Integrating Quality, Compliance, & Clinical Teams: Examples of Improved Compliance and Patient Safety

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Children’s Hospital of Orange County
Orange, California

Quality, Compliance, & Clinical Teams—Why Work Together?

• Changing healthcare climate & impact of healthcare reform
  − Greater emphasis on outcomes and quality
  − Increased transparency of quality data available to the public
  − Emphasis on documentation & coding matching acuity and care provided

• With funding & reimbursement now tied to quality measures:
  − Compliance professionals need to understand the language and practices of quality improvement
  − Quality professionals need to have a better understanding of business processes and compliance
  − Clinical staff need to help drive care to ensure quality and understand proper documentation for compliance and reimbursement
One Hospital's Experiences

• How Quality, Compliance, & Clinical Teams partnered to improve outcomes at CHOC Children’s using 2 project examples
  − Breastmilk Handling Best Practices Initiative
  − Enhanced Documentation of Pediatric Malnutrition Initiative

• How these programs served to create awareness, collaboration, & communication throughout the organization, to the leadership team, and the board

Our Journey at CHOC Children’s

Who are we?

• Free standing children’s hospital
• Tertiary care center
• Level II trauma center
• 279 beds
  − 67 bed NICU
  − 30 bed PICU
  − 12 bed cardiovascular ICU
  − 52 bed oncology unit
  − 118 med/surg beds
Important Considerations for All Process Improvement Initiatives

• Assemble the correct people (key stakeholders & champions)
• Understand current processes, gaps, and vulnerabilities
• Understand the regulations & best practices
• Understand market trends (What are other similar facilities doing?)
• What are the risks/consequences of doing nothing?
• What are the benefits of change?
• What is the cost of making the change?
• Consider steps & timing to implement change
• Remember ongoing monitoring

Initiative 1: Breastmilk Handling Best Practices
Is the handling of infant feedings a concern?

“In an era of sophisticated technology in medicine, safe feeding of infants may be presumed to be a relatively mundane function of a modern hospital. In fact, when subjected to close scrutiny, this is an area that has often been fraught with practices more typical of a home kitchen than a facility providing state-of-the-art medical nutrition therapy.”


Primary Concerns

• Quality Concerns
  - Contamination
  - Accuracy of preparation
  - Misadministration

• Compliance / Regulatory Concerns
  - HIPAA
  - TJC
  - State regulations
Getting Started: Assembling the Correct People & Understanding Current Processes, Gaps, and Vulnerabilities

Failure Mode Effects & Analysis (FMEA)

- Initiated as a result of 3 errors occurring in a short time period
- Complete review of every step of a process
  - Collection
  - Storage
  - Transport
  - Administration
  - Discharge
- Identified all potential failure points.
- Failure points scored for severity, occurrence, and detectability to obtain a Risk Priority Number (RPN)
Risk Priority Number (RPN) Scoring

<table>
<thead>
<tr>
<th>Severity</th>
<th>Likely Occurrence</th>
<th>Detection</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>No effect</td>
<td>Almost never</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
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<tr>
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<tr>
<td>5</td>
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<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Hazardous</td>
<td>Failure almost certain</td>
</tr>
</tbody>
</table>

RPN = Severity Score x Occurrence Score x Detection Score

Breastmilk FMEA Results

- 282 potential failure points
- RPN ranged from 1-810
- Root causes were identified for each of the 85 failure points with an RPN score of 160 or higher
Evaluation of Potential Failure Points

• Identified the top failure points to assess further

• Determined root causes for each top failure point

• Used root causes to determine course of action

Sample Root Causes

2011 Failure Mode and Effects Analysis
Breast Milk Collection, Storage, Administration and Discharge Processes

<table>
<thead>
<tr>
<th>Process</th>
<th>Failure Mode</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detectability</th>
<th>RPN Score</th>
<th>Root Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin</td>
<td>Breastmilk double check not performed at bedside immediately prior to administration</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>810</td>
<td>Staff availability, ambiguity regarding the double check process, accessibility of armband due to positioning, swaddling, and isolation or not perceived to be necessary due to familiarity with patient; habit</td>
</tr>
<tr>
<td>Admin</td>
<td>Breastmilk double check incomplete</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>810</td>
<td>Staff availability, ambiguity regarding the double check process, accessibility of armband due to positioning, swaddling, and isolation or not perceived to be necessary due to familiarity with patient; habit</td>
</tr>
<tr>
<td>Admin</td>
<td>Inconsistency in what is being checked on the armband</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>810</td>
<td>Unclear understanding of the policy; only checks whatever is convenient to view on armband</td>
</tr>
</tbody>
</table>
Detectability of Top 85 Potential Failure Points

