ISO 20387 *Biotechnology – Biobanking – General requirements for biobanking*: A Standard that is Fit for Purpose

Clare M. Allocca, PMP

Secretary, US Mirror Committee to ISO/TC276 *Biotechnology*
Manager, ISO/TC276/WG3 *Analytical methods*
Manager, ISO/TC212-TC276/JWG6

National Institute of Standards & Technology (NIST), USA

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Today's Objectives

- Why did we develop ISO 20387?
- Who are we targeting?
- What is ISO 20387?
- Central Concepts:
  - *Biobanking*
  - *Biological material and associated data* (BMaD)
  - *Fitness-for-an-Intended-Purpose* (FIP)
- ISO 20387 as a Conformity Assessment Standard
- Why pursue ISO 20387, and how thoroughly?
- What is ISO/TR 22758 , and how can it be used as an implementation guide?
- How do these documents work within the biobanker's toolbox?
- What's next?

What Motivated Development of ISO 20387?

Motivation: robustness and reliability of research undertaken with BMaD, supporting quality and reproducibility

Intent: biobanks could choose to pursue all or part of the standard

Development Path:

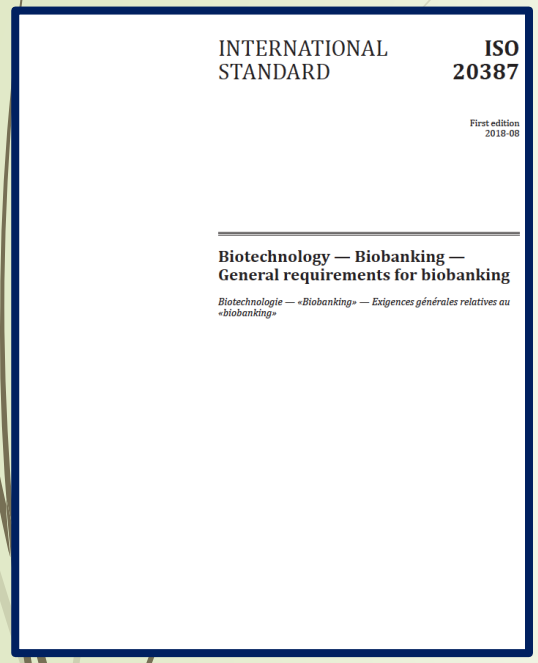
- Comparative analysis of
  - Best Practices & Guidelines: ISBER, IARC, OECD, NCI, NFS96-900
  - Conformity assessment standards: ISO/IEC 17025, 17034, 15189

Gaps identified:

- Terminology interpretation for biobanking community
- Environment
- Premises
- Equipment
- Staff competence and training
- Validation of methods
- QC of BMaD
- Non-conforming products
- Impartiality & confidentiality

All of the above informed the development of ISO 20387

ISO 20387: 2018 *Biobanking – General requirements for biobanking*


INTERNATIONAL STANDARD

ISO 20387

First edition
2018-08

Biotechnology — Biobanking — General requirements for biobanking

Biotechnologie — «Biobanking» — Exigences générales relatives au «biobanking»

- **What?** requirements to enable:
  - Demonstration of **competent biobank operation**
  - Ability to provide BMaD of **appropriate quality for research and development (FIP)**
- **How?**
  - Planning / implementation of **policies, processes and procedures** covering BMaD life cycle
- **Why?**
  - Promote **confidence** in biobanking.
  - **Cooperation /exchange / harmonization** of practices

BMaD = Biological Material and Associated Data
FIP = Fitness for an Intended Purpose

What is included in ISO 20387?

1,2,3. Scope, Normative References, Terms & Definitions

4. General Requirements

5. Structural Requirements

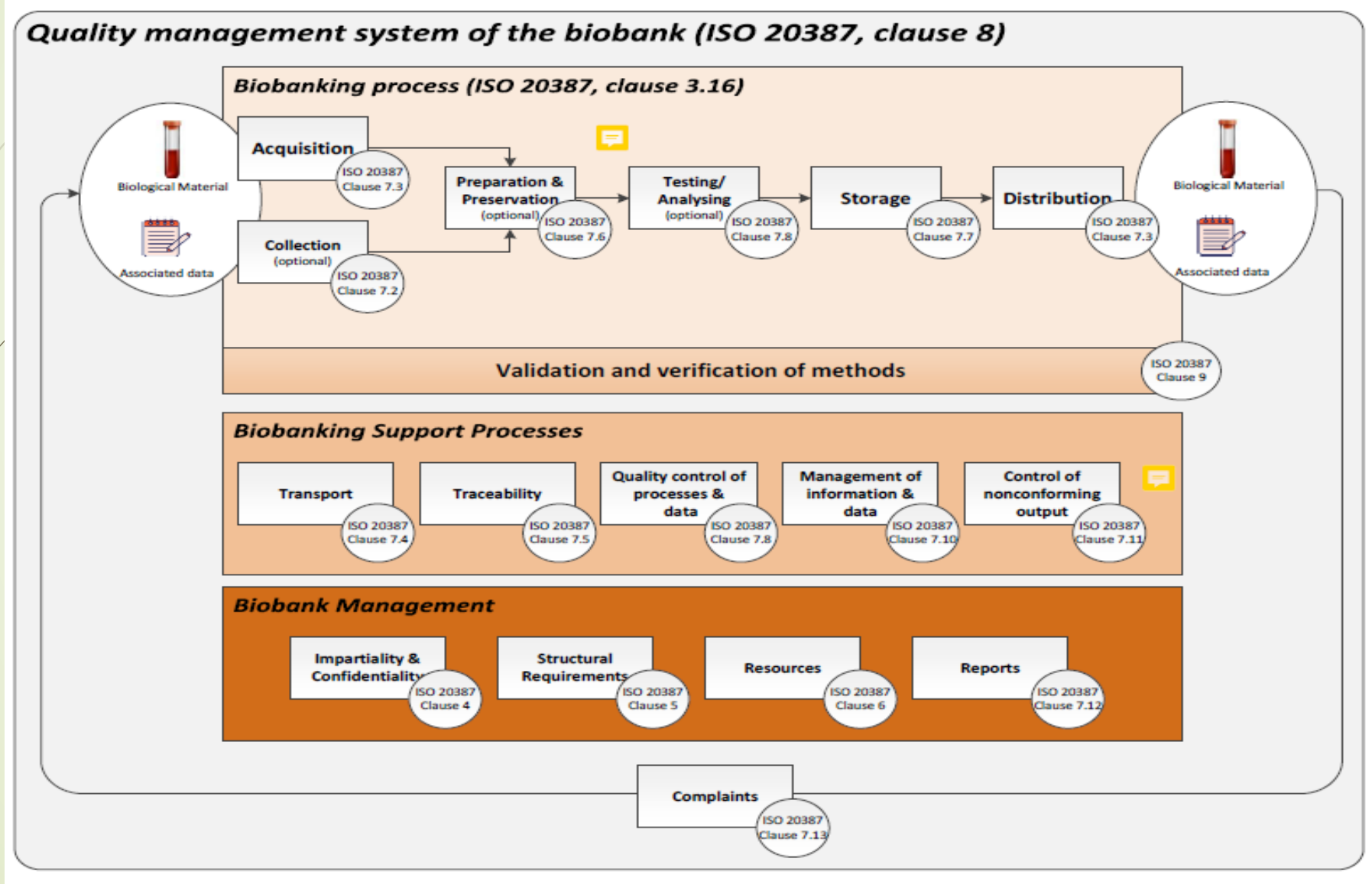
6. Resource requirements

7. Process Requirements

8. Quality Management System Requirements

Biobanking:
process of *acquisitioning* (3.2) and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data
(Ref: ISO 20387)

