ISO standards for research tissue banking

Dr Fay Betsou

Research tissue banking and Quality

Research tissue banks must meet the high standards of quality and expertise demanded by the international community of scientists and industry for the **delivery** of biological information and materials.

The OECD recommends the establishment of an international system for accreditation that would ensure the quality of a system of national BRCs linked together into a global network.

Terms and definitions

Best Practice:

A management idea which asserts that there is a technique, method, process, activity, incentive or reward that is more effective at delivering a particular outcome than any other technique, method, process, etc…

« What is somebody else doing ? »

or

« What is possible ? »

Terms and definitions

Guidelines:

A guideline is any document that aims to streamline particular processes according to a set routine.

Guidelines are an essential part of the larger process of governance.

Following a guideline is never mandatory

Terms and definitions

Standards:

Standards or norms design a format applicable because recognized by an instance or because used by a majority of users. Standards allow compatibility of systems.

What ISO means

IOS, International Organisation for Standardization

OIN, Organisation Internationale de Normalisation

……..

➔ Greek word «ISOS» = equal

ISOCRATES

International system for standards

- International level :
  - ISO (International Organisation for Standardization)
- European level :
  - CEN (European Comittee for Standardization)
- National level :
  - AFNOR (France)
  - BSI (UK)
  - DIN (Germany)
  - ……

How ISO decides what standards to develop

The sectors which need the standards are at the origin of their development.

Acceptance

- If accepted, the work item is assigned to a specific technical committee.
- Proposals may also be made to set up technical committees to cover new sectors of activity.
- ISO only launches the development of new standards for which there is clearly a market requirement.

➔ ISO standards are used to reduce business risk, improve efficiency, assure the integrity of supply chains and enhance market credibility.

Why ISO for Biobanks?

Biobanks

= providers of services and products

= international

Public/private Research end-users

= market requirements

= management AND technical requirements

flexibility («where applicable»)

What ISO?

ISO 9001:2000

Quality Management Systems Requirements

ISO 17025:2005

General Requirements for the competence of testing and calibration laboratoires

ISO 15189:2003

Medical Laboratories: particular requirements for quality and competence

ISO Guide34:2000

General requirements for the competence of reference material producers

ISO9001:2000

- What is concerned?
  - All processes that have an impact on the quality of the product
- What is the objective?
  - Process control and efficiency
- What is the target?
  - Customer
- What is the evaluation tool?
  - Quality Audit

ISO9001:2000…

- Proves the capacity of an organisation to supply regularly a product in conformity with the customer's requirements and with legal and regulatory requirements.

- Aims at customer's satisfaction through implementation of an efficient QMS, prevention of non-conformities and continuous amelioration.

ISO9001:2000 obligatory procedures

- Document control *4.2.3*
- Records control *4.2.4*
- Internal audits *8.2.2*
- Control of non-conformities *8.3*
- Corrective actions *8.5.2*
- Preventive actions *8.5.3*

In order to succeed…

- Think « customer »
- Have an active director
- Prepare initial phases with meticulous care
- Take the time
- Use a sequential approach, project by project
- Listen to the staff
- Training program
- Look for amelioration
- Adjust actions according to results
- Flexibility
- Technical and regulatory update

Certification and Accreditation

Certification : Procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements.

Accreditation : Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Accreditation is the proof (testimony) of the competence, the impartiality and the independence of a certification body in view of existing norms.

Accreditation allows confidence in certificates delivered by third parties.

What is the origin of accreditation?

Accreditation is a consequence of the international willingness to favour commercial exchanges by eliminating technical hindrance.

What is accreditation for?

The objective of accreditation is to confirm, after evaluation, that laboratories and certification bodies are technically competent, respectively, to realise assays, analysis or calibration, and to proceed to inspection or certification, in the domains they declare themseves being competent.

Who is accrediting?

