



2021 DNV-GL Healthcare Secrets to Success

Kelly Proctor, CHFM, CHSP, CHOP
Director of Operations.



April 22, 2021

ACCE gratefully acknowledges the sponsorship of this webinar by



About the Moderator



Binseng Wang ScD, CCE

- Binseng Wang is Vice President, Program Management with Sodexo CTM, an independent service organization
- Previously, Dr. Wang was Director, Quality & Regulatory Affairs for Greenwood Marketing, LLC, as well as Vice President, Quality & Regulatory Affairs, for Sundance Enterprises, Aramark Healthcare Technologies, and MEDIQ/PRN.
- He also worked as a Visiting Scientist at NIH and an Adjunct Professor at the Milwaukee School of Engineering.
- He is a fellow of ACCE and AIMBE. He received the 2010 AAMI CE Achievement Award, the 2015 ACCE Lifetime Achievement Award, and the 2019 AAMI-TRIMEDX Iconoclast Award, and was inducted into the Clinical Engineering Hall of Fame by ACCE in 2017.
- He earned a Doctor of Science degree from MIT and is a Certified Clinical Engineer (CCE).

Logistics

- All attendees have their microphones muted during the presentation.
- Questions to the panelists must be submitted via the “Q&A” feature (not chat) in Zoom at any time.
- If there is any urgent issue, please use the “chat” feature to communicate with the panelists.
- We will try to ask Kelly to answer questions not addressed during the webinar and distribute them to participants via email or post them to ACCE website.
- Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

About the speaker



Kelly resides in Acworth Georgia and has over 30 years of experience in the healthcare field. He is currently employed as the Director of Operations for DNV Healthcare. Kelly has performed over 500 surveys for DNV and has surveyed hospitals all over the United States, South America, Europe and Asia for DNV.

Kelly holds a Master's Degree in Mechanical Engineering and is a Certified Healthcare Facilities Manager and a Certified Healthcare Safety Manager as well as a Certified Healthcare Operations Professional. He is also a certified Lead Auditor for ISO 9001 and 14001 and a certified NIAHO Lead Surveyor.



Kelly Proctor
Director of Operations

Session Description

The attendee of this session should be able to discuss:

- ▶ DNV survey activities, including changes due to the pandemic
- ▶ What NIAHO is and how its used
- ▶ Why is ISO 9001 so important
- ▶ PE.7 Medical Equipment Requirements
- ▶ Common deficiencies cited on surveys pertaining to Medical Equipment Management

A few things to update you on:

- DNV-GL loses the GL association
- Randy Snelling
- Paul Bailey
- Remote surveys and training

NIAHO[®] Surveyors and Survey Activities

DNVGL Accreditation Progression

- **1st visit:**
 - Gain Accreditation to NIAHO® - meet the requirements of CMS
 - ISO introduction & education; compliance or certification within 3 years
- **2nd visit:** 1 year after accreditation
 - Continue Accreditation by undergoing a survey to NIAHO®
 - Survey for progress in implementing ISO 9001
- **3rd visit:** 2 years after accreditation
 - Continue Accreditation by undergoing survey to NIAHO®
 - Continue to work toward ISO 9001 Implementation (ISO dress rehearsal)
- **4th visit:** 3 years after accreditation
 - NIAHO® survey and last year to achieve ISO 9001 compliance/certification
 - If in compliance with ISO 9001 – a statement included in Certificate of Accreditation
 - May choose to demonstrate compliance by obtaining a separate ISO 9001 Certificate

Survey Team Composition

➤ Clinical Surveyor

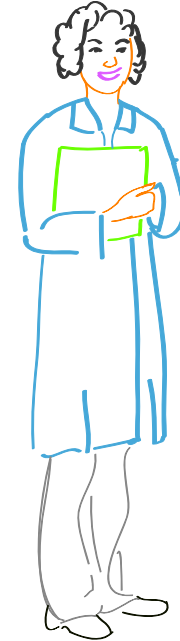
- Patient Care Unit Visits (Clinical Settings)
- Med/ Surg, ICU, CCU, Obstetrics, Emergency Department
- High acuity units

➤ Generalist Surveyor

- Quality Management Review
- Medication Management
- Medical Staff and Human Resources Review
- Utilization Review Interview
- Patient Grievance Interview
- Med/Surg & Ancillary / Support Services Review (Lab, Medical Imaging, Rehab, etc.)

