES AND TRAINING

Inputs: Changes in volume or type of work, Infrastructure, Environment, Staffing Levels, Training Needs

Changes in volume or type of work

Describe known changes in volume or type of work and the plans to address the changes.

Include when the change is expected.

Is the infrastructure adequate?

(Facilities, proper equipment, equipment capacity, layout, hardware, software, etc.)

List what infrastructure changes are needed:

Is the work environment adequate and adequately controlled?

(Temperature control, Humidity Control, lighting, etc.)

List what work environment changes are needed:

Are staffing levels / resources adequate to support the LMS and service to customers?

What processes and/or testing services are experiencing delays or problems due to lack of resources?

Are adequate controls in place for access into and use of the Lab areas which affect laboratory activities? If not, describe actions that will be taken to improve controls.

Are adequate controls in place to prevent contamination, interference, or adverse influences on laboratory activities? If not, describe actions that will be taken to improve controls.

Does the facility layout and physical configuration provide effective separation between areas with incompatible laboratory activities? If not, describe actions that will be taken to improve controls.

Training needs (list):

Comments, suggestions:



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CCR No. N/A

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AUDITS AND ASSESSMENTS

Inputs: Results of Internal Audits and plan, Accreditation Assessments

LMS Internal Audit results:

Necessary actions:

Plan for next LMS Internal Audit:

Technical Internal Audit results:

Necessary actions:

Accreditation Assessment results:

Necessary actions:

Comments, suggestions for all audit results:

CORRECTIVE ACTION STATUS

Inputs: Status of Open Actions, Timeliness

Open Actions (list CA Seq Ref # and discuss):

Timeliness of actions initiated:

Timeliness of implemented actions:

Plans for improving responsiveness (if necessary)

Comments, suggestions:



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IMPROVEMENTS

Inputs: Improvement activities and effectiveness

List of improvements implemented since the last review	State how each improvement identified at the left was effective (or not or still in progress):

List of planned improvements:

OVERALL LMS ADEQUACY AND SUITABILITY

Inputs: Information reviewed above

Conclusion regarding the current state/performance of the LMS:	
Does our LMS allow us to meet customer and ISO 17025 requirements as well as meet the needs of the business?	

Date of Next Meeting:	
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