Implementing an Implementation Strategy for ISO 15189:2012

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What is Quality Management?

Quality Management is a systematic approach to organizational improvement.

Today's Quality Management Systems are the end product over 100 years of knowledge and experience

Quality Management Systems provide a composite approach to address and protect :

Organization	Management	Staff
Suppliers	Customers	Partnerships
Institutions	Community	Environment

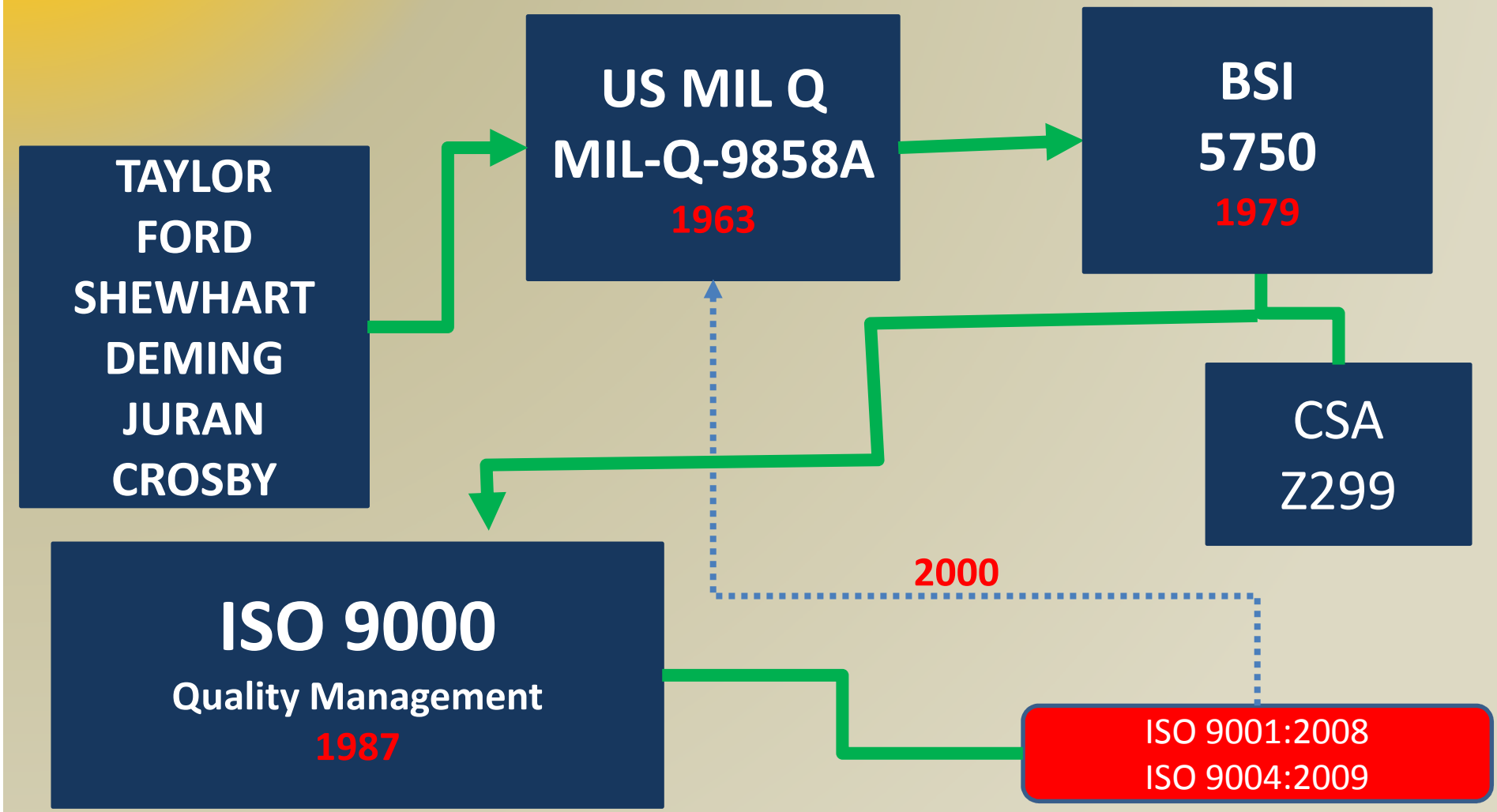
from the hazards and risks associated with faulty and inconsistent practices which result in dissatisfaction, unacceptable outcomes.

Why Quality Management?

The benefits of an active Quality Management System are too powerful to disregard.

- *A structured approach to organization and management*
- *More knowledgeable and effective management*
- *More knowledgeable and cohesive staff*
- *Organizational harmony and culture*
- *More effective and efficient delivery of product and service*
- *Fewer errors (especially repeat errors!)*
- *Reduced cost and Increased savings*
- ***Greater management and staff satisfaction***
- ***Greater customer satisfaction***
- ***Greater community satisfaction***
- *Reduced risk*
- *Reduced liability*

History's Path to Quality Management




ISO 17025
ISO 15189
ISO 9001
CLSI
CAP /CLIA
WHO
Many Avenues to Medical Laboratory Quality Management

What is ISO 15189:2012?

- In 1994 the international community of medical laboratories met to discuss if there was a need to create a set of Quality requirements to help standardize the management principles for medical laboratories anywhere in the world.

What is ISO 15189:2012?

- With the authority of the International Organization for Standardization (ISO) the document developed was entitled ***ISO 15189:2003 - Medical Laboratories: Particular Requirements for Quality and Competence***
- The document is now in its third iteration.

Why Adopt ISO 15189:2012?

ISO 15189 has many positive features:

- It was developed by representative from 33 different countries representing regions across all continents (except Antarctica).
- It has been embraced in total or in part by medical laboratories in more that 55 countries.
- It is written consistent with internationally accepted precepts of Quality Management.
- It is consistent with the common practices accepted by medical laboratories.
- It is consistent with accreditation body requirements for Quality everywhere in the world.
- ISO requires regular review and if appropriate, refreshment, every 5 years

How to Adopt ISO 15189:2012?

The following principles apply to adopted any voluntary Quality Management standard:

1. *Read the document.*
2. *Does it meet your needs?*
3. *Perform a Gap Analysis*
4. *Prepare the Laboratory*
5. *Develop an implementation plan*
6. *Repeat the Gap Analysis?*
7. *Determine your state of readiness*
8. *Make the Accreditation decision*
9. *Commit to the standard*

Steps to Adoption

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Steps to Adoption

1.Read the document.

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- International standards follow precise language patterns that can make interpretation challenging.
  - ***Normative statements***
    - These are statements within the standard that are REQUIRED. They use the word "***SHALL***" which is understood to mean ***"MUST".***
    - Standard writers try to avoid the term ***"SHALL NOT".*** Every attempt to avoid the negative is made. This can cause complication or confusion.

1. Read the document.

- ***Informative statements***
  - These are statements within the standard that are used for recommendations or guidance. They use the words such as ***"MAY"*** or ***"SHOULD"*** or ***"CAN"*** or ***"IT IS RECOMMENDED THAT"***. These are not requirements, but should be considered as helpful advice.
- ***Conditional statements***
  - In some situations, Terms such as ***"TO THE EXTENT POSSIBLE"*** are used with normative clauses. This means that the requirement would apply, unless there is an extenuating circumstance, such as a over-riding national regulation which would take priority.

1. Read the document.

- Style
- ***Standards are written using generalized statements***. Standards are not regulations. They are not written to specifically cover every situation and circumstance.
- ***Standards are written concisely.*** Standards tend to use very clipped language which may be both subtle and nuanced. Standards are not books and rarely contain more than 30 pages of text. While they may contain informative statements, the true meaning of standards may be open to interpretation.

1. Read the document.

- Take away message when considering adopting a new standard.
  - ***The more you learn, the more you know.*** There is value in learning more about voluntary standards from informed people before making a final commitment to adopt and embrace them for your organization.
    - Conferences
    - Courses
    - Colleagues
    - Consultants

Steps to Adoption

2. Does it meet your needs?

2. *Does it meet your needs?*

- Adoption of Voluntary standards has costs:
  - TIME: Count on 2-5 person-years of time
  - EFFORT May require physical changes
  - ENERGY Many decisions and changes will be made
  - MONEY Overtime
    Consultants
    Accreditation
    Active Program Changes.

2. *Does it meet your needs?*

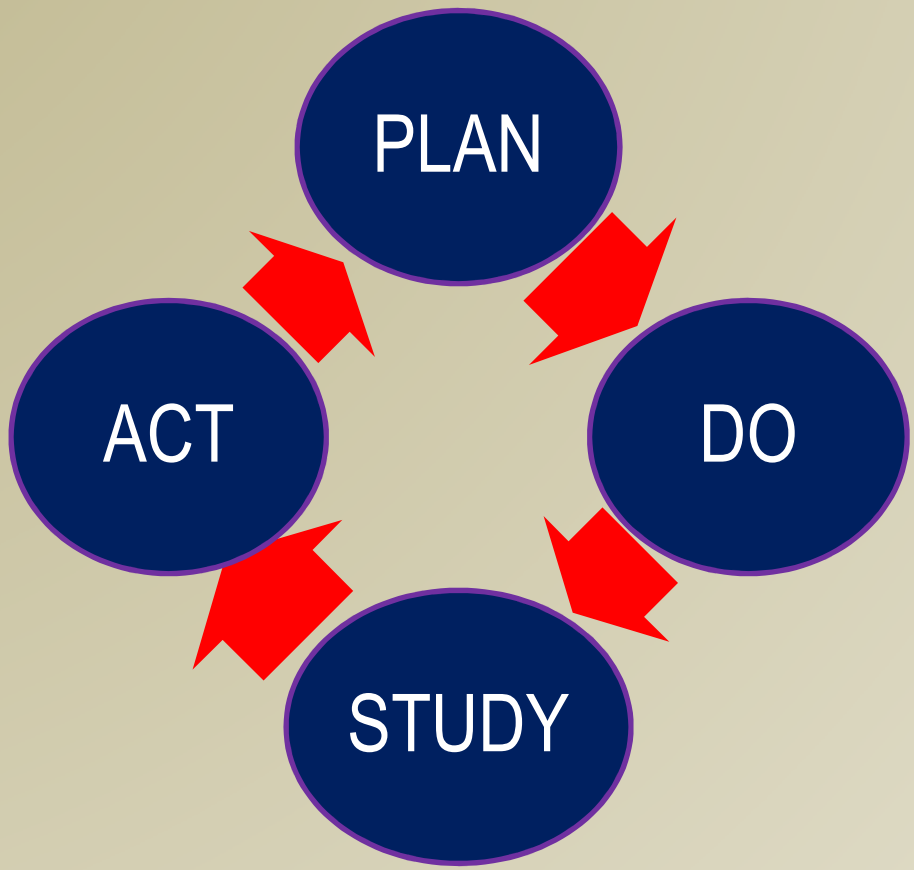
- Adoption of Voluntary standards should be a business decision with a cohesive business cost-benefit plan.
  - Can we afford to adopt the standard?
  - Can we afford to maintain the standard?
  - Will the standard pay for itself over time?
  - Can we afford to ***NOT*** adopt the standard

