Pennsylvania Department of Health
Bureau of Laboratories

A Lean Rapid Improvement Event for Postmortem Alcohol and Drug Testing

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Tom Bannon
Quality Officer

Jennifer Okraska
Director, Division of Chemistry and Toxicology

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Postmortem Alcohol and Drug Testing Program

- Tests blood collected from drivers and pedestrians killed in motor vehicle accidents – deaths must meet certain criteria
- Provides information on the impact of alcohol and drugs on motor vehicle-related fatalities
- County coroners to submit specimens to Bureau of Laboratories (BOL); required by law
- BOL reports results to coroners and Department of Transportation (PennDOT)
- Alcohol testing since 1972
- Drug testing since 2004

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Analytic Methods

- Alcohol determination using GC-FID
- Drug screening using Randox Evidence Investigator
- Drug confirmation by GC-MS at BOL or reference laboratory

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Why This Project?

Reduce Average Results Turnaround Times (TAT)

Baseline: 53 days

Reduce Division Director Involvement in Day-to-Day Program Operations

Baseline: 30% of time spent on program
25% of time spent on day-to-day operations

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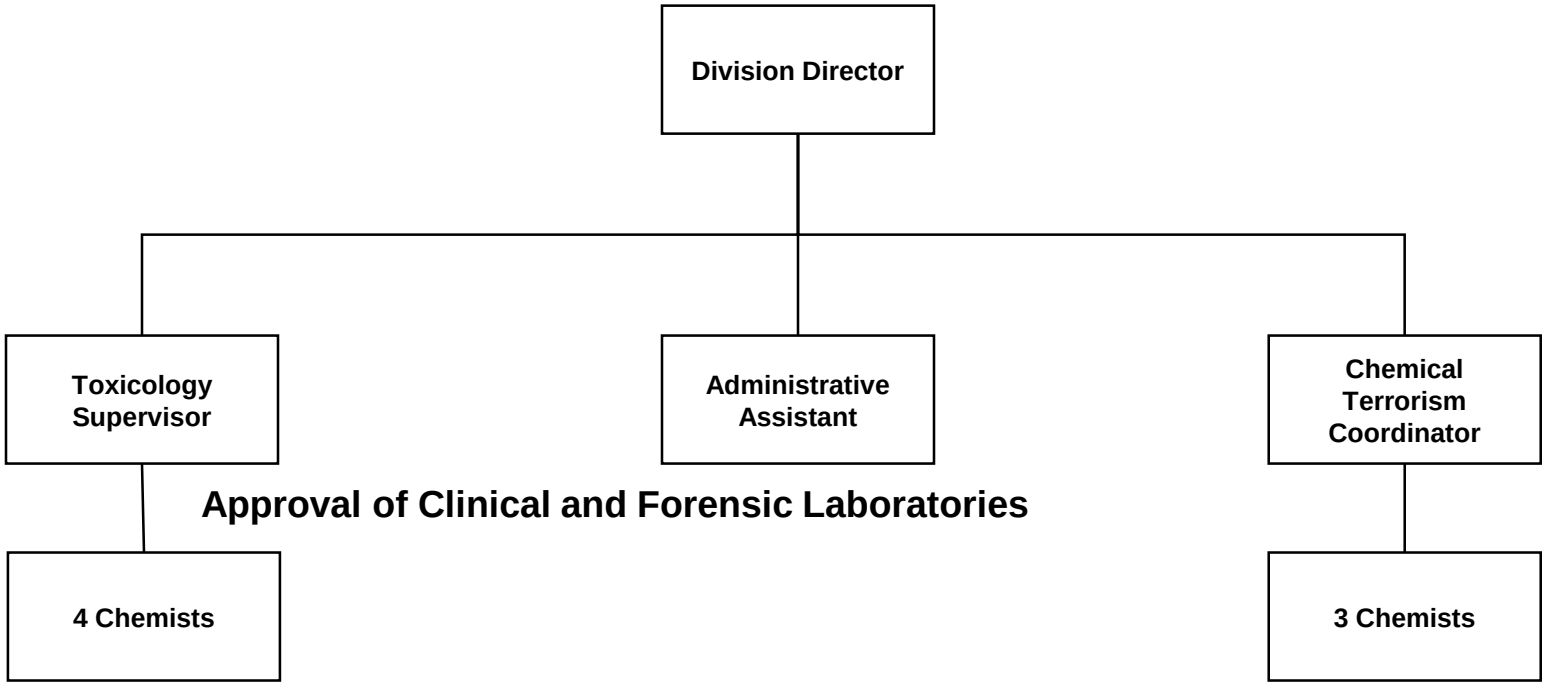
Division of Chemistry and Toxicology



Blood Lead Testing
Environmental Lead Testing
Postmortem Alcohol and Drug Testing
Toxicology Proficiency Testing Programs

LRN-C Testing

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Lean Production (Lean)

A systematic approach to process improvement through the minimization of waste to reduce costs without sacrificing value provided to the customer

- Every process has a customer who is paying for a product based on the value it provides
- Decrease the cost to the producer
- Maintain or improve the value for the customer

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Pennsylvania's Focus on Lean

