QA Checklist

What are they?
Why do we need them?
How do we make them?

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QA Checklist - Agenda

- Background and History
- Checklist Development
- Checklist Usage
What are they? Why do we need them?

- A checklist is a tool used to:
  - Reduce failure by compensating for the potential limits of human memory and attention\(^1\)
  - Ensure consistency and completeness in carrying out a task\(^1\)
  - “They liberate our brains to focus on the hard stuff”\(^2\)
  - Train and Empower people
  - Provide us with a place to begin


\(^2\) Atul Gawande, “The Checklist Manifesto”
Checklists Examples

- To Do List
- Shopping List
- 2009 Airbus A320 landing in Hudson River

- Sullenberger and Skiles used checklists after the collision with the flock of geese
## Checklists Examples

- **Apollo 13**

<table>
<thead>
<tr>
<th>ECS ACT</th>
<th>IMU C/A</th>
<th>TB VERIFICATION</th>
<th>PGNS T/O</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-BD ANT ACT</td>
<td>SUIT FAN/H2O CK</td>
<td>ACT 30</td>
<td></td>
</tr>
</tbody>
</table>

### Docked IMU Coarse Align

1. Verify CSM In Min DEADBAND ATT HOLD
2. Calculate LM Gimbal Angles

<table>
<thead>
<tr>
<th>OG</th>
<th>IG</th>
<th>MG</th>
</tr>
</thead>
<tbody>
<tr>
<td>300.00</td>
<td>180.00</td>
<td>360.00</td>
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\begin{align*}
\text{CM} & = 29.8 \times 0.05 \\
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3. V41 N2OE Coarse Align IMU F 21 22 LOAD ICUD ANGLES OG, IG, MG (.01°)

### TB Verification

- CB(16) ECS: SUIT FAN 2 - Open
  - (Master Alarm, SUIT/FAN Warning, SUIT FAN Comp Lts - On)
- CB(11) ECS: SUIT FAN 1 - Close
  - H2O SEP SEL - PUSH SEP 1
- SUIT FAN - 1 (SUIT/FAN Warning, FAN Comp Lts-Off, ECS Caution, H2O SEP Comp Lts - Off In 2 min)
  - CB(16) ECS: SUIT FAN 2 - Close

### Glycol Pump Check

- CB(11) ECS: GLYCOL PUMP 1 - Open
  - (Master Alarm, ECS Caution, Lt - On Momentarily)
- CB(11) ECS: GLYCOL PUMP 1 - Close
  - (GLYCOL Comp Lt-On)

**Basic Date Changed**: 2/6/70
What’s special about a QA Checklist?

- Serves as a map for audits & inspections
- Provides visual evidence of what was looked at during the audit/inspection
- Can serve as a reference for applicable requirements
Different focus depending on the job

- **Process Inspection Checklist**
  - Prospective checklist - "Things to do" (e.g. shopping list, schedule, work instruction)

- **Data Audit/Report Checklist**
  - Retrospective checklist - "What was done"
Checklist Development

- **Focus Scope**
  - Include all items that need to be checked/verified, as obtained from:
    - Directive documents (e.g. protocol)
    - SOPs
    - Guidelines
    - Regulations
    - Calculations
    - Subject Matter Expert input
    - Professional Expectations/Standards
Checklist Development

- **Limit Scope**
  - Do *not* include items that do not need to be checked or verified.
    - If many items on the checklist are routinely skipped – should they even be there?
    - Is this the appropriate time and place to be checking that item?
    - Consider including the rationale behind each item during checklist development to help weed out extra items.
Checklist Development

- Group items by category
  - Directive document (protocol, SOP, etc)
  - Subject matter (OSL-1 observations, Leaf sample collection)
  - Chronological order (beginning, middle, end)
  - Risk assessment
Checklist Development

- Content: Make each item clear and concise
  - Simple, to-the-point, not open to interpretation
  - Include sub-steps as needed (e.g. check the signoff sheet for appropriate signatures… PI, Sponsor)
  - Use in conjunction with a checklist guide if needed. The checklist guide can provide additional background information and instruction.
  - Potential use as an onboarding tool for new hires.
Checklist Development

- Each item should be action oriented
  - You can point to it and say – “Yes, It’s there.”
  - Check-offs based on witnessing and documentation
Checklist Development

- Peer Review
  - Co-workers
  - Customers
  - Subject matter experts
- Trial runs
  - Dry runs
  - Time Trials
  - Live testing
- Maintenance/Periodic Review
Checklist Development

- Formatting
  - Header information – e.g. Study number, auditors, person audited, date, phase, audit ID, etc.
  - Use tick-boxes (Y/N/NA/NC) as a quick tool to document that the item was looked at
  - Use numbering to help reference each checklist item
  - Leave room for comments
    - Add room for comments for each item, and/or,
    - Add space at the end of the checklist to document all findings. Reference each comment to a checklist item.
What side to put checks on?
More examples
Bad Examples
Checklist Usage

- How is the checklist to be used?
  - Official document to be attached to the audit report
  - Checklist IS the audit report
  - Auditor notes only
- Record Retention
Checklist Watch-Outs

- Checklists are generic
  - Be aware of study design and requirements
  - For non-routine work be prepared to:
    - not use a checklist
    - work beyond the checklist

- Auditor has the responsibility to understand the activity being performed or the data being audited
Wrap up/Closing Thoughts

- The checklist is an important tool for many industries and applications.
- Historically, a relatively recent development
- Provides standardization and empowerment
- Basic checklist development is relatively straightforward and logical
Questions?

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