

	Standard Operating Procedure	SOP Number D-120	Revision 1
	Laboratory Management Structure and Position Requirements	Effective Date 01/21/26	Page Page 1 of 5
Written by/ Date N. L. - 01/21/26	Reviewed by/ Date [Signature] 01/21/26	Approved by/ Date MSM 01-21-26	
Title: QA/QC	Title: QA/QC	Title: QA	

1.0 Purpose

This procedure establishes a process that ensures laboratory information regarding the relationships and interrelation of responsibilities performed by managerial, technical, and support personnel will be structured to perform and verify work affecting the results of the laboratory's activities.

2.0 Scope

This procedure applies to all laboratory personnel and laboratory managerial, technical, and support personnel.

3.0 Responsibility

3.1 It is the responsibility of Management to ensure laboratory information regarding the relationships and interrelation of responsibilities performed by managerial, technical, and support personnel will be structured to perform and verify work affecting the results of the laboratory's activities.

4.0 References

- 4.1 A-113, SOP, Training Procedure
- 4.2 A-117, SOP, Personnel Qualifications

5.0 Procedure

5.1 Management Structure and Position Requirements

5.1.1 Duties, responsibilities, authorities, required qualifications and education, technical knowledge, skill, training, and experience for functions that affect the consistency and quality of laboratory operations are identified in Job Descriptions and Training Records, reference SOP A-113 Training Procedure and SOP A-117 Personnel Qualifications.

5.1.2 The information below regarding the relationships and interrelation of

Standard Operating Procedure Laboratory Management Structure and Position Requirements	SOP No D-120	Rev 0	Page 2 of 5
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responsibilities performed by managerial, technical, and support laboratory personnel will be structured to perform and verify work affecting the results of the laboratory's activities.

- 5.1.3 The duties, responsibilities, and authorities associated with the information below, along with the roles, responsibilities and authorities described in the process procedures, is communicated to assigned personnel during orientation activities, on-the-job training, and during interactions between Management and supervisory staff during routine meetings and/or performance evaluations.
- 5.1.4 The organization and management structure of Ion Labs Laboratory is controlled by Ion Labs Organization chart. The positions listed are the personnel who manage, perform, and verify work affecting the results of the Lab's activities or support the Laboratory in some manner through their assigned work. Some of the specific responsibilities, authorities, and interrelationship of personnel is described below.
- 5.1.5 Director of Quality-General Duties, Responsibilities and Authority
- 5.1.5.1 The Director of Quality is responsible for the overall management of Ion Labs Laboratory. Their management responsibilities include supervision of staff as well as to provide oversight of testing, financial administration, and hiring.
- 5.1.5.2 The Director of Quality to ensure use of good laboratory practices, including maintaining client relationships.
- 5.1.5.3 The Director of Quality works with Sales personnel to oversee the management of customer satisfaction and customer requirements regarding the Laboratory.
- 5.1.5.4 The Director of Quality has responsibility for overseeing the quality, conformance, and effectiveness of the Laboratory Management System. The Director of Quality oversees laboratory activities and related results to identify deviations from the methods for performing tests, evaluates the significance of the deviations, and initiates actions to prevent or minimize any deviations of the laboratory management system or the methods for performing tests to ensure the laboratory achieves intended outcomes. The Director of Quality has primary responsibility for ensuring the effectiveness of laboratory activities.
- 5.1.5.5 The Director of Quality oversees all aspects of the laboratory

<p style="text-align: center;">Standard Operating Procedure Laboratory Management Structure and Position Requirements</p>	<p style="text-align: center;">SOP No D-120</p>	<p style="text-align: center;">Rev 0</p>	<p style="text-align: center;">Page 3 of 5</p>
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management system (LMS), including compliance with the requirements of ISO 17025. The Director of Quality is responsible for and has the authority for implementation, maintenance, identification of deviations and improvement of the LMS. The Director of Quality is also responsible for reporting to the President on the performance of the LMS and any need for improvements, including initiation of actions to prevent or minimize any deviations of the LMS or the procedures for performing laboratory activities.

5.1.5.6 The Director of Quality maintains the Laboratory System Management Manual and oversees and documents training of Ion Labs on the laboratory processes and procedures. This includes laboratory management system development, maintenance and integrity, and guarding impartiality in all tests.

