NOTE: Oxides and doubly-charged species are common interferences in ICP/MS. Oxides of various elements may have overlapping signals with elements of the same mass, thus leading to false-positive findings. Special techniques such as high resolution ICP/MS, dynamic-reaction cell and collision-reaction cell processes may eliminate the concern for oxide interference. Elements with a second ionization potential greater than or equal to 15.8 eV (the ionization potential of argon) may be doubly-charged. Such doubly-charged species may suggest the presence of an element that is not truly present. For example, gadolinium has an isotope at m/e154. It has a doubly-charged species at m/e 77, which is also the same mass as an isotope of selenium.

CHM.20700 Dual Detector Mode **Phase II**

If the dual detector mode is applied, the calibration is verified.

NOTE: In ICP/MS, calibration can be performed in two modes – pulse counting for lower concentrations and analog for higher concentrations. If a range is necessary that overlaps with both modes, then the laboratory should employ a cross-calibration. This is generally accomplished by use of a tuning solution whereby a full calibration is performed in both modes followed by software adjustment for a smooth transition. If a concentration range is needed that only encompasses one mode or the other, then a cross-calibration is unnecessary as long as the appropriate mode is employed.

Evidence of Compliance:

- ✓ Records of calibration verification and cross-calibration, if needed

CHM.20800 Reaction/Collision Cell **Phase I**

If a reaction/collision cell is utilized, the reaction/collision gases are optimized.

NOTE: Optimization of reaction/collision gases will allow for maximization of sensitivity and minimization of background counts. Such optimization is generally accomplished through use of a separate tuning solution and is controlled by a separate part of most software packages than that used for autotuning.

Evidence of Compliance:

- ✓ Records of optimization of reaction/collision gases

CHM.20900 Calibration Curve **Phase II**

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

CHM.21000 Instrument Drift **Phase II**

Performance criteria are defined to detect drift in ICP/MS equipment.

NOTE: Procedures for ICP/MS equipment must include criteria for performance and procedures to detect drift, which can occur rapidly. One way in which instrument drift can be detected is by evaluating control materials at defined intervals during a run.

CHM.21100 Isotope/Standard Criteria **Phase II**

Appropriate criteria are defined for selection of both the isotope(s) and the associated internal standard(s) related to each quantified element.

NOTE: When isotopes and internal standards are measured by ICP/MS, interferences (isobaric and polyatomic species) and relative abundances must be considered and described in written procedures and/or assay validation materials.

CHM.21200 Contamination **Phase I**

Laboratory processes minimize and detect contamination of results obtained by ICP/MS.

NOTE: Potential sources of contamination include specimen collection, reagent handling, carryover between samples, and engineering controls within the analytical environment.

CHM.21300 Gas/Reagent Purity **Phase I**

The purity of each gas and reagent used with ICP/MS is defined and appropriate for the intended use.

NOTE: Purity of gasses and reagents (including water) used with ICP/MS should be defined and validated to identify and minimize interferences and sources of contamination.

CHM.21400 Controls/Calibrators/Blanks **Phase I**

Controls, calibrators and blanks are matrix-matched to the sample type.

NOTE: The matrices of controls, calibrators and blanks may affect the ions generated and should be considered in the design and validation of each ICP/MS assay. If matrices are not an issue, the laboratory should have a record that matrix-matching is not necessary.

IMAGING MASS SPECTROMETRY

Imaging Mass Spectrometry (IMS) is an emerging technology used to provide molecular information on tissue section specimens through visualization of the spatial distribution of proteins, lipids and other molecules by their molecular masses. It is used in conjunction with other pathology findings to make a tissue diagnosis or provide other information on the tissue specimen.

IMS combines the following methods to evaluate the tissues:
- *Whole slide imaging*
- *Matrix-assisted laser desorption ionization mass spectrometry (MALDI MS)*
- *Individual molecular mapping of a tissue*
- *Data analysis process*

This checklist section is not applicable to use of MS imaging for education or research-only use.

Inspector Instructions:

READ

- Sampling of imaging Mass Spectrometry policies and procedures
- Sampling of calibration and maintenance records
- Sampling of quality control records

CHM.21405 Instrument Calibration **Phase II**