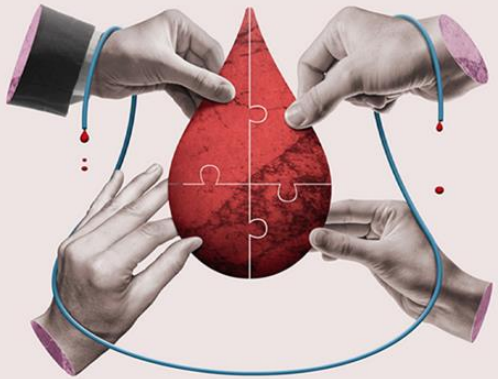
CENTRO NAZIONALE SANGUE

Istituto Superiore di Sanità

with the patronage of Ministry of Health®

Ministero della Salute

SoHOs OVERSIGHT SYSTEM:
A FOCUS ON INSPECTION AND AUTHORISATION PROCESS AT NATIONAL AND EUROPEAN LEVEL



March 28th, 2023
Acquario Romano,
Piazza Manfredo Fanti 47
Rome

The inspection and authorisation processes of the Italian blood system

Simonetta Pupella

Rome, 28th March 2023

BLOOD SYSTEM GOVERNANCE IN ITALY

Ministry of Health	National Blood Centre	Regional blood centres
• Political decisions • Strategic goals	• Technical arm of the MoH • Coordination and technical and scientific control of the national blood network	• Technical arms of regional health authorities • Coordination and technical and scientific control of the regional blood network

CENTRO NAZIONALE SANGUE

THE INSTITUTIONAL FRAMEWORK OF THE ITALIAN BLOOD SYSTEM

Legge del 21 ottobre 2005, N.219

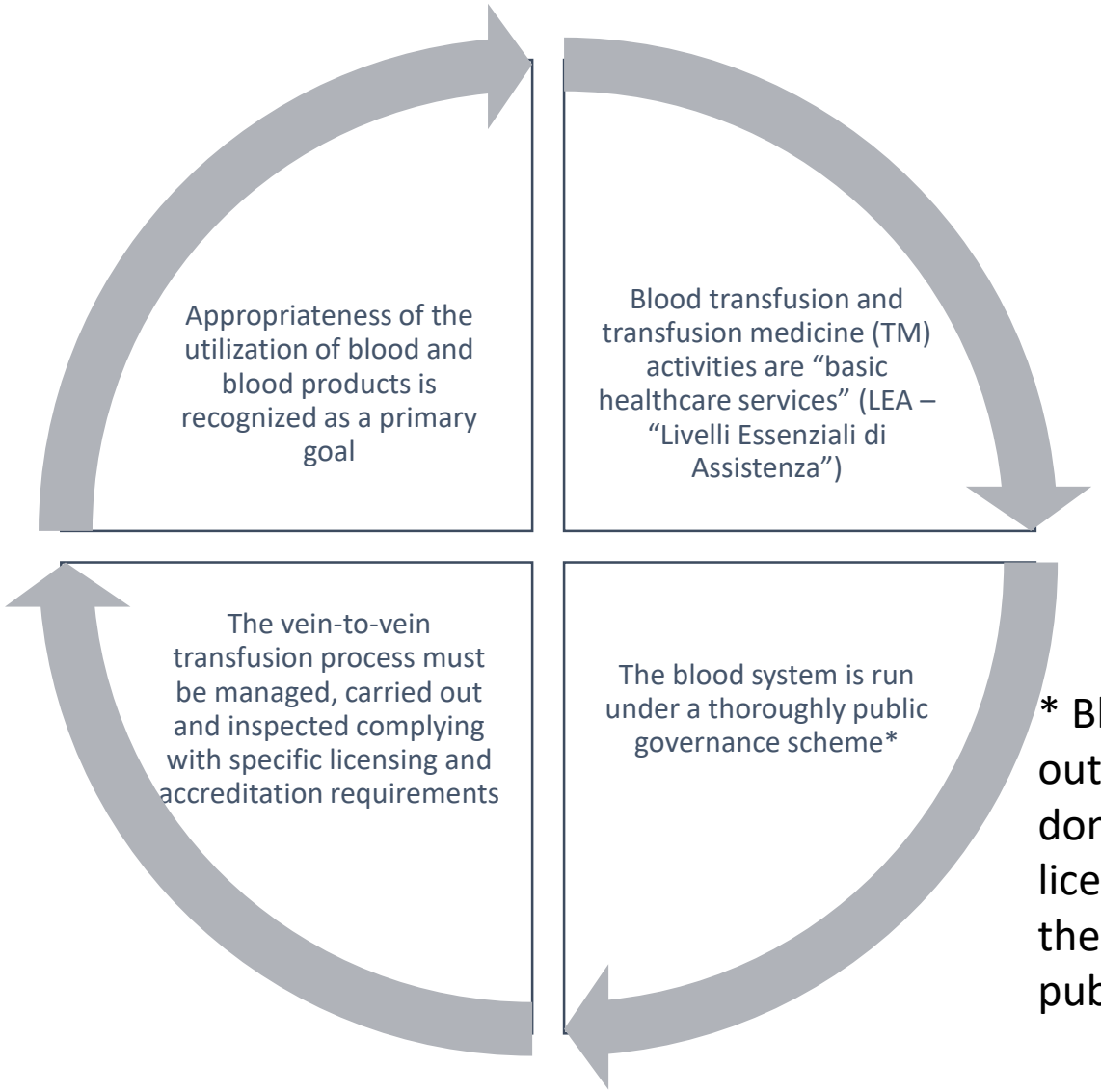
"NUOVA DISCIPLINA DELLE ATTIVITA' TRASFUSIONALI E DELLA PRODUZIONE NAZIONALE DEGLI EMODERIVATI".

(Gazzetta Ufficiale del 27.10.2005 n. 251)

General provisions
Blood system organization
Provisions on the Associations and Federations of voluntary blood donors
Planning of the national blood transfusion service
Measures for the coordination
Measures for national self-sufficiency
Authorization, accreditation or licensing of blood services
Standards of quality and safety of blood and blood products
Final and transitional provisions

CENTRO NAZIONALE SANGUE

THE ITALIAN BLOOD SYSTEM



* Blood collection can be outsourced to qualified blood donor associations upon specific licensing and accreditation, under the technical supervision of public Blood Services.

