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 insolate 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:

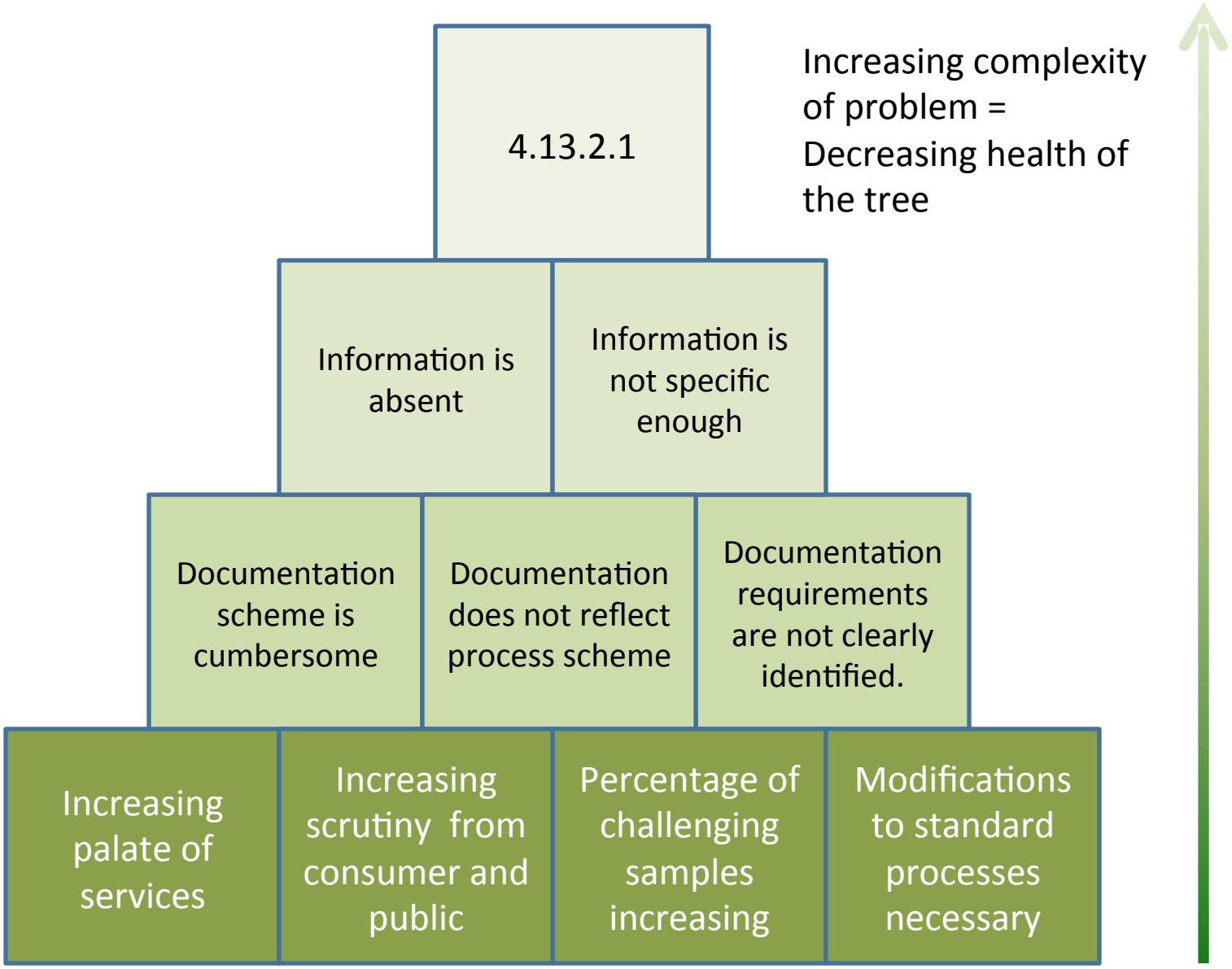
Educated and skilled analysts performing sound science to promote public safety.

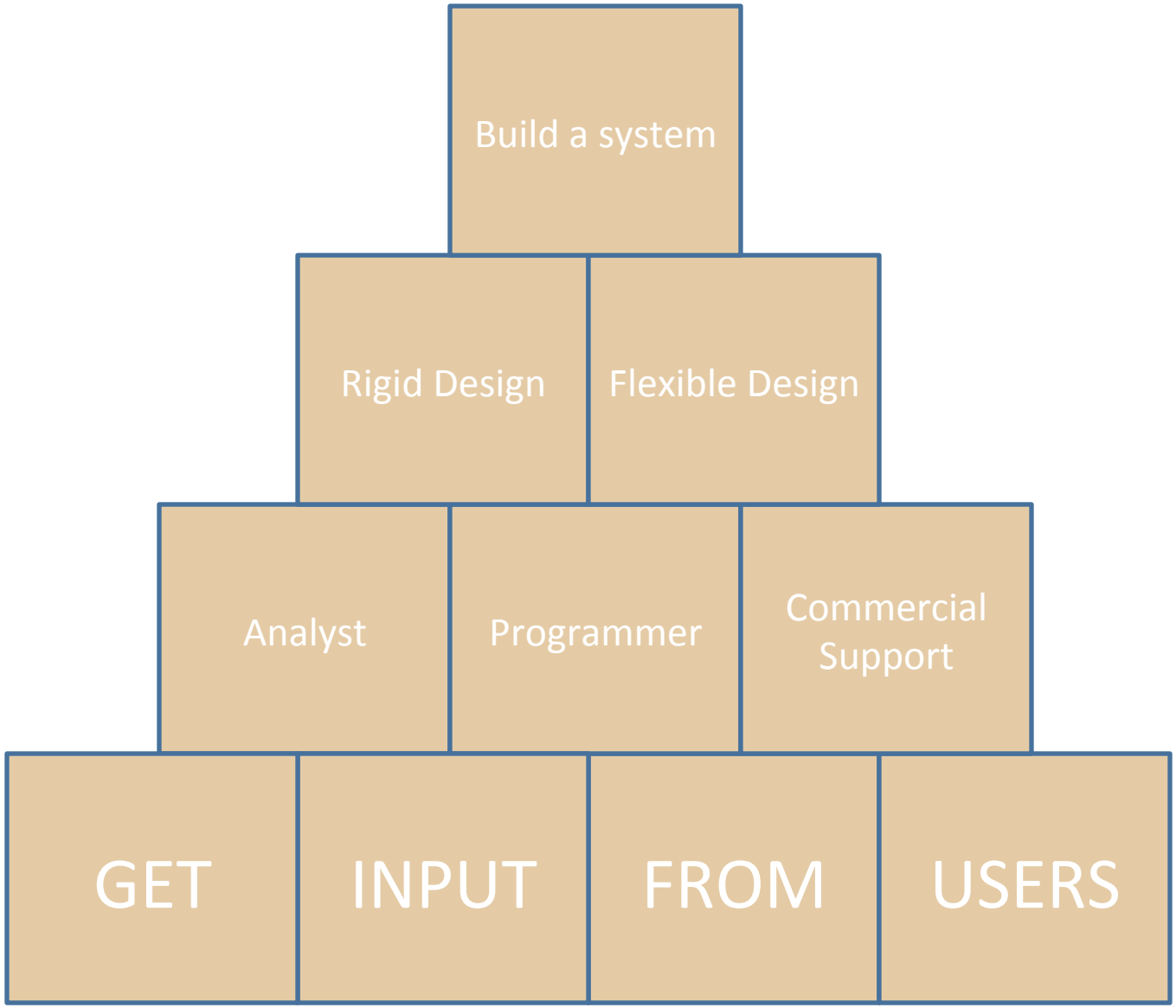
What the Finding does not say

- 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




Build a system
Rigid Design
Flexible Design
Analyst
Programmer
Commercial Support
GET
INPUT
FROM
USERS

