Using ISO-based Nonconformance Management System as Fuel to Power Continuous Improvement in a Lean Lab
The presenter has no conflicts of interest to disclose
Nonconformance
process => human or machine => product or service
-Deviation from standard
-Defective work product

Anything having to do with a process that can be described as-
• defective, in non-ideal or perfect form,
• not right the first time, or
• not following policy or procedure (root cause)

ISO 2015
Do you want to know what your customer experiences?

Would this make you better?

ISO 15189

• implementation of a robust non-conformance management system
• defined procedures to identify and control deviations in the work
• document actions taken to eliminate non-conformities
ISO 15189 Clauses 4.9.1 and 4.9.2

"4.9.1
Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinician....

These shall ensure that
• a) personnel responsible for problem resolution are designated,
• b) the actions to be taken are defined,
• c) the medical significance of the nonconforming examinations is considered and where appropriate, the requesting clinician informed,
• d) examinations are halted and reports withheld as necessary,
• e) corrective action is taken immediately,
• f) the results of nonconforming examinations already released are recalled or appropriately identified, if necessary,
• g) the responsibility for authorization of the resumption of examinations is defined, and
• h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action. ......

4.9.2
• If... nonconforming examinations could recur,.... procedures to identify, document and eliminate the root cause(s) shall be promptly implemented

ISO 15189:2012
How to Detect Problems (Nonconformances)?

(according to ISO 15189)

“Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including:

• Clinician complaints
• Quality control indications
• Instrument calibrations
• Checking of consumable materials
• Staff comments
• Reporting and certificate checking
• Laboratory management reviews
• Internal and external audits”
How effective would those approaches be in surveying the total variation in your processes and the impact on your customers?
What kind of manager are you?

How comfortable are you with not knowing there are problems afoot?

Let’s evaluate your tolerance
Imagine the following scenario

You are captain of a large vessel carrying 300 sailors, explosives & flammable cargo
Please ALL stand now.

The day starts well, as most days do but............

What follows are your views from the bridge as you navigate

Please **SIT DOWN** When You Feel Uncomfortable with the situational Risk
Rollercoaster ride of your life
Manager Profile

Risk Averse, Neutral or Risk Loving?

![Graph showing level of discomfort vs. amount of risk.](image)
Oh boy, oh no!

Risk Averse

Amount of Risk

Level Discomfort
Your mentor
Merrily we go along, go along, go along...

![Diagram with axes labeled Level Discomfort and Amount of Risk, with a line indicating Risk Neutral.]
Your mentors
Bring it on!
“I love the smell of napalm in the morning”
Your mentor
Your communication style

DO YOU FEEL LUCKY.... PUNK?

WELL.... DO YA?
So, what’s out there?
Lesson #1

“No problem is a problem”

Mike Rother on Toyota philosophy
Filling the Diagnostic Funnel from the Visual Workplace

- **Whiteboards**
  - Daily Visual Capture of Select Non-Conformances by Workstations

- **Deviation Management**
  - Daily Tracking of All Non-Conformances
  - With Documented Immediate Resolutions or Root Cause Analysis with Corrective/Preventive Actions

- **Daily Management Boards**
  - Tracking & Trending of Select Performance Metrics by Workstations

**PDCA-Based Continuous Improvements**
Why Nonconformance Management System?

• Variation is a fact of life, a part of all human designed processes

• A system provides structure and expectation for humans to consistently:
  • Identify variation
  • Understand variation
  • Control variation
  • Reduce variation
  • Produce better quality by identifying and improving defective processes
  • Produce better product, service and outcomes
High Functioning Surveillance System

• Breadth
• Depth
• Detection consistency
• Ground view
• Customer focus
• Structured tools and process for consistent and successful use
Nonconformance Management

The System

- System wide quality technical team creation, iterative product
- Excel spreadsheet with logic a pivot tables, located on shared drive
- Manager owned, 720 employee fueled across Lab Product Line
- System wide standardization of:
  - ISO compliant process for defect identification, documentation, tracking and trending
  - Classification of defects (taxonomy of 125 types)
  - Documentation of root causes, corrective and preventive actions
  - Elimination by PDCA based resolution, documentation attached to spreadsheet
- Key aspect of managers’ standard work, weekly, monthly
- System wide roll up and analysis by Quality Specialist
- Priority defects reviewed by System Lab Quality Management Committee
  - Safety related
  - Most frequent
  - Focused source, readily addressed
  - System-wide solutions
Nonconformance Management Process

Nonconformance management cycle begins with step 1 and flows through step 6 with completion of a process improvement.
### Deviation Management General Form