Governor's Office of Performance Through Excellence

Dan Hansen, Director of Continuous Process Improvement

- Provided Lean training to all BOL staff

Department of Health - Bureau of Health Planning

Brian Lentes, Bureau Director

Emily Gibeau, Director of Quality Improvement and Performance Management

- Assisted in the planning, facilitation and monitoring of the Lean project

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Project Charter

Component	Description	Project Examples
Business Process	Simple explanation of the process	Postmortem alcohol and drug testing program; understandable without a laboratory background
Customers	Individuals/organizations that utilize the product	▪ Coroners ▪ Department of Transportation
Scope	Portions of the process targeted for improvement	▪ Preanalytic phase ▪ Postanalytic phase
Benefits	Reasons to undertake the project	▪ Improved relationship with customers ▪ Division Director can focus on other programs
Sponsors	Upper-level managers that can enable process changes	▪ Bureau Director ▪ Department of Health executive staff
Team	Individuals that participate in the process and the improvement project	▪ BOL and Bureau of Health Planning staff
Metrics	Measures to quantify improvement	▪ Results turnaround time in days ▪ Percent of Division Director time spent on program

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Rapid Improvement Event (RIE)

Days	Wednesday through Friday
Time	8:00 AM to 4:00 PM; short breaks and lunches
Locations	Lecture room and Chemistry Laboratory
Trainers / Facilitators	▪ DOH Bureau of Health Planning ▪ Governor's Office of Performance Through Excellence
BOL Participants	▪ Division of Chemistry and Toxicology Director ▪ Toxicology Section supervisor and chemists ▪ Division of Chemistry and Toxicology administrative assistant ▪ BOL Quality Officer
Sponsors	▪ BOL Director ▪ DOH Deputy Secretary for Health Preparedness and Community Protection ▪ DOH Deputy Secretary for Health Innovation

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BOL RIE Participants

Division of Chemistry and Toxicology Director
Jennifer Okraska

Toxicology Section Supervisor
Dave Fardig

Toxicology Section Chemists
Christian Acholonu
Chris Andrychowski
Vince Lan
Antony Purayidathil

Administrative Assistant
Stacey London

Quality Officer
Tom Bannon

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RIE Day One

- Training and schedule
- Review of project charter
- Kick-off teleconference
- Current state process mapping
- Pain point identification
- Value-add determination
- Go to the Gemba (“the real place”) / Wastewalk

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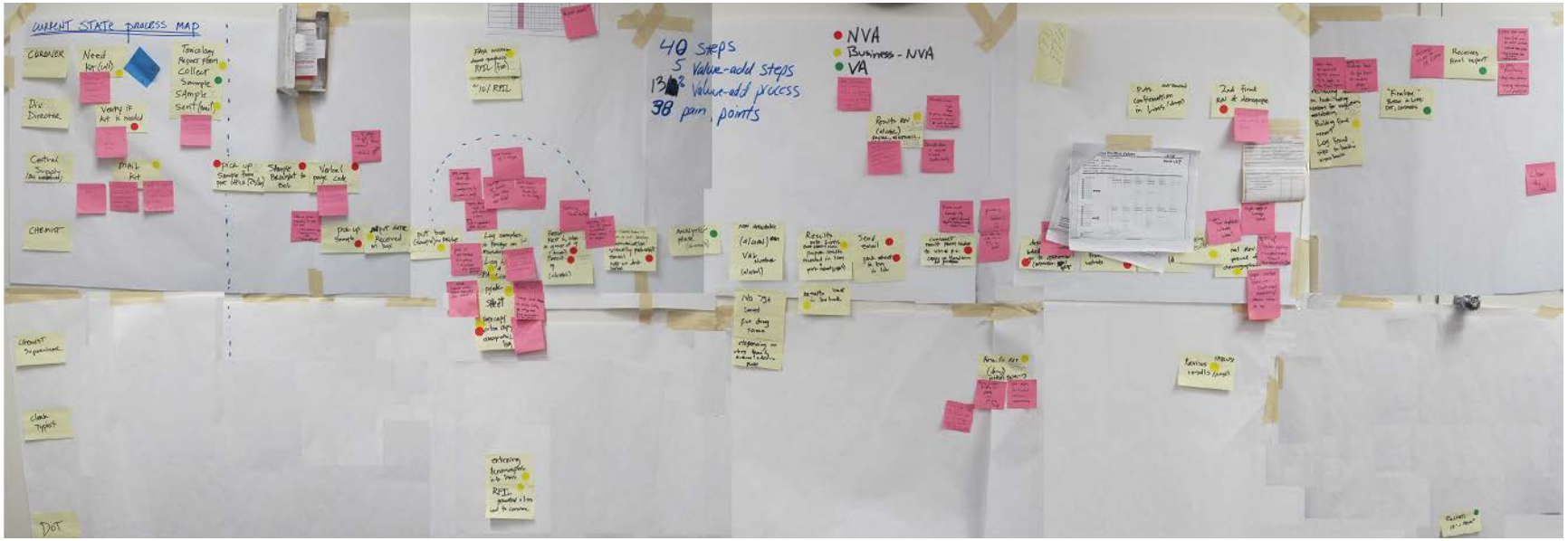
Current State Map



Process Step

Pain Point

Non-value Add (NVA)

