

# **The challenge of auditing technical records generated during complex DNA casework processes**

International Symposium on Forensic Science Error Management

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# ASCLD/LAB Top Ten Nonconformities

## - 2013 # 1 Finding

**4.13.2.1 has multiple components to it. Examples for those components are included below.**

- Insufficient technical records
- Not all original data preserved
- Insufficient documentation to allow for duplication
- Preserved information is not specific enough
- Personnel performing analysis not identified

# Adding some perspective

- Individuals will eventually make errors
- Laboratory systems should be designed to have overlapping oversight.
- This redundancy should prevent error propagation
- Ultimately the best laboratory systems educate the analysts when errors occur and insulate the consumer from the negative impacts of erroneous results.
- In Summary: **“Individuals can and will fail, a Forensic Laboratory System does not have the luxury of displaying these human traits”.**

# What is our product?

Good quality DNA profiles that can be reliably utilized by Investigating Bodies and the Judicial System to assist in the resolution and prevention of criminal activities.

Or My Version:

**Educated and skilled analysts performing sound science to promote public safety.**

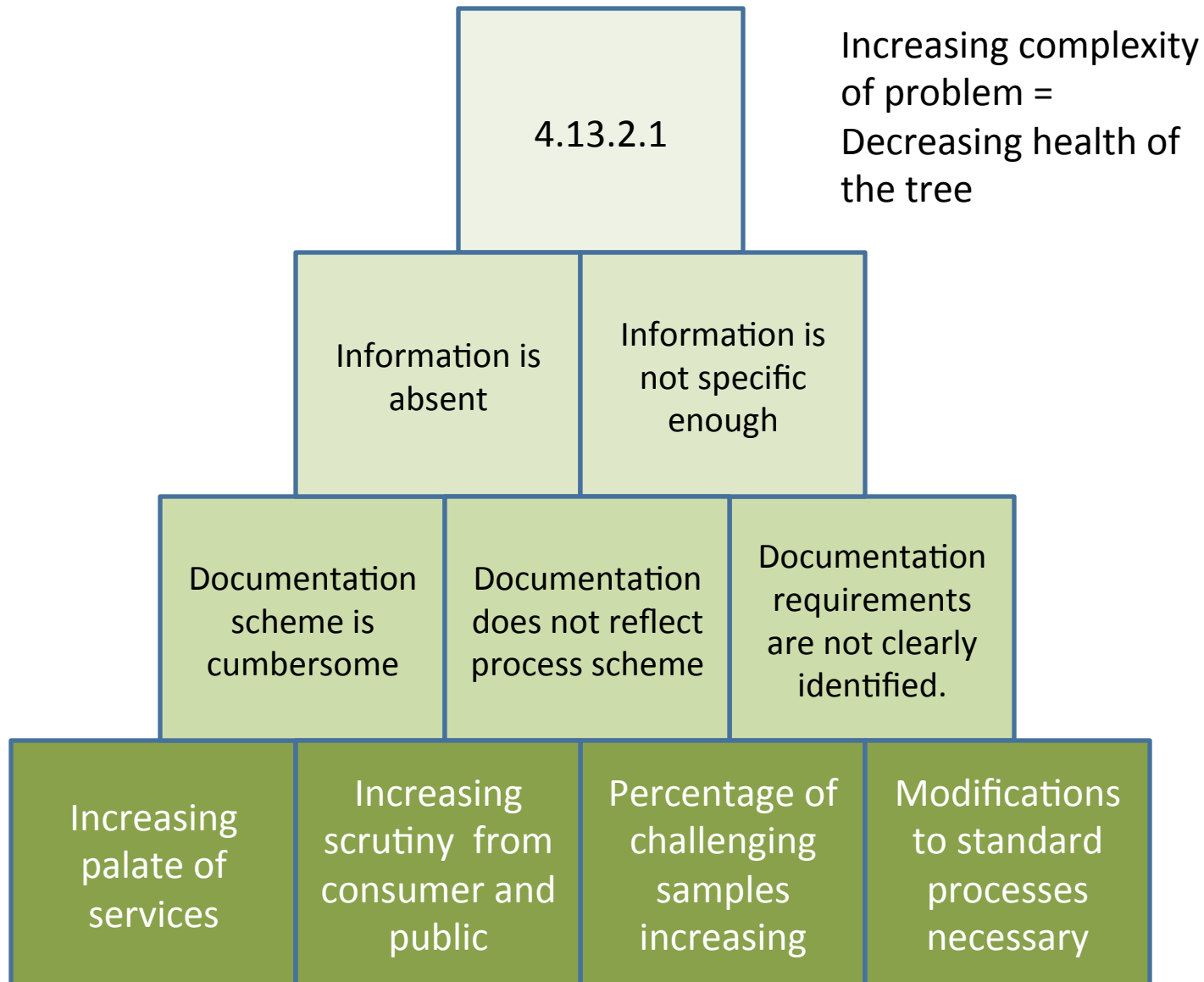
# What the Finding does not say

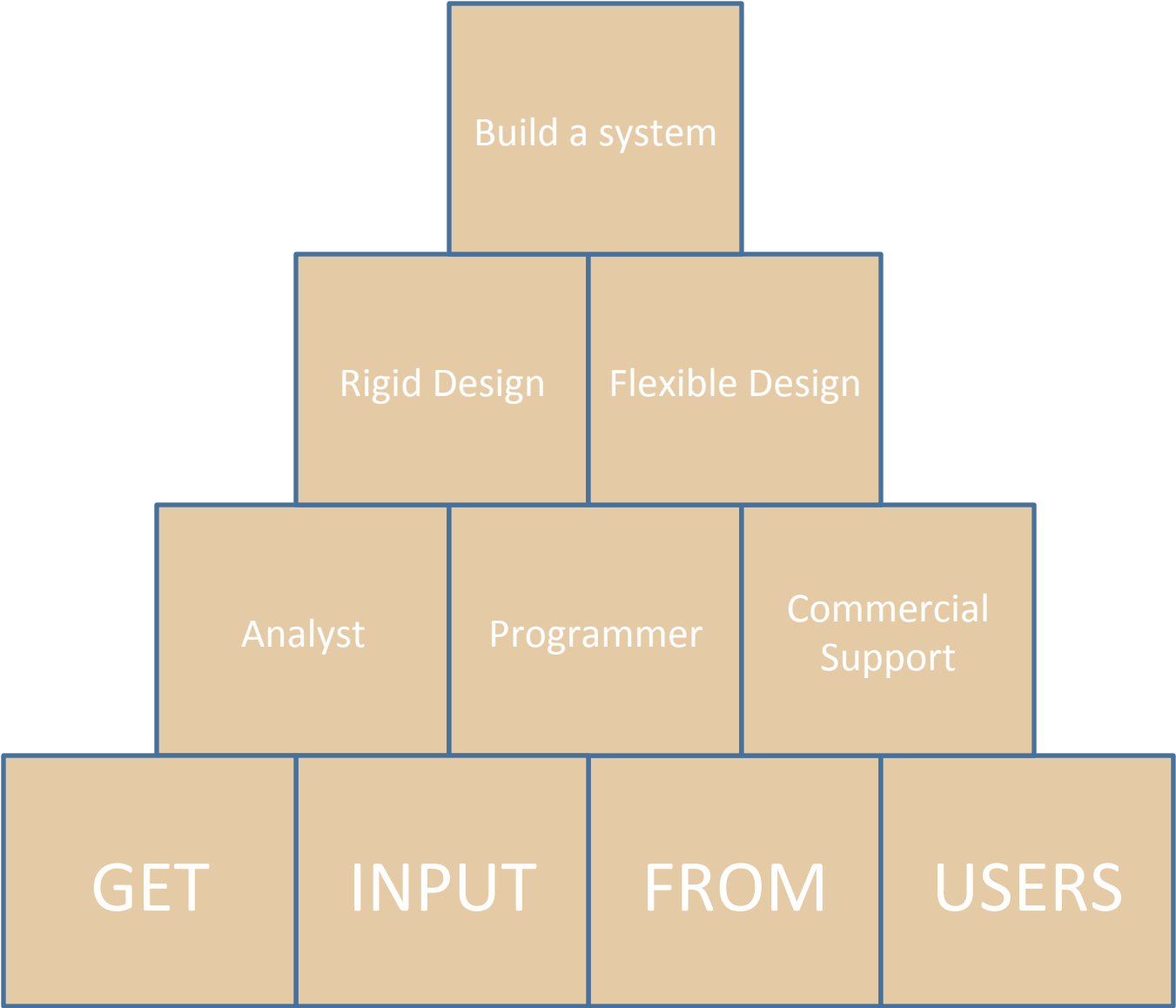
- The quality of the profiles being generated and reported is inferior
- The results being reported are unreliable
- Analysts lack the professional skill necessary to perform the complicated analysis assigned to them.

Use the decision concept tree to describe the problem and map a solution



# SIMPLIFIED TREE OF THE PROBLEM







# Computer Directed system

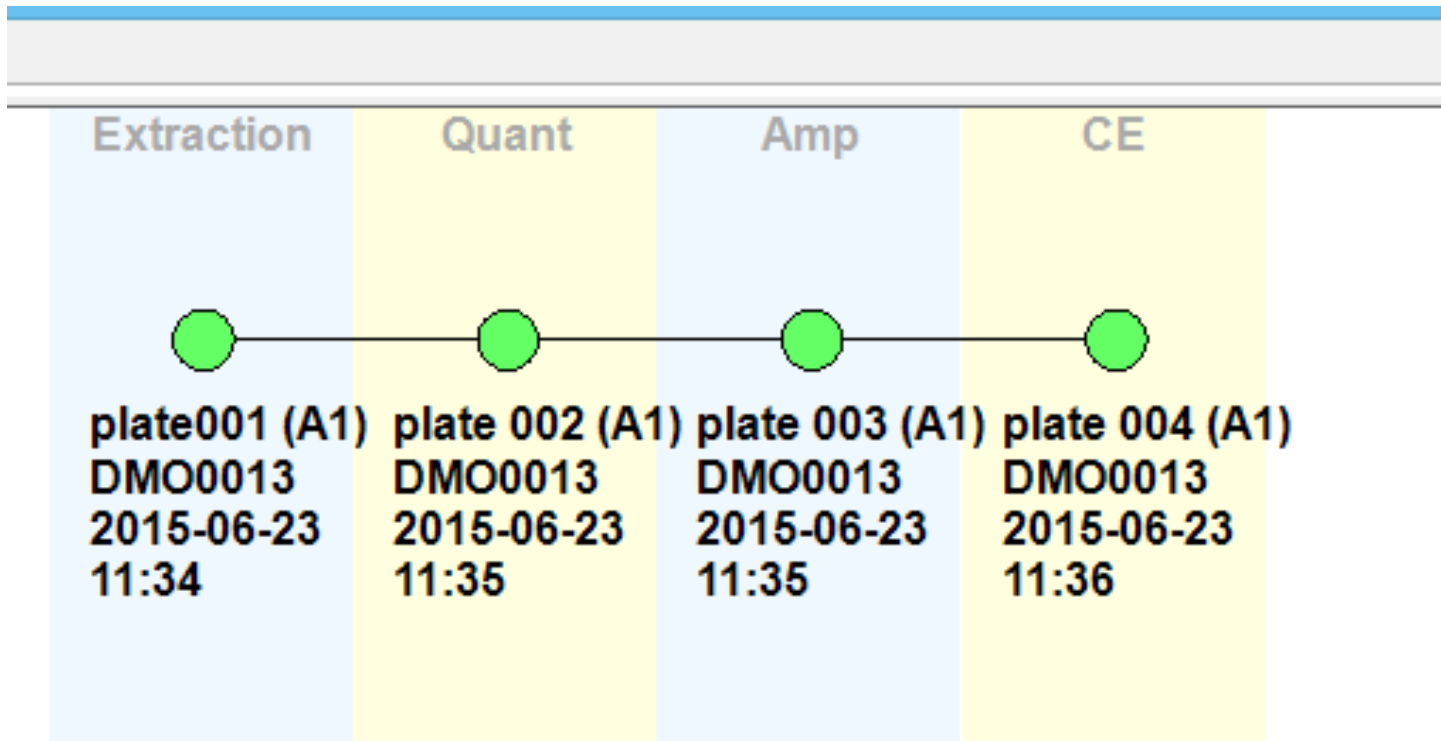
When you talk about a Rigid System what you are really talking about is a Computer Directed system

