

THE NEW ACKNOWLEDGEMENT FROM MINISTRY OF ECOLOGY AND DURABLE DEVELOPMENT

Decree of 29th November, 2006 concerning clauses of acknowledgement of laboratories carrying out analysis in the fields of water and of aquatic environment as code of environment

After two years of work, and many coordination meetings, the Ministry of Ecology and Durable Development (MEDD) has just published its new decree in the French Republic Journal Officiel. (Edition of 21st December 2006 – Text 78 / 166).

This decree of 29th November 2006 concerns the clauses of acknowledgement of laboratories carrying out analysis in the fields of water and of aquatic environment as code of environment. It takes into account some changes in comparison with the previous decree of 12th November 1998 which was legislating on this field. We will try to list the main changes.

Anyway we advise you to read the official document for more information. You will find it easily on the MEDD website in the official report of MEDD n°2 of 30th January 2007 (www.ecologie.gouv.fr / bulletin officiel – n°2)

Please note that the text will be applied after **1st August 2007**.

The main changes

1. It is the instance of accreditation designed by the petitioner laboratory (in France, COFRAC), which is entrusted by the Ministry to check the capacity of the laboratory to satisfy the conditions fixed by the decree (Article 3). So there is no more committee of acknowledgement which was studying every year the files of petitioners. As a matter of fact this checking is made at each regular evaluation of the laboratory by the designed accreditation instance.
2. A laboratory will be able to ask an acknowledgement by matrix and for the list of parameters of its choice. This bigger flexibility is totally different than the 13 previous kinds of

acknowledgement. Of course, the laboratory will have to respect the own characteristics of each selected parameter, the principle of the method and the reference of the method, and to be accredited within NF EN ISO/CEI 17025 standard for this analysis.

3. For each parameter to be acknowledged, the laboratory will have to participate, at least twice a year, in interlaboratory tests including this analysis.
4. The files of acknowledgement will be the object of diverse electronic transactions with a teleservice settled by the ministry. Among other things, the reports including results of interlaboratory tests will be made according to a unique model and common to all the candidate laboratories. It will include a table that the laboratory will have to fill up itself and give a few data for each parameter as:
 - Matrices
 - Methods
 - Assigned values
 - Standard deviations
 - z-score
 - Analyses of causes, corrective actions settled, Etc...

The positioning of Bipea

Bipea which participated to all the meetings, is particularly satisfied by these new clauses for the following reasons:

- The Bipea's ring tests (n°34/35/37/38/48/50/52/53) set up by kind of matrix for a number of parameters listed are from now corresponding perfectly to the wishes of laboratories and that, contrarily to the previous system which was obliging you sometimes to subscribe to several PTS for one acknowledgement only.
- The periodicity of examination of the files becomes the COFRAC's one. Thus **there is no more a notion of civil year to respect**, that will favour again our functioning mode. Actually, several laboratories were reproaching us to be

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organized in campaign from July to June, and not by civil year. From now, it has no more importance.

- ➔ The test reports of Bipea are containing all the necessary elements to fill up correctly your files for the ministry. Moreover all the laboratories will have to fill up themselves their file; this job will not be anymore given to some organizers which were in charge for their members. It was often reproached to us to not do it.
- ➔ Bipea was the only organizer, supported in that way by COFRAC, to ask the Ministry that the ring test organizers should be accredited whenever it is possible, or at least answer the requirements of guides ISO/CEI 43-1 and ILAC G13 in other cases. **Bipea assures its members that it will answer to all these requirements for its environment PTS concerned, from the beginning of the next campaign (July 2007).**
- ➔ This new agreement is perfectly in keeping with a Quality step of progress for laboratories. It seems for us a big step in which we have a main role to play beside you.

We want to thank:

- ➔ The MEDD for the very large coordination that it used to carry through this project
- ➔ Mr Christian JOURDAN chief assistant of the mission Water System Information from MEDD, that you will be able to meet for a detailed presentation of this decree on Tuesday 03rd April 2007 (Committees of Bipea : 34-Feed water : Chemicals Analysis & 52-Waste Water : Chemicals analysis)
- ➔ Mrs Sophie BOYELDIEU (from L.D.A. 28) to have accepted to validate this article, the technical part of the clauses of the new decree.

For more information, join us many on Tuesday 03rd April 2007 at the committee 34/52 presided by Mr Daniel FOIRET to listen to Mr Christian JOURDAN's intervention.

*Jean-Max Rouyer
 Director of Bipea*



To an alternation specialized committees and annual summary

The slow erosion of the participation to specialized committees.

The specialized committees are a primordial element of the interlaboratory comparisons schemes, as they offer to the members the possibility to express their complaints and to influence directly on the progress of the schemes concerning matrices, parameters, criteria as well as methods. These meetings of expression are a particularity offered by the associative and participative structure of Bipea.

However we note very low participation rates, as it is confirmed by the results of the survey organized in 2005, in which less than 30 % of members were affirming to participate in these committees. Rate close from those observed during the previous years.

