Laboratory Director Responsibilities: Part 2- Practical Application

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Family Physician & Laboratory Director
Hutchinson Clinic
Hutchinson, KS

DESCRIPTION:
In Lab Director Responsibilities: Regulatory, Dr. Janzen provided an overview of the regulations and personnel a laboratory director needs in order to be successful. In this session, Dr. Janzen will summarize the laboratory director's responsibilities when it comes to the technical areas of the laboratory in quality control, proficiency testing, and quality assessment, and provide some practical insight and tips for the new Laboratory Director.

OBJECTIVES:
At the end of the session, participants will be able to:
- Implement practical ways of meeting the CLIA requirements for the laboratory director
- Satisfy most CLIA laboratory director requirements with one-hour meetings every month and an additional annual meeting with your laboratory staff
- Plan for what needs to be accomplished in the first weeks of being named “laboratory director” of your POL
Lab Director Responsibilities

Part 2

Part 1 – The “What” you need

Part 2 – the “How & When”

Symposium for Clinical Laboratories

Verlin K Janzen MD
Hutchinson Clinic, PA – Hutchinson, KS

Overview

- Incident Management / Problem Log
  - Root cause analysis
- Competency
- Proficiency Testing
- Laboratory Errors
- Laboratory Meetings
- New Lab Director – getting started
- Resources
Review – LD Responsibilities

1. Overall operation – competency, compliance
2. If qualified – TC, CC, testing personnel – or delegate
3. Accessible – up to 5 labs
4. Testing systems – quality services
5. Safety – OSHA, EPA, nuclear, electrical, fire
6. Testing methods – quality results, verify accuracy/precision/etc, performance by staff
7. Proficiency testing – enroll, review, correct
8. QC/QA – establish, maintain
9. Analytic Performance – establish, maintain
10. Report contents/Consultation
11. Personnel – number, training, competency, monitor
13. Specific responsibilities/roles in writing
14. Liaison

Incident Management Policy

QA 20

› Has the laboratory developed and implemented written policy and procedures to identify, evaluate, manage, and correct any incidents, resulting from non-compliance with stated policies and procedures?

› Does the laboratory have procedures for the identification, evaluation, management, and correction of any unexpected event which has caused, or has the potential to cause, death or serious injury to patients or laboratory staff?

› What do you want to know about? When? How?
Problem Log

- GET your personnel to use – it is a VERY valuable tool
  - Feeds into QA/QI program
- Incident – big things that DID directly affect a patient
- Near miss – big things that COULD HAVE affected patient if not prevented just-in-time
- Occurrence – little things that matter but don’t cause serious patient harm – but when occur repeatedly can affect quality and patient

Incident Management Policy

- Root Cause Analysis
- Written report to you
  - When, what, how
  - What happened
  - Problems identified
  - Corrective action – proposed
- Review @ next mtg – ask questions
- Agree on resolution / corrective action
  - Do we need a change in policy or procedure?
- Sign & date
- QA monitor
Root Cause – ask ‘and this happened because?’ FIVE times

INCIDENT: Protime order was missed on Mrs. Jones @ XYZ nursing home

1. ATHB it wasn’t on the order list given to phlebotomist
2. ATHB the order was taken by the fill-in lab clerk who didn’t record it in the correct place
3. ATHB the substitute clerk didn’t know where to record the request
4. ATHB this wasn’t included in the clerk’s training
5. ATHB it wasn’t on the training checklist
6. Etc

ATHB – and this happened because ...

Occurrences

› Look for patterns – repeated problems in problem log
  ▪ Physician complaints about TAT every Monday
  ▪ Repeated errors involving same tech
  ▪ Staff to summarize each month or 2

› What will correct problem – chg in procedure, training, additional personnel, etc
**COMPETENCY**

Competency

- Remember:
  The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures ....'

