CENTRO NAZIONALE SANGUE

Istituto Superiore di Sanità

The point of view of the European Inspection Expert Sub-group (IES)

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IES

The Commission Expert Sub-Group on Inspections in the Blood and Tissues & Cells Sectors (IES) is an active **sub-group** of the Competent Authorities on Substances of Human Origin (CASoHO) Expert Group

Objectives

- to provide **technical expertise** and formulate advice and comment to the Commission's services
- represent a forum for the **exchange of information and experiences** between the different Member States on technical and procedural matters related to their national inspection programmes
- overall aim is to encourage further **mutual recognition** of inspections in the SoHO sectors across the EU Member States
- provide a platform for EU-level **collaboration**

IES
Commission Expert Sub-Group on Inspection

- Group started with work in January 2019 and work is based on five work clusters
  - WC leaders
  - WC members

- Between 2019 and 2024, seven (7) IES meetings were held

IES members

19 member states

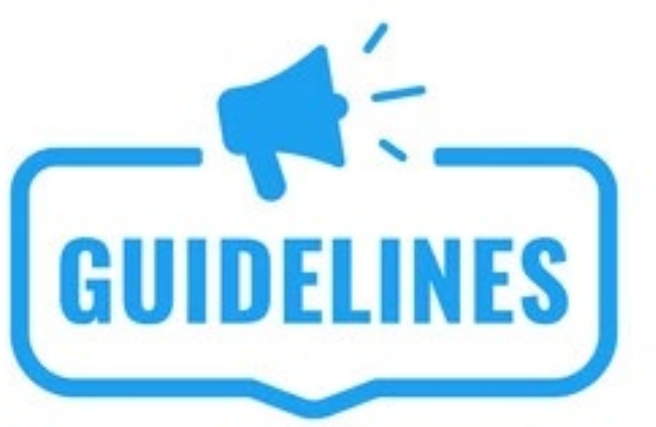
Countries with representatives		Countries without representatives
Austria (AT)	Lithuania (LT)	Croatia (HR)
Belgium (BE)	Luxembourg (LU)	Czechia (CZ)
Bulgaria (BG)	Netherlands (NL)	Denmark (DK)
Cyprus (CY)	Poland (PL)	Slovakia (SK)
Estonia (EE)	Portugal (PT)	Germany (DE)
Finland (FI)	Romania (RO)	Hungary (HU)
France (FR)	Slovenia (SI)	Latvia (LV)
Greece (EL)	Spain (ES)	Malta (MT)
Ireland (IE)	Sweden (SE)	
Italy (IT)		

IES
work clusters

1. Inspection Guidelines
2. Coordination of Training Courses
3. Coordination of Joint Inspection
4. Oversight of Inspection System
5. Dissemination and Monitoring

IES
work clusters

1. Inspection Guidelines



The primary objective of the Guidelines is to provide competent authorities (CAs) with a **common framework for conducting inspections** of blood and tissue establishments.

- **harmonised approach**
- **mutual recognition**

IES
work clusters

1. Inspection Guidelines
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IES
work clusters

WC2 is in charge of the development and coordination of training courses on inspection as **a tool to harmonise inspection** methods across the EU and to **improve the mutual recognition** among MSs in the field of SoHO.

2. Coordination of Training Courses

2024 training

- The online training was held from November 27th 2023, to March 1st, 2024
- 3 workshops of 3 days in Rome

2025 training - on going

IES
work clusters

1. Inspection Guidelines
2. Coordination of Training Courses
3. **Coordination of Joint Inspection**
4. Oversight of Inspection System
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IES
work clusters

Aims to establish a **framework for joint inspection** by multi-member states teams.

Provides assistance to inspectorates in organisation and performance of joint inspections.

The task of WC is to organise joint inspections.

3. Coordination of Joint Inspection

First inspection took place in **France** from 22nd to 24th of October 2024 - hematopoietic stem cells

Second inspection took place in **Spain** from 4th, 11th and 12th November 2024 - tissues and sperm bank.

IES
work clusters

1. Inspection Guidelines
2. Coordination of Training Courses
3. Coordination of Joint Inspection
4. **Oversight of Inspection System**
5. **Dissemination and Monitoring**

IES meeting December 2024

PREPARATION - ONLINE QESTIONNAIRE

Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

- Preamble – 7 recitals, all of them had comments
- Scope and Definitions - 5 sections, 4 of them had comments
- Articles – 23 articles, 19 of them had comments

- 11 countries gave comments

IES meeting December 2024

IES members were divided in three working groups:
Workgroup 1: articles 17,19, 24, 30;
Workgroup 2: recitals 13, 30, 42, 47;
Workgroup 3: articles 27, 28, 60, 61.