**Pathology & Laboratory Medicine**

**OCC-PALM-8.1-pro-frm1: Deviation Management Form**

<table>
<thead>
<tr>
<th>1. Complete Steps A-H</th>
<th>G) Defect Originating Site (complete a &amp; b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) Accession#/ Case #:</td>
<td>a) □ HFH □ HFWH □ HFWBH □ HFMCCT □ HFML</td>
</tr>
<tr>
<td>B) MRN: ________________________</td>
<td>□ Inpatient Dept. (Room) □ Outpatient Dept. (Site) □ Other</td>
</tr>
<tr>
<td>C) Name: ________________________</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>Name                  Date /Time</td>
</tr>
<tr>
<td>Place Label Here</td>
<td>(STEPS A-C)</td>
</tr>
<tr>
<td>D) Physician's Name ________________________</td>
<td></td>
</tr>
<tr>
<td>E) Shift: □ Days □ Evening □ Night</td>
<td></td>
</tr>
<tr>
<td>F) Deviation Form Initiated by:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Defect Classification</th>
<th>a) □ Order Defect □ Specimen Defect □ Testing Defect □ Report Defect</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Customer Complaint</td>
<td>□ RL file # □ Safety/Environment □ Other</td>
</tr>
</tbody>
</table>

| 3. DEFECT Sub Classification | (Refer to subclass list on reverse side): ____________ |

| 4. Significant Occurrence | □ No □ Yes → Name of supervisor notified ____________ |

| 5. Describe Occurrence | filled out by anyone who detects a defect |

| 6. What was the Resolution? | □ Immediate Resolution □ Root Cause with A3 Form |

**Team Leader (Lead, Supervisor, Manager) Complete Below**

<table>
<thead>
<tr>
<th>□ Feedback to Deviation Form Initiator</th>
<th>□ Feedback to Pathologist (if applicable)</th>
<th>□ AP Return slide to: □ Pathologist □ File Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership Close-out (Initials): _____ Date: _____</td>
<td>Deviation Excell Track: ____________</td>
<td></td>
</tr>
</tbody>
</table>
Nonconformance Management Form Customization for VOC

The custom form on the right was created with a defined standard pathway and pre-selected boxes so the individual filling out the form could do so in a more timely manner.
Further Customization

- AP Pathologist
- AP Frozen Section
- OPD Clinic Labs
### Deviation Management Spreadsheet

<table>
<thead>
<tr>
<th>Date</th>
<th>AE Case #</th>
<th># of Incidents</th>
<th>Defect Category</th>
<th>Originating Site Information</th>
<th>Deviation Description (Choose whether it is an Immediate Fix or A3, then describe the deviation in the appropriate column)</th>
<th>A3 Status</th>
<th>Final A3 trained (hyperlink)</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>345</td>
<td>2</td>
<td>Specimen Defect: Non-patient (D)</td>
<td>Originating Facility, Originating Clinic, Originating Floor</td>
<td>Specimen were credited</td>
<td></td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>157</td>
<td>2</td>
<td>Specimen Defect: Non-patient (D)</td>
<td>Originating Facility, Originating Clinic, Originating Floor</td>
<td>Specimen were credited</td>
<td></td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>97</td>
<td>2</td>
<td>Specimen Defect: Non-patient (D)</td>
<td>Originating Facility, Originating Clinic, Originating Floor</td>
<td>Specimen were credited (due to specific TNAO-SDD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>19</td>
<td>2</td>
<td>Specimen Defect: Non-patient (D)</td>
<td>Originating Facility, Originating Clinic, Originating Floor</td>
<td>Specimen were credited</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Cytology - Nonconformance Management Spreadsheet and Graphs

