ASIFOOD

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Short Term Training Course (STTC)
"Safety and Quality in Innovative Food Production Systems"

20-26 May, 2018

Asian Institute of Technology, Thailand

Lecture 6:

Inspection vs Certification- The Inspection Standard

I. Inspection ≠ certification

Inspection

- Definition according to the regulation No 882/2004

  •‘inspection’ means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules;

Audit

- Definition according to the regulation No 882/2004

  - ‘audit’ means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. *(official vet and auxiliary)*

Certification

- Certification = procedure by which a third party gives a written insurance that a product, a process or a service is in compliance with the specified requirements.
- (B. Phuez & D. Cohen-Solal http://slideplayer.fr/slide/176008/)

Accreditation

- Accreditation = procedure by which a recognized authority body recognized formally that a body or an individual is competent to make specific tasks.
- (B. Phuez & D. Cohen-Solal http://slideplayer.fr/slide/176008/)

ISO

ISO – what it is, what it achieves

ISO (International Organization for Standardization) is the world's largest developer of voluntary International Standards providing benefits for business, government and society.
ISO is a network comprising the national standards institutes of 163* countries.
ISO standards make a positive contribution to the world we live in. They ensure vital features such as quality, ecology, safety, reliability, compatibility, interoperability, efficiency and effectiveness – and at an economical cost.
They facilitate trade, spread knowledge, and share technological advances and good management practices.

ISO/IEC 17011:2004

Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies

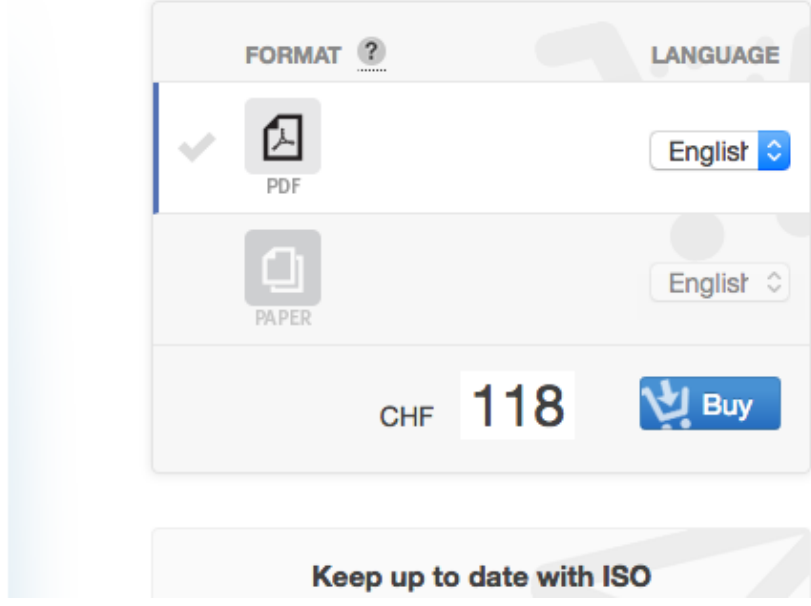
Abstract

Preview ISO/IEC 17011:2004

ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies.

Accreditation bodies operating in accordance with ISO/IEC 17011:2004 do not have to offer accreditation to all types of CABs.

For the purposes of ISO/IEC 17011:2004, CABs are organizations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and, in the context of this document, calibration.



http://www.iso.org/iso/en/home/store/catalogue_tc/catalogue_detail.htm?csnumber=29332

Reference tables of accreditation

Activité	Référentiel
Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies	ISO/IEC 17011:2004
Conformity assessment — Requirements for the operation of different types of bodies performing inspection	ISO/CEI 17020
Conformity assessment– Requirements for bodies providing audit and certification of management systems	ISO/IEC 17021:2011
Conformity assessment — General requirements for certification bodies performing personal certification	ISO/CEI 17024:2012
General requirements for the competence of testing and calibration laboratories	ISO/CEI 17025:2005
Conformity assessment — Requirements for the bodies certifying products, processes and services	ISO/CEI 17065:2012
Conformity assessment— Fundamental elements of the certification of products and guidelines for the certification programmes of products	ISO/CEI 17067:2013

ISO/IEC 17021-1:2015

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements

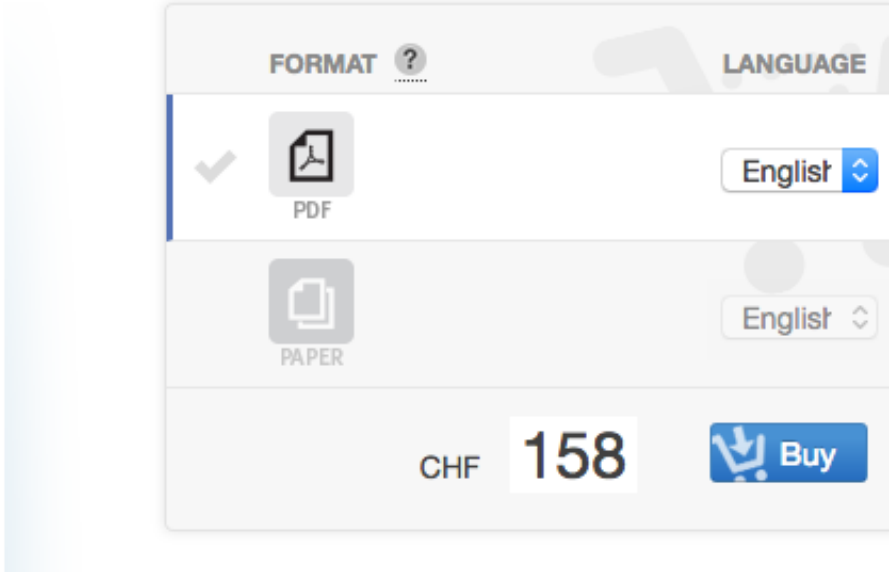
Abstract

Preview ISO/IEC 17021-1:2015

ISO/IEC 17021-1:2015 contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems.

Certification bodies operating to ISO/IEC 17021-1:2015 do not need to offer all types of management system certification.

Certification of management systems is a third-party conformity assessment activity and bodies performing this activity are therefore third-party conformity assessment bodies.



ISO/IEC 17021

The certification bodies which will lean on the new standard ISO/IEC 17021-1 will have competent audit teams with adequate resources and consistency in the process and in reporting their audits results.

This standard will also allow to enhence confidence of standards authorities, consumers, suppliers and other stakeholders about the actual equivalence of certificates issued by different certification bodies.

ISO/IEC 17021 (2)

ISO/IEC 17021 is the very last one of the family of standards about the certification of management systems, which includes six other standards dedicated to various specific types of management systems :

ISO/IEC TS 17021-2 environmental

ISO/IEC TS 17021-3 quality

ISO/IEC TS 17021-4 factual activity

ISO/IEC TS 17021-5 asset management

ISO/IEC TS 17021-6 business continuity

ISO/IEC TS 17021-7 road traffic safety

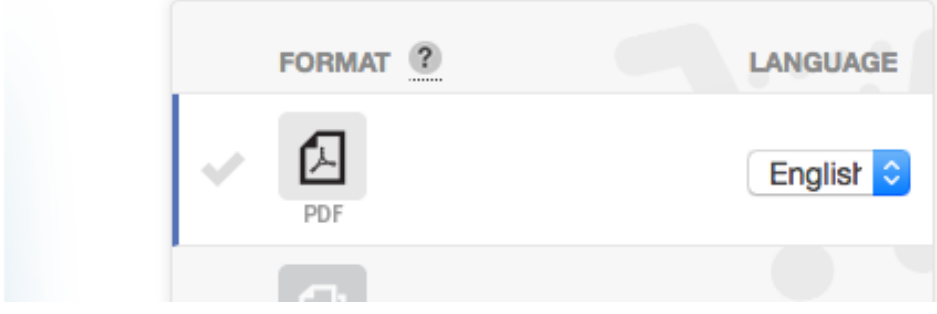
ISO/IEC TS 17021-3:2013

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 3: Competence requirements for auditing and certification of quality management systems

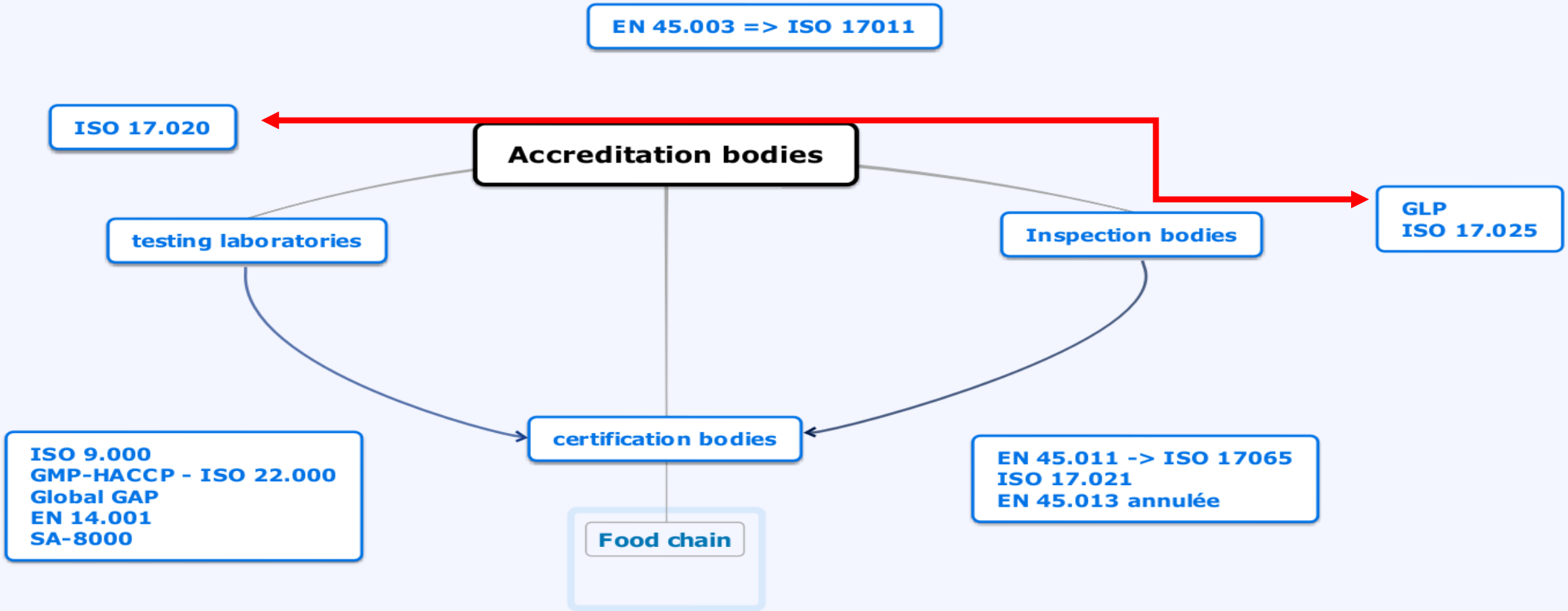
Abstract

Preview ISO/IEC TS 17021-3:2013

ISO/IEC 17021-3:2013 complements the existing requirements of ISO/IEC 17021. It includes specific competence requirements for personnel involved in the certification process for quality management systems (QMS).



