ISO 15189: WHY DO IT?

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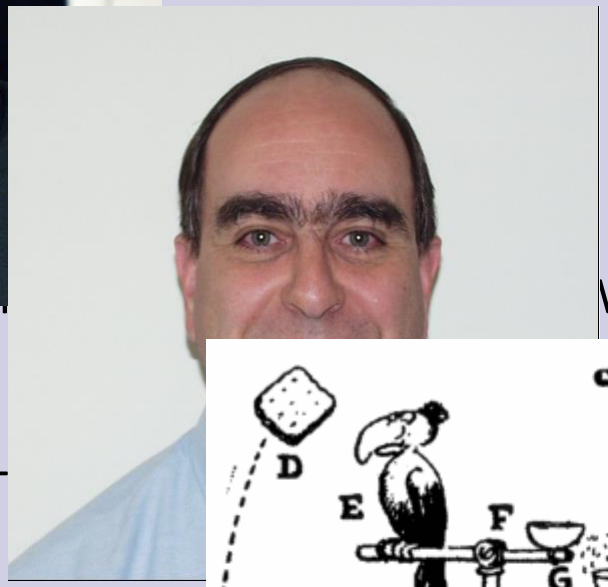
NORTHEAST LABORATORY CONFERENCE
16 OCTOBER 2019

WHO AM I?



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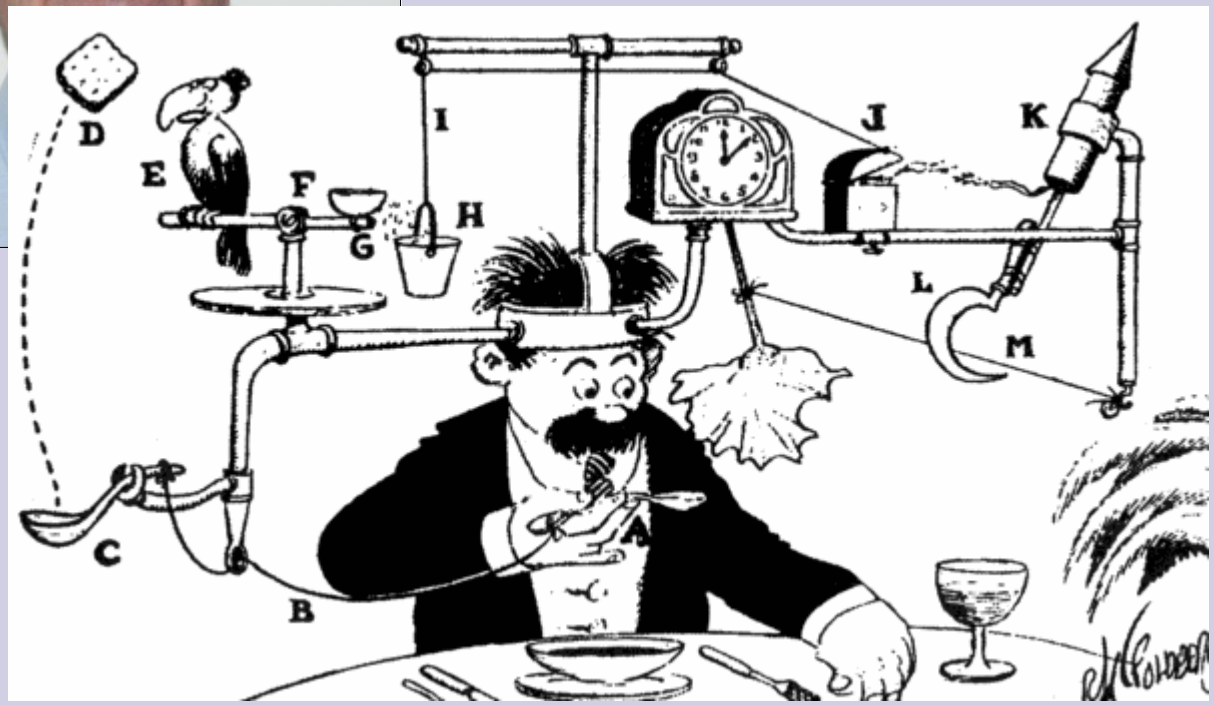

STINKER

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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

A brief overview of the Clinical Laboratory Improvement Act [CLIA]
And
The College of American Pathologist Accreditation [CAPA]

A review of reasons why you should consider implementing ISO 15189 as an **overarching framework to**:

- Rationalize laboratory operations via a single management system to
- Assure complete compliance to
- All regulatory requirements…

Past – Present – Future

UNDERSTAND, WE CAN ONLY SCRATCH THE SURFACE IN 90 MINUTES

PROGRAM OBJECTIVES

Understand the difference between other certification activities and the systems-oriented basis of ISO 15189.

Understand the historical background and value of ISO 15189 standards for directing all laboratory management activities.

Understand how ISO 15189 can be used to organize federal regulations, state licensing requirements, and deemed organization standards into a single comprehensive management activity.

HOWEVER, WE WILL SCRATCH HARD

AN IMPORTANT LESSON TO BE LEARNED

"If no one objects, I'd like to go against tradition and say something I believe to be true."

Mike Shapiro for *Barron's*

TO BE TRUELY SUCCESSFUL WE MUST BE WILLING TO CHALLENGE ACCEPTED TRUTHS

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

However, it's imperative to impose a single, flexible, general management system on your laboratory operations in order to be able to deal with all of this.

THE NUCLEAR REACTOR AT FUKASHIMA CAN'T TOUCH US FOR DEGREE OF REGULATION!

WHAT IS ISO 15189?

The International Standards Organization

The largest source of voluntary standards around the world

Focuses on quality standards for a wide variety of business activities

The clinical laboratory is one of these business activities

It establishes a:

- Systems approach to organizing the activity
- Requires the performance of tools used in driving the system be validated
- Requires processes using the tools driving the system be documented as a procedure
- Requires each person following the procedures be oriented, trained, and competent

[FMEA!]

In addition ISO is based on the following principles inherited from ISO 9001:

- Customer Service
- Leadership Responsibilities
- Continual Improvement
- Fact based decision making
- Supplier relationships

THIS IS MUCH BROADER THAN CLIA OR CAP

THE HISTORY OF ISO 15189

ISO 15189 descends from two other ISO standards

ISO 8402 [1986]	Quality Vocabularty
ISO 9000 [1987]	Quality Systems and guidelines for selection and use of ISO 9001 through 9004
ISO 9001 [1987]	Quality Management Systems Requirements
ISO 9004 [1987]	Quality Management and Quality System Elements
ISO 17025 [XXXX]	General requirements for competence of testing and calibration laboratories

ISO 15189 has gone through three additions growing to over 100 pages of standards:

2003 – 1st edition
2007 – 2nd edition with minor changes
2012 – 3rd edition with improved organization and updated content

THERE'S A LOT TO LEARN FROM ISO 9000, 9001, AND 17025

ISO 15189 – CERTIFICATION VERSUS ACCREDITATION

CERTIFICATION:

Defined in ISO/IEC Guide 2 as:

A procedure by which a third party gives **written assurance** that a product, process, or service conforms to specified requirements. [A thing]

ACCREDITATION:

Defined in ISO/IEC Guide 2 as:

A procedure by which an authoritative body gives **formal recognition** that a business, institution, or person is competent to carry out specific tasks. [An entity]

DON'T GET CONFUSED. WE'RE COVERING ACCREDITATION NOT CERTIFICATION

ISO 15189 – CONTEXT

ISO 15189 Standards are designed for use in a variety of contexts:

VOLUNTARY USE:

Medical laboratories may use it as a means of self assessment

Accreditation bodies use it as the basis for assessing laboratories and granting accreditation

MANDITORY USE:

National accreditation body recognized as having authority over the laboratory [a gray zone]

Government designated regulator mandating accreditation to chosen standards

Government regulator mandating accreditation to chosen standards

IT'S IMPORTANT TO DECIDE WHY YOU'RE IMPLEMENTING ISO 15189

ISO 15189 – WHY DO IT?

For the patient!

For society

For us

For recognition

If you run a competent laboratory, then this competence is verified on a continuing basis through independent organizations [CAP, A2LA, etc.] inspecting your lab against standards appropriate to the scope of services you offer

This confirms your good standing to the patient, clinicians, and the community

And…ISO 15189 is rapidly becoming the worldwide standard governments are settling upon as the basis for allowing laboratories to operate and bill for their services.

THIS MEANS THAT, IN THE FUTURE, YOU MAY BE REQUIRED TO MEET THIS STANDARD

YET ANOTHER IMPORTANT LESSON TO BE LEARNED

IF YOU SHOW ANY ABILITY…

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**].

THERE IS A DIFFERENCE BETWEEN REGULATIONS, SPECIALIZED, AND GENERAL STANDARDS

WHAT INTEGRATED SYSTEMS MANAGEMENT IS

Integrated Systems Management [**ISM**] is a **strategic** approach to running an activity.

ISM combines three interrelated and potentially conflicting areas of healthcare management into a single integrate whole.

Integration provides the comprehensive and effective control we seek; the overall goal being to achieve an Acceptable Balance between benefits and risks inherent in such a complex endeavor – similar to the Acceptable Risk defined in EP23.

ISM brings together the three foundational areas of managing any human activity:

RISK MANAGEMENT	Patient Safety – Threats to the patient that can be managed
QUALITY MANAGEMENT	Quality Assurance – Attributes that can be managed.
RESOURCE MANAGEMENT	Utilization Review – Patterns of use that can be managed

➡ These three areas can act synergistically or

➡ They can come into conflict with each other

➡ Integration provides a means to achieve synergy and avoid conflict

ISM: THE STRATEGIC FOUNDATION FOR THE PURSUIT OF EXCELLENCE

CLIA AND THE THREE MANAGEMENT AREAS

RISK MANAGEMENT: "conditions at the laboratory pose an imminent and serious risk to human health"

QUALITY MANAGEMENT:

§493.1200 Introduction.

