

The IVM service performs and records regular function checks on the IVM system/instrument.

NOTE: Function checks include confirmation that an instrument or item of equipment operates according to manufacturer's specifications before routine use, at prescribed intervals, or after minor adjustment. Depending on the type of system, function checks may include calibration.

Evidence of Compliance:

- ✓ Records of function checks and calibration, as applicable

ANP.57400 Method Performance Specifications Availability - IVM

Phase II

The current IVM methods and all significant changes to analytical methodology, including performance specifications and supporting validation data, are retained by the IVM service.

NOTE: Records should include, but are not limited to, components of IVM equipment, software systems, image viewing systems, and digital image analysis systems. The IVM service must also provide data on clinical performance claims to clients upon request, if clinical performance claims are made. The IVM service may at its option require clients to agree to treat such data as confidential and not to share such data with any other party except as required by law.

Evidence of Compliance:

- ✓ Records of changes to analytical methodology

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): 7163[42CFR493.1291(e)].

IVM ANALYSIS

ANP.57450 Clinical Information Access

Phase I

The individual reviewing cases has access to pertinent clinical information at the time of IVM dataset review.

NOTE: In addition to the usual demographic and clinical information, the individual reviewing cases should have access to information on any special patient preparation and the type of imaging or contrast agent used, if any.

ANP.57500 Confidentiality and Security - IVM

Phase II



The laboratory ensures that sites engaging in IVM provide reasonable confidentiality and security.

NOTE: Procedures might include message security, system and user authentication, activity logs, encryption, and access restrictions.

For laboratories subject to US regulations, the procedures must be in conformance with HIPAA requirements.

ANP.57550 IVM Dataset Identification

Phase II



The laboratory ensures correct patient and IVM dataset identification.

NOTE: There are multiple ways to accomplish positive patient identification, including verbal communications, images of identifiers, etc.