The Inspector is at the Door – Is your QC Ready?

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The “unannounced” inspector

Successful strategy: Be prepared!

Be Prepared – Arrival Plan in Place

Check out inspection information for your agency

Once you know "this" is the day!!

- **Follow organizational policy**
  - Who notifies whom?
    - Contact ALL that need to know
  - Assigned duties for making necessary adjustments
    - Cancel meetings
    - Adjust staffing
    - Obtain rooms
    - Order food
    - Clear space, have coat rack
    - Handle any HIPAA concerns with inspectors
    - Etc., etc., etc.

Be Prepared – Documentation Ready

Have documentation ready (up to date) and accessible (inspection NOT dependent on managers)

- Organization chart
- Goals of laboratory
- Scope of service
- General test site information
- Answers to each checklist/survey item
  - Annotated checklist/survey items
    - Include supporting data or where it can be found

Be Prepared - Documentation Ready

- QA - Plans, monitors, method comparisons, accuracy assessments, IQCP
- Personnel records - Training, competency
- Procedure manuals
- Policies/procedures for all 3 phases of testing
- QC Plan - QC analysis, results, evaluation, corrective actions, and documentation
- PT - Enrollment, performance, review, corrective actions

Be Prepared – Documentation Ready

Records

- Reagent storage temperatures
- Instrument/method records
  - Maintenance and function checks
  - Performance specification verification (accuracy, precision, reportable range, identification of reference range
- IQCP documents if applicable (CAP requires an IQCP list and Summary)
- Patient test results
  - Critical values, documentation with reference ranges

Audit trail established

- Be able to link patient results with appropriate information
  - Order, QC, analyst, date, time, instrument, etc.

Be Prepared

Keep food/drink out of laboratory refrigerators

- Have “no flammables” and “no food” signs on door
- Keep food away from lab entry ways

Understand hazardous chemical labeling

- Know what to do in case of accident

Verify labels on controls, reagents, bottles, kits

- Check expiration dates

Verify records (e.g., log sheets, QC charts, electronic files, etc.) for completeness

- Reviewed, signed, dated, etc.

Be prepared – Be aware of pitfalls

Review frequently cited deficiencies for your inspection agency

CLIA January 2016 Deficiencies

CLIA Standard	Requirement	Deficiency%
§493.1252(b)	Defined criteria for essential for storage of reagents and specimens; reliable test system operation ; test result reporting	5.3%
§493.1251(b)	Procedure manual that includes step-by-step performance of procedure	4.4%
§493.1289(a)	Lab much follow written policies to monitor, assess and when indicated correct problems	4.4%
§493.1291(c)	Test results must indicate positive patient identification (name or number), name and address of the lab location etc.	4.2%
§493.1235	The lab must establish and follow policies to assess employee and consultant competency	4.1%

CAP 2016 Deficiencies

CAP Standard	Requirement
GEN.55500	Competency Record
COM.01200	Accurate Activity Menu
COM.10000	Procedure Manual
COM.04200	Instrument/Equipment Record Review
COM.10100	Procedure Manual Review
COM.30300	Reagent Labeling
COM.30600	Maintenance/Function Checks
COM.01700	PT Evaluation
COM.01400	PT Attestation Statement
COM.40000	Method Validation and Verification