(a) Each laboratory that performs nonwaived testing must establish and maintain **written policies and procedures** that **implement and monitor a quality system for all phases of the total testing process** (that is, preanalytic, analytic, and postanalytic) as well as **general laboratory systems**.

(b) The laboratory's quality systems **must include a quality assessment component** that ensures **continuous improvement** of the laboratory's performance and services **through ongoing monitoring** that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

UTILIZATION MANAGEMENT:

§491.11 Program evaluation:

(c) The purpose of the evaluation is to **determine** whether:

(1) The utilization of services was **appropriate**;
(2) The established **policies** were **followed**; and
(3) Any **changes** are **needed**.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

CLOSE TO ISM BUT THERE IS NO EXPLICIT INTEGRATION OF RISK MANAGEMENT

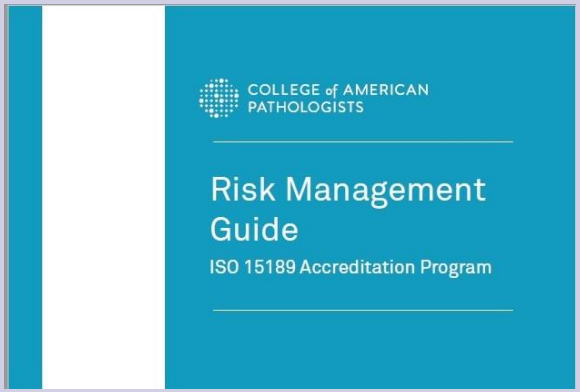
CAP AND THE THREE MANAGEMENT AREAS

RISK MANAGEMENT

"GEN.20208 QM Patient Care Services Phase II

The QM system includes a program to identify and evaluate errors, incidents and other problems that may interfere with patient care services.

NOTE: There must be an organized program for documentation of problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The program must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must document investigation and resolution of these problems. Laboratories must perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including "near misses" and sentinel events). ***Laboratories must be able to demonstrate appropriate risk-reduction activities based on such root cause analyses.***" [Page 12]



NOTE THAT ISO 15189 IS REFERENCED FOR RISK MANAGEMENT

CAP AND THE THREE MANAGEMENT AREAS [CONTINUED]

QUALITY MANAGEMENT

"The laboratory must have a documented quality management program to systematically ensure the quality of laboratory services. In laboratories that are part of a larger institution (e.g. a hospital), the laboratory quality management program must be integrated with the institutional program.

"GEN.13806 Documented QM Program Phase II
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 QMS01-04**; the **ISO 9000** series or **ISO 15189**; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design. If the laboratory is part of a larger organization, the laboratory QM program is coordinated with the organization's QM plan."* [Page 11]

Plus 131 additional references to quality…

UTILIZATION MANAGEMENT

Generally utilization of laboratory is referred to in external references.

NOTE THAT ISO 15189 IS REFERENCED FOR QUALITY MANAGEMENT

ISO 15189 AND THE THREE MANAGEMENT AREAS

RISK MANAGEMENT:

4.11 Preventive action

"The laboratory shall determine action to eliminate the causes of potential **nonconformities** in order to prevent their occurrence. ***Preventive actions shall be appropriate to the effects of the potential problems***.

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NOTE Preventive action is a proactive process for identifying opportunities for improvement **rather than a reaction to the identification of problems or complaints** (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and ***risk analyses*** and external quality assessment (proficiency testing)." [Page 13]

4.14.6 Risk management

"The laboratory shall **evaluate the impact** of work processes and potential failures on examination results as they affect **patient safety**, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken." [Page 16]

5.6.2.2 Quality control materials

"Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and ***the risk of harm to the patient*** from an erroneous result." [Page 30]…

SO…QUALITY CONTROL IS ACTUALLY…RISK CONTROL

ISO 15189 AND THE THREE MANAGEMENT AREAS [CONTINUED]

QUALITY MANAGEMENT:

"The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008, *Quality management systems — Requirements*…" [Page V]

"3.20 Quality management system management system to direct and control an organization with regard to quality

NOTE 1 The term "quality management system" referred to in this definition relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement.

NOTE 2 Adapted from ISO 9000:2005, definition 3.2.3." [Page 4]

Plus 50 additional references to Quality Management!

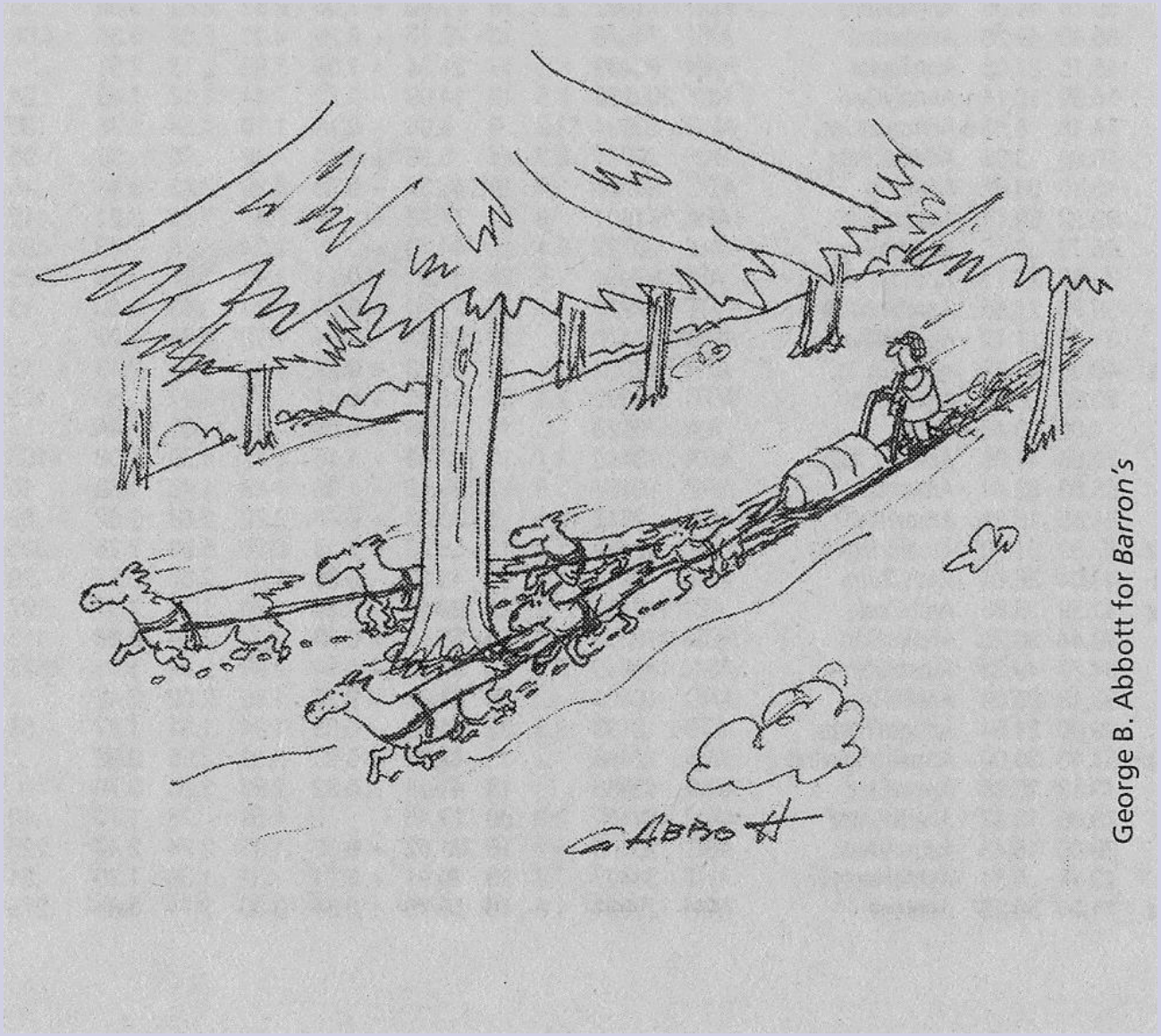
UTILIZATION MANAGEMENT:

4.7 Advisory Services

d) Promoting the effective utilization of laboratory services;

A BIT LIGHT ON UTILIZATION MANAGEMENT BUT COVERS UTILIZATION BY THE LABORATORY

YET ANOTHER IMPORTANT LESSON TO BE LEARNED



LIFE IN THE LABORATORY AS A MANAGER

WHEN DEALING WITH CLIA REGULATIONS

WHAT ARE WE UP AGAINST?

CLIA – REGULATIONS FOR DIFFERENT LABORATORY DISCIPLINES AND SERVICES

PROFICIENCY TESTING BY SPECIALTY AND SUB-SPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS:

493.821	Condition	Microbiology.
493.823	Standard	Bacteriology.
493.825	Standard	Mycobacteriology.
493.827	Standard	Mycology.
493.829	Standard	Parasitology.
493.831	Standard	Virology.
493.833	Condition	Diagnostic immunology.
493.835	Standard	Syphilis serology.
493.837	Standard	General immunology.
493.839	Condition	Chemistry.
493.841	Standard	Routine chemistry.
493.843	Standard	Endocrinology.
493.845	Standard	Toxicology.
493.849	Condition	Hematology.
493.851	Standard	Hematology.
493.853	Condition	Pathology.
493.855	Standard	Cytology: gynecologic examinations.
493.857	Condition	Immunohematology.
493.859	Standard	ABO group and D (Rho) typing.
493.861	Standard	Unexpected antibody detection.
493.863	Standard	Compatibility testing.
493.865	Standard	Antibody identification.

