Policies and Procedures:

It’s not OUR fault that nurses won’t read our SOPs!

Lou Ann Wyer, MS, MT(ASCP), CQA(ASQ)
Speaker Financial Disclosure Information

- Grant/Research Support: None
- Salary/Consultant Fees: Biofire
- Board/Committee/Advisory Board Membership: None
- Stocks/Bonds: None
- Honorarium/Expenses: None
- Intellectual Property/Royalty Income: None
Sentara Healthcare

Elevate your career.
Objectives

*Participant will be able to:*

Upon completion, the attendees should be able to:

◦ Describe a process for writing effective and efficient P&Ps
◦ Compile and analyze a Process Map
◦ Create documents that
  ◦ are easy for the intended audience to understand and follow as instructed
  ◦ consistently produce an expected outcome
Why do POCT Operators avoid SOPs?

- Too Busy
- Don’t know how to find them
  - Difficult to retrieve
- Don’t understand them
  - Too technical
  - Easy to skip over details
- Don’t need a procedure

It’s waived testing – anyone can do this!
Is this SOP written for the audience?

VII. Quality Control Procedure

A. Quality control material must be assayed in all sections of the Clinical Laboratory and at least two levels which, if available, representing medical action levels, must be incorporated into the daily runs and treated like patient specimens. The QC material used is specified for each method/analyte combination in the sectional procedure manual.

The frequency of assays is determined by either previous experience or by the recommendations of the manufacturer of the method. In general, one assay every 12 hours or one assay every eight hours (to monitor the performance of each shift) are used by the Chemistry sections and it is specified in the sectional procedure manual for each method/analyte combination.

B. The results of a QC run determine whether the previous (between QC runs) and the subsequent instruments linked to the LIS patient assays are accepted.

1. If the QC results exceed the procedure acceptance limits, the LIS branches automatically to QMR where the corrective action must be documented in the QCC (quality control correction) function. A corrective action must be entered by choosing between RERUN, ACCEPT, CHANGE, or REJECT and entering a footnote describing the corrective action taken. If the RERUN option is chosen, the previous QC observations are saved in the database. The corrective actions (e.g., recalibration) are reported in the troubleshooting log sheet (page ).

2. Instruments not linked to the LIS: The QC observations are recorded either in the instrument’s microprocessor QC log or in a manual log. The
How Can You Help?

• Write to your audience
• Say what you do, and do what you say
• Design the SOP to avoid error
Define required *high-level expectations*
Fewer in number
Informational and reference use
Typically no more than one (1) page

Define action steps and provide tools *to achieve policy expectations*
Continuous and reference use

Edited from CLSI QMS02-A6
Document Differentiation

1. **Policy**
   - High level expectation mandated by a regulatory requirement or self-imposed requirement
   - The “what” and “why”

2. **Process**
   - Sequence of activities
   - Inputs into outputs
   - Describe operations of a workflow
   - The “how it happens”
Document Differentiation

• Procedure
  o Step-by-step required actions to perform activities in a process
  o The “how to do”
  o Steps in column one; supplemental guidance in column two
  o Job aids referenced within action steps
  o Adherence to required actions = policy compliance
Document Differentiation

3.

• **Job Aids** (“More Tools”)
  - Tools needed in the workplace to effectively carry out the procedure and work in the process
  - Condenses procedure information into a shorter format for rapid access
  - Instructions, lists, quick reference materials
  - Written, graphical, combination
  - Subject to document control
    ▪ Should connect to the related procedure
Document Differentiation

• Forms

  o Records - what was done

  o NOTE\textsuperscript{1}: Documents are created by planning what needs to be done; Records are created when something is done.

  o NOTE\textsuperscript{2}: Documents can be revised; records should never be revised.
11 Steps: Simplify Work Process

1. Map the current process
2. Identify requirements the process must meet
3. Evaluate the process for risk and effectiveness
4. Modify the process to reduce risk and improve effectiveness
5. Assess document needs
   - Policy, Process, Procedure, Job Aid, Form
Process Map

• What is a process map?
  ◦ A process map is a tool/technique used to illustrate the steps of a process in sequence
    ◦ Swim Lane Chart

