optimization and utilized during validation. These should include criteria for determining when the data analysis process has failed and the data are either re-processed or not further processed.
- *Limitations in the test methodology for each test*
- *Written procedures for any portion of the data analysis process performed by a referral laboratory, if applicable*

REFERENCES
1) Jones EA, Deininger SO, Hogendoorn PC, Deelder AM, McDonnell LA. Imaging mass spectrometry statistical analysis. *J Proteomics.* 2012; 75(16):4962-89.
2) Kriegsmann J, Kriegsmann M, Casadonte R. MALDI TOF imaging mass spectrometry in clinical pathology: a valuable tool for cancer diagnostics (review). *Int J Oncol.* 2015; 46(3):893-906.

CHM.21450 Data Analysis Process Validation — Phase II

The laboratory validates the data analysis process on a control tissue sample and revalidates the entire process and/or confirms the performance of the components of the process as acceptable when modifications are made.

Evidence of Compliance:
- ✓ Records of validation and revalidation and/or confirmation studies, including metrics and QC parameters used to establish and assess performance **AND**
- ✓ Written approval of validations, revalidations and/or confirmation studies **AND**
- ✓ Records of review of referral laboratory, if applicable

REFERENCES
1) Jennings L, et al. Recommended practices and principles for validating clinical molecular pathology tests. *Arch Pathol Lab Med.* 2009; 133(5):743-755.

CHM.21455 Data Analysis Process - Updates — Phase I

The laboratory has a defined process for monitoring, recording, and implementing patch-releases, upgrades, and other updates to the data analysis process.

NOTE: The data analysis processes are composed of multiple components - open source or other software packages, additional scripts, and databases for managing content and aspects of analysis and reporting. Due to the ongoing evolution of the field, laboratories need to establish a procedure for regular monitoring of updates, patch-releases, and other upgrades for each component of the process. Congruent with the procedure, the laboratory must demonstrate that acceptable performance specifications are met when a change to the process is implemented. The extent of revalidation and/or confirmation is modification dependent. Revalidation/confirmation may cover all or a subset of steps in the data analysis process and must designate specific monitoring intervals and address when such updates will be implemented.

Evidence of Compliance:
- ✓ Records of monitoring activities **AND**
- ✓ Records of revalidation/confirmation data including the type of upgrade, metrics, and quality control (QC) parameters monitored to assess analytical run performance **AND**
- ✓ Approval of revalidation/confirmation data by the laboratory director **AND**
- ✓ Dates of implementation

CHM.21460 Data Storage — Phase I

The laboratory retains data necessary to support primary results generated and re-analysis for a minimum of two years and as required by national, federal, state (or provincial), and local laws and regulations.

NOTE: The data retained must include the files necessary to re-review cases as originally performed for original results reporting. Examples include specimen tacking and quality metrics

data/files, sequencing run quality metrics reports, log or configuration file information regarding data analysis process parameters, and exception log information. The retained files and records must also be structured to facilitate inter-laboratory replication of the original analyses, annotations and/or interpretation, whether initiated by the laboratory or at the request of the referring physician or patient tested.

The policy must be in accordance with national, federal, state (or provincial), and local requirements for storage of data, as applicable.

CHM.21465 Version Traceability **Phase I**

The specific version(s) of the data analysis process used to generate data files are traceable for each patient report.

NOTE: Data analyses processes are typically comprised of a combination of different software packages, scripts, and databases. The versions and configuration of each component in the process (eg, command line flags or other configuration items) must be traceable for each patient report. Records of each process component do not need to appear in the patient report. Rather, it is acceptable to refer to the process as a whole, using a laboratory-specific designation and/ or include log files if generated with each analysis of a patient dataset. Laboratory-specific designations must be unique to each version of process components and configurations. Any changes to software packages, scripts, databases, configuration files or other process components require tracking in the version control system and updating to a new version.

Evidence of Compliance:

- ✓ Records identifying software packages, scripts, and databases with associated version numbers and configuration items for a given patient report, as appropriate

ATOMIC ABSORPTION SPECTROPHOTOMETERS

Inspector Instructions:

	• Sampling of AA Spectrophotometer policies and procedures • Calibration records
	• How does your laboratory ensure optimal lamp performance?

CHM.21600 Burner Head/Aspirator **Phase II**

The burner head and aspirator are flushed thoroughly with water each day of use.

Evidence of Compliance:

- ✓ Record of burner head and aspirator maintenance

CHM.21700 Optical Beam Alignment **Phase II**

The optical beam alignment is checked at defined frequencies, and results are recorded.

NOTE: This should be done at least weekly, although daily checking is preferred.