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## Excel Spreadsheet Validation with Multiple Versions

Medical device manufacturers must validate computer software employed in device production or the Quality Management System (QMS). The requirement comes from 21 CFR §820.70(i) Automated Processes, “When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.”

A common situation occurs where a manufacturer must validate software in an Excel spreadsheet. The manufacturer develops a protocol that demonstrates the Excel spreadsheet performs the calculations correctly and that it can detect errors. Basically, the protocol demonstrates that the formulas calculate correctly. You are not demonstrating that the functions and features in Excel work, but, rather, that your use of them produces the desired result.

In other cases the spreadsheet may employ Data Validation to help detect incorrect entries and restrict entry of the wrong kind of data. All of these methods depend on the version of Excel, since it is the source of the functions and other capabilities.

As the versions of Excel change, a company may employ multiple versions at the same time. For example, an employee with a longer employment time may have the 2003 version, while a newer employee may have 2007 or 2010. This raises a potential issue when a spreadsheet validated in one version runs on another version.

### An Example

Consider, as a simple example, a spreadsheet used to track calibration due dates for inspection, test, and measuring equipment (IM&TE). Each piece of IM&TE is on a separate row. Enter the calibration due date in a cell and use Conditional formatting to change the cell color as follows:

- If the due date is before today, color the cell red;

- If the due date is up to (and including) 30 days after today, color the cell yellow;

- If the due date is more than 30 days after today, color the cell green.

Figure 1 is a simple example, for illustration, developed in Excel 2003. In addition to changing the cell colors, the conditional formatting also changes the text color to white in some cases to make it easier to read. In addition, the spreadsheet suppresses the gridlines to reduce the clutter.

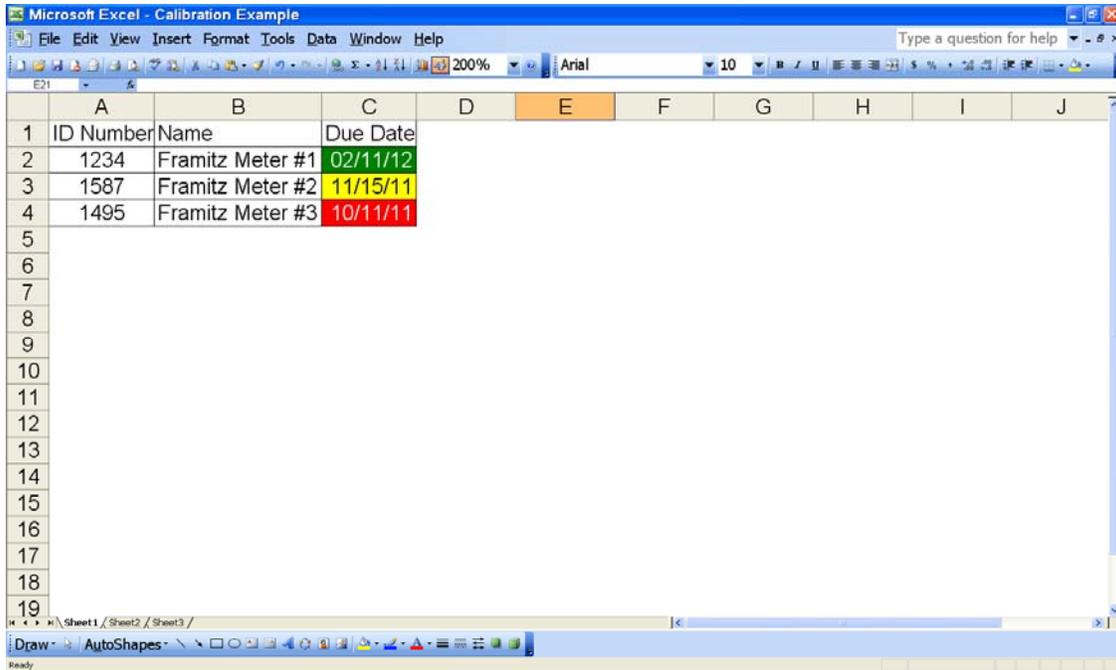


Figure 1 A Simple Example in Excel 2003

Figure 2 shows the Conditional formatting for Cell C2.

