Excel Spreadsheets and FDA Device Regulations

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Outline

- Overview of the FDA regulations
- Excel Validation
- Using the Excel Convert Function
- Excel Formula Auditing
- Excel Protection
- Track Changes
- Automated Processes
- Electronic Records (Part 11)
- Summary & Conclusion
- Q&A session

Automated Processes for Production or the Quality System

Scope

The Requirements – 820.70(i)

The FDA Guidance Documents

Scope

- We are not looking at the purchase of a major software system
- We limit our scope to “homegrown” applications
  - A skilled employee builds an application in Excel
  - This is analogous to writing a procedure or work instruction
- The same principles apply if you contract the work
  - The manufacturer retains responsibility for validation and system performance

Our Examples

- We will use two simple examples
  - A manufacturer makes a chemical mixture, a buffer, used in an IVD reagent. The recipe, written in an SOP, has a variable quantity depending on production volume. The operator currently calculates the amount of each required component using a calculator. As a preventive action opportunity, a Manufacturing Engineer automates the calculation using a Excel spreadsheet.
  - A Quality Engineer automates the disposition information for nonconforming material. The Excel spreadsheet is the start of a system to track the frequency of dispositioned part numbers as part of the CAPA system statistical analysis. The information will also be used for Management Review.

The FDA Requirement

- 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.

The ISO 13485 Requirement

- Clause 7.5.2.1

  The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.

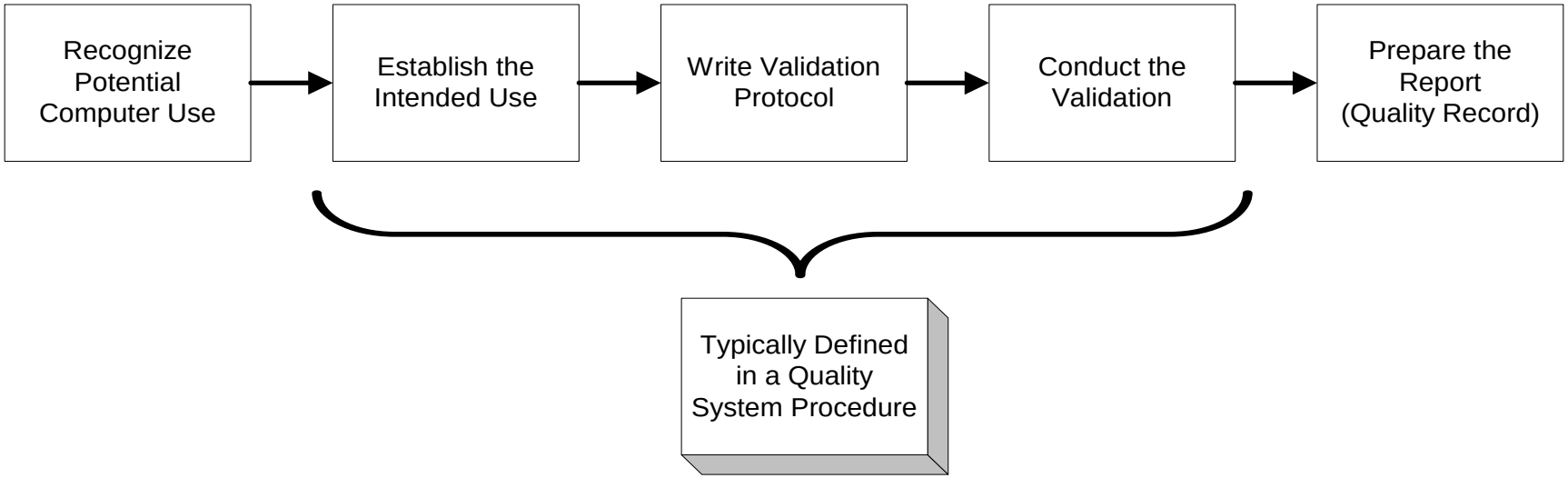
Parsing the FDA Requirements

- Application
  - Computers (or automated data processing systems) used as part of production
  - Computers (or automated data processing systems) used as part of the quality system
- What Needs to be Done
  - Validate computer software
  - For its intended use
  - According to an established protocol
- Performed by Whom?
  - The manufacturer

Parsing the FDA Requirements (Cont.)

- Records
  - The validation activities and results shall be documented.
- Change Control
  - Software changes shall be validated before approval and issuance.

Typical Process Flow Diagram



FDA Guidance Documents

- The Quality System Regulation appeared in the Federal Register on October 7, 1996
- The FDA issued *Medical Device Quality Systems Manual: A Small Entity Compliance Guide* in December 1996
  - Chapter 7 discusses the validation requirements for computers used in production or the quality system
- The FDA issued *General Principles of Software Validation* on January 11, 2002
  - Section 6 discusses the validation requirements for computers used in production or the quality system

Recognize Potential Computer Use

- Computers are so prevalent in our work environment, that we don't notice them
  - Consequently, we must be vigilant to recognize the use of computers in production or quality system
- Our examples are clear cases of automating a process by incorporating computers.
  - The first example (production chemical mix) converts from pencil, paper, and calculator to Excel.
  - The second example (CAPA tracking) is a conversion from a paper based system to an automated system providing information for management review.
- Recommendations
  - During review and approval of documents, look for new or revised computer applications
  - During internal quality audits, check for new or revised computer applications

Is the Spreadsheet an Electronic Record?

- Part 11 says, "*Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system."
- The guidance document says, "FDA considers part 11 to be applicable to . . . [r]ecords that are required to be maintained under predicate rules, that are maintained in electronic format *in addition to paper format*, and that *are relied on to perform regulated activities*."

Establish the Intended Use

- The software guidance document (section 6.2) lays out an approach to successful validation.
- Define:
  - The “intended use”
  - The extent of dependence for device production
- The dependence question should lead you to consider risk management

Establish the Intended Use (cont.)

- Define the expected operating environment
- Document the requirements for:
  - Performance, error handling, security, *etc*.
  - Safety functions (alarms, interlocks, *etc*.)
  - Acceptable performance, stated as objective criteria

Intended Use – Our Examples

Production Mixing

- Intended Use
  - Perform calculations for a chemical mix buffer incorporated into an IVD reagent
- Dependence for Device Production
  - Incorrect calculations can lead to an improper mix. A large error can impact the reagent
  - Risk: Medium

NCM Disposition

- Intended Use
  - Track disposition of nonconforming material for CAPA analysis
- Dependence for Device Production
  - Device production is not impacted by this software
  - Risk: Low

Write Validation Protocol

- Write the protocol
  - Write test cases that demonstrate the correct answer
    - Determine the correct answer in advance and where it will appear in the workbook
  - Write test cases that show what happens with incorrect data
    - Determine what can go wrong and how the workbook will handle the error.
  - Use the tools described in the next sections to build the workbook and develop the test cases
  - Use Formula Auditing (documented with screen shots) to demonstrate the inputs come from the expected cells

Conduct the Validation

- Perform the protocol
  - Run every test case (positive and negative)
  - Compare the expected results with the actual results
    - Note when they match and when they don't
  - Take screen shots for documentation
  - Turn on Track Changes and save the Change log

Prepare the Report

- Write a report showing that all the test cases (positive and negative) produced the expected results
  - Illustrate the report with screen shots
  - Put printed output into the report
  - Add the Change log as an Appendix to the report

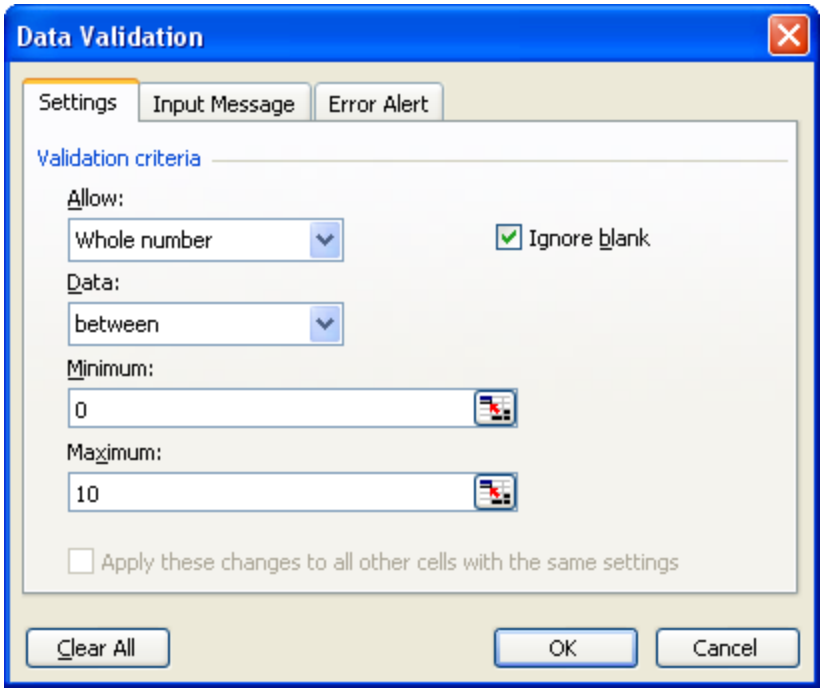
Excel Data Validation

Data Validation

- Most worksheets require the user to enter data for desired calculations and results, so ensuring valid data entry is very important.
- You can, for example, restrict data entry to:
  - a certain range of dates
  - limit choices to entries from a list you create
  - allow only positive whole numbers in a cell
- You can also create:
  - immediate help messages
  - messages when invalid data are entered

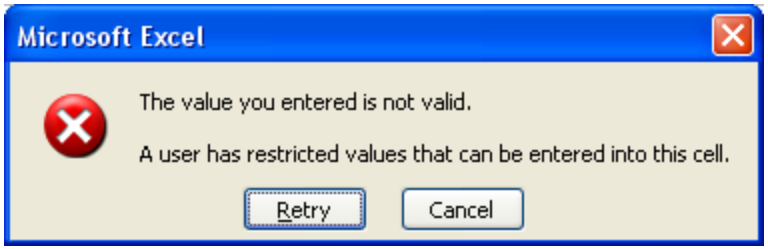
Setting Data Validation – Whole Number

- As an initial example, we want the value in cell B4 to be a whole number between 0 and 10.
  - Select Cell B4
  - Choose Data, Validation
  - Select the Settings tab
  - Select Whole Number from the Allow list and complete the entries as shown
  - Click OK



