Responsibilities and obligations of EQA organizers in the event of laboratories or methods with poor performance.

Stéphanie Albarède, CTCB, France

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This presentation will be supported by examples of current practices across Europe, based on the results of the survey conducted this spring.

Dear members,

As part of the preparation for the symposium in Leuven, you are invited to complete a survey on the following topic: **"Responsibility and obligation of EQA providers in case of underperforming labs/methods."**

This survey will take no more than ten minutes to complete. Please use the link below: (**deadline = the 3rd of July, 2026**) :
https://www.surveymonkey.com/r/KSHKP2V

The results will be presented by Stéphanie Albarede as part of the scientific program during the symposium.
We would like to reassure you that your anonymity will be maintained in the presentation at the congress.
Your results will not be stored for longer than 3 years
.
If you have any questions, please contact Stéphanie Albarède at : s.albarede@ctcb.com

We thank you in advance for your collaboration and valuable contribution.

On behalf of:
Symposium 2026 Planning Committee

Participants' countries

A total of 32 PT providers, representing three continents and 20 countries, responded to this survey.

Countries	Number of participating provider	Countries	Number of participating provider
Australia	1	Hungary	1
Austria	1	Italy	3
Belgium	1	Netherlands	2
Brazil	2	Norway	1
Croatia	1	Portugal	1
Czech Republic	1	Romania	1
Denmark	1	Spain	1
France	3	Sweden	1
Finland	1	Switzerland	1
Germany	2	United Kingdom	6

81% of the participating PT providers are accredited, and one third of them have more than 90% of their PT schemes accredited.

% accreditation	n PTP
90-100	7
70-89	5
50-69	6
30-49	3
<30	1

Two organizations are not accredited, while four are in the process of obtaining accreditation.

Prerequisites before identifying a laboratory as a poor performer

What are we actually assessing?

Before identifying poor performance, the EQA provider must clarify the level of assessment :

- **Automated / analytical systems**
  - **ISO 15189:** appropriate EQA coverage + comparability between systems
  - **National regulations may go further** — e.g. France: EQA for each analytical system..
- **Manual or visually interpreted methods**
  - Can an individual operator be considered part of the analytical system?
  - Where does EQA end, and where does staff competency management begin — particularly the responsibility for assessing and maintaining the competence of all authorized staff?
  - Should poor performance by an individual operator be managed? should EQA assess the laboratory's overall performance, while individual competency remains the laboratory's responsibility?

How do EQA providers handle visually interpreted methods?

Should each operator performing visual interpretation be treated as a separate analytical system for EQA and and participate individually in EQA schemes?	
Yes	22
No	8

For analyses involving visual reading (subjective qualitative tests) do you allow to return data obtained by different persons of the same laboratory ?	
No	12
Yes but with only one global evaluation for the laboratory	5
Yes with as many evaluations as there are people who submitted a result	12

Prerequisites before identifying a laboratory as a poor performer

- **What is "poor performance" ?**
  - isolated poor result;
  - repeated / persistent poor performance;
  - poor performance of an individual laboratory;
  - poor performance of a peer group or a method;
  - systematic bias affecting many laboratories;
  - performance that is statistically poor but may still be clinically acceptable, and conversely.

  The EQA provider's obligations differ depending on whether the poor performance concerns an individual laboratory or a method-related issue.

- **Who defines the poor performance ?**
  - EQA provider
  - Authorities
  - Others

- **Which model of analytical performance specifications (APS)?**
  - Model 1 – Clinical outcomes
  - Model 2 – Biological variation
  - Model 3 – State of the art

Prerequisites before identifying a laboratory as a poor performer

- **Responsibilities of the EQA provider :** To check that there are no errors related to the EQA scheme;
  - Verify homogeneity, stability, the assigned value, and the performance evaluation criteria;
  - Check for any potential matrix effect;
  - Analyse peer-group performance;
  - Confirm that the poor performance is attributable to the laboratory or the method.



Before identifying a participant as a poor performer, the EQA provider must first ensure that the EQA result itself is valid, reliable and interpretable.

Where do responsibilities and obligations come from?

- **Professional consensus and educational mission**
  Support improvement, not punishment.
- **Ethical and professional responsibility**
  Protect patient safety and respond appropriately to poor performance.
  (☞IVD vigilance and post-market surveillance)
- **Normative framework**
  ISO/IEC 17043 and ISO 15189 expectations: confidentiality, impartiality, evaluation, reporting and follow-up.
- **Regulatory framework**
  National requirements, competent authorities, accreditation context and possible reporting obligations.
- **Advisory role towards regulatory and oversight authorities**
  Provide expertise to help authorities define relevant, proportionate and evidence-based criteria for managing poor laboratory performance.