- How can I do this?
  - Delegate to TC/TS – verify being done
Competency

- Training, training, training
- MT/MLT training – often hospital based
- Your training
  - Your lab procedures, policies, methods, instruments, expectations (TAT, volumes)
  - POL ≠ hospital (nothing to do with quality)
  - 2 days to 2 months
  - Technical consultant, current employees, instrument company
  - Document
- Training ≠ read & initial procedure!

Competency

- Re–train – continuous need
  - new procedures, changes in procedures, new job responsibilities
- Competency assessment
  - Proficiency testing – rotate between staff, record
  - TC – observe maintenance, calibration, QC, etc. –> document
  - Tests requiring interp (manual diff, gram, ANA) – all do & compare results
  - Keep slides from unusual cases & PT – use for training & competency
  - Unknowns, patient repeats
6 Components of Competency

1. Direct observation test performance – as applicable
   - patient prep, specimen handling/processing, testing
2. Monitoring recording & reporting of results
3. Review of intermediate test results/worksheets, QC, PT, PM
4. Direct observation of instrument maintenance & function checks
5. Assessment of test performance – testing previous samples, blind testing, PT
6. Assessment of problem solving skills
Personnel

- Do I need to hire MT’s?

<table>
<thead>
<tr>
<th>Level of personnel</th>
<th>1</th>
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<tbody>
<tr>
<td>Lab Director’s time</td>
<td></td>
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</table>

- Use consultants as needed
  - Local hospital vs. professional consultants

Personnel

- BS – Laboratory
  - Medical Technologist – MT(ASCP)
  - Clinical Laboratory Scientist – CLS(NCA)
  - Medical Laboratory Scientist – MLS(ASCP) (1)

- Associate – Laboratory
  - Medical Laboratory Technician – MLT(ASCP)
  - Clinical Laboratory Technician – CLT(NCA)
  - Medical Laboratory Technician – MLT(ASCP) (1)

- Other
  - CMA, MA
  - RN, LPN
  - OJT – high school grad (moderate complexity)

(1) Oct 2009 – ASCP BOR & NCA merging to ASCP Board of Certification
(8/09 G2 Reports)
Hutchinson Clinic

- 70+ physician multi-specialty clinic
- Laboratory
  - Employs:
    - 10 FT + 3 PT Phlebotomists
    - 10 full-time + 5 part-time MTs
    - 5 full-time + 1 part-time MLTs
    - 3 HS diploma (drug screen technician, processing, courier)
  - 2 secretary
  - Performs over 1.3 million tests a year

Delegation of Responsibilities

- Delegate but verify
- Delegate in writing (CLIA requirement)
  - Example – see addenda after pg ___
- Before testing  §493.1407(e)(14)
  - LD must sign-off (based on TC recommendation)
  - Do they need supervision – Y/N?
- REMEMBER – lab director involvement is key to a successful POL
PROFICIENCY TESTING

Proficiency Testing (PT)

- **Required** for *regulated analytes*
- **Recommend** PT for all tests that you can
  - Fewer twice yearly QA accuracy checks the better
  - Easier – while more costly
- **WARN** employees that inter–laboratory communication a **NO NO**
- Look first to your specialty’s program
  - IntMed (MLE), FamMed (AAFP–PT)
Proficiency Testing (PT)

- PT is the LD’s best view of lab quality – much better than patient results you order
- While CLIA says you *can* delegate to TC – I recommend that you NOT
  - PT failures = frequent cause of cease testing
  - Early warning system
- RECOMMEND – you look at ALL PT reports
  - Don’t just look at Pass/Fail summary
    - Only includes regulated analytes
  - Investigate ALL failures – even 1 of 5
  - Also – external comparison to other labs

Evaluation of PT Failures

- USE a checklist to investigate cause
  - Clerical error
  - Instrument Maintenance
  - QC – was it okay
    - QAP
    - Calibration up to date
    - Expirations dates (reagents, QC, etc)
  - PT material – condition on arrival
  - PT instructions followed
  - Equipment operating procedures followed
  - Did repeat testing on residual sample produce similar results?
  - Other
So, for PT ...

