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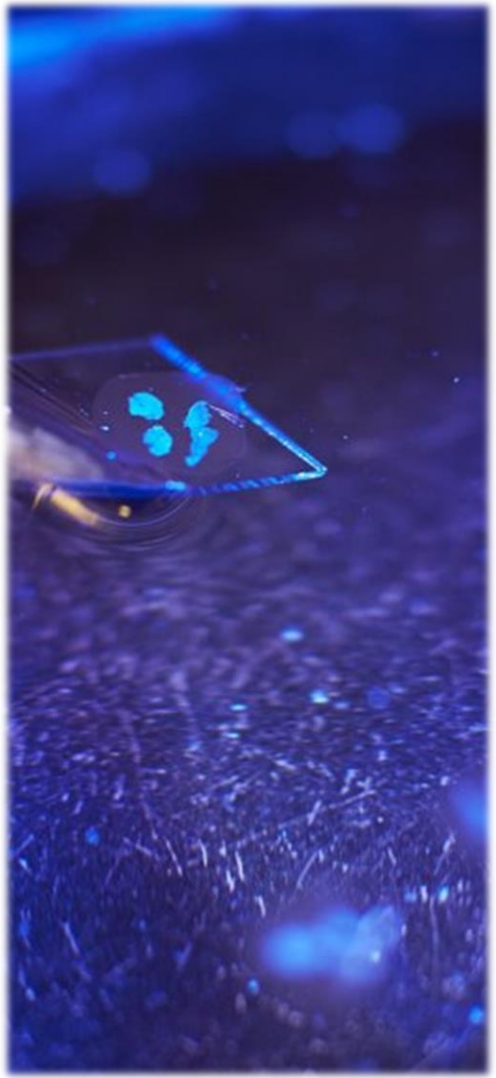
24.03.2020

Revisjon av ny ISO 15189

Revisjon av ny ISO 15189



Bakgrunn

- Deltaker i speilkomiteen for
  - «Pasientnær analyse og selvtesting hos Standard Norge», SN/K 116
  - 16 deltakere
  - (Representanter fra sykehus, apotek, Noklus, utstyrsleverandører, høgskolen, sykepleierforbundet, Lab-Norge etc.)

- Administreres av Hilde Aarefjord (Standard Norge)
  Ledes av Kari Nerhus (Noklus)

- SN/K 116 får ulike ISO standarder til høring og deltar i ulike stemmesaker for Norge

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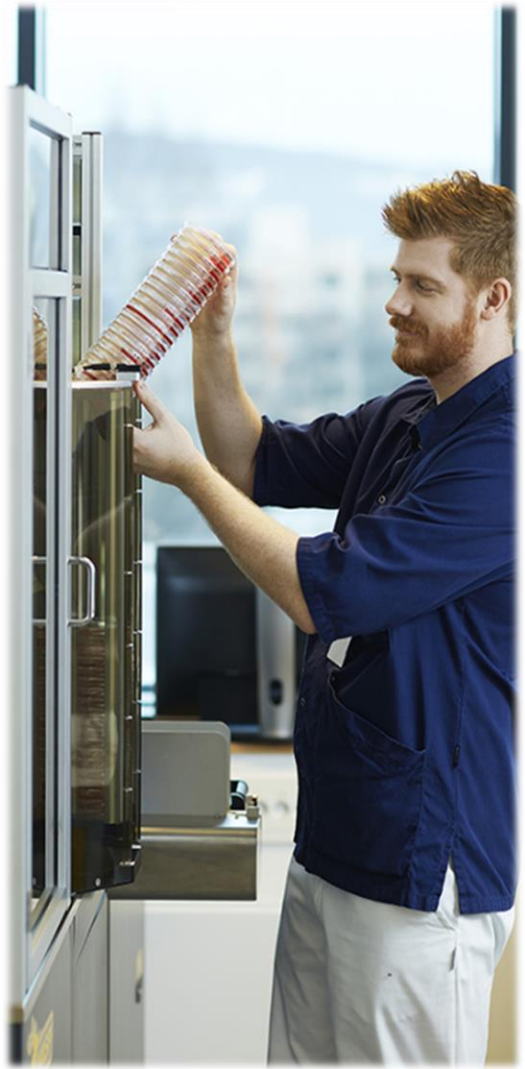
Revisjon av ny ISO 15189