Biobanking Process Landscape



Concepts: Biological Material and Associated Data (BMaD)

Biological Material:
any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi) (Ref: ISO 20387)

Associated Data:
any information affiliated with biological material including but not limited to research, phenotypic, clinical, epidemiologic, and procedural data (Ref: ISO 20387)

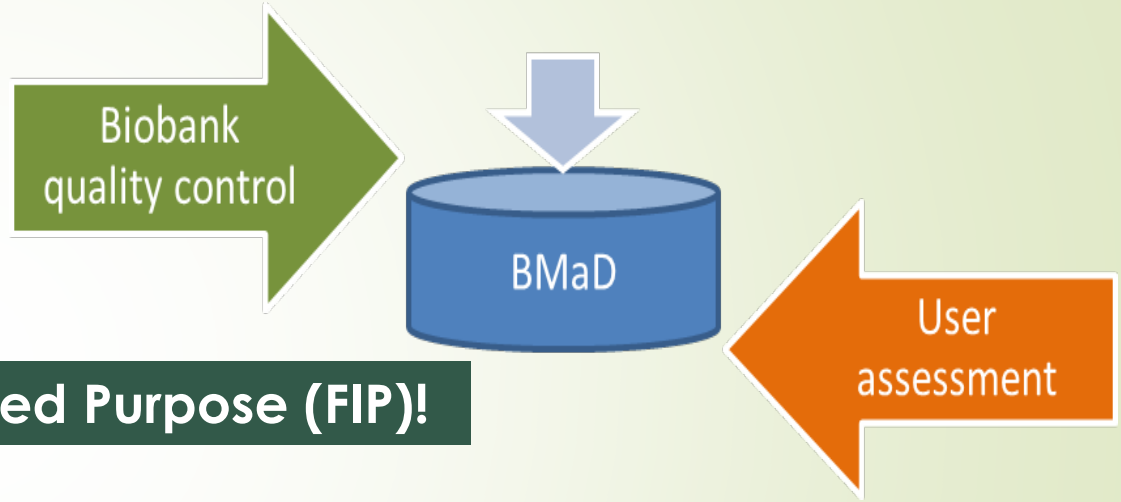
Biological Material & Associated Data (BMaD) objective:

to enable robust and reliable research and development.

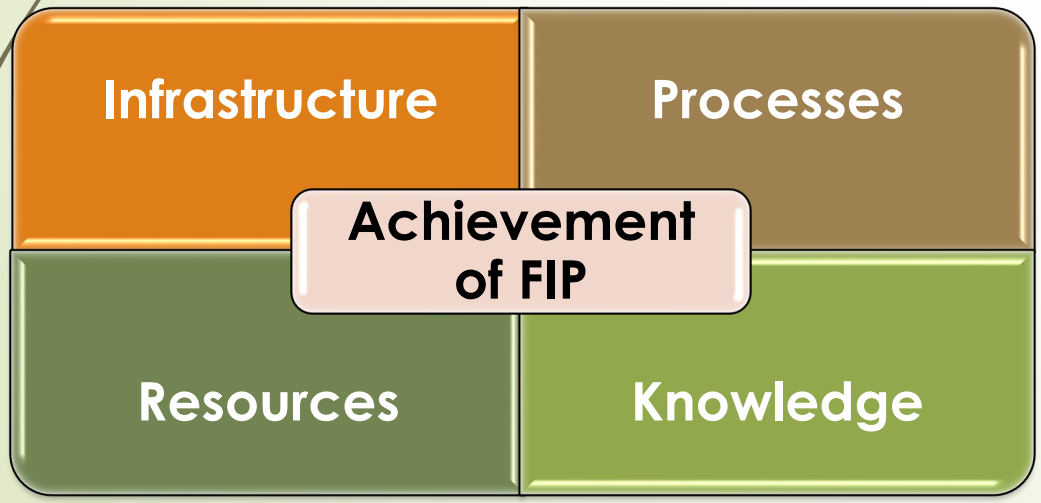
Requirements developed around Central Concepts: Fitness for an Intended Purpose (FIP) for BMaD

Biological Material and Associated Data (BMaD)…

BMaD objective: to enable robust and reliable research and development.



…that is Fit for an Intended Purpose (FIP)!

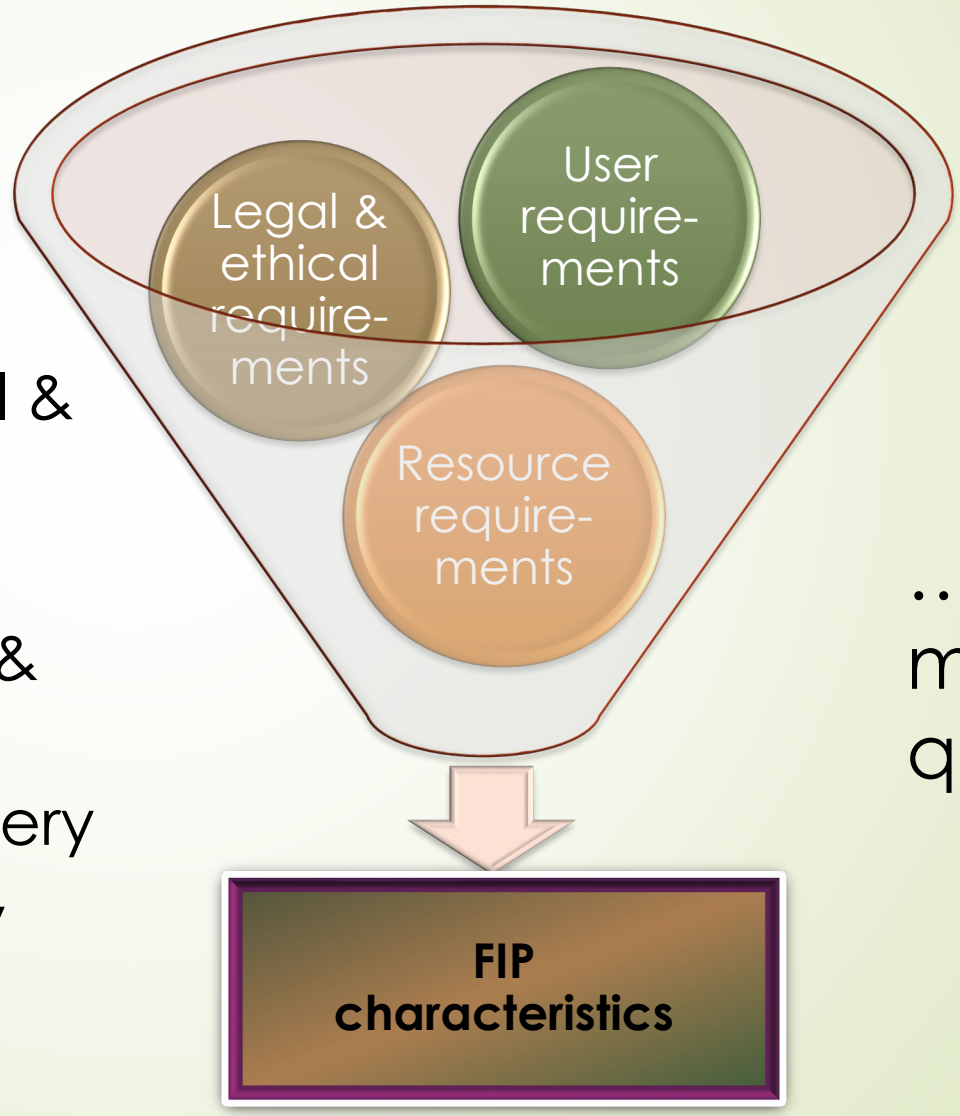


FIP: in line with prearranged requirements for an intended use (ISO 20387)

