



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

"Quality Management - ISO 17025 accreditation" Training Workshop

Ispira, 20-22 May 2014

PROGRAMME

DAY 1 (Tuesday 20 May 2014)

Morning: 9:00 – 12:30 (incl. coffee break 10:30-11:00)

General welcome and training programme introduction (M. Querci)

Introduction to the EC JRC, European legislative context in relation to GMOs, the EU-RL GMFF, the BTSF-MBG Unit Project (M. Querci)

Presentations on general concepts related to Quality Management and implementation of GMO testing laboratory

- ISO 9001 and ISO 17025 standards (S. Cordeil)
- Accreditation in a GMO laboratory (M. Schulze)
- Quality assurance for GMO testing laboratories (overview on ISO technical standards and the accreditation guide) (P. Philipp)
- Structure of the quality documentation and flexible scope (in France) (P. Philipp)

Lunch break: 12:30-13:30

Afternoon: 13:30 – 16:50 (incl. coffee break 15:30 - 15:45)

Presentation of three supporting documents (lead: S. Cordeil)

(Quality Management Manual "template", Guidelines for implementation of a quality system in a GMO testing laboratory and European Technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs)

Auditing techniques (lead: M. Schulze)

Presentations and discussion on specific ISO 17025 topics:

(Identification of check-list of ISO17025 questions specific to a GMO lab to be audited)

Discussions will be structured around 5 general "topics" and related ISO 17025 chapters



Objective: after a short introduction to the topic, participants will identify through interactive discussions a specific check-list of audit questions relevant for each topic. Examples will be shown on how the quality and technical requirements were implemented in different laboratories.

1. **Technical Requirements** (lead: P. Philipp + M. Schulze)

- a. **Environmental conditions** [ISO 17025 § 5.3](introduction by M. Schulze)
- b. **Calibration, maintenance of the equipment, metrology** [ISO 17025 § 5.5] (detailed by P. Philipp and G. Moris on day 2 morning)
- c. Measurement traceability [ISO 17025 § 5.6]
- d. Suppliers [ISO 17025 § 4.6]
- e. Goods [ISO 17025 § 4.6]
- f. Handling tests / calibration items [ISO 17025 § 5.8]
- g. Reference materials / reference standards [ISO 17025 § 5.6.3]
- h. **Uncertainty of the measurement** [ISO 17025 § 5.4.6] (G. Moris on day 2 morning)
- i. Control of data [ISO 17025 § 5.4.7]
- j. Sampling [ISO 17025 § 5.7]

2. **Methods** (lead: P. Philipp + M. Schulze)

- a. References to international standards/documents [ISO 17025 § 5.4.1]
- b. **Method validation** [ISO 17025 § 5.4.5] (illustrated by P. Philipp for sample preparation (grinding) on day 1)
- c. **Method verification** [ISO 17025 § 5.4.5] (detailed by G. Moris on day 2 morning)

16:50 Guided tour to the JRC Visitors' Centre



DAY 2 (Wednesday 21 May 2014)

Morning: 9:00 – 12:45 (incl. coffee break 10:15 – 10:30)

**Presentations and discussion on specific ISO 17025 topics (continuation from previous day)
(identification of check-list of ISO17025 questions specific to a GMO lab to be audited)**

3. **Management Requirements** (lead: S. Cordeil/ M. Schulze)

- a. Implication of the management [ISO 17025 § 4; 4.2; 4.10]
- b. Description of the laboratory and description of processes [ISO 17025 § 4.1]
- c. Customers management [ISO 17025 § 4.1.5; 4.4.1; 4.7]
- d. Contract review [ISO 17025 § 4.4]
- e. Subcontracting [ISO 17025 § 4.5]
- f. Complaints [ISO 17025 § 4.8]
- g. Non-conforming work [ISO 17025 § 4.9]
- h. **Reporting results (tests reports/calibration reports)** [ISO 17025 § 5.10](M. Schulze)
- i. Opinions and Interpretation [ISO 17025 § 5.10.5]

4. **Personnel**

- a. Availability [ISO 17025 § 5.2.3; 5.2.4; 5.2.5]
- b. **Initial qualification and monitoring** [ISO 17025 § 5.2.1; 5.2.2; 5.2.5] (detailed on day 2 morning by G. Moris)
- c. Training [ISO 17025 § 5.2.2]

5. **System Control** (lead: S. Cordeil)

- a. Control of the documentation [ISO 17025 § 4.3]
- b. Control of records [ISO 17025 § 4.13]
- c. Assuring the quality of test and calibration results [ISO 17025 § 5.9]
- d. Identification non conformities [ISO 17025 § 4.12]
- e. Corrective / Preventive actions [ISO 17025 § 4.11; 4.12]
- f. Audits [ISO 17025 § 4.14]
- g. Review of the system [ISO 17025 § 4.15]

11:45 – 12:45 Presentation of training simulation exercise (S. Cordeil)

Step 1 of Training Exercise: ISO 17025 audit preparation

The +/- 25 training participants are sub-divided in 4 groups (together with a "coach") and prepare a list of questions for running a ISO 17025 audit simulation including:

- "General quality" questions (e.g. about topics related to "Management Requirements", "System Controls")



- "Specific technical" questions (e.g. about topics related to "Personnel", "Technical Requirements", "Validated Methods")

Note: supporting documents (JRC templates) to be distributed

Lunch break: 12:45 -13:45

Afternoon: 13:45 – 17:30 (incl. coffee break 15:45 – 16:00 pm)

Step 2 of Training Exercise: ISO 17025 audit simulation in GMO lab

Each group (accompanied by its "coach") runs an ISO17025 audit in "real conditions" (inside the EU-RL GMFF lab* and asking questions to 4 different categories of auditee (QM quality manager, TM Technical Manager – LH Laboratory Head and an LS Laboratory Staff) +/- 30 min. of questions/auditee

After interviews, each group prepares its audit report to be presented on following day

	Team 1	Team 2	Team 3	Team 4
14:00-14:30	QM	LS	TM	LH
14:35-15:05	LH	QM	LS	TM
15:10-15:40	TM	LH	QM	LS
15:45-16:15	LS	TM	LH	QM
16:30-17:30	Report Preparation	Report Preparation	Report Preparation	Report Preparation

*

QM: Stephane Cordeil (building 20A, room 1.5)

TM: Cristian Savini (building 20A, room 1.15)

LH: Marco Mazzara (building 20A, meeting room)

LS: Gregor Pinski (building 20A, room 1.14)



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DAY 3 (Thursday 22 May 2014)

Morning: 9:00 – 12:30 (incl. coffee break 10:00-10:30)

Report Preparation: the groups will finalise their audit reports

Step 3 of Training Exercise: ISO 17025 audit reporting

Each group reports to the others (PowerPoint slides or draft audit report) on its audit findings (30 min/group incl. Q&A) + debriefing from “team coaches”

Lunch break: 12:30-13:30

Afternoon: 13:30 – 16:00

AoB: Discussion on topics of interest to the participants and/or emerged during the training

Conclusions: wrap-up on key learning from the training + feed-back from participants

16:00 End of training programme