

Achieving Inspection Preparedness in the ISO 15189 Accredited Laboratory

Objectives

- Identify strategies commonly used to prepare for inspections
- Describe how software can be utilized with inspection checklists
- Describe how the use of software can improve the efficiency, effectiveness, and overall continual preparedness for inspections

Avera McKennan Hospital & University Health Center

A 545-bed tertiary care hospital in Sioux Falls, South Dakota

Avera McKennan is an integrated health care delivery network, providing a full continuum of care in 115 locations in 50+ communities

Avera system, the health ministry of the Benedictine and Presentation Sisters, is a regional partnership of health professionals who share support services to maintain excellent care at 300 locations in eastern South Dakota and surrounding states.

Avera McKennan Laboratory

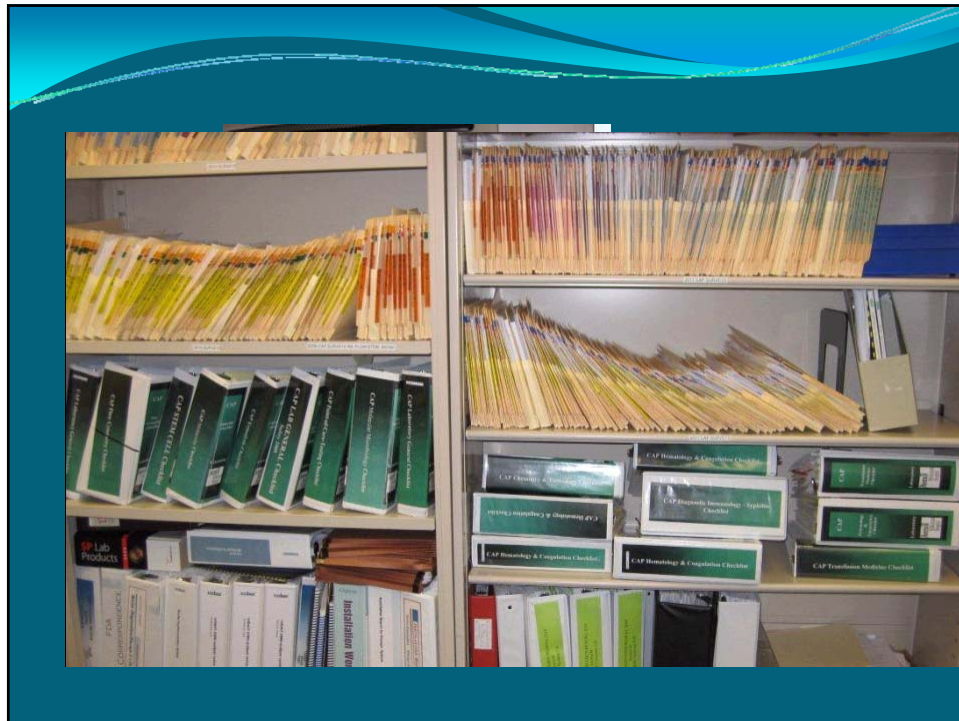
- Hospital based + reference laboratory
- Average 144,000 reportable tests/month
- 1.7 million reportable tests/year
- Lean 2004
- Accreditations/inspections include CAP, AABB, FACT, FDA, Joint Commission, ISO 15189
- First hospital based laboratory in U.S. to achieve ISO 15189 accreditation through CAP 15189 in 2008
- MLO Laboratory of the Year 2010
- First Laboratory in U.S. to undergo assessment for 2nd accreditation cycle CAP/ISO 15189

Inspection Preparedness – Historical Perspective

- Scheduled inspection – knew exact date
- Primarily a management duty
- Procrastinated until weeks/days prior
- Panic set in
- Read checklist – may/may not have handwritten in “answers”
- Crisis mode in days/hours prior

