FDT.17430 QC Range Verification **Phase II**

For quantitative tests, a statistically valid target range has been established for each lot of control material by repetitive analysis in runs that include previously tested control materials.

Evidence of Compliance:

✓ Records of control range verification for each lot

FDT.17530 Pure Controlled Substances **Phase II**

If the laboratory uses chemicals (for standards, controls, etc.) covered by the Controlled Substances Act, the laboratory maintains appropriate licenses.

NOTE: The intent is to be compliant with national, federal, state (or provincial), and local laws and regulations.

For US laboratories, a DEA license, and in some states a State license, is required for controlled substances. A DEA license is not required for certain commercial solutions of controlled substances.

PROCEDURES AND TEST SYSTEMS

Inspector Instructions:

DISCOVER

- If problems are identified during the review of the methods and instrument systems, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions
- Select a representative assay and follow the entire process from specimen receipt to final result reporting
- Inspect instruments and equipment using requirements found in both the Forensic Drug Testing (FDT) Checklist as well as the All Common (COM) Checklist. The FDT Checklist contains items that are method-specific, whereas the COM Checklist contains requirements that apply broadly to all types of instruments and equipment (eg, maintenance, function checks, records availability). If deficiencies are identified, cite the specific requirement that reflects the issue observed.

METHOD PERFORMANCE VALIDATION

The laboratory must validate all analytical methods. All current screening and confirmatory analytical methods for drugs must have method performance validation data on file and available for review.

Inspector Instructions:

READ

- Initial validation and method validation evaluation policy and procedure
- Method validation records