• Benefits of a Swim lane chart
  ◦ Identify who is responsible
  ◦ Identify hand-offs
  ◦ More detailed workflow
Process Map Template

- Organizes the process map by roles
- Indicates process states and transitions

<table>
<thead>
<tr>
<th>Role</th>
<th>Assessment</th>
<th>Application</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td><img src="image1.png" alt="Diagram" /></td>
<td><img src="image2.png" alt="Diagram" /></td>
<td><img src="image3.png" alt="Diagram" /></td>
</tr>
<tr>
<td>Nurse</td>
<td><img src="image4.png" alt="Diagram" /></td>
<td><img src="image5.png" alt="Diagram" /></td>
<td><img src="image6.png" alt="Diagram" /></td>
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<tr>
<td>LPN</td>
<td><img src="image7.png" alt="Diagram" /></td>
<td><img src="image8.png" alt="Diagram" /></td>
<td><img src="image9.png" alt="Diagram" /></td>
</tr>
</tbody>
</table>
Document Control Workflow

- Planning
  - Start Review
- Post Draft Review
  - Review Complete
  - Start Review
- Post Validation Review
  - Review Complete
  - Start Review
- Post Quality Review
  - Review Complete Pending Approval
  - Yes
- Post Approval
  - Approved
  - Due Soon
  - Expired
- Draft Review
- Validation Review
- Quality Officer Review
- Approval
  - Approved?
Control of Documents Lifecycle

START

Need for new/revised document is identified

Document is drafted

Draft document is evaluated and verified

Changes needed?

YES

Revise document as needed

Obtain approvals

Identify training needs

Implement document

Maintain document

Review of document

Changes needed?

YES

Retire document?

YES

Retire document

END

NO

Review is recorded
Process Evaluation

- Flow
  - bottlenecks
  - duplication
  - redundancies
  - excessive hand-offs

- Complexity
  - detail
  - necessity of steps

- Risk (patient, employee, quality, financial)
  - likelihood of error
  - severity of error if occurs
  - likelihood of catching the error

- Compliance with requirements
Modify Process

• Remove any unnecessary steps
• Consider alternate workflows to address bottlenecks
• Balance complexity with level of knowledge and skills of the individuals
• Address areas of risk:
  o Avoid areas of risk – remove cause of risk
  o Decrease risk – add checks into the process
  o Bring attention to unavoidable risk – Stop gaps in the computer system, signs, job aids, etc.
  o Poka Yolk (mistake proof)
• Ensure compliance with regulatory and accreditation requirements
• Develop & assess process monitors
11 Steps: Simplify the Procedure

6. Create needed documents
7. Obtain appropriate reviews and approvals
8. Educate/Train
9. Implement
10. Maintain Document Control
11. Develop methods to monitor the document for compliance
Format the procedure effectively

- Title
  - Brief, unique, descriptive
  - Unique identifier
- Two columns for novice-to-expert application
  - “Required Action Steps” for all
  - “Supplemental Guidance” when further information is needed
- Three columns for multi-actor procedure
- Sequential action steps written as clear, concise phrases beginning with an action word and written in the order needed
Format the procedure effectively

- Required headings: equipment, reagents/supplies, action steps
- Cautions and notes and limitations placed **before** the step to which they apply
- Job aids referenced with related action steps
- Related documents
- **Clear instructions reduce the risk of error**
Terms to Convey Compliance Expectations

• **Shall**

  Individual must follow the directive exactly and in all situations. STOP if the directive cannot be met.

• **Should**

  Directive is highly recommended, but there may be extenuating circumstances that make the action inappropriate for the situation at hand. Consult with manager before choosing not to perform the action.

