

Healthcare and Pharmaceutical Label Printing

Tools for 21 CFR Part 11 Compliance

This applies to versions 7.x or greater of LABELVIEW Gold



LABELVIEW™ Gold label design software provides features to aid in the FDA's 21 CFR 11 compliance process. These software features can be configured to meet your internal requirements, as well as those of the FDA, to set up a compliant solution.

LABELVIEW Features:

Secure Access for Label Design

System Security

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.

Label Security

The Label Setup > Password tab allows you to set up passwords to control access to specific labels, unlike 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.

Manage Variable Data

Pick List

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.

Audit Trail Options

Logging

When you enable logging, LABELVIEW 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 (lblview.rpt) is generated every time you print labels. Reports are stored as text files that can be viewed and/or imported into databases or other reporting applications.

LABELVIEW Configuration Steps for 21 CFR Part 11 Compliance

Follow these three simple steps to configure LABELVIEW Gold to meet your compliance requirements:

Step I – Set up secured access for label design

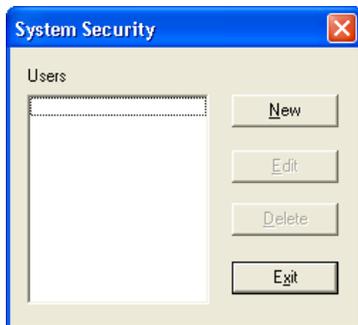
Step II – Configure security for variable data

Step III – Save printed data to a logfile

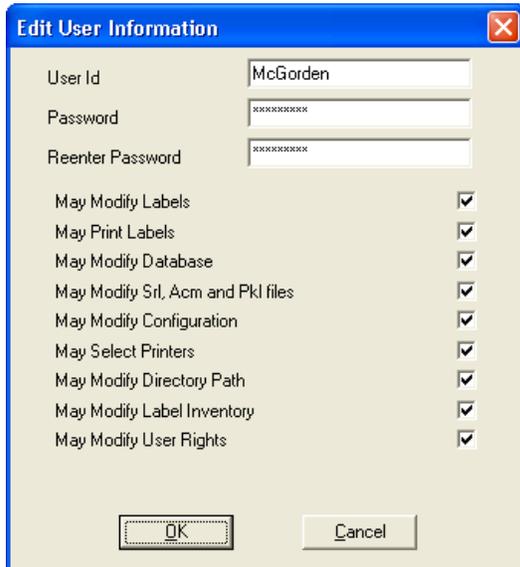
Step I – Set up secured access for label design

Global Security

1. Choose **Security** from the **Options** menu.
2. Click the **New** button.



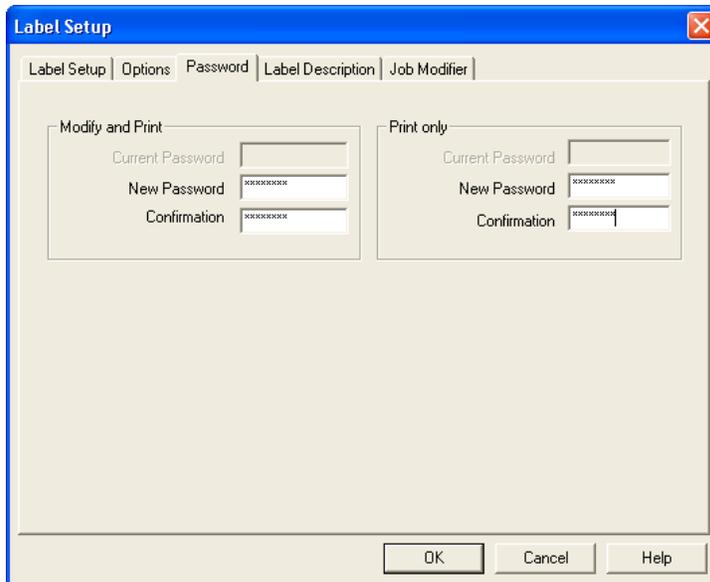
3. Add a username and password.
4. Check the appropriate boxes to enable each user's features.



Upon exiting LABELVIEW all users will be required to log in. Only users who have been set up can perform functions in LABELVIEW.

Label Specific Security

1. Choose **Label Setup** from the **Edit** menu.
2. Click the **Password** tab.



3. Here you can enter a password to control who may edit and who may print the label. This level of security precedes global security.

