

“Quality Management: DNV, ISO 9001, & YOU”

HPP Session: July 12, 2022

**Jeffrey S. Bennett, MD, MBOE
Director of Quality for CLER
UT College of Medicine Chattanooga and
Department of Pediatrics Faculty**

Learning Objectives

As a result of this activity, learners should be able to:

- Understand High Reliability Principles as they relate to Hospital Accreditation with DNV
- Explain how ISO 9001:2015 requirements support the creation of a Quality Management System
- Understand how these things impact you as a resident, fellow, or faculty member

High Reliability Organizations

“operate under very trying conditions all the time
and yet manage to have fewer
than their fair share of accidents.”

Risk is a function of **probability** and **consequence**.
By decreasing the probability of an accident, HRO's
recast a high-risk enterprise as merely a high-
consequence enterprise. HROs operate as to make
systems ultra-safe.

Definition of *Reliability* for Health Care

The capability of a process, procedure or health service to perform its intended function in the required time under existing conditions.

“...it is not possible in such dynamic settings to anticipate and write a rule for every circumstance....(we need) to foster real-time problem solving and...institute safety systems that incorporate a knowledge of human factors....”

Framework for Safe, Reliable and Effective Health Care

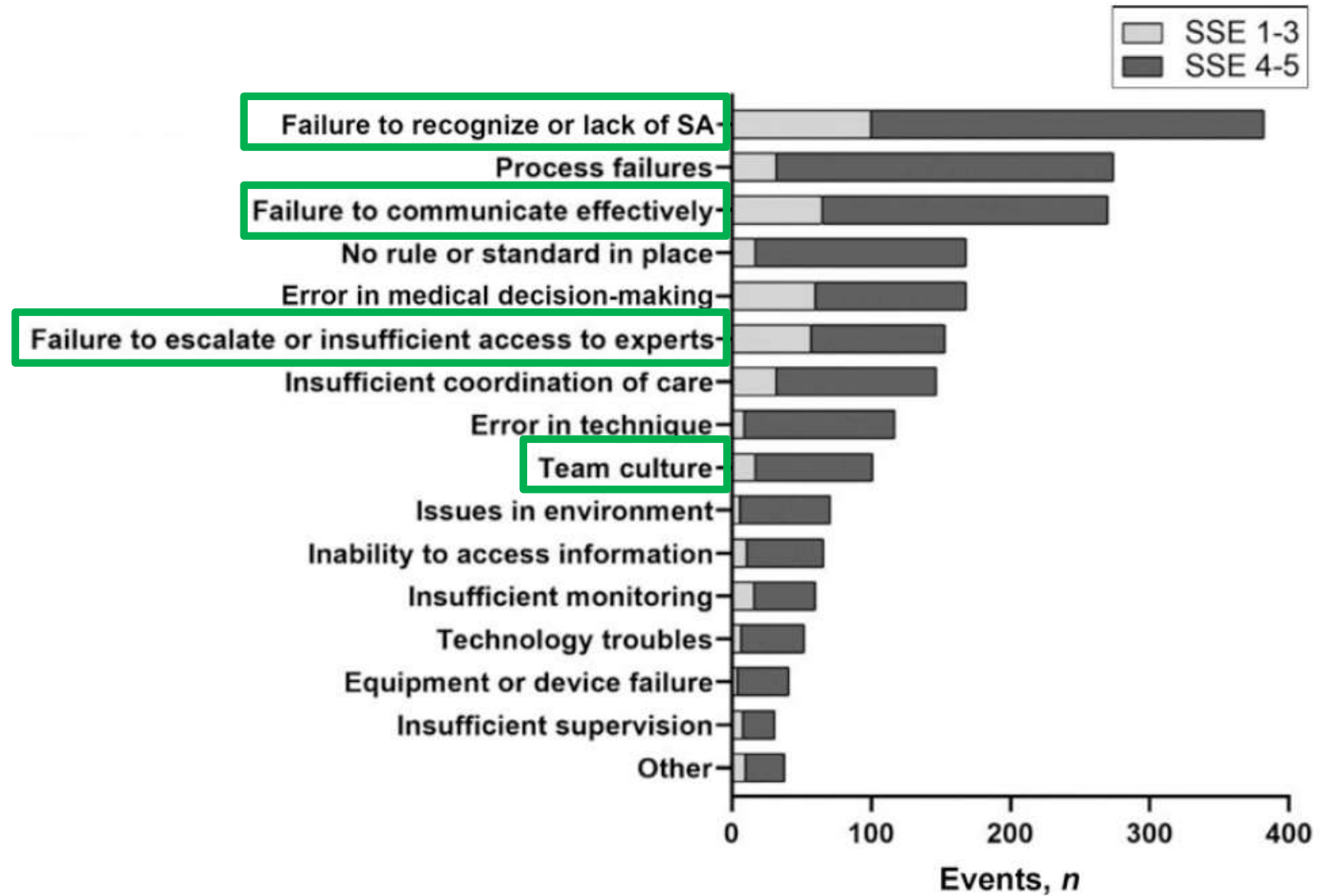
Learning System



© 2017 Institute for Healthcare Improvement and Safe & Reliable Healthcare

Source: Frankel A, Haraden C, Federico F, Lenoci-Edwards J. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017. (Available at ihi.org)

Serious Safety Event Contributing Factors



How do we measure quality and safety levels in healthcare?

In industry this is called [reduction of nonconformities](#), and [increasing yield](#)

In healthcare, we:

- Reduce infections
- Reduce falls
- Reduce untimely documentation