Steps to Adoption

3. Perform a Gap Analysis

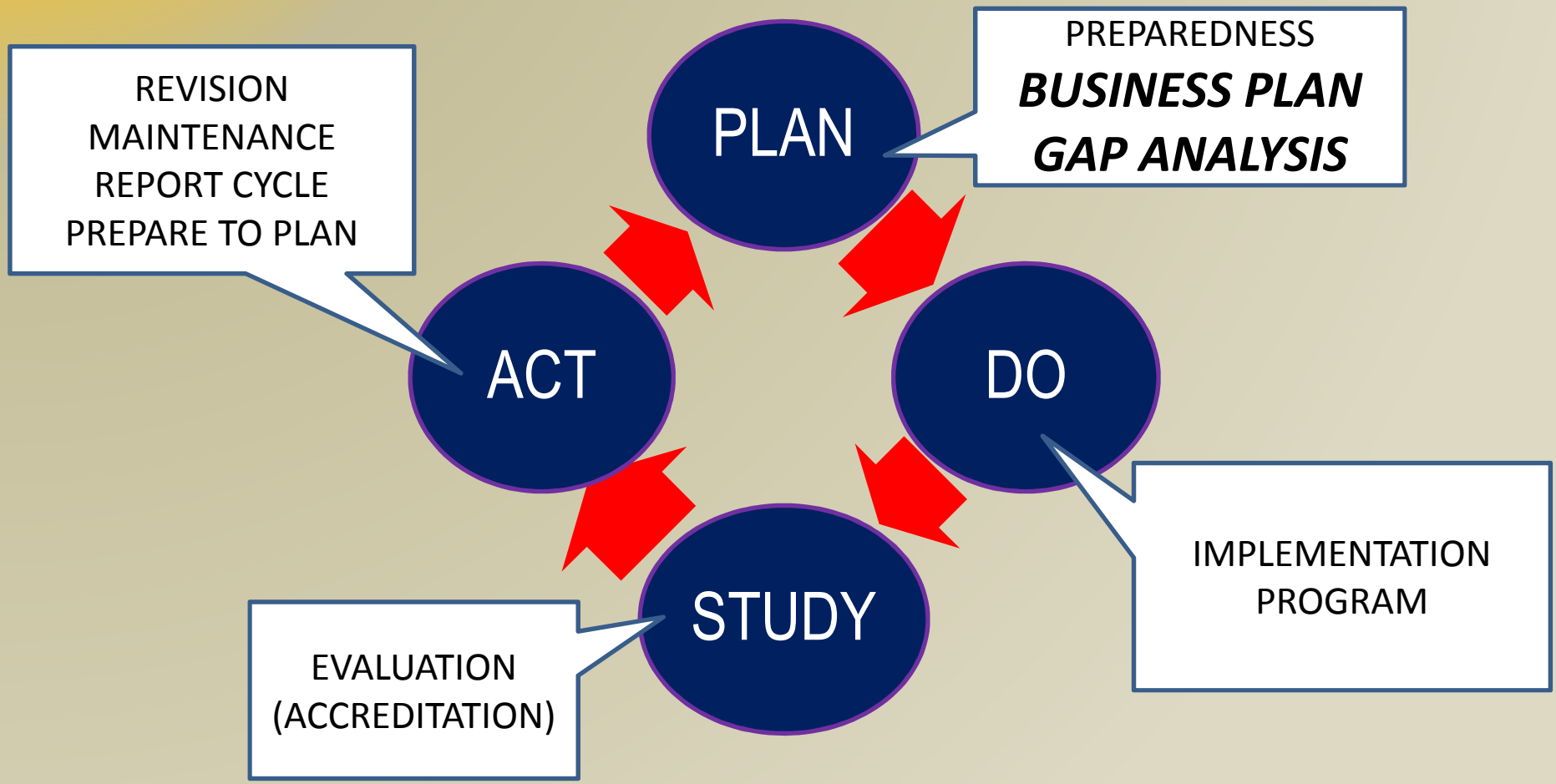
3. *Perform a Gap Analysis*

- W. Edwards Deming and the Quality Cycle



3. *Perform a Gap Analysis*

- W. Edwards Deming and the "Standards" Cycle



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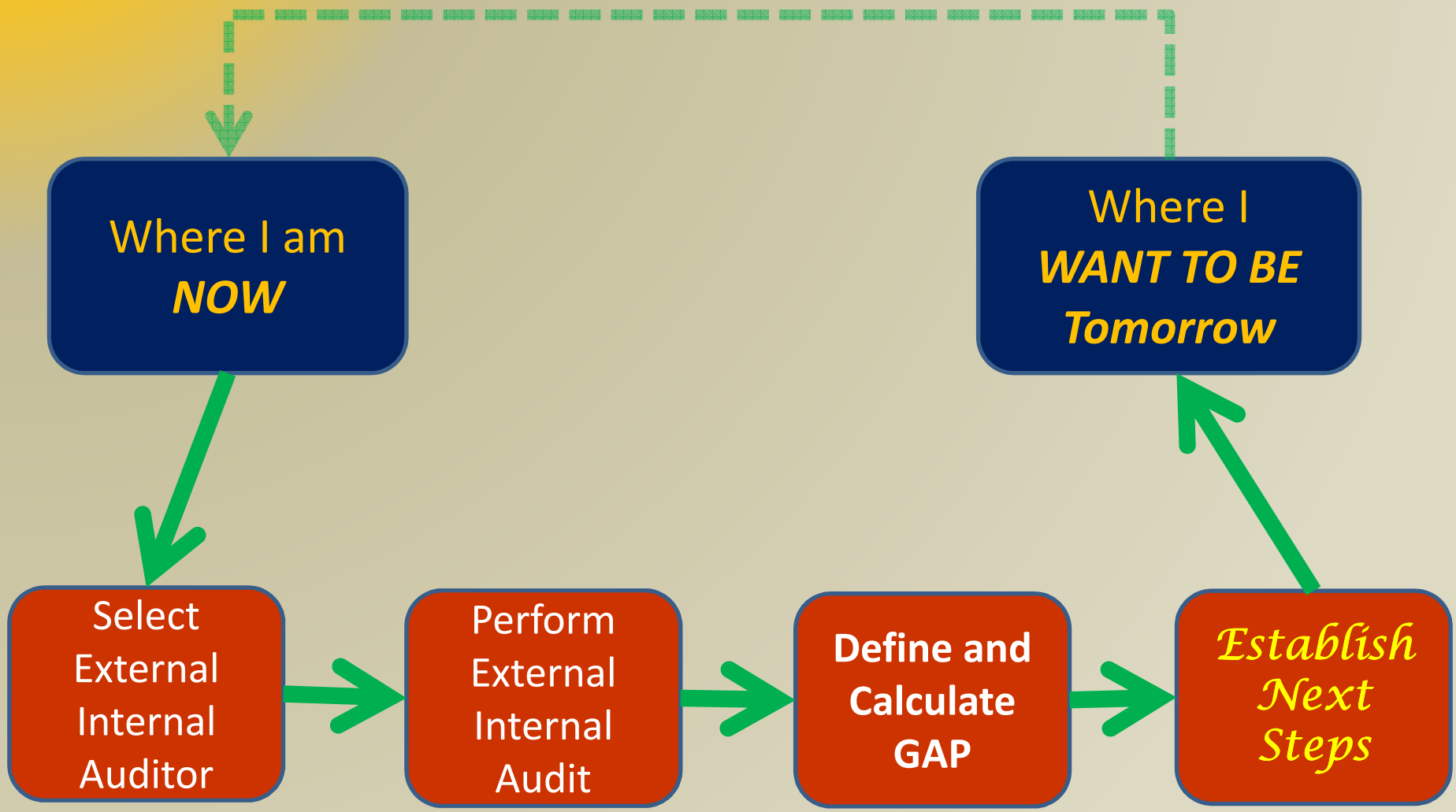