- Discuss National Practices and Experiences
- Identify Potential Implementation Challenges
- Explore Best Practices
- Propose Clear Instructions or Guidelines
- Identify Specific Areas Needing Clarification

IES meeting outcomes

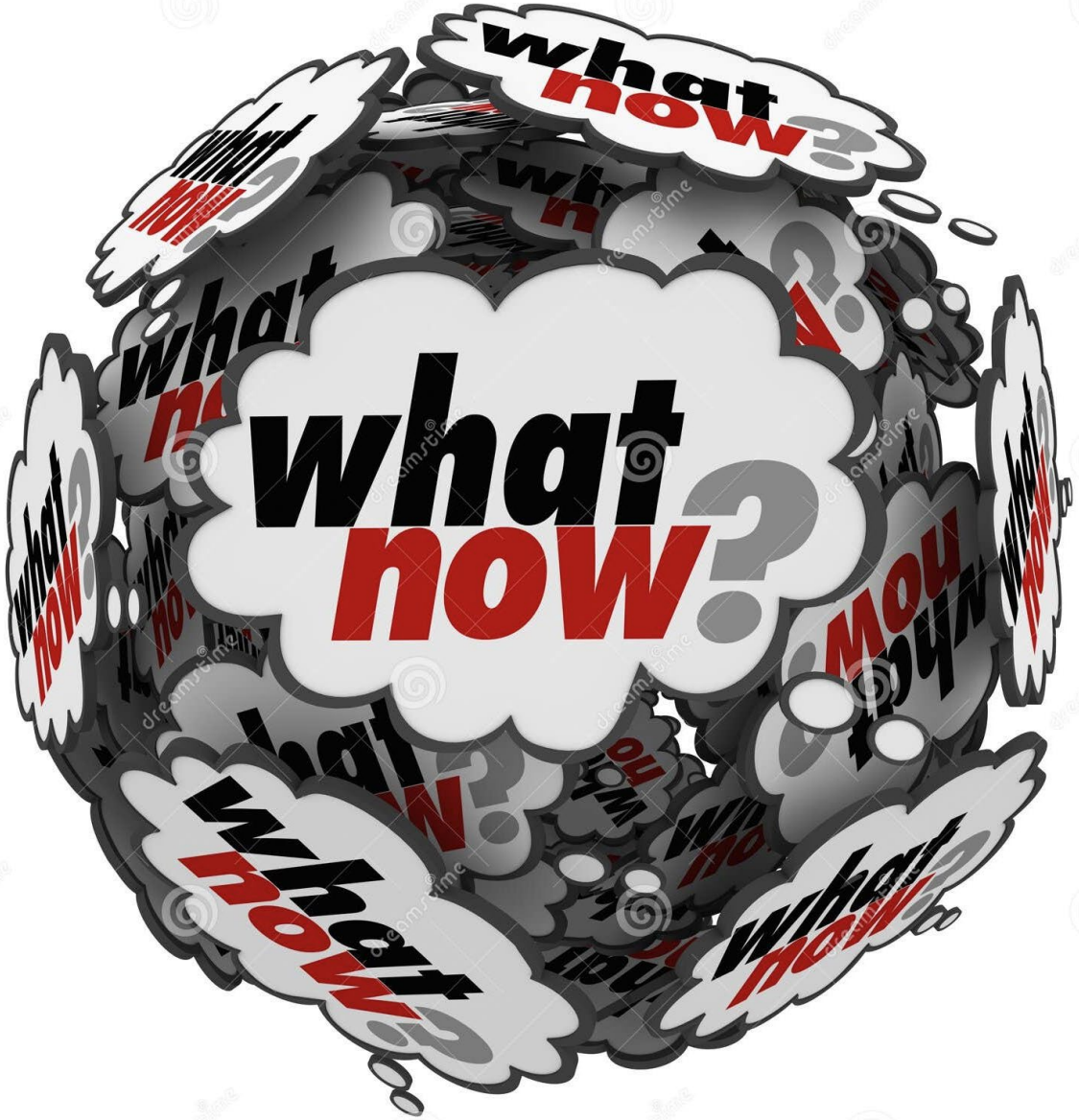
IES Group has identified priorities for 2025 to support harmonised inspections under the new SoHO Regulation.