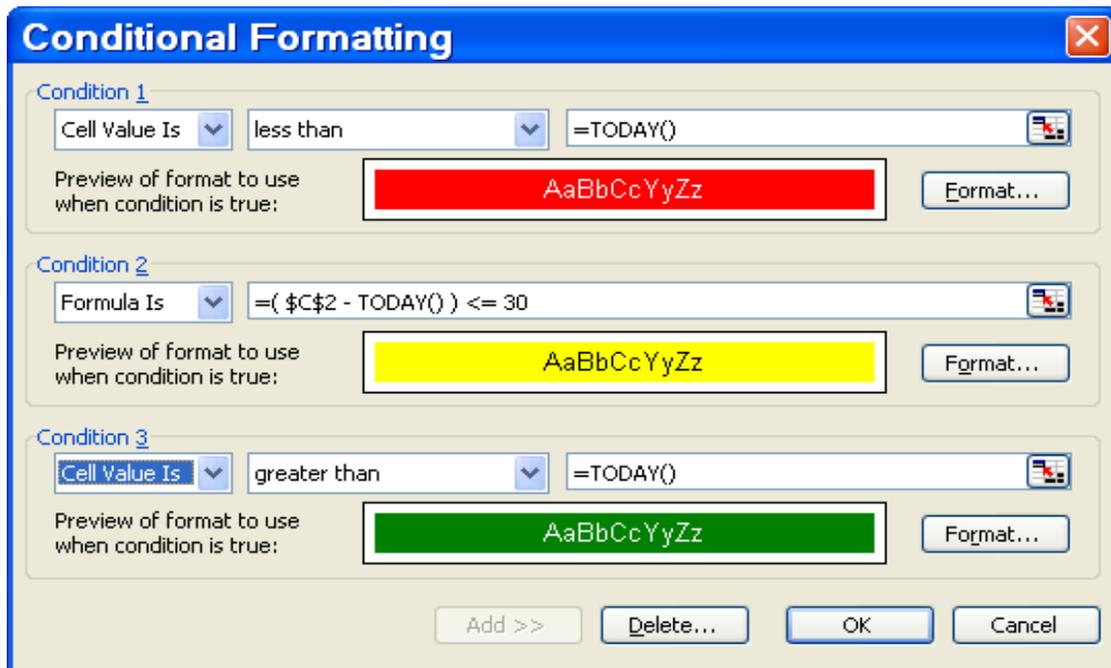


Figure 2 Conditional Formatting in Excel 2003

Importing this spreadsheet into Excel 2007, doesn't make any changes. The spreadsheet operates the same way. The options available in Conditional Formatting however are more extensive in Excel 2007 as shown in Figure 3.

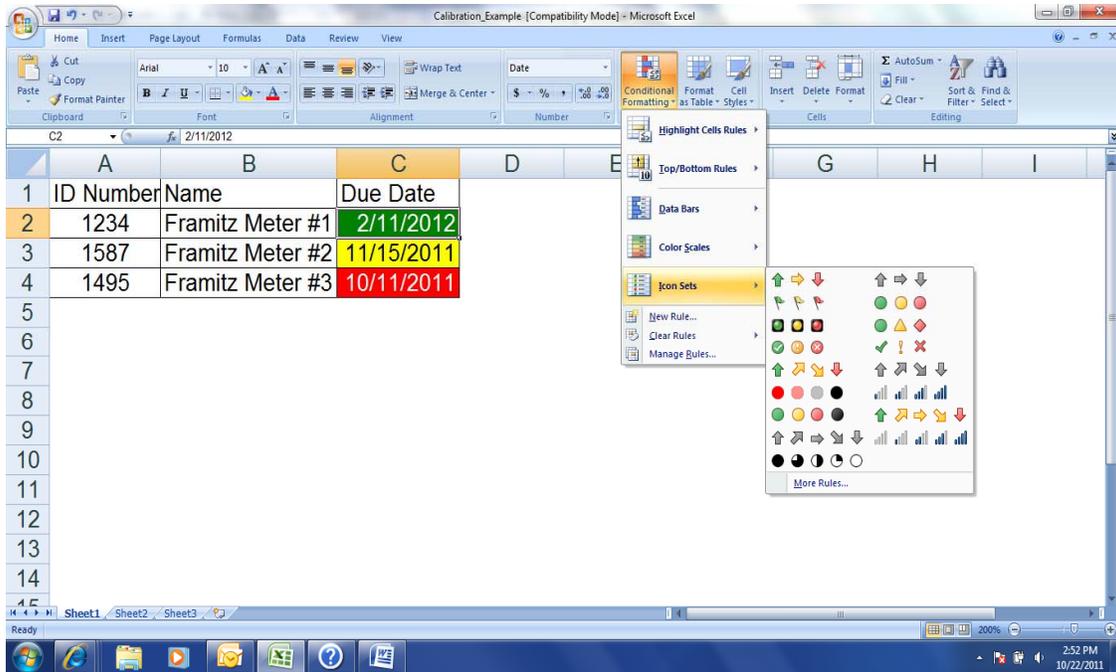


Figure 3 The Example in Excel 2007

The corresponding Conditional Formatting dialog box, for rules, is different, as shown in Figure 4, but the rules stay the same.

