ION LABS	Standard Operating Procedure **Sales - Laboratory Sample Submission**	**SOP Number** **D-119**	**Revision** **0**
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Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
11/04/21	11/04/21	11-04-21
Title: QC Laboratory Director	**Title: Quality Systems Manager**	**Title: VP of Quality & Regulatory Affairs**

1.0 Purpose

1.1 The objective of the Sales-Laboratory Sample Submission process is to ensure requirements of customers, regulatory authorities, and accreditation organizations are met. Another objective is to ensure information provided to customers regarding Ion Labs' capability and testing requirements are accurate and communicated clearly.

1.2 The purpose of this procedure is to describe the process requirements including responsibilities and controls for ensuring all test activities are completed per customer requests. This procedure describes the requirements for communicating the scope of accreditation to potential customers. This procedure also describes the process for collecting, reviewing, and responding to customer feedback.

2.0 Scope

2.1 This procedure is applicable to all ISO 17025 accredited test activities performed by Ion Labs.

3.0 Responsibility

3.1 Management is responsible for ensuring tests are performed as requested by customers. Management includes the Lab Director and Analytical Development Manager.

3.2 Management is responsible for reacting and responding to customer feedback regarding lab activities including complaints and notifications of suspected nonconforming test activities. Management is also responsible for determining the customers' level of satisfaction and their perception of Ion Lab's laboratory performance. When complaints are received, Management will be responsible for all decisions at all levels of the handling process for complaints in accordance with the QS-112 Core Quality Systems and Quality Events.

3.3 All personnel participating is Sales-Laboratory Sample Submission activities are responsible for ensuring that information communicated to customers or potential customers, correctly identifies the test services accredited to ISO 17025.

3.4 Sales personnel are responsible for communicating with customers to determine their requirements and ensuring they are documented on Ion Lab's quotes and Sales Orders.

The completed quote documents Ion Lab's understanding of customer's requirements.

3.5 The Sales Manager and Lab Director are responsible for ensuring that this procedure is accurate, understood and implemented effectively. No changes may be made to this procedure without the authorization of the Sales Manager and Lab Director.

4.0 Definition

4.1 **Customer** – A person or organization that could or does receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external to the organization.

4.1.1 Examples include but are not limited to customer, client, end-user, retailer, receiver of product or service from an internal process beneficiary and purchaser.

5.0 References

5.1 D-201, SOP, QC Laboratory Sample Log Book Recording

5.2 D-201-F1, Form, QC Laboratory Sample Log

5.3 C-502, SOP, Record Storage, Retention, and Destruction

5.4 QS-108, SOP, Corrective and Preventive Action

5.5 E-601, SOP, Vendor Qualification

5.6 D-117, SOP, Laboratory Purchasing and Receiving

5.7 D-103, SOP, Analytical Method Validation

6.0 Procedure

6.1 Inputs to the Sales-Laboratory Sample Submission process include, but are not limited to:

- Customer requests for test services,
- Test deviation requests,
- Accreditation policies,
- Customer feedback, including complaints.

6.2 General

6.2.1 Customers may be internal customers of Ion Labs and the same process applies.

6.2.2 If Ion Labs subcontracts testing, whether planned or due to unforeseen circumstances, this work is awarded to a competent subcontractor that is accredited to ISO 17025 for the required test. Customers are advised in writing of the proposed use of subcontractors, and written approval of the customers is required before proceeding with the tests. The written communications occur via email.

6.2.2.1 Ion Labs remains responsible to the customer for any subcontracted work, except in cases where the customer or regulatory authorities specify the use of subcontractors.

6.2.2.2 A list of approved subcontractors and the subcontracted work is maintained in accordance with the E-601 Vendor Qualification and D-117 Laboratory Purchasing and Receiving procedure.

6.2.3 Ion Labs utilizes laboratory-developed methods which modify established test methods to accommodate the purpose and intent of the published established test methods. Deviations to established test methods will be identified and documented as described in section 6.3.10 below. Test methods selected will be established methods published either in international, regional, or national standards, or by reputable technical organizations, in relevant scientific texts or journals, or by the original equipment manufacturer. Lab-developed methods will be based on published methods in accordance with the D-103 Analytical Method Validation.

6.2.4 Confidentiality

6.2.4.1 Ion Lab's legally enforceable responsibilities for the management of information obtained or created during the performance of test activities is documented within a Customers Purchase Order executed with each customer.

6.2.4.2 Ion Labs does not typically place information obtained or created during the performance of test activities into the public domain. In the event Ion Labs intends to place information into the public domain, affected customers will be notified in advance in writing of this intention, including details regarding the information to be disclosed, and the methods of disclosure. Information placed in the public domain will not violate the legally enforceable responsibilities documented in

Customers Purchase Order established with affected customers.