→ effective, efficient biobank operations

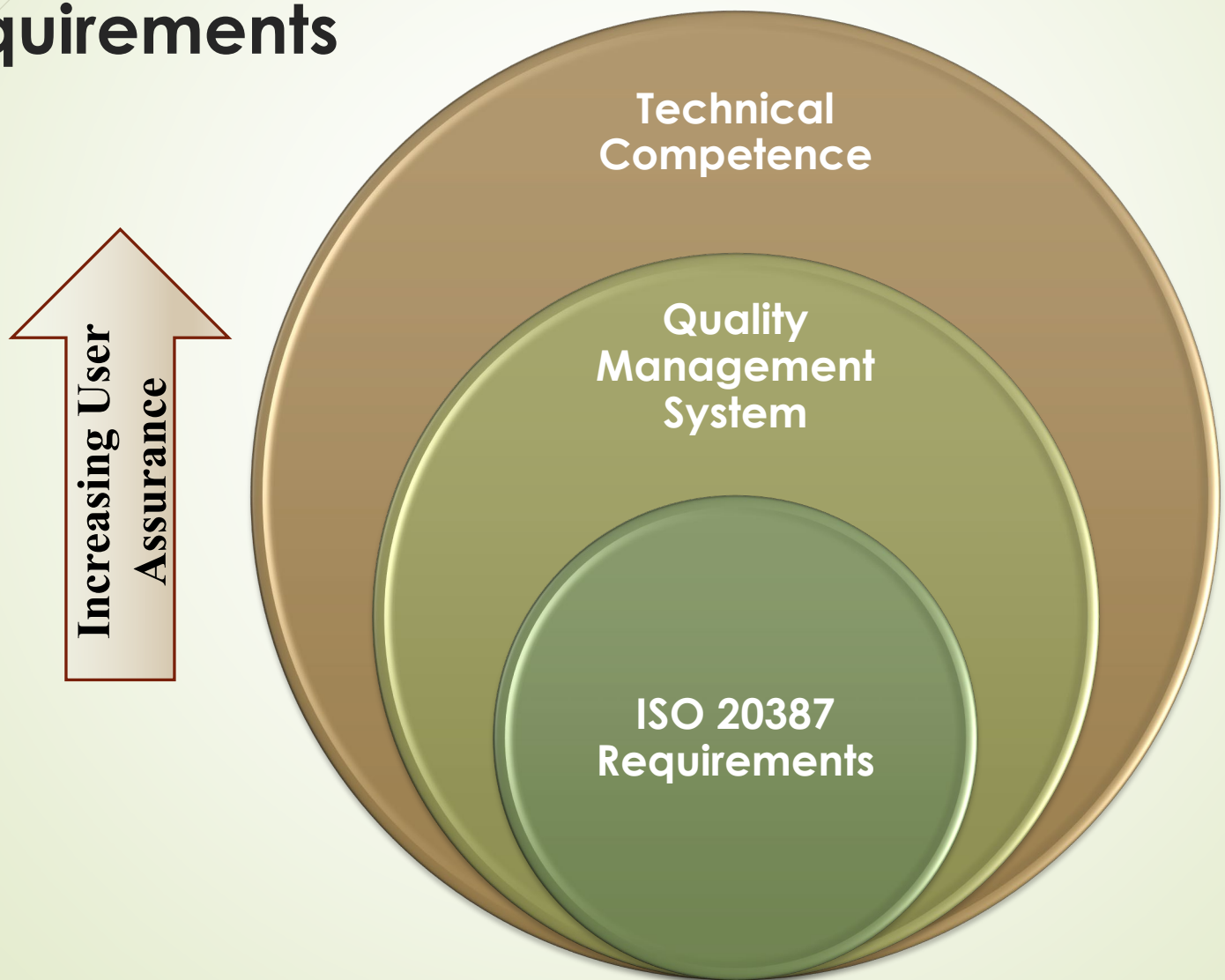
Considerations of *Fitness for an Intended Purpose (FIP)*

- Client requirements
- Risk tolerance
- Rarity of specimens
- Regional, environmental & economic status
- Specimen stability
- Biobank size, resources, & experience
- Pace of scientific discovery
- Need for interoperability



…much more than quality

ISO 20387, a Conformity Assessment (CA) Standard: "Triple Play" of Competence, Management System Principles & Specific Requirements

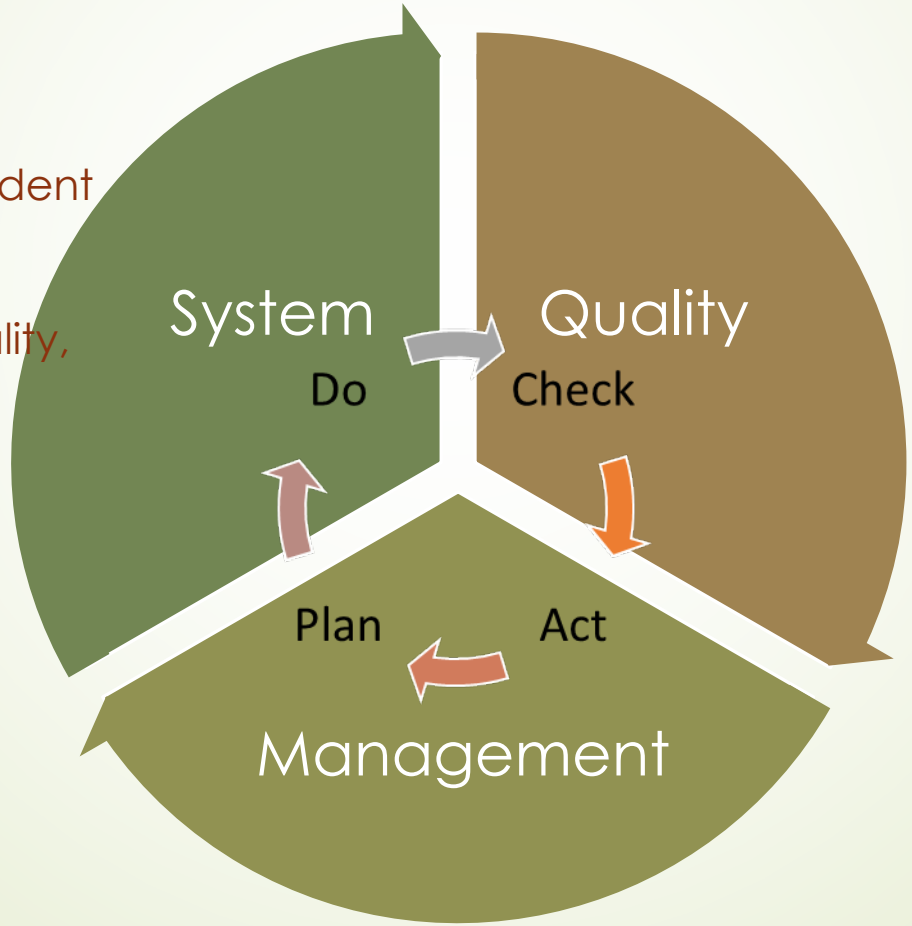


Quality Management System (QMS): Necessary Component of CA Standard

A **QMS** operational platform enables a Biobank to:

- capture needs & requirements (input)
- transfer inputs in processes facilitating the production of compliant BMaD (output)
- add fitness to legacy BMaD (esp. biodiversity samples) for FIP

- Set of interrelated and dependent components (e.g. processes, resources) working together
- Common objectives (e.g. quality, satisfaction, compliance)
- Inputs and outputs
- Collaboration
- Defined boundaries



- Design of criteria
- Fit for intended purpose
- Degree of fulfilment
- Conformance and compliance
- Use and value of resources
- Liability

- Planning
- Organizing recourses
- Leading
- Monitoring
- Reflection
- Communication

Conformity with ISO 20387: Opportunity for Demonstration of Competence

Conformity Assessment may include the following & more:

- ☑**Quality Mgt:** Does QMS include all elements required by the standard?
- ☑**Competence**: Are staff trained and tested on procedures?
- ☑**Compliance:** Are procedures and policies appropriate and being followed? Are any metrics being monitored?