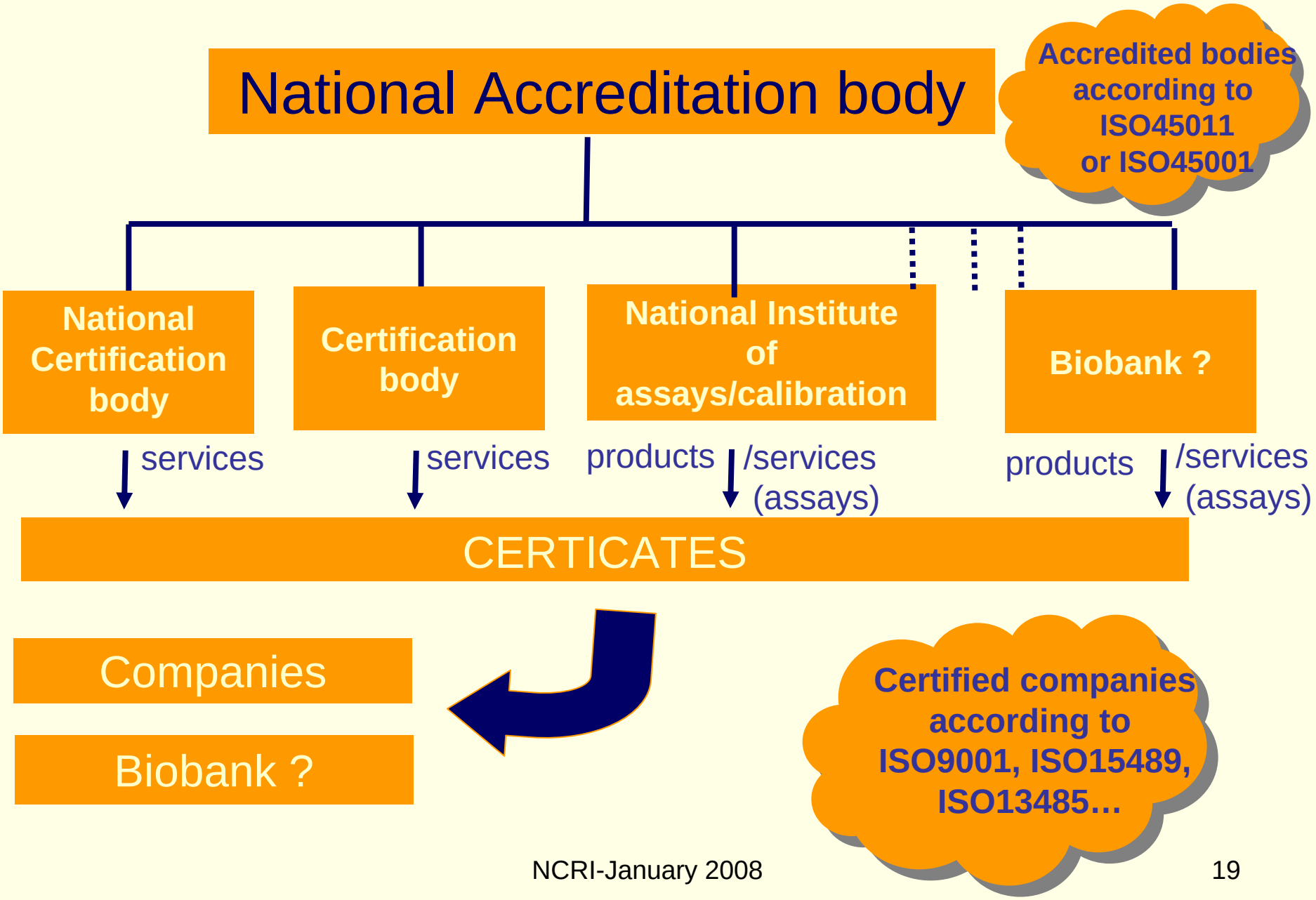
Accreditation systems are established and supported in order to deliver impartial judgements based on european/international recognized norms.

UKAS: UK

COFRAC:France

A2LA, CAP, COLA, JCAHO: USA

CAEAL: Canada



ISO17025:2005

- Accreditation of testing and calibration laboratories
- Management requirements: ISO9001:2000 with new elements (independence in relation to customer, systematic corrective actions and causative analysis, regular updating of documents, etc)
- Technical requirements: competence of personnel, adequate technical infrastructure, **validated methods**, adequate material, traceability of measurements, etc

ISO15189:2003

- Adaptation of ISO17025 to medical biology laboratories
  - Explicitely specifies pre-, per- and post-analytical phases
  - Attributes important responsibilities to the laboratory director
  - Integrates requirements relative to security
  - Integrates requirements relative to consulting services

ISO Guide 34

General Requirements for the competence of reference material producers.