Founding principles

CENTRO NAZIONALE SANGUE

THE ITALIAN BLOOD SYSTEM

CENTRO NAZIONALE SANGUE

THE REGULATORY FRAMEWORK

First transposition
Directive 2002/98/EC
August 2005

Transposition
Directive 2004/33/EC
March 2005

Transposition
Directive 2005/61/EC
November 2007

Transposition
Directive 2005/62/EC
November 2007

Update transposition
Directive 2002/98/EC
December 2007

BLOOD

Transposition
Directive 2004/23/EC
November 2007

Transposition
Directive 2006/86/EC
January 2010

Transposition
Directive 2006/16/EC
January 2010

CELLS TISSUES

Transposition
Directive 2016/1214/EC
March 2018

MEDICINAL PRODUCTS

CENTRO NAZIONALE SANGUE

«Licensing» in the EU regulatory framework

DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 January 2003

setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

In order to ensure that there is an **equivalent level of safety and quality of blood components**, whatever their intended purpose, technical requirements for the collection and testing of all blood and blood components including starting materials for medicinal products should be established by this Directive.

Member States should ensure that an appropriate mechanism for **designating, authorising, accrediting or licensing** exists to ensure that the activities of blood establishments are performed in accordance with the requirements of this Directive.

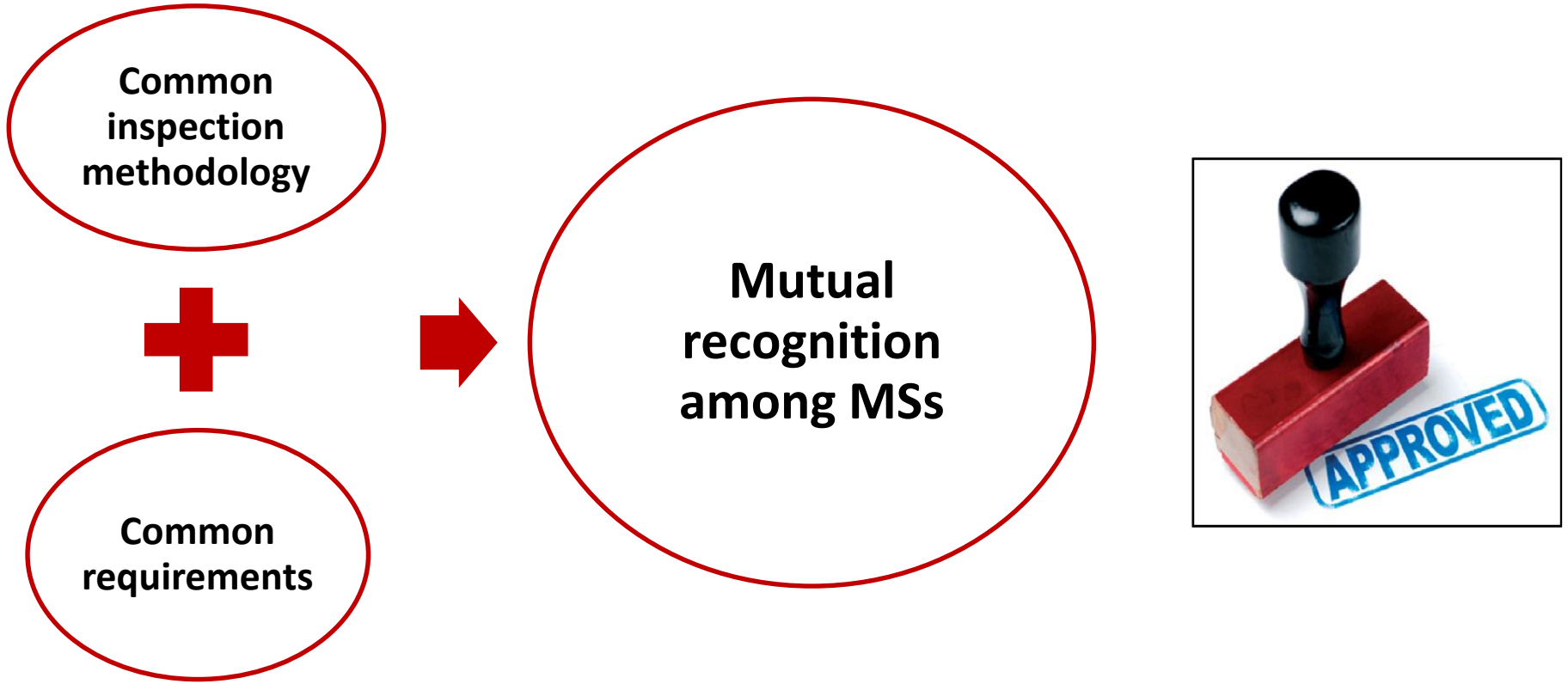
Member States shall organise **inspection and control measures**, to be carried out **by officials representing the competent authority**, to ensure the compliance of the blood establishment with the provisions of this Directive

Key words

In an organisational contest quite homogeneous, based on a high level of concentration of blood prepration processes

«Licensing» in the EU regulatory framework

The oversight activities are in charge of the Competent Authorities (CA) of the MS with the aim to formally assess the compliance of BEs with the national and Eu regulatory requirements



«Authorisation/accreditation» in the Italian regulatory framework

Update transposition
Directive 2002/98/EC
December 2007

OBLIGATIONS ON MEMBER STATES AUTHORITIES

Article 5

Designation, authorisation, accreditation or licensing of blood establishments

1. Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.

In charge of the CAs

DECRETO LEGISLATIVO 20 dicembre 2007, n. **261.**

Revisione del decreto legislativo 19 agosto 2005, n. 191, recante attuazione della direttiva 2002/98/CE che stabilisce norme di qualità e di sicurezza per la raccolta, il controllo, la lavorazione, la conservazione e la distribuzione del sangue umano e dei suoi componenti.

Art. 4.

Autorizzazione e accreditamento dei servizi trasfusionali

3. La regione o la provincia autonoma, previo accertamento della conformità del servizio trasfusionale e della unità di raccolta ai requisiti previsti, ai sensi della normativa vigente, ne autorizza l'esercizio delle attività consentite, prescrivendone le condizioni.

