

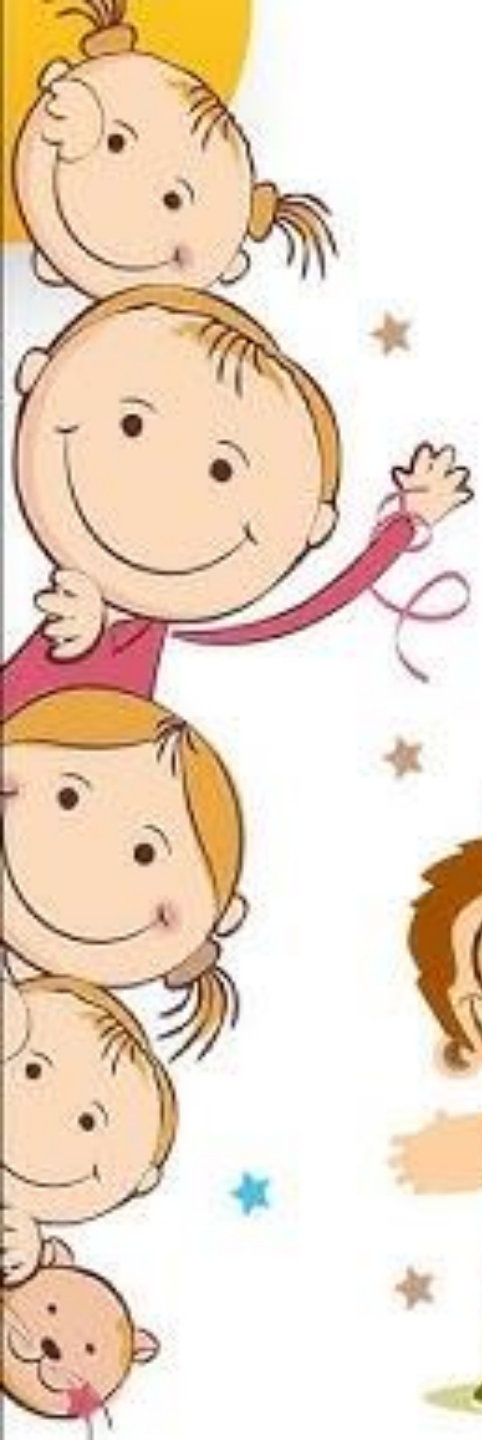
Meeting Regulatory and Accreditation Standards for POCT in Poland

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GENERAL KNOWLEDGE





Polskie Centrum Akredytacji
Polish Center for Accreditation



Warszawa/Warsaw



**Centrum Monitorowania
Jakości w Ochronie Zdrowia**
Center for Quality Monitoring
in Healthcare



Kraków/Cracow

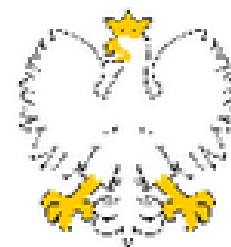


Polskie Centrum Akredytacji



Centrum Monitorowania
Jakości w Ochronie Zdrowia

- State agency but independent and self financing
- member of international organizations:



Ministry of Health
Republic of Poland

- FALB - Forum of Accreditation and Licensing Bodies



Polskie Centrum Akredytacji

ISO standard

The accreditation processes, grants accreditation and supervision of the granted accreditation of medical laboratories are based on the requirements of the **PN-EN ISO 15189: 2023-02 Medical Laboratories standard**. Quality and competence requirements (accreditation standard).



