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.

BCS
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Say what you're going to do.

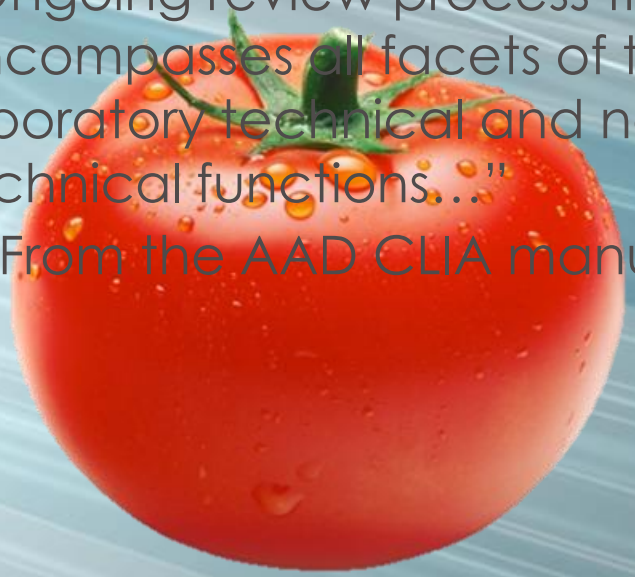
Do what you say.

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

Say what you're going to do.

Do what your manual

Be able to prove it with records

Must meet Quality Standards

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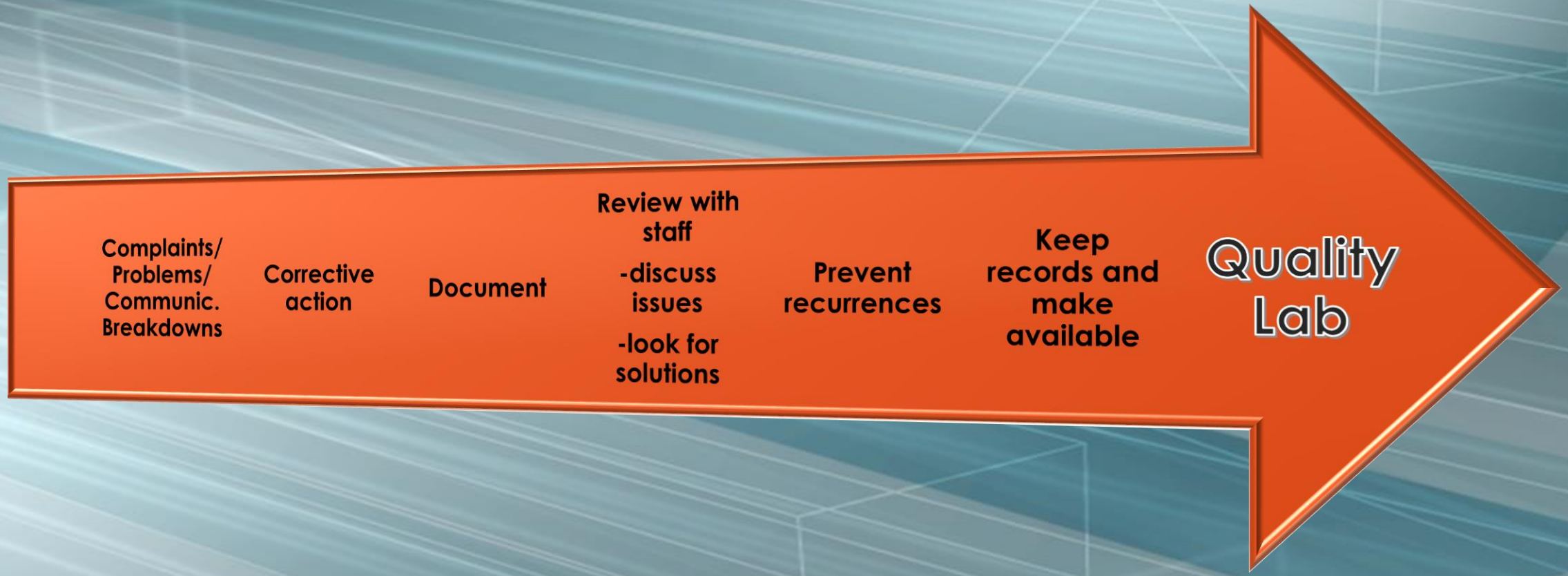
General Requirements