Computer Directed system

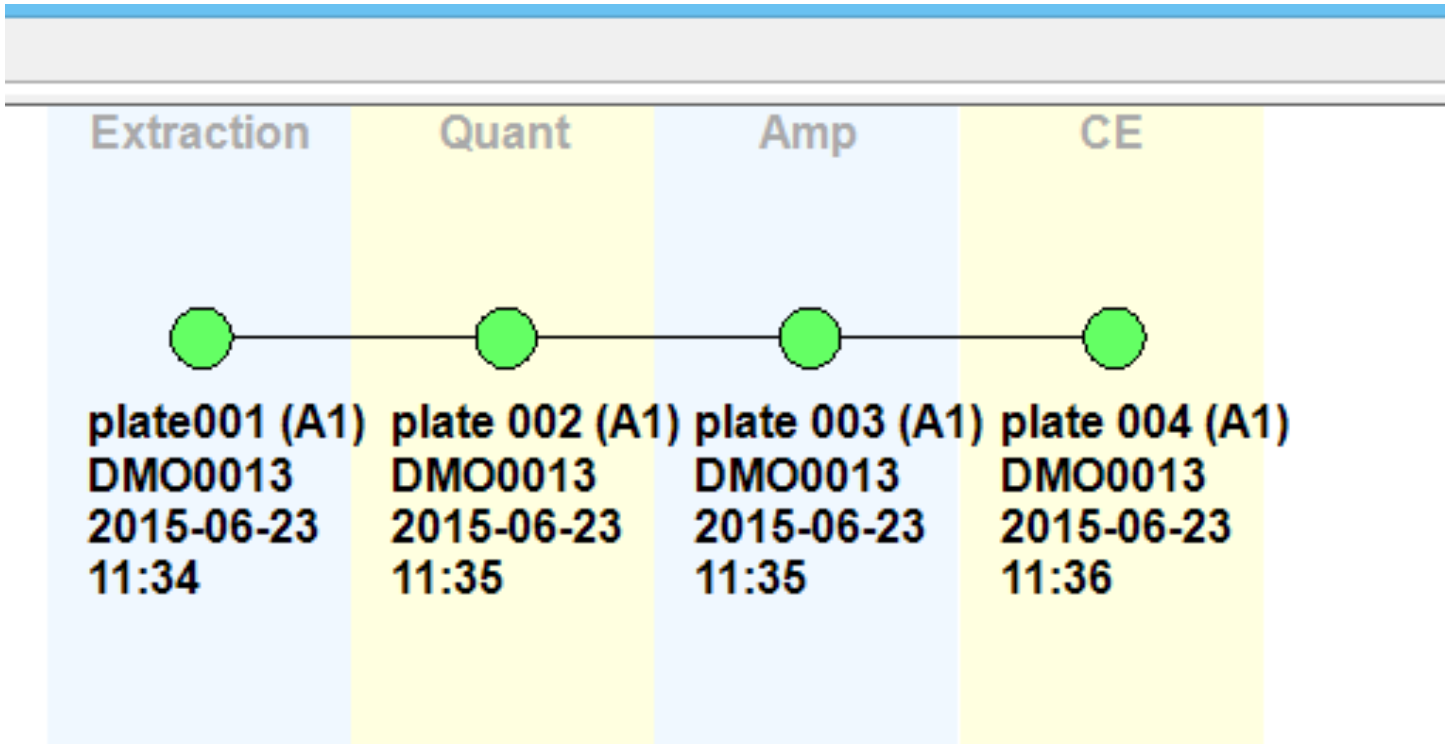
When you talk about a Rigid System what you are really talking about is a Computer Directed system

- 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

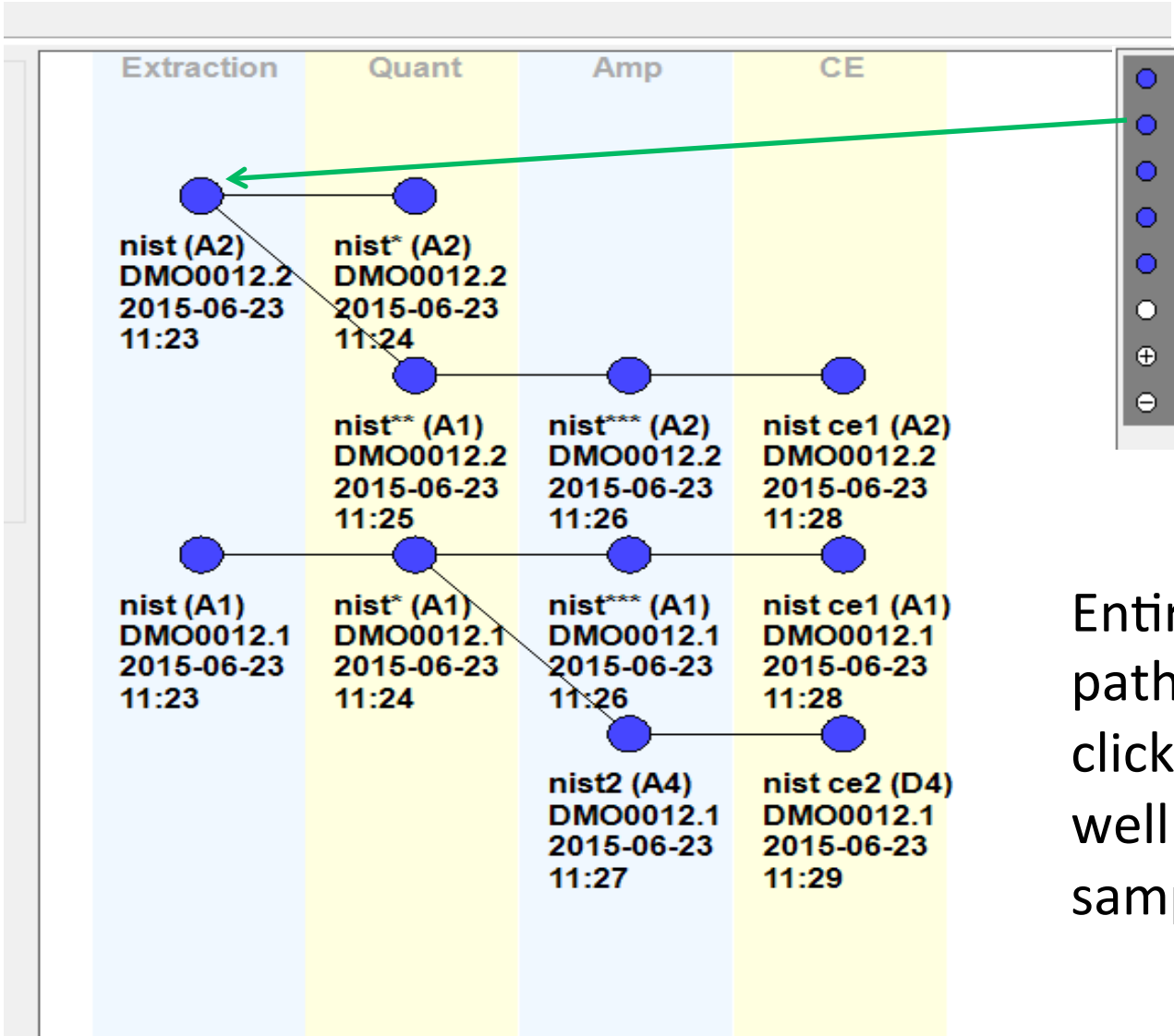
Computer Assisted

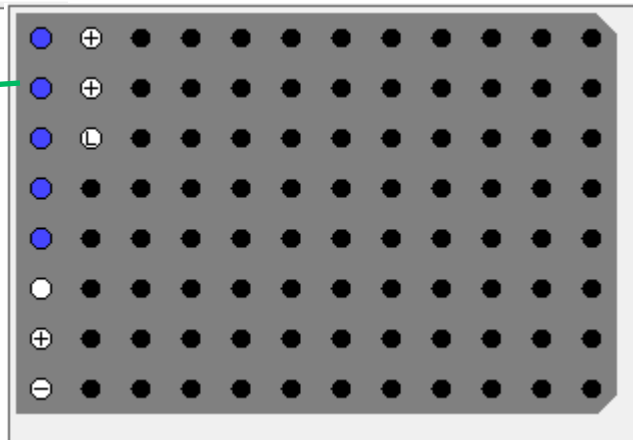
- Should be very information rich
- Efficient with linear sample process pathways
- Good at inventory and chain of custody
- Allow for very complex sample process pathways
- Can be easily adapted to changing process. (Ideally the user would be able to make most of the changes)
- Provide QA/QC flags as 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





Entire sample process pathway(s) can be seen by clicking on any sample well on any plate in the samples history

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)