- Reduce readmissions
- Increase patient flow efficiency
- Many more...

[Improvement Science Methods \(like Lean Six Sigma\)](#) is a “non-conformity” and variation reduction strategy, increasing effectiveness and efficiency of services and products

Driving the Mission, Vision and Values



DNV



- Det Nordske Veritas Healthcare, Inc. (DNV Healthcare) received deeming authority from CMS September 26, 2008.
- DNV is a Norwegian Risk Management Company that was started in 1864 and began operating in the USA in 1898.
- Their focus is improved quality through Risk Mitigation and Quality Controls, utilizing the International Organizational Standards (ISO) model.
- As of 2022, they are accrediting around 800 US hospitals with an ever growing footprint.

Quality Management Principles



FOCUS

- **Understand:** Current & Future patient needs
- **Interaction:** Intentional patient and family focus
- **Attract and Retain:** Create brand loyalty
- **Relationships:** Maintain relationships with all interested parties



LEADERSHIP

- **Unity:** Strategic Purpose and Direction
- **Alignment:** Strategies, Policies, Processes & Resources
- **Engagement:** Create an environment where the team is engaged



TEAMING

- **Involve:** All staff at All levels
- **Respect:** All team members for their past experiences and ideas
- **Recognition, Empowerment, and Enhancement of People**



PROCESS/DATA APPROACH

- **QMS:** Composed group of interrelated processes
- **Work Systematically:** Break down the silos
- **Results:** The most successful results are achieved by the system – not individual processes
- **Focus:** Continuous improvement not instant perfection



FOCUS

LEADERSHIP

TEAMING

**PROCESS/
DATA
APPROACH**

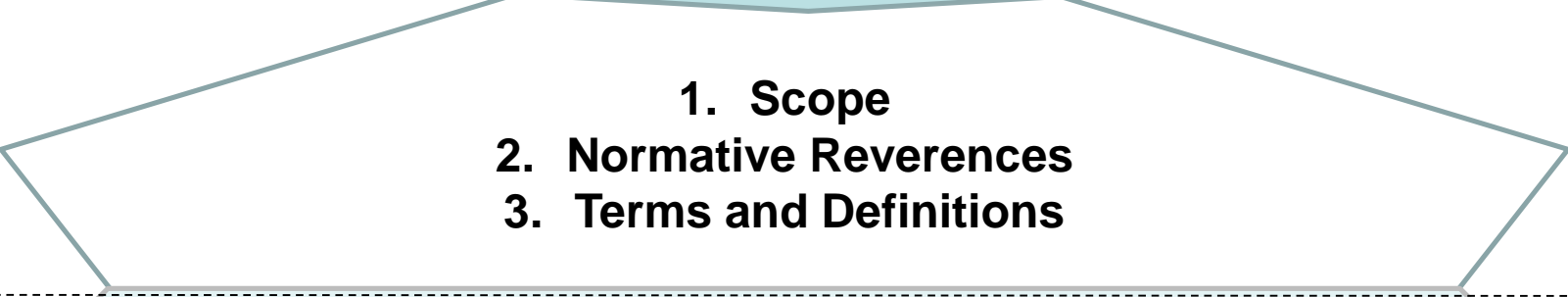
ISO Principles of Quality Management

ISO Model

- 9000: Fundamentals
- 9001: Service Systems**
- 9002: Manufacturing Systems
- 9003: Inspection/Testing
- 9004: Application/Mgmt of Quality Systems

