

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 attention¹
 - Ensure consistency and completeness in carrying out a task¹
 - “They liberate our brains to focus on the hard stuff”²
 - Train and Empower people
 - Provide us with a place to begin

¹ <http://en.wikipedia.org/wiki/Checklist>

² Atul Gawande, “The Checklist Manifesto”



APPROVED B-17F and G CHECKLIST

REVISED 3-1-44

PILOT'S DUTIES IN RED

COPILLOT'S DUTIES IN BLACK

BEFORE STARTING

1. Pilot's Preflight—COMPLETE
2. Form 1A—CHECKED
3. Controls and Seats—CHECKED
4. Fuel Transfer Valves & Switch—OFF
5. Intercoolers—Cold
6. Gyros—UNCAGED
7. Fuel Shut-off Switches—OPEN
8. Gear Switch—NEUTRAL
9. Cowl Flaps—Open Right—
OPEN LEFT—Locked
10. Turbos—OFF
11. Idle cut-off—CHECKED
12. Throttles—CLOSED
13. High RPM—CHECKED
14. Autopilot—OFF
15. De-icers and Anti-icers, Wing and
Prop—OFF
16. Cabin Heat—OFF
17. Generators—OFF

STARTING ENGINES

1. Fire Guard and Call Clear—LEFT Right
2. Master Switch—ON
3. Battery switches and inverters—ON &
CHECKED
4. Parking Brakes—Hydraulic Check—On—
CHECKED
5. Booster Pumps—Pressure—ON &
CHECKED
6. Carburetor Filters—Open
7. Fuel Quantity—Gallons per tank
8. Start Engines: both magnetos on
after one revolution
9. Flight Indicator & Vacuum Pressures
CHECKED
10. Radio—On
11. Check Instruments—CHECKED
12. Crew Report
13. Radio Call & Altimeter—SET

ENGINE RUN-UP

1. Brakes—Locked
2. Trim Tabs—SET
3. Exercise Turbos and Props
4. Check Generators—CHECKED & OFF
5. Run up Engines

BEFORE TAKEOFF

1. Tailwheel—Locked
2. Gyro—Set
3. Generators—ON

AFTER TAKEOFF

1. Wheel—PILOT'S SIGNAL
2. Power Reduction
3. Cowl Flaps
4. Wheel Check—OK right—OK LEFT

BEFORE LANDING

1. Radio Call, Altimeter—SET
2. Crew Positions—OK
3. Autopilot—OFF
4. Booster Pumps—On
5. Mixture Controls—AUTO-RICH
6. Intercooler—Set
7. Carburetor Filters—Open
8. Wing De-icers—OFF
9. Landing Gear
 - a. Visual—Down Right—DOWN LEFT
Tailwheel Down, Antenna in, Ball
Turret Checked
 - b. Light—OK
 - c. Switch Off—Neutral
10. Hydraulic Pressure—OK Valve closed
11. RPM 2100—Set
12. Turbos—Set
13. Flaps $\frac{1}{2}$ — $\frac{1}{2}$ Down

