Implementation of ISO/IEC 17025:2017 at National Institute of Biology (NIB)

Manca Pirc and Marjana Camloh

EPPO Training Workshop on ISO Standard 17025:2017 and PM 7/98 (4)

14.-15. December 2020

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NATIONAL INSTITUTE OF **BIOLOGY**

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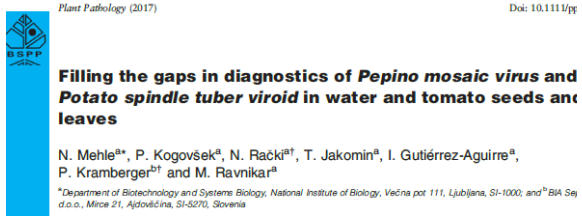
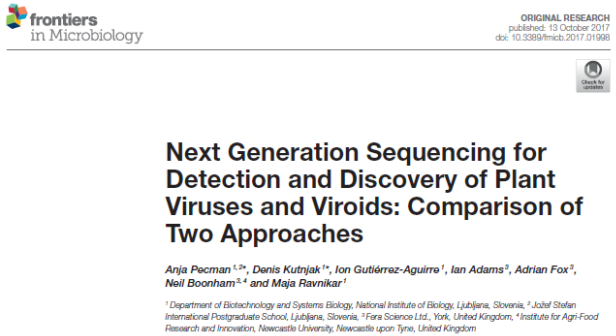
Introduction

- **National Institute of Biology (NIB),** independent Public Research Institution for Life Sciences in Slovenia, established in 1960 (http://www.nib.si/eng/, above 140 employees in 4 research departments).
- **FITO - Department of Biotechnology and Systems Biology,** the largest department of NIB (4 working units, 3 diagnostic labs, currently 63 employees)
  - **2 National Reference Laboratories** for viruses and phytoplasmas and for bacteria
  - **Partner of EURL** for:
    - Bacteria (dr. Tanja Dreo)
    - viruses, viroids and phytoplasmas (dr. Nataša Mehle)
  - **Development of new detection tests, methods and international standards**, qPCR, dPCR
  - Members of 3 EPPO panels


Plant Pathology (2017)

Filling the gaps in diagnostics of *Pepino mosaic virus* and *Potato spindle tuber viroid* in water and tomato seeds and leaves

N. Mehle, P. Kogovšek, N. Rački, T. Jakomin, I. Gutiérrez-Aguirre, P. Kramberger and M. Ravnikar


frontiers in Microbiology

ORIGINAL RESEARCH

Next Generation Sequencing for Detection and Discovery of Plant Viruses and Viroids: Comparison of Two Approaches

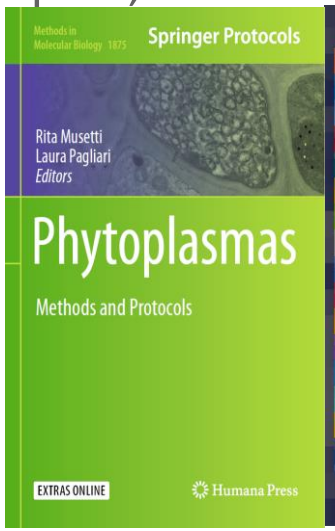
Anja Pecman, Denis Kutnjak, Ion Gutiérrez-Aguirre, Ian Adams, Adrian Fox, Neil Boonham and Maja Ravnikar

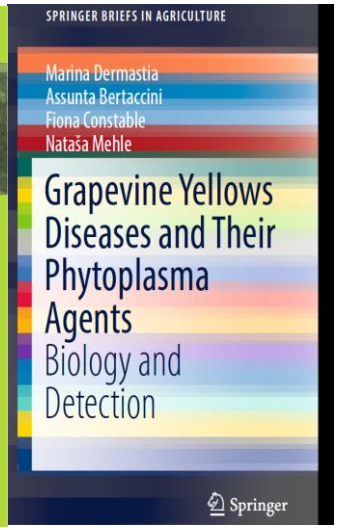

BMC Genomics

RESEARCH ARTICLE Open Access

Genomic characterisation of the new *Dickeya fangzhongdai* species regrouping plant pathogens and environmental isolates

