MANAGING RISK

Making Healthcare Healthier™

DNV Healthcare

NIAHO® Accreditation for Hospitals

Challenges in the Physical Environment

Interlink 2013 April 8, 2013

Driving Value Through Efficiency - Weathering the Storm

Randall Snelling
Chief Physical Environment Officer, DNVHC Inc.

Learning Objectives for this Session

MANAGING RISK

- The attendee will know the latest developments in Life Safety issues including new required processes in barrier wall control management and CMS waiver requests.
- The attendee will know areas in which DNV has identified in hospitals where inadequate processes to monitor staff exposure to hazardous materials are common.
- The attendee will know the scope of issues directly related to managing infection risk that DNV surveyors are currently focusing
- The attendee will know issues related to the application of the ISO 9001:2008 Standard to Medical Equipment Management including processes controlling calibration traceability and nonconformance, ensuring the adequate confirmation of specified purchased product, and issues related to identification of nonconforming equipment including that which is "unable to locate".

Core Competence: Third Party Evaluations

MANAGING RISK

Maritime

Defense

Food & Beverage

Transportation

Energy

Managing risk

IT & Telecom

Public Sector

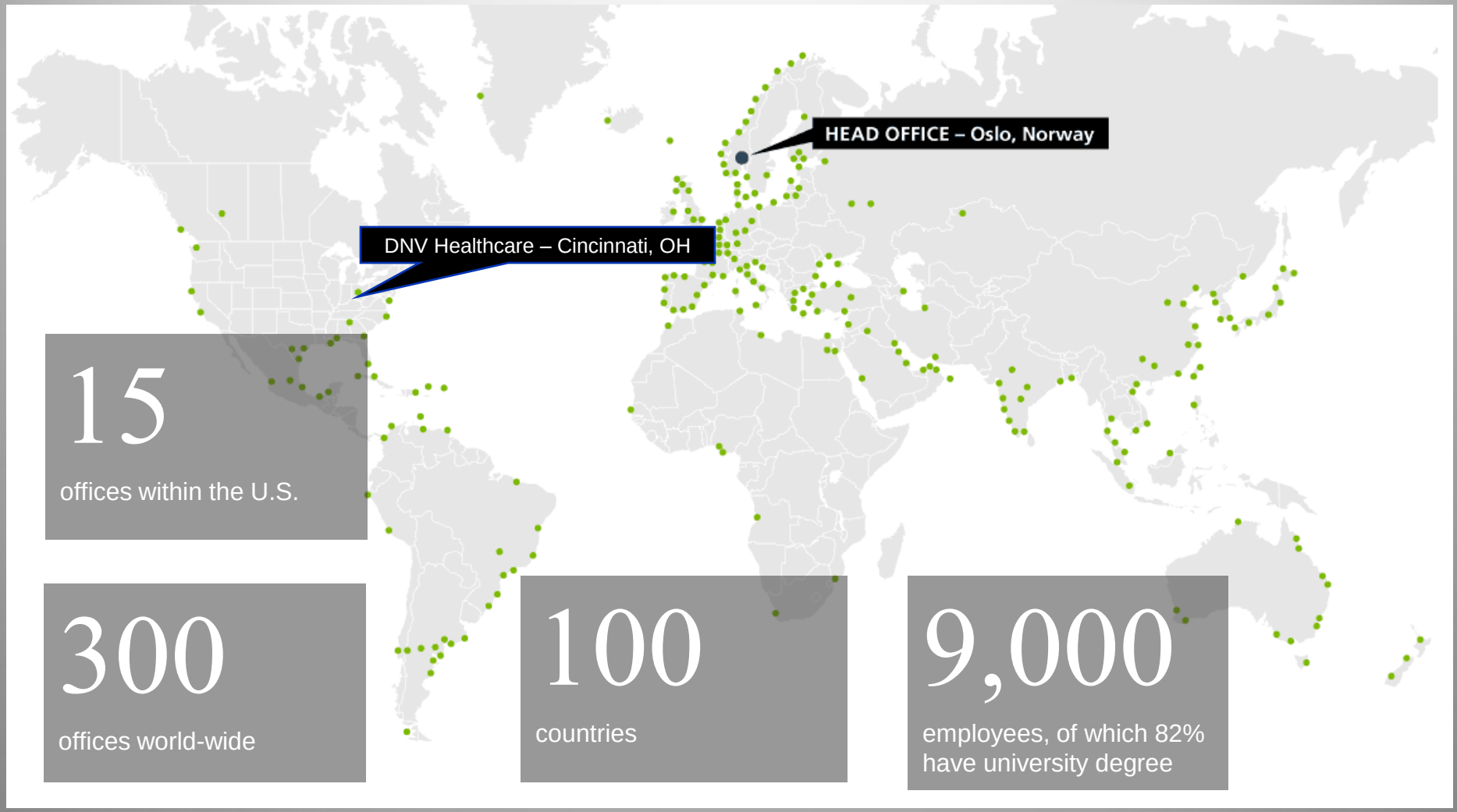
Automotive

Finance

Health Care

Highly skilled people across the world

MANAGING RISK



15
offices within the U.S.

300
offices world-wide

100
countries

9,000
employees, of which 82% have university degree

Key Features

MANAGING RISK

Feature of NIAHO®	Benefit to Hospital
Stable standards, infrequent change	Sustainable system
Annual Surveys	**Constant readiness**
ISO 9001 Gradual Introduction @ no additional staff	More value, lower $
Focus on sequence and interactions of processes throughout the hospital	Clear, traceable pathway to improve
Demeanor of the survey team	Collaboration, sharing of ideas
No survey findings "tipping" point	**Fear becomes confidence**

DNV Healthcare Inc.