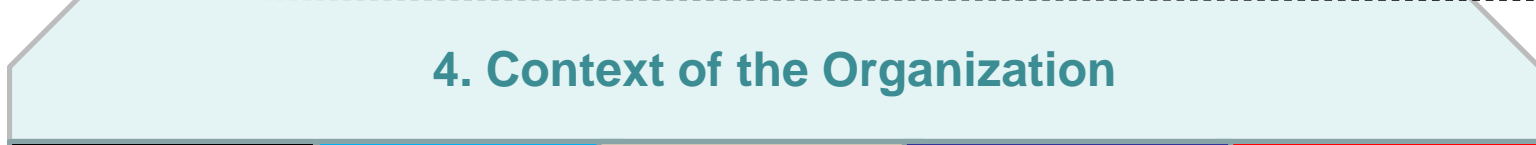


High Level Structure

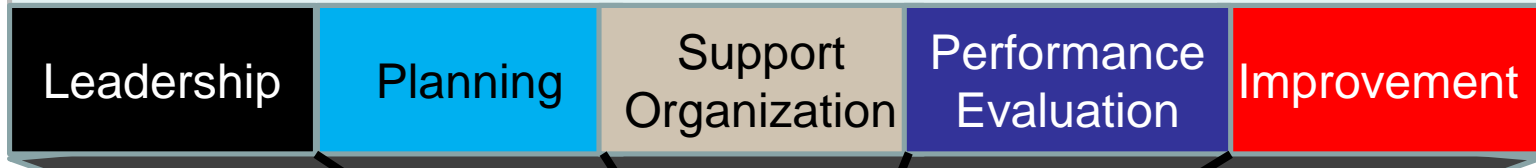


- 1. Scope**
- 2. Normative Reverences**
- 3. Terms and Definitions**

ISO Sections



4. Context of the Organization



Leadership

Planning

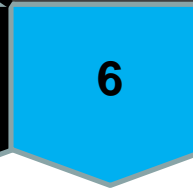
Support
Organization

Performance
Evaluation

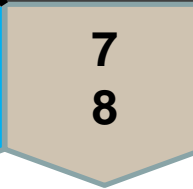
Improvement



5



6



7
8



9



10

EHS Quality Management System



Quality Management Systems

ISO 9001: 2015 is defined as the international standard that specifies requirements for a **quality management system (QMS)**

A **quality management system (QMS)** is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives

Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements

ISO 9001:2015 QUALITY MANAGEMENT STRUCTURE AND NIAHO INTEGRATION- SYSTEM APPROACH

- ISO 9001:2015
 - Provides structure (Skeleton) for:
 - Understanding
 - Who you are
 - What you do
 - Improving
 - How you do it
 - » Identification and mitigation of Risks
 - » Planning
 - » Internal Process Audit
- NIAHO standards (Muscle):
 - “Rules and Regulations”
 - CMS standards
 - NFPA standards



Section 5: Leadership



- Demonstrate leadership accountability (5.1.1)
- Customer focus (5.1.2)
- Establish and communicate quality policy (5.2.1-2)
- Oversee QMS (5.3)

Section 6: Planning



- Address risks and opportunities (6.1.1-2)
- Strategic Objectives (6.2.1-2)
- Anticipate and plan changes (6.3)

Section 7: Support



- Assess capability/provide resources (people, infrastructure, environment: 7.1.1-4)
- Measurement (7.1.5)
- Organizational knowledge and competencies (7.1.6; 7.2)
- Documented information (7.5)

Section 8: Operations



- Plan services, processes and products needed (8.1-2)
- Design and develop services (8.3)
- Control externally provided services (8.4)
- Control of non-conforming outputs (8.7)

Section 9: Performance Evaluation



- Monitor, measure and analyze performance for all key processes and outcomes (9.1)
- Internal audits (9.2)
- Management review (9.3)

Section 10: Improvement



- Opportunity prioritization (10.1)
- Root cause analysis (10.2)
- Continual improvement, standard QI methods (10.3)

QMS Engine

System Inputs

Voice of the Patient and Family

Unit/Department Top 10 Problem Lists (Risk-based Management)

Opportunity Identification by Frontline (Rounds/Audits)