Business need but NVA

Value Add

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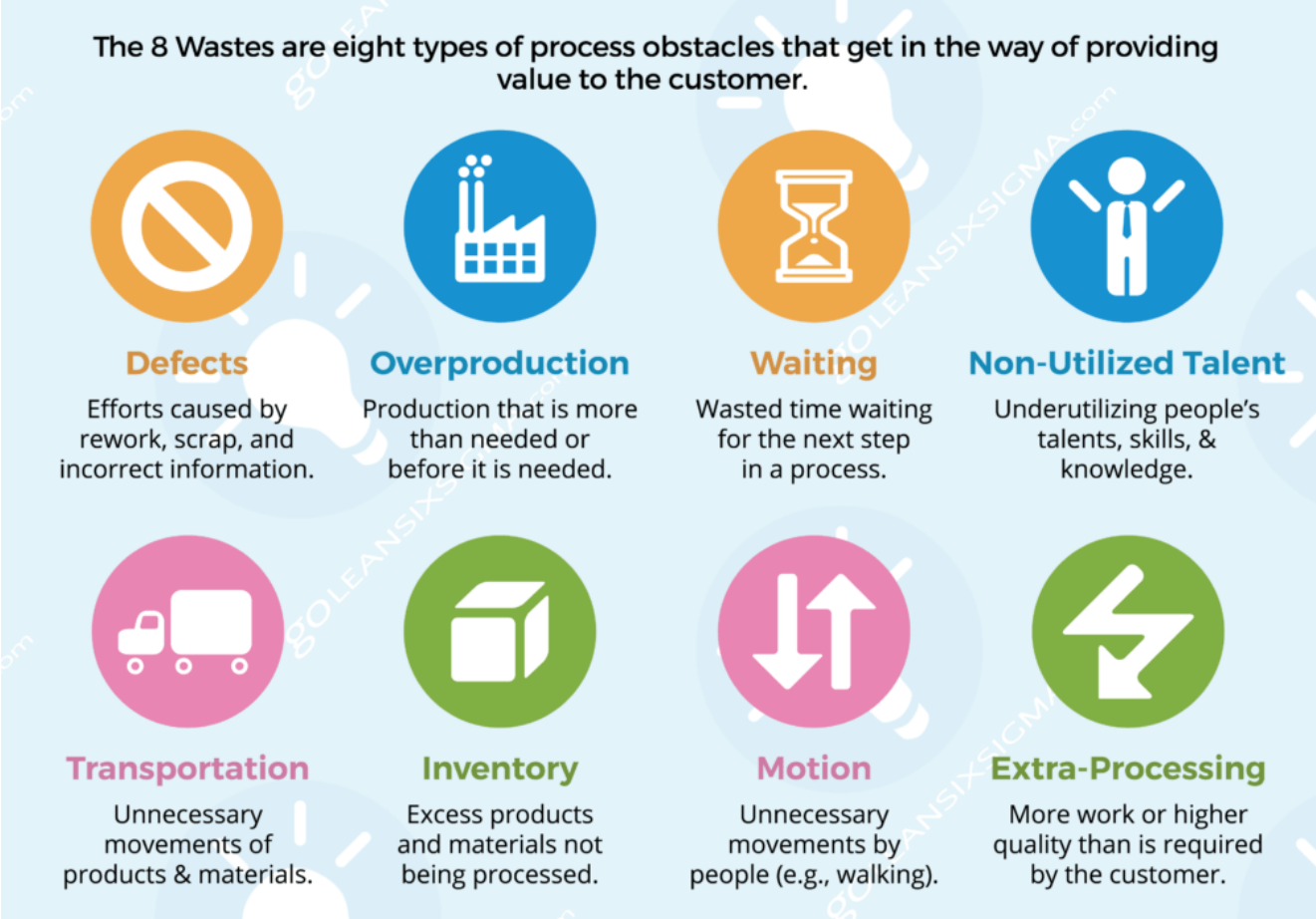
8 Wastes = DOWNTIME



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Wastes Identified From Process Mapping

- Waiting – Delays in specimen receipt
- Defects – Quality of submission form information
- Waiting – Resolution of submission form problems
- Transportation – Broken printer, flash drive use
- **Waiting – Batching specimens to reduce costs**
- Motion / Transportation – Retrieval of materials and records
- Extra Processing – Recording information in multiple locations
- Defects – Correction of LIMS data entry errors (quality of info received)

