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RRE Rapid Results Entry and Policy Definition

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RRE Session Objectives

- At the completion of this session you should be able to:
 - Explain the concept of RRE
 - Locate and use example resources in your copy of EP Evaluator to
 - Copy and paste data from excel into
 - Single experiments
 - Multiple experiments
 - Create a policy definition and make it your Master project.

EP Evaluator Concepts

- Project – a special database folder to contain a <u>collection of</u> <u>Experiments</u> for one or more Statistical Modules
- Statistical Module Does calculations and report for a specific type of experiment - Like method comparison.
- Experiment one set of data collected for a specific purpose for one analyte
- Instrument = method (think outside the box!)
- (RRE) Rapid Results Entry mechanisms to efficiently enter data into EE
- Policy Definitions A MASTER template of parameters used in RRE.

RRE Techniques "Rapid Results Entry"

- Pasting results from Excel into existing experiment
 - Pasteextdetail.xls
- Paste with Policies into the Overview screen
 - Paste with policies table
 - Paste with Policies list
- Efficient keyboard entry of results using printouts for multiple analytes
 - RRE\create experiments \ Keyboard
- Instrument Interface: data capture directly from instruments, or from an instrument export file for Vendors only
- ODBC Data Acquisition from Instrument Manager the Best way
- EE Users Guide Chapters 35, 36, 37
- Help Topics are available for most all of the setup screens

Which statistical modules use RRE?

- RRE does not apply to modules where experimental results aren't input
 - Cost per Test, Incident Tracking, Inventory, Performance Standards, Six Sigma Metrics
- A few modules use RRE techniques that are a bit "different"
 - Hematology Method Comparison, ROC, Establish Reference Interval,
 Average of Normals (advanced techniques)
- Everything else
 - Simple Precision, Alternate Method Comparison, Two Instrument Comparison, Linearity, Complex Precision, etc.
 - RRE is very similar though not exactly alike

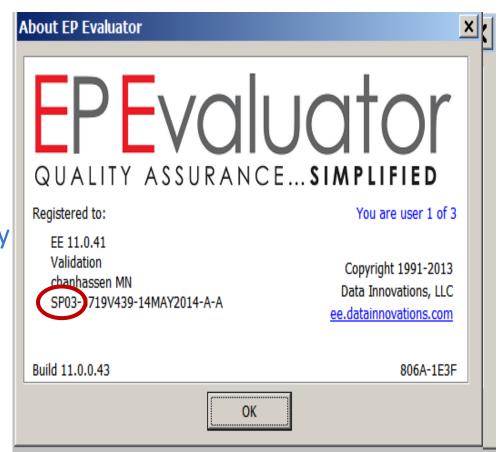
Data Entry Type	Considerations	Product code	Grade
Manual Entry	Slow Speed of entry, typos, one analyte at a time	All	Good
Rapid Keyboard entry from Instrument printouts using a panel defined worksheet	RRE wizard walks through the process, but still subject to typos and speed of entry	Standard	Good
Copy and paste from Microsoft Excel	RRE Wizard for Multiple analytes, multiple instruments – but still need to put the data into the worksheet.	Standard	Better
Instrument Data Capture - RRE Wizard Drive	Cable hookup, or instrument generated file ers for IVD Manufacturers Only	Data Capture	Better
Data Capture from Instrument Manager	RRE - Simple Data query for thousands of results	Data Capture	Best 6

EP Evaluator® and Instrument Manager®

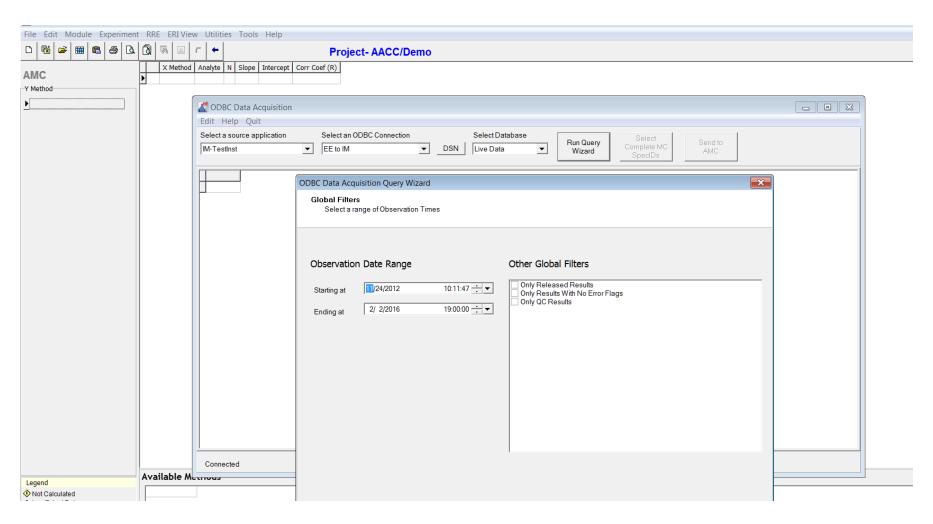
- Data stored within the Instrument Manager's Cache database can be easily transferred to EE9 or EE10 or EE11 via Data Capture.
- Requirements
 - IM version 8.08 or greater
 - Specimen Management licensed
 - ODBC driver licensed
 - Minimum: Standard version with Data capture license (unlock code 2nd letter is Q, V, or P)

EP Evaluator Data Capture Versions

- Standard (Q)
 - 30 Stat and 4 LabManagement Modules
 - Data Capture
- Professional Version (P)
 - Everything plus User security and audit trail
- Available as single user, or upgrade to multiple user networks
- Part # EE-D-xxxx



ODBC Demo



ODBC Query from Instrument Manager 4 Filters

- Date / time range
- Instrument ID
- Test codes
- Specimen ID

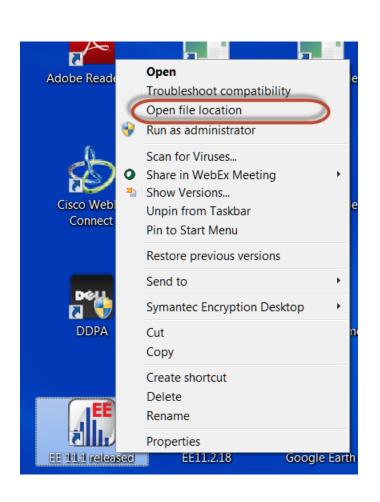
In this session, we will use:

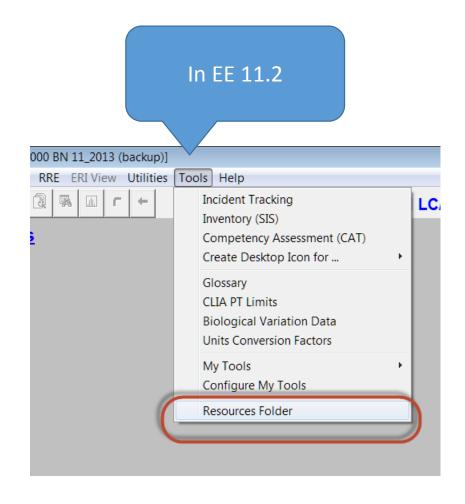
- Project "Example Policies"
 - Restore using Utilities \ file Manager if you don't see it in your open project menu
- Spreadsheets in the Resources folder
 - Pasting results from Excel into existing experiment
 - Pasteextdetail.xls
 - Paste with Policies into the Overview screen
 - Paste with policies table
 - Paste with Policies list
- Technique
 - Efficient keyboard entry of results on printouts for multiple analytes
 - RRE \ create experiments \ Keyboard