#### Defect Information

<table>
<thead>
<tr>
<th>Defect Category</th>
<th>Defect Subclass</th>
<th>Originating Facility</th>
<th>Originating Class</th>
<th>Originating Phrase</th>
<th>Deviation Description (Column 6 describes the deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3O: Order defect present</td>
<td>HFML</td>
<td>O2: Order defect present</td>
<td>Interface error</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3O: Order defect present</td>
<td>HFML</td>
<td>O2: Order defect present</td>
<td>No registration</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3O: Order defect present</td>
<td>HFML</td>
<td>O2: Order defect present</td>
<td>No printed orders</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O1: Patient name/ID mismatch</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>Name does not match</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O1: Patient name/ID mismatch</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No date and time</td>
<td></td>
</tr>
<tr>
<td>Specimen Defect Patient ID</td>
<td>S1: No sample ID</td>
<td>HFMC7</td>
<td>O3: Test name</td>
<td>Unlabeled container</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3: Test name</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No part type</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3: Test name</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No date and time</td>
<td></td>
</tr>
<tr>
<td>Specimen Defect Patient ID</td>
<td>S1: No sample ID</td>
<td>HFMC7</td>
<td>O3: Test name</td>
<td>No printed orders</td>
<td></td>
</tr>
<tr>
<td>Specimen Defect Patient ID</td>
<td>S1: No sample ID</td>
<td>HFMC7</td>
<td>O3: Test name</td>
<td>No printed orders</td>
<td></td>
</tr>
<tr>
<td>Specimen Defect Patient ID</td>
<td>S1: No sample ID</td>
<td>HFMC7</td>
<td>O3: Test name</td>
<td>No part type</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3: Test name</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No date and time</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3: Test name</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No date and time</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3: Test name</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No date and time</td>
<td></td>
</tr>
<tr>
<td>Order Defect Not Present ID</td>
<td>O3: Test name</td>
<td>HFH</td>
<td>O3: Test name</td>
<td>No date and time</td>
<td></td>
</tr>
</tbody>
</table>

#### Graphs

**2015 January, HFH: Cytology; Summary of Deviations**

- **O06: Wrong collect time/date**
- **O08: Practitioner code**
- **S15: Mislabeled specimen container**
- **O06: No date or time**
- **O03: Test name**
- **O30: Order did not transact**
- **O41: Specimen Source missing**
- **O18: Incorrect procedure date**
- **O33: Laterality missing**
- **O02: Other identifier issues (Date of Birth)**
- **O01: No sample ID**
- **O07: Practitioner name**
- **R3: Amendments**
- **O1: Patient name/ID mismatch**
### Taxonomy of Defect Types

#### Subclass Category Progression

<table>
<thead>
<tr>
<th>Main Category</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Defects</td>
<td>21</td>
<td>29</td>
<td>36</td>
<td>41</td>
</tr>
<tr>
<td>Specimen Defects</td>
<td>10</td>
<td>13</td>
<td>22</td>
<td>18</td>
</tr>
<tr>
<td>Testing Defects</td>
<td>31</td>
<td>38</td>
<td>38</td>
<td>44</td>
</tr>
<tr>
<td>Reporting Defects</td>
<td>10</td>
<td>12</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>RadicaLogic</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Complaints</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Safety</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

| Total Types           | 81   | 101  | 117  | 125  |
Pick List of nonconformances

125 defect subclasses

Order (41) Specimen (18) Testing (44) Report (13) Complaints (3) RadicaLogic (4) Safety/Environmental (2)

Pre-analytic 47%
Analytic 35%
Post-analytic 18%
Deviations Per Quarter

2012
DM piloted in 8 Labs:
2 core lab sections, 2 community hospitals & 4 medical centers

2013
DM used in 18 Labs:
10 core lab sections, 3 community hospitals & 5 medical centers
Spreadsheet and form update
Increase taxonomy

3Q 2014
Epic roll out at 2 hospitals

2014
DM used in 19 Labs:
11 core lab sections, 3 community hospitals & 5 medical centers
Automated SunQuest deleted test log: specimen defects due to credited tests

2Q 2014
QMS monthly DM summaries by managers

2Q 2015
Automated defect report Core lab. Visiun data derived from specimen location, canceled tests and appended test comments

2015
DM Optimization: new taxonomy, forms & spreadsheet

2Q 2015
DM used in 20 Labs:
12 core lab sections, 3 community hospitals & 5 medical centers

“You couldn’t know what you didn’t know, but now you know”
Lesson #2

95% of problems are handed to you (pre-analytic)

2015 data from Henry Ford Health System
2013 Deviations by Quarter  n=12,000

Deviations Tended per Quarter- 2013

Order Defects PT.ID  Order Defects Non-PT.ID  Sample Defects PT.ID  Sample Defects Non-PT.ID  Testing Defects  Not Reported  Report Delayed  Complaint

Pre-analytic  Analytic  Post-analytic

Totals 1Q 2Q 3Q 4Q
Quality Management System - Pathology & Laboratory Medicine 2013 Deviation Management for PALM System wide [1-4 QTR]