Evidence or Attestation

3rd Party*: Accreditation or Certification

Certificate

2nd Party: Agreement

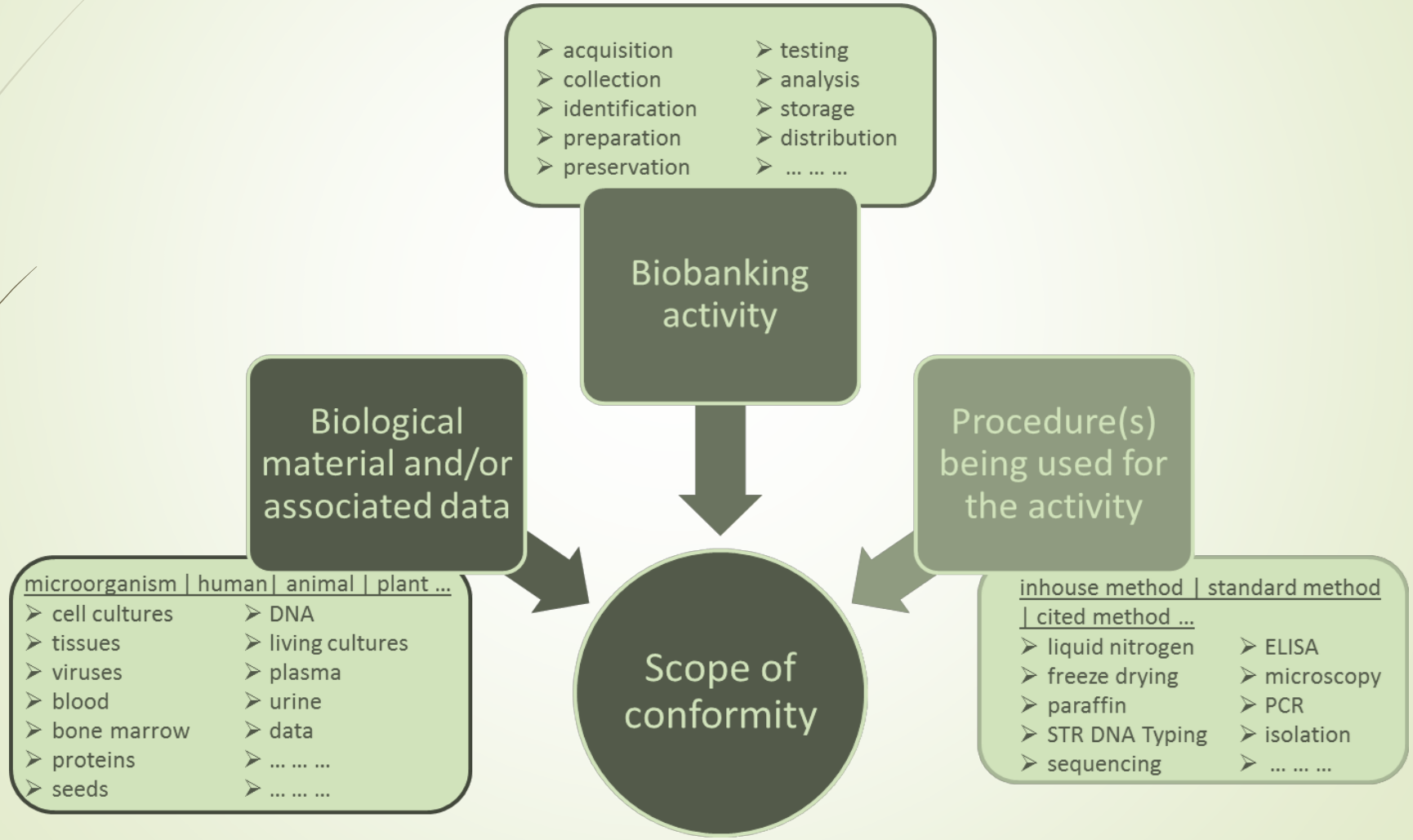
Contract

1st Party: Self-declaration

Assertion

*Example: CAP provides certificate of accreditation for a competence standard like ISO 17025, or certification for QMS per ISO 9001

Components of a Scope of Conformity



ISO 20387, a Conformity Assessment Standard: How does its Implementation Differ from other Standards?

Development of Standard

- ISO/TC276/WG2
- Coordinate with CASCO
- Communication with ISO/TC176
- Consider context of related standards and other tools

Implementation of Conformity Assessment

- Establish ISO 20387 in Accreditation Structure (e.g. ILAC, APAC)
- Create MRAs to establish reciprocity in accreditation for involved countries

Create Infrastructure to enable Assessment

- Value proposition for ABs and assessors
- Value proposition for Biobankers
- Value to Biobank users
- Relation to existing standards

Each step is a multi-year process

Why (and How Thoroughly) Pursue ISO 20387?

- Demands of biotech products are increasing in complexity and diversity while decreasing in product development cycle times
- Biological materials and associated data must be increasingly more characterized, predictable, and assured
- I want my biobank to be as fit for purpose as it can possibly be!
- My customers require it to do business at all
- Regulations require it
- I must do it to demonstrate product differentiation from my competitors
- For cooperative research with another lab, want to make sure processes are harmonized

Keep in Mind: ISO 20387 at any Level is a Business Evaluation of Return on Investment

- What does FIP mean to your biobank?
- Return on Investment: This calculation requires understanding:
  - Requirements
  - QMS
  - Conformity Assessment
  - FIP criteria
  - Other biobanking considerations
  - Integration with Business Plans and Other Tools and Resources

ISO/TR 22758:2020 *Biotechnology – Biobanking - Implementation guide for ISO 20387*

Scope

- What? Guides biobanks on:
  - Implementation of quality management, management, and technical requirements of ISO 20387.
    - Expands and provides illustrative examples
  - How to address competency of personnel and appropriate quality of BMaD collections
- Who? All organizations performing biobanking:
  - Includes biobanking of biological material from multicellular organisms (e.g., human, animal, fungus and plant) and microorganisms for research and development.
  - Excludes biological material intended for feed/food production, laboratories undertaking analysis for food/feed production and/or therapeutic use.

Topics

- Implementation of ISO 20387
- Fitness for the Intended Purpose (FIP)
- Biological Material and Associated Data (BMaD)
- Process Landscape
- Conformity with ISO 20387
- Guidance on interpretation of specific text in ISO 20387

How a Biobank might use ISO 20387 along with the Implementation Guide (ISO 22758)

- Consider ISO 22758 in the context of your own goals when deciding what to use and how to use it
  - As a foundational standard, ISO 20387 was intentionally broad…its later revisions may become more specific
- Consider your intended use of the document:
  - Maximize FIP?
  - Become accredited
  - Take actions with your intended goal in mind
- Consider the many tools in the context of your biobank's purpose and goals, and select accordingly
- The FIP tools that you use need to be fit for purpose for your particular biobank!