Shift from Reactive to Proactive

- Newer supervisors, technical specialists began preparing more in advance of announced time
- Notebook or 3-ring binder with checklist and answers
- Unannounced inspections improved preparation
- Evolved to binder with printed copy of downloaded checklist complete with typed in answers and documentation for each question
- Time consuming upkeep of binders



Investigated Use of Software

- Fall of 2010
- Maplewood Scheduling Software
- Introduced to additional software available - Maplewood Inspection Ready
- Did not require capital expense
- Available on internet, not requiring additional server
- Software maintenance by company
- Software development “continual”
- Web based – available anywhere

Checklist Manager - Windows Internet Explorer

https://tom1.maplewoodsoftware.com/ESS/Checklist?IsQualificationPk=2147483552&wicket.page#

File Edit View Favorites Tools Help

License Manager Checklist Manager

InspectionReady Checklist Manager

License Site: Main Lab Checklist: Laboratory General

MAPLEWOOD SOFTWARE
Traditional Craftsmanship for the Digital Future

License Site Inspection Checklist Requirement Author

View Checklists By License Site
Main Lab

- ABB Stem Cell
- ABB Transfusion
- Anatomic Pathology
- Chemistry and Toxicology
- Cytopathology
- Director and Quality
- Flow Cytometry
- Hematology and Coagulation
- Hematology Coagulation (hist)
- Immunology
- ISO 15189
- Laboratory General**
- Microbiology
- Microbiology Molecular
- Molecular Pathology
- Point-of-Care-Testing
- Transfusion Medicine (ABB)
- Transfusion Medicine (stem)
- Urinalysis

Save New Delete Report Push All Requirements To: Incomplete Publish

Checklist Laboratory General [show] Checklist

Checklist Id * Laboratory General Department link to set.. Title Laboratory General

Agency Choose One License (not set)

Binder Laboratory General Checklist Folder Laboratory General Document Laboratory General

Author General Checklist Team [show] Author

Schedule Inspection schedule [show] Schedule

Version 06/17/2010 [show] Version

Messages [show] Messages

License Site Inspection Checklist Requirement Author

Search By Id [Go]

Save Previous Next Current Status: Confirm Change To: Choose One

Response The laboratory has a documented quality management (QM) program. [show] Response

GEN.13806 Phase 2 Complete - Yes

The laboratory has a documented quality management (QM) program.

NOTE: There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program. The QM plan may be based upon some reference resource such as CLSI H501-A2, GP22-A2, or GP26-A3; the ISO 9000 series or ISO 15189, ABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design.

Compliance Notes [Update Notes]

YES

SOP-Quality Management System Plan ADM.001

Relevant Documents

Document	Directory	Description	New
SOP ADM.001	file://Q:\Lab\Lab Master Policies & Procedures\Admin QA Management Policies\Quality Management System Plan ADM.001.PDF	Q:\Lab\Lab Master Policies & Procedures\Admin QA Management Policies	Edit Remove

License Manager Checklist Manager

License Site Inspection Checklist Requirement Author

Search By Id Go

Save Previous Next Current Status: Confirm Change To: Choose One

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Compliance Notes Update Notes

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Relevant Documents

Document	Directory	Description	New
SOP ADM.001	file:///Q:/Lab/Lab Master Policies & Procedures/Admin QA Management Policies/Quality Management System Plan ADM.001.PDF	Master Policies & Admin QA Management Policies	Edit Remove

Avera McKennan Hospital & University Health Center

Sioux Falls, SD
Department of Pathology & Laboratory Medicine
SECTION: Administration/Quality Management
POLICY: ADM.001
LAST REVISION: 10/04/11

QUALITY MANAGEMENT SYSTEM PLAN

PURPOSE:
To assure quality patient care, the laboratory at Avera McKennan Hospital provides quality services through an all-inclusive quality management system which includes Process Excellence, a combination of Lean and Six Sigma. The Quality Management System (QMS) is a systematic process-oriented approach to quality. The QMS plan includes all phases of laboratory testing including the pre-examination, examination and post-examination processes (also known as pre-analytical, analytical and post-analytical). The QMS integrates all system processes for continual improvement and risk reduction, ensures that the laboratory runs efficiently and effectively, and thus assures the quality through the entire process of delivery of laboratory services.