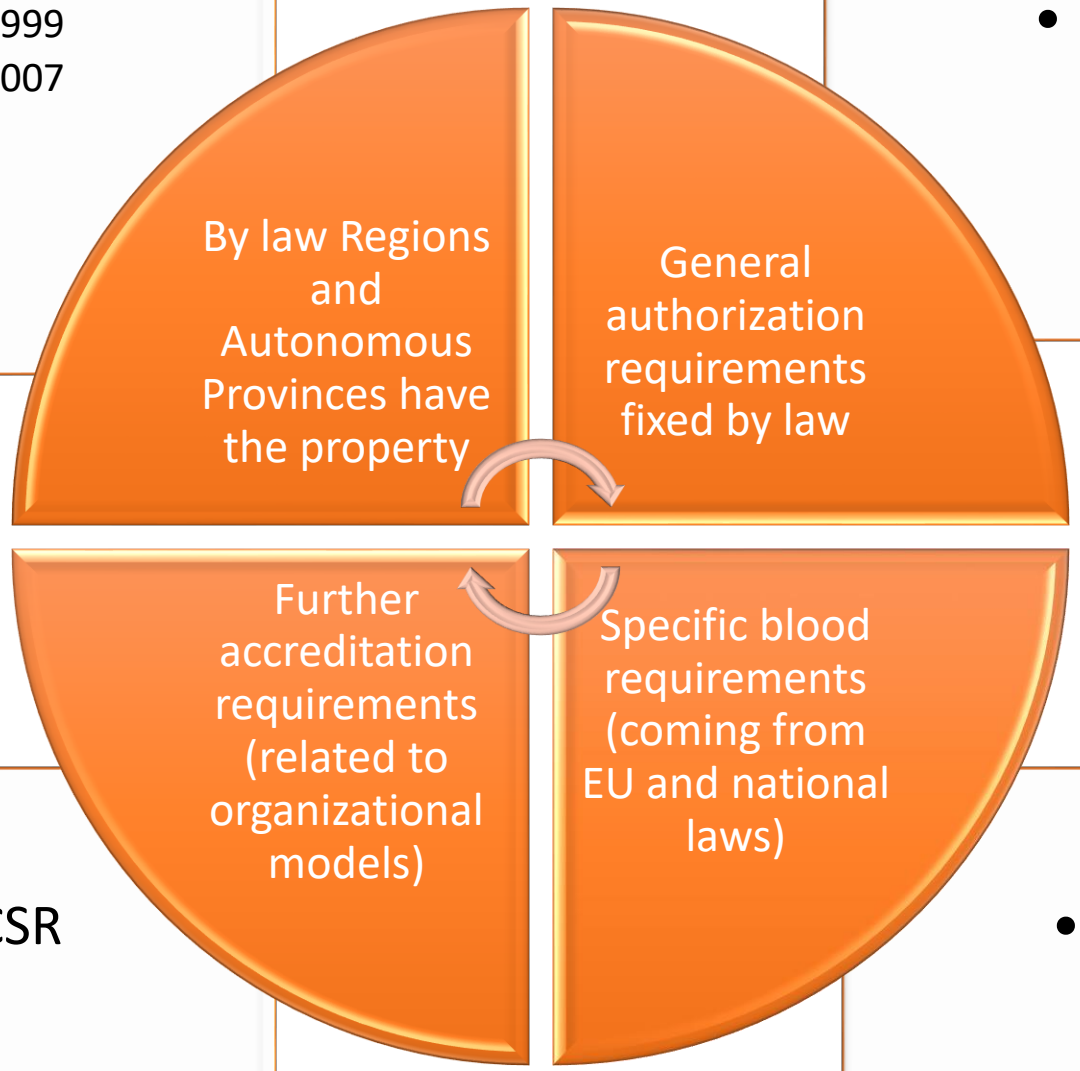
In charge of the Regional/Autonomous Provinces CAs

CENTRO NAZIONALE SANGUE

«Authorisation/accreditation» in the Italian regulatory framework

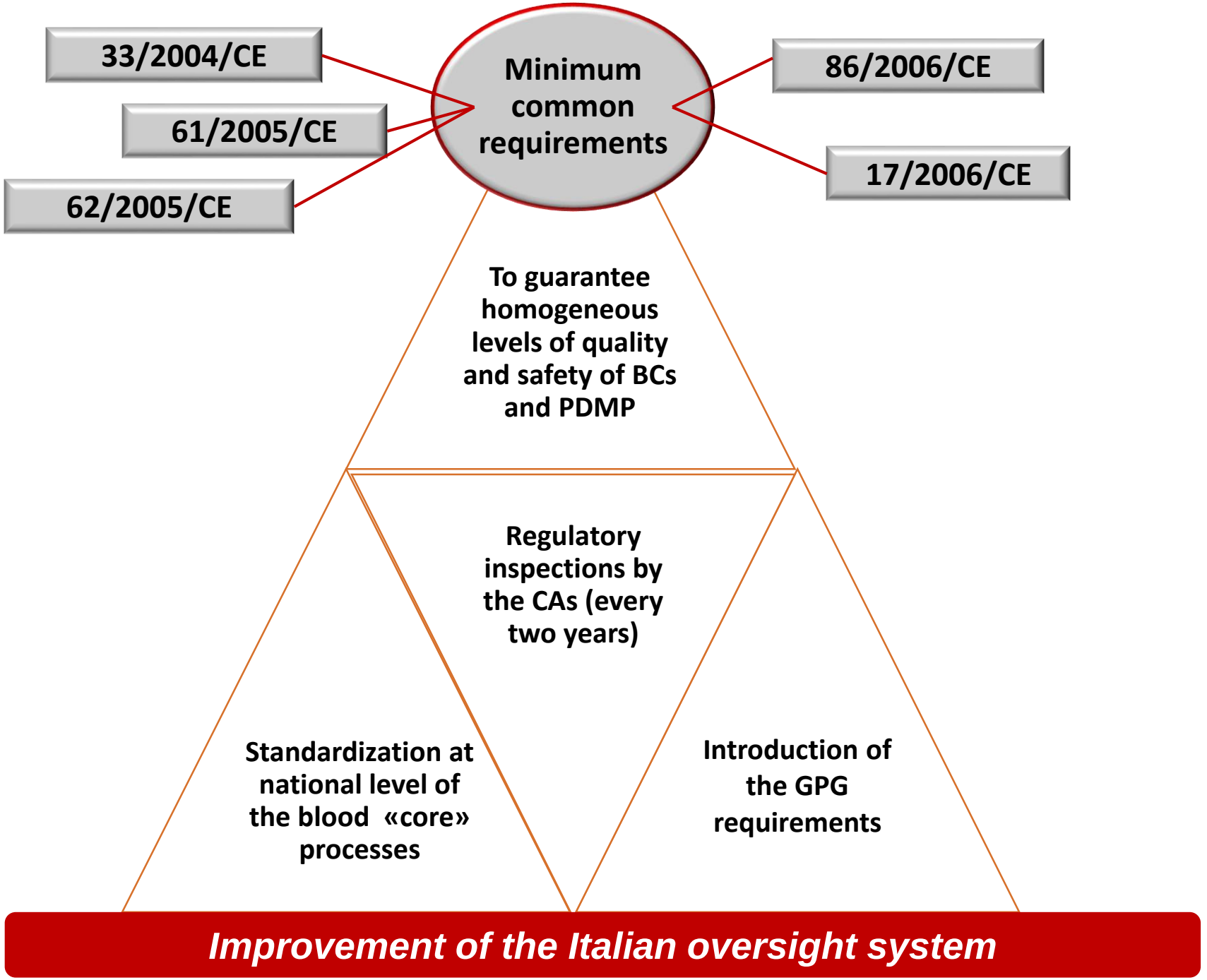
- D.Lgs. n. 502/1992
- D.Lgs. n. 229/1999
- D.Lgs. n. 261/2007