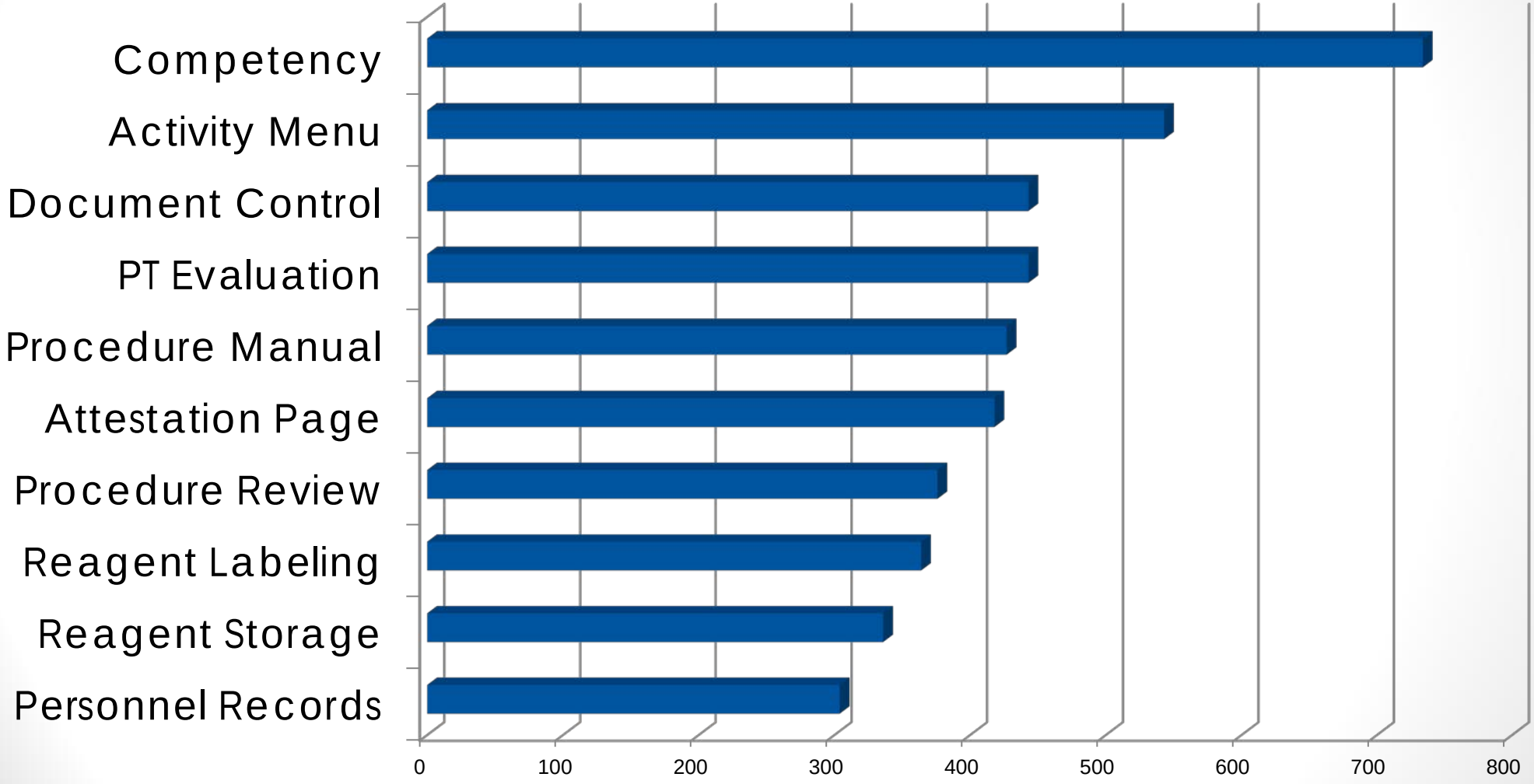
TJC Top (2016) Lab Concerns

TJC Standard		Requirement
HR.01.06.01	(42%)	Staff are competent to perform their responsibilities
QSA.02.08.01	(34%)	The lab performs correlations to evaluate results of the same test performed with different methodologies , instrument or different locations
DC.02.03.01	(31%)	The lab report is complete and is in the patient's clinical record
QSA.01.03.01	(31%)	The laboratory has a process for handling and testing PT samples
LD.04.05.07	(30%)	The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining lab performance
EC.02.04.03	(28%)	The laboratory inspects, tests and maintains lab equipment
QSA.02.03.01	(28%)	The lab performs calibration verification
QSA.02.10.01	(27%)	The lab participates in CMS approved PT program for all regulated analytes
QSA.01.02.01	(27%)	The lab maintains records of PT participation

COLA Frequent (2016) Citations

COLA Standard	Requirement
PER 5	Lack of complete or current competency records
LDR 5	Lab Director not fulfilling responsibility for QC/QA
PT16	Lack of documented review of PT
LDR 4	Lab Director not fulfilling responsibilities for PT
PER 4c	Technical Consultant or Technical Supervisor not fulfilling responsibilities
WAV 2	Waived testing QC not performed per manufacturer
QC 16	Lack of quantitative QC review using graphs or statistical tools
PER 4e	Testing staff not fulfilling responsibilities
CA 2	Lack of Calibration Verification
PT 4	Lack of 2x per year accuracy verification for unregulated analytes

Most Commonly Cited CAP POCT Deficiencies in 2013



Find problems BEFORE inspection

Leadership saves the day – BE PROACTIVE!

Self-Inspection -- Discovery….

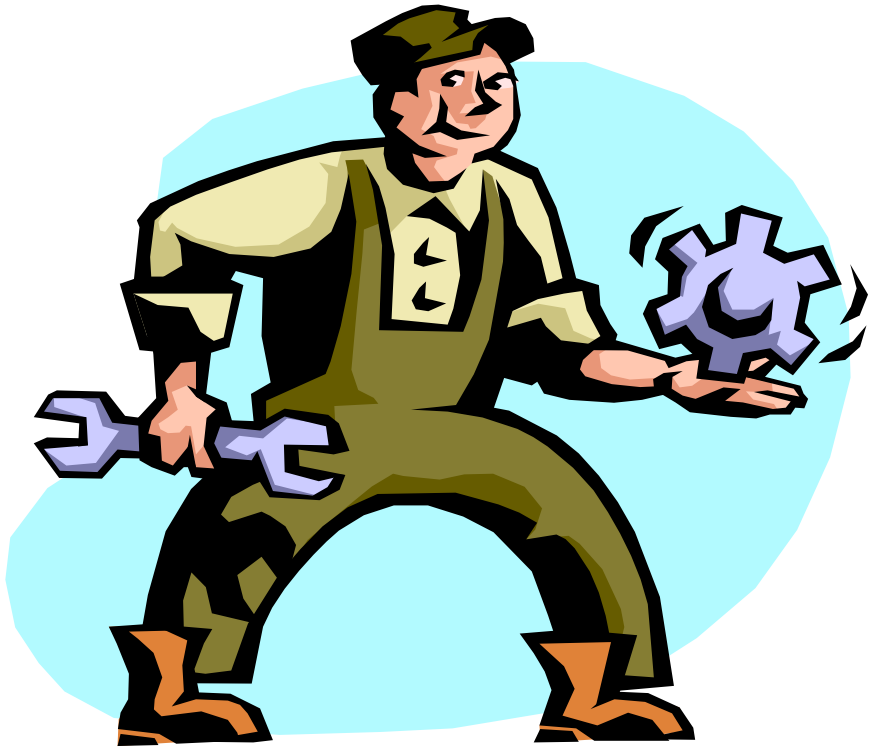
Find and fix problems BEFORE the inspector does!