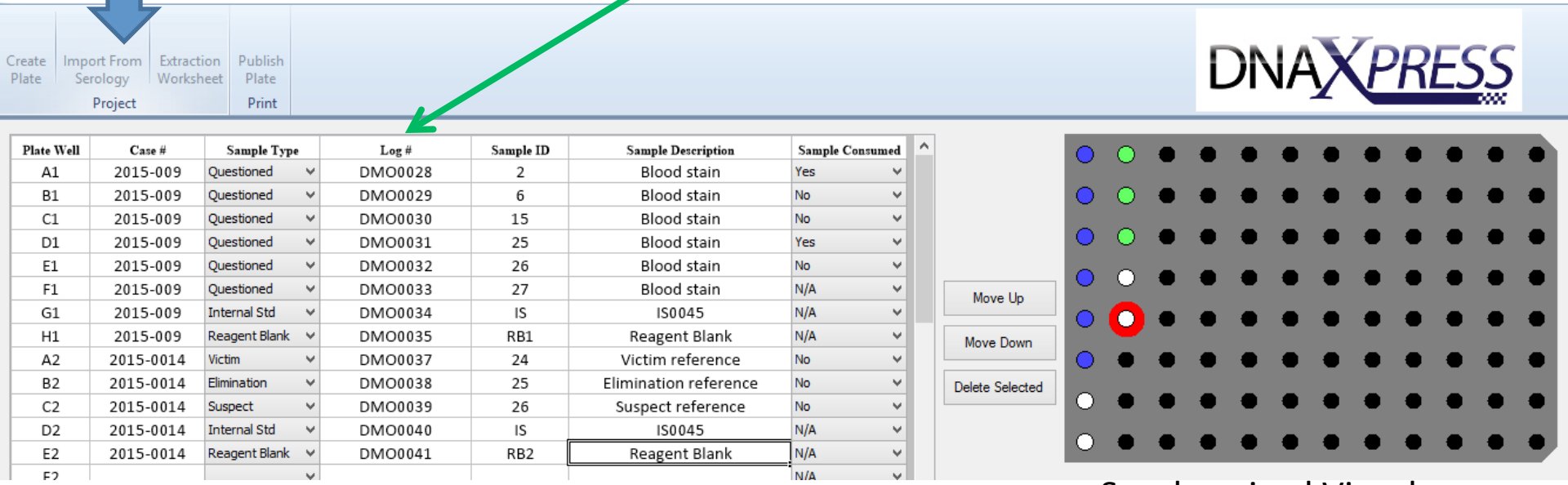
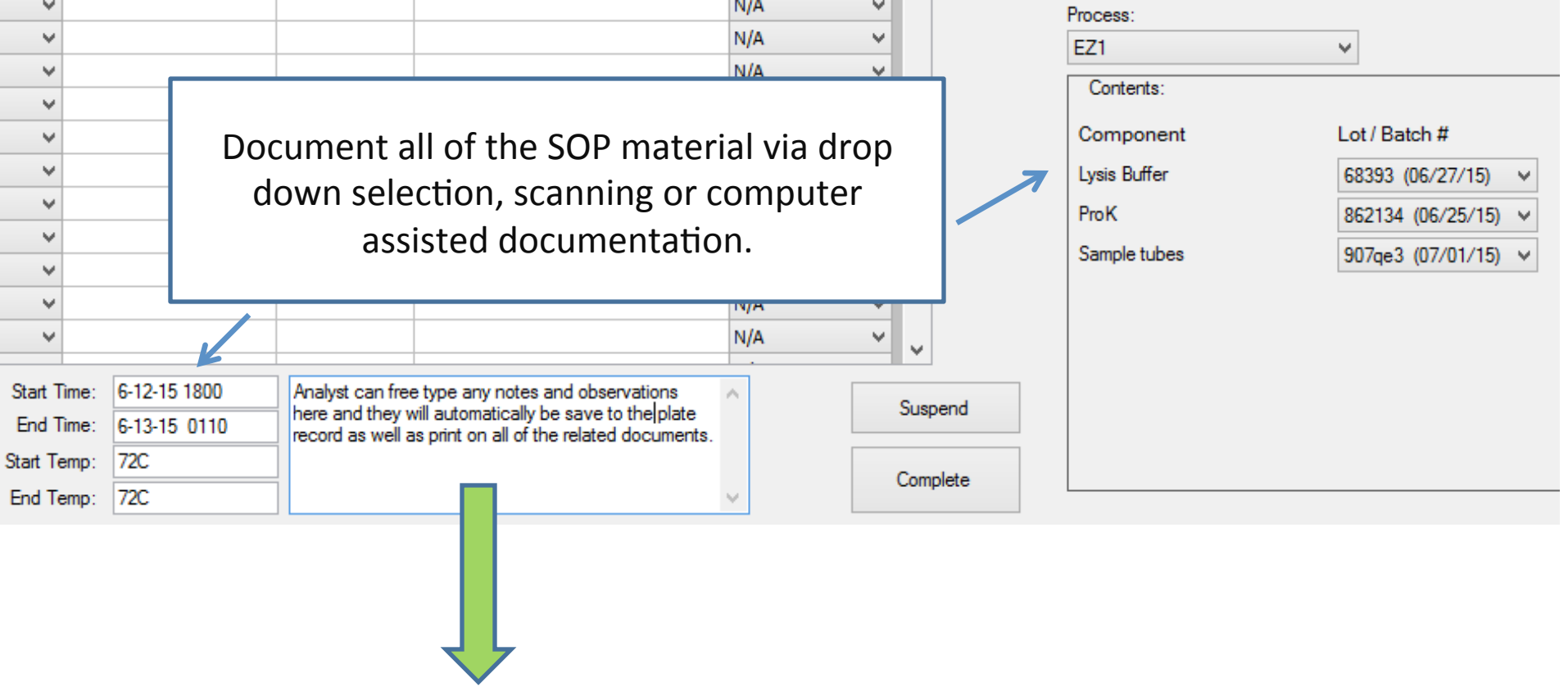
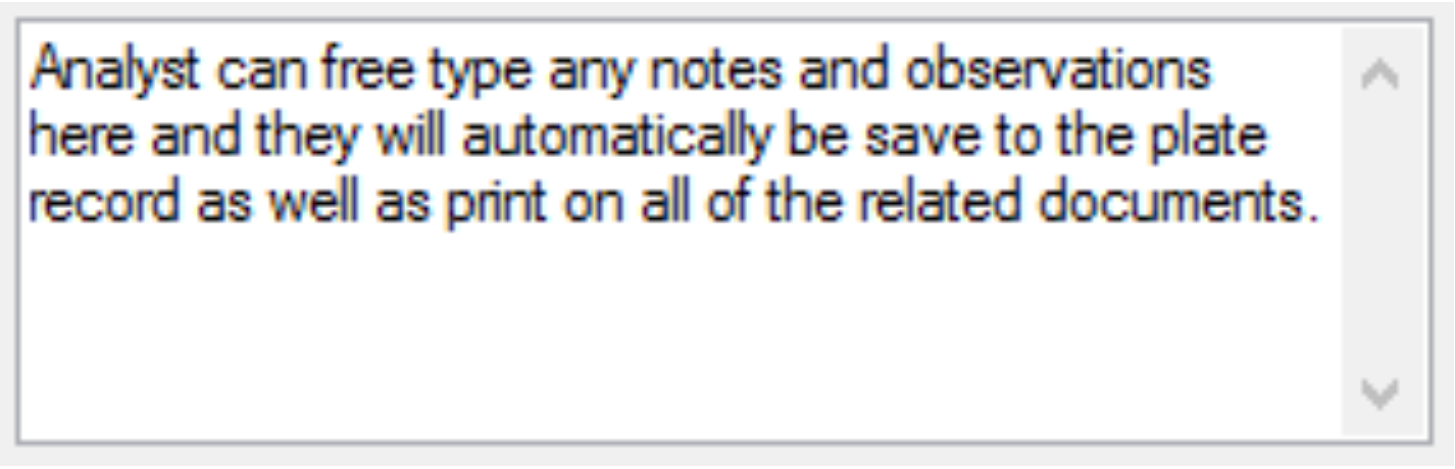


Plate Well	Case #	Sample Type	Log #	Sample ID	Sample Description	Sample Consumed
A1	2015-009	Questioned	DMO0028	2	Blood stain	Yes
B1	2015-009	Questioned	DMO0029	6	Blood stain	No
C1	2015-009	Questioned	DMO0030	15	Blood stain	No
D1	2015-009	Questioned	DMO0031	25	Blood stain	Yes
E1	2015-009	Questioned	DMO0032	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


Process:
EZ1
Contents:
Component
Lot / Batch #
Lysis Buffer
68393 (06/27/15)
ProK
862134 (06/25/15)
Sample tubes
907qe3 (07/01/15)
Document all of the SOP material via drop down selection, scanning or computer assisted documentation.
N/A
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.

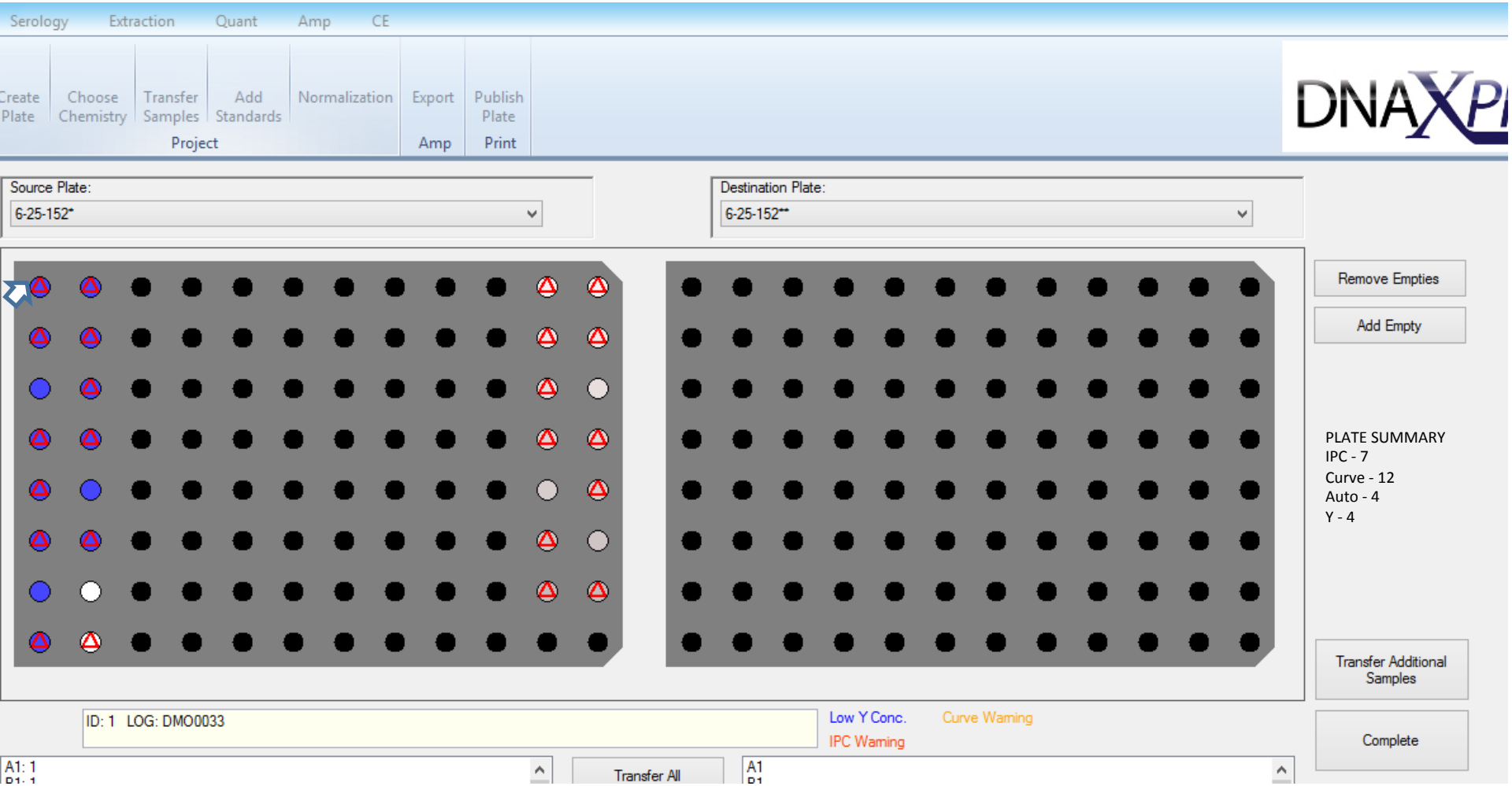
Computer Assisted DNA Quantification Assessment