All the Quality management systems are based on ISO 9001: 2008 standard



Management system standards

ISO management system standards provide a model to follow when setting up and operating a management system. Like all our standards, they are the result of international, expert consensus and therefore offer the benefit of global management experience and good practice.

These standards can be applied to any organisation, large or small, whatever the product or service and regardless of the sector of activity.

The benefits of an effective management system include:

- more efficient use of resources
- improved risk management, and
- increased customer satisfaction as services and products consistently deliver what they promise.

Audits

Audits are a vital part of the management system approach as they enable the company or organization to check how far their achievements meet their objectives and show conformity to the standard.

In order to help the auditing related to these standards, ISO has released ISO 19011:2011 providing specific guidance on internal and external management system audits.

Certification

Certification to management system standards is **not** a requirement. You can still benefit from implementing these standards without having to be certified to them.

If you are looking to get certified to one or more of our management system standards must contact an external certification body. **ISO does not perform certification**.

Read more about certification to ISO standards.

Certification is not the only way to show conformity to standards. Read more about conformity assessment.

ISO 19011:2011

Guidelines for auditing management systems

Abstract

Preview ISO 19011:2011

ISO 19011:2011 provides guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits, as well as guidance on the evaluation of competence of individuals involved in the audit process, including the person managing the audit programme, auditors and audit teams.

ISO 19011:2011 is applicable to all organizations that need to conduct internal or external audits of management systems or manage an audit programme.

The application of ISO 19011:2011 to other types of audits is possible, provided that special consideration is given to the specific competence needed.

Management system standards

We have a number of management system standards, each focusing on different issues affecting global business. More information can be found by clicking on the following links.

ISO 50001 - Energy management

ISO 14000 family - Environmental management

ISO 9000 family - Quality management

ISO 22000 - Food safety management

ISO/IEC 27001 - Information security management

ISO 20121 - Sustainable events management

ISO 45001 - Occupational health and safety

ISO 37001 - Anti-bribery management systems

http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm

ISO 9000 family - Quality management

ISO 9000 - Quality management

The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved.

Standards in the ISO 9000 family include:

- ISO 9001:2015 - sets out the requirements of a quality management system
- ISO 9000:2015 - covers the basic concepts and language
- ISO 9004:2009 - focuses on how to make a quality management system more efficient and effective
- ISO 19011:2011 - sets out guidance on internal and external audits of quality management systems.

ISO 9001:2015

ISO 9001:2015 sets out the criteria for a quality management system and is the only standard in the family that can be certified to (although this is not a requirement). It can be used by any organization, large or small, regardless of its field of activity. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001.

This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement. These principles are explained in more detail in the pdf Quality Management Principles. Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.

Get an overview of ISO 9001 in this powerpoint presentation

If you want to know more about the revision of ISO 9001:2015 see our revision page or watch the video:

Video on ISO

https://www.youtube.com/embed/Op-Xmk5XCH8?fs=1&autoplay=1&rel=0

Video on ISO 9000

https://www.youtube.com/embed/Lp6xP-We5yY?fs=1&autoplay=1&rel=0

ISO 9000 family - Quality management

Certification to ISO 9001:2015

Checking that the system works is a vital part of ISO 9001:2015. It is recommended that an organization performs internal audits to check how its quality management system is working. An organization may decide to invite an independent certification body to verify that it is in conformity to the standard, but there is no requirement for this. Alternatively, it might invite its clients to audit the quality system for themselves. Read more about certification to management system standards.

Learn more about transitioning from ISO 9001:2008 to ISO 9001:2015 [.pptx]

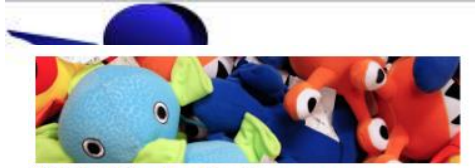
Preview ISO 9001:2015

You can preview the freely available sections of ISO 9001:2015 on ISO's Online Browsing Platform.
To purchase this standard please visit the ISO Store.

Sector-specific applications of ISO 9001

ISO has a range of standards for quality management systems that are based on ISO 9001 and adapted to specific sectors and industries. These include:

ISO/TS 29001 – Petroleum, petrochemical and natural gas industries
ISO 13485 – Medical devices
ISO/IEC 90003 – Software engineering
ISO 17582 – Electoral organizations at all levels of government
ISO 18091 - Local government



ISO 9000 – the seven quality management principles

The seven quality management principles are:

QMP 1 – Customer focus

QMP 2 – Leadership

QMP 3 – Engagement of people

QMP 4 – Process approach

QMP 5 – Improvement

QMP 6 – Evidence-based decision making

QMP 7 – Relationship management

ISO 22000 - Food safety management

Why ISO standards for food ?

Today more than ever, food products regularly cross national boundaries at every stage of the supply chain, from farm to fork. ISO International Standards create confidence in the products we eat or drink by ensuring the world uses the same recipe when it comes to food quality, safety and efficiency.

ISO provides a platform for developing practical tools through common understanding and cooperation with all stakeholders on board, from agricultural producers, to food manufacturers, laboratories, regulators, consumers, etc. Working through its network of national members, its standards bring together the foremost expertise in the world and disseminate it to both developed and developing countries.

ISO standards are powerful tools for taking action on global challenges like sustainability and climate change by for example, disseminating best practice on new technologies less detrimental to the environment.

By implementing voluntary ISO standards, companies make a proactive commitment to the principles they stand for: quality, transparency, accountability and safety.

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Who benefits from ISO standards?

Industry: Farmers, manufacturers, retailers and service providers benefit from not having to comply with multiple specifications and requirements for different markets. ISO standards make industry more competitive and promote global trade. They disseminate best practice and innovations so that industry does not need to reinvent the wheel, while at the same time facilitating market access to the latest technologies.

Regulators: Regulators can rely on trusted internationally harmonized solutions, which are continually reviewed and improved, as a technical basis for market-friendly regulations that meet the expectations of citizens.

Consumers: ISO standards ensure the safety and quality of products to protect consumers worldwide. They address issues of concern to consumers such as nutritional value, labeling and declaration, taste, hygiene, genetically modified organisms, limits on additives, pesticides, contaminants, and so on.

ISO 22000 - Food safety management

ISO 22000 - Food safety management

What ISO standards for food ?

From agricultural machinery to logistics, from transportation to manufacturing, from quality and safety to management and traceability, from labeling and packaging to storage – ISO standards cover every step of the food and feed supply chain.

Some 1 000* ISO standards out of a current total of some 19 000* are specifically dedicated to food, most of them developed by the following technical committees (TCs) :

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Technical committee ISO

- **Food products (ISO/TC 34)** – Covers the food and feed chain from primary production to consumption for practically all products, from cereals to coffee, from spices to milk and cheese. Nearly 800* standards provide terminology, tests, analysis and sampling methods (including for sensory analysis), product specifications, quality management and requirements for packaging, storage and transportation for food and animal feed. Its recent work addresses food irradiation, detection of genetically modified organisms and molecular biomarkers.

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Technical committee ISO (II)

- **Essential oils (ISO/TC 54)** – Focuses on essential oils used in food products, perfumes, cosmetics, phytotherapy, aromatherapy, and so on.

Its more than 120* ISO standards help ensure quality in testing, transport, labeling, nomenclature, terminology etc.

- **Starch and its by-products (ISO/TC 93)** – Found in foods like potatoes, maize and wheat, starch provides about half of the world's daily calorie intake, and its extraction is one of the most important agro-industries worldwide. ISO standards provide valuable methods of analysis for the industry.

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Technical committee ISO

ISO 22000 - Food safety management

- **Fisheries and aquaculture (ISO/TC 234)** – Aims to promote sustainable development of the sector ; outline specifications for technical equipment adapted to local environments ; improve surveillance and management of marine resources ; generate international agreement on terminology and sampling methods ; and ensure safety. Examples of standards under development include environmental monitoring of the seabed impacts from finfish farms (ISO 12878) and methods for calculating fish-in/fish-out ratios (ISO 16566).