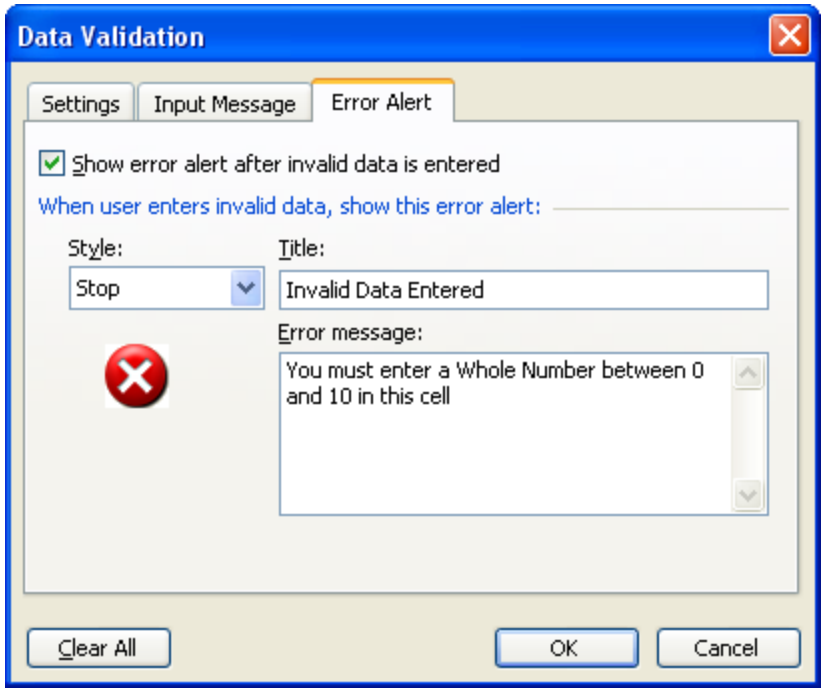
Setting Data Validation – Whole Number

- Now, enter some test values.
  - Enter 5 in Cell B4. The Spreadsheet will accept the value.
  - Enter 15 in Cell B4. You will get the message shown to the right.
  - Click Retry, and you can enter a new value.
  - Click Cancel and the prior value remains in the cell



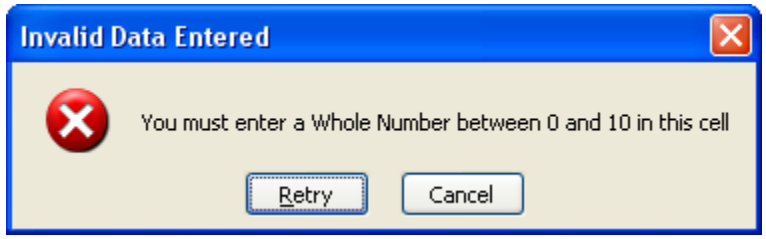
Setting Data Validation – Whole Number

- If you want a more specific error message, you can create it.
  - Select Cell B4
  - Choose Data, Validation
  - Select the Error Alert tab and complete the entries as shown
  - Click OK



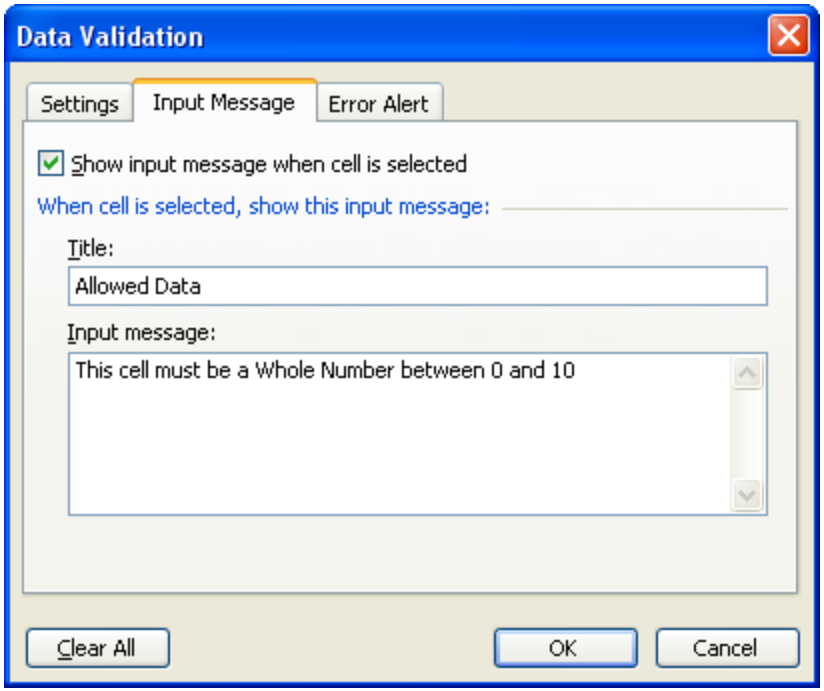
Setting Data Validation – Whole Number

- Now, enter some test values.
  - Enter 5 in Cell B4. The Spreadsheet will accept the value.
  - Enter 15 in Cell B4. You will get the message shown to the right – the new version we created
  - Click Retry, and you can enter a new value.
  - Click Cancel and the prior value remains in the cell



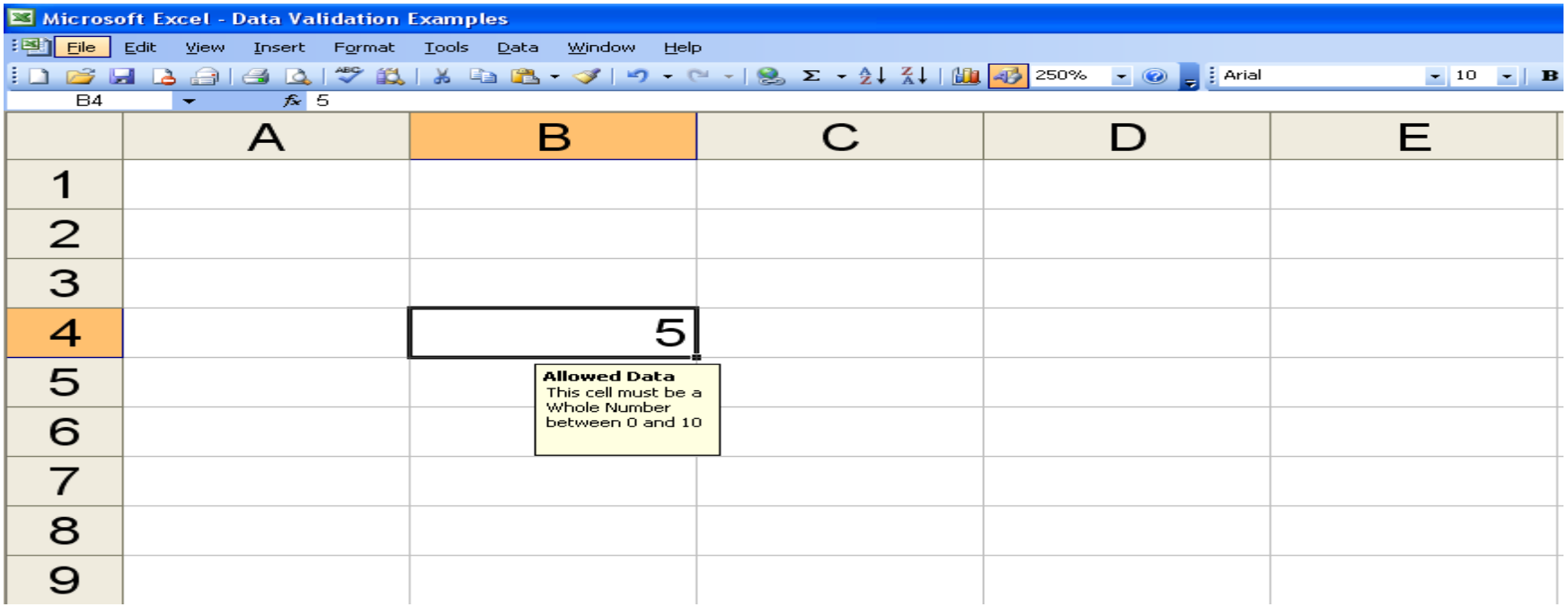
Setting Data Validation – Whole Number

- You can really helpful to your users by creating a prompt to describe the allowed data.
  - Select Cell B4
  - Choose Data, Validation
  - Select the Input Message tab and complete the entries as shown
  - Click OK



Setting Data Validation – Whole Number

- Try your new feature
  - Select Cell B4
  - You should see your new Input Message



