

# Using Our Lean-Based Deviation Management System to Identify, Trend and Prioritize Defect Resolution in Your laboratory



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# Learning Objectives

1. To design a defect management system to identify, trend & drive improvements from the level of the bench
2. To empower employees to root cause from the level of the bench and promote the Deviation Management [DM] System
  - a. By customizing the Deviation Forms
  - b. By embracing the organizational structure for resolutions
3. To promote waste reduction and improve safety by mitigating risk to patients



## Deviation Management

### Key Management Subsystem Driver of Knowledge-Based Continuous Improvement in the Henry Ford Production System

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**Key Words:** Deviation management; Lean; Continuous improvement; ISO 15189; Henry Ford Production System

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#### ABSTRACT

**Objectives:** *To develop a business subsystem fulfilling International Organization for Standardization 15189 nonconformance management regulatory standard, facilitating employee engagement in problem identification and resolution to effect quality improvement and risk mitigation.*

**Methods:** *From 2012 to 2016, the integrated laboratories of the Henry Ford Health System used a quality technical team to develop and improve a management subsystem designed to identify, track, trend, and summarize nonconformances based on frequency, risk, and root cause for elimination at the level of the work.*

A business system is defined as “a set of detailed methods, procedures, and routines created to carry out a specific activity, perform a duty, or solve a problem.”<sup>1</sup> In most business systems, strategic opportunities and desired improvements are expected to be defined at the top of the organization and cascaded to the operational level of work for execution by managers. In the Henry Ford Health System, we have used Lean management as our business system over the past 12 years to achieve not only a top-down but also a bottom-up approach to deliver on strategy deployment and continuous improvements throughout our laboratory product line. To function as a business system, Lean requires a series of management subsystems that guide human behaviors toward expected outcomes.

<https://academic.oup.com/ajcp/article/doi/10.1093/ajcp/aqx084/4110210/Deviation-ManagementKey-Management-Subsystem?guestAccessKey=9bec2c6f-70e9-4f2f-a306-6c571f4b9495>

# Henry Ford Production System

## **What is it to be Lean?**

Lean is the basis of our management system that empowers our culture of continuous improvement

## **What is my role here?**

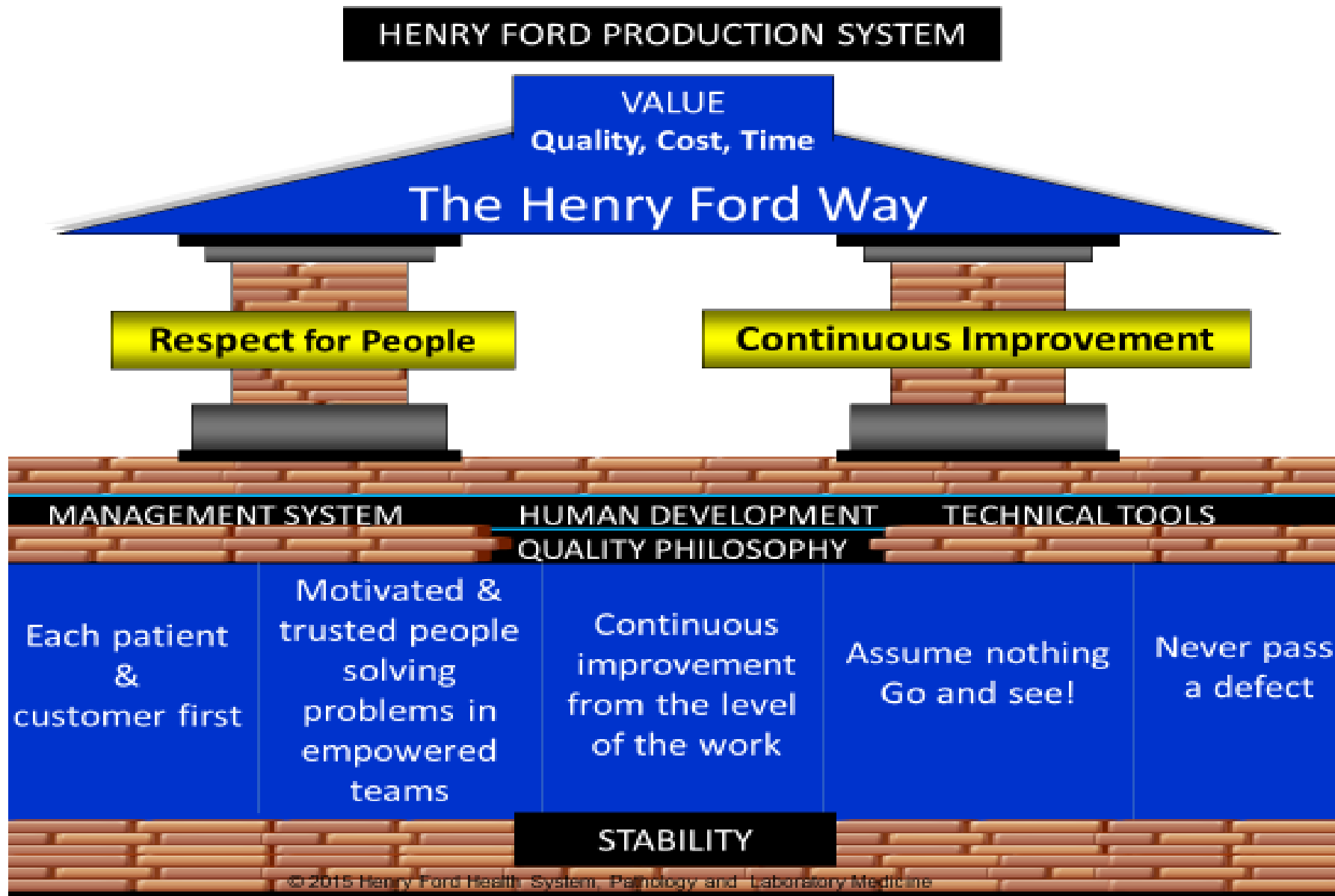
To achieve our system goals and improve operations every day

- Goals are managed by leadership and
- Daily improvements is managed by the entire workforce

## **What is employees empowerment?**

Is to embrace the values, tools of improvements and problem solve as expected within the system of work to improve the work continuously

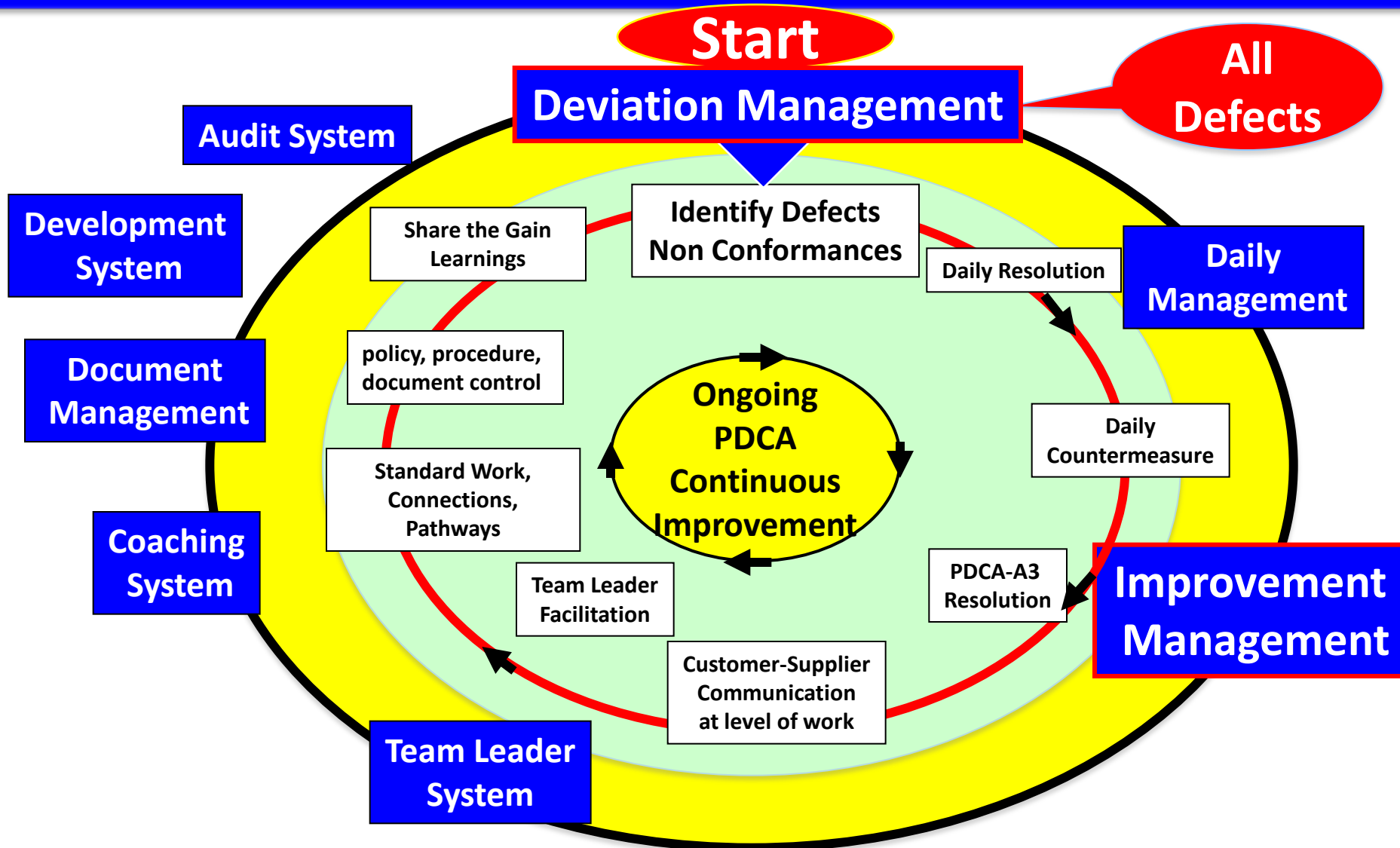
# Our Philosophy that Promotes People



# Our Lean Culture of Empowerment

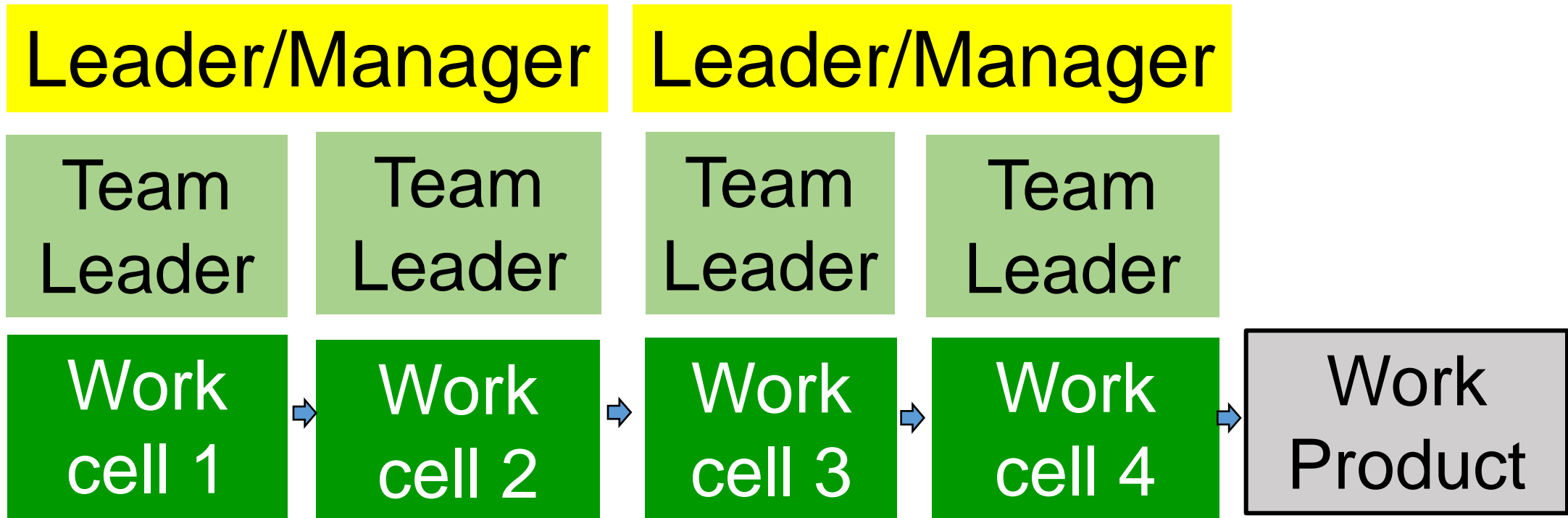


# Lean System to Facilitate Continuous Improvement from the Level of the Bench



# Our Lean Organizational Structure

Find Your Role





# The Responsibility in the Structure

## Team Member Duties

### Daily:

- **Identify defects and document on deviation management forms**
- **Identify defects/gaps in policies, procedures and standard work and report to your team leaders and manager**
- Complete daily logs and document corrective action when needed (e.g. Temperature, QC, maintenance logs)
- Complete 5S Checklist as assigned
- Update Daily Management Boards as assigned and be present at daily huddle
- Collect data on process improvement A3s your are involved in
- Notify defects/gaps in Inventory and Kanban and notify the team leader

