ISO 15189: HOW YOU SHOULD DO IT

Mark Gusack, M.D.
President
MANX Enterprises, Ltd.®
Huntington, WV

NORTHEAST LABORATORY CONFERENCE
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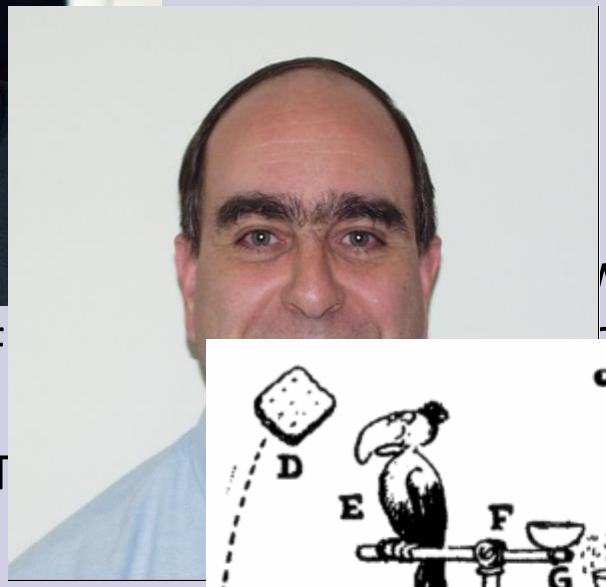
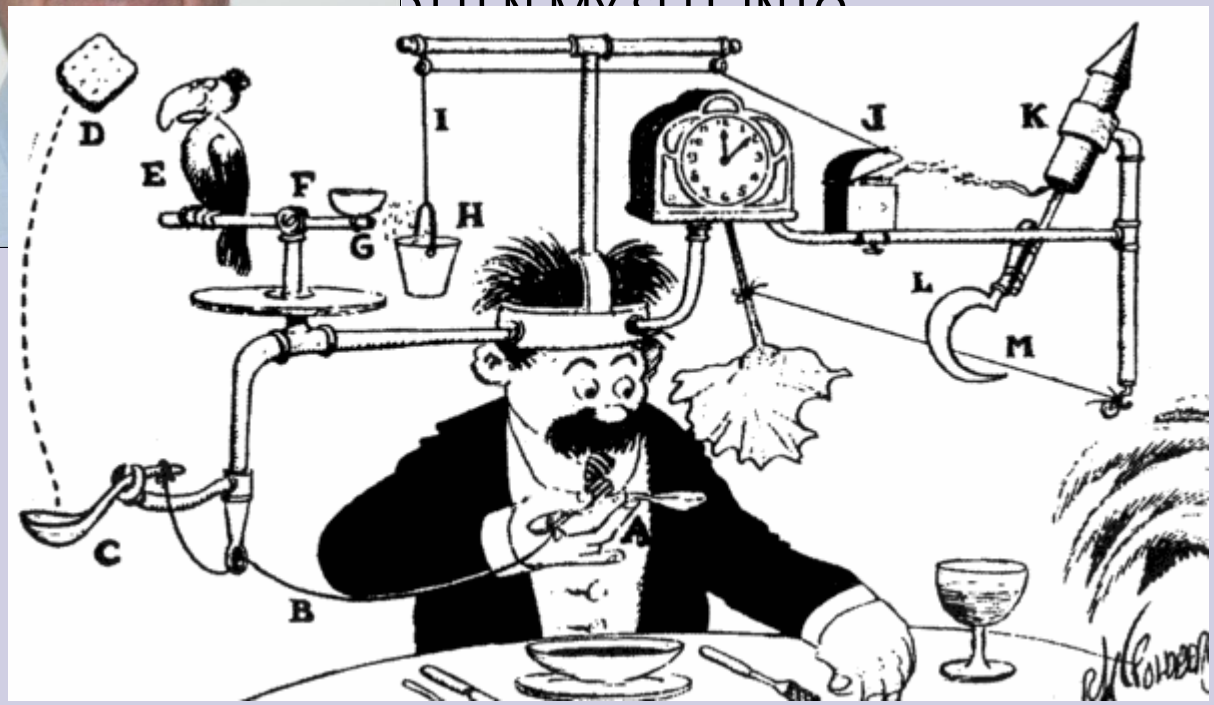
WHO AM I?



WITH A LAUNDRY LIST

OF

INST



STINKER

Mark Gusack, M.D., OCD [Overly Concerned Doctor]
President
MANX Enterprises, Ltd.
Huntington, WV
www.manxenterprises.com
mark@manxenterprises.com

Dr. Gusack has 47 years experience in the Laboratory field starting as a **Nuclear Medicine Technologist** in the early 1970's, then working as a **Clinical Engineer** in the mid 1970's, and then becoming a **Physician** and finally, a **Pathologist** serving ten years in the Army and thirteen in the VA. He is AP/CP boarded. Dr. Gusack has held positions in a variety of hospital and reference based laboratories as a medical director or staff pathologist. During this time he has also been a **Consultant in Healthcare Management and Information Technology**. In addition, Dr. Gusack has practiced as a **Licensed Health Care Risk Manager** in Florida. Over the years he has been involved with all aspects of laboratory development and management including **Startups**, **Expansions**, **Inspecting**, **Licensing**, **Sale**, **Moves**, and **Shutdown**. Dr. Gusack pioneered a unique management approach called **Integrated Management Systems** [**ISM**] for which he won a meritorious service medal at Keller Army Community Hospital, West Point, New York in 1985 and which he subsequently published in 1997. He is a **Certified ISO 15189 Assessor**.

MY BACKGROUND IN ISO

ISM:	1986 – To the present
ISO 9000/9001:	1996 – To the present
ISO 15189:	2010 – To the present
TRAINING:	Licensed Healthcare Risk Management Training 1993 - 2000 American Association of Laboratory Assessors [**A2LA**] March 2018
EXPERIENCE:	Assessment of large reference laboratories, specialty laboratories, and esoteric reference laboratories for ISO 15189 accreditation that have CLIA certification and CAP accreditation. Past CAP inspector.
INFORMATION MANAGEMENT:	1969 – To the present
DOCUMENT MANAGEMENT:	1978 – To the present
KNOWLEDGE MANAGEMENT:	1998 – To the present

MY EXPERIENCES HAVE PROVIDED ME WITH MANY VALUABLE LESSONS

WHAT WE'RE GOING TO DO TODAY IN A NUT SHELL

An operational overview of how ISO 15189 can be used to organize and manage all those regulations and standards.

Technical examples of how ISO 152189 can be used to address specific issues that arise with regulations and standards

Past – Present – Future

HOWEVER, WE CAN ONLY SCRATCH THE SURFACE IN 90 MINUTES

PROGRAM OBJECTIVES

Understand how the ISO 15189 standards form a system of systems optimal for management purposes.

Design the components of a document management system needed to implement an ISO 15189 activity that covers all regulatory and licensing standards.

Use ISO 15189 as a framework for implementing Failure Mode and Effect Analysis as an operational Risk Management tool to effectively manage the laboratory activity.

ISO 15189, ISM, AND FMEA ARE A VERY POWERFUL COMBINATION!

THE LESSON TO BE LEARNED

A comprehensive overview of how to implement ISO 15189 as a system of systems

Through effective document management and internal audits.

Suggested operational tools and example implementations are presented

Along with recommendations on how to prepare for assessment and certification

THE LEARNING IS IN THE DOING

THE LABORATORY IS ONE OF THE MOST REGULATED OF HUMAN ACTIVITIES

Joint Commission

College of American Pathologists ◀ We'll be focusing here

American Association of Blood Banks

Clinical Laboratory Improvement Act ◀ And here

State Licensing Regulations

Hospital Internal Audits

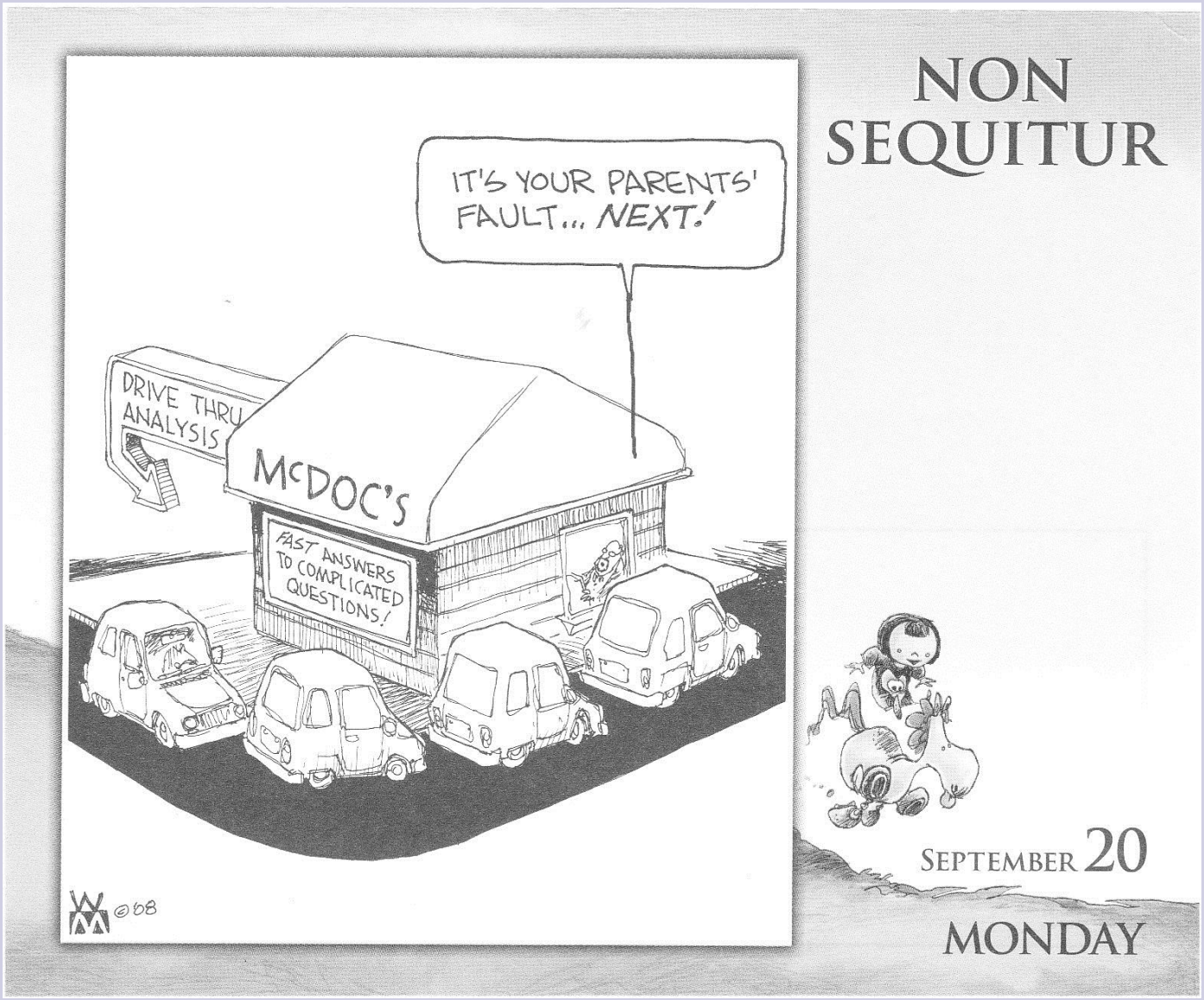
Inspector General

Legal Review

With ISO 15189 you can design a single, flexible, general management system for your laboratory operations – document/record/change control in order to deal with all of this.

WONDER HOW THINGS ARE GOING AT FUKASHIMA?

AND NOW FOR SOMETHING WE CAN ALL CONTEMPLATE



ANYONE REMEMBER THE HOUSE CALL? SOON IT WILL BE VIRTUAL HOUSE CALLS

THE DIFFERENCE BETWEEN ISO 15189, CLIA, AND CAP STANDARDS - SCOPE

CLIA [42CFR493]	Clinical Laboratory Improvement **Act**
Litigation/Legislation/➡	Federal Regulation – A Legal Requirement for Clinical Laboratories
CAPA	College of American Pathologists Accreditation
Used to Meet CLIA	Professional Organization – Accreditation to **Specific** Standards
ISO [15189]	Medical laboratories — Requirements for Quality and Competence
Systems/Processes	International Organization – Accreditation to **General** Standards

Although **ISO 15189** emphasizes quality management, it also addresses matters of risk management and resource management – utilization review; the three management areas that make up Integrated Systems Management [**ISM**].