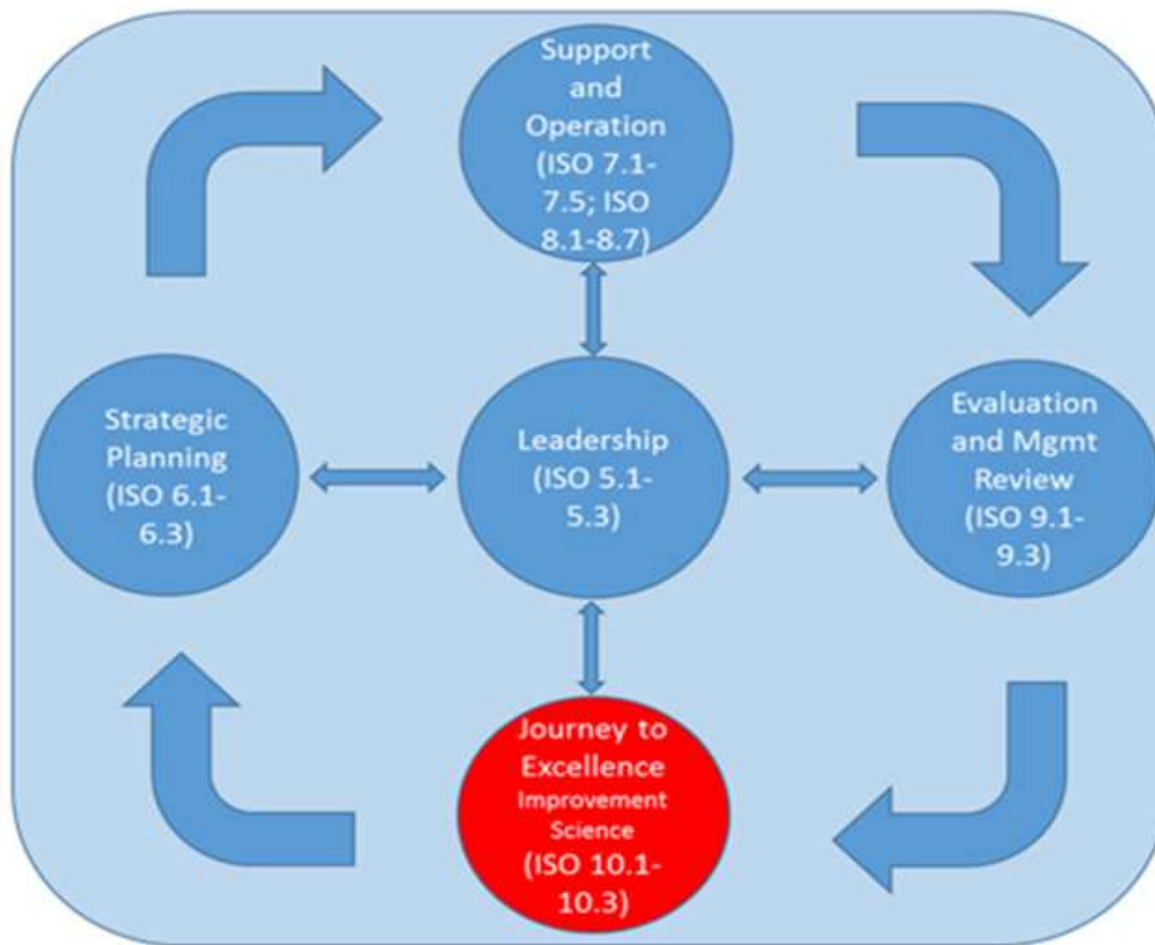
Regulatory Expectations

Staff Expectations

Community Responsibilities

Organizational Values

Best Practices



System Outputs

Patient/Family Satisfaction

Quality Outcomes

Zero Harm (Patients and Staff)

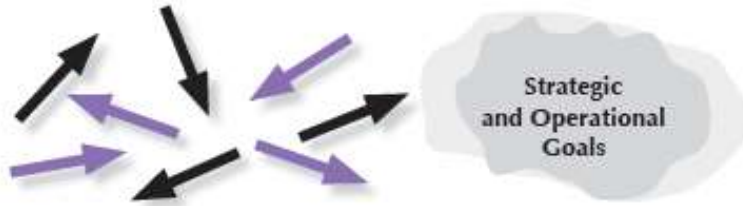
Regulatory Compliance

Staff Satisfaction and Retention

Community and Financial Value

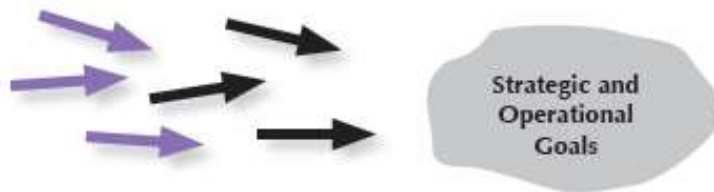
DNV and ISO 9001: 2015 Goal: Process Maturation