<table>
<thead>
<tr>
<th></th>
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</thead>
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<tr>
<td>1Q</td>
<td>67</td>
<td>1748</td>
<td>39</td>
<td>1426</td>
<td>151</td>
<td>7</td>
<td>190</td>
<td>66</td>
</tr>
<tr>
<td>2Q</td>
<td>35</td>
<td>1208</td>
<td>41</td>
<td>1409</td>
<td>129</td>
<td>3</td>
<td>228</td>
<td>58</td>
</tr>
<tr>
<td>3Q</td>
<td>70</td>
<td>1271</td>
<td>52</td>
<td>1234</td>
<td>180</td>
<td>16</td>
<td>30</td>
<td>14</td>
</tr>
<tr>
<td>4Q</td>
<td>66</td>
<td>698</td>
<td>55</td>
<td>700</td>
<td>447</td>
<td>3</td>
<td>108</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totals for 2013</td>
<td>238</td>
<td>4925</td>
<td>187</td>
<td>4769</td>
<td>907</td>
<td>29</td>
<td>556</td>
<td>261</td>
</tr>
</tbody>
</table>

Total Defects $n=11,872$

Registration issues
Order transmission
Wrong test

QNS, Clotted, Hemolyzed, Improper Collection
2014 Deviations by Quarter
n=27,000

~94% Pre-Analytical
~3.4% Analytical
~1.6% Post Analytical
~1.4% Other
PALM 4Q-2014 Deviation Management - Top 35 Categories

4th QTR 2014 PALM Subclass Summary Graph

**Order Defects**
- Registration - 710
- Wrong Test Ordered - 455
- Order not transmitted - 245

**Sample Defects**
- QNS - 1757
- Hemolyzed - 721
- Clotted - 877
- Improper Collection - 208
2014 Big 11 All-Star Team of Deviations

Most frequent critical quality defects in each of main categories- (order, specimen, testing, reporting) in the testing cycle

Lean Translation of Wastes

- Pre-analytic
- Analytic
- Post-analytic

1. Transportation
2. Inventory
3. Motion
4. Waiting
5. Over production
6. Over processing
7. Defective product/service
Lesson #3

Problem resolution

Push it Down

Engage Supplier

Take out the trash?
Nah, I'll just push it down with more trash.
Core Lab Epic Order Defect Reduction in 8 mos.

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

- Patient is seen by the provider and labs are ordered in Epic
- Labs are collected and sent to the lab
- Lab specimens are received in Sunquest by lab personnel
- Lab specimens are analyzed
- Lab specimens results are filled in Sunquest which interface with Epic

Graph showing reduction in defective Epic lab orders over 8 months from December 2013 to July 2014, with a 90% reduction by July 2014.
Fairlane OPD Lab Order Defect Reduction in 3 mos.

78% reduction in defective orders! (February to April 2014)

Reduction in lab order defects
EPIC implementation period at Fairlane Regional Medical Center

Root Cause (RC) Analysis.

- 1. Why?
  - A: PathQuest is a "lab collect" model and cannot receive specimens that are ordered as "clinic collect" because of the Epic PathQuest electronic interface.

- 2. Why?
  - A: The providers do not know that it makes a difference or that "lab collect" has to be selected when ordering, if the patient was not going to have specimens collected at the clinic that day.

- 3. Why?
  - A: They were lacking training and education on the difference and the importance of choosing lab collect or clinic collect based on where the patient will have their EPIC implementation period at Fairlane Regional Medical Center.

Final RC: Unfamiliarity with the new Epic order process

- Tracked and trended all incoming defects in the Pathology defect management system
- Customer-supplier meeting (CSM) with clinics
- Continue with CSM and focus on clinics with large numbers of order defects
- Trended Defects with Deviation Management
- Customer-Supplier meetings Clinics with data
- Focus on Clinics with Large volumes

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Lesson #4

No one solution can eliminate the problem entirely

But people can if armed with knowledge, tools and power with repeated PDCA intervention cycles
Surgical Pathology Part Type Defect Reduction

Deviation and Daily Management Monthly Review

- Customer-Supplier Meeting with OR staff & Mgmt. at HFH
- Direct Hand-Off to Pathology Chain of Custody Education
- Optime Dictionary updated & Distributed to ORs
- Standard Work Posted in OR’s & Team Leaders assigned in each specialty
- Best Practice model Implementation at Affiliate Hospitals via Laboratory Medical Directors meetings with ORs
- Ongoing data Managed via Deviation Mgmt Forms & monthly Summary Meetings

