

## Device maintenance contract for laboratory operation

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Today's clinical laboratories generate most results by methods using analytical instruments, the selection of medical device is one of the most important decision in clinical laboratory. Regulations require laboratories to engage in preventive and corrective maintenance of testing equipment and instruments to ensure that they are operating properly. The CLSI guideline GP31 A: 2009 provides information about evaluating the need for a service contract. Some selected issues will be presented here.

### Manufacturer Relationships

The complexity of many of laboratory instruments necessitates a good relationship with the manufacturer, though the laboratory user is ultimately responsible for instrument operation and maintenance. Following installation, continued good function and accuracy depend on the efforts of both the user and the manufacturer. The following are some of the points that should be considered.

#### 1.1 The Laboratory's Maintenance Requirements (4 factors)

The specific service needs of the laboratory

The complexity of the instrument

The maintenance skill levels of laboratory personnel and the institutional electronics department

The remoteness of the laboratory and the adequacy of transportation mechanisms

#### 1.2 Evaluation of the Manufacturer

- Has the instrument in question been adequately tested in the field?
- Does the manufacturer have a technical support "hotline?"
- Will they come to the laboratory, even if it is remote?
- What response time does the manufacturer claim?
- Is the manufacturer willing to continue teaching the user about the instrument after the initial training period?
- Will the manufacturer provide system component diagrams and a list of locally obtainable parts to limit downtime and the manufacturer's expense in providing long-distance service?
- Does the manufacturer provide periodic updates to its manuals?

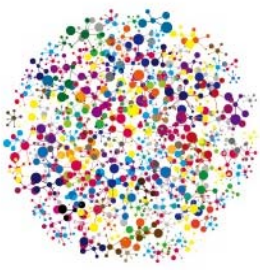
#### 1.3 Evaluating the Need for a Service Contract

The services performed by the manufacturer, as well as the availability of the service, should be considered. Generally, flat-rate service contracts must be compared to fee-for-service charges. The laboratory should be aware of what is and is not covered by a service contract. Some of the factors that need to be considered are:

Charge unit and extra charge for night or weekend calls

Transportation payment

Inclusion of routine preventive maintenance



Inclusion of parts replacements, payment and stock of parts  
Written warranty/guarantee and modification of them  
No service call charge  
The size of the fee linked to the age of the equipment, etc.

#### 1.4 Electronics and Maintenance

Many institutions have maintenance and electronics departments with a defined level of responsibility for repair of laboratory instruments. The department directors should ensure that instruments are maintained and repaired only by qualified personnel in accordance with manufacturers' recommendations. An adequate and comprehensive maintenance record of the work performed should be provided to the laboratory to ensure that the work meets all necessary documentation requirements. The laboratory director should establish the tolerance ranges for the testing performed by another department.

#### 1.5 Informatics and Networking

Most laboratory analyzers are controlled by computerized system and linked to a postanalytical middleware and/or premaintenance network system. The laboratory should confirm the range of informatics service whether that include these software or network system and can be repaired when the information system is changed according to the hospital or laboratory policy. The laboratory should be determine the significance and possibilities of errors that could be affect to patient safety.

### **Documentation and economic feasibility**

An adequate and comprehensive maintenance record of the work performed should be provided to the laboratory to ensure the work meets all necessary documentation requirements. Follow-up should be conducted to ascertain that the services were properly performed. Laboratory director should review the records regularly to evaluate the economics of the particular instrument and whether replacement would be more economical than maintenance or repair.

### **Discussion**

Laboratory staffs desires that the instruments and equipment be maintained in good working order. Such maintenance services is to include periodic inspections; routine, scheduled repairs and replacements of parts as needed; and emergency repairs made whenever any of the analyser breaks down unexpectedly. Sometimes it is necessary to make contract of equipment maintenance services, and the first service contract will be made in the time of instrument purchase. In this symposium, I will share the author's experiences about several maintenance problem cases following by sevice contracts on the aspect of laboratory physician.

### **References**

1. CLSI EP31 A-IR: 2012 - Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.
2. American Association of Blood Banks (AABB). *Technical Manual*, 18th edition, 2014.