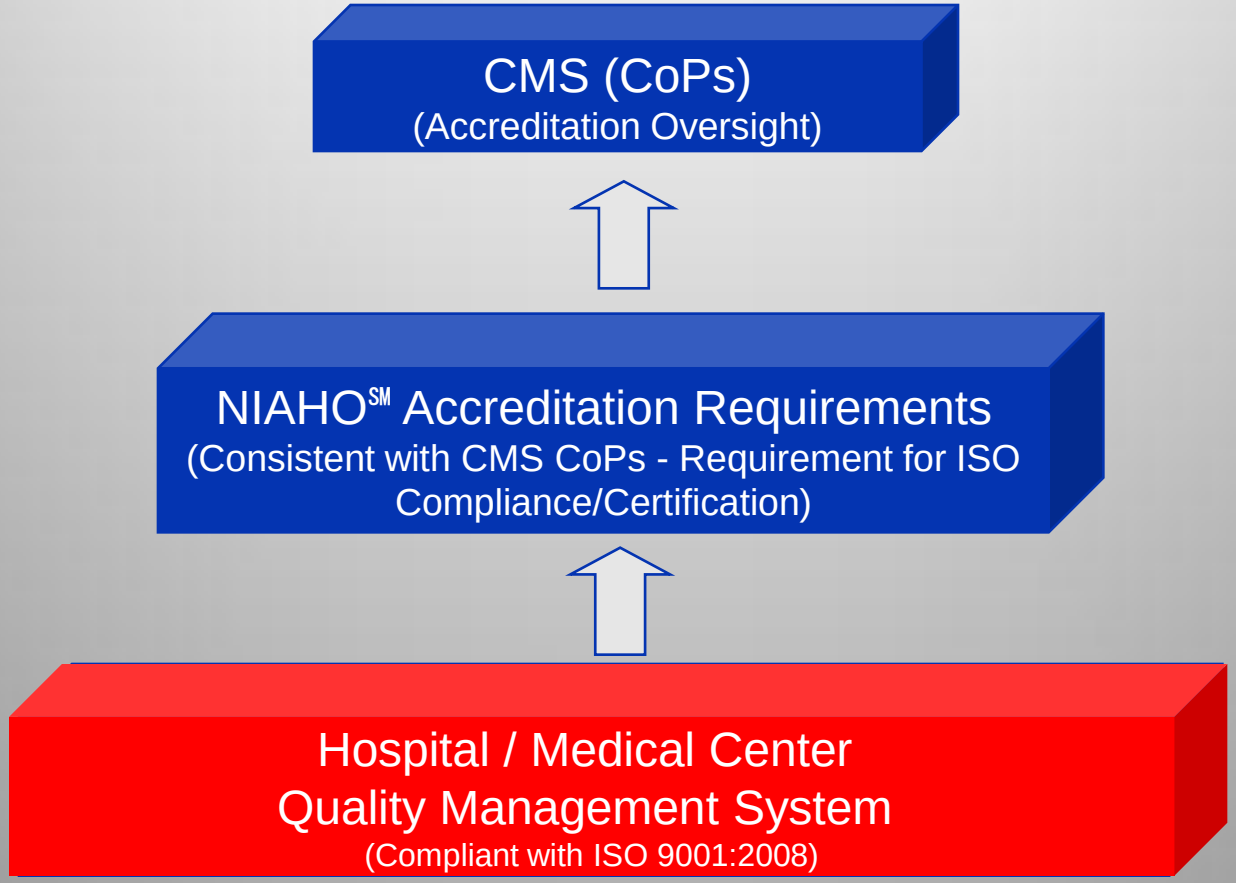
MANAGING RISK

NIAHO℠ and ISO 9001 Quality Management System

Hospital Accreditation: Integration of NIAHO℠ Standards with ISO 9001 Quality Management System Standards

Infrastructure and Accreditation

MANAGING RISK



MANAGING RISK

NIAHO℠ Surveyors & Survey Activities

DNV Survey Process Innovations

MANAGING RISK

- 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

Survey Team Composition

MANAGING RISK

- **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

Survey Activities

MANAGING RISK

Survey activities are carried out as follows:

- **A comprehensive review includes observation of care/services provided to the patient in all patient care areas, both in and out, patient and/or family interview(s), staff interview(s), and medical record review.**
- **Using Tracer methodology, department/patient unit visits to include staff interviews and open medical record review as appropriate (both clinical and support departments)**
  - **identify performance issues**
  - **handoff between steps**
  - **Tracer methodology**
- **Visits to non-clinical support areas**
- **Comprehensive Building Tour (days, not hours)**

NIAHO Standards - Chapters

MANAGING RISK

- Quality Management System
- Governing Body
- Chief Executive Officer
- Medical Staff
- Nursing Services
- Staffing Management
- Rehabilitation Services
- Obstetric Services
- Emergency Department
- Outpatient Services
- Dietary Services
- Patient Rights
- Infection Control
- Medical Records Service
- Medication Management
- Surgical Services
- Anesthesia Services
- Laboratory Services
- Respiratory Care Services
- Medical Imaging
- Nuclear Medicine Services
- Discharge Planning
- Utilization Review
- Physical Environment
- Organ, Eye and Tissue Procurement

DNV Physical Environment Management Systems

MANAGING RISK

PE.1 Facility

PE.2 Life Safety Management System

PE.3 Safety Management System

PE.4 Security Management System

PE.5 Hazardous Material (Hazmat) Management System

PE.6 Emergency Management System

PE.7 Medical Equipment Management System

PE.8 Utility Management System

MANAGING RISK

NIAHO®PE.1 Facility Management System

NIAHO®PE.1 Facility Management System

MANAGING RISK

- SR.3 The organization shall have policies, procedures and processes in place **to manage staff activities,** as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization's patients, staff, and others.
- SR.4 The organization shall have a **documented process, policies and procedures** to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are **prevented, controlled investigated, and reported throughout the organization.**
- SR.5 The organization shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be **forwarded to Quality Management oversight.**
- SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to **identify any patterns or trends.**
- SR.8 Significant physical environment data/information shall be **disseminated regularly to Quality Management oversight.**

MANAGING RISK

NIAHO®PE.2 Life Safety Management System

CMS Waiver Process

MANAGING RISK

- Hospital is cited for Life Safety Deficiency
- Hospital documents desire to apply for CMS waiver in Accreditation Organization (AO) Corrective Action Plan (CAP)
- Waiver Request Approved by Accreditation Organization (AO)
- Forward to State Agency (SA)
- State Agency forwards to CMS Regional Office
- RO grants/refuses waiver

CMS Waiver Process Steps posted by SA

MANAGING RISK

1. **Floor Plan indicates the location** of the LSC deficiency on a simplified floor plan showing the floor, wing, and room names affected.
2. **Cost Estimate (required)** analyzes a range of cost alternatives to correct the deficiency, then forwards a reasonable cost estimate from a reputable third party, that is two years or less in age. Costs can include relocation of residents during construction and disruption of services. Provider must ensure that the scope of work is identified within the cost estimate.
3. Financial Hardship (required) explains **how strict compliance would pose a financial hardship** to the facility's viability: simplified fiscal year 'profit & loss" statement; availability of financing; payback period if deficiency is corrected, or; remaining useful life of the building.
4. Residents health & Safety (required). Provider evidence that the LSC **deficiency does not pose a hazard to occupants** by detailing compensating safeguards that exceed code-minimum is required.