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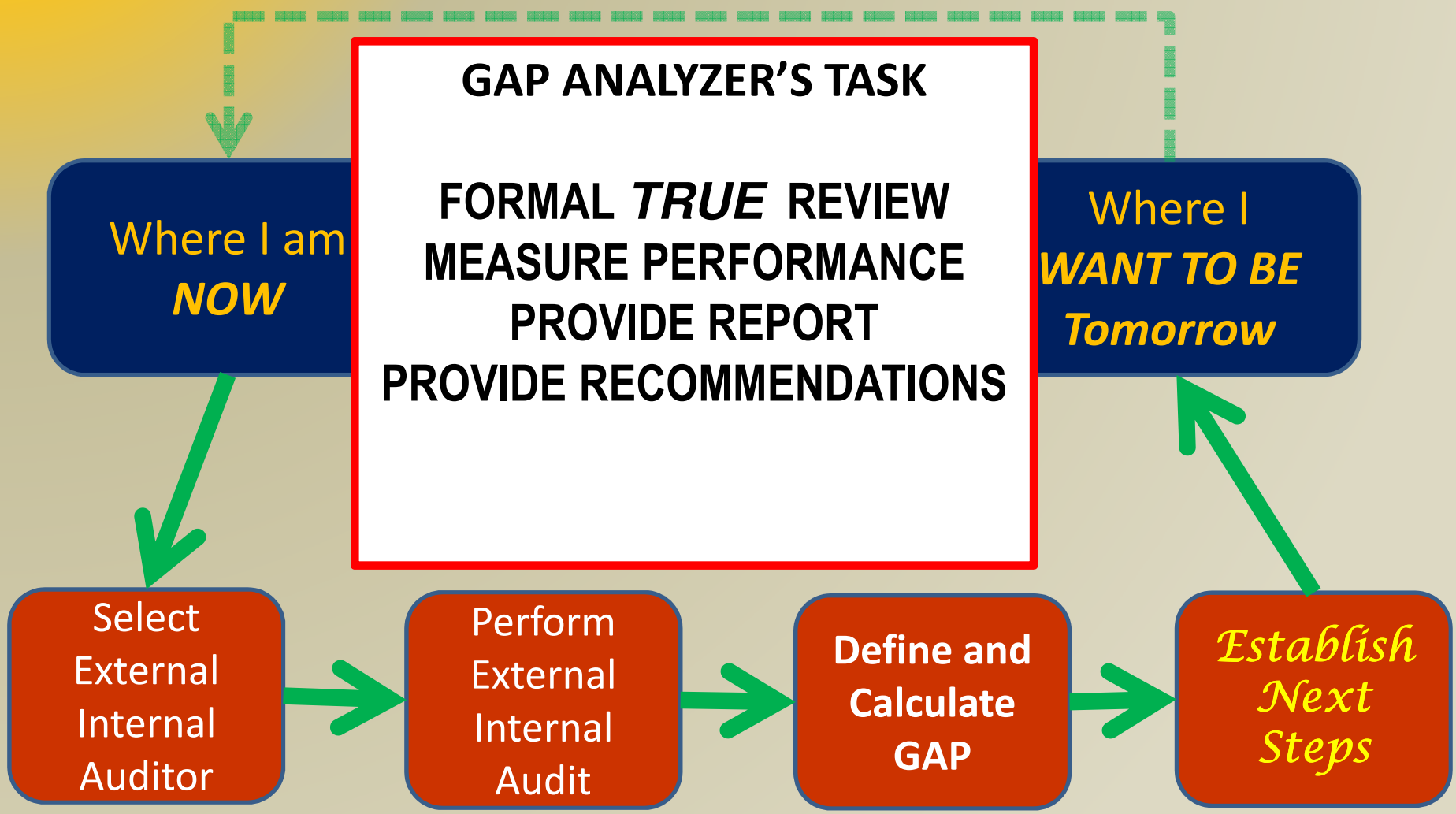

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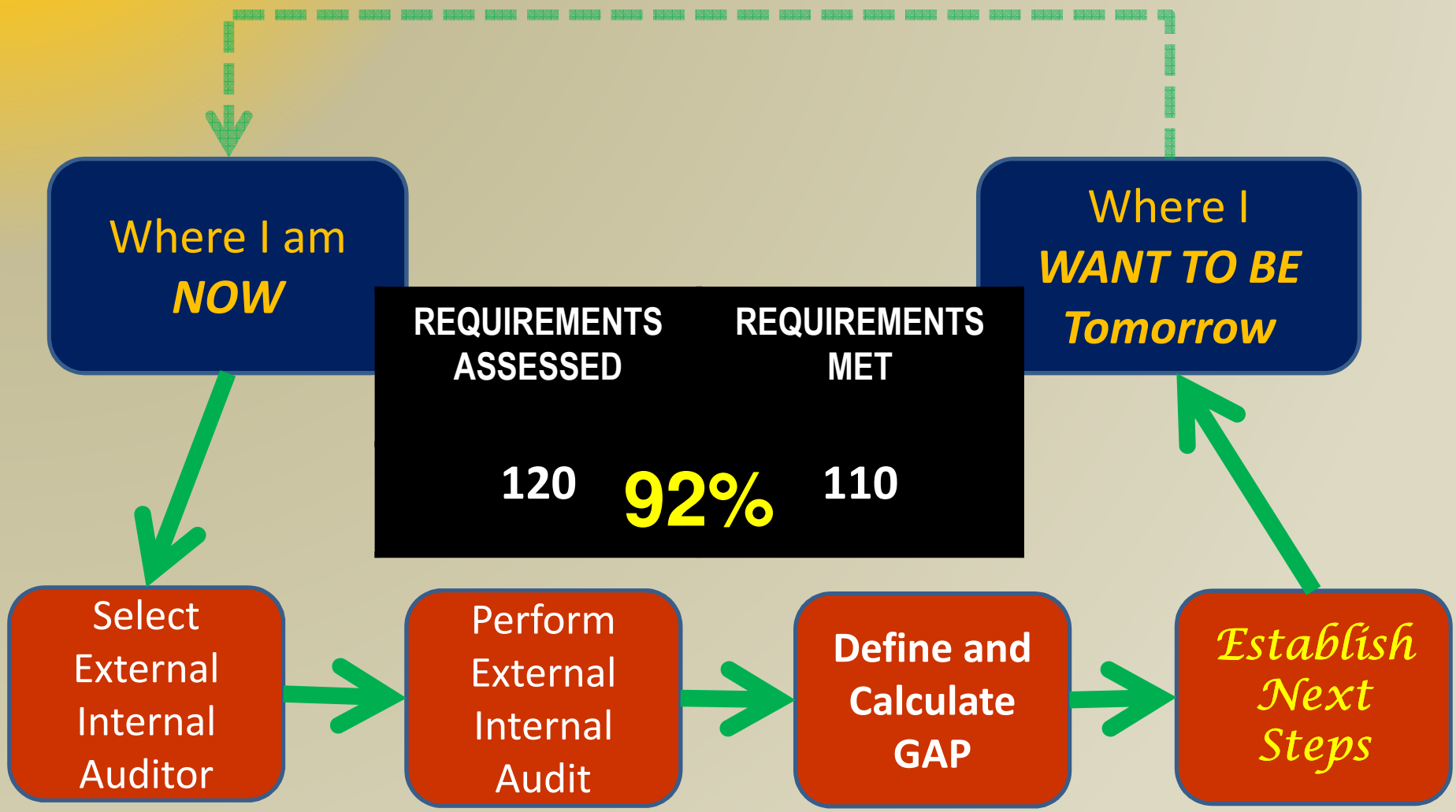

Steps to Adoption

4. Prepare the Laboratory

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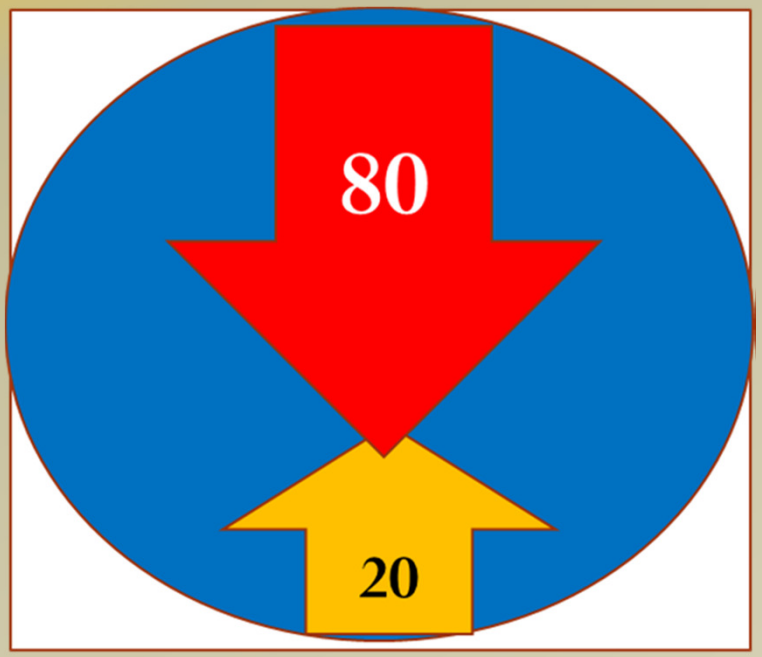
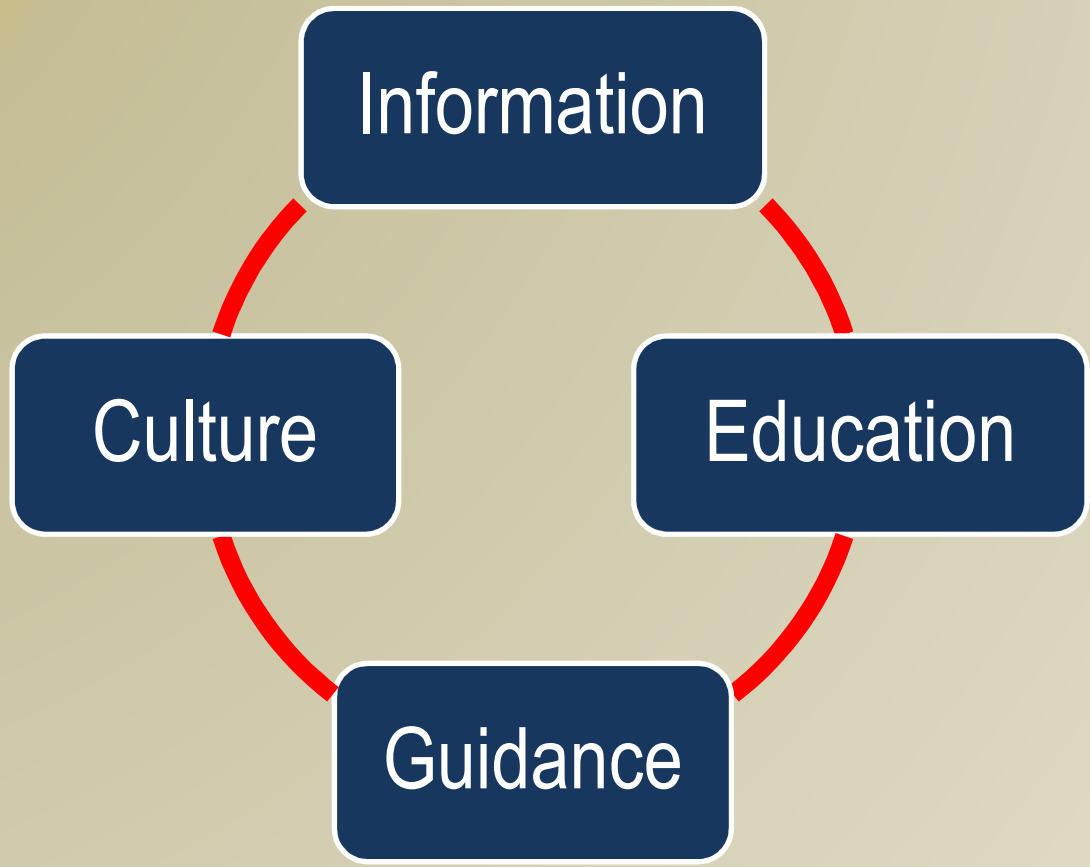
Feigenbaum Rule