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

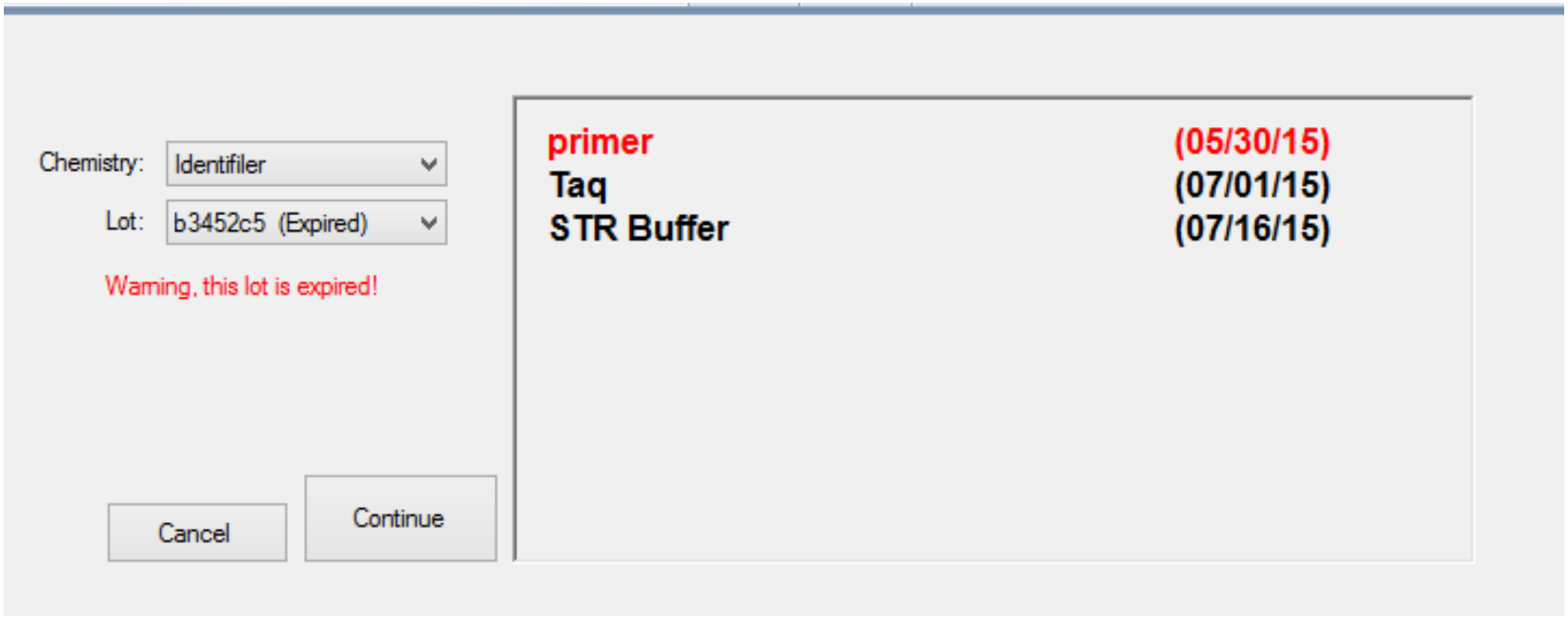
Transfer Window View



Examples of Policy Rule Firings

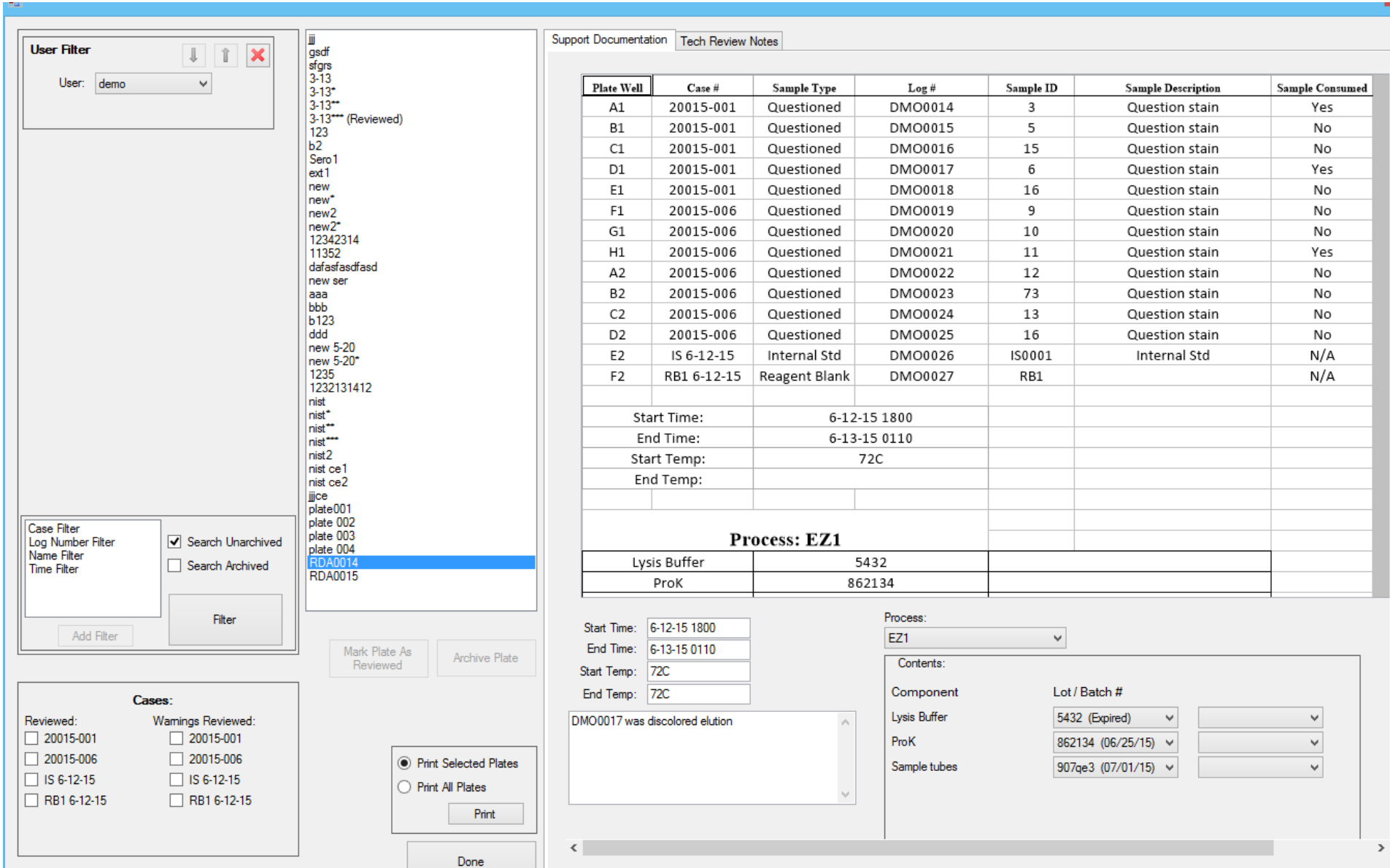
- Extraction
  - Expired Reagents
  - Notes Added
  - Documentation Incomplete
  - Missing Controls
- Quantification
  - Check IPC
  - Check Melt Curves
  - Autosomal Low
  - Y Low
  - Elevated Auto/Y ratio
  - Notes Added
  - Expired Reagents
  - Documentation Incomplete
  - Missing Controls