- Usually very information rich
- Very efficient with linear sample process pathways
- Good at inventory and chain of custody
- Require a lot of initial customization from manufacturer (because of rigid design framework)
- Systems can be difficult to adapt to changing process paradigms
- Often information needed for analysts to determine the appropriate sample process pathway not preserved or not is not specific enough
- Usually require the laboratory and analysts to adapt their workflow to the design of the system

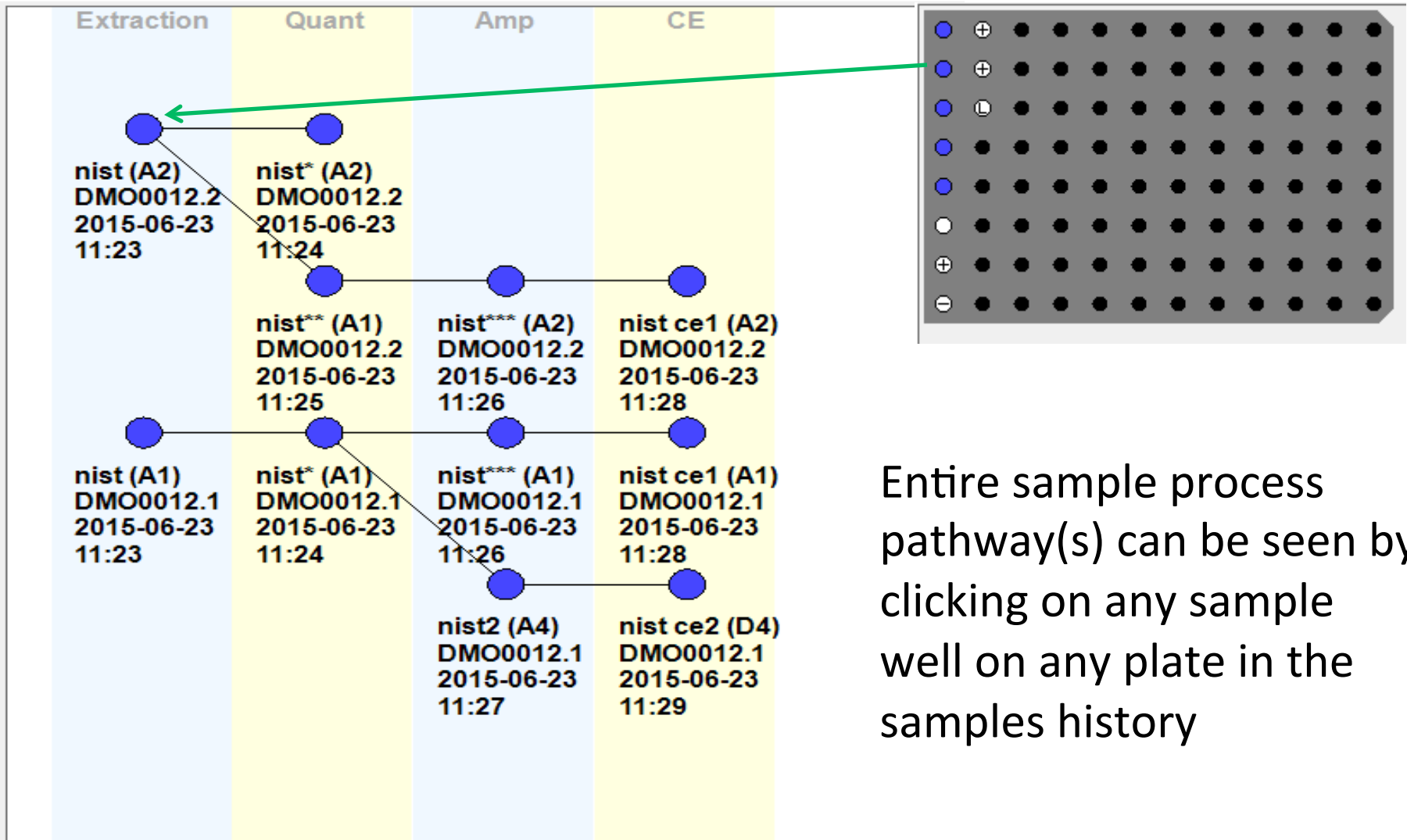
# Computer Assisted

- Should be very information rich
- Efficient with linear sample process pathways
- Good at inventory and chain of custody
- Allow for very complex sample process pathways
- Can be easily adapted to changing process. (Ideally the user would be able to make most of the changes)
- Provide QA/QC flags as well a sample assessment information to the analyst during processing
- Means for trouble shooting and event identification
- Provide convenient means for user to document observations
- Assist the reviewer in performing technical reviews.
- Work the way the laboratory and analysts work.