Required Barrier Penetration Permit Programs

MANAGING RISK

- SR.4 The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.
- The fire control plan shall provide for the following (NFPA 101-2000, 18.7.2.2 & 19.7.2.2):
  - SR.4a. Use of alarms
  - SR.4b. Transmission of alarm to fire department
  - SR.4c. Response to alarms
  - SR.4d. Isolation of fire
  - SR.4e. Evacuation of immediate area
  - SR.4f. Evacuation of smoke compartment
  - SR.4g. Preparation of floors and building for evacuation
  - SR.4h. Extinguishment of fire

Required Barrier Penetration Permit Programs

- ***The Life Safety Management System shall: include in the elements of SR.4d a written plan for the protection of the integrity of hospital smoke and fire barriers.***

- ***The plan should include:***
  - ***Name(s) of Responsible hospital staff for barrier protection program***
  - ***Requirement for written permission for anyone (including all hospital staff, contractors and vendors) to penetrate a smoke or fire barrier wall, ceiling or floor***
  - ***Input from Infection Control and Prevention Practitioner on critical clinical areas prior to issuance of written permit for performing work on barriers***
  - ***Establishment of monitoring process to ensure all work is completed correctly***

MANAGING RISK

NIAHO®PE.3 Safety Management System

PE.3 JHA and PPE

- 1910.132(d)(1)The employer shall assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE). If such hazards are present, or likely to be present, the employer shall
  - 1910.132(d)(1)(ii)Communicate selection decisions to each affected employee; and,
  - 1910.132(d)(1)(iii)Select PPE that properly fits each affected employee. Note: Non-mandatory Appendix B contains an example of procedures that would comply with the requirement for a hazard assessment
- 1910.132(d)(2)The employer shall verify that the required workplace hazard assessment has been performed through a written certification that identifies the workplace evaluated; the person certifying that the evaluation has been performed; the date(s) of the hazard assessment; and, which identifies the document as a certification of hazard assessment.
- 1910.132(d)(1)(i)Select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment;

NIAHO®PE.3 Safety Management System: Radiation Monitoring

MANAGING RISK

- **1910.1096(d) Precautionary procedures and personal monitoring.**
- **1910.1096(d)(1) Every employer shall make such surveys as may be necessary for him to comply with the provisions in this section. Survey means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.**
- **1910.1096(i)(2) All individuals working in or frequenting any portion of a radiation area shall be informed of the occurrence of radioactive materials or of radiation in such portions of the radiation area; shall be instructed in the safety problems associated with exposure to such materials or radiation and in precautions or devices to minimize exposure; shall be instructed in the applicable provisions of this section for the protection of employees from exposure to radiation or radioactive materials; and shall be advised of reports of radiation exposure which employees may request pursuant to the regulations in this section.**

NIAHO®PE.3 Safety Management System: Radiation Monitoring

MANAGING RISK

- *The hospital policies and procedures must address the safety standards for the following:*
  - ***Adequate shielding*** *for patients, personnel and facilities;*
  - *Labeling of radioactive materials, waste, and hazardous areas;*
  - ***Transportation of radioactive materials*** *between locations within the hospital;*
  - ***Securing radioactive materials****, including determining limitations of access to radioactive materials;*
  - *Testing and maintenance of equipment for prevention of radiation hazards;*
  - *Maintenance monitoring and measuring devices for equipment;*
  - *Proper storage of radiation monitoring badges when not in use;*
  - *Storage and disposal of radio nuclides and radio pharmaceuticals as well as radioactive waste; and,*
  - *Methods of identifying patients who may be pregnant.*

NIAHO®PE.3 Safety Management System: Glutaraldehyde Monitoring

MANAGING RISK

- **Health effects of glutaraldehyde exposure include:**
- **Short term (acute) effects:** Contact with glutaraldehyde liquid and vapor can severely irritate the eyes, and at higher concentrations burns the skin. Breathing glutaraldehyde can irritate the nose, throat, and respiratory tract, causing coughing and wheezing, nausea, headaches, drowsiness, nosebleeds, and dizziness.
- **Long-term (chronic) effects:** Glutaraldehyde is a sensitizer. **This means some workers will become very sensitive to glutaraldehyde and have strong reactions if they are exposed to even small amounts.** Workers may get sudden asthma attacks with difficult breathing, wheezing, coughing, and tightness in the chest. Prolonged exposure can cause a skin allergy and chronic eczema, and afterwards, exposure to small amounts produces severe itching and skin rashes. **It has been implicated as a possible cause of occupational asthma**.

NIAHO®PE.3 Safety Management System: Glutaraldehyde Monitoring

MANAGING RISK

- **Limit exposure to glutaraldehyde through work practice, engineering controls and personal protective equipment (PPE) including: Make sure that rooms in which glutaraldehyde is to be used are well ventilated and large enough to ensure adequate dilution of vapor, with a minimum air exchange rate of 10 air changes per hour.**
  - ✓ Ideally, **install local exhaust ventilation** such as properly functioning laboratory fume hoods (capture velocity of at least 100 feet per minute) to control vapor.
  - ✓ Keep glutaraldehyde baths **under a fume hood** where possible
  - ✓ Use only enough glutaraldehyde to perform the required disinfecting procedure.
  - ✓ Store glutaraldehyde in closed containers in well ventilated areas. Air-tight containers are available. Post signs to remind staff to replace lids after using product.
  - ✓ Use specially designed, mobile, compact, disinfectant soaking stations to facilitate sterilization of heat sensitive equipment such as endoscopes, or GI scopes. These soaking stations provide an enclosed area for sterilizing trays, and remove fumes from glutaraldehyde and other disinfectants.
- *Best Practices for the Safe Use of Glutaraldehyde in Health Care*, Pub 3258-08N 2006