Are we reference material producers?

Technically competent body responsible for the supply of reference materials or certified reference materials and authorises the property values assigned to reference material or certified reference material.

Categories of Reference Material

Category B: Biological and clinical properties

Materials characterised for one or more biochemical or clinical property values

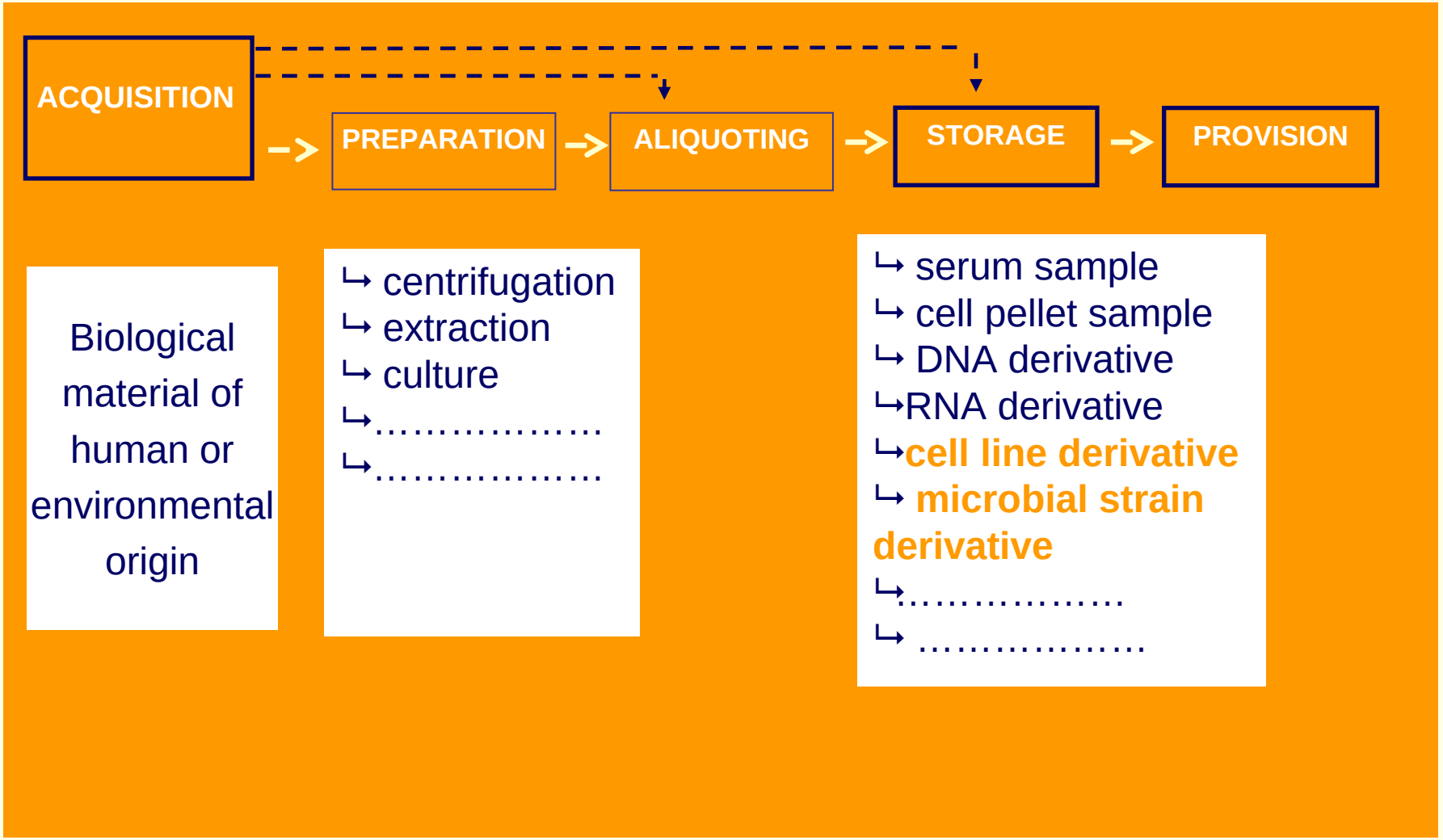
- General Medecine (human serum materials)
- Clinical Chemistry (proteins, hormones…)
- Tissue Pathology
- Haematology and Cytology (blood)
- Immunohaematology
- Immunology
- Parasitology
- Bacteriology and Mycology (reference cultures)
- Virology
- Other biological and clinical reference material

A compilation approach

Compilation into an ISO accreditation norm (ISO17025) compatible format:

- OECD Best Pratice Guidelines for Biological Resource Centers
- ISBER Best Practices for Repositories
- NCI First-Generation Guidelines for NCI-supported Biorepositories.