While Management has 80 percent of the responsibility for Quality and Change Management, if everyone does not participate, the chances for success are ***NIL***

4. Prepare the Laboratory



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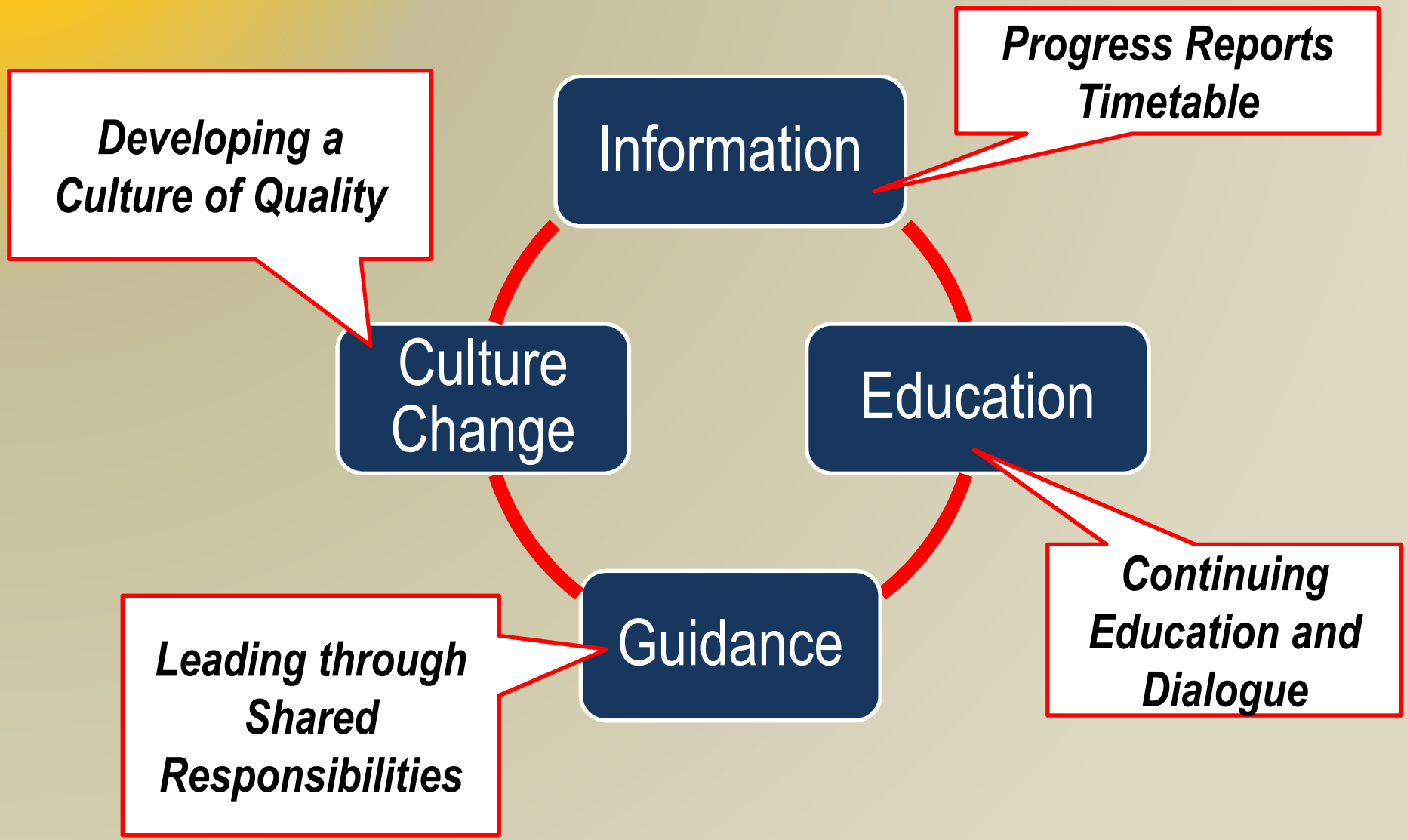


Many Faces to Continuing Education

Lunch and Learn" Seminars

Discussion Programs

Internal Speakers

Invited Speakers

Workshops and Conferences

Educational Postings

Newsletters

Blogs

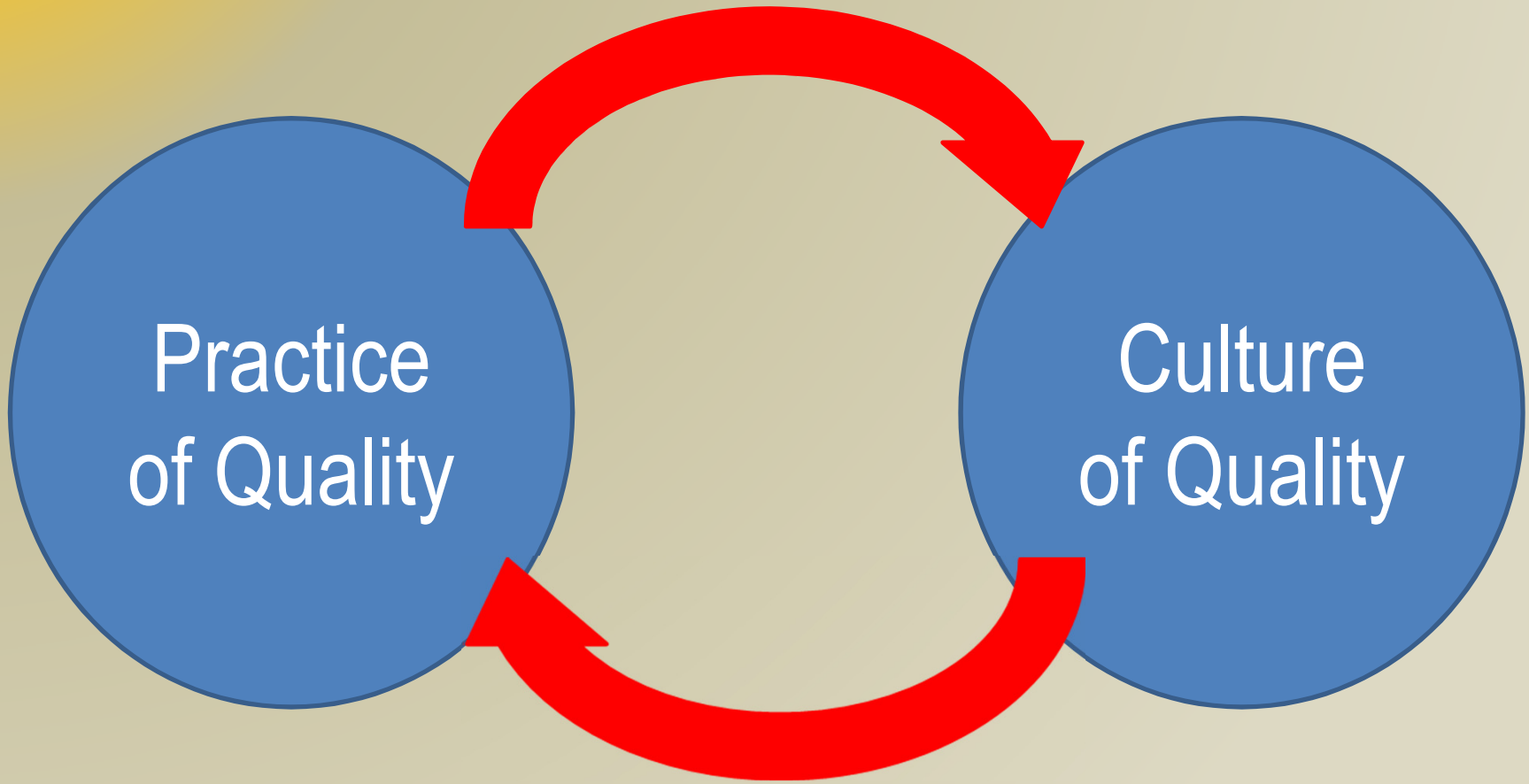
Twitter

4. Prepare the Laboratory

Organizational Culture

1. A *measurable* pattern of such collective behaviors and assumptions that people share within an organization.
2. The meanings that the people attach to their actions
3. Organization values, visions, norms, working language, systems, symbols, beliefs and habits.
4. Organizational culture affects the way people and groups interact with each other, with clients, and with stakeholders.
5. The pattern of behaviours and values that are taught to new organization members.

Culture of Quality



4. Prepare the Laboratory

As you go through the process of preparation consider:

1. If you are running a successful laboratory, you likely only need fine tuning rather than an overhaul.
2. The concept of "*Meet or Exceed*" standards is ***NONSENSE***.
3. When writing procedures, write down **WHAT YOU ARE DOING** and not **WHAT YOU WANT OTHERS TO THINK WHAT YOU ARE DOING**.
4. If there is a **HARD WAY** and an **EASY WAY**, do it the ***EASY WAY***.
5. The point of the exercise is to build a **SUSTAINABLE CULTURE** that will support **SUSTAINABLE PRACTICES**.