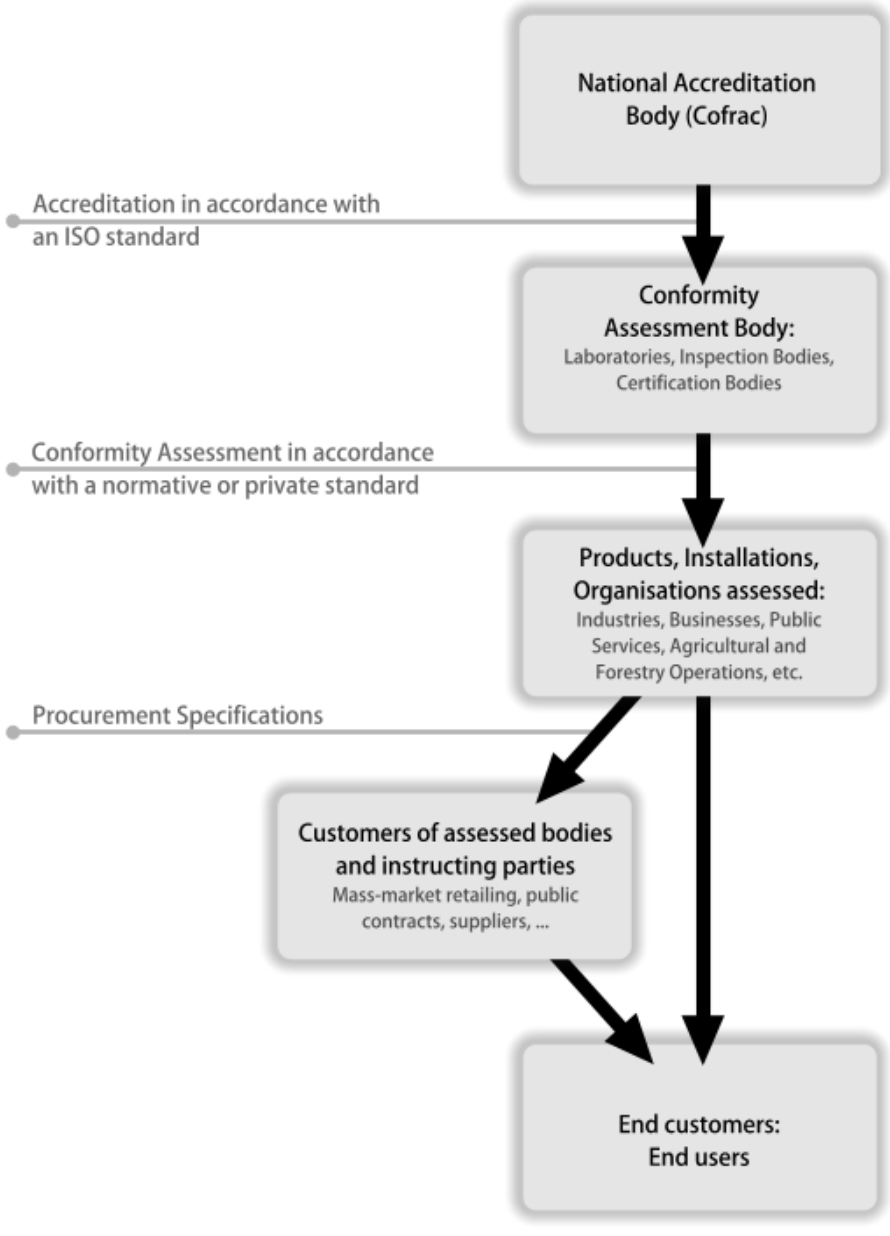
ISO 22000 - Food safety management

The ISO 22000 family of International Standards addresses food safety management.

The consequences of unsafe food can be serious and ISO's food safety management standards help organizations identify and control food safety hazards. As many of today's food products repeatedly cross national boundaries, International Standards are needed to ensure the safety of the global food supply chain.

The ISO 22000 family contains a number of standards each focusing on different aspects of food safety management.

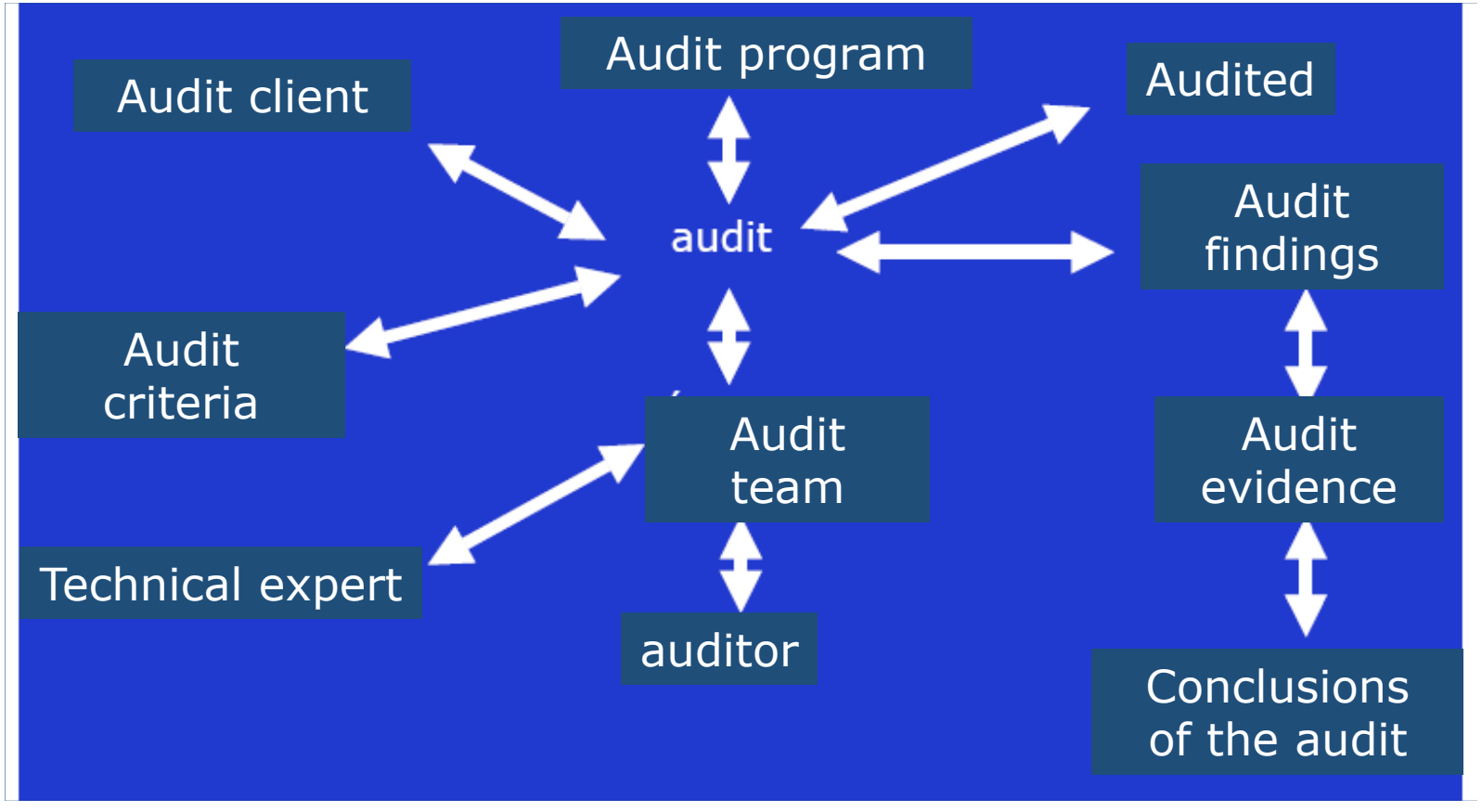
- ISO 22000:2005 contains the overall guidelines for food safety management.
- ISO 22004:2014 provides generic advice on the application of ISO 22000
- ISO 22005:2007 focuses on traceability in the feed and food chain
- ISO/TS 22002-1:2009 contains specific prerequisites for food manufacturing
- ISO/TS 22002-2:2013 contains specific prerequisites for catering
- ISO/TS 22002-3:2011 contains specific prerequisites for farming
- ISO/TS 22002-4:2013 contains specific prerequisites for food packaging manufacturing
- ISO/TS 22003:2013 provides guidelines for audit and certification bodies



http://www.cofrac.fr/en/accreditation/

Concepts

(ISO 9000:2000)