### Weekly:

- **Discuss with deviations with your team and team leader**
- **Brainstorm the root cause of defects and suggest corrective actions to team leads and manager**
- Document your process improvement on the paper A3 form
- Post A3 forms in the work area

### Monthly

- Present your A3 at Share The Gain (STG)

### Periodically

- Be ready to rotate to an alternate team as required by management

# Defining Defects

Poor Quality of  
Products or  
Service



Defective Products

That makes YOU:

Stop your work & rework to correct  
Reject & ask to redo  
Return it to sender to verify information  
Delay your work to fix it yourself  
Not pleased, could be better

Customer  
Complaints

I am:  
Satisfied  
Dissatisfied  
with my experience

**Error** Hurting someone due to  
diagnostic errors

# Terminology

## **Lean Standard:**

Any product/service that  
does not meet the  
customers expectation  
is a  
Defect or Waste

## **ISO Standard:**

Any product/service that  
does not meet the standard  
in all phases of testing is a  
Non-conformance  
(Deviation)

**Defects = Deviations = Non-conformances**

# The WHITE BOARD The Start

# White Board - Visual Workplace

| Types of Waste  | Root Cause Analysis   | 4 Rules of Work   | The Improvement Process                       | Education by Leader          |
|---|-----------------------|---|---|------------------------------|
| <b>7 Types of Waste</b><br><b>Waiting</b> – wasted time between steps<br><b>Defects</b> – process & product mistakes<br><b>Transportation</b> – unnecessary movement of material & products<br><b>Overproduction</b> – more than needed<br><b>Over-processing</b> – redundant steps, rework<br><b>Motion</b> – unnecessary movement of people<br><b>Inventory</b> – over or under stock | <b>Root Cause</b><br> | <b>4 Rules of Work Design</b><br><small>Decoding the DNA of the Toyota Production System, Spear &amp; Bowen, Harvard Business Review, Sept 2003, 19pp</small><br><b>Rule 1 – STANDARD ACTIVITIES</b><br>Specifications document all work processes to include content, sequence, timing, location, & expected outcome (how do you do your work)<br><b>Rule 2 – STANDARD CONNECTIONS</b><br>Connections with clear YES/NO signals directly link every customer & supplier (requests & responses)<br><b>Rule 3 – STANDARD PATHWAYS</b><br>Every product & service travels a predefined, single, simple, & direct flow path (no looping or forking)<br><b>Rule 4 – IMPROVEMENT &amp; WORKER EMPOWERMENT</b><br>Workers at level where work is done, guided by a teacher, improve their own work using data | <b>HFPS Process Improvement Procedure</b><br> | Wednesday's Words of Quality |

## Capture Daily Defects

1. Wrong patient identification
2. Ran out of gloves- size medium
3. Not enough specimen collected for lab test

## Daily Resolution of Defects

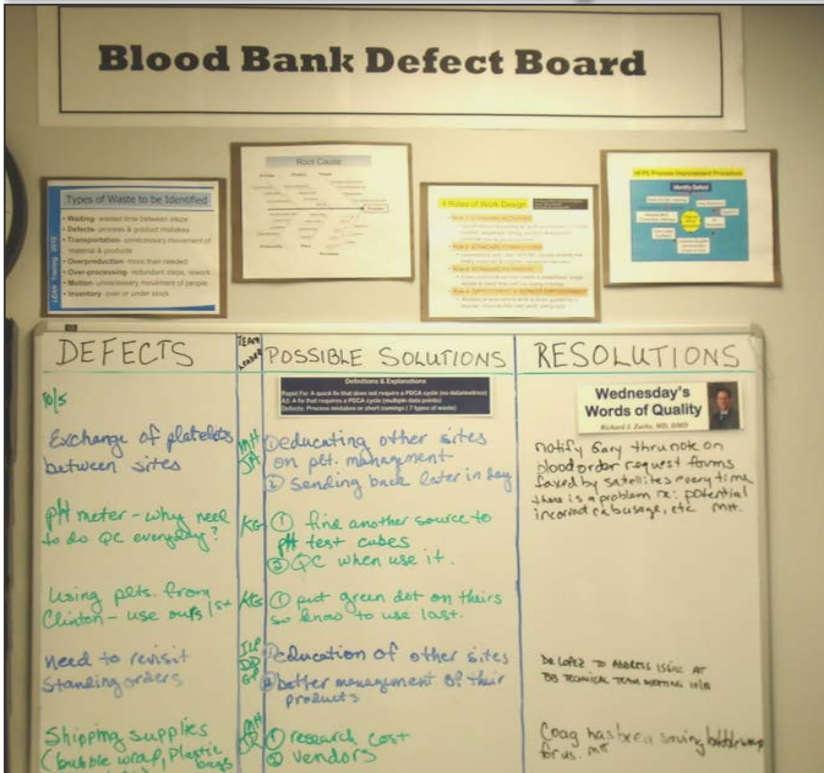
**Rapid (Defects corrected on the spot)**  
**A3 (PDCA analysis and customer-supplier involvement)**

## Communication & Education

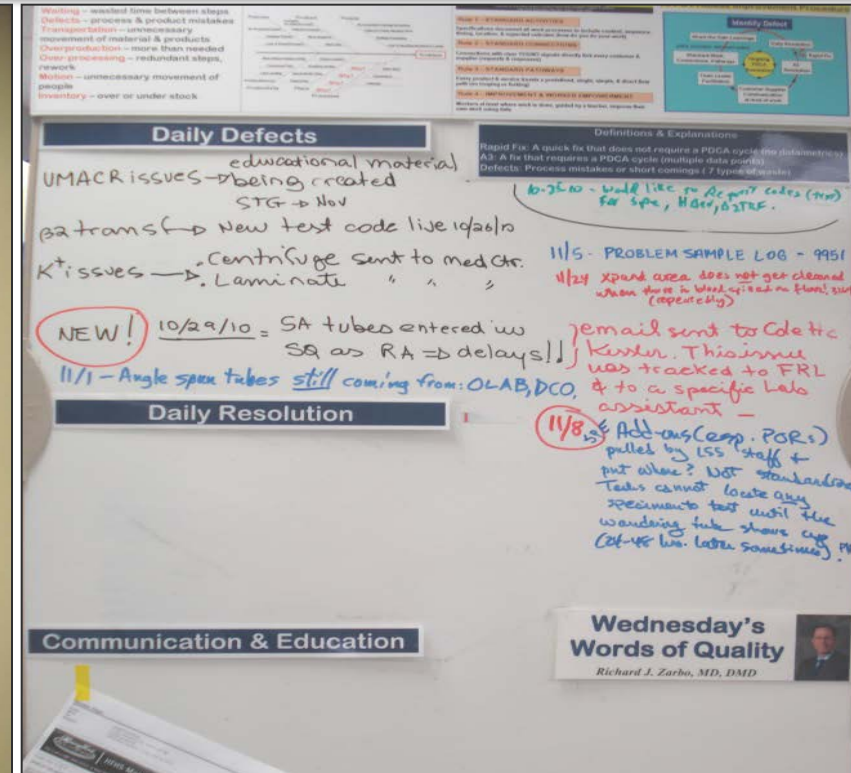
All shifts  
 (New policy, standard work, hours, competency, quality tool)



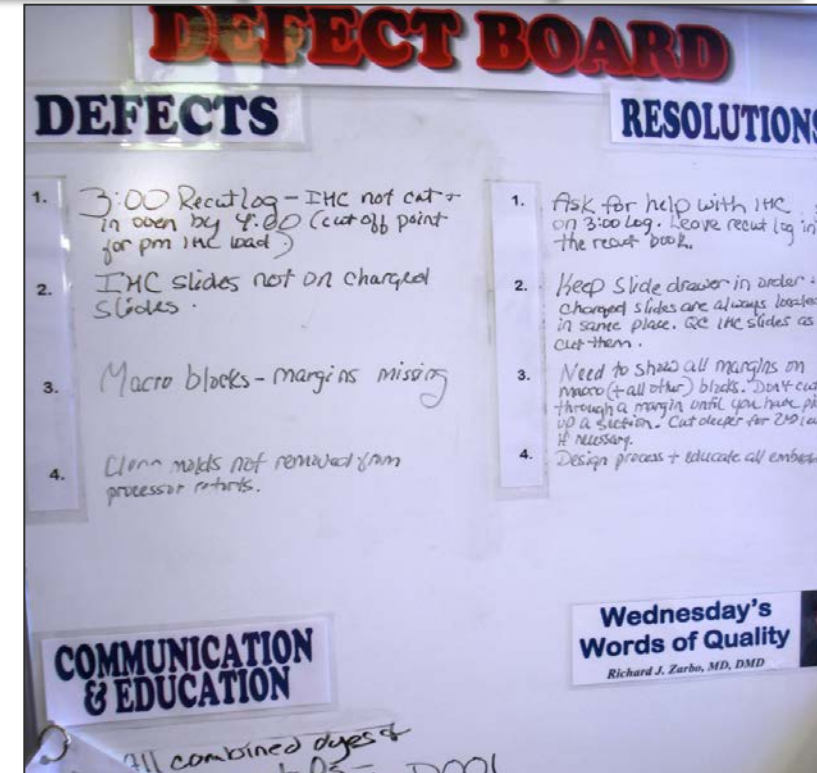
# Examples of White Boards (2010)



- Each defect is assigned to a team leader for resolution
- Some with possible solutions & some with resolution documented



- Documentation in a dialogue format for old & new defects
- Leadership comments dated & in a different colored font



- More structured documentation for each defect but no dates

# Lessons Learned from White Boards

## For Employees

1. Not everyone was enthusiastic about writing their defects on the board
2. Defect follow-up documentation not consistent and afternoon and midnight shifts becomes disengaged
3. Defect huddles not consistent & timely leading to frustration and became a whining board