Špela Alič, Jacques Pedron, Tanja Dreo and Frédérique Van Gijsegem





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Introduction

- **Organizers of proficiency tests** on bacteria, viruses and phytoplasmas starting in 2015, thereafter organized yearly with increasing number of participants worldwide (2018, 45 participants, 26 counties, three continents)
- **Characterization of reference materials** for GMOs and plant pests
- **Regular trainings on diagnostic** for international participants, etc.
- **Validation and verification** (EU project Valitest)

PT	Plant pest	Number of participant (number of countries)	
2015_01	*R. solanacearum*	18 (16)	
	E. amylovora	17 (16)	
2016_01	*R. solanacearum*	2 (2)	
2016_02	*phytoplasma (FD / BN)*	17 (16)	
	X. fastidiosa	29 (22)	
	‚Ca. L. solanacearum‘	20 (15)	
2017_01	*E. stewartii*	20 (14)	
	RSSC (detection & phylotyping)	29 (21)	
	phytoplasma (AP, ESFY, PD)	23 (16)	
2017_02	*phytoplasma (FD / BN)*	1 (1)	
2018_01	*RSSC*	29 (19)	
	E. amylovora	27 (19)	
	TSWV/INSV/CSNV	4 (4) / 18 (14)	
2018_02	*Small ILC on detection of Cms DNA*	2 (2)	

Valitest

Validation of diagnostic tools for animal and crop – Resilient and resource efficient value chains (GA No. 773139)

Valitest EU Project @ValitestProject · Apr 9

TPS starting!samples and reagents for the TPSs on Erwinia amylovora (fire blight) are already with most participants. impressive figures below
6 tests (real-time PCR, LFDs and LAMP)
32 participants
20 different countries
46 panels of samples
920 samples
thanks to @NIB_FITO_SI

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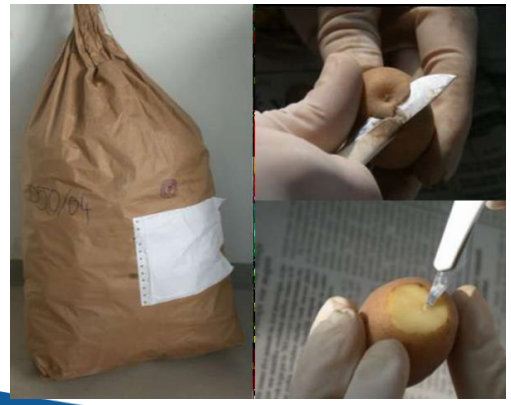
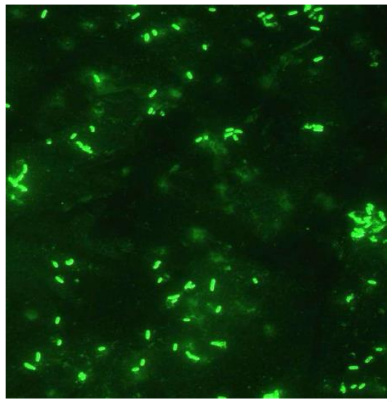
Quality management system and accreditation based on ISO/IEC 17025

- **Beginnings of QMS in plant pest diagnostic activity in 1997**
- **NIB obtained ISO 9001 certificate in 2004**
- **GMO detection accredited in 2003; since 2006 - flexible scope of accreditation**
- **Detection of microorganisms – plant pathogens, flexible scope**
  - detection of phytoplasmas accredited in 2012
  - detection of bacteria accredited in 2018
  - **accreditation scopes:** Annex to the accreditation certificate (LP-028) and in the List of accredited methods for detection of GMOs and microorganisms – plant pathogens on the web site of Slovenian accreditation http://www.slo-akreditacija.si/acreditation/nacionalni-institut-za-biologijo/





A: Dried crust from black and rusty-brown exudate at the edge of the infection and cracked, dead bark; B: Infection possibly caused by cuts; C: Infection possibly caused by a nail; D: Infected tree in April 2017 with small leaves, bark dieback, and oozing; E: Dead tree in August 2017; F: Old horse chestnut tree with oozing rusty-brown exudate from the infected bark (as denoted by arrows); G: Dried exudate on an old tree.

