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Implementation of ISO 17025:2017 National Phytosanitary Laboratory of Latvia

G. Bokuma
Head of Laboratory, Quality Manager

EPPO Training Workshop

2020-12-10



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National Phytosanitary Laboratory

The only laboratory specialized in regulated pests in Latvia

Unit of the State Plant Protection Service

Plant Quarantine Department





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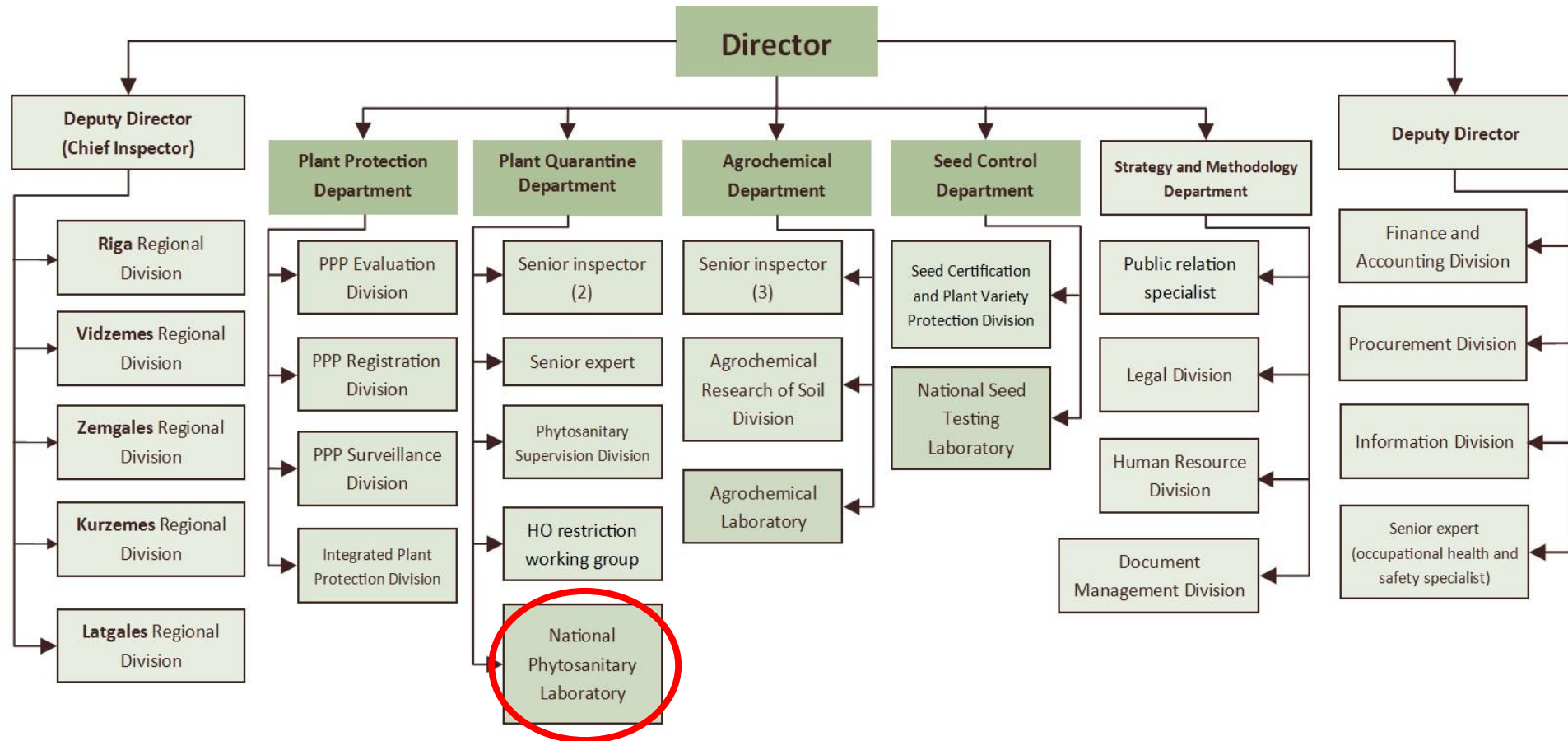