## For Leadership

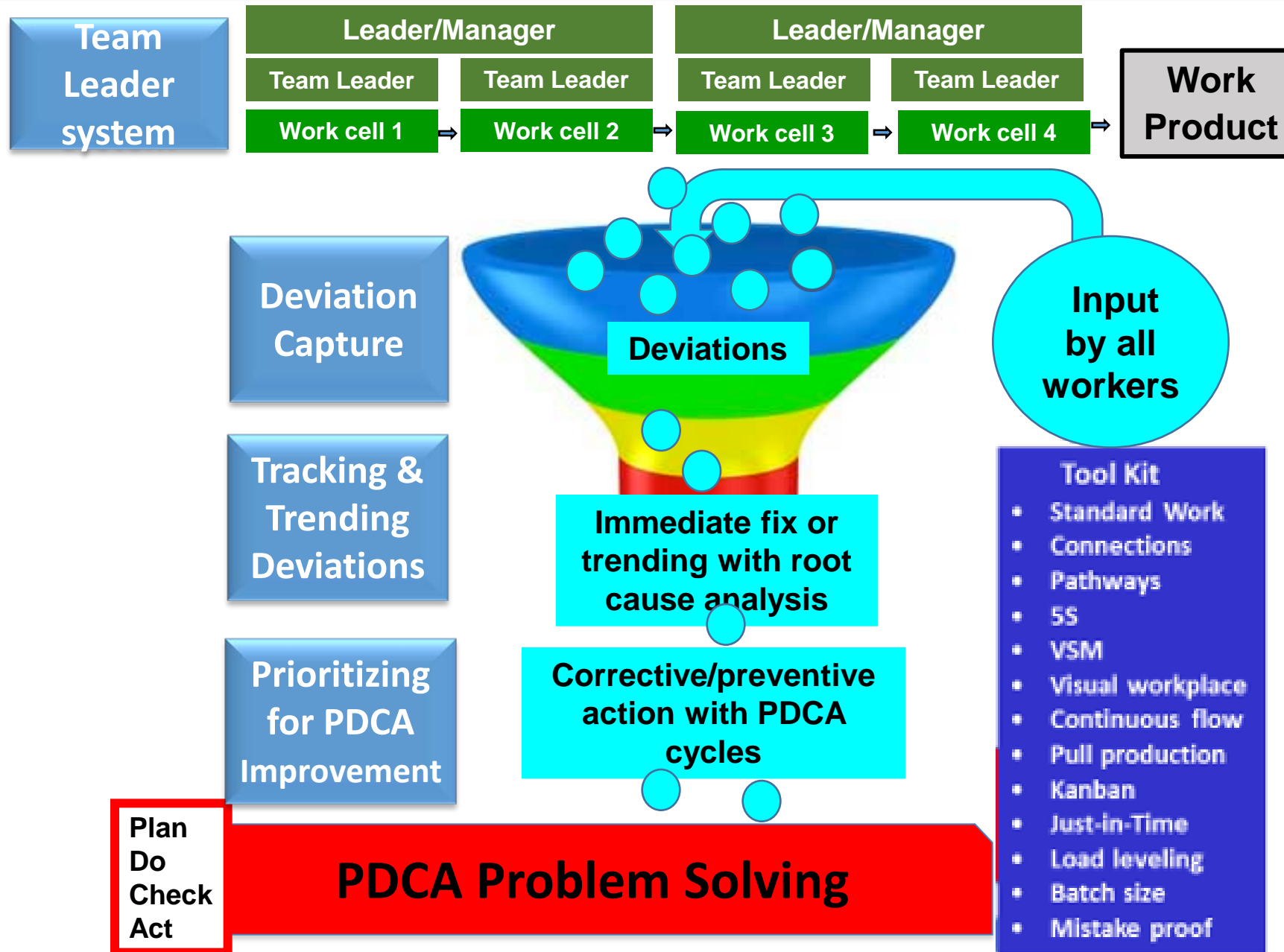
1. Participation of defect identification became sporadic over time
2. Documentation of defects/resolution is lost [erased] over time & led to no tracking or trending
3. Missed opportunities for improvements

# The Deviation Management System

# Why a Deviation Management System?

- To improve compliance and ownership of defects
- Consistent feed back to front line staff of their defects
- A structured process for defect documentation, tracking, trending and prioritization for improvements
- Data to engage with external customers and suppliers

# Responsibility, Knowledge & Execution of Defects





# The Deviation Management Process

## Step 1: Complete form when a defect is encountered


1. All employees to complete a deviation form with defect details
2. If the defect belongs to you, fix document and place the form in the defect bin for huddle discussion
3. If not, place form in designated bin for appropriate work cell for resolution

|  |  |  |   |
|--|--|--|---|
| <b>1. Complete Steps A-H</b>   |  | <b>G) Defect Originating Site (complete a &amp; b)</b> |   |
| A) Accession#/ Case #: _____   |  | a) <input type="checkbox"/> HFH                        | b) <input type="checkbox"/> ED <input type="checkbox"/> OR (room #)     |
| B) MRN: _____  |  | <input type="checkbox"/> HFWH                          | <input type="checkbox"/> Inpatient                                      |
| C) Name: _____   |  | <input type="checkbox"/> HFWBH                         | <input type="checkbox"/> Outpatient                                     |
| <b>Patient demographics or Case #</b>  |  | <input type="checkbox"/> HFHCT                         | <input type="checkbox"/> Other  |
|  |  | <input type="checkbox"/> HFMG (Site) _____             |   |
|  |  | <input type="checkbox"/> HFML (Site) _____             |   |
|  |  | <b>H) Work Cell Affected or/ Cr</b>                    |   |
| D) Physician's Name _____  |  | <b>Clinical Pathology:</b>                             |   |
| E) Shift: <input type="checkbox"/> Days <input type="checkbox"/> Night   |  | <input type="checkbox"/> Coagulation                   | <input type="checkbox"/> Hematology <input type="checkbox"/> Urinalysis |
| F) Deviation Form Initiated by: _____  |  | <input type="checkbox"/> Phlebotomy                    | <input type="checkbox"/> LSC  |
| <b>Form Initiator</b>  |  | <input type="checkbox"/> Microbiology                  | <input type="checkbox"/> Molecular                                      |
|  |  | <input type="checkbox"/> Send Outs                     | <input type="checkbox"/> Chemistry                                      |
|  |  | <input type="checkbox"/> Specimen Processing           | <input type="checkbox"/> Information                                    |
|  |  | <b>Surgical Pathology:</b>                             |   |
|  |  | <input type="checkbox"/> Accession                     | <input type="checkbox"/> Autopsy <input type="checkbox"/> Frozen Re     |
|  |  | <input type="checkbox"/> Histology                     | <input type="checkbox"/> IHC <input type="checkbox"/> Pathologis        |
|  |  | <b>Cytopathology:</b>                                  |   |
|  |  | <input type="checkbox"/> GYN                           | <input type="checkbox"/> Non-GYN  |
| <b>2. Defect Classification</b> <input type="checkbox"/> Order Defect <input type="checkbox"/> S <input type="checkbox"/> Customer Complaint <input type="checkbox"/> RL file # _____ <input type="checkbox"/> Sa            |  |  |   |
| <b>3. DEFECT Sub Classification</b> (refer to subclass list on reverse side):  |  |  |   |
| <b>4. Significant Occurrence:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes → Name of superv  |  |  |   |
| <b>5. Describe Occurrence:</b>   |  |  |   |
| <b>Describe the defect as encountered</b>  |  |  |   |
| <b>6. What was the Resolution?</b> <input type="checkbox"/> Immediate Resolution <input type="checkbox"/> Root Cause with A3 Form  |  |  |   |
| <b>What is the Immediate Fix and was it communicated to form originator?</b>   |  |  |   |
| <b>Team Leader (Lead, Supervisor, Manager) Complete Below</b>  |  |  |   |
| <input type="checkbox"/> Feedback to Deviation Form Initiator <input type="checkbox"/> Feedback to Pathologist (if applicable) (AP) Return slide to: <input type="checkbox"/> Pathologist <input type="checkbox"/> File Room |  |  |   |
| Leadership Close-out (Initials): _____ Date: _____ Deviation Excel Track#:   |  |  |   |
| <b>Tracking # for documentation</b>  |  |  |   |

1. Most commonly used defect codes
2. Immediate Fix performed

| I. Lab Staff  |  |
|---|--|
| <u>Place label here /Pat Info:</u>  | 1. Ordering Dr. _____<br>2. Clinic _____<br>3. Tech initials _____<br>4. Shift: <input type="checkbox"/> AM <input type="checkbox"/> PM <input type="checkbox"/> MN  |
| What was the <u>immediate resolution</u> ?<br><input type="checkbox"/> Credited<br><input type="checkbox"/> Called to Clinic<br><input type="checkbox"/> Clinic closed, reordered<br><input type="checkbox"/> Other _____ | What is the <u>defect</u> ? Choose one<br><input type="checkbox"/> O37 Clinic vs lab collect<br><input type="checkbox"/> O23 No Lab Orders<br><input type="checkbox"/> O22 Wrong test ordered<br><input type="checkbox"/> S4 QNS<br><input type="checkbox"/> O27 Cancelled by Epic/HIS<br><input type="checkbox"/> O36 No collection date and time<br><input type="checkbox"/> S6 Clotted<br><input type="checkbox"/> S1 No spec ID/unlabeled<br><input type="checkbox"/> S7 Hemolyzed<br><input type="checkbox"/> O21 Other |
| II. Supervisor or Manager   |  |
| <input type="checkbox"/> OK immediate resolution<br><input type="checkbox"/> Added to Deviation Excel<br><input type="checkbox"/> Does Root-cause qualify for A3/deep dive (Y/N)  | <input type="checkbox"/> Sent to :<br><input type="checkbox"/> Other _____<br><input type="checkbox"/> Feedback to lab staff<br><input type="checkbox"/> Closed-out  |
| Comments:   | Tracker #  |

### 3. Work cell identified for defect resolution



**Pathology & Laboratory Medicine**  
OCC-PALM-8.1-pro-sbf3 :Deviation Management for Pathologist  
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DO NOT DISCLOSE UNLESS AUTHORIZED BY A DESIGNEE OF THE HFHS BOARD QUALITY COMMITTEE.


**Pathologist**

Case # \_\_\_\_\_  
Part type \_\_\_\_\_  
Your Name \_\_\_\_\_  
Today's date \_\_\_\_\_

Describe Problem

Work Cell  
☐ Surgery/client  
☐ Frozen Room  
☐ Accession  
☐ Grossing  
☐ Histology  
☐ IHC  
☐ Residents  
☐ Cytology  
☐ Autopsy  
☐ IT

1. If **Urgent** case please give, to **AP Manager**  
2. If Not urgent - place in deviation box (Pathology hallway)  
**AND** Please check one:  
☐ I am requesting final feedback  
☐ I am not requesting final feedback



**URGENT Closure**  
☐ Yes  
☐ NO

**Manager/Supervisor**

Class/Subclass  
\_\_\_\_\_

Resolution

NOTES

Documentation in DM  
1. Excel Tracking # \_\_\_\_\_  
2. Closed with Pathologist, if requested  
☐ Yes    ☐ No

# Defect Classification Codes

Order Defects  
Specimen Defects  
Specimen  
Transport Defects

Testing Defects

Report Defects  
Complaints  
RadicaLogic  
Safety/  
Environmental  
Daily/Wkly Act.

Pre-  
analytic

Analytic

Post-  
analytic

## Order Defects(O)

01- Patient Name/MRN mismatch  
02- Other Identifier issues (Date of Birth)  
03- Test name  
04- Test Code  
05- Diagnosis  
06- Diagnostic code/ICD code  
07- Practitioner Name  
08- Practitioner Code  
09- Wrong part type  
010- Part type not accessioned  
011- Laterality incorrect (changed from Laterality Switched)  
012- Case assigned to incorrect pathologist  
013- Incorrect specimen class type  
014- Visual control not used [when required]  
015- Order received without a specimen container  
016- Requisition not scanned  
017- Type of specimen missing/incomplete  
018- Incorrect procedure date  
019- No clinical history  
020- Incorrect batch log  
021- Other  
022- Wrong test ordered  
023- Test NOT ordered  
024- Registration Issue (Demographics, transcription error)  
025- Duplicate  
026 - Wrong collect time/date  
027 - Cancelled by epic/his  
028 - Wants us to add-on  
029 - Add on Work around  
030- Order did not transmit  
031- No Sign off by RN  
032- No ADT label  
033 - Surgery time  
034 - Specimen out of sequence  
035- Laterality Missing  
036- No Time or Date  
037- Clinic vs Lab Collect  
038-Test not "collected" in Epic  
039- Order not placed in Epic  
040- Specimen Description Discrepancy  
041- Specimen Source missing  
042- Requisition not sent with Specimen  
043- Wrong Epic order ID number  
044 Requisition received with incorrect epic #

045 Specimen received but no test requested  
046 Order Expired  
047 Case assigned to the wrong pathologist  
048 Order mishandling due to Elug information  
049- Duplicate RTG cancelling in SQ  
050- Add on order not placed in SunQuest  
051- Insufficient information/data submitted to reference lab  
052- Specimen Source incorrect  
053- Specimen Source needed verification (questioned)  
054- Specimen Volume missing  
055- Specimen Volume incorrect  
056- Order verification needed for processing  
057- Test ordered is no longer available

## Specimen Defect (S)

S1- No spec ID/ unlabeled  
S2- Inadequate sample ID  
S3- No sample  
S4- Quantity not sufficient (QNS)  
S5- Wrong container  
S6- Clotted sample  
S7- Hemolyzed sample  
S8- Inappropriately timed sample  
S9- Specimen initially NOT fixed  
S10- Other  
S11- Improper handling/transport/storage  
S12- Contaminate (e.g. I.V. TPN)  
S13- Improper specimen collection  
S14 Improper tube type drawn for test request  
S15- Mislabelled specimen container  
S16 -Suspect Anti coagulate contamination  
S17 -Poor Quality Specimen  
S18 -No Date/Time on specimen container  
S19 - Specimen collection container broken  
S20- Specimen Spilled  
S21- Specimen leaking  
S22- Unable to locate specimen  
S23- Patient refused specimen collection  
S24- excessive number of specimens collected  
S25- Specimen mishandled due to elug information

