Learning Objectives

• After participating in this audioconference you will be able to:
  – Describe the requirements for validating computer interfaces
  – Understand the principles for validating autoverification
  – Apply accreditation requirements regarding LIS in your own laboratory setting
Topics

• Remote hosting of LIS
• Validation of EMR interfaces
• Autoverification
• Incorporating results from outside sources
Remote Hosting

![Diagram of remote hosting setup]

- Analyzer
- Data Manager
- Router
- Firewall
- VPN
- Laboratory
- Remote Host Location
- LIS Server
Remote Hosting

• All checklist requirements apply regardless of where the computer hardware is located

• If hardware is located remotely, it is up to the lab being inspected to arrange for evidence of compliance in advance
  – An annotated copy of this section of the checklist is ideal
Evidence of Compliance
GEN.42195 (note)

• “...evidence that the (remote) computer facility has been provided a copy of this checklist, and has satisfactorily addressed the contents...”
  – CAP accreditation certificate (remote site)
  – Copies of policies, procedures, logs, etc.
  – Arrange telephone interview if questions arise
Remote Hosting Documentation

• Any function that the remote facility is responsible for should be documented
  – Backups
  – Routine monitoring of hardware and software
  – Installing patches, upgrades
  – Responding to problems, unanticipated downtime, etc
EMR Interface Validation

• Why test?
  – For many doctors, these systems have completely replaced the traditional printed lab report

• What to test?
  – You *must* test all directly connected systems

• When to test?
  – Initially at implementation, periodically thereafter
Report Regulations - CLIA

• The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to **final report destination**, in a timely manner.
“Final Report Destination”

• This implies that the report or display that the clinician expects to use or routinely uses to view results must be validated.
• If a lab is using a middleware product with a web viewer, but the results are also sent to the office EMR, lab is responsible for ensuring that the display in the EMR is valid, because the EMR is the “final report destination”
Where do Results Go?
Report Requirements - CLIA

1. Patient’s name and ID #, or a unique patient identifier and ID #
2. Name and address of testing lab
3. Test report date
4. Test performed
5. Specimen source (when appropriate)
6. Test result including
   • Interpretation (if applicable)
   • Units of measure (if applicable)
7. Any information regarding the condition and disposition of specimens that do not meet the laboratory’s criteria for acceptability
Additional Report Requirements
CAP – GEN.41096

• Physician of record or ordering person
• If applicable/appropriate:
  – Date/time of specimen collection
  – Time of release of report
  – Reference Intervals

• For electronic reports, data elements need not all be present on one screen, but must be readily available
• A “reference” lab is any lab with a different CLIA number
Validating Client EMR Reports/Displays

- Collaborative process which must involve staff at client site
- Usually ask for screen prints to be emailed/faxed
- Try to use a mix of simple and more complex tests (e.g. glucose, FSH, CBC and urine culture)
Initial Validation

• Should be extensive and include:
  – Numeric and textual results (short and long)
  – Normal and abnormal results
    • Are abnormal textual valued flagged correctly?
  – Critical values (check flagging)
  – Reflex results
  – Corrected results
  – Reference lab test results
  – Blood Bank, Micro, Cytology, Surgical Path
• Doesn’t have to include every possible test
• Try to use test system if possible at least in the initial phases of implementation
Common Problems

- Long text results
- Comments - result and specimen
- Performing lab statements
- Formatting of micro results
- Result mapping
Reference Ranges

• Pertinent “reference intervals” or “normal” values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

• Best practice is to include reference ranges on reports

• This section provides some flexibility for electronic displays which can’t accommodate reference ranges (e.g. grid formats)
Periodic Re-testing of EMR Interfaces (GEN.48500)

• Verification required prior to go live of an interface and

• Periodically thereafter
  – Best practice is annually
  – Intervals longer than 2 years may be problematic

• You may use a subset of tests, but you must test **ALL** systems
## Periodic Reassessment

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GA Reviewed By: ____________________________

Date Reviewed: _____________

Comments: ____________
Excluded Systems

• GEN.48500 allows an exception for systems that are “downstream” and are not the “final report destination”
• The idea is that the lab has a duty to and influence on their direct clients and/or the hospital systems
• But that if one of your clients decides to send results to additional systems, the lab may not even be aware of this, so the lab can’t reasonably be expected to ensure the validity of the data transfer to secondary systems
Excluded Systems

- If these systems are not directly interfaced, they MAY be excluded from validation:
  - Network or regional data warehouses intended for research
  - Regional data aggregators
  - Clinical systems that only interface as a “second layer”
Where Must You Validate?

- LIS
- HIS
- Public Health Agency
- Web Portal
- Data Repository
- 2nd Level EMR
- EMR
- 2nd Level EMR
- EMR
- Public Health Agency
- Data Repository
Where Should You Validate?