- Detectible: 16%
- Slight Chance of Detection: 45%
- Remote Chance of Detection: 33%
- Almost Impossible to Detect: 6%

Understanding Regulations, Best Practices, & Market Trends
Contamination/Preparation Errors

- Separate room away from pt care
  - Support aseptic technique
  - Conform to all other standards for handling patient food/nutrition
  - Feeds prepared in NICU 24x more likely to show microbial growth than centralized prep

- Technique/Sanitation

- Monitoring expiration dates/times

- Personnel
  - In no other unit would the employee responsible for diapering, IV placement, etc. be responsible for preparing meals

- Accuracy of calculations and measurements of additives


TJC

- PC.02.02.03
  - .01 The hospital assigns responsibility for the safe and accurate provision of food and nutrition products.
  - .06 The hospital prepares food and nutrition products using proper sanitation, temperature, light, moisture, ventilation, and security.

- IC.01.05.01
  - All hospital components & functions are integrated into infection prevention activities.

- NPSG.01.01.01
  - Use at least two patient identifiers when providing treatments or procedures.

- Hospitals throughout the country (including CHOC) have reported breastmilk storage temperatures as a primary focus of TJC in 2014-2015.
Best Practices

• American Dietetic Association Guidelines (now Academy of Nutrition & Dietetics)

• Human Milk Banking Association of North America (HMBANA)

• American Society for Enteral & Parenteral Nutrition (ASPEN)

• National Association of Neonatal Nurses (NANN)

• Physical Facilities
  − Physically separated from direct patient care areas
  − Used solely for breastmilk & formula preparation
  − Supports aseptic technique

• Specially Trained Staff

• Refrigeration/Temp Control

• Infection Control

• Quality Assurance

• Unit Dosing

• Proper Labeling

• Bar Code Scanning


State Health Department & Building Code Examples

• Office of Statewide Health Planning & Development
  − CA building code will now require a separate area for prep separate from patient care areas.
  − Must include refrigerator, work counter, storage facilities, hand-washing station, and separate cleanup area for washing & sanitizing.

• CA Department of Health Dietitian Surveyors
  − In absence of state regulations, use Academy of Nutrition & Dietetics guidelines as the standard
Other Agency Endorsements

• Agency for Healthcare Research & Quality (AHRQ)

• Institute for Safe Medication Practices (ISMP)

• National Patient Safety Foundation (NPSF)

• Healthcare Information and Management Systems Society (HIMSS)

2015 US News & World Report Questions

• Does your hospital offer a dedicated area within the facility but away from the bedside for milk and formula preparation? (Must meet both criteria)
  − Infant feeding prep room using the aseptic technique
  − The room requires restricted access and healthy personnel with no other activity occurring in the room

• Does your NICU program offer a specific risk reduction program with processes designed to reduce breast milk errors including:
  − Individual breastmilk warmers at each bedside
  − Bar code system for correct breastmilk identification
  − Dedicated breastmilk technician who prepares milk for proper identification & distribution
Benefits of Making a Change vs. the Costs of Not Making a Change

Misadministration Consequences

- Medical/infectious disease concerns
  - Hepatitis C
  - HIV
  - Exposure to drugs/medications
  - Allergic, GI, or metabolic complications from receiving the wrong additives

- Economic concerns
  - Bodily fluid exposures may be a reportable event
  - May be viewed as a HIPAA breach (Fines of $25,000 or more per incident are possible)
  - Blood work-up costs for each party (donor & recipient) are >$500
  - Costs of any medical complications

- Regulatory scrutiny increases with each event

- Patient and family satisfaction
Evaluation of Process

• NICU alone administers over 10,000 feedings per month
  – RN may handle breastmilk 12x per shift
  – Risk of confirmation bias & reduced sensitivity

• Results identified need for process redesign
  – Unclear and cumbersome process for the bedside nurse
  – Inadequate double check at key points
  – Human error/confirmation bias
  – Contamination risk due to space constraints

• Consequences of not taking action
  – Patient harm
  – Regulatory citations
  – Financial impact
  – Family satisfaction
CHOC Nutrition Lab

