

Healthcare and Pharmaceutical Label Printing

White Paper

Tools for 21 CFR Part 11 Compliance

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1 Regulation Description

In March 1997, the Food & Drug Administration (FDA) issued the final Part 11 regulations providing FDA acceptance criteria when under certain circumstances electronic records, electronic signatures, and handwritten signatures executed to electronic records are equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, are intended to permit the widest possible use of electronic technology compatible with FDA's responsibility to protect the public health.

In March 2004, the FDA released its final rule requiring bar codes on drug and biological products. With improved bar code tracking, the FDA hopes to reduce the number of preventable medication errors and reduce the cost of healthcare.

The final rule applies to most drug manufacturers, re-packers, re-labelers, private label distributors and blood establishments. Starting April 26, new medications covered by the rule will have to include bar codes within 60 days of their approval; most previously approved medicines and all blood and blood products will have to comply within two years.

This white paper introduces some of the FDA regulation 21 CFR (Code of Federal Regulation) Part 11 and discusses how NiceLabel enables you to meet these requirements.

Requirements

Any organization governed by the FDA can use NiceLabel to comply with the following areas stated in the FDA regulation 21 CFR Part 11:

- Electronic Signatures
- Audit Trail for Printing
- Audit Trail for Documents
- Approval (Record Signing)

1.1 Electronic Signatures

FDA regulation 21 CFR Part 11 concerns pharmaceutical manufacturers because it governs the agency's acceptance of electronic records as authentic and electronic signatures as legally binding. The scope of the ruling is wide: Part 11 applies to all electronic signatures and records that are submitted to the FDA or in response to FDA requirements and to all such submissions throughout the FDA-regulated industry. According to the FDA requirements, each electronic signature should have a unique user ID and password combination. In addition, only authorized users may modify format files.

NiceLabel addresses these requirements with the following features:

- **Secure Access for Label Design**
The system security feature allows you to restrict users to certain features of the program. You can set up system security by assigning a user ID and password and then selecting the tasks the user may perform.
- **Manage Variable Data**
The Pick List data source allows you to specify a list of valid choices, so that at print time you can enter a value by selecting it from a list. You can limit user input to only items in the pick list to ensure valid entries, or allow other entries besides those on the list.

- **Clear After Print**
The Clear after Print option automatically clears variable values after a label prints. This feature eliminates the risk of retaining variable values between print jobs.

1.2 Audit Trail for Printing

Regulation 21 CFR Part 11 requires any organization governed by the FDA to track their authentic and electronic signatures. The 'Audit Trail of Printing' requirement refers to the logging of printed activities. FDA requires organizations to create tracking reports stating the following: Job ID (label name), operator name, date/time, and quantity in batch. Other data is optional.

NiceLabel addresses this requirement with the following feature:

- **Audit Trail Option**
Logging When you enable logging, NiceLabel generates reports that record the label formats being printed and the content of specific fields that you have set to be logged. With logging enabled, a report (NICELABEL.LOG) is generated every time you print labels. Reports are stored as text files that can be viewed and imported into databases or other reporting applications.

1.3 Audit Trail for Documents

Regulation 21 CFR Part 11 also requires 'Audit Trail' in the form of a 'Revision Historical Log' which is a form of data storage that holds historical document information about changes made and includes document information like user name, date/time, revision number, etc.

NiceLabel addresses this requirement with the following feature:

- **Label Security**
The Label Setup Password tab allows you to set up passwords to control access to specific labels in contrast to the main system security password settings which control access to the program itself. Use of this feature is optional and is specific to each label. Whenever a password-protected label is called up, the user will be prompted to enter a password before the label is displayed.

1.4 Approval (Records Signing)

FDA regulations require that all labels undergo some form of approval process before they are printed.

NiceLabel addresses this requirement with the following feature:

- **Approval Process**
Combination of log in protection and label design locking in addition to file, folder, and user system rights of the Windows operating system.

See the appendix how to configure NiceLabel for US FDA Regulation 21 CFR Part 11 compliance.

2 NiceLabel Identification Options

NiceLabel offers the industry's widest range of identification options to comply with FDA standards and regulations. Regardless of the ideal methodology, NiceLabel will output Bar Codes, RF Tags and InfoGlyph Secure Glyphs.

Bar Codes

NiceLabel products provide support for all industry-standard bar codes, including 2-D. With multiple options for check-digit calculation, NiceLabel supports any possible requirement.

Users are often confronted with particular customer- or industry-specific (chemical, automotive, etc.) compliance requirements. NiceLabel provides pre-designed templates and performs automatic bar code validation control. Thanks to leading support for all the latest automatic identification standards and emerging radio frequency tags, NiceLabel addresses all current or future compliance issues.