# Simple process pathway



# More complex sample process pathway



# Why make the distinction?

- The more branch points in a particular tree the more the analyst is interacting with the sample
- Each branch point is also a decision point where the analyst uses their discretion
- Very complex trees usually involve some modifications (not deviations 😊) to the typical sample process paradigm (e.g. extra washes)
- This relates directly back to the first 3 components of 4.13.2.1

# Demonstrating the Computer Assisted Concept using DNA Extraction

All pertinent sample information can be recorded

Unique identifying reference number (customizable format)

The screenshot displays the DNA EXPRESS software interface. At the top, there are navigation buttons: 'Create Plate', 'Import From Serology Project', 'Extraction Worksheet', and 'Publish Plate Print'. The 'DNA EXPRESS' logo is in the top right. Below the navigation is a table with the following columns: Plate Well, Case #, Sample Type, Log #, Sample ID, Sample Description, and Sample Consumed. The table contains 17 rows of data. To the right of the table is a 'Synchronized Visual Summary of Plate' showing a 12x12 grid of wells. Each well is represented by a colored circle: blue, green, black, or white. A red circle highlights the well at row 6, column 2. Below the grid are three buttons: 'Move Up', 'Move Down', and 'Delete Selected'. A blue arrow points from the text 'All pertinent sample information can be recorded' to the 'Import From Serology Project' button. A green arrow points from the text 'Unique identifying reference number (customizable format)' to the 'Log #' column header in the table. A blue arrow points from the text 'Drop down boxes' to the 'Sample Type' column header in the table.

Plate Well	Case #	Sample Type	Log #	Sample ID	Sample Description	Sample Consumed
A1	2015-009	Questioned	DMO0028	2	Blood stain	Yes
B1	2015-009	Questioned	DMO0029	6	Blood stain	No
C1	2015-009	Questioned	DMO0030	15	Blood stain	No
D1	2015-009	Questioned	DMO0031	25	Blood stain	Yes
E1	2015-009	Questioned	DMO0032	26	Blood stain	No
F1	2015-009	Questioned	DMO0033	27	Blood stain	N/A
G1	2015-009	Internal Std	DMO0034	IS	IS0045	N/A
H1	2015-009	Reagent Blank	DMO0035	RB1	Reagent Blank	N/A
A2	2015-0014	Victim	DMO0037	24	Victim reference	No
B2	2015-0014	Elimination	DMO0038	25	Elimination reference	No
C2	2015-0014	Suspect	DMO0039	26	Suspect reference	No
D2	2015-0014	Internal Std	DMO0040	IS	IS0045	N/A
E2	2015-0014	Reagent Blank	DMO0041	RB2	Reagent Blank	N/A
F2						N/A

Synchronized Visual Summary of Plate

Drop down boxes

Document all of the SOP material via drop down selection, scanning or computer assisted documentation.

Process: EZ1

Contents:

Component	Lot / Batch #
Lysis Buffer	68393 (06/27/15)
ProK	862134 (06/25/15)
Sample tubes	907qe3 (07/01/15)

Start Time: 6-12-15 1800  
End Time: 6-13-15 0110  
Start Temp: 72C  
End Temp: 72C

Analyst can free type any notes and observations here and they will automatically be save to the plate record as well as print on all of the related documents.

Suspend  
Complete

Analyst can free type any notes and observations here and they will automatically be save to the plate record as well as print on all of the related documents.

# Computer Assisted DNA Quantification Assessment

2		4.47E+00	3.60E+00	1.24E+00	2.16E+01	Check IPC	OK
2		3.25E+00	3.01E+00	1.08E+00	2.08E+01	OK	Check MELT
2		2.87E+00	2.75E+00	1.05E+00	2.15E+01	OK	Check MELT
2		4.66E+00	3.62E+00	1.29E+00	2.18E+01	Check IPC	Check MELT
2		1.98E+00	2.81E+00	7.03E-01	2.15E+01	Check IPC	OK
2		9.42E-01	2.45E+00	3.85E-01	2.17E+01	Check IPC	Check MELT
2		3.79E+00	3.44E+00	1.10E+00	2.16E+01	OK	Check MELT
2		2.78E+00	2.74E+00	1.02E+00	2.14E+01	OK	OK
3		2.91E+00	3.78E+00	7.69E-01	2.14E+01	Check IPC	Check MELT
4		1.61E+00	2.57E+00	6.26E-01	2.16E+01	OK	Check MELT
4		3.68E+00	2.64E+00	1.40E+00	2.14E+01	OK	OK
4		2.86E+00	1.75E+00	1.63E+00	2.12E+01	OK	Check MELT
4		1.70E+00	3.17E+00	5.36E-01	2.18E+01	Check IPC	OK
4		1.43E+00	1.60E+00	8.97E-01	2.18E+01	OK	OK
4		2.74E+00	2.77E+00	9.92E-01	2.15E+01	OK	Check MELT
4		2.80E+00	4.44E+00	6.31E-01	2.20E+01	OK	Check MELT
5		2.76E+00	2.54E+00	1.09E+00	2.12E+01	OK	OK
5		3.11E+00	4.07E+00	7.64E-01	2.11E+01	Check IPC	OK
5		2.39E+00	2.81E+00	8.49E-01	2.17E+01	Check IPC	Check MELT
5		3.68E+00	7.15E-01	5.15E+00	2.21E+01	OK	Check MELT
5		3.04E+00	2.58E+00	1.18E+00	2.13E+01	Check IPC	Check MELT
5		4.01E+00	2.80E+00	1.43E+00	2.12E+01	OK	Check MELT
5		3.43E+00	2.89E+00	1.19E+00	2.20E+01	OK	OK

IPC Warning

Curve Warning

Low Auto Conc.

Low Male Conc.