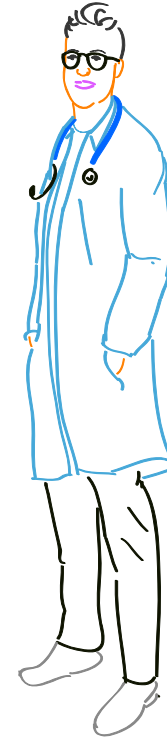
➤ Physical Environment / Life Safety Surveyor

- All Physical Environment aspects and Management Plans
- Physical Environment / Comprehensive Building Tour
- Biomedical Engineering & Calibration of Equipment



DNV Survey Process Innovations

- Annual on-site surveys
- Collaborative
- Less prescriptive
- Allows organization innovation
 - More than one way to accomplish a goal
 - Encourages best practices
 - ISO Tenets
 - Document what you do
 - Do what you document
 - Prove it
 - Improve it



What does NIAHO stand for?

National Integrated Accreditation for Healthcare Organizations

What is NIAHO?

NIAHO is the DNV standards that incorporate the Center for Medicaid and Medicare Services (CMS) Conditions of Participations (COP's), NFPA, OSHA and other standard requirements.

How do the NIAHO standards apply to medical equipment and what is expected from the maintainer?

Why is this important?

What's expected from the NIAHO side

The hospital has a responsibility to ensure that an effective process is in place for obtaining new equipment, the safe use of equipment, and appropriate selection of equipment.

How is this done?

The hospital has a responsibility and shall address issues related to the organization's initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.

What does this mean?

What's expected from the NIAHO side

The Medical Equipment Management System shall address criteria for the selection of equipment

The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).

The hospital shall have a process for reporting and investigating equipment management problems, failures, and user errors.

The hospital shall address a process for determining timing and complexity of medical equipment maintenance.

NIAHO® PE.7 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

The hospital shall have a process for reporting and investigating equipment management problems, failures, and user errors.

What is this and how is this done?

The Hospital shall address a process for determining timing and complexity of medical equipment maintenance.

The hospital shall address the process of receiving and responding to recalls and alerts.

A Discussion of the ISO 9001 2015 Concepts that affect the Accreditation of the PE with DNV Healthcare

- **Who Developed ISO 9001?**

- ISO 9001 was developed through the **International Organization for Standardization**

- This organization began in 1946 and published the first revision of the ISO 9001 standard in 1987
 - The current revision of ISO 9001 is the revision four dated 2015
 - The 2015 9001 standard is a Quality Management System that requires the organization to perform risk based thinking

- **When did ISO 9001 become recognized by healthcare?**

- Healthcare has started to embrace ISO 9001 within the last several years (primarily since 2008)
 - More recently with DNV-GL receiving deeming authority from the Centers for Medicare and Medicaid Services, (CMS) to accredit hospitals in 2008, ISO 9001 is rapidly gaining recognition in healthcare

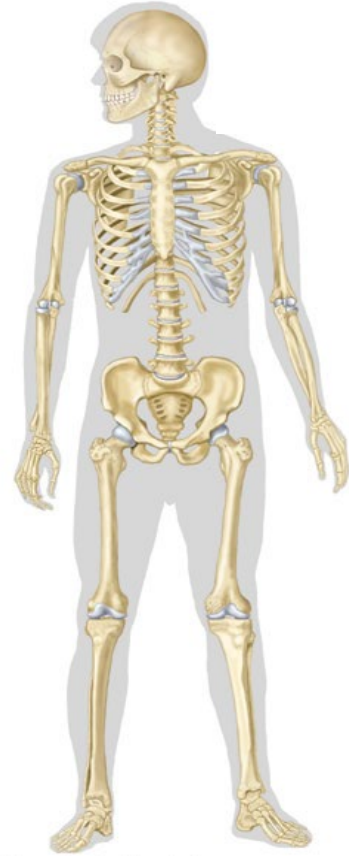
About ISO 9001

What is ISO 9001?