RFID

As a radio technology, RFID requires no line-of-sight between the reader and the tag to exchange data. RFID tags can be read through packaging, including cardboard containers and plastic wrap. However, RFID is subject to interference, particularly from metal, which you should consider when you use RFID tags.

Because no line-of-sight is required, tagged objects can be read regardless of their orientation through the use of optimized RFID systems. Items don't have to be placed with the label side up onto conveyors if their tags should be read, which paves the way for unattended handling. If workers are used to place items on conveyors, they will be more productive if they don't have to locate and align labels when handling objects.

RFID readers can automatically recognize and differentiate all the RFID tags in their reading field. This simultaneous processing capability provides additional flexibility for material handling, packaging and sorting operations because there is no need to maintain spacing between objects to ensure they will be read. The ability to read dozens or even hundreds of tags per second makes RFID ideal for high-speed sorting, receiving, cross-docking and other applications.

The data capacity of RFID tags enables them to carry all the same information as bar codes and more. Just like bar code, RFID tags are available with different memory sizes and encoding options.

3 Summary

No vendor can claim that his or her software products are certified Part 11 compliant. However, a vendor can say that his or her product offers all of the technical control features for 21 CFR Part 11 compliance. Please remember, it is the responsibility of the organization governed by the FDA to implement FDA Regulation 21 CFR Part 11 correctly and consistently.

NiceLabel software helps healthcare organizations and their partners to comply with FDA Regulation 21 CFR Part 11. Using proper design techniques and tools make compliance easy with the following areas:

- Electronic Signatures
- Audit Trail for Printing
- Audit Trail for Documents
- Approval (Record Signing)

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4 Appendix

Configuration of NiceLabel for 21 CFR Part 11 Compliance

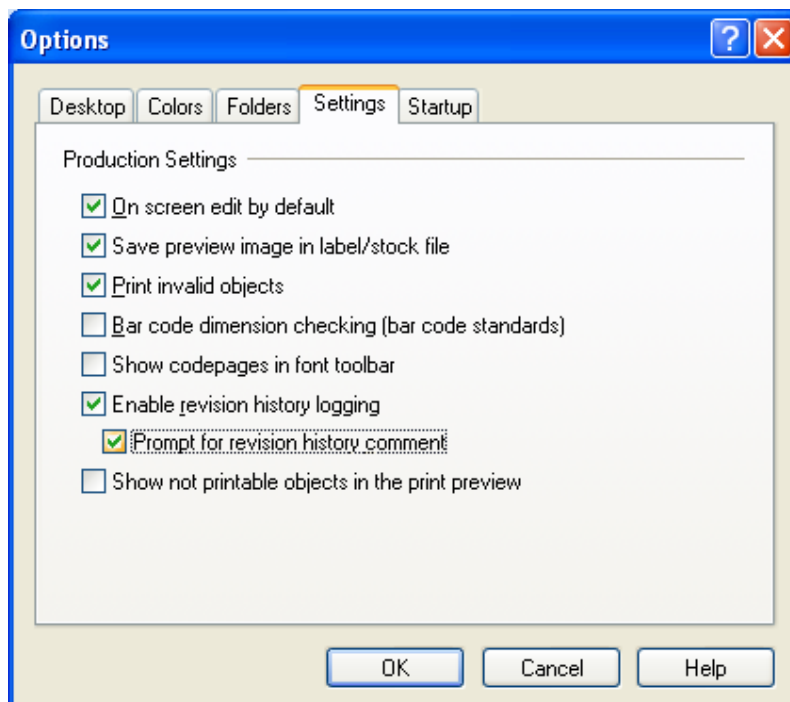
To meet the compliance requirements, use the following steps to configure NiceLabel Pro:

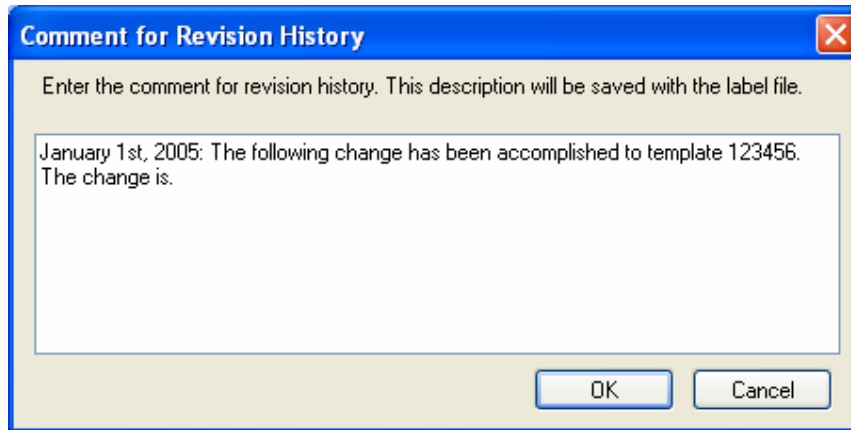
- Step I – Set up secured access for label design
- Step II – Configure security for variable data
- Step III – Save printed data to a log file

4.1 Step I – Set up secured access for label design

Label Specific Security

1. Choose **Options** from the **Tools** menu.
2. Click the **Settings** tab.
3. Check 'Enable revision history logging' and 'Prompt for revision history comment' to track who has edited and what has been edited from the label.

