Implementation of ISO 17025:2017
National Phytosanitary Laboratory of Latvia

G. Bokuma
Head of Laboratory, Quality Manager

4th EPPO Workshop for Heads of
Plant Pest Diagnostic Laboratories
ANSES, Maisons-Alfort (FR), 09.-11.09.2019
National Phytosanitary Laboratory

The only laboratory specialized in regulated pests in Latvia

Unit of the State Plant Protection Service /
Plant Quarantine Department
State Plant Protection Service of Latvia designated NPhL as National Reference Laboratory of Latvia for the diagnosis of plant pests (bacteria, nematodes, viruses, viroids, phytoplasmas, insects, mites, fungi, oomycetes, weeds) in accordance with Article 100 of OCR (EC) 2017/625 and Article 4 (8) of the Plant Protection Law
Location of the Laboratory
Samples in 2018

**External customers:**
- Food and Veterinary Service, Border Control Department (BCD) inspectors from 10 Border Control Posts (BCP) – 1.5% of samples
- Farmers, companies, private persons – 2% of samples

**Internal customers**
- PPS inspectors from 5 regional units – 96.5% of samples

<table>
<thead>
<tr>
<th>Total</th>
<th>Import</th>
<th>EU</th>
<th>BCD/BCP</th>
<th>Private persons</th>
<th>Integrated Pest Management</th>
<th>Domestic origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>5860</td>
<td>90</td>
<td>182</td>
<td>87</td>
<td>122</td>
<td>168</td>
<td>5211</td>
</tr>
</tbody>
</table>
## Testing of Samples in 2018

<table>
<thead>
<tr>
<th>Sector</th>
<th>Samples / Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virology</td>
<td>1234 / 24252</td>
</tr>
<tr>
<td>Bacteriology</td>
<td>2400 / 7440</td>
</tr>
<tr>
<td>Mycology</td>
<td>610</td>
</tr>
<tr>
<td>Nematology</td>
<td>2112 / 8327</td>
</tr>
<tr>
<td>Entomology</td>
<td>1196</td>
</tr>
<tr>
<td>Herbology</td>
<td>129</td>
</tr>
<tr>
<td>Molecular biology</td>
<td>550 / 3219</td>
</tr>
</tbody>
</table>
173 samples in one day
Accreditation According to ISO 17025

02.06.2005

We received accreditation on:


Accreditation According to ISO 17025

Extension of accreditation scope in 2007

Accreditation on “ME.E.002.2007 method for identification of Liriomyza huidobrensis
Quality Management System (QMS)

- Complaints
- Facilities
- Meeting minutes
- Data transfers
- Suppliers evaluation
- Customer satisfaction surveys
- Technical manager
- Purchase
- Audits
- Equipment
- Reagents

Head of lab / quality manager
ISO 17025:2017

✓ Includes many changes

✓ There are three main points to keep in mind:
  - more options,
  - involvement of risk,
  - updates in current technology – focuses more on information technology, which incorporates the use of computer systems, Laboratory Information Management System software and the provision of electronic results
How to ensure a smooth transition to the new ISO 17025 standard in laboratories?
How to ensure a smooth transition to the new ISO 17025 standard in laboratories?

✓ Step 1
Talk to your accreditation body
Contact and ask for support from the national accreditation body (trainings)

✓ Step 2
Get familiar with the new standard
Obtain the new standard edition and understand its message
In parallel get acquainted with EPPO standard PM 7/98 version 4
How to ensure a smooth transition to the new ISO 17025 standard in laboratories?

✓ Step 3
Develop a transition plan
Conduct a gap analysis between the existing quality system and the requirements in the revised standard

✓ Step 4
Training and awareness
Create a training plan and a communication plan for the laboratory personnel

✓ Step 5
Update QMS to meet new requirements
Implement the new and revised management system
ISO 17025:2017 8.5
Actions to address risks and opportunities

✓ This clause is completely new and replaces the concept of preventive actions

✓ We are developing the document (procedure?) where risks and opportunities are identified, as well as are planning to implement action to minimize risks and maximize opportunities
For each laboratory activity the critical points are identified:

Bacteriology – 51
Nematology – 3
Entomology – 10
Mycology – 21
Molecular biology – 17
Virology – 9
Sample reception, registration, sending test reports – 5
Risks and Opportunities

✓ The sample escapes
✓ The sample is damaged by parasitoids
✓ During testing, the pest loses an important part
✓ Two samples with the same numbers (inspector has made a mistake on the label)
✓ Label comes off from the sample
Risks and Opportunities