The reasons given for these absences were mainly:

- ➔ Cost and travelling time,
- ➔ Availability.

The next questions of the survey could absolutely not allow displaying solutions to cure this fact. None of the suggestions of change in the content or in the form of these committees has significantly held the attention of members.

It was decided to place this subject in the agenda of the meeting of the Technical Board (CDT) organized on 16th November 2006, at the Castle of Montchat, in Lyon, under Mrs Jacqueline LE BRUN's presidency.

The decisions of the Technical Board of 16th November 2006

After reminding the context and a constructive exchange of opinion, the Board decided the following points:

- ➔ Upholding of committees: large favourable opinion
- ➔ Frequency of committees: at a large majority, it is proposed to reduce the frequency to one committee every two years.
- ➔ Annual evaluation: it is however asked to Bipea to send to members an annual evaluation the year without committee
- ➔ Technical Group: Bipea will have to rely as much as necessary on the Technical Group for every decision to take in the interval of two years between committees.

To take into account remarks from some presidents who regretted the change of the frequency of committees, the Direction of Bipea has proposed as a consensus that an annual committee should be upheld in the PTS when the presidents will make a motivated demand to Bipea. The estimated planning shown in annex does not take into account the changes which could be carried out after these demands of presidents.

z-score and tolerance values. The option of Bipea

In its chapter 7, the **NF ISO 13528:2005 standard** suggests eight different statistical criteria to evaluate the performance of a laboratory which participated to an intercomparison test (see box n°1 and bibliography 1).

The standard does not give any recommendation to choose the criterion which should be the best adapted. But it explains, for each of these statistics of performance, which data are necessary at their calculation, how to use them, how to interpret them and what their limits are.

The *z-score* is one of the eight possibilities suggested (see box n°1).

Calculation of z-score.

The *z-score* is calculated as following:

$$z - score = \frac{(x - X)}{\hat{\sigma}} \quad (\text{Eq.1})$$

where x is the result given by the laboratory;

X is the value assigned to the scheme or reference value;

$\hat{\sigma}$ is the standard deviation for the proficiency assessment.

The **guide ISO 43-1:1997** uses the symbol s to call the standard deviation $\hat{\sigma}$ (see bibliography 2). It is appropriate, in the case of the standard deviation for the assessment of the proficiency is defined from the results of a certain number of laboratories participating to the intercomparison, but not in other cases listed in the **ISO 13528:2005 standard**. For instance, it is not appropriate when the standard deviation for the assessment of the proficiency is deduced from a regulatory requirement or from an objective of performance, because it is not an experimental standard deviation, in the mathematical meaning of the word.

In the **InterLaboratory Comparison Reports (ILCR)** of Bipea, the standard deviation for the assessment of the proficiency is got back, to within a factor 2, under the denomination of tolerance value (VT). The tolerance value which corresponds to the objective of performance wished for the test, equals to:

$$VT = 2\hat{\sigma} \quad (\text{Eq.2})$$

To calculate your *z-score* from the data given by Bipea, it is just necessary to replace the value $\hat{\sigma}$ in the formula by $\frac{1}{2}$ tolerance value.

$$z - score = \frac{(x - X)}{\frac{VT}{2}} \quad (\text{Eq.3})$$

Note: You also can calculate a reduced centred difference (centred on the reference and reduced by the tolerance (ECR)) which is, to within a factor 2, equivalent to *z-score*. The calculation is:

$$ECR = \frac{(x - X)}{VT} \quad (\text{Eq.4})$$

Step of assessment of your laboratory performance.

Within Bipea tests, we propose you the following step to examine your results from the tolerance value.

1. Calculate the difference or the bias to the reference value.
2. Calculate your *z-score* (Eq.3) or your reduced centred difference (Eq.4).
3. Interpret individually your *z-score* or your reduced centred difference.
4. Construct your following accuracy monitoring chart.
5. Interpret your accuracy monitoring chart:
 - Globally, from the last points positioned to show tendencies;
 - Periodically, to make an assessment of your performance.

Individual interpretation of z-score.

The interpretation of a *z-score* value can be made by different ways which depend on the approach considered to determine the standard deviation of assessment of the proficiency, so of the tolerance value. In the previous Contact letter Bipea n°97, we detailed, on page 4, the five possible steps.

Prefixed performance.

The first approaches described in the **ISO 13528:2005 standard** allow evaluating the proficiency of the laboratory in comparison with an objective of performance, defined before the beginning of the comparison.

The objective of performance can be:

- A regulatory value deduced from an exigency of the legislation;
- A common objective of performance or a « customer » objective, fixed to a level of performance wished by the organizer or the participants;
- A global performance of methods of analysis deduced from a general model (as Horwitz's model);
- A performance of the method used, calculated

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using the standard deviations of reproducibility and repeatability of the standard.

For the interpretation, only one of these limit values is considered. It allows deciding if the objective of performance is reached or not. In this context, a *z-score* superior to 2.0 or inferior to -2.0 has to be considered as a warning signal.