5. Develop an Implementation Plan

There are a number of laboratory domains that will likely need revisions:

1. Policies, Mission, Vision
2. Quality Indicators (Measurement tools)
3. Document Creation and Document Control
4. Supply Management
5. Physical Plant
6. Equipment
7. Quality Control routines (including Measurement Uncertainty)
8. Personnel training and competencies
9. Proficiency testing
10. Management Review

Steps to Adoption

5. Develop an implementation plan

5. Develop an Implementation Plan

Set your Goals with
Identified Tasks, Assigned Responsibilities and
Achievable Timelines.

Start with the
Major Deficiencies
on the Gap Analysis.

Fine tune the
Minor Deficiencies

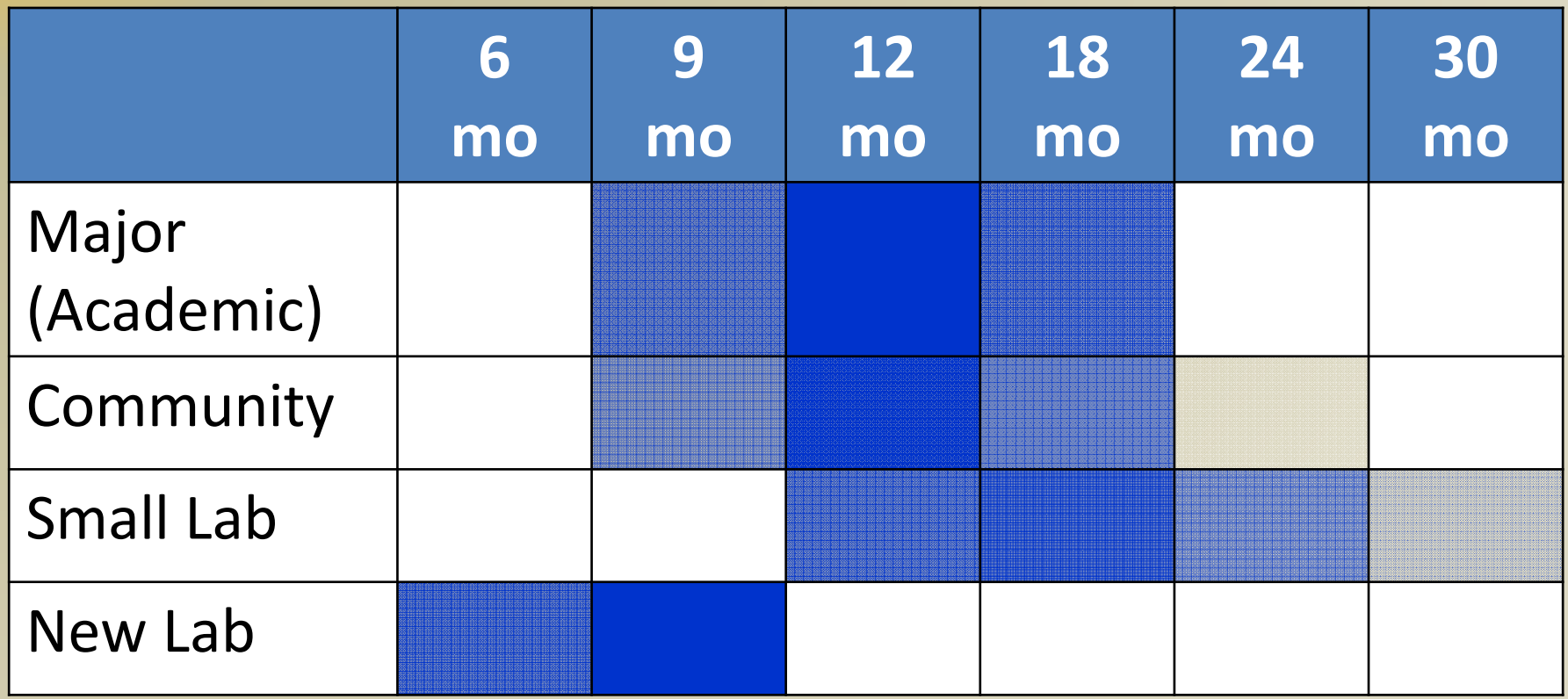
Keep Everyone informed about Progress

Stick to the Plan

Gantt Chart your plan

Time	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	M/ISSION		CREATE QUALITY AND POLICY MANUAL											
2	REVIEW QIs						QI2			QI2				
3	DC REVIEW			NEW DC PLAN										
4	REVIEW SUPPLIERS				CONTACT SUPPLIERS									
5	SINKS		COUNTERS											
6	EQUIPMENT REVIEW													
7	REVIEW QC			IMPLEMENT AND MONITOR QC CHANGES										
8	PLAN / DEVELOP CA PLAN						IMPLEMENT NEW CA PLAN							
9		MONITOR AND ADDRESS ALL PT ERRORS												
10	GATHER REPORTS REQUIRED FOR MANAGEMENT REVIEW										WRITE MR			
11	DEVELOP AND MONITOR LABORATORY SAFETY PLAN													
						CUSTOMER SATISFACTION PROGRAM								

Timetable to Success
How long does preparation take?

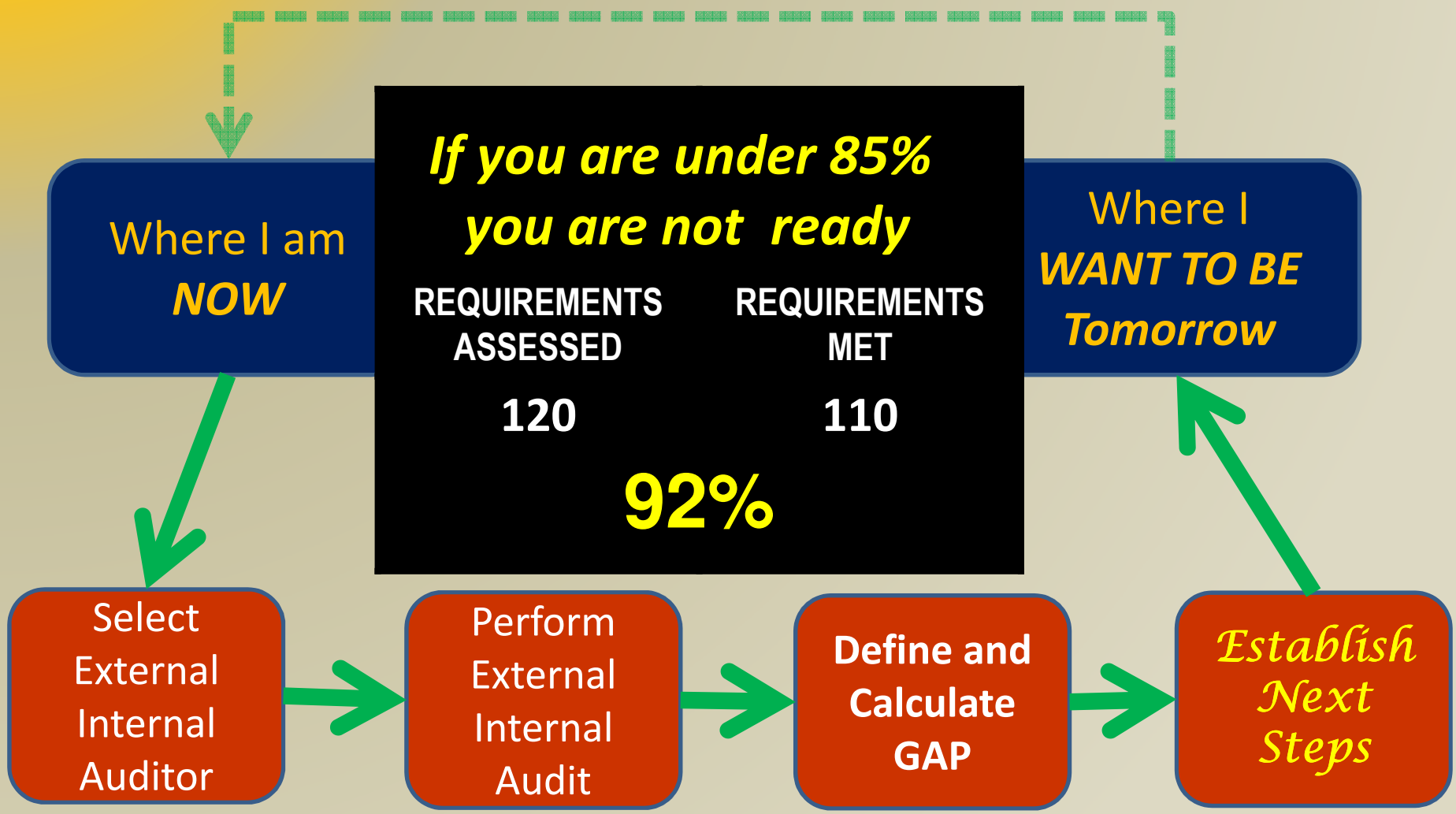


Steps to Adoption

6. *Repeat the Gap Analysis?*

7. *Determine your state of readiness*

What is a *Gap* Analysis?