• **May**

  Individual discretion or professional judgment is used to determine if the action is appropriate.
**Procedure Example**

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### Procedure Details

- **Procedure:** POC.112 Urine Dipstick testing by Clinitek STATUS
- **Division:** Sentara Hospitals
- **Manual:** Laboratory Services
- **Section:** Point-of Care Testing
- **Location(s):** SNVMC
- **Original Date:** 12/8/04
- **Revision Date:** 10/13/2016
- **Approved By:** Laboratory Medical Director
- **Process Owner:** Clinical Specialist, POCT

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<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Revision Description (Most Recent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/13/2016</td>
<td>Revised control stability to 10 days when stored at 2 - 25°C. Updated BioRad control package insert revision to 3/2015.</td>
</tr>
</tbody>
</table>

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**AACC**

*Better health through laboratory medicine.*
**Procedure Example, 2 Column**

<table>
<thead>
<tr>
<th><strong>A. Required Action Steps: Chemistry and ABG Testing</strong></th>
<th><strong>Supplemental Guidance</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Caution:</strong></td>
<td></td>
</tr>
<tr>
<td>▪ Barcoded cartridge pouch must be scanned to allow testing to proceed.</td>
<td></td>
</tr>
<tr>
<td>▪ Do not scan the barcode on the box.</td>
<td></td>
</tr>
<tr>
<td>1. Scan the barcode on the cartridge pouch.</td>
<td>▪ All cartridge pouches are barcoded and shall be scanned.</td>
</tr>
<tr>
<td></td>
<td>▪ The cartridge lot number is encoded in the barcode on the cartridge pouch.</td>
</tr>
<tr>
<td></td>
<td>▪ A Code 140 will display if the analyzer detects an expired cartridge lot number.</td>
</tr>
<tr>
<td></td>
<td>▪ The i-STAT screen display will remain at the “insert cartridge” prompt for 15 minutes before the analyzer turns off allowing time for immediate sample collection and testing.</td>
</tr>
<tr>
<td>2. Collect specimen.</td>
<td></td>
</tr>
<tr>
<td>3. Mix specimen well by inverting gently ten (10) times.</td>
<td>▪ Invert blood collection tubes gently 10 times. Remove an aliquot using transfer device and syringe.</td>
</tr>
<tr>
<td></td>
<td>▪ Roll syringe between palms 5 seconds in one direction, then roll in a second direction, then gently invert repeatedly for 5 seconds. Discard first 2 drops of blood before filling the cartridge.</td>
</tr>
<tr>
<td></td>
<td>▪ Samples from 1ml syringes should not be used to determine Hematocrit if testing is delayed.</td>
</tr>
</tbody>
</table>

**Caution:** Remove the needle from collection devices prior to inoculating cartridge.
## Procedure Examples, 3 Column

<table>
<thead>
<tr>
<th>Required Action Steps</th>
<th>Performed By</th>
<th>Supplemental Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prepare and perform testing according to the instructions using routine methods.</td>
<td>Testing personnel</td>
<td>• Specimens are to be handled in the same manner as patient specimens.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• If CAP survey materials are used for an internal proficiency test, testing shall not be performed until after the due date for submission of the intended (CAP reported) method has passed.</td>
</tr>
<tr>
<td>2.</td>
<td></td>
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<tr>
<td>3. Assemble documents needing signature.</td>
<td>Laboratory Staff</td>
<td></td>
</tr>
<tr>
<td>4. Sign all assembled documents.</td>
<td>Medical Director</td>
<td></td>
</tr>
<tr>
<td>5. File all documents in appropriate location.</td>
<td>Laboratory Staff and Laboratory Manager</td>
<td>• Signed documents (i.e. CAP Survey Summaries, Monthly QC summaries, etc.) are filed according to the type of document.</td>
</tr>
</tbody>
</table>
Result Interpretation

10. Set the timer for 15 minutes.

11. Read the results at 15 minutes through the device window.

- It is recommended to tilt the device to reduce glare on the test window if necessary.
- Results read before or after 15 minutes may be inaccurate.
- Result Interpretations:
  - **T1 Positive**: Any pink-to-purple Test Line (T1) along with a pink-to-purple Control Line (C) is a positive result for the detection of *P. falciparum* infection.
  - **T2 Positive**: Any pink-to-purple Test Line (T2) along with a pink-to-purple Control Line (C) is a positive result for the detection of *P. vivax*, *P. malariae*, *P. ovale*, infection or a mixture of 2 or more.
  - **T1 + T2 Positive**: Any pink-to-purple Test Lines (T1 and T2) along with a pink-to-purple Control Line (C) is a positive result for the detection of mixed infection of *P. falciparum* with *P. vivax*, *P. malariae*, and/or *P. ovale*.
  - **Negative**: A pink-to-purple Control Line (C) with no pink Test lines (T1 or T2) is a negative result.
  - **Invalid Result**: A pink-to-purple Control Line
Document Reviews