- Look at ALL reports
- Learn to interpret reports
  - Look for more than P/F
  - Get MT or consultant to explain
- Investigate all failed challenges
  - Not just if fail (< 4/5)
- Periodically – look at summary booklet
  - Is your instrument commonly in use
  - How does it typically perform vs others
  - Often has educational material

Lab Errors

Most are instrument or testing errors – right?
Lab Errors – Primary Care

<table>
<thead>
<tr>
<th>Phase of Testing</th>
<th>Errors (%)</th>
<th>Effect on Patient Care</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Pre-analytic</td>
<td></td>
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</tr>
<tr>
<td>Test Initiation</td>
<td>100 (55.6%)</td>
<td>21 (42.9%)</td>
</tr>
<tr>
<td>Specimen Collect/Hand</td>
<td>39 (21.1%)</td>
<td>4 (6.2%)</td>
</tr>
<tr>
<td>Specimen Collect/Hand</td>
<td>61 (33.9%)</td>
<td>17 (34.7%)</td>
</tr>
<tr>
<td>Analytic</td>
<td>24 (13.3%)</td>
<td>8 (16.3%)</td>
</tr>
<tr>
<td>Post-Analytic</td>
<td>50 (27.8%)</td>
<td>16 (32.6%)</td>
</tr>
<tr>
<td>Inconsistent Results</td>
<td>6 (3.3%)</td>
<td>4 (8.2%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>180 (100%)</td>
<td>49 (100%)</td>
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</tbody>
</table>

Nutting PA. JAMA 1996; 275:635-639
Laboratory Errors

Of 92 Pre–analytic Errors

<table>
<thead>
<tr>
<th>Description</th>
<th>No. (%)</th>
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</thead>
<tbody>
<tr>
<td>Requisition incorrect</td>
<td>6 (5%)</td>
</tr>
<tr>
<td>Patient injured during phlebotomy</td>
<td>7 (5%)</td>
</tr>
<tr>
<td>Patient unhappy with phleb customer service</td>
<td>7 (5%)</td>
</tr>
<tr>
<td>Specimen not labeled or mislabeled</td>
<td>13 (10%)</td>
</tr>
<tr>
<td>No specimen collected</td>
<td>5 (4%)</td>
</tr>
<tr>
<td>Incorrect tube used</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Specimen suboptimal or ruined</td>
<td>8 (6%)</td>
</tr>
<tr>
<td>Specimen lost/delayed in transport</td>
<td>20 (26%)</td>
</tr>
<tr>
<td>.... In laboratory</td>
<td>17 (13%)</td>
</tr>
<tr>
<td>.... Other</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Failure to order, add, or change test request</td>
<td>14 (11%)</td>
</tr>
<tr>
<td>Data entry error</td>
<td>16 (12%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (2%)</td>
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</tbody>
</table>
### Of 23 Analytic Errors

<table>
<thead>
<tr>
<th>Description</th>
<th>No. (%)</th>
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</thead>
<tbody>
<tr>
<td>Instrument Error</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Human Error</td>
<td>18 (14%)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (3%)</td>
</tr>
</tbody>
</table>

### Of 14 Post–Analytic Errors

<table>
<thead>
<tr>
<th>Description</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results not reported, delayed reporting, or reported to wrong provider</td>
<td>7 (5%)</td>
</tr>
<tr>
<td>Incorrect report due to post-anal data entry error</td>
<td>5 (4%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (2%)</td>
</tr>
</tbody>
</table>
So ..

- Most errors ARE NOT instrument or even testing related
- Most are pre-analytic

MEETINGS

Do you have lab meetings?

How much time do you spend annually?
Lab Meetings

- Regular schedule: ~1 hr monthly
- Have agenda (see addenda after pg ____)
  - Expectations, miss less, more efficient
- Keep minutes – brief, action oriented
- Provide lunch / rolls !!