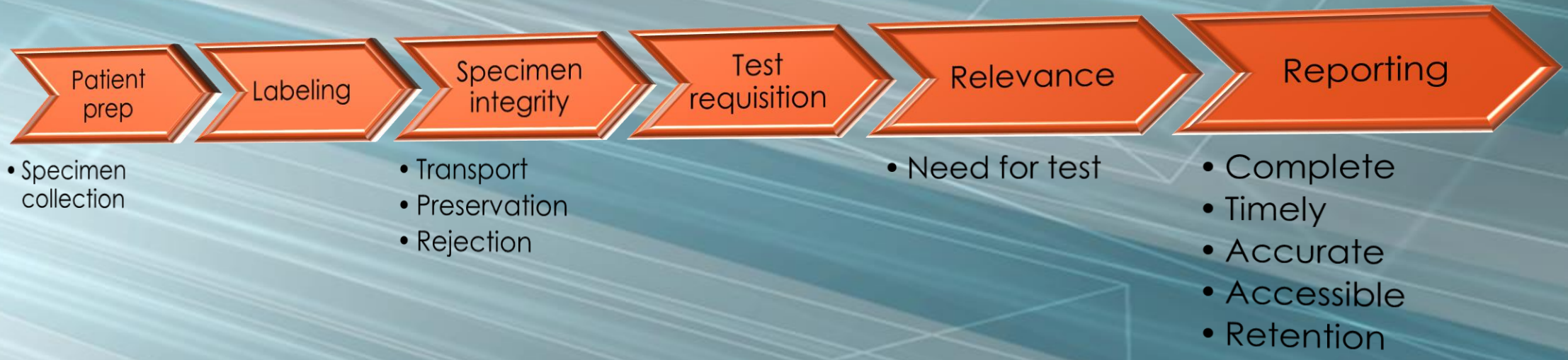
- Confidentiality
- Addressing complaints
- Facility
  - Space
  - Ventilation/air flow
- Communication

QA: Meeting Quality Standards - Communication



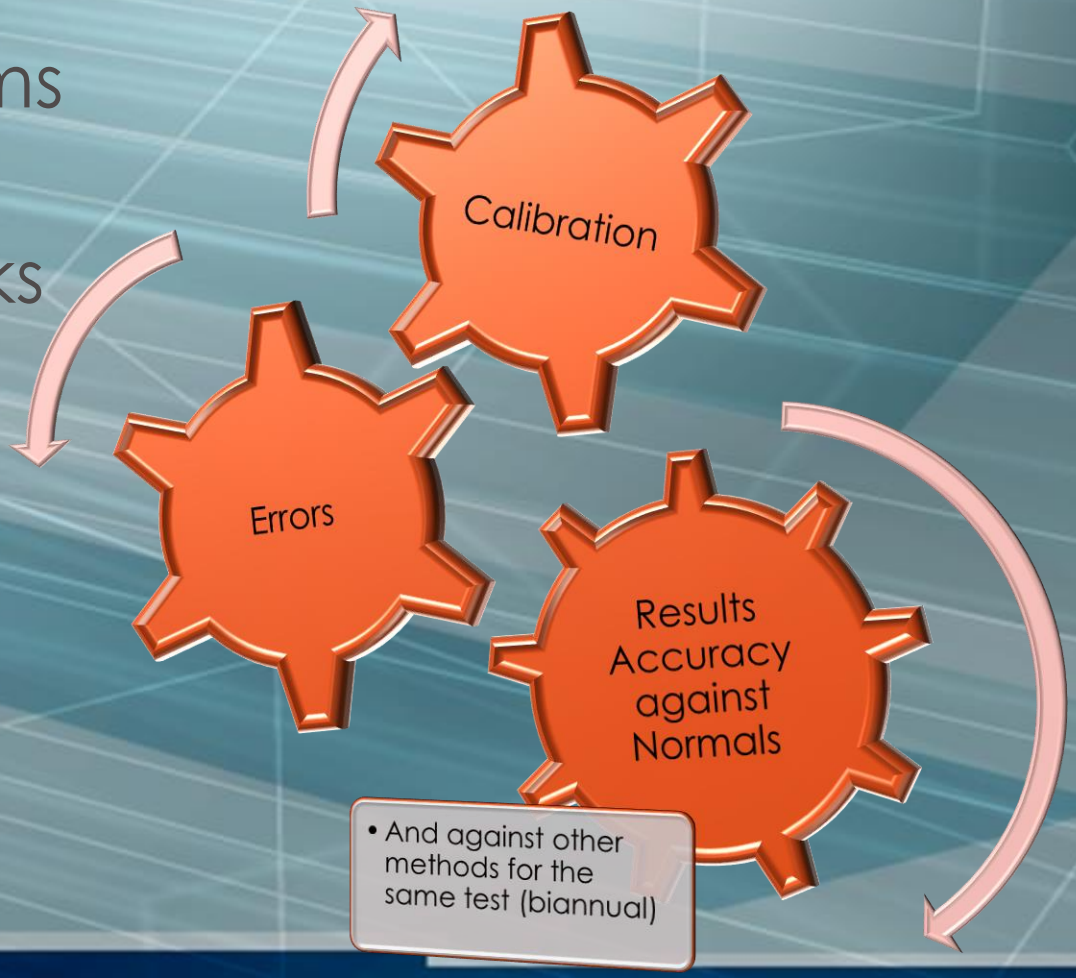
QA: Meeting Quality Standards - testing procedures