THIS IS JUST TO REMIND US THAT ISO IS MORE GENERALIZED THAN CLIA OR CAP

IMPLEMENTING ISO 15189 – THE GENERAL APPROACH

ESTABLISHMENT OF TEAMS/TASK FORCES WITH TEAM LEADERS

ASSIGNMENT OF CLEAR CUT AUTHORITY AND RESPONSIBILITY

- By Team/Task Force first
- By Person via the Team/Task Force Leader or via Upper Management

MAKE LISTS – PAPER-BASED AND ELECTRONIC

- Documents – Look for everything no matter what version or even if active…
- Records/Forms/Logs – Do the same.
- Applicable Regulations and Standards – Federal, State, and Local along with Facility Policies

ASSIGN TASKS TO TEAMS WITH A PROPOSED SCHEDULE OF COMPLETION

CARRY OUT ACTIVITIES WITH ONGOING REVIEW AND DOCUMENTATION

INTEGRATE THE RESULTS TO PROVIDE A FOUNDATION FOR PLANNING

DESIGN AND TEST THE NEW APPROACH TO COMPLIANCE

FULL IMPLEMENTATION OF THE NEW APPROACH TO COMPLIANCE

THE BETTER YOU ORGANIZE THIS UP FRONT THE MORE LIKELY YOU WILL BE SUCCESSFUL

ESTABLISHING A HIERARCHY OF TEAMS/TASK FORCES FROM THE TOP DOWN

TOP MANAGEMENT:

- Laboratory Owner/Laboratory Contractor/Medical Director
- Risk Manager/Quality Manager/Resource Manager
- Personnel Manager/Client Services/Purchasing ◀ Yes! Even Purchasing
- Information Technology Manager

MID MANAGEMENT:

- Department Directors
- Department Supervisors
- Department Quality Managers

TEC MANAGEMENT:

- Section Lead
- Bench Technologist(s) ◀ Do not leave these people out!

THE MOTIVATION TO MAKE THE CHANGE MUST COME FROM THE TOP BUT…

AUTHORITY MUST MATCH RESPONSIBILITY FOR IMPLEMENTING ISO 15189

TOP MANAGEMENT: [SECTION 4: MANAGEMENT REQUIREMENTS]

- High level assessment of laboratory operations: CLIA/CAP/ISO 15189/Etc.
- Identify, document, and collate deficiencies
- Review high level documents against ISO 15189: Mission Statement/Plans/Policies/Records
- Redesign and reorganize documents and document management system

MID MANAGEMENT: [SECTION 4: MANAGEMENT REQUIREMENTS/SECTION 5 TECHNICAL REQUIREMENTS]

- Mid level assessment of the departmental operations: CLIA/CAP/ISO 15189/Etc.
- Identify, document, and collate deficiencies
- Review mid level documents against ISO 15189: Policies/Procedures/Guidelines/Records
- Review and comment on document designs and document management system

TEC MANAGEMENT: [SECTION 5: TECHNICAL REQUIREMENTS]

- Technical level assessment of the section operations: CLIA/CAP/ISO 15189/Etc.
- Identify, document, and collate deficiencies
- Review technical level documents against ISO 15189: Procedures/Guidelines/Forms/Records
- Review and comment on designed documents and document management system

ALLOW EACH LEVEL TO ASSESS ITS OWN OPERATIONS FIRST! THEN DO IT GLOBALLY

NOW COMES THE HARD PART

MAKE LISTS:

- ISO 15189 standards pertaining to the scope of your laboratory
- CLIA regulations pertaining to the scope of your laboratory
- CAP standards pertaining to the scope of your laboratory
- AABB, State, and Other regulations and standards as needed

CHECK THEM TWICE:

- Execute a crosswalk between all the regulations and standards and put them in a grid
- Do a gap analysis and document these for future reference and resolution
- Determine how various regulations and standards overlap and do the same
- Determine if there are any conflicts between regulations and standards and resolve them

MAKE MORE LISTS:

- All the facility's documents against the standards
- All the facility's records against the standards [this may be the same as or overlap with logs/forms]
- All the facility's forms/logs against the standards
- Then begin to organize them under the umbrella of ISO 15189

CHECK THEM TWICE:

- Now do the same crosswalk/gap analysis between your documents/records and document them in the grid

THIS IS THE BIG MOUNTAIN YOU HAVE TO CLIMB TO GET TO THE LUSH VALLEY BELOW

TOP MANAGEMENT TASKS – ROLLING THE STONE DOWN HILL

NOW DO A LABORATORY WIDE ASSESSMENT OF COMPLIANCE:

- Schedule the laboratory assessment as if it were an outside inspection
- Provide all personnel assurance that no actions will be taken for deficiencies identified
- Perform the assessment giving time for personnel to explain any deficiency identified
- And…identify best practices in each area that could be used elsewhere in the lab (and give credit)

But not for deficiencies hidden

BUILD A DEFICIENCY/BEST PRACTICES LIST:

- Collate all findings and organize them regarding CLIA/CAP/ISO 15189 headings
- Create a master report upon which future corrective actions can be based

INCLUDE A THOROUGH DOCUMENT AND RECORD REVIEW:

- Identify documents and records related to deficiencies/best practices for editing or a complete rewrite
- Assign appropriate personnel to the project in each area at the appropriate level

BASED ON THE RESULTS OF THE ASSESSMENT REDESIGN YOUR DOCUMENT MANAGEMENT SYSTEM:

- Redesign the structure and content to link each document to the CLIA/CAP/ISO 15189 heading

UPDATE MISSION, PLANS, POLICIES, AND OPERATIONS:

- Establish the mission, develop plans, write policies, and hand over to middle level management

WHILE THIS ACTIVITY IS EXECUTED ON, DO NOT PASS JUDGEMENT!

MID MANAGEMENT TASKS – SHOULDERING THE ROLLING STONE

DEPARTMENTAL ASSESSMENT OF COMPLIANCE:

- Schedule the department assessment as if it were an outside inspection
- Provide personnel assurance no actions will be taken for deficiencies identified
- During the assessment give direction to personnel in answering questions

BUILDING A DEFICIENCY/BEST PRACTICES LIST:

- Focus on departmental findings and investigate for underlying causes
- Create a departmental report to be feed upward into the master report

DEPARTMENTAL DOCUMENT AND RECORD REVIEW:

- Review structure, format, and content of key departmental policies, procedures, and forms
- Assign appropriate departmental personnel to cooperate with upper level management

DEPARTMENTAL DOCUMENT DESIGN RECOMMENDATIONS:

- Evaluate document designs proposed by upper level management and provide recommendations

REORGANIZE, REWRITE, AND DEVELOP POLICIES, PROCEDURES, AND FORMS:

- Based on the results of the assessment rework the departmental documents to meet new document designs and required content to match CLIA/CAP/ISO 15189 headings

THIS TAKES TIME. DO NOT RUSH IT BUT ESTABLISH A CADENCE OR RATE OF WORK.

TEC MANAGEMENT TASKS – PUSHING THE STONE BACK UP HILL

TECHNICAL ASSESSMENT OF COMPLIANCE:

- Schedule the sectional or instrument based assessment as if it were an outside inspection
- Assign a person to prepare for the assessment and act as the POC during the inspection
- The assigned person should be the primary person to answer questions

BUILDING A DEFICIENCY/BEST PRACTICES LIST:

- Focus on sectional findings and investigate for underlying causes
- Create a sectional/instrument/methodology report to be feed upward into the departmental report

DEPARTMENTAL DOCUMENT AND RECORD REVIEW:

- Review sectional/instrument/methodology procedures, guidelines, forms, and logs/records
- Assign appropriate sectional personnel to cooperate with mid level management

DEPARTMENTAL DOCUMENT DESIGN RECOMMENDATIONS:

- Evaluate document designs proposed by upper level management and provide recommendations

REORGANIZE, REWRITE, AND DEVELOP POLICIES, PROCEDURES, AND FORMS:

- Based on the results of the assessment rework any documents that don't meet new specifications for content and restructure/reformat

REMEMBER. THEIR HANDS ARE FULL. GIVE IT TIME. BUT NOT TOO MUCH TIME.

BREAKOUT OF ASSESSMENT ACTIVITIES – THE FOUR STEPS TO DETERMINE COMPLIANCE

READ:

- Policies — Is there at least one clear cut measurable objective(s) meeting standards
- Procedures — Does the procedure(s) provide the means of meeting the objective(s)
- Guidelines — Is there a place where lessons learned are preserved for reference
- Logs — Does the log(s) record all critical events/observations/deviations of standards
- Deviations — How they are identified, mitigated, investigated, analyzed, and solved

OBSERVE:

- Watch those responsible for any policy/procedure carry out the tasks defined in the documents
- If possible, have the person describe what they're doing and why while they do it
- Avoid allowing the department director/section leader to interject during the observation

ASK:

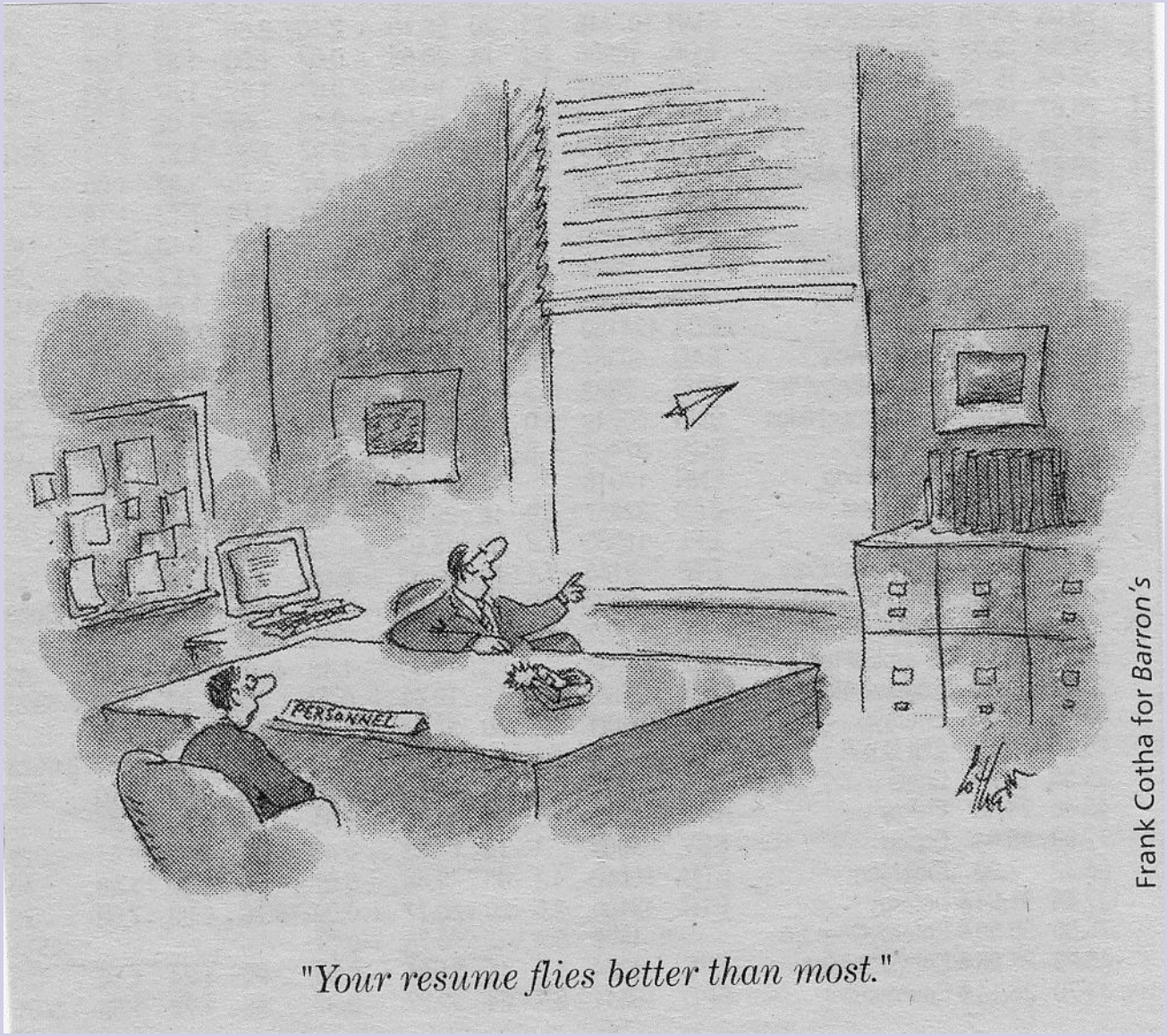
- During or after an operation, ask questions to probe the depth of knowledge of standards
- In addition, ask "what if" questions to probe the depth of experience and judgement of standards

DISCOVER:

- As the observations and questions are occurring, identify where the particular department or section is "**potentially**" deficient and document it but do not state a deficiency. Instead, ask for documentation regarding your discovery and allow time for the appropriate personnel to produce it if possible. Only then check off on this as a "**probable**" deficiency. Confirmation comes later.

THE CAP ACRONYM FOR THIS IS **R.O.A.D.** AND THIS IS A VERY EFFECTIVE APPROACH

EVER WONDER WHAT HAPPENS TO YOUR RESUME?



NOW YOU KNOW

MERGING MANAGEMENT ACTIVITIES

The above recommendations are based on the “large laboratory model”.

Large laboratories generally have enough personnel available to carry out the recommended steps.

Mid sized and small laboratories will not have enough personnel resources to do such a highly structured assessment.

However, the three tiered assessment can easily be flattened to two or one tier.

It is not necessary to do the assessment all at once. It can be carried out as a series of smaller assessments For example:

- Department-by-department or
- Section-by-section or
- Instrument-by-instrument or
- Method-by-method
- Over a period of time that allows for allocation of scarce personnel time to the activity

This requires assigning the project to a person with enough authority and energy to see it through and developing a means of documenting and tracking the project.

