

LABORATORY MANAGEMENT TECHNIQUES AND PRACTICES

CREATING A CULTURE WHERE QUALITY IS TOP PRIORITY

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LabCorp Specialty Testing Group

FOCUS AND PURPOSE



- Focus: evolution of our quality control plan
- Who we are and what we do – service offerings
- Baseline standard practices
- Identified need for an enhanced system
 - Communication mediums
 - Staff involvement
 - Change and continual improvement

LABORATORY OPERATIONS

Technical offerings

- STR
- Y-STR
- MiniSTRs
- mtDNA
- 2 extraction chemistries – 3 robotic systems
- 4 quantification kits
- 8 amplification kits

Operations Team Makeup

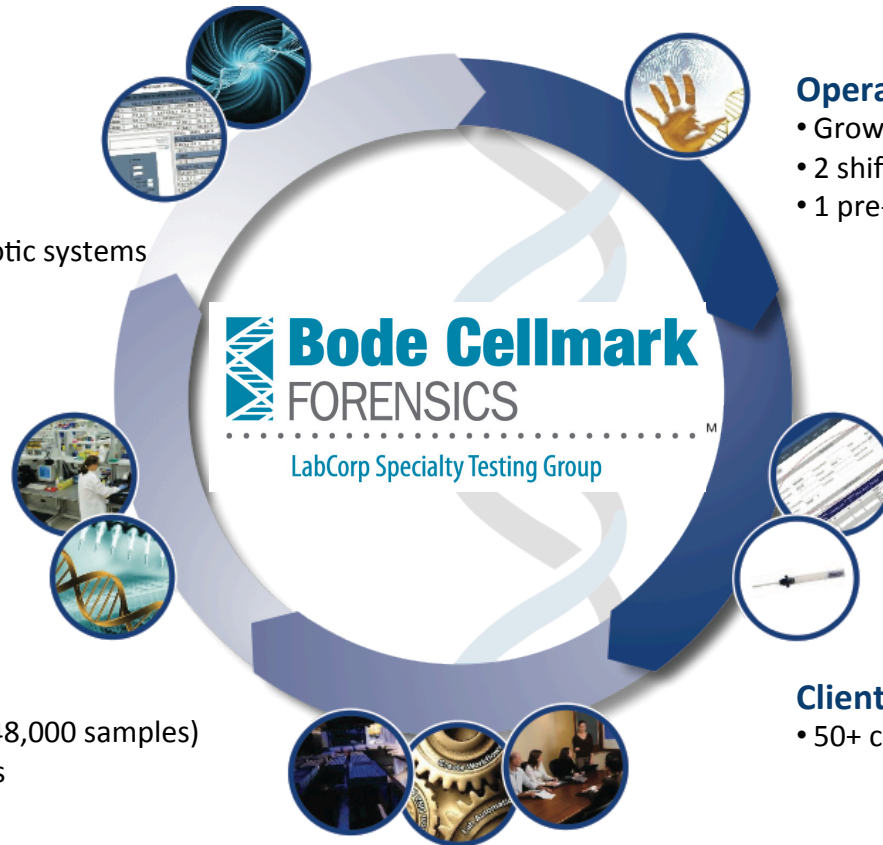
- Growing staff of 90 analysts and technicians
- 2 shifts implemented
- 1 pre-amp and 1 post-amp laboratory

2014 Throughput

- 16,000 forensic cases (~48,000 samples)
- 80,000 database samples


Client Base

- 50+ clients across our operational teams



CURRENT PROCESS

BASELINE STANDARD PRACTICES

- 
- Maintain staff and visitor database
 - Use batched sample processing to visualize trends in reagent and substrate control
 - Repurpose existing computer programs to detect sample comparisons within a data tray
 - Engage client and manufacturer relationships to optimize laboratory procedures

IDENTIFIED NEED

ENHANCED QUALITY PLAN

- Compartmentalized group structure similar to the discipline separation in a traditional crime laboratory
- Ineffective hard copy notification process
- Inability to determine trends that happen across teams, reagents, laboratory spaces, shared equipment and/or personnel



We needed a culture change: we needed more transparency between groups and real time error identification/tracking system!

HOW CAN WE ENHANCE OUR QUALITY PLAN?


