# 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.*

***Results:*** *Programmatic improvements and training resulted in markedly increased documentation culminating in 71,641 deviations in 2016 classified by a taxonomy of 281 defect types into preanalytic (74.8%), analytic (23.6%), and postanalytic (1.6%) testing phases. The top 10 deviations accounted for 55,843 (78%) of the total.*

***Conclusions:*** *Deviation management is a key subsystem of managers' standard work whereby knowledge of nonconformities assists in directing corrective actions and continuous improvements that promote consistent execution and higher levels of performance.*

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."[1] 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.

In brief, Lean is the name taken from Womack's 1990 book, *The Machine That Changed the World: The Story of Lean Production—Toyota's Secret Weapon in the Global Car Wars That Is Now Revolutionizing World Industry*, to describe Toyota's business system for more efficient or just-in-time Lean production.[2] This is derived from a culture of continuous improvement with employee engagement and accountability to relentlessly pursue elimination of waste or non-value-added work at all levels of the organization.[2] In our experience, to function as a business system, Lean requires human knowledge of the numerous approaches of good work design, a customer-focused and blameless work philosophy, data-driven problem solving at the level of the work in the pursuit of more efficient processes, and a series of supporting management



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subsystems that guide human behaviors toward expected business outcomes.

Using this foundational approach over time has defined our Lean transformation from the status quo to a cultural mind-set empowered through management subsystems to achieve continuous improvement as an enterprise. Therefore, we have matured in our understanding of Lean implementation beyond tools of improvement, recognizing Lean as our comprehensive business system that drives quality through continuous improvement at all levels of the organization. We rely on data-driven problem solving at all levels of the systemwide laboratory enterprise with the expectation that managers and team members continually identify opportunities for improvement at the level of the work itself. This comprehensive business system, the Henry Ford Production System, is modeled after the management principles of W. Edwards Deming and the successful business practices of the Toyota Production System.[3-12]

Since achieving the International Organization for Standardization (ISO) accreditation to medical laboratory standard ISO 15189 in 2013, we have integrated into our laboratory business system all management requirements of the systems- and process-oriented ISO 15189.[13] Our melding of Lean operational goals and principles with those of ISO 15189 has resulted in creation of additional aligned quality management subsystems that provide structure, organization, and processes to guide human behaviors toward the goal of working continuously toward quality improvement and highly consistent regulatory performance throughout the enterprise.

One of the key drivers of our continuous improvement business system is managerial knowledge of the reliability and consistency of the work in these highly regulated laboratories. Our management subsystem that provides structure and process to this activity is known as deviation management. It is designed to accomplish occurrence management under ISO 15189 with structure to perform root cause, corrective, and preventive actions. As a Lean tool, deviation management also engages our people who actually do the work to contribute knowledge from continual identification of workplace process defects as they are encountered. Therefore, deviation management is structured to drive identification, classification, and prioritization of opportunities for continuous improvements to be made from the level of the work wherever that may be, from the executive suite to the lowest level of the organization. Deviation management is a key management system that can be used in any laboratory, whether ISO 15189 accredited or not, and fulfills the US federal Clinical Laboratory Improvement Amendments (CLIA) regulatory requirement of problem identification and resolution that all must demonstrate.

Herein, we present our 5-year experience in developing the philosophy, structure, standardized defect taxonomy, and processes of deviation management that we have implemented to understand, prioritize, control, and eliminate laboratory workplace deviations in pursuit of our goal of zero defects.

## Materials and Methods

This work was done from 2012 to 2016 in the system laboratories of the Henry Ford Health System. Pathology and Laboratory Medicine is an integrated product line overseeing laboratory testing at one main full-service hospital composed of 24/7 core laboratories and outreach with 14 unique sections, three community hospitals, and 18 medical clinic laboratory sites. It is a Lean management laboratory enterprise and accredited as a system of laboratories to the standards of federally required CLIA of 1988 and voluntarily to the standards of ISO 15189. The department is composed of 46 senior staff pathologists and clinical scientists, complemented by 750 technical staff, with volumes of 30 million reportable clinical laboratory tests, including over 80,000 surgical pathology and 70,000 cytopathology case accessions and over 15,000 molecular and cytogenetic tests each year.

### Defect Surveillance Systems

*Workplace Whiteboards*

Our Lean transformation to a continuous improvement culture has been 12 years in the making.[3] We have progressed in our understanding and definition of opportunities for improvement and the identification and collection methods we have created for our employees to be engaged in the process Figure 1.

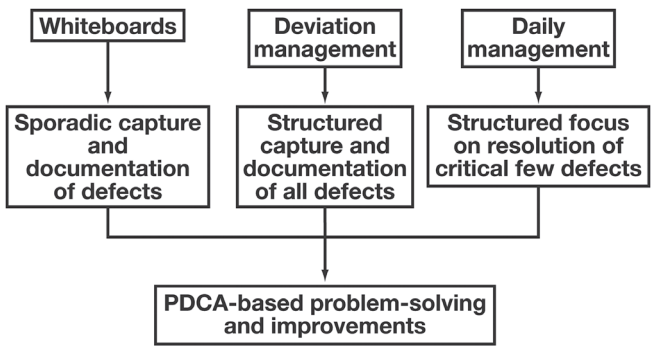


**Figure 1** Defect surveillance systems designed to fill the diagnostic funnel with knowledge to guide process improvements. PDCA, plan, do, check, and act.

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Our early efforts in defect detection began with an employee survey of workplace defects encountered and then progressed to whiteboards and visual data-display dry-erase boards for workers to document defects and waste as this was encountered in real time.[4-6] Our simplistic definition of a defect was any flaw, imperfection, or deficiency in specimen processing that required us to delay or stop our work or return work to the sender. We did not include interpretive or diagnostic errors. Our intent was to expose process improvement opportunities by documenting types of waste that included process flaws associated with overproduction, time waiting, transportation, processing, stock on hand, movement, and defective products. This served us well, as evinced by the more than 1,000 process improvements made each year in these laboratories by fostering a blame-free environment. However, we were well aware that this unstructured method of documentation was sporadic and did not represent the totality of waste encountered.

*Daily Management*

To deepen our effectiveness in continuous improvement, in 2013 we innovated a standardized visual daily management system.[6] This structured workplace board was composed of metric categories of quality, time, inventory, productivity, and safety; trending frequency; root cause analysis; corrective/preventive actions; and resulting process improvements. The intent was to provide a managerial and local team-owned structure to ensure a consistent and visual focus on critical but failed process metrics that were critical to operational success and therefore were priorities for immediate improvement.

Daily management became a key business accountability subsystem that enabled our culture of continuous improvement to function more efficiently at the managerial level in a visible manner by daily review of facts that promoted more rapid action based on data and root cause analysis. Ergo, data-driven problem solving using the discipline of PDCA (plan, do, check, and act) was enhanced. PDCA is a problem-solving approach that results in changed and improved processes. It relies on data collection to define the current state, to plan, to measure the impact of changes, and to determine the successful outcomes of process change that is designed to affect the root cause of the problem.