- 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

Quality Manual

- Yup – that means you too doc.
- Reviewing updates as well

Mohs Surgery Procedure Manual
Review page

This procedure manual contains standard operating procedures, maintenance schedules and procedures, and quality control and assurance procedures and statements. Charts and logs are kept in separate areas of this notebook. The Laboratory Director and Mohs surgeon review these procedures annually and after any changes are made. Testing personnel must read the manual prior to performing

Laboratory Director	Date	Testing personnel	Date
Mohs surgeon	Date	Testing personnel	Date
Laboratory Director	Date	Testing personnel	Date
		Testing personnel	Date

LABORATORY MANUAL SIGN OFF SHEET

I have read and understand these procedures and updates and agree to comply with them.

Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
		Testing personnel	Date
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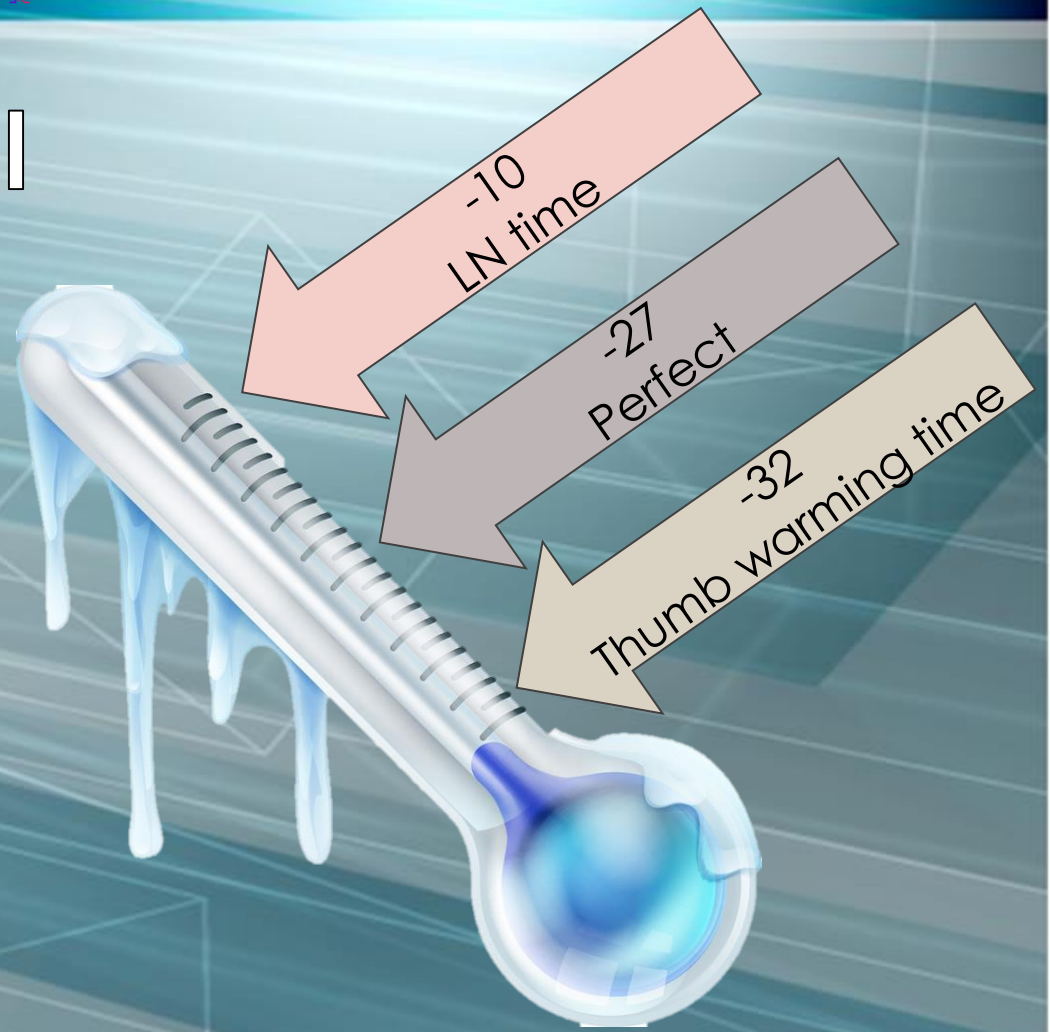
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date
Testing personnel	Date	Testing personnel	Date