State Plant Protection Service of Latvia designated
NPhL as National Reference Laboratory of Latvia for the
diagnosis of plant pests (bacteria, nematodes, viruses, viroids,
phytoplasmas, insects, mites, fungi, oomycetes, weeds) in
accordance with Article 100 of OCR (EC) 2017/625 and Article 4
(8) of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



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Laboratory's Location in Service's Structure



Abbreviations:

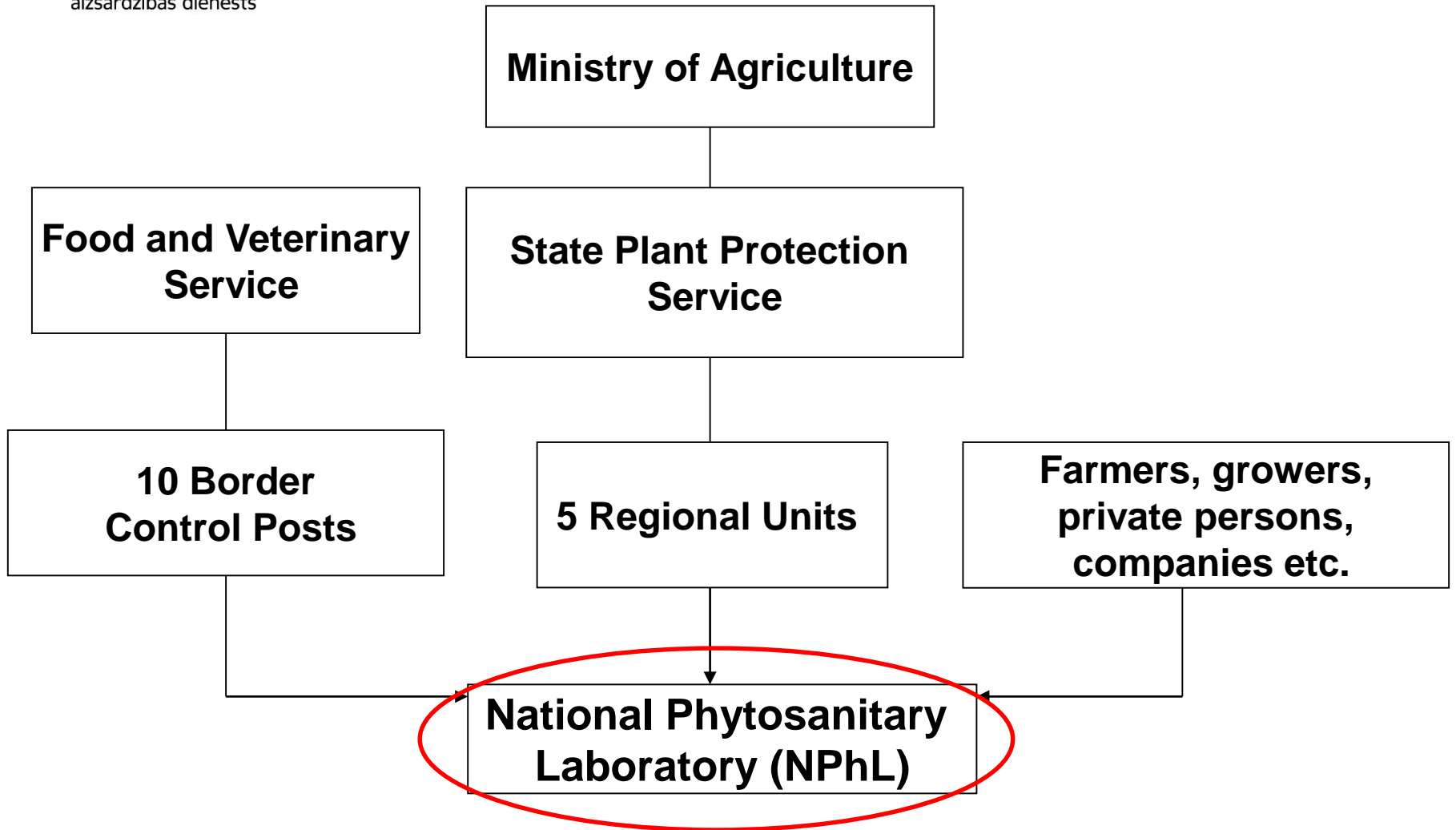
PPP—Plant Protection Products

HO—Harmful Organisms



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Laboratory Location





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Location of the Laboratory





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Samples in 2019



External customers:

