



Association pour la Promotion du Contrôle de Qualité des Analyses de Biologie Médicale en Radiotoxicologie



A-1035

INTERCOMPARISON CAMPAIGN PLAN 2021

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1. Annual programme plan

This plan details the design and objectives of the annual proficiency testing programme (or annual intercomparison programme) under the auspices of PROCORAD.
It is available on Procoweb.

1.1 Name/Head office/Legal status

Association for the **PRO**motion of Quality **CON**trol in **RAD**iotoxicological Analysis (PROCORAD)
Bureau du Conseiller médical du CEA (Medical Advisor's Office) – 18 Route du Panorama BP n°6 –
92265 FONTENAY AUX ROSES CEDEX
Website: www.procorad.org

PROCORAD is a non-profit-making association governed by the law of 1 July 1901 and the decree of 16 August 1901. It was declared and registered at the Paris Prefecture on 17 November 1995 under no. 123046. This declaration was modified on 8 March 2016 at the Antony sub-prefecture and registered under no. W751123046.

1.2 Objective

The purpose of this association is to organize an intercomparison in the field of radiotoxicology in order to control the quality of the results and promote good laboratory practices. In this context, PROCORAD enables customers to meet in particular the requirements of standards NF EN ISO 15189, NF EN ISO 22870, ISO / CEI 17025 and the regulatory requirements of the French Decree of June 26, 2019 relating to individual exposure monitoring. workers with ionizing radiation

1.3 People involved in designing the programme

Coordinator: Michel Tricotti – President of Procorad michel.tricotti@cea.fr
Secretary: Claude Guichet claud.guichet@cea.fr
Scientific Council coordinator: Christian Hurtgen procorad-hurtgen@voo.be
Quality manager: Tiphaine Legrand tiphaine.legrand@cea.fr
Webmaster: Philippe Corrèze philippe.correze@orano.group
Treasurer: François Briot: briot.procorad@gmail.com

1.4 Outsourcing

The interlaboratory comparisons campaign requires a wide variety of skills that PROCORAD does not possess, requiring it to look outside the organisation. Preparation, inspection (homogeneity and stability, target values), packaging and distribution are currently outsourced as follows:

Proposed intercomparison	Subcontracted laboratory	Expert
Actinides in faecal ashes	LBM ORANO La Hague 50444 Beaumont Hague Cedex	<i>Philippe Correze</i>
Actinides in urine Uranium in urine (activity and mass)	LBM CEA Marcoule BP17171 Bagnols sur Ceze Cedex	<i>Géraldine Lecoix</i>
Strontium 90 in urine Polonium 210 in urine DTPA-actinides urine	LBM CEA Paris Saclay 91191 Gif sur Yvette Cedex	<i>Xavier Millot</i>
Gamma-X emitters in urine	LBM CEA Cadarache 13108 St Paul Lez Durance	<i>Mariette Ruffin</i>
Tritium in urine Total alpha emitters in nasal swabs (flags and tissues)	LBM CEA Valduc 21120 Is sur Tille	<i>Michel Tricotti</i>
Carbon-14 in urine Sulphur-35 in urine	LBM CEA Grenoble 38054 Grenoble Cedex 9	<i>Véronique Chanel</i>

PROCORAD's requirements towards the subcontracting laboratories are contained in the service agreement between these two parties.

1.5 Required criteria for participation

Member of the PROCORAD association. Membership is renewed every year.

1.6 Number and type of participants expected

Each year around 75 laboratories participate in the intercomparison exercises offered by PROCORAD. The participating laboratories are mainly medical or environmental monitoring laboratories conducting radiotoxicological analyses, internal dosimetry laboratories and research laboratories in the field of radiotoxicology or the environment.

We remind you that the orders are confirmed by order of reception and within the limits of available stocks.

1.7 Type of measurands

Different isotopes need to be identified and quantified according to the type of intercomparison. The levels of activity are defined by intercomparison and communicated via PROCORAD website to the participants (information available before registration on-line: www.procorad.org and in section 2 of this document).

1.8 Risks of collusion/Falsification

In order to avoid risks of collusion as far as possible, anonymous numbers are assigned to the participating laboratories, which are known only to the secretary and the scientific council moderator and not the subcontracted laboratories.

To avoid the risk of falsification, the results are input into PROCORAD website using login details specific to the participating laboratory. A result validated by the participant can only be modified before the results input deadline (8 May).

The PROCORAD history of intercomparisons shows that these risks are non-existent.

1.9 Timetable and information for participants

The timetable for the different phases of the annual exercise is in sections 2 and 3 of this document. It emphasizes that the schedule must be complied with. For example, results may not be input after 8 May of the year of the campaign.

1.10 Instructions

Instructions relating to handling intercomparison samples are specified in sections 2 and 3 of this document, which is on-line at www.procorad.org.

The analysis methods are not prescribed. A technical questionnaire to be completed by the participating laboratory may enable PROCORAD, with the collaboration of experts from the Scientific Board, to interpret the results by technique.

1.11 Procedures for homogeneity and stability tests

PROCORAD ensures that the samples are sufficiently homogeneous and stable to guarantee the validity of the results, by following the procedures described in standard NF ISO 13528 (Appendix B). The homogeneity and stability tests are carried out on a sample of entities subjected to the test. The evaluation criteria for checking homogeneity and stability is based on a robust standard deviation estimate from information from previous campaigns.

The modalities (number of samples tested, frequency) of the homogeneity and stability checks may vary according to the intercomparisons. The conclusion regarding the verification of homogeneity and stability is indicated in the final results report.

1.12 Input of results by participants

Results are input directly onto the PROCORAD website via a secure login (username + password specific to each participant). Measured activity and $k=2$ uncertainty are requested in a defined format.



Warning: in order to validate your results for an exercise, it is essential to click on the green button “Validate” and to confirm the following message “Are you sure you want to validate your results?”

If so, this following message will appear “An automatic confirmation e-mail will be sent in the next few days”. A downloadable .pdf file will then be proposed and it will be used for an acknowledgement of receipt.

You can then all the time correct your results until May 8th 11:59 PM. **The procedure described above must be followed for each result correction in order to validate the correction.**

An e-mail will be send to you later for each intercomparaison (from a few minutes to a few days)

1.13 Description of statistical analysis

This description is available in the technical report at www.procorad.org and in section 6 of this document:

- calculation of the robust mean from all the results
- calculation of the bias of each result in relation to the selected assigned value
- production of diagrams
- performance evaluation using the z-score test for each result associated with its uncertainty in relation to the assigned value and its uncertainty.

The selected performance criterion: z-score; bias and E_n score are provided for information (see section 6.3).

1.14 Annual meeting

The results are reviewed at an annual meeting scheduled for June of each year.

Each intercomparison is presented by an expert in the form of a slide presentation approved by the scientific council coordinator. Among other items, the presentation includes:

- A description of intercomparison preparation
- The results of the homogeneity and stability tests
- The assigned values and their uncertainties
- The statistical processing of the results (robust mean and graphs of results, bias and distribution by anonymous number)
- The intercomparison result in terms of overall performance and/or by technique
- Preliminary results

It will be published on the website after the annual meeting.

1.15 Reports

- An overall final proficiency test report is available for each intercomparison. This report presents the results of all participating laboratories, confidentiality being guaranteed by the anonymity number. This report is very detailed and meets the main requirements of chapter 4.8.2 of standard NF ISO / CEI 17043. It presents, among other things, elements concerning:

- o Description of the preparation for intercomparison
- o The results of the homogeneity and stability tests
- o Assigned values and their uncertainties
- o Statistical treatment of the results: robust average and graphs of results, bias, distribution by anonymity number)
- o The results of the intercomparison in terms of overall performance and / or by technique

It is available on the member page of the website (accessible by login + password) and can be viewed by all members, including those who have not participated in the intercomparison tests.

- An individual report is also available for the laboratories that participated in the intercomparisons, grouping together all the results of the same laboratory for all the intercomparisons to which it is registered. This individual report is available on the member page of the website (accessible by login + password) but can only be viewed by the participating laboratory. This individual report is a personalized appendix to the overall test report.

Due to the anonymous number, PROCORAD does not consider this report to be confidential in that each participating laboratory may disseminate it for local or national regulatory reasons and/or PROCORAD may use the data in various presentations or publications. The reports cannot be used for scientific publication without the agreement of PROCORAD.

The participating laboratories are informed of this fact.



The reports must be downloaded and saved by the participating laboratories during the current campaign, as they will no longer be available on the website during the next campaign.

1.16 Potential sources of error

There are numerous potential sources of error when conducting an interlaboratory comparison. Incorrect scores can be obtained as a result of a fault at any stage of the process:

- Pre-analytical:
 - poor internal identification of samples upon receipt in the participating laboratory
 - sample homogeneity problem prior to proportioning or sample-taking, particularly for urine
 - use of some rather than all the faecal ashes
 - analysis of a single flag out of the 2 for the xxPNA and xxPNB samples
- Analytical:
 - the test materials may have a matrix effect on some analysis systems
 - inappropriate use of the sample
 - interference between radionuclides in mixtures for a specific intercomparison (double-tracer beta measurement for example)
 - reactive, technical, calibration, etc.
- Post-analytical:
 - copy and transcription errors
 - incorrect data input onto the website
 - input of a result higher than the maximum concentration supplied in the technical characteristics
 - lack of validation of the results according to the procedure described in section 1.12

1.17 Loss or deterioration of samples submitted for testing

In the event of duly documented loss or deterioration of samples, the subcontracted laboratory may decide, at the request of PROCORAD, whether or not to send other samples up to the allowed number of samples remaining to them for the stability study and within the transport lead times compatible with performing the measurements. This additional dispatch of samples may be invoiced.

2. Technical characteristics of the intercomparisons

The technical characteristics of the intercomparisons are reviewed annually and are available on the website before the participating laboratories register.

2.1 General points

2.1.1 Shipments-Transport-Storage

The samples are shipped by a carrier at ambient temperature. Proof of receipt is sent to PROCORAD.


There are no special conditions for storing samples until analysis: the storage conditions routinely used in the laboratory for equivalent samples are sufficient.

2.1.2 Sample handling

- ✓ Open the metal box carefully and remove the plastic bottle
- ✓ Check that there are no leaks
- ✓ Mix the urine well before using (analysis or taking an aliquot).
- ✓ Process the whole faecal ash sample
- ✓ Perform the analysis according to your usual protocol
- ✓ For the Total alpha emitters in nasal swabs, process both flags of the xxPNA at the same time and process both flags of the xxPNB at the same time.

NB: the pH of urine samples is < 4 . For some analysis, it may be necessary to acidify the samples in order to restore the analytical treatment conditions of the laboratory.

2.1.3 Reporting of results

- ✓ The reference date for reporting results is 15 March of the year of the exercise. The LNHB table (accessible at www.nucleide.org) is the reference for the radioactive periods used in calculations.
- ✓ All the results from the various exercises are reported in scientific notation in **X.XX E+XX** format.
- ✓  Total alpha emitters in nasal swabs intercomparison : the input of qualitative results will be carried out in the « Technical questionnaire » section.
- ✓ Expanded uncertainty (95%) will be calculated by participants for all exercises.
- ✓ Only report your results using the Procorad website www.procorad.org by entering your e-mail address and password sent to you by e-mail
- ✓ The results reporting deadline is **8 May** of the year of the exercise. Results submitted to Procorad after this date will not be included in collective statistical analysis.

2.2 Tritium in urine (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 55.

2.2.1 Tritiated urine

5 samples of approximately 60 mL of urine

- **3** urine samples including 2 spiked samples (21HTOA, 21HTOB, 21HTOC)
- **1** sample of contaminated urine (21HTOD)
- **1** solution of tritiated water (21HTOE) obtained by dilution of the source used for spiking

The levels of activity will not be specified for the 5 samples (blank, spiked urine, contaminated urine and tritiated water solution) ($< 1.00 \text{ E}+04 \text{ Bq.L}^{-1}$ for each sample).

2.2.2 Organically bound tritium

For requesting laboratories only

- 1 sample of approximately 60 mL of urine (21OBTF): urine spiked with tritiated thymidine between 1.00 E+04 and 6.00 E+04 Bq.L⁻¹

2.3 Carbon-14 (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 50.

- ¹⁴C:** 5 samples of approximately 50 ml of urine including
- 4 urine samples including 3 spiked samples (21CA, 21CB, 21CC, 21CD)
 - 1 sample (20CE) containing a mixture of ¹⁴C and ³H.

The concentration for each isotope will be < 3.00 E+03 Bq.L⁻¹.

2.4 Sulphur-35 in urine (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 30.

³⁵S: 2 samples of approximately 50 mL of urine identified as 21SF and 21SG containing ³⁵S at a concentration less than 1.00 E+03 Bq.L⁻¹

For the ¹⁴C and ³⁵S intercomparisons participants, the blank (no spiked) to be used is that of the ¹⁴C intercomparison.

For the only ³⁵S intercomparison participants, a complementary sample, no spiked, identified as 21SH, will be provided.

2.5 X and/or γ emitters in urine (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 60.

3 samples of approximately 500 mL identified 21XGA, 21XGB, 21XGC:

- 1 no spiked sample.
- 2 samples of urine spiked with various X and/or γ emitting radioactive elements at levels of activity less than or equal to 2.00 E+01 Bq.L⁻¹ for each (not including ⁴⁰K). The number of radioactive elements to be identified and quantified will not be specified.

Stable carriers corresponding to the radioactive elements may have been used in preparing the urine samples.

The ⁴⁰K will be measured and only the arithmetical average of the 3 samples (21XGA, 21XGB, 21XGC) will be indicated on the results form in item "⁴⁰K results".

2.6 Uranium in urine (µg.sample⁻¹ (mass) and Bq.sample⁻¹ (activity))

The maximum number of participants for the intercomparison is 50.

3 samples: 21UA, 21UB and 21UC of 500 mL ± 0.75%:

- 1 sample with a concentration of < 50 µg.L⁻¹ and < 1.25 E+00 Bq.L⁻¹ (not including ²³²U)
- 1 sample with activity < 2.00 E-01 Bq.L⁻¹ (not including ²³²U)
- 1 sample without spike

MEASUREMENT OF ACTIVITY

- Thoroughly homogenize the content of the bottles by successive reversals.

- Transfer the whole urine sample from the plastic bottle to an appropriate recipient. In case of associated measurement by mass, take the required aliquot before transfer.
- Rinse the plastic bottle and top with a high purity acid solution that will be attached to the sample (to be taken into account in mass or activity calculations if necessary).
- Perform the analysis according to your usual protocol.

MEASUREMENT OF MASS

- Thoroughly homogenize the content of the bottles by successive reversals.
- Take the required aliquot.
- Perform the analysis according to your usual protocol.

2.7 Actinides in urine (Bq.sample⁻¹)

The maximum number of participants for the intercomparison is 50.

3 samples of 500 ml ± 0.75% (21ACTUA, 21ACTUB, 21ACTUC):

- 1 no spiked sample
- 2 samples containing plutonium and americium in at least one case. The samples may be spiked with one or more actinides, apart from ²⁴²Pu, ²³⁶Pu, ²⁴³Am and ²²⁹Th.
NB: One of the active samples will have total activity of between 0 and 5.00 E-03 Bq while the other will have total activity of between 5.00 E-03 and 2.00 E-02 Bq.

MEASUREMENT OF ACTIVITY

- Thoroughly homogenize the content of the bottles by successive reversals.
- Transfer the whole urine sample from the plastic bottle to an appropriate recipient.
- Rinse the plastic bottle and top with a high purity acid solution that will be attached to the sample (to be taken into account in activity calculations if necessary).
- Perform the analysis according to your usual protocol.

2.8 Actinides in faecal matter ashes (Bq.sample⁻¹)

The maximum number of participants for the intercomparison is 40.

3 samples of approximately 2.0 grams of ash each (21ACTSA, 21ACTSB, 21ACTSC).

- 1 sample is not spiked.
- 2 other samples are spiked with plutonium and/or transplutonic elements and uranium. These spikes are prepared by adding dilutions of certified radioactive standards.

A sample genuinely contaminated by an industrial compound may be proposed.

The total activity of each sample in alpha emitters of artificial origin is less than 5.00 E-01 Bq.

Uranium and thorium assays must be carried out for each sample.

- Transfer the whole sample into a recipient for dissolution.
- Rinse the plastic bottle and top with a high purity acid solution that will be attached to the sample.
- Perform the analysis according to your usual protocol

As the homogeneity of the intra-sample spike cannot be guaranteed, you need to perform the analysis on the whole sample.

2.10 Strontium in urine (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 60.

3 samples 21SRA, 21SRB and 21SRC of approximately 500 mL, composed of:

- **1** no spiked sample
- **2** samples with an activity of $^{90}\text{Sr} < 1.00 \text{ E}+01 \text{ Bq.L}^{-1}$

2.11 Total alpha emitters in nasal swabs (Bq.sample⁻¹)

The maximum number of participants for the intercomparison is 25.

2 samples 21PNA and 21PNB of pair of flags and **2** samples 21PNC and 21PND of tissues:

1 sample is spiked with an activity less than $0.50 \text{ E}+00 \text{ Bq.sample}^{-1}$.

1 pair of flags sample **and** **1** tissue sample with an activity in total alpha emitters (^{238}Pu and/or ^{239}Pu and/or ^{241}Am and/or ^{244}Cm) $< 1.50 \text{ E}+00 \text{ Bq.sample}^{-1}$

- Perform the analysis according to your usual protocol
- The participants will have to provide for flags and/or tissues a qualitative response (like Presence or absence) and/or a quantitative response.

The input of qualitative results will be carried out in the “Technical questionnaire” section.

In case of analysis of flags and tissues with different technics (with pre-treatment for one support, without for the other one, scintillation liquid for one support, proportional counting for the other one...), please choice in the drop-down menu the technic used for the flags and in the free field (named “If other”) the technic used for the tissues. This principle is also applied for the input of quantitative results.



The quantitative results are total alpha emitters: it is possible that the spike is a mix of different isotopes. The results don't need a specific characterization of the different isotopes. That is why Procorad has defined a fictional radioisotope named ^{999}Pn to identify the total alpha emitters. This fictional radioisotope cannot be changed when entering the results.

2.12 Polonium 210 in urine (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 30.

1 or **2** samples of approximately 500 mL (21POA, 21POB) with an activity of $^{210}\text{Po} < 1,00 \text{ E}+00 \text{ Bq.L}^{-1}$.

This intercomparison is not suitable for techniques that do not include mineralization step(s).

2.13 Urine DTPA-actinides (Bq.L⁻¹)

The maximum number of participants for the intercomparison is 20.

1 sample of approximately 500 mL (21DTPA) with a total activity of plutonium and/or americium and/or curium and/or uranium $< 3,00 \text{ E}-01 \text{ Bq.L}^{-1}$ in chemical complex with DTPA.

3. Registration procedure

3.1 General points

Registration is carried out on the PROCORAD website: www.procorad.org.

An anonymous code and random password are provided to each registered participant. Former members keep the same password. The reply e-mail received by each participating laboratory serves as proof of registration.

Computer prerequisites:

- ✓ **Cookies:** the website and the tools provided by PROCORAD don't use the cookies technology. No data is recorded.
- ✓ **How to use the PROCORAD tools:** the use of the services requires a connection and a web browser. In order to ensure the functioning of the service, it is recommended to use the following version of browsers:
 - Firefox version 31 or higher
 - Safari version 7 or higher
 - Internet Explorer 10 or higher
 - Microsoft Edge
 - Chrome version 35 or higher

List of e-mail addresses to be authorized by the laboratory computer system: we invite you to send this information to your IT department to include these addresses in the list of authorized e-mail addresses:

extranet@procorad.org

intercomparaison@procorad.org

3.2 Timetable

The timetable below refers to the 2020 exercise (year n) which starts in October of year n-1 (2019 in the table) and ends in October of year n (2020).

2021 RADIOTOXICOLOGY INTERCOMPARISONS			
INTERCOMPARISONS TIMETABLE			
SUBJECT	SENT BY	TO	DEADLINE
IC campaign plan and registration form	Secretarial office via website	Participating laboratories	31 October 2020
Registration form	Participating laboratories	Secretarial office via website	15 December 2020
Estimate - pro forma	Procorad treasurer	Participating laboratories	30 December 2020
Order form	Participating laboratories	Procorad treasurer	15 February 2021
Dispatch of samples	Subcontracted laboratories	Participating laboratories	28 February 2021
Receipt of samples		Participating laboratories	Before 22 March 2021
Dispatch of invoice	Procorad treasurer	Participating laboratories	15 April 2021
Results forms	Participating laboratories	Procorad experts via website	8-May -21 midnight GMT
RESULTS MEETING Vienna (Austria)			14-16 June 2021
Final report	Scientific council coordinator via website	Participating laboratories	31 August 2021

3.3. Participation fees

These are determined by the board of directors and can be viewed on the website prior to registration.

All the amounts indicated below exclude VAT as the Association is exempt from VAT.

1 exercise	: 950 Euros
2 exercises	: 1550 Euros
3 exercises	: 2000 Euros
4 exercises	: 2350 Euros
5 exercises	: 2650 Euros
6 exercises	: 2850 Euros
7 exercises	: 3000 Euros
8 exercises	: 3150 Euros
9 exercises	: 3300 Euros
10 exercises	: 3400 Euros
11 exercises	: 3500 Euros
12 exercises	: 3600 Euros

The registration fees represent a lump-sum contribution to the organization costs of intercomparisons and the results meeting during which the Association's General Meeting is held.

