A. **PURPOSE:**

The Division follows state guidance for the purchasing of goods and services, including the use of state approved vendors as appropriate. Additionally the Division assesses vendors internally to verify that they can meet and support the normal operating requirements of the laboratory system.

RESPONSIBILITY:

1. Managers: Responsible to provide direction to subordinate staff under their purview as indicated by the organization chart.
2. Supervisors: Responsible to provide supervision to subordinate staff under their purview as indicated by the organization chart.
3. FSE2: responsible as a working lead to subordinate staff as indicated on the organizational chart.
4. FSE1 and Lab Assistants: Responsible to adhere to this procedure as it pertains to their Unit.
5. ECO: Responsible to adhere to this procedure as it pertains to their Unit.
6. Support Personnel (however titled): Responsible to adhere to this procedure as it pertains to their Unit.

B. **DEFINITIONS:**

Purchasing Coordinator: anyone (however titled) assigned to facilitate all purchases within the Division of Scientific Services (DSS) and track orders through a central electronic repository. They are the conduit between the Division and Accounts Payable with respects to purchases. This is usually an office assistant, secretary or administrative assistant.

ePro: the current State software used for purchasing requests, including tracking of the approval with creation of purchase orders and for the payments for supplies and services.

Critical items: any item that will affect the quality of testing performed. Approval via a 'Laboratory Vendor Approval' workflow is required for these vendors.

Non-Critical items: Items that do not affect the quality of work performed. These may include office supplies, subscriptions, building supplies, books, some general laboratory supplies and similar items. A vendor approval workflow is not required for these types of products.

Approved vendors: vendors of supplies or services whom are either:

- ISO 17025, ISO 17020, ISO 17043, ISO 17032, ISO 14001, ISO 13485, ISO Guide 34 or equivalent certified or
- Have completed a laboratory survey to demonstrate their ability to provide products or services that meet the requirements of the laboratory.

Note: ISO 9001 cannot be used for critical supplies that can influence the test results. A supplier evaluation form must accompany any ISO 9001 certification.

Approved vendors will be documented in the Quality Management Software (QMS) via 'Laboratory Approved Vendor' workflows.

Service: this can be a repair or service of an instrument/equipment, a calibration, or a verification/validation of an instrument/equipment (such as balances or pipettes that will demonstrate that they are in proper working condition). Services that affect the quality of testing are designated as critical. Non-critical services include those that do not affect the quality of testing such as annual hood checks or copier repairs.

ILAC: International Laboratory Accreditation Cooperation

NIST: National Institute of Standards and Technology

BIPM: International Bureau of Weights and Measures (Bureau International des Poids et Measures)

C. **PROCEDURE:**

1. Needed purchases will be communicated to the Unit Manager, Supervisor or their designee.
   a. For non-critical items or services the individual arranging the purchase will obtain a quote for the needed items. This type of purchase does not require the vendor to be on the approved vendor list.
   b. For Critical services and supplies, the individual arranging the purchase will verify that the company is on the approved vendor list and then obtain a quote.

   Top Management will assess purchase requests based on the availability of funding, cost and urgency. They will determine and approve appropriate funding.
2. Approved Vendors List:
   a. A list of 'Laboratory Approved Vendors' will be maintained within the QMS. 'Laboratory Approved Vendor' workflows in the QMS will be used to add and review the appropriateness of vendors.
   b. If a vendor is not on the approved vendor list it must first be determined whether they can supply the item or service needed to the specifications required. If not automatically approved by their scope of accreditation, the vendor will be supplied with a questionnaire (See GL-6.1). The completed GL 6.1 will be attached to a vendor workflow for the vendor. The workflow will capture the approval/review of the GL-6.1 and add the vendor as approved to use.
      (a) Note additional information may be required based on current state purchasing requirements, for the types of items needed. Individuals should work with the section manager and purchasing coordinator to verify all needed records are completed.
   c. A GL-6.1 'Supplier Evaluation' form is not required, but the vendor must still be vetted through the QMS workflow for critical services or supplies when:

i. Vendors that are sole source suppliers may be deemed as approved by the Unit Manager or Quality Manager based on the needs of the DSS.

ii. Vendors, which are ISO 17025, ISO 17034 or ISO 13485 accredited or similar and the scope of their accreditation meets the needs of the laboratory. A copy of the current accreditation certificate will be attached to the workflow.

(a) For reference materials, vendors must be accredited to ISO 17034 (see Reference Materials section below).

(b) For calibration services or for items that require calibration certificates the vendor must be ISO 17025.