- Food and Veterinary Service, Border Control Department (BCD) inspectors from 10 Border Control Posts (BCP) – **2%** of samples
- Farmers, companies, private persons – **3%** of samples

Internal customers

PPS inspectors from 5 regional units – **95%** of samples

Total	Import	EU	BCD/ BCP	Private persons	Integrated Pest Management	Domestic origin
5369	107	169	112	140	73	4768



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Testing of Samples in 2019

Sector	Samples / Tests
Virology	638 / 21235
Bacteriology	2679 / 8035
Mycology	578
Nematology	1928 / 7492
Entomology	1122
Herbology	194
Molecular biology	594 / 4485

The main samples for testing:

soil, potatoes, wood, peat, samples from fruit trees, green plants, insects etc.



173 samples in one day

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Rajons: < ... >
sanitārā pieteikuma nr.:
Parauga Nr.:
Izcelsmes valsts: < ... >
Eksportētājvalsts: < ... >
Suga: < ... >
Botāniskais nosaukums:
Inspektors: < ... >
Periods no - līdz: 01.08.2019. - 02.08.2019.
Nav id kartiņa:
Ir id kartiņa:
Meklēt Iztīrīt

Tips	Skaitis
IMPORTS	2
Privātpersonas	3
Vietējie	168

1 2 3 4 5 6

Suga	Botāniskais nosaukums
Feramanu dzārds: Anoplonhara	Anoplonhara fer.





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2000



Do we need accreditation? Why do we need accreditation?

- ✓ Many accredited laboratories in other spheres appeared: veterinary, food quality, medical pathology, water biology
- ✓ Clients became more knowledgeable and educated, especially in lawmaking
- ✓ Conflict situations appeared
- ✓ SPPS management's aim
- ✓ We should be prepared for conflict situations



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- ✓ At that time one of our external customers Sanitary Border Inspection (SBI) was preparing for accreditation according to standard ISO 17020 “General Criteria for the operation of various Types of Bodies Performing Inspection”
- ✓ In their regulations it was foreseen to cooperate only with accredited laboratories after the accreditation
- ✓ We were the only laboratory for testing the samples in the Phytosanitary field in our country and SBI was very interested in developing of a quality system in our lab





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Accreditation According to ISO 17025

02.06.2005



We received accreditation on:

- ✓ ME.B.001.2003 - Method for detection and identification of *Clavibacter michiganensis* subsp. *sepedonicus* in potato tubers
(IF, Bioassay, PCR)
- ✓ ME.B.002.2003 - Method for detection and identification of *Ralstonia solanacearum* in potato tubers
(IF, Bioassay, PCR)

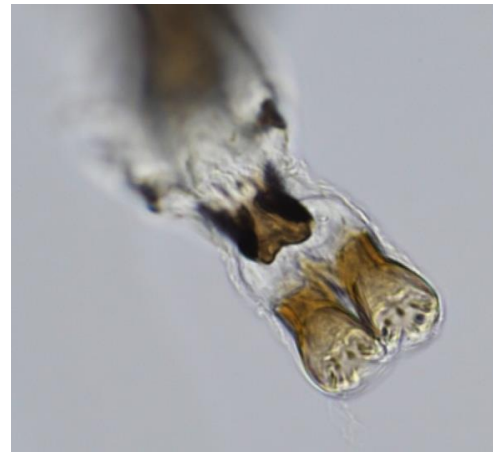


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Accreditation According to ISO 17025