Source :
Georges Daube, 2008

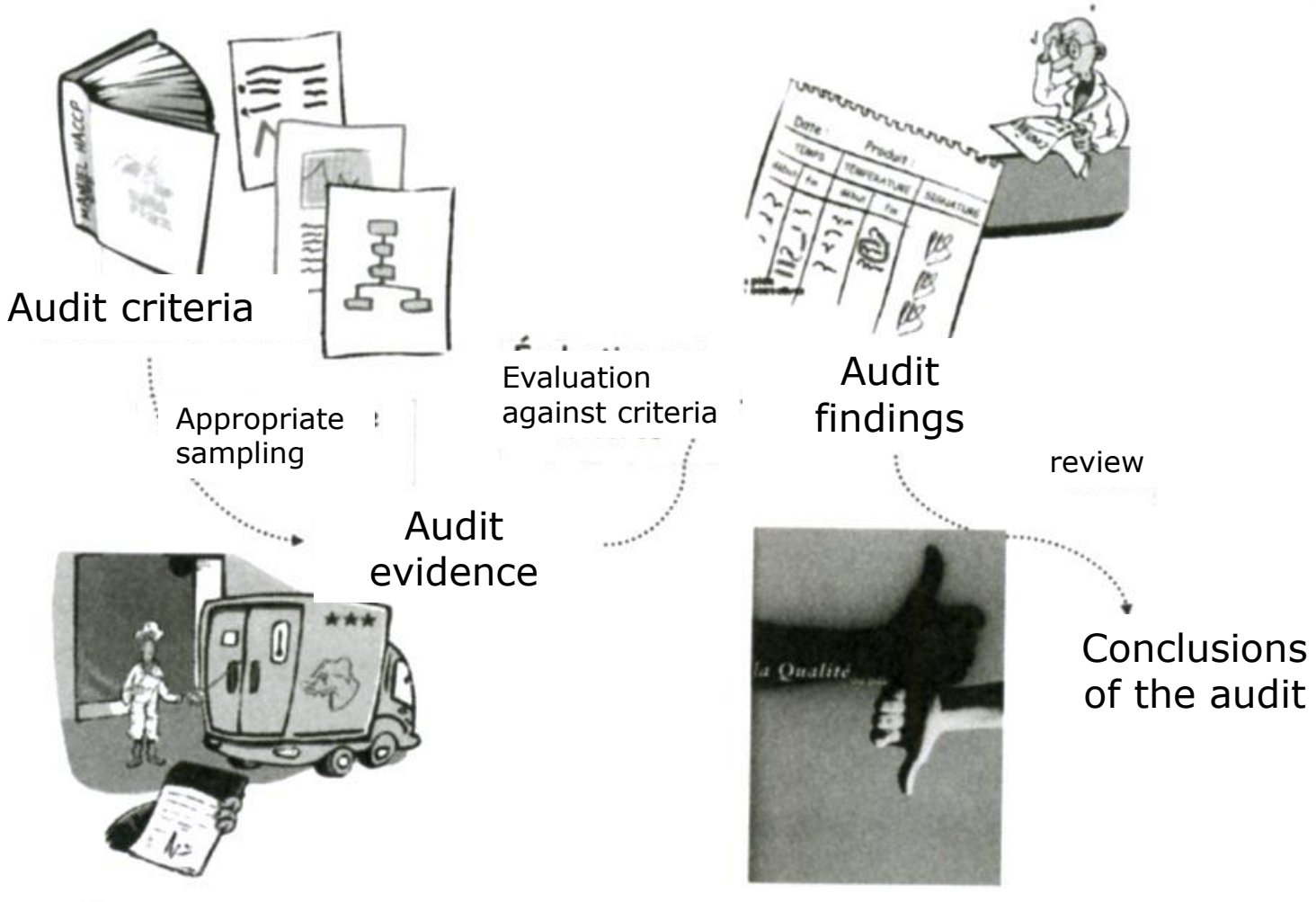


Figure 6.16 From the audit criterion to the audit findings

Source :
Olivier Boutou, 2008

Figure 6.17 The objectives of the audit

Source :
Olivier Boutou, 2008

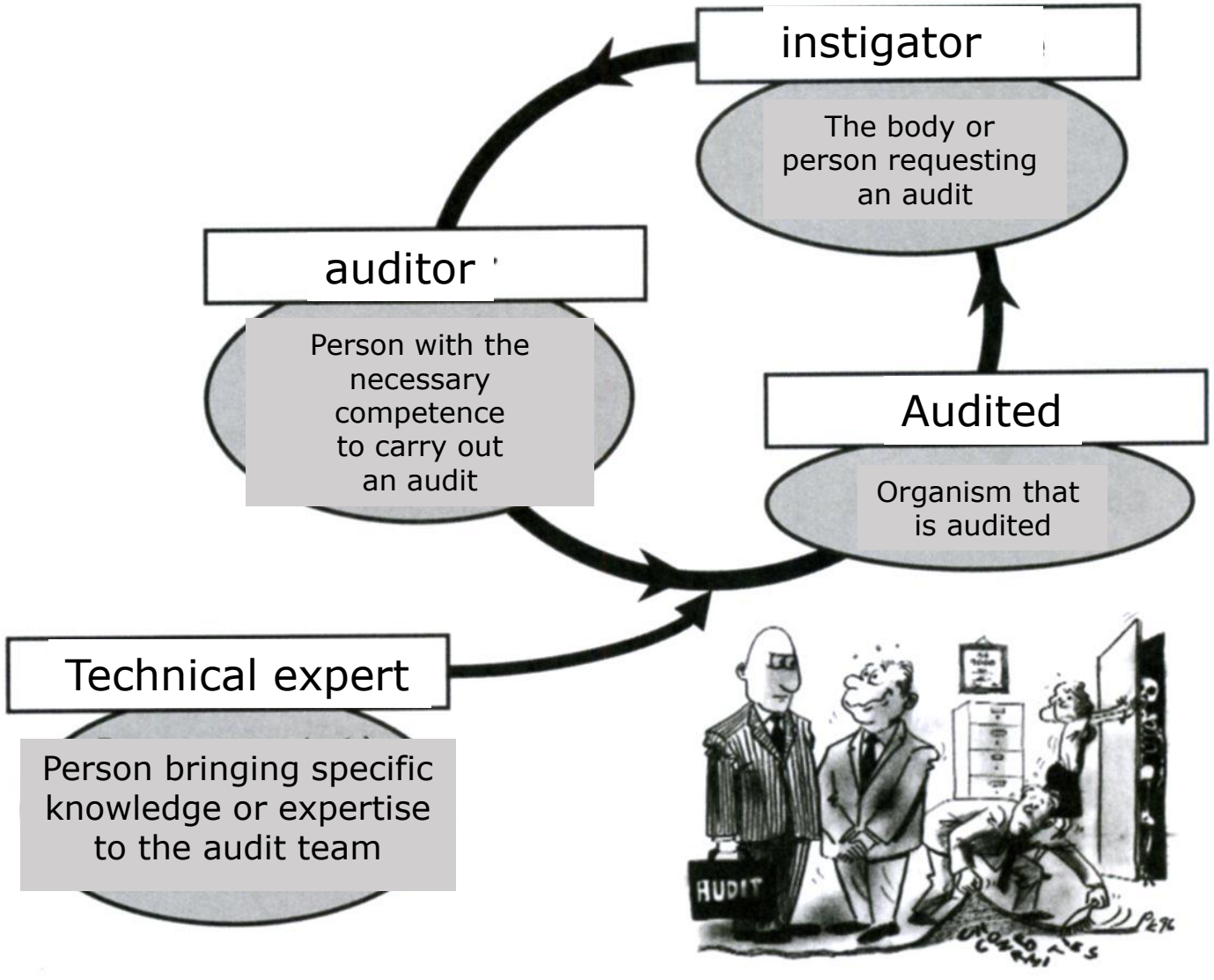


Figure 6.18 The actors of the audit

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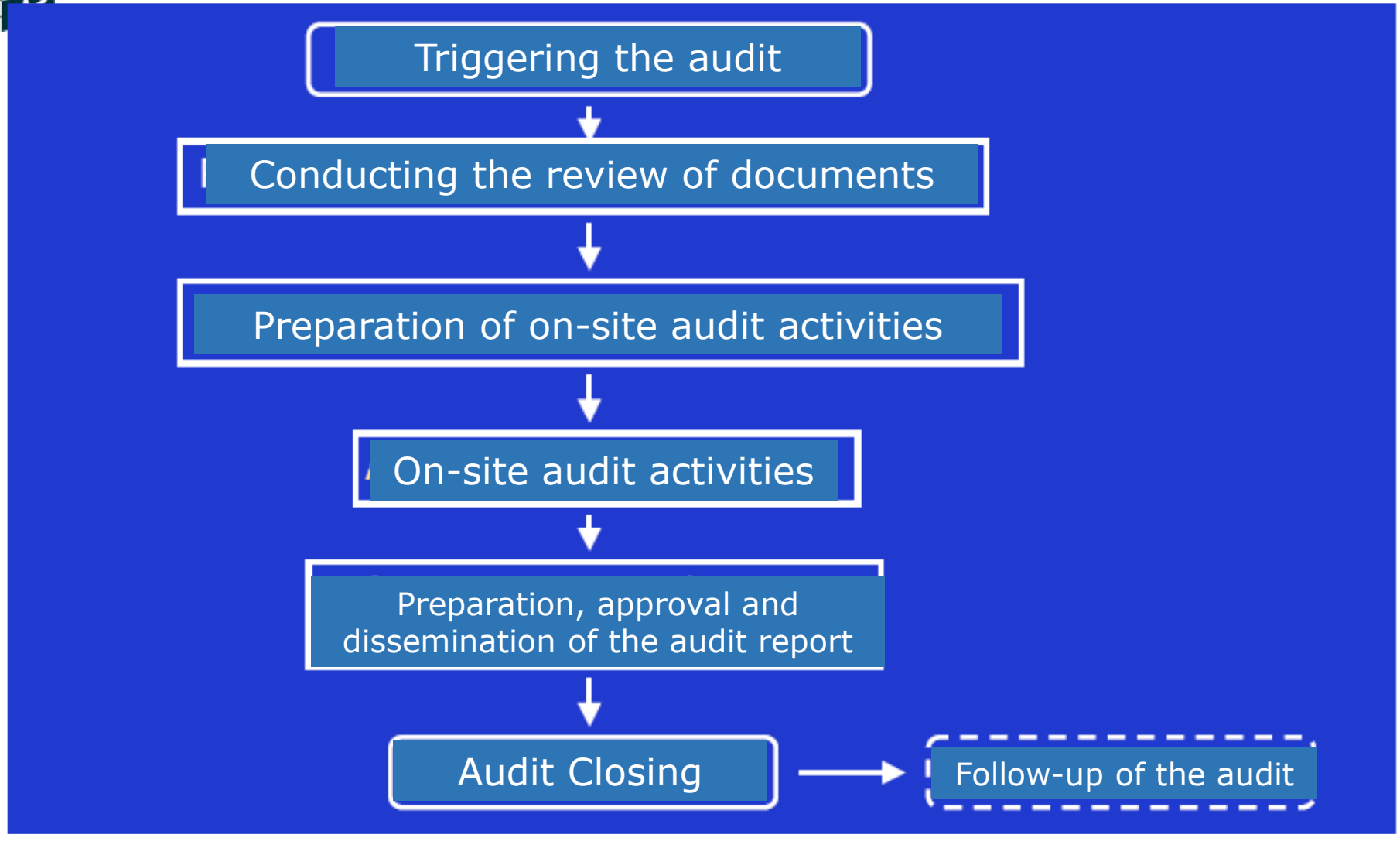
Typical activities of an audit



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Beginning of the audit

- Name the persons in charge of the team of audit
- Define the objectives, the criteria and the field
-Determine the feasibility of the audit
-Establish the team of audit

Documentation review

-Establish the initial contacts with the audited
-Examine the documentation of the management system audits adequacy
-Prepare the audit plan
-Specify the responsibilities within the team of audit
-Prepare work papers

Preparation of the audit on-site

-Liven up the opening session
-Lead the conversations during the audit
-Roles and responsibilities of guides and observers
-Collection and check of the information
-establish audit findings
-Prepare audit conclusions
-Liven up the final meeting
-Prepare audit report