CAP encourages to "ramp up" interim self-inspections!*

- CAP's Inspection Process and Continuous Compliance Committees encourage more CAP-accredited laboratories to ramp up their self-inspection efforts and suggest:
  - Treat a self-inspection like a real event.
  - Begin the self-inspection process, by reviewing the deficiencies cited in the last CAP inspection.
    - Reconcile these with your deficiency responses to see if you're really doing what you told CAP
  - Add authenticity, when possible, in ferreting out as many deficiencies as possible by using "inspectors" from sister institutions

*New push to strengthen interim self-inspections. CAP Today. January 2013

Self-inspection to Identify Problems



Promotes learning and Continuous Quality Improvement (QCI)

What are we doing?
How are we doing it?
Why are we doing it?
Can we do “it” better?

Identify problems

- Follow samples through entire testing process
  - Tracer methodology
    - Follow a charted result back through pre-analytical, analytical and post-analytical phases
    - identify who, what, where, when and why
      - Include everything that impinges on the test
- Review policies/procedures with all staff
  - Staff needs to know the what, how and why
    - Quiz staff; have staff explain why something is handled in a particular way

Tracking Tools for (all) analytes*

- Tracker (tracer) tools
  - Ordering
  - Specimen collection
  - Specimen processing
  - Sample testing
    - QC analysis, evaluation, documentation
    - Corrective actions
  - Resulting

*Anne Belanger, MT(ASCP) consultant, former TJC director laboratory accreditation

Tracking Tool for (all) analytes*

- Is QC run at appropriate intervals?
- Is the “right” QC run?
- Is QC performed/checked for acceptability before reporting results?
  - If QC is not acceptable, is corrective action taken?
  - Is sample reviewed and rerun, as necessary?
  - Are corrective actions documented?
- Are QC results documented?
- Are QC materials stored correctly?
- Are materials used before expiration dates?
- Are QC results reviewed regularly to evaluate accuracy and precision of method?

Impress the inspector with preparation!

Fail-Safe Tips: With Inspectors

Things that should never occur

- Dirty laboratory
- Unsafe practices
- Uncorrected old citations
  - Always have a plan!
- Messy storage areas
- Staff who are not in the loop regarding policies/procedures/inspection process

Fail-Safe Tips: With Inspectors

- Be courteous, cordial and professional
- Be honest; display a positive attitude
- Just answer the question; Be to the point - Ask for clarification, suggestions; Don’t volunteer “extra” information
- Have everyone ready to explain the why and how
- Don’t argue; resolve if possible, otherwise explain in writing later
- Always use safe practices; follow stated practices and protocols

Inspection - DOs / DON'T

Don't delegate duties to unprepared staff	• Unknowledgeable staff communicating with the inspector is disastrous
Do have alternative plans when assigned staff is not available	• All staff must be prepared; inspectors will talk to most
Do present an organized front	• Quality NOT associated with mismanagement, hostilities, "in-fighting," disorganization
Do understand proper utilization of plan of correction	• State your case in the written plan of correction

After the inspection

- Realize final decision usually up to regulator's oversight function, e.g., its board
- Review all citations
- Perform follow up per regulator's guidelines
  - Prepare plan of correction
  - Implement needed corrections
  - Provide evidence to regulator per guidelines
- Keep inspection ready
  - Goal of unannounced inspections

Planning for Quality and Benefiting from Inspections

Good	Bad
Make quality a philosophy with top priority	Quality is a good concept, but just a plan
Be inspection ready	Prepare just prior to inspections
Implement self inspections to identify problems and potential problems	Let inspectors/assessors identify the problems
Know, follow , answer all relevant CLIA or AOs requirements. Document policies and procedures	Be inconsistent and unorganized in meeting the requirements
Implement continuous quality improvement based on collected data	Don't worry about CQI and/or don't react to problems and improve processes

To benefit from inspection,
a laboratory must have both a:

Manager and Leader

Managers vs. Leaders

A manager does the thing right

A leader does the right thing

THANK YOU!