Open File

Apply Import to  
Plate

Continue



# Transfer Window View

Serology   Extraction   Quant   Amp   CE

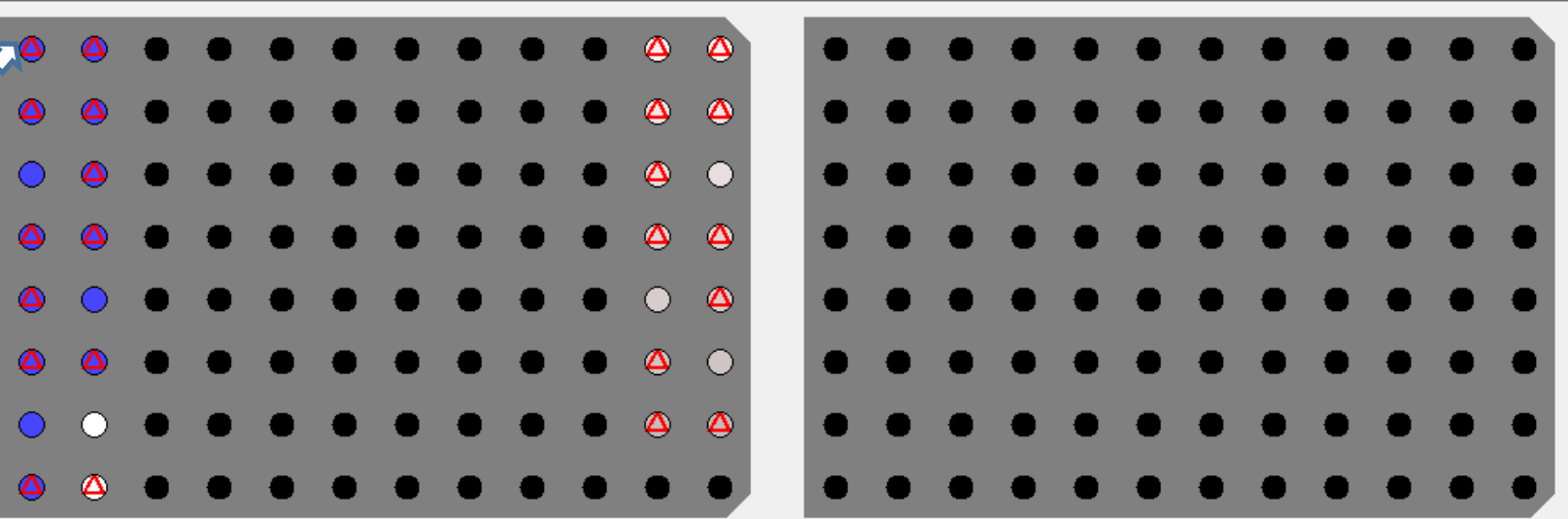
Create Plate   Choose Chemistry   Transfer Samples   Add Standards   Normalization   Export   Publish Plate

Project   Amp   Print

**DNA XP**

Source Plate: 6-25-152\*

Destination Plate: 6-25-152\*\*



Remove Empties

Add Empty

PLATE SUMMARY  
IPC - 7  
Curve - 12  
Auto - 4  
Y - 4

Transfer Additional Samples

Complete

ID: 1 LOG: DMO0033   Low Y Conc.   Curve Warning  
IPC Warning

A1: 1   D1: 1   Transfer All   A1: 1   D1: 1

# Examples of Policy Rule Firings

- Extraction
  - Expired Reagents
  - Notes Added
  - Documentation Incomplete
  - Missing Controls
- Quantification
  - Check IPC
  - Check Melt Curves
  - Autosomal Low
  - Y Low
  - Elevated Auto/Y ratio
  - Notes Added
  - Expired Reagents
  - Documentation Incomplete
  - Missing Controls

# Expired Amplification Reagent Warning User View

The screenshot shows a software interface with a warning dialog. On the left, there are two dropdown menus: 'Chemistry: Identifiler' and 'Lot: b3452c5 (Expired)'. Below the lot dropdown is a red warning message: 'Warning, this lot is expired!'. At the bottom left are two buttons: 'Cancel' and 'Continue'. On the right, a table lists reagents and their expiration dates.

<b>primer</b>	<b>(05/30/15)</b>
<b>Taq</b>	<b>(07/01/15)</b>
<b>STR Buffer</b>	<b>(07/16/15)</b>

The reagent can still be used which is often important in training and trouble shooting

# Support View for Tech Review

**User Filter**

User:

Case Filter

Log Number Filter

Name Filter

Time Filter

Search Unarchived

Search Archived

Filter

**Cases:**

Reviewed:  20015-001  20015-006  IS 6-12-15  RB1 6-12-15

Warnings Reviewed:  20015-001  20015-006  IS 6-12-15  RB1 6-12-15

Support Documentation **Tech Review Notes**

Plate Well	Case #	Sample Type	Log #	Sample ID	Sample Description	Sample Consumed
A1	20015-001	Questioned	DMO0014	3	Question stain	Yes
B1	20015-001	Questioned	DMO0015	5	Question stain	No
C1	20015-001	Questioned	DMO0016	15	Question stain	No
D1	20015-001	Questioned	DMO0017	6	Question stain	Yes
E1	20015-001	Questioned	DMO0018	16	Question stain	No
F1	20015-006	Questioned	DMO0019	9	Question stain	No
G1	20015-006	Questioned	DMO0020	10	Question stain	No
H1	20015-006	Questioned	DMO0021	11	Question stain	Yes
A2	20015-006	Questioned	DMO0022	12	Question stain	No
B2	20015-006	Questioned	DMO0023	73	Question stain	No
C2	20015-006	Questioned	DMO0024	13	Question stain	No
D2	20015-006	Questioned	DMO0025	16	Question stain	No
E2	IS 6-12-15	Internal Std	DMO0026	IS0001	Internal Std	N/A
F2	RB1 6-12-15	Reagent Blank	DMO0027	RB1		N/A
Start Time:		6-12-15 1800				
End Time:		6-13-15 0110				
Start Temp:		72C				
End Temp:						
<b>Process: EZ1</b>						
Lysis Buffer			5432			
ProK			862134			

Start Time:

End Time:

Start Temp:

End Temp:

Process:

Contents:

