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# **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



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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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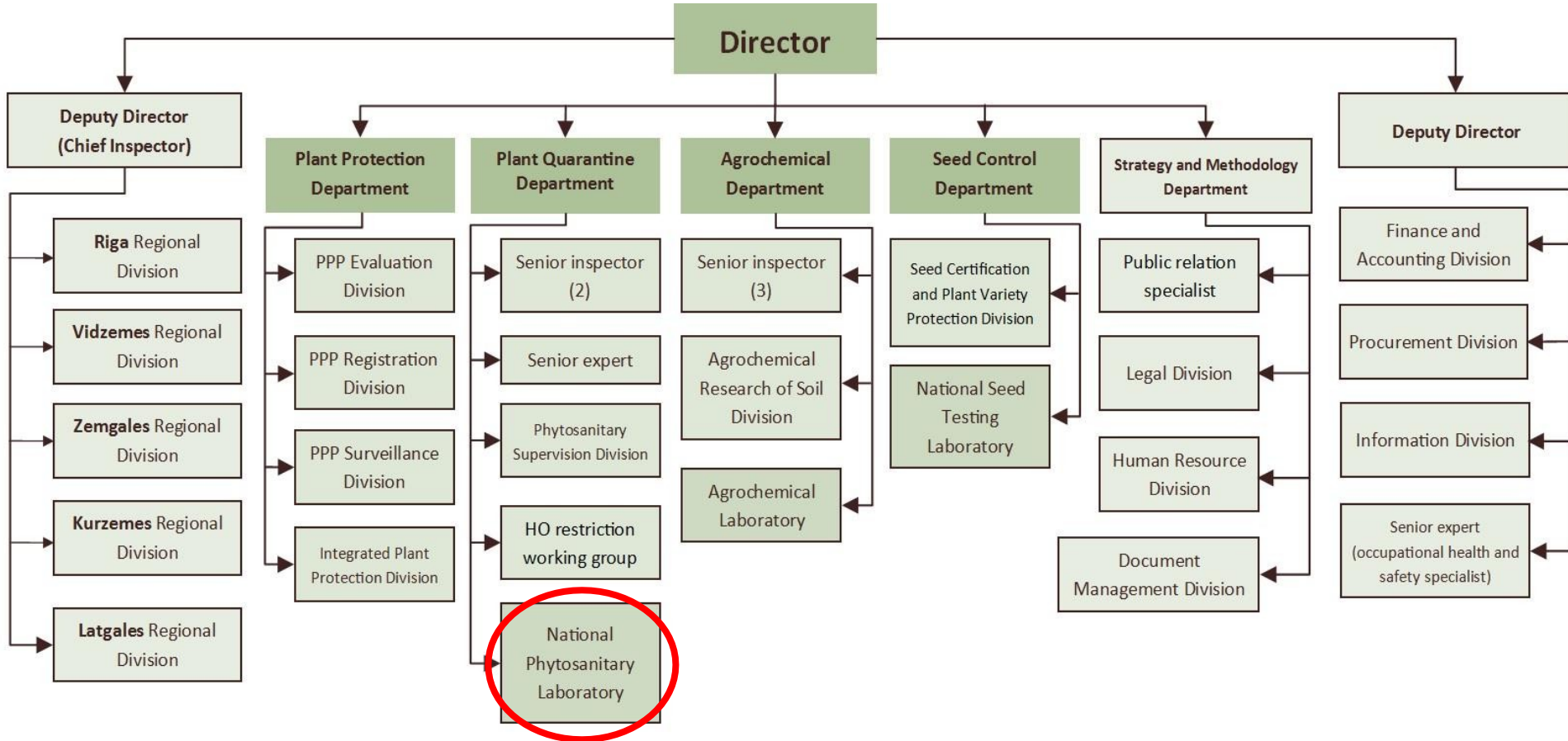


State Plant Protection Service of Latvia designated  
NPhL as **National Reference Laboratory** of Latvia for the  
diagnosis of plant pests (bacteria, nematodes, viruses, viroids,  
phytoplasmas, insects, mites, fungi, oomycetes, weeds) in  
accordance with Article 100 of OCR (EC) 2017/625 and Article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