General NIB/FITO approach to implementation of ISO/IEC 17025:2017

- The majority of new requirement were already implemented in QMS, including risks and opportunities, however some of them have to be additionally clarified or documented
- To implement new requirements to upgrade and improve QMS without too many changes

Implementation of new requirements of ISO/IEC 17025:2017 in QMS of NIB, FITO

Main phases of implementation:

- studying the changes of the new standard, beginning of 2018
- presentation of new requirement to employees
- preparation of the implementation plan
- coordination / harmonization of changes between diagnostic labs, define final changes of the QMS documentation
- gradual implementation of changes (adaptation of existing documents, adoption of changes in practice, first documents changed in 2018)
- internal audits performed in spring 2019 according to ISO/IEC 17025:2017
- final approval of QMS by National Accreditation Body (external audit in November 2019, new annex to accreditation certificate according to ISO/IEC 17025:2017 in April 2020)

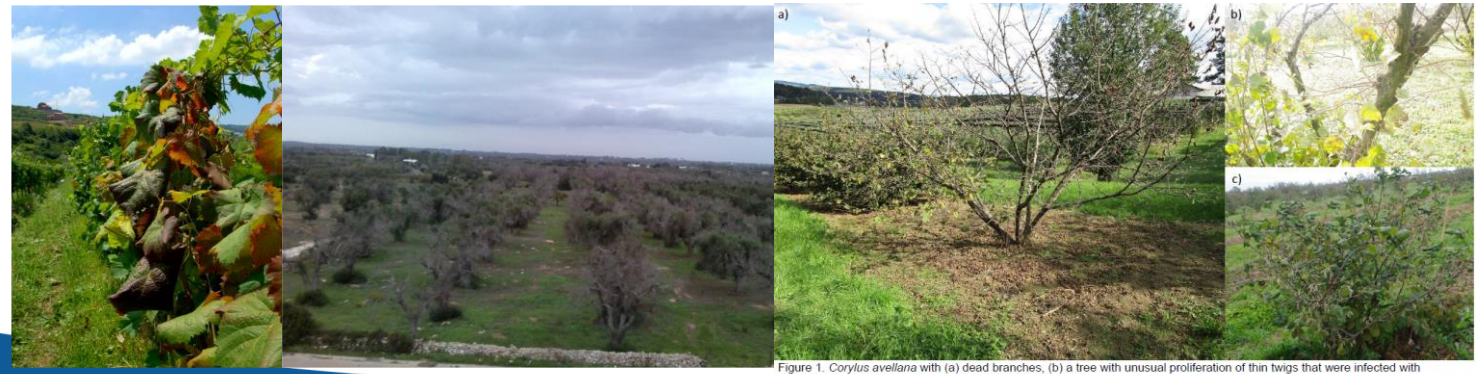


Figure 1. *Corylus avellana* with (a) dead branches, (b) a tree with unusual proliferation of thin twigs that were infected with 'Candidatus Phytoplasma fragariae', and (c) a healthy tree.

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change in the standard	Solution at NIB, FITO	New / updated documents
4 General requirements				
4.1	impartiality	clarifying **and risks identification**	**risk analysis performed** including but not limited to: management, ownership, personnel, customers, etc.	**Document on risk analysis; Confidentiality statement**
4.2	confidentiality	clarifying (customer should be informed in advance about intends to make information publicly available)	risk analysis performed;	**Document on risk analysis; Quality manual**
5 Structural requirements				
5.3	range of lab activities	lab activities have to be defined and documented	lab activities defined in list of accredited methods, regularly updated because of flexible scope	/
5.6	personnel and other resources	organizational changes – quality / technical manager and deputies not necessary	functions still exists, therefore no changes were implemented	/