Documentation - Attach vs. Link

- Attach – imports copy of actual document as it is at that point in time
- Link – links to document location
 - Revisions can occur to documents
 - Automatically links to latest edition
 - Always up-to-date
 - Works for Websites, SOP's from other departments on company intra-net, etc.

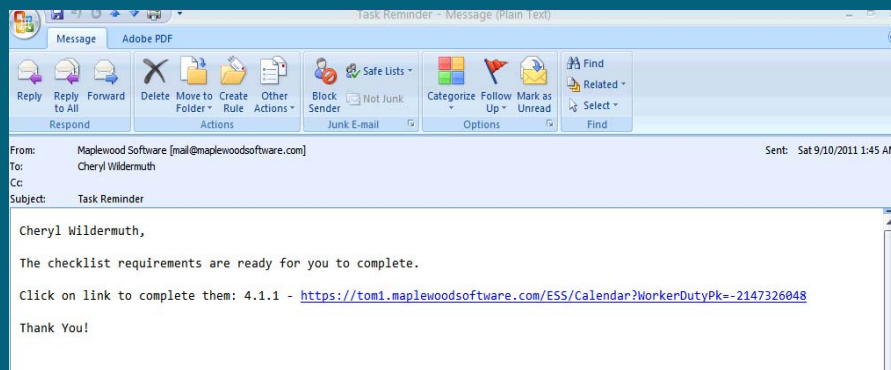
Documentation all in one place

- SOP's – policies, procedures
- Process flow charts
- Forms
- Examples (Can scan in, then link to)
 - Sample reports
 - Completed maintenance worksheets
 - Meeting minutes
 - Photos
- Web pages

Ensuring that the work gets completed

- Assign to specific individuals by entire checklist or by checklist clause
- Schedule – date assignments go out and deadline for completion
- Once assigned – access available through calendar or through accessing checklist through website
- Can include documentation – everything in one place
- Ability to track completion

Assign checklist review and updating through the software



Task appears on employee calendar – including deadline

InspectionReady MAPLEWOOD SOFTWARE
Traditional Craftsmanship for the Digital Future

Calendar

Work Leave Reports Options

<< previous | October | 2011 | Show | This Month | next >>

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
25	26	27	28	29	30	
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
		New Task				Deadline

Tuesday October 18, 2011

Icon	Subject	Overdue	Pending	Upcoming
B	Card	0	0	1

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Calendar

Work Leave Reports Options

<< previous | May | 2011 | Show | This Month | next >>

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4	5	6	7
	D-ED 8:00-14:30		D-QA 8:30-15:00	***Day - Specials 1 9:00-10:00 D630-Sc 8:30-15:00	D-QA 8:30-15:00	D7-8 7:00-15:30
8	D7-8 7:00-15:30	9	10	11	12	13
		D-QA 8:30-15:00	D-QA 8:30-15:00	***Day - Specials 1 9:00-10:00 D630-Sc 8:30-15:00	D430-8 4:30-13:00 D630-Sc 4:45-4:57	
15	Deadlines 11 New Task	16	17	18	19	20
	D-ED 8:00-14:30	D-QA 8:30-15:00	***Day - Specials 2 9:00-10:00 D630-Sc 8:30-14:00	D430-8 4:30-13:00 ***Day - core 4:45-4:57	D-QA 8:30-15:00	
22	D5-8 5:00-13:30 ***Day - core II 9:00-10:00	23	24	25	26	27
				***Day - Specials 2 9:00-10:00 D630-Sc 8:30-15:00	***Day - Specials 1 9:00-10:00 D630-Sc 8:30-15:00	D-QA 8:30-15:00
29	30	31	1	2	3	4