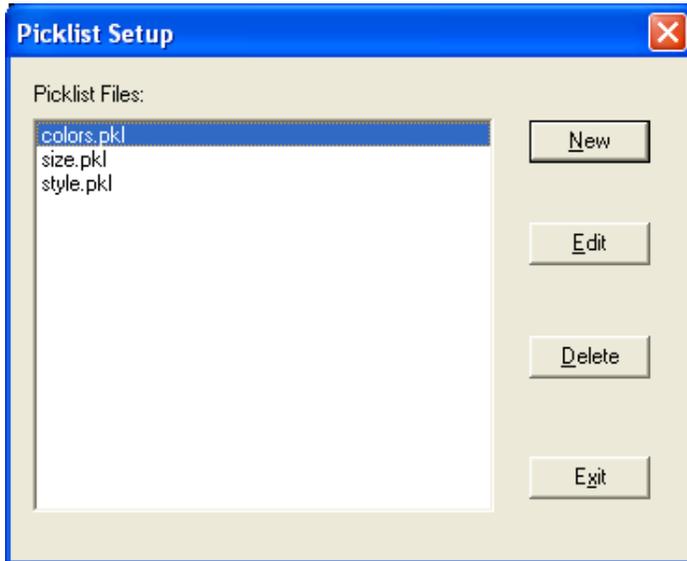
Step II - Configure security for variable data

Pick list Fields

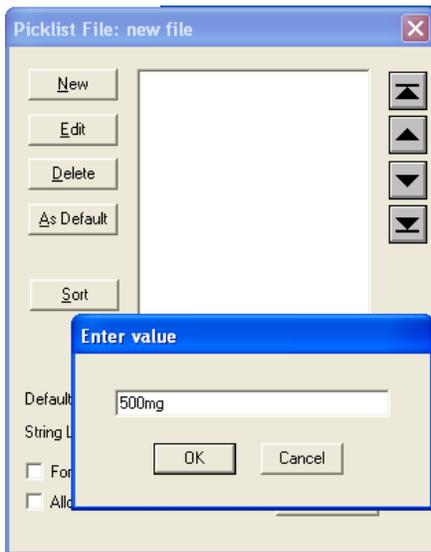
1. Select **Pick list Setup** from the **Options** menu.



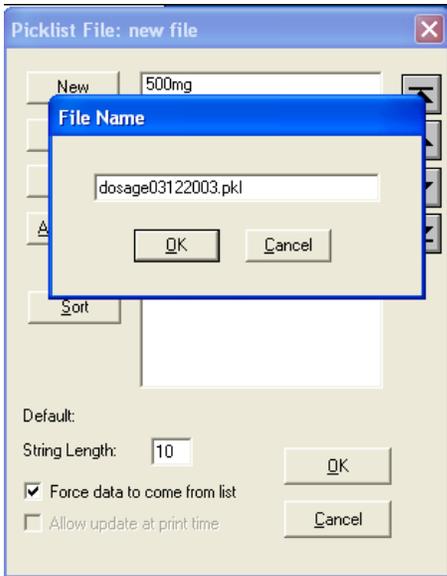
2. The Pick list Setup dialog box will open. Verify that the Pick list you wish to use is listed. If the Pick list is not listed, click **New**.



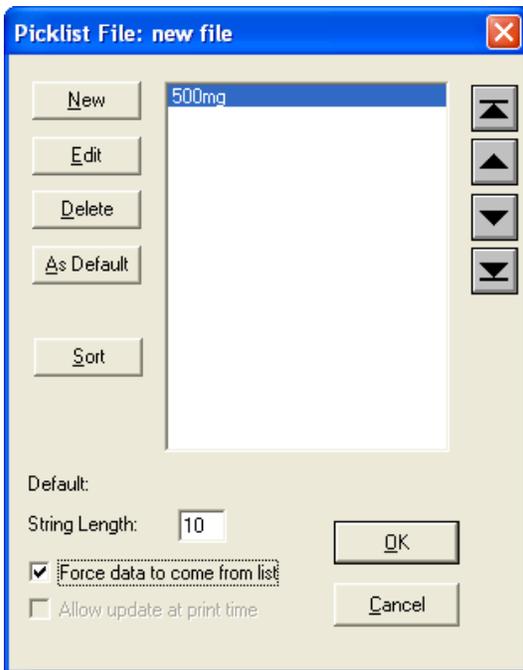
3. To add values to the new Pick list, click **New** and enter the values you wish to make available.