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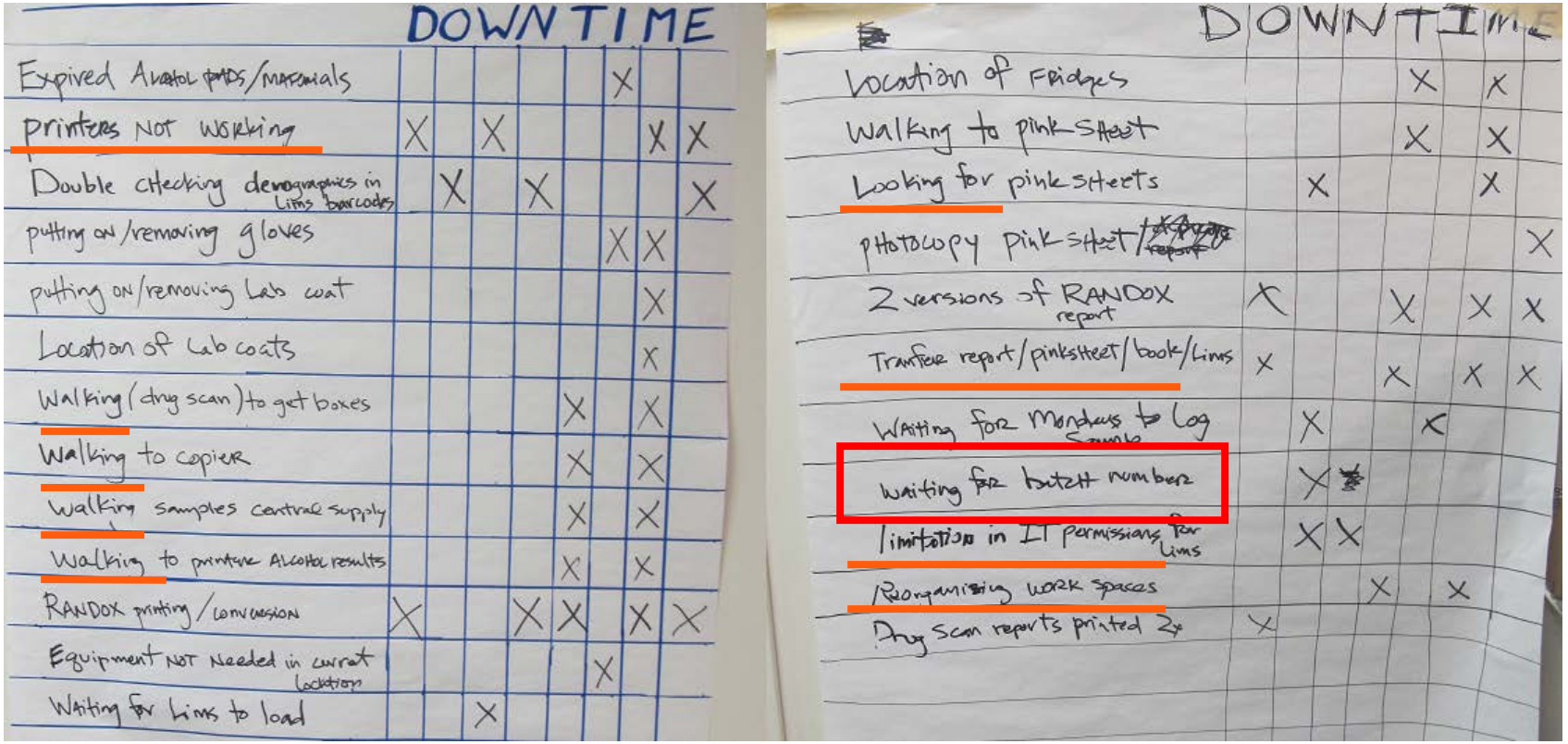
Wastewalk Results



Scope Changes

Initial Scope	
In Scope	**Out of Scope**
	Submission form
Shipping	
Accessioning	
Accession data review	
	Entire analytic phase
Reference lab use	
Results data review	
Reporting	
Staff duties	Number of staff
No-cost LIMS changes	Costly LIMS changes

Final Scope	
In Scope	**Out of Scope**
Submission form	
	Shipping
Accessioning	
Accession data review	
Analytic phase workflow	Test procedures
Reference lab use	
Results data review	
Reporting	
Staff duties	Number of staff
No-cost LIMS changes	Costly LIMS changes

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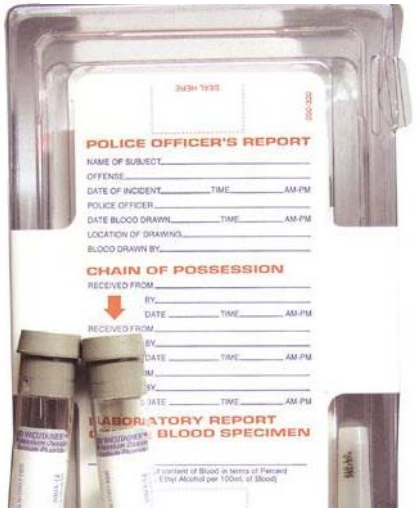
Shipping – Removed from Scope

- Receipt of specimens dependent on when coroner ships
- Limited number of problem counties – distance, coroner efficiency
- Plans to change collection kits to reduce costs
- Can address with additional communication in the future



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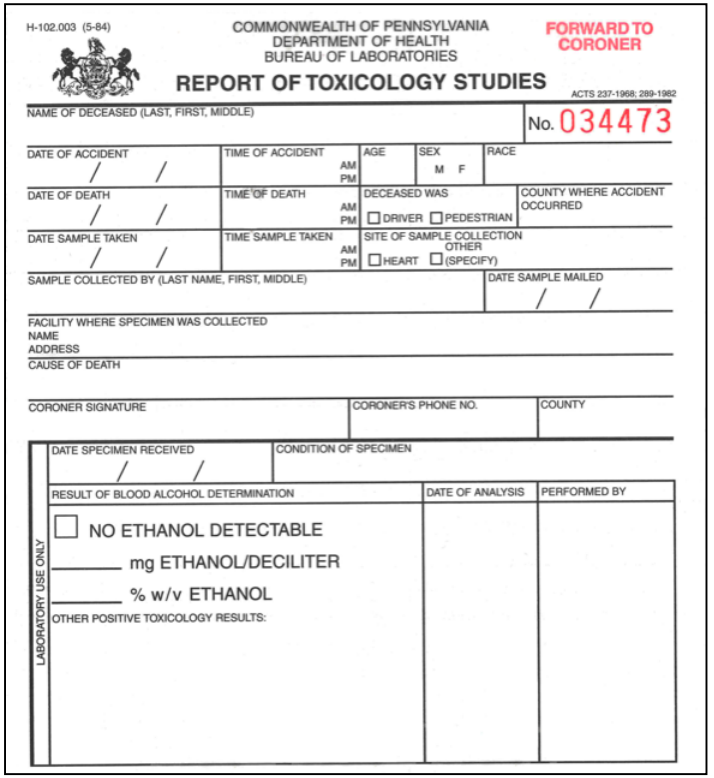
Submission Form – Added to Scope