(i) Example: For calibrations that will be performed at the DSS the vendor's scope of accreditation for the specific type of calibration needed must allow for on-site calibrations.

iii. Note if a vendor is a supplier of a reference material or of a critical item (not the manufacturer of the material), a GL-6.1 is needed to assess the supplier, the unit is responsible to verify that they can supply the item that meets the needs of the testing.

(a) Example – Fisher Scientific is a supplier – if a NIST thermometer is purchased where a calibration certificate is required, the unit must verify the calibration certificate that is supplied with the item is appropriate.

d. The Approved vendors workflow is set to expire based on the vendor and what they supply.

i. Critical items including reference materials and calibration service where the company is ISO accredited (other than ISO 9001): workflows will be set to expire based on the related ISO accreditation certificate of the vendor.

(a) Note that there may be a delay in the time an accreditation certificate expires and the new one issued to the vendor, in these cases the vendor can be accepted based on past ability to supply needed items/service. The workflow should be reset to expire 3 months past the initial date to act as a reminder to obtain the updated certificate.

ii. Critical items where the company is not ISO accredited can be set for a 5 year review period. They may be re-accepted based on the vendors historic ability to meet the needs of the DSS.

iii. Sole supplier vendors: the workflow expiration will be set at 5 years, this can be re-approved based on the vendors historic ability to meet the needs of the DSS.

iv. If Unit Managers choose to assess vendors of non-critical items related to case analysis they will be reviewed on a 5-year cycle. If no issues have been noted for items they supply the expiration can be reset for 5 years.

(i) Example of non-critical items related to casework may include transfer pipettes, weigh boats, Kimwipe and similar.

v. If a vendor is no longer needed or used, the expiration date of the workflow should be extended 20 years and the 'approval of vendor' field should be set to 'no longer used'. Additionally it is suggested that after the name of the company the words 'no longer used' be added to clearly communicate the company needs to be re-assessed prior to using them as a vendor in the future.

3. Purchasing Methods:

   a. In general, supplies can be obtained through purchase orders, blanket purchase orders, or through the use of a purchasing card (state credit card).

      i. Purchase orders (PO): obtained by submitting a request through an ePro requisition. This request is forwarded for approval through administration to headquarters and the Department of Administrative Services (if the request involves an IT related item).

      ii. Blanket Purchase orders: These are POs set up for vendors that may be used repeatedly throughout the year. These POs set aside funds that are anticipated to be used with the vendor throughout the fiscal year. Verify needed funds are available before using these POs.

      iii. Purchasing Cards (P cards): State issued credit cards. Specific Managers have purchasing cards assigned to them. When an item is needed, usually on an emergency basis, the purchasing card can be used to facilitate the purchase. Specific guidelines are set forth by the State of Connecticut for the use of these cards. The DESPP Purchasing Department is responsible to explain the proper use of the card. It is the responsibility of the cardholder to comply with those regulations. The use of P-Cards is limited and generally reserved for approved emergency purchases.

   b. Obtaining Quotes:

      i. Generally, quotes will be obtained for all purchases or services prior to requesting a PO. This may not be required for purchases covered under some POs.
      ii. Shipping fees should be included with the total cost represented on the quote from the vendor.
         (a) Some vendors that have state contracted pricing may include shipping.
         (b) Vendors should be informed that delivery will require the truck to have a lift gate for larger items.
      iii. Taxes should not be included on quotes.
         (a) If needed the CT Tax exempt number can be provided by the Purchasing Coordinator.
      iv. If possible 6-8 week expiration dates should be requested for quotes to avoid issues if any delays occur with the ePro approval process.

4. Purchasing Critical Items: (Supplies deemed critical, meaning they may affect the quality of the laboratory activity).

a. The Unit designee will verify the requirements of the needed materials and obtain a quote for the items from the approved vendor. Requirements may include concentration of a chemical, grade of glassware or similar parameters.
   i. The Section Manager or other designee will review the request and approve/deny the purchase. They will then determine the proper method of purchasing.
   ii. Once approved and the payment method determined, the purchase request is given to the Purchasing Coordinator to complete the order.
      (a) If the purchase involves grant funding then the quote should be sent to the Grant Coordinator for the DESPP to update the grant spreadsheet.
      (b) Once a quote is obtained, an 'Approval Justification Supplemental Form' is completed. Once the supplemental form is approved, an ePro requisition is completed by the Purchasing Coordinator.
      (c) The Director or their designee approves all ePro requests. A PO will be issued once approvals are made.
      (d) If a P-card or blanket PO is used, the Purchase Coordinator or designee can communicate with the company to complete the purchase. If purchases are made by the P-card holder the order paperwork will be sent to the Purchase Coordinator.

