The Why’s & Wherefore’s of CLIA Competency Evaluation

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Topics for Discussion

• Introduction
• Rationale for Competency Requirements
• Competency Regulations & Procedures
• Guidance & Problems to Avoid
• Questions
Introduction

- **Personnel Competency** introduced as a CLIA standard in 1992 regulations.
- Competency is required for all technical, supervisory & testing personnel.
- Various related requirements are interspersed throughout the regulations.
- Competency is NOT the same as a performance evaluation/training.
Rationale for Personnel Competency

• CLIA’s intent is to ensure accurate, reliable & timely testing.
• Studies indicate that more education & training produce higher quality results.
• The means to confirm training effectiveness is competency evaluation.
• In CLIA, the laboratory director’s qualifications are stringent due to the overall quality responsibility.
Rationale for Personnel Competency

• But qualifications for testing personnel are minimal, based on test complexity.
• Highlights importance of competency, regardless of education.
• Quality management includes personnel, processes, & procedures, as does competency.
• Competency is recognized by CLIA law.
Rationale for Personnel Competency

- CLIA survey experience indicates many problems caused by personnel errors.
- Many laboratory test mistakes may have a patient impact.
- Routine competency evaluations will help prevent errors.
- CMS permits flexibility in achieving compliance.
Competency Regulations

- 493.1413(b)(8)(9) & 1451(b)(8)(9)—
- Technical Consultant/Supervisor Responsibilities—
- Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently.
Competency Regulations

- 493.1413(b)(8)(9) & 1451(b)(8)(9)—
- Technical Consultant/Supervisor Responsibilities—
- Evaluating & documenting individuals’ performance at least 2X/yr. for the 1st yr. of testing & annually thereafter, unless method or instrument changes, prior to reporting patient results; re-evaluate w/ new tests systems.
Competency Regulations

- **493.1235—Personnel Competency Assessment Policies—**
- *As specified in the personnel requirements in Subpart M, the laboratory must establish & follow written policies & procedures to assess employee, & if applicable, consultant competency.*
Competency Regulations

- **493.1407(e)(12) & 1445(e)(13)—Laboratory Director Responsibilities—**

- Ensure that policies & procedures are established for monitoring individuals who conduct pre-analytical, analytical & post analytical phases of testing to assure that they are competent & maintain their competency to process specimens, perform tests & report results promptly & proficiently, & whenever necessary, identify needs for remedial training or CE to improve skills.
Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
  - 1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.
Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
  
  - 2. Monitoring the recording & reporting of test results
Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:

  3. Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records
Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
  
- 4. Direct observation of performance of instrument maintenance & function checks
Competency for all tests performed must include:

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and
Competency for all tests performed must include:

6. Assessment of problem solving skills
Competency Assessment Guidance & Problems to Avoid

• Operator training prior to testing is critical & required.

• Competency assessments must demonstrate testing personnel (TP) are performing testing accurately.

• See TP responsibilities in regulations.

• Competency assessments must be documented.
Competency Assessment Guidance & Problems to Avoid

- Individual conducting competency assessments must be qualified.
- Competency is not PT!
- Competency records should match the laboratory’s actual procedures performed by its personnel.
- When observing test performance, use the procedure manual (PM) /package insert (PI) to ensure PM is current.
Competency Assessment Guidance & Problems to Avoid

- Can use competency assessment for QA when confirming tests ordered match reported & charted results.
- Follow up on QC corrective actions will demonstrate problem solving ability.
- Checklists are only minimally ok.
- Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.
Competency Assessment Guidance & Problems to Avoid

• Laboratory director serving as TC, CC, TS &/or GS isn’t subject to competency requirements.

• Personnel who perform pre & post analytic activities & who are not listed in the regulations as required positions aren’t subject to competency.

• But laboratory may want to do similar evaluations for QA or if a problem.
• Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals.

• Pathologists should be evaluated by the laboratory director as technical supervisors.

• CMS permits (encourages) creativity in meeting competency requirements.
CMS CLIA DATA UPDATE
### CMS CLIA DATA UPDATE

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Laboratories</td>
<td>232,548</td>
</tr>
<tr>
<td>Total Non-Exempt</td>
<td>225,746</td>
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<tr>
<td>Compliance</td>
<td>19,319</td>
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<tr>
<td>Accredited</td>
<td>15,787</td>
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<tr>
<td>Waived</td>
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<tr>
<td>Provider Performed Microscopy</td>
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<tr>
<td>Exempt</td>
<td>6,802</td>
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<tr>
<td>• NY</td>
<td>3,336</td>
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<tr>
<td>• WA</td>
<td>3,466</td>
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</table>

CMS data base 6/2011
CLIA Labs by Certificate Type
(Non-Exempt Only)

- Provider Performed Microscopy: 17%
- Accreditation: 7%
- Compliance: 9%
- Waiver: 67%

Source: CMS CLIA database 06/2011
Physician Office Laboratories by CLIA Certificate Type
(Non-Exempt Only)

- Provider Performed Microscopy: 27%
- Accreditation: 5%
- Compliance: 11%
- Waiver: 57%

Source: CMS CLIA database 06/2011
Decade Trend

Source: CMS CLIA database 12/14/2010
CMS CLIA DATA UPDATE

Decade Trend

- Total Labs
- Compliance Labs
- Accreditation Labs

CLIA

Total Labs trend from 2002 to 2011 shows a steady increase, with a significant jump from 2010 to 2011.