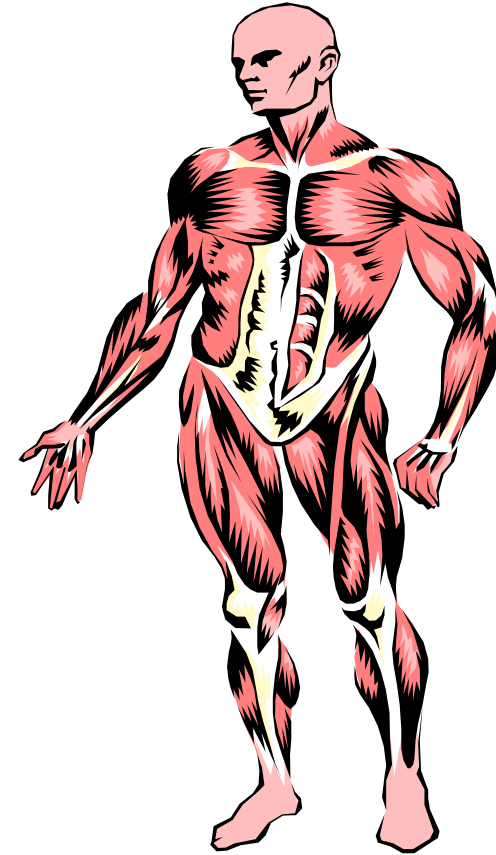
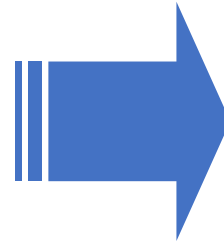
ISO 9001 is a quality management system that forces continual improvement through risk based thinking.

- ISO 9001 is an international standard by which organizations manage the quality, business and compliance of the organization
- ISO 9001 is currently being embraced in healthcare to:
 - Improve patient care and organizational performance
 - Provide a team oriented culture for management
 - Close serious gaps in the current accreditation process