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Polish laws and regulations

- Laboratory Medicine State **Act** (2022)
- **Regulation** of the Minister of Health on organizational standards for laboratory tests of critical parameters performed in biological material, enabling a quick therapeutic decision (2023)
- **Announcement** of the Minister of Health on accreditation standards for medical activities(2024)

Targets/effects



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The ISO standard provides a framework for:

-
- continuous improvement,
- development of management systems,
- ensuring the consistency of the services provided
- enabling laboratories to identify and solve problems,
- minimizing errors



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Conformity with CMJ accreditation standards ensuring:

- innovation and continuous improvement
- efficiency in entity management
- Facilitating the comparison of healthcare entities
- the high quality of health services provided and the safety of patient care by defining and maintaining high standards of operation of healthcare entities.
- Supporting the professionalism of medical staff

Accreditation process



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- review of the submitted documentation,
- On-site assessment
- observation of conformity assessment activities carried out under real conditions (where applicable)
- Conversations with staff



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Period of granted accreditations



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- 4 years, every 12 months surveillance visits, then re-review with an assessment of improvement over the previous assessment



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- Granted for 3 years, when mild problems were detected, the certificate could be granted for 1 year.



Certificates – based on the auditors' assessment

The PCA makes its own, independent, decision and grants accreditation.



The Accreditation Council of the CMJ applies for accreditation of the medical unit to the Minister of Health. Accreditation is granted by the Minister of Health. The certificate is valid in Poland



The main practical difference 1



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Accreditation of medical labs only

- 37 medical laboratories/2763 in Poland
- 34 – private corporate labs
- 3 governmental units – parts of bigger units
 1. Warsaw University – Forensic Genetics Laboratory
 2. Lesser Silesia – Oncology Center – molecular diagnostic of cancers
 3. **Oncology Center Bydgoszcz**



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Accreditation of entire medical units like hospitals or polyclinics

- 212 hospitals/1214 (including ~250 for short-time hospitalization)
- 110 polyclinics/~24000

The main practical difference 2



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- Accredited laboratories are perceived as facilities that guarantee high quality of medical services, which can translate into a larger number of patients/determinations.
 - And potentially more revenue for private laboratories in the form of more contracts with health care units and more paid tests commissioned by private patients
 - Thanks to international cooperation, the certificates are recognized in other countries
- Accredited health care units are perceived as facilities that guarantee high quality of medical services, which can translate into a larger number of patients (and better contracts with the National Health Fund).
 - Additional funding that accredited hospitals receive from the National Health Fund (NFZ) in addition to the standard lump sum.

POCT



GENERAL PROBLEMS

Tips for professionals and legislators

Problem 1

TRANSITION



Difficult to see. Always in motion is the future.

PCA

- The ISO 15189:2022 includes requirements for point-of-care testing (POCT) and replaces the ISO 22870 standard. And review of POCT is a part of ever accreditation process according to that ISO standard, BUT detailed accreditation regulations are delayed.
- ISO 15189: 2023 is relatively new, translated Polish version was published in September 2025.



Also, CMJ is in transition period, due to new
(2023/2024) regulations

- The accreditation process according to the old national accreditation standards (with no connections to POCT), are valid for units that applied for accreditation to CMJ by the end of last year and are visited by the end of this year,
- We were accredited last month according to the old regulations, but the auditors referred to the current legal acts, so we were actually accredited LIKE according to the new standards.

Problem 2 – merging standards

- The incorporation of ISO 22870 into laboratory standard 15189 is in my opinion, a mistake.
- In my country, the number of hospitals without their own laboratories is growing. Some of them are one-day short-stay hospitals without laboratories, but with POCT, other have outsourced labs. This raises problems with the application of POCT regulations in those units the ISO standard dedicated to laboratories.



mistake

Problem 3

LABORATORY OUTSOURCING

A WINNING BUSINESS STRATEGY



**ISO/PCA POCT accreditation and
outsourced lab**

ISO15189/PCA – actual (new) POCT accreditation points

6.3.1 Determining the requirements of the rooms in which POCT tests are performed and their monitoring. Documenting monitoring.