Expired Amplification Reagent Warning User View

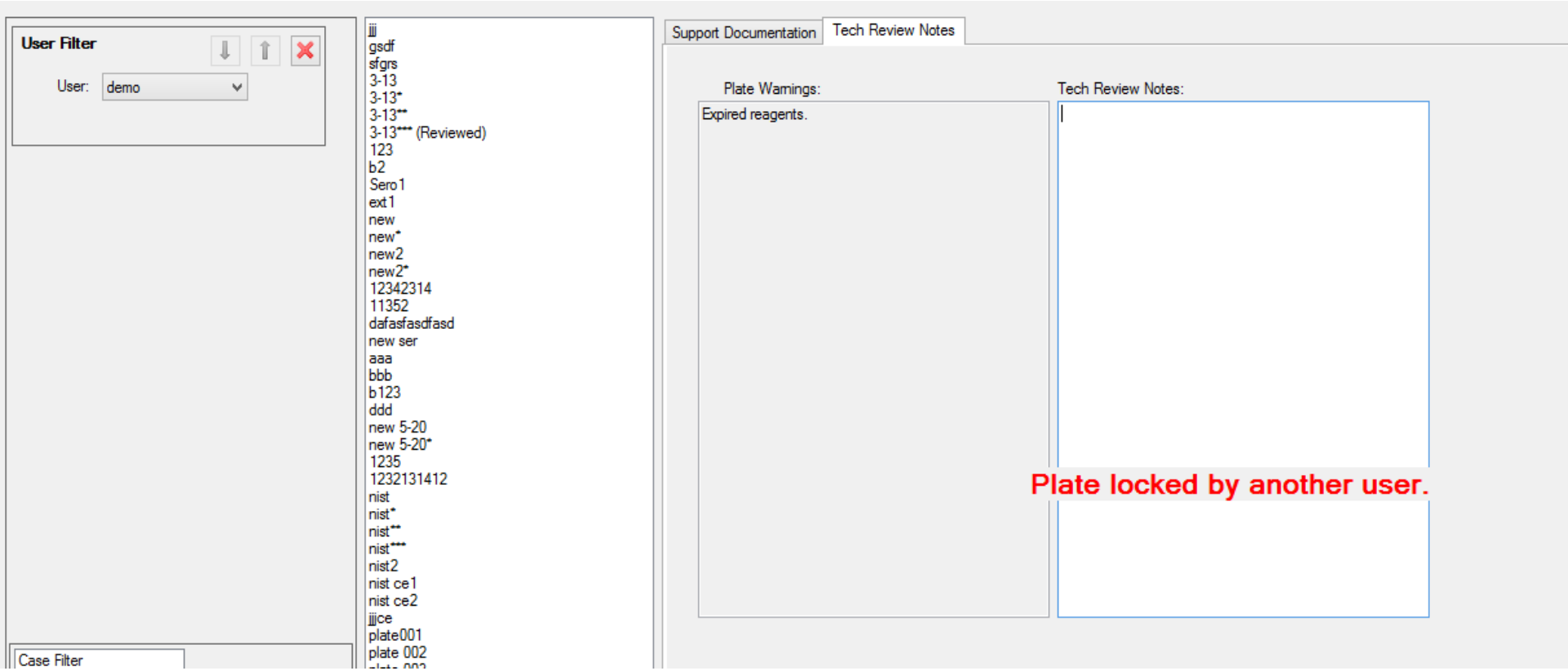


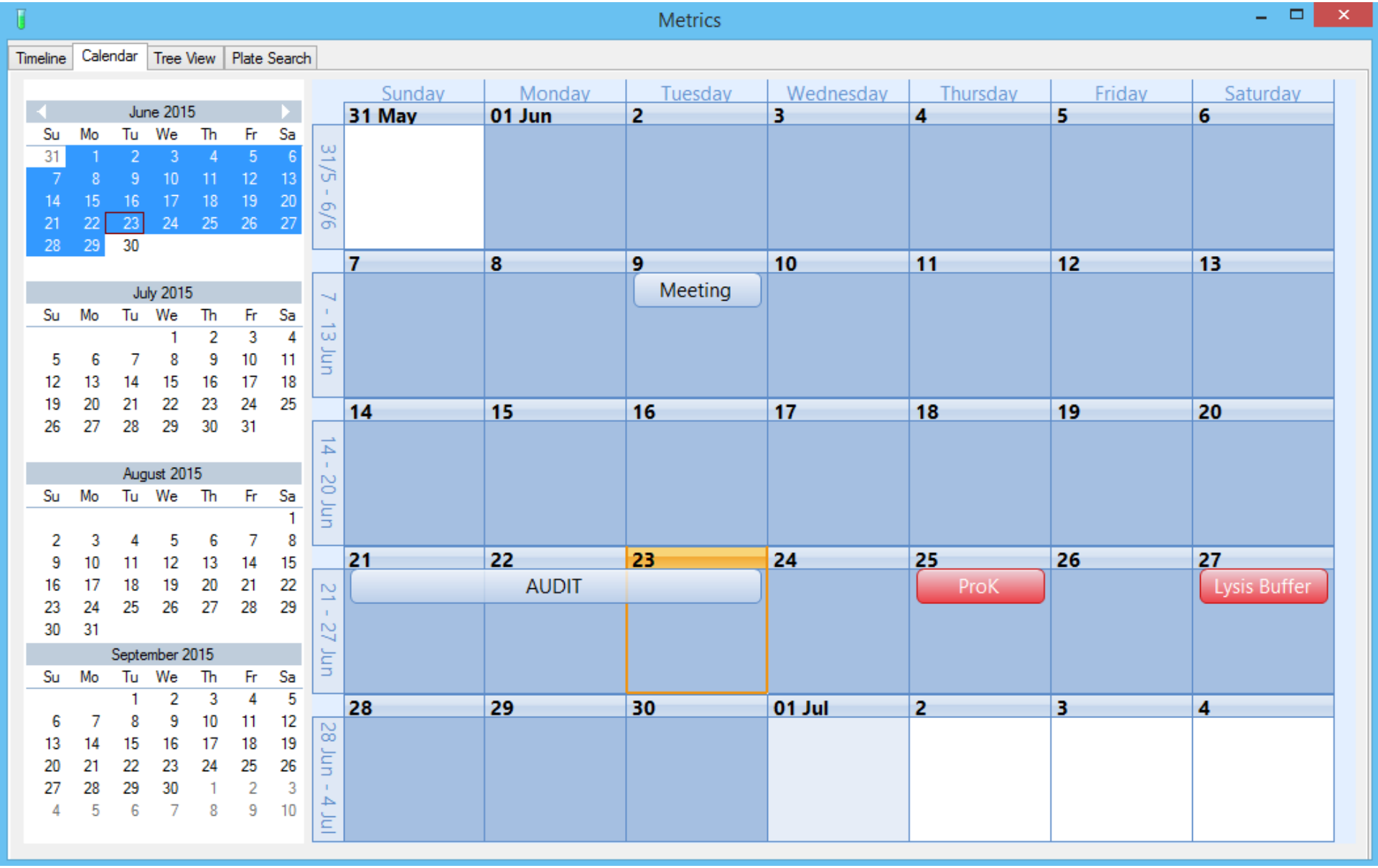
The reagent can still be used which is often important in training and trouble shooting