Extension of accreditation scope in 2007

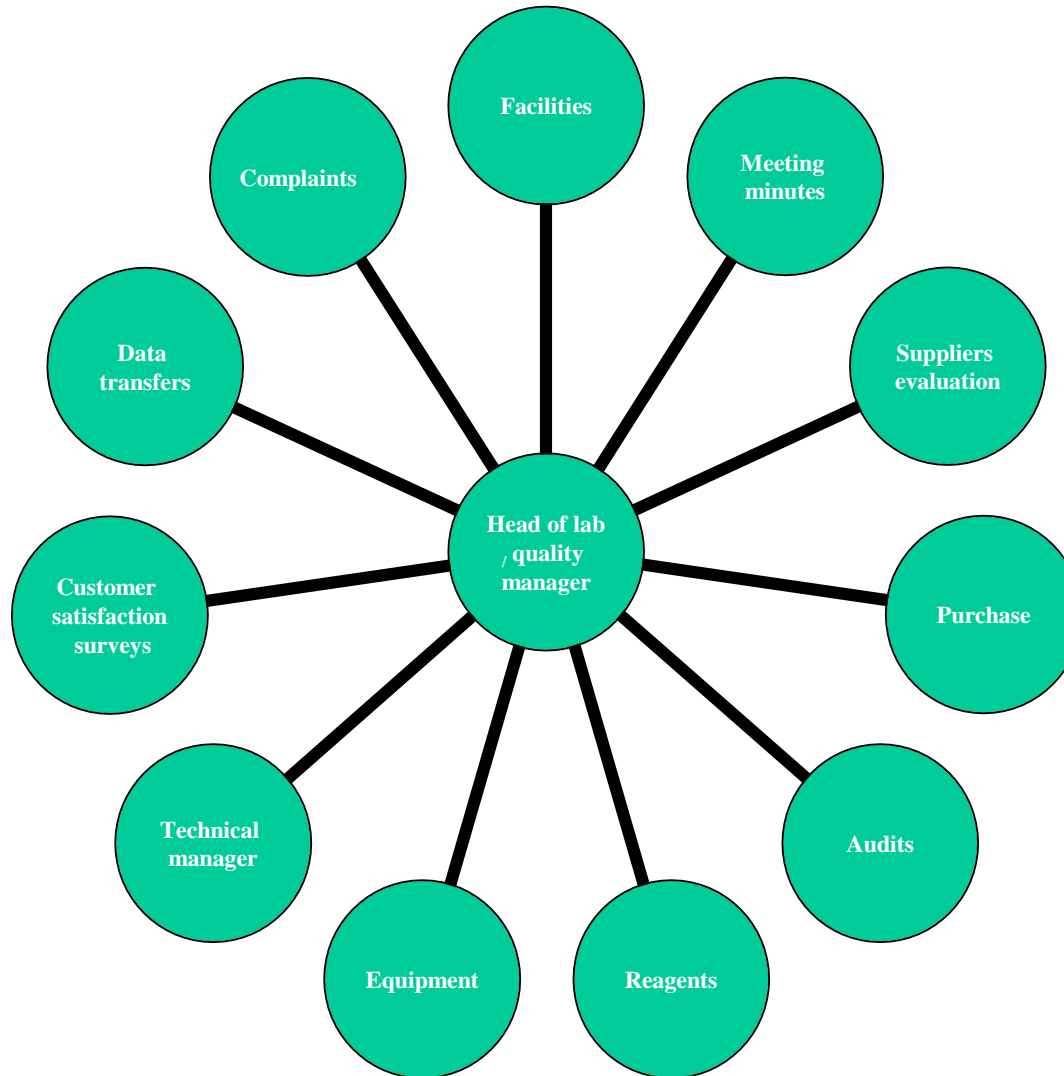
Accreditation on “ ME.E.002.2007 method for
identification of *Liriomyza huidobrensis* “





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Quality Management System (QMS)





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ISO 17025:2017

- ✓ Includes many changes

- ✓ There are three main points to keep in mind:
 - more options,
 - involvement of risk,
 - updates in current technology

- ✓ ISO 17025:2017 standard had to be implemented by **2020-12-01**



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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



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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



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ISO 17025:2017 8.5

Actions to address risks and opportunities

- ✓ This clause is completely new and replaces the concept of preventive actions
- ✓ We developed the document where risks and opportunities are identified, as well as are planning to implement action to minimize risks and maximize opportunities



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Risks and Opportunities

✓ For each laboratory activity the critical points were identified:

Bacteriology – 51

Entomology – 10

Mycology – 21

Molecular biology – 17

Sample reception, registration, sending test reports – 5 etc.