Educational mission (responsibility)

There is a longstanding professional consensus that EQA should not merely identify poor performance, but should also contribute to education and continuous quality improvement, to share of best practices :

- **“EQA organisers must accept an educational role.” ,“to act as an educational stimulus to improvement ”** — *Hill P, Uldall A, Wilding P. Fundamentals for External Quality Assessment (EQA). Monograph. IFCC, July 1996*
- **“A typical feature of EQA programmes is to provide education to participants and promote quality improvement.”**— *EQALM, Articles of Association, Annex 1*
- **“The main purpose of an EQA programme is to improve performance and to provide assistance to address any problems detected. Education should therefore be inherent in all activities of an EQA programme.”**— World Health Organization, *Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion-Transmissible Infections*

Educational mission : From performance assessment to laboratory improvement

EQA organizers should not only detect poor performance, but also help laboratories understand, correct, and prevent errors.

EQA/PT providers can support laboratories through:

- **Educational comments in reports**
  Interpretation of results, possible causes of errors, and practical recommendations, guidance towards external ressources (references, and professional recommendations, relevant publications…)
- **Collective feedback sessions**
  Workshops or webinars to discuss common difficulties and good practices.
- **Targeted training** when several participants encounter the same difficulty: microscopy, interpretation, statistics, pre-analytical issues, etc.
- **Individual support for laboratories in difficulty**
  Direct contact in case of significant, repeated, or clinically relevant errors.

Educational mission : From performance assessment to laboratory improvement

EQA/PT providers can support laboratories through:

- **Root-cause analysis support**
  - Helping laboratories distinguish analytical, methodological, pre-/post-analytical, or interpretative issues.
  - Promotion of good practices, for example by anonymously sharing approaches that have led to good performance
- **Additional or repeat samples**
  - Allowing laboratories to verify corrective actions and consolidate learning.
  - Checking in a subsequent EQA round that the improvement is effective and sustained
- **Peer-group and trend analysis**
  Identifying method-related issues, recurrent bias, or progressive drift over time.
- **Educational cases**
  Educational cases or additional exercises, possibly without formal performance assessment, to reinforce learning or expose participants to rare and diagnostically challenging cases.

Educational mission : current practices

In the case of underperforming labs or methods, do you have general educational actions (= for all participants) ?	
No	1
Yes, the general report contains advice and comments to improve the performance but without Targeted and personalized messages	25
Yes, we organize free workshops / Webinars for all labs.	14
Yes we propose training for all labs	7
Yes, we organise Symposium	2
Yes, in a Newsletter	1

In the case of underperforming labs or methods, do you have individual educational actions (= only for labs concerned) ?	
No	7
Yes, the general report contains advice and comments to improve the performance with Targeted and personalized messages, without compromising anonymity.	11
Yes, we put a personal message on their individual report	5
Yes, we phone them to discuss their nonconformity and/or give advice	2
Yes, we write to them to discuss their nonconformity and/or give advice	7
Yes, we organize free workshops/webinars for underperforming labs	2
An auditor from the EQA organisation visits or the worst underperforming laboratories, and looks for solutions.	1
A root cause analysis is required for all cases of unsatisfactory performance	1

The 11 EQA providers who responded « Yes, the general report contains advice and comments to improve the performance with Targeted and personalized messages, without compromising anonymity. » are included in the 25 who responded « Yes, the general report contains advice and comments to improve the performance but without Targeted and personalized messages, »

⇨ **None of the EQA providers answered “No” to both questions.**

Educational mission : current practices

If stability allows, do you have a small stock of samples to allow laboratories to repeat the analysis?	
Yes	30
No	2

In case of many labs with poor performances, do you verify the impact of your educational actions by another survey with the same type of sample (example: the same bacterium) ?	
Yes	17
No	14

Ethical and professional responsibility

- **Protect patient safety**
  Do not ignore poor performance that may have a clinical impact.
- **Act proportionately to the risk and persistence of poor performance**
  Adapt the response to the severity, recurrence and potential clinical consequences.
- **Identify collective signals**
  Recognize when a problem affects several laboratories, a method, a reagent or a device rather than a single participant.
- **Escalate when patient safety may be at risk**
  Consider appropriate escalation when a serious risk persists, while respecting confidentiality and the applicable legal framework.

