Objectives

• Review the Centers for Medicare & Medicaid Services (CMS) regulations that all accrediting agencies must comply with
• Describe each organization given CMS deemed stated to inspect Labs
• Compare and contrast each organization’s standards, questions, and process style for pre-inspection, inspection, and required follow up for any cited deficiencies
### 2008 CMS Changes

- Law requiring all accrediting organizations to apply for deemed authority through CMS
- CMS grants deemed status to Det Norse Veritas (DNV)
- The Joint Commission (TJC) must apply to CMS
- Now competition in the hospital accreditation arena

### CMS and CLIA Deemed Status

<table>
<thead>
<tr>
<th>CMS Hospital Wide</th>
<th>CLIA Laboratory</th>
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<tbody>
<tr>
<td>Det Norse Veritas (DNV)</td>
<td>American Association of Blood Banks</td>
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<tr>
<td>Healthcare Facilities Accreditation Program (HFAP)¹</td>
<td>American Osteopathic Association</td>
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<tr>
<td>The Joint Commission (TJC)</td>
<td>American Society for Histocompatibility &amp; Immunogenetics</td>
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<td>College of American Pathologists</td>
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<td>COLA</td>
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<td>DNV¹</td>
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<td>HFAP¹</td>
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<td>Regional Offices &amp; State Agencies ...Florida</td>
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<td></td>
<td>· Agency for Healthcare Administration</td>
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<td>· (ACHA)</td>
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<td>· The Joint Commission</td>
</tr>
</tbody>
</table>

* Lab inspection only if doing hospital wide inspection

¹ The Big Three: A Side by Side Matrix Comparing Hospital Accrediting Agencies, Synergy: January/February 2009.
Our Inspections, Past Two Years

- Pam
  - CAP
  - COLA
  - DNV
  - TJC
  - State...ACHA

- Greg
  - CAP
  - DNV
  - State...ACHA

Number of Accredited Hospitals

- TJC, 50 years
  - 5,000 hospitals
  - 10,000 other healthcare organizations

- HFAP, 60 years
  - 200 hospitals
  - 200 other healthcare organizations

- DNV, since September 2008
  - 50 hospitals
CLIA ’88: 42 CFR Part 493

- Subpart E – Accreditation by a Private Non Profit Accreditation Organization or Exemption Under an Approved State Laboratory Program
- Subpart H & I – Proficiency Testing
- Subpart K – Quality Systems for Nonwaived Testing
- Subpart M – Personnel for Nonwaived Testing
- Subpart Q – Inspection
- Subpart R – Enforcement Procedures

CLIA Certificates

- Certificate of Waiver
- Certificate for Provider-Performed Microscopy Procedures
- Certificate of Compliance
- Certificate of Accreditation
- CLIA Exempt Laboratories
  - Washington
  - New York
Other Licensing Requirements

- State Laboratory Licensure
  - California
  - Florida
  - New York
  - Washington
- Accreditation Requirements
  - Nonwaived Testing: Biannual Inspection

CMS or CMS Agent

- CLIA deemed status for Inspections
- Florida state agency;
  - Agency for Health Care Administration (AHCA)
- CMS or CMS Agent can do the following Inspections for any CLIA-Certified and CLIA-exempt labs
  - Basic Inspection
  - Validation Inspection
  - Complaint Inspection
  - Reinspection
Comparison Categories

- History and Focus of Organization
- Governance and Surveyors
- Chapter, Checklist, or Criteria Categories
- Survey Process
- Post Inspection

CAP History and Focus

- Medical Society, with >17,000 physicians
- CAP Lab Accreditation Standards
- Detailed checklists
  - “blueprint of quality practices”
- 2008, ISO15189 Accreditation
- Proficiency Testing
- Quality Management Tools
- Competency Assessment Program
CAP Governance and Surveyors

- Oversight by Board Certified Pathologists
- Peer to Peer Inspection Teams
- Pathologist lead, with licensed clinical staff
- Online training required before doing Inspection
- Try to match size and type of hospitals

CAP Checklists

- General Leadership and Laboratory
- Rest defined by department
- Separate Point of Care Testing
CAP Survey Process