Evy-body gotta read it

By Tom Mu
https://co

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



QA Section of the 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

QC Section from the AAD Manual

From the "old" AAD lab manual – we're still using it in our office.

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.

"…facilities, test methods and equipment… …maintenance; calibration and calibration verification…"

- Records 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

"…control procedures…remedial action…"

- 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 .....

From the "old" AAD lab manual.

Equipment Quality Control — Microscope

Note: Indicate frequency of activity in appropriate space, e.g., every six months.

1. Microscope stage and ocular eye pieces are to be cleaned each day of use or as needed Stage is to be cleaned with alcohol or similar cleaner and ocular eye pieces are to be cleaned with lens paper.
2. Grounding check is monitored every year.
3. Notify the supervisor if any problems occur with instrumentation.
4. Every action is documented on the maintenance record form.
5. Annual checks done by Optitech – [no scopes with ocular micrometers.]

Protocol for Dealing with a Nonfunctioning Microscope

(Check applicable statement)

If, during an examination of specimens, the microscope should become nonfunctioning:

✓ A back-up microscope is available at all times.

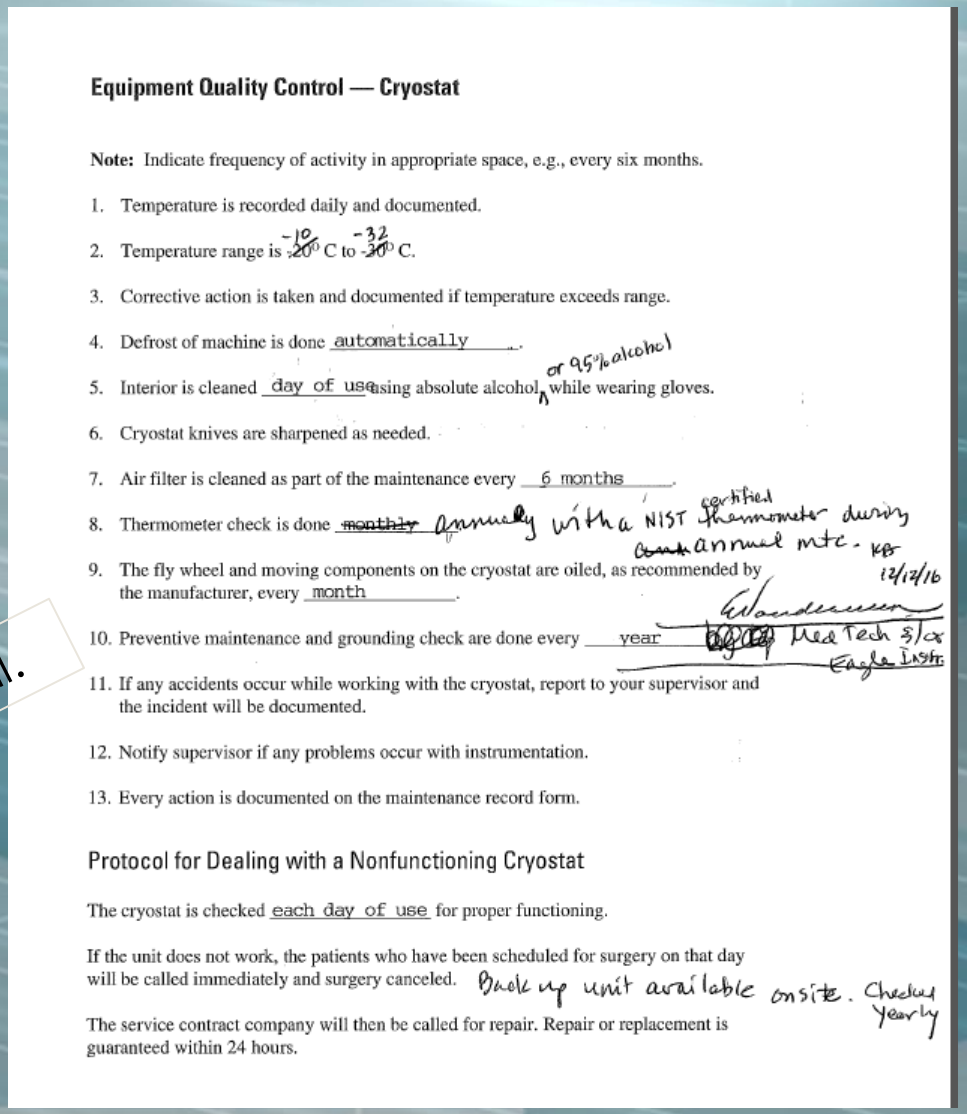
✓ The test will be postponed until the microscope is repaired.

