EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

"Quality Management - ISO 17025 accreditation" Training Workshop

Ispra, 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 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 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)

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