S26- Specimen mis-collected due to incorrect Elug information  
S27- ADD-On Specimen QNS  
S28- Specimen stored/tracked without being tested  
S29- Specimen stored in a location different from specified storage location  
S30- Specimen not aliquoted for send out  
S31- Specimen aliquoted is QNS for testing  
S32- Specimen is too old to be add-on to  
S33- Specimen received after delay is an is too old for testing  
S34- Specimen container is overfilled  
S35- Aliquot or decant not made for testing  
S36- Specimen container is empty

## Testing Defects (T)

T1- Quality control failure (QC)  
T2- Test condition defect (temp., etc.)  
T3- Kit failure  
T4- Reagent defect  
T5- Specimen not aliquoted for additional testing  
T6- Procedure (SOP) deviation  
T7- Quality Assurance failure (e.g. No action for out of control result)  
T8- Insufficient triage of specimen submitted  
T9- Frozen section measurements missing  
T10- Inadequate blocks  
T11- Missing or extra blocks  
T12- Slides/Blocks do not match  
T13- Tissue too thick  
T14- Not sectioned enough to get tumor/block not adequately cut  
T15- Specimen not fixed properly  
T16- H&E staining sub-optimal  
T17- Incomplete gross description  
T18- Contaminant/footer  
T19- Embedding/orientation incorrect  
T20- Cassette Mis-id  
T21- Processor not run  
T22- No coverslip on slide  
T23- Slides not received by pathologist  
T24- Wrong special stain/IHC

T25- Not on charged slides  
T26- Mismatch-tissue on slide & slide label  
T27- Tissue lost in processing  
T28- Wrong recut block  
T29- ID Check not performed  
T30- Pathologist received incomplete case  
T31- Other  
T32- Blocks not edited in Co-path  
T33 Protocol not Ran  
T34 autolysis of sepc  
T35 No gross photo  
T36- Staples in tissue  
T37 - Tissue not taken for studies (FTB,CYTGEN)  
T38 FS Slides labeled incorrectly  
T39 -Testing Repeated  
T40-Contamination during testing  
T41 -Freezer/Fridge alarm  
T42-Instrument Downtime  
T43 -Equipment/ Instrument malfunctions  
T44 -Technique Error  
T45-resulting in wrong procedure  
T46-Communication Failure resulting in wrong specimen processing  
T47- Missing band Length  
T48- Karyotype/image missing patient demographics  
T49- Karyotype/image has incorrect patient label/ID  
T50- Karyotype issues  
T51: No Karyotype/image on file  
T52: Case overdue (cytogenetics)  
T53 Test performed after prolonged delay  
T54- Improper processing, autolysis  
T55- Incomplete fixation or poor fixation  
T56- Incomplete dehydration, clearing or infiltration  
T57- Cut sections too thick  
T58- Folds in section  
T59- Holes in section  
T60- Bubbles on slide  
T61- Microchatter or Venetian blind effects in sections  
T62- Fragmented, cracked, or torn section  
T63- Dry sections  
T64- Brittle sections  
T65- Poor staining quality  
T66- Desired structures poorly or not demonstrated

T67- Nonspecific staining obscures desired structures  
T68- Uneven staining  
T69- Heavy precipitate obscures tissue  
T70- Light nuclear stain  
T71- Dark nuclear stain  
T72- Cytoplasm or counter stain too light  
T73- Cytoplasm or counter stain too dark  
T74- Excessive background staining  
T75-Weak staining  
T76- Poor orientation, embedding  
T77- Band Length Issues  
T78- Block not in file  
T79- Slides not in file  
T80- Block misfiled  
T81- Slides misfiled  
T82- Block and/or slides unable to locate  
T83- Tissue lost in processor  
T84- Tissue lost at embedding  
T85- Processor not loaded/not run  
T86- Tissue does not match gross description  
T87- Block/slides does not ping  
T88- Batch log not edited  
T89- IHC stain delayed  
T90- Recut order not on Recut Log  
T91- Duplicate Recut order  
T92 Slides not out  
T93 Slides not received by special stains  
T94 Slide not received by IHC  
T95 Slides places in wrong testing area  
T96 Slides sent to the wrong lab location  
T97 Slides delivered to the wrong pathologist  
T98- Partial case delivered to pathologist  
T99 Block/cassette put through cleaning cycle  
T100- Misrouted paperwork needed for testing  
T101- Testing incomplete, specimen on pending log  
T102-Wrong slide colored chosen for hospital  
T103- Tissue Cut Away  
T104- Tissue loaded to wrong processor  
T105- IHC control slide not used  
T106- Interface/communication errors

## Report Defects (R)

R1- Post-verification delay in manual results entry  
R2- Failure of results to cross computer interface  
R3- Failure to initiate critical value/alert results call  
R4- Difficult, delayed, failed attempted critical value/alert call  
R5- Absent or incomplete documentation of critical value/alert call  
R7- Results reported to be unavailable to clinicians  
R9- Transmit failure of (CO Path) results to EMR  
R10- Other  
R11- Manual entry error  
R12- Auto validation / Interface Middle ware  
R13- Results are inconsistent with history  
R14 Result Modification: Specimen over diluted during testing  
R15 Result Modification: Specimen not diluted to end point  
R16 Result Modification: Specimen dilution calculation incorrect  
R17 Result Modification: manual keystroke error  
R18 Result Modification: Instrument transmitting error  
R19 Result Modification: Result filled under an incorrect accession number or CID  
R20: Typographical Error identified prior to the release of results  
R21 Test not result: test not listed on specimen label  
R22: Copy to provider not listed in report  
R23- Amendment do to misinterpretation  
R24- Amendment do to misidentification  
R25- Amendment do to specimen defect  
R26- Amendment do to report defect  
R27- Result autoverified before technologist intervention  
R28- Result type  
R29- Dilution incorrect technical or SQ process  
R30- Dilution not entered into instrument or SQ

## Complaints (C)

C1- Clinician complaints about TAT  
C2- Clinician complaint about report

C3- Clinician other  
C4 Patient complaint about wait time  
C5 Patient complaint about service level  
C6- Patient complaints about report TAT  
C7- Patient complaint about report  
C8 Pathologist complaint about TAT  
C8 Clinician complaint about ADD-ON TAT

## RadicaLogic (RL)

RL1- Behavior  
RL2- Safety  
RL3- Miss-ID (External)

## Safety/Environment: Non-RadicaLogic Issue (SE)

SE1-Concern  
SE2- Ergonomic

## Billing (B)

B1 Billing issue: No Part Type  
B2 Billing issue: Wrong Part Type  
B3 Billing issue: No HAR in Epic  
B4 Billing issue: Wrong Date of Service  
B5 Billing issue: Wrong CPT Code  
B6 Billing issue: CPT Code Removed  
B7 Billing issue: No CPT Code  
B8 Billed Client instead of insurance  
B9 Billing insurance instead of client  
B10 Billing is inconsistent between LIS systems  
B11- Other Billing defect  
B12- Billing info missing

## Specimen Transportation (ST)

ST1- No manifest/transport batch sent with specimens  
ST2- Specimen not listed on manifest/transport batch  
ST3- Specimen type not noted on manifest/transport batch  
ST4- Specimen marked on manifest/transport batch but not sent  
ST5- Manual Specimen manifest sending site information incomplete

ST6- Incorrect specimen type checked off on manifest  
ST7- Out of Date Manual Manifest sent  
ST8 - Sample is misrouted  
ST9 Specimen transport delayed/late  
ST10- missed specimen pick up  
ST11-out bound slides not picked up  
ST12- Batch pick up late  
ST13 Batch drop off late  
ST14- No sign off on batch pick up  
ST15 - no sign off on batch delivery off  
ST16- Batch not received  
ST17- Batch not sent  
ST18- Batch not sealed  
ST19- Batch not scanned: scanner not working  
ST20- Batch not scanned other  
ST21- Batch incorrectly packed  
ST22- No Batch I D on Batch  
ST23- Doors looked specimen could not be picked up at sending site  
ST24- Specimen delivered to incorrect laboratory for testing  
ST25- Other Specimen Transportation Defect  
ST26- Re-routed specimen not documented

## Daily/Weekly Activities (DW)

DW1-SS not completed  
DW2- Communication not documented  
DW 3-Instrument Maintenance not completed  
DW 3-Instrument problem log not completed  
DW4- Temperature log not completed  
DW5 - PT Failure clerical error  
DW6 - PT Failure Technical error  
DW7 - PT Failure Instrument error  
DW8 - PT Failure Other  
DW9 - Other Daily/Weekly defect  
DW10- Unable to make phone contact with a department (no answer)  
DW11- Communication breakdown  
DW12- Cleaning not completed

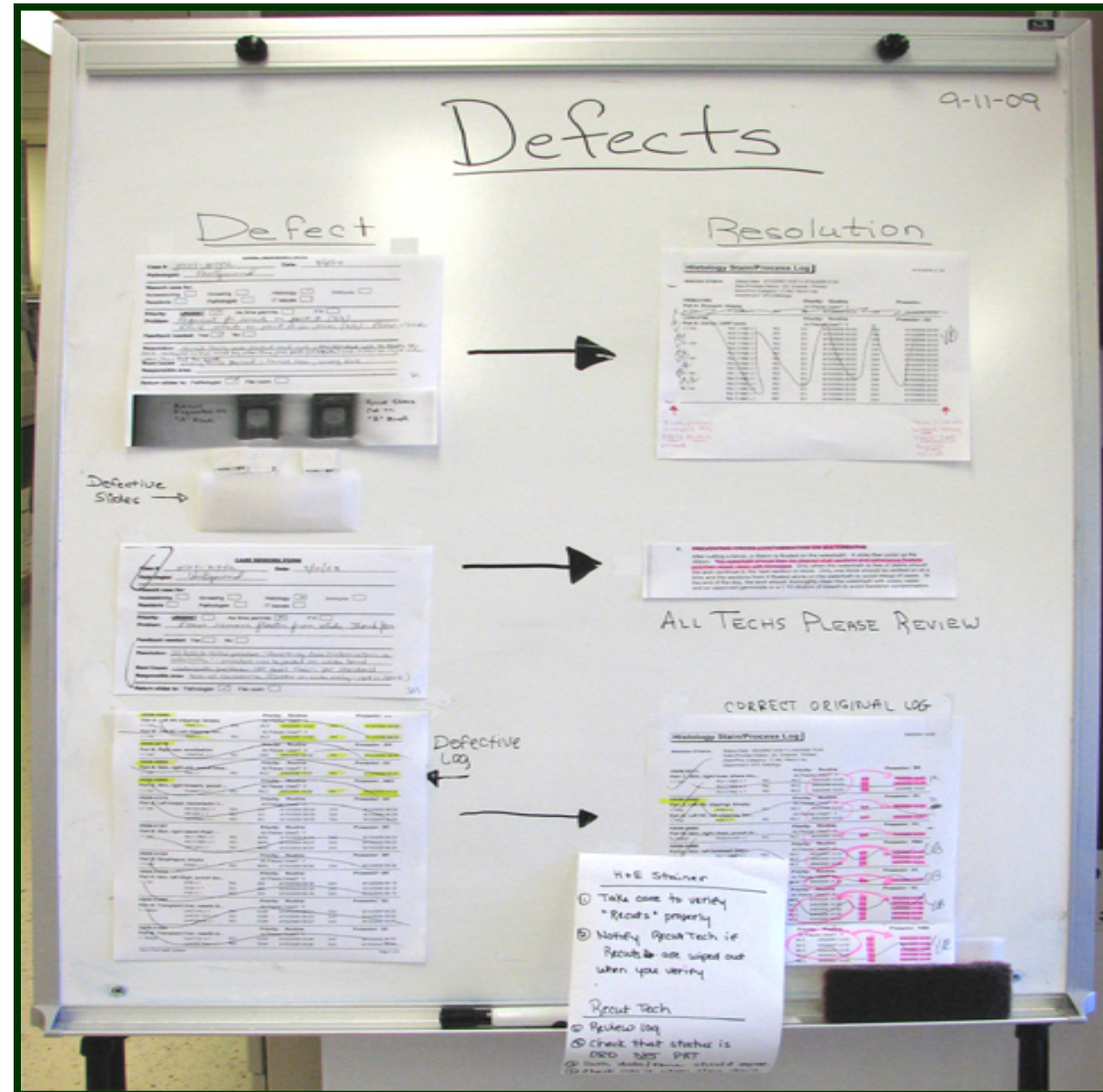
# Defect Classification Categories Expanded per Voice of Customer

| 2012, 2013, 2014, 2015       | 2016, 2017                   |
|------------------------------|------------------------------|
| Ordering Specimen <b>125</b> | Ordering Specimen <b>280</b> |
| Testing                      | Specimen Transportation      |
| Reporting                    | Testing                      |
| RL                           | Reporting                    |
| Complaint                    | Billing                      |
| Safety                       | RL                           |
|                              | Complaint                    |
|                              | Safety                       |
|                              | Daily/Weekly Activities      |