7. When is your laboratory "Ready for Quality" ?

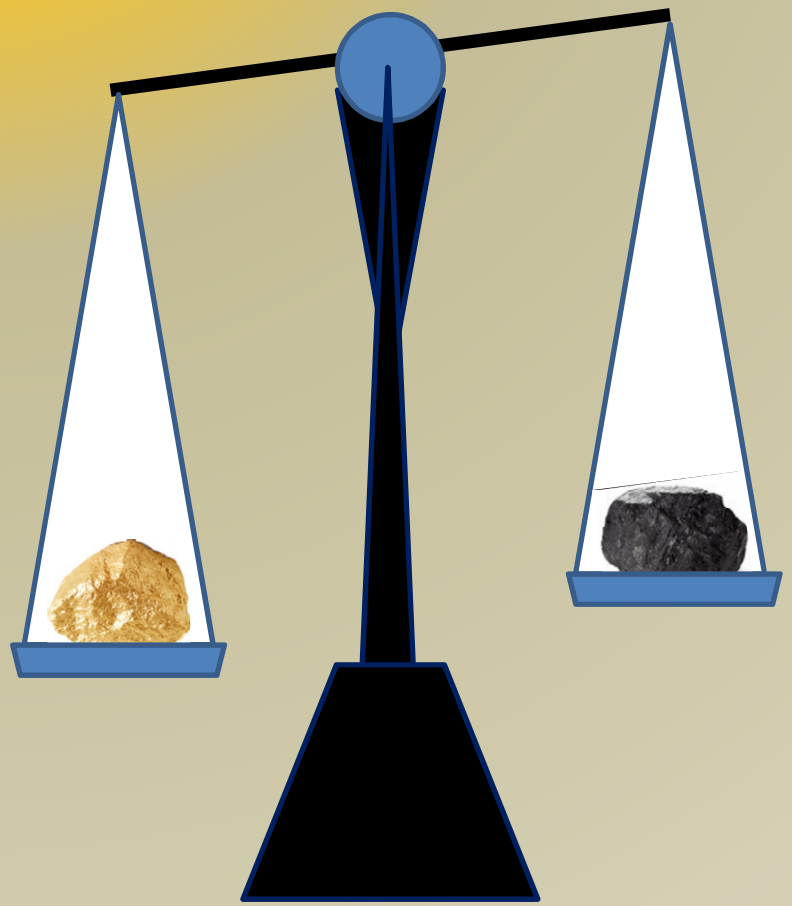
- On a metric level
  - Have a Gap Analysis measure of meeting 90 % plus of requirements and NO major deficiencies.
- On a process level
  - Going to full accreditation mode is not a major or immediate priority.

Steps to Adoption

8. Make the Accreditation decision

8. Make an Accreditation Decision

Do you want Quality or Accreditation or Both?



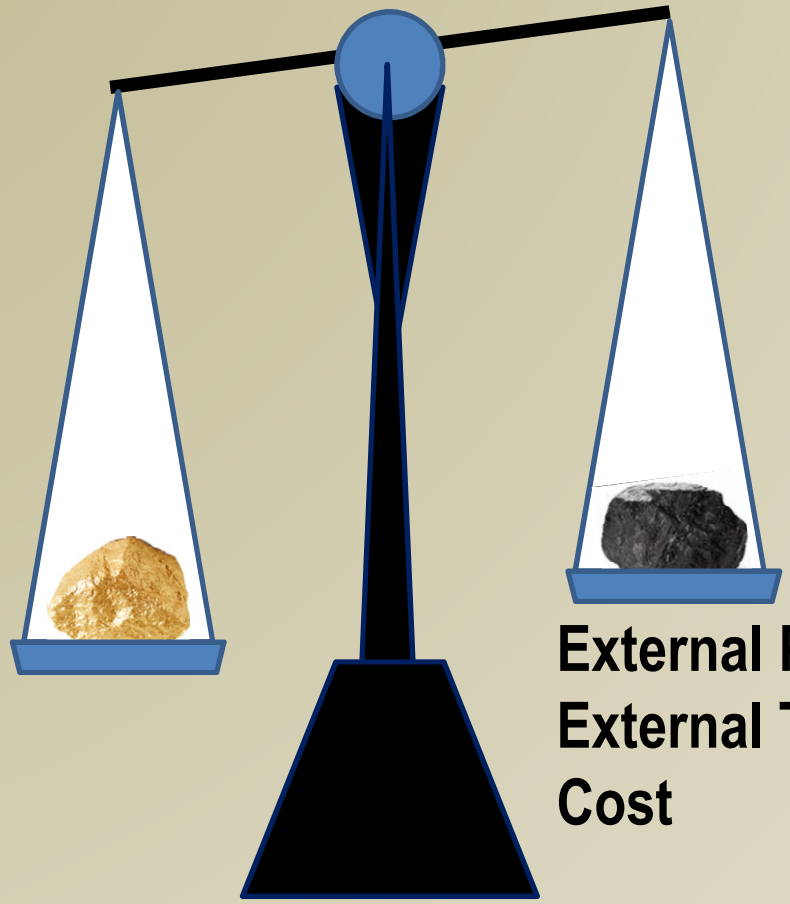
Laboratory Accreditation can be a valuable asset but is NOT the only choice.

8. Make an Accreditation Decision

Do you want Quality or Accreditation or Both?

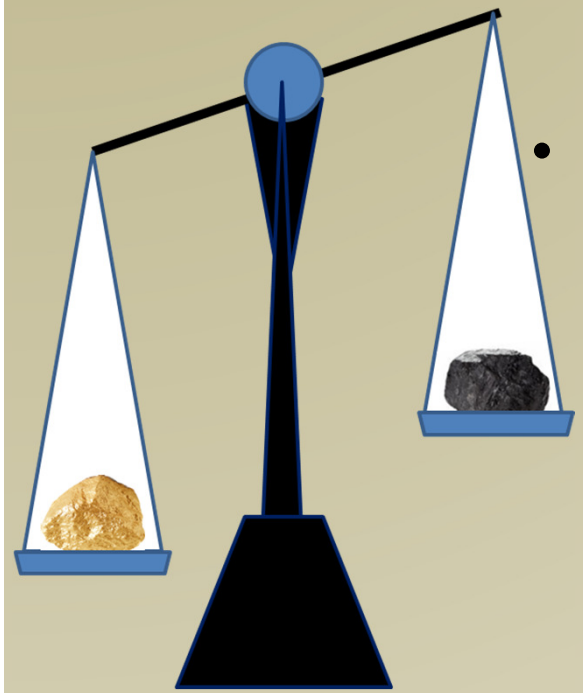
ACCREDITATION IS A VALUABLE PROCESS THAT CONTRIBUTES GREATLY TO QUALITY, BUT IT IS NOT A UNIVERSAL REQUIREMENT FOR ALL MEDICAL LABORATORIES IN ALL COUNTRIES

External Assessment
Recommendations
Positive Support
Updates
Support Commitment
Validation
Confirmation
Certificate



External Point of View
External Timetable
Cost

Quality without Accreditation
Rarely Works



- It is very difficult to sustain even over the short term the commitment and effort required without external validation and support.
- 75 percent of organizations that commit to ISO9001:2000 fail to maintain their quality system.

Paradoxes of ISO 9000 Performance: A Configurational Approach

Olivier Boiral and Nabil Amara

QMJ VOL. 16, no. 3/© 2009, ASQ: 36-60

Steps to Adoption

9. Commit to the standard

9. Commit to the Standard

- Being accredited the first time is an *ACHIEVEMENT* for which a laboratory can be pleased.
- Being accredited the second time is an ***ACCOMPLISHMENT*** of which the laboratory can be proud.

- ***The goal of process is not the receipt of a certificate; it is the confidence that the laboratory provides better and safer care with fewer errors and continuous focus on improvement.***

Workshop Exercise

- In the next phase of this workshop we will look at a number of clauses within ISO15189:2012, and discuss:
    1. What is the purpose off the clause
    2. How would you implement the clause
    3. How would you accomplish the clause
    4. How would you document the activity.

4.2.2.2 Quality manual

The laboratory shall establish and maintain a quality manual that includes:

a) the quality policy (4.1.2.3) or makes reference to it;

b) a description of the scope of the quality management system;

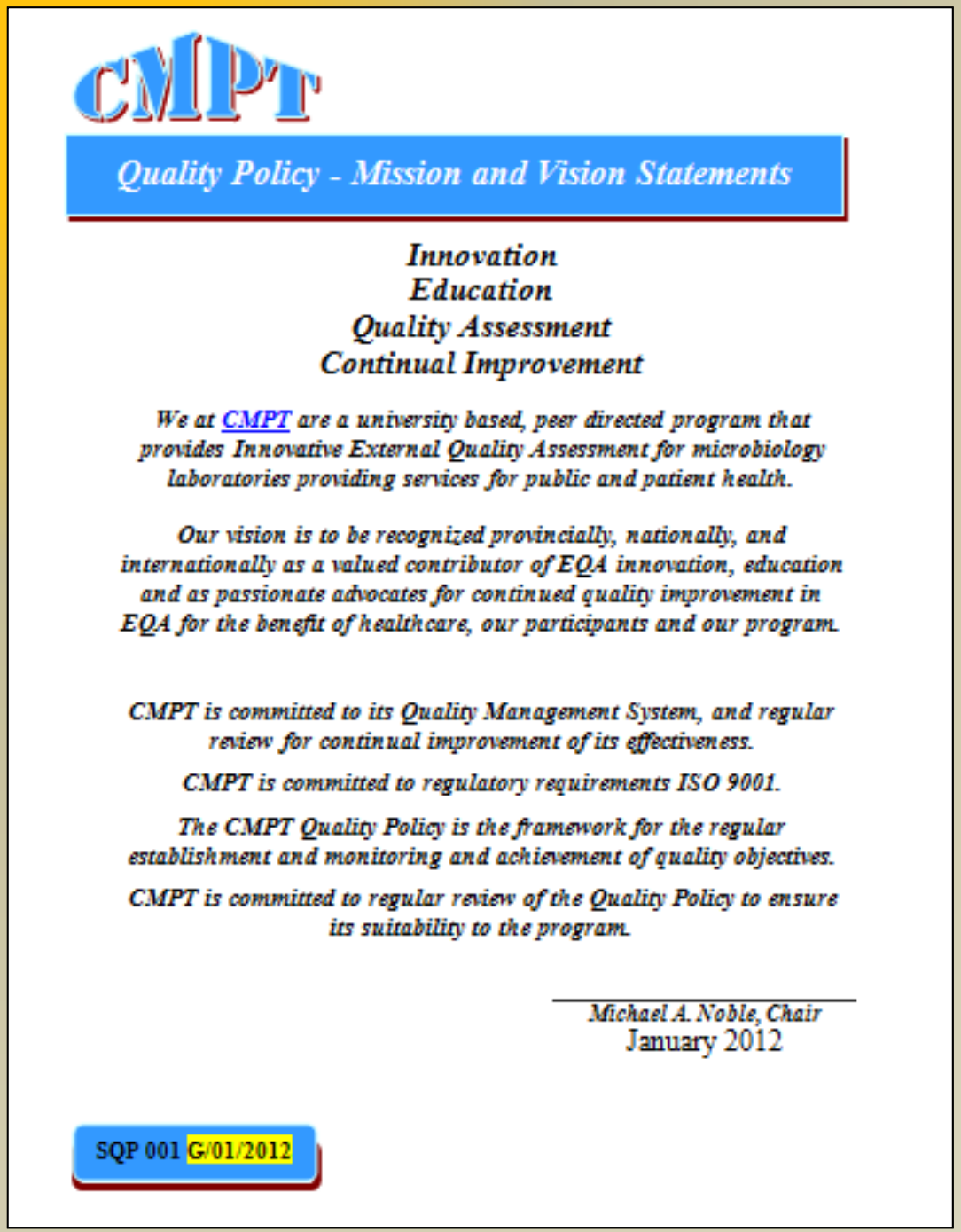
c) a presentation of the organization and management structure of the laboratory and its place in any parent organization;

d) a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard;

e) a description of the structure and relationships of the documentation used in the quality management system;

f) the documented policies established for the quality management system and reference to the managerial and technical activities that support them.