EACH SECTION DEFINES REPETITIVE TEST SPECIFIC REGULATIONS THAT MUST BE MET

CLIA – REGULATIONS FOR DIFFERENT LABORATORY DISCIPLINES AND SERVICES

Subpart K—Quality System for Nonwaived Testing

493.1200 Introduction.
493.1201 Condition: Bacteriology.
493.1202 Condition: Mycobacteriology.
493.1203 Condition: Mycology.
493.1204 Condition: Parasitology.
493.1205 Condition: Virology.
493.1207 Condition: Syphilis serology.
493.1208 Condition: General immunology.
493.1210 Condition: Routine chemistry.
493.1211 Condition: Urinalysis.
493.1212 Condition: Endocrinology.
493.1213 Condition: Toxicology.
493.1215 Condition: Hematology.
493.1217 Condition: Immunohematology.
493.1219 Condition: Histopathology.
493.1220 Condition: Oral pathology.
493.1221 Condition: Cytology.
493.1225 Condition: Clinical cytogenetics.
493.1226 Condition: Radiobioassay.
493.1227 Condition: Histocompatibility.

WAIT…DIDN’T WE JUST SEE THIS EARLIER IN THE REGULATION?

CLIA – REGULATIONS ARE BOTH BROAD AND VERY DETAILED

§493.25 Laboratories performing tests of high complexity.

A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in §493.17(a).

A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at §§493.1773 and 493.1777.

If the laboratory also performs waived tests, the requirements of subparts H, J, K, and M are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e), 493.1773, and 493.1775.

AND IT ONLY GETS WORSE…

CLIA – EXAMPLE REGULATION FOR A SPECIFIC DISCIPLINE AND SERVICE

§493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

§493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

AND THIS IS JUST A TINY SUBSECTION OF THIS 100 + PAGE REGULATION!

CAP – SPECIFICATIONS FOR DIFFERENT LABORATORY DISCIPLINES AND SERVICES

Notice all the changes that can take place in just one year!

Then consider up to 21 subspecial-ties across which this change occurs!

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	200	15	35	0	3
BAP	171	1	5	0	0
CBG	83	0	3	0	0
CHM	165	13	5	0	0
COM	75	0	11	0	6
CYG	57	1	7	0	1
CYP	82	0	10	0	1
DRA	18	0	1	0	0
FDT	125	0	16	0	0
FLO	49	2	5	0	1
GEN	331	3	30	0	0
HEM	193	0	8	0	34
HSC	158	1	6	0	0
IMM	65	0	7	0	0
LSV	280	2	17	0	25
MIC	253	0	17	0	2
MOL	164	1	6	0	1
POC	56	0	2	0	0
RLM	116	1	20	0	2
TRM	257	1	30	0	1
URN	29	0	0	0	0
TOTAL	**2927**	**41**	**241**	**0**	**77**

UP TO ~3000 REQUIREMENTS FOR A LARGE REFERENCE LABORATORY!

CAP – SPECIFICATIONS FOR DIFFERENT LABORATORY DISCIPLINES AND SERVICES

CAP Accreditation Checklists—2018 Edition – Some Examples

CHECK LISTS	SUBDISCIPLINES	DESCRIPTION OF CONTENTS
Chemistry and Toxicology	▪ Blood Gases ▪ Chemistry ▪ Special Chemistry ▪ Toxicology	▪ Automated chemistry procedures ▪ Chemistry • Blood gas analysis ▪ Special Chemistry • Therapeutic drug monitoring ▪ Toxicology • Toxicology screening and confirmatory testing ▪ Prenatal screening ▪ Cystic fibrosis sweat testing ▪ Hemoglobin separation ▪ Methods, such as TLC, GC, HPLC, MS, Imaging MS, ▪ RIA, and electrophoresis
Flow Cytometry	▪ Flow Cytometry	▪ Blood lymphocyte subset enumeration ▪ CD34 stem cell enumeration ▪ Leukemia and lymphoma immunophenotyping ▪ DNA content and cell cycle analysis ▪ Rare event flow cytometric assays
Immunology	▪ Immunology	▪ General immunology assays, manual and automated ▪ Immune system profiles ▪ Microbial antigen/antibody testing ▪ ABO/Rh and antibody screening (non-transfusion related) ▪ Syphilis serology ▪ Western blot

EACH SECTION DEFINES TEST SPECIFIC STANDARDS THAT MUST BE MET

OVERVIEW OF ISO 15189:2012(E) TAKEN DIRECTLY FROM THE STANDARD

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies).

The work of preparing International Standards is normally carried out through ISO technical committees.

ISO 15189 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test* ***systems***.

This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies requirements for competence and quality that are particular to medical laboratories

Each laboratory should also provide suitable educational and scientific opportunities for professional staff working with it.

A medical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the *technical competence requirements* and the *management system requirements* that are necessary for it to consistently deliver technically valid results.

This has become a worldwide standard and Canada has adopted it as their standard for clinical laboratories. Recently CAP has begun to move to ISO 15189.

ISO 15189 COVERS MANAGEMENT SYSTEMS AND TECHNICAL COMPETENCE

MAJOR SECTION HEADINGS OF ISO 15189

This standard is organized into a small number of major sections each of which is broken down into a number of easy to understand subsections:

1 SCOPE

2 NORMATIVE REFERENCES

3 TERMS AND DEFINITIONS ⬅ CAP HAS THIS TOO!

4 MANAGEMENT REQUIREMENTS ⬅ WE'LL FOCUS ON THIS

5 TECHNICAL REQUIREMENTS ⬅ AND THIS

NOT TOO BAD SO FAR…

MATCHING UP CLIA AND CAP TO THE MAJOR SECTION HEADINGS OF ISO 15189

You will find that it is possible to match up about 70% of the highly specific CLIA regulatory requirements and CAP standards to the ISO 15189 headings or subheadings.

Where there is no clear cut match identified, they can be organized under the ISO 15189 heading that appears most appropriate.

Where no heading appears most appropriate, additional subheadings can add to supplement the ISO 15189 heading.

By doing this you are developing a structure where compliance is driven by a systems oriented approach instead of being implemented and maintained in a hodge-podge manner.

This places a complex overlapping set of regulations and standards into a generalized set of more easily handled containers.

In addition, ISO 15189 may not be adequately structured for your particular laboratory so you can use its more general systems-based architecture to design your own approach to getting control over all the regulations and specialized standards.

THIS IS CRITICAL FOR SUCCESSFULLY IMPLEMENTING AND MAINTAINING ALL THIS

1 SCOPE

As noted above, **ISO 15189** specifies requirements for quality and competence in medical laboratories and can be used:

INTERNALLY: By medical laboratories in developing integrated management systems and assessing their competence to deliver reliable laboratory services.

EXTERNALLY: For confirming or recognizing the competence of medical laboratories by:

- Laboratory customers
- Regulating authorities – Federal/State [CLIA] and
- Accreditation bodies – National [CAP]/International [A2LA]

REMEMBER, ISO 15189 ACCREDITATION BY A RECOGNIZED ORGANIZATION IS WORLDWIDE

2 NORMATIVE REFERENCES

ISO/IEC 17000: Conformity assessment —Vocabulary and general principles

ISO/IEC 17025:2005: General requirements for the competence of testing and calibration laboratories [**Metrology**; a requirement long time in coming to the clinical laboratory]

ISO/IEC Guide 2: Standardization and related activities — General vocabulary

ISO/IEC Guide 99: International vocabulary of metrology — Basic and general concepts and associated terms

STAY TUNED. METROLOGY AND MEASUREMENT UNCERTAINTY ARE GOING TO GET BIG!

3 TERMS AND DEFINITIONS

3.0	Terms and definitions
3.1	Accreditation
3.2	**Alert interval/critical interval [Much better to use the term "Alert Value" for regulatory and legal reasons]**
3.3	Automated selection and reporting of results
3.4	Biological reference interval reference interval
3.5	Competence
3.6	Documented procedure
3.7	Examination
3.8	Interlaboratory comparison
3.9	Laboratory director
3.10	Laboratory management
3.11	Medical laboratory clinical laboratory
3.12	**Nonconformity [This is becoming the standard term for screwing up…]**
3.13	Point-of-care testing POCT near-patient testing
3.14	Post-examination processes postanalytical phase
3.15	Pre-examination processes preanalytical phase
3.16	Primary sample specimen
3.17	Process
3.18	Quality
3.19	Quality indicator
3.20	Quality management system
3.21	Quality policy
3.22	Quality objective something sought, or aimed for, related to quality
3.23	Referral laboratory
3.24	Sample
3.25	Turnaround time
3.26	**Validation [determine if a test meets requirements for a specific intended use prior to implementation]**
3.27	**Verification [assure a test complies with specified requirements during routine use]**

STANDARDIZED TERMINOLOGY IS VERY IMPORTANT IN CAP AND ISO TO AVOID CONFUSION

IF YOU HAVE ANY DEALINGS WITH THE GOVERNMENT; ANY GOVERNMENT…

CAN’T WAIT TO SEE WHAT CONGRESS DOES TO EXTEND CLIA IN THE NEAR FUTURE!