Component	Lot / Batch #	
Lysis Buffer	5432 (Expired)	<input type="text"/>
ProK	862134 (06/25/15)	<input type="text"/>
Sample tubes	907qe3 (07/01/15)	<input type="text"/>

iii  
gsdf  
sfgrs  
3-13  
3-13\*  
3-13\*\*  
3-13\*\*\* (Reviewed)  
123  
b2  
Sero1  
ext 1  
new  
new\*  
new2  
new2\*  
12342314  
11352  
dafasfasdfasd  
new ser  
aaa  
bbb  
b123  
ddd  
new 5-20  
new 5-20\*  
1235  
1232131412  
nist  
nist\*  
nist\*\*  
nist\*\*\*  
nist2  
nist ce1  
nist ce2  
jjice  
plate001  
plate 002  
plate 003  
plate 004  
**RDA0014**  
RDA0015

Mark Plate As Reviewed

Archive Plate

Print Selected Plates

Print All Plates

Print

Done

# QC Flags and Warnings for Tech Review

The screenshot displays a software interface with the following components:

- User Filter:** A control panel with a dropdown menu set to 'demo' and navigation buttons (down, up, and close).
- Item List:** A vertical list of identifiers including 'iii', 'gsdf', 'sfgrs', '3-13', '3-13\*', '3-13\*\*', '3-13\*\*\* (Reviewed)', '123', 'b2', 'Sero1', 'ext1', 'new', 'new\*', 'new2', 'new2\*', '12342314', '11352', 'dafasfasdfasd', 'new ser', 'aaa', 'bbb', 'b123', 'ddd', 'new 5-20', 'new 5-20\*', '1235', '1232131412', 'nist', 'nist\*', 'nist\*\*', 'nist\*\*\*', 'nist2', 'nist ce1', 'nist ce2', 'jijce', 'plate001', 'plate 002', and '---- 003'.
- Case Filter:** A small input field at the bottom left.
- Support Documentation / Tech Review Notes:** A panel with two sub-sections: 'Plate Warnings:' (containing the text 'Expired reagents.') and 'Tech Review Notes:' (a large empty text area).
- Warning:** A red text overlay 'Plate locked by another user.' is positioned over the 'Tech Review Notes' area.

Metrics



Timeline Calendar Tree View Plate Search

June 2015

Su	Mo	Tu	We	Th	Fr	Sa
31	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

July 2015

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

August 2015

Su	Mo	Tu	We	Th	Fr	Sa
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

September 2015

Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	1	2	3
4	5	6	7	8	9	10

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	31 May	01 Jun	2	3	4	5	6
31/5 - 6/6							
	7	8	9	10	11	12	13
7 - 13 Jun			Meeting				
	14	15	16	17	18	19	20
14 - 20 Jun							
	21	22	23	24	25	26	27
21 - 27 Jun	AUDIT				ProK		Lysis Buffer
	28	29	30	01 Jul	2	3	4
28 Jun - 4 Jul							

# Layered Inventory

The screenshot displays the 'Inventory' application interface, which is divided into three main sections:

- Inventory Tree (Left):** A hierarchical list of items. The 'Identifiler' item is expanded, showing sub-items: 'primer', 'Taq', and 'STR Buffer'. A blue bracket highlights the 'Identifiler' and its sub-items.
- Item Details (Center):** A form for editing item properties. The 'Name' field contains 'Daily Decontamination'. Other fields include 'Requires QC?' (unchecked), 'Process' (set to 'None'), 'Virtual Item?' (checked), 'Instrument?' (unchecked), and 'Multiple Components' (unchecked). A large empty box is present below the form, and a 'Volume' field is at the bottom.
- Lots (Right):** A section for managing lots. It contains a 'Lots:' label, a text area with 'yes' and 'no' entries, and two buttons: 'Add Lot' and 'Remove Lot'.

At the bottom of the window, there are several control buttons: 'Delete Item', 'Edit Item', 'New Item', 'Apply', and 'Cancel'.

# Virtual items

Process:  
EZ1

Contents:

Component	Lot / Batch #		
Lysis Buffer	68393 (06/27/15)	▼	▼
ProK	862134 (06/25/15)	▼	▼
Sample tubes	907qe3 (07/01/15)	▼	▼
Daily	yes	▼	▼

You can record information that may not be associated with an expiration date or deemed critical but is still very important.

This is a great way to remind analysts to include information that may not have a barcode or are intangible items. Also a convenient way to keep track of things like witnesses (e.g. Lot #s would be initials). One of the advantages is that the computer assisted review will warn both user and reviewer if any of the information is not populated.