- Unannounced inspection
- Generally 1 day, with several Surveyors
- Each Checklist has an Inspector
  - May cover more than one list, depending on size of the laboratory
- Given written Recommendations and Deficiencies at end of day
- Must provide corrective action within 30 days
  - May or may not require documentation

CAP Post Inspection

- Accredited for two years
- Self-inspection required on off year
- Conduct CAP Inspection on off year
- Monitor performance, including Proficiency Testing
- Continue Quality Management process
COLA History & Focus

- Stress accreditation through education and consultation
- Client portal for compliance, self assessment, etc.
- 1993 – CMS deemed authority
- 1997 – JCAHO (TJC) deemed status
- Began surveying Physician Office Labs
- Now survey
  - Physician office, Reference, POCT, Community hospital, Mobile Clinic, VA, & DOD Labs

COLA Governance & Surveyors

- Physician-directed organization
- Surveyors are
  - COLA employed, licensed Medical Technologists
- Accredits following specialties
  - Chemistry
  - Hematology
  - Microbiology
  - Immunology
  - Immunohematology/Transfusion Medicine
COLA Criteria

- Criteria follow CLIA Quality Management Flow
  - Pre-Analytical, Analytical, Post-Analytical
- Less detailed list than CAP, but cover CLIA regulations
  - Organization
  - Facility
  - Personnel
  - Proficiency Testing
  - LIS
  - Pre-analytic
  - Analytic
  - Post-analytic
  - Quality Assessment

COLA Survey Process

- Unannounced, except first Survey, for all TJC-affiliated labs
- Six month window
- Biannual inspection
  - Off year self assessment
- One or more surveyors
  - Generally for one day
COLA Survey Process & Post Inspection

- More documentation review than Lab workflow
- Summation includes written “Plan of Required Improvement” (PRI), if any deficiencies
- 30 days to reply
  - with or without documentation, depending on severity
- Two year accreditation
- Monitor with proficiency testing
- Off year Self Assessment

DNV Healthcare, Inc.
Accreditations

- Hospital
- Primary Stroke Center
- Critical Access Hospital
DNV: ISO 9001:2008 Standards
International Organization for Standards

- Quality
- Management
- System
- US Representative: ANSI
  - American National Standards Institute

DNV History & Organization

- Established in 1864
- Independent, self supporting Foundation
- Tax paying entity (in every country it operates)
- 300 Offices in 100 Countries
- 9000 Employees (locally employed)
- Operating in the U.S. since 1898
New Face for Hospital Accreditation

- 1951 Joint Commission established
- 1964 CMS established
  * Accreditation or State Survey required to receive for CMS reimbursement.
  * TJC has statutory privilege – no accountability to CMS.
- 1999 IOM report on medical errors.
- **12/19/2007** DNV applies to CMS to become an approved AO for hospitals
- **7/15/2008** HR 6331 becomes public law #110-275
  * Removing TJC’s special statutory privileges as AO
  * TJC will have to receive CMS approval within 2 years

DNV History, Cont.

- **9/26/2008** DNV granted CMS approval as an AO for hospitals

- **10/13/2008** IJC survey reports “19% of respondents stated their hospitals were considering switching to DNV”
DNV’s Reasoning for Alternative Accrediting Agency

Medical Errors/Adverse Events...
• Evidence is present to indicate that medical errors are still occurring at an alarming rate despite current efforts to impact reduction
• Fear of legal ramifications and other protections under the law have created reporting barriers for hospitals
• Hospitals feel compelled to implement measures to address these events, yet are struggling with managing their effectiveness
• Poorly designed and ineffective processes that lack consistency are the primary cause for these outcomes:
  Lack of quality management system infrastructure

DNV’s Reasoning, Cont.
• Processes in healthcare organizations are very complex and require a great deal of communication and validation to be effective.
• Processes become more difficult to manage and control when they become more decentralized.
• The improvement of quality, performance and outcomes is directly related to the accountability for the processes.
• Hospitals struggle with introducing new methodologies to focus their efforts and abandon one methodology only to replace it with another producing the same results
DNV Hospital Accreditation Progression: 3 Year Process

