ANP.57600 IVM Dataset Acceptability Criteria **Phase II**

There are defined criteria for acceptability of IVM datasets for the intended clinical application.

NOTE: IVM datasets must be of adequate quality for the intended clinical application. This requirement does not imply that all "unsuitable" datasets are discarded or not interpreted. However, there must be a mechanism to notify clinical personnel responsible for patient care when dataset quality is unacceptable for interpretation or if sub-optimal dataset quality impacts the quality of interpretation, with records of notification retained.

IVM REPORTS

ANP.57650 Report Review - IVM **Phase II**

IVM reports are reviewed and signed by the physician who interprets the IVM datasets.

NOTE: The inspector must review a sampling of reports issued since the previous on-site inspection, representing at least the most common types of IVM datasets interpreted in the IVM service. When diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the physician may not appear on the report. It is nevertheless essential that the IVM service have a procedure that ensures and records that the responsible physician has reviewed and approved the completed report before its release. In the occasional situation when the diagnosing physician is not available for timely review and approval of the completed report, there may be a procedure for review and approval of that report by another physician. In that circumstance, the names and responsibilities of both the physician who made the diagnosis and the physician who performed final verification must appear on the report.

Evidence of Compliance:

✓ Signed IVM reports

ANP.57700 Final Report Elements - IVM **Phase II**

The final report includes the dataset source, the imaging technology, as well as any limitations of the result, if applicable.

NOTE: In addition to the requirements above, the IVM system used and name of the vendor may be included in the report to provide users of the report with access to more information about the IVM system. For locally developed IVM systems, this may be in the form of a link to more information about the system on the internet. If a scoring system is used in interpretation, it should be referenced in the report.

The format of the final report is up to the medical director. The IVM report may be part of an encompassing surgical pathology report or stand on its own. Because the discipline is so visually-based, consideration should be given to including IVM images in the final report that reflect the final interpretation or pertinent findings.

Evidence of Compliance:

✓ IVM reports containing appropriate report elements

ANP.57750 Verbal Reports - IVM **Phase II**

If verbal reports are given, the physician speaks directly with medical/surgical personnel performing the IVM procedure and retains a record of the verbal report.

ANP.57800 Verbal Report Patient ID - IVM **Phase II**

The patient's identification is checked and confirmed before delivery of a verbal report.

ANP.57850 IVM Dataset Retention **Phase II**

IVM datasets used for interpretation or diagnosis are retained in accordance with policy.

NOTE: IVM datasets must be retained for 10 years (data must be retrievable for this period). IVM datasets are stored as digital files. Storage of the entire original data is not required. Stored data should include, at a minimum, the data (original data or derived data) used for interpretation or diagnosis.