# Customize your processes on the fly

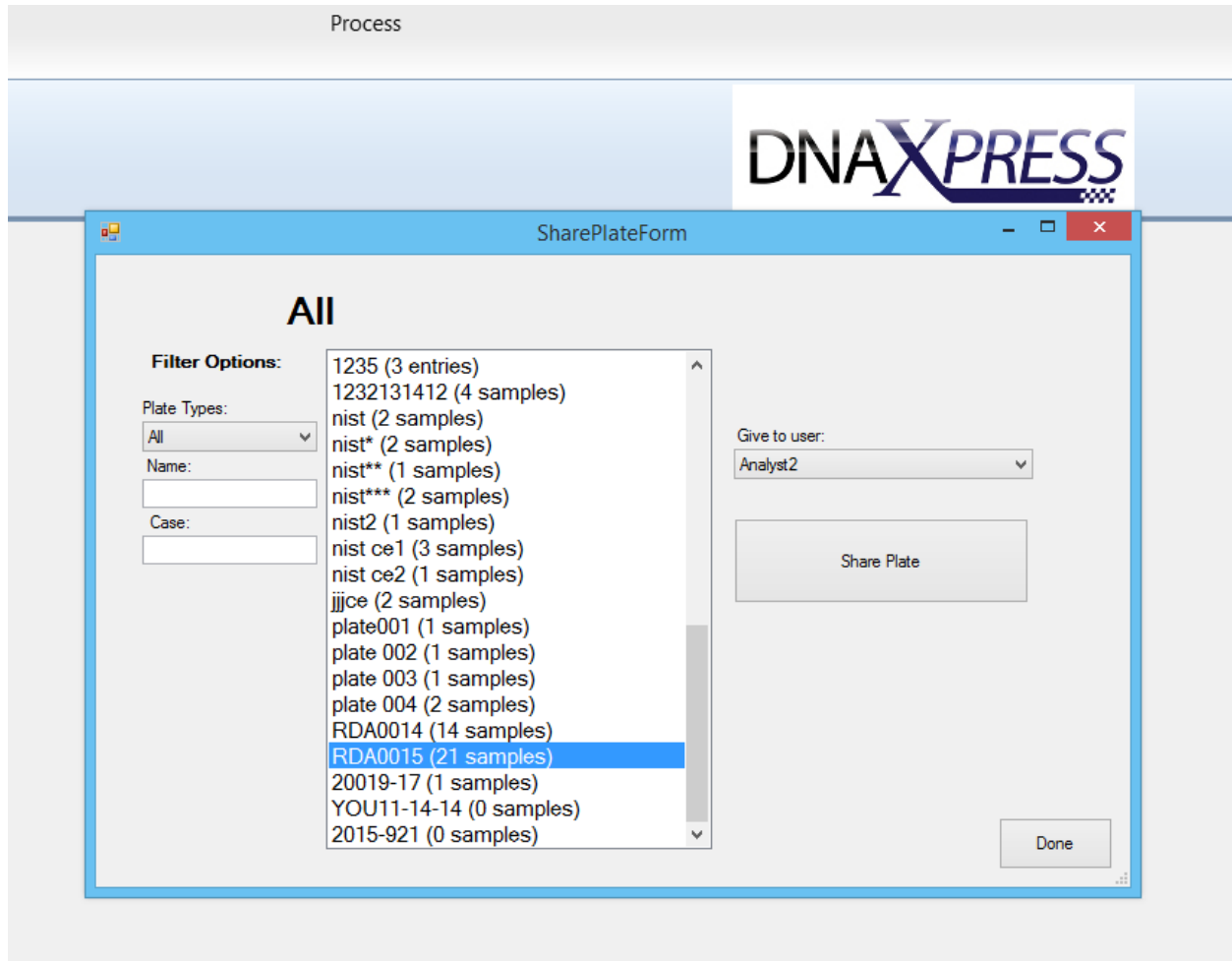
The screenshot displays the 'Inventory' software interface, which is divided into several functional areas:

- Process List:** Located on the left, it features a 'Process:' dropdown menu currently set to 'Extraction'. Below the menu is a list of process names: 'EXT1', 'EZ1', and 'New Process2'. At the bottom of this panel are three buttons: 'New Process', 'Edit Process', and 'Delete Process'.
- Process Details:** The central area, titled 'Process Details', contains an 'Inventory:' list of items. The items are: 'New', '9700', 'New1', 'New2', '7500', 'PP16', 'primer', 'water', 'PCI', 'Plexor', 'PP16 post Amp', 'ladder', '3130', 'Lysis Buffer', 'ProK', 'Sample tubes', 'Filter Tips' (highlighted in blue), 'Human Std', 'Taq', 'STR Buffer', 'Identifiler', 'Quant Duo', and 'pxn mix'. To the right of this list are two buttons: 'Add >' and 'Remove'.
- Name Field:** A text input field labeled 'Name:' is positioned above the 'Contents:' panel, containing the text 'EZ1'.
- Contents:** A large text area on the right, labeled 'Contents:', contains the text 'Lysis Buffer', 'ProK', and 'Sample tubes'. Below this area is an 'Apply' button.

# Advantages of Layered Approach

- Allows you to create any number of process paradigm templates and use them in any combination
- Individual paradigms can be adjusted to the types of samples being received without affecting previous analysis
- Simple interface doesn't require significant computer programming skills to adjust.

# Sharing and batch case work



Only one  
“user” is  
permitted to  
edit a plate at  
any given time

# Computer Assisted Troubleshooting

Metrics

Timeline Calendar Tree View Plate Search

**Time Filter** [Down Arrow] [Up Arrow] [X]

Start: Monday, April 6, 2015 [Calendar Icon]

End: Friday, June 26, 2015 [Calendar Icon]

**Process Filter** [Down Arrow] [Up Arrow] [X]

Process: ce

**Lot Number Filter** [Down Arrow] [Up Arrow] [X]

Lot #: 123

Case Filter  
Log Number Filter  
Name Filter  
User Filter

Search Unarchived  
 Search Archived

Add Filter Filter

**Plates:**

new  
6-25\*\*\*

ID: 4 LOG: DMO0005

**# of Samples: 26**

Plate: testnorm3\*  
(Amplification)

Plate: extractor  
(Extraction)

Plate: newamp  
(Amplification)

Plate: testamp  
(Amplification)

Plate: new ce 3  
(CE)

Plate: newamp 2  
(Amplification)

Plate: tce2  
(CE)

Plate: extr  
(Extraction)

Plate: Demo1-30  
(Extraction)

Plate: demotest

# ASCLD/LAB Top Ten Nonconformities

## - 2013 # 1 Finding

### Proposed resolution of each of the components of 4.13.2.1

- **Insufficient technical records** – Computer assisted review of the Analysis in real time and the informed Review process
- **Not all original data preserved** – Means for convenient addition of analyst observations via free type notes as well as virtual item documentation
- **Insufficient documentation to allow for duplication** – Support Documentation view provides a summary of all of the documentation associated with a particular sample
- **Preserved information is not specific information** – Tree View provides concise history of the sample process pathway that when combined with the Metrics Engine maximizes data preserved
- **Personnel performing analysis not identified** – Password secured user login for primary users with user locked plate sharing, as well as virtual items for indirect users

