

Conformance of SQCPack to Code of Federal Regulations, 21 CFR 11.1

If an organization has determined that 21 CFR 11.1 is applicable to the maintenance quality data/chart records, PQ Systems, Inc., recommends that users of *SQCPack* 6.5 (and above) implement the following steps to ensure compliance. In order to be compliant with 21 CFR 11.1, the *SQCPack* user needs to do the following:

1. Use *SQCPack* and enable security to require User Login.
2. Limit user access to *SQCPack* databases using user rights supplied with your Operating System.
3. Set the computer to time-out after a specified time interval when no action has occurred. A password should be required in order to get back in. Setting passwords is also a function of the Operating System.
4. Enable Auditing. Additional security provisions that are offered by the *SQCPack* software to meet the requirements of the Code include the following:

A. **Electronic signature:** *SQCPack* may be set to require an individual login with a unique, current password (using User Login required). Only a supervisor can create and delete users, although this right can be extended to other designees. Using User Login, a login name cannot be re-used. The supervisor can globally designate the period of time for which a particular password can be used without changing it.

B. **Auditing:** In the current version of the software, an auditing feature can be activated to record the identities of all who sign in, as well as all their activities after sign-in. Each activity has Date, Event type, User, ID, ID2, Name, and Reason. These fields are automatically filled with the identity of the individual signed in. The Reason field can be set to require for various actions such as when records are modified or deleted.

C. **Access:** A user's access rights can be limited by means of the User Access Form, completed at the time the user's identity is created. (A user's access rights can be modified at a later date by an individual with appropriate rights.) In general, users may be given permission to add, edit, or delete groups and data. Permission to access other activities can be restricted. Access rights can be limited to as little as View and Print Reports.

D. **Data entry:** Using choice list options, data entry can be set so the user can be required to match an item on the corresponding choice list.

