ION LABS QUALITY FIRST	Standard Operating Procedure **Laboratory Purchases and Receiving**	**SOP Number** **D-117**	**Revision** **0**
		Effective Date 11/02/21	**Page** **Page 1 of 7**
Written by/ Date 10/06/21	**Reviewed by/ Date** 10/06/21	**Approved by/ Date** 10-11-21	
Title: QC Laboratory Director	**Title: Analytical Development Manager**	**Title: VP of Quality & Regulatory Affairs**	

1.0 Purpose

The objectives of the Purchasing process are to ensure that purchased products and services are provided in accordance with specifications and/or requirements. This will ensure that needed items arrive in a timely manner, without quality problems, and at the best possible cost and that outsourced services are provided as necessary. The objective of the General Receiving process is to verify that purchased items are verified to meet the requirements as stated on the Purchasing documents prior to use and purchased services satisfy Ion Lab's requirements.

2.0 Scope

This procedure applies to purchased products and services that affect the quality of Ion Labs services and processes, and to suppliers and subcontractors providing products and services affecting the service quality.

3.0 Responsibility

3.1 This procedure is applicable to QC Laboratory Management or Analytical Development Management, who performs procurement activities and the evaluation and approval of suppliers and service providers.

3.2 This procedure applies to the receipt of purchased items delivered to the Ion Labs.

3.3 It is the responsibility of QC Laboratory management and personnel to verify incoming goods against the purchasing requirements prior to making them available for use.

3.4 It is the responsibility of QC Laboratory Management to manage incorrect receipts and communicate any issues to suppliers and service providers.

3.5 QC Laboratory Management is responsible for ensuring that this procedure is accurate, understood, and implemented effectively. No changes may be made to this procedure without the authorization of QC Laboratory Management.

4.0 Definitions

4.1 **Supplier** – For the purpose of this procedure, the term "supplier" includes any external providers such as supplier, vendor, subcontractor, technical specialist or laboratory.

4.2 **Purchase Order-** For the purpose of this procedure, "purchase order" includes any document or method used to procure a product or service, including email communications, on-line orders, direct credit card purchases, purchases at retail outlets, or completed Purchase Orders.

4.3 **CoC** – Certificate of Conformance

4.4 **CoA** – Certificate of Analysis

5.0 References

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

5.2 E-601, SOP, Vendor Qualification

5.3 D-202, SOP, Outsourced Testing Procedure

5.4 QS-108, SOP, Corrective and Preventative Action

6.0 Procedure

6.1 Process Inputs

6.1.1 Inputs to the Purchasing and Receiving process include, but are not limited to:

- Information for Lab supplies and purchasing needs required to conduct and improve operations including outsourced calibration services, proficiency testing, consulting, etc.
- Records of placed purchases, incoming purchased products (Lab supplies and consumables) and their accompanying packing lists (or equivalents) and any supporting documentation (e.g., certifications).

6.2 Identification of Need

6.2.1 Test Methods and Equipment Manuals identify the items, equipment, and consumables (products) that are required for the testing. The Approved Vendor List identifies the supplier or vendor used.

6.2.2 Lab Management or Analytical Development Manager identifies the need to procure calibration services or equipment for performing testing. Communication to Calibration Service Suppliers will include the requirement for calibration to traceable to national or international measurement standards. (NIST)

6.2.3 Management identifies the need to procure services such as consultants, contract

auditors to perform internal audits, and other services necessary to support the quality management system and accredited testing requirements.

6.2.4 Infrastructure and work environment procurement needs, supporting services, and utilities are identified and provided by top management.

6.2.5 Any Lab employee may identify the need to purchase goods and services to support, operate, or improve processes affecting quality.

6.2.6 The employee who has identified the need for a purchase of goods or services contacts Lab Management or the Analytical Development Manager if a purchase order will be required to complete the purchase. The employee will define the requirements for the purchase and communicates to Lab Management or the Analytical Development Manager (verbally or via a documented method such as an email) a description of the needed goods and/or services and their quantities, due dates, and other applicable information required for the Lab to receive goods and/or services meeting the lab's requirements. The employee requesting the goods and/or service will be responsible for ensuring the technical content is accurate.

6.2.7 Lab Management or the Analytical Development Manager will review the information provided to ensure it is sufficient and that purchasing generates a purchase order based on the information provided.

6.2.7.1 Approval of the lab's requirements for the goods and/or services purchased will be indicated by the generation of the purchase order.

6.2.7.2 The purchase order will be sent to the Supplier to communicate the purchase requirements.

6.2.7.3 The purchase order will be the record of the purchase made, the defined requirements and the review and approval of the lab's requirements for the purchase.

6.2.7.4 Subcontracted work for accredited testing is only placed with competent laboratories. Competent laboratories can demonstrate compliance with ISO 17025 requirements for the work provided. If accredited testing is outsourced, Lab Management advises the customer of the arrangement in writing (i.e., via email), and when appropriate, gains the approval of the customer (preferably in writing as well).

6.2.7.5 Test Reports resulting from outsourced servicing are received and verified before being released to the customer. Verification includes confirmation

that supplied reports demonstrate conformity to specified requirement.

6.2.8 Where the employee will select goods and/or services using websites, catalogs, or selection of in-stock items at a retail establishment, the employee will review the information available for the required goods and/or services, compare the information available to the established requirements, select the goods and/or services which satisfy the defined requirements, and complete the purchase using a credit card.