Setting Data Validation

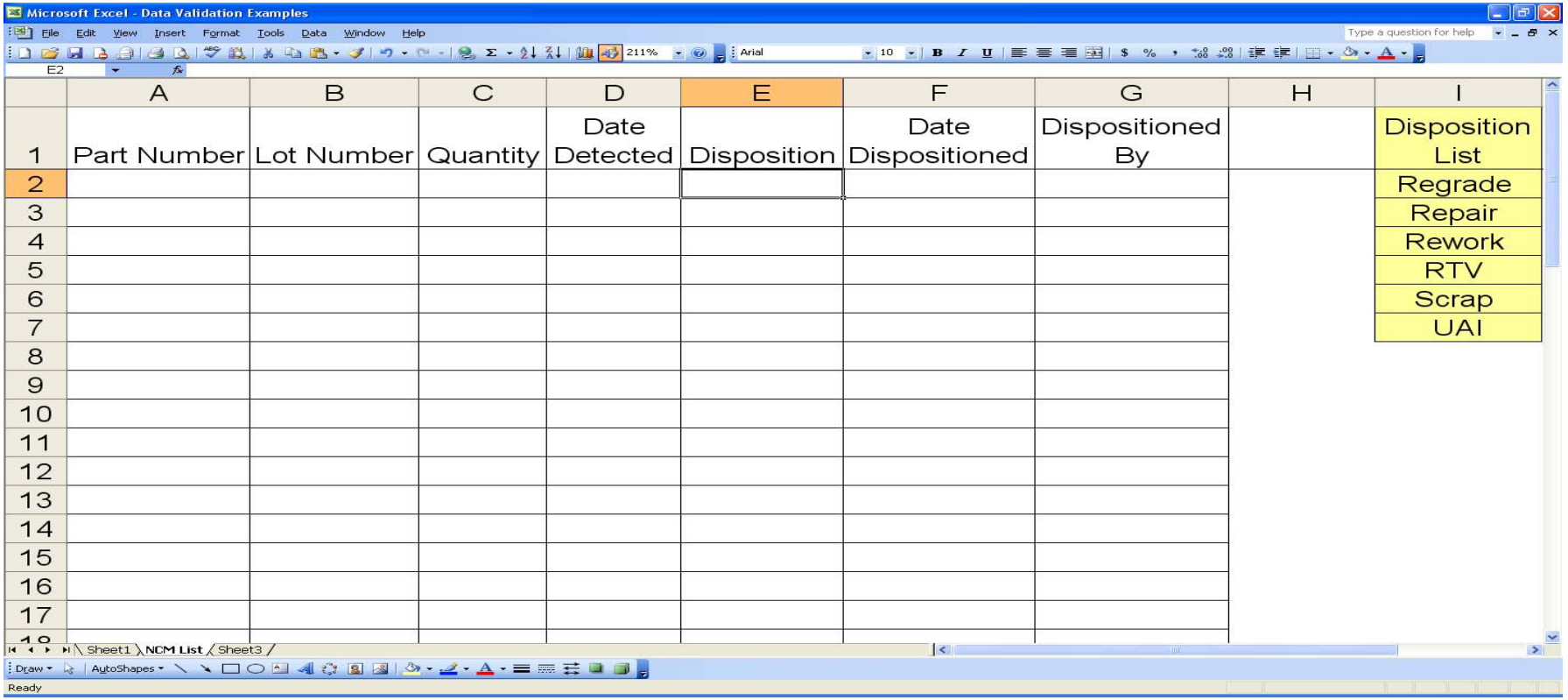
- The Data Validation dialog box, under the Setting tab, has a list of choices in the Allow list.
  - Any value
  - Whole number
  - Decimal
  - List
  - Date
  - Time
  - Text length
  - Custom
- We give examples of the List and Custom choices because they are particularly valuable

Setting Data Validation - List

- Assume we are setting up simple spread sheet to track the disposition of nonconforming material.
- We have column headings:
  - Part Number
  - Lot Number
  - Quantity
  - Date Detected
  - Disposition
  - Date Dispositioned
  - Dispositioned By
- We want to restrict the list of allowed dispositions so they match or QMS and are always entered the same way. Our list is:
  - Regrade
  - Repair
  - Rework
  - RTV
  - Scrap
  - UAI

Setting Data Validation - List

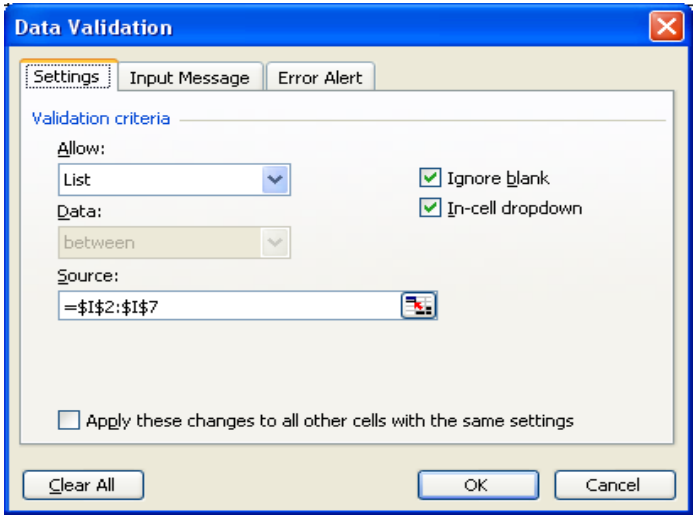
- Starting in Cell A1, enter the column headings – the last one is in Cell G1.
- We will need a list the possible dispositions, so we enter it into Cells I2 to I7. (I colored them for identification.)

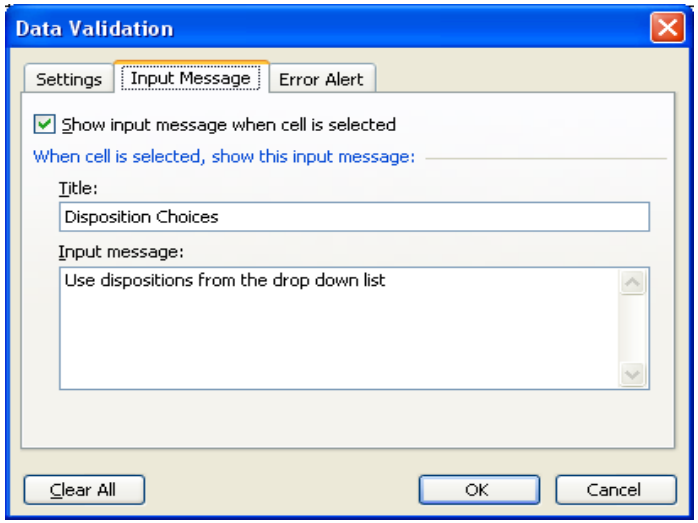


	A	B	C	D	E	F	G	H	I
1	Part Number	Lot Number	Quantity	Date Detected	Disposition	Date Dispositioned	Dispositioned By		Disposition List
2									Regrade
3									Repair
4									Rework
5									RTV
6									Scrap
7									UAI
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									

Setting Data Validation - List

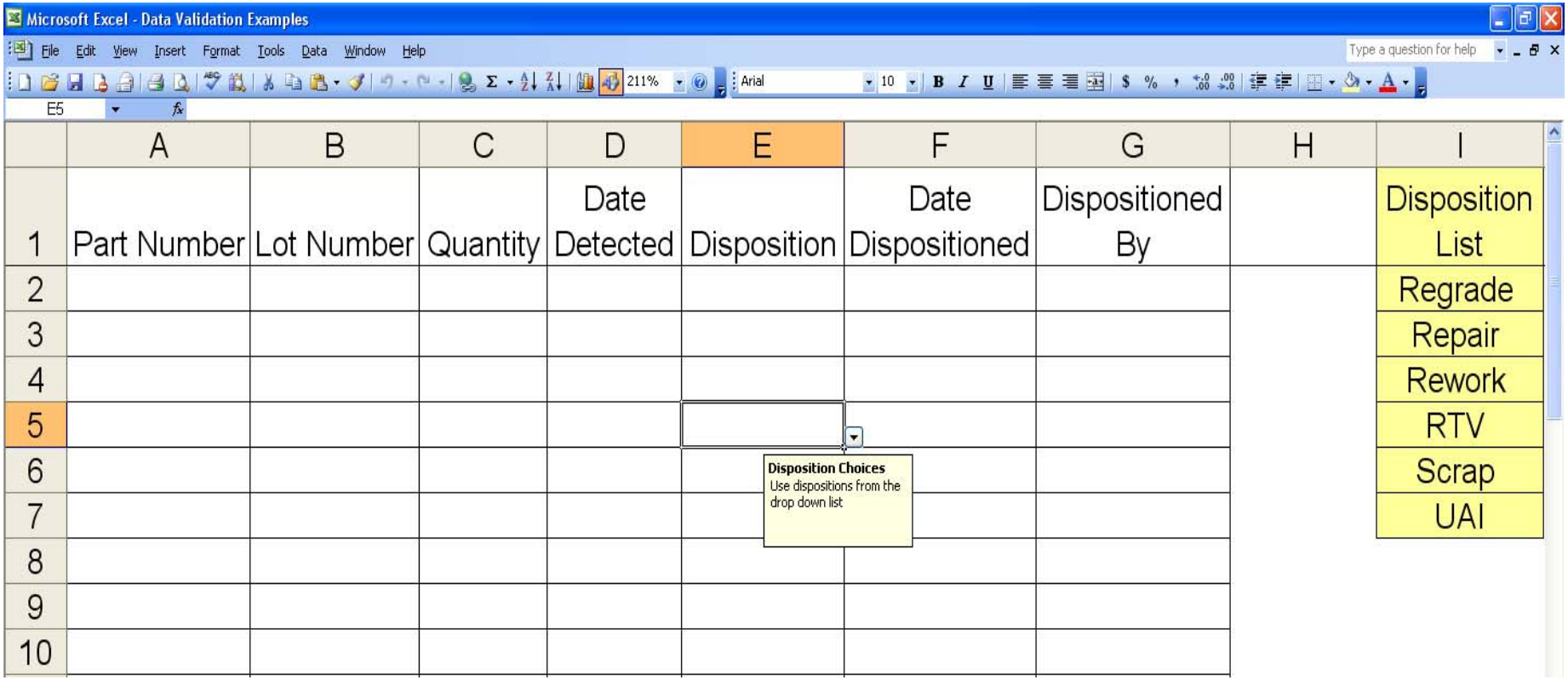
- We want to restrict entries in the Disposition column to the list of dispositions.
  - Select Column E (not an individual cell or group of cells)
  - Choose Data, Validation
  - Select the Settings tab
  - Select List from the Allow list and complete the entries as shown
  - Select the Input Message tab and complete the entries as shown
  - Click OK