INCREASE TRANSPARENCY

- Big question – how do we increase transparency across our operational teams?
 - Take a look at how we could improve or implement various methods for communication
- GOAL: simple and cheap!!
 - Compliance management software
 - Social business enterprise system
 - Meetings: Huddle format/traditional
 - Email



COMMUNICATION MEDIUM #1

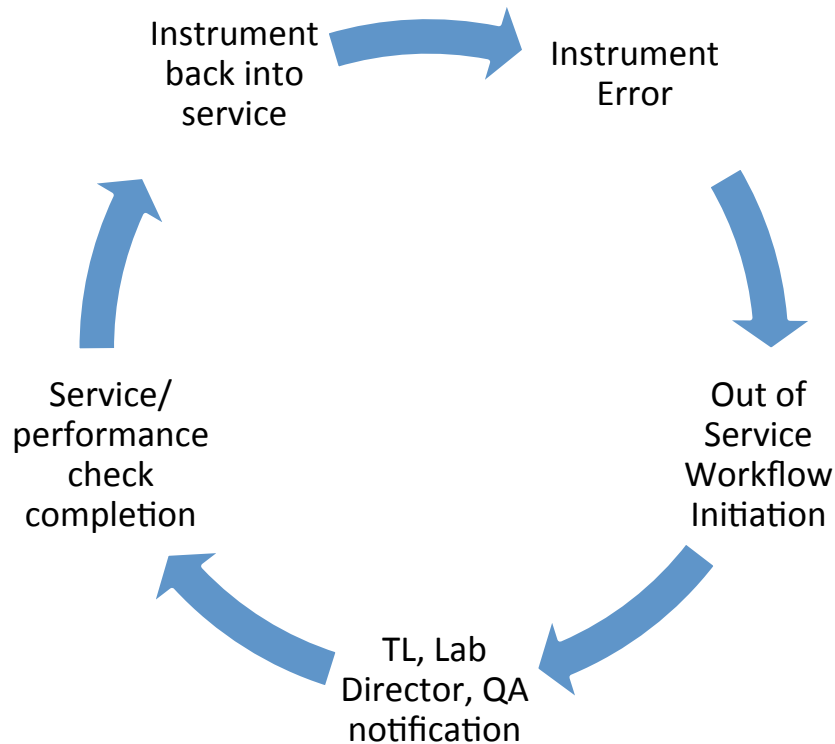
COMPLIANCE MANAGEMENT SOFTWARE

- Pre-existing system -  Qualtrax®
- Central repository of information; email notifications of document changes; electronic workflows instead of paper forms and manual processes; data reporting
- Electronic workflow feature: trend analysis
 - Equipment status (e.g. out of service)
 - Non-conformance process

COMMUNICATION MEDIUM #1

COMPLIANCE MANAGEMENT SOFTWARE

Out of service workflow process



Equipment - Out of Service/Retire

ID 89749

Current State is Completed

Initiated by Naeem Khan

Out of Service by Naeem Khan on 5/4/2015 10:50:33 AM

In Service by Naeem Khan on 5/13/2015 9:23:23 AM

File by Amanda Thomas on 5/27/2015 11:10:40 AM

Completed

CE Number

CE-A006

Serial Number

1586-030

Out of Service Date 5/4/2015

Reason Placed Out of Service

Provide short description of why unit is being placed out of service.

Engineer is performing preventative maintenance. NK050415

Released Back into Service Date

When applicable, calibration/performance verification must be completed prior to 5/13/2015

COMMUNICATION MEDIUM #1

COMPLIANCE MANAGEMENT SOFTWARE

Non-conformance reporting process

Non-conformance occurs; workflow initiated



```
graph TD; A[Non-conformance occurs; workflow initiated] --> B[TL, Supervisor, Lab Director and QA notified]; B --> C[TL feedback on planned actions]; C --> D[Analyst verifies actions completed and submits follow up workflow]; D --> E[TL and QA review for completion or additional actions required];
```

TL, Supervisor, Lab Director and QA notified

TL feedback on planned actions

Analyst verifies actions completed and submits follow up workflow

TL and QA review for completion or additional actions required

COMMUNICATION MEDIUM #1

COMPLIANCE MANAGEMENT SOFTWARE

- A robotic instrument sporadically failed to elute purified extracts or failed to elute the total volume of expected purified extract across multiple shipments from multiple clients. This issue spanned for 8 months.
 - 31 identified non-conformances, 7 client projects
- Troubleshooting and investigations were ongoing from the initial occurrence leading up to the resolution of the identified issue.
- Resolutions: software upgrade, validation, process change

COMMUNICATION MEDIUM #2


SOCIAL BUSINESS ENTERPRISE SYSTEM



- Project management website –
- Real time “Facebook” feed with conversation threads; dedicated project pages and associated tasks for management; direct tagging of individuals to call attention to topics; automatic weekly task summary via email
- Groups/project team members (manager based/project owners) assignments determine who sees what, but allows information to be “publically” available to all associated individuals; maintains historical thread; allows for document storage
 - Client specific: expected volumes, potential issues
 - QA topics: corrective action process