✓ Risks will be scored according to:
  – Severity
  – Probability
  – Frequency

✓ Risks with highest scores will be managed

✓ This allows to prioritize the risks
Risks and Opportunities

✔ ISO/IEC 17025 is used for the accreditation of competence of testing and calibration laboratories worldwide

✔ It includes requirements for laboratories in order to: demonstrate competence in issuing valid results

✔ This requires people, knowledge, equipment, methods etc.
Structure

16 permanent staff members
3 on maternity leave
3 on contract (fixed – term employment)

Head of the Lab

Deputy of Head of the Lab
(Molecular biologist)

Chief expert (Virologist)

Senior expert entomologist

Expert entomologist

2 Nematologists

Senior expert bacteriologist

Bacteriologist

Virologist

2 Mycologists

Molecular biologist

2 Technicians

Sample receptionist
Risks and Opportunities

☑ Lack of experts
☑ Loss of competence
Risk Management

✔ What cannot be planned?
  – When staff goes on maternity leave

<table>
<thead>
<tr>
<th>Years</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>People</td>
<td>4</td>
<td>-</td>
<td>1</td>
<td>2</td>
<td>???</td>
<td>???</td>
<td>???</td>
</tr>
</tbody>
</table>
Risk Management

✔ Table of Delegation of Responsibilities:
- each process, method is divided in steps,
- at least 3 people (!) to ensure substitutability

✔ Major problems with morphological methods
## Risk Management

### Pienākumu un atbildības delegēšanas kārtība

**Revidēja:** J. Mihailova  
**Apstiprinu:** G. Bokuma  
**Data:** 06.02.2013

| Testēšanas pārskata parakstīšana | A | I |
| **1. ME.B.001.2014.3v (2; 3; 4)** | ME.B.002.2014.3v (5; 6; 7) |
| 1.1. Bumbuļu mazgāšana | I | I | I | I | I | A | A |
| 1.2. Vadaudu izgriešana | I | I | I | I | I | A | A |
| 1.3. Vizualās konstatējums | I | I | I | I | A | A |
| 1.4. Ielikšana krāftājā | I | I | A | A | A | A |
| 1.5. Paraugu noliešana | I | I | I | A | A |
| 1.6. Paraugu centrifugēšana | I | I | A | A |
| 1.7. Paraugu uzpiliņašana uz priekšmetstikla un fiksēšana IF testam | I | I | A | A |
| 1.8. Parauga IF testa veikšana | I | I | A | A |
| 1.8.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana | I | I | A | A |
| 1.9. Indikatoraugu audzēšana | I | I | I | I | A |
| 1.10. Inficēto indikatoraugu sagatavošana testēšanai | I | I |
| 1.11. Biotesta veikšana | I | I | A |
| 1.11.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana | I | I | A |
| 1.12. Baktēriju kultūru izdalīšana | I | I | A |
| 1.12.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana | I | I | A |
| 1.13. PCR | A | I | I |

Kods: VD.4.1.(6).001

Piezīme: 1/6
Risk Management

- Communication and consultation: informing about maternity leave (ASAP!)
- Hiring people on contract, while the expert has not yet gone on maternity leave
- Preparation of a training plan
- Exam
- Authorization
- Monitoring
Risk Management

✔ What can I plan?
– When staff retire

Monitoring and review

<table>
<thead>
<tr>
<th>Years</th>
<th>2021</th>
<th>…</th>
<th>2026</th>
<th>2027</th>
<th>2028</th>
</tr>
</thead>
<tbody>
<tr>
<td>People</td>
<td>2</td>
<td>…</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Conclusions
Conclusions During the Transition

✓ Decide on the overall timeline:
  – Implementation of new ISO 17025 will be required by 2020-12-01
  – LATAK visit is scheduled for the first quarter of 2020

✓ Train the lab personnel who will be responsible for transition and implementation:
  – LATAK training courses
  – EPPO workshop on the revision of PM 7/98 (2019-02-11/13)
  – Visit the lab which has already implemented the new version
  – Create a working group to implement the standard
Conclusions During the Transition

✓ Update documentation of management system:
  – This includes updates to existing policies and procedures as required, plus the removal/modification/addition of policies and procedures
    o We have: 36 procedures, 7 policies
    o New standard version require: 9 procedures, 3 policies

✓ Check procedures in place in order to be in line with risk-based approach and evaluate if these are relevant for your activity
✓ Identify the requirements that seem to need new procedures
Conclusions During the Transition

✓ Seize / grab the opportunity provided by the new standard in order to reduce the documentation of management system
  – No requirement for quality manual

✓ Learn how to read, interpret and implement the new standard requirements:
  – Lectures on internet
Nordic-Baltic Laboratories Network
Meeting in Latvia, 2018
Thank you!