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# Laboratory Location in Service Structure



Abbreviations:

PPP—Plant Protection Products

HO—Harmful Organisms



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# Location of the Laboratory





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# 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

Total	Import	EU	BCD/ BCP	Private persons	Integrated Pest Management	Domestic origin
<b>5860</b>	90	182	87	122	168	5211



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# Testing of Samples in 2018

Sector	Samples / Tests
Virology	1234 / 24252
Bacteriology	2400 / 7440
Mycology	610
Nematology	2112 / 8327
Entomology	1196
Herbology	129
Molecular biology	550 / 3219





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# 173 samples in one day

Rajons: < . . . >

Administratīvā 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







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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

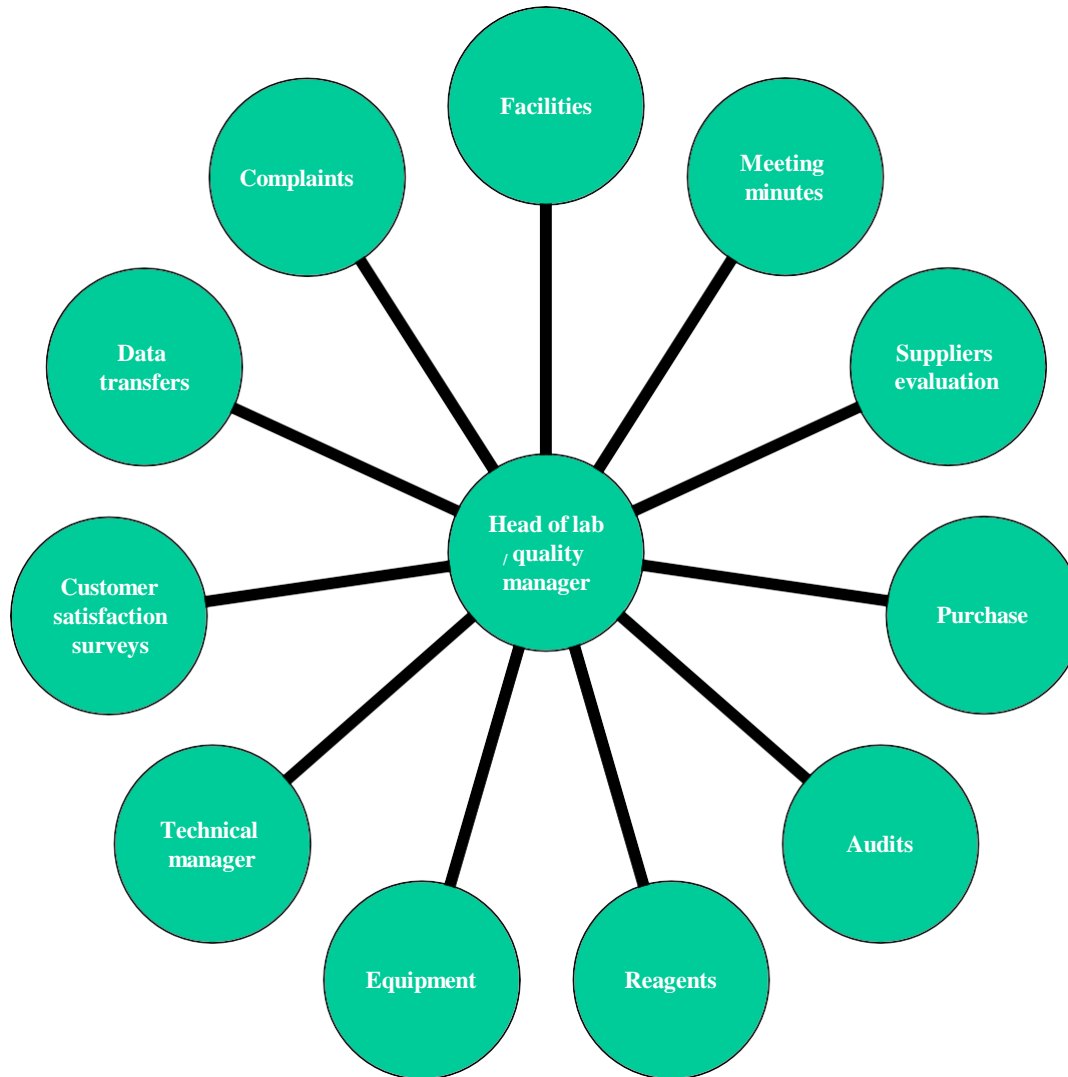
Accreditation on “ ME.E.002.2007 method for  
identification of *Liriomyza huidobrensis*