- 2 phase implementation
- Emphasis
  - Sanitation
  - Documentation accuracy
  - Preparation accuracy
  - HIPAA compliance
  - Proper patient identification through bar code scanning

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Wrong Baby’s Milk</th>
<th>Wrong labels on bottles noted when milk dropped off</th>
<th>Expired Breastmilk</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Wrong milk actually fed</td>
<td>Wrong milk scanned (near misses)</td>
<td>Expired milk actually fed</td>
</tr>
<tr>
<td><strong>Prior to Process Change</strong></td>
<td>3</td>
<td>---</td>
<td>16</td>
</tr>
<tr>
<td>• May 2010-Dec 2012</td>
<td>• Bedside Prep</td>
<td>• Manual Double Check</td>
<td></td>
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<tr>
<td><strong>PI Phase I</strong></td>
<td>0</td>
<td>---</td>
<td>4</td>
</tr>
<tr>
<td>• Jan 9-Nov 11, 2013</td>
<td>• Centralized Prep</td>
<td>• Manual Double Check</td>
<td></td>
</tr>
<tr>
<td><strong>FY 2014</strong></td>
<td>0</td>
<td>110</td>
<td>1</td>
</tr>
<tr>
<td>• Centralized Prep</td>
<td>• Bar Code Scanning</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Other Outcomes

- Improved nursing staff satisfaction
  - Better use of nursing time for other duties

- Improved family satisfaction

- Recognition from:
  - California Dept of Health
  - TJC
  - HIMSS

Sharing Results
### Ongoing Monitoring

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<tr>
<td><strong>FY 2014</strong></td>
<td>0</td>
<td>110</td>
<td>1</td>
</tr>
<tr>
<td>• Centralized Prep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Bar Code Scanning</td>
<td></td>
<td></td>
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<tr>
<td><strong>FY 2015</strong></td>
<td>2</td>
<td>163</td>
<td>0</td>
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</table>

### Ongoing Monitoring & Follow Up

- Reconvened Breastmilk Handling PI Team
  - Both errors were breastmilk exposures & HIPAA issues

- Conducted root cause analysis of the 2 errors
  - Storage and label integrity issue
  - Bedside inconsistencies for time of scanning

- Updated process and provided education to bedside staff
  - Recognized the need for ongoing monitoring and education
  - Easy to become too comfortable
Updated Process

Breastmilk Scanning Process—NICU

- RN retrieves prepared breastmilk from pt bin in refrigerator.
- **NOTE:** Bins are to remain in alphabetical order NOT in order by bed space.
- Practice Change Alert: Breastmilk Time Out
- RN compares name & RNs on bottle or syringe label to pt name on warm milk warmer liner & initiates the label on the feeding.
- W or feeding thermopod scales milk IMMEDIATELY prior to feeding.

**Reminders:**
- Confirming ID visually with the label on the liner & initialing the label serves as a “time out” to ensure you are warming the correct milk at the correct bedside.
- The last step BEFORE feeding or connecting to a feeding tube must always be the scan.
- Scanning at any other step puts the patient at risk for receiving the wrong milk. This should mirror the medication scanning practice.
- We must stop scanning milk before it goes into the warmer.
- The inexistence of scanning times have led to 2 administration errors as well as NAKED near misses.
- By having everyone scan at the same step (immediately before feeding), we reduce the risk of error.
- Explain to parents that we scan milk just before feeding for their baby’s safety so that they understand the process—particularly when they get close to D/C and may be participating more in care.
- In the event of an exposure, pull the patient’s tube immediately (if gavage fed)
  & reference general infection Prevention Policy 512 “Breast Milk Exposure” which is found on POI or the link from the NICU page on PAWS.