Audit on-site

-Approve and spread the audit report

Audit report

Audit follow-up

Source :
Olivier Boutou, 2008

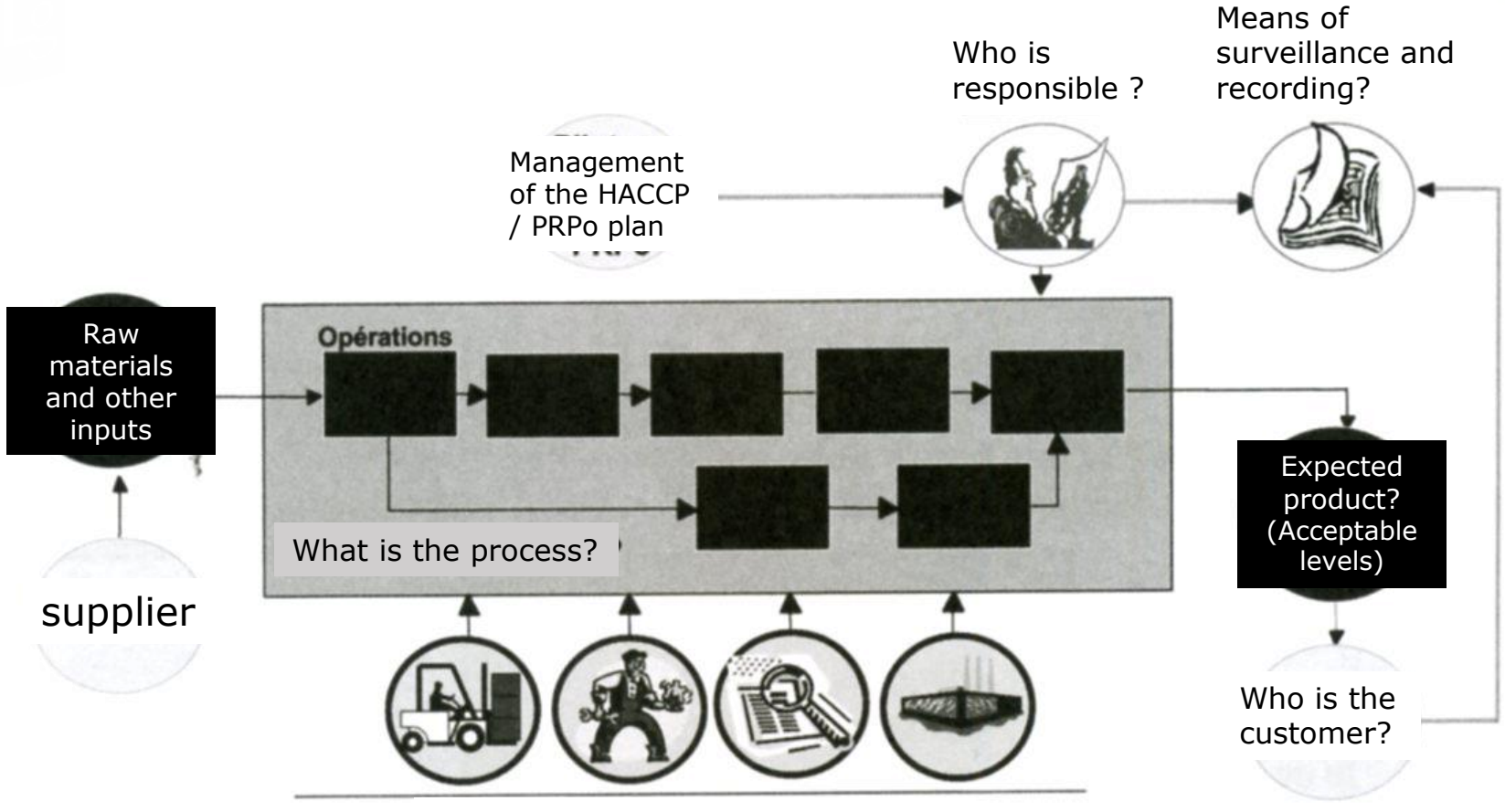
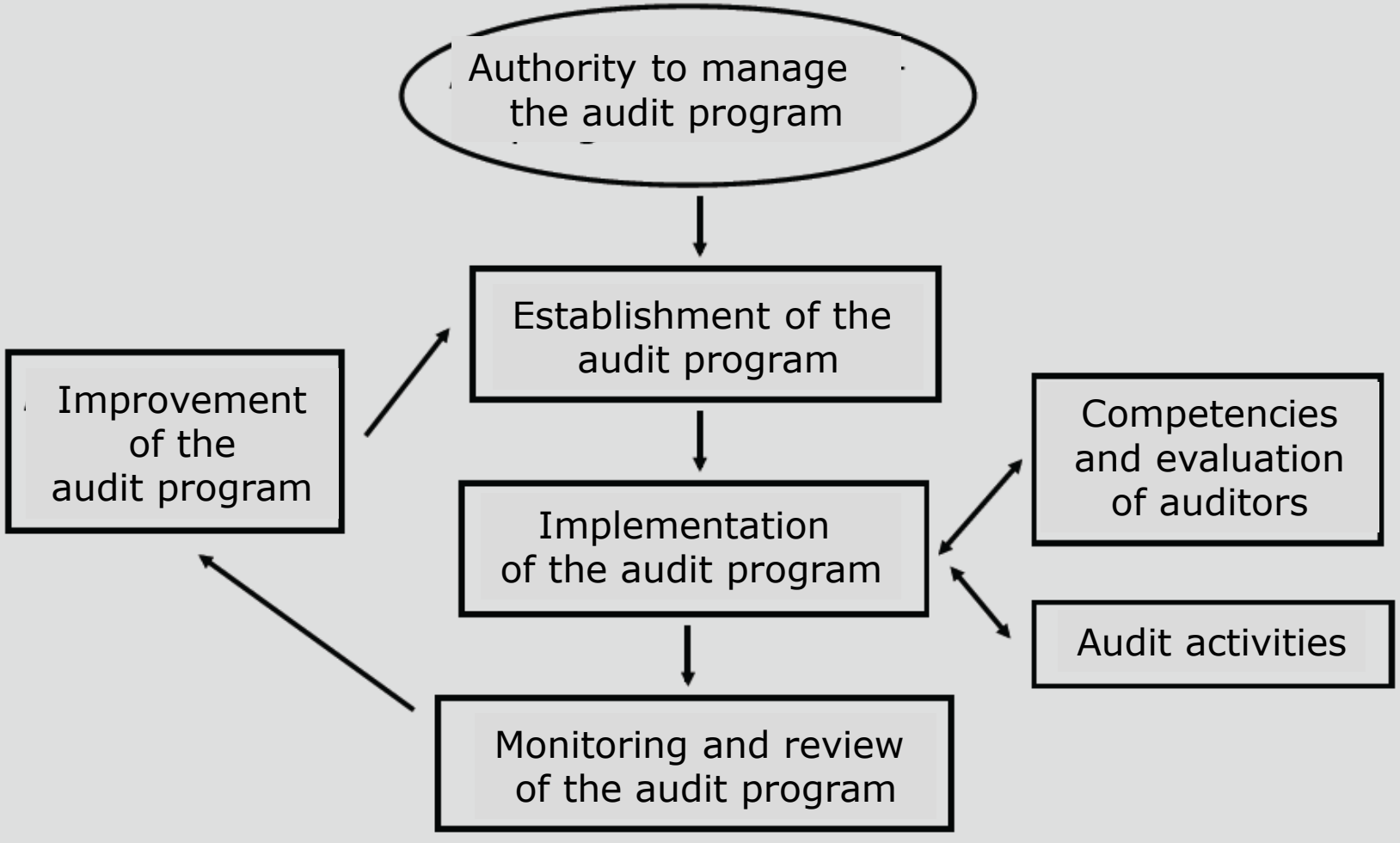


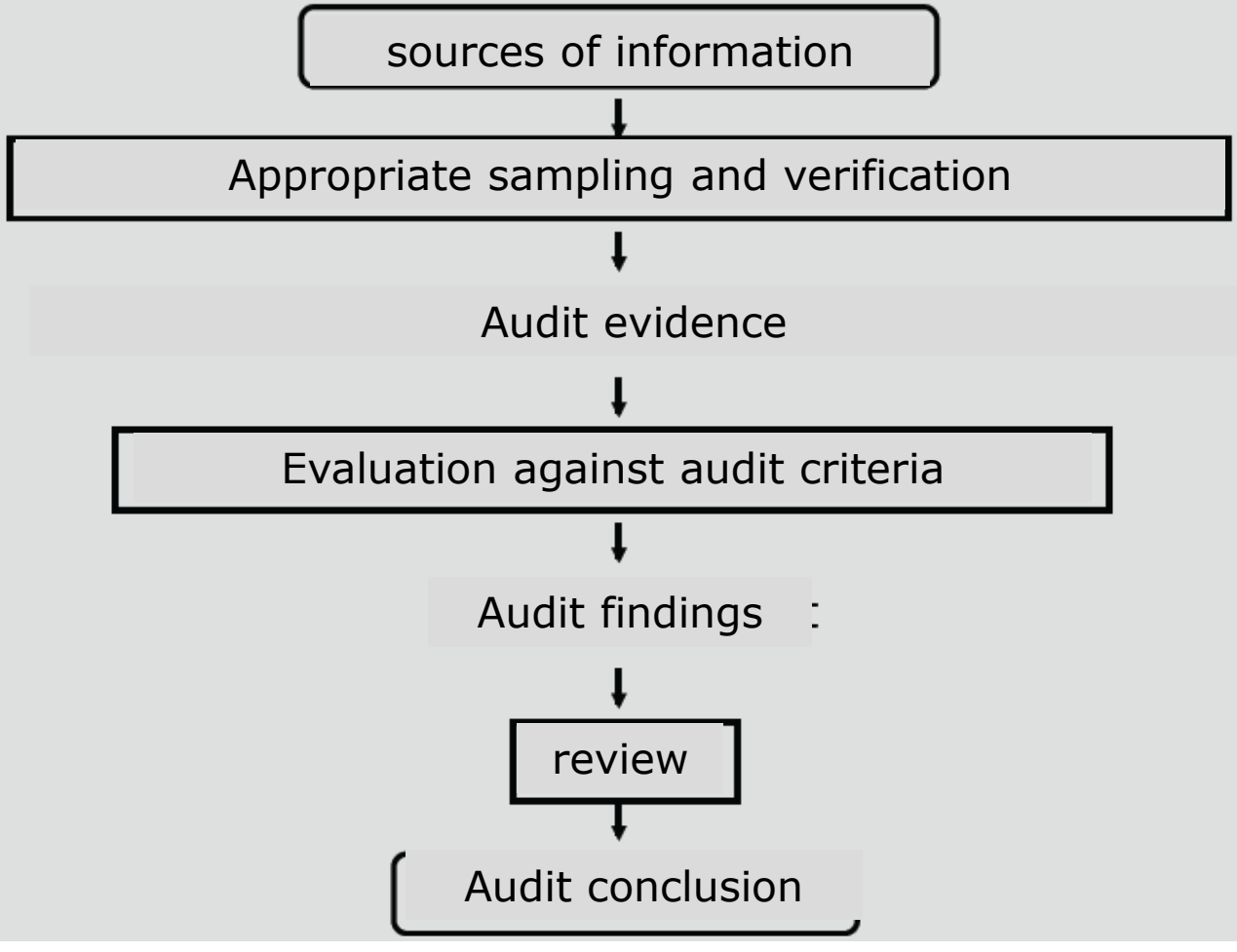
Figure 6.21 The course of the HACCP auditor

