

SECURE DATA INTEGRITY = EASY COMPLIANCE

Ensure complete, consistent, and accurate data according to ALCOA+ principles. Ease of compliance comes from having a centralized location for user management, instrument configuration, and report generation. No need to have each Airborne Particle Counter (APC) operate as an independent system like other APCs that claim FDA 21 CFR Part 11 compliance. TSI AeroTrak® Portable APCs can be configured to operate in Data Integrity (DI) Mode. Working with TSI TrakPro™ Lite Secure (TPLS) software that is supplied as standard and is designed for Part 11 compliance, DI Mode is a complete, secure data integrity solution.



TSI AeroTrak Portable APCs in DI Mode

Attributable

- + All users managed in one location (TPLS)
- + User roles defined by the user

Legible

- + No thermal printouts
- + Records stored in an easy to read, enduring format (paper or PDF)

Contemporaneous

- All metadata attached to record at time of sampling

Original or True Copy

- Minimizes risk of having multiple copies of same record that could result in conflicting records

Accurate

- Must select location prior to sampling - prevents having the wrong location associated with a result

Complete

- + Operator cannot delete or edit a record during sampling
- + Records created for all samples, even those that were aborted

Consistent

- Metadata automatically recorded with date/time stamps

Enduring

- Relies on users established system for data storage

Available

- + Sample records stored in user document system and not on the instrument
- + One audit trail maintained in TPLS

Major Advantage

Variable Advantage
Depends on APC and user procedures

Disadvantages

Other APCs that claim Part II Compliance

Attributable

- + Users must be managed on all instruments
- + Users limited to predefined user roles

Legible

- + Thermal printouts become illegible
- + Records may be stored in a format which requires special software to read

Contemporaneous

- All metadata attached to record at time of sampling

Original or True Copy

- Records often reside in multiple locations thus risking the creation of conflicting records

Accurate

- No prompt to select a location before taking each sample may result in an inaccurate record

Complete

- + Some may allow operators to delete records
- + May not create a record for aborted samples

Consistent

- Metadata automatically recorded with date/time stamps

Enduring

- Limited storage if utilizing record storage on instrument

Available

- Sample records and audit trails remain on each instrument—all instruments need to be available to access

Major Disadvantage

Variable Disadvantage
Depends on APC and user procedures