SECTION 4 MANAGEMENT REQUIREMENTS

4 MANAGEMENT REQUIREMENTS – OVER VIEW OF PROCESSES

SEC #	SECTION	DOC	CLIA
4.1	Organization and Management Responsibility		-
4.2	Quality Management System		
4.3	Document Control		
4.4	Service Agreements		
4.5	Examination by Referral Laboratories		
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		
4.15	Management Review		

NOTICE ISO 15189 INCLUDES THINGS OUTSIDE THE LABORATORY

4 MANAGEMENT REQUIREMENTS – HIGH LEVEL ORGANIZATIONAL STANDARDS

SEC #	SECTION	DOC	CLIA
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		§493.1355
4.1.2	**Management Responsibility**		§493.1425 + Many
4.1.2.1	Management Commitment		§493.1 + Many
4.1.2.2	**Needs of Users**		-
4.1.2.3	Quality Policy	POL	§493.1200
4.1.2.4	Quality Objectives and Planning	PLN	-
4.1.2.5	**Responsibility, Authority and Interrelationships**	**POL**	**-**
4.1.2.6	**Communication**	REC	§493.1234
4.1.2.7	Quality Manager		-

NOTICE ISO 15189 INTEGRATES QUALITY, RESPONSIBILITY, AND AUTHORITY

4 MANAGEMENT REQUIREMENTS – MORE HIGH LEVEL MANAGEMENT STANDARDS

SEC #	SECTION	DOC	CLIA
4.2	**Quality Management System**		§493.1200
4.2.1	General Requirements		-
4.2.2	**Document Requirements**		**-**
4.2.2.1	General		-
4.2.2.2	**Quality Manual**	POL/PRC	-
4.3	**Document Control**		**-**
4.4	Service agreements	PRC	-
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	PRC/REC	-
4.5.2	Provision of Examination Results		-
4.6	External Services and Supplies	PRC/LST	-
4.7	Advisory Services		-

NOTICE ISO 15189 INTEGRATES QUALITY AND DOCUMENT MANAGEMENT; CAP +/-

4 MANAGEMENT REQUIREMENTS – DOCUMENT CONTROL

"Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include." [ISO 15189:2012 Page 9]

- Policy statements
- Instructions for use – Vendor Inserts, Manuals, Updates, etc.
- Flow charts/Lists
- Procedures
- Specifications
- Forms
- Calibration tables
- Biological reference intervals and their origins
- Charts
- Posters
- Notices
- Memoranda
- Software documentation
- Drawings
- Plans
- Agreements, and
- Documents of external origin such as regulations, standards and text books from which examination procedures are taken.

Gain control over your documents. Otherwise, your documents will control you!

DOCUMENT CONTROL IS CENTRAL TO THE VALUE OF ISO 15189

CAPA– DOCUMENT CONTROL

COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

Document Control Essentials

What is the goal of document control?

A system to ensure that

- Everyone sees the same document
- The current version is accurate
- The laboratory performs critical tasks in a consistent way

What are the key elements of the system?

DOCUMENT CONTROL HAS ALSO BECOME CENTRAL TO CAPA

CAPA– DOCUMENT CONTROL

What documents need to be controlled?

Need to control	No need to control
1. Policies, processes, and procedures that instruct on how to perform work	1. Documents with no instructional content, created for a short-term purpose (eg, agendas, meeting notes, and emails)
2. Factual references that support a work process (eg, calibration tables, biological reference intervals)	2. Documents with background scientific information (eg, textbooks, conference materials)
3. Training materials that provide instruction on a process or procedure	3. Nonwork related documents (eg, lunch menus, phone list)
4. Standards and regulations (eg, ISO 15189, CAP Checklists)	4. Information that never changes (eg, Fahrenheit to Celsius table)
5. Customer agreements that explain requirements for project work	

Ah! ISO 15189 shows up again.

What are some effective ways to keep work aids under document control?

1. Make the work aid an APPENDIX to the larger procedure.
2. Create a secondary document log to track all posted work aids that are copies (or parts) of other documents.

Secondary Documents

Name	ID	Date	Revision	LOCATION
				X
				X
				X
				X

Key Terms

Policy	A general guideline or statement of overall intentions. (eg, policy on critical result notification)
Process	A set of interrelated activities that transform inputs to outputs. Processes typically involve more than one person, starts and stops, and multiple procedures. (eg, preanalytic process) • Core process—bears directly on the product or service that the customer purchases (eg, preanalytic, analytic, postanalytic) • Support process—supports a core process (eg, purchasing, complaint handling, corrective action)
Procedure	Set of instructions that describe a specified way to perform an activity. Can typically be done by one person at one time. (eg, blood gas sample collection)
Work aid/ Job aid	A procedure, or portion of procedure, created to serve as a visible reference while a worker performs.
Form	A blank document used to capture results. It provides instruction on what information to gather. Usually classified as a procedure.
Record	Captures results or other critical information from the documented procedure.

Interested in learning more about document control? The CAP's QM*Ed* online course on document control will give you more information about requirements and methods. Earn two CE credits with the completion of the course.
For more information, visit cap.org and search QM*Ed*.

cap.org

THIS IS A NICE OVERVIEW OF THE 'NEEDS' AND 'NO NEEDS' OF CAPA

4 MANAGEMENT REQUIREMENTS – NONCONFORMITY AND INTERNAL AUDITS

SEC #	SECTION	DOC	CLIA
4.8	Resolution of Complaints	PRC/REC	§493.1233
4.9	**Identification and Control of Nonconformities**	**PRC/REC**	§493.1256
4.10	Corrective Action	PRC/REC	§493.1282
4.11	**Preventive Action**	**PRC/REC**	-
4.12	Continual Improvement	POL/PLN	§493.1200
4.13	**Control of Records**	**POL/PRC**	§493.801/903
4.14	Evaluation and Audits		-
4.14.1	General	PLN	-
4.14.2	Periodic Review of Requests and Suitability of Procedures and Sample Requirements		-
4.14.3	Assessment of User Feedback	REC	-
4.14.4	**Staff Suggestions**	REC	-
4.14.5	**Internal Audit**	**PRC/REC**	**-**
4.14.6	**Risk Management**		**-**
4.14.7	Quality Indicators	LST	-
4.14.8	Reviews by External Organizations	REC	-

NOTICE ISO 15189 EMPHASIZES PROSPECTIVE RISK MANAGEMENT

4 MANAGEMENT REQUIREMENTS – RECORD CONTROL

"Records shall include, at least, the following:" [ISO 15189:2012 Page 14]

- Supplier selection and performance, and changes to the approved supplier list;
- Staff qualifications, training and competency records;
- Request for examination;
- Records of receipt of samples in the laboratory;
- Information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);
- Laboratory work books or work sheets;
- Instrument printouts and retained data and information;
- Examination results and reports;
- Instrument maintenance records, including internal and external calibration records;
- Calibration functions and conversion factors;
- Quality control records;
- Incident records and action taken;
- Accident records and action taken;
- Risk management records;
- Nonconformities identified and immediate or corrective action taken;
- Preventive action taken;
- Complaints and action taken;
- Records of internal and external audits;
- Interlaboratory comparisons of examination results;
- Records of quality improvement activities;
- Minutes of meetings that record decisions made about the laboratory's quality management activities;
- Records of management reviews.

Gain control over your records. Otherwise, your records will control you!

NOTICE ISO 15189 INCLUDES RECORD CONTROL AS WELL. CAPA IS ONTO THIS TOO

AN EVEN MORE IMPORTANT LESSON TO BE LEARNED

DON’T WAIT UNTIL IT’S TOO LATE

4 MANAGEMENT REQUIREMENTS – DOCUMENT/RECORD CONTROL

IF IT WERE UP TO ME…

I WOULD PLACE

RECORD CONTROL

UNDER

DOCUMENT CONTROL

BUT I'M NOT ISO. SO… I WOULD STILL PLACE RECORDS UNDER DOCUMENT CONTROL

4 MANAGEMENT REQUIREMENTS – INTERNAL AUDITS CONTINUED

SEC #	SECTION	DOC	CLIA
4.15	Management Review		-
4.15.1	General		-
5.15.2	Review Input		-
4.15.3	Review Activities		-
4.15.4	Review Output	REC	-

ISO 15189 IS BIG ON INTERNAL AUDITS AND REVIEW OF OPERATIONS

4 MANAGEMENT REQUIREMENTS – SOME CAVEATS

This is not exactly how I would organize high level management.

There are some gaps that require modification to assure coverage of all CLIA regulations.

There are some gaps that require modification to assure coverage of all CAPA standards.

However, given this was developed by a committee, I'm impressed with the final result.

If you don't plan to obtain ISO 15189 accreditation for your laboratory, you can still use it as the basis for a management system that fits your local needs and preferences.

Furthermore, as noted above, where there are gaps between ISO 15189 and CLIA/CAPA you can expand one or more of the ISO headings to assure coverage.