FINAL APPROACH

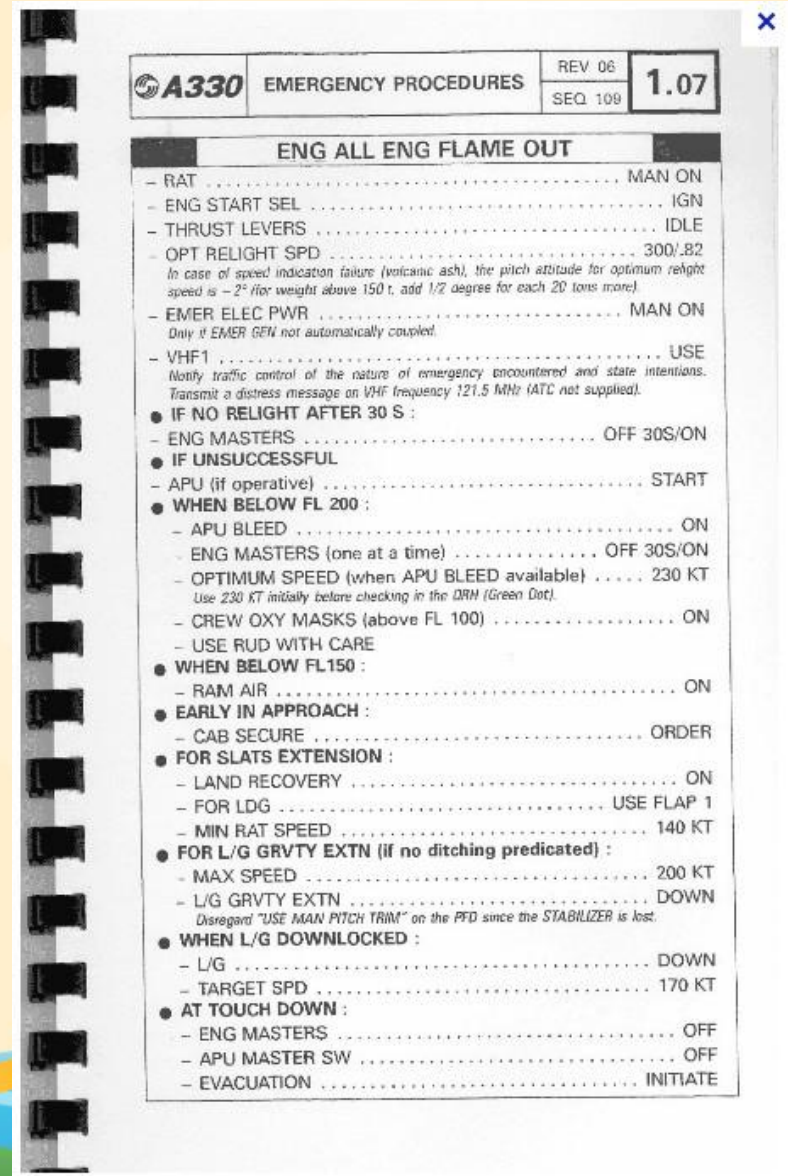
14. Flaps—PILOT'S SIGNAL
15. RPM 2200—PILOT'S SIGNAL

The First Checklist?



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

ECS ACT S-BD ANT ACT	IMU C/A SUIT FAN/H2O CK	TB VERIFICATION	PGNS T/O																								
ACT 30																											
<u>97:26</u>		<u>97:26</u>																									
<u>DOCKED IMU COARSE ALIGN</u>		<u>SUIT FAN/H2O SEP CHECK</u>																									
1	Verify CSM In Min DEADBAND ATT HOLD	1	CB(16) ECS: SUIT FAN 2 - Open (Master Alarm, SUIT/FAN Warning SUIT FAN Comp Lts - On)																								
2	Calculate LM Gimbal Angles	2	CB(11) ECS: SUIT FAN 1 - Close H2O SEP SEL - PUSH SEP 1																								
	<table border="0"> <tr> <td style="text-align: center;"><u>OG</u></td> <td style="text-align: center;"><u>IG</u></td> <td style="text-align: center;"><u>MG</u></td> </tr> <tr> <td style="text-align: center;">300.00</td> <td style="text-align: center;">180.00</td> <td style="text-align: center;">360.00</td> </tr> <tr> <td style="text-align: center;">- 2.00</td> <td style="text-align: center;">+Rc (See TLC-1)</td> <td></td> </tr> <tr> <td style="text-align: center;">298.00</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">355.57</td> <td style="text-align: center;">-CM 167.78</td> <td style="text-align: center;">+CM 351.87</td> </tr> <tr> <td style="text-align: center;">(7.5)</td> <td style="text-align: center;">(112.5)</td> <td style="text-align: center;">(22.5)</td> </tr> <tr> <td style="text-align: center;">302.43</td> <td style="text-align: center;">LM 347.78</td> <td style="text-align: center;">LM 508.13</td> </tr> <tr> <td style="text-align: center;">(292.5)</td> <td style="text-align: center;">(292.5)</td> <td style="text-align: center;">(337.5)</td> </tr> </table>	<u>OG</u>	<u>IG</u>	<u>MG</u>	300.00	180.00	360.00	- 2.00	+Rc (See TLC-1)		298.00			355.57	-CM 167.78	+CM 351.87	(7.5)	(112.5)	(22.5)	302.43	LM 347.78	LM 508.13	(292.5)	(292.5)	(337.5)	3	SUIT FAN - 1 (SUIT/FAN Warning, FAN Comp Lts-Off,ECS Caution, H2O SEP Comp Lts -Off In 2 min)
<u>OG</u>	<u>IG</u>	<u>MG</u>																									
300.00	180.00	360.00																									
- 2.00	+Rc (See TLC-1)																										
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(292.5)	(292.5)	(337.5)																									
			CB(16) ECS: SUIT FAN 2 - Close																								
			<table border="0"> <tr> <td style="text-align: right;">360.00</td> <td></td> </tr> <tr> <td style="text-align: right;">302.43</td> <td></td> </tr> <tr> <td style="text-align: right;">57.57</td> <td></td> </tr> </table>	360.00		302.43		57.57																			
360.00																											
302.43																											
57.57																											
			<u>97:28</u>																								
3	V41 N20E COARSE ALIGN IMU F 21 22 LOAD ICDU ANGLES OG,IG,MG (.01°) (NO ATT Lt - On, FDAI Torques)	1	CB(11) ECS: GLYCOL PUMP 1 - Open (Master Alarm, ECS Caution Lt - On Momentarily)																								
	*PROG Lt-On *		CB(11) ECS: GLYCOL PUMP 1 - Close (GLYCOL Comp Lt-On)																								
	*V05 N09E 00211 COARSE *																										
	* ALIGN ERROR,Go*																										
	* To 3 *																										
LM 7																											
	Basic Date	2/6/70																									
	Changed																										

