



Position Paper

RamanSoft v. 2.0

&

21 CFR Part 11 Compliance

Validation

I. Explain your validation plan:

1. Is a Certificate of Validation provided for your software?

Yes, a 2-page certificate of validation detailing the entire software development life cycle (SDLC) process followed and the corresponding documents maintained at Lambda Solutions is included in the Validation Manual for RamanSoft.

2. Will you provide us a Checklist of Compliance Testing Matrix you used on your system?

All validation documents at Lambda Solutions are available for audits by our customers.

3. Is a Validation script for use in our validation provided by you?

IQ, OQ, and PQ documents are provided as part of our on-site validation service.

4. Who performs the validation for our system implementation?

We offer on-site validation services and perform and document all IQ and OQ activities per written protocols. We also offer to assist in the execution of PQ protocols.

5. Do you have any validation recommendations?

Yes, we have written IQ, OQ, and PQ procedures and worksheets for documenting all on-site validation activities.

6. What happens if deficiencies are discovered during our validation?

Lambda Solutions will correct all deficiencies discovered during the validation process. Lambda Solutions maintains a formal configuration management system as an integral part of its quality system.

II. 21 CFR Part 11 compliant?

1. Are they compliant and what does that mean to us?

Yes we have addressed the requirements of 21 CFR Part 11 regulation. Throughout the system, the concept of electronic signature is implemented. A combination of multi-level security system and a detailed audit trail is implemented to address the requirements of this regulation related to the electronic records.

III. Does your software have these Key elements for a validated electronic signature/records environment?

1. Adequate security measures

- **2 components – ID and password** (Yes)
- **Disablement of user after certain number of failed logon attempts** (Yes)
- **Additional login required for access to security administrative features** (Yes)
- **Automatic lockout when software is idle for certain amount of time** (Yes)
- **User voluntary lockout at any time when the software is left unattended** (Yes)
- **Forgotten passwords** (Yes. Computer administrator can reset forgotten passwords)
- **Alarm/reminder to change password** (Yes. Through recommended operating procedures).

2. Verification of critical data entries

Enforced date, pull down lists, field value conditions, etc. are utilized for such verification.

3. Installation and operational qualifications performed (testing critical functions)

The system has gone through all such testing at Lambda Solutions. On-site IQ and OQ services are offered by Lambda Solutions. Lambda Solutions assists in the execution of PQ protocols.

4. Configuration management and system maintenance

Each released system is configuration controlled. Annual maintenance contract assures that the system is kept in compliance with the latest regulations. All upgrades and the corresponding data compatibility are documented. Lambda Solutions maintains files on the system version and its status for each of its customer's system.

5. Signature logs and meanings of approval signatures defined

- **Printed name of signer** (Yes)
- **Time and date stamp** (Yes, local and GMT)
- **Meaning of signature (Approval)** (Yes)

6. Periodic re-evaluation of performance

All system changes, including customization, upgrades, and platform changes are fully validated and documented.

7. Efficient and accurate retrieval of records

All data saving and retrieval functions are documented and validated.

IV. What, if any, are the implications of upgrades, fixes, new boards or new service packs. Are they tested beforehand to assure no problems with other parts of the software?

All system changes, including customization, upgrades, and platform changes are fully validated and documented.

V. If there is a system failure, how are data recovered?

Nightly backup is strongly recommended so that in the worst case situation the data can be restored to the previous day's status. Several other provisions, described below, are designed to recover up-to-the-second data in the event of a system failure.

- **Mirror drive**

All data are saved simultaneously in the hard drive and its mirror drive. In case of the hard drive failure, the mirror drive continues the data saving activities.

- **Is there a controlled shutdown**

MS Windows standard command for terminating an application results in the controlled shutdown of this application in the event of a system freeze.

- **Extent of support**

Over-the-phone and e-mail based support is included in the maintenance contract. System file corruption and recovery is treated as a high priority item and generally addressed and resolved the same day. On-site service for a fee is offered, but is rarely needed.

- **Virus protection**

The system is delivered on a CD and undergoes a thorough virus scan as part of the final system release process. Any e-mailed or downloadable file from our site is similarly protected.