

Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	Chris Parker	Date	2/18/2020
A. Requested deviation applies to (Technical Procedure – include specific section):			
<p>Procedure for Procurement and Receipt</p> <p>4.2.6 The Assistant Director of Administrative Operations shall make the final determination as to whether a vendor is considered Acceptable or Not Acceptable. The Assistant Director of Administrative Operations also has the authority to reinstate vendors to the Acceptable list.</p>			
B. Requested deviation:			
<p>4.2.6 The Assistant Director of Administrative Operations or designee shall make the final determination as to whether a vendor is considered Acceptable or Not Acceptable. The Assistant Director or designee shall review all Vendor Evaluation Forms, but will only sign the forms of Vendors determined to be Not Acceptable. A memorandum citing review of all Acceptable vendor evaluations will be retained with the vendor evaluations. The Assistant Director of Administrative Operations or designee also has the authority to reinstate vendors to the Acceptable list.</p>			
C. Necessity for the deviation:			
<p>In the event the Assistant Director of Administrative Operations is unavailable to review the Vendor Evaluation forms, this allows for the Assistant Director to designate someone to review them in their place. To increase efficiency of this evaluation process, only those evaluation forms from Vendors deemed Not Acceptable will be signed off on.</p>			
D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)			
Comments(to include merits and impacts):			
Approved	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/> No
Signature	Amanda W. Thompson <small>Digitally signed by Amanda W. Thompson DN: cn=Amanda W. Thompson, o=North Carolina State Crime Laboratory, ou=Assistant Director, email=athompson@ncdcl.gov, c=US Date: 2020.02.18 10:55:58 -05'00'</small>		Date 2/18/2020
E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)			
Acceptable within general QA guidelines and good laboratory practice?	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/> No
Significant negative impact to Crime Laboratory Quality System?	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/> No
Restrictions/limitations:			
<input checked="" type="checkbox"/>	Authorized	<input type="checkbox"/> Rejected	Signature Timothy G. Suggs <small>Digitally signed by Timothy G. Suggs DN: cn=Timothy G. Suggs, o=North Carolina State Crime Laboratory, ou=Quality Manager, email=tsuggs@ncdcl.gov, c=US Date: 2020.02.19 06:44:35 -05'00'</small>
			Date 2/19/2020

Procedure for Procurement and Receipt

1.0 Purpose - To ensure that all supplies, equipment and services purchased by the State Crime Laboratory (Laboratory) are properly procured and received.

2.0 Scope – This procedure applies to the procurement of supplies, equipment, and services.

3.0 Definitions

- **Commercial reagent** – A chemical purchased to conduct a specific forensic test.
- **Contract** – A written agreement between a supplier and customer.
- **Critical reagents** – Chemicals which affect the quality of tests and which have been determined by empirical studies or routine practice to require reliability testing on established samples before use on evidentiary samples.
- **eProcurement system** – The online method by which supplies, equipment, and services may be purchased and contracted by North Carolina government entities.
- **Material** – The hardware, software media, raw materials or components used in the development or testing of samples.
- **Prepared reagent** – A chemical generated within the Laboratory.
- **Supplies** – The inventory necessary to perform the work processes of an organization.

4.0 Procedure

4.1 Purchasing and Purchase Orders

4.1.1 The State Crime Laboratory shall observe all requirements of the North Carolina Division of Purchase and Contract and any additional policies of NC Department of Justice (DOJ), the Department of Administration, or other policies relevant to purchasing equipment, supplies and services.

4.1.2 The Laboratory shall purchase only those supplies, services, and equipment of specified quality as required in Technical Procedures.

4.1.3 Purchase orders for items affecting the quality of analysis shall be described in detail. All purchase order requests shall contain at a minimum:

- Vendor (address, telephone and fax numbers).
- Purchaser (address, telephone and fax numbers).
- Quantity.
- Item description.
- Catalogue number, if applicable.
- Unit cost.
- Total cost.
- Date of request.

Purchase orders may also include other clearly stated needs such as essential physical characteristics, performance criteria, technical specifications, terms, conditions, delivery point, and serial numbers of equipment being serviced or repaired.

4.1.4 The Assistant Director of Administrative Operations certifies in eProcurement that the order is appropriate and that funds are available. All purchase orders shall be reviewed and approved in the

eProcurement system before any procurement action is authorized and received by a vendor for processing.

4.2 Evaluation Criteria of Vendors

4.2.1 Vendors shall be selected in accordance with accepted State procedures. Vendors of items affecting the quality of analysis shall be evaluated and selected based on the ability to meet contract conditions (including any quality assurance criteria).

4.2.2 To ensure quality, the Forensic Scientist Manager or designee shall evaluate vendors of critical laboratory equipment, services, and supplies. Reference standards, reference materials, and calibrations of equipment/reference standards used to establish and/or maintain measurement traceability shall be viewed as critical. These items shall be purchased from approved vendors with an "Acceptable" rating.

4.2.3 Vendors are rated as "Acceptable" or "Not Acceptable" based on the level of service provided and registrations or certifications held. The following criteria are required for a vendor to be considered "Acceptable":

4.2.3.1 Vendor meets international standards such as ISO 9000.

4.2.3.2 Vendor meets nationally certified standards such as those of the National Institute of Standards and Technology (NIST) or United States Pharmacopeia (USP).