ISO 15189 STANDARDS ARE GENERALIZED SO EASILY ADAPTED TO CLIA/CAPA

SECTION 5 TECHNICAL REQUIREMENTS

MEANS OF DEVELOPING A TECHNICAL APPROACH TO COMPLY WITH REGS AND STANDARDS

5 TECHNICAL REQUIREMENTS – OVER VIEW OF PROCESSES

SEC #	SECTION	DOC	FMEA
5.1	Personnel		Svc
5.2	Accommodation and Environmental Conditions		Dsn
5.3	Laboratory Equipment, Reagents, and Consumables		Dsn
5.4	Pre-examination Processes		Prc
5.5	Examination Processes		Prc
5.6	Ensuring Quality of Examination Results		Prc
5.7	Post-examination Processes		Prc
5.8	Reporting of Results		Prc
5.9	Release of Results		Prc
5.10	Laboratory Information Management		Dsn

These standards lend themselves to being simultaneously organized according to categories defined by Failure Mode and Effect Analysis [FMEA]:

- System
- Design
- Processes
- Service

NOTICE ISO 15189 IS VERY COMPREHENSIVE SYSTEM DRIVEN BY PROCESSES

WHAT FAILURE MODE AND EFFECT ANALYSIS IS

FMEA provides an operational tool by which an institution can:

- Categorize Risks – supporting Risk Assessment
- Assign Severity – supporting determining Risk Acceptability
- In and existing activity or in the design of an activity

FMEA breaks down an institution's activities into a fully encompassing set of features that can be addressed comprehensively using Integrated Systems Management. These are defined below:

mFMEA	DESCRIPTION – A GENERAL TAXONOMY
SYSTEM	The overall structure defining **inputs and outputs**, task order and chronology, as well as the **logical flow** including decision and branch points, feedback loops, and end points
DESIGN	The actual **physical characteristics** of each component used in the system, whether related to the manufacturing process or the product/service provided by the institution
PROCESS	The actual **procedural directives** that define the tasks required to employ physical components within the system structure to successfully deliver a product or service
SERVICE	The **personnel** and associated activities necessary to apply human intellectual and physical energy to execute the processes using physical components and according to the system

FROM THIS DEFINITION THE SYSTEMS AND LIFE CYCLE APPROACH CAN BE MERGED

5 TECHNICAL REQUIREMENTS – PERSONNEL

SEC #	SECTION	DOC	CLIA
5.1	**Personnel**		§493.1351
5.1.1	General		-
5.1.2	Personnel Qualifications	LST	§493.1423
5.1.3	Job Descriptions	LST	-
5.1.4	Personnel Introduction to the Organizational Environment	PRG	§493.1462
5.1.5	Training	REC	Many
5.1.6	Competence Assessment	POL/PRC	§493.1235
5.1.7	Reviews of Staff Performance	REC	§493.1236
5.1.8	Continuing Education and Professional Development	REC	Many
5.1.9	Personnel Records	REC	Many

NOTICE ISO 15189 FOCUSES ON PERSONNEL QUALIFICATIONS AND DEVELOPMENT

5 TECHNICAL REQUIREMENTS – FACILITIES

SEC #	SECTION	DOC	CLIA
5.2	**Accommodation and Environmental Conditions**		§493.1407
5.2.1	General		-
5.2.2	Laboratory and Office Facilities		§493.1101
5.2.3	Storage Facilities		§493.1252
5.2.4	Staff Facilities		-
5.2.5	Patient Sample Collection Facilities		§493.1242
5.2.6	Facility Maintenance and Environmental Conditions	REC	-

Here, Failure Mode and Effect Analysis is focused on global Design/Tools:

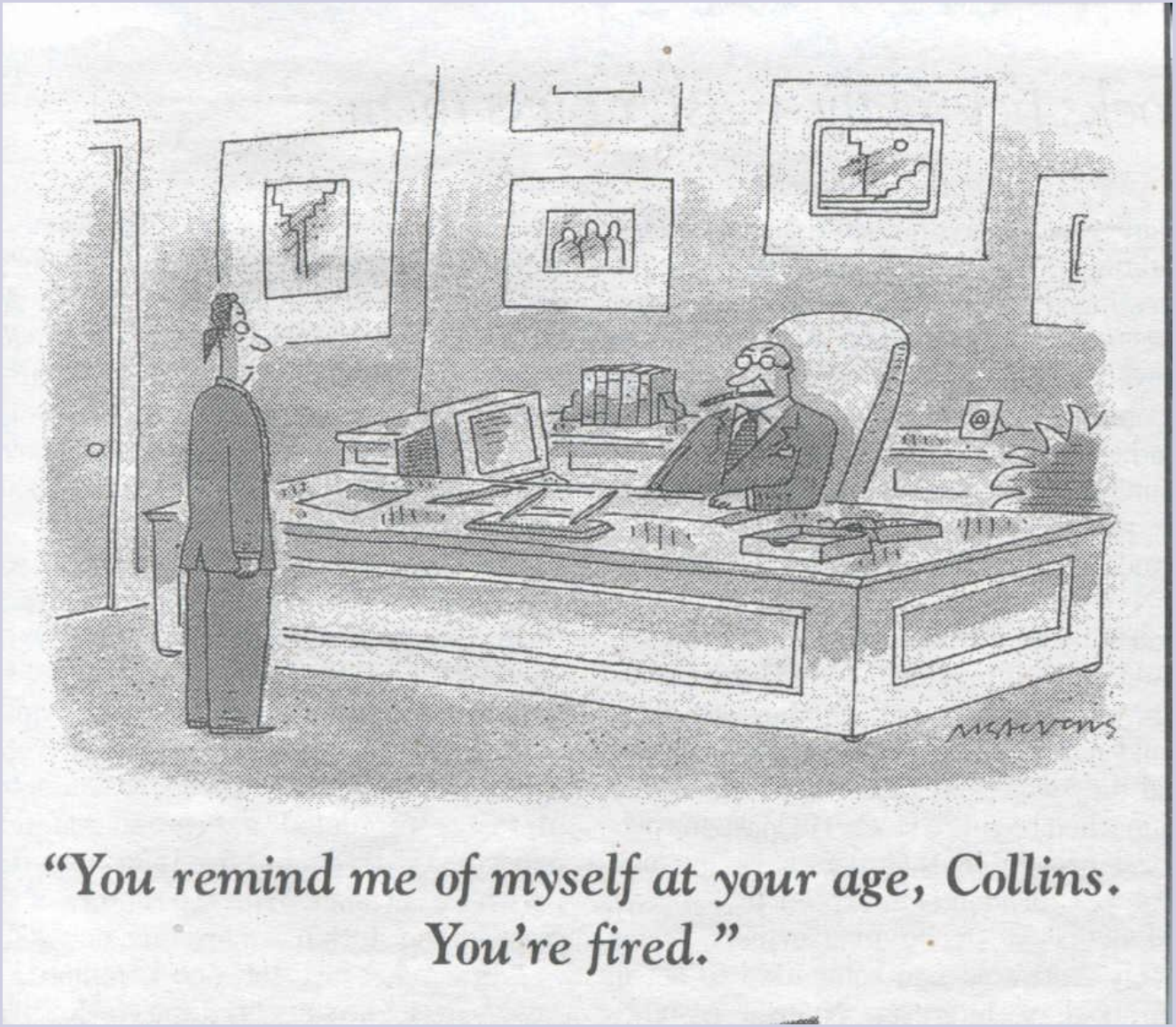
ISO 15189 FOLLOWS A TOP DOWN APPROACH TO TECHNICAL ISSUES

5 TECHNICAL REQUIREMENTS – TOOLS

SEC #	SECTION	DOC	CLIA
5.3	**Laboratory Equipment, Reagents, and Consumables**		§493.1252
5.3.1	Equipment		§493.1252
5.3.1.1	General	PRC	-
5.3.1.2	Equipment Acceptance Testing	PRC/REC	-
5.3.1.3	Equipment Instructions for Use	PRC	§493.551
5.3.1.4	**Equipment Calibration and Metrological Traceability**	PRC/REC	§493.1255
5.3.1.5	Equipment Maintenance and Repair	PRG/REC	§493.1254
5.3.1.6	Equipment Adverse Incident Reporting	PRC/REC	§493.1425
5.3.1.7	Equipment Records	REC	-

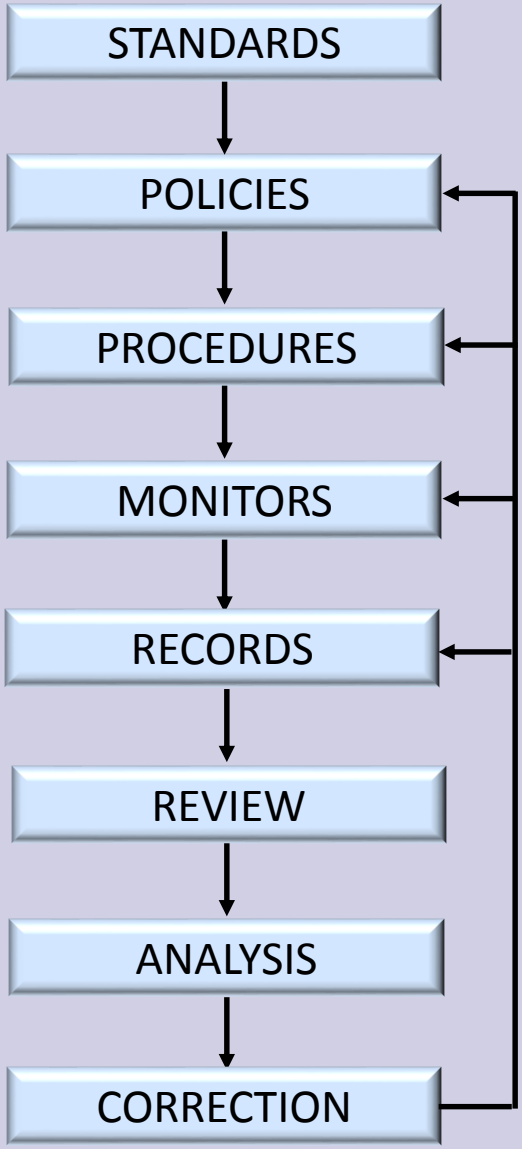
HERE SEE ISO 15189 APPLIES A LIFE CYCLE TO THE TOOLS USED TO RUN THE SYSTEM

REMEMBER THE POTENTIAL CONSEQUENCES OF YOUR WORDS AND ACTIONS



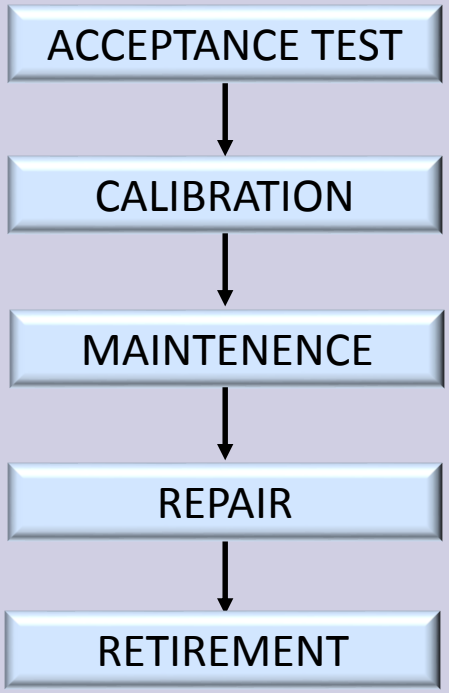
WHEN YOU TRY TO IMPLEMENT A NEW SYSTEM THERE MAY BE SOME PUSH BACK…

5 TECHNICAL REQUIREMENTS – SYSTEMS



ISO 15189 CAN BE FLOW CHARTED

5 TECHNICAL REQUIREMENTS – TOOLS



Throughout the standard you have to have these three things along with review, analysis, and corrective actions.