⇨ **The EQA provider is not directly responsible for patient care, but it has a professional responsibility not to remain passive when faced with a concerning signal.**

Ethical and professional responsibility

- Identify collective signals ⇨IVD vigilance ?

When no specific reporting obligation applies to the EQA provider, acting on a collective signal suggesting an IVD-related problem is primarily a matter of professional and ethical responsibility.

- In Europe, EQA providers' reporting of potential IVD-related issues currently relies largely on professional responsibility and judgement rather than on a harmonized regulatory or normative obligation, despite EN 14136:2004

The 17043 standard does not provide for a specific IVD vigilance mechanism or an obligation to report to the manufacturer collective poor performance associated with an IVD medical device.

Ethical and professional responsibility

EN 14136:2004 = Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedure

- **Current European standard**, originally developed under Directive 98/79/EC.
- **Not currently harmonised under IVDR (EU) 2017/746**; revision is planned in support of the IVDR (a target date of 27 May 2028)
- It recognises the potential role of **EQA data in post-market surveillance**, but does **not by itself create a general regulatory obligation** for all EQA providers to submit an IVD vigilance report.

Ethical and professional responsibility

- In Clause 7.2 of EN 14136:2004, it is stated that, in the event of an apparent malfunction of an IVD medical device, **the EQA provider shall first inform the manufacturer or its authorised representative**. The associated note states that **the EQA provider may also inform the competent authorities**.
- There is a very important distinction between these two statements: **"shall inform"** the manufacturer constitutes a normative requirement, whereas **"may also inform"** the competent authorities indicates an option rather than a requirement under EN 14136. The decision to inform the competent authorities therefore falls, in the absence of an applicable regulatory reporting obligation, within the EQA provider's **ethical and professional responsibility and judgement**.

Evidence suggesting a device-related safety or performance issue : current practices

- EQA provider **shall inform the manufacturer**

In the case of underperforming methods and in absence of problems of commutability, do you carry out specific actions concerning the manufacturer ?	
No	4
You only inform the IVD manufacturer	2
You inform the IVD manufacturer and can provide them some samples to conduct investigations but don't report conclusions to the participants labs	12
You inform the IVD manufacturer, give them some items to make investigations and send their conclusion to the participant labs after verifying the accuracy of this conclusion.	13

- **Competent authority may** also be informed

In the case of underperforming methods and in absence of problems of commutability, do you make an IVD vigilance notification ?	
No, you consider it's not your responsibility	10
No, because your regulatory system only allows declarations from users or manufacturers of in vitro diagnostic devices.	9
Yes, you submit an IVD vigilance report. to the competent authority concerned, but you never receive their conclusion	6
Yes, you submit an IVD vigilance report to the competent authority concerned, and you receive their conclusion	7

IVD vigilance professional responsibility to regulation : example in France

In France, detection of poor performance in EQA does not in itself trigger mandatory vigilance reporting,

However

Under French law, healthcare professionals are required to report serious incidents or risks of serious incidents involving IVD medical devices without delay. Therefore, where individuals who become aware of such an incident within an EQA provider qualify as healthcare professionals under the French Public Health Code, a mandatory reporting obligation may apply.



the same EQA signal may lead to different reporting obligations depending on the national regulatory framework and the legal status of the person or organisation identifying it.

Ethical and professional responsibility

ISO 15189 → "What my participants need from my EQA scheme"

ISO 15189 **does not define the responsibilities** of the EQA provider, but it defines what laboratories are expected to do (Investigate the causes; take appropriate actions…) when poor EQA performance is identified. This should be considered by EQA organizers when deciding how poor performance is reported and followed up.

7.3.7.3 External quality assessment (EQA) :*h) Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken (see 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.*

⇨**Professional/ethical responsibility** of the EQA provider: provide the laboratory with the information and support necessary to enable it to fulfil these obligations and improve its performance.

Normative framework : General normative duties of EQA providers

ISO/IEC 17043 → "What I am required to do as an EQA provider" :

- **Confidentiality**
  Protect participant identity and individual results.

- **Impartiality**
  Ensure fair, unbiased and independent evaluation of performance.

- **Appropriate performance evaluation**
  Use predefined, relevant and transparent criteria for assigned values, statistics and interpretation.