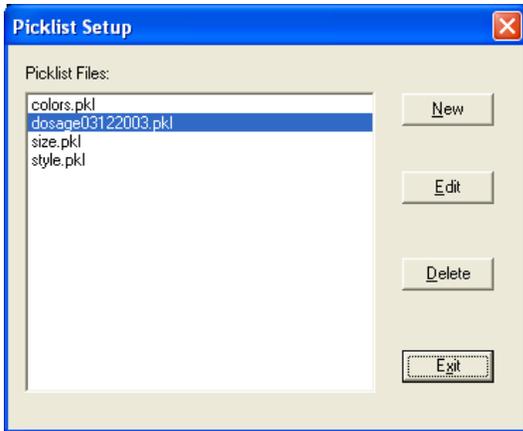
4. When you are finished entering values for the Pick list, click **OK**. Enter a filename for the Pick list you have created.



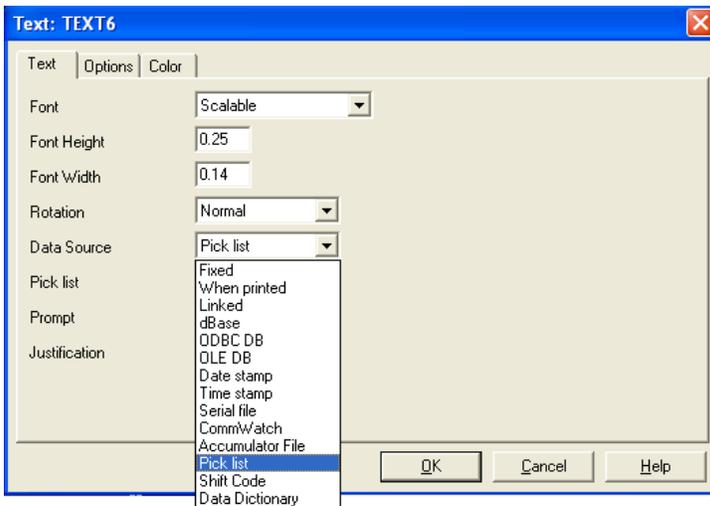
5. Click the **Force Data to Come From List** check box and click **OK** to exit the New Pick list dialog box.



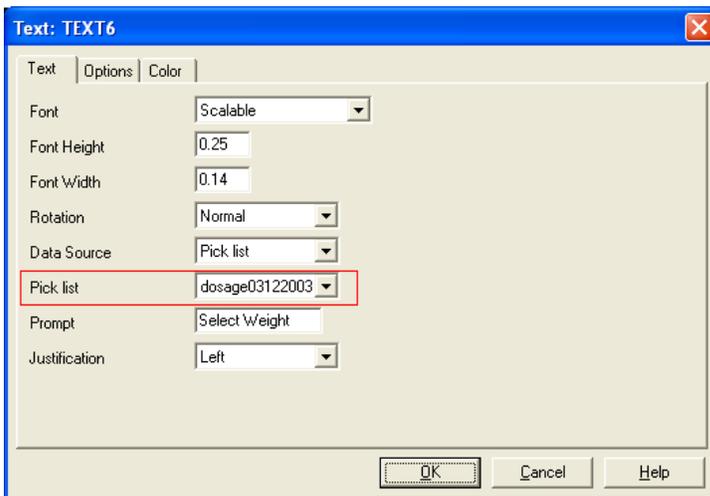
6. Click **Exit** to close the Pick list Setup dialog box.



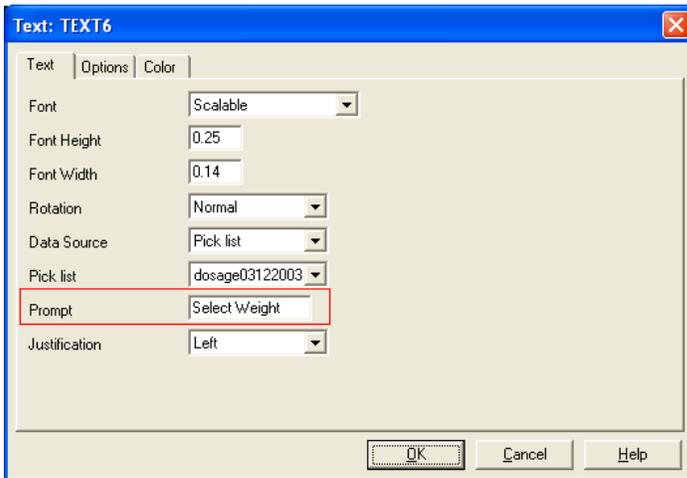
7. Double-click an existing text field or create a new text field on a label. In the properties dialog box, select the **Pick list** data source option.