Reacting to Problems
(0–25%)



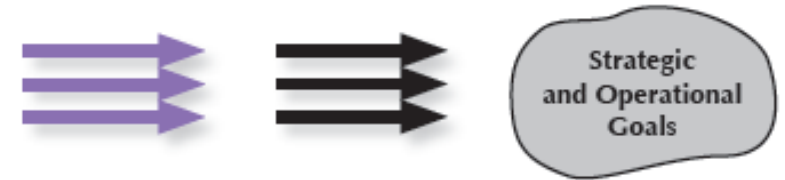
Operations are characterized by activities rather than by processes, and they are largely responsive to immediate needs or problems. Goals are poorly defined.

Early Systematic Approaches
(30–45%)



The organization is beginning to carry out operations with repeatable processes, evaluation, and improvement, and there is some early coordination among organizational units. Strategy and quantitative goals are being defined.

Aligned Approaches
(50–65%)



Operations are characterized by repeatable processes that are regularly evaluated for improvement. Learnings are shared, and there is coordination among organizational units. Processes address key strategies and goals.

Integrated Approaches
(70–100%)



Operations are characterized by repeatable processes that are regularly evaluated for change and improvement in collaboration with other affected units. The organization seeks and achieves efficiencies across units through analysis, innovation, and the sharing of information and knowledge. Processes and measures track progress on key strategic and operational goals.

DNV and ISO 9001: 2015 Goal: Learning Organization

Learning is an essential attribute of high-performing organizations. Effective, well-deployed organizational learning can help an organization improve from the early stages of reacting to problems to the highest levels of organization-wide improvement, refinement, and innovation.

1



Reacting to the problem (0–5%)
Run with the hose and put out the fire.

2



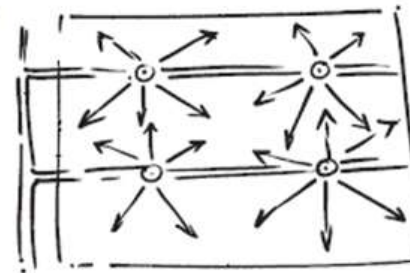
General improvement orientation (10–25%)
Install more fire hoses to get to the fires quickly and reduce their impact.

3



Systematic evaluation and improvement (30–45%)
Evaluate which locations are most susceptible to fire. Install heat sensors and sprinklers in those locations.

4



Learning and strategic improvement (50–65%)
Install systemwide heat sensors and a sprinkler system that is activated by the heat preceding fires.

5



Organizational analysis and innovation (70–100%)
Use fireproof and fire-retardant materials. Replace combustible liquids with water-based liquids. Prevention is the primary approach for protection, with sensors and sprinklers as the secondary line of protection. This approach has been shared with all facilities and is practiced in all locations.