- Poor handwriting
- Misinterpretation of fields
- Missing information
  (Request For Information Letter- RFIL)
- Need to photocopy and reduce size to retain form in logbook
- Changes in data collection needs
- No longer using form to report results



H-102.003 (5-84)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES

FORWARD TO CORONER

REPORT OF TOXICOLOGY STUDIES

ACTS 237-1968; 289-1982

NAME OF DECEASED (LAST, FIRST, MIDDLE) | No. 034473

DATE OF ACCIDENT / / | TIME OF ACCIDENT AM PM | AGE | SEX M F | RACE

DATE OF DEATH / / | TIME OF DEATH AM PM | DECEASED WAS ☐ DRIVER ☐ PEDESTRIAN | COUNTY WHERE ACCIDENT OCCURRED

DATE SAMPLE TAKEN / / | TIME SAMPLE TAKEN AM PM | SITE OF SAMPLE COLLECTION OTHER ☐ HEART ☐ (SPECIFY)

SAMPLE COLLECTED BY (LAST NAME, FIRST, MIDDLE) | DATE SAMPLE MAILED / /

FACILITY WHERE SPECIMEN WAS COLLECTED
NAME
ADDRESS
CAUSE OF DEATH

CORONER SIGNATURE | CORONER'S PHONE NO. | COUNTY

LABORATORY USE ONLY

DATE SPECIMEN RECEIVED / / | CONDITION OF SPECIMEN

RESULT OF BLOOD ALCOHOL DETERMINATION | DATE OF ANALYSIS | PERFORMED BY

☐ NO ETHANOL DETECTABLE
_____ mg ETHANOL/DECILITER
_____ % w/v ETHANOL
OTHER POSITIVE TOXICOLOGY RESULTS:

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Analytic Phase – Added to Scope

- Amount of movement and paperwork needed to support testing
- Batching specimens, especially for drug screening, was a major factor in TAT
- Had to accept drug screen cost increase

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RIE Day Two

- Root cause analysis
- Division director duties
- Brainstorming
- Benefit and effort matrix
- Mid-project update / teleconference