Providing Ongoing Feedback

- Quarterly tracking of all near misses (and errors)

- Sharing that information with all bedside staff
  - Frequency of near misses was eye opening to bedside staff
  - Helps staff understand that these are not rare occurrences & to be diligent

- Regular reinforcement of the process
Initiative 2: Enhanced Identification & Documentation of Malnutrition

Getting Started: Assembling the Correct People & Understanding Current Processes, Gaps, and Vulnerabilities
Identification of the Problem

• Clinical dietitians initiated project based on new definitions
  − Malnutrition has significant impact on patient outcomes
  − National standardized definitions launched to assist documentation

• CHOC Children’s Baseline Data (2014)
  − 0.8% of inpatient discharges (excluding NICU) coded with malnutrition
  − Audit suggested 23% of cases reviewed could have been coded
  − Suspected number didn’t reflect actual number or care being provided

Concerns

Lack of proper documentation/coding of malnutrition

Lack of appropriate hospital reimbursement

Inaccurate documentation of care
Goals and Objectives

• Goal
  − Accurately identify & document malnutrition in all pts > 30 days old
  − Anticipated to be ~10% of all non NICU inpatients

• Objectives
  − Integrate 2013 standard pediatric malnutrition definitions into EMR
  − Increase awareness among medical team of standard definitions and importance of properly identifying malnutrition to ensure optimal outcomes and appropriate reimbursement
  − Ensure proper documentation to support coding by the Health Information Management to reflect accurate level of care and ensure appropriate reimbursement

Multidisciplinary Collaboration

• Registered Dietitians
  − Trained on new pediatric malnutrition definitions and nutrition focused physical assessment

• HIM / Revenue Cycle (CDI’s and Coders)
  − Ensure documentation accurately reflected the care being provided
  − Ongoing audits to identify gaps and opportunities

• Electronic Medical Record
  − Clinical nutrition note updated to include standardized language
  − Malnutrition added to problem /diagnosis lists by RD
  − Malnutrition portion of note sent to attending physician for review and signature

• Healthcare Team
  − Work together to implement and document appropriate interventions
### Implementing Change: Malnutrition Dx Documented in RD Note

<table>
<thead>
<tr>
<th>Chronicity</th>
<th>Etiology</th>
<th>Diagnosis</th>
<th>Related To</th>
<th>Evidenced By</th>
<th>Z-Score</th>
<th>Comment</th>
<th>Status</th>
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<tr>
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<td>MultAlpha</td>
<td>MultAlpha</td>
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<td>Initial</td>
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</table>

#### Malnutrition Diagnosis Added to Problem and Diagnosis List

**Malnutrition Diagnosis**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Diagnosis</th>
<th>Clinical Dx</th>
<th>Code</th>
<th>Dx Type</th>
<th>Date</th>
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<tbody>
<tr>
<td>1</td>
<td>Abdominal distension</td>
<td>Flatulence, Enuclei</td>
<td>787.3</td>
<td>Admitting</td>
<td>9/25/2015</td>
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<tr>
<td>2</td>
<td>Celiac obstruction</td>
<td>Unspecified Intest</td>
<td>560.0</td>
<td>Working</td>
<td>9/25/2015</td>
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<tr>
<td>3</td>
<td>Leukocytosis</td>
<td>Leukocytosis, Unreg</td>
<td>788.60</td>
<td>Discharge</td>
<td>9/26/2015</td>
</tr>
<tr>
<td>4</td>
<td>Celiac mass with obstruction</td>
<td>Other-Specific-Diag</td>
<td>560.80</td>
<td>Discharge</td>
<td>9/26/2015</td>
</tr>
<tr>
<td>5</td>
<td>Mild malnutrition</td>
<td>Malnutrition of Mid</td>
<td>260.1</td>
<td>Discharge</td>
<td>9/26/2015</td>
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<tr>
<td>6</td>
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<td>Diarrhea</td>
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<td>Mild malnutrition</td>
<td>Mild protein calori</td>
<td>44.1</td>
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<td>8</td>
<td>Abdominal distension</td>
<td>Abdominal disten...</td>
<td>R14.0</td>
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<tr>
<td>9</td>
<td>Chronic diarrhea</td>
<td>Noninfective gastric</td>
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<td>Discharge</td>
<td>10/1/2015</td>
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<td>10</td>
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<td>Other specified dis...</td>
<td>56.69</td>
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</table>

**Problems**

<table>
<thead>
<tr>
<th>Name of Problem</th>
<th>Annotated Display</th>
<th>Code</th>
<th>Onset Date</th>
<th>Vocabulary</th>
<th>Life Cycle St.</th>
<th>Course</th>
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<tbody>
<tr>
<td>Malnutrition of mild degree...</td>
<td>Mild malnutrition</td>
<td>12896/2015</td>
<td>SNOMED CT</td>
<td>Active</td>
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<td></td>
</tr>
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</table>
Malnutrition Diagnosis Sent to Attending Physician