Februar 2018

- Stemmesak for ny revisjon av ISO 15189 (ja/nei/avstå)
- Vi stemte for en ny revisjon
  (Utgåtte referanser, ikke samsvar med HLS-struktur, tidsintervall etc.)
- Norge har aldri deltatt med en «ISO expert»
- Fremmet et forslag om at det bør vi gjøre noe med

August 2018

- Resultatet fra avstemmingen klar, internasjonalt flertall for revisjon av ISO 15189
- Norge meldte inn en «ISO expert» til arbeidsgruppen til revisjonsarbeidet:
  «ISO TC/212 /WG1 Quality and competence in the medical laboratory»

«There has been an overwhelming response to the revision of this standard, which is great and tells me how widely it is used in the world"

Jeanette Wassung, ISO

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Revisjon av ny ISO 15189

September 2018

- Tilgang til arbeidskomiteens nettverk (ISOlution)
- Forespørsel til BFI om et samarbeid/høringsinstans
- Forespørsel til Norsk Akkreditering, informasjon om hvordan de har meldt inn synspunkter tidligere

Oktober 2018

- Første internasjonale samling for alle kandidater i TC212 (Seoul)

«The ISO TC212 Clinical laboratory testing and in in vitro diagnostic test systems committee develops standards for clinical laboratories. They are used by laboratories around the world, as well as by many accreditation bodis. The best known one being ISO15189 Clinical laboratories - Requirements for quality and competence"

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Hvem/hva/hvor er TC 212?

ISO / Technical Committee 212

CLSI manages the committee's program of work through the ISO consensus process according to the ISO Directives, and provides administrative support.

The scope of ISO/TC 212 is: "Standardization and guidance in the field of laboratory medicine and *in vitro* diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance."

The following is excluded:

- Generic quality management standards addressed by ISO/TC 176
- Quality management standards for medical devices addressed by ISO/TC 210
- Reference material guidelines addressed by the ISO Committee on Reference Materials (REMCO)
- Conformity assessment guidelines addressed by the ISO Committee on Conformity Assessment (CASCO)

Dr. David Armbruster is the ISO/TC 212 chairman, and ISO/TC 212 is divided into five working groups, as follows:

- Working Group 1, Quality and competence in the medical laboratory (convenor – Ms. Sheila Woodcock, Canada)
- Working Group 2, Reference systems (convenor – Dr. Neil Greenberg, USA)
- Working Group 3, *In vitro* diagnostic products (convenor – Dr. Claude Giroud, France)
- Working Group 4, Microbiology and molecular diagnostics (convenor – Dr. Uwe Oelmueller, Germany)
- Working Group 5, Laboratory biorisk management (convenor – Dr. Gary Burns, UK)

https://clsi.org/about/clsi-and-international-standards-development/iso-committees/technical-committee-212/

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Prosjektorganisering fra ISO

• Convenor/Project leader	Sheila Woodcock (Canada)
• Deputy Convenor	Stewart Bryant (Australia)
• Experience with ISO 17025 revision and CASCO	Christina Draghici (Canada)
• Accreditation body representative	Randy Querry (USA, A2LA)
• Experience with revision of ISO 15189:2007	Anne Vassault (Frankrike)

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Drafting teams

Convenor/Project leader; Sheila Woodcock (Canada)

TC/212, arbeidsgruppe 1:
Delt inn i 7 ulike arbeidsområder for revisjon av ISO 15189

Section	Team Leader
General	Bev Rowbotham
Structural	Bill Castellani
Resource/Personnel	Sabrina Chavez Lemus
Resource/Equipment	Adrian Yeo
Process/pre-examination & examination	David Ricketts
Process/ensuring quality & post examination	Mark Thelen
Management system	Janette Wassung

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Medlemmer i gruppe 7, Management systems

NAVN	LAND	ORG.TILHØRIGHET
Helene Mehay	Frankrike,	AFNOR
Luci Berte	USA	ANSI
Frank Schneider,	USA,	ANSI
Tania Motschman,	USA,	ANSI
Lorie Erikson,	USA,	FDA ANSI
Conrad Quinn,	USA,	ANSI
Ben Courtney,	England,	BSI
Katsuji Shimoda,	Japan,	JISC
Yong Joon Choi	Korea,	KATS
Jeanine Kruijsbeek	Nederland,	NEN
Katharina Holscbach-Bussian	Tyskalnd,	DIN
Julie Coffey	Canada,	SCC
Ida Mari Haugom	Norway,	SN
Zhai Peijun	Kina,	ILAC
Fredrik Trossö	Sverige,	SIS
Mathieu Kuenz	Frankrike,	AFNOR
Patrick Corstiaans	Nederland,	NEN
Bob Rej	USA,	ANSI
Chris Lehman	USA,	ANSI
Rodolfo Aquino Caceres	OSN,	El Salvador
Serhat Gok	Tyrkia,	TSE
Vandana Jain	India,	BIS
Punam Bajaj	India,	BIS