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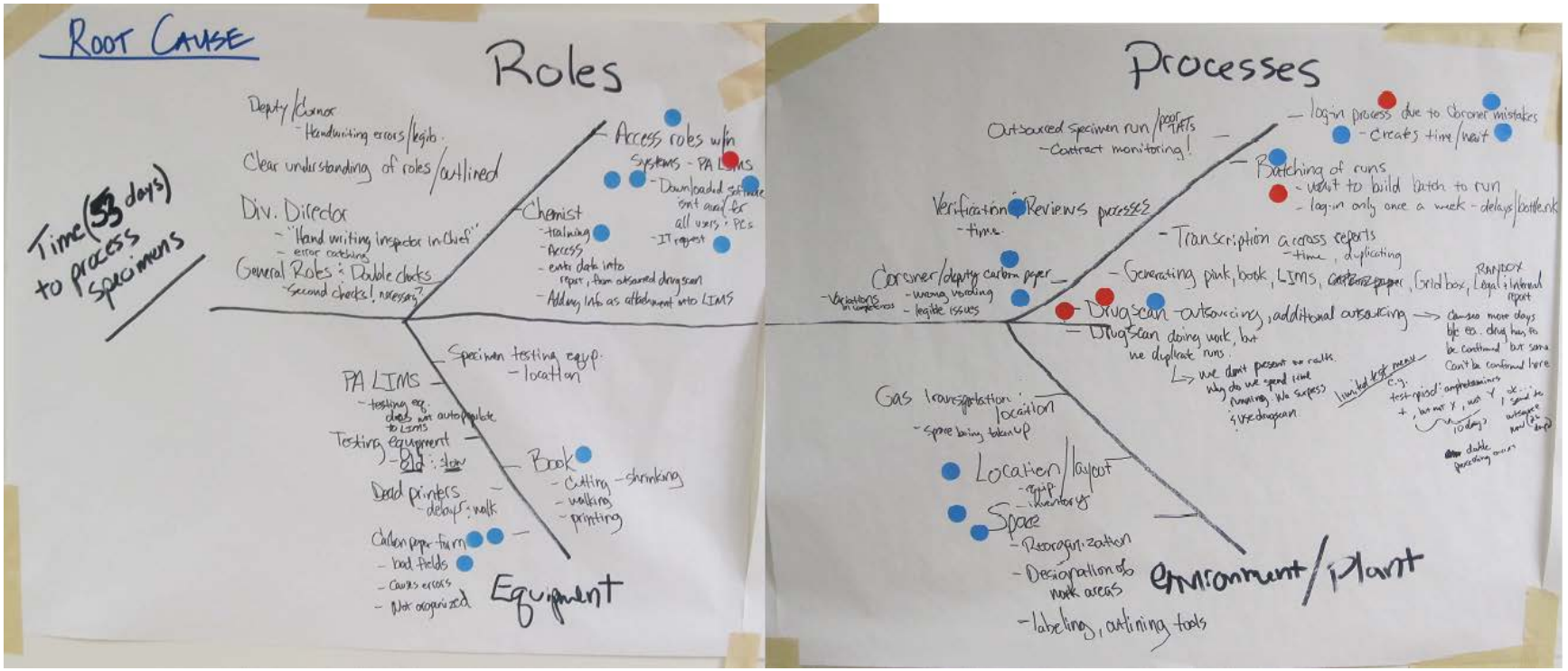
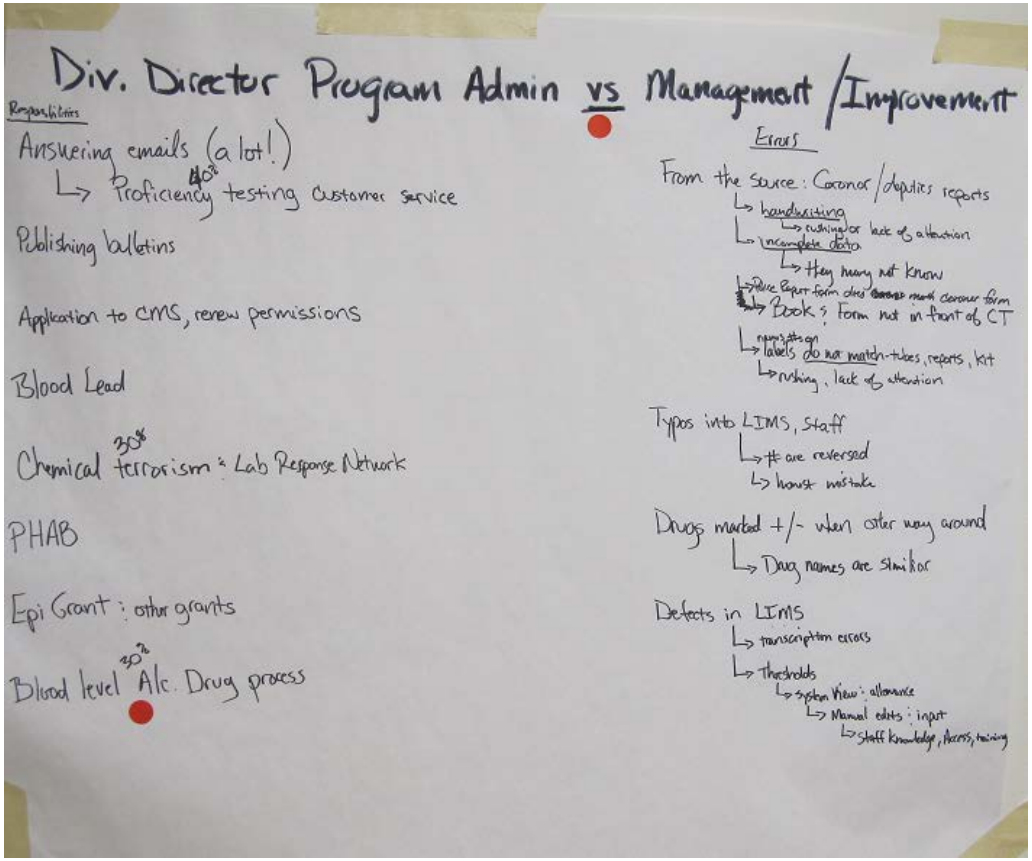
Root Cause Analysis



Major issue

Minor issue

Division Director Duties



Final Data Review, Results Approval, Report Release

- Interpreting handwriting
- Correcting data entry errors
- Locating logbook
- Entering reference laboratory results
- LIMS workarounds

