



ATF-LS-4.6 Purchase and Receipt of Materials That Matter	Published Online: March 2018
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1. Purpose

- 1.1. This procedure establishes a standard system for ensuring the quality of critical, equipment, services, consumables, and supplies used in laboratory analysis. For the purposes of this procedure, critical equipment, services, consumables, and supplies will be deemed materials that matter.

2. Policy

- 2.1. Each scientific discipline will maintain a list of materials that matter with the appropriate discipline methods manual. Materials that matter are defined as services, consumables and/or supplies that affect the quality of laboratory analysis. These lists will include a reference to the specific performance criterion required by the analysis in which it is being used. This may be accomplished by referencing a specific method of analysis document that contains the performance criterion of the identified material that matters. The materials that matter list for each of the discipline areas will be maintained as a controlled document in Qualtrax. All laboratory supplies, materials and/or services identified on the discipline-specific materials that matter list will be checked prior to use in laboratory analyses.
- 2.2. This policy is not intended to replace discipline specific control or quality checks required by discipline method manuals. Any control or quality checks required by specific discipline protocol or procedure will be performed and recorded as directed by the specific protocol in addition to this initial check of receipt.
- 2.3. Laboratory equipment deemed critical is identified as such in the equipment inventory records. These records will include at minimum, vendor evaluation information, a record of technical and administrative reviews and purchase authorizations as directed by the laboratory chief and Bureau policy. The procedures for receipt and placing into service of newly purchased critical laboratory equipment and the purchase of critical equipment repair or maintenance services are also documented in ATF-LS-5.5 Laboratory equipment.
- 2.4. Services deemed critical, provided by contracted technical personnel working in the laboratory under the direct supervision of a laboratory manager, are acquired as directed by the Laboratory Chief and Bureau policy. Contract technical personnel working in the laboratory are evaluated, authorized to perform work and monitored for performance according to ATF-LS-5.2 Personnel standards and training program.

3. References

Discipline specific materials that matter lists
Discipline specific method documents

Approved vendor list

Vendor records

ATF-LS-F-4.6 A Request for expenditure form

ATF-LS-4.13 Control of records

ATF-LS-5.2 Personnel standards and training program

ATF-LS-5.5 Laboratory equipment

Laboratory equipment logbooks and records

Laboratory Services equipment inventory

4. Procedure

4.1. Purchase and receipt process

4.1.1. Purchase requisition and approval

- 4.1.1.1. The laboratory employee making a purchase of a material that matters will complete ATF-LS-F-4.6A Request for expenditure form and submit the form to their Section Chief for approval.
- 4.1.1.2. The request will contain, at a minimum, the following information: name of person placing the order, the name, address and phone number of the qualified vendor from the approved vendor list, catalog number/item identifier number, vendor part number (if known), description of the services or supplies, quantity ordered, price per item, and total cost of order. The appropriate Section Chief will review the request to see that it meets laboratory purchasing policy requirements and authorize the purchase by signing the form. The form is then returned to the employee requesting the purchase so that they can place the order.
- 4.1.1.3. Employees placing orders for critical supplies or services must also follow the authorization, budget and credit card reporting requirements of their particular laboratory. This includes providing copies of purchasing documents to laboratory analysts for budget reporting purposes.

4.1.2. Receipt and initial inspection

- 4.1.2.1. Upon receipt of a supply package, the person receiving the package will contact the person named on the package or an appropriate discipline representative.
- 4.1.2.2. The laboratory employee who placed the order, or an appropriate discipline representative receiving a material that matters, will check to see that at a minimum, the supply received meets the requirements noted on the request for expenditure form and the materials that matter list. The employee will document

this check by placing their initials in a conspicuous manner on the outside supply packaging prior to placing the supply in the laboratory for use. If the shipping package contains more than one container of the same material, and it appears not to be under original manufacturer seal, or is not clearly labeled as to the package contents, each immediate container should be pulled from the container and checked and marked prior to being placed for use in the laboratory.

4.1.2.2.1. This initial check documentation is not intended to replace discipline specific control or quality checks required by a specific protocol. Any control or quality checks required by specific discipline protocol or procedure will be performed and recorded as directed by the specific protocol in addition to this initial check of receipt. This includes logging, initialing and dating supply containers as they are opened for use.

4.1.2.2.2. The use of blank stickers is a suggested means to conspicuously mark a package.

4.1.2.3. If the initial check reveals that the supply does not meet the criteria stated on the request for expenditure form, or materials that matter list, the order will be repackaged and returned to the vendor. Returns will be documented on the original request for expenditure form.