RRE Techniques "Rapid Results Entry"

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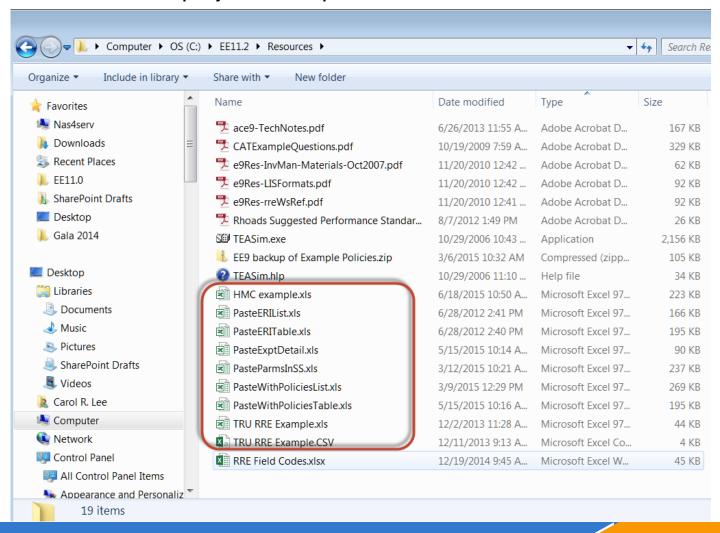
Find your Resource folder





Resources in EE11

Annotated examples for RRE techniques are available in your EE\Resources folder. Use with the project ExamplePolicies



The easiest RRE Technique ... Paste into Experiment Detail Screen

- Paste results into an experiment instead of typing them
- One experiment at a time
- Policy Definition not required

Applicable Statistical Modules:

- ☑ Simple Precision
- ⊗ Complex Precision
- ✓ Linearity
- ✓ AMC
- ☑ EP9 MC
- ☑ QMC
- ☑ 2IC
- ☑ INR Geo Mean
- ✓ Factor Sensitivity
- ☑ STB Stability

- ☑ MIC
- ☑ Glucose POC
- ⊗ Hematology MC
- ⊗ Sensitivity-LOB
- ⊗ Sensitivity-LOQ
- ☑ VRI
- ⊗ ERI/ROC
- ✓ INR Meth Comp
- ☑ TRU Trueness

- ⊗ EP10
- ⊗ Carryover
- ⊗ 6 Sigma Metrics
- ⊗ Performance Standards
- ⊗ Interference
- ⊗ Cost per Test
- ⊗ AON
- ☑ INR Check
- ☑ HIS Histogram

Available in CLIA version? Yes

Paste into Experiment Detail Screen

- Create an experiment as if you were going to type the results ...
 - Experiment New
 - Experiment New from Policies
- Then paste the results instead of typing them
- Paste just the numbers not column headings or Sample IDs.

Note: This technique doesn't work for all statistical modules

Exercise: Simple Precision detail screen

Open project ExamplePolicies –

(you might need to restore it in Utilities / File Manger / restore backups)

- Open spreadsheet pasteExptDetail.xls.
 - Go to the SP tab
- In EE, Create a new Simple Precision experiment

Instrument: MED-E

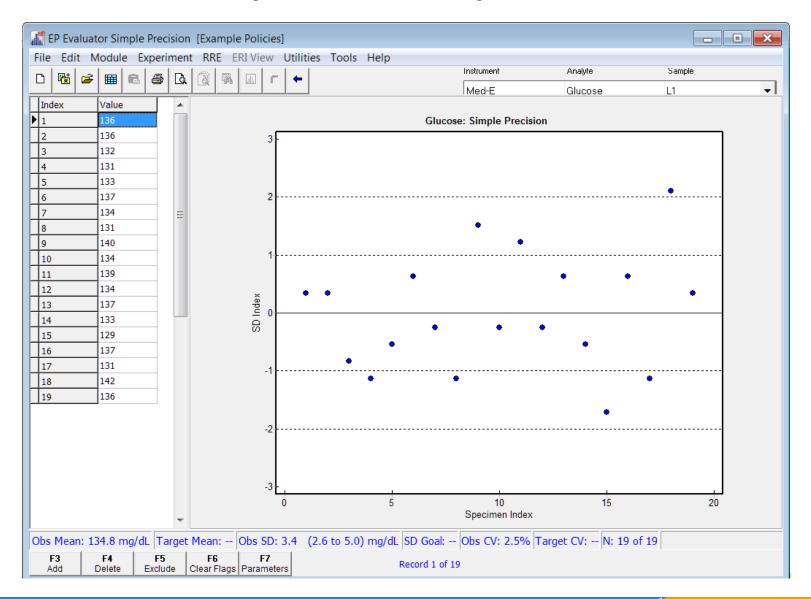
Sample: L1

Analyte: Glucose

Units: mg/dL

- At the point where you would normally type results:
 - Switch to Excel. Select and copy <u>just the results</u>
 - Switch back to EE and do Edit/Paste

Outcome of the Simple Precision Experiment



Exercise: Alternate Method Comparison

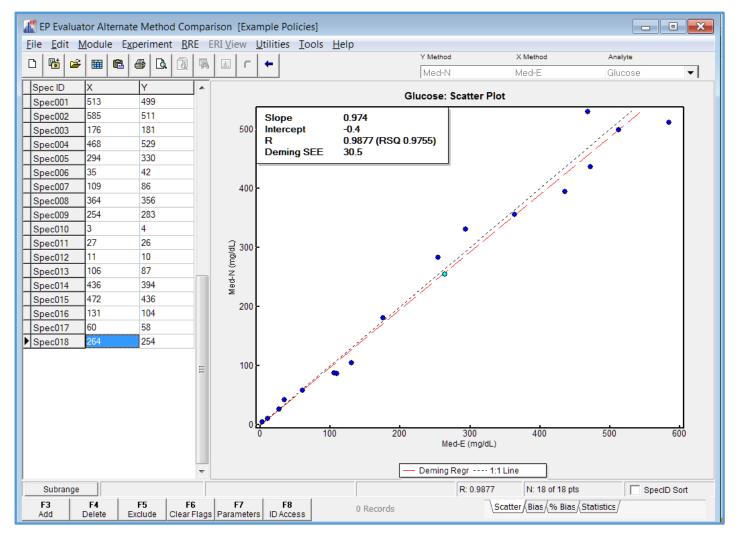
- Open spreadsheet PasteExptdetail.xls.
- Go to the AMC module overview screen
- Create a new AMC experiment for Glucose:

X Method: MED-E Y Method: MED-N

Analyte: Glucose Units: g/dL

- When you would normally type results:
 - Switch to Excel. Select and copy the three columns of specIDs and X and Y results. Do not copy column headings.
 - Switch back to EE and do Edit/Paste

Outcome of the AMC Experiment



Specimen IDs

- Very important for RRE
- Method Comparison SPECID used to link the data pairs
- Linearity SPEC IDS needed for each level of "standards" LIN-01, LIN-02, LIN-03,
- SPECID is alphanumeric
- SPECID sort is alphanumeric, not numeric. 1, 10, 2, 20, 3, 30,
- Default SPECIDs for EE follow the format S00001
- Pasting from spreadsheets requires SPECID as a Header name for spreadsheets