Setting Data Validation - List

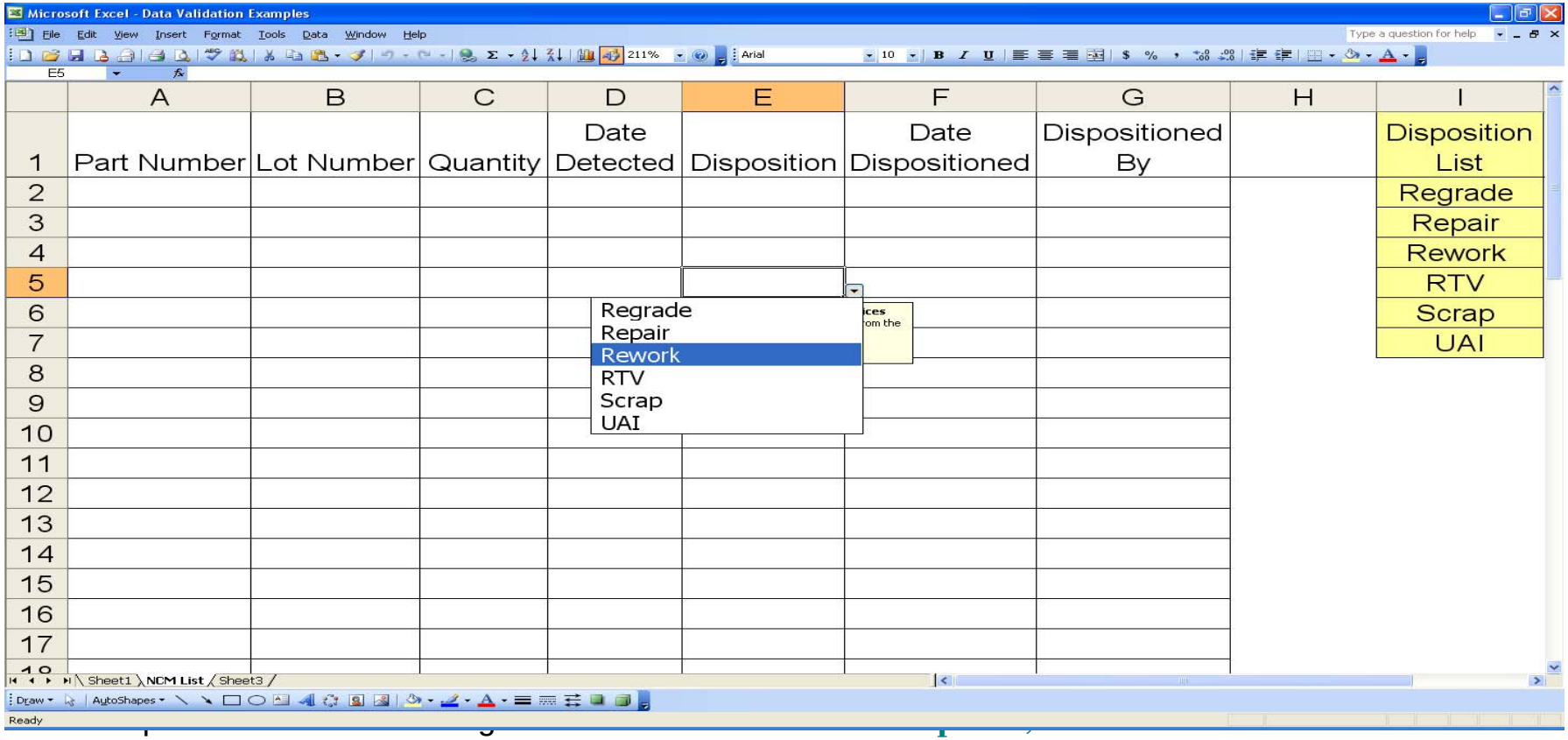
- Try this
  - Select any cell in column E
  - You will see the input message below the cell and an arrow next to the cell



	A	B	C	D	E	F	G	H	I
1	Part Number	Lot Number	Quantity	Date Detected	Disposition	Date Dispositioned	Dispositioned By		Disposition List
2									Regrade
3									Repair
4									Rework
5									RTV
6									Scrap
7									UAI
8									
9									
10									

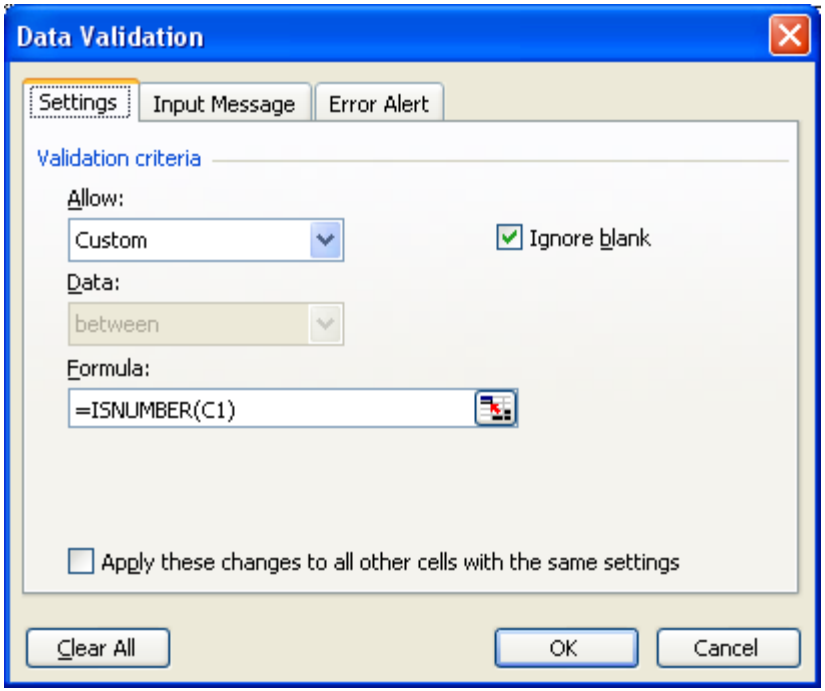
Setting Data Validation - List

- Click on the arrow next to the selected cell
  - A list drops down giving the allowed choices
  - They come from the Disposition List we created earlier
  - Click on an entry from the list an it goes into the cell



Setting Data Validation - Custom

- In this case we want to be sure that the entries in the Quantity column is a number.
  - Select Column C
  - Choose Data, Validation
  - Select the Settings tab
  - Select Custom from the Allow list and enter the formula =ISNUMBER(C1) in the Formula box.
  - Click OK



The ISNUMBER function returns TRUE if the cell contains a number.

Excel Convert Function

The Convert Function

- You may enter a value in one measurement system, but you need to convert to another.
  - You enter a quantity in fluid ounces, but need to convert it to milliliters.
  - To convert measurements, use the CONVERT function.
  - The CONVERT function converts a wide range of measurements, including measures of weight, distance, time, pressure, force, energy, power, magnetism, temperature, and liquid measure.
  - If the CONVERT function is not available, install and load the Analysis ToolPak add-in.
- To convert 4 fluid ounces to milliliters, enter the formula =CONVERT(4, "oz", "ml")

The Convert Function

- The CONVERT function includes a number of measurement systems:
  - Weight and mass
  - Distance
  - Time
  - Pressure
  - Force
  - Energy
  - Power
  - Magnetism
  - Temperature
  - Liquid measure

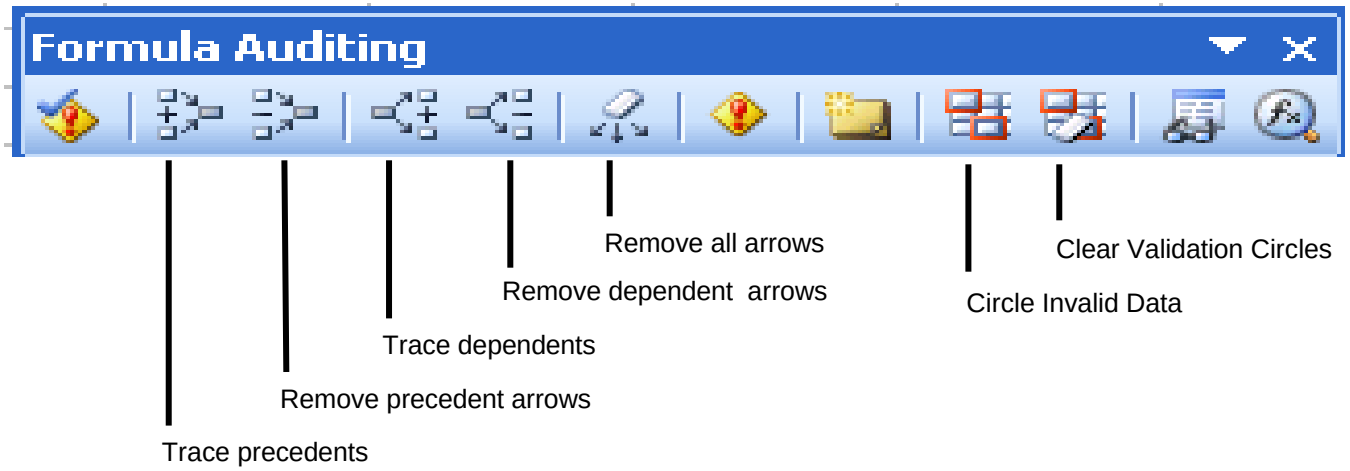
- It also includes a set of prefixes:

Prefix	Multiplier	Abbreviation
exa	1E+18	"E"
peta	1E+15	"P"
tera	1E+12	"T"
giga	1E+09	"G"
mega	1E+06	"M"
kilo	1E+03	"k"
hecto	1E+02	"h"
dekao	1E+01	"e"
deci	1E-01	"d"
centi	1E-02	"c"
milli	1E-03	"m"
micro	1E-06	"u"
nano	1E-09	"n"
pico	1E-12	"p"
femto	1E-15	"f"
atto	1E-18	"a"