Wednesday May 4, 2011

Icon	Subject	Overdue	Pending	Upcoming
CAP	checklist	0	11	0

Click any day number to see tasks in progress

InspectionReady
Calendar

Log Off MAPLEWOOD SOFTWARE
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Work Leave Reports Options

previous June 2011 Show This Month next >>

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14 Deadline	15 New Tasks 2	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	1	2	3

any day number to see tasks in progress

Tuesday June 14, 2011 CAP checklist

Icon	Document	Type	Starts	Deadline
	GEN 10000	Compliance Document	04/15/2011	05/15/2011
	GEN 11226	Compliance Document	04/15/2011	05/15/2011
	GEN 12258	Compliance Document	04/15/2011	05/15/2011
	GEN 13032	Compliance Document	04/15/2011	05/15/2011
	GEN 13805	Compliance Document	04/15/2011	05/15/2011
	GEN 20316	Compliance Document	04/15/2011	05/15/2011
	GEN 20372	Compliance Document	04/15/2011	05/15/2011
	GEN 20373	Compliance Document	04/15/2011	05/15/2011
	GEN 20426	Compliance Document	04/15/2011	05/15/2011
	GEN 23584	Compliance Document	04/15/2011	05/15/2011
	GEN 30070	Compliance Document	04/15/2011	05/15/2011
	GEN 16902	Compliance Document	05/15/2011	06/14/2011

If not completed – shows as overdue and remains on calendar

InspectionReady
Calendar

Log Off MAPLEWOOD SOFTWARE
Traditional Craftsmanship for the Digital Future

Work Leave Reports Options

<< previous November 2011 Show This Month next >>

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
30	31	1	2	3	4	5
6	7	8 Overdue	9	10	11	12
13	14	15	16	17	18	19

Tuesday November 8, 2011 Filter

Icon	Subject	Overdue	Pending	Upcoming
	BCard	1	0	0

Management can check on checklist progress at any time

InspectionReady Checklist Manager License Site: Main Lab Checklist: Laboratory General

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License Site Inspection Checklist Requirement Author

Search By Id

Save Previous Next Current Status: Publish Change To:

Incomplete For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented. [\[show\]](#) Response

GEN.16902 Phase 2

For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed.

Evidence of Compliance:

* Evidence that the plan has been implemented as designed requires all of the following:

- * quality measurements/assessments specified in the plan are being substantially carried out;
- * there is evidence of active review of quality measurements;
- * if target performance levels are specified in the plan and the targets are not being met, there is documented follow-up action;
- * any interventions/changes to operations that are specified in the plan has been carried out as scheduled, or the reason for delay documented; AND
- * any communication of information that is required by the plan have taken place

Compliance Notes [Update Notes](#)

YES

Quality Management System Plan ADM.001
[Click to open ADM.001](#)

Example-Laboratory QA Committee Meeting minutes and reports

Relevant Documents

Document	Directory	Description	New
SOP ADM.063 file:///Q:/Lab/Lab Master Policies & Procedures/Admin QA Management Policies/Proficiency Testing Program ADM.063.PDF	Q:\Lab\Lab Master Policies & Procedures\Admin QA Management Policies		Edit Remove

Matching Requirements

Department	Id	Title	New
			Search

Response History CRettedal@Apr 11 2011 11:52:34:670AM [\[show\]](#) Response History

Author GEN.12258 [\[show\]](#) Author

Schedule Inspection schedule [\[show\]](#) Schedule

Messages [\[show\]](#) Messages

Many additional features – Example “Search”

YES

SOP-Proficiency Testing Program ADM.063

Relevant Documents

Document	Directory	Description	New
SOP ADM.063 file:///Q:/Lab/Lab Master Policies & Procedures/Admin QA Management Policies/Proficiency Testing Program ADM.063.PDF	Q:\Lab\Lab Master Policies & Procedures\Admin QA Management Policies		Edit Remove

Matching Requirements

Department	Id	Title	New
			Search

Response History CRettedal@Apr 11 2011 11:52:34:670AM [\[show\]](#) Response History