4.2.3.3 Vendor has been awarded NC DOJ contracts for identified products and services. The State Crime Laboratory is bound to use only these vendors when applicable (i.e., outsourcing).

4.2.4 A vendor shall be considered "Not Acceptable" and shall not be used when the quality of the product or service does not consistently meet expectations or specifications. The following criteria are described for a vendor considered "Not Acceptable":

4.2.4.1 Vendor's documented history has demonstrated its inability to meet product specifications including the quality system and quality assurance criteria.

4.2.4.2 Vendor does not meet product specifications and delivery schedule.

4.2.4.3 Vendor does not respond expeditiously in resolving problems and discrepancies.

4.2.4.4 Vendor does not provide consistent service and product performance.

4.2.5 In January, each Forensic Scientist Manager or designee shall evaluate the vendors of critical laboratory equipment, services, and supplies, if used during the previous year. This evaluation shall be conducted using a Vendor Evaluation Form.

4.2.6 The Assistant Director of Administrative Operations shall make the final determination as to whether a vendor is considered Acceptable or Not Acceptable. The Assistant Director of Administrative Operations also has the authority to reinstate vendors to the Acceptable list.

4.2.7 Records of vendor evaluations and a list of approved vendors are maintained on the Laboratory shared drive by the Assistant Director of Administrative Operations and accessible to all Laboratory employees.

4.2.8 Records of this evaluation shall be maintained according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources.

4.3 Standards and Reagents

4.3.1 Standards and reagents may be purchased ready-to-use or prepared in-house from materials provided by vendors.

4.3.2 As defined in Section Technical Procedures, standards and reagents shall be verified and shall contain protocols describing the verification procedures. If stability is a problem, re-verification shall be performed at periodic intervals.

4.3.3 All commercial reagents and standards shall be labeled according to the Quality Manual.

4.4 Receipt, Inspection and Storage

4.4.1 Materials and supplies are distributed to the Section or the individual is notified of receipt of material for pick-up.

4.4.2 Upon receipt by the Section, supplies shall be inspected and inventoried against the packing slip and/or the purchase documents. These inventories shall be sent to the Assistant Director of Administrative Operations after they have been reconciled and shall include 1) the date the goods were received; 2) that the invoice is approved for payment; and 3) the initials of the person approving payment. Discrepancies shall be brought to the attention of the vendor immediately. If a discrepancy is found that could affect the product quality, the material shall be either discarded or returned to the vendor, according to the request of the vendor. Documentation of unsatisfactory materials and supplies and their disposition shall be reported on the Vendor Evaluation Form to establish trends in vendor performance and ensure that quality material is accepted.

4.4.3 Equipment, supplies, reagents, and consumable materials that critically affect the quality of tests shall not be used until tested or verified. Section Procedures shall contain protocols describing verification procedures and record maintenance.

4.4.4 Supplies shall be stored in a manner that maintains their quality (to include controlled temperature and/or humidity requirements, storage in the dark, or other specific conditions). Each Section shall be responsible for the storage of supplies. All chemicals shall be properly stored as provided in the Crime Laboratory Safety Manual.

4.5 New Equipment

4.5.1 The Forensic Scientist Manager of each Section, or designee, shall be responsible for developing the specifications to be used in purchasing/contracting for equipment. Equipment provided by the selected vendor shall meet or exceed these specifications.

4.5.2 Upon receipt, the equipment shall be inspected and inventoried against the packing slip and purchase documents. These inventories shall be sent to the Assistant Director of Administrative Operations after they have been reconciled and shall include 1) the date the goods were received; 2) that the invoice is approved for payment; and 3) the initials of the person approving payment. Discrepancies shall be brought to the attention of the vendor immediately. If vendor installation is required, the shipment shall be secured as received until the vendor arrives. After vendor installation, the Assistant

Director of Administrative Operations shall be provided the inventoried packing slip/purchasing documents to complete the payment process.

4.5.3 Performance verification of new equipment shall take place according to the Laboratory's Procedure for Equipment Calibration and Maintenance.

5.0 Records

- Vendor Evaluation Forms
- eProcurement and other electronic records
- Receiving documents including packing slips

6.0 Attachments – N/A

7.0 References – NC eProcurement webpage: <http://eprocurement.nc.gov/>

NC Department of Administration – Division of Purchase and Contract webpage:
<http://www.doa.state.nc.us/PandC/>

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document
05/14/2013	2	4.4.2 – detailed information to be placed on packing slip/purchase documents; 4.5.2 – detailed information to be placed on packing slip /purchase documents and included when to turn over to Deputy Assistant Director
10/31/2013	3	Added issuing authority to header
04/18/2014	4	4.2.5 - Changed annually to January
12/19/2014	5	Replaced Deputy Assistant Director/ Operations Manager with Assistant Director of Administrative Operations throughout the document
12/18/2017	6	4.2.2 – added requirements for reference standards, materials, and calibration standards to be designated as critical 4.3.3 – updated to Quality Manual 4.4.4 - added properly