A.2 Establishing processes for monitoring the quality and accuracy of POCT

Agreements between the laboratory and all locations using POCT including agreements with POCT operators [full version - ISO 15189 p.6.7.2]

Responsibilities and Powers

A.3 Quality Assurance Program

Staff responsibility

A.4 Training program

Responsibility of staff for the management of training and assessment of the competence of personnel performing POCT

Training Program for POCT users

Outsourcing - cascade of problems

- The knowledge of hospitals` management how POCT system should work and cost (a lot) is weak
- The manufactures of POCT equipment and their representatives also are guilty mainly due to sharing info like – *our analyzers do not require any support from the lab*
- So finally, the cost of maintaining POCT system is not recognized by management and is not considering when decision about outsourcing of laboratory is undertaken.

Outsourcing of hospital/polyclinics laboratories

- The outsourced labs in hospitals have SERIOUS CONFLICT OF INTEREST in the term of POCT –
 1. To increase the attractiveness of the outsourcing, bidders do not reveal the costs of operating the POCT system, and later i.e. due to lack of sources, do not maintain hospital POCT
 2. Probably, in many cases the costs of maintaining a laboratory, including supervision over POCT, make keeping in-house laboratory more profitable than outsourcing
 3. POCT minimize income of outsourced lab, because of lower number of samples tested in lab,



Oursourced
lab

- The only way for accreditation is PCA

ISO
requirements

- Agreements between the laboratory and POCT operators

Is it optimal for us
(outsourced lab)?

- Are new regulations responsible for small number of ISO licensed outsourced hospital labs?

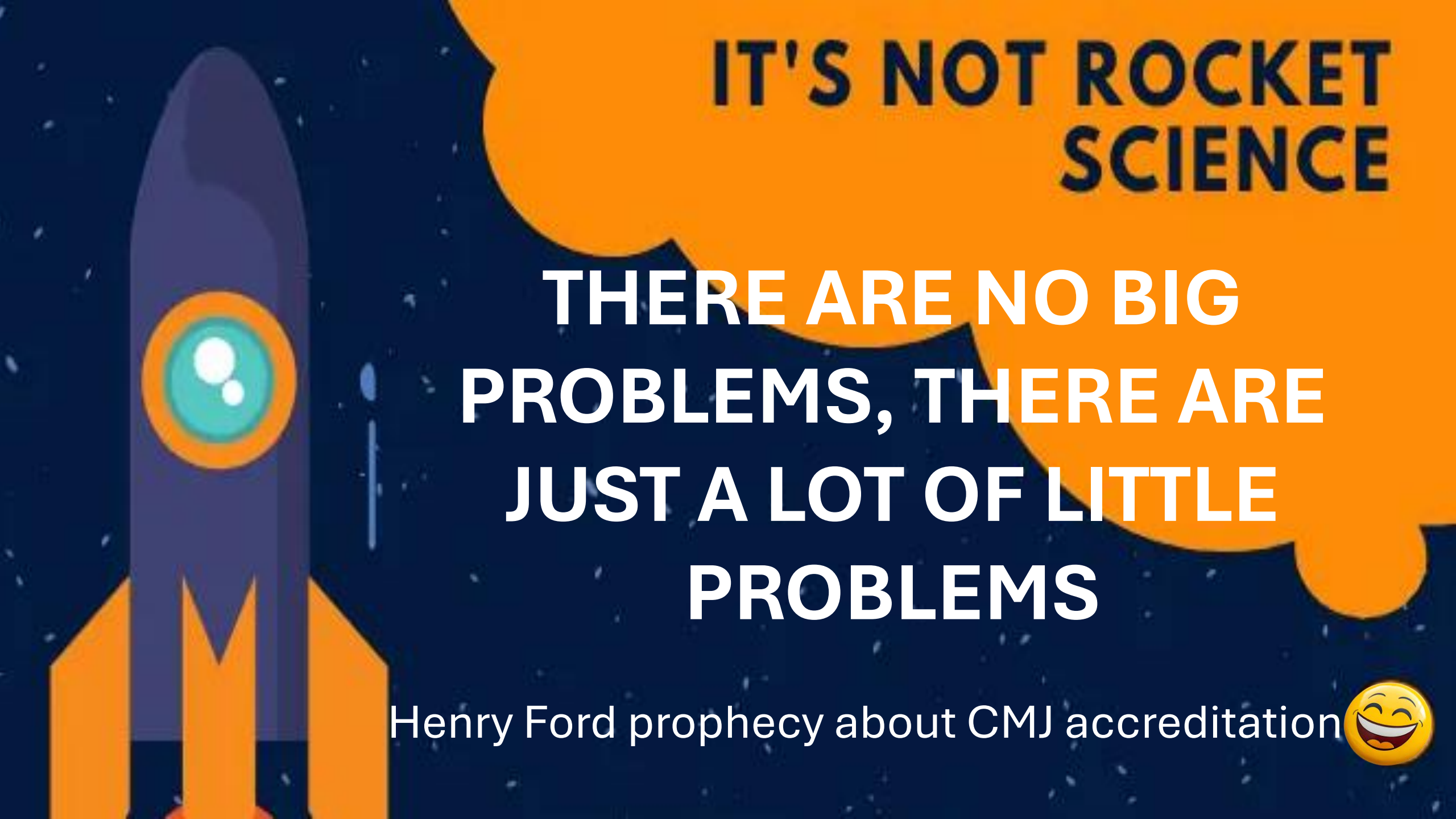
Problem 4 – limited verification of POCT