- USE INSTRUCTIONS
- INCIDENT REPORTS
- RECORDS

- REVIEW
- ANALYSIS
- CORRECTION

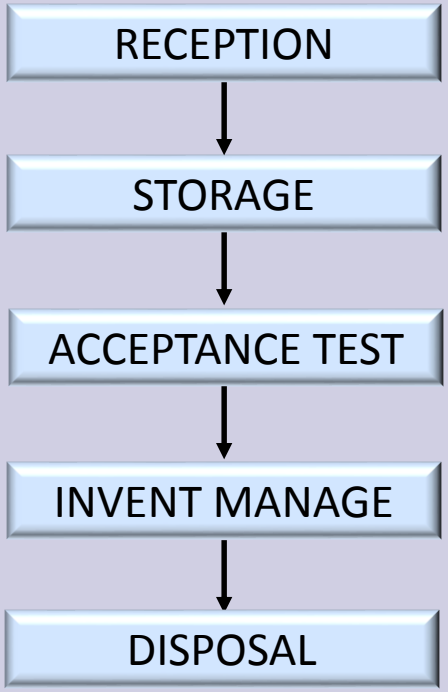
ISO 15189 CAN BE FLOW CHARTED TO EASE IMPLEMENTATION AND MAINTENANCE

5 TECHNICAL REQUIREMENTS – SUPPLIES

SEC #	SECTION	DOC	CLIA
5.3.2	**Reagents and Consumables**		§493.1252
5.3.2.1	General		-
5.3.2.2	Reagents and Consumables – Reception and Storage	PRC/REC	§493.1252
5.3.2.3	Reagents and Consumables – Acceptance Testing	PRC/REC	-
5.3.2.4	Reagents and Consumables – Inventory Management	PRC/REC	-
5.3.2.5	Reagents and Consumables – Instructions for Use	PRC	§493.551
5.3.2.6	Reagents and Consumables – Adverse Incident Reporting	PRC/REC	-
5.3.2.7	Reagents and Consumables – Records	REC	-

NOTE ISO 15189 BREAKS TOOLS DOWN INTO SUNK CAPITAL ITEMS AND EXPENSED ITEMS

5 TECHNICAL REQUIREMENTS – SUPPLIES



USE INSTRUCTIONS

INCIDENT REPORTS

RECORDS

REVIEW

ANALYSIS

CORRECTION

AS YOU'LL SEE, THIS TYPE OF SYSTEM FLOW IS FOUND THROUGHOUT THE STANDARD

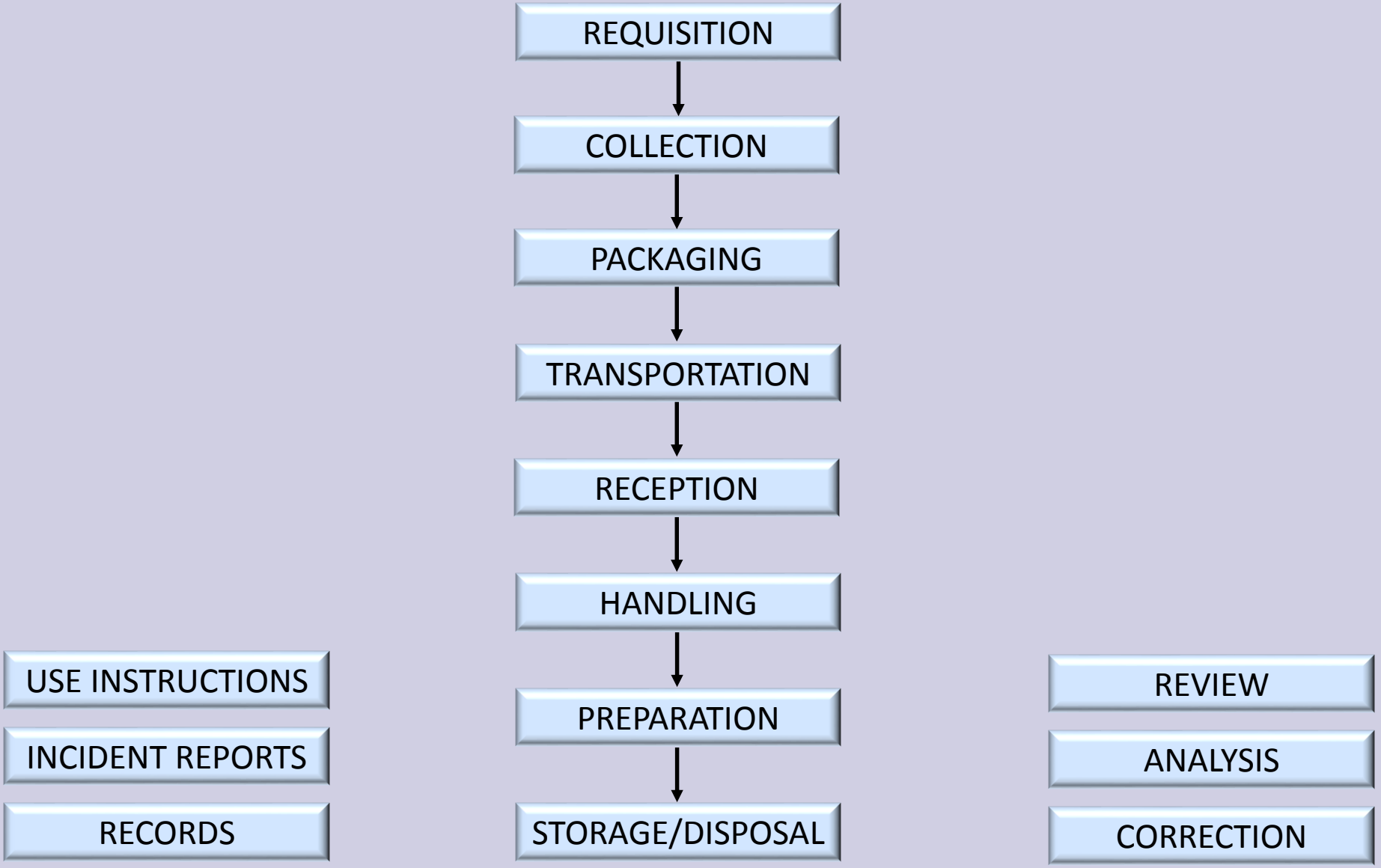
5 TECHNICAL REQUIREMENTS – TRADITIONAL PRE-ANALYTIC

SEC #	SECTION	DOC	CLIA
5.4	**Pre-examination Processes**		**-**
5.4.2	Information for Patients and Users	PRC/REC	-
5.4.3	Request Form Information [Requisition]	PRC/REC	§493.1241
5.4.4	Primary Sample Collecting and Handling	PRC/REC	§493.1242
5.4.4.1	General		-
5.4.4.2	Instructions for Pre-collection Activities	PRC/REC	§493.1251
5.4.4.3	Instructions for Collection Activities	PRC/REC	§493.1251
5.4.5	Sample Transportation	PRC/REC	§493.1242
5.4.6	Sample Reception	PRC/REC	-
5.4.7	Pre-examination Handling, Preparation, and Storage	PRC/REC	§493.1241

Here's the beginning of the patient specimen life cycle.

ISO 15189 INCORPORATES THE BEST OF PRIOR APPROACHES TO LAB MANAGEMENT

5 TECHNICAL REQUIREMENTS – TRADITIONAL PRE-ANALYTIC



FROM SOUP TO NUTS. AND…YOU WILL SEE THAT CAPA IS MOVING TO THIS AS WELL

5 TECHNICAL REQUIREMENTS ANALYTIC WITH METHOD LIFE CYCLE

SEC #	SECTION	DOC	CLIA
5.5	**Examination Processes**		
5.5.1	Selection, Verification, and Validation of Examination Procedures	PRC/REC	
5.5.1.1	General		
5.5.1.2	Verification of Examination Procedures	PRC/REC	
5.5.1.3	Validation of Examination Procedures	PRC/REC	
5.5.1.4	**Measurement Uncertainty of Measured Quantity Values**	PRC/REC	
5.5.2	Biologic Reference Intervals or Clinical Decision Values	PRC/LST	
5.5.3	Documentation of Examination Procedures	PRC/REC	

Here's the middle of the patient specimen life cycle.