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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 –  
focuses more on information technology, which incorporates the  
use of computer systems, Laboratory Information Management  
System software and the provision of electronic results



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# How to ensure a smooth transition to the new ISO 17025 standard in laboratories?





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# 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 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



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# Risks and 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



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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 will be scored according to:
  - Severity
  - Probability
  - Frequency
  
- ✓ Risks with highest scores will be managed
  
- ✓ This allows to prioritize the risks





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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.





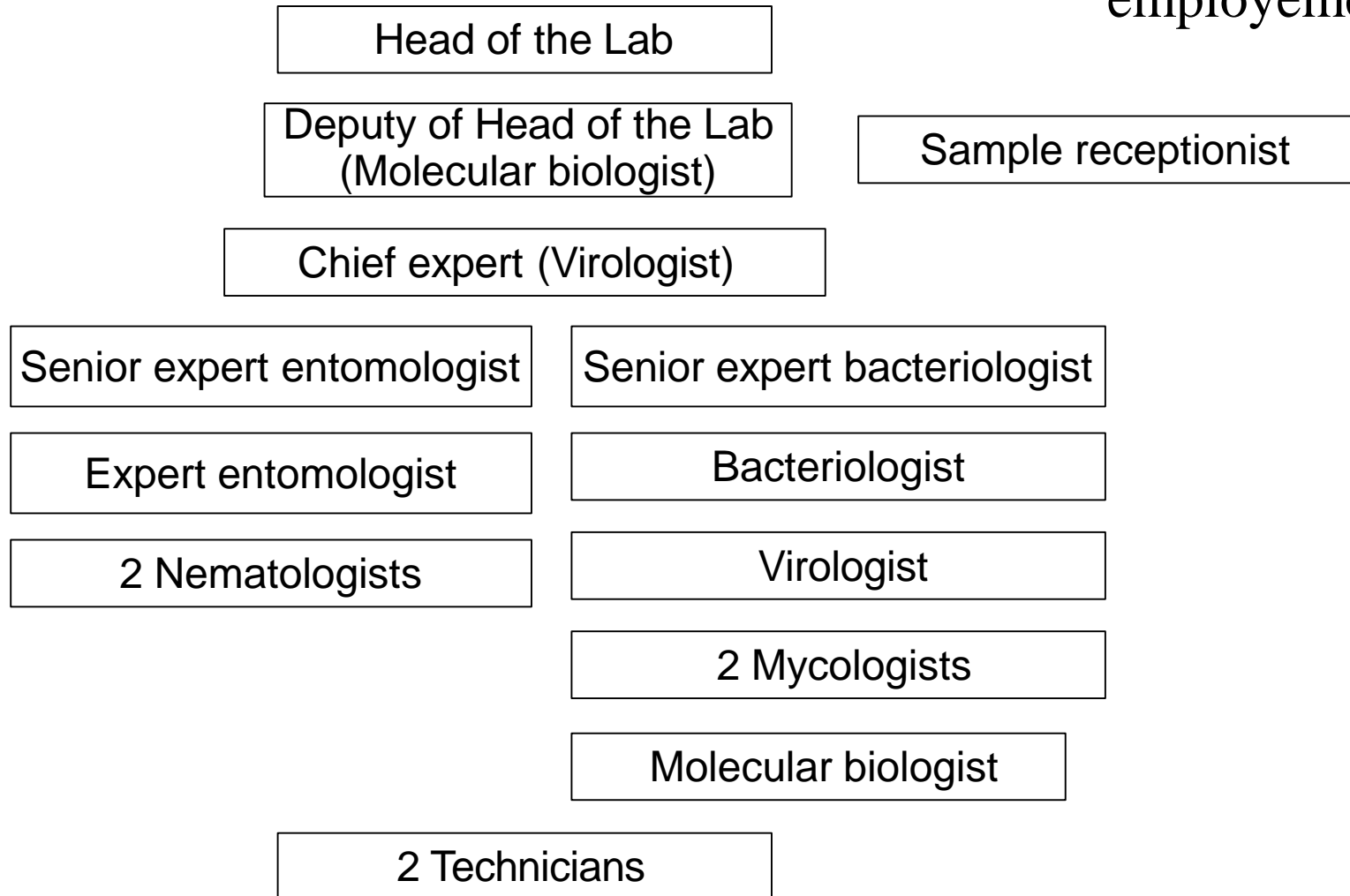
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# Structure