# Addressing ASCLD/LAB Top Ten Nonconformities – 2013 Bonus

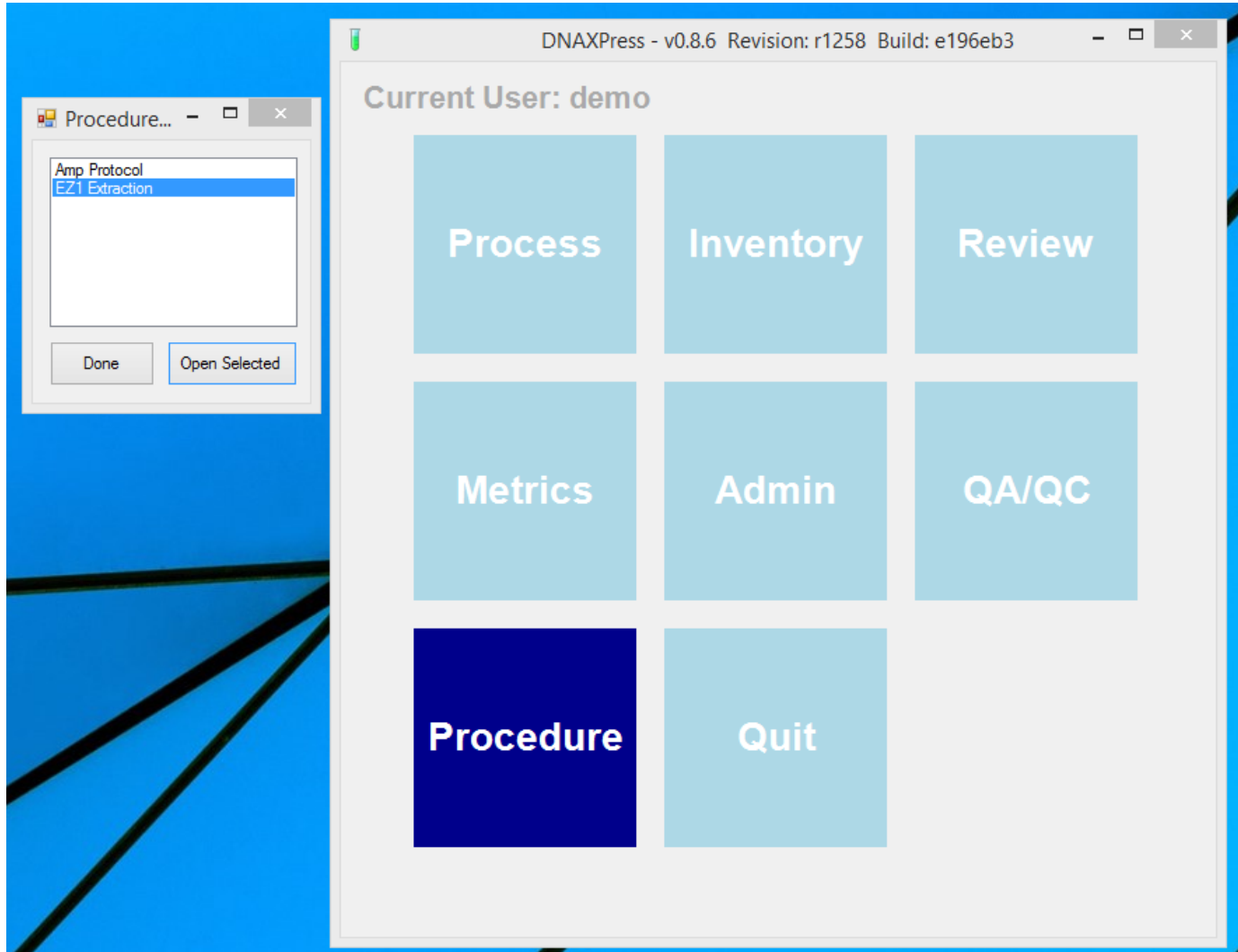
## Standard Cited 4.2.1

Laboratory personnel are not aware of and/or following their own lab procedures. The last sentence of 4.2.1 requires ‘documentation shall (must) be communicated to, understood by, available to and implemented (followed) by appropriate personnel.’ Remember the difference between documents (policies, procedures, instructions) vs. records (objective evidence that you did what you are asked/directed to do). This clause is also used when there is not enough detail in a procedure / instruction ‘to assure the quality of the test result’.

# Bonus



# Procedure Tile





Administration Panel

Users Extraction Quantification Amp CE Review Reporting Procedures

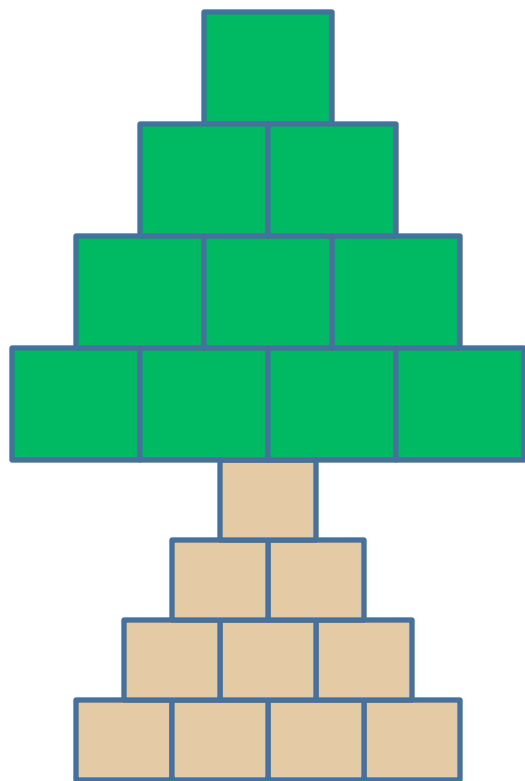
Message:

Notify Users of Update

Last Update:  
2015 23, Jun (14:05)  
Changes have been made to the amplification SOP. Please re

There has been a change to procedures since you last viewed them:  
"Changes have been made to the amplification SOP. Please review changes before resuming casework."

OK



# Thank You

- Nathaniel Caldwell and NicheVision
- Various contributing Agencies
- NIST
- For being a great audience

Enjoy the Fruits of your Labor