Results

% of Non-NICU Discharges with Documented Malnutrition
Results

• Baseline 0.8% FY 2014 → 4.4% November 2015
  - RD documentation at 5.5% FYTD

• Increase of ~$800K in revenue annually

• Provided support for hospital-wide initiative to improve accuracy of lengths and heights

Ongoing Monitoring

• Malnutrition (as % of total discharges) is tracked weekly

• Coding Supervisor compares list from dietitians to those coded
  - Increased from 77% in November to 91% in December & January

• Regular agenda item at HIM Committee & Medication/Nutrition Committee
Summary of Projects

Impact of Projects on Collaboration

• Paired departments not previously as connected
  - Clinical Nutrition & HIM
  - Clinical Nutrition & IT

• Collaboration allowed others to make connections between their jobs and outcomes in other areas
  - RD understanding of necessary documentation for coding & billing
  - IT understanding of breastmilk handling workflow
Focus on Quality and Compliance

• Benefits of FMEA or Formal Evaluation of the Issues
  − Ensured multidisciplinary approach → partnership between Quality, Compliance, & the Clinical Teams
  − Provided concrete details to secure support from administration
  − Provided specifics to share with staff to secure support for process change

• Initiation of Formal Quality Improvement Initiatives
  − Provided a spotlight for both projects
  − Ensured accountability/follow up

• Compliance Concerns Driving Forces for Support of Initiatives
  − HIPAA issues for breastmilk initiative
  − Accuracy of documentation & proper coding for malnutrition initiative

Sharing of Information (Internally & Externally)

• Hospital Meetings
  − Department Head Meetings
  − Executive/Board Meetings
  − Compliance Committee
  − Patient Safety Committee
  − Medication/Nutrition Committee
  − Physician Technology Action Committee
  − Nurse Practitioner Meetings
  − Unit Staff Meetings

• National Meetings

• Guests/Teams from Other Hospitals
Practical Considerations for Successful Quality & Compliance Partnerships

Sharing Best Practices and Tips For Success

Board Oversight & Engagement

• Do you have a dedicated Board Quality Committee?

• How do you keep your Committee engaged?

• What topics are included on Committee agendas?

• Can your Board Quality Committee connect the dots?
  – Quality concern may also be a potential compliance issue

• Have you shared OIG co-authored resources for Health Care Board Oversight & Quality with your Board/Quality Committee?
Metrics

• How do you determine metrics?

• How are metrics made available?

• Are these included in organizational performance evaluations and/or bonus triggers?

• Are metrics routinely reviewed to consider evolving risks?

• What methods have you found to be successful in keeping your organization focused on and improve specific important metrics?

Enterprise Risk Management (ERM)

• Do you have an ERM process to routinely identify and mitigate risks facing your organization?
  - Are Quality & Compliance elements included?

• Do you have a management committee that provides oversight of ERM activities?

• Does the committee have representatives from Compliance, Clinical &/or Quality?

• Are ERM activities shared with Medical Staff Committees? Board?
Enterprise Risk Management

• What risk areas can you envision Quality and Compliance partnering together on in your organization?

• EHR Documentation
  − Copy/Paste, Auto populate, Cloning, Shared Notes, Incomplete Documentation, Note Bloat
  − Use of Scribes, Mid-level Providers, Residents, Student Documentation, Note Templates
  − Quality Documentation Issues, EHR Work Flow, etc.

• Patient Safety Reporting System Trends

• Organizational Data Integrity Issues

• Privacy & Security Incidents/Risks
Potential Quick Starts for Quality/Compliance Collaboration

- Accreditation Compliance Working Group
- Compliance Rounding
- EHR Documentation Quality Audits
- Culture of Safety/Culture of Compliance Survey Results Sharing
- Data Mining
  - Re-admission rates, Short I/P Stays, Coding Utilization, etc.
- Ethical Decision Making Breakdowns
- Work Force Education/Competency Requirements
- Population Health/ACO Development & Monitoring Activities
- Other

Multidisciplinary initiatives involving Quality, Compliance, and Clinical Teams can improve patient care and safety and promote better collaboration—all of which assist the organization in achieving its mission!
Resources

- OIG Co-Authored Resources for Health Care Governance
  - Corporate Responsibility and Health Care Quality
    http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf

- Practical Guidance for Health Care Governing Boards on Compliance Oversight
  http://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp