



Joint FAO/IAEA Programme
Nuclear Techniques in Food and Agriculture



World Health
Organization

Global Survey of Laboratory Quality Standards and External Quality Assessment Schemes (EQAS)

Laboratories are an integral part of the health system. Several types of laboratories are involved in health care or in the detection or confirmation of public health events: human health (microbiology, biochemistry, haematology, toxicology, blood bank etc.), food safety, environmental health (water, air, soil, etc.) and animal health laboratories. It is essential that these laboratories are engaged in quality assurance programmes and participate successfully in inter-laboratory comparison programmes (i.e. External Quality Assessment Schemes (EQAS) also known as Proficiency Testing Schemes).

To build better knowledge of how to help Member States, the World Health Organization (WHO), in collaboration with the World Organization for Animal Health (OIE), the Food and Agriculture Organization (FAO) and the International Atomic Energy Agency (IAEA), is going to carry out an inventory of the written laboratory quality standards or guidelines in use in Member States and the national and international laboratory EQAS available worldwide. The global database will allow WHO, OIE, FAO and IAEA to better identify the resources and/or needs for developing laboratory quality standards and EQAS, and guide the organizations in providing support to Member States where significant gaps are identified.

In order to achieve these goals, WHO, OIE, FAO and IAEA invite relevant government officials and professionals to fill in the questionnaire below.

This questionnaire is targeted towards representatives of the following institutions: ministries of health, agriculture, environment, commerce and any other relevant ministries, national public health laboratories, national reference laboratories, national animal health laboratories, national standardization agencies, national accreditation bodies, non governmental organizations, or any other relevant organizations or institutions involved in quality systems (professional organizations, scientific or professional societies, etc.), and organizers/providers of EQAS and Proficiency Testing Schemes.

We thank you in advance for responding to this questionnaire within the scope of your expertise or for forwarding it to the relevant person in your professional circle. If you have queries, or require clarification regarding the information requested, please do not hesitate to contact us.

We thank you for filling it out and for returning it by fax, e-mail, or post to:

Global Survey
WHO Lyon Office
58, avenue Debourg
69007 Lyon, France
Fax. +33472716471
E-mail labsurvey@who.int

Laboratory quality standards and External Quality Assessment Schemes (EQAS)

In this questionnaire, the term “standards” refers to any **written document** available nationwide for laboratories as a reference to conduct tests: national laboratory quality policies, regulations or requirements (e.g., the Guide de Bonne Exécution des Analyses de Biologie Médicale (GBEA) in France, Clinical Pathology Accreditation (CPA) in United Kingdom or the Clinical Laboratory Improvement Amendments (CLIA) in United States for the medical testing laboratories), national laboratory quality guidelines, national quality manuals, national Standard Operating Procedures, or international norms and standards (e.g., ISO 15189, ISO 17025, WHO polio, OIE Quality Standard and Guidelines for Veterinary Laboratories). If such standards exist and are being followed, it infers that your country is already meeting some of the core capacities for accurate and reliable laboratory testing.

In this questionnaire, EQAS is used in the sense of **proficiency testing**, i.e. a systematic assessment made by an external organization administering surveys to participating laboratories, and these laboratories then being evaluated according to their responses to the surveys. If you provide several EQAS with different objectives, contents or participating laboratories, please don't hesitate to fill out other questionnaire(s).

You may choose between five questionnaires according to the type of samples the EQA or laboratory is processing:

- Human samples (page 5)
- Food samples (page 11)
- Environmental samples (page 16)
- Terrestrial animal samples (page 21)
- Aquatic animal samples (page 26)

If you are processing different type of samples, please don't hesitate to fill out other corresponding questionnaire(s).

Please provide information as accurately as possible. Any additional information is welcome. All information will be treated confidentially and an authorization to publicly use your answers is asked at the end of the questionnaire.

Questionnaire respondent:

Date (dd/mm/yyyy):

Identification

Last name of the respondent

Given (first) name of the respondent

Institution

Position in the institution

Address

Postal address

City

Postal code

Country

Contact details

Telephone (country code + number)

Cell (country code + number)

Fax

E-mail

Web site

Questionnaire for laboratories/EQA provider processing human samples

Laboratory quality standards

1. Are there any regulations authorising laboratory practice (licensing)

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

2. Is there any legislation in your country governing laboratory quality standards?

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

3. What quality standards are in use in your country?

National standards/requirements/guidelines

Please specify the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...):

Mandatory Voluntary I don't know

International standards

Please specify the name, date and the author of the standards:

Mandatory Voluntary I don't know

Other standards

Please specify the name, date and the author of the standards:

Mandatory Voluntary I don't know

No specified standards

I don't know

Do you have different quality standards for different categories of pathogens or laboratories?

Yes

No

I don't know

If yes, please indicate the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...) and categories of pathogens or laboratories implicated

Can you provide any URL of any published documents?

4. Is there any agency or service for supervising the application of the standards (e.g., inspection, certification, or accreditation)?

Yes

Please specify the name and function of the agency or service:

No

I don't know

5. Additional information and comment(s):

External Quality Assessment Schemes (EQAS)

The following questions are intended for the provider or organizer of EQAS:

6. Please indicate the area of specialization of the scheme:

- Microbiology** (*includes bacteriology, parasitology, mycology, mycobacteriology, and virology*)

Please specify the pathogens, diseases or syndromes, and the methods used (e.g., tuberculosis microscopy, malaria microscopy, HIV serology, antibiotic susceptibility testing, virus molecular detection...):

- Clinical Chemistry** (*includes endocrinology and urine analysis*)

Please specify

- Clinical Toxicology** *Please specify*

- Haematology** (*includes coagulation*) *Please specify*

- Immunology** *Please specify*

- Transfusion medicine** *Please specify*

- Histopathology** *Please specify*

- Radionuclides measurements**

Please specify (alpha, beta, gamma radiation, whole-body counters and lung monitors)

- Biodosimetry laboratories**

Please specify (cytogenetic, Electron Paramagnetic Resonance, molecular assays)

- Other** *Please specify*

7. Objectives of the EQAS:

- Comparability of laboratory results
- Improvement of accuracy of measurement
- Continuing education
- Provide information for official licensing/working authorization
- Provide information for reimbursement by health insurance
- Provide information for accreditation scheme
- Provide information on quality of animal or food product export testing
- Post-marketing medical diagnostic devices vigilance
- Other (*please specify*):

8. Participating laboratories:

- | <i>Status:</i> | <i>Total number of participating laboratories</i> |
|---|---|
| <input type="checkbox"/> Public | <input type="checkbox"/> 0-10 |
| <input type="checkbox"/> Private | <input type="checkbox"/> 10-100 |
| <input type="checkbox"/> Public and private | <input type="checkbox"/> 100-500 |
| | <input type="checkbox"/> 500-1000 |
| | <input type="checkbox"/> > 1000 |

9. What is the geographical scope of your scheme?

- National
- Sub-national (*please specify the provinces or regions*):
- International (*please specify the participating countries*):

10. Is the participation in the EQAS

- Mandatory
- Voluntary
- Other situation (for example: mandatory for some laboratories and voluntary for other labs)
Please specify:

11. Challenge/survey frequency of EQAS:

- Less than one per year
- One per year
- 2-4 per year
- More than 5 per year
- Other *Please specify:*

12. Fees for the participating laboratories:

Yes

No

If no, who covers the cost?

13. Communication between the EQAS organizer/provider and the participating laboratories:

Reporting mechanism from the participating laboratories to the EQAS organizer/provider:

By post By fax By email Via a web site

Other (*please specify*):

Feedback mechanism from the EQAS organizer/provider to the participating laboratories:

By post By fax By email Via a web site

Other (*please specify*):

14. EQAS organizer / provider accreditation, certification, participation to international EQA?

Is your EQAS accredited? Yes No

Is your EQA scheme certified? Yes No

If yes, specified the standard (e.g. ISO 43, ISO 9001...)

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Do you participate yourself to an international EQAS?

Yes No

If yes, please indicate the name and organizer

--

15. In what year was the EQAS established?

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16. Additional comment(s):

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17. May WHO/IAEA/FAO/OIE have your permission to publicly share your answers?

Yes No

18. May we contact you if more information is needed?

Yes No

Thank you very much for your participation in the survey!

Questionnaire for laboratories/EQA provider processing food samples

Laboratory quality standards

1. Are there any regulations authorising laboratory practise (licensing)

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

2. Is there any legislation in your country governing laboratory quality standards?

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

3. What quality standards are in use in your country?

National standards/requirements/guidelines

Please specify the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...):

Mandatory

Voluntary

I don't know

International standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

Other standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

No specified standards

I don't know

Do you have different quality standards for different categories of pathogens or laboratories?

Yes

No

I don't know

If yes, please indicate the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...) and categories of pathogens or laboratories implicated

Can you provide any URL of any published documents?

4. Is there any agency or service for supervising the application of the standards (e.g., inspection, certification, or accreditation)?

Yes

Please specify the name and function of the agency or service:

No

I don't know

5. Additional information and comment(s):

External Quality Assessment Schemes (EQAS)

The following questions are intended for the provider or organizer of EQAS:

6. Please indicate the area of specialization of the scheme::

Microbiology (includes bacteriology, parasitology, mycology, and virology)

Please specify the the pathogens or the diseases, and the methods used:

Chemistry (includes veterinary drugs, pesticides and other agrochemicals, heavy metal/trace elements, natural toxins, and industrial chemical and their byproducts)

Please specify

Radionuclides measurements Please specify (alpha, beta, gamma)

Other Please specify

7. Objectives of the EQAS:

Comparability of laboratory results

Improvement of accuracy of measurement

Continuing education

Provide information for official licensing/working authorization

Provide information for reimbursement by health insurance

Provide information for accreditation scheme

Provide information on quality of animal or food product export testing

Post-marketing medical diagnostic devices vigilance

Other (please specify):

8. Participating laboratories:

Status:

- Public
 Private
 Public and private

Total number of participating laboratories

- 0-10
 10-100
 100-500
 500-1000
 > 1000

9. What is the geographical scope of your scheme?

National

Sub-national (please specify the provinces or regions):

International (please specify the participating countries):

10. Is the participation in the EQAS

- Mandatory
 Voluntary
 Other situation (for example: mandatory for some laboratories and voluntary for other labs)

Please specify:

11. Challenge/survey frequency of EQAS:

- Less than one per year
 One per year
 2-4 per year
 More than 5 per year
 Other *Please specify:*

12. Fees for the participating laboratories:

- Yes
 No

If no, who covers the cost?

13. Communication between the EQAS organizer/provider and the participating laboratories:

Reporting mechanism from the participating laboratories to the EQAS organizer/provider:

- By post By fax By email Via a web site
 Other (*please specify*):

Feedback mechanism from the EQAS organizer/provider to the participating laboratories:

- By post By fax By email Via a web site
 Other (*please specify*):

14. EQAS organizer / provider accreditation, certification, participation to international EQA?

Is your EQAS accredited? Yes No

Is your EQA scheme certified? Yes No

If yes, specified the standard (e.g. ISO 43, ISO 9001...)

Do you participate yourself to an international EQAS?

Yes No

If yes, please indicate the name and organizer

15. In what year was the EQAS established?

16. Additional comment(s):

17. May WHO/IAEA/FAO/OIE have your permission to publicly share your answers?

Yes No

18. May we contact you if more information is needed?

Yes No

Thank you very much for your participation in the survey!

Questionnaire for laboratories/EQA provider processing environmental samples (water, air, soil ...)

Laboratory quality standards

1. Are there any regulations authorising laboratory practise (licensing)

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

2. Is there any legislation in your country governing laboratory quality standards?

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

3. What quality standards are in use in your country?

National standards/requirements/guidelines

Please specify the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...):

Mandatory

Voluntary

I don't know

International standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

Other standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

No specified standards

I don't know

Do you have different quality standards for different categories of events or laboratories?

Yes

No

I don't know

If yes, please indicate the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...) and categories of events or laboratories implicated

Can you provide any URL of any published documents?

4. Is there any agency or service for supervising the application of the standards (e.g., inspection, certification, or accreditation)?

Yes

Please specify the name and function of the agency or service:

No

I don't know

5. Additional information and comment(s):

External Quality Assessment Schemes (EQAS)

The following questions are intended for the provider or organizer of EQAS:

6. Please indicate the area of specialization of the scheme:

- Microbiology** (includes bacteriology, parasitology, mycology, mycobacteriology, and virology)

Please specify the pathogens or the diseases, and the methods used:

- Chemistry** (includes veterinary drugs, pesticides and other agrochemicals, heavy metal/trace elements, natural toxins, and industrial chemical and their byproducts)

Please specify

- Radionuclides measurements** Please specify (alpha, beta, gamma)

- Other** Please specify

7. Objectives of the EQAS:

- Comparability of laboratory results
- Improvement of accuracy of measurement
- Continuing education
- Provide information for official licensing/working authorization
- Provide information for reimbursement by health insurance
- Provide information for accreditation scheme
- Provide information on quality of animal or food product export testing
- Post-marketing medical diagnostic devices vigilance
- Other (please specify):

8. Participating laboratories:

Status:

- Public
- Private
- Public and private

Total number of participating laboratories

- 0-10
- 10-100
- 100-500
- 500-1000
- > 1000

9. What is the geographical scope of your scheme?

- National

- Sub-national (*please specify the provinces or regions*):
 International (*please specify the participating countries*):

10. Is the participation in the EQAS

- Mandatory
 Voluntary
 Other situation (for example: mandatory for some laboratories and voluntary for other labs)

Please specify:

11. Challenge/survey frequency of EQAS:

- Less than one per year
 One per year
 2-4 per year
 More than 5 per year
 Other *Please specify:*

12. Fees for the participating laboratories:

- Yes
 No

If no, who covers the cost?

13. Communication between the EQAS organizer/provider and the participating laboratories:

Reporting mechanism from the participating laboratories to the EQAS organizer/provider:

- By post By fax By email Via a web site
 Other (*please specify*):

Feedback mechanism from the EQAS organizer/provider to the participating laboratories:

- By post By fax By email Via a web site
 Other (*please specify*):

14. EQAS organizer / provider accreditation, certification, participation to international EQA?

Is your EQAS accredited? Yes No

Is your EQA scheme certified? Yes No

If yes, specified the standard (e.g. ISO 43, ISO 9001...)

Do you participate yourself to an international EQAS?

Yes No

If yes, please indicate the name and organizer

15. In what year was the EQAS established?

16. Additional comment(s):

17. May WHO/IAEA/FAO/OIE have your permission to publicly share your answers?

Yes No

18. May we contact you if more information is needed?

Yes No

Thank you very much for your participation in the survey!

Questionnaire for laboratories/EQA provider processing **terrestrial animal samples**

Laboratory quality standards

1. Are there any regulations authorising laboratory practise (licensing)

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

2. Is there any legislation in your country governing laboratory quality standards?

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

3. What quality standards are in use in your country?

National standards/requirements/guidelines

Please specify the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...):

Mandatory

Voluntary

I don't know

International standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

Other standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

No specified standards

I don't know

Do you have different quality standards for different categories of pathogens/events or laboratories?

Yes

No

I don't know

If yes, please indicate the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...) and categories of pathogens/events or laboratories implicated

Can you provide any URL of any published documents?

4. Is there any agency or service for supervising the application of the standards (e.g., inspection, certification, or accreditation)?

Yes

Please specify the name and function of the agency or service:

No

I don't know

5. Additional information and comment(s):

External Quality Assessment Schemes (EQAS)

The following questions are intended for the provider or organizer of EQAS:

6. Please indicate the area of specialization of the scheme:

Microbiology (includes bacteriology, parasitology, mycology, and virology)

Please specify the pathogens or the diseases, and the methods used:

Other *Please specify*

7. Objectives of the EQAS:

- Comparability of laboratory results
- Improvement of accuracy of measurement
- Continuing education
- Provide information for official licensing/working authorization
- Provide information for reimbursement by health insurance
- Provide information for accreditation scheme
- Provide information on quality of animal or food product export testing
- Post-marketing medical diagnostic devices vigilance
- Other (*please specify*):

8. Participating laboratories:

Status:

- Public
- Private
- Public and private

Total number of participating laboratories

- 0-10
- 10-100
- 100-500
- 500-1000
- > 1000

9. What is the geographical scope of your scheme?

- National
- Sub-national (*please specify the provinces or regions*):
- International (*please specify the participating countries*):

10. Is the participation in the EQAS

- Mandatory
- Voluntary
- Other situation (for example: mandatory for some laboratories and voluntary for other labs)

Please specify:

11. Challenge/survey frequency of EQAS:

- Less than one per year
- One per year
- 2-4 per year
- More than 5 per year

16. Additional comment(s):

17. May WHO/IAEA/FAO/OIE have your permission to publicly share your answers?

Yes No

18. May we contact you if more information is needed?

Yes No

Thank you very much for your participation in the survey!

Questionnaire for laboratories/EQA provider processing aquatic animal samples:

Laboratory quality standards

1. Are there any regulations authorising laboratory practise (licensing)

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

2. Is there any legislation in your country governing laboratory quality standards?

Yes

Please specify the date of the legislation, the authority of legislation:

No

I don't know

3. What quality standards are in use in your country?

National standards/requirements/guidelines

Please specify the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...):

Mandatory

Voluntary

I don't know

International standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

Other standards

Please specify the name, date and the author of the standards:

Mandatory

Voluntary

I don't know

No specified standards

I don't know

Do you have different quality standards for different categories of pathogens/events or laboratories?

Yes

No

I don't know

If yes, please indicate the name, date and the author of the standards (e.g., normalization agency, Ministry of Health, professional society...) and categories of pathogens/events or laboratories implicated

Can you provide any URL of any published documents?

4. Is there any agency or service for supervising the application of the standards (e.g., inspection, certification, or accreditation)?

Yes

Please specify the name and function of the agency or service:

No

I don't know

5. Additional information and comment(s):

External Quality Assessment Schemes (EQAS)

The following questions are intended for the provider or organizer of EQAS:

6. Please indicate the area of specialization of the scheme:

Microbiology *(includes bacteriology, parasitology, mycology, and virology)*

Please specify the pathogens or the diseases, and the methods used:

Other *Please specify*

7. Objectives of the EQAS:

- Comparability of laboratory results
- Improvement of accuracy of measurement
- Continuing education
- Provide information for official licensing/working authorization
- Provide information for reimbursement by health insurance
- Provide information for accreditation scheme
- Provide information on quality of animal or food product export testing
- Post-marketing medical diagnostic devices vigilance
- Other (*please specify*):

8. Participating laboratories:

Status:

- Public
- Private
- Public and private

Total number of participating laboratories

- 0-10
- 10-100
- 100-500
- 500-1000
- > 1000

9. What is the geographical scope of your scheme?

- National
- Sub-national (*please specify the provinces or regions*):
- International (*please specify the participating countries*):

10. Is the participation in the EQAS

- Mandatory
- Voluntary
- Other situation (for example: mandatory for some laboratories and voluntary for other labs)

Please specify:

11. Challenge/survey frequency of EQAS:

- Less than one per year
- One per year
- 2-4 per year
- More than 5 per year

Other *Please specify:*

12. Fees for the participating laboratories:

Yes

No

If no, who covers the cost?

13. Communication between the EQAS organizer/provider and the participating laboratories:

Reporting mechanism from the participating laboratories to the EQAS organizer/provider:

By post By fax By email Via a web site

Other (*please specify*):

Feedback mechanism from the EQAS organizer/provider to the participating laboratories:

By post By fax By email Via a web site

Other (*please specify*):

14. EQAS organizer / provider accreditation, certification, participation to international EQA?

Is your EQAS accredited? Yes No

Is your EQA scheme certified? Yes No

If yes, specified the standard (e.g. ISO 43, ISO 9001...)

Do you participate yourself to an international EQAS?

Yes No

If yes, please indicate the name and organizer

15. In what year was the EQAS established?

16. Additional comment(s):

17. May WHO/IAEA/FAO/OIE have your permission to publicly share your answers?

Yes No

18. May we contact you if more information is needed?

Yes No

Thank you very much for your participation in the survey!