## 16 permanent staff members

3 on maternity leave

3 on contract (fixed – term  
employment)



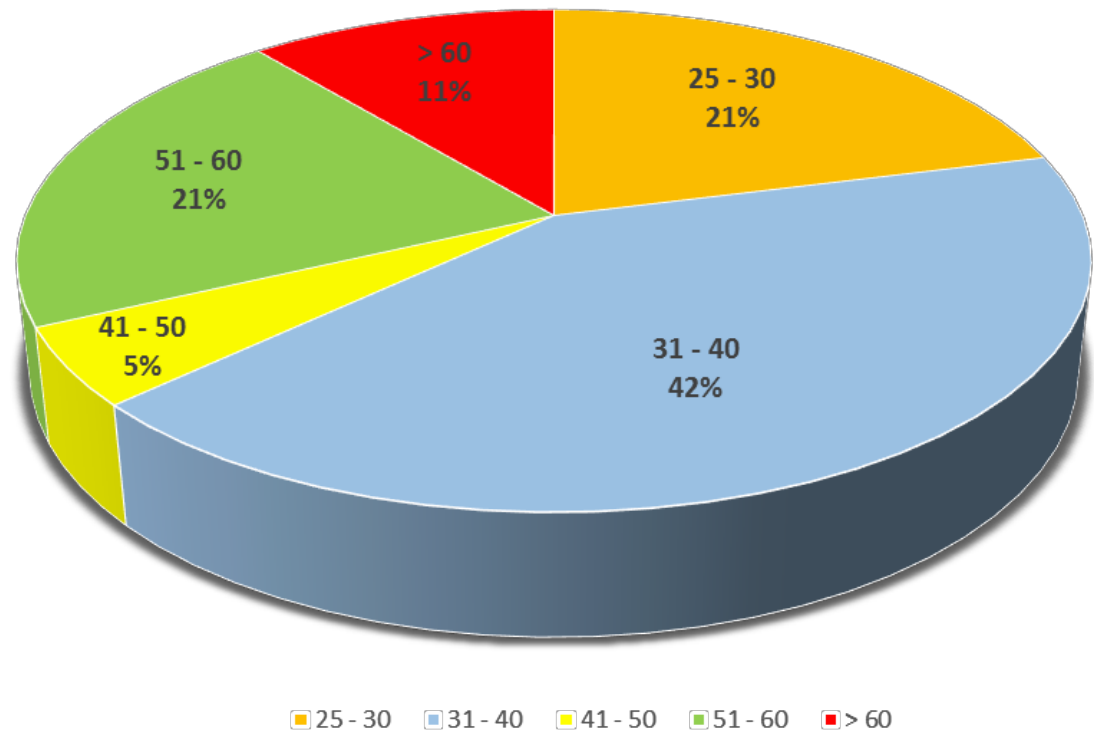


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# Risks and Opportunities

- ✓ 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	???	???	???