COMMUNICATION MEDIUM #2

SOCIAL BUSINESS ENTERPRISE SYSTEM



TEMPLATE - QA-CAR

Start a new template for every CAR

0% Settings ▾

Activity

Groups

Active ▾ tasks sorted by Objective ▾
Add Objective

Client communication +

? Send initial notification email +

? Investigation status update to clients +

+ Add Task

NCR Submission +

? Submission of NCR by analyst +

+ Add Task

Investigation +

? Root Cause Analysis +

+ Add Task

CAR Write Up +

? Draft Copy Completed +

? Draft routed for review +

? Upload final document to CAR follow-up workflow for e-signature +

Project Activity

Messages

Update
 Question

Je Cell
ENSICS
Sports/Info

Michelle Donohue

I spoke to Courtney Larson earlier. She wanted to know if we had used the FBI database had in their state cases. I explained they are not affected since post 2016. Their DA's office is having them re-do all fees for cases going to trial.

Like Comment Thanks View message - July 1 at 11:39 am from web

Amanda Thomas

Just heard from an attorney in Harris County and thought I would pass it along: "3 minutes ago the Court of Criminal Appeals issued an opinion that says we don't have to have testimony from everyone in the chain."

This means the reporting analyst should be able to issue the certificate of analysis saying that they analyzed the data and reviewed/confirmed that the COD was handled properly, and that if needed specific to the specific of this case.

See more

Comment View message - June 3 at 11:32 am from web

★ Melissa Murphy, Natalie Morgan and Amy Jeanguenat like this

Write a comment...

Leslie Watkins

Track communication by type ▶ Client Feedback

Mar with Irma at AAFS-she has informed me that their lab is a fee for service lab and they will now be charging LE agencies...and may even have a booth set-up at next year conferences.

Like Comment Thanks View message - February 23 at 7:19 pm from web

Je Cell
ENSICS
Sports/Info

Melissa Murphy

Houston PD extended their contract until March 31, 2016.

Like Comment Thanks View message - January 21 at 2:43 pm from web

★ Natalie Morgan likes this

Write a comment...

Amy Jeanguenat

Track communication by type ▶ Client Meeting Notes (on site, off site, conference)

from SPK. Praised @JenniferHornad over and over again as always good job. Hoping validation contract will be worked out soon as their grant cycle will end and they need to spend the money.

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COMMUNICATION MEDIUM #3 AND #4

MEETINGS AND EMAIL

Team Huddles

A daily 10 minute meeting is being introduced throughout operations teams as an alternative to the weekly sometimes hour long meeting.

Huddle Goals

- Coordinate processing when possible.
- Traffic light: describe if assignment is on track (green), slightly off (yellow), or really off (red).
- Come with solution to keep projects on track or get it back on track.

Suggestions:

- Weekly change who leads the team huddle.
- Meet in the morning or during shift overlap.
- Stand-up; will make sure the meeting is kept short.
- Have an agenda
- Try- 3 minutes what is working, 3 minutes what is not, 3 minutes

Traditional meeting plans

- Set agenda
- Less frequent
- Email
 - User notification system
 - Team huddles have reduced traffic

STAFF PARTICIPATION



NCR submission and remediation follow up

Permission to initiate edits/updates for procedures and documents

Huddle interactions

Training updates and training effectiveness reviews

Shipment or case processing updates/progress

Qualifications maintenance: continuing education, etc.

Testimony, client contact

Focus groups

STAFF PARTICIPATION

Overall, the key is active engagement at all levels

Operation Bodemization

If you would like to become a part of a focus group to tackle laboratory efficiency improvement with Lean Six Sigma approaches please let Amy Jeanguenat know. She is currently identifying 4-7 people who would like to dedicate 30-60 minutes every day (incremental acts) and up to 4 days a month to participate in laboratory efficiency improvements. If you are interested in being a part of this focus team please let Amy know your interest level how you plan to handle the time commitment.

**CHANGE
BEGINS WITH
me.**

CHANGE

CONSTANT IMPROVEMENTS

Avenues for change

- Determination of validation needs
 - Contract/client driven
 - Required for efficiency purposes
- Process evaluation as weaknesses are identified
 - Preventive actions
 - Streamline as much as possible (e.g. new hire process, electronic templates)