Source :
Olivier Boutou, 2008

Management of an audit program



From the collection of information to the conclusions



II. Inspection standards

Norme NBN EN ISO/IEC 17020

ICS: 03.120.20

norme belge enregistrée

NBN EN ISO/IEC 17020

2e éd., avril 2012

Indice de classement: X 30

Évaluation de la conformité - Exigences pour le fonctionnement de différents types d'organismes procédant à l'inspection (ISO/IEC 17020:2012)

Conformiteitsbeoordeling - Algemene criteria voor het functioneren van verschillende soorten instellingen die keuringen uitvoeren (ISO/IEC 17020:2012)

Conformity assessment - Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012)

3. **Terms and definitions** ISO/CEI 17000

Inspection

= examination of a product design, product (3.3), process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements

Product

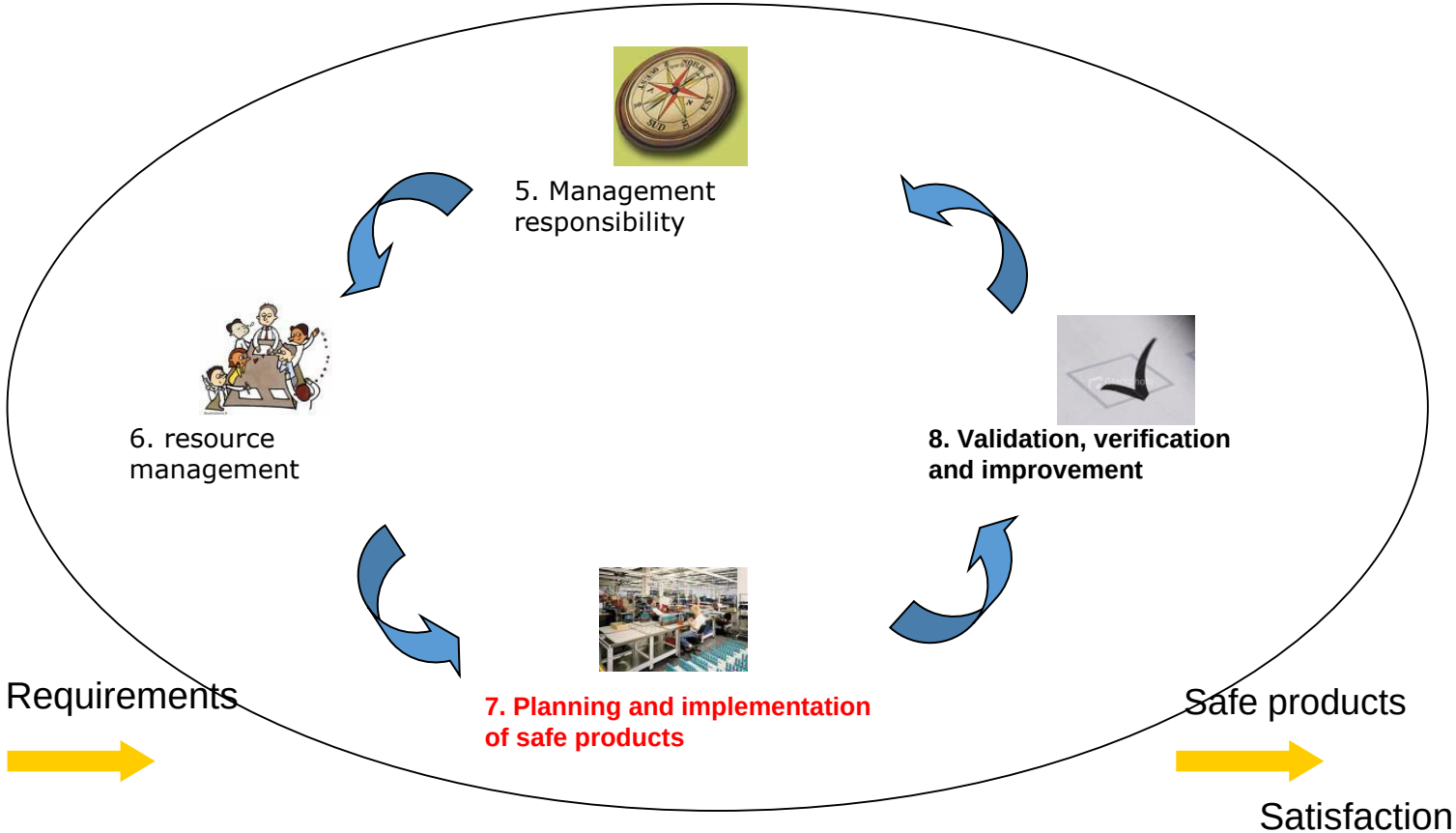
= result of a process

Process : correlated or interactive activities which transform elements « in » into elements « out ».

Approach of hazard control

4. General and Documentation Requirements

Customers and other parties



Customers and other parties

Service :
Result, generally immaterial, of an activity inevitably realized between the supplier and the customer

Inspection body :
Body proceeding to the inspection

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Inspection system :
Standards, procedures and management used to proceed to the inspection

Inspection plan :
Inspection system for which the same specific requirements, standards and procedures apply

Impartiality :
Objectivity

Appeal :
Request from the supplier of object of inspection to the inspection body to reconsider a decision already taken

Complaint :
Expression of a dissatifaction, other than an appeal, from a person or a body to an inspection body about activities of this body. An answer is needed

General requirements of Inspection standards

- 4.1 Impartiality and independence
  - no commercial, financiat pressure, or other
  - Identify threats and risks (show how to react)
  - Impartiality
  - Independence
  - Management commitment

General requirements of Inspection standard

- 4.2 confidentiality
  - Management commitment
  - Customer information for the disclosure of information
  - Sometimes overhangs towards the law (always warn the customer in this case)

Structural requirements of Inspection standard

- 5.1 Administrative requirements
  - Legal entity (or part)
  - Description of the activities
  - Professional indemnity insurance
  - Define the conditions of the contract in which are made the inspections

Structural requirements of Inspection standard

- 5.2 Organisation and management
  - Good structure and good management for impartiality
  - Responsibilities / organizational structure
  - If it is, relation with other structure
  - Technical officer(s) / people in charge of the activities of inspection
  - Back-up for the people
  - Job description

Requirements regarding resources of Inspection standard

- 6.1 Staff
  - Skill requirements (initial and continuing training)
  - Qualifications, experience, knowledge (technology, defects in the process…)
  - Definition of the obligations, responsibilities…
  - Documented procedures to watch the inspectors (on-site observations...)
  - Maintain a register of these supervisions, initial, continuing trainings, technical knowledge

Requirements regarding resources of Inspection standard

- 6.1 Staff (continuation)
  - No link between remuneration and results of the inspections
  - Act in an impartial way of the entire staff of inspection
  - Preserve the confidentiality (except laws)

Requirements regarding resources of Inspection standard

- 6.2 Installations and equipments
  - Appropriate Installations and equipments
  - Define the equipments used
  - Calibration of some equipments
  - Correlation against standards
  - Estimate the state of equipments
  - If computers: soft ware OK + data protection
  - Procedure to manage defective equipments
  - Record of equipments and software

Requirements regarding resources of Inspection standard

- 6.3 Sub-contracting
  - Check the skills of the subcontractor
  - Warn the customer
  - Record the skills of the sub-contractor
  - The body keeps the final responibility

Requirements relative to the processes of standard inspections

- 7.1 Methods and procedures of inspection
  - Define the procedures of inspection
  - Planification of the inspections
  - System of control of contrats (can the body lead this mission ?)
  - Recordings not to lose data
  - Check if intermediate calculations
  - Instructions to realize safe inspections

Requirements relative to the processes of standard inspections

- 7.2 manipulations of samples and objects presented to the inspection
  - Unique Identification of the samples
  - Recording any abnormality before inspection
  - Documented procedures to avoid damages at inspected objects

Requirements relative to the processes of standard inspections

- 7.3 records
  - Records to prove good execution
  - Prove which inspector made the inspection

Requirements relative to the processes of standard inspections

7.4 Inspection reports and certificates

(Identification, results, date of inspection, declaration of conformity)

Precision, clarity,…

Indicate if subcontracting

Requirements relative to the processes of standard inspections

7.5 Complaints and appeals

-Procedure to receive complaints

-Inform the people for whom the body works

-Responsability of the inspection body

-No discriminatory action

Requirements relative to the processes of standard inspections

- 7.5 Complaints and appeals
  - A procedure should exist (reception, recording, follow-up)
  - Acknowledgement of receipt and follow-up
  - Decision made by a person not involved in theinspection