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / updated documents
6 Resource requirements				
6.2	personnel	- competence requirements for each function has to be **defined and monitored,** - personnel **shall act impartially**	- competence requirements for some key functions e.g. responsible analyst updated; - **monitoring already performed**: regular meetings, internal audits, annual personal reports, proficiency tests, blind samples, etc.; - **text on impartiality prepared**, - importance of impartial work presented to employees	**Quality manual;** **Confidentiality statement**
6.4	equipment	- **equipment extended** to reagents measurement standards, RMs, software, consumables, etc.; - reference to ISO 17034 for RM producers	- control system for key reagents, standards, RMs, software already in place**,** **- the definition of equipment updated** including also the reference to ISO 17034	**Quality manual;** **Document on equipment control**
6.5	metrological traceability	lab shall establish metrological traceability of **measurement results**	- already established – when possible equipment **calibration is provided by accredited calibration labs**; - RMs are provided from competent producers (when available), the text clarified	**Quality manual;** **Document on equipment control**

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / updated documents
7 Process requirements				
7.1	review of requests, tenders, contracts and subcontracts	- deviations requested by the customer **shell not impact the integrity** of the lab or the validity of results	- **text on maintaining the integrity added**	**Document on review of contracts**
7.2	methods - selection, verification, validation	the concept of "**method verification**" is introduced	the concept of **verification already introduced** and verifications performed	/
7.3	sampling	sampling highlighted as a lab activity as testing and calibration	not relevant for NIB	/
7.4	handling of samples	when the customer requires to perform a test despite **the deviation**, the lab shall **indicate in the report** which results may be affected	**the text on reporting was clarified and updated**	**Document on control of records and reporting**
7.6	measurem. uncertainty (MU)	new terminology **– evaluating MU instead of estimation of MU**	critical factors influencing MU are already defined and controlled, described in QMS document and published (Mehle et al., **EPPO Bulletin** 44 (3), 2014)	/

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / Updated documents
7.7	ensuring the validity of results	- **extended list for monitoring the validity of results**; - **PT providers that meet the ISO/IEC 17043** requirements are competent	**updated text on monitoring the validity of results**, although the majority of monitoring activities was already performed (use of RMs when available, participation in PTs, checks of equipment, replicate tests, retesting retained samples, blind samples, etc.)	**Quality manual**
7.8	reporting	- the **results shall be reviewed and authorized**; - data provided by a customer shall be clearly identified; - when lab isn't responsible for sampling it shall be stated in the report that the **results refer only to the received samples** which have been tested	- **updated and clarified text on the reporting**, - **updated Report**	**Document on control of records and reporting;** **Report**
7.9.	complaints	- **handling process for complaints shall be available** to interested parties; - when possible **the complaint shall be handled by person not involved in the lab activities** in question	**complaint handling procedure was updated**	**Document on control of actions, complaints and improvements**
7.10	nonconforming work	- **consideration of risks** - actions based upon the risk levels established by the laboratory	**risks included** in the nonconformance handling procedure	**Quality manual; Document on control of actions…; Document on control of nonconformances; Form for nonconformances**

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / Updated documents
7.11	control of data and information management	- requirements **adapted to computerized lab information management systems**; - external provider of the system that meets all applicable requirements of ISO/IEC 17025 is competent	**all QMS documents, key data and information are in paper versions;**	**/** **nonconformance from NAB** **Document on control of computerized systems and software**

NC: In the regular internal audit the requirements of point 7.11 of ISO 17025:2017, (Control of data and information management) **has not been sufficiently assessed.**

Solution: we performed additional internal audit were all the requirements of 7.11., relating management of computerized information systems and software were assessed (protection from unauthorized access, validation for functionality, procedure for validation after changes, maintenance, recording system for failures, etc.)

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / Updated documents
8 Management system requirements				
8.1	options A, B	- **A - QMS established according to ISO/IEC 17025**, clauses 8.2-8.9 **- B - QMS is established according to ISO 9001**, In both options fulfillment of the clauses 4-7 of ISO/IEC 17025 are necessary	**option** A and ISO 9001	/
8.2-8.4	management system documentation control of documents and records	- no significant change; - quality manual and quality policy were withdrawn	no changes were implemented	/
8.5	**actions to address risks and opportunities**	lab **shell consider the risks and opportunities (R&O)** to: - achieve intended results - enhance opportunities to achieve the purpose and objectives - prevent, reduce undesired impacts and failures - achieve improvements, lab shall plan: - actions to address this R&O - How to integrate and implement these actions to QMS - Evaluate the effectiveness	**FITO has been focused on identifying R&O and minimize risks and maximize opportunities for years** (positive business results, projects, new customers, increasing number of employees…) - additionally the **R&O identification table was introduced** and is fulfilled regularly on meetings of senior staff; - additionally the **process of risk management was prepared**	**Quality manual;** **Table on risks and opportunities;** **Document on control of risks**