Exercise: Linearity

Create a new experiment in the EE Linearity Module

Instrument: Eximer

Units: mg/dL

TEa: 1.0 (mg/dL)

Reportable Range: 0 - 20

Analyte: Calcium

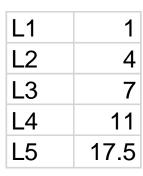
Confirm Lin, Acc, RR

Systematic Error Pct: 50%

Prox. Limits: 50% low, 10% high

Click the yellow Edit button to enter Assigned Values

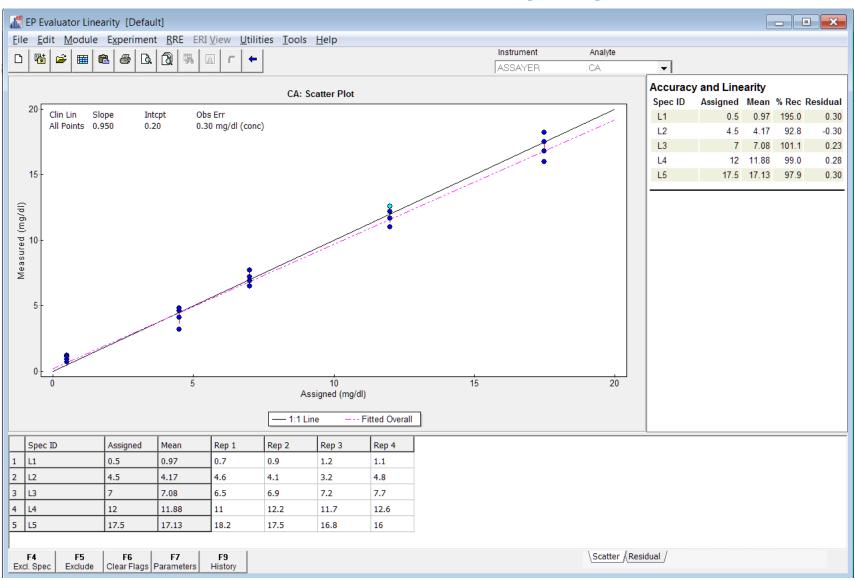
- Type L1, L2, ..., L5 in the Spec ID Column
- Type your assigned values in the assigned value column.
 - TIP: if you have your assigned values in excel, you can copy the grid with the specIDs and assigned values to the clipboard
 - In EE, right-click the cell for the L1 value and select Paste from the popup menu



Linearity Exercise (continued)

- Select OK to close the Parameters Screen and get to the Experiment Detail Screen
- Go to the Linearity tab of the pasteExptDetail spreadsheet
- In Excel, copy just the measured results from the spreadsheet.
 - Note that the results are laid out in a square in Excel, similar to how they look in EP Evaluator
- Switch to EE and do Edit/Paste to enter the results

Outcome of the Linearity Experiment



There is an easier way ...

- First, go back to the Linearity Module Overview Screen and delete the experiment you just created.
- Then select Experiment / New from Policies

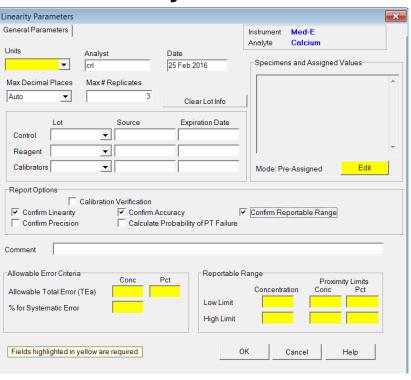
Instrument: Med-E Analyte: Glucose

Specimen Kit: PreAsgKit PRK

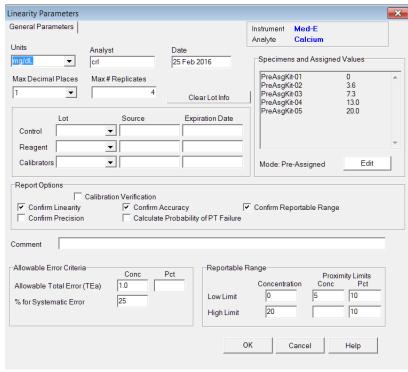
- Note that there are <u>no yellow fields</u> on the Parameters Screen
- The reason is Policy Definition

Policy Definition will auto-fill the yellow fields in all the Parameter Screens

Without Policy Definition



With Policy Definition



With defined Policies

- You can paste data to create multiple experiments
 - Multiple analytes
 - Multiple Instruments
 - Multiple specimens
- The Parameters screen for each experiment is automatically filled in
- Immediately calculate and review results

Step-by-step Approach to Policy Definition

TIP: You can create a MASTER project at any point in the process

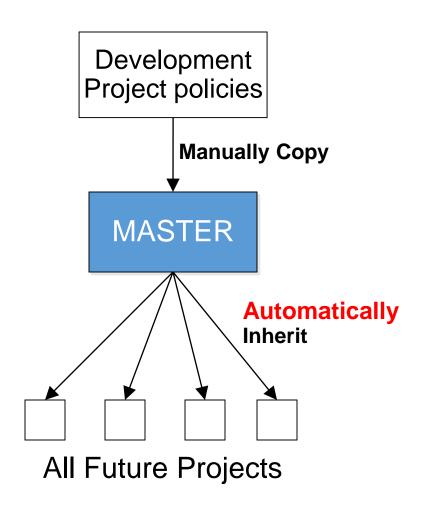
3. Linearity Materials

2. Performance Standards

1. Instrument Class, Analytes & Units

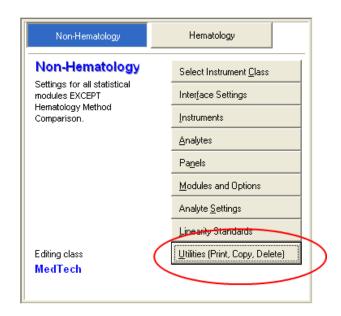
Use the MASTER Project to propagate your Policies to your future Projects

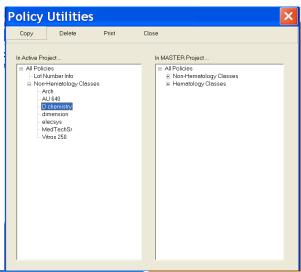
- When policy definition is complete, use RRE\define Policies\Utilities to create a MASTER Project
- The MASTER project template contains only Policies (no experiments).
- You cannot open, delete or rename your master project.
- You can only modify the policies within it, plus backup and restore)
- When you create a new project, that new project is initialized to contain whatever Policies are in MASTER.