Laboratory Minutes with Dr. Janzen

Sept. 9, 2010

1. Tongue Scrapings for KOH – At this point, Dr. Janzen decided that he will continue to perform his own tongue scrapings. Dohm Fast informed me that there are very few physicians that order a KOH from a tongue scraping. What they do get usually comes from Dr. Janzen’s office. Dr. Janzen will let me know if the phlebotomists need to start performing this collection.
2. Physicians on Call Saturday’s and after hours – Dr. Janzen wrote a Policy and Procedure for contacting Physicians regarding panic values. Larry will add what is needed and get back to Dr. Janzen for review and completion.
3. Hospital fire (incident) – Larry will E-mail Dr. Janzen phone numbers for Dohn, Kristin and Eileen for emergency purposes. It was also discussed that a contingency plan be written in-case the hospital needed lab services outside clinic hours. Larry will put something together for next meeting. Also, Dr. Janzen wanted to make certain that his phone number is available for the Technical staff, for emergency purposes.
4. Lipid Cascade tests – LabCorp has new testing that has to do with Lipid Cascading. Larry will get some documentation from LabCorp on these tests so Dr. Janzen can speak with his colleagues.
5. E-screen – Larry will get Dr. Janzen price differences between the 5 and 10 panel drug screens.
6. Microbiology – Dohn Fast
   a. Campylobacter – discussed testing options between culture and Ag assay. We have found that the Ag assay is a much better test. The assay of interest is from Meridian. Dohn and Larry will work up cost analysis for Dr. Janzen along with more information for his review.
   b. Clostridium difficile – discussed testing options for the C. diff. Dohn stated that the preferred method is toxiginic culture. However, this is very time consuming and tedious. Illumagene tests for the toxiginic gene of C. diff. We will work up cost analysis for Dr. Janzen and get some literature on comparisons.
   c. Chlamydia and Gonorrhea probes – The Gen Probe will be discontinued in 2012. Only other real option is amplified technique at this point. We will continue to look at all options throughout the next year or so.
   d. Space issue - All these new tests brought up the issue of more space needed in microbiology. It was discussed that perhaps we could somehow move Dohn out of the department and into an office of his own, freeing up his bench for these tests. Possible solutions are taking space from Sp. Chem, the lab break room or even moving toward the accounting dept. We will continue to look at the set-up of the lab and other options.

Next Meeting
Oct 6, 2010

Annual Meeting – 1–2 hr

- Annual signing of procedure manuals
- Personnel appraisals
- Review/approve QA plan for upcoming year
- Technology needs – planning
  - Review send–outs for new testing opportunities
- Personnel needs
Meetings
How much time do you spend annually for lab meetings?

~14 hours +

Monthly mtgs with LD – Agenda

1. Review of previous meeting minutes
   - Follow-up of items from previous month
2. QC Review
3. Review of PT reports
4. Problem Log / Incidents – review
5. QA Monitors
   - Monthly
   - Follow-up of previous corrective actions and reassessments
   - New – based on problem log, etc
6. Department of Month – meeting with Technical Supervisors of departments on rotating basis
   - Hematology – January, June
   - Chemistry – February, July
   - Special Chemistry – March, August
   - Microbiology – April, Sept
   - Urinalysis – May
   - Phlebotomy – October
7. Personnel issues
   - New - training, 6 mo competency
   - Needs
   - Problems
8. Technical / Instrument Issues
   - New tests – review data, sign-off on new procedures
   - Instrument problems – downtime, maintenance issues
9. New Items
   - General Supervisor
   - Lab Director
10. Industry News / Updates
11. Next meeting

› This works for us – devise what works for you
Periodic Agenda Items

1. QA plan – review @ January meeting
2. Budget – review in June
   ▪ Technology
   ▪ Personnel
   ▪ Other
3. Proficiency Testing – October
4. Reference Lab issues – November
5. Annual review of test menu – look for new tests – January
6. Test volume review – January
7. Annual Surveys
   ▪ Employees
   ▪ Physicians
   ▪ Patient satisfaction

This works for us – devise what works for you!