Handwritten notes:
 298
360
658
355.57
298.00
302.43
355.57
302.43



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?

JOB NUMBER				PROOFED AGAINST
DESIGN	VISUAL	DIGITAL	FINAL	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Information Bug
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Item Number <input type="checkbox"/> FOH
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Barcode Number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Barcode Specs - OCRB outlined font, 100k
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Barcode/UPC scan <input type="checkbox"/> FOH
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Distribution Statement <input type="checkbox"/> FOH
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Information
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Die Guide
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Artwork Dimensions
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Crop/Reg Marks
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Product Placement
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bleed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pre-Price Information <input type="checkbox"/> FOH
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Logo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Title — Spelling, Grammar, Consistency
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Title — Styleguide
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Body Copy — Spelling, Grammar, Consistency
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Body Copy — Styleguide
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other Elements
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other Elements — Styleguide
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Photography
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Photography — Styleguide
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Photography — Links, Resolution, Color
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Warnings/Disclaimers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Warnings/Disclaimers — Supplied vs. Standard
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Font Usage : Styleguide
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Font Usage : Consistency
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Prepress Notes / Barcode notes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Layers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Swatches
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Object Colors
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Overprinting & Transparency
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Spellcheck/Proofcheck : _____ (signature)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Page Setup
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dummy Box
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Intake sheet <input type="checkbox"/> FOH

Text S2: Example of an Audit Checklist


Organization and Personnel	Yes	No	NA	Observations/Recommendations
Organizational chart exists and accurately represents the organization?				
Is the laboratory affiliated with other organizations? Identify the organizations:				
Are training records available? List the components of the training record:				
Are there personnel curricula (training matrix/plan) established and documented for each individual?				
Does the training program include new hire training and re-qualification training for personnel?				
Has personnel been appropriately trained to perform functions required by job descriptions?				
Is there a procedure to assess and document personnel competency on an annual basis?				
Is there an escalation process by which personnel that do not pass competency are retrained etc.?				
Has the Laboratory manager received GCLP training? If so, by what organization and when?				
Has personnel received regulatory training? GCLP <input type="checkbox"/> GCP <input type="checkbox"/> GLP <input type="checkbox"/> Other:				
Has personnel received				