8. Select the desired Pick list file in the **Pick list** drop-down list.



9. Enter the Prompt the user will see at print time



10. Click **OK** to exit the text field properties dialog box.

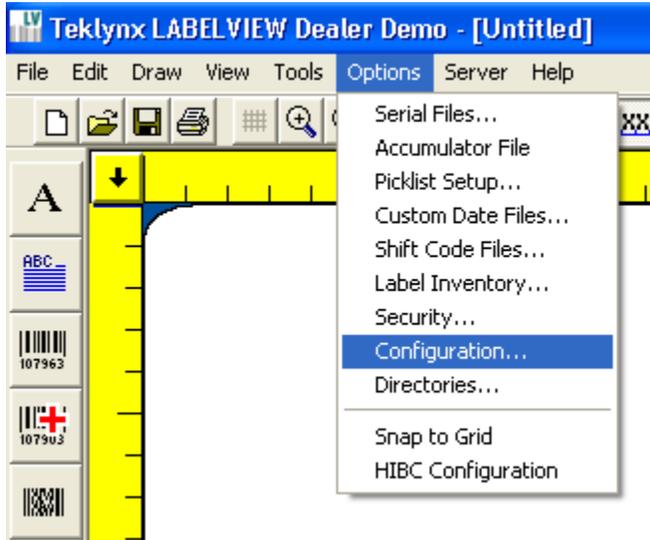
Clear After Print

1. Double-click on each When Printed, Pick list, and Database key field.
2. Click the **Options** tab and set the **Clear After Print** option to **Yes**..

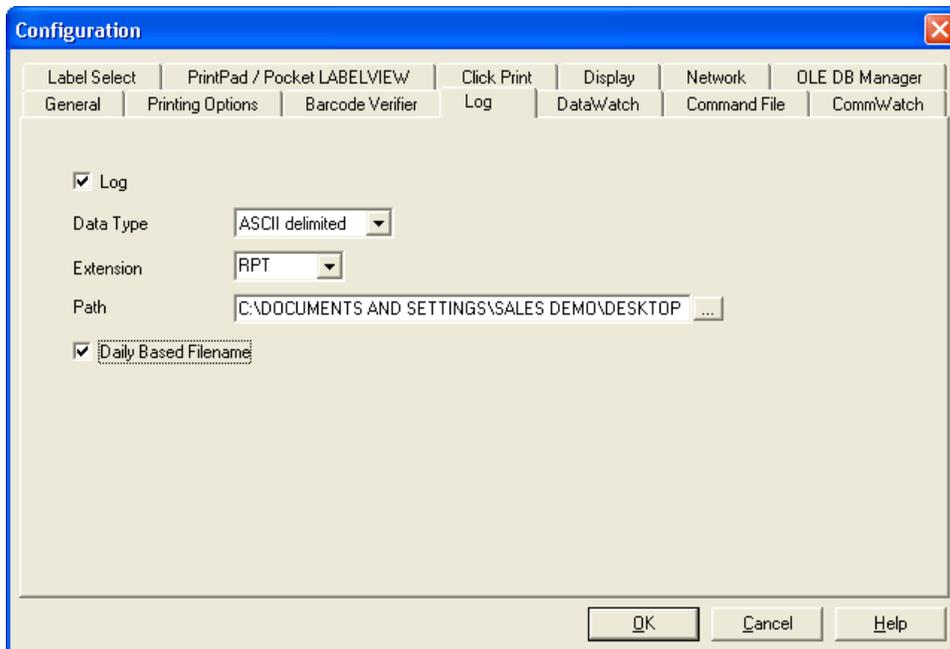


Step III - Save printed data to a logfile

1. Choose **Configuration** from the **Options** menu.



2. Click the **Log** tab and then click the **Log** check box.



3. Select the preferred data type.
4. Select the preferred log extension
5. Specify the location where the log files will be saved
6. Check the **Daily Based Filename** option to generate a log for each day of printing.

7. Open each label that requires logging.
8. Double-click each field that requires logging and set the **Log this Object** option to **Yes**.

The screenshot shows a dialog box titled "Text: TEXT1" with three tabs: "Text", "Options", and "Color". The "Options" tab is selected. The dialog contains the following settings:

- Increment:** 0
- Copies:** 1
- When Printed Options:**
 - Required: No
 - Must Fill: No
 - Clear After Print: Yes
- Field Name:** TEXT1
- Acm File:** none
- Reversed:** No
- Log this Object:** Yes
- Leading Zeros:** No
- Hidden:** No
- Custom Spacing:** (empty text box)

Buttons for "OK", "Cancel", and "Help" are located at the bottom of the dialog.

Summary

TEKLYNX software assists companies and its investigators in complying with 21 CFR Part 11. Using proper design techniques and tools can make compliance easier. This document is intended to make it easier for you to comply with any future FDA regulations on discovery using LABELVIEW.