- **Clear reporting and follow-up**
  Provide results and comments that help participants understand poor performance and take action where needed.

*Note: This **educational role** is also explicitly supported by several clauses of ISO/IEC 17043 §7.4.2.2 et Annex A.*

Normative requirements when poor performance is identified

ISO/IEC 17043 → "What I am required to do as an EQA provider" :

- **Verify the validity of the EQA result** *(§7.3 – Homogeneity and stability ; §7.4 – Statistical design ; §7.5 – Assigned values ; §7.7 – Evaluation of performance)*
  Exclude any issue related to the EQA scheme itself before concluding that performance is poor.
- **Ensure impartial evaluation** *(§4.1 – Impartiality)*
  Assigned values and performance criteria should be based on objective, predefined and scientifically justified principles, without favouring for example an expert's own method or considering it as the reference by default.
- **Apply evaluation criteria consistently** *(7.2.2 - Statistical design; 7.4.1 - Data analysis; 7.4.2 - Evaluation of performance)*
  Use the same predefined judgement rules for all participants and comparable situations.
- **Provide clear and useful feedback** *(7.4.3 - PT reports)*
  Give participants sufficient information to understand the result and identify possible causes.
- **Allow complaints and appeals** *(§7.6– Handling of complaints ; 7.7 – Handling of appeals)*
  Maintain a documented process for participants to question or challenge an evaluation. To safeguard impartiality, appeals shall be reviewed by a person who was not involved in the original evaluation. ***(7.7.6** The decision on the appeal shall be made by, or reviewed and approved by, persons not involved in the decision that is the subject of the appeal in question.)*
- **Maintain confidentiality** *(§4.2 – Confidentiality)*
  Poor performance must not compromise participant anonymity except where disclosure is legally required or explicitly agreed.
- **Support appropriate** *(7.4.3 - PT reports)*
  Ensure that EQA reports provide participants with relevant information to understand and follow up on poor performance

Accreditation Body Guidance on Poor Performance: Survey Result

Has your accreditation body conducted a formal normative and regulatory compliance review and issued guidance or opinions on the actions that EQA organizers should implement regarding underperforming laboratories?	
yes	2
No	20
I don't know	9

We are being audited in this regard, but more indirectly—through compliance with the requirements of the guidelines of the German Medical Association: If the reference institution determines that participants frequently fail to receive a certificate following a measurement or examination using reagents or devices from certain manufacturers, and if causes for this have been ruled out in these laboratories and at the
The accrediting body evaluates the statistical data generated by the EQA and give suggestions. We have more:17.034, 9.001, 17.043 GML

Where the Standard Ends and Regulation Begins

📄 ✓ **ISO/IEC 17043** → ⚖️ **Regulatory / legal requirements**

ISO/IEC 17043 primarily provides a framework for **how EQA providers evaluate and communicate poor performance**; it does not automatically give EQA providers an **enforcement role with regard to laboratories**.

Regulatory framework
current situation : survey results

In the case of underperforming labs, what are the regulatory obligations for EQA provider? (except IVD vigilance)	
No regulatory obligations	11
An auditor from Sciensano visits the laboratory and proposed solutions. Only in case of continuous underperformance over a long term, Sciensano can propose to the ministry of public health to suspend the license of the laboratory.	1
We inform the Croatian Chamber of Medical Biochemists and they schedule the professional audit of the laboratory.	1
Guideline of the German Medical Association	1
UK has an EQA Oversight programme for PPP which has currently paused, however this is not a regulatory obligation. It consists of RCPath QAPC Oversight group that has representation from the regulators and accreditation bodies. Initial response for persistent poor performance is for EQA to report to the specialty specific panel (NQAAP) who makes contact with the laboratory. If no resolution then	1
participant shall repeat participation in the next available EQA round of the same programme	1
underperforming identified in participating laboratories located in the Lombardy Region are reported to the Lombardy Regional Health Authority (competent supervisory authority)	1
The Swiss regulatory body (QUALAB) could ask the laboratory to show what has been done to address the insufficient result.	1
According to the regulations: As part of its operating license, the laboratory is required to participate in EQA four times a year with at least	1
We are required to notify the Regional Health Agency, which will conduct an inspection and determine the appropriate sanctions	3 (1 country)

⇨ The survey results reveal a **lack of harmonization in regulatory provisions**, with **60% of respondents reporting no specific regulatory requirements** for managing poor laboratory performance.