# Weekly Huddle for Resolution

1. Weekly review of defects
2. Defects & resolution posted for follow-up and lessons learned
3. Discussion of root causes, corrective/ preventive action





# Documentation in Standardized Excel

## Step 2: Enter & document details in spread sheet

|    |   |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
|----|---|-----------|--|--|-----------------------------------|------------------------------|--------------------|-------------------|---|-----------------------------------|---|----------------------------|
| 4  | 2015  |           | CONFIDENTIAL PATIENT SAFETY WORK PRODUCT AND QUALITY ASSURANCE DOCUMENT. Protected under the Patient Safety and Quality Improvement Act of 2005 and the following Mlstatutes: MCL 333.21513; 333.21515; 333.20175(8); 330.1143a; 331.531, 331.532, 331.533 and 333. 534. DO NOT DISCLOSE UNLESS AUTHORIZED BY A DESIGNEE OF THE HFHS BOARD QUALITY COMMITTEE |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 5  | January   |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 6  |   |           | Defect Information   |  |                                   | Originating Site Information |                    |                   | Deviation Description (Choose whether it is an Immediate Fix or A3 then describe the deviation in the appropriate column) |                                   | Enter Date Finalized in status cell and enter the hyperlink for the A3. |                            |
| 7  | Date of Incident(s)   | AP Case # | # of Incidents   | Defect Category  | Defect Subclass                   | Originating Facility         | Originating Clinic | Originating Floor | Document Immediate Fix  | Document A3 (Root Cause Analysis) | A3 Status:  | Final A3 scanned hyperlink |
| 8  | dd/mm/yy  |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 9  |   |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 10 |   | #VALUE!   | 245  | Specimen Defect: Non-patient ID  | S4- Quantity not sufficient (QNS) |                              |                    |                   | Specimens were credited   |                                   |   |                            |
| 11 |   | #VALUE!   | 157  | Specimen Defect: Non-patient ID  | S6- Clotted sample                |                              |                    |                   | Specimens were credited   |                                   |   |                            |
| 12 |   | #VALUE!   | 97   | Specimen Defect: Non-patient ID  | S4- Quantity not sufficient (QNS) | Originating Site             |                    |                   | Specimens were credited (coag specific UNAC-SHRT)   | Root Cause                        |   |                            |
| 13 |   | #VALUE!   | 19   | Specimen Defect: Non-patient ID  | S7- Hemolyzed sample              |                              |                    |                   | Specimens were credited   |                                   |   |                            |
| 14 | Defect Tracking #   |           |  |  |                                   |                              |                    |                   | Immediate Fix   |                                   |   |                            |
| 15 |   |           |  | 01- Patient Name/MRN mismatch<br>02- Other Identifier issues (Date of birth)<br>03- Test name<br>04- Test Code<br>05- Diagnosis<br>06- Diagnostic code/ICD code<br>07- Practitioner Name |                                   |                              |                    |                   |   |                                   |   |                            |
| 16 |   |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 17 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 18 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 19 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 20 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 21 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 22 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 23 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 24 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 25 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 26 | Documentation is done after discussing defect with owner for root cause |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 27 |   |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 28 |   |           |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 29 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 30 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 31 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 32 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 33 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 34 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |
| 35 |   | #VALUE!   |  |  |                                   |                              |                    |                   |   |                                   |   |                            |

Documentation is done after discussing defect with owner for root cause

# Defect Information in Standardized Excel

## Step 3: Review & verify details and give feed back to defect originator

|    |                     |           |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
|----|---------------------|-----------|---|---------------------------------|-----------------------------------|------------------------------|--------------------|-------------------|---|-----------------------------------|---|------------------|
| 3  |                     |           | CONFIDENTIAL PATIENT SAFETY WORK PRODUCT AND QUALITY ASSURANCE DOCUMENT. Protected under the Patient Safety and Quality Improvement Act of 2005 and the following Mltatutes: MCL 333.21513; 333.21515; 333.20175(8); 330.1143a; 331.531, 331.532, 331.533 and 333. 534. DO NOT DISCLOSE UNLESS AUTHORIZED BY A DESIGNEE OF THE HFHS BOARD QUALITY COMMITTEE |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 4  | 2015                |           |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 5  | January             |           |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 6  |                     |           | Defect Information  |                                 |                                   | Originating Site Information |                    |                   | Deviation Description (Choose whether it is an Immediate Fix or A3 then describe the deviation in the appropriate column) |                                   | Enter Date Finalized in status cell and enter the hyperlink for the A3. |                  |
| 7  | Date of Incident(s) | AP Case # | # of Incidents  | Defect Category                 | Defect Subclass                   | Originating Facility         | Originating Clinic | Originating Floor | Document Immediate Fix  | Document A3 (Root Cause Analysis) | A3 Status:  | Final A3 scanned |
| 8  | dd/mm/yy            |           |   |                                 |                                   |                              |                    |                   |   |                                   | Pending   | Final            |
| 9  |                     |           |   |                                 |                                   |                              |                    |                   |   |                                   |   | hyperlink        |
| 10 |                     | #VALUE!   | 245   | Specimen Defect: Non-patient ID | S4- Quantity not sufficient (QNS) |                              |                    |                   | Specimens were credited   |                                   |   |                  |
| 11 |                     | #VALUE!   | 157   | Specimen Defect: Non-patient ID | S6- Clotted sample                |                              |                    |                   | Specimens were credited   |                                   |   |                  |
| 12 |                     | #VALUE!   | 97  | Specimen Defect: Non-patient ID | S4- Quantity not sufficient (QNS) | Originating Site             |                    |                   | Specimens were credited (coag specific UNAC-SHRT)   | Root Cause                        | PDCA  |                  |
| 13 |                     | #VALUE!   | 19  | Specimen Defect: Non-patient ID | S7- Hemolyzed sample              |                              |                    |                   | Specimens were credited   |                                   |   |                  |
| 14 | Defect Info         |           |   |                                 |                                   |                              |                    |                   | Immediate Fix   |                                   |   |                  |
| 15 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 16 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 17 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 18 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 19 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 20 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 21 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 22 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 23 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 24 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 25 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 26 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 27 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 28 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 29 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 30 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 31 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 32 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 33 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 34 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |
| 35 |                     | #VALUE!   |   |                                 |                                   |                              |                    |                   |   |                                   |   |                  |

Defect Classification

Feedback to defect originator provided by defect owner

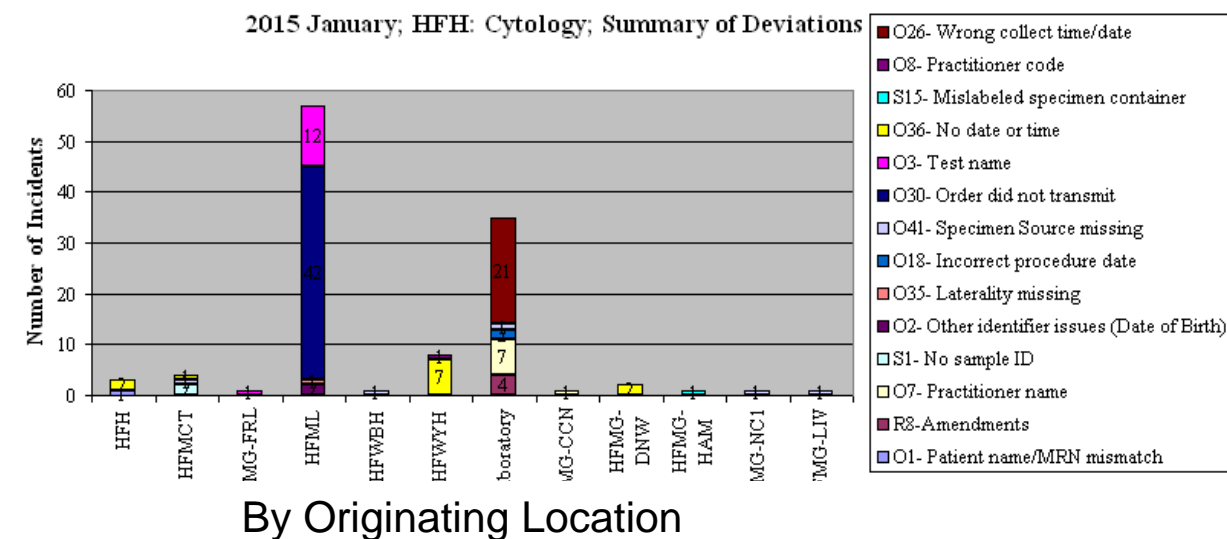
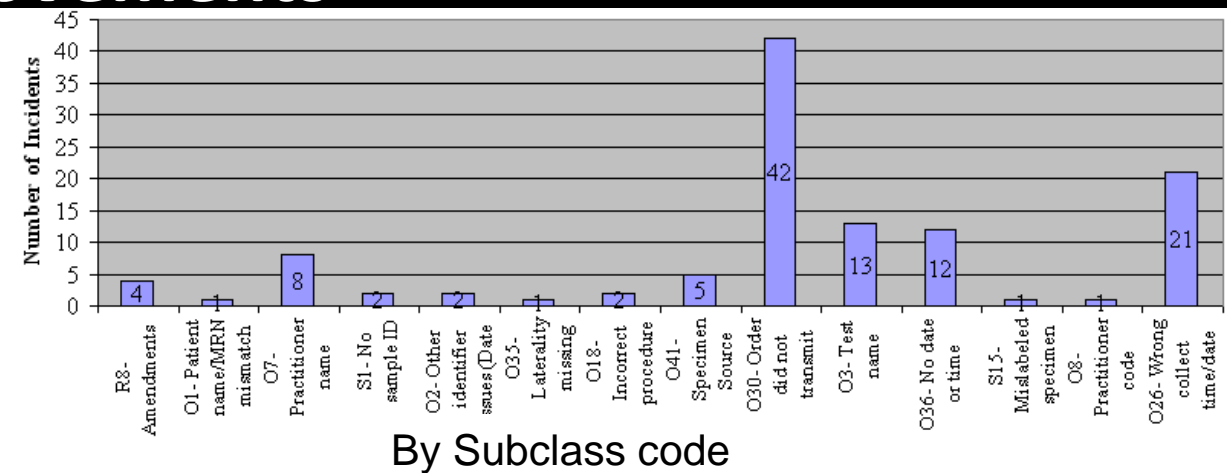
# Defect Summary in Standardized Excel Sheet

## Step 4: Summarize monthly to monitor trends and prioritize for PDCA improvements

### Summary

- Prioritized by managers
- posted at work place for feedback
- Encouraged for PDCA improvement

| OCC-PALM-8.1-pro-fm3 DEVIATION MANAGEMENT SITE SPECIFIC TRACKING LOG-HIGH VOLUME AREAS |                              |   |                    |                             |                              |                      |                    |   |                             |
|--|------------------------------|---|--------------------|-----------------------------|------------------------------|----------------------|--------------------|---|-----------------------------|
| Facility:  | HFH                          | CONFIDENTIAL PATIENT SAFETY WORK PRODUCT AND QUALITY ASSURANCE DOCUMENT. Protected under the Patient Safety and Quality Improvement Act of 2005 and the following Michigan: MCL 333.2613; 333.2615; 333.2075(9); 330.1143; 331.531; 331.532; 331.533 and 333.534. DO NOT DISCLOSE UNLESS AUTHORIZED BY A DESIGNEE OF THE HFHS BOARD QUALITY COMMITTEE |                    |                             |                              |                      |                    |   |                             |
| Dept:  | Cytology                     |   |                    |                             |                              |                      |                    |   |                             |
| Year:  | 2015                         |   |                    |                             |                              |                      |                    |   |                             |
| Month:   | January                      |   |                    |                             |                              |                      |                    |   |                             |
|  |                              |   | Defect Information |                             | Originating Site Information |                      |                    | Deviation Description (Choose then describe the defect) |                             |
| Track #  | Date of Incident(s) dd/mm/yy | AP Case #   | # of Incidents     | Defect Category             | Defect Subclass              | Originating Facility | Originating Clinic | Originating Floor                                       | Document Immediate Findings |
| CYP1-17  | 1/16/15                      | #VALUE!   | 1                  | Order Defect Non-patient ID | O36- No date or time         | HFH                  |                    |   | No date and time            |
| CYP1-18  | 1/14/15                      | #VALUE!   | 7                  | Order Defect Non-patient ID | O36- No date or time         | HFH                  |                    |   | No date and time            |
| CYP1-19  | 1/20/15                      | #VALUE!   | 1                  | Order Defect Non-patient ID | O8- Practitioner code        | HFH                  |                    |   | No dr code provided         |
| CYP1-20  | 1/20/15                      | #VALUE!   | 1                  | Order Defect Non-patient ID | O41- Specimen Source missing | HFH                  |                    |   | No part type                |