- DPR 14.01.1997

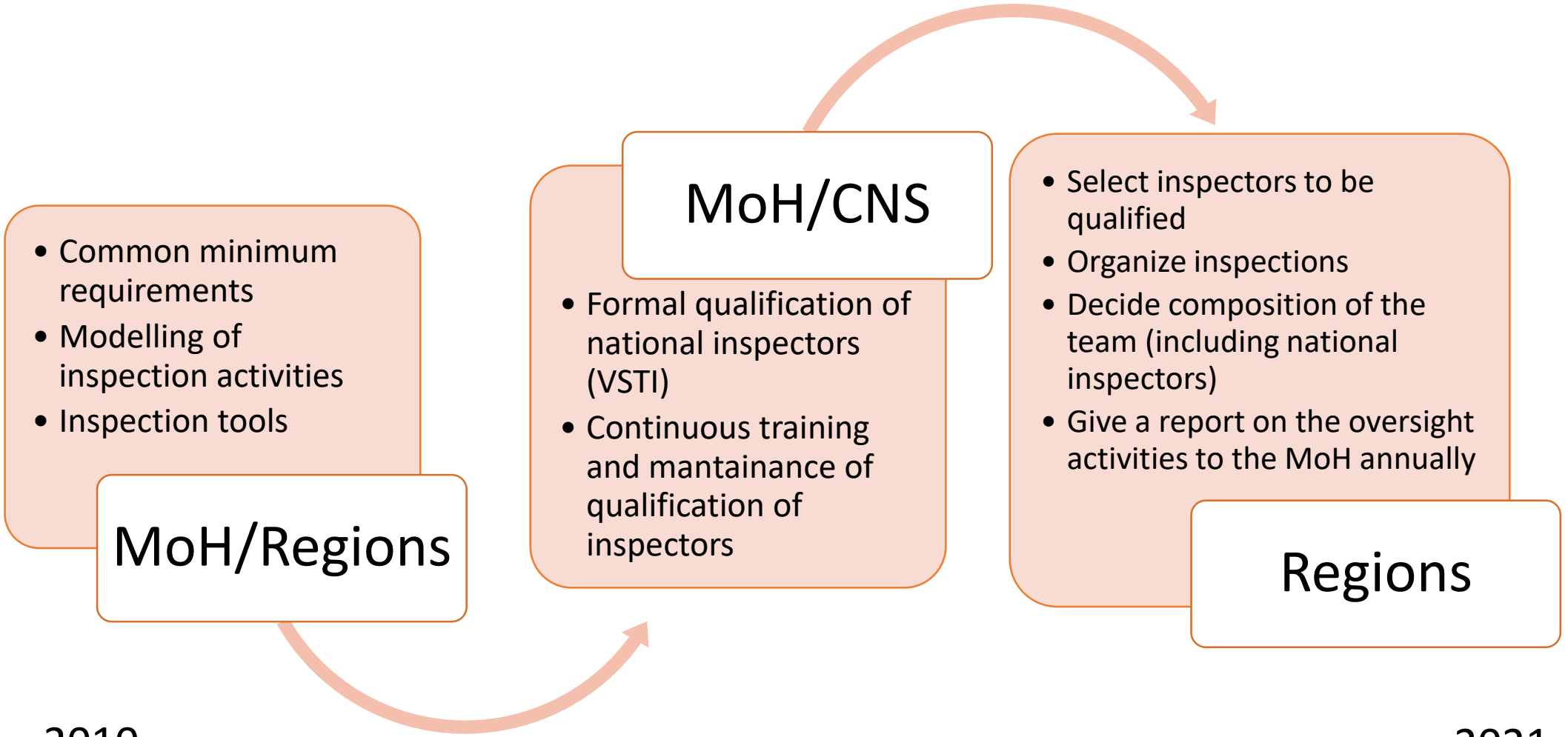


- Accordo CSR 25 luglio 2012

- Accordo CSR 16 dicembre 2010

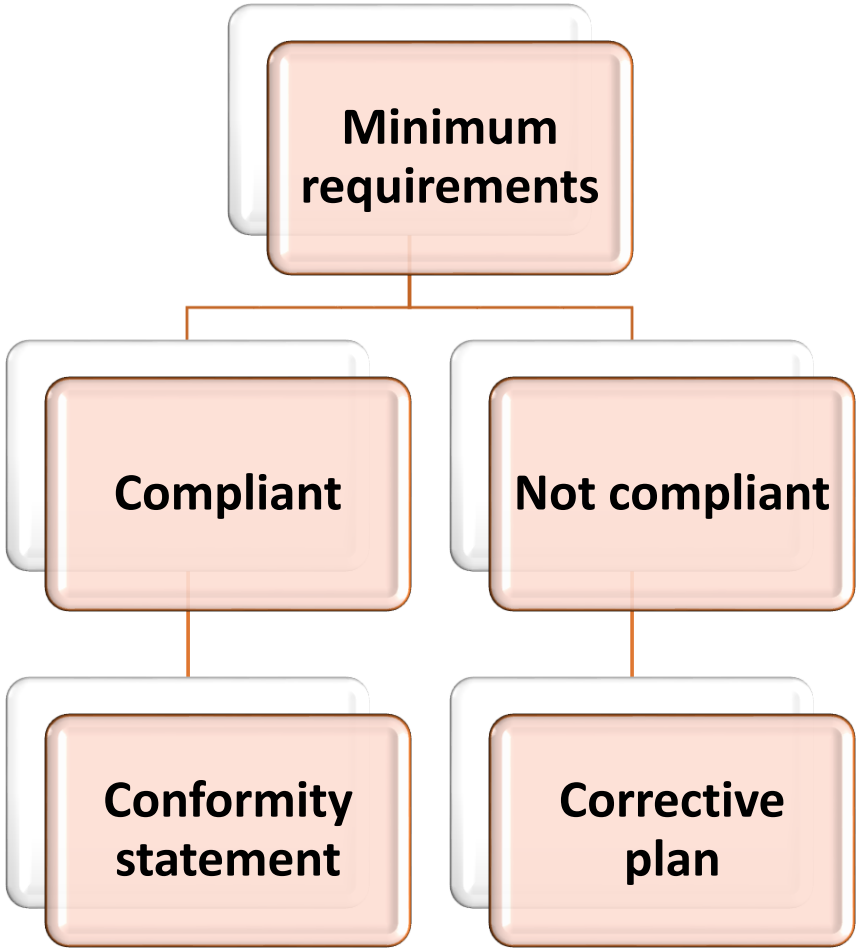

33/2004/CE
61/2005/CE
62/2005/CE
Minimum common requirements
86/2006/CE
17/2006/CE
To guarantee homogeneous levels of quality and safety of BCs and PDMP
Regulatory inspections by the CAs (every two years)
Standardization at national level of the blood «core» processes
Introduction of the GPG requirements
Improvement of the Italian oversight system