Accreditation by PCA is not complete for POCT – it reviews ONLY (?) LABORATORY part of POCT system.

Due to other location than laboratory, the certification process focuses on documents -lack of proper links to clinical staff and lack of clear for POCT support from the lab.

CMJ accreditation for complete health unit (hospital) also has similar problem – POCT verification points are in the laboratory section.

There are no POCT verification points in the clinical departments



**IT'S NOT ROCKET
SCIENCE**

**THERE ARE NO BIG
PROBLEMS, THERE ARE
JUST A LOT OF LITTLE
PROBLEMS**

Henry Ford prophecy about CMJ accreditation



Observations



- Auditors could also check compliance with other requirements listed in governmental acts and regulations of Minister of Health,
- These regulations are also new for them, and they aren't prepared to these new conditions and they haven't unified internal procedures and expectations, yet
- CMJ auditors are mainly doctors and nurses, their knowledge about laboratory is weak and POCT as well!, so it generates misunderstandings.



CMJ – POCT accreditation standards

The hospital has appointed a team for POCT.

The hospital specified the POCT tests performed, their methodology and equipment, consumables, reagents, calibrators and control materials.

In the hospital there are described and implemented the rules for performing POCT tests, confirmed by appropriate records which include:

- 1) the method of approval by the person performing the test;
- 2) daily confirmation of the correctness of the POCT diagnostic process;
- 3) the method of communicating the test results to the client;
- 4) keeping documentation and archiving it;
- 5) the method of recording the results of POCT tests in medical records;
- 6) Laboratory test results report form;
- 7) validation of test methods;

Continuation, and additional points of CMJ accreditation standards

- 8) documented quality control of POCT tests;
- 9) servicing equipment used for POCT tests;
- 10) a list of persons authorized to perform specific tests in the POCT mode;
- 11) training and control of the skills of personnel performing POCT tests,

Additional points

The hospital ensures the quality of POCT tests, comparable to those performed in the laboratory in accordance with the requirements of the standard.