_____ Other (specify) _____.

Update Regularly

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

From the "old" AAD lab manual.



Equipment Quality Control — Cryostat

Note: Indicate frequency of activity in appropriate space, e.g., every six months.

1. Temperature is recorded daily and documented.
2. Temperature range is ~~-20~~ -10° C to ~~-30~~ -32° C.
3. Corrective action is taken and documented if temperature exceeds range.
4. Defrost of machine is done automatically.
5. Interior is cleaned day of use using absolute alcohol or 95% alcohol while wearing gloves.
6. Cryostat knives are sharpened as needed.
7. Air filter is cleaned as part of the maintenance every 6 months.
8. Thermometer check is done ~~monthly~~ annually with a NIST certified thermometer during annual mtc. KB 12/12/16
9. The fly wheel and moving components on the cryostat are oiled, as recommended by the manufacturer, every month.
10. Preventive maintenance and grounding check are done every year ~~day of use~~ Med Tech 5/ea Eagle Instr.
11. If any accidents occur while working with the cryostat, report to your supervisor and the incident will be documented.
12. Notify supervisor if any problems occur with instrumentation.
13. Every action is documented on the maintenance record form.

Protocol for Dealing with a Nonfunctioning Cryostat

The cryostat is checked each day of use for proper functioning.

If the unit does not work, the patients who have been scheduled for surgery on that day will be called immediately and surgery canceled. Back up unit available onsite. Checked Yearly

The service contract company will then be called for repair. Repair or replacement is guaranteed within 24 hours.

"Like all magnificent things, it's very simple."
— Natalie Babbitt, Tuck Everlasting

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.

From the Mohs Surgery manual of the Dermatology Center of Grand Rapids, P.C.

Say what you're goin
Do what you say.
Be able to prove it w

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- If your manual says one thing and you do another ….

QC Section from the AAD Manual – here's what you said

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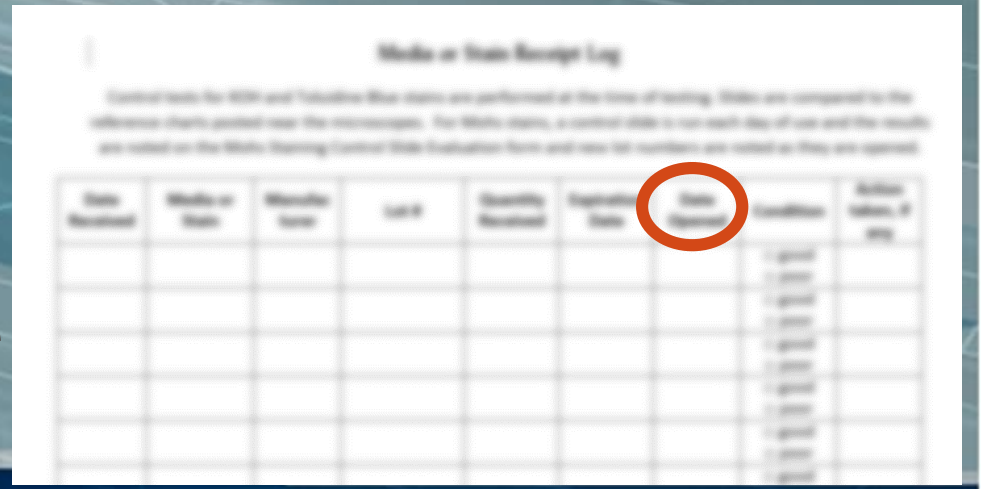
"…reagents, materials, and supplies…" Do what you say