The Biobanker's Toolbox: Types

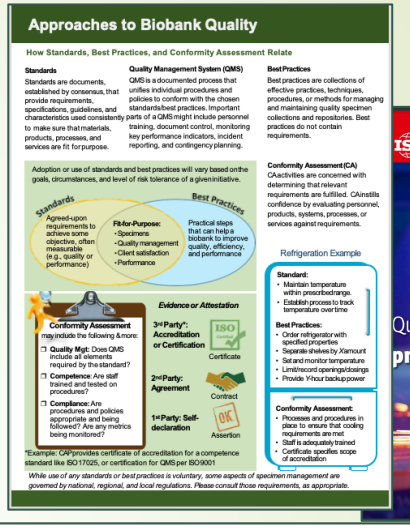
*Fitness for an Intended Purpose

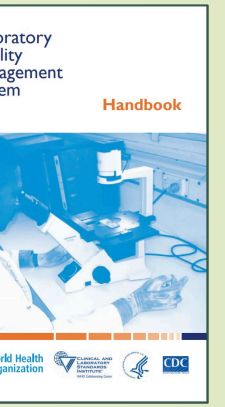
The Path Forward: Developing Mechanisms for an ISO 20387 Revision

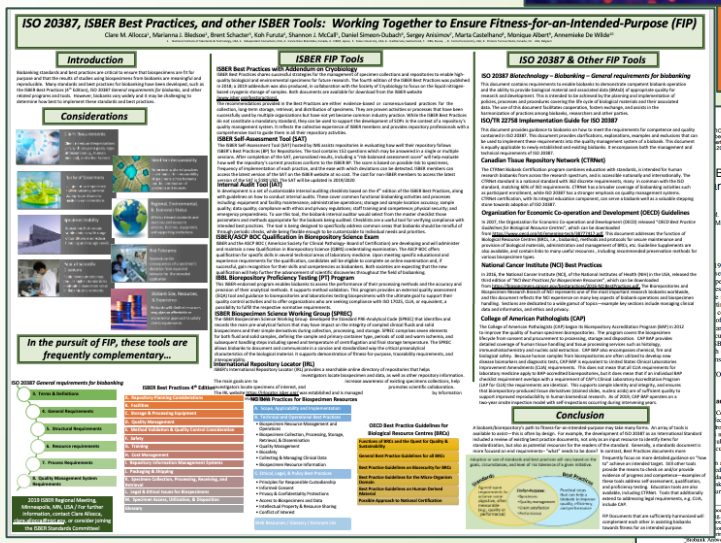
- ISO 20387 is preparing for its first systematic review: Your input is needed!
  - ISBER will be soliciting input, as well as other groups
- Conformity assessment infrastructure will continue to solidify
- Education and awareness opportunities will be available, including some that will broadly address standardization, accreditation, conformity assessment, combined/aggregated use of tools and resources along with ISO 20387

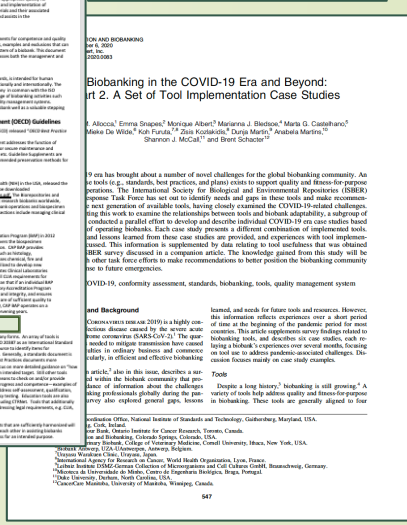
Resources for ISO 20387 Awareness

- Handout:
  - Allocca, CM with ISBER Standards Committee, **Approaches to Biobank Quality**
- QMS Publications:
  - ISO, Quality Management Principles
  - WHO et al, Laboratory Quality Management System Handbook
- Poster:
  - Allocca, CM et al, **ISO 20387, ISBER Best Practices, and other ISBER Tools: Working Together to Ensure Fitness-for-an-Intended-Purpose (FIP)**
- Articles:
  - Allocca, CM et al, Biobanking in the COVID-19 era and Beyond: Part 1. How Early Experiences can Translate into Actionable WIsdom
  - Allocca, CM et al, Biobanking in the COVID-19 era and Beyond: Part 2. A Set of Tool Implementation Case Studies









Thank you.

Any questions?

Scope: Who is our Audience?

- **Applicable** to organizations performing biobanking:
  - **Domain**: biological material from multicellular organisms (e.g., human, animal, fungus and plant) and microorganisms for research and development.
  - **Maturity**: , e.g., newly established and existing biobanks.
  - **Processes**: with processes for acquisition and storage, as a minimum, but may also include such processes as collection / procuring and/or acquiring and receiving, tagging, accession into / logging, cataloguing / classifying, examining, preparing preserving, storing, managing data, destroying, packaging as well as safeguarding, distributing and transporting
  - **Location / Economic Status**: in countries of diverse economical scales
  - **Intended Use of ISO 20387**: e.g., applying conformity assessment principles to biobanking
  - **Structure**: multiple sites, virtual…
- **Not applicable** to
  - biological material intended for feed/food production, laboratories undertaking analysis for food/feed production and/or therapeutic use.

Terminology: Guiding Principles

Standards are documents, established by consensus, that provide requirements, specifications, guidelines, and characteristics used consistently to make sure that materials, products, processes, and services are fit for purpose.

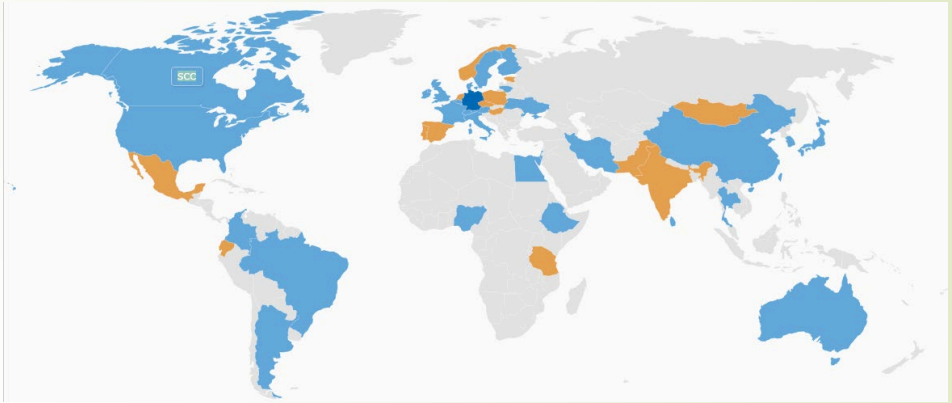
Quality Management System (QMS) is a type of standard that unifies individual procedures and policies to conform with the chosen standards/best practices. planning, etc

Best Practices are collections of effective practices, techniques, procedures, or methods for managing and maintaining quality specimen collections and repositories.

Conformity Assessment activities are concerned with determining that relevant requirements are fulfilled.