How to copy policies to the MASTER project

- Menu command RRE / Define Policies
- Select the Utilities button
- Policy Utilities shows
 - Left: active current project
 - Right: Master project contents
- On your active project policies, highlight the policy you wish to copy
- Select the Copy button
- The policy is copied to the Master project.
 - Same name classes get replaced
 - New classes get added

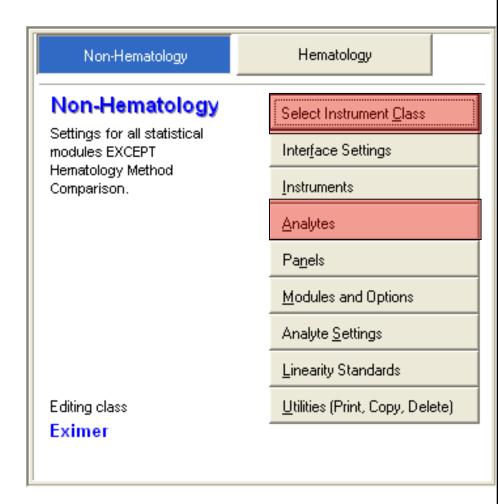




Step 1 – Instrument Class, Analytes, and Units

 Go to Statistical Modules Screen

Select RRE / Define
 Policies from the menu;
 select the Non Hematology Tab



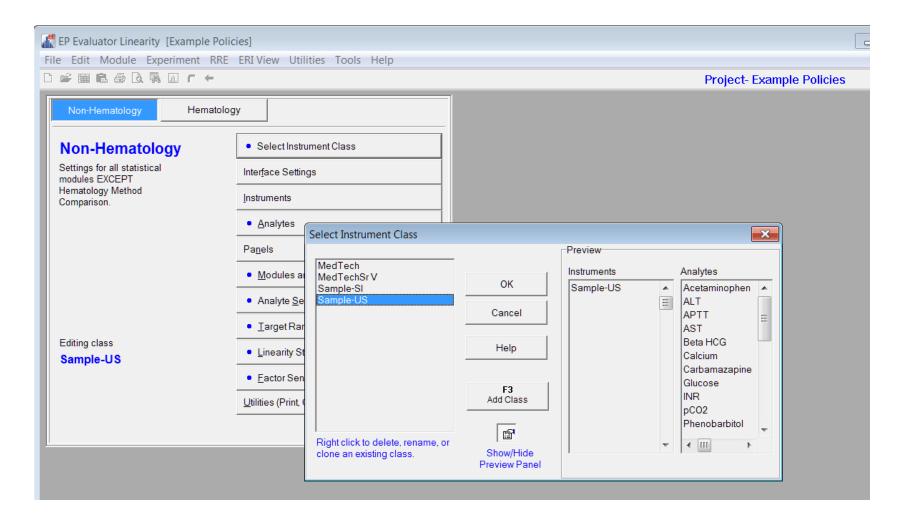
Instrument Class

- Instrument Class contains policy definitions for instruments having the same analytical properties – like a peer group
- Policy Definition always starts by adding or Selecting an Instrument Class.
 - All the other buttons apply changes to the selected class
- When you "add" an instrument class, EE automatically puts one instrument, with same name as the class, in the new class.
- Add additional instruments, either
 - in policy definition or
 - while creating experiments

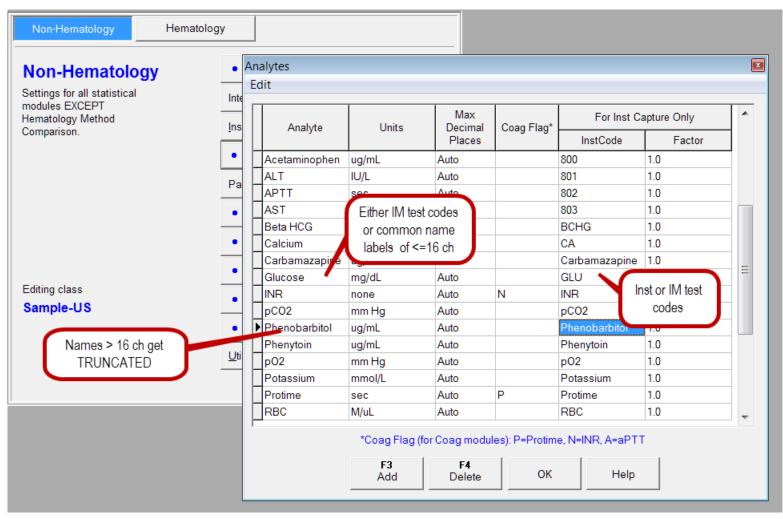
Add an instrument class

- F3 adds a new instrument class
- Right click (clone) duplicates an existing instrument class with the same instruments, analytes and parameters that you can modify.
- Add a new instrument class called EXAMPLE
- Enter new analytes and their units
 - Albumin
 - T Bili
 - D Bili

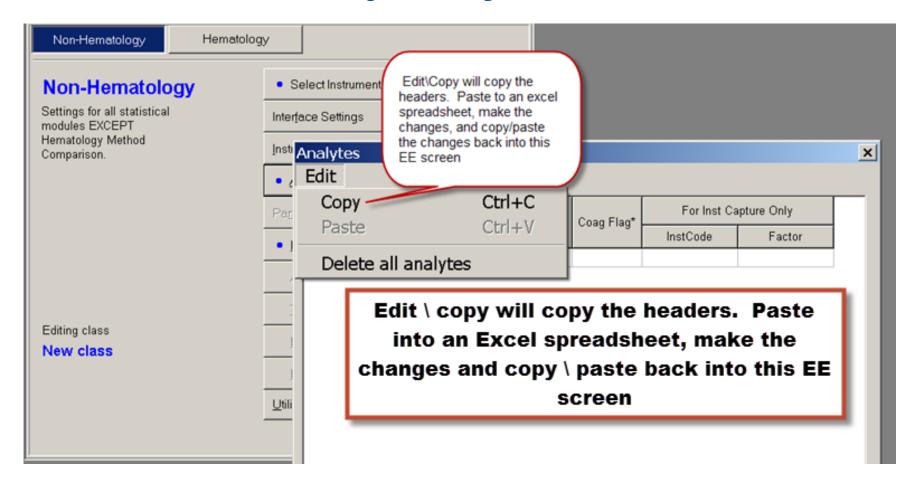
RRE Policy Definitions



Policy Definition Analytes

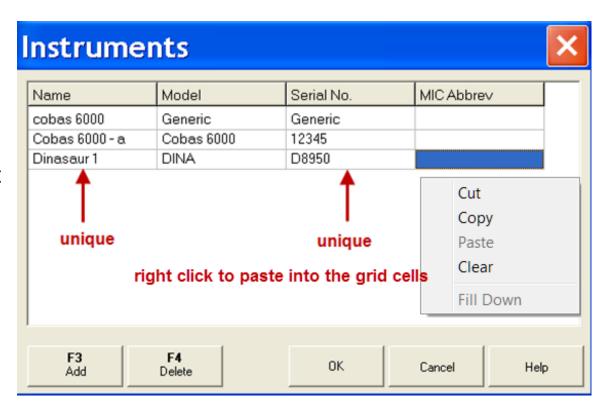


The edit copy/paste feature updates the policy screens



Instrument settings

- Add all instruments you will use here
- Instrument name must be unique
- Serial numbers must be unique,
- Within an instrument, a S/N can be the same as it's name.
- MIC abbrev <= 10 characters (must have if using MIC)



Paste with policies Table – applicable modules

Applicable Statistical Modules:

☑ Simple Precision

☑ Linearity

☑ AMC

☑ EP9 MC

☑ QMC

☑ 2IC

☑ INR Geo Mean

☑ Factor Sensitivity

☑ Histogram

☑ MIC

☑ Glucose POC

⊗ Hematology MC

☑ Sensitivity-LOB

☑ Sensitivity-LOQ

☑ VRI

⊗ ERI/ROC

☑ INR Meth Comp

☑ EP10

☑ Carryover

⊗ 6 Sigma Metrics

Performance Standards

☑ Interference

⊗ Cost per Test

⊗ AON

⊗ INR Check

✓ Simple Acc

Available in CLIA version? Yes - BUT

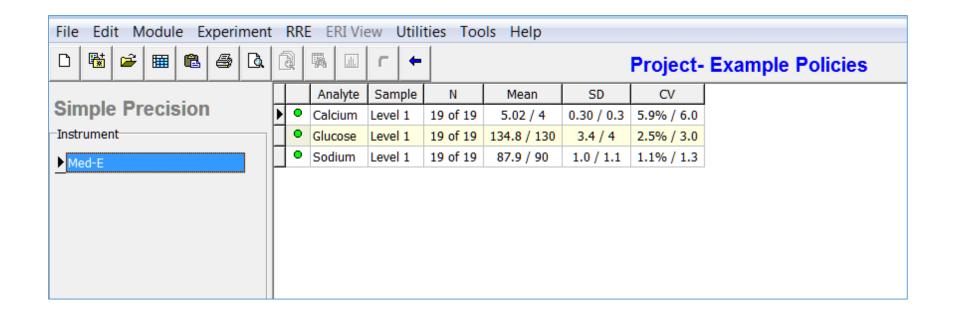
but while the data can be pasted, the parameters screen needs to be filled in manually

Exercise: Paste with Policies into Simple Precision

(this technique works great for a spreadsheet with multiple analytes)

- Use the EE Project "Example Policies"
- In Excel, open spreadsheet PastePoliciesTable.xls
- Select the entire SP tab sheet and copy it to the clipboard
 - For Paste with Policies, we DO want to copy the column headings and Spec IDs
- Switch to EP Evaluator and open the Simple Precision module, but do not create an experiment
 - Paste with Policies starts from the Module Overview
 Screen, not the Experiment Detail Screen
- Select Edit / Paste with Policies / Data in Table Format from the menu. Instrument Example.
- Do Module / Recalc All

Screen after Pasting



Exercise: Paste with Policies into AMC

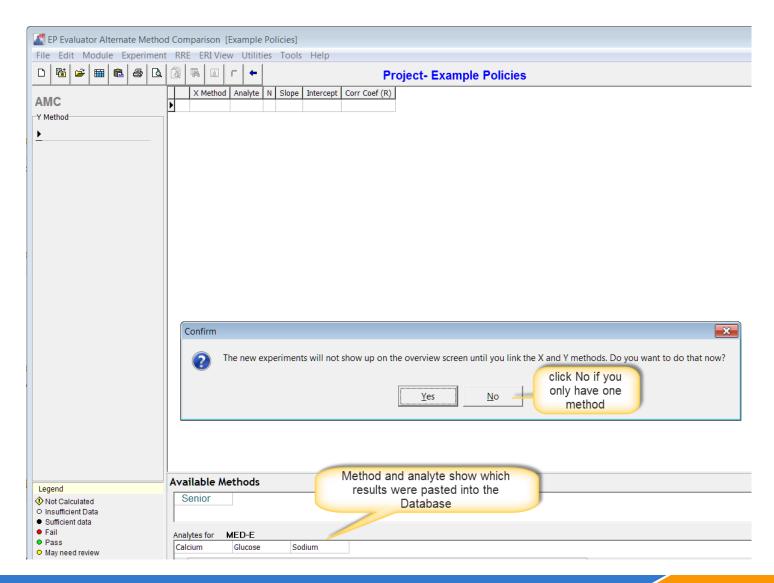
- In Excel, open spreadsheet pastepoliciesTable.xls
- Go to the AMC Tab Sheet in the spreadsheet.
 - Note that the sheet is organized with X values and Y values in separate arrays.
 - The headers must include "SpecID" and Analyte Names.
 - the Analyte Names must be spelled exactly as in the policy definition.
- Copy the X values, spec Ids and include the headers.
- Switch to EP Evaluator and open the AMC module
- Select Edit / Paste with Policies / Data in Table Format from the menu. Select "New instrument and call it "senior"
- When asked if you want to link, answer No.

Paste Data from Spreadsheets – into the Overview screen

- Spreadsheet Data looks like "paste with policies table".
 - EE\Resources\PastePoliciesTable.xls
- SPECID required
- Results in columns with analyte names as headers
 - Spelled the same as in your Policy definition class

<u>InstSerNo</u>	SpecID	Calcium	Glucose	Sodium
AAA-1001	S001	3.4	170	187
AAA-1001	S002	17.4	500	81
AAA-1001	S003	19.7	541	92
AAA-1001	S004	6.9	463	172
AAA-1001	S005	16.3	290	180
AAA-1001	S006	5	410	56
AAA-1001	S007	19.3	36	162
AAA-1001	S008	2.6	488	156
AAA-1001	S009	11.9	535	85
AAA-1002	S001	8	177	189
AAA-1002	S002	17.2	487	82
AAA-1002	S003	14.3	542	90
AAA-1002	S004	8	519	171
AAA-1002	S005	15.5	292	185
AAA-1002	S006	11.9	402	55
AAA-1002	S007	22.5	32	164
AAA-1002	S008	6.7	511	157
AAA-1002	S009	8.1	463	82

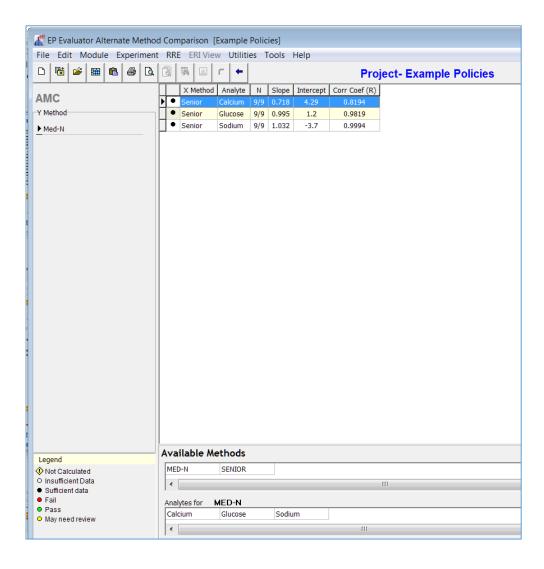
Screen after Pasting X Method



Exercise: Paste Second Method and Calculate (All)

- Repeat the Paste with Policies for the Y-Method area the spreadsheet.
 - Remember you need to include the headers for the analyte and SPECID. In Excel, you can right click the group of rows for the X values and hide them from being copied.
- Differences:
 - Select instrument Med-N instead of adding a new instrument
 - When asked if you want to link, answer Yes.
 - X method is "Senior", Y method is "Med-N".
 - After linking, do Module Recalc All

Screen after Pasting Y Method



Paste with policies into Module Overview Screen - Summary

- · This method will paste
 - Multiple analytes
 - One instrument or 2 (or more) instruments
- In EE, Open the module and remain in the Module Overview Screen. AMC in this example.
- Switch to your excel spreadsheet formatted for each method like so:
 - Analyte Results are in columns with header names spelled exactly the same for both methods,.
 - a **SpecID** column is required as the first column.
- For the X method, Highlight the Analyte names and results, but NOT the method name From the Excel menu, select Edit/Copy.
- Switch to EE. From the Module Overview Screen, select **Edit/Paste** with policies table from the EE menu. When EE asks whether you want to link the methods, answer No. because you only have one set of data.
- Switch back to Excel, and repeat the steps for the Y method. This time, when EE asks whether you want to link, answer Yes.

	X Me	thod	
SpecID	Calcium	Glucose	Sodium
ABC123	10.5	513	164
AQQ344	11.5	585	123
QBZ555	8.8	176	192
AOQ123	20.3	468	83

	Y Me	thod	
SpecID	Calcium	Glucose	Sodium
ABC123	10	500	159
AQQ344	11.5	600	123
QBZ555	8.9	182	189
AOQ123	20.1	467	87

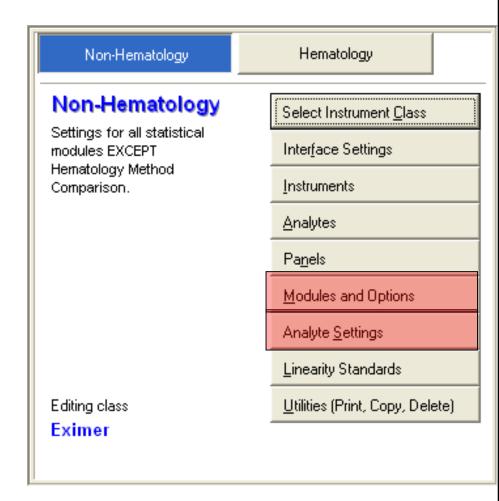
EE\resources\PasteWithPoliciesTable.xls

Linking and Unlinking

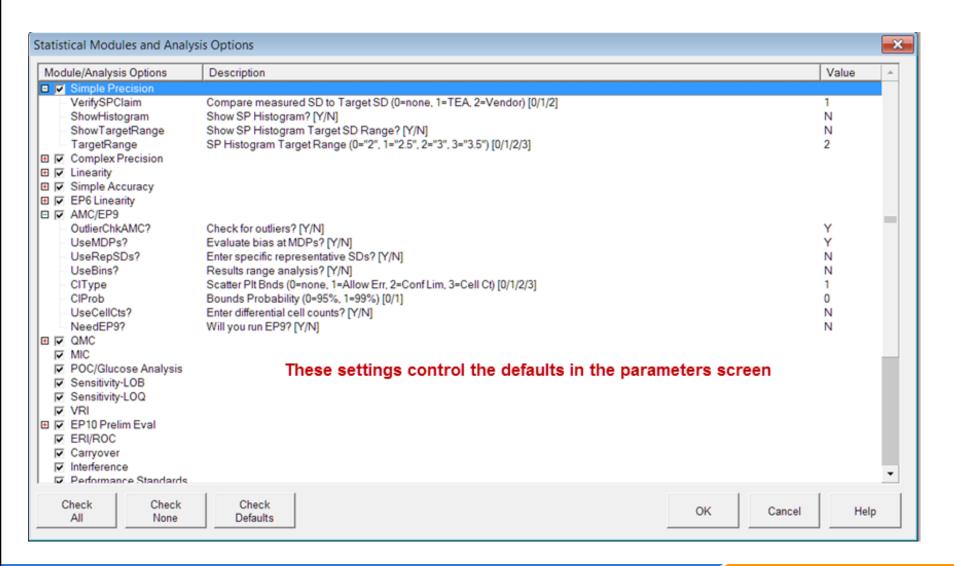
- Each data set is a separate data file within the EE database.
- Scatter plots for two methods are created by linking matching specIDs
- To link the scatter plots:
 - Say "Yes" to the prompt when using "Paste with Policies" if you have two methods.
 - You can link any two methods at any time with the Experiment \ "Link X/Y methods" command.
- To unlink a scatter plot:
 - Right click on the specific experiment in the Overview screen and choose "unlink"

RRE Step 2 – Performance Standards

- We have just done a lot of Rapid Results Entry
- We created many experiments at once
- We calculated instantly
- But we have no Performance Standards

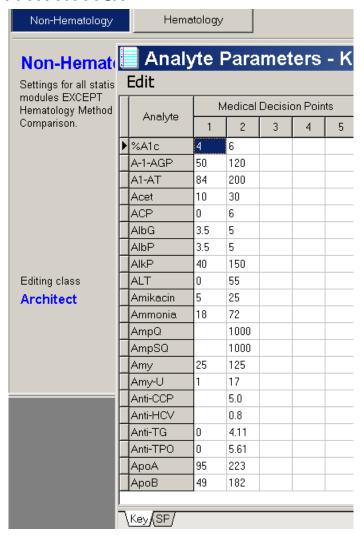


Modules and options

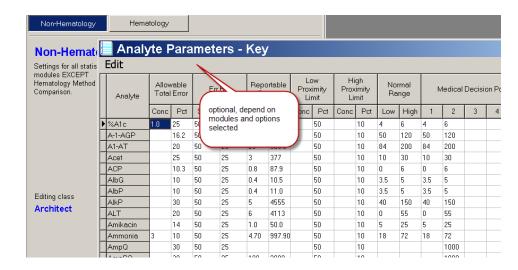


The tabs and input columns appearing in Analyte settings depend on selections in Modules / Options

Minimal



Most pass/fail options selected

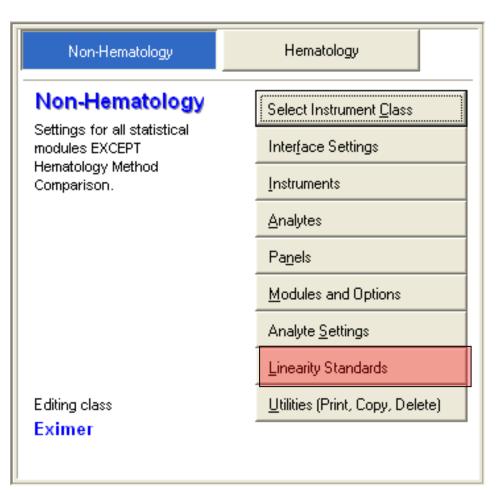


Exercise

- Do RRE/Define Policies, and select the Sample-US class.
- Select Modules and Options. Check the five standard modules: Simple Precision, Linearity, AMC, VRI, and 2IC
- Select Analyte Settings. Define the settings for your analytes.
- Go to the Linearity Module and do Experiment / New from Policies for your analyte. Are all the yellow fields filled in?

Step 3 – Linearity Materials

- Go to RRE / Define Policies
- Select Instrument Class Example
- Select the Linearity Standards button



Exercise

- Add a Linearity Kit
 - Value Mode: Pre-Assigned
 - Kit Name: Juicy
 - Number of Specimens: 5
 - Instrument Code: J
- Set Assigned Values for the Kit as defined on the following Slide

Juicy Linearity Kit Package Insert

Lot Number: A2345B

Expiration Date: 03/31/2009

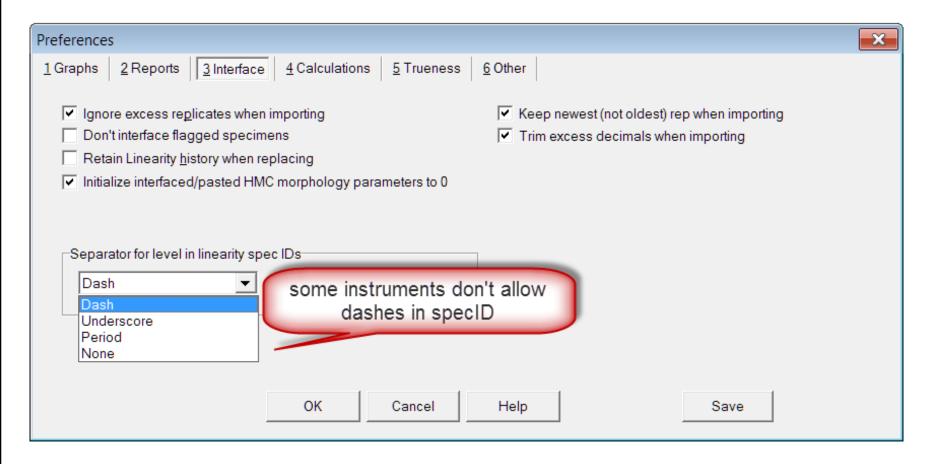
Calibrated using National Reference Method Values