RESOURCES
Meeting Syllabus / Flash Drive

- Contains ALL handouts
  - General Sessions (notebook)
  - Breakout Sessions
- COLA Accreditation Criteria
- Laboratory Resources
  - CMS Brochures
  - COLA Lab Guides

www.cola.org
www.labuniversity.org

www.COLAcentral.com
More Resources I like

- Clinical Laboratory Standards Institute (CLSI) – [www.clsi.org](http://www.clsi.org)
- [www.labtestsonline.org](http://www.labtestsonline.org)

More Resources I like

- Publications
  - MLO – [www.mlo-online.com](http://www.mlo-online.com)
    - Clinical Laboratory Reference (CLR) – critical values, reference ranges, equipment, services for labs
  - ACP – [www.acponline.org/running_practice/mle/edu_cat.htm](http://www.acponline.org/running_practice/mle/edu_cat.htm)
  - CAP Today – access @ [www.cap.org](http://www.cap.org)
    - Lab Instrumentation Product Guides
    - Clinical Laboratory News – [www.aacc.org/publications/cln/Pages/default.aspx](http://www.aacc.org/publications/cln/Pages/default.aspx)
New Lab Director – Getting Started

- Get YOUR job description – duties
- Insist on being paid (unless responsibilities divided equally)

Tasks:
1. Review & sign policy & procedure manuals
2. Go over personnel files/training records with TC/GS
3. Review past year’s PT – ask MT to explain – especially failure’s & corrective action

Tasks (con’t)
4. Review copy of QA plan – monitors for past year
5. Work out delegation of duties – what you want to see and be informed of
6. Review problem log – incident reports for last yr
7. Review last survey – has everything been corrected?
8. Inform CMS / COLA of change in lab director
9. Review alert (AKA panic) values
10. Review self-assessment questions in accreditation manual with your technologist(s)
   ▪ or, CMS Interpretive Guidelines
New Lab Director – Getting Started

- Continuing Education
  - Attend another symposia
  - COLA Lab University
  - Journals / throw aways
  - From lab personnel / consultants

Next Survey

- Relax
- Prepare ahead of time – manuals, etc
  - Make 100% sure previous citations are FIXED!
- If new LD – have credentials available
- Meet surveyor in morning – indicate that you want to be at exit conference – ask for time (& be there!)
- Use surveyor as ‘free’ consultant – ask them to help solve 1–2 problems you’ve identified (they see a lot of labs and ideas)
- Don’t worry – you will have deficiencies
PROFICIENCY TESTING ISSUES
Comparing Results or Referring Specimens

Most, if not all, laboratory personnel recognize that CLIA requires that proficiency testing (PT) specimens must be handled in exactly the same manner as patient specimens. And, most probably recognize that it is not right, or might be against CLIA requirements, to compare your results with those from another laboratory – especially before the report is submitted for grading.

Few, however, realize the disastrous consequences that can befall a laboratory if PT materials are referred to another laboratory for analysis, or even if PT results are compared with results from another laboratory. Specifically, the CMS (formerly HCFA) has been revoking the CLIA certificate of any laboratory that refers PT specimens or that compares PT results with another laboratory. This has even occurred when an employee has done this secretly – without the knowledge of the laboratory supervisor or director – or honestly did not know it was forbidden. Without a CLIA certificate – the laboratory cannot operate. That would be catastrophic for the Hutchinson Clinic, our patients, and you – our employees.

We have been advised to notify all laboratory employees in writing of this requirement and to maintain documentation of such notification. Therefore, the purpose of this notice is to notify you of this prohibition, our laboratory’s policy in this regard, be sure you understand it, and to document your understanding and acknowledgement of this policy.