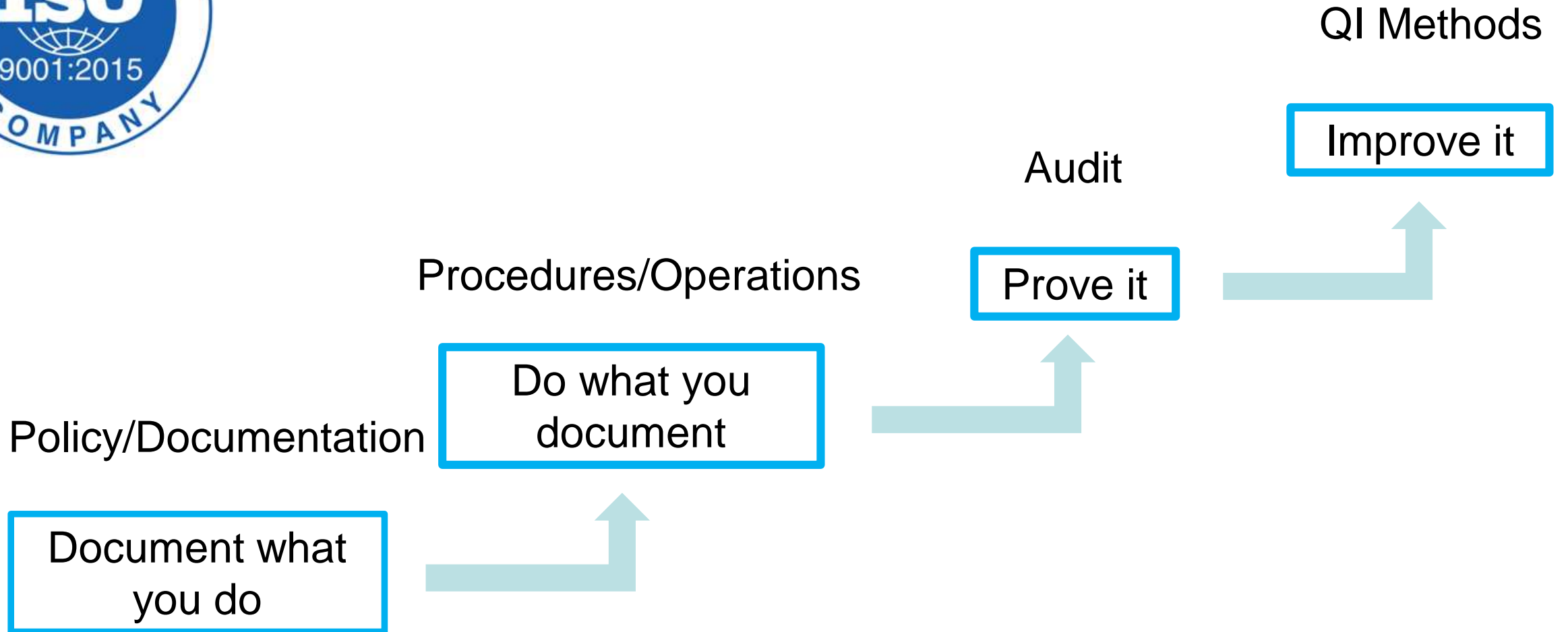
DNV Site Survey July 2022

Survey Process

- Annual survey cycle
 - Year 1: Re-accreditation survey
 - Year 2: Intra-cycle survey
 - Year 3: Intra-cycle survey
 - Year 4: Re-accreditation survey
- Surveyors
 - Clinical (Doctor/Nurse)
 - Generalist
 - Life Safety/ Physical Environment

(number of surveyors depends on facility size and type of survey)
- Review (Interviews/Documentation)
 - Mission/Vision/Values
 - Patient Care Processes
 - Environment of Care
 - Data, data, data, data





Achievements



Survey Mantra

- **SAY WHAT YOU DO**
 - Know your policies, procedures, plans, guidelines, etc.
- **DO WHAT YOU SAY**
 - Surveyor direct observation; show me your process
- **PROVE IT**
 - How do you validate the process/data?
- **IMPROVE IT**
 - Corrective action, performance improvement, sustainability

Tips and Review Recommendations

- Know our mission and be able to describe how you contribute to it.
- Comply with **hand hygiene, masking requirements** and wear **appropriate PPE**
- Be polite, respectful, courteous and **honest** – we are not trying to hide anything
- Make sure all unit logs are completed
- Remove the clutter, make sure your areas appear neat and organized
- Know your role in an emergency (fire drills, power failure, etc)
- Know your quality improvement activities – use your visual management board to display your actions
- Know how to confirm physician privileges
- Know how to locate policies
- Know how to find SDS sheets for chemicals used in your area

Documentation

- Patient Assessment and Re-assessment
 - Pain medications
 - Titrated medications based on an assessment (CIWA/RASS/TO4/vasopressors)
 - Required re-assessment based on procedures
- Plan of care
 - Include all active diagnosis
 - Include **Restraints** as indicated
- Document use of Interpreters for **key portions of care**
- Safety
 - Bar code scanning: medications, blood products, new lab labeling process
 - Fall prevention
 - Be able to describe how you report a safety event

Acknowledgements

- Quality, Safety and Service Leadership
 - Adam Campbell
 - Mike Bettinger
 - Jackie Bishop
 - Renee Grayson-Eubanks
 - Brooke Horne
 - Eileen Shrum
- And the whole Quality, Safety and Service Team
- Erlanger Health System leaders and frontline
- UT College of Medicine

*Thank
you*



Adam.Campbell@Erlanger.org
Jeffrey.Bennett@Erlanger.org