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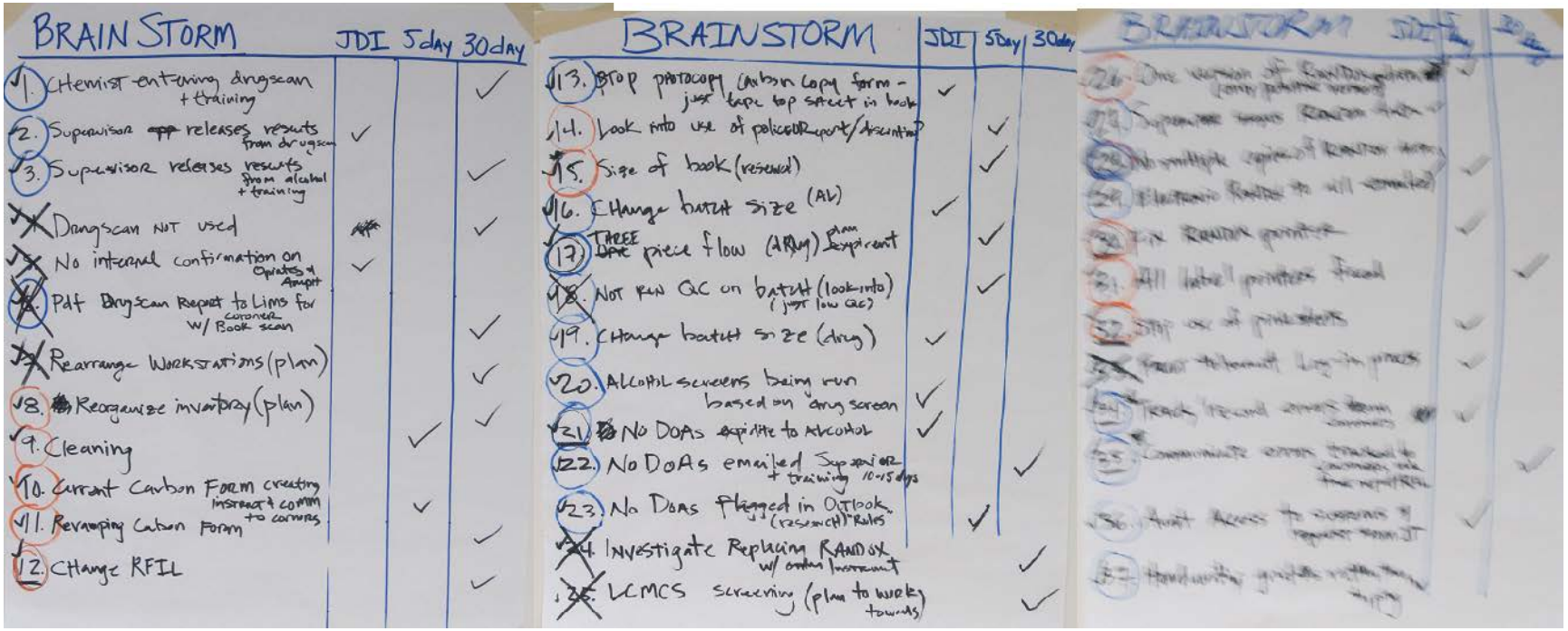
Brainstorming



- JDI = Just Do It!
- 5 Day = Accomplish within 5 days
- 30 Day = Accomplish in 30 days or more

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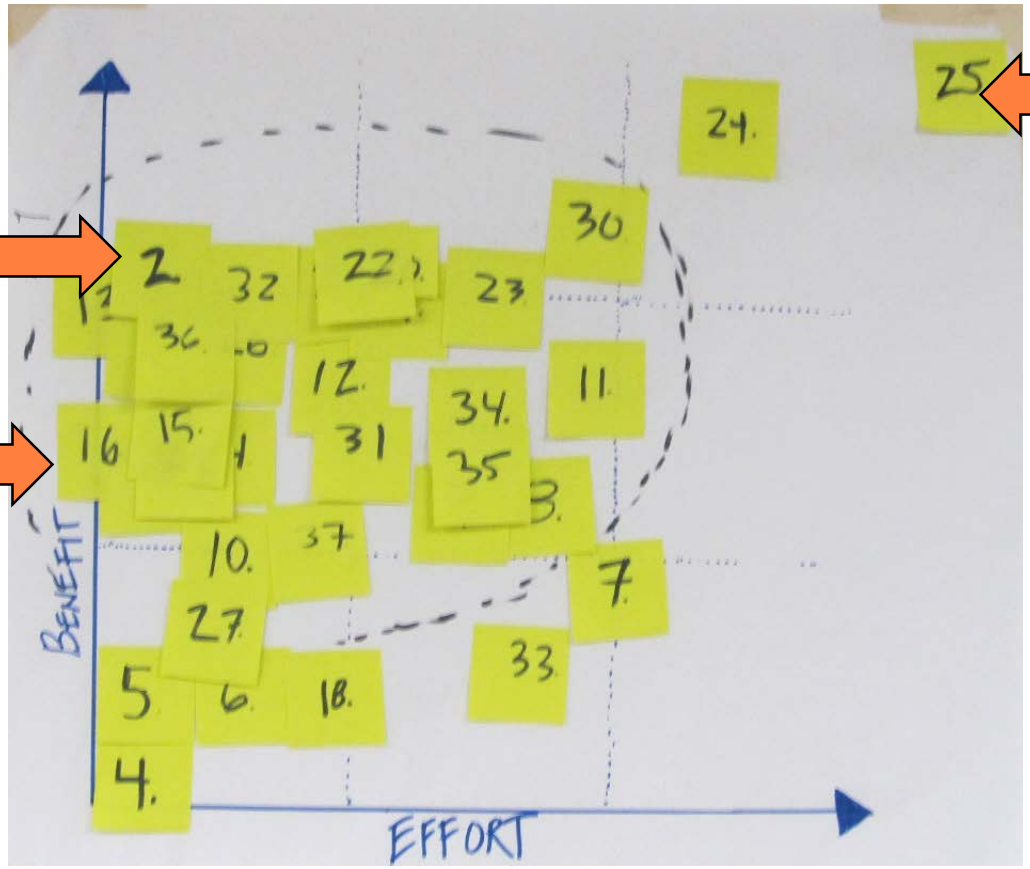
Benefit and Effort Matrix