«Authorisation/accreditation» of the blood system in the Italian regulatory framework

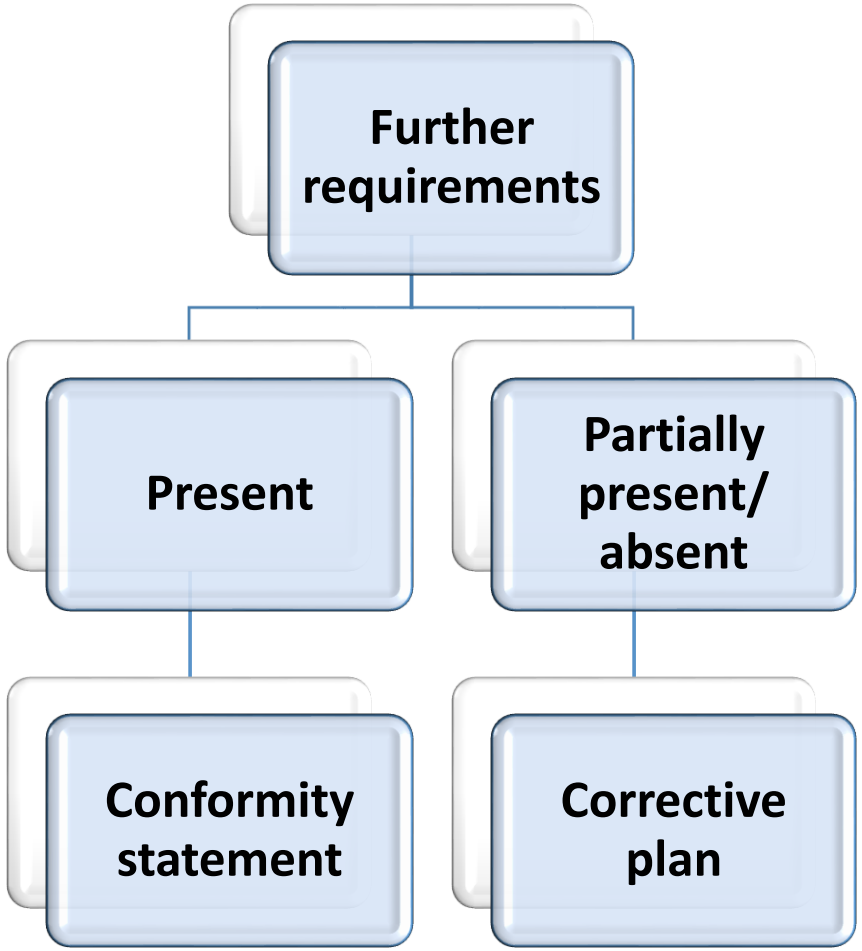


CRITICALITY

AUTHORIZATION



ACCREDITATION



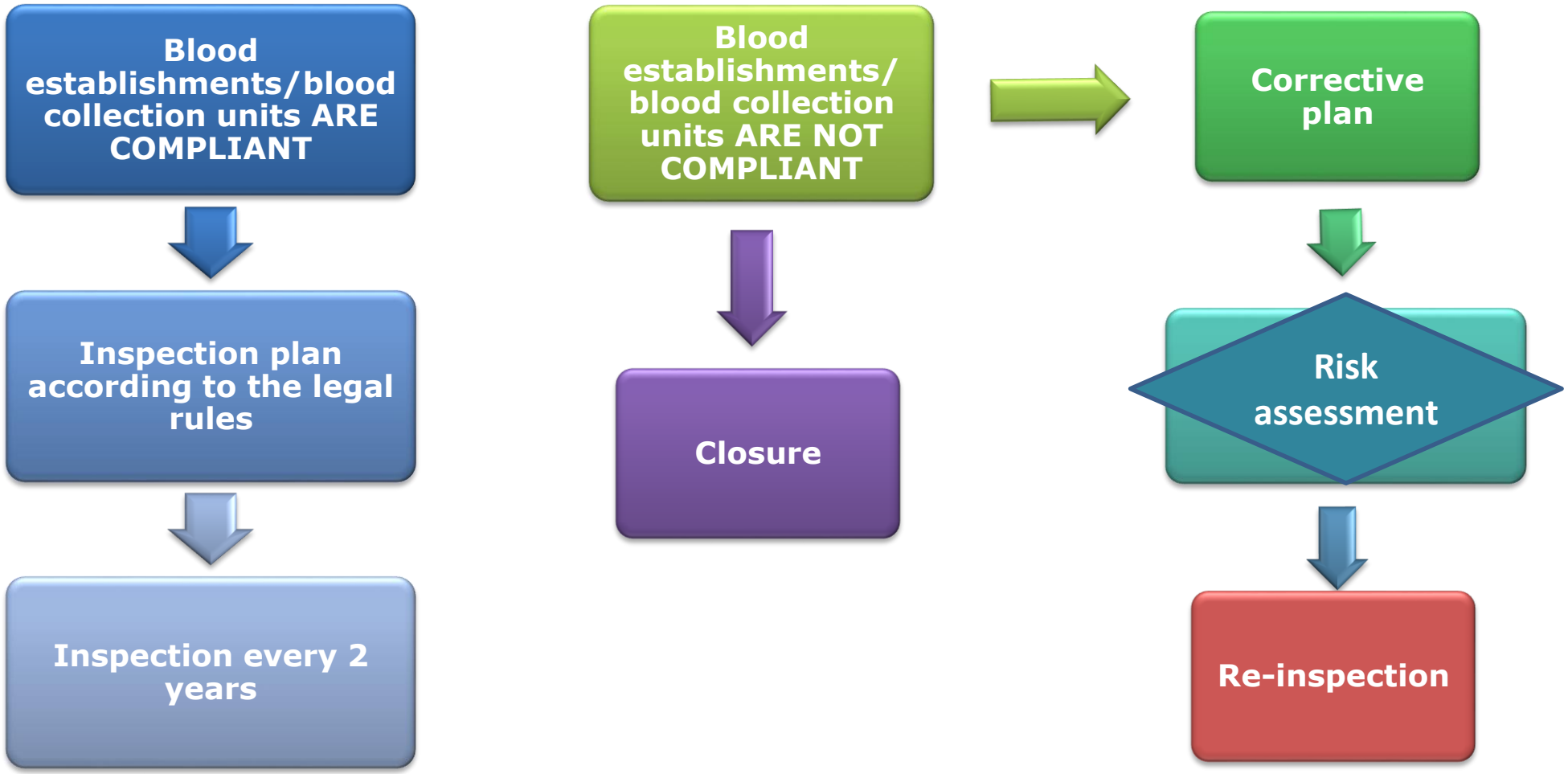
Is the same approach applied to assess the requirements?