Requirements regarding the management system of the Inspection standards

- 8.1 Options

  - Option A : documentation of the management system, control of the documents, records, management review, internal audit, corrective actions, preventive actions, complaints and appeals

  - Option B : system based on ISO 9001

Requirements regarding the management system of the Inspection standards

- 8.2 Documentation of the management system (option A)

  - Quality policy : objectives
  - Management commitment
  - “Quality Manager”
  - Documentation of the management system
  - Access to this system by the staff members

Requirements regarding the management system of the Inspection standards

- 8.3 Control of the des documents (option A)
  - Procedure of the control of the documents : approval, revision, distribution, readibility, diffusion control

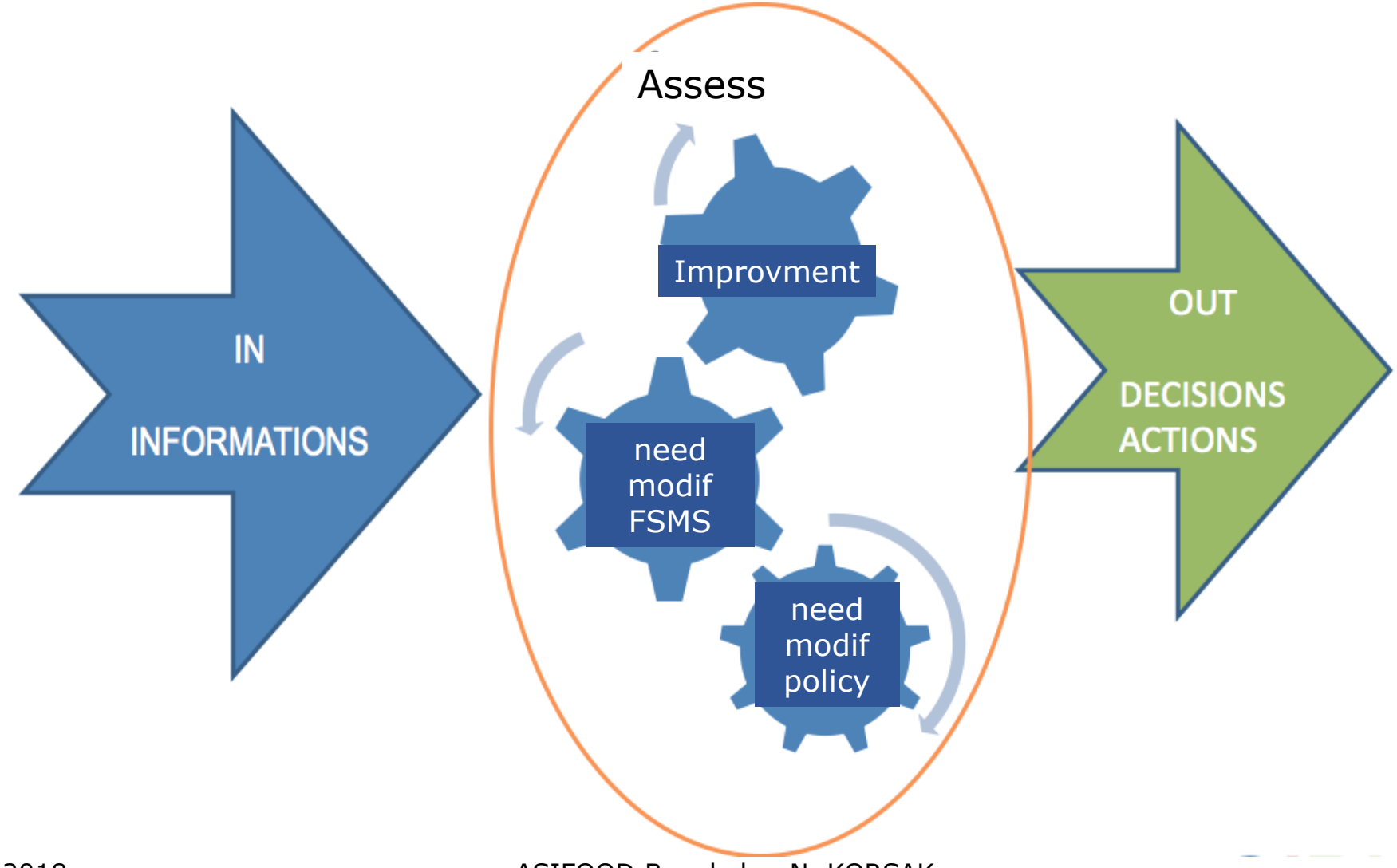
Requirements regarding the management system of the Inspection standards

- 8.4 Recordings control (option A)
  - Procedure : storage, protection, accessibility, shelf life
  - Define a shelf life

Requirements regarding the management system of the Inspection standards

- 8.5 management review (option A)
  - Revise the management system + politics + objectives (relevant, adequate and effective)
  - Once a year
  - Record the management reviews

Processus

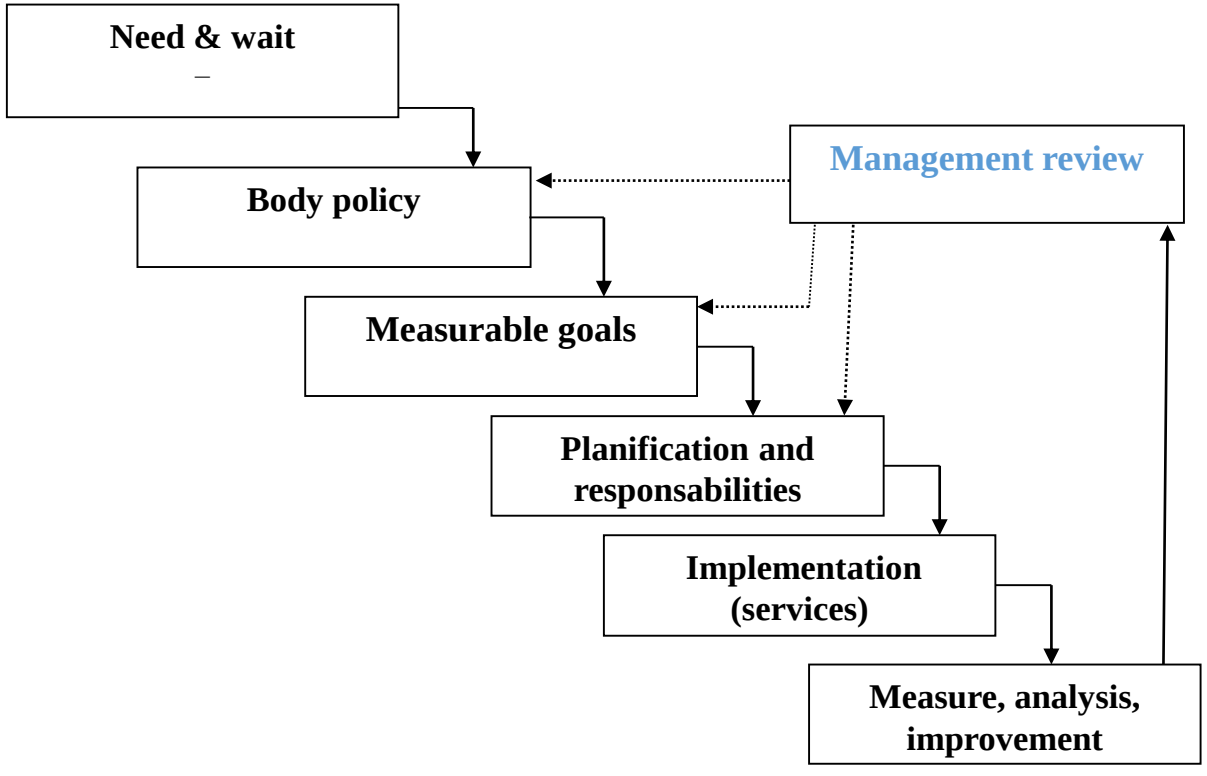

IN
INFORMATIONS
Assess
Improvment
need
modif
FSMS
need
modif
policy
OUT
DECISIONS
ACTIONS

Relevant, adequate, effective ?

- Relevant –> the right questions ?
- Adequate -> *not too much, not too few*
- Effective -> reach the fixed objectives ?

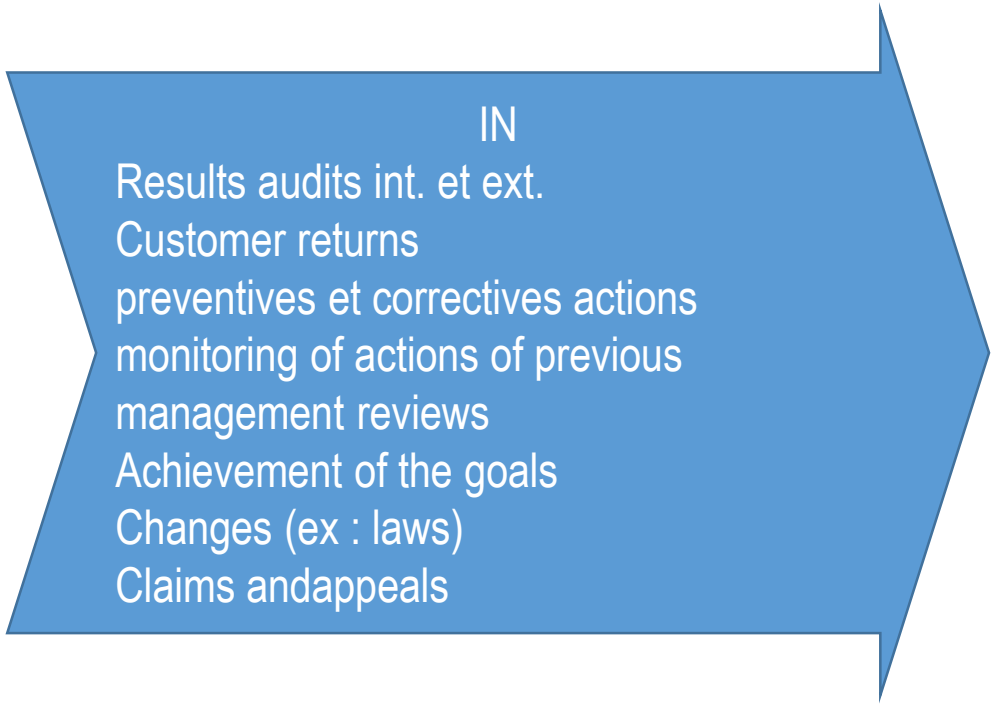
Management responsibility

Principle of coherence :