4.1.2.3.1. Repeated returns specific to one vendor should be brought to the attention of the appropriate technical leader, who will initiate and document a corrective action appropriate to the issue.

4.1.2.4. Copies of all materials that matter order, receipt and/or return records shall be maintained.

4.1.2.5. Any certificates supplied by the vendor, indicating a guarantee of quality or performance, shall be maintained. Copies of these certificates should also be maintained with any discipline specific reagent or supply logbook that is regularly maintained within discipline work or chemical storage areas.

4.1.3. Storage of materials that matter

4.1.3.1. Reagents and other consumables will be stored according to manufacturer's storage recommendations.

4.2. Vendor selection process

4.2.1. Vendors will be selected based on their ability to meet the requirements and provide objective evidence that the critical consumables, services and supplies on the materials that matter lists can consistently meet the critical supply or service requirement.

4.2.2. Vendor selection and qualification

- 4.2.2.1. The following factors will be used to evaluate and qualify a vendor to supply the laboratory with materials that matter.
 - 4.2.2.1.1. Third party registration
 - 4.2.2.1.1.1. Vendor accredited to ISO/IEC 17025 or other appropriate standard.
 - 4.2.2.1.2. Historical evidence
 - 4.2.2.1.2.1. Evidence that a vendor has consistently and reliably supplied goods conforming to agreed upon specifications over a period of time.
 - 4.2.2.1.3. Sole source
 - 4.2.2.1.3.1. Instances in which the services, or materials required by the laboratory are available only through a sole source vendor
 - 4.2.2.1.4. Feasibility
 - 4.2.2.1.4.1. When vendor assessment is not feasible, examiners with Section Chief approval, may make the purchase from a vendor not on the approved vendor list. In these instances, an appropriate inspection or testing will be performed and documented during the receiving process to verify the quality of the materials. Documentation of these types of one-time purchase request quality checks will include the reason for the one-time purchase. The documentation shall be maintained.
- 4.2.2.2. Vendor qualification
 - 4.2.2.2.1. The appropriate Technical Leader or Section Chief will produce vendor qualification memos, documenting the vendor name, product description and the manner in which the vendor was evaluated. These records shall be maintained.
 - 4.2.2.2.2. A list of approved vendors shall be maintained as a controlled document in Qualtrax.
 - 4.2.2.2.3. New vendors will be evaluated using the evaluation standards noted above. Vendors who have maintained the performance standard from which they were initially qualified will remain on the vendor list and need not be requalified as an approved vendor.
 - 4.2.2.2.4. Vendor evaluation is an on-going process and discrepancies will be noted as they occur. These ongoing evaluation criteria may include but not be limited to such factors as accurate and timely deliveries, quality of goods received, quality of service, compliance to contract terms (if applicable), product and technical support, ability to resolve any problems that are addressed, history of corrective actions, etc. All pertinent data related to any reported

discrepancies will be reviewed by the appropriate Technical Leader who will determine the appropriate action(s). Documentation of these reviews shall be maintained.

4.2.2.3. Vendor disqualification

4.2.2.3.1. A vendor may be disqualified for the following reasons:

- poor quality performance
- failure to respond to a corrective action request
- poor delivery performance
- displacement by another appropriate supplier
- competitive bidding requirements

4.2.2.3.2. Any employee, who believes there is just cause for removing a vendor from the approved vendor list, should contact the appropriate Technical Leader or Section Chief. If it is determined that the vendor is disqualified, the reason(s) shall be documented. The vendor will then be removed from the list.

4.2.2.4. Vendor Records

4.2.2.4.1. The records shall be maintained according to ATF-LS-4.13 Control of records.

5. Controls

5.1. Laboratory Chiefs and Section Chiefs

5.1.1. Laboratory supervisors authorizing purchases of material that matter will ensure that the information required by this policy is contained on the initial request for expenditure. This review will be documented by the supervisor's signature on the form.

5.2. All laboratory employees

5.2.1. All laboratory employees will ensure that requests for expenditures involving materials that matter are completed according to this policy and that the vendor(s) are on the list of approved vendors. This review will be documented on the request for expenditure form by the person making the purchase.

5.2.2. All laboratory employees will check the containers for documentation of the initial receipt check for materials that matter, prior to using in analysis. Any control or quality checks required by specific discipline protocol or procedure will be performed and recorded as directed by the specific protocol in addition to this initial check of receipt. These quality checks will be made and documented according to the discipline protocol.

5.3. Quality Programs

5.3.1. Quality Programs will maintain the lists of qualified vendors. Annual internal audits will include a review of a sampling of vendor and purchase and receipt records for materials that matter.