

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:

	<ul style="list-style-type: none"> • Sampling of AA Spectrophotometer policies and procedures • Calibration records
	<ul style="list-style-type: none"> • 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.

CHM.21800 Atomizer Phase II

The atomizer is cleaned and flow rate optimized at regular, specified intervals, and the results recorded.

CHM.21900 Sampler System Phase II

Automatic sampler systems (eg, on graphite furnace) are checked for precision at specified periodic intervals.

Evidence of Compliance:

- ✓ Records of sampler system checks at defined frequency

CHM.22000 Graphite Furnace Phase II

If a graphite furnace is used, the blank value of a graphite tube is verified for each element tested.

NOTE: Residue from assayed samples may accumulate on the graphite tube, thus potentially resulting in false positive findings should the residue contain the element of interest. In addition, checking for the response of a blank may also serve as one of the indicators that the graphite tube may need replacement.

Evidence of Compliance:

- ✓ Record of graphite tube checks at defined frequency

CHM.22100 Calibration Curve Phase II

An adequate and appropriate calibration curve is established for quantitative testing.

CHM.22200 Lamp Energy Phase II

The lamp's energy is verified and recorded for each run.

NOTE: Atomic absorption spectrophotometric lamp energy must be verified and recorded for each run. Lamps lose performance characteristics over time. Decrements in lamp performance may be observed by a loss of sensitivity. Poor lamp performance may also serve as an indicator of another system failure, eg, loose connections.

COLORIMETERS, SPECTROPHOTOMETERS, AND FLUORIMETERS

The following requirements apply to stand-alone instruments; they are not applicable to instruments embedded in automated equipment for which the manufacturer's instructions must be followed.

Inspector Instructions:



- Sampling of colorimeter/spectrophotometer policies and procedures
- Sampling of manufacturer required system checks



- How does your laboratory verify calibration curves?

CHM.22300 Absorbance/Linearity**Phase II**

Absorbance and/or fluorescence linearity is checked and recorded at least annually or as often as specified by the manufacturer, with filters or standard solutions.

Evidence of Compliance:

- ✓ Records of absorbance and linearity checks at required frequency

CHM.22400 Spectrophotometer Checks**Phase II**

Spectrophotometer (including ELISA plate readers) wavelength calibration, absorbance, and linearity are checked at least annually (or as often as specified by the manufacturer), with appropriate solutions, filters or emission line source lamps, and the results recorded.

NOTE: Some spectrophotometer designs, eg, diode array, have no moving parts that can alter wavelength accuracy and do not require routine verification. The manufacturer's instructions should be followed.

Evidence of Compliance:

- ✓ Records of spectrophotometer checks at required frequency

CHM.22500 Stray Light**Phase II**

Stray light is checked at least annually with extinction filters or appropriate solutions, if required by the instrument manufacturer.

Evidence of Compliance:

- ✓ Records of stray light checks at required frequency

CHM.22600 Calibration Curves**Phase II**

For procedures using calibration curves, all the curves are rerun at defined intervals and/or verified after servicing or recalibration of instruments.

NOTE: Calibration curves must be run following manufacturer's instructions, at minimum, and as defined in laboratory procedure.

Evidence of Compliance:

- ✓ Records of calibration curve rerun and/or verification at defined frequency

FLAME PHOTOMETERS

Inspector Instructions:



- Sampling of flame photometer policies and procedures
- Sampling of system cleaning