Support View for Tech Review

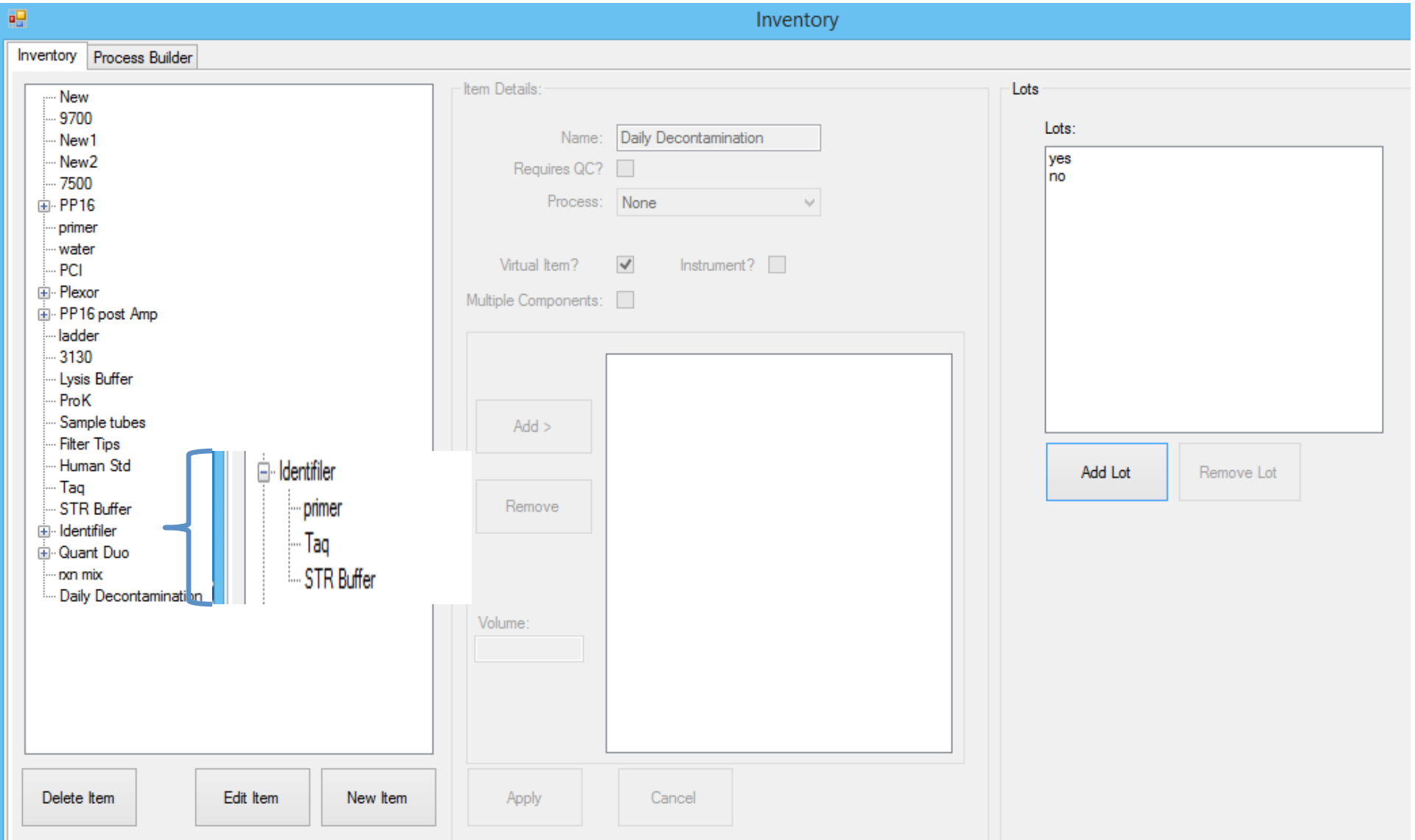


QC Flags and Warnings for Tech Review

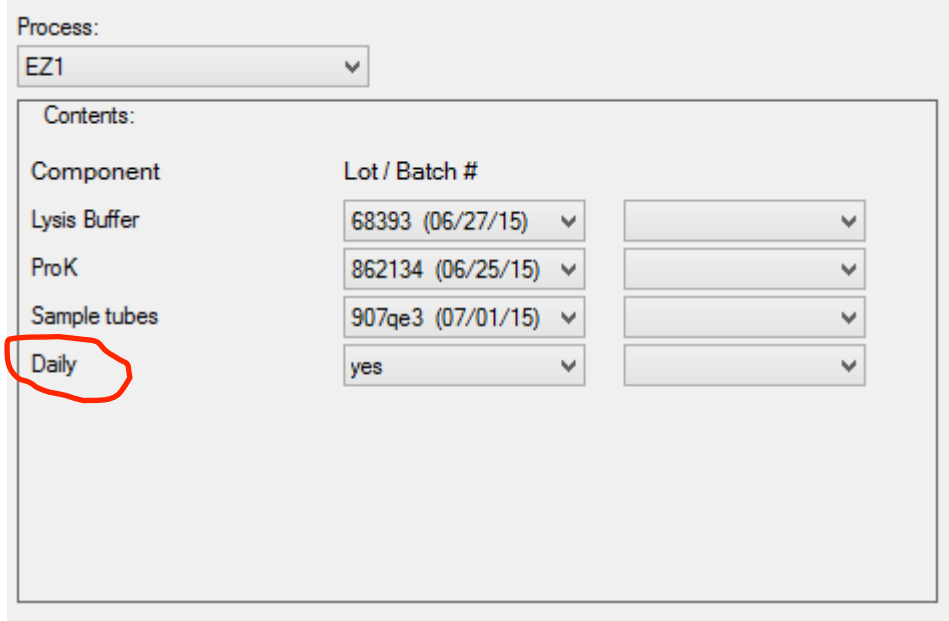



Metrics
Timeline
Calendar
Tree View
Plate Search
June 2015
Su Mo Tu We Th Fr Sa
31 1 2 3 4 5 6
7 8 9 10 11 12 13
14 15 16 17 18 19 20
21 22 23 24 25 26 27
28 29 30
July 2015
Su Mo Tu We Th Fr Sa
1 2 3 4
5 6 7 8 9 10 11
12 13 14 15 16 17 18
19 20 21 22 23 24 25
26 27 28 29 30 31
August 2015
Su Mo Tu We 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
31/5 - 6/6
31 May
01 Jun
2
3
4
5
6
7 - 13 Jun
7
8
9
Meeting
10
11
12
13
14 - 20 Jun
14
15
16
17
18
19
20
21 - 27 Jun
21
22
23
24
25
26
27
AUDIT
ProK
Lysis Buffer
28 Jun - 4 Jul
28
29
30
01 Jul
2
3
4

Layered Inventory



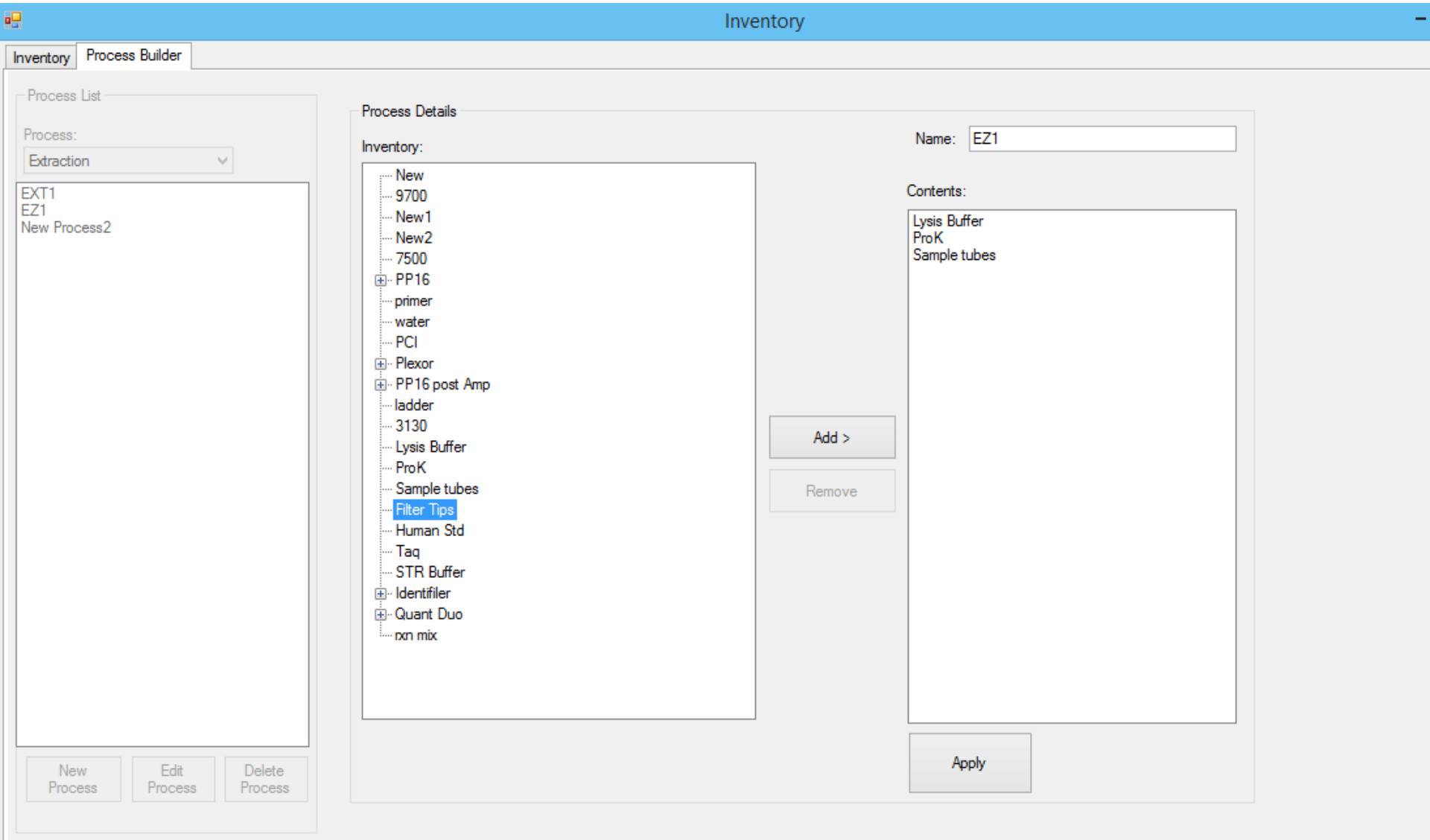
Virtual items



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.

