QA and QC in the Mohs Lab

What will make your CLIA surveyor smile?

Some forms have been blurred for proprietary reasons. Please contact the author at brockconsulting1@aol.com for more information.

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Say what you're going to do.
Do what you say.
Be able to prove it with documentation.
What is QA and What is QC?

QA is Quality Assessment/Assurance
- Assessment or Assurance?
- “Ongoing review process that encompasses all facets of the laboratory technical and non-technical functions…”
- From the AAD CLIA manual

QC is Quality Control
- Detecting errors
- Monitoring accuracy and precision
- Control procedures ≥ manufacturer specifications
The Difference between QA and QC

QA is preparation
- Assessment:
  - Developing policies & procedures
  - Where/when can things go wrong?
  - How can errors be prevented
- Assurance:
  - Ongoing monitoring of systems
  - Preventing the errors
  - Checking up regularly

QC is the everyday
- How to know if something goes wrong
  - With test system
  - With environmental conditions
  - With operator performance
  - With accuracy/precision over time
- Controls!
  - Test runs
  - Comparisons
General Requirements

- Confidentiality
- Addressing complaints
- Facility
  - Space
  - Ventilation/air flow
- Communication
QA: Meeting Quality Standards - Communication

Complaints/Problems/Communic. Breakdowns → Corrective action → Document → Review with staff (-discuss issues -look for solutions) → Prevent recurrences → Keep records and make available

Quality Lab
QA: Meeting Quality Standards - testing procedures

Systems for monitoring and evaluating testing procedures
QA: Meeting Quality Standards - QC problems

- Systems to correct for QC problems
- Verification of performance
- Maintenance and function checks
QA: Meeting Quality Standards - Proficiency

- Proficiency testing and competence
- Addressing failures
Yup – that means you too doc.
Reviewing updates as well

Evy-body gotta read it
What to put in your manual

- Procedures in detail
- Allow for latitude
- e.g. Use a range of temps
- Copies of all your forms
- Update forms
- Update manual
Monitor and evaluate the quality of the testing process
- Test management
- Corrective actions for QC
- Twice a year proficiency testing and annual competency
- Inconsistent results
- Methods to hand review issues
QA Section of the Manual

- How will you make sure your tests are accurate and precise?
  - What does the manufacturer require?
  - Equipment, media
- Where can things go wrong?
  - How will you attempt to keep them from going wrong?
  - What are you going to do if/when they do?
QC Section of the Manual

- Day to day monitoring of your processes
- Problem solving methods and remediation
Quality Control Program

It is the policy of the Dermatology Center laboratory to maintain a Quality Control Program to ensure accuracy of results reported. All employees of this laboratory must be familiar with and adhere to all the policies herein stated with regard to quality control.

The Quality Control Program involves monitoring the facilities; test methods and equipment; reagents, materials and supplies; procedure manual; method verification; equipment maintenance; calibration and calibration verification; control procedures; remedial actions; and maintenance of quality control records.
Record must be kept of anything that might affect results.
- Maintenance, grounding/safety, and cleaning, plus...
  - Scopes – calibration
  - Cryostats – temperature
  - Stainers – function, manufacturer recommendations
  - Fridges – temperatures
  - Hoods – airflow, filter changes
- Look to manufacturer recommendations
- If none, then Lab Director decides – document rationale
- Keep copies of equipment manuals with records
...reagents, materials, and supplies...

- How will you assure quality?
- Say what you will be recording and understand why
  - Record lot numbers to hold manufacturer accountable
  - Record expiration dates to avoid using degraded products
  - Pay attention to your everyday tools
  - Detail what you will do if items are substandard
“...procedure manual...”

- Perform an annual review
- Read through all your procedures
- Imagine your daily routine
  - Is there anything missing?
  - Have you adapted or changed a procedure?
  - Have you changed your suppliers or service companies?
“...method verification...”
Did you learn something new at a conference?