b. When the laboratory receives the items, it is the responsibility of the Unit designee to ensure that the items received are of the quality requested.
   i. Concentration, volume or any other critical detail of the purchased item (which can affect testing) will be assessed.
   ii. If the Unit designee finds that something was received that was not intended, they will alert the Unit Supervisor (or designee). They will work with the Section Manager and/or Purchasing Coordinator or designee to determine how to correct the issue.
   iii. To indicate that the item is acceptable, an appropriate notation is made next to the item listed on the packing slip. The packing slip is initialed and dated to indicate items received and any issues should be noted. The appropriate notation can be a check mark next to the item or other similar notation.
   iv. Return the checked, initialed and dated packing slip to the Purchasing Coordinator or designee for filing (the original hardcopy packing slip, or a scanned copy is acceptable). In the absence of a packing slip, an email from the person receiving the order to the Purchasing Coordinator or designee is acceptable to document the item(s) were received and acceptable. The Purchasing Coordinator will maintain a record of the packing slips for a minimum period of five years.
   v. All chemicals/reagents shall be marked with the date received, on the actual item(s).

c. Some equipment may require a CT DESPP asset tag for asset inventory purposes. An asset inventory audit of all tracked equipment takes place in conjunction with the Asset Control

Section within DESPP, as designated by the Department. The DESPP inventory control number may be used as the unique identifier for pieces of equipment. It is recommended that the corresponding PO number be placed on such items. Additionally for equipment purchased through a grant it is suggested that the grant number be placed on the equipment.

(a) Equipment that does not have an asset control tag, but is involved in the analytical case results will be uniquely identified by individual Units. This may include equipment such as pipettes.

d. Purchased equipment must be stored in a manner as to not negatively affect their suitability for use or quality.

5. Reference Materials:

i. Vendors used for the purchase of reference materials must be a reference producer that is accredited to ISO 17034 by an accrediting body that is a signatory of ILAC.

ii. The scope of the vendor's accreditation must meet the specifications of the reference materials.

iii. The Unit requiring the reference material will obtain a quote from a vendor that meets the requirements above. The Unit will verify that the quoted items meet the needs of the testing.

iv. When the laboratory receives the reference material(s) it is the responsibility of the Unit designee to ensure the suitability of the item(s).

v. Concentration, volume or any other critical detail of the purchased reference material (which can affect its use as a reference material) will be assessed as appropriate.

vi. If the Unit designee finds that something was received which was not intended, they will alert the Unit Supervisor or Manager.

vii. To indicate that the item is acceptable, an appropriate notation is made next to the item on the packing slip. The packing slip is initialed and dated to indicate items received and any issues are noted. The appropriate notation can be a check mark next to the item or other similar notation.

viii. Return the checked, initialed, and dated packing slip to the Purchasing Coordinator or designee for filing (the original hardcopy packing slip, or a scanned copy is acceptable). In the absence of a packing slip, an email from the person receiving the order to the Purchasing Coordinator or designee is acceptable to document the item(s) were received. The Purchasing Coordinator will maintain a record of the packing slips for a minimum period of five years.

ix. Appropriate documentation of the reference material (such as a certificate of analysis form) will be maintained by the Unit per Unit SOPs.

x. All reference items will be marked with the date received on the item or their proximal container. If applicable the period of validity should be on the item (example – a NIST thermometer should have the calibration due date on the device).

xi. Purchased materials will be stored in a manner to prevent deterioration as per guidance provided in Unit SOPs.

6. Purchasing Services:

When the need for service is identified, the appropriate Manager will be informed. A quote will be obtained and upon approval by the appropriate Manager the request will be submitted to obtain a PO. Upon receiving the PO the Unit designee will arrange for the service. The exact requirements (such as acceptance criteria in the case of calibration services) will be communicated to the vendor.

i. Calibration of analytical equipment:

Managers (or their designees) are responsible to ensure that instrument calibration schedules are met within their sections. The Quality Section is responsible to ensure that the calibration schedule for general laboratory items (such as pipettes, balances and weights) is met.

(a) The vendor must be traceable to a National Metrology Institute (NIST or BPIM).

or

(b) The vendor must be accredited to ISO/IEC 17025 by an accrediting body that is a signatory of ILAC.

(c) The scope of the accreditation for the vendor must meet the needs of the service to be provided.

(d) If for any reason a vendor meeting the needs of the DSS cannot be obtained the vendor must be approved by the Manager of the Unit or a member of the Quality Section. A Supplier Evaluation form (GL-6.1) must be completed. The record of the review will be maintained in the QMS.