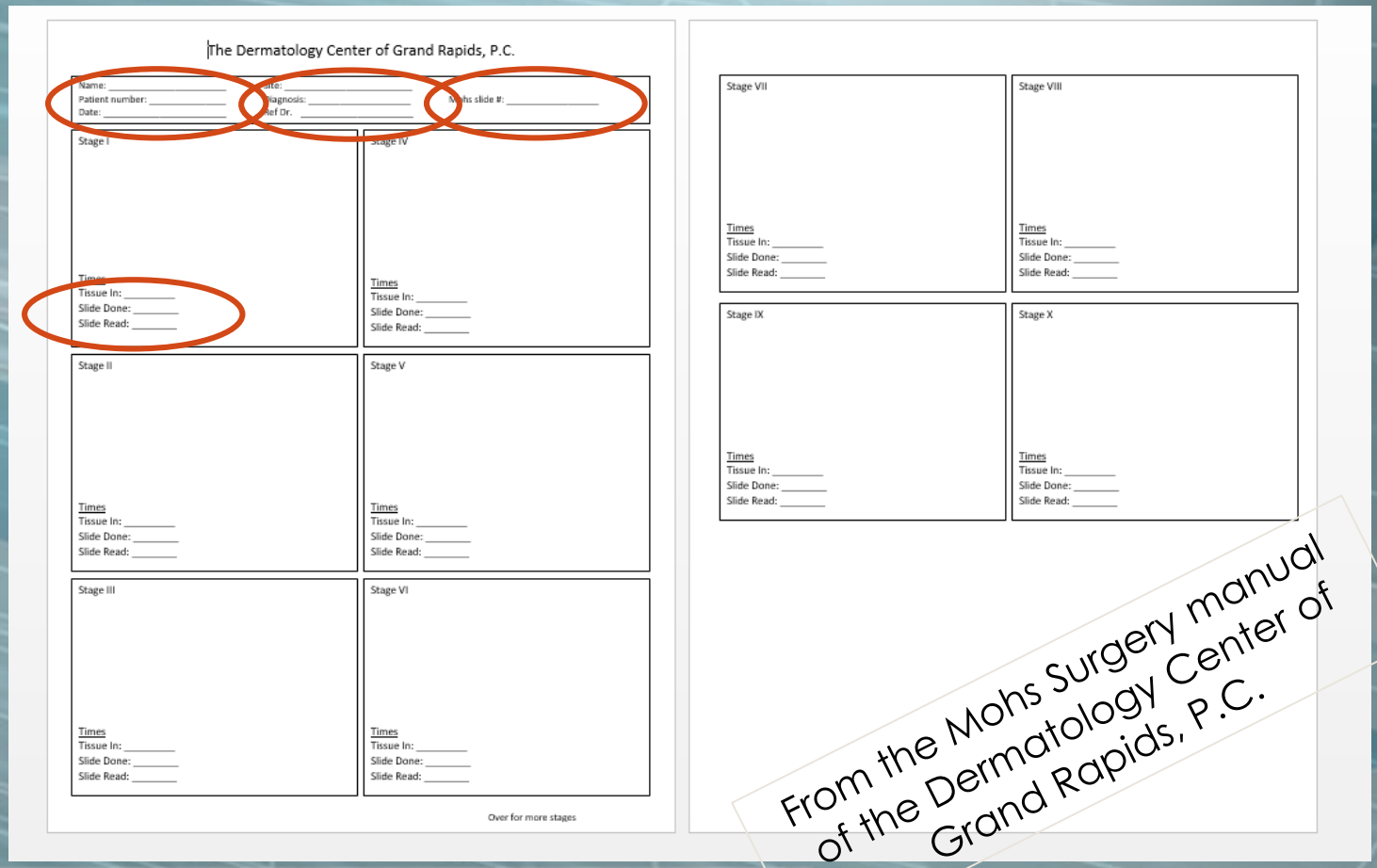
- You said what you would be recording
  - Record lot numbers to hold manufacturer accountable
  - Record expiration dates to avoid using degraded products
  - Pay attention to your everyday tools
  - Detail what you will do if items are substandard

- 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


The Dermatology Center of Grand Rapids, P.C.