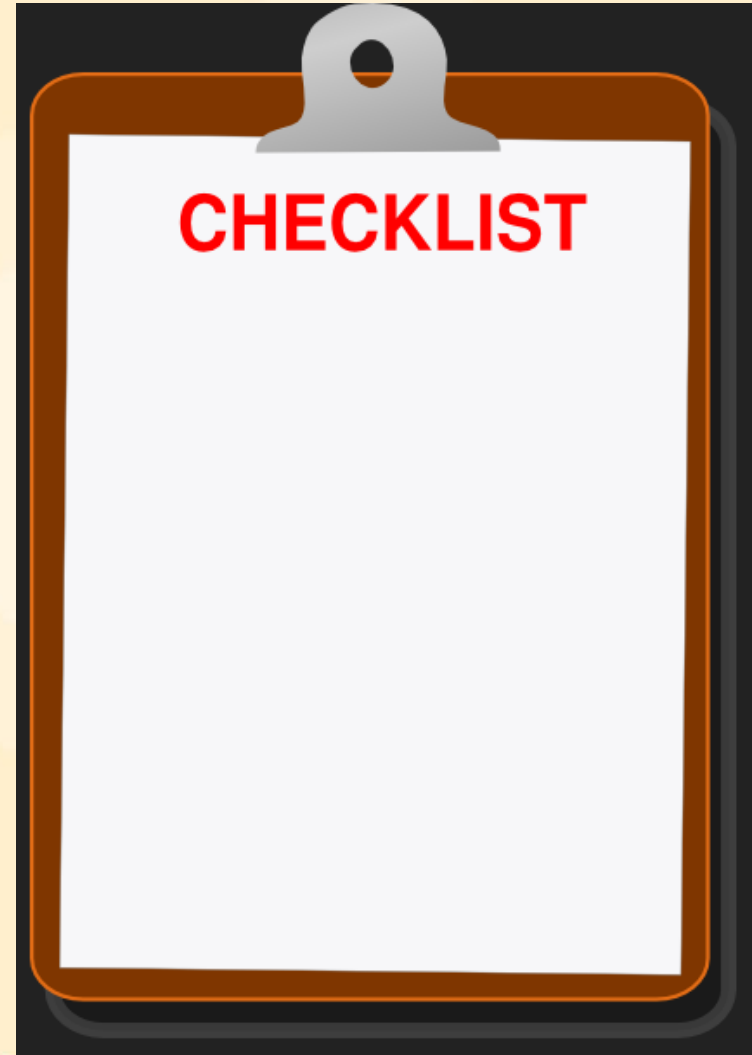
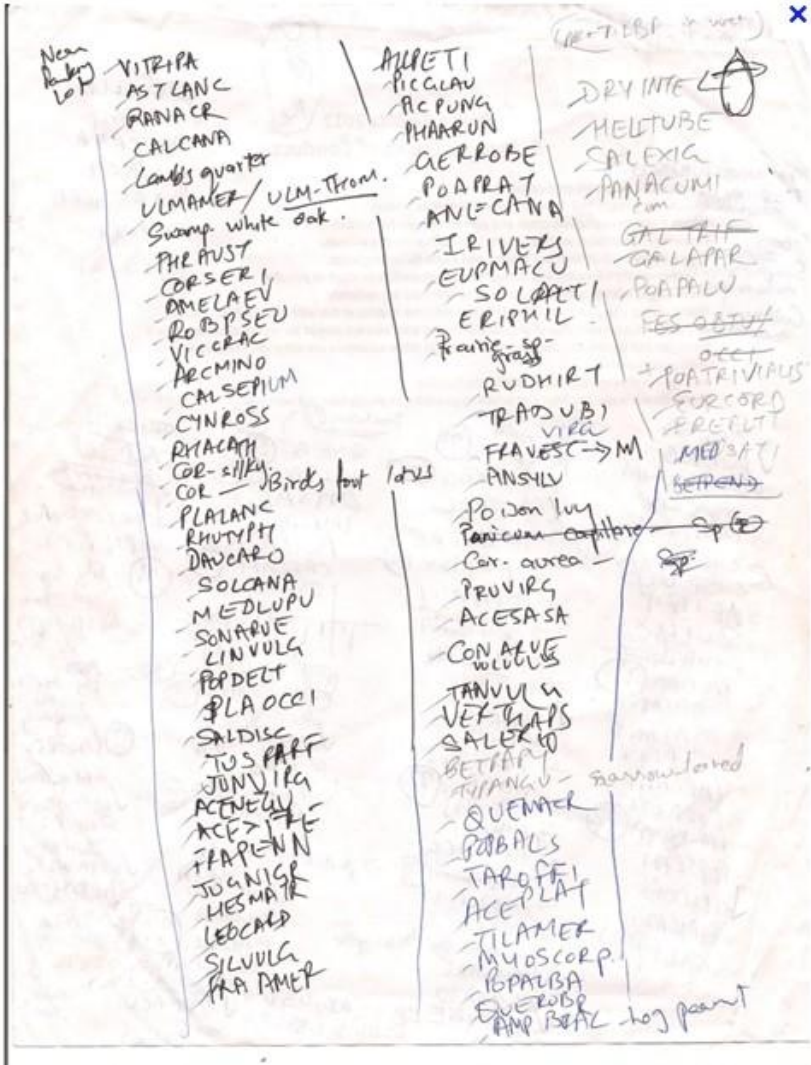
ERING FOR SUCCESS