# Standardized Summary Review

| 1st Quarter Summary |          |          |            |               |                           |                               |                  |                              |                                  |                 |                |                              |                         |               |            |        |
|---------------------|----------|----------|------------|---------------|---------------------------|-------------------------------|------------------|------------------------------|----------------------------------|-----------------|----------------|------------------------------|-------------------------|---------------|------------|--------|
| Year                | Month    | Facility | Department | Order Defects | Order Defects: Patient ID | Order Defects: Non-patient ID | Specimen Defects | Specimen Defects: Patient ID | Specimen Defects: Non-patient ID | Testing Defects | Report Defects | Report Defects: Not reported | Report Defects: Delayed | Radical Logic | Complaints | Safety |
| 2016                | January  | HFH      | Surge Path | 57            | 1                         | 56                            | 4                | 0                            | 4                                | 267             | 53             | 0                            | 53                      | 0             | 0          | 0      |
| 2016                | February | HFH      | Surge Path | 63            | 8                         | 55                            | 2                | 0                            | 2                                | 780             | 18             | 0                            | 18                      | 0             | 1          | 0      |
| 2016                | March    | HFH      | Surge Path | 43            | 3                         | 40                            | 4                | 1                            | 3                                | 799             | 43             | 0                            | 43                      | 1             | 2          | 2      |
| Quarter Totals      |          |          |            | 163           | 12                        | 151                           | 10               | 1                            | 9                                | 1846            | 114            | 0                            | 114                     | 1             | 3          | 2      |

Summary review documented & presented by managers at Quality Management System mtg.

| 1st Quarter Summary Review  |     |     |      |  |
|---|-----|-----|------|--|
| <p><b>Measure:</b> Measure: The top 3 defects are T87, R26 and O13. T87 is blocks don't ping. This is accounts due to a report defect account specimen class accounts for</p> <p><b>Observation(Trends)</b> Amended reports are trending downwards. There were 409 amendments in the 4th quarter of 2015 and we are down to 94 in the 1st quarter of 2016. Another upward trend is noticed in T87. This is a defect new defect arising from the newly activated the integrity of the barcodes uncover the root cause. O13 is reporting this quarter. 1361 defects were collected in the 4th quarter and 2131 were collected in the first quarter of 2016. T31 other continues to be high. AHS- 4/18/16</p> <p><b>RootCause(5 Whys):</b> The likely due to the Copath-Epic interface more granular with our data collected causes. AHS- 4/18/16</p> <p><b>Action Plan:</b> 1). A team has improvement. There are multiple Continue to work with PI to detect process improvement is underway that includes visual cues for O13. Target pilot start date is May 1. 4). Update expanded defect subclass list to get granular defects in the T31 other category. AHS- 4/18/16</p> |     |     |      |  |
| <p>(changed from Laterality Switched)</p> <p>O13- Incorrect specimen class type</p> <p>O16- Requisition not scanned</p> <p>O21- Other</p> <p>O41- Specimen Source</p> <p>O9- Wrong part type</p> <p>R26- Amendment do to report defect</p> <p>T1- Quality Control Failure (QC)</p> <p>T15- Specimen not fixed properly</p> <p>T31- Other</p> <p>T58- Folds in section</p> <p>T87- Block/slides does not ping</p> <p>T89-IHC stain delayed</p> <p>Grand Total</p>  |     |     |      |  |
| 1   | 4   | 5   | 10   |  |
| 42  | 10  |     | 52   |  |
| 5   | 1   | 6   | 12   |  |
| 1   | 4   | 5   | 10   |  |
| 3   | 13  | 4   | 17   |  |
|   | 6   | 3   | 12   |  |
| 43  |     | 51  | 94   |  |
| 1   | 4   | 5   | 10   |  |
| 13  |     |     | 13   |  |
| 1   | 13  | 17  | 31   |  |
| 1   | 8   | 1   | 10   |  |
| 216   | 701 | 738 | 1655 |  |
|   | 1   | 20  | 21   |  |
| 8   | 24  | 3   | 35   |  |
| 335   | 789 | 858 | 1982 |  |

Measure: Top 3 defects

Trends observed?

Root causes?

The Action Plan?

# Standardized Process for Defect Resolution

## Step 5: Defect Resolution with PDCA-A3 form

Date:

**PROJECT NAME:**

**Problem Background**

- Describe the problem
- Narrow down to specifics

**TEAM NAME:**

**Target Condition**

- Desired outcome

**Hypothesis**

- Your proposed solution

**Corrective Action Plan**

- Develop & agree on new plan of action

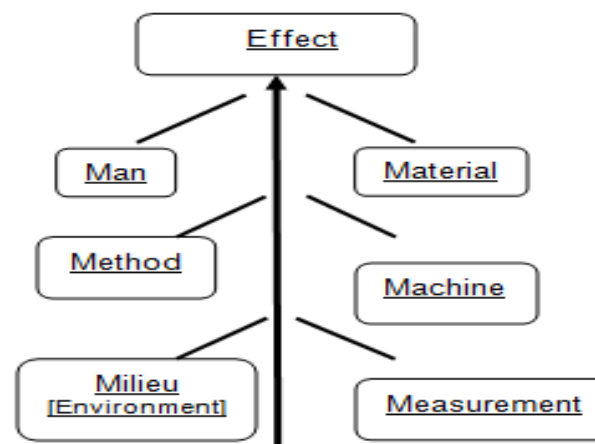
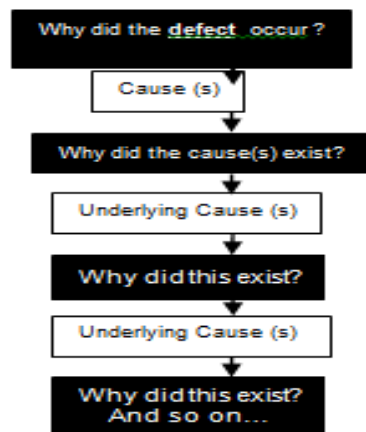
**Curr**

- Data- quantify & prioritize

- Assign responsibility as to who, when & how roll out will be done

**Defects prioritized for problem solving by managers**

**Problem Analysis:** Identify the root cause Ask "why" 5 times OR 5M- Fish Bone diagram [Man, Method, Material, Machine, Milieu [Environment]



**Results**

- Collect post data to confirm effectiveness of new plan

**Metrics for Effectiveness Check:**

- Measure for monitoring to know if it's working as designed

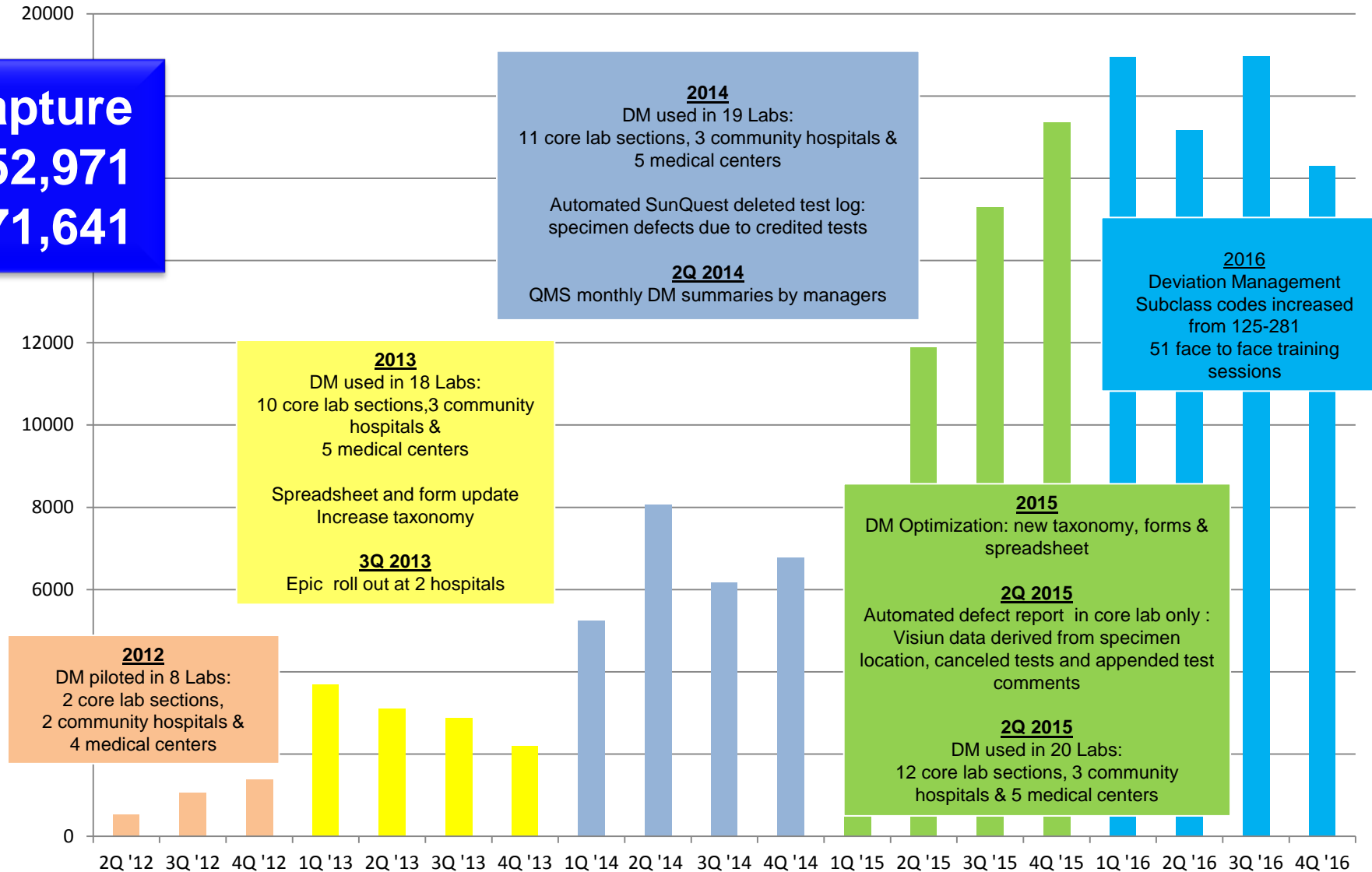
**Standardization**

- Standardize the new process: Document Control [Edit policy/Procedure, Standard Work "Job Aide"]
- Healthstream modules with competency questions
- Present at "Share the Gain" for lessons learned



# Progression of Deviations Captured Quarterly throughout the Product Line 2012-2016

**Total Capture**  
**2015 = 52,971**  
**2016 = 71,641**



# Defect Classification Distribution By Testing Phase

|      | Pre- Analytic | Analytic | Post- Analytic |
|------|---------------|----------|----------------|
| 2013 | 84%           | 8%       | 8%             |
| 2014 | 93%           | 3.4%     | 3.6%           |
| 2015 | 91%           | 5%       | 4%             |
| 2016 | 74.8%         | 23.6%    | 1.6%           |

**Result of 51 face-to-face training sessions of DM system in 2016**

# The Outcomes

# Defective Epic Lab Orders in Clinical Labs

## 1. Customized form to capture defects & resolution in real time

**Pathology & Laboratory Medicine**  
OCC-PALM-S-1-pre-6b2: DEVIATION MANAGEMENT CORE  
LABORATORY

This form is intended to capture Epic related ordering defects so that the laboratory can provide effective feedback to our specimen suppliers. Your participation is critical to make this a success !!!