Compliance Labs trend from 2002 to 2011 shows a moderate increase, with a slight dip in 2009.

Accreditation Labs trend from 2002 to 2011 shows a steady increase, with a significant jump from 2010 to 2011.
CLIA Laboratory Registration
Self-Selected Laboratory Types

Source: CMS CLIA database 06/2011
CMS CLIA DATA UPDATE

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization

- COLA: 6,623
- CAP: 5,602
- TJC: 2,431
- AABB: 219
- ASHI: 124
- AOA: 110

Source: CMS CLIA database 06/2011
# CMS CLIA DATA UPDATE

## Transfusion Fatalities

<table>
<thead>
<tr>
<th>Type</th>
<th>FY 2010</th>
<th>FY 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRALI (Transfusion Related Acute Lung Injury)</td>
<td>36</td>
<td>31</td>
</tr>
<tr>
<td>Hemolytic (Immune)</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>TACO (Transfusion Related Circulatory Overload)</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Bacterial Contamination</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Other (Anaphylactic, Graft vs. Host Disease, Babesiosis, Hyperhemolysis Syndrome, Allergic, Non-Immune Hemolytic, Unknown)</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>TOTAL</td>
<td>71</td>
<td>75</td>
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</table>
### CMS CLIA DATA UPDATE

#### Transfusion Fatalities

<table>
<thead>
<tr>
<th></th>
<th>FY 2010</th>
<th>FY 2009</th>
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</thead>
<tbody>
<tr>
<td>Investigations</td>
<td>4</td>
<td>11</td>
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<tr>
<td>2567’s</td>
<td>0</td>
<td>7</td>
</tr>
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</table>

#### 2567’s issued
- Specimens mixed up in the lab
- Specimen drawn from the wrong patient
- Testing errors—missed antibodies
- Wrong FFP type issued
- Wrong patient transfused
<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mod. complexity LD qualif./respons.</td>
<td>4.2%</td>
</tr>
<tr>
<td>Successful PT participation</td>
<td>3.2%</td>
</tr>
<tr>
<td>PT enrollment</td>
<td>1.8%</td>
</tr>
<tr>
<td>Analytic Systems (QC)</td>
<td>1.7%</td>
</tr>
<tr>
<td>Mod. complexity TP</td>
<td>1.5%</td>
</tr>
<tr>
<td>Citation</td>
<td>% Labs Cited</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>High complexity director qualif./respons.</td>
<td>1.3%</td>
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<tr>
<td>Technical consultant qualif./respons.</td>
<td>1.0%</td>
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<tr>
<td>Hematology</td>
<td>0.6%</td>
</tr>
<tr>
<td>Gen. Lab Systems QA</td>
<td>0.3%</td>
</tr>
<tr>
<td>Gen. Lab Systems preanalytic</td>
<td>0.3%</td>
</tr>
<tr>
<td>Citation</td>
<td>% Labs Cited</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>• Policy for proper reagent storage</td>
<td>5.8%</td>
</tr>
<tr>
<td>• Analytic Systems’ QA</td>
<td>5.5%</td>
</tr>
<tr>
<td>• Verify accuracy non-PT’d tests</td>
<td>5.5%</td>
</tr>
<tr>
<td>• Follow mfgr’s. instructions</td>
<td>4.9%</td>
</tr>
<tr>
<td>• Procedure manual</td>
<td>4.6%</td>
</tr>
<tr>
<td>Citation</td>
<td>% Labs Cited</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>LD responsibility-QA plan</td>
<td>4.4%</td>
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<tr>
<td>Mod. complexity LD qualif./respons.</td>
<td>4.2%</td>
</tr>
<tr>
<td>Calibration verif.</td>
<td>4.2%</td>
</tr>
<tr>
<td>Use of expired reagents</td>
<td>4.1%</td>
</tr>
<tr>
<td>Gen lab systems QA</td>
<td>3.7%</td>
</tr>
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</table>
CMS CLIA DATA UPDATE
Partners’ Deficiencies 2007-9
CMS CLIA DATA UPDATE
Waived Lab Growth

ACCRED/COMP
PPM
WAIVER
CMS/CLIA Contact Information

- **CMS/CLIA web site:**
  Includes States, Regulations, Guidelines

- **CMS/CLIA Central Office:**
  410-786-3531

- **Judy Yost’s Email:**
  judith.yost@cms.hhs.gov