	Level 1	Level 2	Level 3	Level 4	Level 5
Glucose	25	200	375	550	725
Sodium	110	130	150	170	190
Asparagu s	2	25	60	95	110

Exercise: Pasting Linearity Results with Policies

- Go to the Linearity tab in the RRE-Examples spreadsheet and correct the spec IDs
 - If the Kit's Instrument code is "J", then J-01, J-02, etc must be the specIDs of the specimens
 - when run on the instrument
 - the specID of the specimens in the paste file
 - Select the entire tab page and import it to the Linearity module using Paste with Policies / Data in Table Format

Preferences – Interface Tab



4 ways to create a new experiment using manual or copy/paste techniques

- 1. Experiment / New experiment
 - Must enter instrument, analyte names, units, TEa, everything!
 - 1st Icon does the same thing.
- 2. Experiment / New from Policies
 - if policy definitions are set up, no need to re-enter analyte parameters
- 3. Copy and paste from spreadsheet to automatically create new experiments
 - In Module Overview Screen, paste data copied from spreadsheet.
 - Can paste multiple analytes from multiple instruments with spec IDs.
 - With or without policy definitions set up.
 - If you don't have policy definitions established, then you will need to enter the values for required fields in the parameter screen.

Example spreadsheets in EE/resources folder

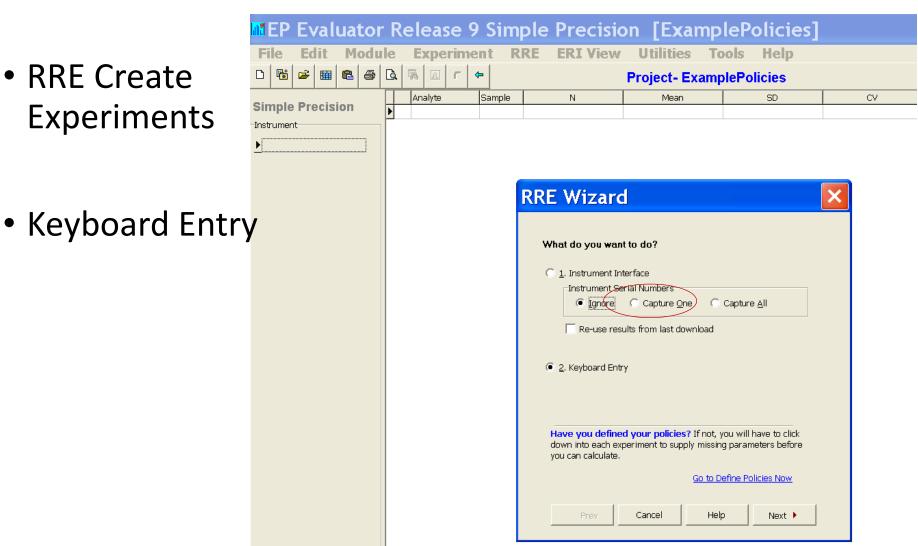
4. Keyboard entry from Printouts

Best way to transcribe data from printed reports

- 1. RRE \ Create experiment
 - 1. Must have some policies defined
 - 2. Must have panels defined in printout order
 - 3. Entry of spec IDs is recommended to ensure correct linking of data.
- 2. Select keyboard entry and follow the prompts
 - 1. Can enter a new instrument
 - 2. Can create new panels
- 3. A worksheet appears for you enter data.
- 4. Press F9 to send data to the experiment
 - For method comparison, Answer No to "Link X and Y"
- 5. Repeat for second instruments data
 - 1. Answer YES to "Link X and Y"

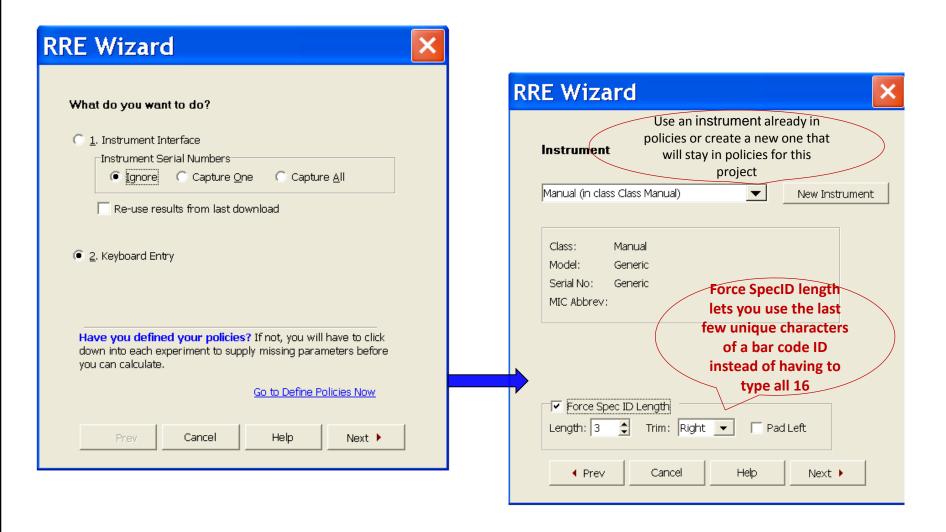
Keyboard entry from Printouts

 RRE Create **Experiments**



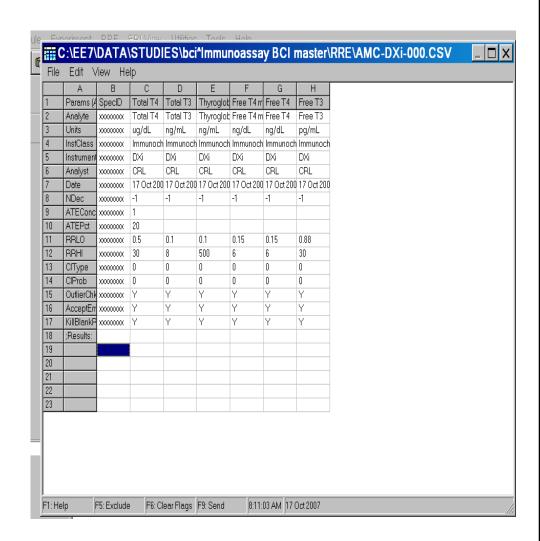
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RRE \ Create experiment



RRE Worksheet

- Enter data from printouts in specified panel order
- Go to desired module overview screen
- Click RRE create experiments
- Follow prompts to popup RRE worksheet.
- Note that it is automatically named and will be saved in the EE\Data\studies\"project name"\RRE folder
- Manually enter specIDs and data
- Press F9 to send data to new experiment
- You will be prompted to save the RRE worksheet



Related documents

When using policies

- Paste policies /table or list
- Example policies project
- RRE worksheet

Without policies

- PasteParmSS.xls can paste and create experiments in any EE version
- Paste Parms SS is very similar to the RRE worksheet
- RRE field codes.xls
 provide the correct codes
 for the required
 parameters.

What is the File Format?