SET A CADENCE; A RATE, TO ASSURE THAT THE JOB GETS DONE

THE KEY TECHNICAL TOOL TO ASSURE A COMPREHENSIVE AND SYSTEMATIC ASSESSMENT

FORMS, FORMS, FORMS!

Design and employ a standardized form to assure that all those involved in making the assessment will be working from the same piece of music and so, singing the same song.

It can also be used by those being assessed to prepare by collecting documents and doing their own "assessment"

It is critical to design and test a form that is short but detailed enough to assure the following:

- All major standards are listed to assure nothing significant is missed
- List standards in such a manner as to create a natural, efficient progression of the assessment
- Provide space with each standard to document 80% of the findings with check boxes, etc.
- Provide additional space to accommodate the 20% that cannot be located with the standard
- Minimize the number of pages but understand that, to assess for CLIA, CAP, and ISO you need a lot

IDEALLY, THE FORM SHOULD MATCH A SET OF DATABASE FIELDS / SPREAD SHEET COLUMNS

EXAMPLE: SCOPE REVIEW FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 1

SCOPE REVIEW FOR ISO 15189:2012 ASSESSMENT

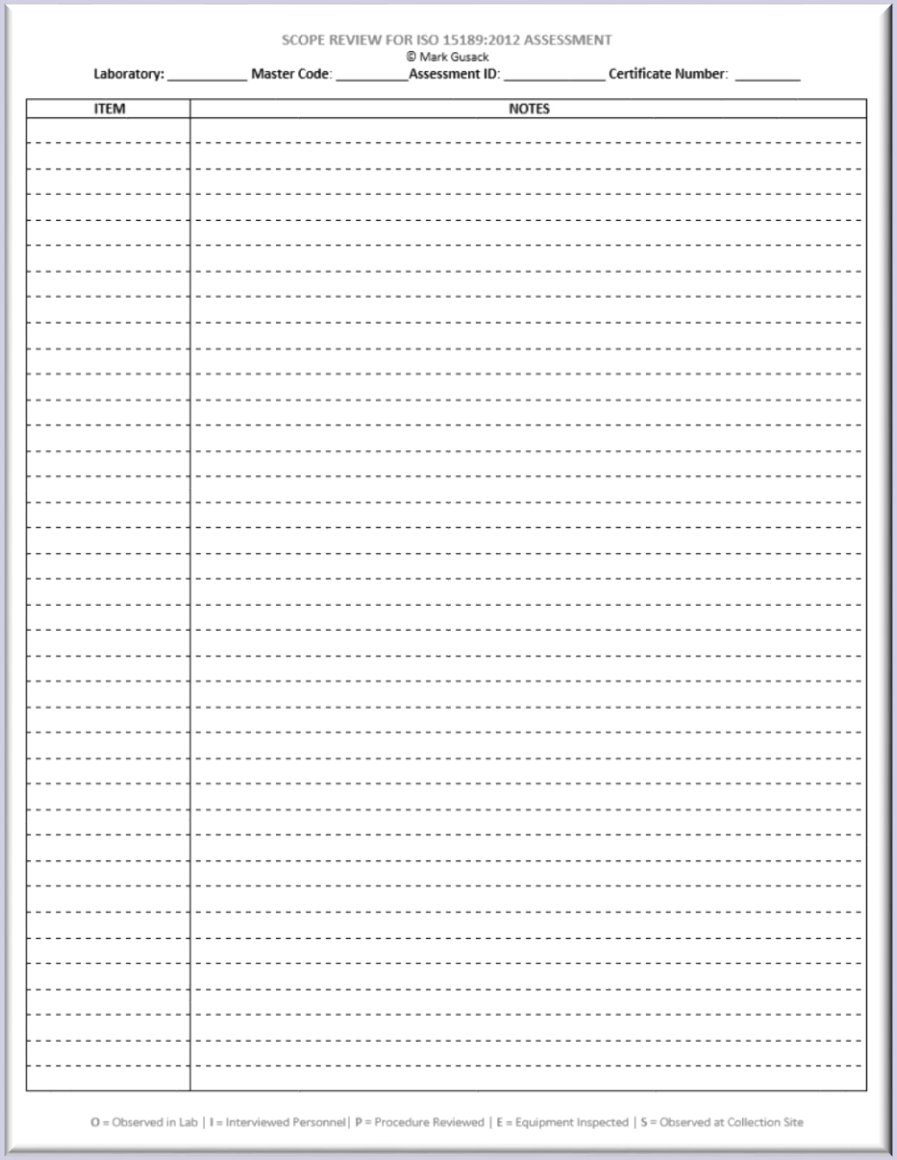
Laboratory: _____ **Master Code:** _____ **Assessment ID:** _____ **Certificate Number:** _____

ISO STANDARD	PROC/REC#	ENTRY
SPECIALTY/SUBSPECIALTY		
INSTRUMENT/METHOD		
TESTS [ANALYTES SAMPLED + ALLIED]		
DEPTH OF ASSESSMENT		☐O ☐I ☐P ☐E ☐S
PERSONNEL INTERVIEWED		
TEST ENVIRONMENT		☐ Space ☐ Light ☐ Vent ☐ Elect ☐ Plumb ☐ Sound ☐ Video ☐ Clean
WORK ACCOMMODATIONS		☐ Space ☐ Light ☐ Vent ☐ Elect ☐ Bath ☐ Sound ☐ Video ☐ Clean
VALIDATION PROCEDURE		
VALIDATION CRITERIA		
VALIDATION RECORDS		
BIO REF RANGE/ALERTS/CLIN DEC VAL		
TEST PROCEDURE [may refer to ⬇]		
OPERATING INSTRUCTIONS?		☐ Vendor Insert ☐ Outside Documents:
MEASUREMENT UNCERTAINTY		Category: ☐1 ☐2 ☐3 ☐4 ☐5 ☐ Bias ☐ Imprecision ☐ Total Error
REFERENCE MATERIALS		Traceable to: ☐ Vendor Reference ☐ Internal ☐ Outside:
CALIBRATION TRACEABILITY		Traceable to: ☐ Vendor Reference ☐ Internal ☐ Outside:
CALIBRATION CERTIFICATES		☐ Instrument: ___/___/___ ☐ Centrifuge: ___/___/___ ☐ Pipette: ___/___/___
SPECIMEN REQUISITION/PAT ID		
SPECIMEN PRESERV/TRANS/RECEIPT		
SPECIMEN ACCESSION/INSPECTION		
SPECIMEN PROCESS/STORAGE		Temp Sensor ☐ Alarm ☐ Calibration:
SPECIMEN ACCESS/DISPOSAL		
TEST REAGENTS/QC MATERIALS		☐ Vendor Insert ☐ Segregated ☐ Acceptance ☐ Lot Change Validate ☐ Outdate
TEST REAGENTS/QC MATERIALS		Temp Sensor ☐ Alarm ☐ Calibration:
QUALITY CONTROL CRITERIA USED		
QUALITY CONTROL/RESULT RELEASE		
QUALITY CONTROL LOGS/TRENDING		
QUALITY CONTROL OUT/ACTIONS		☐ Timely ☐ Immediate Actions ☐ Investigation/Solution
MAINT SCHED/REPAIRS/UPGRADES		
INSTR OUT OF SERV ID/REVALIDATION		
REPORT FORMAT/CONTENT/PAT ID		☐ Patient ID ☐ User ID ☐ Format ☐ Content ☐ Comments ☐ Interpretation
REPORTS ALERT/COMMUNICATE LOG		☐ Patient ID ☐ User ID ☐ Caller ID ☐ Time & Date ☐ What Communicated
REPORTS AMENDED/CORRECTED		☐ Identified as Such ☐ Original Report Referenced ☐ Form of Communication
TRAINING AND EDUCATION		
COMPETENCY TESTING		
PROFICIENCY TESTING		
PT FAILURE INVESTIGATION/ACTION		

O = Observed in Lab | I = Interviewed Personnel | P = Procedure Reviewed | E = Equipment Inspected | S = Observed at Collection Site

YOU CAN START WITH A SIMPLE ONE PAGE FORM FOR INITIAL ASSESSMENTS

EXAMPLE: SCOPE REVIEW FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 2



SCOPE REVIEW FOR ISO 15189:2012 ASSESSMENT

Laboratory: _____ Master Code: _____Assessment ID: _____ Certificate Number: _____

ITEM	NOTES

O = Observed in Lab | I = Interviewed Personnel| P = Procedure Reviewed | E = Equipment Inspected | S = Observed at Collection Site

AND, PERHAPS, ADD A FREE TEXT FORM ON THE BACK

EXAMPLE: ONE PAGE FORM FOR ISO 15189:2012 ASSESSMENT

But there's something missing…

Actually, there's a lot missing.

There's not enough room and this may matter early on

And not enough headings

With enough specificity for an in depth assessment

SO, WE CAN EXPAND TO A TWO PAGE FORM WITH BETTER ORGANIZATION

EXAMPLE: TWO PAGE FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 1

General Information

Validation

Metrology

Calibration

Procedure

Specimen Handling

SCOPE REVIEW FOR ISO 15189:2012 ASSESSMENT

Department: _____ Section: _____ Assessment Date: _____ Assessor: _____

ISO STANDARD ITEM	DOCUMENT#/DATES	ENTRY
SPECIALTY/SUBSPECIALTY		
INSTRUMENT/METHOD		
TEST [ANALYTE FOCUS]		
DEPTH OF ASSESSMENT		☐ O ☐ I ☐ P ☐ E ☐ S
PERSONNEL INTERVIEWED		
TEST ENVIRONMENT		☐ Space ☐ Light ☐ Vent ☐ Elect ☐ Plumb ☐ Sound ☐ Video ☐ Cleanliness
WORK ACCOMMODATIONS		☐ Space ☐ Light ☐ Vent ☐ Elect ☐ Bathrooms ☐ Sound ☐ Video ☐ Clean
VALIDATION		
PROCEDURE		
VALIDATION CRITERIA		
VALIDATION RECORDS		
INSTRUMENT COMPARISONS		
REF RANGES/ALERTS/CLIN DEC VAL		
METROLOGY		
PROCEDURE		
MEASUREMENT UNCERTAINTY		Category: ☐ Bias ☐ Imprecision ☐ Total Error
REFERENCE MATERIALS		Traceable to: ☐ Vendor ☐ Internal ☐ Outside:
CALIBRATION TRACEABILITY		Traceable to: ☐ Vendor ☐ Internal ☐ Outside:
CALIBRATION CERTIFICATE(S)		
INSTRUMENTS		
THERMOMETERS		
CENTRIFUGES		
PIPETTES		
TEST PROCEDURE		
VENDOR INSTRUCTIONS/INSERTS		
PROCEDURE - OPERATING		
SPECIMEN HANDLING		
PROCEDURE		
PATIENT IDENTIFICATION		
PATIENT PREPARATION/CONSENT		
SPECIMEN PRESERVATION		
SPECIMEN TRANSPORTATION		
SPECIMEN ACCESSIONING		
SPECIMEN INSPECTION		
SPECIMEN PROCESSING		
SPECIMEN TESTING		
SPECIMEN STORAGE AND RETRIEVAL		
SPECIMEN DISPOSAL		

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NOTICE ISO 15189 PROVIDES A CONVENIENT WAY TO ASSESS EACH DEPT/SECT

EXAMPLE: TWO PAGE FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 2

Reagents and QC Materials

Calibrators and Quality Control

Instrument Performance

Requisitions and Reports

Personnel

SCOPE REVIEW FOR ISO 15189:2012 ASSESSMENT

ISO STANDARD ITEM	DOCUMENT#/DATES	ENTRY
REAGENT/QC MATERIALS		
PROCEDURE/VENDOR INSERTS		
MATERIALS RECEIPT/ACCEPTANCE		
MATERIALS INVENTORYING		
MATERIALS LOT CONTROL/VALIDATION		
MATERIALS STORAGE/SEGREGATION		
STORAGE ENVIRONMENT ALARMS		
MATERIALS OUTDATING/DISPOSAL		
CALIBRATORS AND QUALITY CONTROL		
PROCEDURE		
RECORDS/LOGS		
CALIBRATION OUT PROTOCOL		
QUALITY CONTROL OUT PROTOCOL		
RESULT RELEASE PROTOCOL		
TRENDING/INVESTIGATING QC DATA		
INSTRUMENT PERFORMANCE		
PROCEDURE		
INSTRUMENT ID/OUT OF SERVICE		
MAINTENANCE RECORDS		
REPAIR RECORDS		
REVALIDATION RECORDS		
RETIREMENT RECORDS		
REQUISITIONS AND REPORTS		
PROCEDURE		
REQUISITION CONTENT		☐ Patient ID ☐ User ID/Location ☐ Times & Dates ☐ Comments
FORMAT READABILITY		
ROUTINE CONTENT		☐ Patient ID ☐ User ID ☐ Ref Ranges ☐ Comments ☐ Interpretation
ALERT CONTENT		☐ Patient ID ☐ User ID ☐ Caller ID ☐ Time & Date ☐ Comments
ALERT COMMUNICATION		
AMMENDED/CORRECTED CONTENT		☐ Identified as ☐ Original Report Referenced ☐ Comments
AMMENDED/CORRECTED COMMUNIC		
PERSONNEL		
PROCEDURE		
CREDENTIALING		
TRAINING		
COMPETENCY TESTING		
PROFICIENCY TESTING		
CONTINUING EDUCATION		
PT FAILURE INVESTIGATION/ACTION		

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WITH JUST TWO PAGES AND YOU CAN DO AN EFFECTIVE ASSESSMENT OF EVERYTHING!