Activities focus on:

- Updating the Inspection Guidelines in line with Regulation
- Providing recommendations to the SCB
- Clarifying key definitions and processes
- Training of inspectors
- Joint inspections

IES meeting outcomes

1. Give input on Critical SoHO Entities Definition
2. Preventing Wastage of Critical SoHO
3. Development of recommendations for shortfalls
4. Review and Assess VISTART Guidelines part for Specific requirements concerning inspectors
5. Proposing definitions and standardized terminology for “same surgical procedure” with illustrative examples
6. Develop and formalize guidelines for inspection frequency based on risk assessment criteria and update Inspection guidelines
7. Develop a proposal and give input for the standardization of PPA dossiers
8. Develop a proposal and give input for the level of detail required in shared information on the EU SoHO Platform
9. Submit a proposal to the SCB recommending that authorisations for imported SoHO preparations involve joint assessments by multiple Member States
10. VES and IES collaboration (VES-IES group) to discuss and make recommendation regarding inspection triggered by SAR or SAE



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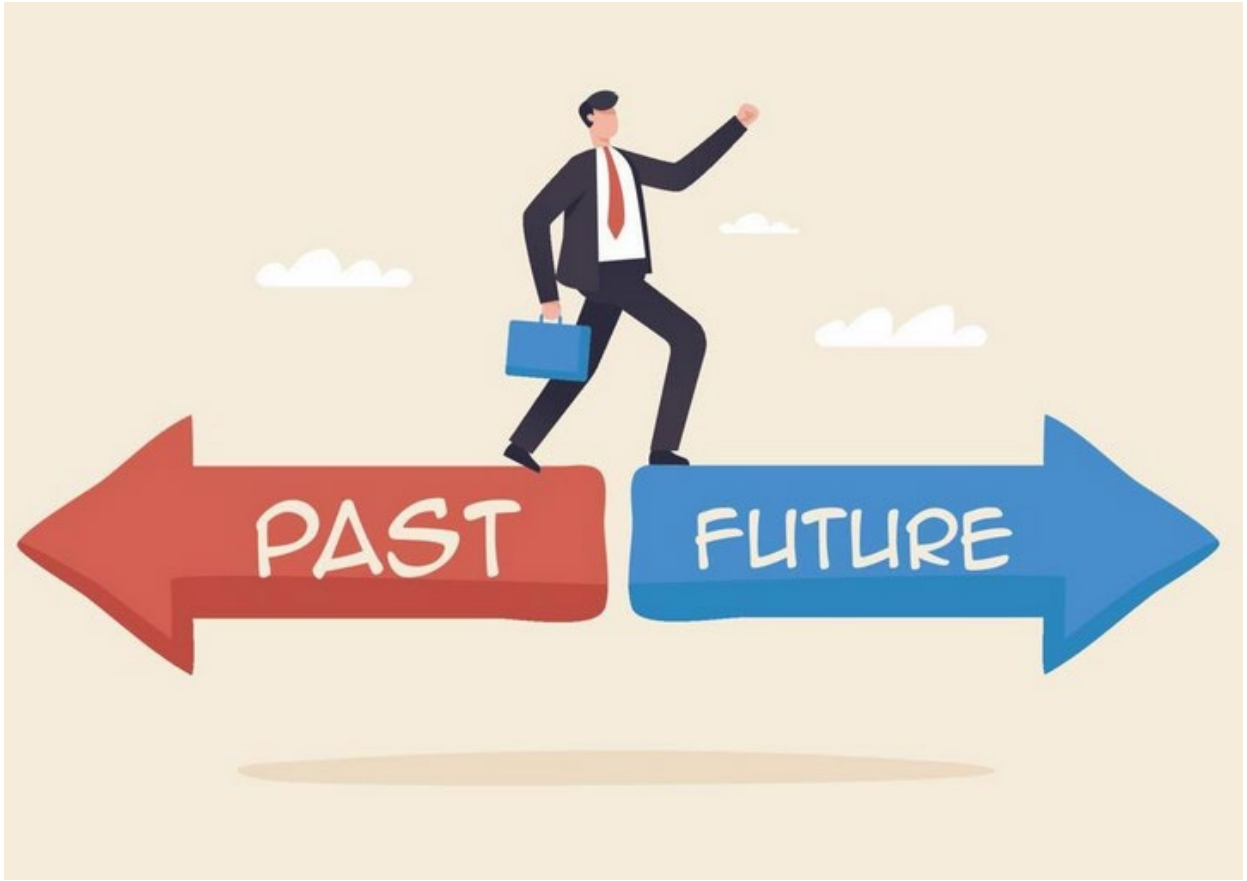
SoHO oversight system:
the implementation of the new EU regulation with a focus on the obligations for competent authorities

TASKS

IES
Sub-Group on Inspection in SoHO



Working Group (WG) on Inspections

CONCLUSION

Discussions highlighted the need for further clarification and alignment in several areas to **ensure the effective and consistent implementation** of the SoHO Regulation.

Key aspects include the development of a **harmonised approach** across Member States, the facilitation of **mutual recognition** of procedures and assessments, and the reinforcement of measures that safeguard the **quality and safety of SoHO preparations and safety of donors and patients**.

The importance of **joint inspections** and **joint assessments** was also underlined, particularly in the context of imported SoHO and cross-border collaboration.

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