POLICY:
It is the policy of the Hutchinson Clinic Laboratory that 1) no proficiency testing (PT) specimen shall ever be referred to another laboratory for analysis under any circumstance, 2) there shall not be any communication of any type with another laboratory or another laboratory’s employee to discuss or compare results of PT challenges, and 3) if any other laboratory submits a PT specimen to our laboratory for analysis, that the laboratory manager and director shall immediately be notified.

Violation of this policy may be grounds for immediate dismissal.

ACKNOWLEDGEMENT:

I have read and understand the above information and policy and agree to abide by it.

Name (printed) ________________________________________________________________

Signature _________________________________________________ Date _______________
# MONTHLY LAB MEETINGS

## AGENDA

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<td><strong>7.</strong></td>
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<td></td>
<td>b. Instrument problems – downtime, maintenance issues</td>
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<td><strong>8.</strong></td>
<td>New Items</td>
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<tr>
<td></td>
<td>a. General Supervisor</td>
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<td>b. Lab Director</td>
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<td><strong>9.</strong></td>
<td>Industry News / Updates</td>
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<td><strong>10.</strong></td>
<td>Next meeting</td>
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## PERIODIC ITEMS

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<tr>
<td><strong>1.</strong></td>
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<tr>
<td><strong>2.</strong></td>
<td>Budget – review in June</td>
</tr>
<tr>
<td></td>
<td>a. Technology</td>
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<td></td>
<td>b. Personnel</td>
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<td></td>
<td>c. Other</td>
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<td><strong>5.</strong></td>
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<td>Test volume review – January</td>
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<td>Annual Surveys</td>
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<tr>
<td></td>
<td>a. Employees</td>
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<tr>
<td></td>
<td>b. Physicians</td>
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<tr>
<td></td>
<td>c. Patient satisfaction</td>
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<tr>
<td>Task / Function</td>
<td>Laboratory Responsibility</td>
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<tr>
<td>---------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Personnel Records</td>
<td>• GS – to maintain required information in personnel folders</td>
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<tr>
<td></td>
<td>• GS – have each new employee sign the PT Comparing Results or Referring Results notice – and give to LD</td>
</tr>
<tr>
<td></td>
<td>• GS – inform LD of all new hires &amp; resignations</td>
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<tr>
<td></td>
<td>• GS – assess personnel needs annually at budget time</td>
</tr>
<tr>
<td></td>
<td>• TS – training &amp; competency assessments</td>
</tr>
<tr>
<td>Job descriptions</td>
<td>• GS develop w/input from TS</td>
</tr>
<tr>
<td></td>
<td>• GS – periodically review</td>
</tr>
<tr>
<td>Personnel Evaluations</td>
<td>• TS shall be responsible for evaluating their staff</td>
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<td>• GS shall evaluate TS</td>
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<td>• LD &amp; COO shall evaluate GS</td>
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<tr>
<td>Training &amp; Competency Evaluations</td>
<td>• TS shall be responsible for ALL training and competency assessments in their area</td>
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<td>• TS shall be responsible for all documentation of training, competency assessments, re-education, etc, for personnel files</td>
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<td></td>
<td>• TS shall train or supervise training of all new staff in their area – and shall sign off before any new staff member can perform any test or procedure without supervision</td>
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<td>• TS shall be responsible for training of staff when procedures are modified or new procedures are implemented – and shall sign off on all staff prior to them performing the new procedure</td>
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<tr>
<td>Quality Control / Calibration/ Calib Verif / Preventive Maintenance</td>
<td>• TS – supervise &amp; monitor these items in their area – including:</td>
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<td>o weekly review of QC charts for trends / shifts, etc</td>
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<td></td>
<td>o monthly review of PM logs</td>
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<td></td>
<td>o monthly review of calibration logs</td>
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<td>o Review corrective actions for completeness &amp; resolution of problem – and repeated problems</td>
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<tr>
<td>Proficiency Testing</td>
<td>• GS shall order PT each year – based on input &amp; discussions with TS</td>
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<td>• TS shall assign PT challenges to staff so that over the course of the year, all staff participate – so that it is one measure of competency</td>