The fees include the cost of one or two representatives **named on the registration form** participating in the June meeting.

They do not include the cost of:

- **transport to the meeting location**
- **hotel accommodation**
- **lunch on the first day of the meeting**

More than 2 members from a laboratory may participate in the meeting. However, a contribution of 200 euros ex. VAT will be required for each additional person (**prior membership is mandatory**).

A simultaneous French-English and English-French interpreting service will be provided to members during the meeting and detailed minutes in French and English will be available for download from the website.

Comments:

There will be no reduction in registration fees for anyone who registers for intercomparisons but does not attend the results meeting.

3.4 Invoicing

The invoices are sent by e-mail around 15 April to the billing address provided at registration if that address is different from that of the laboratory manager. This invoice is an original one.

The special requirements as sending of a paper invoice by post will cost 20 euros for handling fee.

The payment period is 30 days end of month.

In case of non-payment of the invoice before the 31 July of current year, the technical report will not be available and Procorad reserves the right to refuse a registration for the next intercomparaison campaign.

Customs duties, royalties or miscellaneous taxes that may be required for the importation of samples are the responsibility of the consignee according to local regulations. PROCORAD can not be held responsible for the non-fulfilment of these obligations nor the delays, errors or damages related to the supply and transport of the samples.

3.5 Membership criteria

There are no membership criteria for laboratories to participate in intercomparisons except the one exposed in section 3.4.

There is, however, a maximum number of participants per intercomparison.

4. Communication with participants

PROCORAD has a website (www.procorad.org) which details its activity, ISO 9001 certification, operating rules, fees, the various programmes and the names and e-mail addresses of its committee members.

Other methods of communication are the annual meeting and the Ordinary General Meeting, the PROCORAD brochure, the contact section on the website, Cofrac's listing of PROCORAD as an external quality assessment body, the satisfaction survey, claims management system and any other communications (e-mail, mail, telephone calls, etc.).

All communication documents are in French and English whether on the website or in e-mail announcements.

5. Confidentiality-Protection of personal data

5.1 Confidentiality

A password, which is assigned after joining the association, is required to access the PROCORAD website. An anonymous unique number is assigned to each participating laboratory registering for intercomparisons. The PROCORAD association does not define any restrictive conditions for disseminating final reports by the participating laboratory as the anonymity of the laboratories is ensured by the anonymous number.

The final reports will only be accessible to intercomparison participants. They do not include the list of members.

Furthermore, anyone involved in running PROCORAD:

- is prohibited from disseminating or communicating any confidential information in any form (written, spoken, electronic, etc.) that they have access to within the scope of PROCORAD's activities;
- agrees to maintain their integrity and professional objectivity when carrying out their work;
- must inform the president of any attempts to pressurize or exert commercial, financial or any other influence on them, internally or externally, that may affect the quality of their work.

The experts of the different intercomparisons may only access the identity of participants within the context of ongoing training or to provide advice at the participant's request.



Memorandum (only for french medical laboratories): PROCORAD may send to the General Manager of the Regional Health Agency a state of participation and results of the External Quality assessments. Following the Health Public Code and other regulatory obligations, PROCORAD may notify to the Regional Health Agency the discrepancies in the intercomparison results that may lead to a major risk to patient health.

5.2 Protection of personal data.

The General Data Protection Regulation (EU) 2016/679 ("GDPR") became enforceable beginning 25 May 2018. PROCORAD changed his privacy policy to reflect this.

6. Statistical exploitation of results

Exploitation of results and performance evaluation are conducted in accordance with ISO standard 13528 "Statistical methods for use in proficiency testing by interlaboratory comparison" and document IUPAC 2006 "The International Harmonized Protocol for the proficiency testing of analytical chemistry laboratories (IUPAC Technical Report)".

This is a public document which is available to members via the PROCORAD website.

6.1 Descriptive statistics

For an intercomparison, the following data is provided for each sample and radioactive element:

Number of participating laboratories

Each participating laboratory provides one result per radioactive element for a specific sample.

Robust mean

The robust mean is calculated following the algorithm A described in the Annex C of the ISO 13528 standard.