- Practice first using extra tissue
- Perfect it for your practice
- Write it up
  - Include results comparison
  - Include literature citations
- Have the Laboratory Director sign and date it
- Begin using on patient tissue
How will you make sure the results are valid
- Running control before or with patient specimens
- Comparison to photographs of standards
- Basic remediation – What if something goes wrong?
  - Stain doesn’t look right
  - Piece crumbles out of block
- Re-do test
- Take another stage at no charge
- Etc.
- Document on QC Problems Sheet - Details for each occurrence
Say what you’re going to do .....
Update Regularly

- Document changes
- Date
- What changed
- Signed by the Lab Director

From the “old” AAD lab manual.
VI. Quality Control and Quality Assurance – All quality control is performed by the surgeon at the time of the slide reading. Any artifacts in the tissue will be noted on the “QC Problems” sheet and signed by the Laboratory Director. All efforts will be made to preserve the integrity of the specimens and the solutions. Any problems will be noted on the “QC Problems” sheet and brought to the attention of the surgeon and Laboratory Director. Solutions to these problems may be made by the technician, noted as “action taken” and approved by the surgeon. Any trend in problems will be solved by the technician and the surgeon and recorded appropriately as “action taken.” Controls are taken from tissue used on previous days as available, stored on slides and run through the staining sequence prior to use on current patients. In the absence of tissue from a previous day to run as a control, the first slide of the day will serve as the control. The quality of the stain (good or poor) and any comments about the control tissue are recorded on the Control Slide Log. Poor staining quality requires adjustment of the staining process and is noted on the log.
If your manual says one thing and you do another ....
Quality Control Program

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“...reagents, materials, and supplies...” Do what you say

- You said what you would be recording
  - Record lot numbers to hold manufacturer accountable
  - Record expiration dates to avoid using degraded products
  - Pay attention to your everyday tools
  - Detail what you will do if items are substandard

- Use to record all stains and media
- Helps to have date opened on log in case you forget to put it on the bottle
Labeling, transport, need for testing – Do what you say.

- Labeling
  - Patient Name (site)
  - Unique identifier
  - Slide/case number
  - Date
- Reason for test
- Diagnosis
- Timeliness
  - Time in and time out
    - Tech
    - Surgeon

From the Mohs Surgery manual of the Dermatology Center of Grand Rapids, P.C.
Complete and accurate records win the day.

Be able to prove it with documentation.

We're going to do.

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# Maintenance Records - Microscope

**MAINTENANCE RECORD – MICROSCOPE**
Stage and oculars cleaned each day of use or as needed

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<th>KRB Scope Mohs Lab</th>
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From the Mohs Surgery manual of the Dermatology Center of Grand Rapids, P.C.
# Maintenance Records - cryostat

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## Maintenance Record - Cryostat 2023

The interior of the cryostat is cleaned each day of use. The inside surface is treated with 70% isopropyl alcohol and the outside is treated with a disinfectant wipe. At the end of the week, before turning off, the interior is treated with 70% isopropyl alcohol and the exterior is wiped and allowed to air dry at room temperature. If the temperature automatically switches to wait, it is supposed to wait until the switch is turned on.

The temperature is recorded daily and documented in a log. This temperature data is different from the outside temperature reading. Using an AWS-certified instrument, the temperature is recorded and logged in the logbook by the operator during the maintenance. The temperature on the cryostats are recorded daily and documented in the logbook every day. Includes any at annual inspection.

### Field Cleaning and Validation

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Temperature Logs
Control Runs for Slides

- Include what you're looking for
- Include lot #'s
- Evaluate your own slide
- Surgeon OK’s it
- Poor quality?
  - How is it addressed?
QC Problems

- Make sure you write it down
- Surveyors don’t like a blank QC Problems sheet
Check up on yourself regularly - Monthly

- Personnel
- Instruments/Environment
- Recordkeeping
- mediums/Reagents
  - Lot numbers
  - Control runs
  - Expiration dates
- Sign and date
- Lab Director signs off
Choose or randomize a slide
Send out or do in house if more than one dermpath
Must be blind reading
Tester should know methodology
Frozen section/H & E
Frozen section/immune staining(type)
Retain both reports for documentation
Detail and address all failures
And Annually

- Personnel
  - CME
  - Competency
  - Confidentiality
- Instrument annual checks
- Records
  - Forms collected
  - Proficiencies done
  - Manual review
  - Updates reviewed
- QA
- Problems addressed
- Communications
Annual Competency Evaluations

- Lab Director reviews all testing personnel
  - Knowledge – give a test
    - Pathologist
    - Technician
  - Direct observation
    - Procedure manual
    - Reagent handling
    - Knows procedure
    - Follows quality measures
    - Reports properly
    - Follows HIPAA
Annual Competency Evaluations

- Supervisors and consultants as well
- Give a different test
  - Offer study guide
  - Then give blank form
- Also need observation
- Others can observe
- Lab director signs off
Say what you're going to do.
Do what you say.
Be able to prove it with documentation.