100/100

70/100

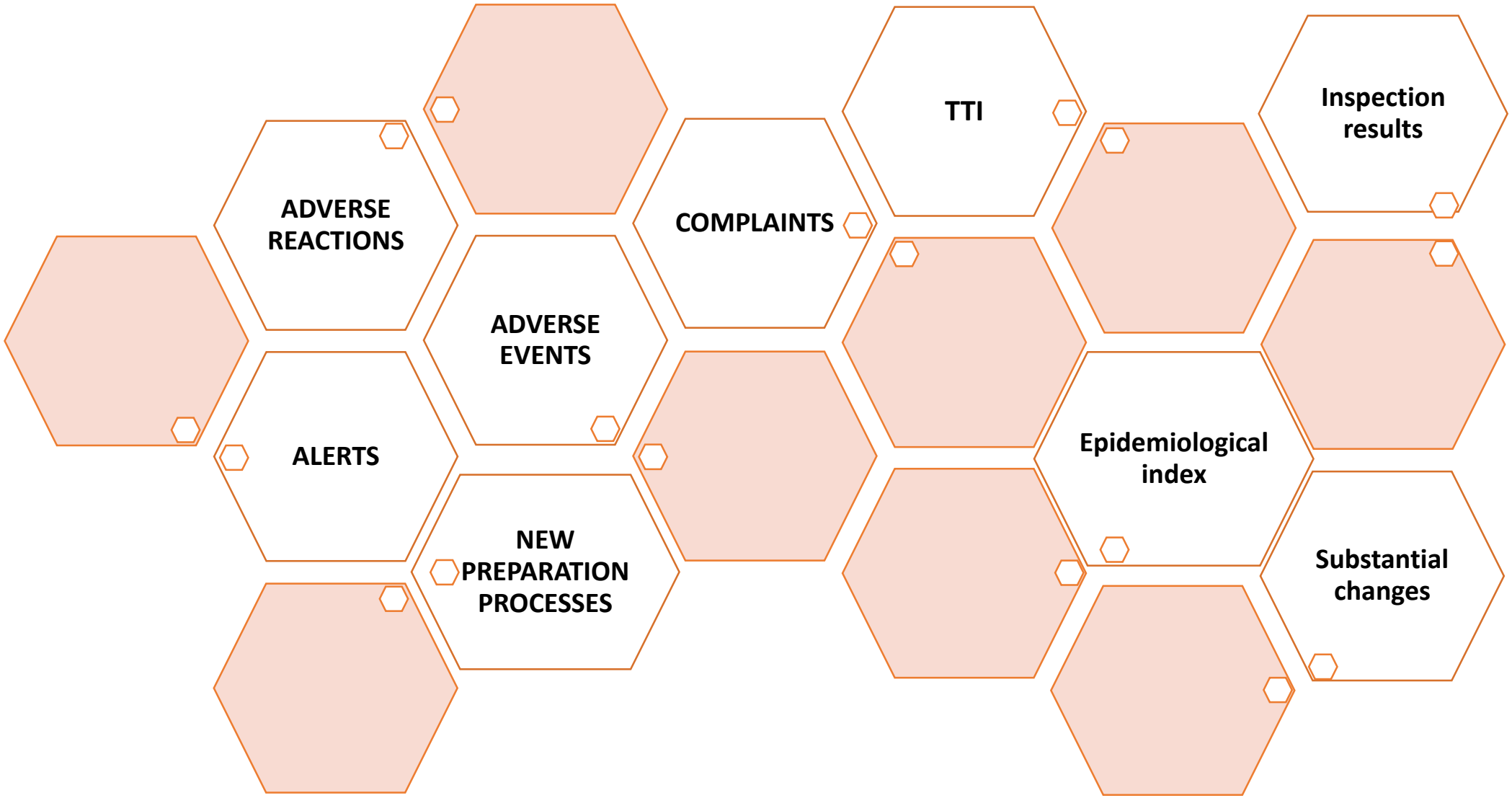
CENTRO NAZIONALE SANGUE

CRITICALITY



Ia there the same approach/methodology for planning the routine inspections?

CRITICALITY



Is there the same approach/methodology for planning not-routine inspections?

CENTRO NAZIONALE SANGUE

CRITICALITY

Inspection	Formal and objective control according to adopted standards to assess compliance with this Directive and other relevant legislation and to identify problems	Directive 2002/98/EC
Inspection / audit, external (regulatory)	An inspection carried out by the Competent Authority or accreditation body. Formal and objective control	EuBIS Guide
Audit	Documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to written SOPs, standards, or government laws and regulations, conducted by professional peers, internal quality system auditors or certification body auditors.	Adapted from the Council of Europe Guide for Safety and Quality Assurance for Organs, Tissue and Cells for Transplantation, 3rd Edition. Council of Europe Publishing January 2007

EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202

May be the independence and tertietarity ensured only through the «inspectors»?

CENTRO NAZIONALE SANGUE

«Authorisation/accreditation» of the National Health Care System

GOVERNMENT/REGIONS AGREEMENT (CSR 19-02-2015)

ORGANISMI TECNICAMENTE ACCREDITANTI (OTA)

Perform audits of healthcare facilities

*Technical Accreditation Body

OTA* = Regional inspectorate
Independent
Impartial
Transparent
Manages auditors
Plans and performs audits
Provides audit reports to the Regional CA

D.M. 26 maggio 2011
National list of regional blood Inspectors, selected by the Regions, managed by CNS
(specialized initial training, ongoing training, assessment of the maintainance of competences)

OTA are involved also in the authorization/accreditation process of blood establishment and blood collection units. The main goal is to integrate homogenously the regulatory inspection pathway of the blood system in the existing regional systems

CENTRO NAZIONALE SANGUE

Spediz. abb. post. - art. 1, comma 1
Legge 27-02-2004, n. 46 - Filiale di Roma

GAZZETTA UFFICIALE
DELLA REPUBBLICA ITALIANA

Anno 163° - Numero 8

MINISTERO DELLA SALUTE

DECRETO 5 novembre 2021.

Istituzione e modalità di funzionamento del sistema nazionale di verifica, controllo e certificazione di conformità delle attività e dei prodotti dei servizi trasfusionali.

