

December 5, 2012

## **Wednesday's Words of Quality**

### **HFPS version 2.0, the Pursuit of ISO 15189 Accreditation**

All Laboratory Staff,

I am sharing here key messages and points about ISO that you should know as employees of Pathology and Laboratory Medicine (PALM) as we approach our first ISO accreditation inspection this coming January 2013.

The International Organization for Standardization (ISO) *creates "international standards that promote safe, reliable and high quality services and products with strategic tools to minimize waste, reduce costs and increase productivity."*

**If this sounds a lot like what we have been perfecting these past 8 years with our focus on Lean management in these Henry Ford laboratories, then you're right! This is the next step in our pursuit of ever higher quality.**

**I consider compliance with ISO 15189 to be our 2.0 version of The Henry Ford Production System (HFPS)- the management system that drives our culture of continuous improvement that we have created to focus on all aspects of quality, customers and employee engagement.**

Pursuit of ISO international accreditation specific for medical laboratories has been a long-range goal for us. This has been built upon 4 years of preparations that have entailed acquiring and creating education, building teams, conducting audits, integrating into a system of Henry Ford laboratories, creating management systems and adopting standard practices with ISO compliant policies and procedures that are under paperless document control across the system.

Below and attached as a PowerPoint are the few slides that contain the basics of what you need to know for the inspection. Your leaders and managers will be reviewing the materials and answering your questions locally. You have also been assigned PALM education module #1 of ISO training created by the Institute for Quality Management in Healthcare (Ontario) as a HealthStream learning requirement.

The ISO inspectors (4) will be here for a week to visit all sites in January. This education is meant to prepare you for the inspectors' questions to verify that you know what to do and that we do what we say we do.

**We are approaching this accreditation as a SYSTEM of INTEGRATED LABORATORIES so your part in this is very important to our success.**



ISO 15189

# ISO

## The Basics You Need to Know

Pathology and Laboratory Medicine (2012)



ISO 15189

### ISO 15189 Accreditation

We are voluntarily seeking ISO accreditation  
as a **System of Laboratories, Why?**

*To differentiate ourselves at a higher level of quality & performance  
in order to serve our patients better and maintain a competitive  
edge/advantage in a challenging healthcare market*

- *Therefore we ALL are accountable for ISO compliance. We are as strong as our weakest link. If any of us fails, we all fail ISO accreditation*
- We have selected the **College of American Pathologists** to be our ISO accrediting body
- This is separate from our federally required CLIA-based CAP laboratory accreditation (interim and biennial inspections)



## ISO- Key Learning Points

### **ISO (International Organization for Standardization)**

-Is an international group comprised of representatives from 33 member countries who create standards that benefit business, society and the environment (approx. 16,500 standards to date)

***-ISO standards promote safe, reliable and high quality services and products with strategic tools to minimize waste, reduce costs and increase productivity***

### **ISO TERMS:**

#### **•“Should” and “Shall”**

- “Should” -is meant to be informative, advice or a recommendation
- “Shall” – means that something is required

•“Compliance” =adherence to the requirement



## ISO 15189 for Medical Laboratory

- Is an accreditation standard – accreditation is a procedure by which an authoritative body gives formal recognition that an organization is **competent** to carry out specific tasks  
(e.g., audits must demonstrate that we can produce product competently)
- ISO 15189 = Specific international standard for medical laboratory quality & competence
- Entails ISO 9001 based management requirements but with an expectation to demonstrate lab competence
- To be ISO accredited we must develop Quality Management Systems that evaluate lab performance  
**These are listed on the next slide**



**ISO 15189**

## **Every employee must know the following**

- 1- Quality Management Plan (QMP)  
*(Do you know where to find it? What's in it?)*
- 2- We have established quality goals and indicators, perform internal audits & Proficiency Testing, assess & manage risk and system-wide competency systems
- 3- We address non-conformities or potential non-conformities  
*(Laboratory's Deviation Management System and HFHS Radical Logic)*
  - Prompt corrective and preventive actions
  - Conducted in a "no blame" environment driving continual improvements*(How is this addressed in your department or division?)*
- 4- Customer complaint process *(Where is it logged and followed up?)*
- 5- Assessments of our own competency *(How is it documented?)*
- 6- Ensure focus on the maintenance and continual improvements of services provided to our users *(Lean management with customer focus)*
- 7- Document Control *(Where and how do you find documents, policies, procedures, standard work, job aids, etc)*



**ISO 15189**

**Management's responsibility to provide a safe work environment and conduct an annual management review consisting of an objective evaluation of the effectiveness of the system implemented and the need for resources.**

### **Did you know that.....**

All of our PALM leaders and managers conducted a formal management review of our quality systems in November 2012 and the summation of those findings were communicated to all PALM employees by email on November 29, 2012. That report is available to all upon request from the Chairman.