Name: _____ Site: _____
Patient number: _____ Diagnosis: _____ Mohs slide #: _____
Date: _____ Ref Dr. _____

Stage I
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage IV
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage II
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage V
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage III
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage VI
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Over for more stages

Stage VII
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage VIII
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage IX
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

Stage X
Times
Tissue In: _____
Slide Done: _____
Slide Read: _____

From the Mohs Surgery manual of the Dermatology Center of Grand Rapids, P.C.

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Do what you're going to do.

Be able to prove it with documentation.

- Complete and accurate records win the day.

Maintenance Records - microscope

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

Location of Scope:

EEV Scope Mohs Lab		KRB Scope Mohs Lab	
Date	**Initials**	**Date**	**Initials**

From the Mohs Surgery manual of the Dermatology Center of Grand Rapids, P.C.

Maintenance Records - cryostat

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Temperature Logs

Control Runs for Slides

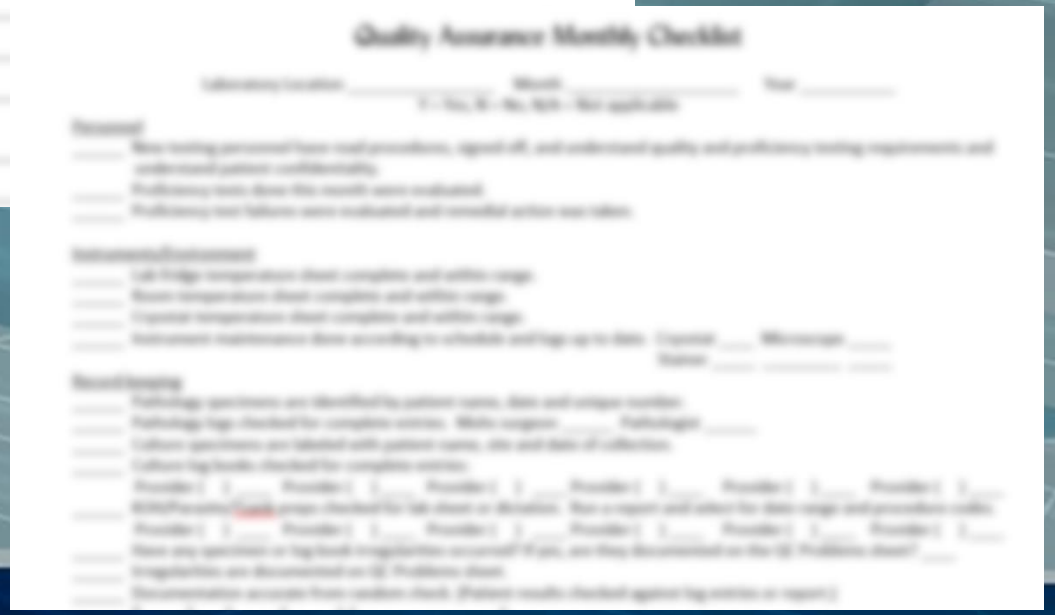
- Include what you're looking for
- Include lot #'s
- Evaluate your own slide
- Surgeon OK's it
- Poor quality?
  - How is it addressed?

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



….And Biannually (Proficiency Testing)

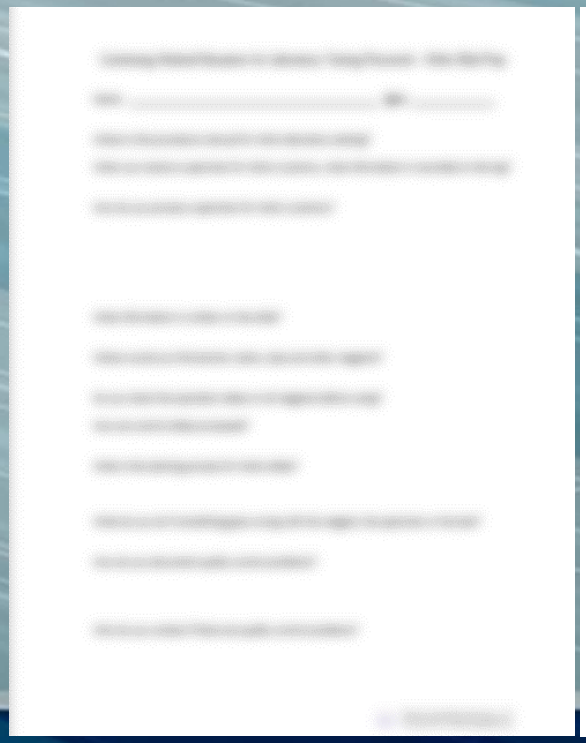
- Choose or randomize a slide
- Send out or do in house if more than one dermpath
  - Must be blind reading
  - Tester should know methodology
    - Frozen section/H & E
    - Frozen section/immune staining(type)
- Retain both reports for documentation
- Detail and address all failures