Identification table for risks and opportunities

IME IN PRIIMEK TER DATUM VP	DECRIPTION OF RISK WITH RISK LEVEL*	UKREP /ACTION	ROK / DEADLINE	RESPONSIBLE	CARRIED OUT (DESCRIPTIONS OF ACTIONS)	USPEŠNOST UKREPA/ EFFECTIVENESS
Jana Žel / 23.4.2019	Zaradi dela z GSO v različnih oblikah na večih dejavnosti je možnost kontaminacij	Skličemo sestanek na katerem preverimo procese, kjer bi lahko prišlo do kontaminacij med oz. znotraj procesov.	Maj 2019	Žel	17.5.2019 izvedeno izobraževanje in sestanek - dokumenti pri neskladnosti GSO-KV-01/2019 z dne 3.4.2019	ukrep je uspešen
Vodja oddelka / 23.4.2019	Zaradi velikega števila projektov in omejenega števila projektnih sodelavcev je izvajanje projektov oteženo	Bo obravnavano na sestanku vodij	konec junija 2019	Vodja oddelka	Študentsko delo, v planu so nove zaposlitve	ukrep je uspešen
Nataša Mehle, 8.4.2019	Tveganje, da ključne kemikalije, ki so potrebne za izvajanje dejavnosti za naročnike, niso več na voljo (prenehanje proizvodnje).	Bo obravnavano na sestankih diagnostike, kjer bomo identificirali možne rešitve oz. pristope za zmanjšanje tveganj in na sestanku vodij, kot npr. Pregled zalog in pravočasna nabava ključnih kemikalij.	konec 2019	Nataša Mehle, Tanja Dreo, Jana Žel	Obravnavano na sestankih diagnostike	ukrep je uspešen
Notranja presoja 20.6.2019 (presojevalke Mojca Milavec, Maja Ravnikar, Marjana Camloh, Tanja Dreo)	Evropska zakonodaja predvideva do leta 2022 akreditacijo metod, ki se uporabljajo za uradni nadzor. Za to je potrebno pridobiti dodatna sredstva. V teku so pogajanja z možnimi financerji. Obstaja tveganje, da pogajanja ne bodo uspešna in dodatnih sredstev za ta namen ne bo.	Bo obravnavano na sestanku SR Pripravljena je bila projekcija sredstev do 2022. Poslali le to na Upravo in imeli z njimi več sestankov (S Alenko Zupančič in Katarino Groznik). Organiziran sestanek pri Posediju, 2.7.2019 (MajaR, TanjaD, NatašaM) Organiziran sestanek pri ministrici 18.7.2019	Konec 2020 za sprotne aktivnosti, 2022 pa zaključek	Maja Ravnikar, Tanja Dreo in Nataša Mehle	glej napisano v rubriki ukrep	dogovori za dodatna sredtva v teku 3.9.2020
Marjana Camloh 16.3.2020	Prilagoditve laboratorijskih aktivnosti zaradi SARS-CoV-2 bi lahko vodile v neizpolnjevanje zahtev standarda 17025	O prilagoditvah se odloča na rednih sestankih, določajo se tako, da ne vplivajo na kakovost izvedbe analiz in rezultatov. O prilagoditvah / odstopanjih se sprotno obvešča naročnike in izvajalce preskusov. Pripravi se povzetek vseh prilagoditev. Kjer je potrebno, se ustrezno dopolnijo dokumenti sistema kakovosti.	sprotno	Maja Ravnikar, Marjana Camlo, Tanja Dreo, Nataša Mehle in Jana Žel	16.3.2020 poslano obvestilo o spremembah načina dela ključnim naročnikom. Prilagoditve lab aktivnostih se sprotno vpisujejo v zapise sestankov MO in GSO. 16.3. po mailu obvestilo o prilagojenem načinu sprejemanja dok SK, 17.3. dopolnjeno 02R-Nav 02-19, 31.3. povzetek prilagoditev poslan na koronco, 2.4. dopolnjeno navodilo 02R-Nav 01-22 (oprema) ter 02R-Nav 02-20. 6.4. povzetek prilagoditev poslan na FITO.	Ukrep je uspešen, glej tudi: O:\SISTEM KAKOVOSTI\Covid - 19\Prilagoditve dela v razmerah Covid 19 verzija01 06 april 2020.doc