EXAMPLE: SCOPE REVIEW FORM FOR ISO 15189:2012 ASSESSMENT

But there's still something missing…

The ISO 15189 section heading numbers to correlate with the standard.

In portrait format there's still not enough room

In addition, there's not a lot of space to write notes right next to the standard

That means we need to look at another model form

SO, LET'S FLIP THE PAGE TO LANDSCAPE!

EXAMPLE: THREE PAGE FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 1

ISO 15189:2012 ASSESSMENT – BY INSTRUMENT/METHODOLOGY

PAGE: 1

Department: _____ **Section:** _____ **Assessment Date:** _____ **Assessor:** _____

ISO SEC#	ISO STANDARD ITEM	DOCUMENT#/DATES	ENTRY
	GENERAL MANAGEMENT		
-	SPECIALTY/SUBSPECIALTY		
-	INSTRUMENT/METHOD		
-	TEST [ANALYTE FOCUS]		
-	DEPTH OF ASSESSMENT		☐ O ☐ I ☐ P ☐ E ☐ S
-	PERSONNEL INTERVIEWED		
5.2.6	TEST ENVIRONMENT		☐ Space ☐ Light ☐ Vent ☐ Elect ☐ Plumb ☐ Sound ☐ Video ☐ Cleanliness
5.2.2	WORK ACCOMMODATIONS		☐ Space ☐ Light ☐ Vent ☐ Elect ☐ Bathrooms ☐ Sound ☐ Video ☐ Clean
5.3.1/5.5.1	**VALIDATION**		
5.5.3.1/5.5.1.3	PROCEDURE		
	VALIDATION CRITERIA		
	VALIDATION RECORDS		
5.6.4	INSTRUMENT COMPARISONS		
5.5.2/5.5.3	REF RANGES/ALERTS/CLIN DEC VAL		
	METROLOGY		
5.3.1.4	PROCEDURE		
5.5.1.4	MEASUREMENT UNCERTAINTY		Category: ☐ Bias ☐ Imprecision ☐ Total Error
5.6.3.2	REFERENCE MATERIALS		Traceable to: ☐ Vendor ☐ Internal ☐ Outside:
5.3.1.4 b)	CALIBRATION TRACEABILITY		Traceable to: ☐ Vendor ☐ Internal ☐ Outside:
5.3.1.4 d)	**CALIBRATION CERTIFICATE(S)**		
-	INSTRUMENTS		
-	THERMOMETERS		
-	CENTRIFUGES		
-	PIPETTES		
	TEST PROCEDURE		
5.3.1.3	VENDOR INSTRUCTIONS/INSERTS		
5.5.1.1	PROCEDURE - OPERATING		

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NOTICE ISO 15189 SECTION NUMBERS ARE NOW PRESENT

EXAMPLE: THREE PAGE FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 2

ISO 15189:2012 ASSESSMENT – BY INSTRUMENT/METHODOLOGY PAGE: 2

ISO SEC#	ISO STANDARD ITEM	DOCUMENT#/DATES	ENTRY
	SPECIMEN HANDLING		
5.4.1	PROCEDURE		
5.4.3 a)	PATIENT IDENTIFICATION		
5.4.4.2	PATIENT PREPARATION/CONSENT		
5.4.4	SPECIMEN PRESERVATION		
5.4.5	SPECIMEN TRANSPORTATION		
5.4.6 a)	SPECIMEN ACCESSIONING		
5.4.6 b)	SPECIMEN INSPECTION		
5.4.7	SPECIMEN PROCESSING		
5.5	SPECIMEN TESTING		
5.7.2	SPECIMEN STORAGE AND RETRIEVAL		
5.7.2	SPECIMEN DISPOSAL		
5.3.2/5.6.2.2	**REAGENT/QC MATERIALS**		
5.3.2.5	PROCEDURE/VENDOR INSERTS		
5.3.2.3	MATERIALS RECEIPT/ACCEPTANCE		
5.3.2.4	MATERIALS INVENTORYING		
5.3.2.4	MATERIALS LOT CONTROL/VALIDATION		
5.3.2.2	MATERIALS STORAGE/SEGREGATION		
5.3.2.7	STORAGE ENVIRONMENT ALARMS		
5.3.2.7	MATERIALS OUTDATING/DISPOSAL		
5.6.2	**CALIBRATORS AND QUALITY CONTROL**		
5.3.1.4/5.5.3 k)	PROCEDURE		
4.13/5.6.2.3	RECORDS/LOGS		
4.9/5.6.2.3	CALIBRATION OUT PROTOCOL		
4.9/5.6.2.3	QUALITY CONTROL OUT PROTOCOL		
5.6.2.3	RESULT RELEASE PROTOCOL		
4.10	TRENDING/INVESTIGATING QC DATA		

O = Observed in Lab | **I** = Interviewed Personnel| **P** = Procedure Reviewed | **E** = Equipment Inspected | **S** = Observed at Collection Site

AND THERE'S MORE ROOM FOR ENTERING TEXT

EXAMPLE: THREE PAGE FORM FOR ISO 15189:2012 SECTION 5 ASSESSMENT – PAGE 3

5.3.1.5	**INSTRUMENT PERFORMANCE**		
5.3.1.5	PROCEDURE		
5.3.1.5	INSTRUMENT ID/OUT OF SERVICE		
5.3.1.5	MAINTENANCE RECORDS		
5.3.1.5	REPAIR RECORDS		
5.3.1.7	REVALIDATION RECORDS		
5.3.1.7	RETIREMENT RECORDS		
5.8	**REQUISITIONS AND REPORTS**		
5.8.1	PROCEDURE		
5.4.3	REQUISITION CONTENT		☐ Patient ID ☐ User ID/Location ☐ Times & Dates ☐ Comments
5.8.2/5.9.1	FORMAT READABILITY		
5.8.3	ROUTINE CONTENT		☐ Patient ID ☐ User ID ☐ Ref Ranges ☐ Comments ☐ Interpretation
5.5.3 q)	ALERT CONTENT		☐ Patient ID ☐ User ID ☐ Caller ID ☐ Time & Date ☐ Comments
5.9.1	ALERT COMMUNICATION		
5.9.3	AMMENDED/CORRECTED CONTENT		☐ Identified as ☐ Original Report Referenced ☐ Comments
5.9.3	AMMENDED/CORRECTED COMMUNIC		
5.1	**PERSONNEL**		
5.1.1	PROCEDURE		
5.1.1	CREDENTIALING		
5.1.5	TRAINING		
5.1.6	COMPETENCY TESTING		
5.1.7	PROFICIENCY TESTING		
5.1.8	CONTINUING EDUCATION		
5.6.3.1	PT FAILURE INVESTIGATION/ACTION		

BUT, NOW, THERE ARE THREE PAGES INSTEAD OF ONE OR TWO

15189:2012 OUTLINE OF STANDARDS – SYSTEMS ORIENTED

FACILITIES/EQUIPMENT/INSTRUMENTS

Order – Receipt – Installation – Calibration – Validation – Acceptance – Use – Verification – Maintenance - Retirement

REAGENTS/CONTROLS/CALIBRATORS

Order – Receipt – Accession – Storage – Validation – Use – Verification – Outdating – Retirement

SPECIMENS

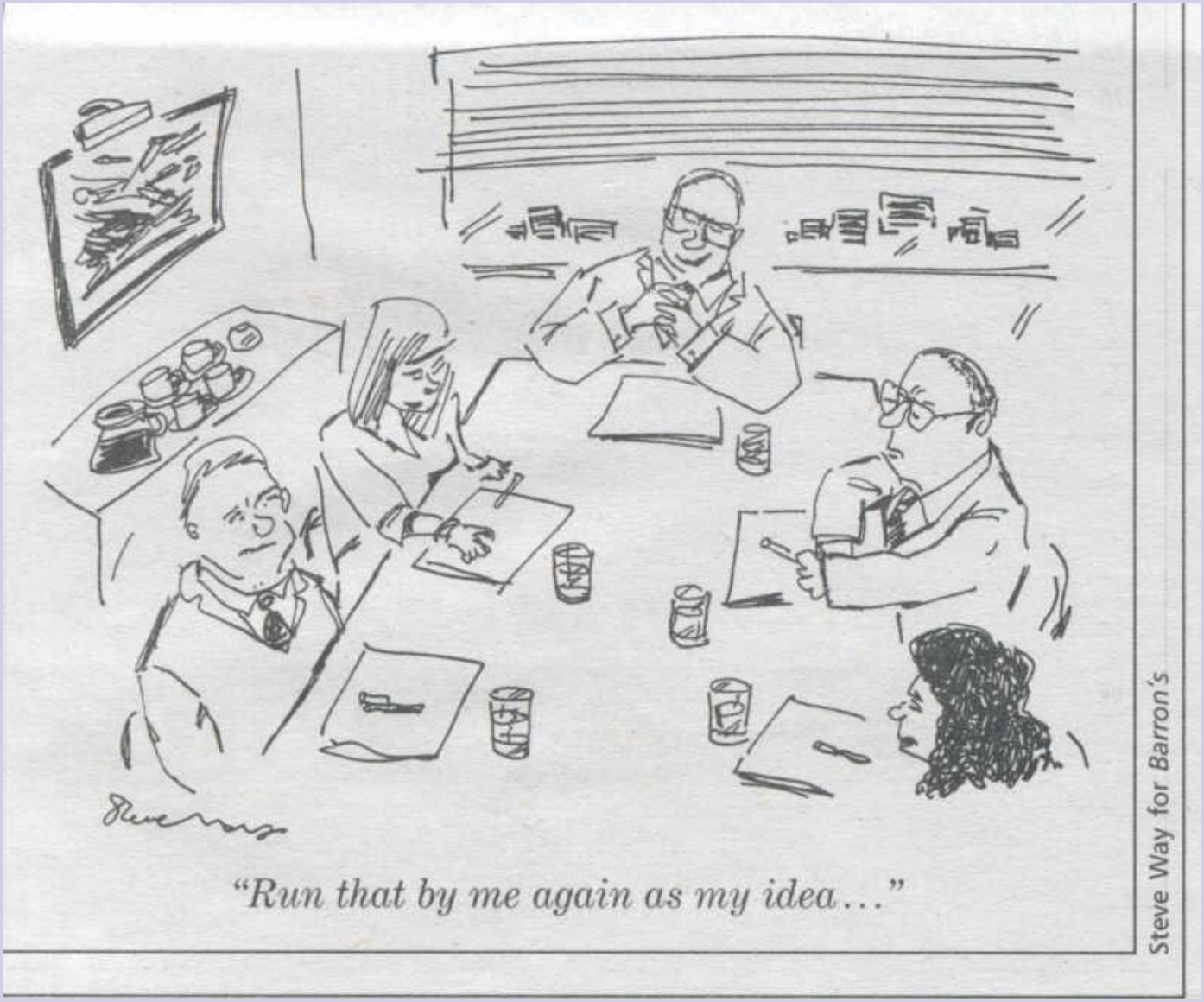
Order – Receipt – Accession – Assessment – Distribution – Testing – Storage – Release – Reporting – Amend/Correct

PERSONNEL

Hire – Orientation – Training – Competency – Work – Proficiency – Continuing Training/Education – Retirement/Separation

USING ISO 15189 YOU CAN VIEW THINGS MANY DIFFERENT WAYS

YOU MAY NEED TO REDEFINE AUTHORITY AND RESPONSIBILITY



AND THEN THERE ARE THOSE NASTY THINGS CALLED EGOS…

15189:2012 CROSSWALK FORM FOR MS WORD

- In the following slides the entire set of headings for ISO 15189 are shown
- In this case, the headings are stored in an MS WORD document
- This set of headings can be used by each separate department and section of the laboratory
- The document can be used as a walk around paper-based system
- The document can also be used in a portable computer/tablet for direct entry
- Direct entry allows for expanding the individual rows of each standard as needed to include lists of documents, logs, records, and any comments regarding what will be done or what is being done
- So, this form can be used as a project management tool as well as a way to do a preliminary collection and categorization of the laboratory documents
- Even better, as we will see, entries in the document can be linked out to the actual documents and reports!

