

## **ANNEX I-Considerations when Procuring Laboratory Equipment and Negotiating Contracts**

When procuring laboratory equipment and reagents at the program level, the following steps should be taken:

1. Assess the laboratory system needs: Evaluate the clinical testing needs of the patient populations at the laboratory sites in order to determine volumes and test menu requirements. If in a laboratory system, evaluate the needs of all laboratories in the system.
2. Research the international market to identify available equipment that may meet your needs; request information on the equipment from all vendors as well as from organizations such as the FDA that certify/approve equipment.
3. Develop the specifications for the equipment purchase (see example below).

### **Specifications for the purchase of the automated Chemistry System are as follows:**

- a. The new system must include user-friendly software including a backup system that is capable of patient data management including test autoverification, QC management and equipment function management.
  - b. The new system will provide an integrated chemistry and immunoassay solution that will provide analytical TAT for STAT testing of less than 20 minutes for critical testing including chemistry panels and cardiac markers.
  - c. The new system will provide throughput of at least 1000 tests per hour.
  - d. The proposal must include the capability to perform all current tests on the test menu of the various laboratories on the primary platform or provide an acceptable alternative solution. Tests provided by third parties must be fully validated and supported by the system vendor. Any tests not fully validated and supported by the vendor should be noted as such.
  - e. The proposal must include a scalable chemistry system (high, moderate, and low testing volumes) that will meet the needs of each hospital/health center in the system.
  - f. A mirror image backup chemistry/immunoassay system will be provided for any equipment placed at the hospital sites.
  - g. All correlations for tests on the system will be done by the vendor for the life of the contract.
  - h. Mean time between failure rate must be described for the equipment and must be standard for the industry.
  - i. Guaranteed response time on urgent and non-urgent service calls must be included.
  - j. The system must interface with LIS Cerner Classic version 3.06.
  - k. The system must be installed with minimum renovations. If any renovations will be required, then they must be stipulated in the proposal.
  - l. Complete technical training on all systems and related middleware will be provided for at least two key operators per system.
  - m. All software updates, other than enhancements, must be installed at no additional charge for the life of the systems.
  - n. Complete operational training will be provided to all laboratory staff who will be operating the equipment.
4. Issue a request to vendors/suppliers for proposal or tender for the equipment.

5. Review proposals to determine if the system meets your written specifications.
6. To determine the best system for your needs, use prioritized criteria in a decision matrix; use this matrix to evaluate all systems and then determine which equipment meet your needs (include local service availability as an important criteria).
7. Ask several vendors (usually the top rated two or three on decision matrix) to provide proposals that describe equipment, reagents, controls/calibrators, consumables and service (all systems regardless of procurement method should include these costs).
8. Ask vendors to provide proposals for different procurement options including direct purchase, lease and reagent rental. Each proposal should include costs for equipment, reagent, consumables and service (after the warranty).
9. Review the proposals to determine the exact costs of equipment, reagents, calibrators, consumables and service for each procurement option. Evaluate service options in the proposals.
10. Make it clear to each vendor/supplier that you are negotiating with other vendors/suppliers and that competition for your business exists.
11. Determine what you are willing or able to pay for the equipment and negotiate that price.
12. Negotiate group discounts on equipment from list price based on number of equipment, total value of contract and your budget.
13. Negotiate discounts on reagent list pricing based on total test volumes projected.
14. Negotiate for calibrators and controls to be included at no cost in the contract.
15. Negotiate payment for any water systems required.
16. Negotiate on-site training for all sites at no expense.
17. Negotiate upgrades to equipment if released during term of a lease or reagent rental.
18. Negotiate additional needs if not already included in the proposal (e.g., manufacturer training for additional lab key operators or engineers; number of available local service engineers for the systems).
19. Assure the contract has an uptime guarantee of at least 98%.
20. The contract must include stipulations for shipment method for reagents including calibrators and controls (standing order, on demand) and any freight charges that may apply. Negotiate free shipping for standing orders at defined frequencies. Negotiate shipment charges.
21. Contract should stipulate expected time for fulfillment of non-standing reagent orders.
22. Contract should stipulate terms for reimbursement if reagents/kits are recalled or withdrawn from market.
23. Contract should include at no cost software upgrades that are needed for existing system operation.
24. Contract should include terms of the warranty provided.
25. Contract should include conditions for termination of the contract (especially on lease or reagent rental agreements).
26. Contract should include payment terms.
27. Reagent rental contracts will specify a reagent commitment that must be carefully evaluated; contract should include defined pricing schedule for reagents and any price increases over the term of the contract.
28. The contract should contain details of the service contract provided after the warranty period; service contracts should be negotiated at time of purchase based on number of equipment purchased; cost of contract should never exceed 10% of equipment cost.
29. Service contracts should include at a minimum the following items:
  - a. Defined number of service visits and cost of any additional calls.

- b. Acceptable response for routine and urgent service calls (e.g., 95% of all urgent calls for such issues as equipment down will be responded to within 24 hours).
- c. At least two preventative maintenance visits per year.
- d. Coverage for costs of freight if parts or equipment must be shipped out.
- e. Coverage for parts, labor and travel.
- f. Stipulation for service and maintenance training for staff/engineers.
- g. Loaner equipment available within defined period.
- h. Access to spare parts may need to be included.
- i. Mechanism for shipping back unreparable equipment at vendor cost.
- j. Penalties and mechanisms for escalation when defined service response rate is not met.
- k. Details of hotline services including hours of operation.
- l. Service documentation provided to user.
- m. Define the term and cost of the contract.
- n. Define all equipment covered under the contract.
- o. Mechanism for contract review.