All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.



CMPT

Quality Policy - Mission and Vision Statements

Innovation
Education
Quality Assessment
Continual Improvement

We at CMPT are a university based, peer directed program that provides Innovative External Quality Assessment for microbiology laboratories providing services for public and patient health.

Our vision is to be recognized provincially, nationally, and internationally as a valued contributor of EQA innovation, education and as passionate advocates for continued quality improvement in EQA for the benefit of healthcare, our participants and our program.

CMPT is committed to its Quality Management System, and regular review for continual improvement of its effectiveness.

CMPT is committed to regulatory requirements ISO 9001.

The CMPT Quality Policy is the framework for the regular establishment and monitoring and achievement of quality objectives.

CMPT is committed to regular review of the Quality Policy to ensure its suitability to the program.

Michael A. Noble, Chair
January 2012

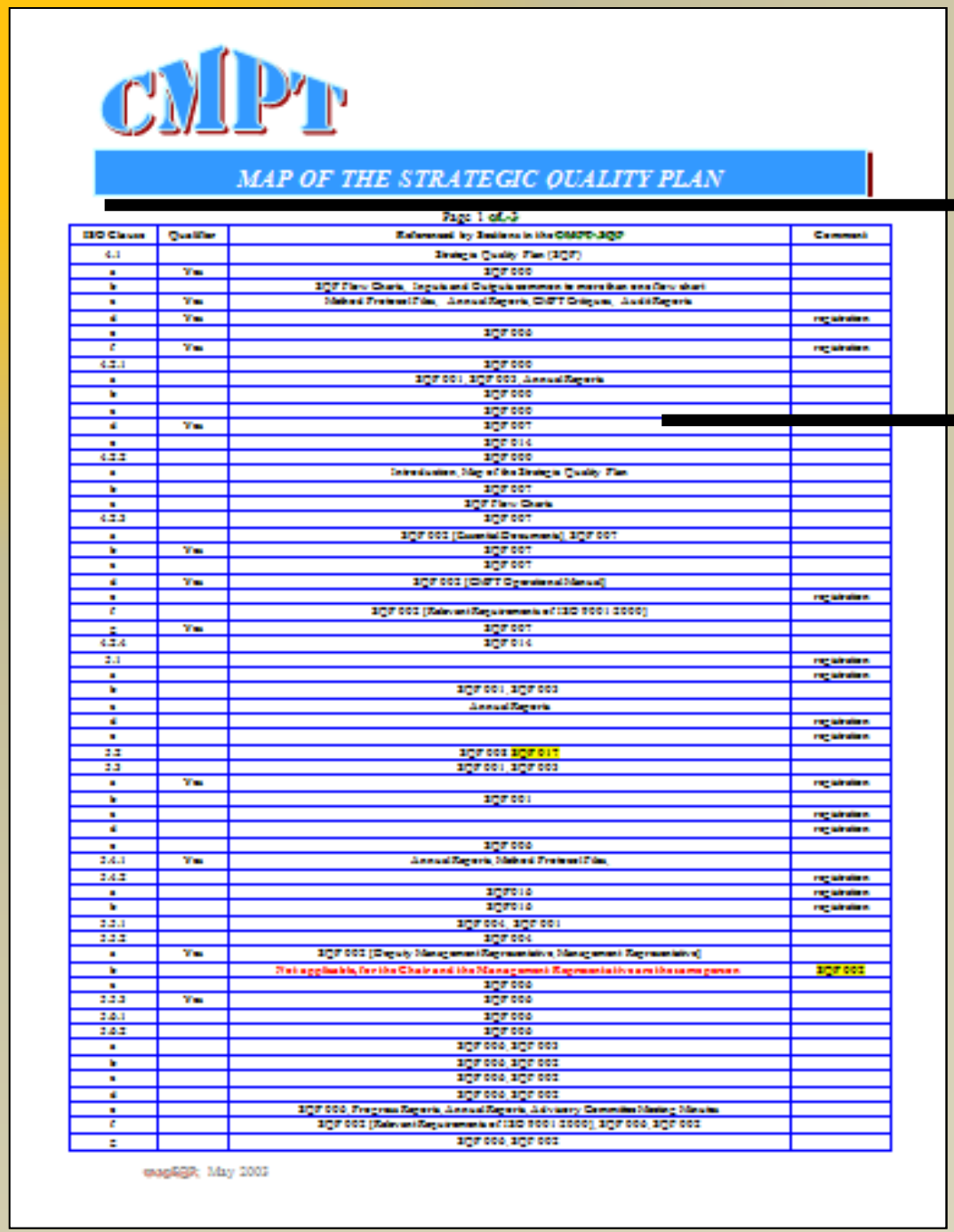
SQP 001 G/01/2012

→ SCOPE

→ STRUCTURE

→ ROLES

→ **DOCUMENT CONTROL**



CMPT

MAP OF THE STRATEGIC QUALITY PLAN

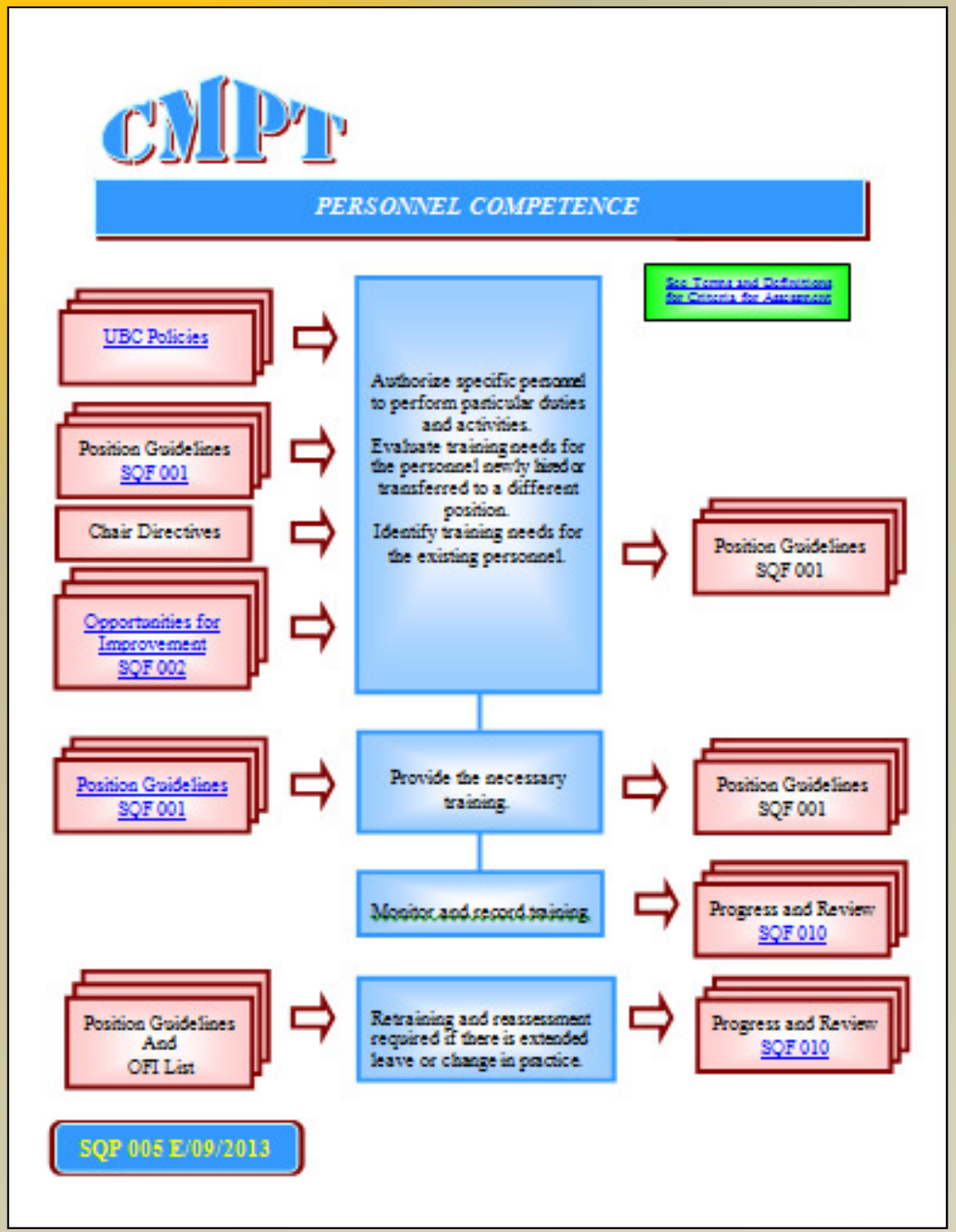
Page 1 of 2

ISO Clause	Qualifier	Reference by Sections in the CMPT-SQP	Comment
4.1		Strategic Quality Plan (SQP)	
a	Yes	SQP 000	
b		SQP Flow Charts, Inputs and Outputs common to more than one flow chart	
c	Yes	Method Protocol Files, Annual Reports, CMPT Critiques, Audit Reports	
d	Yes		registration
e		SQP 000	
f	Yes		registration
4.2.1		SQP 000	
a		SQP 001, SQP 002, Annual Reports	
b		SQP 000	
c		SQP 000	
d	Yes	SQP 007	
e		SQP 014	
4.2.2		SQP 000	
a		Introduction, Map of the Strategic Quality Plan	
b		SQP 007	
c		SQP Flow Charts	
4.2.3		SQP 007	
a		SQP 002 [Essential Documents], SQP 007	
b	Yes	SQP 007	
c		SQP 007	
d	Yes	SQP 002 [CMPT Operational Manual]	
e			registration
f		SQP 002 [Relevant Requirements of ISO 9001:2000]	
g	Yes	SQP 007	
4.2.4		SQP 014	
5.1			registration
a			registration
b		SQP 001, SQP 003	
c		Annual Reports	
d			registration
e			registration
5.2		SQP 003 SQP 017	
5.3		SQP 001, SQP 003	
a	Yes		registration
b		SQP 001	
c			registration
d			registration
e		SQP 000	
5.4.1	Yes	Annual Reports, Method Protocol Files	
5.4.2			registration
a		SQP 010	registration
b		SQP 010	registration
5.5.1		SQP 004, SQP 001	
5.5.2		SQP 004	
a	Yes	SQP 002 [Deputy Management Representative, Management Representative]	
b		Not applicable, for the Chair and the Management Representative are the same person	SQP 002
c		SQP 000	
5.5.3	Yes	SQP 000	
5.6.1		SQP 000	
5.6.2		SQP 000	
a		SQP 000, SQP 003	
b		SQP 000, SQP 003	
c		SQP 000, SQP 003	
d		SQP 000, SQP 003	
e		SQP 000, Progress Reports, Annual Reports, Advisory Committee Meeting Minutes	
f		SQP 002 [Relevant Requirements of ISO 9001:2000], SQP 000, SQP 003	
g		SQP 000, SQP 003	

map6QP, May 2003

CLAUSE IN STANDARD

CLAUSE IN MANUAL



A QUALITY MANUAL IS NOT ALWAYS
A BOOK

POLICIES DO NOT HAVE TO BE WRITTEN IN PARAGRAPHS IF OTHER FORMATS ARE EASIER TO UNDERSTAND:

- ***FLOW CHARTS***
- ***PICTURES***
- ***AUDIO CLIPS***
- ***VIDEO CLIPS***

POLICIES NEED REGULAR REVIEW AND DOCUMENT CONTROL

ISO 15189:2012:

4.14.5 Internal Audits

The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:

a) conform to the requirements of this International Standard and to requirements established by the laboratory, and

b) are implemented, effective, and maintained.

Microbiology Bench
Self Evaluation Survey

Bacteriology Bench

Manuals	Examine all manuals relevant to	**Yes**	**No**	**NA**