Implementation and performance of a **NATIONAL SYSTEM** for

ASSESSMENT
CONTROL
CERTIFICATION OF COMPLIANCE
OF **PROCESSES AND PRODUCTS**
OF THE BLOOD ESTABLISHMENT

WITH THE AIM TO GUARANTEE:

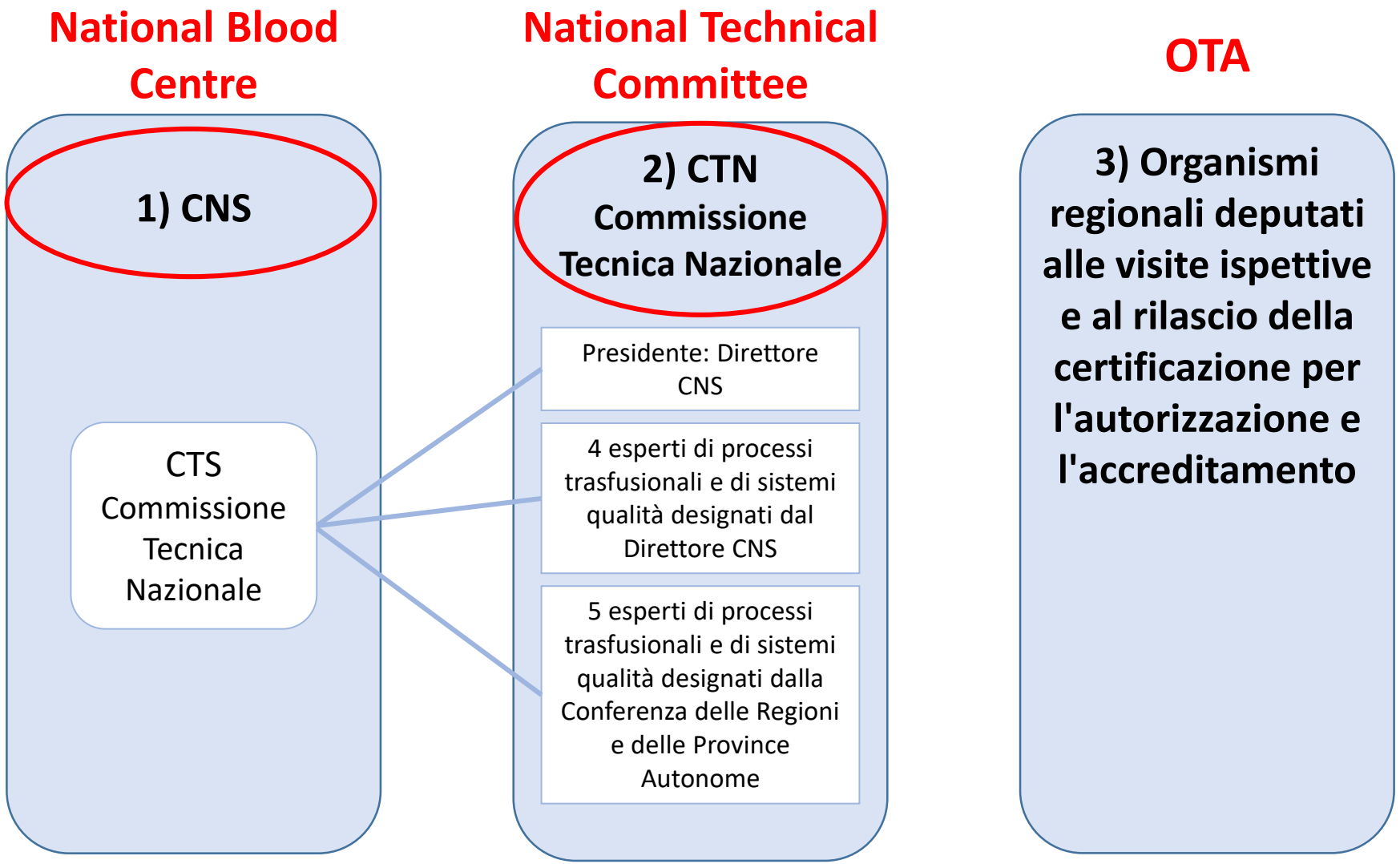
a) UNIFORM AND HIGH LEVEL OF QUALITY AND SAFETY OF THE BLOOD PROCESSES AND PRODUCTS (blood components and PDMP)

b) HARMONIZATION OF THE INSPECTION PROCEDURES AS AN ESSENTIAL TOOL FOR THE AUTHORIZATION/ACCREDITATION OF THE BEs

c) MONITORING AND CONTROL OF THE OVERSIGHT ACTIVITIES PERFORMED BY THE REGIONS

CENTRO NAZIONALE SANGUE

New «Authorisation/accreditation» system: arms



New «Authorisation/accreditation» system: CTN functions

Monitoraggio e controllo sulle Regioni

- Recepimento e attuazione normativa
- Modalità di armonizzazione dei relativi modelli di autorizzazione e accreditamento

Atti e procedure adottati per:
- autorizzazione e accreditamento ST e UdR
- svolgimento attività di verifica e controllo

Di carattere documentale su svolgimento attività di verifica, controllo e certificazione di conformità attuate

MONITORING

Elaborazione di raccomandazioni per la formazione dei valutatori nazionali e regionali

Supporto alla formazione dei valutatori

Valutazione del mantenimento delle competenze dei valutatori

TRAINING

Rapporto annuale stato avanzamento SN e SR di autorizzazione e accreditamento del ST da trasmettere al Ministero della Salute e alla Conferenza delle Regioni

Formulazione di proposte per la risoluzione di problemi e criticità rilevati

REPORTING

Effettuazione, in base al monitoraggio e controllo documentale, di:

Audit presso i competenti organismi regionali, al fine di stabilire interventi e azioni di miglioramento

AUDITING

CENTRO NAZIONALE SANGUE

New «Authorisation/accreditation» system: CTN WORK PLAN

a) To identify an information scheme to be implemented
   - contact with regional OTA;
   - supported by specific tools (IT)

b) To define the minimum dataset for monitoring

c) To start the monitoring and control activities of the CTN according to the mandate assigned by law

New «Authorisation/accreditation» system: CTN WORK PLAN

MINISTERO DELLA SALUTE

DECRETO 5 novembre 2021.

Istituzione e modalità di funzionamento del sistema nazionale di verifica, controllo e certificazione di conformità delle attività e dei prodotti dei servizi trasfusionali.

