21CFR 11 Requirements for ATC Software

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ATC • *AdvancedTechnologyConsortium*

Providing support in quality assurance and data management for radiation therapy clinical trials

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- Standard Operating Procedures
  - Policies and practices to maintain data integrity and security
- Software Validation
  - Methodology for functional specification, implementation, testing of changes to database
  - Test data sets, plan, execution, results
- Auditing
  - Process for auditing data
  - Audit Trail
- Risk Assessment
  - Backup, network security, disaster recovery