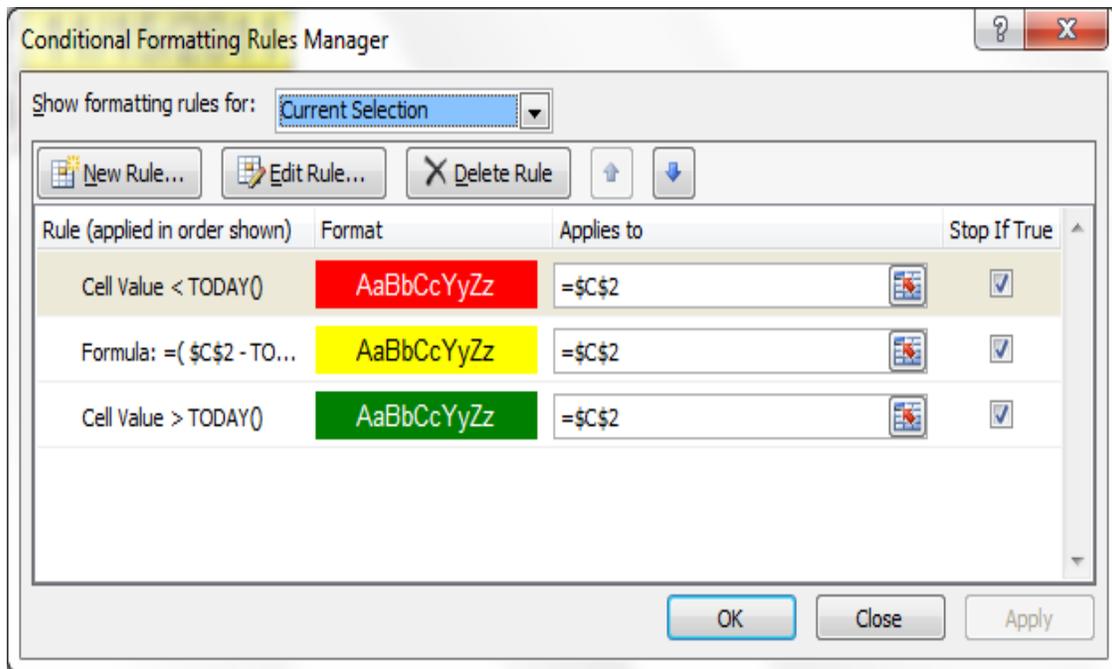


Figure 4 Conditional Formatting in Excel 2007

Excel 2003 allows only three conditions, but Excel 2007 allows sixty-four conditions. You can see that in Figure 2, the “ADD >>” is not available, because the example uses three rules. In Figure 3 the “New Rule ...” box is available; one could add more rules (up to sixty-four total).

In contrast, Excel 2007 has even more capabilities with new conditional formatting types that earlier versions don't support.

- Color scales
- Data bars
- Icon sets
- Top or bottom ranked values
- Above or below average values
- Unique or duplicate values
- Table column comparison to determine which cells to format

### **Compatibility Mode**

In Excel 2007, when you open a workbook created in an earlier version, Excel uses Compatibility Mode. The phrase "Compatibility Mode" shows in the square brackets next to the file name in the Excel title bar. In Compatibility Mode, any new or enhanced Excel 2007 features are not available to prevent loss of data and fidelity in an earlier of Excel.

### **The Recommendation**

If your company has multiple versions of Excel, develop and validate the spreadsheet in the "earlier" version, *i.e.*, use Excel 2003. If you apply the spreadsheet in a subsequent version, say Excel 2007, be sure to use Compatibility Mode.

Because of upward compatibility, an Excel 2003 will work in Excel 2007. However, the reverse is not true. Features from Excel 2007 may not be available in Excel 2003.

The prudent company would rerun any Excel 2003 based validations in Excel 2007. For a company with a large number of legacy Excel 2003 applications, this can be a larger task. For low risk applications, the manufacturer can rely on the upward compatibility. For higher risk applications, conduct another validation in the new version.

For applications developed and validated in Excel 2007, an Excel 2003 validation is essential. The functions and features are not backward compatible, so you must detect cases where the spreadsheet may not work. For example, the calibration spreadsheet, developed in Excel 2007 could have used an Icon Set instead of a cell color. You will not get satisfactory result in Excel 2003.