USING ISO 15189 YOU CAN VIEW THINGS MANY DIFFERENT WAYS

15189:2012 CROSSWALK FORM FOR MS WORD – PAGE 1

ISO 15189:2012 STANDARDS CROSSWALK FORM

		ISO 15189:2012 STANDARD HEADINGS	☐ CLIA ☐ CAP ☐ OTHER:
			CLIA SECTION/CAP CHECK LIST:
✓	4	MANAGEMENT REQUIREMENTS	
	4.1	ORGANIZATION AND MANAGEMENT RESPONSIBILITY	
	4.1.1	Organization	
	4.1.1.1	General	
	4.1.1.2	Legal entity	
	4.1.1.3	Ethical conduct	
	4.1.1.4	Laboratory director	
	4.1.2	Management responsibility	
	4.1.2.1	Management commitment	
	4.1.2.2	Needs of users	
	4.1.2.3	Quality policy	
	4.1.2.4	Quality objectives and planning	
	4.1.2.5	Responsibility, authority and interrelationships	
	4.1.2.6	Communication	
	4.1.2.7	Quality manager	
	4.2	QUALITY MANAGEMENT SYSTEM	
	4.2.1	General requirements	
	4.2.2	Documentation requirements	
	4.2.2.1	General	
	4.2.2.2	Quality manual	
	4.3	DOCUMENT CONTROL	
	4.4	SERVICE AGREEMENTS	
	4.4.1	Establishment of service agreements	
	4.4.2	Review of service agreements	
	4.5	EXAMINATION BY REFERRAL LABORATORIES	

USING MS WORD IS VERY SIMPLE AND EASY AND WE CAN USE IT FOR THE ASSESSMENT

15189:2012 CROSSWALK FORM FOR MS WORD – PAGE 2

	4.5.1	Selecting and evaluating referral laboratories and consultants	
	4.5.2	Provision of examination results	
	4.6	**EXTERNAL SERVICES AND SUPPLIES**	
	4.7	**ADVISORY SERVICES**	
	4.8	**RESOLUTION OF COMPLAINTS**	
	4.9	**IDENTIFICATION AND CONTROL OF NONCONFORMITIES**	
	4.10	**CORRECTIVE ACTION**	
	4.11	**PREVENTIVE ACTION**	
	4.12	**CONTINUAL IMPROVEMENT**	
	4.13	**CONTROL OF RECORDS**	
	4.14	**EVALUATION AND AUDITS**	
	4.14.1	General	
	4.14.2	Periodic review of requests, and suitability of procedures and sample requirements	
	4.14.3	Assessment of user feedback	
	4.14.4	Staff suggestions	
	4.14.5	Internal audit	
	4.14.6	Risk management	
	4.14.7	Quality indicators	
	4.14.8	Reviews by external organizations	
	4.15	**MANAGEMENT REVIEW**	
	4.15.1	General	
	4.15.2	Review input	

USING MS WORD PROVIDES A SIMPLIFIED OVERVIEW OF YOUR OPERATIONS

15189:2012 CROSSWALK FORM FOR MS WORD – PAGE 3

	4.15.3	Review activities	
	4.15.4	Review output	
	5	**TECHNICAL REQUIREMENTS**	
	5.1	Personnel	
	5.1.1	General	
	5.1.2	Personnel qualifications	
	5.1.3	Job descriptions	
	5.1.4	Personnel introduction to the organizational environment	
	5.1.5	Training	
	5.1.6	Competence assessment	
	5.1.7	Reviews of staff performance	
	5.1.8	Continuing education and professional development	
	5.1.9	Personnel records	
	5.1.8	Continuing education and professional development	
	5.2	**ACCOMMODATION AND ENVIRONMENTAL CONDITIONS**	
	5.2.1	General	
	5.2.2	Laboratory and office facilities	
	5.2.3	Storage facilities – Location | Size| Lighting | Temperature | Humidity | Safety	
	5.2.4	Staff facilities	
	5.2.5	Patient sample collection facilities	
	5.2.6	Facility maintenance and environmental conditions	
	5.3	**LABORATORY EQUIPMENT, REAGENTS, AND CONSUMABLES**	
	5.3.1	***Equipment***	
	5.3.1.1	General – Instrument ID's and Infrastructure Support	
	5.3.1.2	Equipment acceptance testing – Validation Method | Acceptance Criteria | Multiple Instrument Validation	
	5.3.1.3	Equipment instructions for use – Vendor Documents | Laboratory Procedures	

USING MS WORD PROVIDES A MEANS OF ASSIGNING TASKS AS WELL IF YOU WISH

15189:2012 CROSSWALK FORM FOR MS WORD – PAGE 4

	5.3.1.4	Equipment calibration and metrological traceability – Vendor Certificate | Calibration | QC: Total Error	
	5.3.1.5	Equipment maintenance and repair – Vendor | Laboratory Schedule | Vendor Response | Revalidation	
	5.3.1.6	Equipment adverse incident reporting	
	5.3.1.7	Equipment records – Validation | Implementation | Lifetime History | Retirement	
	5.3.2	***Reagents and consumables***	
	5.3.2.1	General	
	5.3.2.2	Reagents and consumables — Reception and storage – Inspection | Dating | Environment	
	5.3.2.3	Reagents and consumables — Acceptance testing – By Change in Supplier | Batch | Lot Number	
	5.3.2.4	Reagents and consumables — Inventory management – First in First Out | Outdating	
	5.3.2.5	Reagents and consumables — Instructions for use – Vendor Documents | Laboratory Procedure	
	5.3.2.6	Reagents and consumables — Adverse incident reporting	
	5.3.2.7	Reagents and consumables — Records – QC data | Rules | Trending | Actions	
	5.4	**PRE-EXAMINATION PROCESSES**	
	5.4.1	General	
	5.4.2	Information for patients and users – Informed Consent | Utilization Resources	
	5.4.3	Request form information - Patient ID | Specimen Parameters | Orders | Ordering Authority and Location	
	5.4.4	Primary sample collection and handling – Who | Where | When | How	
	5.4.4.1	General	
	5.4.4.2	Instructions for pre-collection activities – Procedures	
	5.4.4.3	Instructions for collection activities – Procedures | Preservation	
	5.4.5	Sample transportation – Environment | Delays | Condition of Specimens	

USING MS WORD ELECTRONICALLY ALLOWS YOU TO EXPAND EACH ROW IN THE TABLE

15189:2012 CROSSWALK FORM FOR MS WORD – PAGE 5

	5.4.6	Sample reception – Receipt | Opening | Inspection | Rejection Criteria | Incident Handling	
	5.4.7	Pre-examination handling, preparation and storage – Identifiers | Splitting | Holding Areas	
	5.5	**EXAMINATION PROCESSES**	
	5.5.1	Selection, verification and validation of examination procedures – Acceptance Criteria	
	5.5.1.1	General	
	5.5.1.2	Verification of examination procedures	
	5.5.1.3	Validation of examination procedures	
	5.5.1.4	Measurement uncertainty of measured quantity values – QC data stats	
	5.5.2	Biological reference intervals or clinical decision values – Vendor | Published | Internal	
	5.5.3	Documentation of examination procedures	
	5.6	**ENSURING QUALITY OF EXAMINATION RESULTS**	
	5.6.1	General	
	5.6.2	Quality control	
	5.6.2.1	General	
	5.6.2.2	Quality control materials – Vendor | Third Party | Internal	
	5.6.2.3	Quality control data - Procedures	
	5.6.3	Interlaboratory comparisons – Proficiency Testing	
	5.6.3.1	Participation	
	5.6.3.2	Alternative approaches – Split Testing	
	5.6.3.3	Analysis of interlaboratory comparison samples	
	5.6.3.4	Evaluation of laboratory performance – Internal | External	
	5.6.4	Comparability of examination results – Internal | External	
	5.7	**POST-EXAMINATION PROCESSES**	
	5.7.1	Review of results	
	5.7.2	Storage, retention and disposal of clinical samples	

USING MS WORD PROVIDES THE MEANS OF COOPERATIVE EDITING BUT IT'S NOW 6 PAGES

15189:2012 CROSSWALK FORM FOR MS WORD – PAGE 6

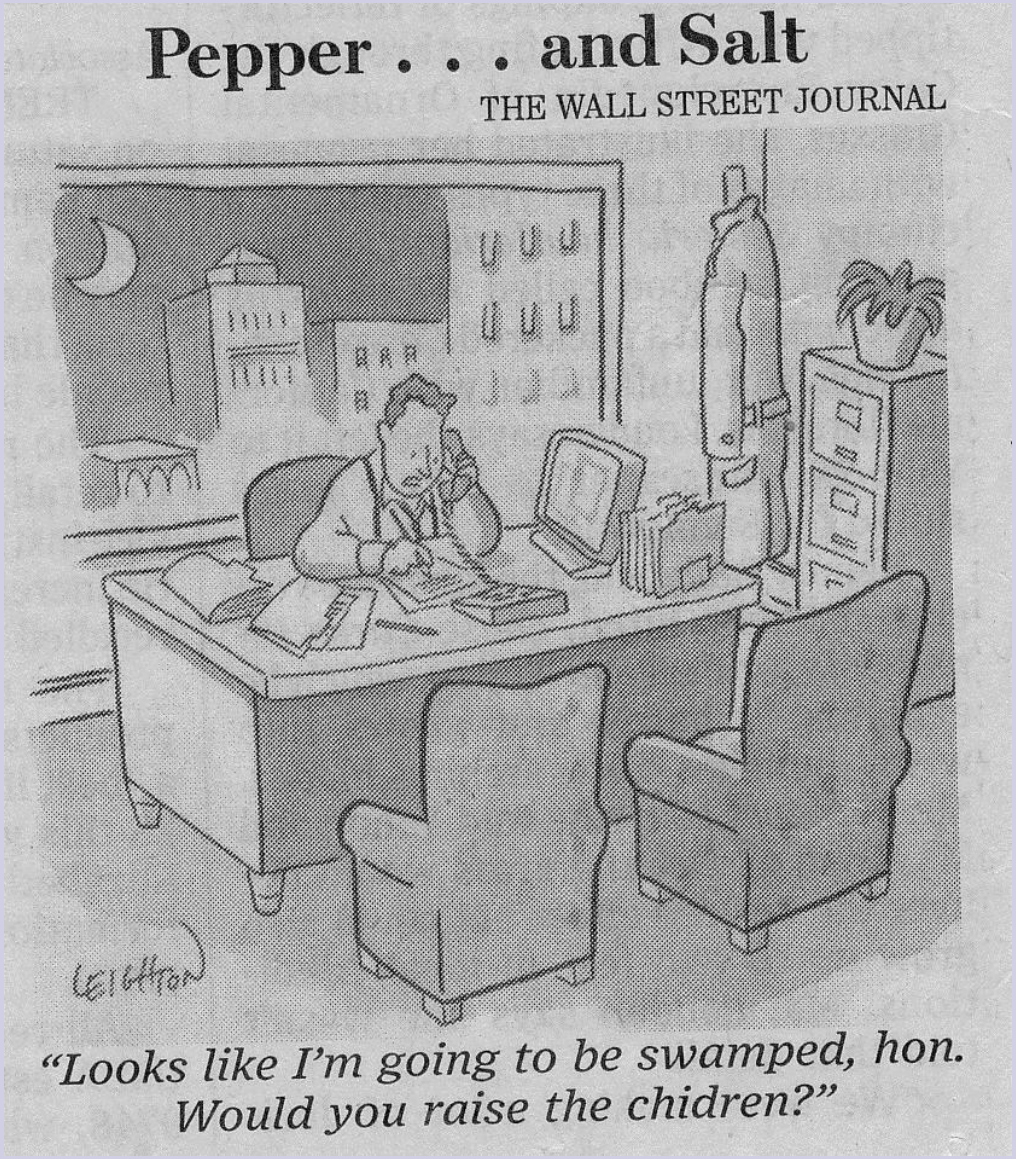
	5.8	**REPORTING OF RESULTS**	
	5.8.1	General	
	5.8.2	Report attributes	
	5.8.3	Report content	
	5.9	**RELEASE OF RESULTS**	
	5.9.1	General	
	5.9.2	Automated selection and reporting of results	
	5.9.3	Revised reports	
	5.10	**LABORATORY INFORMATION MANAGEMENT**	
	5.10	Laboratory information management	
	5.10.1	General	
	5.10.2	Authorities and responsibilities	
	5.10.3	Information system management	

NOTE: In addition to using this form for a crosswalk and to organize your documents, you might want to use it to assign authority and responsibility over the entire enterprise, or keep track of the implementation and maintenance of ISO 15189.

NOTE: There is a problem we face when trying to centralize many highly technical requirements under various departments and sections under general headings in a static word document.

SO, USING MS WORD IS LIMITING WHEN BUILDING A COMPREHENSIVE SYSTEM

IS THERE TIME TO DO ALL THIS?