NIAHO®PE.3 Safety Management System: Formaldehyde Monitoring

MANAGING RISK DNV

- **1910.1048(d)(1)(i)**Each employer who has a workplace covered by this standard **shall monitor employees to determine their exposure to formaldehyde.**
- **1910.1048(d)(1)(ii)**Exception. **Where the employer documents**, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace **cannot result in airborne concentrations** of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, **the employer will not be required to measure employee exposure to formaldehyde**
- **1910.1048(d)(2)**Initial monitoring. The employer shall **identify all employees who may be exposed** at or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.
- **1910.1048(d)(2)(iii)**If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer **shall promptly monitor the affected** employee's exposure

NIAHO®PE.3 Safety Management System: Formaldehyde Monitoring

MANAGING RISK

- **1910.1048(d)(3)(i)**The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.
- **1910.1048(d)(3)(ii)**If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.
- **1910.1048(d)(3)(iii)**If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.
- **1910.1048(d)(4)**Termination of monitoring. The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation

NIAHO®PE.3 Safety Management System: Anaesthetic Gas Monitoring

MANAGING RISK

- **OSHA recommends that air sampling for anesthetic gases be conducted every 6 months to measure worker exposures and to check the effectiveness of control measures. Furthermore, OSHA recommends that only the agent(s) most frequently used needs to be monitored, since proper engineering controls, work practices and control procedures should reduce all agents proportionately. However, the decision to monitor only selected agents could depend not only on the frequency of their use, but on the availability of an appropriate analytical method and the cost of instrumentation. [ASA emphasizes regular maintenance of equipment and scavenging systems, daily check-out procedures for anesthesia equipment, and education to ensure use of appropriate work practices. It does not believe that a routine monitoring program is necessary when these actions are being carried out. ASA prefers to use monitoring when indicated such as in the event of known or suspected equipment malfunction. The Academy of General Dentistry also emphasizes properly installed and maintained analgesia delivery systems.]**
- **Nitrous Oxide monitoring is to be performeed quarterly**
- ***Anesthetic Gases: Guidelines for Workplace Exposures :*** www.OSHA.gov

NIAHO®PE.3 Safety Management System Sound Pressure Monitoring

MANAGING RISK

- **Occupational exposure to high noise levels from loud machinery in the laundry area, generator rooms, boiler rooms, and lawn maintenance equipment can lead to occupationally induced hearing loss, hearing impairment, hypertension, elevated blood pressure levels and other health hazards.**
- **OSHA 1910.95(c)(1)The employer shall administer a continuing, effective hearing conservation program, as described in paragraphs (c) through (o) of this section, whenever employee noise exposures equal or exceed an 8-hour time-weighted average sound level (TWA) of 85 decibels measured on the A scale (slow response) or, equivalently, a dose of fifty percent. For purposes of the hearing conservation program, employee noise exposures shall be computed in accordance with appendix A and Table G-16a, and without regard to any attenuation provided by the use of personal protective equipment.**

MANAGING RISK

NIAHO® (IC) INFECTION PREVENTION AND CONTROL

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Cleaners

MANAGING RISK

- **Cleaners and EPA-registered hospital disinfectants are used in accordance with manufacturer's instructions (e.g., dilution, storage, shelf-life, contact time).**
- **High touch environmental surfaces in procedure rooms are cleaned and disinfected between patients**
- **Reusable noncritical items (e.g., blood pressure cuffs, oximeter probes) are cleaned and disinfected between patients.**

NIAHO® (IC) INFECTION PREVENTION AND CONTROL –Hepatitis B and TB

MANAGING RISK

- **The hospital system for identifying, reporting, investigating, and controlling infections includes provisions to train Hospital Staff that are in contact with Bloodborne pathogens on the Bloodborne pathogen standards upon hire and when problems are identified.**
- **The hospital system for identifying, reporting, investigating, and controlling infections addresses needle sticks, sharps injuries, and other employee exposure events.**
- **The hospital system for identifying, reporting, and investigating infection control incidents includes providing Hepatitis B vaccine and vaccination series to all employees who have occupational exposure and conducting post-vaccination screening after the third vaccine dose is administered.**
- **The hospital system for identifying, reporting, and investigating infection control incidents includes provisions that all Hospital Staff (paid and unpaid) who have potential for exposure to TB are screened for TB upon hire and annually (if negative).**

NIAHO® (IC) INFECTION PREVENTION AND CONTROL -Respiratory Program

MANAGING RISK

- The hospital system for identifying, reporting, investigating, and controlling infections includes provisions that ensure the facility has a **respiratory protection program that details required worksite-specific procedures and elements for required respirator use.**
- The hospital system for identifying, reporting, investigating, and controlling infections includes provisions that ensure that respiratory **fit testing is provided at least annually** to appropriate staff.
- The hospital system for identifying, reporting, and investigating infection control incidents includes provisions that ensure that **all staff are offered annual influenza vaccination.**
- Infection Control Practitioner has written protocols for handling job-related and community-associated infectious diseases exposures.

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Hand Hygiene

MANAGING RISK

- **Soap, water, and a sink are readily accessible in patient care areas including but not limited to direct care areas (such as food and medication preparation areas).**
- **Alcohol-based hand rub (ABHR) is readily accessible and placed in appropriate locations.**
- **Hand hygiene is performed in a manner consistent with hospital infection control practices, policies, and procedures to maximize the prevention of infection and communicable disease**

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Hand Hygiene

MANAGING RISK

- **Gowns and gloves are removed and hand hygiene is performed immediately before leaving the patient's environment.**
- **The hospital has policies and documented training that demonstrates staff is educated regarding appropriate indications for hand washing with soap and water versus hand rubbing with alcohol-based hand rub?**
- **The hospital has developed and implemented policies and procedures for hand hygiene that ensure an environment minimizing risk for spread of infection and maximizing prevention of infection and communicable disease.**

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Cleaning Schedule

MANAGING RISK

- Clean, (laundered if not disposable), cloths are used for each room or corridor
- Mop heads and cleaning cloths are laundered at least daily using appropriate laundry techniques (e.g., following manufacturer instructions when laundering microfiber items).
- Facility has established and follows a cleaning schedule for areas/equipment to be cleaned/serviced regularly (e.g., HVAC equipment, refrigerators, ice machines, eye wash stations, scrub sinks, aerators on faucets).
- All surfaces, including but not limited to floor, walls, and ceilings have cleanable surfaces, are visibly clean, and there is evidence that all surfaces are cleaned regularly in accordance to hospital policies and procedures.