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RIE Day Three

- Benefit and effort matrix (continued)
- Planned changes
- Future state map
- Action plan
- Project presentation

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Planned Changes

- Change logbook; no photocopying forms
- Replace broken printer
- LIMS access and label printers at all PCs
- Smaller run size for alcohol and drug screening
- Email drug screen results to all section staff
- Negative drug screen = priority for alcohol testing
- Decrease use of worksheets

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Planned Changes

- Track number and types of errors on submission form
- Train supervisor and chemists in LIMS processes
- Chemists enter reference lab results
- Supervisor approves results and releases all reports
- Update specimen collection instructions
- Clean and organize laboratory
- Revise specimen submission form

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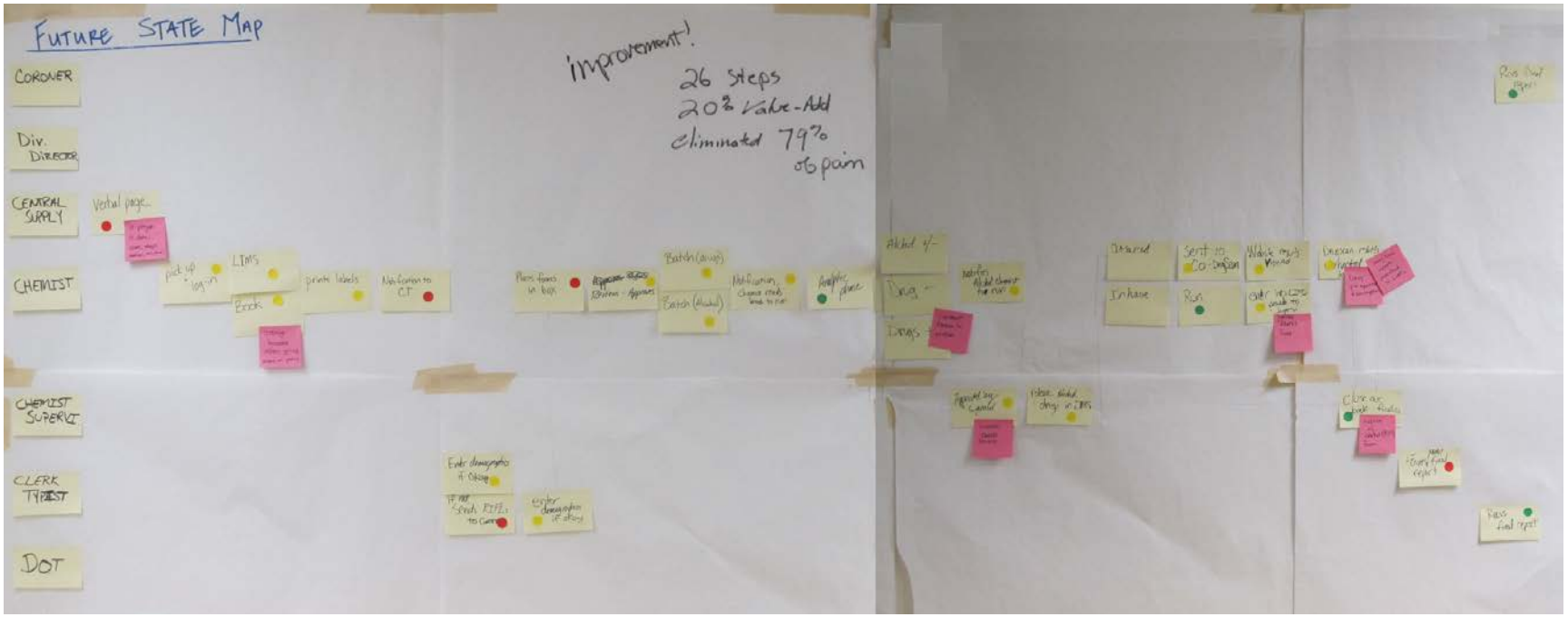
Future State Map



From 40 steps to 26 steps

From 5% value add steps to 20% value add steps

From 30 pain points to 8 pain points

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Metrics

Reduce Average Results Turnaround Times (TAT)

- Baseline: 53 days
- Target set at RIE (October 2018): 46 days
- December 2018: 29 days
- January to April 2019: 16 days

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Metrics

Reduce Division Director Involvement in Day-to-Day Program Operations

- Baseline: 30% of time spent on program
  25% of time spent on day-to-day operations
- Target set at RIE (Oct 2018): 30% / 5%
- Target met!

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Future Plans

- Clean and organize laboratory
- Revise specimen submission form
- Identify possible LIMS changes and funding needs
- Additional drug confirmation methods

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Challenges

- Setting aside full days for RIE
- Maintaining engagement / motivation after RIE
- Resistance to changes in staff roles / responsibilities
- Finding optimal balance of TAT, cost, time for program improvement
- New projects fill time intended for program improvement
- Potential program expansion in response to opioid crisis

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Lessons Learned

- Hold frequent post-RIE meetings to maintain engagement
- Be realistic about timeframes for accomplishing changes
- Pay attention to the small steps required to implement planned changes
- Keep project charter and action plan up-to-date
- Some costs may have to increase in order to improve value provided to customer

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Questions

Curious?

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