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Mal/regelverk for utarbeidelse av ISO/CASCO standarder

QS-CAS-PROC/33

August 2015

COMMON ELEMENTS IN ISO/CASCO STANDARDS

Contents

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Alle kommentarer registreres i en mal

Template for comments

Date: 07 December 2018	Documents: **ISO 15189:2012 Table and Text**	Project: **ISO 15189:2012 Revision**

RETURN COMMENTS TO JANETTE WASSUNG at janette@quality-first.co.za by Monday 14 January 2019

Name / Country/ I Representing Body	Clause/ Subclause (e.g. 8.2.1)	Paragraph/ Figure/ Table/ (e.g. Table 1)	Comments	Proposed change	Observations of the Team Lead

- Det har blitt noen kommentarer underveis……
- 34 A4 sider med kommentarer etter første gjennomgang for WG 8

- **Different Highlights were added-**
  - These comments need to go to the London meeting, as it involves the entire WG1
  - Suggested changes were made and incorporated into DRAFT 2
  - No Changes were made, with reason
  - No Changes were made yet – up for discussion
  - Text need debating at our web-conferences

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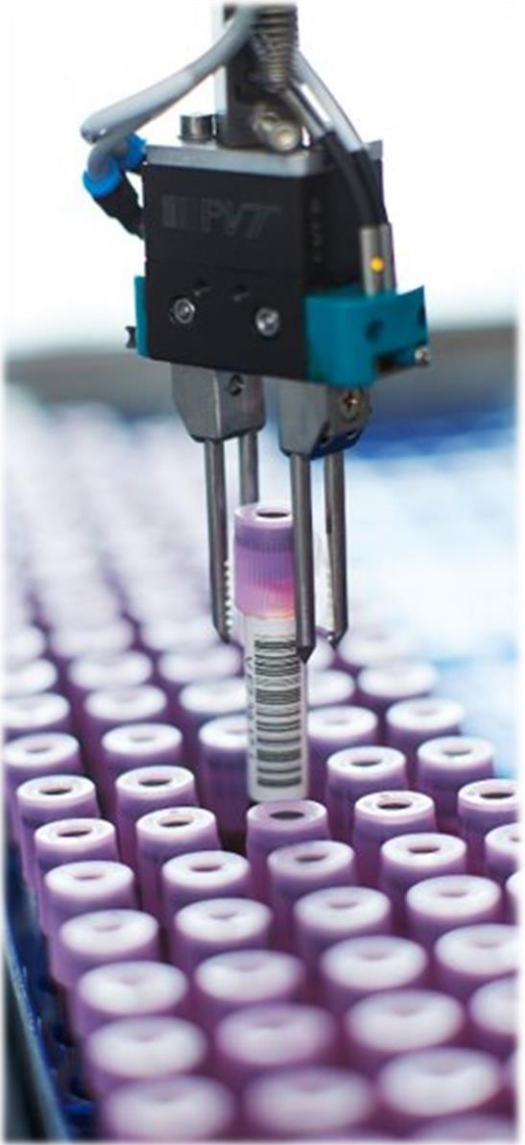
Konkrete endringer som er vedtatt



- ISO 17025:2017 er modellen for oppbygging av ny ISO 15189
- ISO 22870 (POCT) inkluderes inn i ny versjon av ISO 15189
- ISO 15190 (Safety), ISO 22367 (Risk management lab.examinations) og ISO/TC 20658 (Sample handling) som referanser i ISO 15189