Is there a written manual (or clearly identifiable sections in a number of manuals) readily available that describes the procedures required to fulfill the work requirements for processing Bacteriology samples				
Is the manual (or the sections of manuals pertaining to Bacteriology samples) up to date and signed off by the appropriate person?				
If there is more than one copy of the manual available, are all copies identical in content and sign-off				
If sections pertaining to Bacteriology samples are located in different books, or locations, is there a documented pathway to give guidance to finding to relevant sections as required?				
Additional comments on manuals and documentation available for working on Bacteriology samples.				

Accessioning verification	Examine all samples received for Bacteriology samples TODAY	**Yes**	**No**	**NA**
Are all Bacteriology samples received in the correct container as identified in the manual as being required and appropriate for the sample?				
When samples were received in incorrect containers, were they rejected for Bacteriology analysis?				
Are all Bacteriology samples traceable to the patient (are they labeled by either name or number?)				
Additional comments on the initial accessioning of Bacteriology samples:				

For a copy of the Internal Audit Master form

visit

www.POLQM.ca

ISO 15189:2012

4.14.3 Assessment of user feedback

The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users.

The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users.

Records shall be kept of information collected and actions taken.

How to collect user feedback

Complaints *and* ***Kudos***

Deposit forms

Paper Surveys

On-line Satisfaction Surveys

Social Media

Information Days

Interviews

ISO 15189:2012

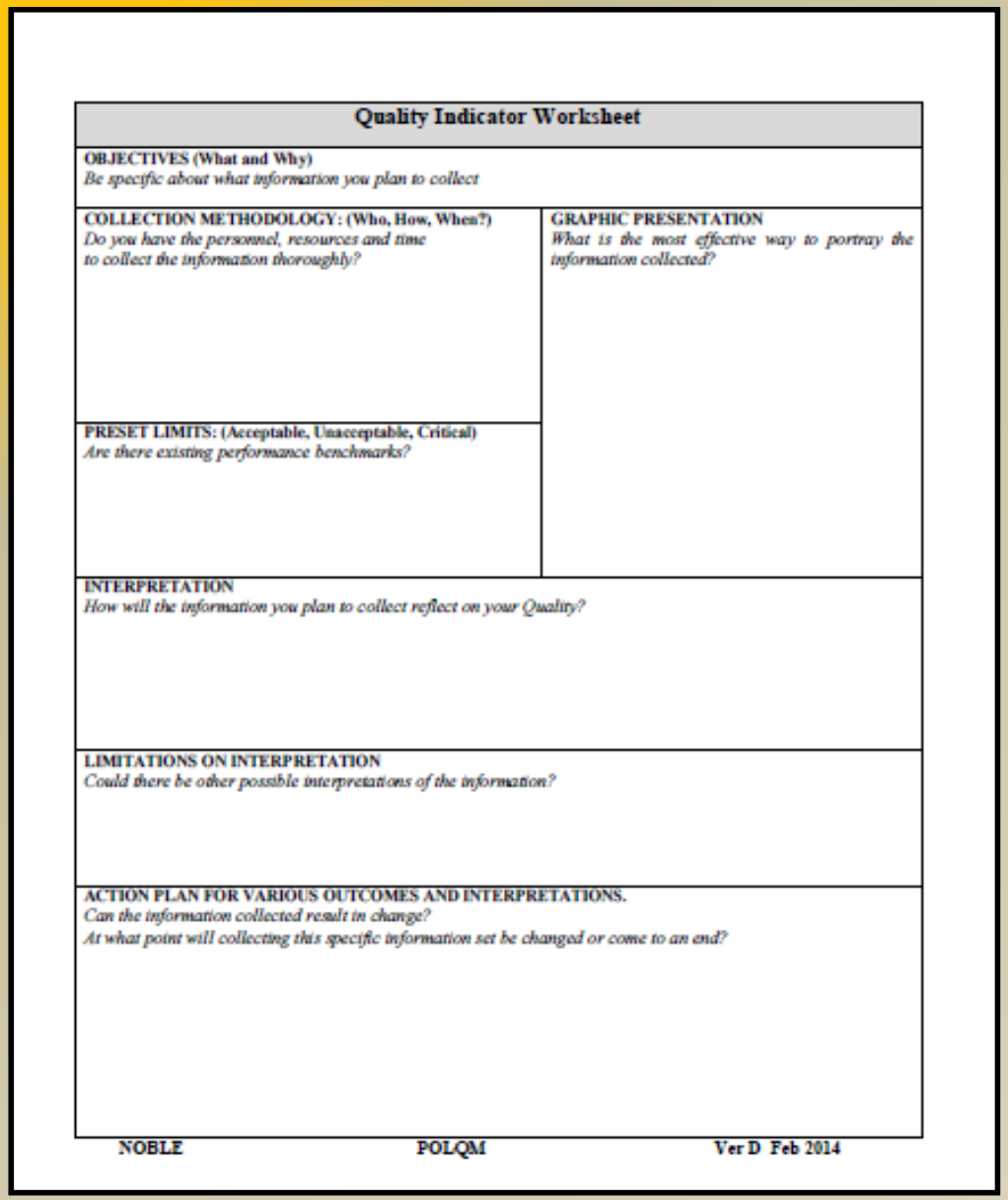
4.14.7 Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

EXAMPLE *Number of unacceptable samples, number of errors at registration and/or accession, n umber o f corrected reports.*

The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

The indicators shall be periodically reviewed, to ensure their continued appropriateness.



Quality Indicator Worksheet

OBJECTIVES (What and Why)
Be specific about what information you plan to collect

COLLECTION METHODOLOGY: (Who, How, When?)
Do you have the personnel, resources and time to collect the information thoroughly?

GRAPHIC PRESENTATION
What is the most effective way to portray the information collected?

PRESET LIMITS: (Acceptable, Unacceptable, Critical)
Are there existing performance benchmarks?

INTERPRETATION
How will the information you plan to collect reflect on your Quality?

LIMITATIONS ON INTERPRETATION
Could there be other possible interpretations of the information?

ACTION PLAN FOR VARIOUS OUTCOMES AND INTERPRETATIONS.
Can the information collected result in change?
At what point will collecting this specific information set be changed or come to an end?

NOBLE POLQM Ver D Feb 2014

For a copy of the Quality Indicator Worksheet

visit

www.POLQM.ca

ISO 15189:2012

5.1.6 Competence assessment

Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria.

Reassessment shall take place at regular intervals. Retraining shall occur when necessary.

How to measure Competency

- Direct observation
- On-line information challenge
- Proficiency Testing challenges
- Simulation challenges

How to measure Competency

- Direct observation
- On-line information
- Proficiency T
- Sim

The more threatening the challenge, the less useful the result

In summary

- Implementing a Quality Standard will take Time, Effort, Energy and Money
- Is the ***COST*** worth the ***PRICE***?

Yes ? **or** *Yes !*