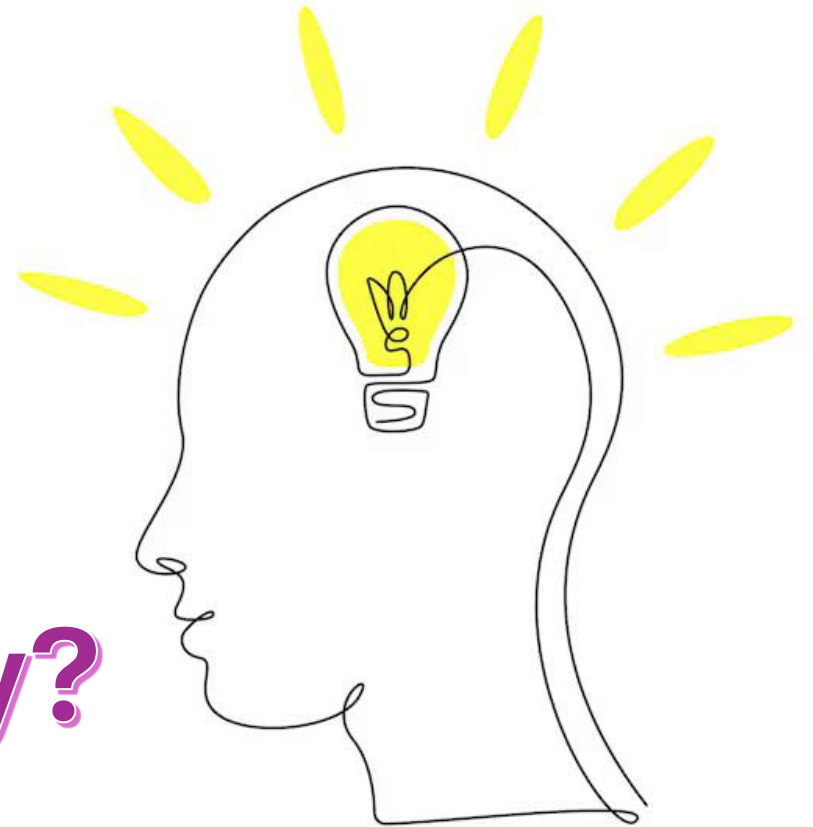
The **laboratory** conducts quality control of the tests performed, including in the POCT mode

Example of misunderstanding (I hope)

1) the method of approval by the person performing the test (CMJ accreditation standards)

Auditor during preaudit „all results from POCT testing should be autenticated by entitled **laboratory** staff”

Why?



POCT definitions in Poland

- **State act: POCT - laboratory tests** of critical parameters performed in biological material, enabling a quick therapeutic decision, performed by medical staff authorized to do so at the place of provision of health services.
- **CMJ accreditation standards:** POCT: diagnostic examination at or near the site of patient care
- **ISO 15189:** POCT: examination performed near or at the site of a **patient***

*person who is the source of material for an examination

More mess

- In regulation of MoH is stated:
- A **laboratory specialist** with a specialist title in a field applicable to laboratory medicine develops, implements and **uses procedures for issuing POCT results**.
- **The POCT report includes:** 1) the date of printout and performance of the test; 2) the type of examination; 3) data identifying the patient; 4) the place where the test is performed; 5) **data identifying the person collecting the biological material and performing the test**; 6) the results of the test in numerical or descriptive form.
- *There is nothing about authentication by laboratory staff*

Example of misunderstanding

- Auditor (preaudit) – *it is prohibited to use glucometers for selfcontrolling in hospital wards.*

Why?

- This type of glucometers is for selfcontrolling only

And

The hospital ensures the quality of POCT tests, comparable to those performed in the laboratory in accordance with the requirements of the standard (CMJ standards).



Glucometers intended users according to manufacturer's manual

The Accu-Chek Instant test strips with the Accu-Chek Instant meter are intended for in vitro **diagnostic self-testing by people with diabetes.**

The Accu-Chek Instant test strips with the Accu-Chek Instant meter are intended for **in vitro diagnostic use by healthcare professionals in clinical settings.** Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

This system is not for use in the diagnosis of diabetes mellitus, nor for testing neonate cord blood samples.