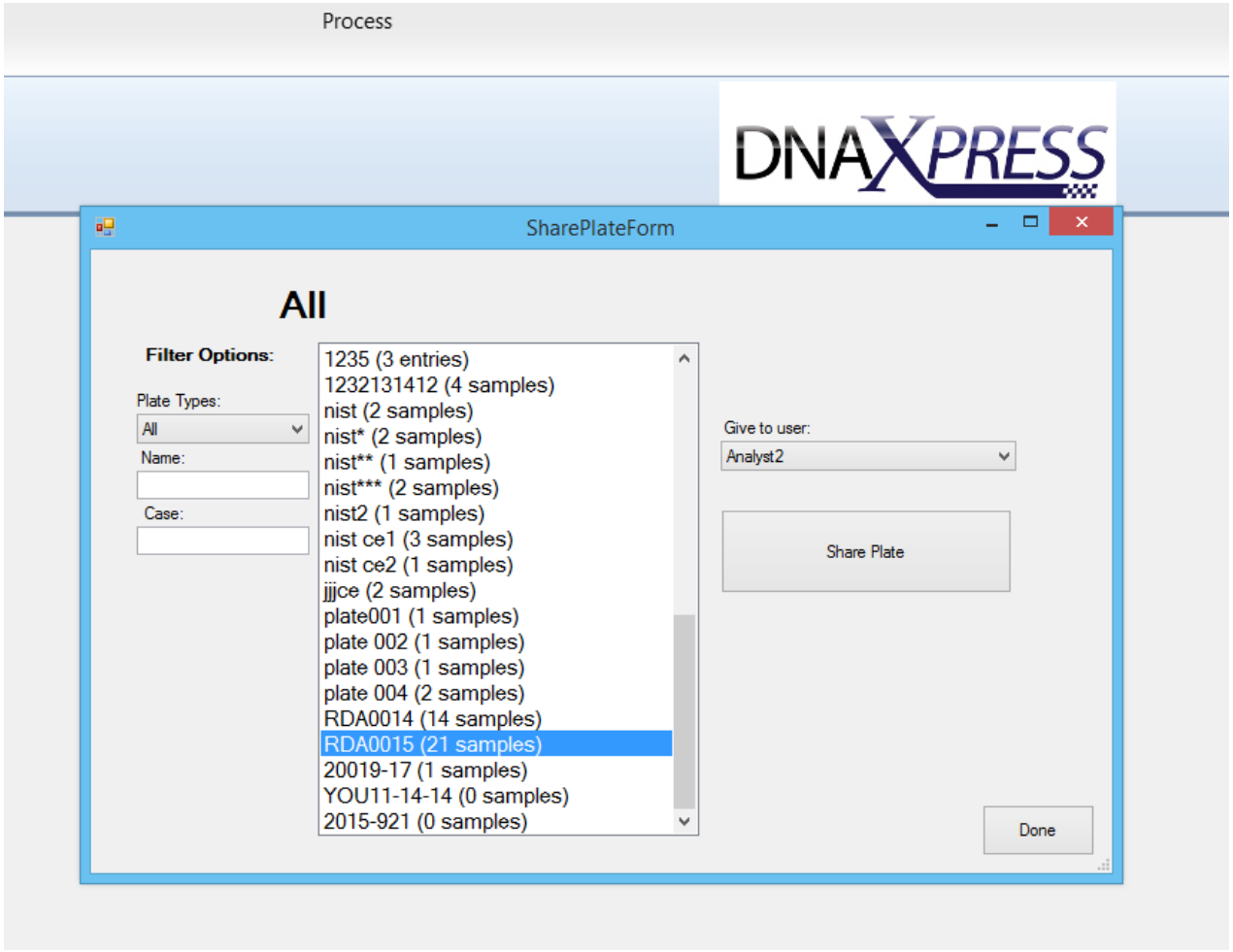
Customize your processes on the fly



Advantages of Layered Approach

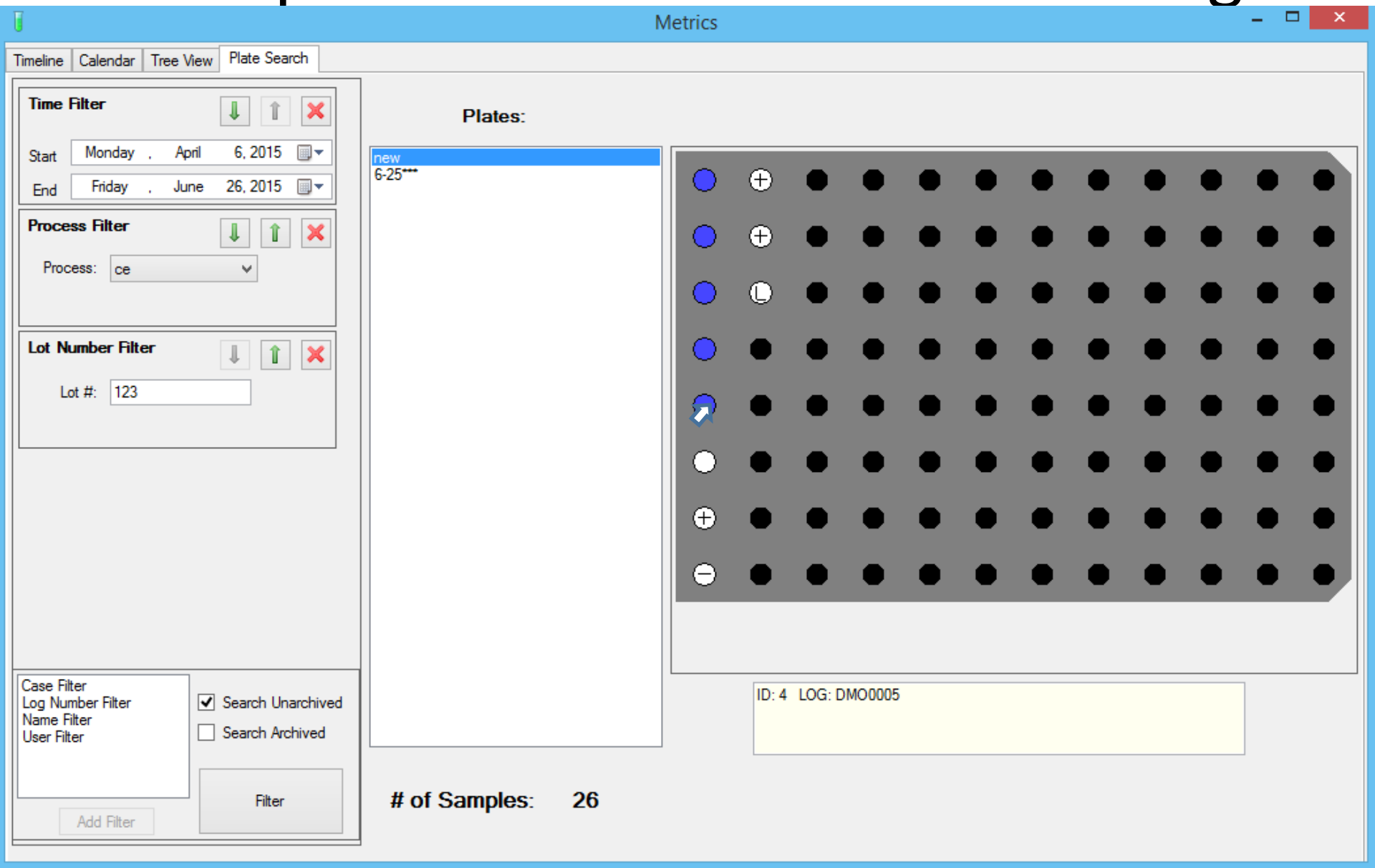
- Allows you to create any number of process paradigm templates and use them in any combination
- Individual paradigms can be adjusted to the types of samples being received without affecting previous analysis
- Simple interface doesn't require significant computer programming skills to adjust.

Sharing and batch case work



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

Computer Assisted Troubleshooting



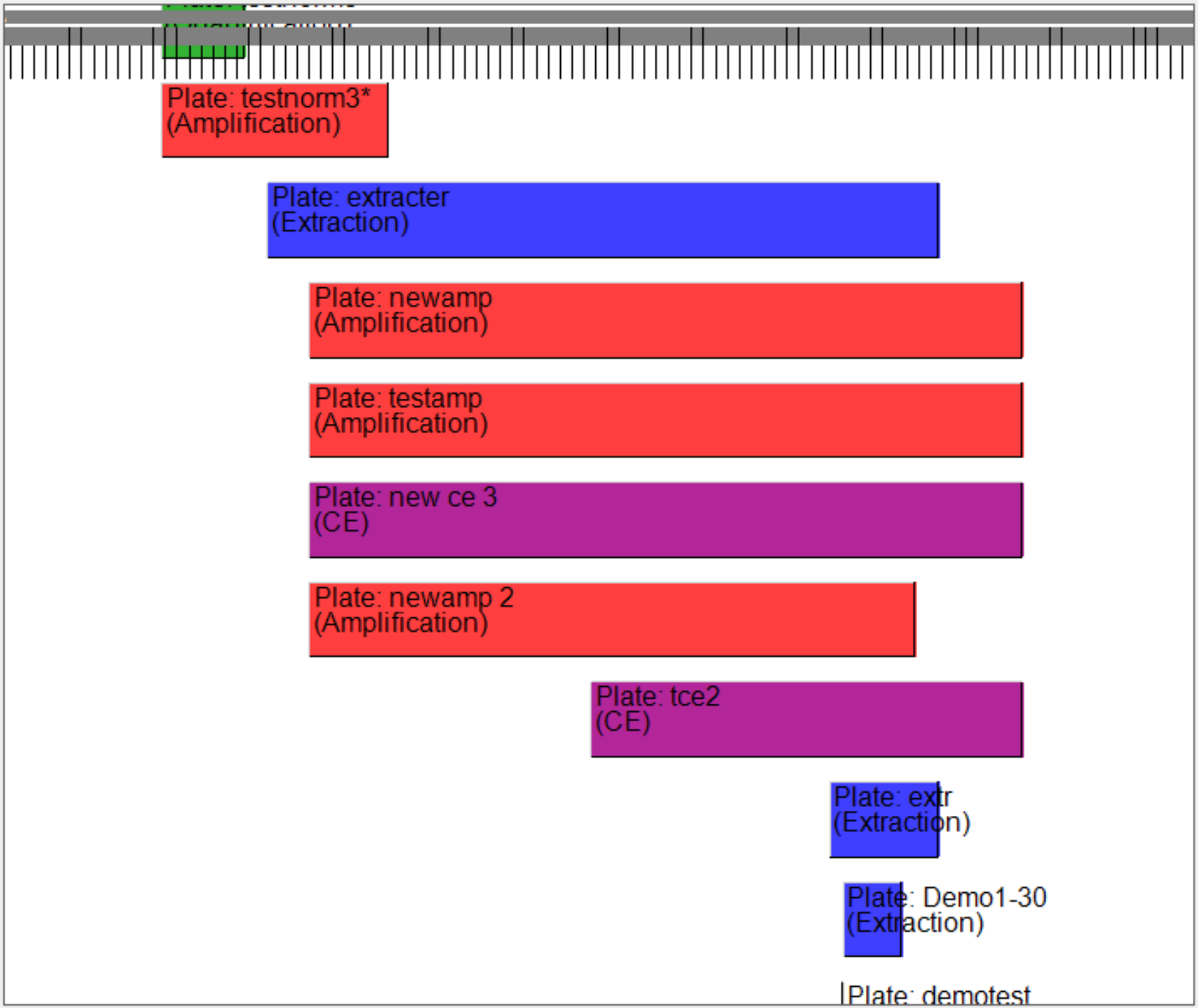


Plate: testnorm3*
(Amplification)
Plate: extracter
(Extraction)
Plate: newamp
(Amplification)
Plate: testamp
(Amplification)
Plate: new ce 3
(CE)
Plate: newamp 2
(Amplification)
Plate: tce2
(CE)
Plate: extr
(Extraction)
Plate: Demo1-30
(Extraction)
Plate: demotest