CHANGE CONSTANT IMPROVEMENTS

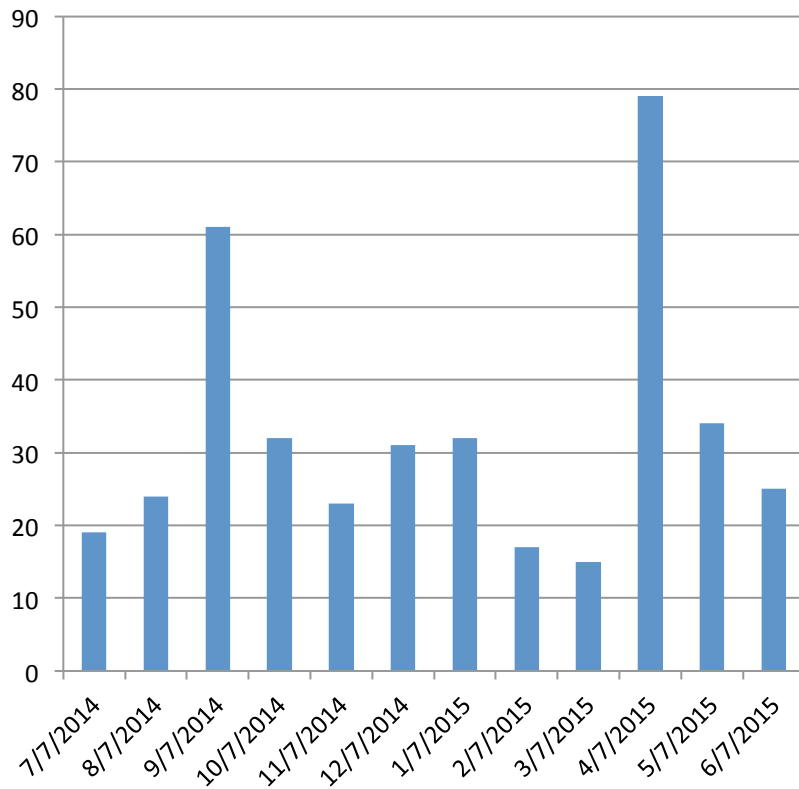
- Management review
 - Summary review of quality actions within previous ~6 month time period
 - Outlines future initiatives for process and/or procedural updates or improvements
- Performance evaluation process enforces commitment to quality goals
- Client feedback (regular communications/site visits)
 - Additional 100% technical review performed by client laboratories
 - Fosters discussions regarding laboratory practices such as interpretation guidelines and identifies ways to clarify procedures



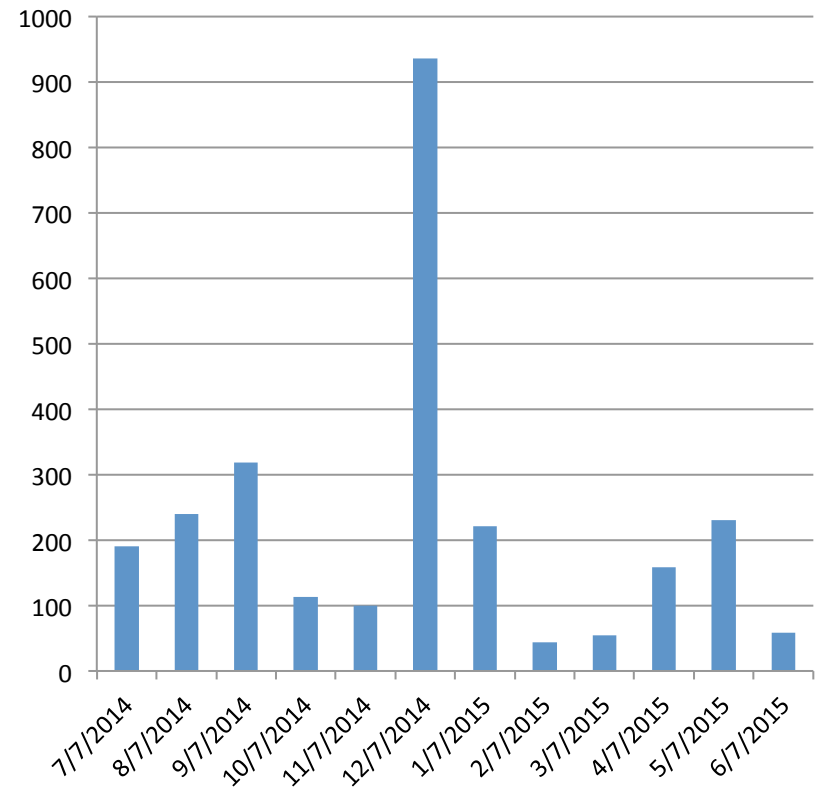
CHANGE

CONSTANT IMPROVEMENTS

Qualtrax – documents edited



Qualtrax – documents published



SUMMARY

- Started with a solid standard baseline in terms of quality
- Increased scrutiny within the field and increased surge of cases/people forced the need to identify different avenues for quality improvement and constant monitoring
- Created a transparent management system and required staff to be part of the solution through active engagement
- Error detection practices and quality applications can be used as a model across the field and applied to challenges faced in cross-discipline situations

FURTHER INFORMATION

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Thank you!

- Amanda Thomas, Director of Compliance & QA
- Amy Jeanguenat, Laboratory Director
- Karin Crenshaw, Technical Leader
- Entire Bode Cellmark operations staff!