*Deviation Management*

In 2012, our goal to achieve ISO 15189 medical laboratory accreditation as an integrated system of laboratories was the impetus for us to begin exploring a much more comprehensive approach to documenting work-related nonconformances. This stems from the ISO 15189 requirement that "the laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes."[3] That may include "nonconforming examinations or activities [that may] occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, interlaboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits."[13]

Our Lean interpretation of these ISO standards go farther in defining a nonconformance as any deviation from standard; a defective work product or process that is defective, nonideal, or imperfect in form; a product or service not done right the first time; or any person not following policy or procedure as a root cause of the nonconformance. With our broadened definition of workplace defects to include any deviation from expected work process outcomes by instrument or human and any identified process wastes and inefficiencies, we have sought the potential totality of work-related nonconformances or deviations as a knowledge base to target process improvements. This led to the development of this comprehensive key Lean business accountability subsystem of deviation management designed for managers and supervisors to own to better understand and be accountable for the variation and consistency in the work they were charged with overseeing.

Our deviation management subsystem was also designed to incorporate documentation of resolution of nonconformances as required by ISO 15189 that specifies the following: "When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented."[13]

Through the Henry Ford Laboratory Quality Systems Technical Team with representation across the laboratory product line hospitals and core laboratory divisions and business units, 50 laboratorians contributed to the development of this new deviation management subsystem in 2012. We agreed on three expressed goals: (1) implementation of a robust Excel-based (Microsoft, Redmond, WA) systemwide deviation management system, (2) defined taxonomy of defects and procedures to identify and control deviations in the work, and (3) a system to document actions taken to correct and eliminate nonconformities. The responsibility for creation of the deviation management program for the laboratory product line of the


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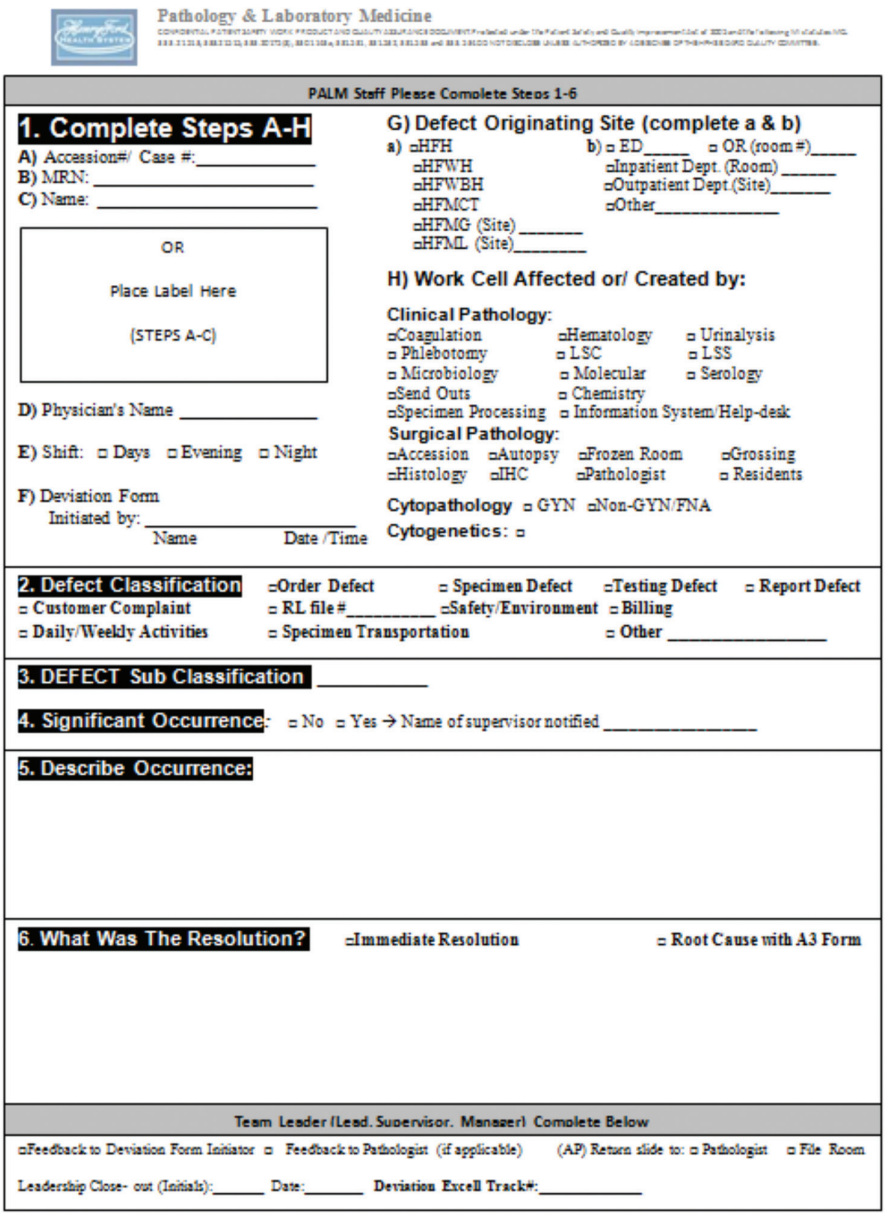
Henry Ford Health System was delegated to the Quality Systems Division manager and quality management engineer. A main intent was to produce broad and deep knowledge about nonconformities or defects in work processes and outcomes, both received and made by the laboratory, to guide managers in prioritizing improvement activities. The deviation management subsystem was designed to promote engagement of all laboratory employees in transparent defect documentation, trend identification, root cause documentation where trends were apparent, and prioritization of problem resolution by use of the data-driven PDCA in repetitive process improvement cycles.

The Quality Systems Technical Team was responsible for testing all iterations and improvements over time. The method of this deviation management subsystem was designed to be manual rather than electronic, beginning with employees using a standardized paper-based input form **Figure 2** designed by group consensus to document the nonconformities (defects) as they were encountered in all aspects of laboratory testing: the preanalytical, analytical, and postanalytical phases. The front of the form defined information required about the defect, while the back of the form contained the taxonomy of defects for the employee to



Pathology & Laboratory Medicine

PALM Staff Please Complete Steps 1-6

**1. Complete Steps A-H**

A) Accession#/ Case #:_____
B) MRN: _____
C) Name: _____

OR

Place Label Here

(STEPS A-C)

D) Physician's Name _____

E) Shift: ◻ Days ◻ Evening ◻ Night

F) Deviation Form Initiated by: _____ Name Date /Time

**G) Defect Originating Site (complete a & b)**

a) ◻HFH ◻HFWH ◻HFWBH ◻HFMCT ◻HFMG (Site) _____ ◻HFML (Site)_____

b) ◻ ED_____ ◻ OR (room #)_____ ◻Inpatient Dept. (Room) _____ ◻Outpatient Dept.(Site)_____ ◻Other_____

**H) Work Cell Affected or/ Created by:**

**Clinical Pathology:**
◻Coagulation ◻Hematology ◻ Urinalysis ◻ Phlebotomy ◻ LSC ◻ LSS ◻ Microbiology ◻ Molecular ◻ Serology ◻Send Outs ◻ Chemistry ◻Specimen Processing ◻ Information System/Help-desk

**Surgical Pathology:**
◻Accession ◻Autopsy ◻Frozen Room ◻Grossing ◻Histology ◻IHC ◻Pathologist ◻ Residents

**Cytopathology** ◻ GYN ◻Non-GYN/FNA

**Cytogenetics:** ◻

**2. Defect Classification** ◻Order Defect ◻ Specimen Defect ◻Testing Defect ◻ Report Defect ◻ Customer Complaint ◻ RL file #_____ ◻Safety/Environment ◻ Billing ◻ Daily/Weekly Activities ◻ Specimen Transportation ◻ Other _____

**3. DEFECT Sub Classification** _____

**4. Significant Occurrence:** ◻ No ◻ Yes → Name of supervisor notified _____

**5. Describe Occurrence:**

**6. What Was The Resolution?** ◻Immediate Resolution ◻ Root Cause with A3 Form

Team Leader (Lead, Supervisor, Manager) Complete Below

◻Feedback to Deviation Form Initiator ◻ Feedback to Pathologist (if applicable) (AP) Return slide to: ◻ Pathologist ◻ File Room

Leadership Close- out (Initials):_____ Date:_____ Deviation Excell Track#:_____

**Figure 2** Deviation management input form presents a standardized methodology for paper-based capture of defects at the level of the work.