- **1st Visit**
  - Get accredited to NIAHO℠ - meet the requirements of CMS
  - Gap analysis to ISO 9001 with 2 year road map
- **2nd Visit – 1 year after Accreditation**
  - Continue accreditation by undergoing NIAHO℠ Survey
  - Survey for progress in implementing ISO 9001
  - If in ISO 9001 Compliance
    - Statement included in Certificate of Accreditation
  - May choose to demonstrate compliance by obtaining a separate ISO 9001 Certificate
- **3rd Visit**
  - Continue accreditation by undergoing NIAHO℠ Survey
  - Be in compliance with ISO 9001

DNV Laboratory Survey
Chapter Categories

- **LS1**: Organization
- **LS2**: Infectious Blood and Product
- **LS3**: Patient Notification
- Accepts CAP, etc. accreditation, like TJC
DNV Survey Process & Post Inspection

- Accreditation not based on quantity of deficiencies
- Only LS1: Organization, is scored separately from Lab accrediting organization, like CAP
- Other two categories are considered acceptable, if accredited by separate lab agencies
- With hospital, annual inspection
- Must receive ISO 9001 certification

HFAP Accreditations

- Acute Care
- Critical Access Hospital
- Ambulatory Surgery Center
- Clinical Laboratory
- Behavioral/Mental Health
- Ambulatory Care/Office Based Surgery
- Primary Stroke Center
Regional/State CMS Agents:
History and Focus

- Florida AHCA deemed CMA Agent
- Can do all types of inspections listed
- Originally licensed all Certificate categories
- Now do not license nor inspect Waived Testing Labs
- FL Waived Testing Labs now only need CLIA license
- Also license Lab Personnel

AHCA Governance and Surveyors

- Board of Clinical Laboratories
- State Rules and Federal Regulations
- State Agency with Medical Technologists
- Branch offices have Medical Technologists
- Board reviews all complaints
  - May include loss of license
Survey Process: Validation Inspection

- After exemplary CAP Inspection
  - St. Petersburg office of AHCA did the Inspection
    - Given 2 weeks notice
- One MT Inspector for 2 days
- Checklists follows CLIA’88 and updated Subparts
- Majority of time spent reviewing documents
- Little time in actual Lab
- Any deficiencies require corrective action within 30 days
- Validation accreditation sent to CMS and CAP

The Joint Commission: History and Focus

- Founded in 1965, Accredited freestanding labs
  - Accredited Hospital Labs since 1979
- Provides accreditation and certification
- TJC Standards revised in 2009 through RPI
  - Robust Process Improvement
- Surveys individualized to each hospital
- Based on compliance to their standards
- Changed name from JCAHO to TJC in 2009
TJC Governance and Surveyors

- Most staff are employed by TJC
  - physicians, nurses, PhD, hospital administrators
- Experienced staff in areas acting as Surveyor
- Laboratory specific Surveyors are licensed laboratorians

TJC Chapter Categories

- Follow the hospital chapters and standards
  - Document and Process Control
  - Environment of Care
  - Emergency Management
  - Humans Resources
  - Infection Prevention and Control
  - Information Management
  - Leadership
  - National Patient Safety Goals
  - Performance Improvement
  - Quality System Assessment for Nonwaived Testing
  - Transplant Safety
  - Waived Testing
TJC Survey Process

- Unannounced survey
- One or more Surveyors, 3-5 days
- Tracer Methodology
- Majority of time on document review from Tracers criteria
- Competency review
- Exit conference
  - No written summary
  - Final document with RFI’s from TJC main office

TJC Post Inspection

- Final written summary found on TJC website
- Any corrective action must be produced in 45-60 days, based on severity
- Evidence of Standards Compliance (ESC) or Measure of Success (MOS) entered on TJC website
- If receive accreditation, becomes public
- For hospital, TJC publishes Quality Check®
  - Core Measures for CMS
Choices

Hospital
- DNV
- HFAP
- TJC

Laboratory
- CAP
- COLA
- DNV*
- HFAP
- CMS Agents
- TJC

Websites

- www.cms.gov
- www.iso.ch
- www.cap.org
- www.cola.org
- www.dnvaccreditation.com
- www.hfap.org
- www.jointcommission.org
- www.aabb.org
- www.osteopathic.org
- www.ahsi-hla.org
- www.fdhc.state.fl.us
- www.cms.hhs.gov/CLIA
QUESTIONS