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Cleaning Patient Care Devices

MANAGING RISK

- The facility has and follows policies and procedures to ensure that **reusable patient devices are cleaned and reprocessed** appropriately before use on another patient.
- This would include **clear delineation of responsibility among Hospital Staff.** Manufacturers' instructions for cleaning noncritical medical equipment are followed
- The hospital Infection Control Practitioner has developed and implemented **policies and procedures for cleaning and disinfecting point of care devices** that ensure an environment minimizing risk for spread of infection and maximizing prevention of infection and communicable disease.

NIAHO® (IC) INFECTION PREVENTION AND CONTROL-Laundry

MANAGING RISK

- HCP handle soiled textiles/linens in a manner that **ensures segregation of dirty from clean textiles/linens** and ensure that there is not cross contamination of clean textiles/linens prior to use
- There is **clear separation** of soiled laundry space from clean laundry areas and soiled laundry is maintained
- Soiled textiles are bagged at the point of collection and kept in a **covered leak-proof container or bag at all times** until they reach the laundry facility

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Patient Contact

MANAGING RISK

- Supplies for adherence to Standard and Transmission-based Precautions (e.g., gloves, gowns, mouth, eye, nose, and face protection) are available and located near point of use.
- **Facility has policy limiting movement of patients on Contact Precautions outside of their room.**
- If a patient on Contact Precautions must leave their room for medically necessary purposes, **there are methods followed to communicate that patient's status and policies and procedures to prevent transmission of infectious disease.**
- Dedicated or disposable noncritical patient-care equipment (e.g., blood pressure cuffs) is used or if not available, then **equipment is cleaned and disinfected prior to use on another patient according to manufacturers' instructions**

NIAHO® (IC) INFECTION PREVENTION AND CONTROL-Patient Contact

MANAGING RISK

- If a patient on Droplet Precautions must leave their room for medically necessary purposes, there are methods followed to communicate that patient's status and policies and procedures to prevent transmission of infectious disease (note policy should address that patient wear surgical mask when transported).
- If a patient on Airborne Precautions must leave their room for medically necessary purposes, there are methods followed to communicate that patient's status and policies and procedures to prevent transmission of infectious disease (note policy should address that patient wear surgical mask when transported).
- Facility has policy limiting movement of patients on Airborne Precautions outside of their room to medically-necessary purposes (note policy should address that patient wear surgical mask).

NIAHO® (IC) INFECTION PREVENTION AND CONTROL- Sterile Processing

MANAGING RISK

- All reusable critical instruments and devices are sterilized on site.
- Enzymatic cleaner or detergent is **used and discarded according to manufacturer's instructions** (typically after each use).
- Cleaning brushes are disposable or cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after each use.
- After pre-cleaning, instruments are **appropriately wrapped/packaged for sterilization** (e.g., package system selected is compatible with the sterilization process being performed, hinged instruments are open, and instruments are disassembled if indicated by the manufacturer).

NIAHO® (IC) INFECTION PREVENTION AND CONTROL-

MANAGING RISK

- **Sterile packs are labeled** with the sterilizer used, the cycle or load number, and the date of sterilization.
- For dynamic air removal-type sterilizers, a **Bowie-Dick test is performed each day** the sterilizer is used to verify efficacy of air removal
- A **biological indicator** is used at least weekly for each sterilizer and with every load containing implantable items.
- A chemical indicator (process indicator) is placed correctly in the instrument packs in every load.
- After sterilization, medical devices and instruments are **stored so that sterility is not compromised.**
- **Routine maintenance for sterilization equipment is performed** according to manufacturers instructions (confirm maintenance records are available).
- **Logs** for each sterilizer cycle are current and include results from each load.

NIAHO® (IC) INFECTION PREVENTION AND CONTROL-

MANAGING RISK

- Hydrotherapy equipment (e.g., Hubbard tanks, tubs, whirlpools, spas, birthing tanks) are drained, cleaned, and disinfected using an EPA-registered disinfectant according to manufacturer's instructions **after each patient use**
- Policies and procedures are in place outlining facility response (i.e., **recall of device and risk assessment**) in the event of a reprocessing error/failure that could result in the transmission of infectious disease.

Food and beverage services

MANAGING RISK

- When planning and conducting food and catering activities, the organization should consider issues including but not limited to:
  - a. Ensuring that adequate methods are used to assess and manage food safety issues, especially when highly susceptible patients are being managed (e.g. Hazard Analysis and Critical Control Points (HACCP) approach);
  - b. Ensuring food waste is effectively collected, transported and subject to adequate disposal;
  - c. Ensuring catering workers do not attend work if unwell or suspect they may be a source of infection themselves;

Food and beverage services

MANAGING RISK

- *d. Considering risk from movements of food within the healthcare facility, including but not limited to:*
  - *i. Minimization of journeys (e.g. appropriateness of 'on-demand ' as opposed to communal delivery of meals) and identifying appropriate transport routes;*
  - *ii. Precautions required when catering staff deliver food to patient areas;*
  - *iii. Potential need to decontaminate catering equipment which may have been exposed to contaminated / potentially contaminated areas.*

MANAGING RISK

NIAHO®PE.7 Medical Equipment Management System

NIAHO® PE.7: MEDICAL EQUIPMENT MANAGEMENT SYSTEM

MANAGING RISK

- *Permission from CMS in regards to S&C 12-07*
- *In reference to DNVHC's April 13, 2012 email, CMS is reviewing whether additional clarification of S&C 12-07 is needed. In the interim, DNVHC may reinstitute its previous equipment maintenance program and standards.*

NIAHO® PE.7: MEDICAL EQUIPMENT MANAGEMENT SYSTEM

MANAGING RISK

- ***There must be a regular periodic maintenance and testing program for medical devices. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations, risk assessments, and Federal and State laws and regulations. Equipment maintenance may be conducted using hospital staff, contracts, or through a combination of hospital staff and contracted services.***

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

Item #	Standard	Requirement	Survey Approach	Compliant / Nonconformity			Findings / Comments
				C	NC	O	
1	QM.2 ISO 9001 7.6 *PE.7* *SR.1* *PE.7* *SR.6*	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. *The organization shall establish a Medical Equipment Management System that provides processes for safe use and the appropriate selection of equipment.* *The Medical Equipment System shall address a process for determining timing and complexity of medical equipment*	Any equipment or devices used to evaluate a patient should be in the Bio-Medical Engineering inventory and a schedule set up for calibration or verification. Any exceptions (e.g. personal blood pressure cuffs, thermometers, etc.) should have a documented exclusion.				