6.2.8.1 In these cases, no additional communication of requirements will be necessary, as the supplier has communicated the specifications and claims of performance for the goods and/or services on the website, within the catalog, or on the shelf.

6.2.8.2 Approval of the lab's requirements and the selected goods and/or services will be indicated by the receipt generated in the transaction to document the purchase.

6.2.8.3 The receipt will be the record of the purchase made, the defined requirements, and the review and approval of the lab's requirements for the purchase. The employee making the purchase will be responsible for assuring the goods and/or services purchased meet the lab's requirements.

6.2.9 For all purchases where acceptance criteria (performance specifications which will be used during inspection or monitoring of the goods and/or services purchased) will be applied, the supplier will be informed of the acceptance criteria during the purchasing process.

6.2.9.1 Where purchased services must be provided by personnel with specified competence or qualifications, these requirements will be communicated to the supplier.

6.2.9.2 If the Lab intends to perform verification, inspection, audits, or other activities at the supplier's premises, these activities will be communicated to the Supplier. Methods of communicating this information may be within purchase orders or in documented communication with suppliers maintained by Lab Management.

6.3 Critical Consumables

6.3.1 Critical consumables are materials which directly affect the performance of laboratory activities. Critical consumables will be identified in the contents of established test methods or equipment manuals and by Management's designation

as critical to the consistency and effectiveness of laboratory operations. In addition to the purchasing requirements listed above, this section of the procedure describes additional controls which will be applied to critical consumables.

6.3.2 When ordering critical consumables, an appropriate certificate of analysis or conformance is requested from the supplier when the critical consumable is ordered if deemed appropriate by Lab Management or Analytical Development Manager. This request may be documented on purchase orders where applicable, or via personal contact, or in emails.

6.3.2.1 The certificate will be requested to be shipped with the critical consumable. If the supplier cannot accommodate this request, an alternative method may be provided by the Supplier, such as access to a website where the certificate can be obtained.

6.3.2.2 The requirement for the certificate of analysis or conformance is indicated in the product description in the purchase order or purchasing documents.

6.3.3 When ordering critical consumables, the details of the critical consumable will be specified completely in the purchase order to ensure the proper critical consumable is received. For example, both brand and generic names for chemicals may be specified to ensure the proper critical consumable is received.

6.3.4 Additional work instructions necessary for the proper handling, storage, and/or disposal of these consumables will be developed and made available as deemed necessary by Lab Management or the Analytical Development Manager.

6.3.5 All consumables will be marked with the following information (of verified to be present on the manufacturer's label) or using an equivalent method while in storage. Critical consumables will only be separated from these markings while being used in the performance of laboratory activities:

- Identification of the critical consumable,
- Description of critical consumable and detailed specification if deemed necessary, including both brand and generic names for any chemicals or compressed gases,
- Expiration date indicating the acceptable life of the critical consumable for the laboratory,
- Special storage requirements for the consumable to protect it from damage and or deterioration.

6.4 Order Changes and Cancellations

6.4.1 When purchase order requirements change (or are cancelled) for any reason, Lab Management or designee will notify the supplier, vendor or service provider and make the necessary changes in the Approved Vendor List. Revisions to purchasing requirements are reviewed and approved in the same manner as new purchases.

6.5 General Receiving

6.5.1 When a delivery arrives at Ion Labs, Receiving personnel inspect incoming packages and items for damage while verifying the goods and their quantities against their accompanying packing slips (or equivalents).

- If gross damage is apparent to an incoming shipment (e.g., damage to such a degree that the goods are unusable), Receiving personnel with input from Lab Management or the Analytical Development Manager as needed determines the disposition. Such damage is noted in carriers' logs before their departure if possible.

- If goods arrive without a packing list, receiving personnel confirm the purchasing requirement and resolves the issue, as appropriate.

- Incoming measuring equipment is processed according to the Calibration and Equipment Control procedure.

6.5.2 Receiving lab personnel verifies the purchased item(s) meet all applicable requirements of the purchase information by comparing the information on the packing list to the information on the purchase order submitted to the external provider.

6.5.3 Products failing the above verifications are treated as discrepant. The product is segregated until the issue is resolved with the supplier or vendor. Records of products returned to suppliers are maintained.

6.5.4 Receiving personnel or Lab Management resolves all product or count discrepancy and nonconforming product issues with suppliers and vendors, and where appropriate issues corrective actions in accordance with QS-108 Corrective and Preventative Action procedure.

6.5.5 Receiving forwards copies of Certificates of Conformance or Certificates of Analysis to the Lab Director and/or the Analytical Development Manager for their review. The signature and date will indicate the acceptance of the CoC or CoA.

The hard copy CoC or CoA will be filed in the appropriate hard copy binder.

6.5.6 Receiving records are controlled in accordance with the SOP C-502 Record Storage, Retention, and Destruction.

6.6 Record Management

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

6.7 Process Outputs

6.7.1 Outputs to the Purchasing and Receiving process include, but are not limited to:

- Approved purchasing documentation,
- Purchased products, and services meeting documented procurement requirements,
- Accepted and stored product and evidence of verification.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/01/21	New procedure.	N/A	J. Sassman