No. of "tissue" Submissions

January, February, March, April, May, June, July
<table>
<thead>
<tr>
<th>PROJECT NAME:</th>
<th>TEAM NAME:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Problem Background</strong></td>
<td><strong>Target Condition</strong></td>
</tr>
<tr>
<td>- Describe the problem</td>
<td>- Desired outcome</td>
</tr>
<tr>
<td>- Narrow down to specifics</td>
<td></td>
</tr>
</tbody>
</table>

| | **Hypothesis** |
| | - Your proposed solution |

| | **Corrective Action Plan** |
| | - Develop & agree on new plan of action |
| | - Is root cause(s) considered to prevent defect from re-occurring? |

| | **Implementation Plan** |
| | - Educate all and roll out plan |
| | - Assign responsibility as to Who, When & How roll out will be done |

| | **Problem Analysis:** Identify the root cause. Ask “Why” 5 times OR 5M: Fish Bone diagram (Man, Method, Material, Machine, Milieu [Environment]) |
| | **Effect** |
| | **Cause(s)?** |
| | **Why did the effect occur?** |
| | **Cause(s)?** |
| | **Why did this cause exist?** |
| | **Underslying Cause(s)?** |
| | **Why did this exist?** |
| | **Underslying Cause(s)?** |
| | **Why did this exist?** |
| | **And so on...** |

| | **Man** |
| | **Method** |
| | **Material** |
| | **Machine** |
| | **Milieu [Environment]** |
| | **Measurement** |

| | **Results** |
| | - Collect post date to confirm effectiveness of new plan |

| | **Metrics for Effectiveness Check:** |
| | - Measure for monitoring to know if it’s working as designed |

| | **Standardization** |
| | - Heath training modules with competency questions |
| | - Present at “Share the Gain” for lessons learned |
**PDCA Problem Solving**

Why so difficult?

<table>
<thead>
<tr>
<th>FAST</th>
<th>SLOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>System 1</td>
<td>System 2</td>
</tr>
<tr>
<td>Fast</td>
<td>Slow</td>
</tr>
<tr>
<td>Parallel</td>
<td>Serial</td>
</tr>
<tr>
<td>Automatic</td>
<td>Controlled</td>
</tr>
<tr>
<td>Effortless</td>
<td>Effortful</td>
</tr>
<tr>
<td>Associative</td>
<td>Rule-governed</td>
</tr>
<tr>
<td>Slow Learning</td>
<td>Flexible</td>
</tr>
<tr>
<td>Emotional</td>
<td>Neutral</td>
</tr>
</tbody>
</table>
Nonconformance
process => human or machine => product or service
- Deviation from standard
- Defective work product

Anything having to do with a process that can be described as-
• defective, in non-ideal or perfect form,
• not right the first time, or
• not following policy or procedure (root cause)
Alignment of Nonconformance Management, Lean and ISO

for High Quality and Customer Satisfaction

**ISO**
- Identify, monitor & control nonconformances
- Process change to eliminate the problem
- Effectiveness check to assure the fix
- Employee engagement

**Lean**
- Identify variation-lack standardization (defect/waste VSM) to understand the current condition vs target goal
- Process improvement visa PDCA from level of the work to eliminate the problem
- Continue PDCA cycle until fix is assured
- Employee engagement
“The business of management is to manage. The thing to be managed is work.”

Henry Ford
Management Systems & Culture of Continuous Improvement

Management Systems
- Hoshin Planning/Policy deployment
- Team leader system
- Improvement management (kata)
- Coaching and development (kata)
- Nonconformance management
- Daily management
- Document management
- Audit system

Tools of Improvement
- Standard Work
- 5S
- Visual workplace
- Continuous flow
- Pull production
- Kanban
- Just in Time
- Load leveling
- Batch size
- Mistake proof

Cultural Philosophy
- Customer 1st
- Continually develop your most valuable resource, your PEOPLE
- Continuous improvement
- From the level of the work
- Blameless management

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Key Processes of Managing for Continuous Improvement

- Deviation Management
  - Identify Defects Non Conformances
  - Daily Resolution
  - Daily Countermeasure
  - PDCA-A3 Resolution
  - Customer-Supplier Communication at level of work
  - Team Leader Facilitation
  - Standard Work, Connections, Pathways
  - policy, procedure, document control
- Ongoing PDCA Continuous Improvement
- The Many
  - Defects
- The Few
- Improvement Management
- Team Leader System
- Coaching System
- Document Management
- Development System
- Audit System
Review of Nonconformance Management
THE SYSTEM

*Design the System to...*

1. Find and document all deviations, level of the bench
2. Analyze to root cause
3. Correct, then eliminate via process change
Review of Nonconformance Management

THE ROLES- “Systems don’t make quality, people do”

The Sensors
All employees are inspectors.
Capture all non conformance and pertinent related information.

The Owners
Managers/supervisors are accountable.
Know and understand the variation in your work through regular analysis of captured deviations.

The Repair Persons
Solutions sustain from those who do the work.
Local teams can best determine root causes and suggest testable interventions.

The Leaders
Sustain a culture of engagement. Create management structures for all employees to succeed.
“Quality is doing it right when no one is looking”

Henry Ford

But you are looking!
With your Quality System

Nonconformance Management