General Schema of Biobank processes



ISO norm structure

Standard Norm

Introduction

- Scope
- Terms and definitions

Technical require-ments

- Accommodation and environmental conditions
- Test and calibration methods/method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and results
- Reporting of results

Manage-ment require-ments

- Organization
- Management system
- Document control
- Review of requests, tenders, contracts
- Subcontracting
- Purchasing services and supplies
- Service to the customer
- Complaints
- Control of non conformity testing
- Improvement
- Corrective actions
- Preventive actions
- Control of records
- Internal audits
- Personnel

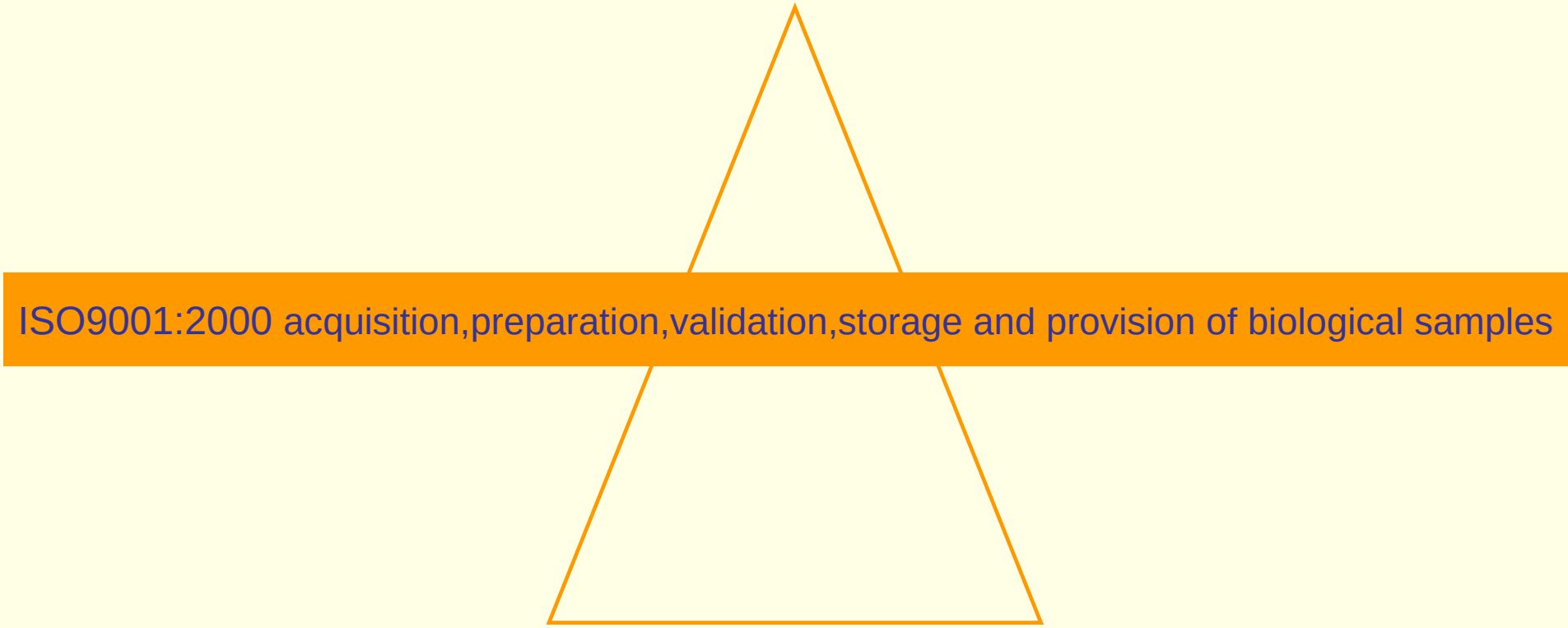
Biobank norm

Additional require-ments

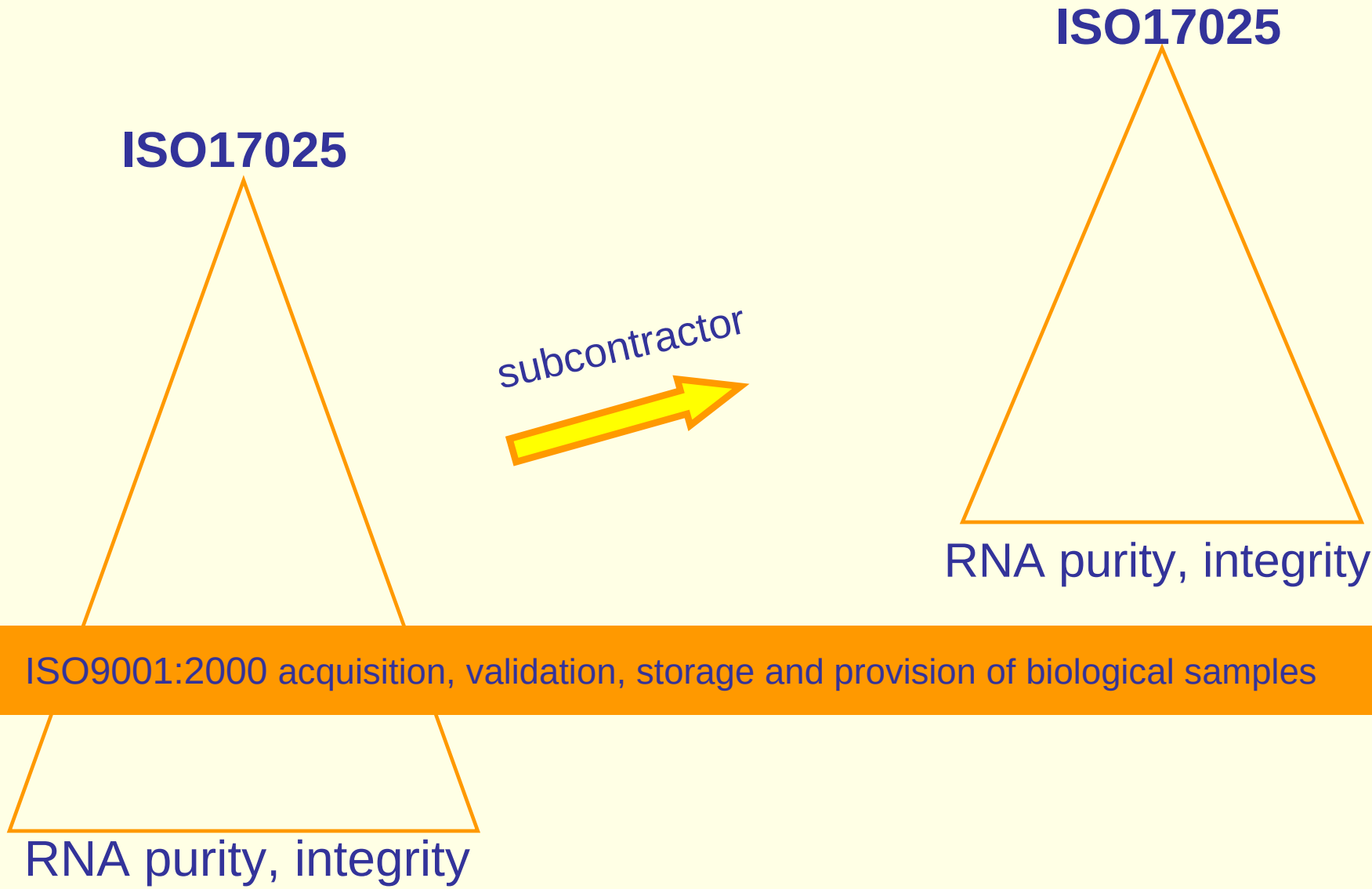
- Supply
- Ethics
  - Privacy
  - Informed consent
  - Access
  - Custodianship
  - Intellectual property