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readily categorize the specific subclassification of defect encountered.

Data from the employee-initiated forms were then reviewed and recorded by managers or designees in a standardized Excel spreadsheet housed on a shared drive. Spreadsheet data elements include defect information and classification as to type from the taxonomy, site of defect origin, immediate resolution taken (fix), root cause, and PDCA resolution (if initiated) Figure 3. The spreadsheet was designed with pivot table logic that enabled managers to readily analyze and summate their defect types according to what, how many, and sources Figure 4.

Individual laboratory leaders were then responsible for curating their own reports on a monthly basis to be reviewed by their teams and then by leadership for trend identification and process improvement selection.

Involvement and participation in this locally maintained nonconformance management system was shared and incorporated into the systemwide Quality Management Plan with quarterly presentations by managers of their analysis of opportunities and reports of actions planned or taken. Process improvements that arose from these identified opportunities and data collected in the nonconformance management system were attached to the specific defect in the Excel spreadsheet as a pdf copy of the PDCA improvement and also entered on a separate Quality Improvement Tracker. The five-step process of employee and manager engagement in the deviation management process is illustrated in Figure 5.

## Results

### Programmatic Improvements

This nonconformance management program was tested and implemented in phases to include all hospital laboratories, sections, and medical center laboratories of the laboratory product line. It was voluntarily piloted in the fourth quarter of 2012 in eight volunteer laboratory sites consisting of two core laboratory sections, two community hospitals, and four medical center laboratories. Participation was expanded to an additional 10 sites in 2013 (10 core laboratory sections, three community hospitals, and five medical center laboratories) with 19 sites active in early 2014 (11 core laboratory sections,

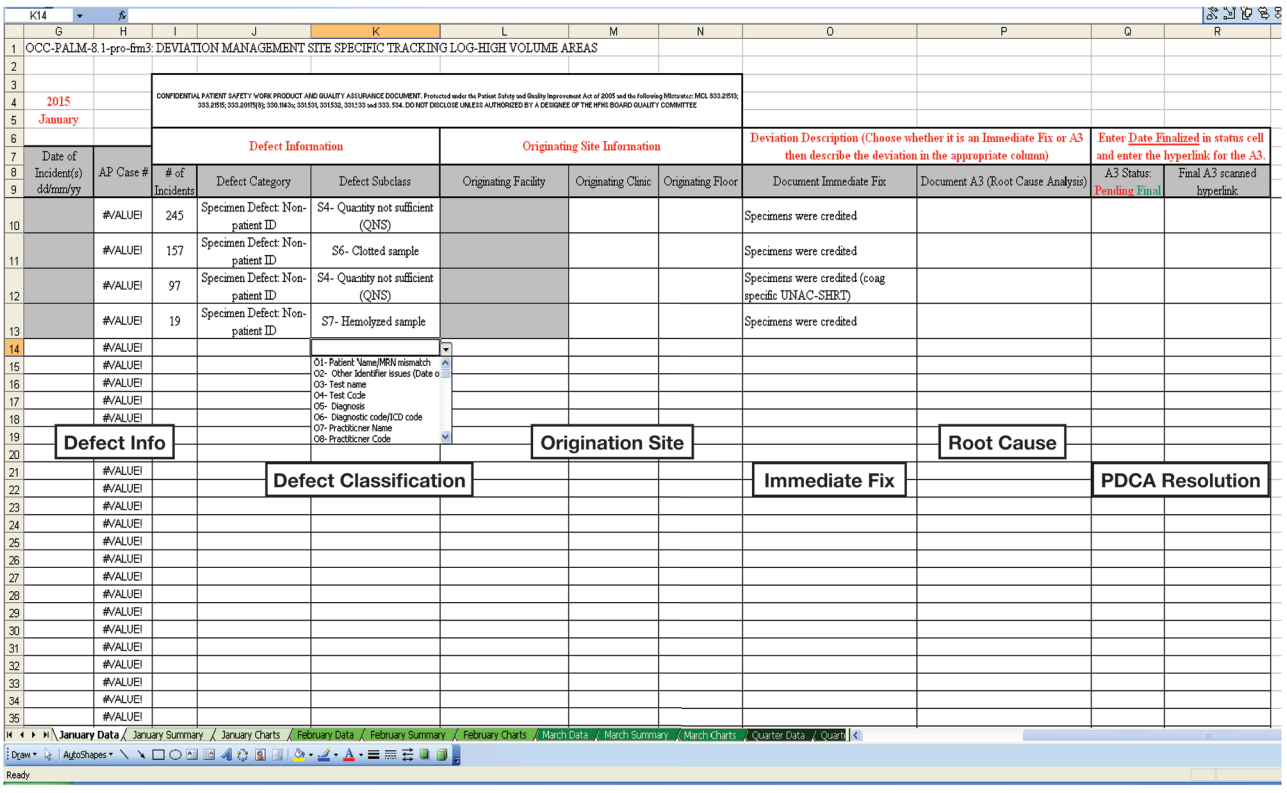


**Figure 3** Data from the employee-initiated input forms are recorded by managers in a standardized Excel spreadsheet on a shared drive. Spreadsheet data elements include defect information and classification as to type from the taxonomy, site of defect origin, immediate resolution taken (fix), root cause, and PDCA (plan, do, check, and act) resolution (if initiated).