Oversikt over supporting standards and technical standards inkludert

ulike guidelines må harmoniseres/inkluderes/sees i sammenheng med ny ISO15189

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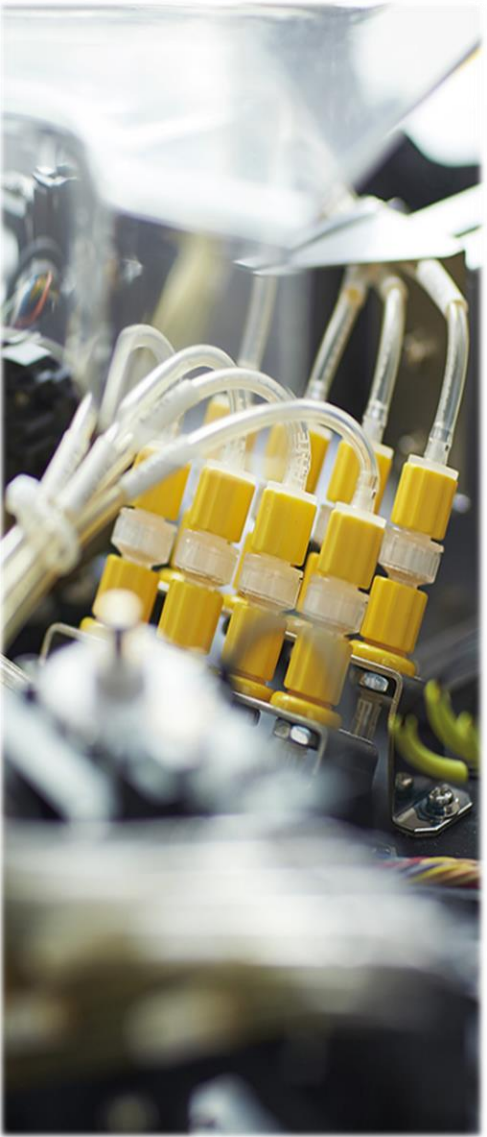
Revisjon av ISO 15189



WG1 porteføljen;

- ISO 15189 Medical laboratories – Requirements for quality and competence
- ISO 15190 Medical laboratories – Requirements for safety
- ISO 22870 POCT – Requirements for quality and competence
- ISO 22367 Medical laboratories – Applications of risk management to medical laboratories
- ISO TS 20658 Medical laboratories – Requirements for collection, transport, receipt and handling of samples
- ISO TS 22583 Guidance for supervisors and operators of POCT equipment
- ISO 23162 Basic semen analyses – Specification and test methods
- ISO guidance for anatomic pathology, emerging teqhnologies and imaging technologies

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Utkast til ny indexering

- Introduksjon

1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
   - 4.1 Impartiality
   - 4.2 Condidentiality
   - 4.3 Ethical conduct
5. Structural requirements
   - 5.1 Legal entity
   - 5.2 Laboratory director
   - 5.3 Laboratory services
   - 5.4 Structure, authority and documented procedures
   - 5.5 Authority and resourcess

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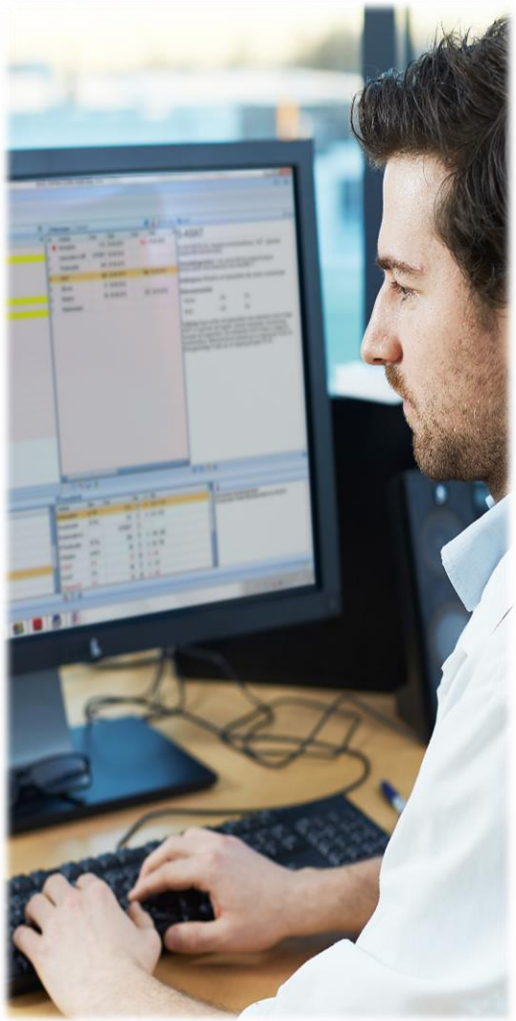
Utkast til ny indexering