- LIS
- HIS
- Public Health Agency
- Web Portal
- Data Repository
- 2nd Level EMR
- EMR
- 2nd Level EMR
- EMR
Autoverification
Autoverification Validation

• Why validate?
  – To ensure that the automated system which verifies thousands of results is functioning as intended

• What to test?
  – You must test all instruments/systems which use autoverification

• When to test?
  – Initially at implementation, annually thereafter
Autoverification Requirements

- Policy
- Initial and yearly revalidation
- Process to ensure QC is acceptable
- Limited range of acceptable values
- Flags or warnings evaluated automatically
- Audit trail
- Delta checks (if used for manual release)
- Process to turn off rapidly
Validation of Autoverification

- Keep a spreadsheet/database for each analyzer
  - Analyte
  - Acceptable range / Critical range
  - Acceptable / Unacceptable flags
  - Other conditions to test
- Initially test a variety of results for each analyte
- Don’t just test samples that will “pass”
- Run actual specimens to test entire system
  - Instrument - (data manager/middleware) - LIS
- Consider using “fake” samples to test errors/flags
  - Water, calibrators, survey samples, linearity samples
Handling Results Flags

- Usual practice is to define which flags are acceptable for autoverification results
- Often this is only high/low flags
- Decide how to handle results below linearity (might be OK to report)
- Usually any technical flags should stop autoverification
# Autoverify Working List

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<td>URNA</td>
<td></td>
<td></td>
<td>Changed upload/download code to 01AU</td>
</tr>
<tr>
<td>42</td>
<td>SRNA</td>
<td>Fail if LIPIND is &gt; 8</td>
<td>Run by Direct ISE (Respiratory Therapy Blood gas instrument)</td>
<td>LIPIND will cause autotesting to fail based on upload code of 01A</td>
</tr>
<tr>
<td>43</td>
<td>K</td>
<td>Fail if HEMIND is &gt; 1</td>
<td>If PL is IP and HEMIND is &gt; 1, then file as HEMSP and have patient redrawn. If PL is OP and HEMIND is 2-3, amend result with HHI. If PL is OP and HEMIND is &gt; 3, then file as HEMOL.</td>
<td>0789 - HEML will cause autotesting to fail based on upload code of 01B - Unable to modify results based on PL until IGC purchased</td>
</tr>
<tr>
<td>44</td>
<td>HEPK</td>
<td>Fail if HEMIND is &gt; 1</td>
<td>If PL is IP and HEMIND is &gt; 1, then file as HEMSP and have patient redrawn. If PL is OP and HEMIND is 2-3, amend result with HHI. If PL is OP and HEMIND is &gt; 3, then file as HEMOL.</td>
<td>HEML will cause autotesting to fail based on upload code of 01B - Unable to modify results based on PL until IGC purchased</td>
</tr>
<tr>
<td>45</td>
<td>SRK</td>
<td>Fail if HEMIND is &gt; 1</td>
<td>If PL is OP and HEMIND is 2-3 amend result with HHI. If PL is OP and HEMIND is &gt; 3, then file as HEMOL.</td>
<td>HEML will cause autotesting to fail for upload code 01B. All SRK patients are inpatients. Unable to modify results until IGC is purchased</td>
</tr>
<tr>
<td>46</td>
<td>URK</td>
<td></td>
<td></td>
<td>Changed upload/download code to 01BU</td>
</tr>
</tbody>
</table>
Annual Validation

- Does not have to be as extensive as initial validation
- Test a variety of results and conditions for each analyzer
- Keep track of the testing with screen shots/printouts and a spreadsheet/database
Calculations (GEN.43450)

- Calculations which give reportable patient results (anion gap, eGFR, etc.) must be validated initially and at least every 2 years or when any change is made that affects it.
- Keep a spreadsheet/database of these calculations and track when they were validated.
- Test with both manually entered and autoverified results.
Remote Hosting and Validation

• If a system is remotely hosted and there are multiple identical analyzers in use at the same or different locations – how extensive should initial/periodic validation be?

• If the exact same computer code/rules are used for a set of instruments, then that set of autoverification rules can be tested (thoroughly) once.

• However, usually there are slight differences in the code/rules and in that case, the testing needs to be done for each instrument/system
Incorporating Outside Results

• Doctors or patients sometimes ask that reports from other laboratories that they or the patients bring be entered into the LIS

• No restriction on doing this, but recommendation is to try to enter this into HIS or EMR directly rather than into the LIS
Incorporating Outside Results

- Problems with entering results from patient supplied reports
  - Is the lab accredited?
  - Are errors introduced by manual transcription of results, comments and reference ranges?
  - Will report be easily readable?
  - Will viewers assume that the results are endorsed by your lab since they were entered into the LIS?
Assistance

http://www.cap.org
Email: accred@cap.org
800-323-4040, ext. 6065