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

2 2 Cont'd	**QM.2** **ISO 9001 7.6** **(a)**	**Measuring equipment shall be calibrated and/or verified, or both, 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 recorded**	**Using the equipment identifiers, verify that calibration records exist and that the record includes the following:** • **The date calibrated vs. date on equipment, that if it was "in tolerance" and what piece of test equipment was used to calibrate it.** • **Next: check the records of the test equipment used (this should be a certificate from an outside calibration lab).** • **Reviewing the certificate: Was this equipment in tolerance? Does it identify who calibrated the equipment, what equipment standard was used? Is this an accredited laboratory that maintains traceability to NIST (National Institute of Standards and Technology). "Ideally" this laboratory should be certified to ISO 17025.**

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

3	QM.2 ISO 9001 7.6 c)	Have identification in order to determine its calibration status.	This is the calibration sticker usually on the equipment itself. It should be on the initial equipment that the identifiers were taken from as well as the test equipment used.
4	QM.2 ISO 9001 7.6 d)	Be safeguarded from adjustments that would invalidate the measurement result;	If there are any adjustment screws on the equipment they should be tamper proofed/tamper evident if possible.
5	QM.2 ISO 9001 7.6 e)	Be protected from damage and deterioration during handling, maintenance and storage.	Check to see if the storage and handling of this equipment might be such as to alter the calibration. Is the equipment isolated, kept in a storage box or crate or is it thrown into the bottom of a tool box?
6 6 Cont'd	QM.2 ISO 9001 7.6	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).	Anytime equipment or Bio-Medical Engineering Test equipment is found to be "out of calibration" then there is a possibility that incorrect previous reading have occurred when this equipment was used. The hospital needs to assess the potential impact of this out of tolerance condition and make appropriate action. The results of these actions need to be recorded.

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

7	QM.2 ISO 9001 7.6	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	Whenever test equipment uses software to display the test results, has this software been verified? This can be done by having a certificate indicating that software validation has been conducted on this version of software by the manufacturer, or using known traceable sample verification can be conducted on the software. Records of this validation need to be maintained.
8	QM.2 ISO 9001 8.3	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.	Any equipment that needs maintenance or calibration and is therefore should not be used shall be clearly identified to prevent unintended use.

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

9	QM.2 ISO 9001 8.3	A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.	Bio-Medical Engineering should have a written procedure describing how equipment which should not be used is identified and what actions should be taken.
10	QM.2 ISO 9001 8.3	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	Bio-Medical Engineering must retain records of the actions taken (repairs and/or calibration).
11	QM.2 ISO 9001 4.2.3	Documents required by the quality management system shall be controlled.	Procedures such as those listed in Item # 9 shall be controlled (approved prior to issues, changes approved, changes and current revision are identified, obsolete documents are prevented from unintended use).
12	QM.2 ISO 9001 6.2.2	The organization shall - determine the necessary competence for personnel performing work affecting conformity to product requirements,	For all individuals working in Bio-Medical Engineering, including subcontractors, there should be a description of competency requirements. This is usually in the form of job descriptions.

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

13 13 Cont'd	QM.2 ISO 9001 6.2.2	The organization shall where applicable, provide training or take other actions to achieve the necessary competence, ensure that the necessary competence has been achieved, e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	Based on the job descriptions there needs to be a record for each individual indicating that they meet the requirements, are competent. If there is a shortfall there needs to be a plan of action to ensure these individuals are competent.
14	PE.7 SR.1	The organization shall establish a Medical Equipment Management System that provides processes for safe use and the appropriate selection of equipment.	This is addressed in Item #1
15	PE.7 SR.2	The Medical Equipment System shall address issues related to use of demonstration or rental equipment.	Ensure that any rental or demonstration maintained in the hospital is included within the equipment log

NIAHO® PE.7 Surveyor Guidance

MANAGING RISK

16	PE.7 SR.3	The Medical Equipment System shall address criteria for the selection of equipment.	There should be a documents procedure as to how equipment is selected for incorporation into the equipment log.
17 17 Cont'd	PE.7 SR.4	The Medical Equipment System shall address incidents related to serious injury or illness or death (See SMDA 1990).	Is there a record of any equipment failure which is related to any serious injury or death? Evaluate/propose if there were an issue regarding equipment failure how it would be handled. Would there be notification back to the manufacturer?
18	PE.7 SR.5	The Medical Equipment System shall have a process for reporting and investigating equipment management problems, failures, and user errors.	See Item #17
19	PE.7 SR.6	The Medical Equipment System shall address a process for determining timing and complexity of medical equipment maintenance	See Items #1 and #2
20	PE.7 SR.7	The Medical Equipment System shall address the process of receiving and responding to recalls and alerts.	Is there a process in place for equipment recalls? Evaluate any recalls and the actions taken.