Jana Žel / 7.4.2020	V kolikor bi se razmere zaradi epidemije z SARS-CoV-2 zaostrile toliko, da bi bil onemogočen transport vzorcev, bi to lahko vplivalo na sodelovanje z naročniki.	Z naročniki ostajamo v stalnem stiku, razmere spremljamo sprotno, delo prilagajamokolikor je možno. Obenem se usmerjamo tudi v raziskave povezane s SARS-CoV-2, ki bi nam potencialno lahko nadomestile eventuelni izpad prihodka (glej priložnost spodaj).	sprotno	Ravnikar, Žel, Kogovšek, Dobnik	Ves čas epidemije v stiku z naročniki	ukrep je uspešen
Jana Žel / 7.4.2020	Priložnost: usmeritev v raziskave SARS-CoV-2	Zaradi epidemije virusa SARS-CoV-2 smo se na osnovi naših znanj usmerili tudi v preučevanje virusa SARS-CoV-2 in z njim povezanih problemov (epidemiologija in mutiranje virusa, prisotnost v odpadnih vodah, uporaba zaščitne opreme)	sprotno	Ravnikar, Žel, Gutierrez, Kogovšek, Dobnik, Kutnjak	31.3.2020-Na nivoju NIB zbiranje raziskovalnih idej za delo s SARS-CoV-2 (objava na internetni strani NIB). 15.4.2020 - javljanje spremembe programov ARRS (usmeritev raziskav v SARS-CoV-2), april 2020-dogovarjanje z neposrednimi naročniki za raziskave povezane s SARS-CoV-2 (čistilne naprave, proizvajalci zaščitne opreme).	ukrep je uspešen
SR 4.8.2020	Kemikalije za molekularno biologijo imajo zelo dolg dobavni rok, nekatere pa ni možno nabaviti	Pregleda se katere kemikalije so kritične in se jih naroči ustrezno prej. Obravnavati v okviru vseh DE, preveriti zaloge (zaradi roka uporabnosti) pred naslednjo nabavo kemikalij za molekularno biologijo	sprotno	vodje enot in projektov ter zadolženi za nabavo	se izvaja sprotno	ukrep je uspešen
SR 4.8.2020	Povečano število okužb z virusom SARS-CoV-2 v jesenskem času in otežkočeno izvajanje projektov in analiz.	Za vse zaposlene se uredi možnost cepljenja proti gripi. Uvede se še bolj striktno čiščenje in razkuževanje skupnih prostorov (čajne kuhinje, WCjev) ter kljuk, stikal, ipd. Ljudi se dodatno opozori, da se naj ne zadržujejo v čajnih kuhinjah. Iz čajnih kuhinj se odstrani skupni pribor in posoda. Ukrepe se skoordinira z GEN. Kadar je izvedljivo se dela od doma. Ustrezno se dopolni navodila. Posodobi se navodila za čiščenje in se zaposli dodaten kader za čiščenje. Za vodenje dela na daljavo je bila v oktobru izvedena delavnica za vodenje dela na daljavo	sprotno	vodstvo NIB in FITO ter INFRA	se izvaja sprotno	