ISO/TC276 *Biotechnology* and ISO/TC276/WG2 *Biobanks & bioresources*

- Established February 2013
- 31 Member Countries
- 16 Observer Countries
- 11 Published Standards



ISO/TC276 Scope:

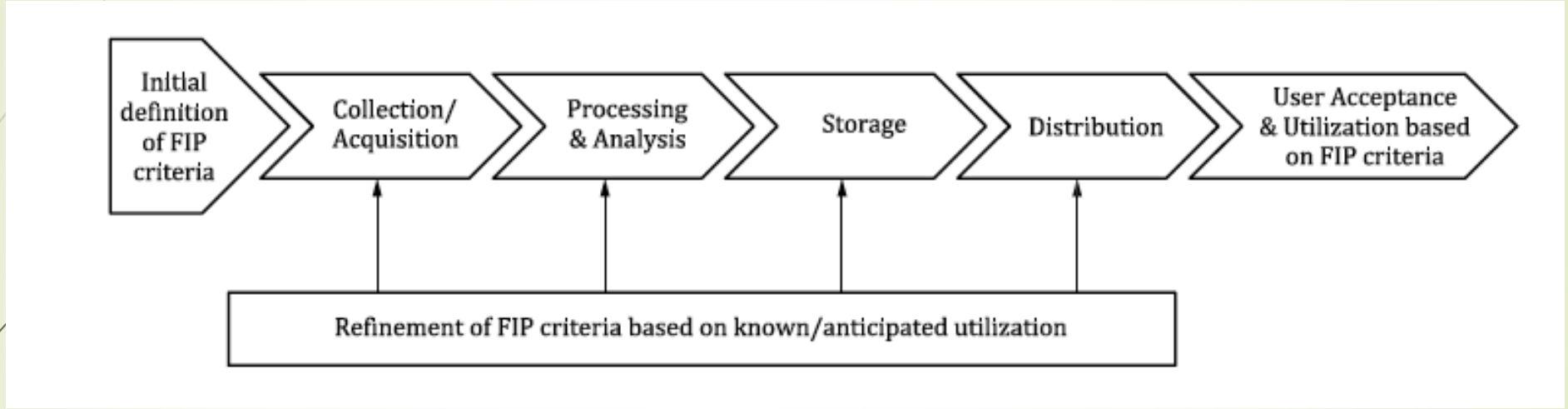
Standardization in the field of Biotechnology processes that includes the following topics:

1) terms and definitions;
2) biobanks and bioresources;
3) analytical methods;
4) bioprocessing;
5) data processing including annotation, analysis, validation, comparability and integration;
6) metrology.

ISO/TC276/WG2 Scope:

The ISO/TC 276/WG 2 will elaborate a package of International Standards in the Biobanks field including human, animal, plant and microorganism resources for Research & Development aspects, but excluding clinical diagnosis and therapeutics as well as highly regulated sectors such as food production and agriculture

Progression of BMaD and associated FIP criteria over its life cycle

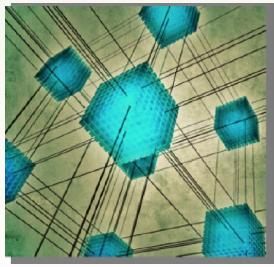


ISO 20387 defines a *biobank* (ISO 20387:2018, 3.5) as *a legal entity or part of a legal entity that performs biobanking*, and the term *biobanking* (ISO 20387:2018, 3.6) as *the process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data*.

FIP Considerations

Client Requirements

Client needs and expectations vary with program goals, type of research (e.g., human medical), and other factors



Need for Interoperability

Adherence to shared practices can enhance the comparability of specimens across biobanks and the combination of specimen and datasets

Rarity of Specimens

Unique or rare specimen collections may present both pros and cons to business considerations

Regional, Environmental, & Economic Status

Affects relevant standards and practices and access to services, facilities, equipment, and supporting institutions

Specimen Stability

Specimens that remain stable under a wide range of conditions may reduce handling and storage needs

Biobank Size, Resources, & Experience

Biobanks with limited resources may plan an affordable or incremental approach to satisfy client requirements

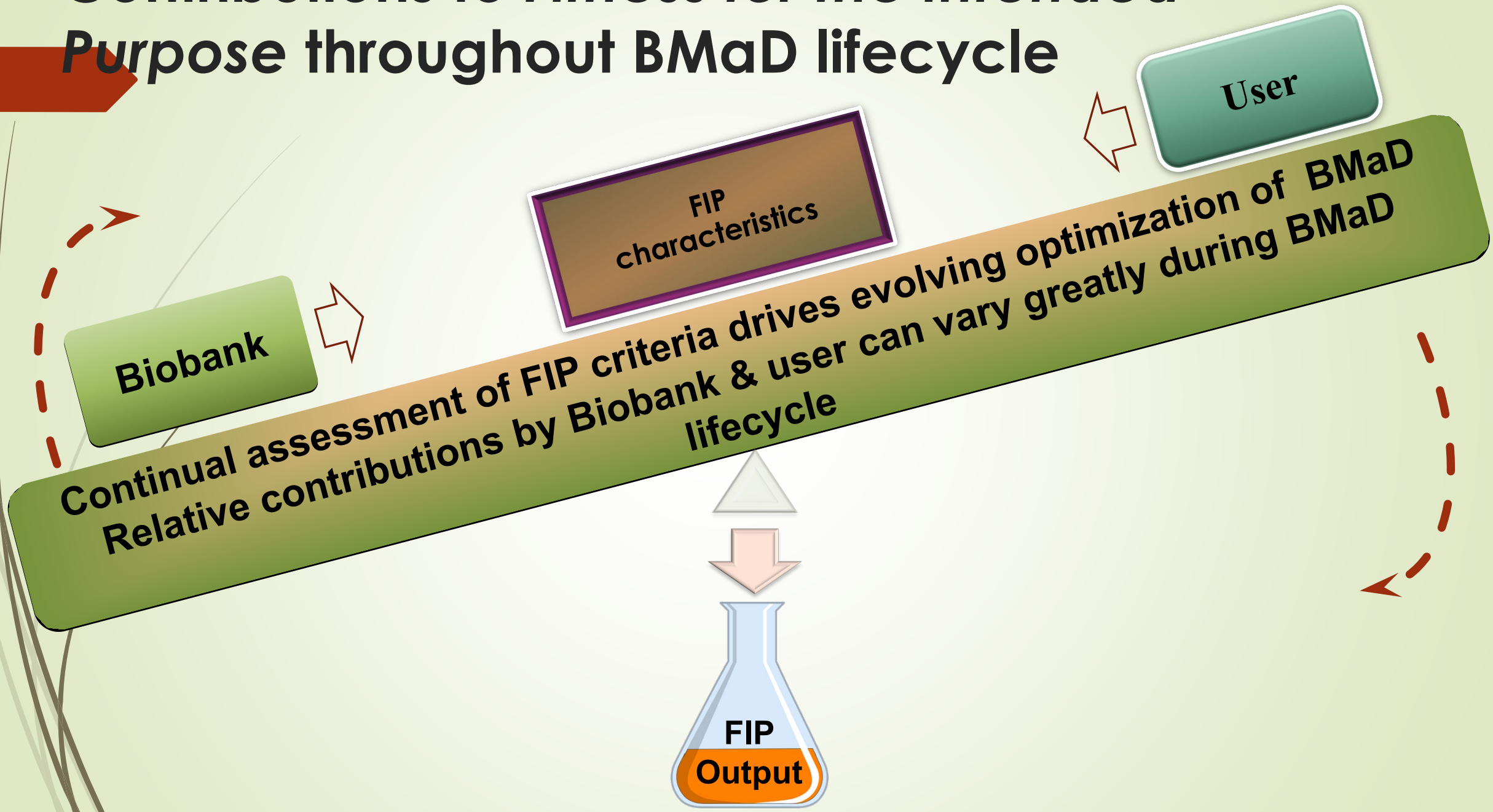
Pace of Scientific Discovery

Rapid developments may require higher standards to maintain biospecimen value in dynamic environments

Risk Tolerance

Depends on the consequences of a specimen's deviation from expected behavior for the intended application

Contributions to *Fitness for the Intended Purpose* throughout BMaD lifecycle



The Biobanker's Toolbox: Examples

Organizational Plans & Resources

- Business Plan
- Business Continuity Plan (BCP)
- Emergency Preparedness Plan
- Other General/Strategic Documents