NIAHO® PE.7: MEDICAL EQUIPMENT MANAGEMENT SYSTEM

MANAGING RISK

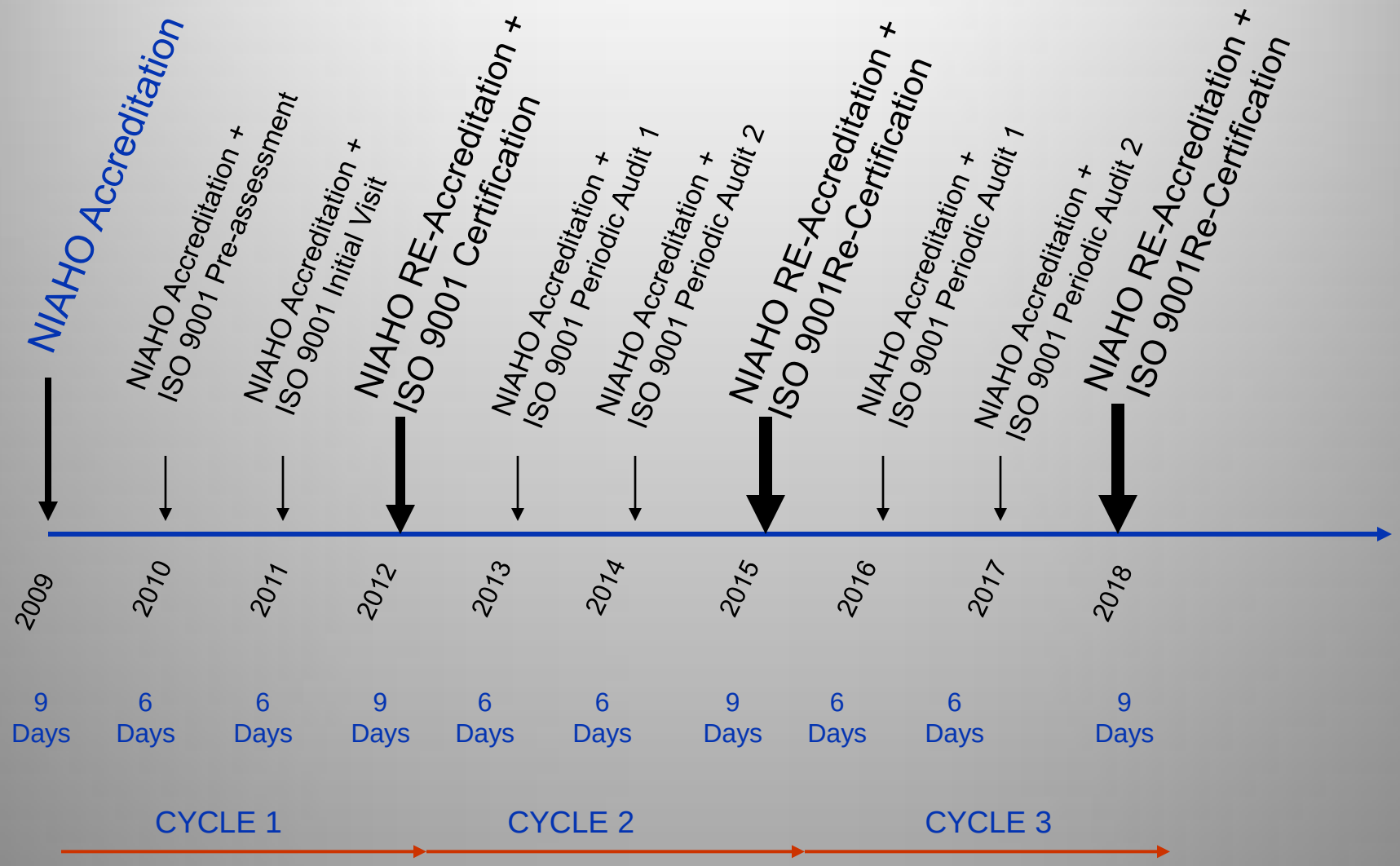
- What is the allowed percentage of “Unable to locate” Equipment?