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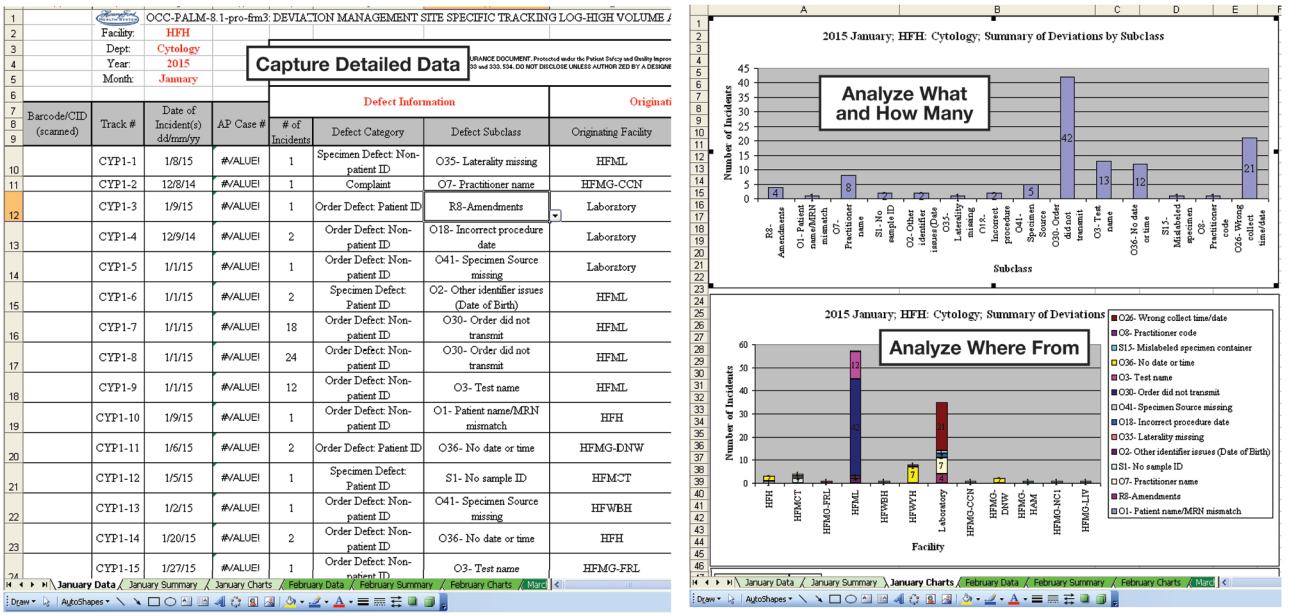


**Figure 4** The spreadsheet is designed with pivot table logic to allow managers to analyze and summate defect types encountered according to what, how many, and source of defect.

| Process Step | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Employee Ownership | All employee team members | Designated lab staff member | Manager supervisor or designee | Manager supervisor or designee | Manager supervisor and team members |
| Process Task | Encounter defect and document | Verify and enter defect data and type | Review all defects; provide feedback to initiator | Analyze trends and corrective actions | PDCA resolution document on project tracker |
| Standard Tool | Deviation management form | Deviation management Excel file | Deviation management Excel file | Deviation management Excel file | PDCA Excel project tracker |
| Tool Location | Paper forms in gemba | File on shared drive | File on shared drive | File on shared drive | File on shared drive |

**Figure 5** Deviation management is a five-step process involving all employees and their manager/supervisor. PDCA, plan, do, check, and act.

three community hospitals, and five medical center laboratories). By 2015, there were 33 sites and hospital core laboratory sections contributing (12 core laboratory sections, three community hospitals, and 18 medical center laboratories) and all 35 sites and hospital core laboratory sections participating by 2016 (14 core laboratory sections, three community hospitals, and 18 medical center laboratories).

The deviation management subsystem was continually improved each year of implementation by the Quality Systems Technical Team, and these improvements affected the numbers of deviations detected over the years **Figure 6**.

The total annual number of deviations detected and documented by employees over 2013 to 2016 and the distribution of those defects by test phase of origin are shown in **Table 1**. Years 2013 to 2015 were dominated by detection of preanalytic phase defects. We believe that additions to the taxonomy and rigorous education and training of all employees in use of the subsystem account for the marked improvement in detection of analytic phase defects in 2016.

Although we made changes to improve the subsystem, the one constant we held to was that all staff had input into the upfront process design and changes that they desired. Local ownership and eventually customization of input forms was a necessity because of the

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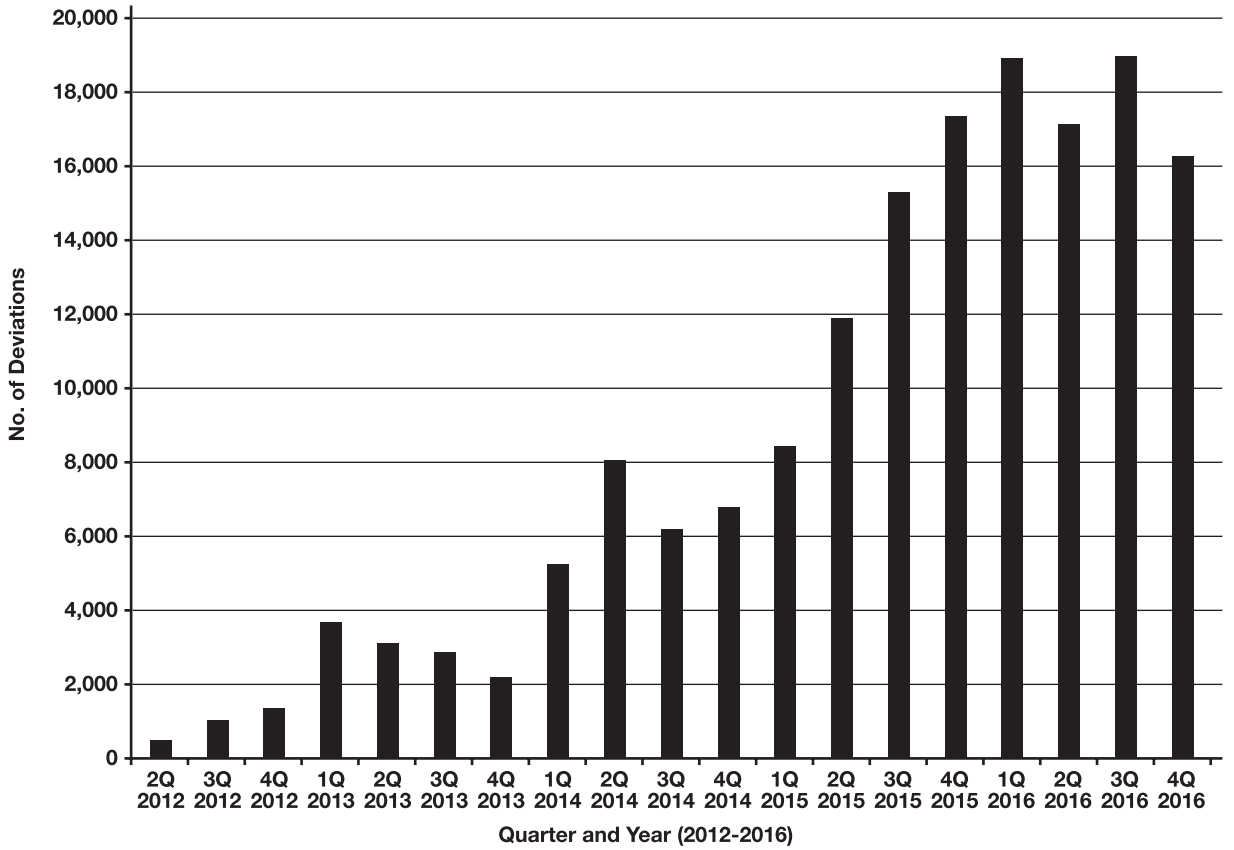


**Figure 6** Number of deviations documented by quarter in 2012 to 2016 throughout the laboratory product line and changes made that improved data capture. In 2013, new taxonomy forms and spreadsheets were implemented; in the third quarter, Epic electronic medical record rollout was done at two hospitals. In 2014, automated deleted test log for specimen defects due to credited tests was implemented; in the second quarter, quality management system meeting monthly deviation management summaries were made by managers. In 2015, new taxonomy forms and spreadsheets were implemented; in the second quarter, an automated defect report in core laboratory automated data derived from specimen location, canceled tests, and appended text comments. In 2016, deviation management subclass codes increased from 125 to 281; there were 51 face-to-face training sessions.

**Table 1**
**Total Number and Percent Distribution of Documented Deviations by Testing Phase (2013-2016)**

| Year | Total No. of Deviations | Preanalytic, % | Analytic, % | Postanalytic, % |
|---|---|---|---|---|
| 2013 | 11,872 | 84.0 | 8.0 | 8.0 |
| 2014 | 27,343 | 93.0 | 3.4 | 3.6 |
| 2015 | 52,971 | 91.0 | 5.0 | 4.0 |
| 2016 | 71,641 | 74.8 | 23.6 | 1.6 |

broad user group that included supervisors, managers, pathologists, pathologists' assistants, residents, secretaries, medical technologists, laboratory assistants, or any other employee of the Pathology Department. Successive years included the following improvements in the deviation management subsystem: definition and expansion of the taxonomy list of potential defects encountered each year, improved Excel spreadsheets with pivot table logic to summate deviations by laboratory, provider site of origin and type and number of defects documented, inclusion of automated data regarding specimen adequacy and credited tests from the Sunquest (Tucson, AZ) Laboratory Information System, optimized paper input forms customized to local user needs, inclusion of summary analytics data from automated reports of specimen location, canceled tests and appended test comments, and requirement for managers to summarize deviation management reports on a monthly basis and report


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targeted improvements on a quarterly basis to the System Laboratory Quality Management Committee.

One of the keys to standardization of analysis and outputs was agreement on defect classification of inputs. By consensus, we created an initial taxonomy of 125 categories to incorporate defects created by the laboratory as well as received by the laboratory. These fell into one of seven categories: preanalytic (order defects and specimen defects), analytic (testing defects), postanalytic (reporting and complaints), and others (safety and institutional incident reporting system [hospital reportable]).

In 2015, we expanded our knowledge of defects encountered to arrive at a more comprehensive and specific taxonomy of 279 defect types. This increase is largely attributable to a combination of newly added analytic phase defect types in anatomic pathology, defects associated with a new fully automated core laboratory and its informatics, and new process defects in cytogenetics as well as our focus on human engagement in 2015. We also deepened our data capture of specimen- and order-related defects by incorporating electronic reports from the Clinical Laboratory Information System. The spreadsheet was again optimized for easy data entry with inclusion of monthly trending summaries, and new customized input forms were created to aid faster data capture. This change had a dramatic impact on defect documentation, increasing from 27,343 defects captured in 2014 to 52,971 in 2015 (Figure 6).

In 2016, we accommodated additional laboratory work groups and increased the original seven defect categories to 10 by expanding the postanalytic category to include as work defects nonconforming billing, complaints, and safety issues. This resulted in a slightly larger taxonomy of 281 defect types. To promote more consistency and inculcate the expectation of employee participation in deviation management, we attempted to influence human behavior by including this module in annual employee Lean training by conducting 51 face-to-face 1-hour training sessions throughout 2016. As can be seen from Figure 4, this resulted in a 35% increase over 2015 with an additional 18,670 defects captured, resulting in a total of 71,641 documented defects in 2016.

### Quality Improvements

Knowledge of nonconformities from deviation management assisted managers and supervisors in directing corrective actions and process changes throughout the laboratories of the product line. Deviation management was used not only in surveillance mode for defect detection but also in monitoring mode for assessment of control of nonconformities and effectiveness in their elimination. Notable improvements were targeted reductions in the most common defects. **Figure 7** illustrates the top 10 deviations in 2016 that accounted for 55,843 or 78% of the annual defect total of 71,641 deviations. These deviations relate to specimen order and integrity defects, surgical pathology barcode nonreads, and duplicate recut orders. Significant improvements in the most common deviations were made in 2016 employing deviation management for defect detection and monitoring, as well as daily management for problem solving and process redesign. This resulted in a 21% increased detection of outreach order defects (1,622 in 2015 vs 2,044 in 2016) and a 33% increase in outreach specimen defects detected (1,206 in 2015 vs 1,820 in 2016). Notable improvements included a 31% improvement in wrong tests ordered (2,471 in 2015 vs 1,712 in 2016), 23% improvement in clinical laboratory specimen integrity defects (32,574 in 2015 vs 25,026 in 2016), 73% improvement in surgical pathology barcode reads (1,055 in first quarter 2016 vs 286 in fourth quarter 2016), and complete resolution of surgical pathology duplicate recut orders (1,925 in May 2016 vs 0 in December 2016) (Figure 7). There was no significant change in specimen order defects.

The following two examples illustrate the use of deviation management, in short- term and long-term surveillance, for detection and monitoring of specific deviations when used in conjunction with daily management to correct high-priority defects. **Figure 8** shows the rapid reduction from 2,000 per month to zero of surgical pathology duplicate recut orders, first identified through deviation management. The increase to nearly 500 defects per month before resolution of this analytic phase defect is attributed to engagement of the human "sensors" in documenting the defective process once it was elevated to the focus of daily management. **Figure 9** illustrates the postanalytic improvement in clinical laboratory performance of notification and documentation of critical values to ordering providers from unsatisfactory levels in 2012 to a stable state of minimal defects in 2017. Identified are major changes associated with systemwide adoption of a new electronic medical record system and laboratory changes in laboratory staffing and standard work procedure and training that influenced the critical value notification success rate. Again, the combined use of humans engaged in deviation and daily management maintains control of this high-priority and safety-related manual laboratory process with minimal deviations.

## Discussion

In our Lean business system, we have created numerous quality management subsystems and structures to support managers and supervisors in understanding the

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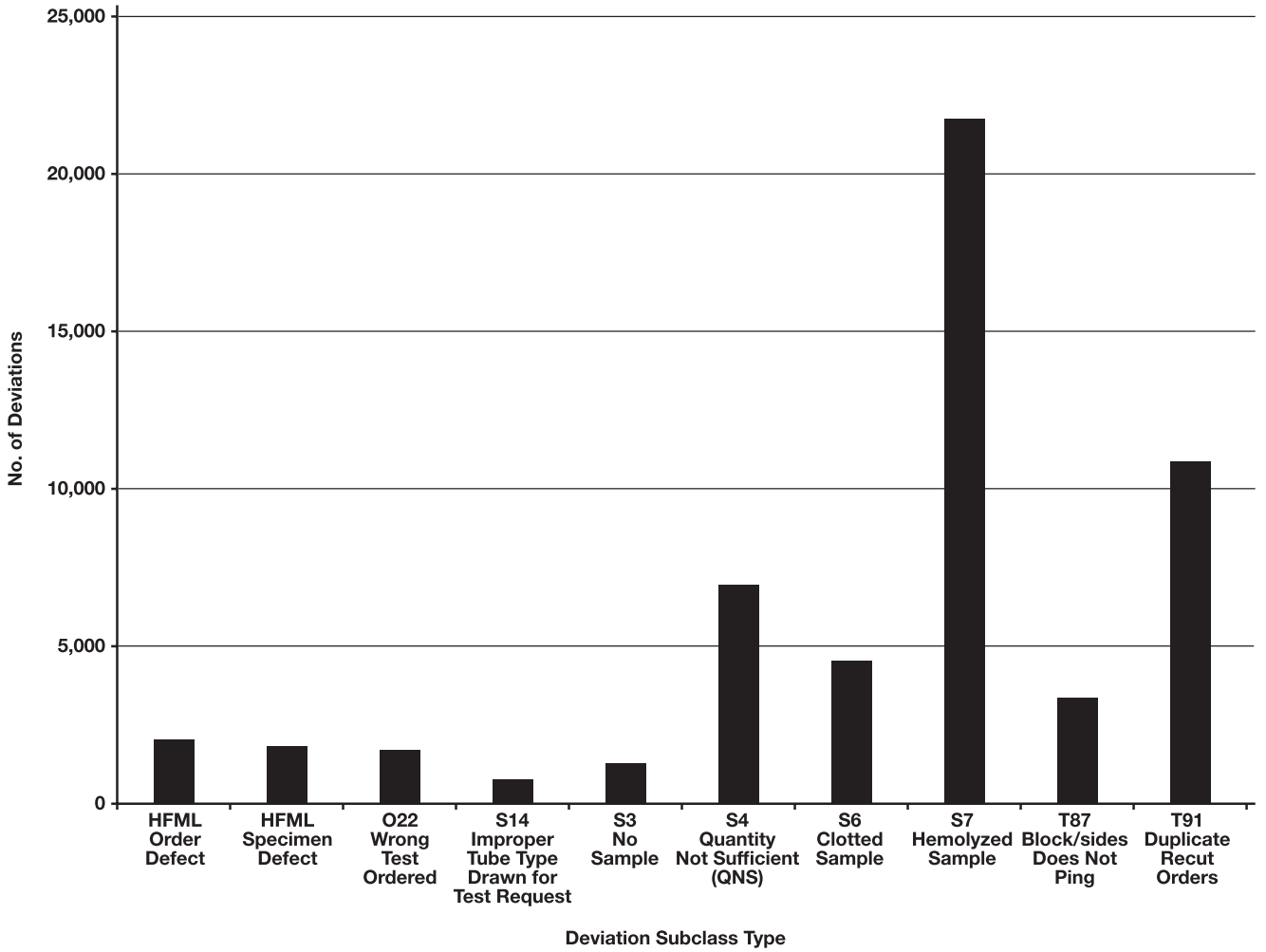


**Figure 7** The top 10 deviations encountered in 2016 account for 78% of the total deviations documented. Deviation management provides managers with knowledge to prioritize improvement activities for maximum impact.

outcomes of their work and driving continuous improvements from the level of the work with their engaged and empowered team members. This is known as the gemba in Lean parlance for the actual place where value is created in the workplace. Our approach to gemba-level PDCA-based problem solving and the supporting subsystems that support that goal is illustrated in **Figure 10**. Our adaptation of a structured daily management system in 2013 allowed us to focus on deviations or nonconformances that were assessed by management to represent the critical few processes required for daily success at each workplace.[6] However, we recognized that there existed yet a large number of deviations experienced by our workforce and our customers that we failed to consistently identify and target for improvement. The apt analogy of flying a plane blind without instruments in zero visibility comes to mind. It was broader and deeper knowledge of these undocumented opportunities that we sought next.

Our continuous improvement culture took a leap forward when we pursued and achieved ISO 15189 accreditation in 2013 as the largest integrated system of medical laboratories in the United States. The primary driver for us to create a standardized health systemwide deviation management system was the ISO 15189 requirement for a robust system to track nonconformances or deviations in the work and the customer experience. Our intent in developing a deviation management subsystem was to provide structure to empower all employees to own the responsibility of more comprehensively recording workplace defects that they encountered, contributing to real-time corrective action and root cause analysis and to subsequently work through our accountable Lean culture to eliminate prioritized deviations with PDCA problem solving and process change.

The fuel that now drives our engine of risk reduction and continuous improvement is derived from deviation management—knowledge of what we receive from


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"suppliers" and what we deliver to "customers" that does not conform to expectations. This manager-owned system with participation of all employees is designed to move beyond sporadically used whiteboards to capture in real time a standardized taxonomy of defects and variations from expected work practices as experienced by all involved.

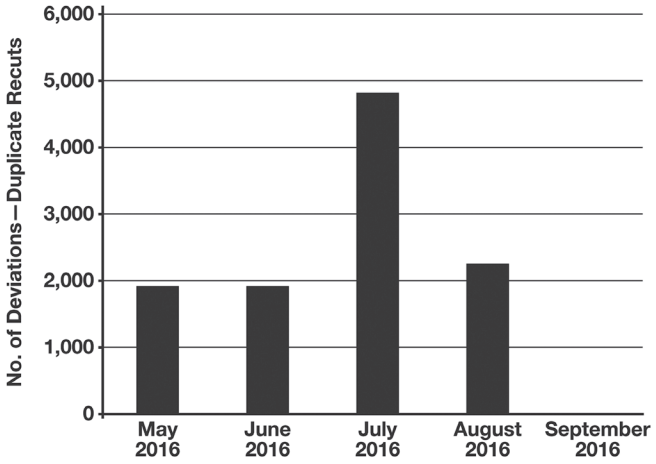


**Figure 8** Short-term reduction in surgical pathology duplicate recuts in 2016. In May, the defect was identified. The root cause of the defect was investigated with pathology informatics. In August, the root cause was identified: there was a defect in the logic of the recut log. By September, pathology informatics had fixed the logic of the recut log.

Most work systems are fraught with process inefficiencies and wastes that dominate the total time of human effort compared with the actual fraction of time involved in creating value. The fact that even well-intentioned business systems are not "Lean" was well articulated 92 years ago by Henry Ford, who recognized in his own operations renowned for efficiency that "we still waste more than we use. We waste men, we waste materials, we waste everything, and consequently we have to work too hard and too long to accomplish what in the end amounts to very little. But at least we are learning that we can not get anywhere without the kind of management which extends from the smallest detail to the whole purpose of what you are about."[14]

This is especially true in the business of health care, where process defects may readily escalate to medical errors that currently account for the number 3 cause of death in the United States.[15] The Joint Commission recognizes the culture of Lean as a component of "robust process improvement" that should be pursued for health care to be effective in achieving high reliability exhibited by consistent excellence in quality and safety.[16] It is our sincere desire that our shared experiences here will serve others to drive

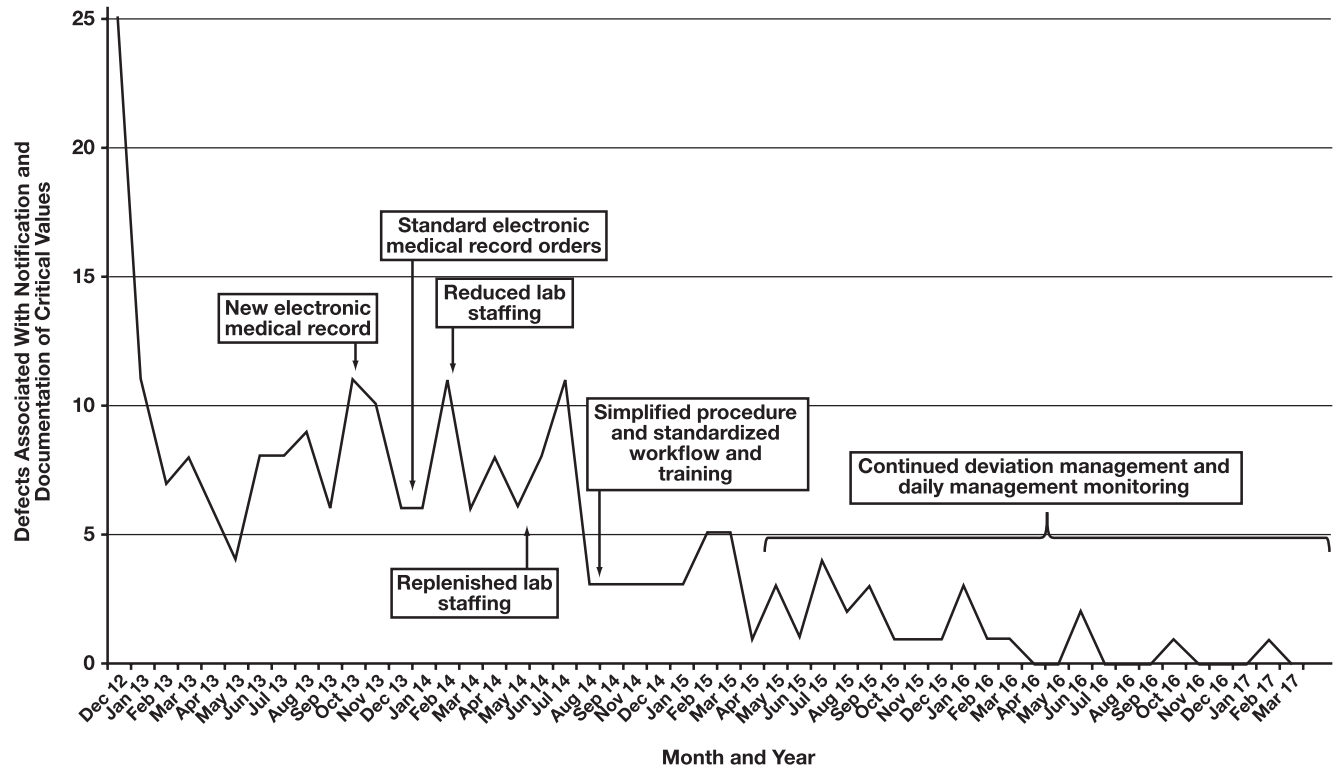


**Figure 9** Long-term reduction in defects in critical value notification and documentation in 2012 to 2017.

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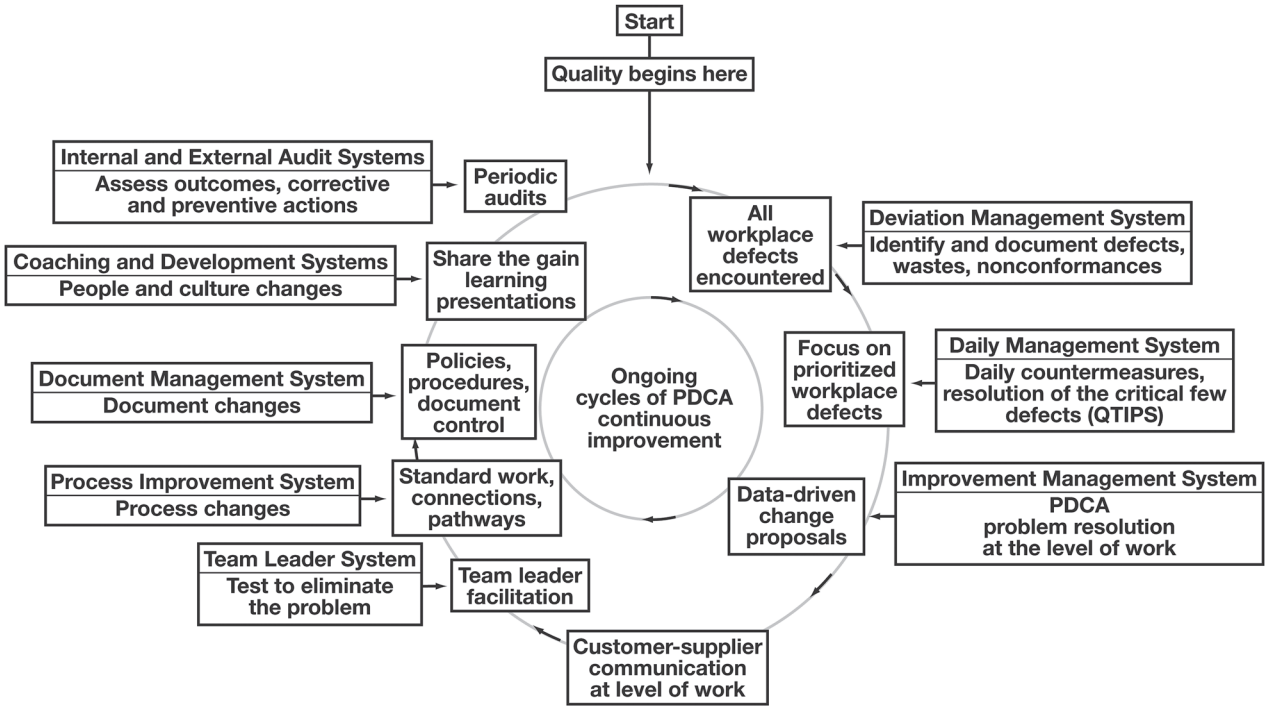


**Figure 10** Continuous process improvements made by engaged employee teams to eliminate work-level deviations required defined supporting subsystems to ensure consistent execution in this business system. PDCA, plan, do, check, and act; QTIPS, quality, time, inventory, productivity, and safety.

continuous improvement through culture change, Deming-style philosophy of management, workforce education, and new business management systems that support this transformation. In our view, these elements are essential to pursue a new condition where health care is highly reliable.

In our pursuit of high reliability, we have focused on creating a Lean laboratory enterprise whose consistency of execution is guided by quality management systems and structures. These management systems are designed to deepen the effectiveness of our continuous improvement culture by promoting managers' understanding of the variation in the work they are charged with overseeing and fostering effective engagement of their employees in process improvement. This has resulted in gains in standardization of processes, workflow efficiency, and mitigation of risk for our employees and customers. This new focus on managers having good knowledge of the quality of their work product in turn promotes consistent execution and higher levels of performance.

In any work system of management that requires continuous improvement, how does one know what to tackle next and specifically how to make effective change to eliminate problems?

Early in a Lean transformation, many implement workplace whiteboards to capture knowledge of deviations. Our experience with this approach was less than optimal over the years. Although whiteboards were an opportunity for the workforce to document variation and waste, the unstructured format commonly led to inconsistency of defect capture and spotty employee participation. Whiteboards often degraded to "whining" boards. Our intent in creating the deviation management subsystem was to provide our employees with a tool to foster real-time defect capture with structured deeper knowledge related to the deviation (case, source, type, and person). We integrated into this process the opportunity to begin the root cause analysis and documentation of the corrective action taken. Ultimately, we have promoted local ownership for documentation and follow-through, pushing solutions down in our organization to the gemba level where expertise lies.

A deviation management subsystem that provides managers with enhanced surveillance of nonconformances, as they are detected daily, becomes a much more powerful system to continually fill the diagnostic funnel of knowledge. We have been influenced by Deming's cautions that "it is not enough to do your best; you must know what to do, and then do your best" and that "information is not knowledge. Let's not confuse the two." By employing deviation management as a standardized and integrated subsystem across the laboratory product line, we have fostered actionable knowledge from structured examination of


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workplace defects. That structure provides for commonality of cause and resolution in all hospitals, core laboratories, and clinic laboratories, as well as outreach sites. In contrast to the free-form whiteboard approach, the power of this subsystem design structures behaviors to identify quality defects at the source with root causes and interventions accomplished temporally closer to the actual event. By operating in this fashion, we have set the daily expectation of work improvement by empowering all managers and employees in efforts to reduce defects, inefficiencies, and variation in processes as an additional requirement of their work. The expectation is that the workforce does the work and improves the work, continually. In essence, we have created the foundation of knowledge to enable continuous improvement. Our experience with deviation management has become our cultural foundation to establish Deming's call for profound knowledge for leaders to affect change and improvement.

Much of the variation represented in the nonconformances that we have identified using the deviation management subsystem can be traced back to a human action or lack of action. This calls for innovative approaches to make human behaviors and actions more reliable, often in a highly visual and accountable work environment. This knowledge and opportunities for work improvement from analysis of nonconformities identified in deviation management become the standard work of the manager to effect consistency and reliability in the work that they are charged with overseeing. In this new culture, armed with knowledge of work quality, or lack thereof, the managers' defining raison d'être and success become prominently apparent and often visual to the entire work team. We have derived three modes of functionality from deviation management that assist managers: surveillance for defect detection, monitoring for assessment of control of nonconformities and effectiveness in their elimination, and employee engagement in detection and process improvement.

Another key quality management subsystem is daily management, which we have described in detail previously in this journal.[6] This is another aspect of the managers' standard work that provides a structured system to prioritize the critical few defects that require repair now and should not be repeated. Daily management allows for deeper dives with employees to focus on a few important defect types on a 24-hour basis. This focus results in further understanding of the problem beyond implementation of daily countermeasures to root cause determination and visual tracking and trending as the problem is solved and eliminated through process change interventions. Deviation management and daily management are two key quality management subsystems that engage all employees in structured Lean problem solving at the level of the work (gemba), as illustrated in Figure 11.

Using our focus on the laboratories as a product line or system, we could identify nonconformances of common root cause for systemwide solution testing. We did this by instituting the discipline of quarterly managerial review and presentation of summarized nonconformities identified in each of our hospitals to the higher management level of the monthly Quality Management System meeting. The lesson for managers of the laboratory product line is that they are not alone and it is not unreasonable that if a vexing nonconformance occurs in one hospital, then it likely occurs in others. In this manner, we achieved global thinking and systemic process improvements.

As we see it, the quality management systems that we have developed provide a framework of processes and procedures structured to ensure that people do the right and expected thing in performing tasks consistently and in continually seeking improvement. This pertains not only to our own laboratory personnel but also to our clinicians, nurses, medical assistants, phlebotomists, and other clinical "customers." Because nearly three-fourths of the more than 70,000 annual documented deviations are handed to the laboratory by these individuals as specimen ordering and process defects, they are rightfully considered the main "suppliers" to the laboratory. Just as in manufacturing where a poor-quality part supplied for assembly can have a costly downstream impact, our version of supplied defects must be addressed at the source. Therefore, we seek to change human behavior to consistently achieve superior results by continually seeking improvement in both

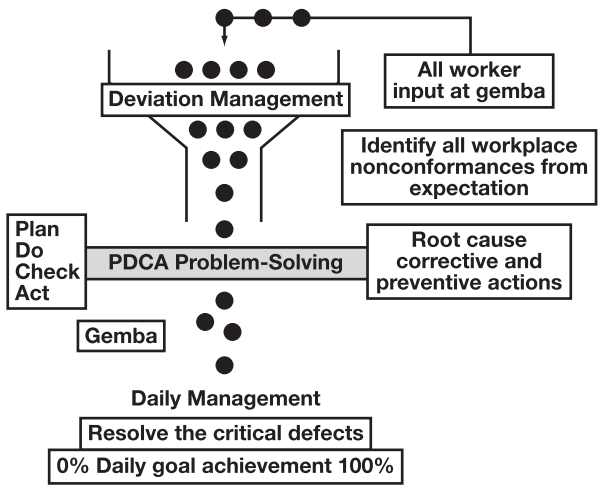


**Figure 11** Deviation management and daily management are two key quality management subsystems that engage all employees in structured Lean problem solving at the level of the work (gemba).

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the work we do and the work that our clinical colleagues do in the form of requests for testing and collected human specimens provided to the laboratory. These are the two largest categories of preanalytic defects, test ordering and specimen collection, and therefore present the greatest opportunities for improvement. Knowledge from deviation management is helpful in providing data when change in the form of supplier standardization is required to improve quality at the source as well.

In this digital age, it is tempting to push "electronic solutions" for data capture. In fact, as we matured in use of the deviation management subsystem, we integrated electronic data related to specimen adequacy from automated analyzers. However, there remain advantages to paper-based data collection. This includes a cost avoidance associated with providing many computer terminals for individual employees across a large system of laboratories and the avoidance of continual developmental costs to improve and upgrade software and changes in taxonomies. We have been able to achieve these changes and improvements using paper and Excel spreadsheets over the years. Our approach also avoids the need for bench employees to get up to access a computer terminal to enter data, thereby promoting participation at the level of work, anywhere a defect is encountered, to avoid increased documentation time and human motion. One of the simplest yet effective aspects of the paper-based system that promotes employee participation with easier input and speeds the selection of defect type is the empowerment of local teams to customize their paper input form. Many work cells have now created a custom layout with a simplified taxonomy list to include only commonly encountered issues. This has fostered local ownership for work quality and improvement.

The aphorism "systems don't produce quality, people do" is very applicable to the success of a deviation management subsystem like this designed for comprehensive capture of workplace wastes and inefficiencies. If employees do not participate in defect identification and documentation, then the human "sensors" at the level of the work are effectively silent. This is the equivalent to unplugging the fuel level gauge in an automobile yet expecting to know when to intervene and refill the tank before becoming stranded. Our intensive 51 face-to-face 1-hour sessions in 2016 of employee training in the use of subsystems and tools of improvement, which included deviation management, promoted engagement of our human "sensors." The success of simplified education focused on key elements of expected human engagement and accountability in improving the work itself is demonstrated in the 35% increase in deviations documented in 2016 after this intensive annual education. At its core, Lean and the management subsystems that support the expected outcome of continuous improvement and employee engagement require continuous education and human development. Systems are not enough. In the words of Deming from his last two management principles (principles 13 and 14), "Institute a vigorous program of education and self-improvement. Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job."[7]

In summary, we strongly believe that for health care to become highly reliable, a culture change is required. We can all agree on the perfect state, but improvement requires continuous knowledge of unreliability or deviation from the expected as it arises so that managers can work to continually improve the work. One key aspect of success in this transformation is to drive consistency in the managers' standard work with structure that functions like this deviation management system. Using this approach in conjunction with a Deming-style philosophy of management will foster continuous improvement at the granular level of the work toward the goal of consistently high quality. The deviation management structure provides for managerial consistency through real-time understanding of the process variation, identification of opportunities, and tests for meaningful process change with participation of their engaged employees that ultimately results in ever higher levels of performance.

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