**I. Laboratory Staff**

Place label here

1. Ordering Physician \_\_\_\_\_  
2. Your Tech code \_\_\_\_\_  
3. Your workstation (check Box)  
a. Coagulation a. Hematology  
b. Urinalysis b. Chemistry  
c. Prolab c. Other \_\_\_\_\_  
4. Shift: ☐ AM ☐ PM ☐ MN

What was the immediate resolution?  
☐ O25- Credited  
☐ O28- T/D changed in SQ  
☐ O27 (stat)- Ordered in SQ  
☐ O27 (routine)- R&R  
☐ O28 Tip-sheet sent  
☐ O29 Combined in ORM  
☐ Other \_\_\_\_\_

What is the defect? choose one  
☐ O25 Duplicate Order  
☐ O28 Wrong Collect Time/Date  
☐ O27 Cancelled by Epic/HIS  
☐ O28 Wants us to add-on\*  
☐ O29 Add-on workaround\*\*  
☐ Other \_\_\_\_\_

**II. Supervisor or Manager**

☐ OK immediate resolution  
☐ Added to Deviation Excel  
☐ Does Root-cause qualify for A3/deep dive (Y/N)

☐ Sent to : ☐ GG (IPD) ☐ JF (ED)  
☐ Other \_\_\_\_\_  
☐ Feedback to lab staff  
☐ Closed-out

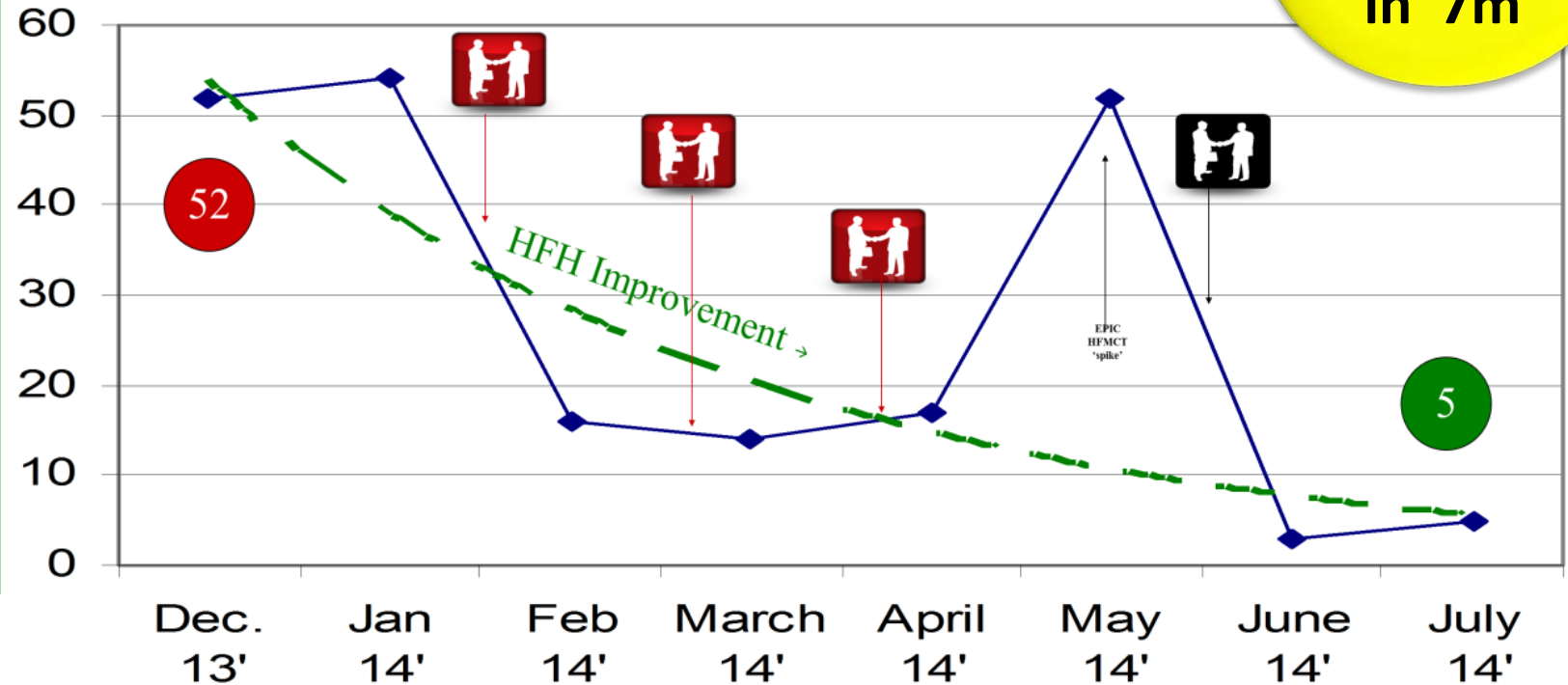
Comments \_\_\_\_\_

Tracker # \_\_\_\_\_

\* Dr. or Nurse Calls asking us to add the test on for them  
\*\* Dr. or Nurse sends multiple labels / multiple ACC #'s

## Reduction in Defective Epic Lab Orders at HFH Core/Stat Lab

90%  
Reduced  
in 7m



## 2. Multiple Customer-Supplier meetings with clinic leadership with data

Duplicate Orders

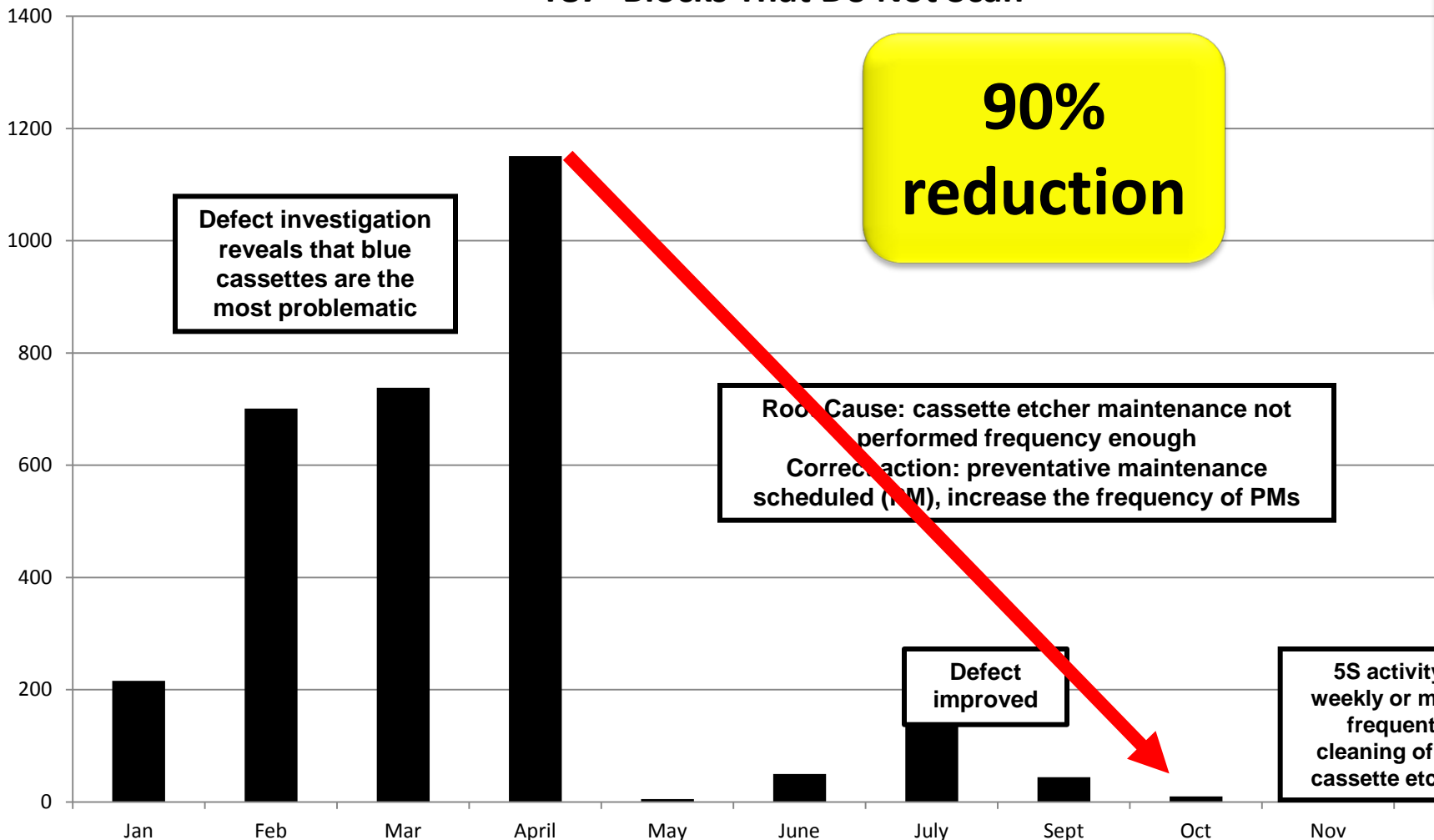
Wrong Collect Date & Time

Canceled by Epic

Test add-on defects

# Defective Barcodes on Cassette Blocks in Histology

T87- Blocks That Do Not Scan



- Barcode is etched on tissue cassettes
- Cassette scanned to print labels
- Scan fails to print due to defective barcode

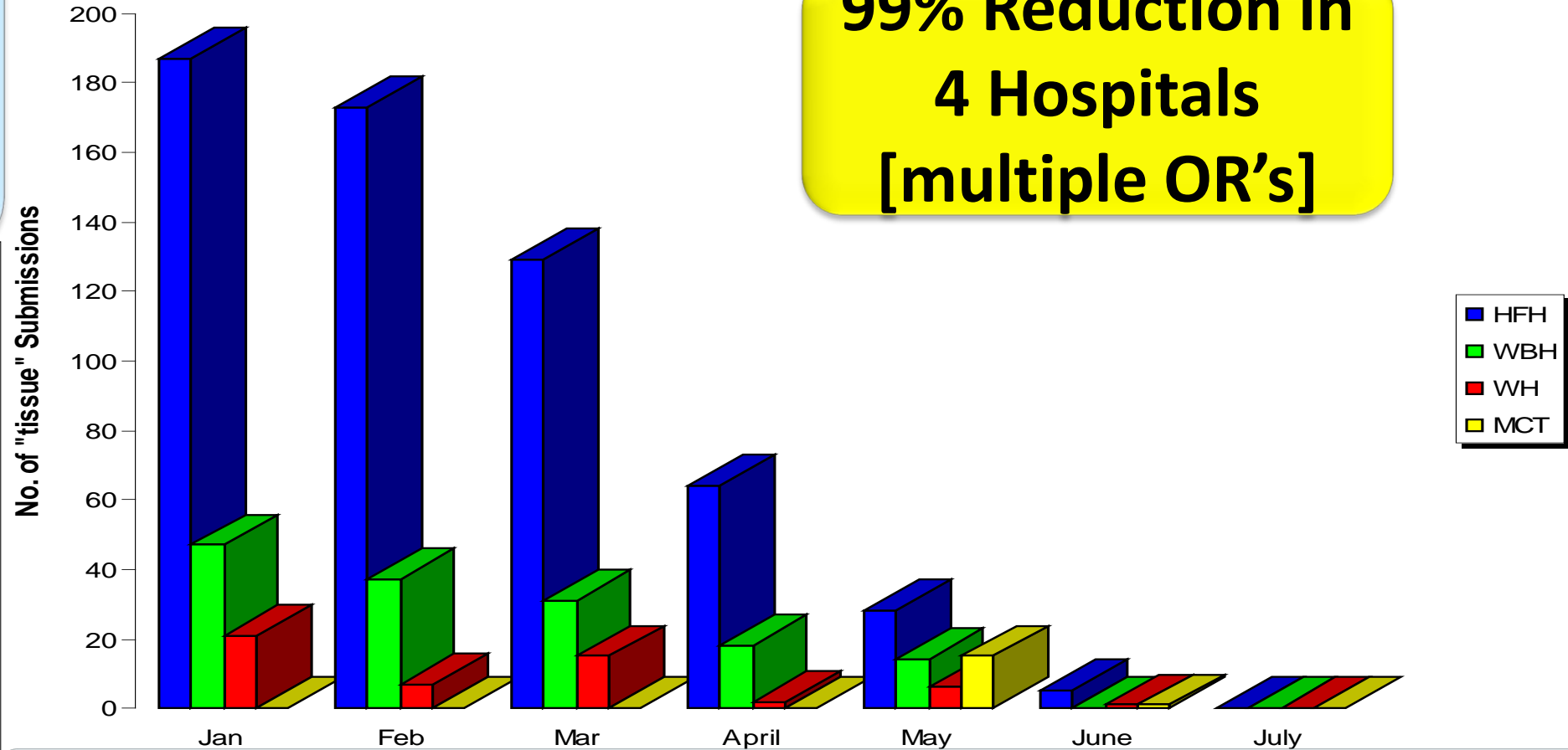
- Standard Form
- Multiple customer/Supplier with vendor & PI division
- RC- Weekly cleaning needed
- Maintain with 5S activity

# Epic Orders for Surgical Specimens

- Epic order submitted with wrong tissue designation
- Unable to process order in the lab

Monthly Deviations

**99% Reduction in  
4 Hospitals  
[multiple OR's]**



**Laboratory Staff**

This form is intended to capture defects so that the laboratory can provide effective feedback to our specimen suppliers. Your participation is critical to make this a success !!!