Author GEN.12258 [\[show\]](#) Author

Schedule Inspection schedule [\[show\]](#) Schedule

Messages [\[show\]](#) Messages

Same question on multiple checklists - compare & standardize

Checklist	Requirement
<input type="checkbox"/> Urinalysis	URN.10650 more
<input type="checkbox"/> Hematology and Coagulation	HEM.13466 more
<input type="checkbox"/> Flow Cytometry	FLO.13540 more
<input type="checkbox"/> Microbiology	MIC.00550 more
<input type="checkbox"/> Molecular Pathology	MOL.13466 more
<input type="checkbox"/> Microbiology Molecular	MIC.00550 more
<input type="checkbox"/> Point-of-Care-Testing	POC.03366 more
<input type="checkbox"/> Hematology Coagulation (hist)	HEM.13466 more
<input type="checkbox"/> Chemistry and Toxicology	CHM.10433 more
<input type="checkbox"/> Immunology	IMM.16466 more
<input type="checkbox"/> Anatomic Pathology	ANP.22994 more

Another feature – Response History

YES

SOP-Proficiency Testing Program ADM.063

Relevant Documents

Document	Directory	Description	New
SOP ADM.063 file:///Q:/Lab/Lab Master Policies & Procedures/Admin QA Management Policies/Proficiency Testing Program ADM.063.PDF	Q:\Lab\Lab Master Policies & Procedures\Admin QA Management Policies		Edit Remove

Matching Requirements [Search](#)

Department	id	Title	New
<input checked="" type="checkbox"/> Response History	CRettedal@Apr 11 2011 11:52:34:670AM		[show] Response History
<input checked="" type="checkbox"/> Author	GEN.12258		[show] Author
<input checked="" type="checkbox"/> Schedule	Inspection schedule		[show] Schedule
<input checked="" type="checkbox"/> Messages			[show] Messages

Ability to track edits

The screenshot shows a 'Response History' window with a header bar containing a green checkmark icon, the text 'Response History', the email 'CRettedal@Apr 11 2011 11:52:34:670AM', and a '[hide] Response History' link. The main content area lists two entries:

- CRettedal@Apr 11 2011 11:52:34:670AM
YES
SOP-Proficiency Testing Program ADM.063
- CRettedal@Feb 10 2011 12:56:46:140PM
YES
Proficiency Testing Program ADM.063
[Click to open ADM.063](#)

Only part of the story...

- Quick overview of a portion of software
- Next steps for us
 - Entering our employee orientation and training checklists
 - Utilizing for our employee competencies

And How Have the Inspectors Reacted?

- AABB
 - Brief review – very paper oriented
- CAP LAP
 - Utilized
 - Positive feedback
- CAP/ISO 15189
 - Viewed
 - ISO assessments not “checklist” based
 - ISO assessment process and staff interview

Lessons Learned

- We think we could have done better
 - Communication to those responsible for checklist completion
 - Difference between “attach” and “link”
 - Paper checklists would no longer be maintained
 - Required to convert to software version complete with appropriate documentation
 - Sign-on for assessors
 - Issues with being logged out of checklists due to hospital’s tight “time-out” settings
 - Create temporary assessor log-ins and passwords

Lessons Learned

- What we did well
 - Design and standardization of how checklist requirements are to be answered
 - Implementation and roll-out to staff through inservice and use of tutorial with screen prints
 - Timely completion of checklists
 - Positively received by staff, liked ease of use, and most saw benefits to change
 - Successful CAP, AABB, and ISO/CAP 15189 inspections

Summary

- Easy to use, intuitive, quick learning curve
- Increases accountability
- Improves checklist maintenance/decreases time
- Available at any time/anywhere
- Less reliance on key individuals being present at time of inspection
- Easy for management to track completion
- Totally electronic - assign access and review at will
- **Comfort** of knowing that you are truly prepared and always ready



Questions?

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