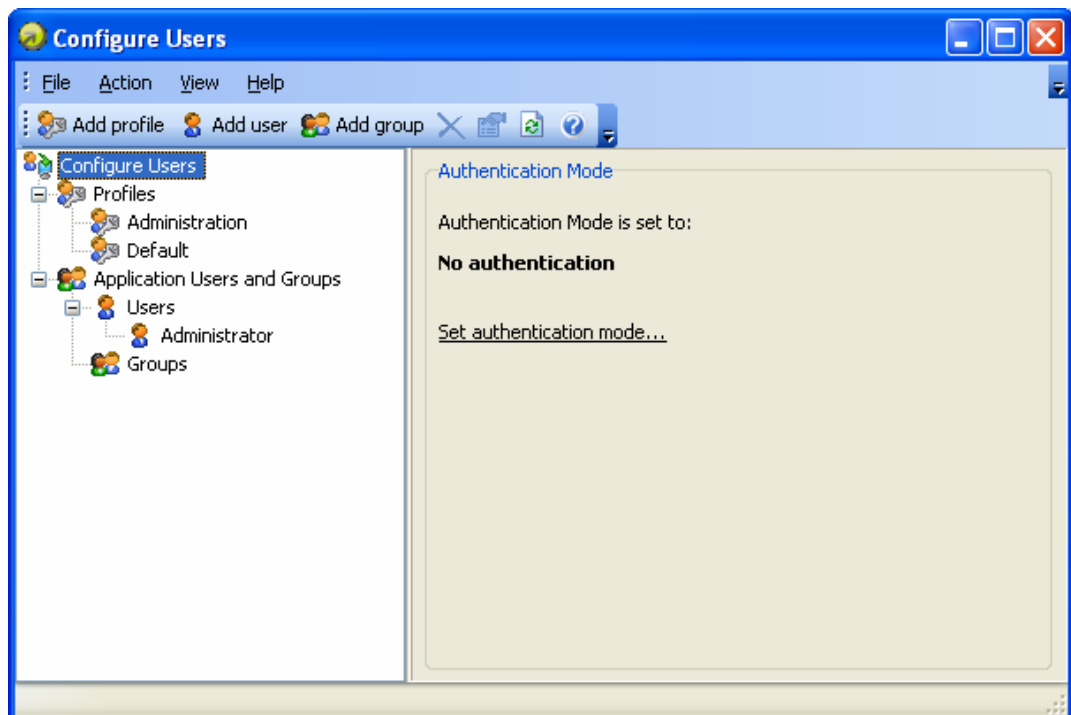




Note: Whenever you want to edit and print a label, you have to enter the revision description in the text field. Once you click the OK button, the information is saved and cannot be changed.

Global Security

1. Choose **Configure Users** from the **Tools** menu.
2. Click on the **Set authentication mode** to enable the user login.
3. Expand **Profiles** section then click on the Default profile.
4. Define the default login properties.
5. Expand **Application Users and Groups** section and then the **Users** section.
6. Right click on the Administrator user and change the password.



7. Click on the **Add user button** in the toolbar.
8. Add a username and password.
9. Click on the **Member Of** tab.
10. Select the appropriate user group to apply permissions from that group to the user.

The screenshot shows the 'Add User' dialog box with the following details:

- General Tab:**
 - User information:**
 - User name: Print Operator
 - Full name: John Doe
 - Description: Has printing permissions only
 - Password settings:**
 - Password: [Masked]
 - Confirm password: [Masked]
 - User must change password at next logon
 - User cannot change password
 - Password never expires
 - Days before password expires: 14
 - User is disabled