6. Diskuteres
7. Diskuteres
8. Management system requirements
    - 8.1 General requirements and options
    - 8.2 Management system documentation
    - 8.3 Control of management system documents
    - 8.4 Control of records
    - 8.5 Actions to adress risks and opportunities
    - 8.6 Improvement
    - 8.7 Corrective Action
    - 8.8 Evaluation and audit
    - 8.9 Management reviews

- Annex 1 PDCA figure
- Annex 2 Relationship of Policies, Processes, Objectives, Measurement and Improvement

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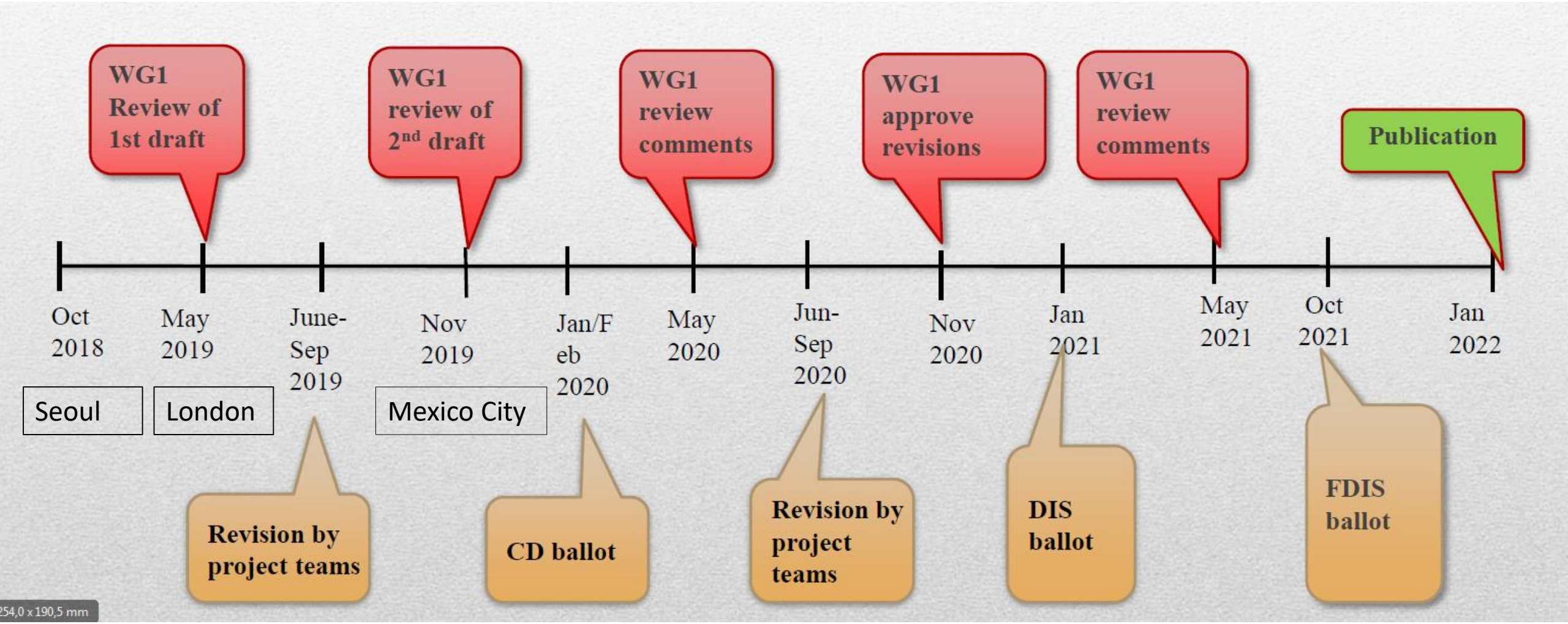
Timeline



254,0 x 190,5 mm

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Hva ønsker vi i Norge?

Hva ønsker vi å påvirke?
Hvem bør delta?
Hvordan samle innspillene?

- RUFKA/BFI «Kvalitetsnettverket» i Norge for medisinske labèr
- Norsk Akkreditering

Vi er et lite land sammenlignet med andre medlemsland i ISO,
har likevel en stemme inn i arbeidet!

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“Like a symphony, it takes a lot of people working together to develop a standard”

www.iso.org

Takk for meg!

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