(e) When a quote is acquired, payment approval will be obtained through Management prior to scheduling the service. The Unit Manager will determine the appropriate payment method. The quote is forwarded to the Purchasing Coordinator to start the ePro process to obtain a PO.

(f) The service cannot be scheduled until a PO is obtained.

(g) Once the calibration is performed and the equipment has been verified as working properly, the person arranging the service (or designee) will initial the vendor paperwork to demonstrate agreement that the equipment functions properly. If no paperwork is available (some vendors may send paperwork electronically at a later date) then the Unit Lead (or designee) will be notified and the initialing of paperwork

will occur upon receipt of the electronic paperwork. Services for annual validations or verifications should be grouped together for efficiency. Duplicate copies of the service record may be maintained within multiple Units.

(h) Record of the calibration will be provided to the appropriate Unit Lead or Supervisor. This will be maintained in the instrument maintenance logbook or as per Unit SOPs.

(i) Calibration certificates provided from the vendor will be maintained as specified in Unit SOPs.

ii. General maintenance of equipment:

(a) Vendors must meet the needs of the DSS for the service to be performed.

(b) When the need for service is identified (whether it is an annual check of a specific item or due to the need for a repair) the Unit Lead or Supervisor will contact Management to inform them of the need and to determine the proper payment method.

(c) After a quote is acquired, the quote is forwarded to the Purchasing Coordinator to start the ePro process to obtain a PO.

(d) The Unit designee will contact the approved vendor and arrange for the service once the PO is obtained. Some services are on contract or a pre-scheduled time frame and vendors may contact the DSS to schedule these services.

(e) Once the service is complete and the equipment has been verified as working properly, the person arranging the service (or designee) will initial the vendor paperwork to demonstrate agreement that the equipment functions properly. If no paperwork is available (some vendors may send paperwork electronically at a later date) then the Unit Lead (or designee) will be notified and the initialing of paperwork will occur upon receipt of the electronic paperwork. Services for annual validations/verifications should be grouped together for efficiency. Multiple copies of the service record may be maintained within multiple Units.

(f) For instrument repair:

(i) Repair documents will be given to the Unit Lead or Supervisor or their designee. This will be maintained in the instrument maintenance log or binder for the instrument, or as per unit guidance.

(ii) The invoice, repair order or other such document provided by the vendor will be initialed and dated to indicate the service was performed. This will then be given to the purchasing coordinator; the Unit may maintain a copy for their records.

(iii) Units will follow Unit SOPs regarding performance checks after instrument maintenance.

(g) For annual maintenance (such as for hoods) the person requesting the service, generally this will be a member of the Quality Section, will document the validation/verification for the item(s).

(i) The repair order, invoice or other such document provided by the vendor will be forwarded to the Purchasing Coordinator. This should be initialed as ok to pay or if forwarded electronically the email will note that the invoice is ok to pay.

(ii) A copy of the documentations may be maintained within the Units(s) as proof of the service. When possible, services for annual validations/verifications will be grouped together for efficiency. Multiple copies of the service record may be maintained within multiple Units.

(h) Individual Units may require specific performance checks on instruments to determine if the maintenance work completed was suitable for the needs of the Unit. Guidance for these performance checks is detailed in Unit specific SOPS.

(i) The Quality Section may maintain electronic copies of services that are general to the DSS.

7. Purchasing Non-Critical Items:

a. Purchasing of non-critical items is done in the same manner as critical items, however the Unit designee is not required to verify what is received; this can be performed by the Purchasing Coordinator or others.

b. Upon receipt of the supplies or materials, all packing slips, with the date and initials of the person verifying the quantities received, will be forwarded to the Purchasing Coordinator or designee (the original hardcopy packing slip, or a scanned copy is acceptable). In the absence of a packing slip, an email from the person receiving the order to the Purchasing Coordinator or designee is acceptable to document the item(s) were received. The Purchasing Coordinator will maintain a record of the packing slips for a minimum period of five years.

Note for all purchases (supplies or service) packing slips or invoices will be forwarded to the Purchasing Coordinator. These can be forwarded via email or provided in paper form.

If an electronic packing slip or invoice is received it is acceptable to forward it via email. In lieu of annotating the document itself the receiver/reviewer can state in the email that the invoice is ok to pay or all items were received and acceptable (or similar). This will document that the individual sending the email has verified the items on the document and they are as expected.

D. **REFERENCES**:

1. CT State Contracting Portal https://portal.ct.gov/Services/Working-with-the-State/State-Contracting-Portal
2. CT State contracting Portal Search https://biznet.ct.gov/SCP_Search/Default.aspx?AccLast=1