

Workshop 1 - INSPECTION PRACTICE

15, 16, 17 May 2024

Tutors and External experts involved:

J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat, S. Tomljenovic (IES Rapporteur), DG SANTE.

Learning objectives:

- To share the common European standards and criteria for preparing and conducting an inspection of BTC establishments, including MAR;
- To harmonise interpretation of inspection findings and inspection reports;
- To exchange experiences on risk management including data management in the inspectorates;
To get familiar with the possibility of organising a joint inspection” (application of the code of practice)

Agenda

Day 0. Tuesday 14/05/2024

Time	Session	Title
14:00 - 17:00	Briefing	Briefing session for Facilitators

Day 1. Wednesday 15/05/2024

Time	Session	Title	Tutor/s - Expert/s
8:30 - 9:00		Registration	
9:00 - 9:15		Welcome message	S. Pupella (Training Coordinator), DG SANTE
9:15 - 9:45		Brief Introduction (overview of related eLearning modules contents outcomes and take-home messages) and Workshop 1 expectations and scope	S. Pupella
9:45 - 10:45	Topic 1	Ongoing EU Legal Provisions towards the new forthcoming Regulation	
9:45 - 10:30		Frontal lectures: Overview on ongoing EU Legal Provisions towards the new forthcoming Regulation, including CAs obligations Inspection experts sub-group: role and tasks also in view of the forthcoming Regulation	DG SANTE S. Tomljenovic (IES Rapporteur)
10:30 - 10:45		Plenary discussion with facilitators	J. Kurz, F. Bariani, S. Pupella, R. Barrio, S.



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			Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat, Observers: S. Tomljenovic, DG SANTE
10:45 - 11:00		Coffee break	
11:00 - 17:00	Topic 2	Preparation of an inspection: pre-inspection activities	
11:00 - 11:15	Exercise 1	<p>Case studies on preparation of an inspection:</p> <ul style="list-style-type: none"> • Preparation for a clean room inspection/assessment; • Preparation for data processing system assessment (electronic cross-matching at the hospital blood bank); • Preparation for MAR donors management inspection/evaluation; • Preparation for outsourced activity management inspection. 	F. Teskrat and S. Pupella S. Masterson and U. La Rocca F. Bariani and R. Barrio J. Kurz and A. Kurzreiter
11:15 - 12:15		Working groups (4)	J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat Observers: S. Tomljenovic, DG SANTE
12:15 - 13:15		Working group rapporteurs presentation, plenary discussion and take-home messages	S. Masterson with all tutors support
13:15 - 14:15		Lunch break	
14:15 - 17:00	Topic 3	Performance of an inspection	
14:15 - 14:30	Exercise 2	Case Study: key quality indicators to assess the performance of an inspectorate and inspectors	F. Teskrat
14:30 - 15:30		Working groups (4)	J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat Observers: S. Tomljenovic, DG SANTE
15:30 - 15:45		Coffee break	
15:45 - 16:45		Working group rapporteurs presentation, plenary discussion and take-home messages	F. Teskrat with all tutors support
16:45 - 17:00		Recap of the day and closing remarks	J. Kurz and S. Masterson
		Social dinner at Gusto restaurant Piazza di Sant'Apollinare, 41, 00186 Rome	



Day 2. Thursday 16/05/2024

Time	Session	Title	Tutor/s - Expert/s
8:30 - 9:00		Registration	
9:00 - 15:00	Topic 4	Mock inspections at: processing Lab of the BE, collection site of the BE, HSC processing lab, HSC cryopreservation room, MAR centre	
9:00 - 9:20	Exercise 3	Introduction and group divisions (4/5) for mock inspections: - preparation according to “Site Master-File” of the sites; - reporting of the findings in a mock inspection report.	S. Pupella, F. Bariani
9:20 - 10:00		Transfer to Centres	
10:00 - 11:30		Start of mock inspections	
11:30 - 12:00		Transfer to Scout Centre	
12:00 - 13:00		Lunch break	
13:00 - 14:00		Inspection report elaboration in working groups	J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat Observers: S. Tomljenovic, DG SANTE
14:00 - 15:00		Working group rapporteurs presentation, plenary discussion and take-home messages	S. Pupella and F. Bariani
15:00 - 15:15		Coffee break	
15:15 - 17:00	Topic 5	Assessment of non-compliances and classification of non-conformances	
15:15 - 15:30		Intro lecture and presentation of different non-conformances to be discussed in plenary for shared classification	S. Masterson and R. Barrio
15:30 - 16:30		Plenary discussion	J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat
16:30 - 17:00		Recap of the day and closing remarks	S. Masterson and R. Barrio



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Day 3. Friday 17/05/2024

Time	Session	Title	Tutor/s - Expert/s
8:30 - 9:00		Registration	
9:00 - 9:30	Topic 6	EU Joint Inspections	
9:00 - 9:15		Frontal lecture on EU Joint Inspections code of practice	S. Tomljenovic
9:15 - 9:30		Q&A	
9:30-10:30		Final Examination (Multiple choice)	All tutors
10:30-10:45		Coffee break	
10:45 - 15:00	Topic 7	Illegal Fraudulent Activities	
10:45 - 11:00		Brief presentation on Illegal Fraudulent Activities (IFA)	F. Teskrat and J. Kurz
11:00 - 11:15	Exercise 4	Introduction and indications for working groups	F. Teskrat and J. Kurz
11:15 - 12:15		Working groups (4)	J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat
12:15 - 13:15		Working group rapporteurs presentation, plenary discussion and take-home messages	F. Teskrat and J. Kurz
13:15 - 14:15		Lunch break	
14:15 - 14:45		Recap of the day	All tutors



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