A DNA bank

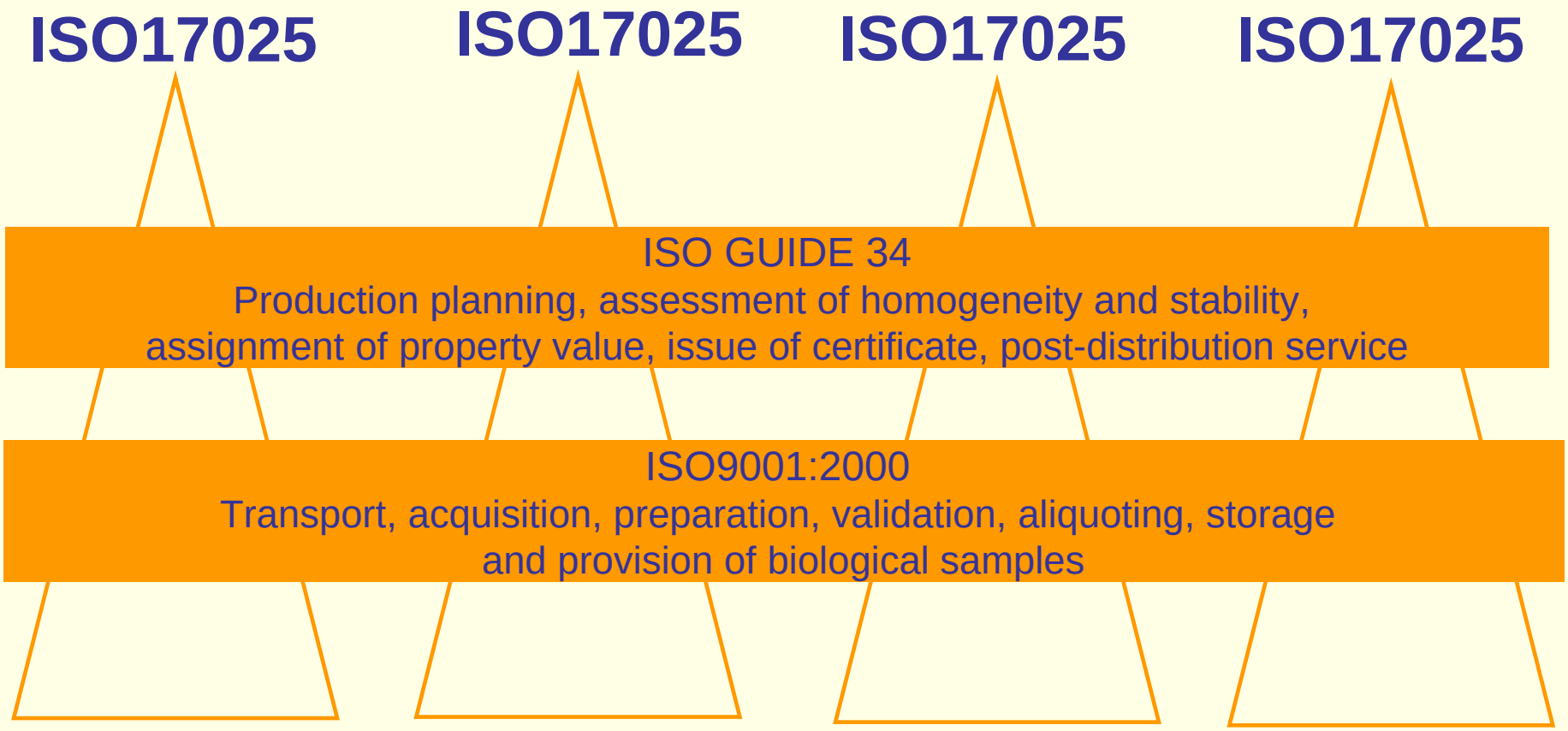
ISO17025



A tumour tissue bank

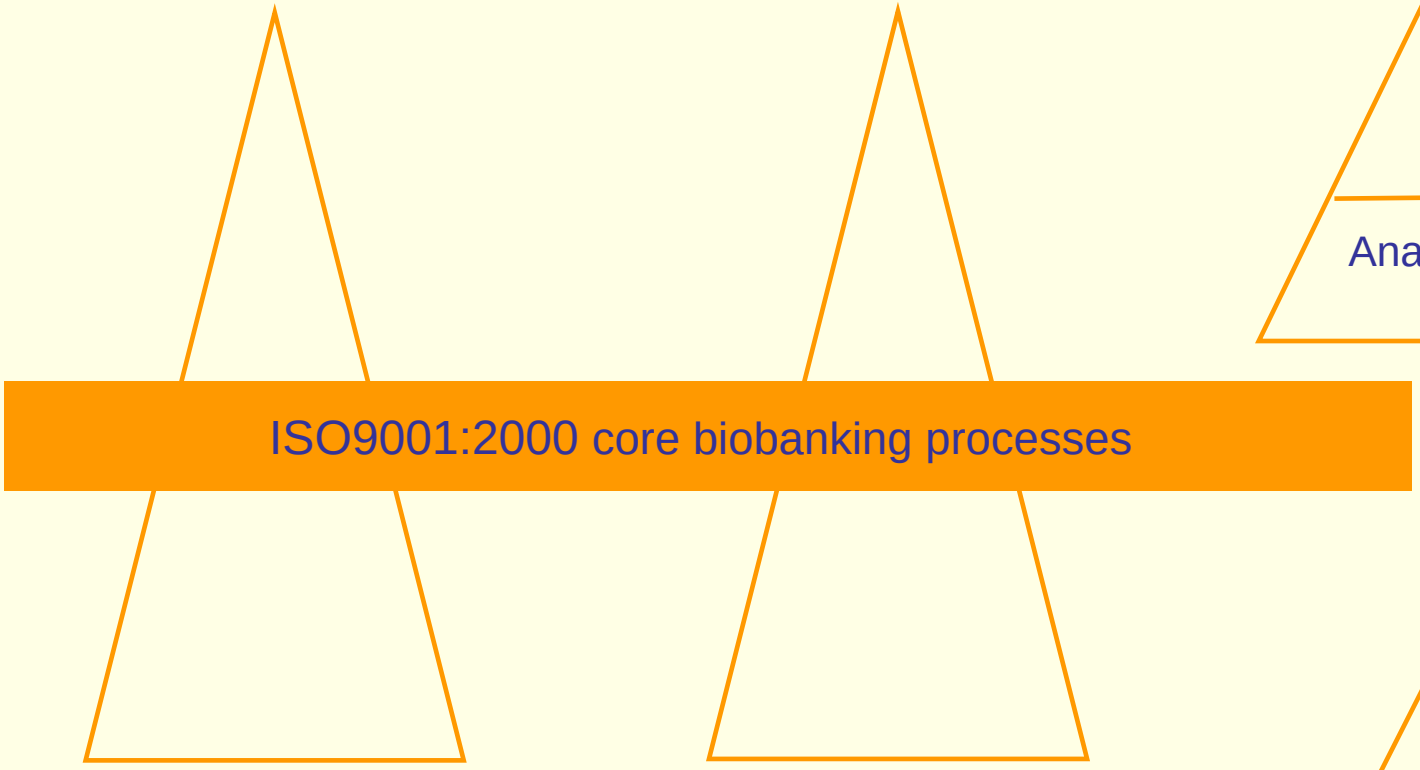


A cell line bank



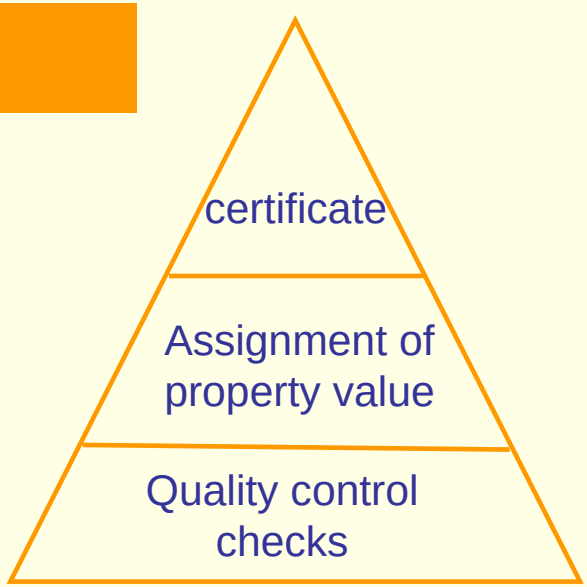