6.2.4.3 As documented on the Customers Purchase Order and the Sales Order, all information (including materials and results) will be considered proprietary information and will be regarded as confidential between the customer and Ion Labs. Where agreed by the customer and Ion Labs, customers may place information generated during test activities into the public domain within the limits established in the Purchase Order.

6.2.4.4 In the event Ion Labs is compelled to release information by court order, information will be provided as required. Unless prohibited by law or court order, the customer or individual concerned will be notified of the information provided in association with the release of information.

6.2.4.5 In the event external sources provide information regarding customers (for example, in the event of complaints or investigations overseen by regulators), this information will remain confidential between the customer and Ion Labs. The source of this information will be confidential to Ion Labs, and will not be disclosed to the customer, unless agreed by the source in writing.

6.2.4.6 Personnel acting on Ion Labs' behalf (including contractors, and other personnel of external bodies) will keep confidential all information obtained or created during the performance of laboratory activities, except where required by law to disclose such information. Communication of these requirements to affected parties will occur as described in E-601 Vendor Qualification and D-117 Laboratory Purchasing and Receiving procedure.

6.2.5 Decision Rule

6.2.5.1 The decision rule is the rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

6.2.5.2 As stated on the Customer's Purchase Order, the decision rule for the test's conformity or nonconformity does not consider the measurement uncertainty for the test activities performed. The decision is based on the actual results. The statement on the form serves as the communication to the customer.

6.2.5.3 However, if the customer requests another specification or standard, the decision rule will be selected and agreed to by the customer. The agreed upon decision rule will be noted on a revised or a new Customer

Purchase Order.

6.2.6 Accreditation References

6.2.6.1 Management will ensure the accreditation body's policy concerning their requirements when making reference to the accredited status will be strictly adhered to. ANAB Accreditation Requirement AR2201, "Control and Use of Accreditation Symbol provides detailed explanations of the requirements generalized below (see the policy located in the Documents of External Origin folder for all requirements). In general, as part of ensuring compliance to the policy, Management will ensure the following during communications with potential customers:

- Ion Labs may refer to its ANAB accreditation on test reports, on its website, in its general literature and promotional materials, and in business solicitations, under the following provisions:
    - Ion Labs may only use the accreditation symbol or reference to ANAB accreditation if the accreditation status is current and remains in good standing.
    - The accreditation symbol or reference to ANAB accreditation shall not be placed on products or items that Ion Labs has tested.
    - Ion Labs shall not use the accreditation symbol or refer the accreditation in any way that may be misleading or misrepresent the accreditation status.
    - Ion Labs shall ensure claims of accreditation are related only to activities within their scope of accreditation and not associated with other activities in which Ion Labs may be involved.
    - Ion Labs shall ensure that the use of the accreditation symbol or reference to the accreditation status is not affixed to a product (or part of it) or used in any way to imply that a product has been certified.
    - Ion Labs shall not use the accreditation symbol or refer to the accreditation in any manner that gives the impression that ANAB accepts responsibility for the results, or for any opinion

or interpretation derived from those results, or that ANAB approves of those results.

- It is Ion Labs' responsibility to use the accreditation symbol or any materials representing our accreditation in such a way as to enhance the reputation and value of accreditation for all stakeholders.
- The ANAB accreditation symbol always shall be used in its original, designed proportions and shall not be modified, distorted, compressed, or stretched in any way. It will not be sized in a way that renders it unreadable.
- Ion Labs will use the accreditation symbol as provided by ANAB, at Ion Labs discretion.
- Ion Labs shall not imply or mislead the scope of its accredited activities using certificates or reports, enclosures, stationery, or other materials. Ion Labs shall not lead any user of the results or interested party to believe that the work is covered by the scope of accreditation when it is not.

6.2.6.2 All records associated with this process, including accepted Customer Purchase Orders, communications regarding the customers' requirements, approved deviations, and feedback indicating customer satisfaction and responses are retained per SOP C-502 Record Storage, Retention, and Destruction.

6.3 Sales Order Establishment and Review

6.3.1 Laboratory activities will be performed based on documented quotes and purchase orders established with customers describing the tests to be performed and the services to be provided. Sales personnel may initiate quotes with customers. Lab personnel review and approve the quotes to ensure customer requirements have been adequately defined, documented, understood, and Ion Labs has the capability and resources to meet customer requirements. Special requirements beyond those documented in the quote may be documented in emails or other correspondence with the Sales personnel and/or Lab personnel and retained with the orders' records.

6.3.2 Requests for quotes will be reviewed to identify risks to impartiality. Management may be contacted prior to processing the request to determine if risks to impartiality potentially exist based on the customer or the service

requested. If no risks to impartiality are determined by Management, the request may be processed as described below, and the quote will document no risk to impartiality was determined. If a risk to impartiality exists, the Lab Director will take steps to address the risk and communicate with the customer as appropriate. Risks to impartiality may arise from Ion Labs' activities, from Ion Labs' relationships with other organizations, or from the relationships of Ion Labs' personnel. If ongoing actions will be required to address the risks, these actions will be documented on the Risks and Opportunities worksheet of the LMS Planning Tool.