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<td>• TS shall review all reports – if any failures occur, shall investigate failure, write up findings, and make recommendations for prevention in the future. Submit to GS.</td>
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<td>• GS shall review reports of failures – and review with LD at monthly mtg</td>
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<tr>
<td>Semi-annual quality assessment for tests without PT</td>
<td>• TS – for their department</td>
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<tr>
<td>Employee satisfaction survey</td>
<td>• GS – ask employees for any concerns as to the running of the lab, safety issues, quality issues, etc – to be reported in confidential manner</td>
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<tr>
<td>Quality Assurance Plan</td>
<td>• Year-end – TS to review QA plan and write draft plan for following year – include staff in development – shall cover any problem areas and all</td>
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Please do not copy without permission
<table>
<thead>
<tr>
<th>Task / Function</th>
<th>Laboratory Responsibility</th>
<th>Lab Director Role</th>
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</thead>
</table>
| phases of testing     | • Monthly – TS to do or assign 2 QA monitors for that month – write up and review with LD at monthly meeting  
• TS – do followup from QA monitors previously done with correction plans                                                                                       |                                                                                  |
| Problem Log / Occurrences / Incidents | • All testing personnel & supervisors are responsible for entering ‘occurrences’ into log as they occur  
• Initial & periodic training in department meetings  
• GS – review monthly before meeting with LD for recurrent problems – develop plans to correct with TS & staff  
• GS/TS – notify LD of any “incidences” | • Review monthly at LD meeting  
• Be notified promptly of any ‘incidents’                                                      |
| Complaints – physician | • GS shall be contact for any physician or client complaints  
• GS – enter into problem log  
• GS develop responses / solutions if needed                                                                                                                    | • Review with problem log review                                               |
| Procedure Manual      | • TS - write policies & procedures  
• TS - review annually re: need for updates  
• GS - review prior to lab director                                                                                                                              | • New LD to sign off on ALL procedures & policies @ outset  
• Review and sign-off @ monthly lab meeting as needed                      |
| Budget                | • GS with input from TS shall develop annual budget  
• GS present to LD in June of each year prior to submission to administration                                                                                   | • Approve budget request                                         |
| Test Menu             | • GS with assistance from TS shall periodically review tests sent to reference labs for opportunities to add tests to our in-house testing menu  
• GS shall bring recommendations to LD at monthly meetings                                                                                                       | • Approve all new tests before added to testing menu |
| CLIA Survey           | • GS shall be primary contact for surveyors during survey  
• GS & TS shall prepare for survey – have requested items available – be sure previous deficiencies have been corrected –  
• GS/TS – implement QA monitors as appropriate to be sure previous deficiencies are corrected and don’t recur                                                                 | • Meeting with surveyors at exit conference  
• Sign off on any plan of corrections                                                                                                                                |
| Monthly newsletter    | • GS with input from TS shall write an monthly newsletter to keep physicians up to date with changes in the lab and to educate physicians on new tests, etc                                                                 | • Review prior to publication                                                                                      |
| Reference Lab – tests sent out | • GS – shall be responsible for assuring that results are returned for all tests sent out  
• GS – assess quality of reference lab service at least annually and report problems/issues to lab director  
• GS – shall sign off on all bills from reference labs for testing – and shall monitor reimbursement of expensive & esoteric tests | • Problems to be reviewed at monthly meeting |
| Panic Value Reporting | • GS/TS – annually review panic results policy – take recommended updates to LD for approval                                                                                                                          | • Approve changes                                                                                                      |
| Laboratory Information System (LIS) | • GS – has overall responsibility for all aspects of LIS                                                                                                             | • Unresolved problems                                                                                                   |