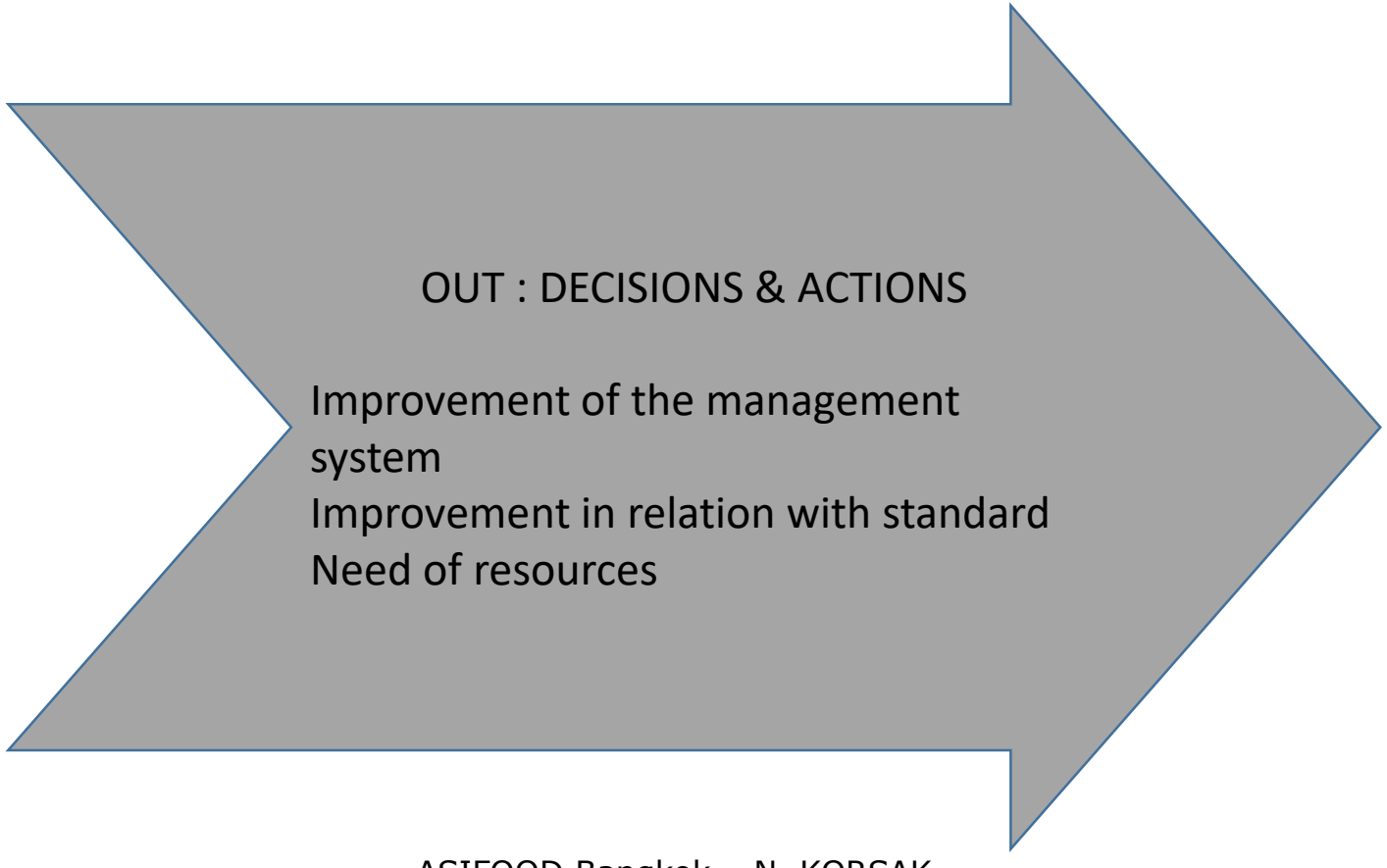
IN

- in


IN
Results audits int. et ext.
Customer returns
preventives et correctives actions
monitoring of actions of previous
management reviews
Achievement of the goals
Changes (ex : laws)
Claims andappeals

OUT

- out


OUT : DECISIONS & ACTIONS
Improvement of the management system
Improvement in relation with standard
Need of resources

Requirements regarding the management system of the Inspection standards

- 8.6 Internal audits(option A)
  - Check the conformity
  - Plan the program
  - Every process
  - > once a year
  - Qualified personnel (independent) and information of the people in the audited sector
  - Identify the tracks of improvement

Internal audit

- **Références**
  - standards
  - Procedures
  - Process

⟷

- **Real**
  - What is done
  - Implementation
  - Records

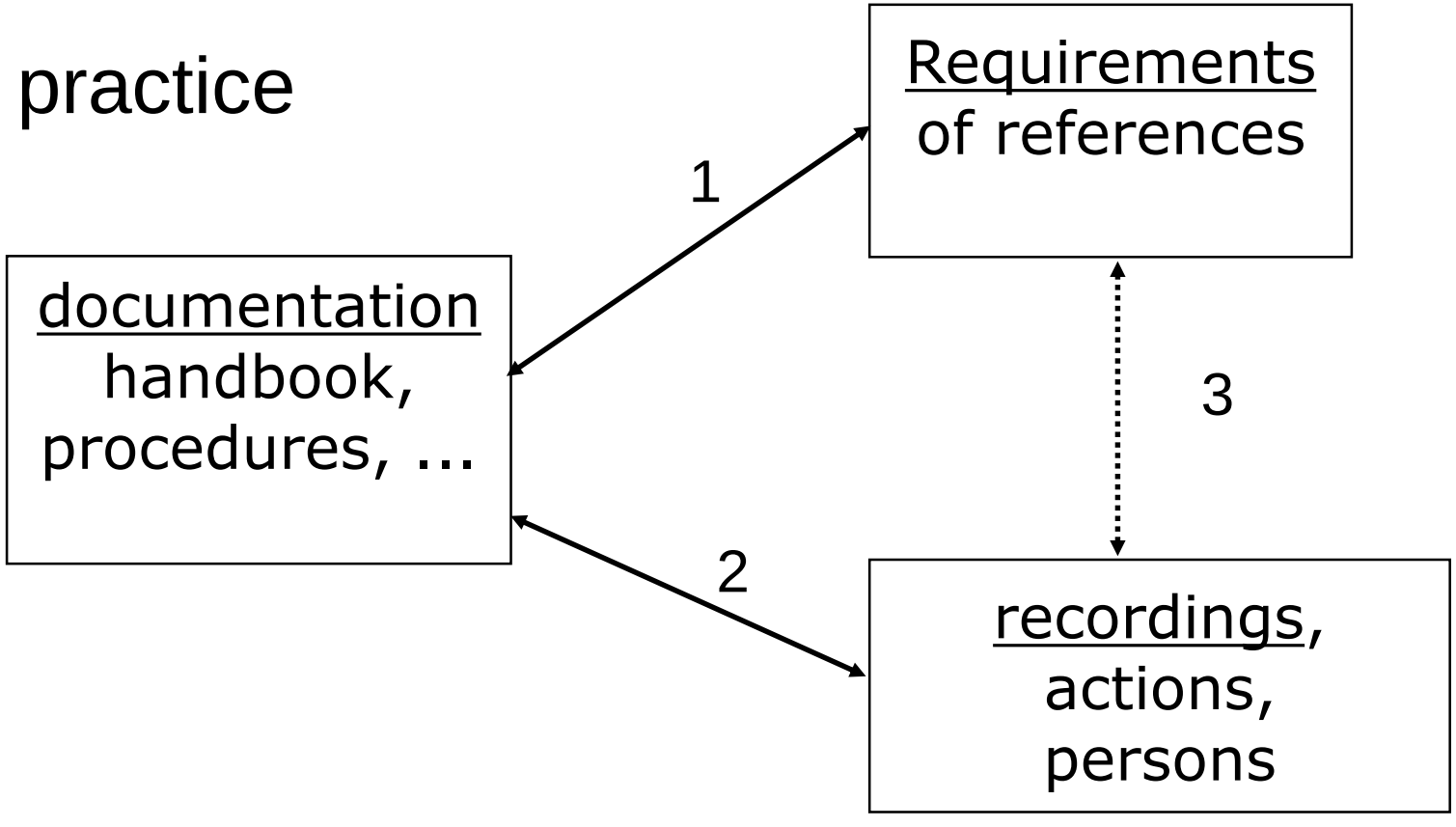
Observations -
Based on objective evidences

DEVIATION
Non-compliant/
Corrective Actions

NO DEVIATION
OK or
Preventive Actions

Internal audit

in practice



Requirements regarding the management system of the Inspection standards

- 8.7 corrective actions (option A)

  - Identify and manage NC, avoid other NC
  - correctives actions adapted to NC
  - Procedures : identification, find the causes of NC, correction, actions to avoid NC, record the results, review efficacity of corrective actions

Requirements regarding the management system of the Inspection standards

- 8.7 preventive actions (option A)
  - Idem but act to the source
  - Avoid the causes of possible NC

Types of inspection bodies

- Type A : real and complete independence
  - Total independence and impartiality
  - separate legal entity from the body and the company that designs, supplies , … the objects which it inspects.
  - No separate legal entity which has something to do with the objects.

Types of inspection bodies

- Type B:
  - Supplies inspections to the organization of which it is a member
  - Separate staff (inspection vs production)
  - inspection body : no role in the conception, production, supply, installation, or in the maintenance of the inspected objects.

Types of inspection bodies

- Type C:
  - Separate responsabilities
  - inspection body : no role in the conception, production, supply, installation, or the maintenance of the inspected objects (except, statutory exception, if it does not compromise the results of the inspection)