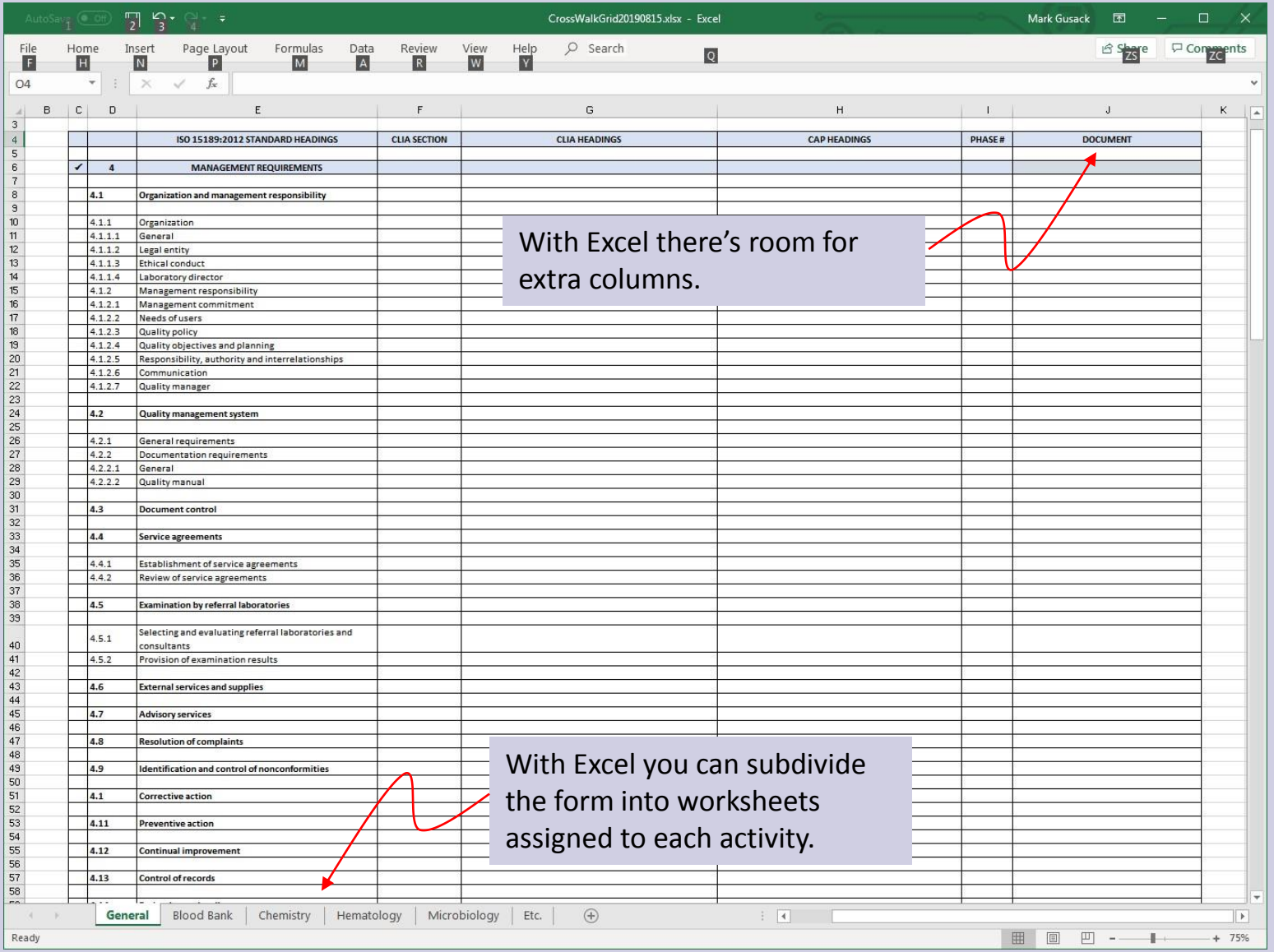
WELL,…IT DEPENDS.

15189:2012 CROSSWALK FORM FOR MS EXCEL

- In the following slides an example extract of headings for ISO 15189 are shown
- In this case, the headings are stored in an MS EXCEL document
- This set of headings can organized by worksheets for departments and sections
- The document can be used as a walk around paper-based system but this can be difficult
- The document can also be used in a portable computer/tablet for direct entry
- Direct entry allows for expanding the individual rows of each standard as needed to include lists of documents, logs, records, and any comments regarding what will be done or what is being done
- So, this form can be used as a project management tool as well as a way to do a preliminary collection and categorization of the laboratory documents
- Even better, as we will see, entries in the spreadsheet can be linked out to the actual documents and reports!

USING ISO 15189 YOU CAN VIEW THINGS MANY DIFFERENT WAYS

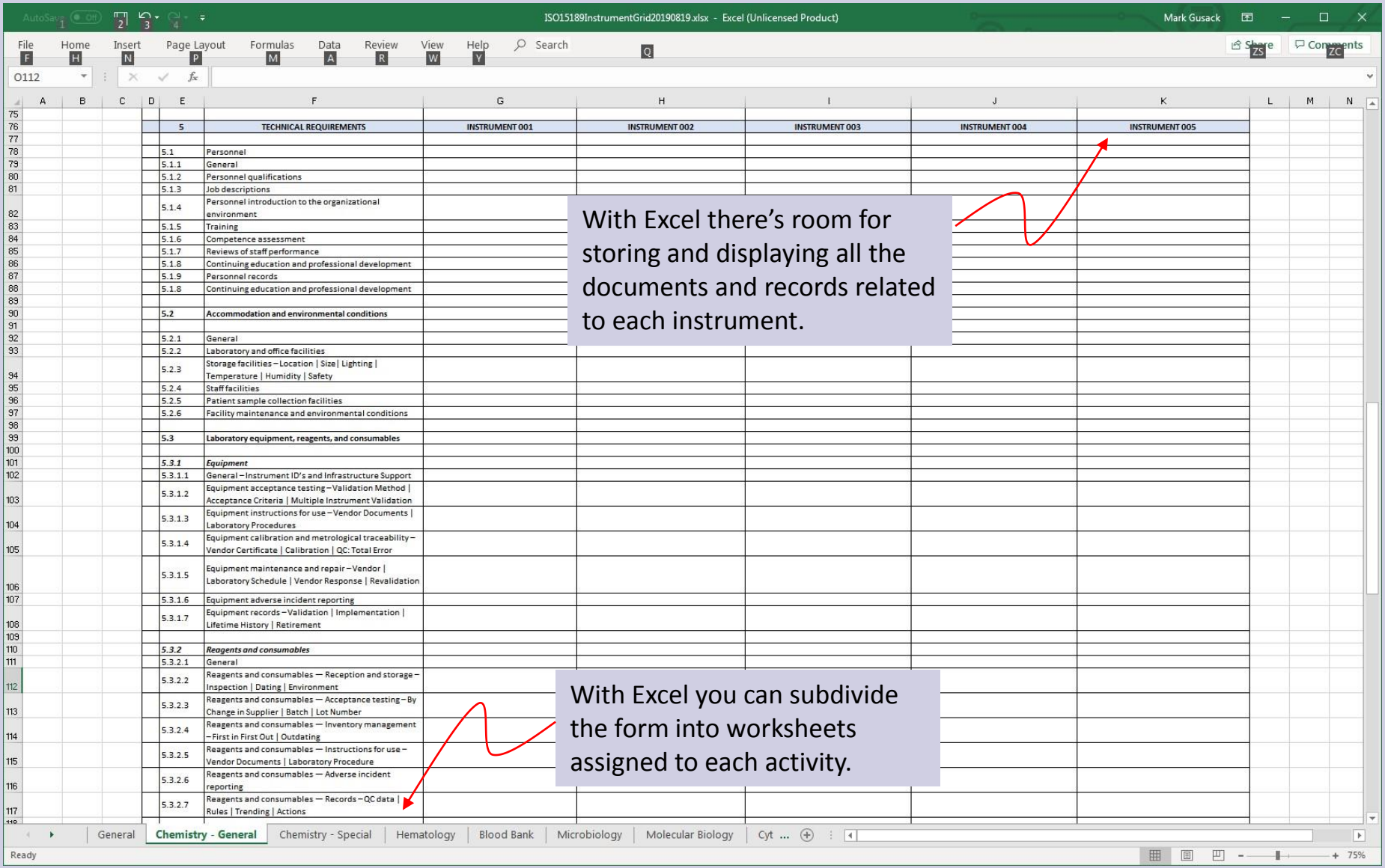
15189:2012 CROSSWALK FORM FOR MS EXCEL – EXAMPLE WORKSHEET



	ISO 15189:2012 STANDARD HEADINGS	CLIA SECTION	CLIA HEADINGS	CAP HEADINGS	PHASE #	DOCUMENT
✓	**4 MANAGEMENT REQUIREMENTS**					
	4.1 Organization and management responsibility					
	4.1.1 Organization					
	4.1.1.1 General					
	4.1.1.2 Legal entity					
	4.1.1.3 Ethical conduct					
	4.1.1.4 Laboratory director					
	4.1.2 Management responsibility					
	4.1.2.1 Management commitment					
	4.1.2.2 Needs of users					
	4.1.2.3 Quality policy					
	4.1.2.4 Quality objectives and planning					
	4.1.2.5 Responsibility, authority and interrelationships					
	4.1.2.6 Communication					
	4.1.2.7 Quality manager					
	4.2 Quality management system					
	4.2.1 General requirements					
	4.2.2 Documentation requirements					
	4.2.2.1 General					
	4.2.2.2 Quality manual					
	4.3 Document control					
	4.4 Service agreements					
	4.4.1 Establishment of service agreements					
	4.4.2 Review of service agreements					
	4.5 Examination by referral laboratories					
	4.5.1 Selecting and evaluating referral laboratories and consultants					
	4.5.2 Provision of examination results					
	4.6 External services and supplies					
	4.7 Advisory services					
	4.8 Resolution of complaints					
	4.9 Identification and control of nonconformities					
	4.1 Corrective action					
	4.11 Preventive action					
	4.12 Continual improvement					
	4.13 Control of records					

STILL, MS EXCEL IS ALSO LIMITING WHEN BUILDING A USABLE CROSSWALK

15189:2012 INSTRUMENT FORM FOR MS EXCEL – EXAMPLE WORK SHEET



5	TECHNICAL REQUIREMENTS	INSTRUMENT 001	INSTRUMENT 002	INSTRUMENT 003	INSTRUMENT 004	INSTRUMENT 005
5.1	Personnel					
5.1.1	General					
5.1.2	Personnel qualifications					
5.1.3	Job descriptions					
5.1.4	Personnel introduction to the organizational environment					
5.1.5	Training					
5.1.6	Competence assessment					
5.1.7	Reviews of staff performance					
5.1.8	Continuing education and professional development					
5.1.9	Personnel records					
5.1.8	Continuing education and professional development					
5.2	**Accommodation and environmental conditions**					
5.2.1	General					
5.2.2	Laboratory and office facilities					
5.2.3	Storage facilities – Location | Size | Lighting | Temperature | Humidity | Safety					
5.2.4	Staff facilities					
5.2.5	Patient sample collection facilities					
5.2.6	Facility maintenance and environmental conditions					
5.3	**Laboratory equipment, reagents, and consumables**					
5.3.1	***Equipment***					
5.3.1.1	General – Instrument ID's and Infrastructure Support					
5.3.1.2	Equipment acceptance testing – Validation Method | Acceptance Criteria | Multiple Instrument Validation					
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5.3.2.6	Reagents and consumables — Adverse incident reporting					
5.3.2.7	Reagents and consumables — Records – QC data | Rules | Trending | Actions					

With Excel there's room for storing and displaying all the documents and records related to each instrument.

With Excel you can subdivide the form into worksheets assigned to each activity.

SO, MS EXCEL IS ALSO VERY GOOD FOR ORGANIZING DOCUMENTS BY INSTRUMENT

15189:2012 CROSSWALK FORM FOR MS ACCESS

- In the following slides an example extract of headings for ISO 15189 are shown
- In this case, the headings are stored in an MS ACCESS relational database
- This set of headings can organized hierarchically as well as by departments and sections
- This set of headings can organized simultaneously by instrument, methodology, and analyte
- The database can also be used in a portable computer/tablet for direct entry
- Record level entry by fields allows for developing sophisticated data structures for querying and to build reports that automatically print as needed
- So, the database is a more powerful form of project management tool as well as a way to collect and categorize of the laboratory documents
- Effective document control can be imposed as well!
- Even better, as we will see, entries in the database can be linked out to the actual documents and reports!

USING ISO 15189 YOU CAN VIEW THINGS MANY DIFFERENT WAYS

I DOCUMENT

THEREFORE

I AM

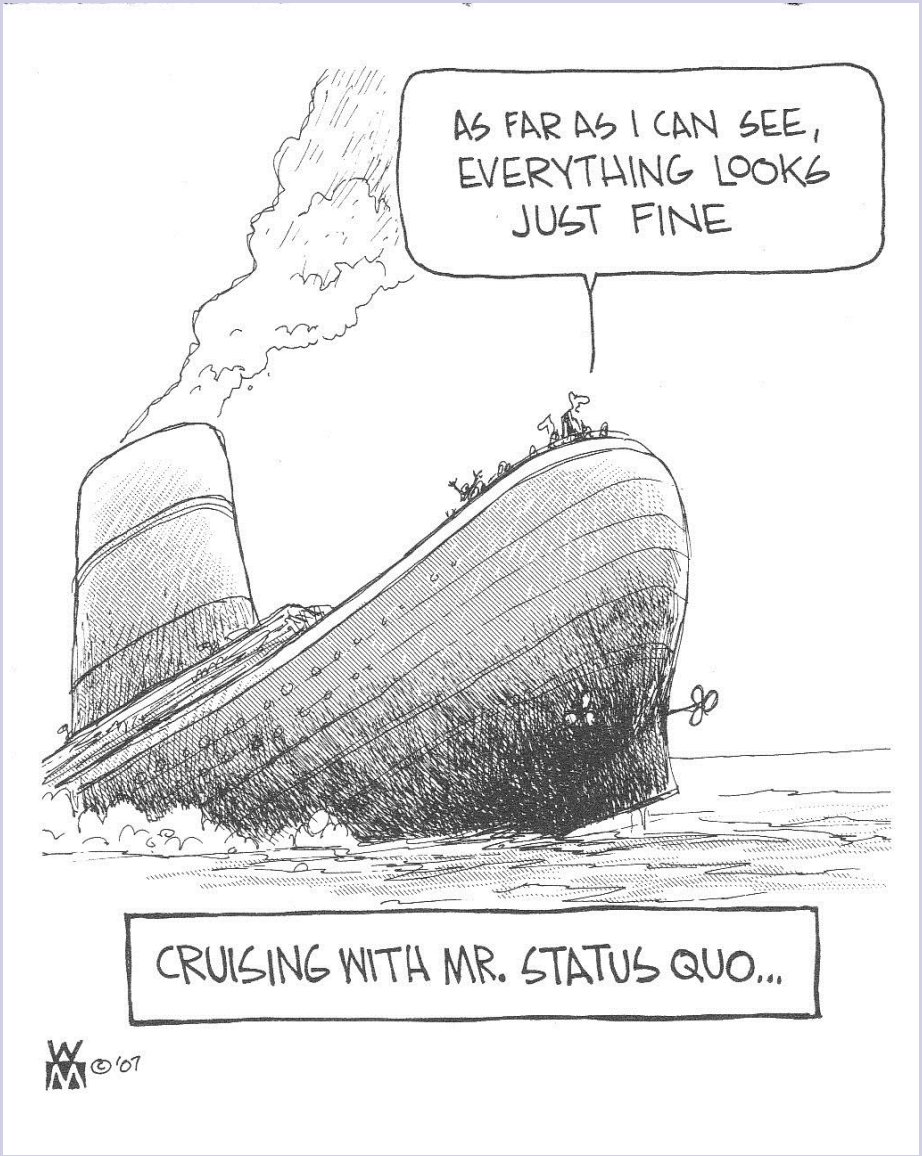
DOCUMENTS – THE SCOURGE OF THE LABORATORY

The fact is;

- Every lab I have worked in
- Every lab I have consulted for
- Every lab I have inspected
- Every lab I have assessed
- Has not been in control of their documents
- Instead, the documents are always in control of them
- And that includes those who deny this!