- Maintain or Identify 100%

MANAGING RISK

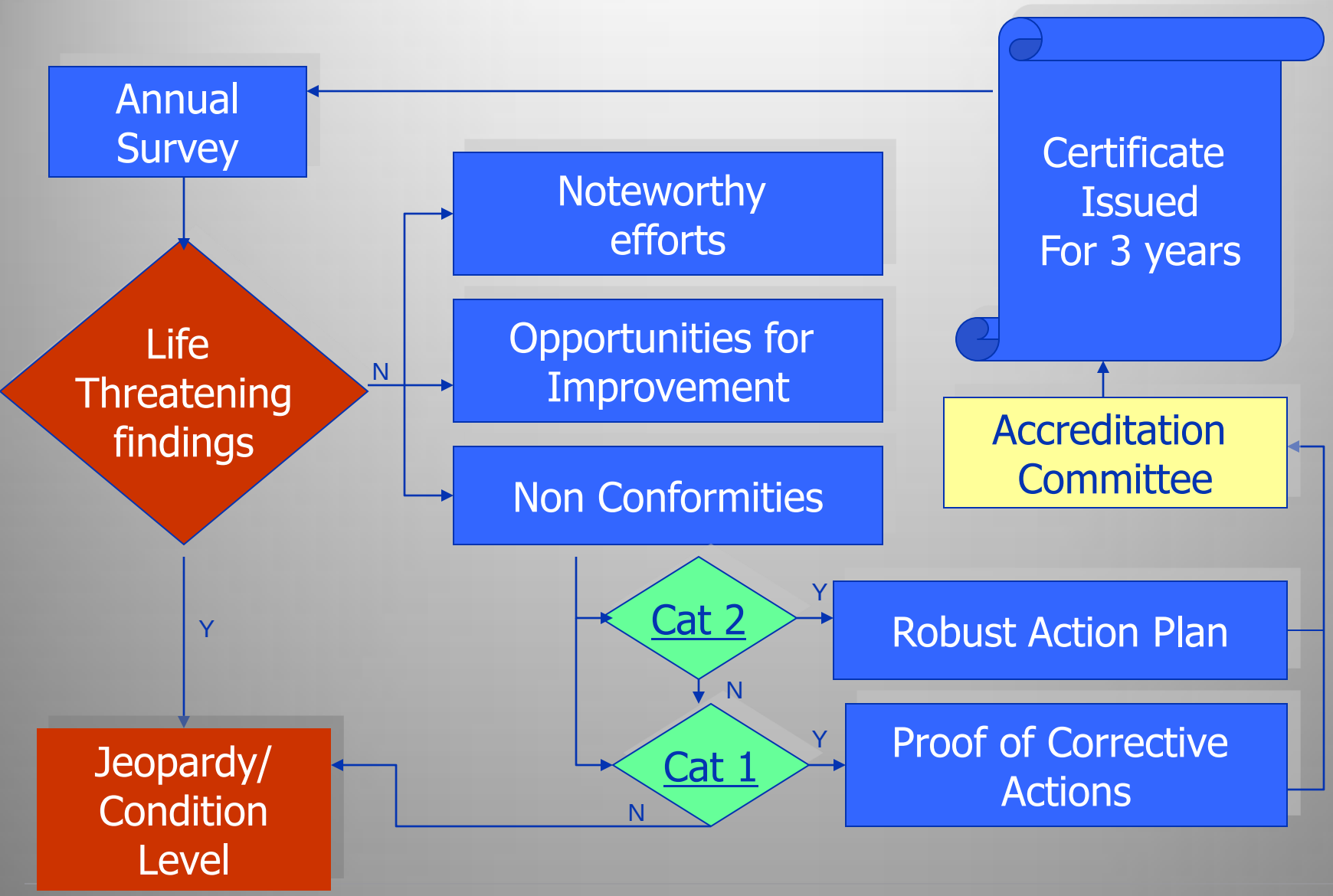
Accreditation and Beyond

Accreditation/Certification Cycles



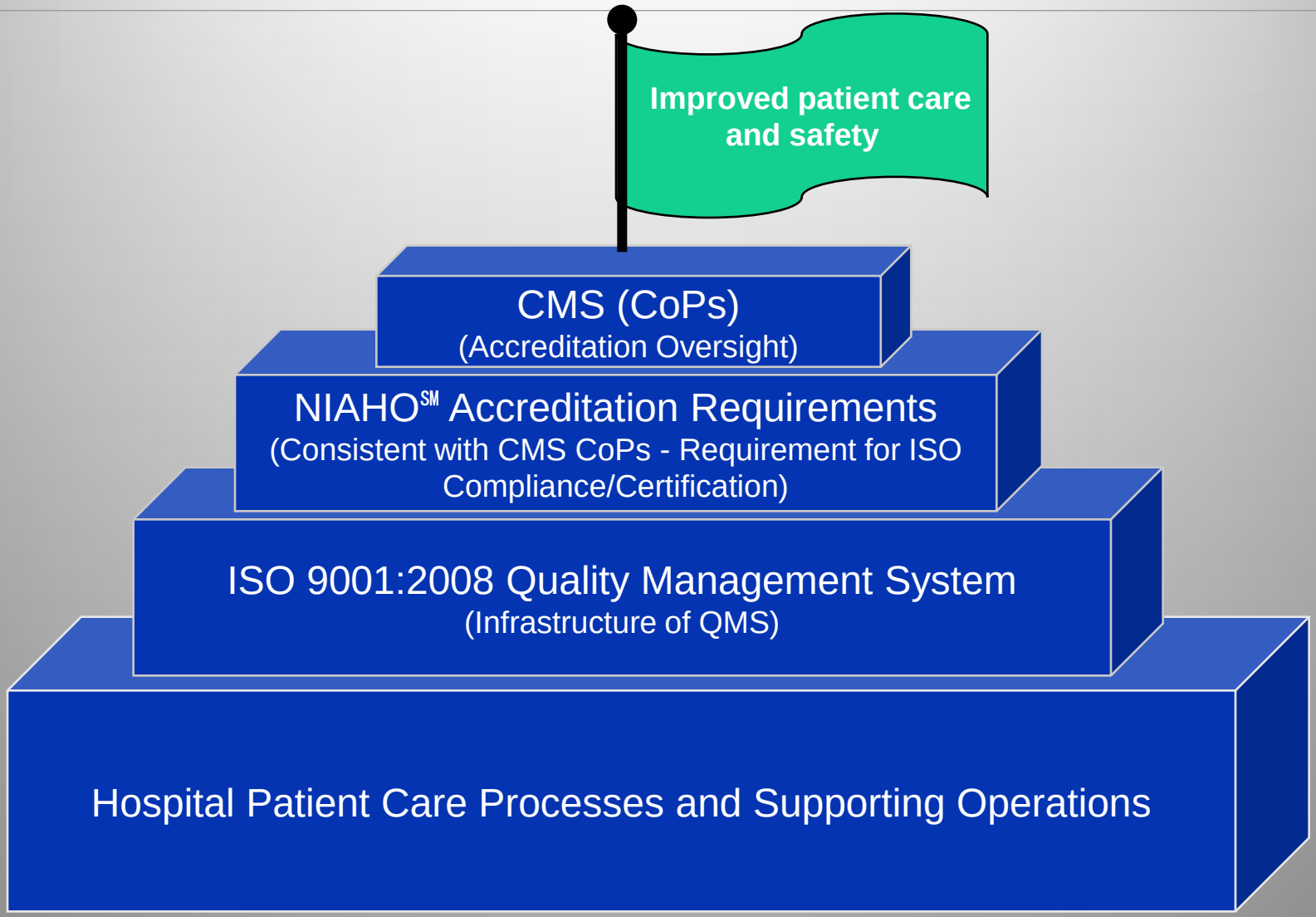
Accreditation Process

MANAGING RISK



Infrastructure and Accreditation

MANAGING RISK



Question & Answer

Session

DNV GUIDING PRINCIPLE

MANAGING RISK

We are judged by the level attained by

those whom we serve,

and we strive to raise that level as high as possible!

DNV HEALTHCARE INC.

CERTIFICATE OF ACCREDITATION

Certificate No. 12345-AHC-USA-NIAHO

This is to certify that

ABC Medical Center

at

1234 Hospital Avenue, Cincinnati, OH 45255

Complies with the requirements of the

NIAHO[SM] Hospital Accreditation Program

Pursuant to the authority granted to Det Norske Veritas Healthcare, Inc. by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, this organization is deemed in compliance with the Medicare Conditions of Participation for Hospitals (42 C.F.R. §482). This certificate is valid for a period of three (3) years from the Effective Date of Accreditation.

Effective Date of Accreditation:
December 1, 2008

Patrick Horine
Executive Vice President, Accreditation

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

for the Accreditation Body:

DET NORSKE VERITAS HEALTHCARE, INC.
HOUSTON, TEXAS

Yehuda Dror
President

Lack of continual fulfillment of the conditions set out in the Certification/Accreditation Agreement may render this Certificate invalid.

DET NORSKE VERITAS HEALTHCARE, INC., 16340 PARK TEN PLACE, HOUSTON, TX 77084, TEL: 281-721-6600 – WWW.DNVACCREDITATION.COM

www.dnv.com

Randall Snelling, CPEO
randall.snelling@dnv.com
513-388-4869

Patrick (Pat) Horine, CEO
patrick.horine@dnv.com
513-388-4888

Darrel Scott, SVP
darrel.scott@dnv.com
513-388-4862

Yehuda Dror, President
Yehuda.Dror@dnv.com

www.dnvaccreditation.com