Excel Formula Auditing

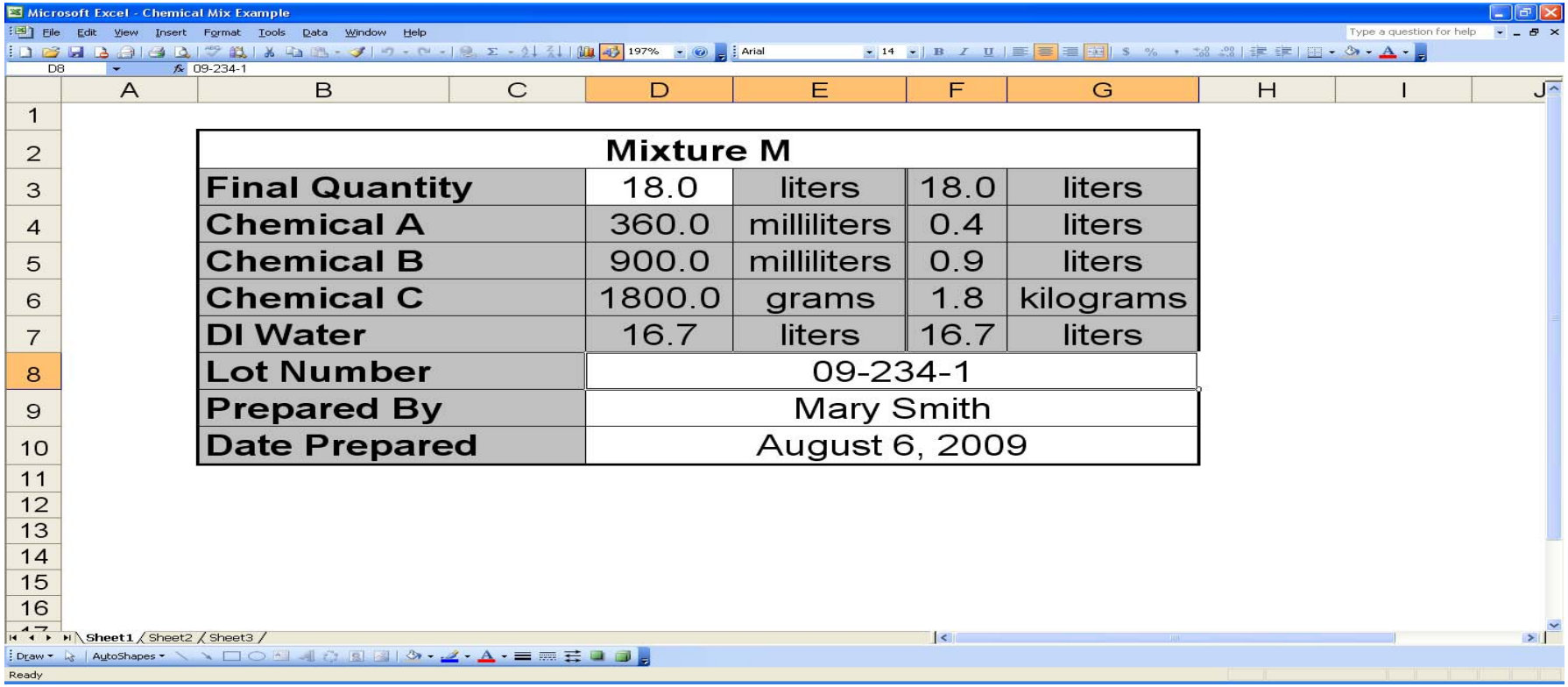
Formula Auditing

- Formula auditing displays the relationships between formulas and cells
  - Precedent cells are cells that are referred to by a formula in another cell
  - Dependant cells are cells that refer to other cells
- The Formula Auditing toolbar has a number of commands shown below: we identify some of them



Chemical Mix

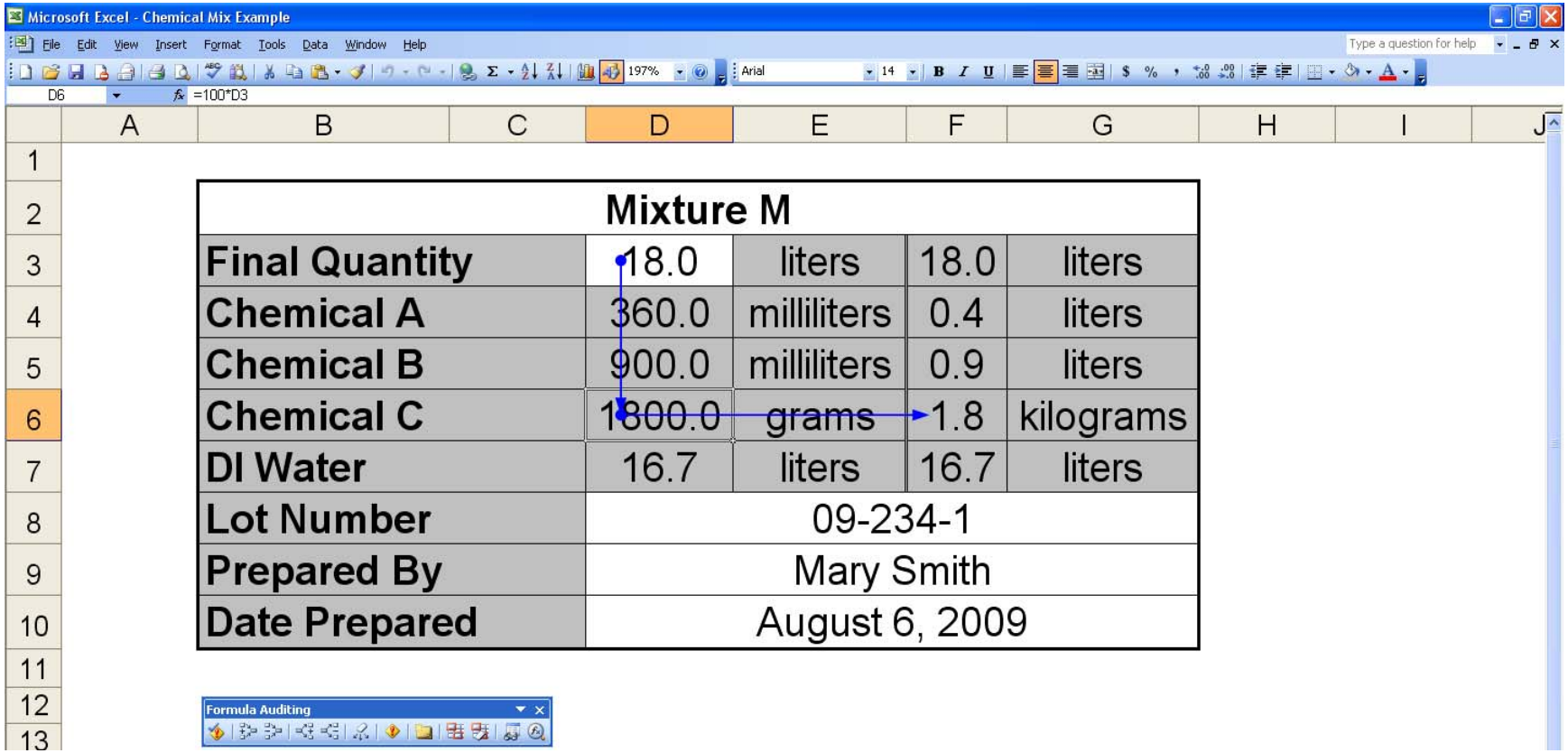
- Recipe
  - Chemical A Liquid 2% milliliters
  - Chemical B Liquid 5% milliliters
  - Chemical C Powder 100g/liter grams
  - DI Water Liquid 93% liters



Mixture M				
Final Quantity	18.0	liters	18.0	liters
Chemical A	360.0	milliliters	0.4	liters
Chemical B	900.0	milliliters	0.9	liters
Chemical C	1800.0	grams	1.8	kilograms
DI Water	16.7	liters	16.7	liters
Lot Number	09-234-1			
Prepared By	Mary Smith			
Date Prepared	August 6, 2009			

Trace Precedents and Dependents

- We would like to know where data comes from in a given cell. Formula auditing tells us!
  - Select Tools, Formula Auditing, then Show Formula Editing toolbar
  - Select cell D6
  - Click the Trace Precedents button on the Formula Editing Toolbar. A blue arrow will appear
  - Click the Trace Dependents button on the Formula Editing Toolbar. Another blue arrow will appear



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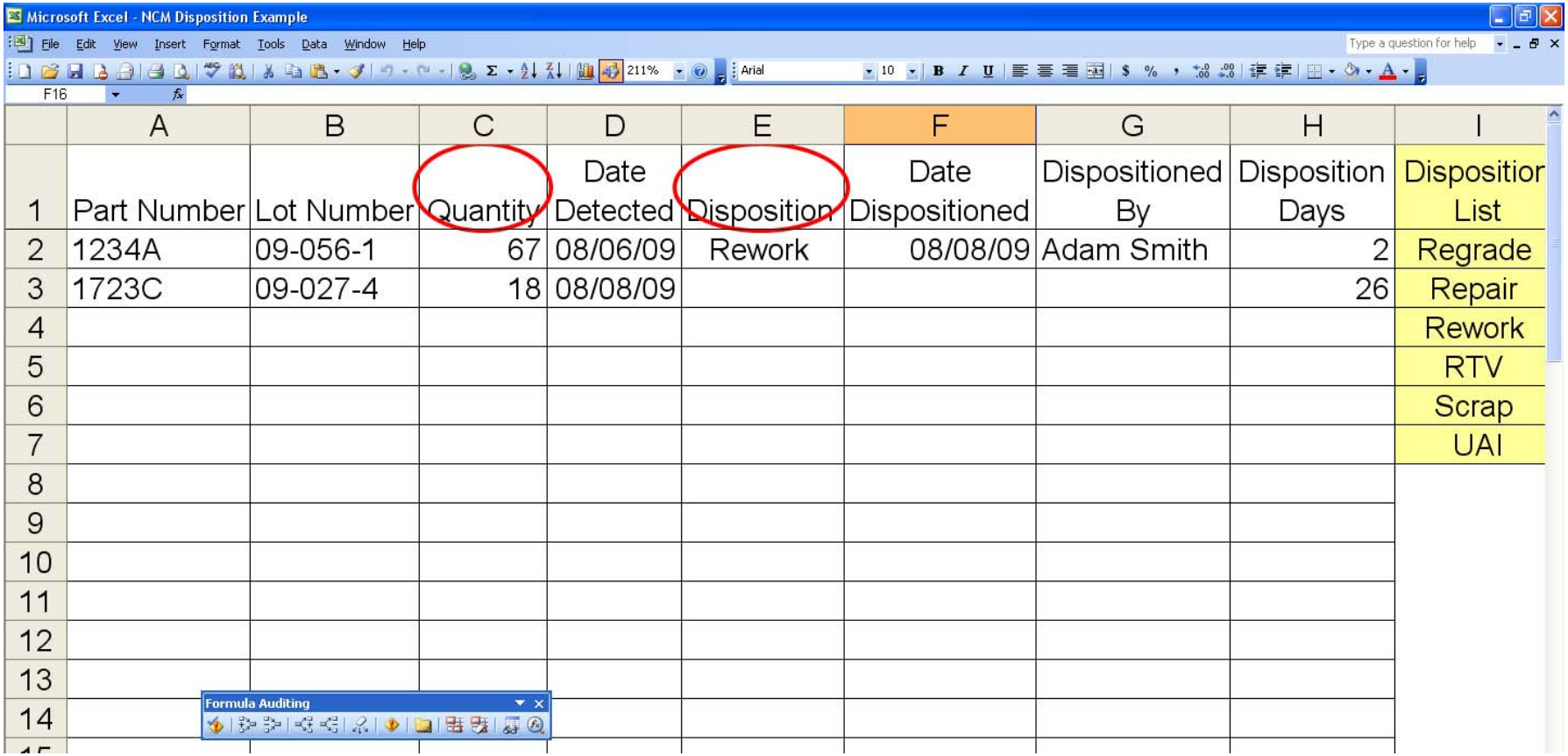
Circle invalid cells

- Formula auditing lets you check for invalid data.
  - Display the Formula Editing toolbar
  - Click Circle Invalid Data
  - The circles show the header. Column C should contain only numbers. Column E should contain only entries from the Disposition List. We created the headers before we created the validations.



	A	B	C	D	E	F	G	H	I
1	Part Number	Lot Number	Quantity	Date Detected	Disposition	Date Dispositioned	Dispositioned By	Disposition Days	Disposition List
2	1234A	09-056-1	67	08/06/09	Rework	08/08/09	Adam Smith	2	Regrade
3	1723C	09-027-4	18	08/08/09				26	Repair
4									Rework
5									RTV
6									Scrap
7									UAI
8									
9									
10									
11									
12									
13									
14									

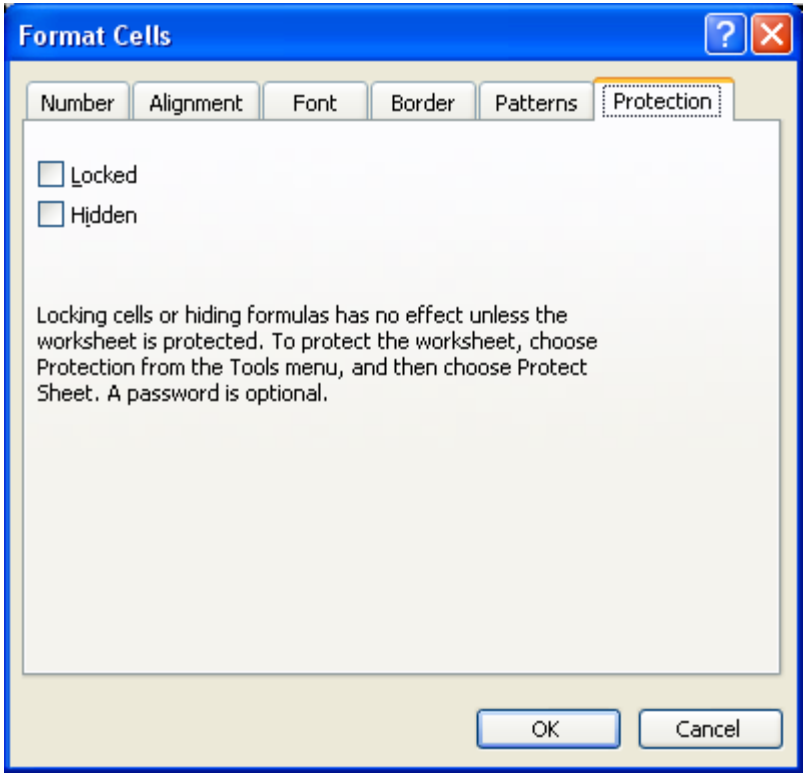
Protecting the Worksheet

Using Protection

- Protection prevents users from making changes to specified cells.
  - This is really important when you have formulas or data validation and don't want a user to change them.
- Protecting a worksheet has two steps, but we add one more.
  1. First, determine the cells to protect and shade them light gray. (This isn't required, but helps the user.)
  2. The remaining cells (without shading) allow data entry. For each cell, unlock it. (See the next slide.)
  3. Protect the worksheet, perhaps with a password. (See the next slide.)

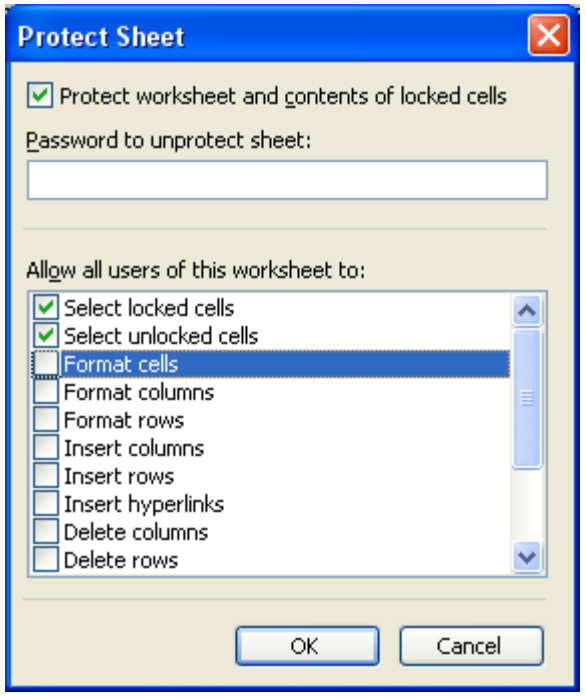
Unlocking a Cell

- The first step is to unlock a cells.
  - The default is that all cells are locked, but it has no effect until protection is turned on.
  - In the Chemical Mix example, unlock the cell with the final volume, cell D3.
  - Select cell D3
  - Choose Format, Cells
  - Select the Protection Tab
  - Uncheck Locked and Hidden (if checked)
  - Click OK



Protecting a Worksheet

- The second step is to turn on Protection
  - Select Tools, Protection, Protect Sheet
  - In the dialog box, check
    - Protect worksheet and contents of locked cells
    - Select locked cells
    - Select unlocked cells.
  - Uncheck all the other choices
  - If you want to use a password, enter it in the password box
  - Click OK

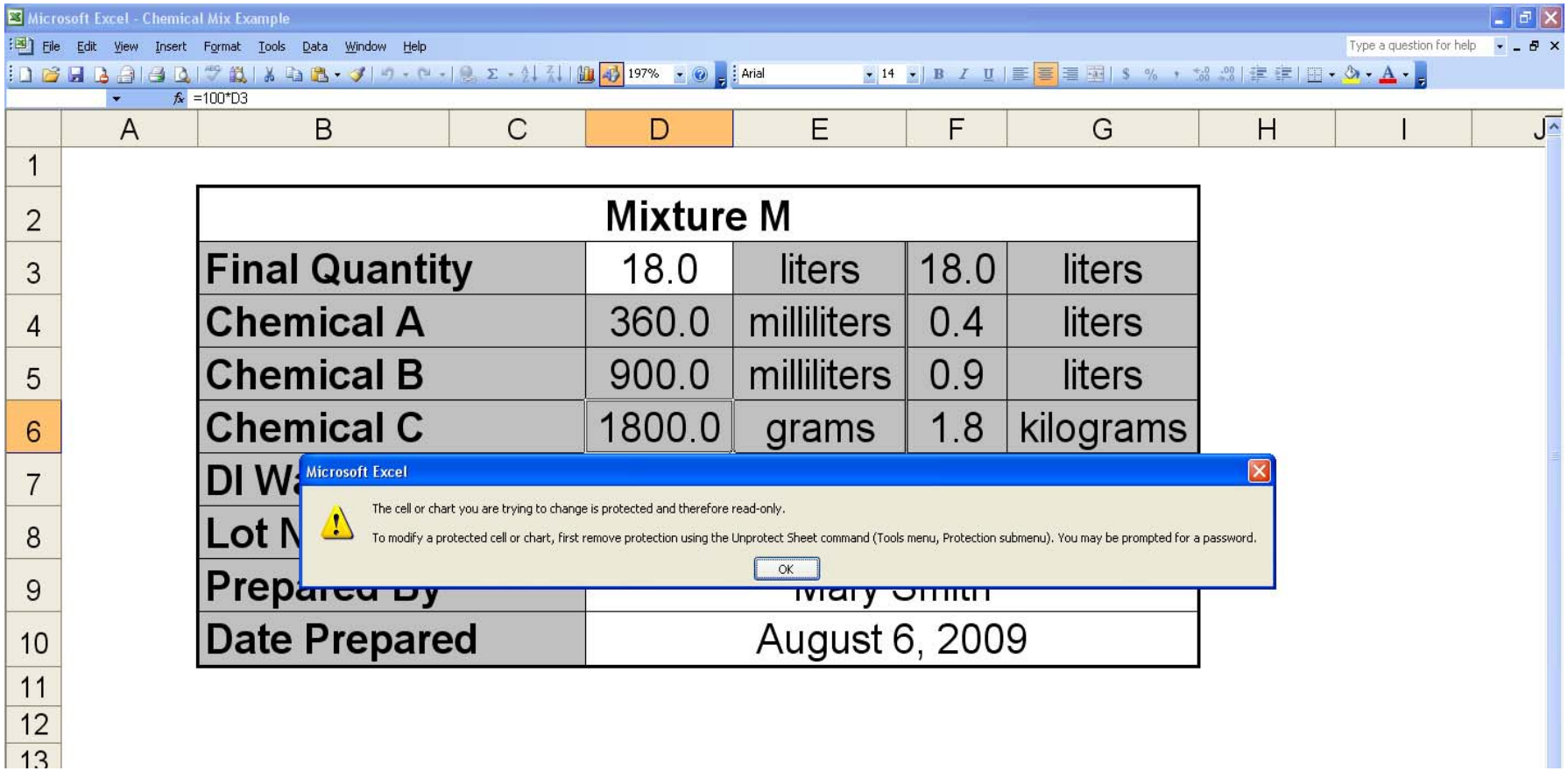


Passwords

If you use passwords, and you should, keep a master list in a safe place. Your successor may need to make revisions.

The Error Message

- If you try to enter data into a protected cell, you get an error message



Track Changes

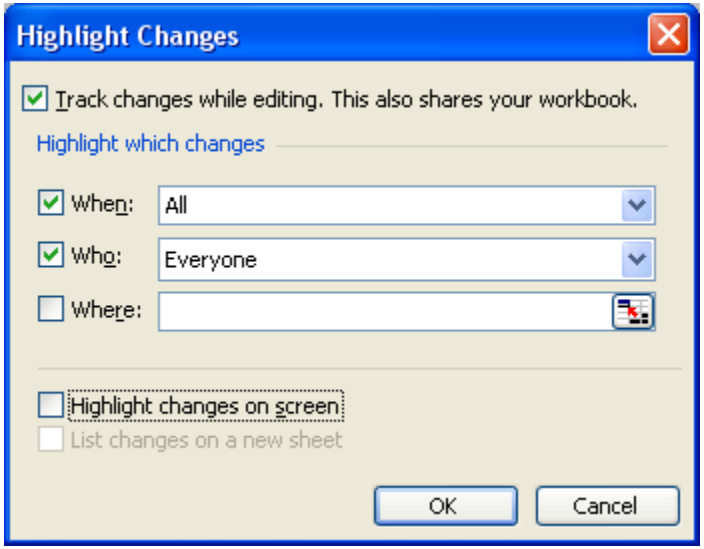
My thanks to
Brad Yundt
Microsoft Excel MVP
who provided valuable information for this section

Using Track Changes

- Excel can keep a record of changes to a spreadsheet, but it has some serious limitations
  - When you view the change history, you see who made each change, what type of change was made, when it was made, what cells were affected, and what data was added or deleted.
  - Some types of changes aren't tracked.
    - Changes you make to cell contents are tracked, but other changes, including formatting changes, are not. Some Excel features are unavailable in shared workbooks and therefore aren't tracked.
  - History is kept only for a set interval When you turn on change tracking, the history is kept for 30 days. This limit keeps workbook size manageable. You can increase or decrease the number of days of history to keep. If you want to keep the history indefinitely, you can specify a large number of days, or you can make periodic copies of the history information.
    - How history gets deleted Excel determines what history is kept by counting back from the current date. Each time you close the workbook, Excel erases any part of the change history that is older than the number of days in effect the last time the workbook was saved.
    - For example, if you're keeping 30 days of change history, and you open a workbook for the first time in two months, you'll be able to view the history from two months ago. However, when you close this workbook, the history from 31 to 60 days ago is deleted.
  - If you turn off change tracking or stop sharing the workbook, all change history is permanently deleted.

Turn On Change Tracking

- To use change tracking, you must turn it on.
  - Select Tools, Track Changes, Highlight Changes
  - The Highlight Changes dialog box will appear
  - Set up the dialog box as shown
  - Click OK

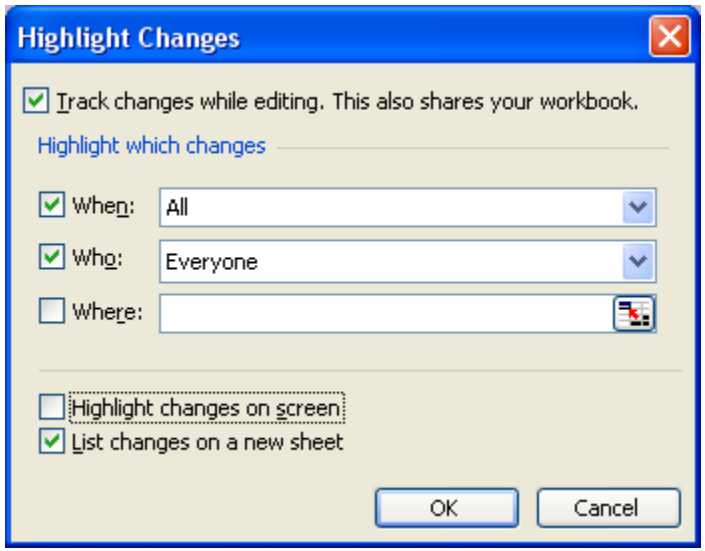


Reviewing Changes

- Excel will keep a record of (most) changes you make after you save them.
  - If you make a change and don't save, Excel will not keep a record.
  - In the chemical mix example, we start with the total quantity at 20 liters.
  - Let's change it to 12 liters and print the worksheet.
  - Then change it to 15 liters, print the worksheet, and save.
  - We will then review the history.

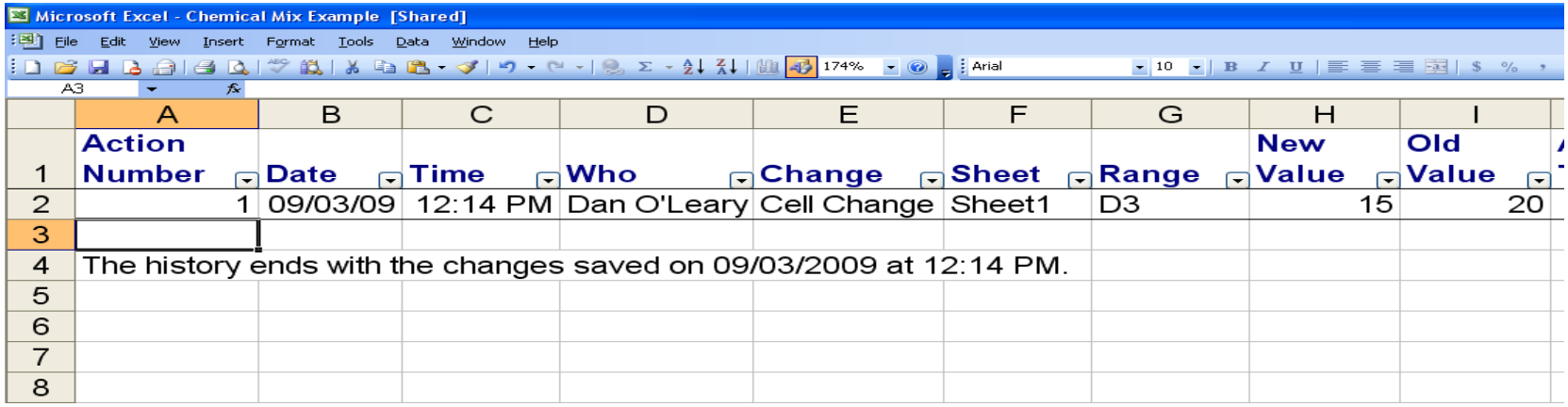
Reviewing History

- To review the history
  - Select Tools, Track Changes, Highlight Changes
  - The Highlight Changes dialog box will appear
  - Set up the dialog box as shown
  - Click OK
  - A new tab, History, will appear in the workbook



Reviewing History

- Notice there is only one entry.
  - It shows the old value of 20 and the new value of 15.
  - Excel didn't keep a record of the change to 12, because we didn't save the spreadsheet after the change.



	A	B	C	D	E	F	G	H	I
1	Action Number	Date	Time	Who	Change	Sheet	Range	New Value	Old Value
2	1	09/03/09	12:14 PM	Dan O'Leary	Cell Change	Sheet1	D3	15	20
3									
4	The history ends with the changes saved on 09/03/2009 at 12:14 PM.								
5									
6									
7									
8									

Automated Processes

What is an Automated Process?

- Automated process – A production or quality system process where computers or automated data processing systems are used
- Automated processes must be validated for intended use
- All changes must be validated be use

Intended Use

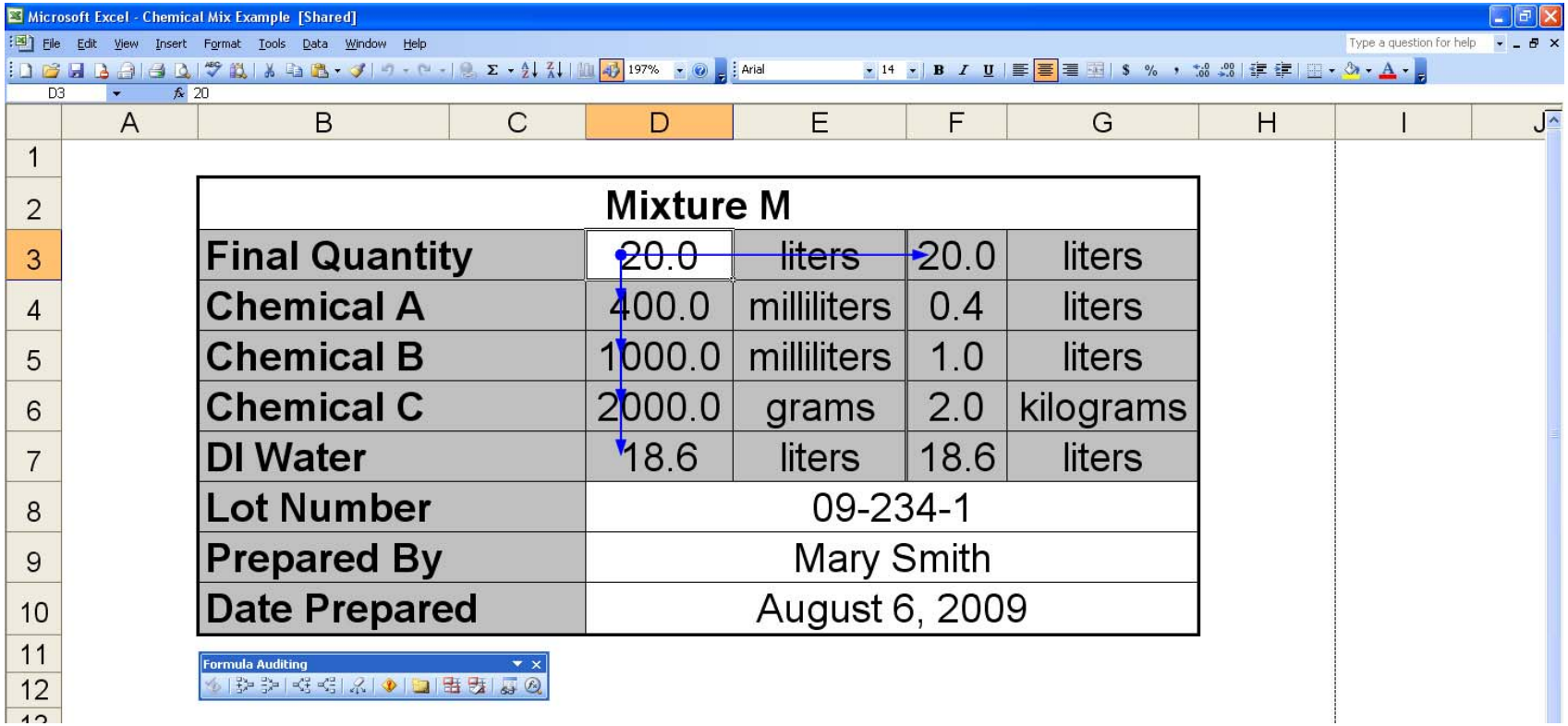
- For each automated process, define the “intended use”
- Use this definition to help define the content of the protocol
- The intended use can also lead to risk management

Validation Protocol and Report

- The validation protocol should include positive and negative test cases.
  - Each test case should state planned inputs and expected outputs
- Use the chemical mix example
  - Positive case
    - Input: 20 liters as total volume
    - Output: Correct quantities of chemicals A, B, C, and DI water
    - Report:
      Take a screen shot showing the correct values
      Take a screen shot showing the formula auditing
  - Negative case
    - Input: 200 liters as total volume
    - Output: This is too much material, so it is a typographical error. The workbook rejects this input value
    - Report: Take a screen shot showing that data validation produced an error

Positive Case Example

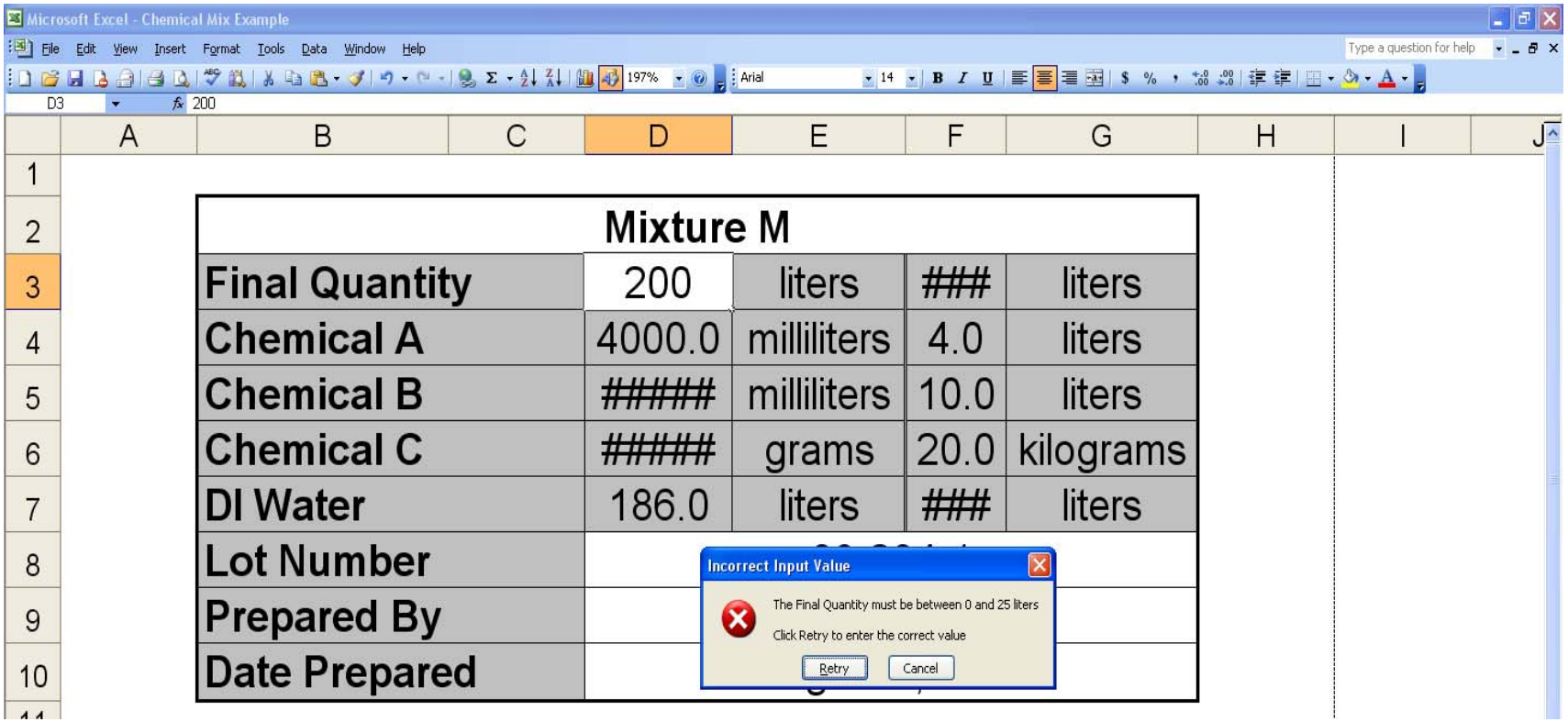
- Input: 20 liters as total volume
- Output: Correct quantities of chemicals A, B, C, and DI water
- Screen shot: Shows output and dependency on the input cell
  - Cells D4, D5, D6, D7 and E3



Mixture M				
Final Quantity	20.0	liters	20.0	liters
Chemical A	400.0	milliliters	0.4	liters
Chemical B	1000.0	milliliters	1.0	liters
Chemical C	2000.0	grams	2.0	kilograms
DI Water	18.6	liters	18.6	liters
Lot Number	09-234-1			
Prepared By	Mary Smith			
Date Prepared	August 6, 2009			

Negative Case Example

- Input: 200 liters as total volume
- Output: This is too much material, so it is a typographical error. The workbook rejects this input value
- Screen shot: Shows that validation detected the error.



How much validation evidence is needed?

- The level of validation effort should be commensurate with the risk posed by the automated operation.
- Consider risk factors such as:
  - The complexity of the process software
  - The degree of dependence on the automated process to produce a safe and effective device
  - Documented requirements and risk analysis of the automated process help to define the evidence needed to demonstrate software validation for intended us.
- For example:
  - An automated milling machine may require very little testing if the device manufacturer can show that the output of the operation is subsequently fully verified against the specification before release.
  - Extensive testing may be needed for:
    - an automated controller for a sterilization cycle
    - Automated test equipment used for inspection and acceptance of finished circuit boards in a life-sustaining / life-supporting device.

Commercial software

- Commercial software applications may be used as part of the quality system
  - A spreadsheet used for quality system calculations
  - A statistical package used in the quality system
  - A graphics package used for trend analysis
  - A commercial database used for recording device history records
- The extent of validation evidence needed for such software depends on the device manufacturer's documented intended use of that software.

Documentation

- The device manufacturer should create a documentation package to objectively confirm the software in validated for its intended use.
- The package should include:
  - Defined user requirements
  - The validation protocol used
  - The acceptance criteria (defined in advance)
  - The test cases and results
  - A validation summary

Warning Letters

Warning Letter
Steris Corporation

- Failure to adequately validate computer software used as part of production, as required by 21 CFR 820.70(i).
- For example, your [redacted] software, used for the sterilization chambers, was not adequately validated in that unapproved ETO sterilization cycle revisions are migrated from the [redacted] server into the software and are not identified as unapproved cycles. The ETO chamber operators can access these unapproved cycles and run the non validated sterilization cycles without the customer's consent.

Warning Letter
Xoran Technologies, Inc.

- Failure to validate and document the validation of computer software used as part of production or the quality system, as required by 21 CFR § 820.70(i).
- For example, the firm failed to validate and document the validation of computer software used to calculate the Geometric Calibration test and the Resolution Phantom test used as part of finished product testing for the MiniCAT System.

Electronic Records
Part 11

What is an Electronic Record?

- Part 11 says, "*Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system."
- The guidance document says, "FDA considers part 11 to be applicable to . . . [r]ecords that are required to be maintained under predicate rules, that are maintained in electronic format *in addition to paper format*, and that *are relied on to perform regulated activities*."

Guidance document: Part 11, Electronic Records; Electronic Signatures — Scope and Application dated August 2003

Requirements for an Electronic Record

- Summary of 21 CFR §11.10
- Procedures and controls for systems that create, modify, maintain, or transmit electronic records shall include:
  - Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.
  - The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying
  - Protection of records to enable their accurate and ready retrieval throughout the records retention period.
  - Limiting system access to authorized individuals.
  - **Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.**
  - Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.
  - Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
  - Use of device (*e.g.,* terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.
  - Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.
  - The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

FDA Enforcement Discretion

- FDA won't enforce the Part 11 regulations for themselves
- It will enforce them when a problem is located in another area
- The guidance document identifies three types of Part 11 records:
  - Required records that are maintained in electronic format *in place of paper format*.
  - Required records that are maintained in electronic format *in addition to paper format*, and that *are relied on to perform regulated activities*.
  - Records submitted to FDA in electronic format

Summary and Conclusion

Summary and Conclusion

- It is easy to make a mistake
  - Automated processes in production and the QMS must be validated for intended use
  - Excel is a common tool to implement processes
  - Well meaning people can introduce Excel spreadsheets without a clear understanding of the regulatory implications
  - Be vigilant when making process changes or conducting internal audits

Summary and Conclusion

- Excel worksheets must be validated before use
- The completed package is a quality record, and should include:
  - Defined user requirements
  - The validation protocol used
  - The acceptance criteria (defined in advance)
  - The test cases and results
  - A validation summary

Summary and Conclusion

- Excel has some built-in tools and functions that can make the validation
  - Data validation
  - Convert function
  - Formula auditing
  - Protection (cells, worksheets, and workbooks)
  - Track changes

Summary and Conclusion

- Part 11 Electronic Records
  - The FDA is using enforcement discretion in applying the Part 11 requirements
  - If you use paper records and handwritten signatures you can probably avoid the Part 11 requirements
  - Track changes in Excel is not adequate for Part 11 because it doesn't leave a permanent audit trail

QUESTIONS