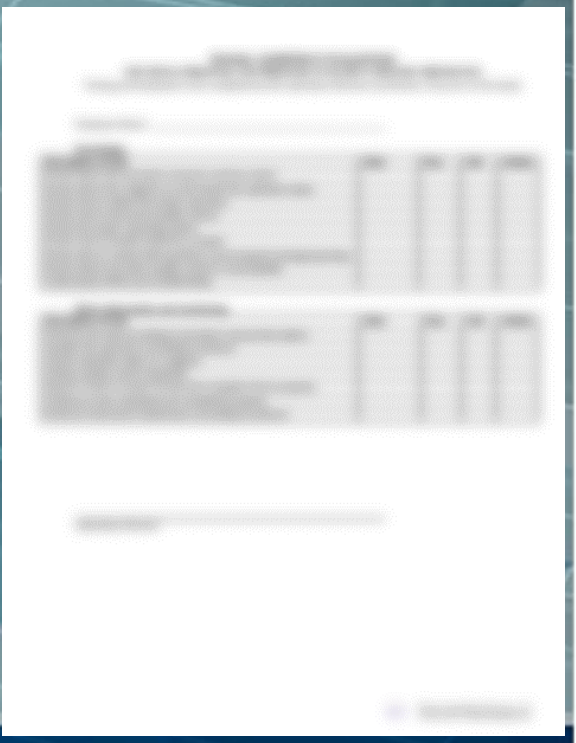
….And Annually

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

Annual Competency Evaluations

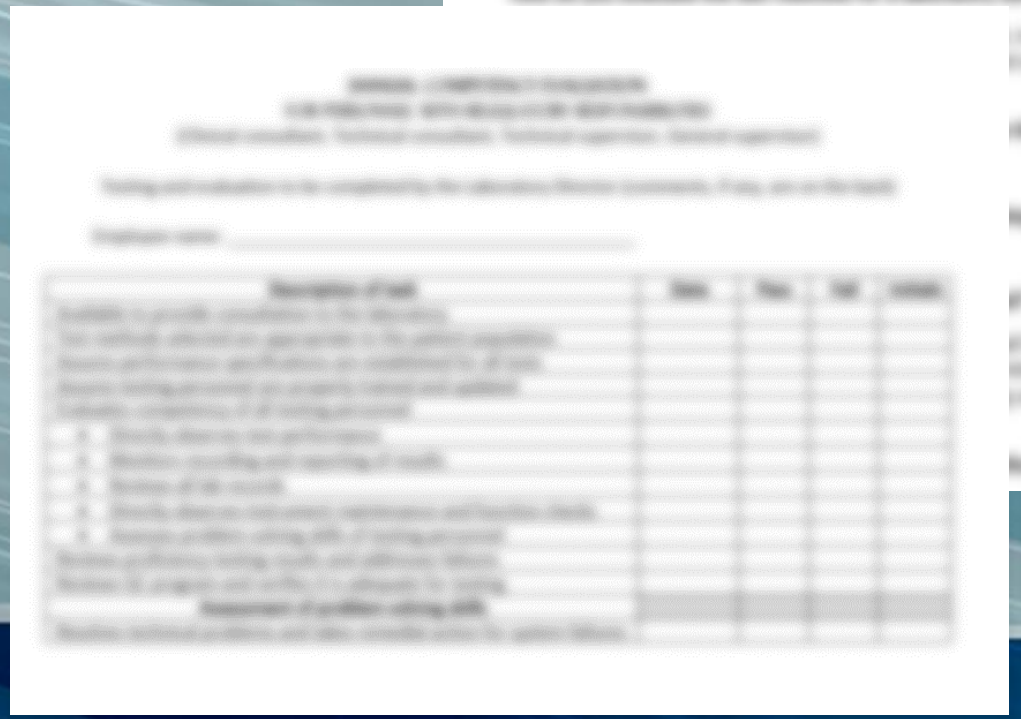
- Lab Director reviews all testing personnel
  - Knowledge – give a test
    - Pathologist
    - Technician
  - Direct observation
    - Procedure manual
    - Reagent handling
    - Knows procedure
    - Follows quality measures
    - Reports properly
    - Follows HIPAA





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



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