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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



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Risks and Opportunities

- ✓ Risks are scored according to:
 - Severity
 - Probability
 - Frequency

- ✓ This allows to prioritize the risks

- ✓ Risks with highest scores will be managed





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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.



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Structure

16 permanent staff members

2 on maternity leave

1 on contract (fixed – term
employment)

Head of the Lab

Deputy of Head of the Lab
(Molecular biologist)

Sample receptionist

Chief expert (Virologist)

Senior expert entomologist

Senior expert bacteriologist

Expert entomologist

Bacteriologist

2 Nematologists

Virologist

2 Mycologists

Molecular biologist

2 Technicians

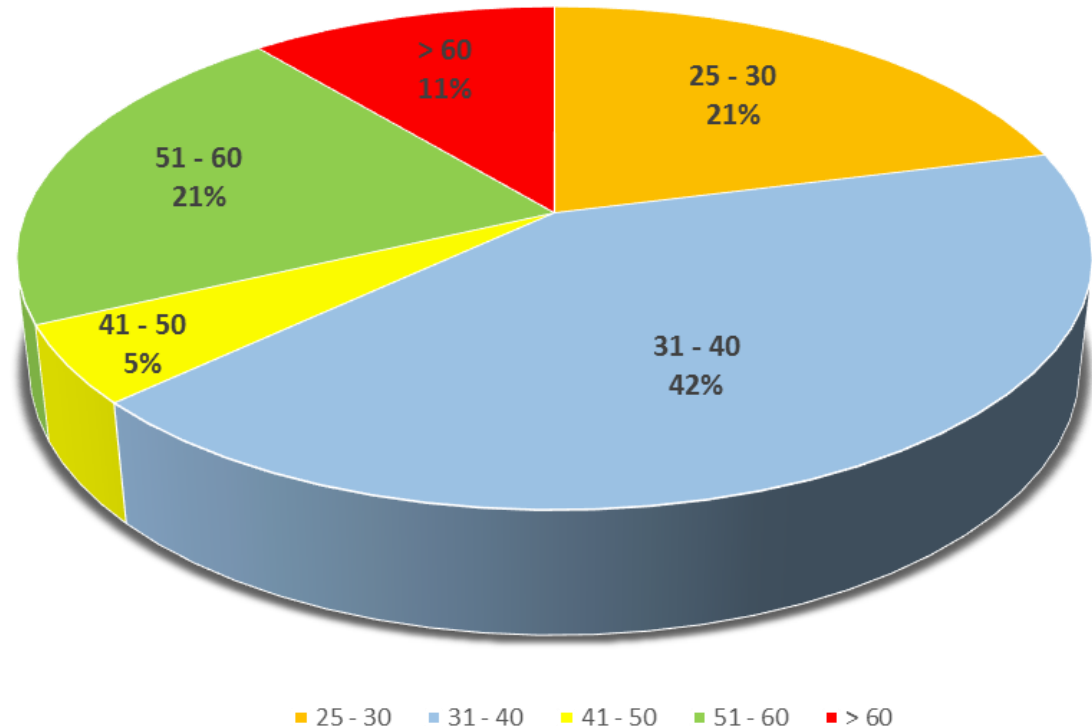


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Risks and Opportunities

- ✓ Lack of experts
- ✓ Loss of competence

Laboratory personnel age chart





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Risk Management



- ✓ What cannot be planned?
 - When staff goes on maternity leave

Years	2016	2017	2018	2019	2020	2021	2022
People	4	-	1	2	2	???	???