More examples

[Your Name] Task Inspection Form Version [Version Date]			
Task (Section#)			
Project ID#	Project Name:	Location/Area:	Subcontractor Company ID#:
Reference Specifications:		Reference drawings:	Name: Crew ID/Name
Compliance Verification <input type="checkbox"/> Compliance with initial job-ready requirements <input type="checkbox"/> Compliance with material inspection and tests <input type="checkbox"/> Compliance with work in process first article inspection requirements <input type="checkbox"/> Compliance with work in process inspection requirements <input type="checkbox"/> Compliance with Task completion inspection requirements <input type="checkbox"/> Compliance with inspection and test plan		Heightened Awareness Checkpoints <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Production Notes:			
Reported Nonconformances:			
Verification of Task Completion (sign and date)			
Subcontractor <i>Task verified complete to specifications (sign and date)</i>		Sign and date*:	
Project Superintendent <i>Score subcontractor performance and feedback notes</i>		Quality: 5 4 3 2 1	
		On-Time: 5 4 3 2 1	
		Safety: 5 4 3 2 1	
<i>Task verified complete to specifications (sign and date)</i>		Sign and date*:	
Quality Manager <i>Score subcontractor performance and feedback notes</i>		Quality: 5 4 3 2 1	
<i>Task verified complete to specifications (sign and date)</i>		Sign and date*:	
* On behalf of the contractor, I certify that this report is complete and correct and equipment and material used and work performed during this reporting period is in compliance with the contract drawings and specifications to the best of my knowledge except as noted in this report.			

 CHECKLIST for GLP OECD No.1			
Organisation and Location		SANAS No.	
Organisation Representative			
Lead Inspector / Technical Expert			
CLAUSE	REQUIREMENT	✓	Comment
1.	TEST FACILITY ORGANISATION AND PERSONNEL		
1.1	Test Facility Management's Responsibilities		
1.1.2	Is there a statement which identifies the individual(s) within the test facility who fulfil the responsibilities of management as defined by the Principles of Good Laboratory Practice?		
a)	Are sufficient qualified personnel, appropriate facilities, equipment and materials available for the timely and proper conduct of the study?		
b)	Are records maintained of the qualifications, training, experience and job description of each professional and technical individual?		
c)	Do personnel clearly understand the functions they are to perform, and, where necessary, is training provided for these functions?		
d)	Have appropriate and technically valid Standard Operating Procedures (SOP's) been established and being followed, and are all original and revised SOP's approved?		
e)	Is there a Quality Assurance Programme with designated personnel and is the quality assurance responsibility being performed in accordance with the Principles of Good Laboratory Practice?		
f)	Is an individual with the appropriate qualifications, training and experience appointed as the Study Director prior to the initiation of the study, is there a procedure for replacement of the Study Director and is this documented?		
g)	In the event of a multi-site study, is, where needed, a Principal Investigator appointed, who is appropriately trained, qualified and experienced, to supervise the delegated phase(s) of the study? Is replacement of a Principal Investigator done according to established procedures, and documented?		

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 straight forward and logical



Questions?

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