Geometric mean

The geometric mean equation is as follows:

$$\text{Geometric mean} = \sqrt[n]{x_1 * x_2 * x_3 \dots x_n}$$

$x_1, x_2, x_3 \dots$ correspond to results from laboratories 1, 2, 3, etc.

The MIN value

Corresponds to the lowest result in the series.

The MAX value

Corresponds to the highest result in the series.

6.2 Statistics used to assess performance

6.2.1 Assigned value X:

The choice of assigned value type is left to the expert

It refers:

- to **reference value** X_{ref} calculated when preparing the sample in the case of a radioactive standard or radioactive standard dilution used as a spike. The value is known **before the comparison**.
We talk about the assigned reference value.
- or to **robust mean** X^* calculated from the results of participants, in the case of natural radioactive elements for example.
We talk about assigned consensual value

Robust mean X^* and robust standard deviation s^* are evaluated using algorithm A in Appendix C of ISO 13528 according to the following steps:

1. initial phase

The initial values of X^* and s^* are calculated by:

- $X^* = \text{median of } x_i (i=1,2,3, \dots, p)$ x_i : participating laboratory result
- $s^* = 1.483 \text{ median of } |x_i - X^*|$

2. iterative phase

The new values of X^* and s^* are updated:

- calculation of $\delta = 1.5 s^*$
- $\left\{ \begin{array}{l} \text{for each } x_i \text{ value, calculation of } x_i^* \\ x_i^* = X^* - \delta \text{ if } x_i < X^* - \delta \\ x_i^* = X^* + \delta \text{ if } x_i > X^* + \delta \\ x_i^* = x_i \text{ if not} \end{array} \right.$
- $X^* = \sum x_i / p$ and $s^* = 1.134 \sqrt{\sum (x_i - X^*)^2 / p - 1}$

X^* and s^* are estimated using an iterative calculation by updating the data until the process converges: usually 5 or 6 iterations.

6.2.2 Uncertainty of assigned value $U(X)$

This takes into account the main sources of uncertainty according to the calculation method of the assigned value.

The enlargement factor is $k=2$

1. If the assigned value is a reference value: **$U(X_{ref})$** . **The uncertainty of the assigned value** is calculated using the GUM method based on the main sources of uncertainty when preparing the radioactive standard or the radioactive standard dilution.
2. If the assigned value is deduced as being a robust mean calculated from the participants' results, **uncertainty $U(X^*)$** . **$U(X^*) = 2 * \frac{1.25 s^*}{\sqrt{p}}$**

 s^* is the robust standard deviation of results
 p is the number of participating laboratories

This uncertainty will be increased to take into account any non-homogeneity and/or instability according to a method described by the expert laboratory (according to ISO standard 13528, based on the inter-sample standard deviation) at the annual meeting and in the final report.

6.2.3 Standard deviation for proficiency assessment

The standard deviation for **proficiency assessment** $\sigma_{\text{proficiency}}$ is set by PROCORAD as being equal to the robust standard deviation.

6.3 Performance criteria

6.3.1 Z-score:

The selected performance indicator is z-score

The z-score value is expressed using the following relationship:

$$Z_{score} = \frac{X_{lab} - X}{\sigma_{aptitude}}$$

X_{lab} : laboratory's result

X : assigned value

$\sigma_{\text{proficiency}}$: S^*

<p> Z score ≤ 2: satisfactory result</p> <p>2 < Z score ≤ 3: questionable result Alert zone: to be monitored</p> <p>3 < Z score Discordant result requiring action.</p>

6.3.2 Other performance statistics provided for information purposes:

If the number of participants is <7, the performance indicator is the bias following the ANSI criteria (ANSI N13-30 2011, ISO 28218 and NF ISO 12790-1)

Bias:

The bias value is expressed using the following relationship:

$$\text{Bias in \%} = \frac{X_{lab} - X}{X} * 100$$

-25% < bias% < 50% (ANSI N13-30 2011, ISO 28218 and NF ISO 12790-1 criteria): **satisfactory result**

E_n number:

The E_n number value is expressed using the following relationship:

$$E_n = \frac{X_{lab} - X}{\sqrt{U^2(X_{lab}) + U^2(X)}}$$

X_{lab} : laboratory's result

X: assigned value

$U(X_{\text{lab}})$: expanded uncertainty (k=2) on the laboratory's result

$U(X)$: expanded uncertainty (k=2) on assigned value

$|En| < 1$: satisfactory result.

$|En| > 1$: unsatisfactory result.