6.3.3 Sales personnel will ensure the quote includes information regarding appropriate test service(s) to satisfy the customer's requirements. All tests will be performed using established test methods (Standard Test Procedures) relevant to the customers' needs and consistent with requirements specified by the customer. For ISO 17025 accredited tests, the quote must indicate if the customer wants the accredited test or not.

6.3.3.1 Accredited tests will provide the customer with all required information including the accreditation logo on the test report. Test Reports for unaccredited tests provide traceability to a national or international standard but may not disclose the measurement uncertainty and will not include the accreditation logo or any reference to the accreditation status of the Lab.

6.3.4 If the customer does not specify the established test method to be used, Lab personnel will review information regarding the customer's intended outcome for the requested tests and if the Lab can satisfy the customer's requirements, an appropriate test method will be selected within the scope of Ion Labs' tests. The Lab Director or Analytical Development Manager indicates the method selected by providing the information to Sales personnel to document it in the quote.

6.3.5 If at any time it is learned the method and/or laboratory activities requested by the customer are found to be inappropriate, out of date, or outside the capability of Ion Labs, the Lab Director or Analytical Development Manager will inform the customer of Ion Labs' capabilities and describe why the methods and/or laboratory activities requested cannot be satisfied. This includes requests for quotes indicating accreditation for tests that are not in Ion Labs' scope of accreditation.

6.3.6 As stated on the quote, the decision rule for the chosen test does not consider the measurement uncertainty of the test performed. The decision is based on the actual results. The statement on the form serves as the communication to the

customer. However, if the customer requests another specification or standard, the decision rule will be selected and agreed to by the customer. The agreed upon decision rule will be recorded on the quote and Test Report.

6.3.7 The Lab Director or Sales personnel will ensure any differences between the customer's requirements and Ion Labs' capabilities are resolved before the quote is sent to the customer and is accepted or before any laboratory activities commence. This will ensure the test activities will be acceptable to both the customer and Ion Labs.

6.3.8 While reviewing, evaluating, and approving quotes with customers, Ion Labs staff members will cooperate with customers (and their representatives as necessary) to clarify the customer's request and describe Ion Lab's capabilities.

6.3.9 Where the customer has specified performance monitoring of laboratory activities in relation to the work performed, Ion Labs will agree to the specified monitoring unless the monitoring activities will cause deviation from the established test method, pose a risk to personnel safety, or negatively affect the outcome of laboratory activities.

6.3.10 If laboratory activities deviate from the accepted test method, customer requirements, and/or the Sales Order, details regarding the deviation will be documented on the test paperwork and the Test Report. The test paperwork will document the deviated requirement, provide a technical justification for the deviation, include a record of authorization for the deviation from Ion Labs' Management, and include evidence of acceptance of the deviation by the customer. The Lab Director will evaluate deviations requested by the customer to ensure they will not impact the integrity of the laboratory or the validity of the results. The customer will be informed of the decision.

6.3.11 Approval of Customer's Purchase Orders will be indicated by the creation of the Sales Order. The Quote and the Customer's Purchase Orders will be retained as records of the requirements review and Ion Lab's capability of satisfying the customer requirements.

6.3.12 If pertinent discussions (determined at the discretion of the Lab personnel based on impact of test results or service delivery) were held relating to the customer's requirements or the results of the laboratory activities, records of these discussions will be retained Sales Order.

6.3.13 If the customer amends their Purchase Order or notifies the Lab for an amendment after test activities have started, the process described above will be repeated to ensure the change can be accommodated and all affected personnel have been

notified.

6.4 Customer Feedback and Complaints

6.4.1 Management will seek feedback from customers, both positive and negative, through information gathered during direct personal contact with customers (including but not limited to in-person meetings, emails, and participation in industry events). Customer feedback will be recorded on the Customer Feedback Log as evidence of analyzing and using feedback to improve the management system, laboratory activities, and customer service.

6.4.2 When the feedback received is determined to be a lab or testing complaint regarding the performance or outcomes of laboratory activities, the QS-112 Core Quality Systems and Quality Events process will be used.

6.4.3 Customer feedback which will be analyzed and used for improvement will be based upon performance factors including (but not limited to) quality, timeliness of reported results, and accuracy and clarity of results.

6.4.4 Information regarding customer feedback will be submitted to Management during management review (see the Management procedure). Management will also review customer feedback as it becomes available and will react appropriately according to the information received, initiating corrective actions as appropriate as described in the QS-108 Corrective and Preventive Action.

6.5 Record Management

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

6.6 Process Outputs

6.6.1 Outputs to the Sales -Laboratory Sample Submission process include, but are not limited to:

- Accepted orders for test services,
- Approved deviations,
- Positive and negative feedback received from customers and follow-up actions, including corrective actions where necessary.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/19/21	New	N/A	J. Sassman