In general

ISO17025 **ISO17025/GUIDE 34**

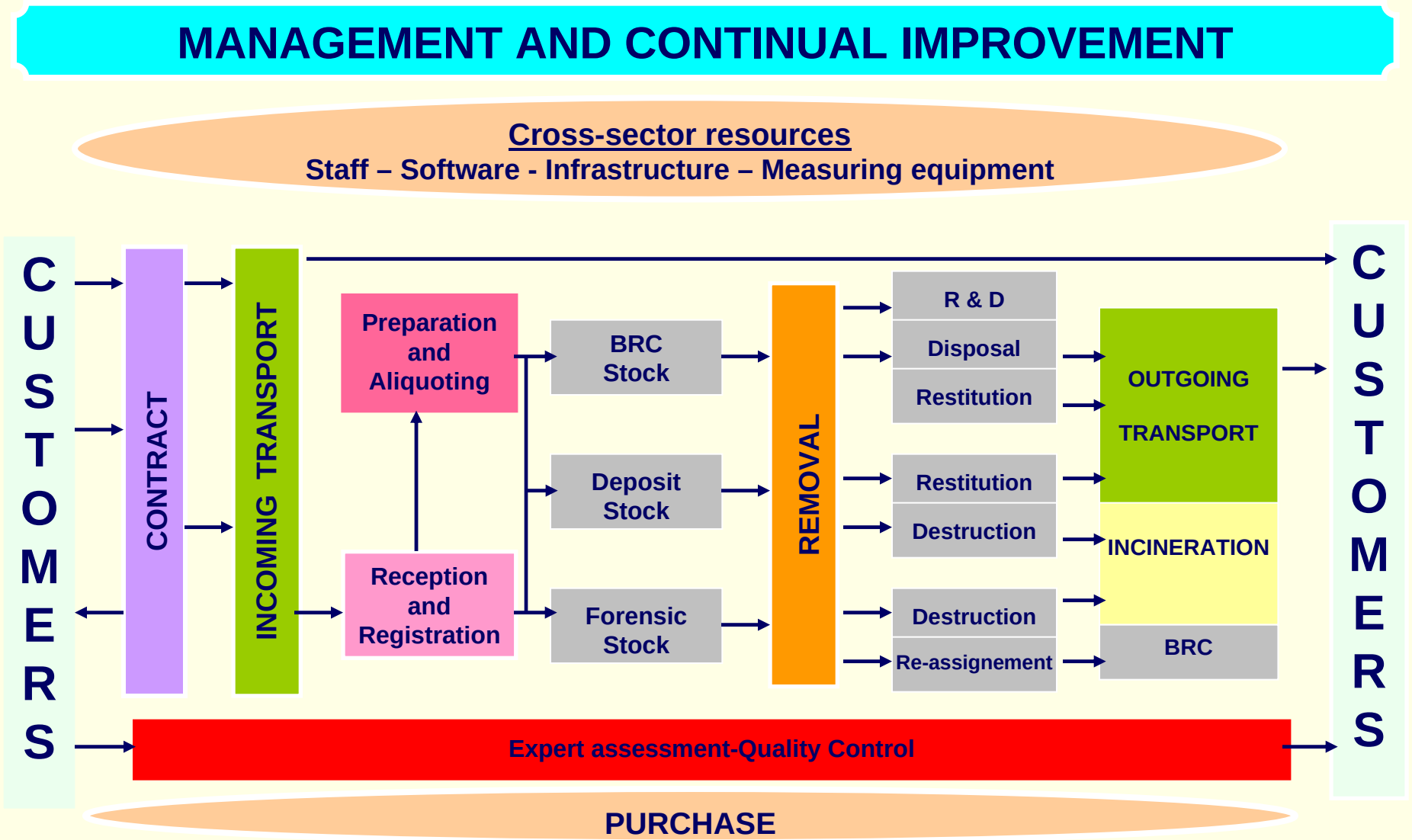


Validation assay 1

Validation assay 2



The process flow



Cost Analysis

Item	Cost (€)
Advisor (1st year)	20 000 – 30 000
Audits	3 000 – 6 000
One Quality Manager	45 000 – 65 000
5% additional workload for staff	

Roadmap for Biobanks

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