To guarantee at national level:

a) uniformi ed elevati livelli di qualità e sicurezza e omogeneità delle attività e dei prodotti dei ST e delle UdR, anche ai fini della produzione di MPD;

b) harmonization of the regional inspection procedures and strengthening of the independence/impartiality of inspectors for the certification of blood processes and products as a preparatory step for the authorization/ accreditation statement of a BE

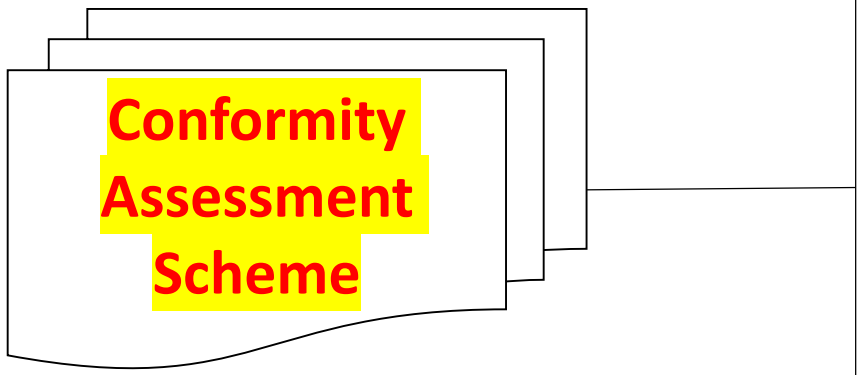
c) il monitoraggio e il controllo dell'attuazione da parte delle regioni e delle PP.AA. delle disposizioni contenute nel presente decreto.

CENTRO NAZIONALE SANGUE

New «Authorisation/accreditation» system

CNS has been recognized as a «certification body for persons»

CERTIFICATION OF BLOOD INSPECTORS COMPETENCES



- CNS is the owner of the scheme
- The scheme has been developed according to the UNI CEI EN ISO/IEC 17024*

*ISO/IEC 17024**: Conformity assessment - General requirements for bodies operating certification of persons** is an International Standard which specifies criteria for the operation of a personnel certification body (also known as a **'certification body for persons**'). The standard includes requirements for the development and maintenance of the certification scheme for persons upon which the certification is based.

CENTRO NAZIONALE SANGUE

The CNS **“certification body for persons”** has been accredited by ACCREDIA*

CNS is the first public health organization, at international level, to have obtained the accreditation according to the ISO 17024 norm as Certification body of inspectors in the blood field

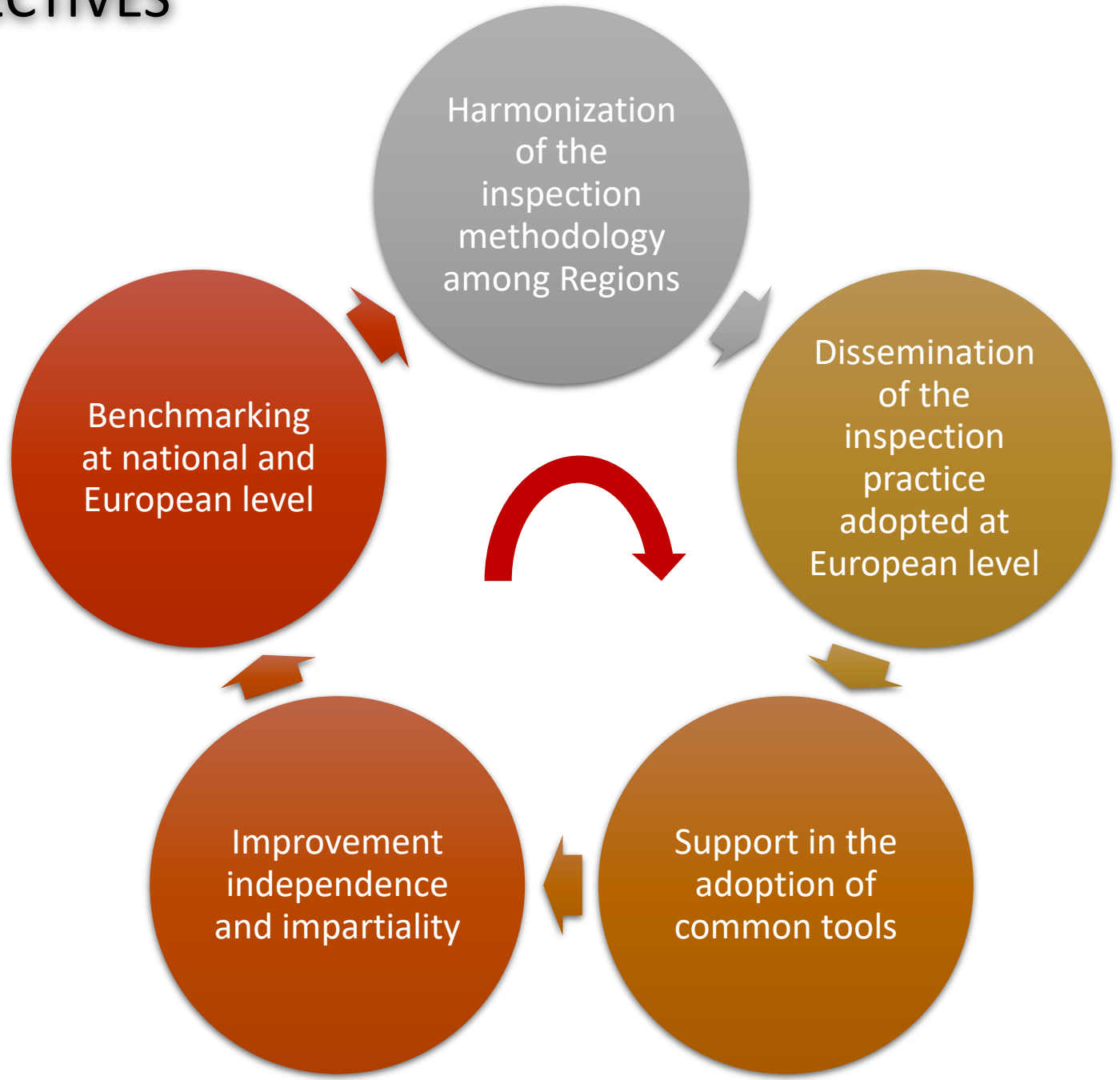
*ACCREDIA is the sole national accreditation body appointed by the Italian government in compliance with the application of the European Regulation 765/2008, attesting the competence and impartiality of certification, inspection, validation and verification bodies, as well as testing and calibration laboratories.

New «Authorisation/accreditation» system

«Qualification" VSTI	"Certification" VSTI
DM 26 maggio 2011 – Institution of the national list of inspectors officially employed by the Regions for the blood inspections	**Norm UNI CEI EN ISO/IEC 17024:2012 Standard** – General requirements for the assessment and certification of the competences
Admission criteria are defined by law	Admission criteria are defined in the Conformity Assessment Scheme (CNS is the Scheme Owner)
Designation of the candidates: by the Regions/PPAA Induction mandatory training: by CNS Formal qualification: by CNS	Participation is on a voluntary basis (still) Final exam for the certification
Admission in the national list: CNS Maintainance in the list: CNS (assessment every two years on the basis of defined criteria)	Admission in the «Registry of certified inspectors. Maintainance of the certification

CENTRO NAZIONALE SANGUE

FUTURE PERSPECTIVES



Thanks for your attention