ISO System Structure

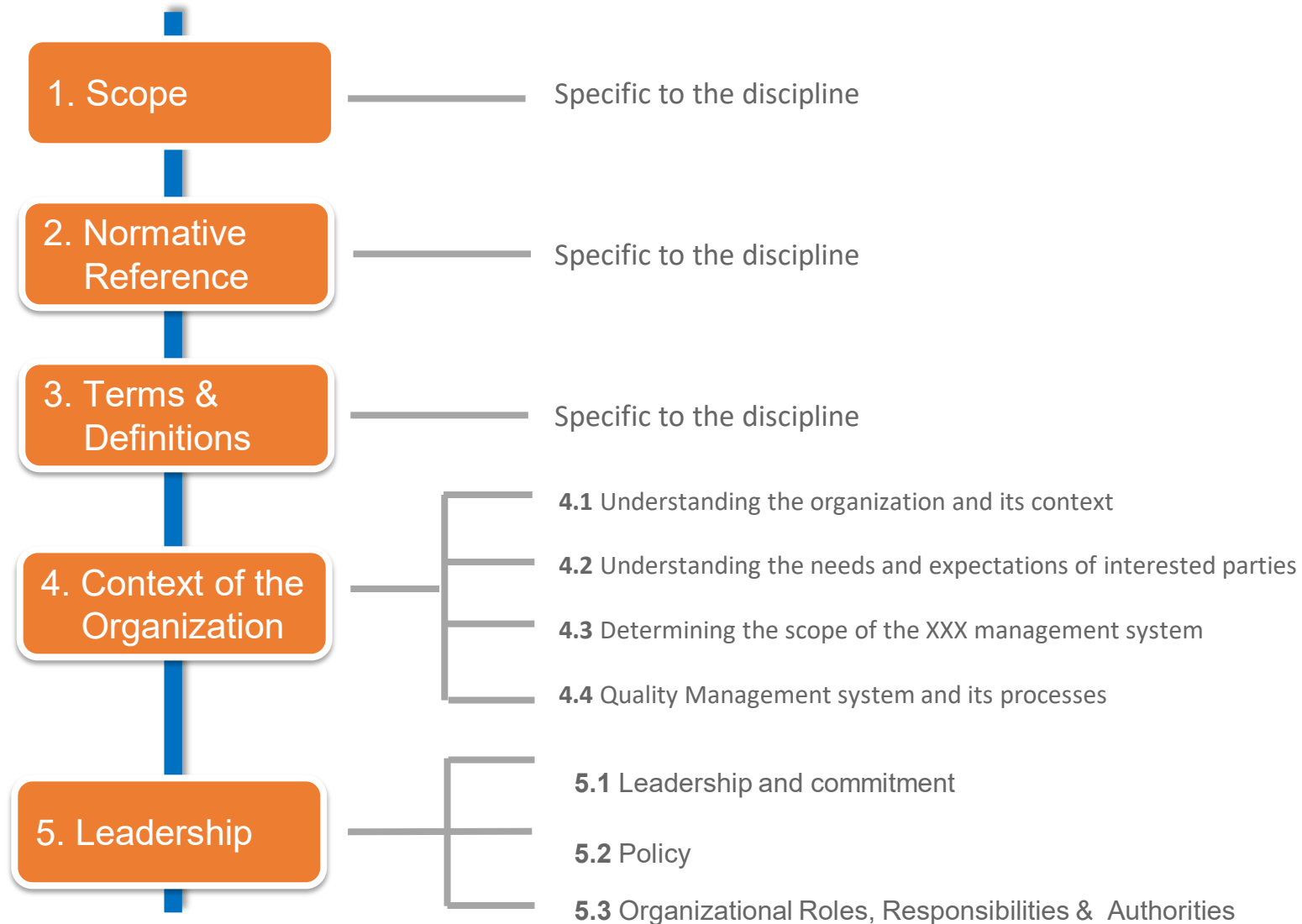


ISO 9001 Systems

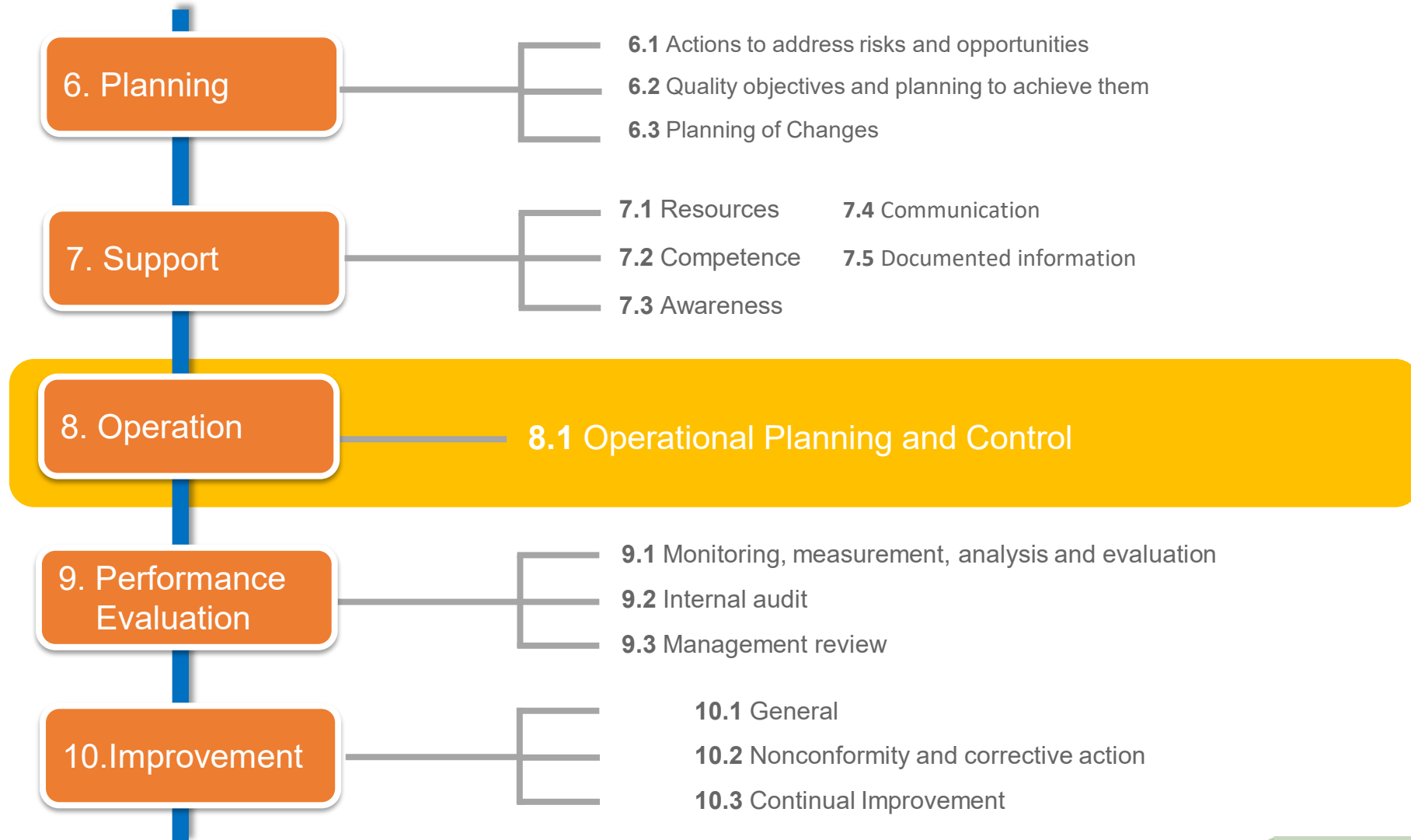


Operational-Business
Practices-Regulatory

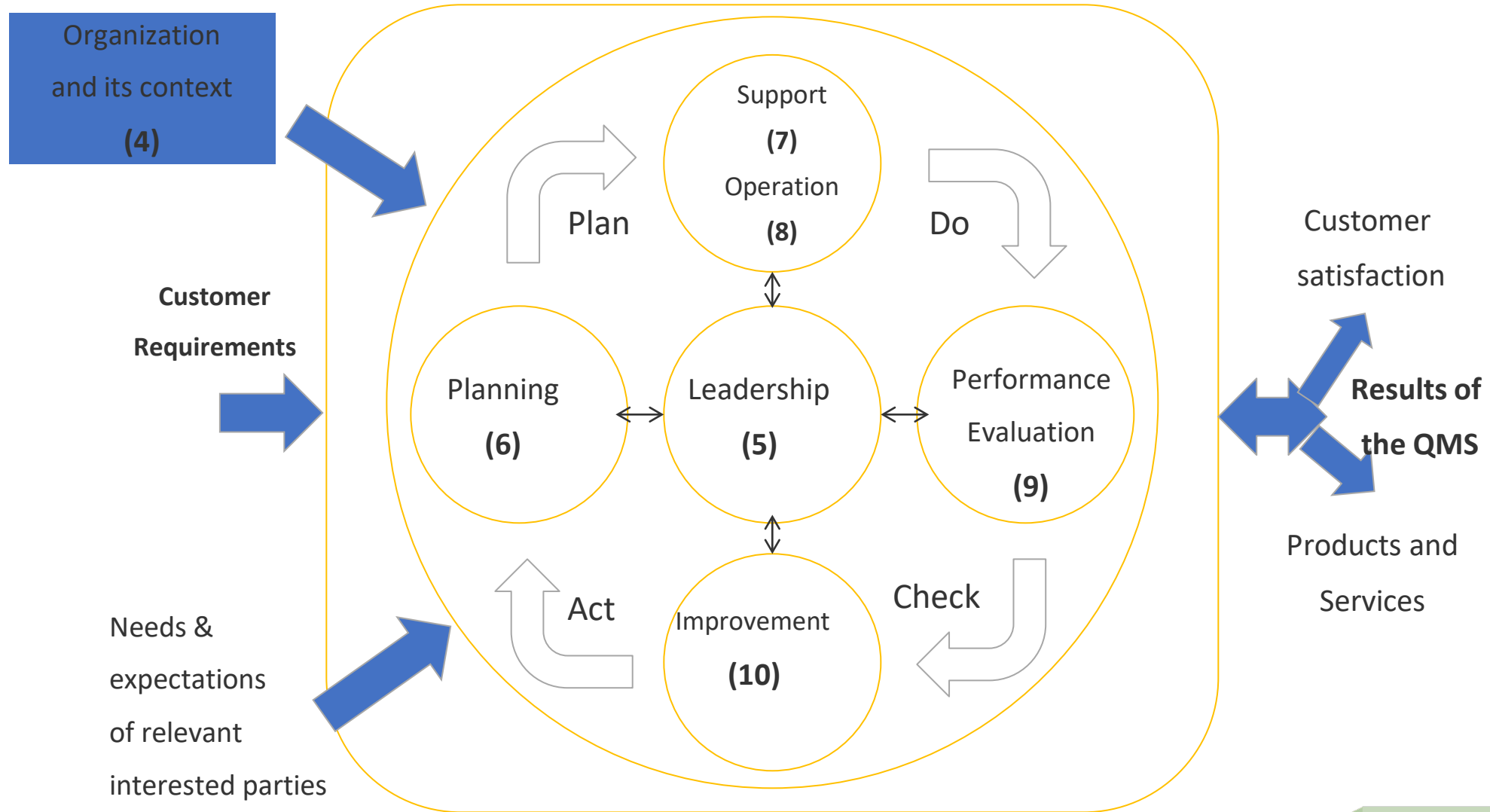
ISO 9001:2015 - 10 Clause structure



ISO 9001:2015 – 10 Clause structure



Quality Management System Standards



PE.7 Medical Equipment Requirements

7.1 Resources

- 7.1.2 People
 - The **Hospital** shall provide the persons necessary for the effective operation of the QMS
- 7.1.3 Infrastructure
 - The **Hospital** shall determine, provide and maintain the infrastructure for the operation of its processes
 - Buildings, workspace, associated utilities
 - Process equipment (hardware and software)
 - Support services (communications, transportation, etc.)

7.1 Resources

- **7.1.4 Environment for the operation of processes**
- The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.
- **NOTE** A suitable environment can be a combination of human and physical factors, such as:
 - Physical, social, psychological, environment (temperature, humidity, ergonomics, cleanliness)