*Pomagalo pri določitvi stopnje tveganja

Stopnja tveganja / risk level
Visoka / high
Zmerna / middle
Nizka (zanemarljiva) / low
priložnost / opportunitie

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8.6-8.7	improvement, corrective actions	- preventive actions are withdrawn - consideration of **R&O**	**risks included** in the nonconformance handling procedure	**described in 7.10**
8.8	**internal audit**	**- no need to conduct internal audits every year**, but at planned intervals - **no need that internal audit program shell address all elements of QMS** in one audit - in the audit program the relevance of the activities to be audited, changes and the results of previous audits have to be taken into account	audit plan prepared for 3 years period,	**Internal audit plan;** **Document on internal audits**
8.9	management reviews	- changed inputs to management review - consideration of risks	updated text on management review	**Quality manual**

Plan of internal audits

Plan of internal audits for 2019-2022;
- depending on the results of previous audits and changes that affect lab activities the plan can be modified what shall be recorded in the audit program and report.
- internal audits on plant pest diagnostic activity includes also requirements on national rules and EPPO documents

		Določanje MO -določanje bakterij			Določanje MO - določanje fitoplazem			Določanje GSO			Opombe
Okvirni termin: leto in mesec presoje:		2019 maj/ junij	2020 september/ november	2022 febr maj	2019 maj/ junij	2020 september/ november	2022 febr maj	2019 april/ maj	2020 september/no vember	2022 marec/ april	
Točke standarda ISO/IEC 17025:2017**											
4	Splošne zahteve	/	/	/	/	/	/	/	/	/	
4.1	Nepristranskost	√	√		√			√		√	
4.2	Zaupnost	√					√	√	√		
5	Strukturne zahteve	√					√		√		
6	Zahteve glede virov	/	/	/	/	/	/	/	/	/	
6.1	Splošno		√				√	√			
6.2	Osebje	√				√		√			
6.3	Prostori in okoljske razmere		√		√					√	
6.4	Oprema	√				√				√	
6.5	Meroslovna sledljivost			√		√		√		√	
6.6	Izdelki in storitve zunanjih ponudnikov	√					√		√		
7	Zahteve glede procesov	/	/	/	/	/	/	/	/	/	
7.1	Pregled naročil, ponudb in pogodb		√		√		√	√			
7.2	Izbira, preverjanje in validacija metod	√		√			√		√		
7.3	Vzorčenje	√					√		√		
7.4	Ravnanje s primerki za preskus ali kalibracijo		√				√	√			
7.5	Tehnični zapisi	√		√		√		√			
7.6	Ovrednotenje merilne negotovosti	√				√				√	
7.7	Zagotavljanje veljavnosti rezultatov	√	√	√	√	√	√	√	√	√	
7.8	Poročanje o rezultatih	√	√	√	√	√	√	√	√	√	
7.9	Pritožbe	√	√	√	√	√	√	√	√	√	
7.10	Neskladno delo	√	√	√	√	√	√	√	√	√	
7.11	Obvladovanje podatkov in upravljanje informacij	√					√		√		
8	Zahteve za sistem vodenja	/	/	/	/	/	/	/	/	/	
	Možnost A	/	/	/	/	/	/	/	/	/	
8.2	Dokumentacija sistema vodenja		√		√					√	
8.3	Obvladovanje dokumentov sistema vodenja	√				√				√	
8.4	Obvladovanje zapisov		√		√			√			
8.5	Ukrepi za obravnavanje tveganj in priložnosti	√	√		√			√		√	
8.6	Izboljševanje	√	√	√	√	√	√	√	√	√	
8.7	Korektivni ukrepi	√	√	√	√	√	√	√	√	√	
8.8	Notranje presoje	√	√	√	√	√	√	√	√	√	
8.9	Vodstveni pregledi		√		√					√	

Conclusions

- The main purpose of QMS at NIB is to obtain reliable, accurate, traceable, etc. results without many changes and with minimal additional administrative work not to increase high expenses for administrative part of diagnosis
- The implementation of new requirements should be gradual (step-by step, especially in completely new clauses of standard like risks)
- When a lab is accredited for years the majority of risks and opportunities were minimized during implementation and continuous improvement of the QMS
- NIB approach to implementation of new requirements was approved by National Accreditation Body in April 2020.

No. of accredited tests	
GMOs	76
plant pests: Phytoplasmas Bacteria	7 3
New documents	4
Updated documents	11

MANY THANKS TO

EPPO FOR ALL WORK DONE DURING LAST 15 YEARS IN QMS!!!!!

- My colleagues at NIB:
- Maja Ravnikar
- Nataša Mehle,
- Tanja Dreo
- Manca Pirc
- Jana Žel
- and many others


THANK YOU FOR YOUR ATTENTION !