

There are records of daily evaluation of the performance of GC columns, auto-injectors, detectors, and maintenance such as septum changes, column clipping, flow rates, etc. including corrective action if performance does not meet requirements.

Evidence of Compliance:

- ✓ Records of evaluation of instrument performance **AND**
- ✓ Records of instrument maintenance when performance exceeds defined limits

FDT.23930 Gas Leakage Phase I



Gas lines and connections are checked for leaks every time tubing or a connection has been manipulated.

Evidence of Compliance:

- ✓ Records of gas line checks

FDT.24130 GC Records Phase II

Specimen run order, chromatographic peak shape, and retention time for calibrators, controls and unknowns are recorded and maintained for review.

FDT.24230 Analytical Data Phase I

The analytical data are presented to permit scientific review by the analyst of the data for calibrators, controls and unknowns.

FDT.24330 Carryover Detection Phase II



The laboratory has a process to detect and evaluate potential carryover.

NOTE: No matter what type of injection is used, the process must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis.

Evidence of Compliance:

- ✓ Records for reassessment of samples with potential carryover

FDT.24380 Reinjection/Reanalysis Phase II



The laboratory defines situations when reinjection or reanalysis are indicated.

MASS SPECTROMETRY (MS)

For requirements on inlet system coupled to the mass spectrometer, see the LC and GC sections

Inspector Instructions:



- Sampling of MS policies and procedures
- Identification criteria compliance