Place label here  
Or MRN

What was the Immediate Resolution?

☐ Phone call  
☐ Sent back to OR for rehab  
☐ RL  
☐ Other \_\_\_\_\_

Check off when complete  
☐ Enter into Deviation Excel

Comments:

OR # \_\_\_\_\_  
Date \_\_\_\_\_  
☐ M-F ☐ After-hours  
☐ Weekends

What is the defect?

☐ O31- No sign off by RN  
☐ O32- No ADT label  
☐ O33- Surgery time  
☐ O34- Spec out of sequence  
☐ O35- Laterality Missing  
☐ O9 - Wrong Part Type, "tissue"  
☐ O38-Phone inquiry of correct Part type  
☐ Laterality Missing  
☐ Other \_\_\_\_\_

Tracker # \_\_\_\_\_

Closure

Feedback to:  
☐ OR/RN Educator \_\_\_\_\_  
☐ Other \_\_\_\_\_

☐ This has been closed out

- Customized form with immediate resolution
- Multiple customer-supplier meetings with OR leadership & staff



# Sustaining Mechanisms

# Lean Training By HFPS Quality Staff

## Bronze

### Front Line Staff

**[New and Current] - 1.5hrs**

Philosophy & Culture, 5S

**Deviation Management**

Document Mgmt.,

Improvement [PDCA] and

Daily Mgmt.

### Pathology Leaders - 2.0hrs

Philosophy & Culture, 5S,

**Deviation Management**, Document  
Management Improvement [PDCA] and  
Daily Management  
Structure & Responsibilities

## Gold

### Pathology Leaders Retreat - 1 Day

HFPS Culture,

Policy Deployment Strategic Planning,  
Leadership Behaviors that Drive Functional  
Teams & Dynamics

**Deviation Management**

Problem-solving [PDCA]

Daily Management

and

Lean Roles

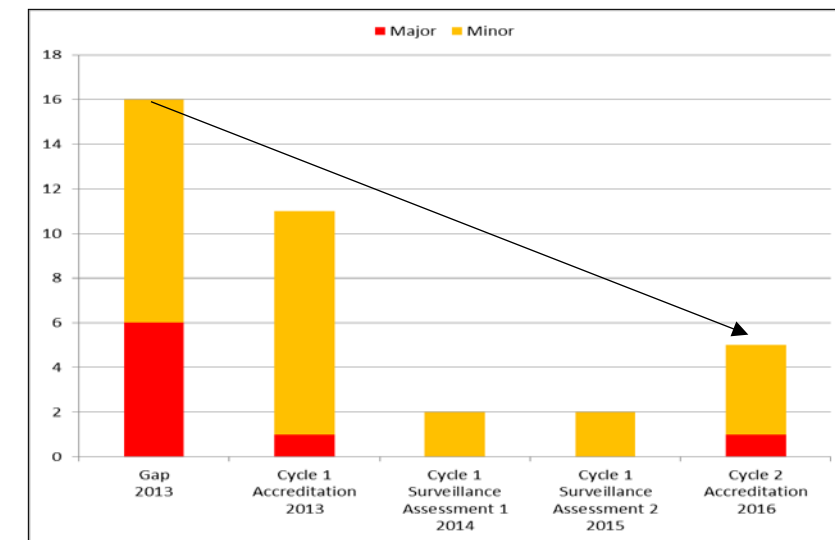
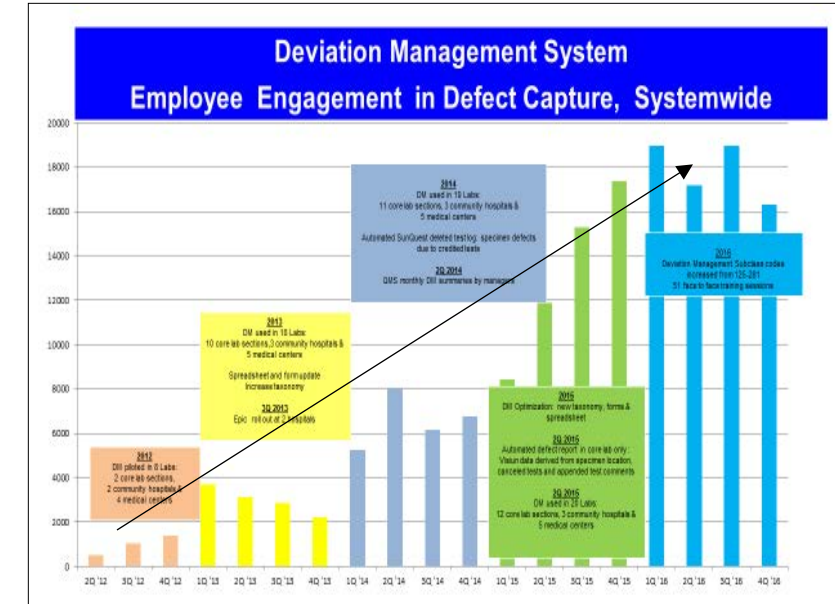
and

Responsibilities

# Benefits of Training & Refresher

## > 51 face to face DM training sessions

- Empowerment of blameless culture for defect capture
- Ownership of defects
- Participation in huddles for root cause discussions
- Understanding compliance with Regulatory Standard [CAP & ISO15189]
- Engagement in process improvement [PDCA-A3]
- Importance of sharing lessons learned for front line staff



# Sustaining Tools

Daily  
Ownership  
of Defects

Weekly Team  
Leader  
Meeting

Weekly  
Huddle  
Board

Monthly  
Visual  
Communication

Monthly  
Share the  
Gain A3s

Monthly  
KPI report out



HFPS APTL Meeting Date: \_\_\_\_\_

Standing Agenda Items:

1. Daily Board Issues
2. Deviations
3. 6S System Issues
4. STG Agenda
5. Other Issue

S:IPALM/Leaders/19. AP Lean Team Leader Meeting/Meeting Minutes...

Accession: Joyce/Nicole

QC PERSON

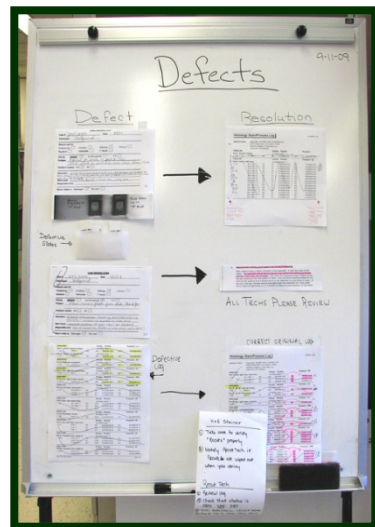
ACCESSIONER ISSUES

P.A. ISSUES

QC PERSON

ACCESSIONER ISSUES

P.A. ISSUES



| TASK              | OWNER     | CURRENT STATUS | NEXT Due Date | TEAM LEADER | TEAM MEMBERS |
|-------------------|-----------|----------------|---------------|-------------|--------------|
| S.M. RECALCULATED | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |
| RECALCULATED      | LAUREN N. | Complete       | 03/10         | None        | None         |



QC person by  
name/work  
area to  
resolve  
defects in the  
day

Team Leader  
mtg. agenda  
for follow-up  
& defect  
resolution for  
work area

Team  
discussion  
for RC,  
Corrective/  
Preventive  
Action

Visual  
communicati  
on board for  
task owners  
responsibility  
& due dates

Completed  
PDCA/A3  
Improvement  
s posted for  
empowerment  
& sharing

Tracked at KPI  
Board for  
Managers  
performance  
of DM system  
compliance

# How to Drive compliance from the level of the Work?

Monthly KPI report out by managers for compliance by individual employees

- What can be done to reach 100% compliance?

| Deviation Management | Lab Manager/<br>Team Leaders | HFH Surgical Pathology-<br>Histology | Employee contribution to<br>Deviation Management<br>[total participated]/total employees | Plan   | 100%  | 100%  | 100%  | 100%  | 100%  | 100%  | 100%  | 100% | 100% |
|----------------------|------------------------------|--------------------------------------|--|--------|-------|-------|-------|-------|-------|-------|-------|------|------|
|                      |                              |                                      |  | Actual | 25/32 | 28/32 | 32/32 | 32/32 | 32/32 | 32/32 | 32/32 |      |      |

| Employee        | Shift        | January | February | March | April | May | June |
|-----------------|--------------|---------|----------|-------|-------|-----|------|
| Lisa M          | 12:00a-8:30a | 7       | 5        | 4     | 6     |     |      |
| Malinda V       | 2:30a-11:00a | 1       | 3        | 4     | 4     |     |      |
| Jessica R- TIC  | 4:00a-12:30p | 2       | 7        | 5     | 7     |     |      |
| Deborah D       | 4:00a-12:30p | 2       | 3        | 3     | 3     |     |      |
| Amy K           | 5:30a-2:00p  | 0       | 0        | 4     | 9     |     |      |
| Janet M         | 5:30a-2:00p  | 0       | 0        | 2     | 2     |     |      |
| Angelica M      | 5:30a-2:00p  | 0       | 0        | 3     | 5     |     |      |
| Suzanna W       | 5:30a-2:00p  | 0       | 0        | 2     | 7     |     |      |
| Asil S          | 6:00a-2:30p  | 4       | 2        | 3     | 3     |     |      |
| Paula M         | 6:30a-3:00p  | 10      | 6        | 4     | 4     |     |      |
| Lei P           | 7:30a-4:00p  | LOA     | LOA      | LOA   | LOA   | LOA | LOA  |
| LaTurra H       | 8:00a-4:30p  | 1       | 2        | 4     | 5     |     |      |
| Clariece O      | 9:00a-5:30p  | 5       | 3        | 3     | 4     |     |      |
| Nataliya D- TIC | 11:00a-7:30p | 3       | 7        | 6     | 7     |     |      |
| Shirley S       | 11:00a-7:30p | 0       | 0        | 3     | 9     |     |      |
| Sue Lynn J      | 12:30p-9:00p | 2       | 3        | 5     | 2     |     |      |
| Kelly A- TIC    | 4:00p-12:30a | 2       | 2        | 3     | 1     |     |      |
| Stephanie D     | 4:00p-12:30a | 1       | 3        | 5     | 5     |     |      |
| Abdulaziz M     | 4:00p-12:30a | 12      | 1        | 4     | 3     |     |      |

Individual employee compliance posted and tracked monthly



# Take Home Lessons

1. **DM is a management system that requires leadership to empower and encourage blameless identification and resolution of defects with frontline staff**
2. **Empowers employees to solve their own problems with data and promote thinking of root causes for corrective/preventive action [PDCA-A3]**
3. **DM structure consistently provides continuous improvement and reduces risk to customers**



<https://academic.oup.com/ajcp/article/doi/10.1093/ajcp/aqx084/4110210/Deviation-ManagementKey-Management-Subsystem?guestAccessKey=9bec2c6f-70e9-4f2f-a306-6c571f4b9495>

Tell me and I forget.  
Teach me and I remember.  
Involve me and I learn.

- *Benjamin Franklin*