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Risk Management

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

- ✓ Major problems with morphological methods





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Risk Management

Pienākumu un atbildības deleģēšanas kārtība

Revidēja:
J. Mihailova

Apstiprinu:
G. Bokuma

G. Bokuma
06.02.2019

Metodes, funkcijas	Personāls																
	M. Sila	I. Garosa	J. Mihailova	O. Kulyeshova	G. Bondare	G. Bokuma	G. Sprūde	M. Gubenko	V. Gavrilova	K. Pārums	L. Pašetovs	D. Saulīte	B. Kalniņa	A. Gluhovs	L. Celma	R. Vaitkeviča	S. Maldute
Testēšanas pārskata parakstīšana			A			I											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	A					A
1.2. Vadaudu izgriešana	I				I			I			I	A					A
1.3. Vizuālais konstatējums	I				I			I			I	A					A
1.4. Ielikšana kratītājā	I				I			A			A	A			A		A
1.5. Paraugu nolicešana	I				I						A	A			A		A
1.6. Paraugu centrifugēšana	I				I						A	A			A		A
1.7. Paraugu uzpildīšana uz priekšmetstikla un fiksēšana IF testam	I				I						A	A			A		A
1.8. Parauga IF testa veikšana	I				I						A	A			A		A
1.8.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana	I				I						A	A					A
1.9. Indikatoraugu audzēšana	I				I			I			I	A					A
1.10. Inficēto indikatoraugu sagatavošana testēšanai	I				I						A	A					A
1.11. Biotesta veikšana	I				I						A	A					A
1.11.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana	I				I						A	A					A
1.12. Baktēriju kultūru izdalīšana	I				I						A	A					A
1.12.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana	I				I						A	A					A
1.13. PCR												A	I		I		



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Risk Management

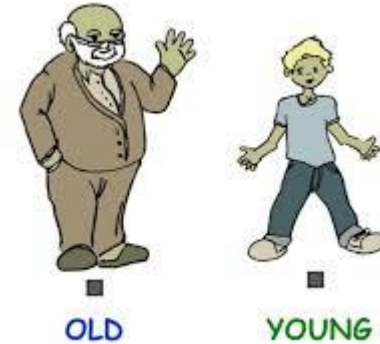
- ✓ Communication and consultation: informing about maternity leave (ASAP!)
- ✓ Hiring people on contract, while the expert has not yet gone on maternity leave
- ✓ Preparation of a training plan
- ✓ Exam
- ✓ Authorization
- ✓ Monitoring



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Risk Management

- ✓ What can I plan?
- When staff retire



Monitoring and review

Years	2021	...	2026	2027	2028
People	2	...	1	2	1



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How was the audit?

- ✓ LATAK audit according new standard was in **2020-03/04-06**
- ✓ They found 6 insignificant discrepancies
- ✓ Next LATAK visit is scheduled for the **second quarter of 2021**



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Conclusions During the Transition

- ✓ Train the lab personnel who will be responsible for implementation ISO 17025:2017
- ✓ Create a working group to implement the standard
- ✓ Consult with already accredited laboratories
- ✓ Seize / grab the opportunity provided by the new standard in order to reduce the documentation of management system (no requirement for quality manual)



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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
 - 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



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Future

✓ One pest / test accredited in:

nematology,

mycology,

virology

✓ Achieve accreditation for a flexible scope in molecular biology (PCR)





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What helped during the transition?

- ✓ LATAK training courses
- ✓ EPPO workshop on the revision of PM 7/98 (2019-02-11/13)
- ✓ Lectures on the internet
- ✓ Handbook ISO/17025:2017 Eurolab
- ✓ Consultations with already accredited laboratories



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EPPO Database on Diagnostic Expertise

- ✓ New pests, small number of samples
- ✓ It is not useful to introduce a new method and buy reagents
- ✓ Thanks to **EPPO Database on Diagnostic Expertise** it is possible to find labs and experts regarding different pests
- ✓ Cooperation between plant diagnostic laboratories
- ✓ Very important – regularly update the Database!!!



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Nordic-Baltic Laboratories Network (LT, EE, PL, FI, NO, LV, DK)





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Thank you!