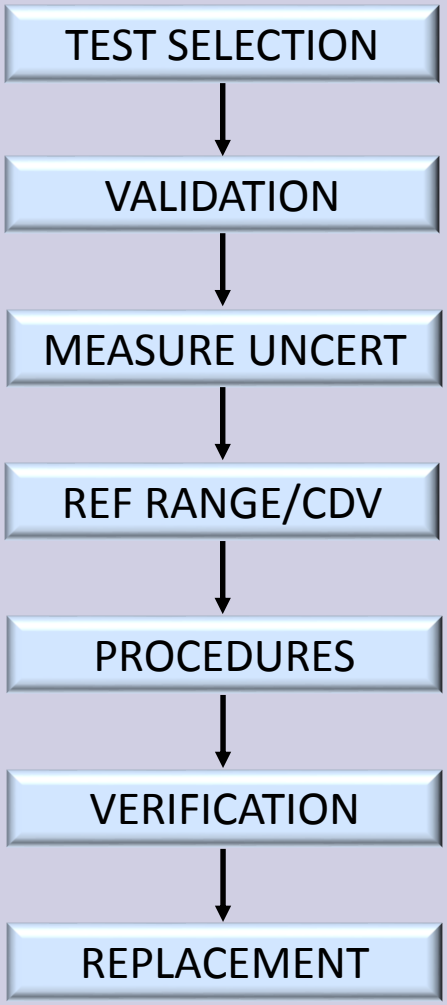
My definition of Validation and Verification are slightly different from ISO:

Validation: Initial testing to assure the examination meets specifications for clinical use.

Verification: Ongoing testing to assure reliability of tests during routine examination.

NOTICE ISO 15189 IS VERY COMPREHENSIVE SYSTEM DRIVEN BY PROCESSES

5 TECHNICAL REQUIREMENTS – ANALYTIC



USE INSTRUCTIONS

INCIDENT REPORTS

RECORDS

REVIEW

ANALYSIS

CORRECTION

HERE THE STANDARDS TEND TO MIX THE EXAMINATION WITH THE METHOD LIFE CYCLE

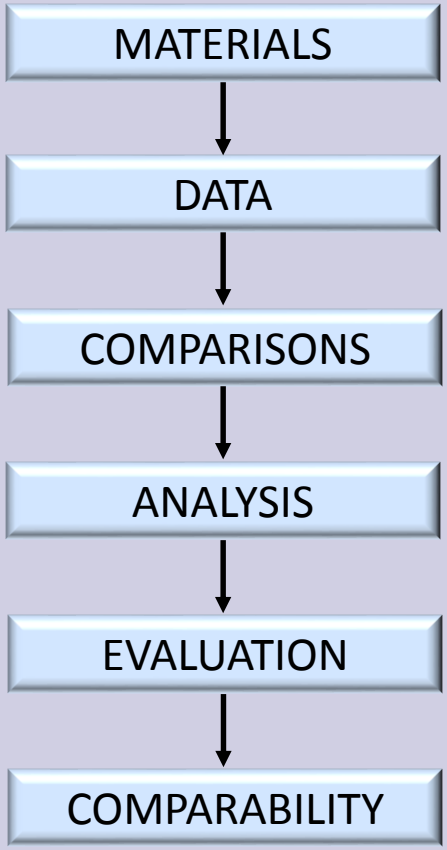
5 TECHNICAL REQUIREMENTS – RISK CONTROL

SEC #	SECTION	DOC	CLIA
5.6	**Ensuring Quality of Examination Results**		
5.6.1	General	PRC	
5.6.2	**Quality Control [This is were verification occurs]**		
5.6.2.1	General		
5.6.2.2	Quality Control Materials		
5.6.2.3	Quality Control Data	PRC/REC	
5.6.3	Interlaboratory Comparisons	PRC/REC	
5.6.3.1	Participation		
5.6.3.2	Alternative Approaches		
5.6.3.3	Analysis of Interlaboratory Comparison Samples		
5.6.3.4	Evaluation of Laboratory Performance	REC	
5.6.4	Comparability of Examination Results	PRC/REC	

Here's where we pause at the middle of the patient specimen life cycle and make sure we aren't going to accidentally or otherwise harm the patient. Although this helps maintain the perceived quality of the laboratory, it is not a quality issue. It's a risk issue.

I HAVE ALWAYS FELT THAT QUALITY CONTROL SHOULD BE TERMED **RISK CONTROL**

5 TECHNICAL REQUIREMENTS – RISK CONTROL

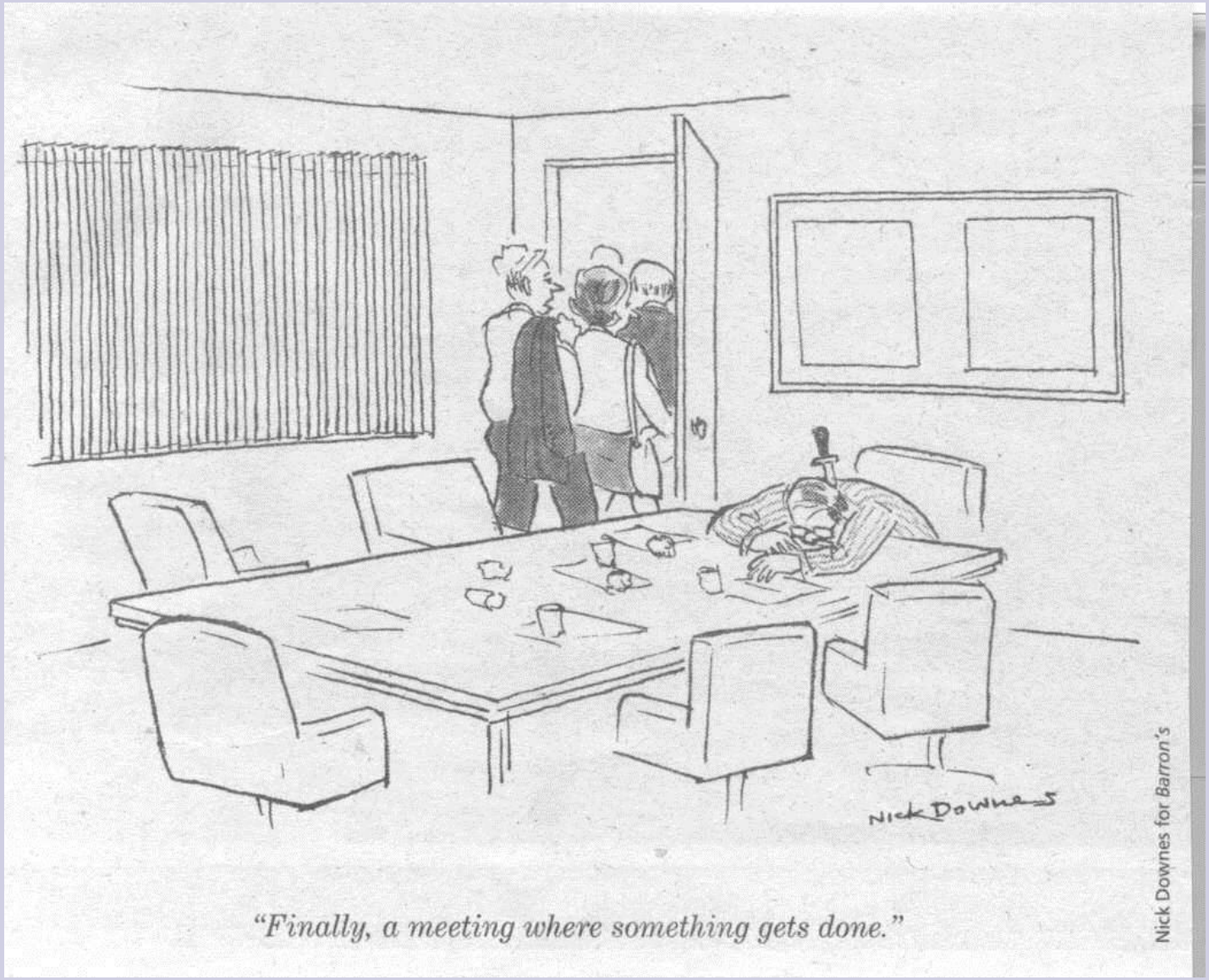


- USE INSTRUCTIONS
- INCIDENT REPORTS
- RECORDS

- REVIEW
- ANALYSIS
- CORRECTION

IT'S NOT QUALITY CONTROL!!! IT'S RISK CONTROL

THIS STUFF SEEMS MORE INTERESTING THAN THE REST OF THE TALK…



"Finally, a meeting where something gets done."

Nick Downes for *Barron's*

DON'T YOU HATE COMMITTEES? I RECOMMEND FORMING TIME LIMITED TASK FORCES.

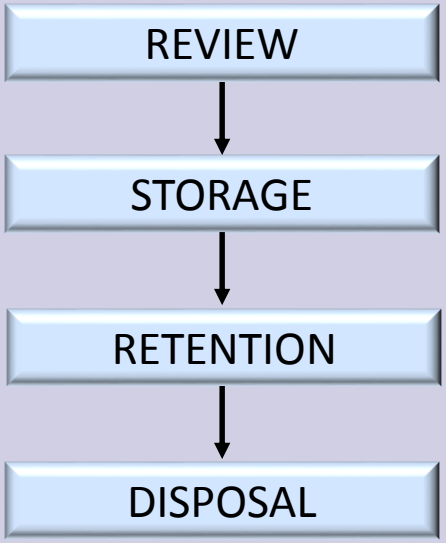
5 TECHNICAL REQUIREMENTS – POST ANALYTICAL/REPORTING

SEC #	SECTION	DOC	CLIA
5.7	**Post-examination Processes**		
5.7.1	Review of Results	PRC	
5.7.2	Storage, Retention, and Disposal of Clinical Samples	PRC	
5.8	**Reporting of Results**		
5.8.1	General	PRC	
5.8.2	Report Attributes	LST	
5.8.3	Report Content	LST	
5.9	**Release of Results**		
5.9.1	General	PRC	
5.9.2	Automated Selection and Reporting of Results	PRC	
5.9.3	Revised Reports	PRC	

Here's the end of the patient specimen life cycle.