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Glucose meters vs lab testing - quality of results based on TAE (proficiency testing)



- CLIA 2025

LABORATORY

Id.	Nazwa metody	± %
13.	Glukoza	± 7%

Glucose (excluding FDA home use)	TV ± 6 mg/dL or ± 8% (greater)
----------------------------------	--------------------------------

- **Glucose meters** (ISO 15197:2013) - 95 % of the measured glucose values shall fall within either $\pm 0,83$ mmol/l (± 15 mg/dl) of the average measured values of the reference measurement procedure at glucose concentrations $< 5,55$ mmol/l (< 100 mg/dl) or within ± 15 % at glucose concentrations $\geq 5,55$ mmol/l (≥ 100 mg/dl)

Critical care analyzers – glucose testing

TAE %	analyzers with creatinine and urea/BUN				analyzers without creatinine and urea/BUN					
pO ₂ [mmHg]→						* microsample 45ul				
glucose [mmol/l]↓	>90	>25 <90	<25		>90		>25 <90		<25	
						*		*		*
2.0	11,8	11,8	11,8		9,9		10,2		10,1	10,9
6.0	7,9	8,4	8,4		9,3	11,1	11,2	11,1	13,2	11,8
10.0	10,5	10,5	12,7		6,2	10,6	9,6		13,2	
15.0	9,4	10,8	10,8						13,9	
25.0	11,3	6,4	9,9		11,6		12	10,2	20,9	15,6
40.0	9,6	12,3			15,1	14,7	15,8	13,7		

Fortunately auditor was wide minded

The laboratory conducts quality control of the tests performed, including in the POCT mode (milestone 14; CMJ)

the developed and implemented rules for the supervision of POCT studies include documented quality control of POCT (regulation MoH).

- We delegate QC of glucose meters in Endocrinology/diabetology to nurse from the ward.
- During accreditation auditor ask why QC of glucometers are performed by ward nurse. The answer was easy and accepted – that girl is nurse, specialist in diabetology, diabetic educator and member of our hospital POCT team.





Other disputable points

2) daily confirmation of the correctness of the POCT diagnostic process;

What does it mean „correctness of the process” – what should be checked and analyzed ?

7) validation of test methods

All methods are commercial, so they should be according to ISO standard veriflicated (simplified validation)



Accreditation standards for POCT in primary health care

(CMJ December 2024)

The unit specifies the rapid diagnostic tests required for dispensary groups, identified as important for the population in the care of the unit, the methodology and equipment, consumables, reagents, calibrators and control materials, if the methodology of determination requires it.

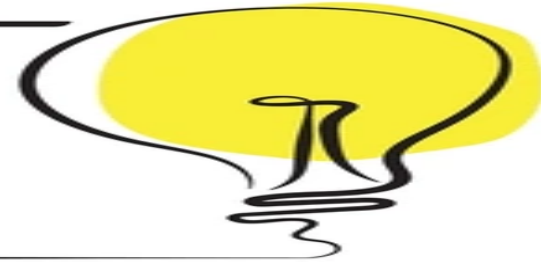
Score/ points

- 5 – The unit uses at least 4 types of rapid diagnostic tests in daily practice.
- 3 – The unit uses 2 or 3 types of rapid diagnostic tests in daily practice.
- 1 – Unit uses fewer or no types of rapid diagnostic tests or does not use such tests.



Competences – who has supervision, training ??????