Regulatory framework current situation : survey results

What is the impact for underperforming labs ?	
Closure	0
The laboratories might be closed, but not only based on EQA results.	1
Fine	3
Suspension of analysis reimbursement	4
This varies depending on the regulations of the relevant Association of Statutory Health Insurance Physicians.	1
The laboratory is notified by the health authority.	1
Persistent or unresolved poor performance can lead to: Non-conformities during accreditation assessments. Additional scrutiny by accreditation bodies. Enhanced surveillance visits. Restrictions to scope of accreditation. In severe cases, suspension of accreditation	1
Professional audit/supervision which is followed by the report from the Croatian Chamber of Medical Biochemists. If failures not corrected or continuous underperforming, the Chamber informs the Ministry of Health.	1
In the UK, depending on the sector (healthcare, commercial testing, or research), penalties range from mandatory corrective action plans and budget cuts to the complete suspension of accreditations, halting their ability to legally operate.	1
up to UKAS currently upon routine inspection, hoping to set up an NQAAP replacement with teeth	1
Possible loss of accreditation	1
none actually but in the future: Declaration to the regional health agency	1
written Rebuke	1
Notification	1

Are these measures by a laboratory inspection?	
Yes	12
No	11

Only one EQA provider reported that such actions are taken after the first failure; in all other cases, action is triggered by repeated poor performance.

Regulatory framework : Analytical Performance specifications (APS)

If there is regulatory obligations in case of underperforming labs, who defined the performance specifications to determine the poor performance ?	
EQA organizer	12
federation of French EQA non-profit organizers	1
EQA organizer, in collaboration with experts in the field.	2
Government	4
Guideline of the German Medical Association	1
Performance specifications can be defined by regional regulatory bodies or relevant professional bodies as appropriate.	1
health insurance companies	1
National Accreditation Body	1

Are these performance specifications based on clinical impact ?	
Yes	12
No	9
Not sure	2

Only **52% of responses** reported the use of APS based on **clinical outcomes**. Comments accompanying these responses indicated that **different APS models may be used in combination** (including biological variation and/or state of the art), and that the choice of APS may **depend on the measurand or examination concerned**.

Regulatory framework : Should regulatory action consider clinical impact?

ISO 15189:2022§ / 7.3.7.3 — External quality assessment

h) Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken (see 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.

i) Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment shall be considered and users advised as appropriate.

ISO 15189 does require an assessment of the clinical impact of poor EQA performance, but this requirement applies to the participating laboratory, not to the EQA provider.

⇨ Should poor EQA performance lead to regulatory sanctions in the absence of demonstrated clinical impact, even when such sanctions are triggered only by repeated poor performance?

Advisory role towards regulatory and oversight authorities

- Regulatory action should be proportionate to the demonstrated or potential clinical risk, not based solely on an EQA result.

- EQA organizers should provide expertise to help authorities define relevant, proportionate and evidence-based criteria for managing poor laboratory performance. Their expertise can help distinguish isolated failures from persistent poor performance, assess potential clinical risk, and identify laboratory-specific versus method-, reagent- or device-related issues.

Key issues

1. Before calling someone a poor performer, know what you are assessing.
2. Before blaming the participant, validate the EQA result.
3. The EQA provider’s primary role is improvement, not punishment.
4. ISO/IEC 17043 defines provider responsibilities, but not an enforcement role.
5. Escalation should be proportionate to persistence and potential clinical risk.

Key issues and unresolved questions

- Where should the EQA provider's responsibility end and that of accreditation or regulatory authorities begin?
- Should EQA providers have a harmonised definitions of poor performance and persistent poor performance ?
- Should there be a common escalation pathway across European EQA organisations ? What should trigger escalation: the number of failures, persistent poor performance, clinical risk — or a combination of these factors?
- Should clinical impact be considered when defining on regulatory action ? Should regulatory sanctions be considered in the absence of demonstrated clinical impact ?
- When poor performance concerns a method rather than a laboratory, who should the EQA provider inform: participants, manufacturers, accreditation bodies or regulators ?
- should EQA assess the laboratory's overall performance, while individual competency remains the laboratory's responsibility?

Conclusion

EQA providers clearly have responsibilities and obligations when laboratories or methods show poor performance.

However, poor performance is not managed consistently across countries or even across EQA providers.

In this context of limited harmonization, EQALM recommendations could help promote a more consistent, proportionate and evidence-based approach.