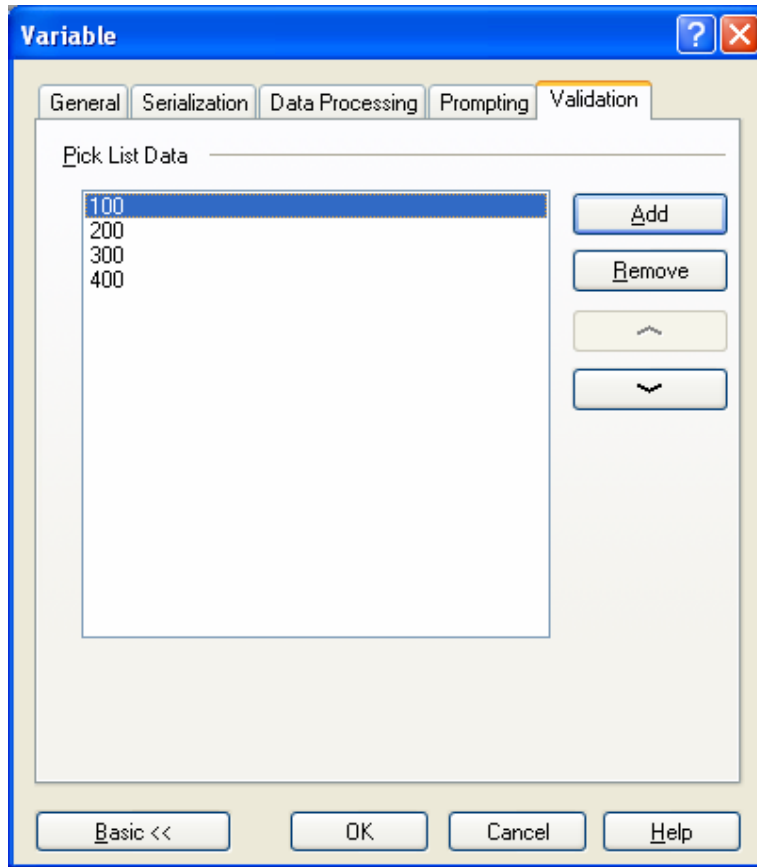
Note: To use NiceLabel all users will be required to log in. Only users who have been set up can perform functions in NiceLabel.

4.2 Step II – Configure security for variable data

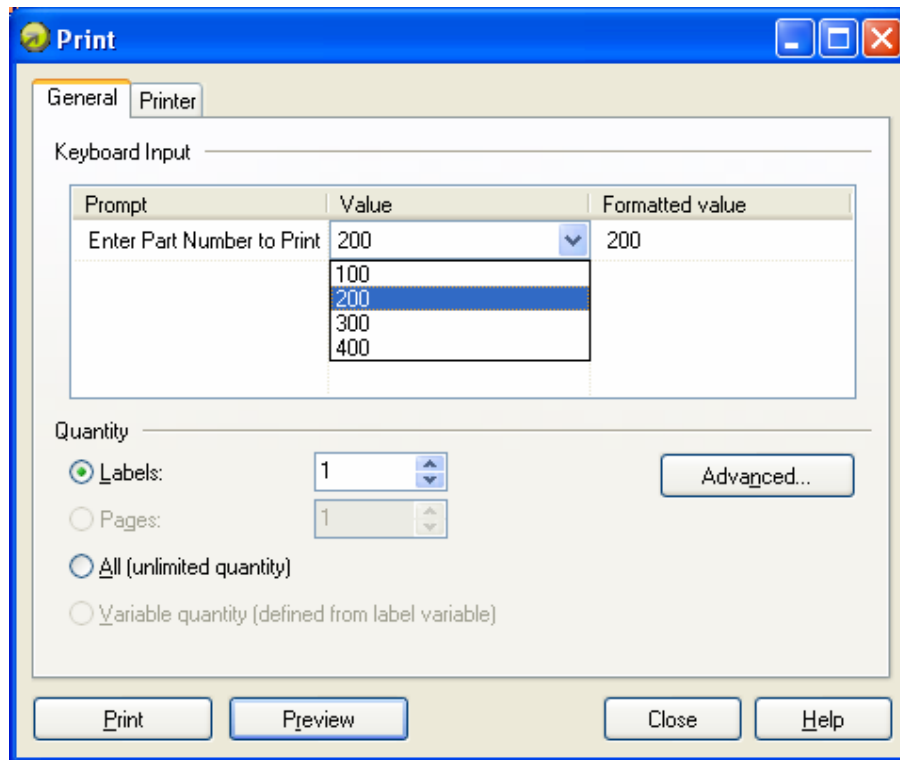
Pick list Fields

To create a standard **Variable** within NiceLabel, do the following:

1. Choose **Variable** from the **Data** menu.
2. Edit existing variable or create new variable.
3. From the Variable Properties, click on the **General** tab.
4. Select the source identified as **Pick List** from the dropdown menu.
5. Click on the **Validation** tab.
6. Enter the pick values.



Note: When you print the label, a prompt will appear asking you to select the part number you want to print. Only the values you entered above will be available from the drop down list. No other value will be available (see figure below).



Clear After Print

The value will automatically be cleared for the next print.

4.3 Step III – Save printed data to a log file

1. Choose **Configure Log File** from the Tools menu.
2. Check **Enable logging**.
3. Select the log file type.
4. Click on the **Advanced** tab.
5. Specify the location where the log files will be saved.