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# 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





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# Risk Management

## Pienākumu un atbildības deleģēšanas kārtība

Revidēja:  
J. Mihailova

Apstiprinu:  
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
<b>Testēšanas pārskata parakstīšana</b>			<b>A</b>			<b>I</b>											<b>I</b>
<b>1. ME.B.001.2014.3v (2; 3; 4)</b>																	
<b>ME.B.002.2014.3v (5; 6; 7)</b>																	
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 noliecšana	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
1.11. Biotesta veikšana	I				I							A					A
1.11.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana	I				I							A					A
1.12. Baktēriju kultūru izdalīšana	I				I							A					A
1.12.1. Rezultātu novērtēšana un kontrole, dokumentu noformēšana, testēšanas protokola un PIK parakstīšana	I				I							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

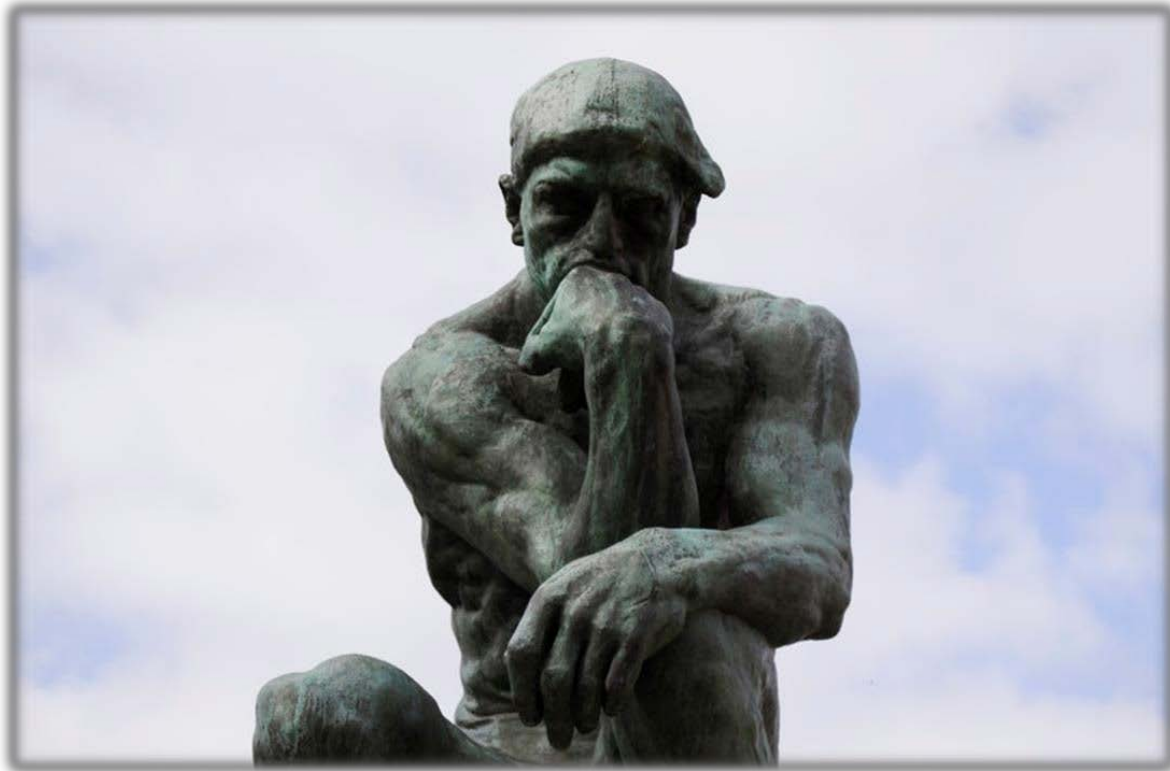


Years	2021	...	2026	2027	2028
People	2	...	1	2	1



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# Conclusions





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# 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



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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
    - We have: 36 procedures, 7 policies
    - 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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# 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
  - Handbook ISO/17025:2017 Eurolab



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# Nordic-Baltic Laboratories Network Meeting in Latvia, 2018







Thank you!