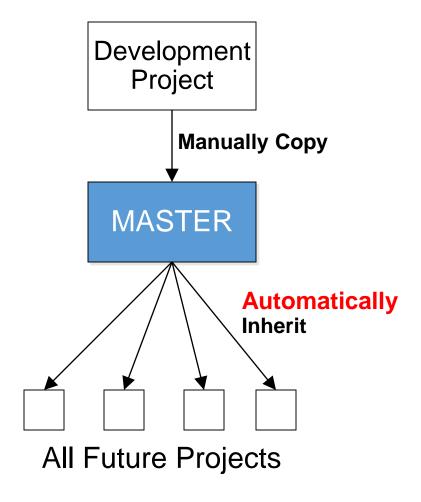
List Form	at (One F	Result per L	₋ine)			
InstSerNo	SpecID	TestDate	TestTime	Analyte	Result	
AAA-1000 \	SPEC1	7-Apr-08	0:08:00	Calcium	10.1	
AAA-1000	SPEC1	7-Apr-08	10:42:00	Glucose	171	
AAA-1000	SPEC1	7-Apr-08	13:25:00	Sodium	120	
AAA-1000	SPEC2	7-Apr-08	10:32:00	Calcium	10.1	
AAA-1000	SPEC2	7-Apr-08	13:18:00	Glucose	81	
AAA-1000	\$PEC2	7-Apr-08	19:55:00	Sodium	111	
Table For	mat (One	Specimen	per Line)			
InstSerNo	SpecID	TestDate	TestTime	Calcium	Glucose	Sodium
AAA-1000	SPEC1	7-Apr-08	0:08:00	10.1	171	120
AAA-1000	SPEC2	7- <u>A</u> pr-08	_10 <u>:3</u> 2 <u>:0</u> 0	10.1	81	111
Optional		Optional in	n some ca	ses		

Without Optional Columns ...

mat (One	Result per	Line
Analyte	Result	
Calcium	10.1	
Glucose	171	
Sodium	120	
Calcium	10.1	
Glucose	81	
Sodium	111	
ormat (One	Specime	n per Lin
Calcium	Glucose	Sodium
10.1	171	120
10.1	81	111
1.2		1
	Analyte Calcium Glucose Sodium Calcium Glucose Sodium Calcium Chalcium	Analyte Result Calcium 10.1 Glucose 171 Sodium 120 Calcium 10.1 Glucose 81 Sodium 111 ormat (One Specime Calcium Glucose 10.1 171

Using the MASTER Project to propagate your Policies to your future Projects

- MASTER is a project template that contains only Policies (no experiments).
- You cannot open, delete or rename your master project.
 You can only modify the policies within it (and backup / restore)
- When you create a new project, that new project is initialized to contain whatever Policies are in MASTER.

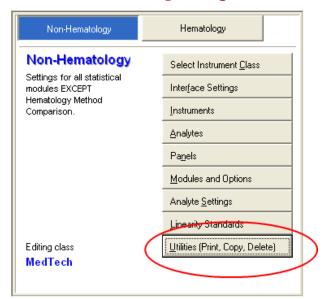


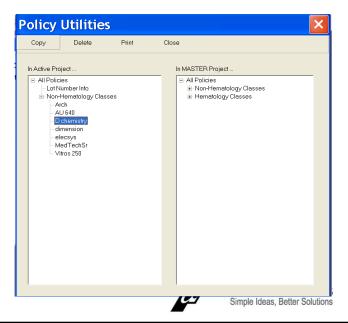
MASTER Project

- Created using Policy Definitions
- Cannot be opened or viewed in the File Open menu
- Cannot be renamed, deleted,
- Contains no inventory
- Can be backed up and restored using the Utilities File Manager.
- New Projects inherit policy definitions from the "Master Project"
- Policy definitions from a current project can be copied to the Master project for future "new projects"

How to copy policies to the MASTER project

- Menu command RRE / Define Policies
- Select the Utilities button
- Policy Utilities shows
 - Left: active current project
 - Right: Master project contents
- On your active project policies area, highlight the policy you wish to copy
- Select radio button Copy
- The policy is copied to the Master project.
 - Same name classes get replaced
 - New classes get added
 - Existing policies in the master do not get deleted unless you select "delete"

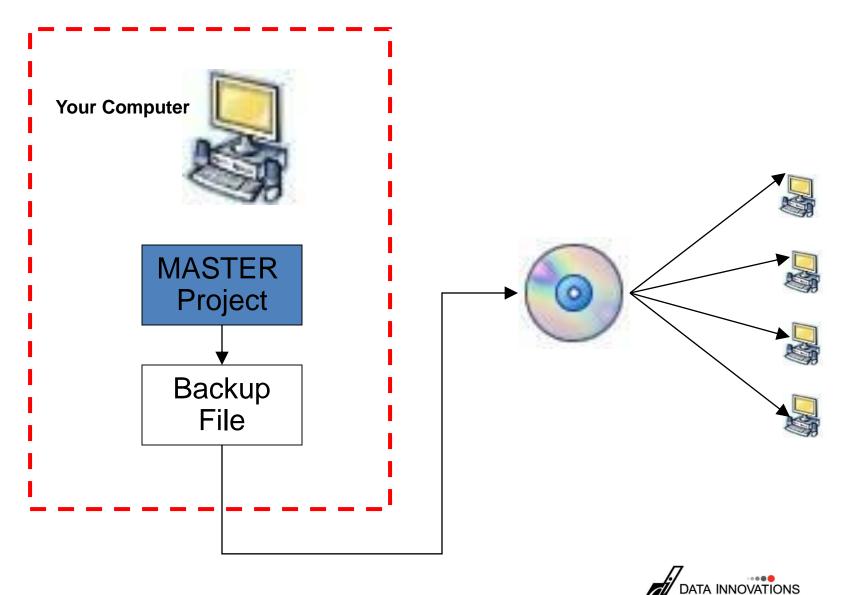




Project Backups:A way to Share Data

- A EP Evaluator "project" contains all the data, policy definitions, experiments with data, and reports for a specific work assignment.
- Projects are portable only by using the backup function.
- To create a backup (archive) file for your project:
 - From the Main Statistical Module screen
 - Open Utilities\file Manager
 - Select the Project Name in the top half of the screen
 - Click on Backup to create a zipped file archived to date and time.
 - Default folder is c:\EE\data\backups
 - Can "copy to" any folder or travel drive. Email to your colleagues.
- Restore when needed, or in EP Evaluator on another computer.

Distributing Your Policies to Other EE Users



Exercise

- Delete all policies from your MASTER
- Copy the Example instrument class to MASTER
- Create a new project
- What policies does the new project have?

For EE Support

- North America Telephone Support (802)-658-1955
 - Northamerica-support@datainnovations.com
- Europe telephone support +32 2 332 24 13
 - Europe-support@datainnovations.com
- Asia Telephone Support 852-2398-3182
 - asia-support@datainnovations.com
- Latin America telephone support 55-11-38013283
 - <u>latinamerica-support@datainnovations.com</u>

Additional Training & Services

- Visit the DI website for information on free training. http://datainnovations.com/services/training/ep-evaluator-training-programs
 - Overview and Getting Started with EP Evaluator
 - Project Management
 - RRE and Policy Definitions
 - Hematology Method Comparison
 - Determining Performance standards
 - Inventory Management
- For more in-depth training or consultation
 - Contact the DI Sales organization for a quote
 - **802-658-2050**
 - Northamerica-sales@datainnovations.com



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Thank You!