7.1 Resources

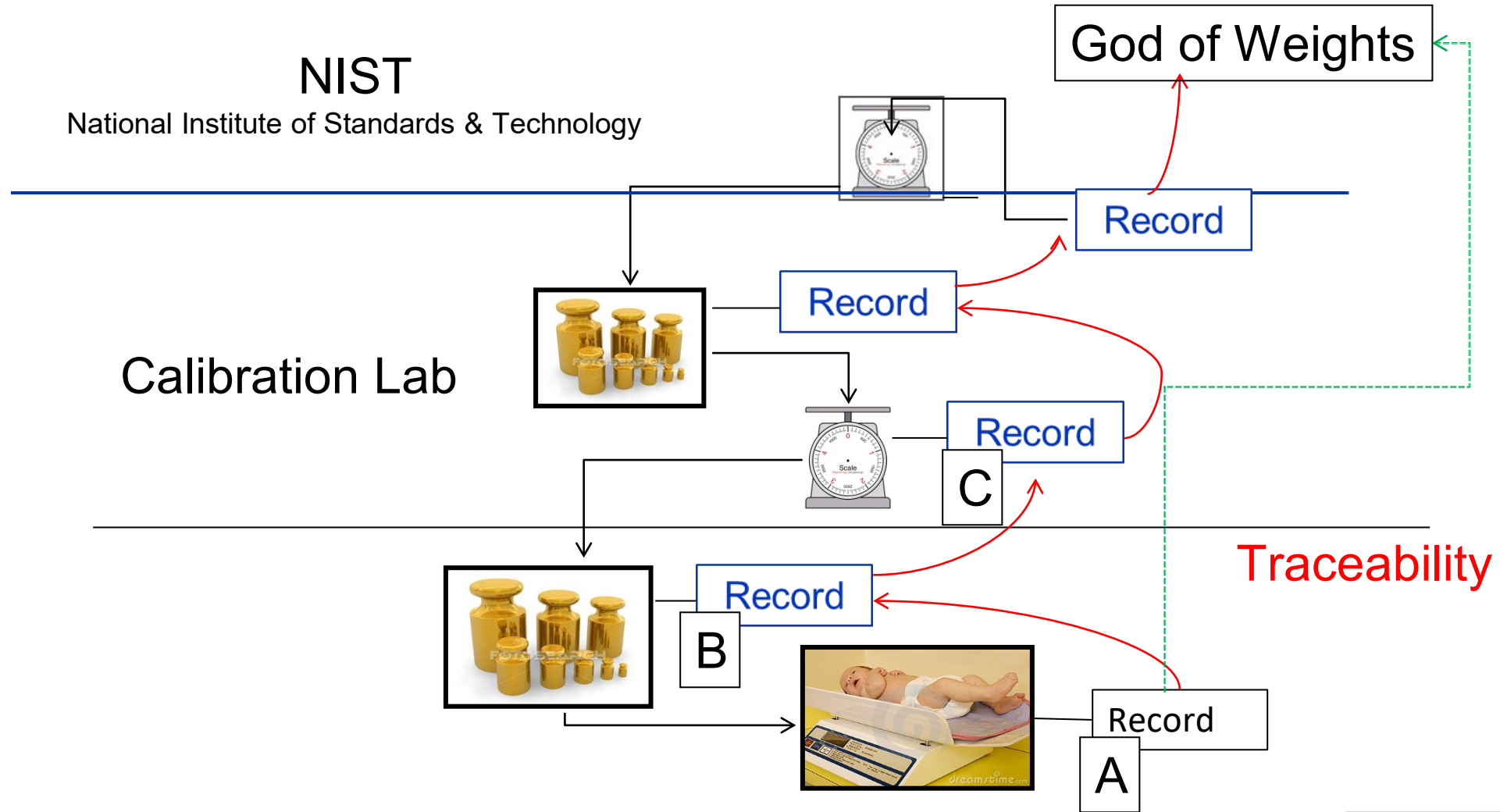
• 7.1.5 Monitoring and measuring resources

- Where measurement traceability is a **requirement**, measuring instruments shall be:

- a) Calibrated or verified at specified intervals or prior to use against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be retained as documented information;



7.1.5 Monitoring and measuring equipment



7.1.5.2 Measurement traceability

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

***WHAT ARE THE TOP 5 DNV
MEDICAL EQUIPMENT FINDINGS?***

Top 5 Common Survey Findings for Medical Equipment

1. Failure to calibrate scales when there is a requirement to do so
2. No traceability to test equipment
3. Hospital leadership unaware of AEM program and what's included in it
4. No process in place to inspect incoming equipment
5. Hospital test equipment past due for maintenance and calibration



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