Best Practices & Guidelines

- ISBER Best Practices with Addendum on Cryobiology 4th Ed.
- OECD Best Practice Guidelines for Biological Resource Centres (BRCs)
- NCI Best Practices for Biospecimen Resources

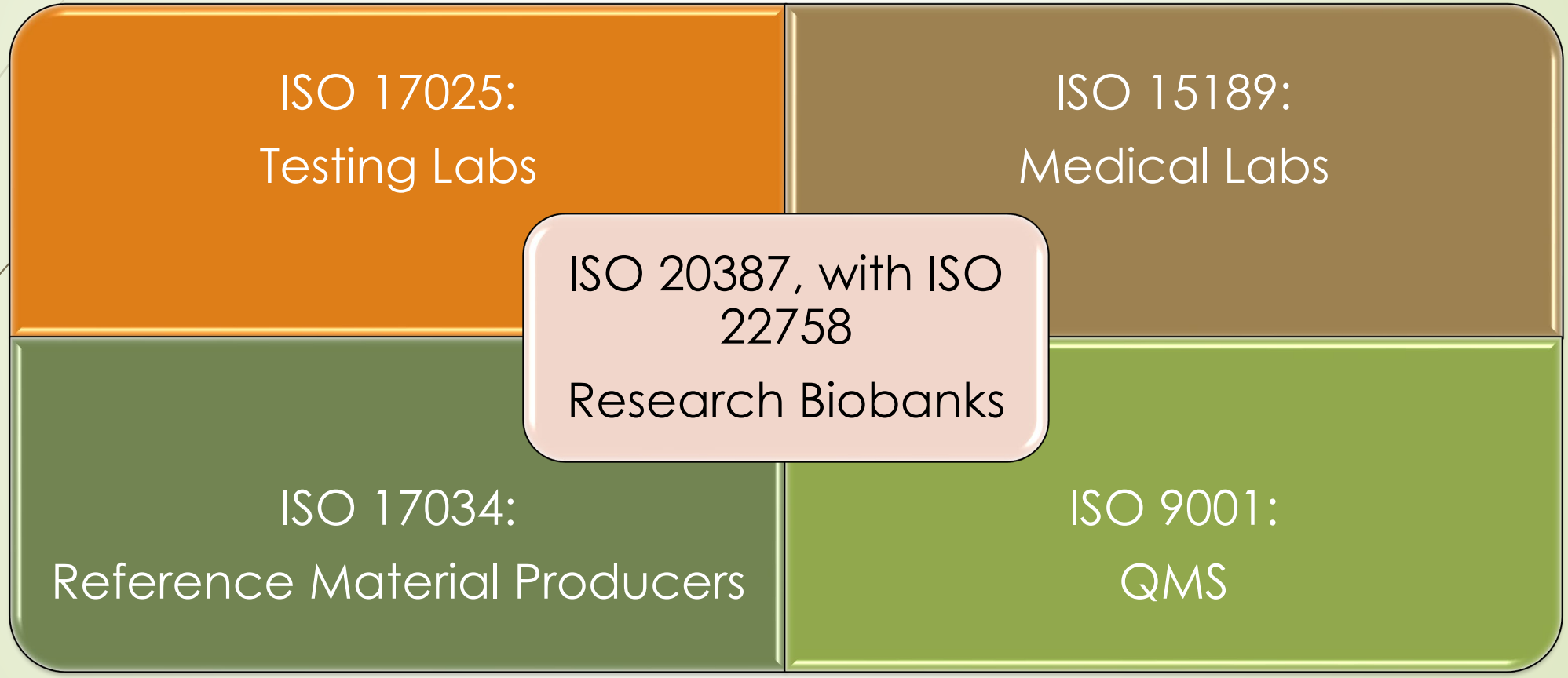
Targeted Tools & Education

- ISBER Self-Assessment Tool (SAT)
- Auditing Tools
- ISBER/ASCP BOC Qualification in Biorepository Science Exam
- IBBL Biorepository Proficiency Testing (PT) Program
- ISBER Biospecimen Science Working group (SPREC)

Standards and Related Documents

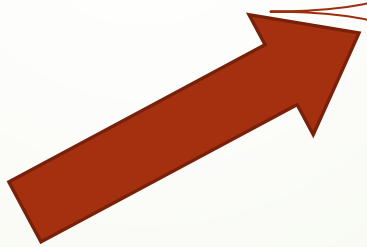
- ISO 20387:2018 *General requirements for biobanking*
- ISO 9001:2015 *Quality Management Systems -- Requirements*
- ISO 15189:2012 *Medical laboratories – Requirements for quality & competence*
- ISO 17025:2017 *Requirements for competence of testing & calibration labs*
- Canadian Tissue Repository Network (CTRNet)
- College of American Pathologists (CAP)

ISO 20387: Complementary Tool to other Conformity Assessment and Management System Standards



ISO 22758 Biotechnology – Biobanking - *Implementation guide for ISO 20387*

- 1,2,3. Scope, Normative References, Terms & definitions
- 4. Background information for the development of ISO 20387
- 5. Fitness for the intended purpose
- 6. Process landscape
- 7. Conformity with ISO 20387
- 8. Guidance on the interpretation of certain ISO 20387:2018 text parts



- 3. Terms & Definitions
- 4. General Requirements
- 5. Structural Requirements
- 6. Resource requirements
- 7. Process Requirements
- 8. Quality Management System Requirements

ISO 20387 vs. ISO 22758

ISO 20387

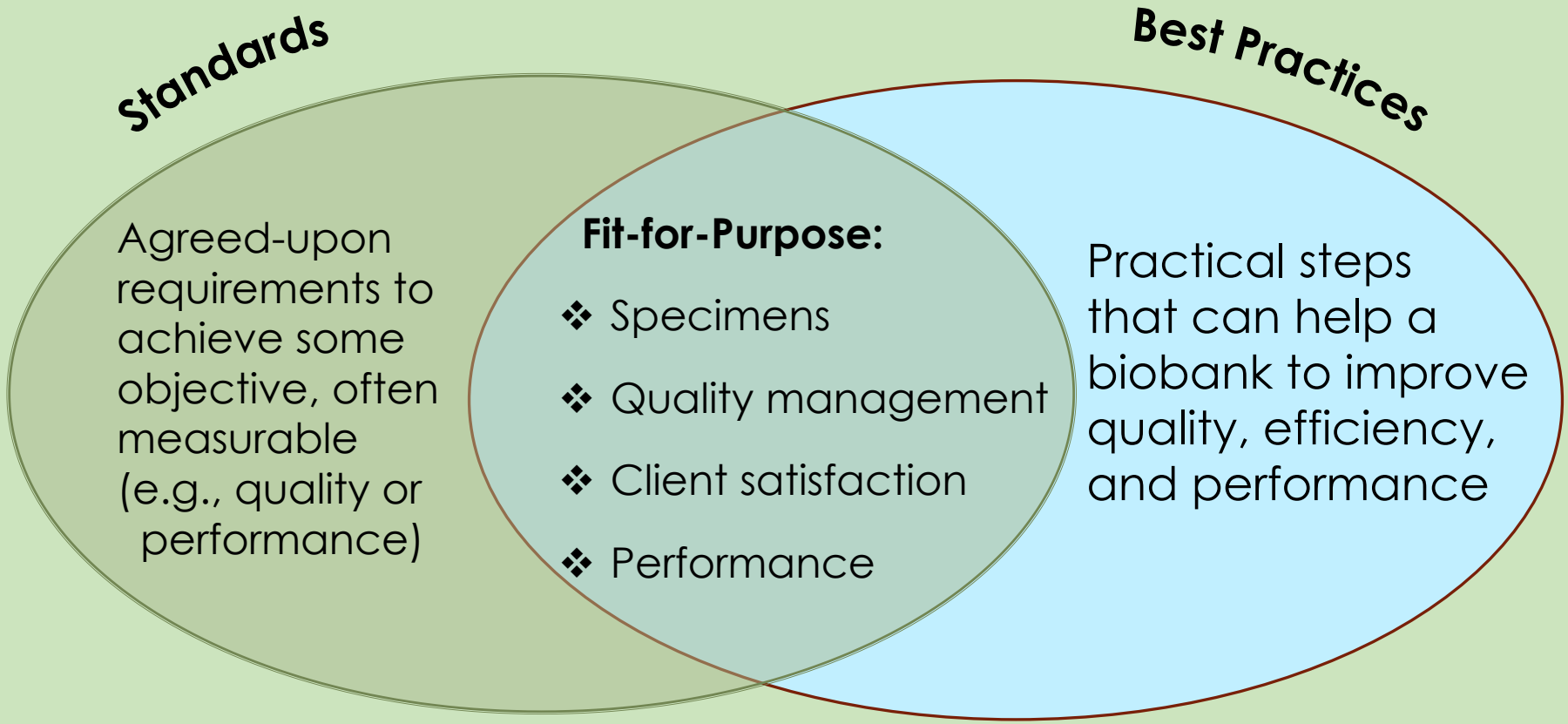
- International Standard (IS)
- Contains Requirements
- Conformity Assessment: Requirements / QMS / Competence
- Intended for Biobanks and users, Regulators, accreditation bodies, and others
- Excludes biological material for therapeutic use, feed/food production and its analysis