ASCLD/LAB Top Ten Nonconformities - 2013 # 1 Finding

Proposed resolution of each of the components of 4.13.2.1

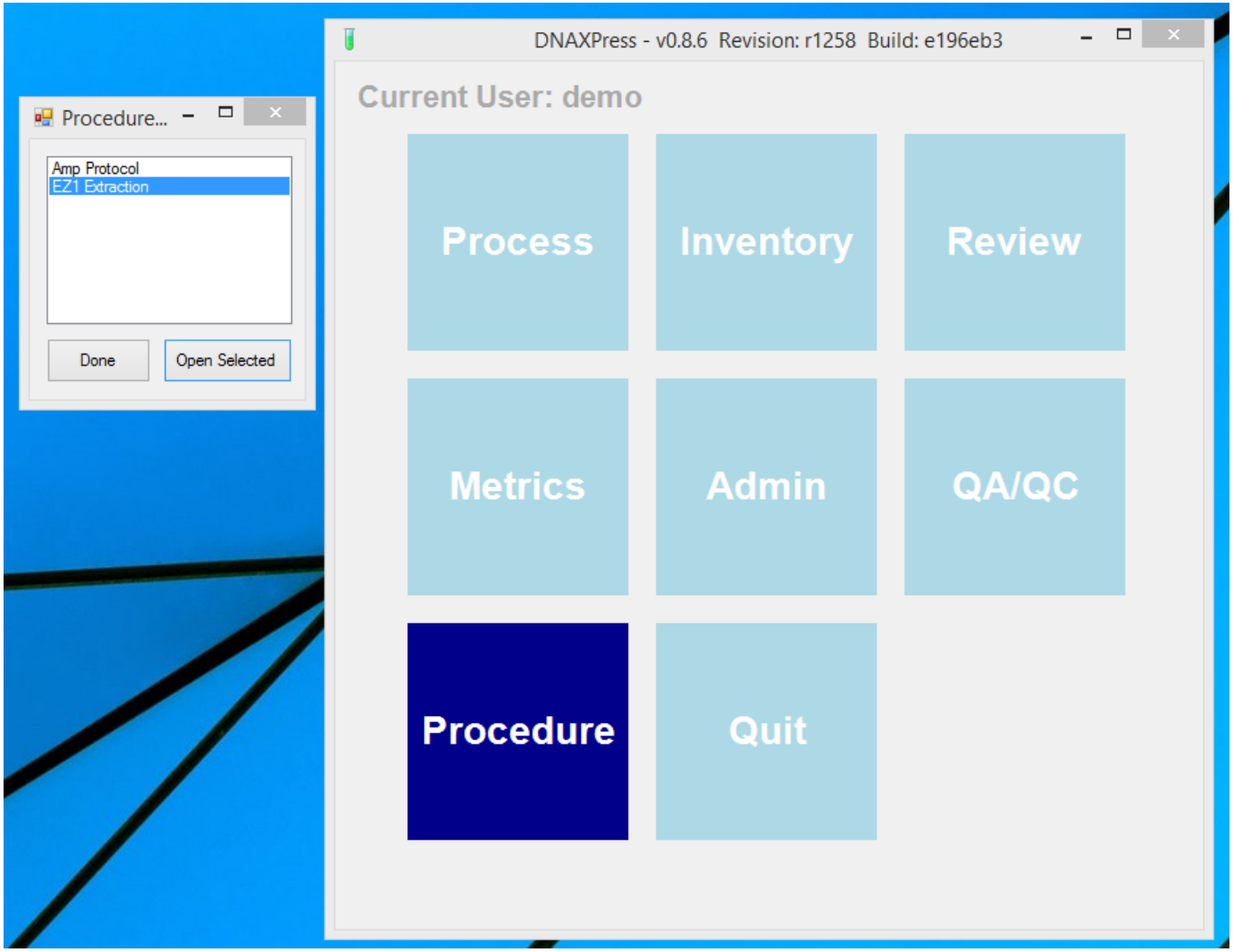
- Insufficient technical records – Computer assisted review of the Analysis in real time and the informed Review process
- Not all original data preserved – Means for convenient addition of analyst observations via free type notes as well as virtual item documentation
- Insufficient documentation to 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

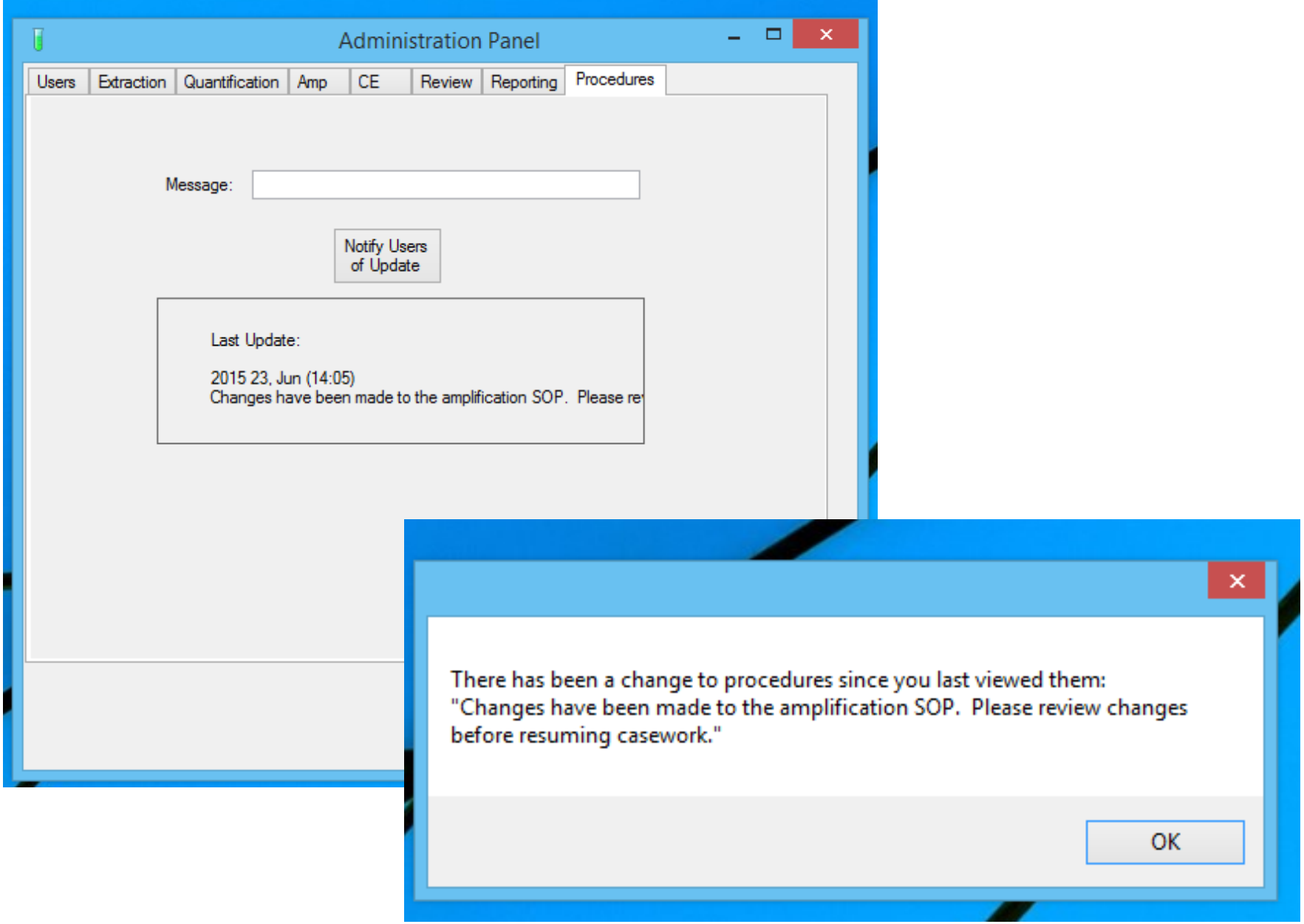
Addressing ASCLD/LAB Top Ten Nonconformities – 2013
Bonus
Standard Cited 4.2.1

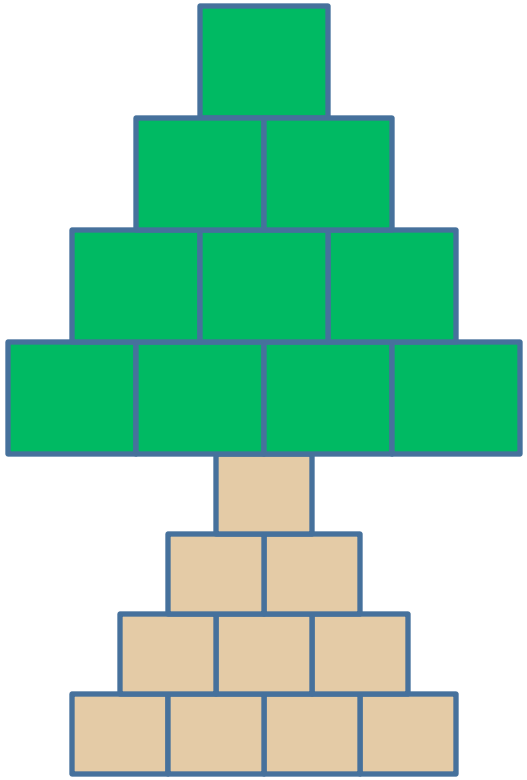
Laboratory personnel are not aware of and/or following their own lab procedures. The last sentence of 4.2.1 requires 'documentation shall (must) be communicated to, understood by, available to and implemented (followed) by appropriate personnel.' Remember the difference between documents (policies, procedures, 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