• Document Reviews:
  o Draft Review – experienced staff (accuracy)
  o Validation Review – inexperienced staff (effectiveness)

• Approval Process (2 levels – Technical documents)
  o Prior to use of the document

• Acknowledgement (Read & Sign) Process
# Draft Review

**Purpose:**
To verify accuracy and completeness of the document

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the title clearly defined and appropriate for the content?</td>
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<tr>
<td>Is the purpose clearly defined and appropriate for the content?</td>
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<td>Are all needed steps included in the document and in the right sequence?</td>
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<tr>
<td>Are all necessary equipment, supplies, and reagents listed?</td>
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<tr>
<td>Is information consistent with manufacturer's recommendations?</td>
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<tr>
<td>Are specimen requirements listed and accurate?</td>
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<td>Are all calculations correct?</td>
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<td>Are all result acceptance criteria and/or ranges accurate?</td>
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<tr>
<td>Are QC and calibration materials and schedules included in the procedure or referenced?</td>
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<tr>
<td>Are preventive maintenance steps and schedules included in the procedure or referenced?</td>
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<td>Is the purpose of the document accomplished?</td>
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<td>Are the spelling and grammar correct?</td>
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<td>Are references relevant and up to date?</td>
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</table>
Validation Review

**Purpose:**
To ensure that the document is understandable and can be followed to find needed information and produce consistent outcomes

<table>
<thead>
<tr>
<th>Questions</th>
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<tr>
<td>Does the title describe the contents or Intent of document effectively?</td>
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<td>Is the purpose of the document accomplished?</td>
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<tr>
<td>Is the content easy to understand / follow?</td>
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<td>Are action steps, when applicable to the document, in a logical sequence?</td>
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<tr>
<td>Is there sufficient guidance to perform the indicated steps or record information, when applicable to the document, consistently with no variation?</td>
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<tr>
<td>Are the formulas and calculations correct, explained and referenced?</td>
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<tr>
<td>Do all related documents provide consistent information and work well together?</td>
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</tbody>
</table>
## Read & Acknowledgement

- **Title:** [Title of Document(s)]

<table>
<thead>
<tr>
<th>Last name</th>
<th>First name</th>
<th>Signature</th>
<th>Date</th>
</tr>
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<tbody>
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</tbody>
</table>

Signing-off on the above document(s) indicates that the staff member has read and understood the document(s).

| Date Posted: | Due Date: |
Are We There Yet?

• Action plan for implementation
  o Document management (load in system)
  o Training & assessment for existing employees
  o Incorporate into new employee orientation curriculum
  o Verification of implementation

• Observe performance to ensure that changes are translated into work practice

• Monitor and track outcomes
Document Maintenance

• Periodic Review Process
  o Review by designated staff
  o Revise as needed
  o Documentation
    ▪ Printed copies

ATTENTION: FOR REFERENCE USE ONLY WHEN PRINTED; PLEASE REFER TO ELECTRONIC DOCUMENT FOR MOST CURRENT VERSION
Review vs Revise

• Review
  o Designated and qualified personnel
  o Periodic as defined (biennial), or
    o Investigation (audit, NCE, RCA, PI)
    o Related processes are revised
  o Keep, Change, Retire
  o Document

• Revise
  o As needed
Standardization

1.

• Efficient way to achieve compliance
• Reduces errors in point-of-care test programs
  o Each staff member performs test in the same way
• Standardizing the following helps with consistent, high quality performance:
  o Format-placement, font type & style, margins, order of sections, numbering
  o Content-headings, abbreviations
Standardization

2.

• Eliminates need for different procedures and maintenance of multiple documents for the same test analyte
• Assures only current documents are available
• Organize for ease of retrieval
• Work with different departments to develop a process = one procedure/process for test facility
References


Questions?

Contact Information: l.wyer@cox.net