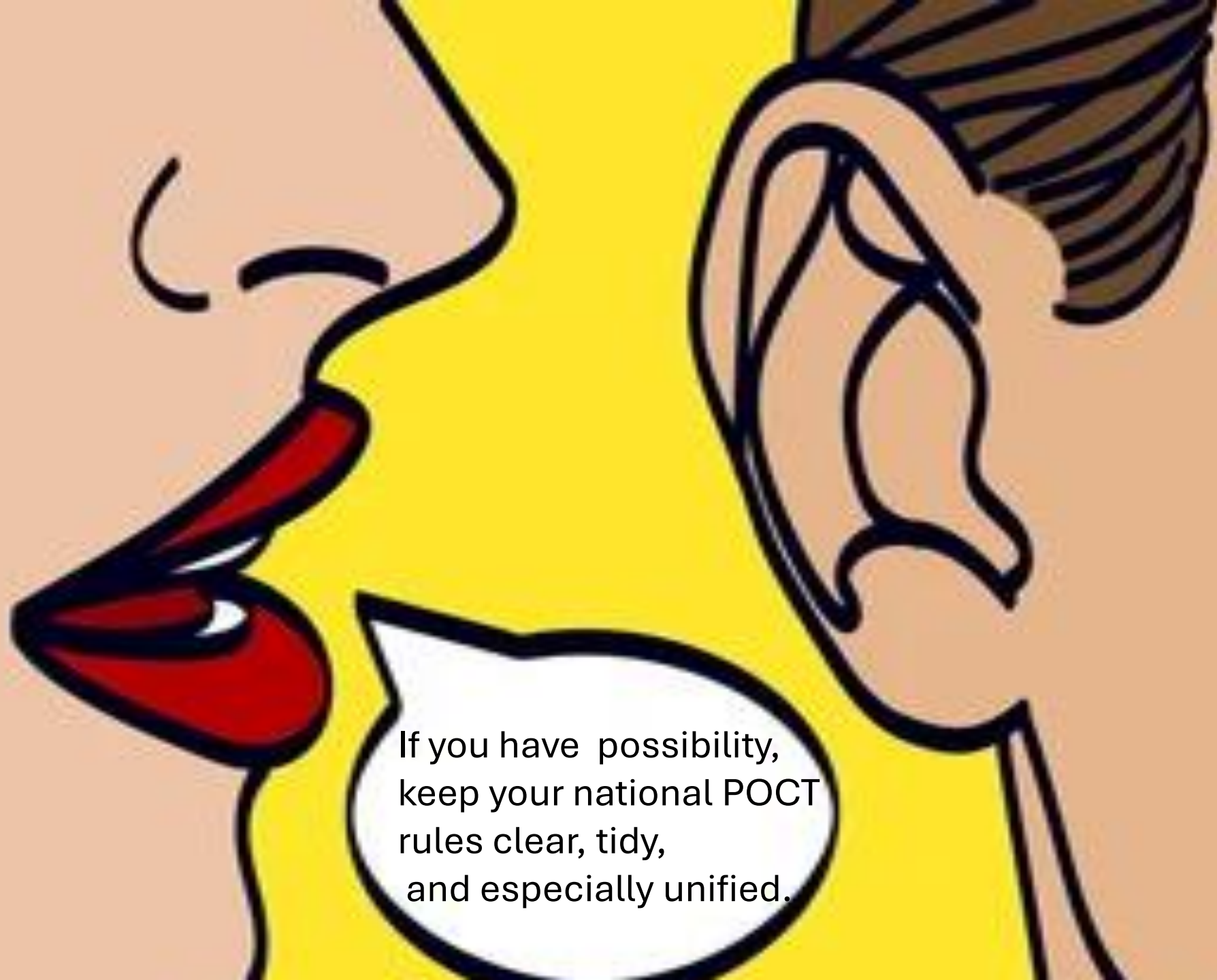
Conclusion



The old Chinese curse says: "May you live in interesting times". And we live in interesting times of transition in term of POCT – new regulation of ISO 15189:2022

In Poland POCT is mostly accredited using state law not ISO standard.

This state law is also new and lightly connected with EU regulations and ISO standards, so sometimes are misunderstandings.



If you have possibility,
keep your national POCT
rules clear, tidy,
and especially unified.

<https://ifcc.org/ifcc-education-division/emd-committees/c-poct/>

Guidelines being preparing

- **Validation/verification of POCT methods (almost ready)**
- **POCT in GP/family doctor`s office (I do hope with some advices about : education of operators, QC rules, support, supervision)**

POCT definition by IFCC

Committee on Point of Care Testing (C-POCT)

Point-of-care testing (POCT) is defined as diagnostic testing at or near the site of patient care performed by healthcare professionals.

Reference: ISO 15189:2022. Medical laboratories — requirements for quality and competence.

Geneva, Switzerland: ISO Copyright office; 2022.

- POCT is defined as **IV** diagnostic testing at or near the site of patient care, performed by healthcare professionals.