ISO TR 22758

- Technical Report (TR)
- Contains NO Requirements
- Guidance / Clarifications / Explanations / Examples…
- Intended audience same as for ISO 20387
- Exclusions same as for ISO 20387

Best Practices and Standards can Work Together to pursue FIP

Adoption or use of standards and best practices will vary based on goals, circumstances, and level of risk tolerance of a given initiative.



Approaches to Biobank Quality & Fitness-for-Purpose

How Standards, Best Practices, and Conformity Assessment Relate

Standards

Standards are documents, established by consensus, that provide requirements, specifications, guidelines, and characteristics used consistently to make sure that materials, products, processes, and services are fit for purpose.

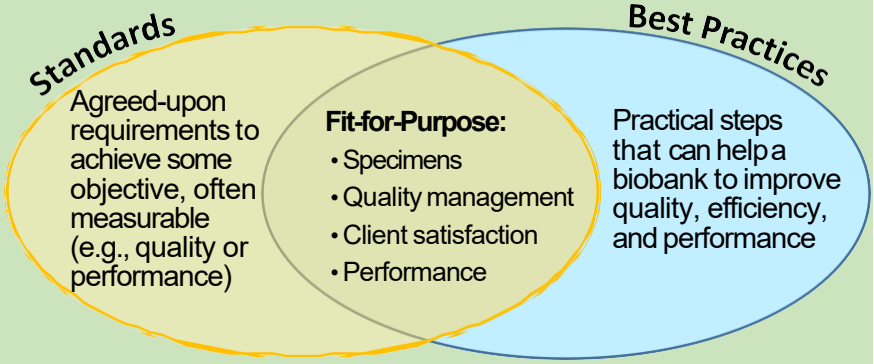
Quality Management System (QMS)

QMS is a documented process that unifies individual procedures and policies to conform with the chosen standards/best practices. Important parts of a QMS might include personnel training, document control, monitoring key performance indicators, incident reporting, and contingency planning.

Best Practices

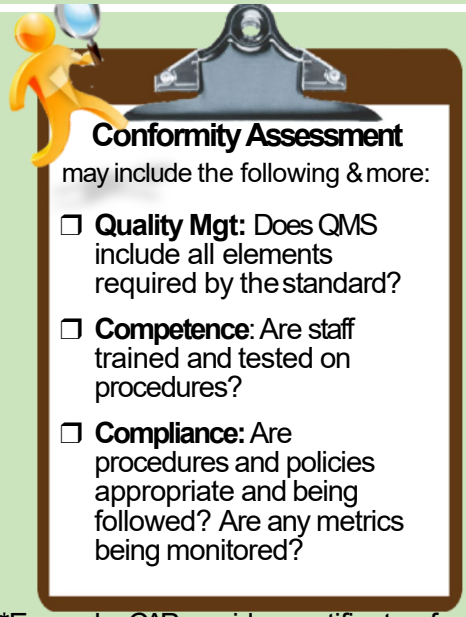
Best practices are collections of effective practices, techniques, procedures, or methods for managing and maintaining quality specimen collections and repositories. Best practices do not contain requirements.

Adoption or use of standards and best practices will vary based on the goals, circumstances, and level of risk tolerance of a given initiative.



Conformity Assessment (CA)

CA activities are concerned with determining that relevant requirements are fulfilled. CA instills confidence by evaluating personnel, products, systems, processes, or services against requirements.



Evidence or Attestation

3rd Party*: Accreditation or Certification

Certificate

2nd Party: Agreement

Contract

1st Party: Self-declaration

Assertion

*Example: CAP provides certificate of accreditation for a competence standard like ISO 17025, or certification for QMS per ISO 9001

Refrigeration Example

Standard:

- Maintain temperature within prescribed range.
- Establish process to track temperature over time

Best Practices:

- Order refrigerator with specified properties
- Separate shelves by *X* amount
- Set and monitor temperature
- Limit/record openings/closings
- Provide *Y*-hour backup power

Conformity Assessment:

- Processes and procedures in place to ensure that cooling requirements are met
- Staff is adequately trained
- Certificate specifies scope of accreditation

While use of any standards or best practices is voluntary, some aspects of specimen management are governed by national, regional, and local regulations. Please consult those requirements, as appropriate.

Considerations in Choosing & Using Standards & Best Practices

Client Requirements

Client needs and expectations vary with program goals, type of research (e.g., human medical), and other factors

Risk Tolerance

Depends on the consequences of a specimen's deviation from expected behavior for the intended application

Rarity of Specimens

Unique or rare specimen collections may present both pros and cons to business considerations

Regional, Environmental, & Economic Status

Affects relevant standards and practices and access to services, facilities, equipment, and supporting institutions

Specimen Stability

Specimens that remain stable under a wide range of conditions may reduce handling and storage needs

Biobank Size, Resources, & Experience

Biobanks with limited resources may plan an affordable or incremental approach to satisfy client requirements

Pace of Scientific Discovery

Rapid developments may require higher standards to maintain biospecimen value in dynamic environments

Need for Interoperability

Adherence to shared practices can enhance the comparability of specimens across biobanks and the combination of specimen and datasets

Selected Resources for Biobanks

Selected Best Practices

- ISBER Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research
- ISBER Self- Assessment Tool (SAT)
- OECD Guidelines for Human Biobanks and Genetic Research Databases
- OECD Best Practice Guidelines for Biological Resource Centres
- National Cancer Institute (NCI) Best Practices for Biospecimen Resources
- Biospecimen Stability Testing Calculator (STABCAL)
- Pre-analytical Biorepository External Quality Assessment (EQA) Survey

Standards, Quality Management, & Competence

- International Standards Organization
  - ISO 20387 *General Requirements for Biobanks*
  - ISO 9001 *Quality Management Systems -- Requirements*
  - ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*
  - ISO 15189 *Medical Laboratories -- Requirements for Quality and Competence*
- College of American Pathologists Biorepository Accreditation Program
- CTRNet Biobank Certification Program