5.1.5.7 The Director of Quality initiates and executes (or oversees) internal audits, monitors improvement actions and corrective actions, and supports external assessors of the Accreditation Body. The Director of Quality works to ensure continuous improvement of the LMS.

5.1.5.8 QC Lab Manager -General Duties, Responsibilities and Authority

5.1.5.9 The QC Lab Manager has responsibility for managing the daily operations of the Laboratory. The QC Lab Manager oversees laboratory activities and related results to identify deviations from the methods for performing tests, evaluates the significance of the deviations, and initiates actions to prevent or minimize any deviations of the laboratory management system or the methods for performing tests to ensure the laboratory achieves intended outcomes.

5.1.5.10 The QC Lab Manager is authorized to perform all laboratory activities, including but not limited to the development, modifications, verification, and validation of methods; analysis of results, including statements of conformity or opinions and interpretations; and report, review, and authorization of results. The QC Lab Manager is responsible for training Laboratory personnel, supervising Laboratory personnel and monitoring their competence.

5.1.5.11 The QC Lab Manager performs training of Ion Labs Laboratory personnel on Laboratory and test processes and procedures. This includes maintenance and integrity and guarding impartiality in all tests. The QC Lab Manager also works to ensure continuous

Standard Operating Procedure Laboratory Management Structure and Position Requirements	SOP No D-120	Rev 0	Page 4 of 5
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improvement of the Laboratory processes.

5.1.5.12 The QC Lab Manager is also responsible for reporting to the Director of Quality on the performance of the LMS and any need for improvements, including initiation of actions to prevent or minimize any deviations of the LMS or the procedures for performing laboratory activities.

5.1.6 QC Supervisor - General Duties, Responsibilities and Authority

5.1.6.1 The QC Supervisor is authorized to perform all laboratory activities, including but not limited to the development, modifications, verification, and validation of methods.

5.1.6.2 The QC Supervisor performs training of Ion Labs laboratory personnel on test methods, processes and procedures.

5.1.6.3 The QC Supervisor also works to ensure continuous improvement of the Laboratory processes.

5.1.6.4 The QC Supervisor provides input to the QC Lab Manager who oversees laboratory activities and related results to identify deviations from the methods for performing tests, evaluates the significance of the deviations, and initiates actions to prevent or minimize any deviations of the laboratory management system or the methods for performing tests to ensure the laboratory achieves intended outcomes.

5.1.6.5 The QC Supervisor is authorized to act as a backup for the QC Lab Manager with regards to maintaining and updating documents and records, objectively judging laboratory operations and their effectiveness in complying with the requirements of the LMS.

5.1.7 Laboratory Analysts -General Duties, Responsibilities and Authority

5.1.7.1 The Laboratory Analysts has responsibility for performing test activities, interacting with customers, and performing activities that support the Lab's operations such as receiving and verifying purchased items and performing maintenance on equipment.

5.1.7.2 The Laboratory Analysts is authorized to perform laboratory activities, including but not limited to analysis of results, including statements of conformity or opinions and interpretations, and report, review, and authorization of results.

<p style="text-align: center;">Standard Operating Procedure Laboratory Management Structure and Position Requirements</p>	<p style="text-align: center;">SOP No D-120</p>	<p style="text-align: center;">Rev 0</p>	<p style="text-align: center;">Page 5 of 5</p>
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- 5.1.7.3 The Laboratory Analysts is authorized to audit on the technical aspects of the Lab’s activities related to the accreditation and tests in general.
- 5.1.7.4 The Laboratory Analysts is authorized to identify deviations from the methods for performing tests, evaluates the significance of the deviations, and initiates actions to prevent or minimize any deviations of the laboratory management system or the methods for performing tests to ensure the laboratory achieves intended outcomes.
- 5.1.7.5 The Laboratory Analysts is authorized to make recommendations to the QC Lab Manager for updates and enhancements to the LMS and recommends approval of correction actions to the QC Lab Manager.

6.0 Revision History

Revision	Date	CCR #
0	10/30/21	N/A
1	01/21/26	CC-26-0026