ISO 15189 COVERS WHAT HAPPENS AFTER THE EXAM AND CLOSES THE CIRCLE

5 TECHNICAL REQUIREMENTS – POST ANALYTICAL

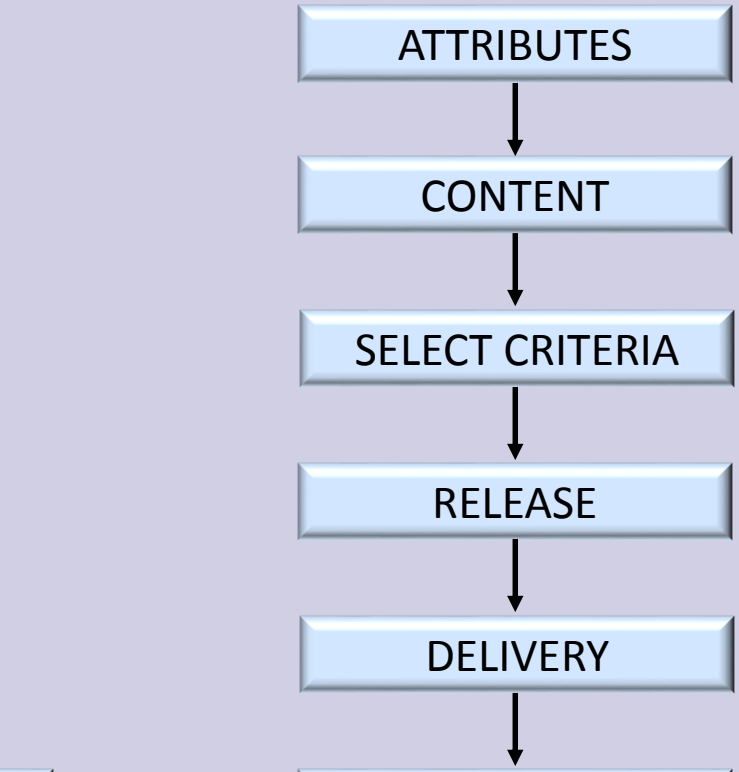


- USE INSTRUCTIONS
- INCIDENT REPORTS
- RECORDS

- REVIEW
- ANALYSIS
- CORRECTION

THE STANDARD COVERS POST EXAMINATION HANDLING OF THE SPECIMEN

5 TECHNICAL REQUIREMENTS – REPORTING



USE INSTRUCTIONS

INCIDENT REPORTS

RECORDS

REVIEW

ANALYSIS

CORRECTION

THE REPORTING STANDARD IS GENERAL BUT COMPREHENSIVE IN SCOPE

5 TECHNICAL REQUIREMENTS – INFORMATION AND AUTOMATION

SEC #	SECTION	DOC	CLIA
5.10	**Laboratory Information Management**		
5.10.1	General	PRC	
5.10.2	**Authorities and Responsibilities**	**POL**	
5.10.3	Information System Management	PRC	

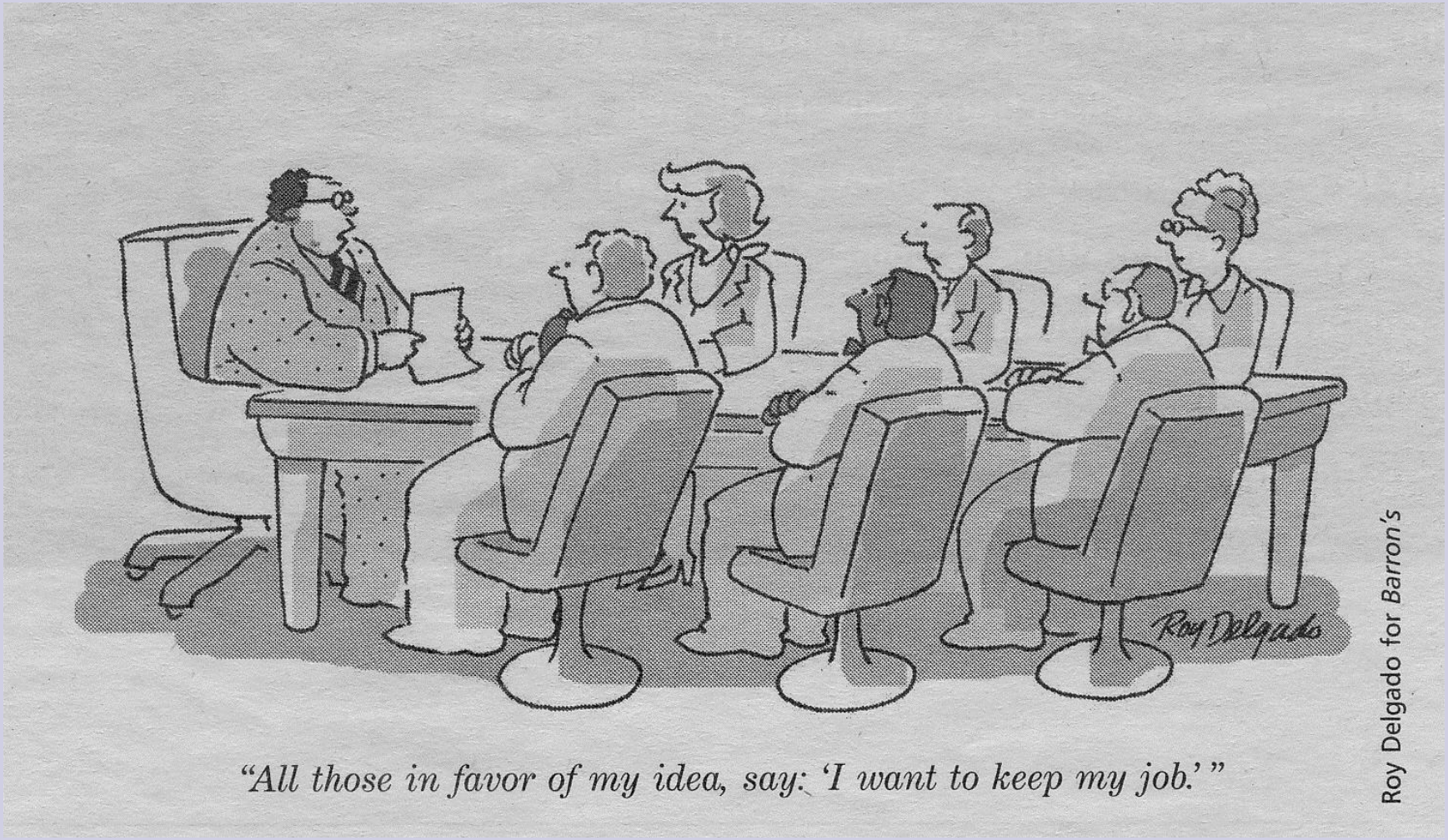
ISO 15189 ALSO COVERS THE AUTOMATION SYSTEM AND PROCESSES

ISO 15 189 IS A SYSTEM OF SYSTEMS EACH WITH ITS OWN LIFE CYCLE

- FACILITY LIFE CYCLE
- SUPPLIER LIFE CYCLE
- REFERENCE/CONSULTANT LIFE CYCLE
- INSTRUMENT/METHODOLOGY LIFE CYCLE
- SUPPLY/CONSUMABLES LIFE CYCLE
- REAGENT/CONTROLS LIFE CYCLE
- SPECIMEN LIFE CYCLE
- PESONNEL LIFE CYCLE

A VALUABLE APPROACH TO ORGANIZE AND EXECUTE REGULATIONS AND STANDARDS

AND THEN THERE'S THE NASTY PROBLEM OF INTERNALIZATION



"All those in favor of my idea, say: 'I want to keep my job.'"

Roy Delgado for *Barron's*

GOOD LUCK!

REFERENCES

1. **42 CFR Part 493** – Laboratory Requirements; 10-1-11 Edition Version 15 Mar 2010
2. **Laboratory General Checklist**; CAP Accreditation Program; 04.21.2014
3. **ISO 15189**; International Standards Organization; Third Edition 2012-11-01
4. Mark Gusack; **Integrated Quality Management and The Scientific Method**; MBG Industries, Inc. 1997.
5. Johnson, PL; **ISO 9000: Meeting the New International Standards**; McGraw-Hill, Inc. 1993.
6. Hutchins Greg; **ISO 9000: A Comprehensive Guide to Registration, Audit Guidelines, and Successful Certification**; Oliver Wight Publications, Inc. 1993.
7. Peach, RW Editor; **The ISO 9000 Handbook** 3rd Edition; Times Mirror Higher Education Group, Inc. 1997.
8. Cianfrani CA, Tsiakals JJ, West JE; **ISO 9001:2000 Explained** 2nd Edition; American Society for Quality 2001.
9. McDermott RE, Mikulak RJ, Beauregard MR; The Basics of FMEA; Productivity, Inc. 1996.
10. Kerzner H; **Project Management: A Systems Approach to Planning, Scheduling, and Controlling** 5th Edition; Van Nostrand Reinhold 1995.