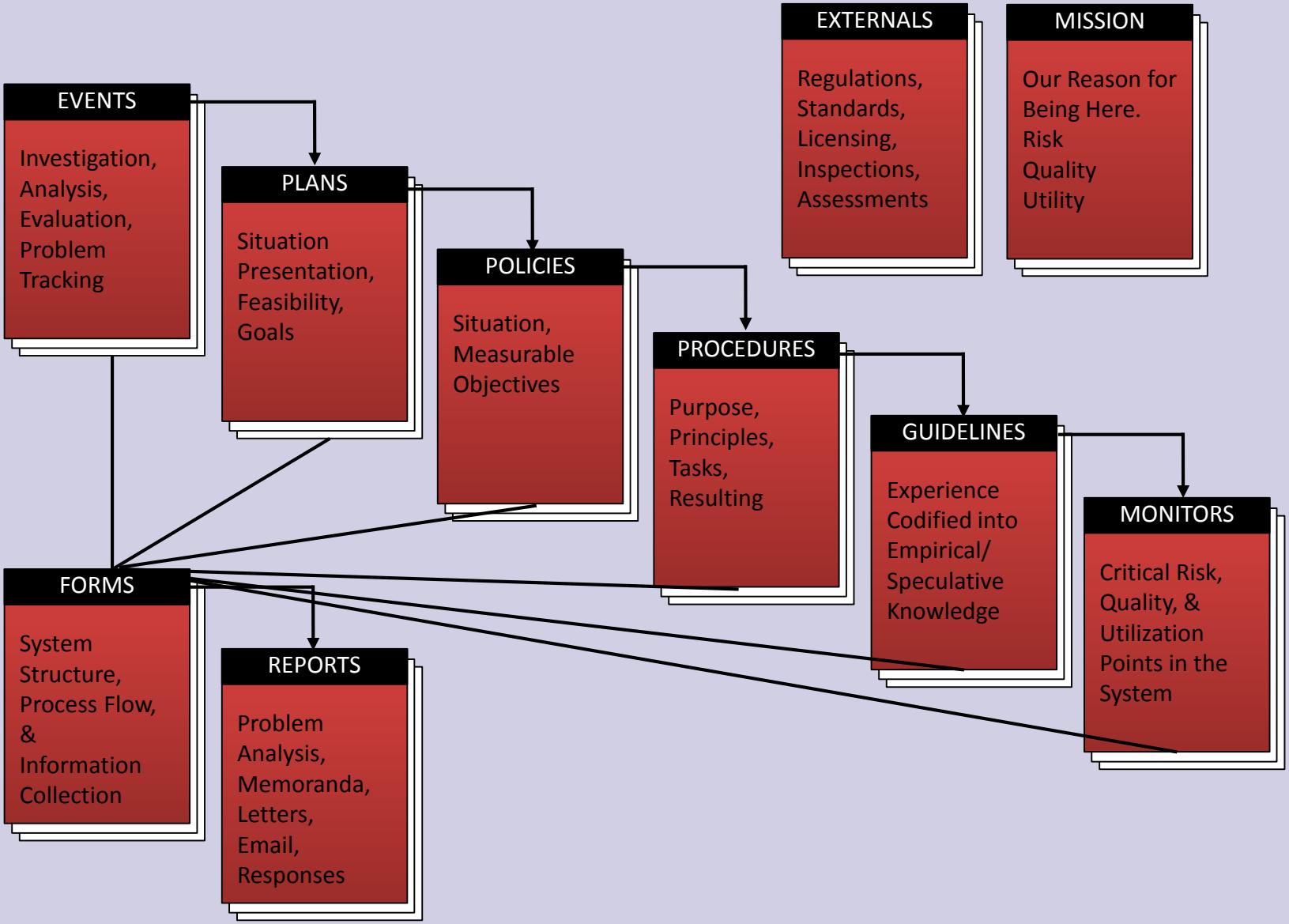
IF YOU WANT TO END THE CONFUSION; THE CHAOS, THEN YOU MUST FIX THIS

WHAT WE ARE ATTEMPTING TO DO REQUIRES ACKNOWLEDGING REALITY



BUT DO NOT FALL FOR THE NEWEST MANAGEMENT FAD AND ITS BUZZ WORDS

THE HIERARCH OF THE INTEGRATED DOCUMENT MANAGEMENT SYSTEM



THE MISSION STATEMENT ALONG WITH EXTERNALS DIRECT THE OTHER DOCUMENTS

THE MISSION STATEMENT; THE KEYSTONE TO IMPLEMENTING ISO 15 189

Successful implementation of an any worthwhile initiative requires a well designed mission statement that leads the employee to behave in a responsible manner towards the patient.

ORIENTATION	Aligns all personnel to the *soul* purpose of their job: **Patient Care**
GOALS	Defines a small number of general goals that directs all strategic activities: **Patient Safety, Quality, and Value**
OBJECTIVES	Each goal leads to the development of measurable objectives to direct all operational activities
FOCUS	Prioritizes the most important goals/objectives that personnel should be paying attention to: **Patient Safety…and their safety**.
GUIDANCE	Gives direction to personnel as to how to achieve goals/objectives through proper use of laboratory systems and technology
MOTIVATION	Generates excitement about the job each person is to do through the concept of achievement as an end in itself when directed to patient care
EMPOWERMENT	Gives personnel a means of getting what they need through established goals and objectives – Directs requests and recommendations
BEHAVIOR	Gives direction to personnel as to how they are to behave towards each other and the laboratory clients: **Disruption Harms the Patient**

IF A DOCUMENT DOES NOT SUPPORT THE MISSION *OR A STANDARD*, IT IS SUPERFLUOUS

COGNITIVE CASCADE TO IMPLEMENT THIS NEW ACTIVITY IN THE LABORATORY

STAGE	CHARACTERISTIC	DESCRIPTION OF GOALS
ORIENTATION	Enculturation	Imprinting of societal and organizational cultural imperatives
PRIMING	Signal Processing	Developing pattern recognition associated with outcomes
TRAINING	Competency	Memorizing, recalling, and applying simple rules - Heuristics
EDUCATION	Knowledge	Learning, recalling, applying associations to solve problems
EXPERIENCE	Proficiency	Learning from error and becoming efficient safely
JUDGMENT	Reliability	Learning to make better decisions under uncertain conditions
WISDOM	Insight	Learning to avoid situations where there is no good decision

It should be noted that each step in the process cannot be fully separated from the others. They are interrelated so the progression needs to be designed to maximize each goal sought through appropriate feedback at each level.

IF YOU DON'T FOLLOW THIS CASCADE YOU WON'T REAP THE BENEFITS

DOCUMENT FORMAT – A BRIEF HOW TO

The key to effective documenting is standardization of terms and explicitly defining them.

DOCUMENT TYPE

NAME	ABBREV
MISSION	MSN
PLANS	PLN
POLICY	POL
PROCEDURE	PRC
GUIDELINES	GDL
MONITORS	MON
POSITION	POS
FORM	FRM
LOG	LOG
RECORD	REC
REPORT	RPT
DOCUMENT	DOC
LETTER	LTR
MEMO	MEM
INSTRUMENT	INS

TASK TYPE

NAME	ABBREV
INSTRUCTIONS	INSTR
VALIDATION	VALID
VERIFICATION	VERIF
CALIBRATION	CALIB
OPERATION	OPERA
CONTROLS	CONTR
MAINTENANCE	MAINT
REPAIR	REPAIR
RETIRE	RETIRE
ACCESSION	ACCSS
RELEASE	RELES
CORRECT	CORRC
AMMEN	AMMND
VENDOR	VEND
CONSULTANT	CON/CNS

REGULATIONS

NAME	ABBREV
STANDARD	STND
CONDITION	COND
COMPLEXITY	CMPLX
COMPETENCE	COMP
COMPLIANCE	CMPLY
EVID OF CMPLY	EOC
DEVIATION	DEVA
DEFICIENCY	DEFIC
NONCONFORMITY	NONC
ACCURACY	ACCR
PRECISION	PREC

IF YOU DO THIS THEN, YOU CAN MORE EASILY FIND THE CORRECT DOCUMENT

EXAMPLE: SOME DOCUMENT CONTROL ELEMENTS YOU SHOULD CONSIDER

DOCUMENT NAME			
☐ MISSION ☐ PLANS ☐ POSITION ☐ OTHER		☑ POLICY ☐ PROCEDURE ☐ GUIDELINES ☐ MONITORS	
ISO 15189	CLIA	CAP	STATE
Author	Editor	Authority	Issued To
Date Created	Date Approved	Date Published	Date Retired

ANNUAL REVIEW			
Review Date	Review by (Signature)	Outcome of Review	
		☐ No changes ☐ Minor changes–see below ☐ Revision initiated	
		☐ No changes ☐ Minor changes–see below ☐ Revision initiated	
		☐ No changes ☐ Minor changes–see below ☐ Revision initiated	
		☐ No changes ☐ Minor changes–see below ☐ Revision initiated	
		☐ No changes ☐ Minor changes–see below ☐ Revision initiated	
Date	Description of change	Approved	Issued To

DISTRIBUTION		
Date	Section/Department	Issued To

THE MORE HIGHLY ORGANIZED THE STRUCTURE THE MORE CONTROL YOU ACHIEVE

DOCUMENT MANAGEMENT SYSTEM DEVELOPMENT – A BRIEF HOW TO

- Build a document management systems team/task force
- Develop a simple, logical file naming system for all documents and records
- Create a global listing of existing file names and their internal document titles
- Enter this listing into MS WORD or MS EXCEL or MS ACCESS as you see fit
- Develop a simple, logical document structure and format for each document type
- Include a table for entering ISO 15189, CLIA, and CAP standard(s) in the document
- Produce a set of template documents for each document type
- Transfer text from the legacy documents to the new documents via templates
- Identify documents that do not fully meet the relevant standards on the global list
- Create empty documents to correspond to all standards not met by existing documents
- Assign the completion of all incomplete or empty documents to appropriate personnel
- Establish a reasonable schedule for completion of all documents

IF YOU WANT TO END THE CONFUSION; THE CHAOS, THEN YOU MUST DO THIS

DOCUMENT MANAGEMENT SYSTEM IMPLEMENTATION – A BRIEF HOW TO

- Identify personnel and a small section that has a high chance of success
- Orient section personnel and do some training and testing of the new document system
- Make modifications indicated during the training and testing
- Complete the document system upgrade for that one section
- Observe the outcome of the upgrade and make any additional modifications
- Begin to roll out the final document upgrade over an adequate time period
- Make sure that all older documents are systematically “archived”
- Watch for back sliding where personnel hide old documents/forms and use them
- Begin a second internal assessment and audit to find any mistakes
- Obtain feedback about the new documents for final “minor” modifications
- Put into place an oversite taskforce to maintain the new document system
- Now, enjoy the next assessment/inspection!

IF YOU WANT TO END THE CONFUSION; THE CHAOS, THEN YOU MUST DO THIS TOO

DOCUMENT UPGRADE – A BRIEF WARNING

- No two laboratories are alike
- No one document management system will fit all laboratories
- Many hospitals have document committees that impose draconian limits on you
- Small things that are missed early on mean a lot so start small and keep a close watch
- Do not impose a Top Down only approach to document management
- Do not let Bottom Up pressures derail the implementation of upgraded documents
- Build a task force that includes upper and middle management and…technical personnel
- That is…do it Top Down and Bottom Up in a cycle of design, testing, and correction
- No matter how careful you are, things might not go too well
- Build in a rollback position to avoid catastrophe during implementation
- Try to make if fun by providing contests and rewards for getting the job done
- Do not worry if, after everything, you realize you could have made it even better

IF YOU WANT TO END THE CONFUSION; THE CHAOS, THEN YOU MUST CONSIDER THESE

AND REMEMBER, SOMEONE'S GOING TO GET A BONUS FOR ALL THIS WORK

"Good news— I'm giving myself a raise."

I DIDN'T SAY YOU

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: CLIA

493.1355 Condition: Laboratories performing **PPM procedures**; laboratory director.
493.1357 Standard; laboratory director qualifications.
493.1359 Standard; PPM laboratory director responsibilities.

493.1403 Condition: Laboratories performing **moderate complexity testing**; laboratory director.
493.1405 Standard; Laboratory director qualifications.
493.1407 Standard; Laboratory director responsibilities.

493.1441 Condition: Laboratories performing **high complexity testing**; laboratory director.
493.1443 Standard; Laboratory director qualifications.
493.1445 Standard; Laboratory director responsibilities.

CONDITION: Is the state of or level of complexity and type of testing being or projected to be offered.
STANDARD: Is the set of criteria or measures that must be met for the **CONDITION**

CLIA HAS A HIGHLY DETAILED MULTITIERED STRUCTURE AS SHOWN ABOVE

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: CLIA

493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

CLIA ALSO HAS A SET OF GENERAL REQUIREMENTS AS SHOWN ABOVE

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: CLIA

493.1445 Standard; Laboratory director responsibilities. [continued]

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

CLIA HAS A HIGHLY DETAILED MULTITIERED STRUCTURE AS SHOWN ABOVE

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: CLIA

493.1445 Standard; Laboratory director responsibilities. [continued]

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

HERE'S MORE OF THAT DETAILED MULTITIERED STRUCTURE

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: CLIA

493.1445 Standard; Laboratory director responsibilities. [continued]

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under §493.1489(b)(4);

(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

WILL IT EVER END?

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: CLIA

493.1445 Standard; Laboratory director responsibilities. [continued]

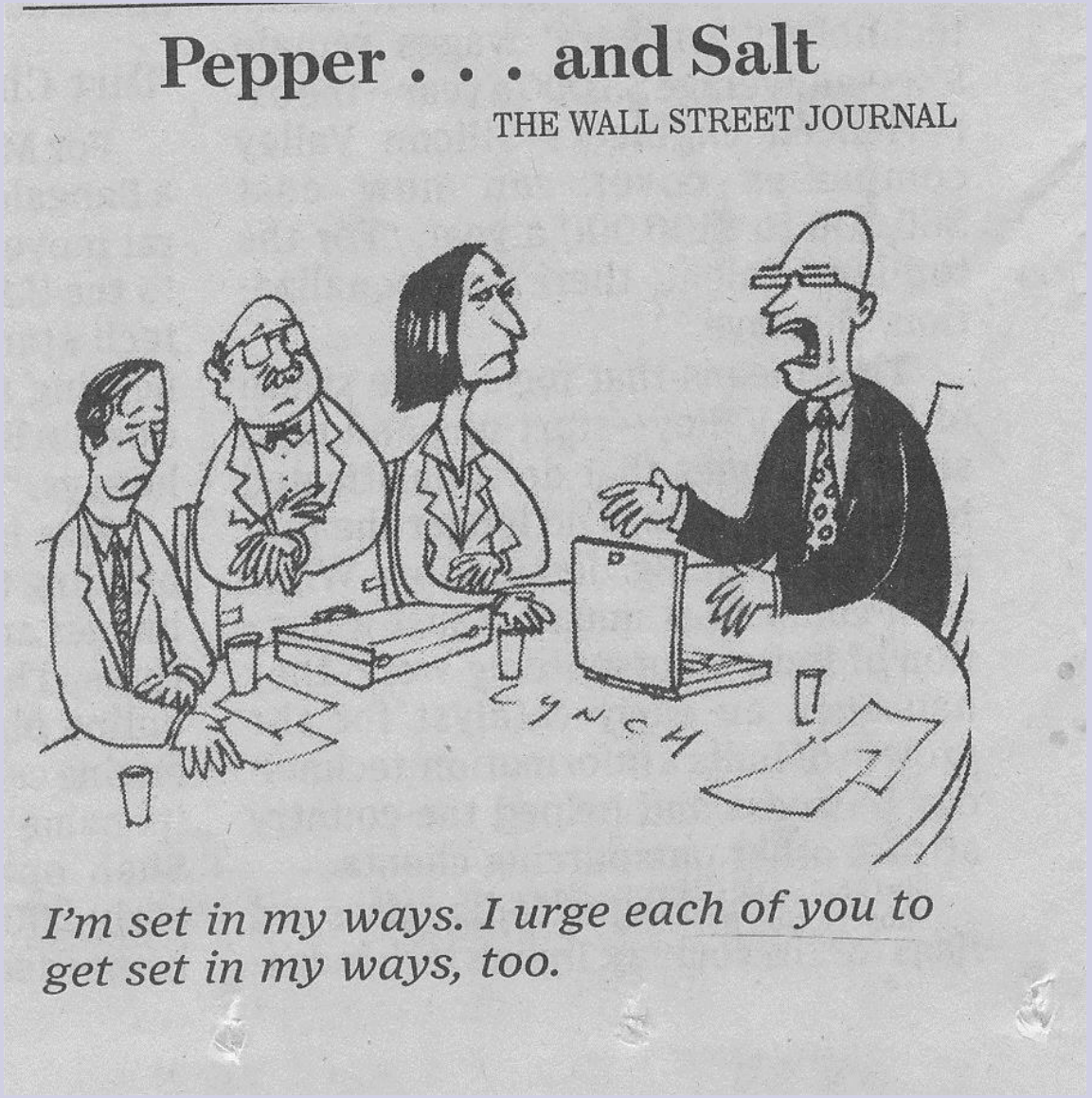
(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

PHEW!

NIH



NOT INVENTED HERE

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: ISO 15189

4.1.1.4 Laboratory director

The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided.

The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.

The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.

The duties and responsibilities of the laboratory director shall be documented.

The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard.

NOTE THAT THE INTRODUCTION IN ISO 15189 IS VERY GENERAL

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: ISO 15189

The laboratory director (or designate/s) shall:

a) provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;

b) relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;

c) ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;

d) ensure the implementation of the quality policy;

e) implement a safe laboratory environment in compliance with good practice and applicable requirements;

f) serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;

g) ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

AND THE DETAILS ARE STILL FRAMED IN GENERAL TERMS WITH ISO 15189

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: ISO 15189

The laboratory director (or designate/s) shall: [continued]

h) select and monitor laboratory suppliers;

i) select referral laboratories and monitor the quality of their service (see also 4.5);

j) provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;

k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

NOTE This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.

l) monitor all work performed in the laboratory to determine that clinically relevant information is being generated;

m) address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);

n) design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;

NOTE Contingency plans should be periodically tested.

o) plan and direct research and development, where appropriate.

AND WE'RE DONE!

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: ISO 15189

4.1.1.4 Laboratory director

The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided. [493.1443 Standard; laboratory director qualifications]

The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.
[493.1445 Standard; Laboratory director responsibilities]

The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.
[493.1445 Standard; Laboratory director responsibilities a)… delegate these responsibilities to personnel meeting the qualifications of §§493.1409, 493.1415, and 493.1421, respectively]

The duties and responsibilities of the laboratory director shall be documented. [None]

The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard.
[493.1443 Standard; Laboratory director qualifications]

NOTE I'M ONLY PUTTING IN HIGH LEVEL HEADINGS HERE

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: ISO 15189

The laboratory director (or designate/s) shall:

a) provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities; [None]

b) relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required; [493.565 Selection for validation inspection—**laboratory responsibilities**]

c) ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users; [493.557(a)(10)]

d) ensure the implementation of the quality policy; [493.1445 (1) , (3i)]

e) implement a safe laboratory environment in compliance with good practice and applicable requirements; [493.1445(e)(2)]

f) serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate; [None]

g) ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results; [493.1445 (c)]

h) select and monitor laboratory suppliers; [None]

ISO DETAILS ARE FRAMED IN GENERAL TERMS AND HAVE A MORE GLOBAL REACH

THE CROSS WALK – THE LABORATORY DIRECTOR AS AN EXAMPLE: ISO 15189

The laboratory director (or designate/s) shall: [continued]

i) select referral laboratories and monitor the quality of their service (see also 4.5); [None]

j) provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations; [None]

k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services; [493.1445(e)(1)]

NOTE This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.

l) monitor all work performed in the laboratory to determine that clinically relevant information is being generated; [493.1413 Standard; **Technical consultant responsibilities**]

m) address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4); [493.553 (a)(4) - Implied]

n) design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; [None]

NOTE Contingency plans should be periodically tested.

o) plan and direct research and development, where appropriate. [None]

SURPRISE! THERE IS NOT A ONE-TO-ONE AND ONTO MAPPING

THE CROSS WALK – DO'S AND DON'TS

DO NOT START THE CROSS WALK:

- Right before a major inspection
- Right after a major inspection
- During the implementation of a critical new facility, instrument, or methodology
- During a major change in management or personnel
- If you don't have the resources to drive the effort to completion – personnel, equipment, financial

DO START THE CROSS WALK:

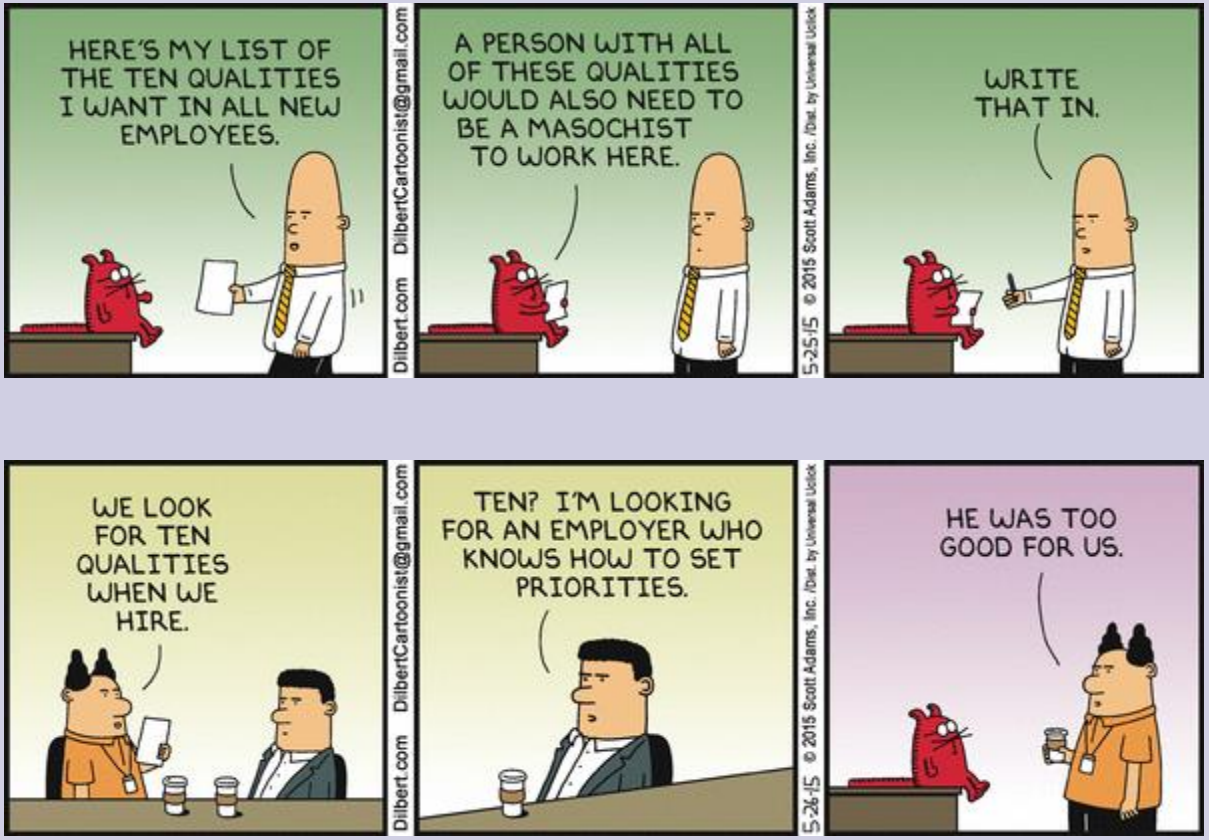
- Long before a major inspection – use the two year cycle
- After making corrections on any inspection findings
- During a period where no major new facility, instrumentation or method replacements or upgrades are planned
- After any major changes in management or personnel have been settled and things are working 'smoothly'

START THE CROSS WALK ON:

- Deficiencies identified during inspections, complaints, regulatory actions, internal observations you just fixed
- Section 4 Management before attempting to implement Section 5 Technical
- Departments/sections that are operated by the best staff
- One small area – management or technical – at a time developing a structure and methodology that can be replicated throughout the laboratory

THE EFFORT SHOULD NOT BE AN EVENT. IT SHOULD BE AN ONGOING PROCESS

AH, THE WONDERFUL WORLD OF WORK



I THINK WE'VE ALL SEEN THIS

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