In presence of a warning signal, the result is judged unsatisfactory compared to the objective of performance. In ILCR of Bipea, this signal is shown in the results charts, by an underlining, of the results called « out of tolerance ».

Note: For the reduced centred difference, the critical value of 1.0 is equivalent to a critical value of 2.0 used with z-score.

Performance not defined.

In absence of data outside the comparison to define an objective of performance, the assessment is carried out by taking into account of the empiric distribution of the results from the laboratories. The standard deviation for the assessment of the proficiency corresponds to:

- A robust value combining the standard deviations of the results calculated with an important number of comparisons;
- The robust standard deviation of the test results.

This last approach has the inconvenient of a high variability of the standard deviation of assessment of the proficiency from one test to another.

So the interpretation of the *z-score* is the following one:

- A *z-score* superior to +2.0 or inferior to -2.0 must be considered as giving a warning signal.
- A *z-score* superior to +3.0 or inferior to -3.0 must be considered as giving an action signal;

The following conditions have to be filled up: 1) $\hat{\sigma}$ deduced from the standard deviation of the results of participants; 2) \bar{X} the mean deduced from a robust method of the results of participants.

Actually, this mode of interpretation supposes that the distribution of results follows a normal rule (Bilateral interval of confidence: 95.4 % of results included between ± 2 standard deviations and 99.7 % of the results included between ± 3 standard deviations). Consequently, in average 4.6 % of the test results will be the subject of a warning signal by default or by excess, whatever the performance of the laboratory.

This step is the most usually proposed and used in the literature, because it appeals only to the generated data during the comparison test. These tests are not proficiency tests in the proper meaning of the word but they allow classifying the laboratories.

Conclusion.

Before all assessment of the proficiency of a laboratory, it is necessary to define an objective of

performance which will be associated to the criteria of acceptability.

For the majority of its proficiency tests, Bipea proposes to its members an objective of performance which was defined by consensus between the participants of the specialized committees.

In Bipea's ILCR, you will find all necessary data in the headings of tables of results to make a calculation of statistics of performance as the *z-score* using the tolerance value which was kept as objective of performance (Eq.3).

This approach can be completed by an assessment:

- Of your proficiency according to an objective of performance proper to your laboratory and duly justified;
- Of the positioning of your result comparing to other laboratories, calculating a new *z-score* using the robust standard deviation of the results of participants (Eq. 1), when an objective of performance has been previously defined.

One of the missions of the organizer of interlaboratory comparisons is to give you the means for evaluating your own performance.

Marie Philippe SEILLER,
Quality manager of Bipea

Validated by Mr Max FEINBERG,
Scientific adviser of Bipea.

Box n°1

The eight calculations of statistic of performance described in the NF ISO 13528 standard are:

- The difference or the bias (D),
- The percentage difference ($D\%$),
- The rank or the percentage rank
- The *z-score* (z),
- The E_n number (E_n),
- The *z'-score* (z'),
- The zeta-score (ζ),
- The E_z score (E_z).

Bibliography

1. **ISO 13528:2005 standard** « Statistical methods used in the proficiency tests by interlaboratory comparisons » Afnor, Paris
2. **Guide ISO 43-1:1997** « Proficiency tests of laboratories by intercomparison. Part 1 : Development and operation of proficiency tests

Monitoring charts and z-score

We remind you that Bipea commercializes since the beginning of this campaign, accuracy monitoring charts, which include *z-score* as well as the warning and action limits.

For any further information, send your request by e-mail to: groine@bipea.org



Estimated planning of committees during 2007-2008 & 2009

P.T. SCHEMES		2007	2008	2009	NOTES
01- Common wheat			OCTOBER		Grouped 01/02/04/25/41
02- Flour : alveograph			OCTOBER		
03- French bread making test		DECEMBER		DECEMBER	Grouped 03/47
04- Baking test			OCTOBER		Grouped 01/02/04/25/41
06- Durum Wheat		JUNE		JUNE	Grouped 06/07/11/12/23
07- Semolina					
08- Impurity determination			SEPTEMBER		
09- Moisture determination (in grains)			DECEMBER		
10- Oilseeds		MARCH		MARCH	
11- Brewing barley		JUNE		JUNE	Grouped 06/07/11/12/23
12- Food pulse		JUNE		JUNE	
13- Animal feeds			NOVEMBER		Grouped 13/42
14- Forage			APRIL		
15- Soils			SEPTEMBER		Grouped 15/24/45
16- Filth test		MAY		MAY	
17- Wines		MAY		MAY	Grouped 17/18/55
18- Spirits		MAY		MAY	Grouped 17/18/55
19- Pesticids		JUNE		JUNE	
20- Health food & dietary product			SEPTEMBER		
21- Fats & oils			MARCH		
22- Silages			APRIL		
23- Brewing barley (specific & varietal purity)		JUNE		JUNE	Grouped 06/07/11/12/23
24- Mineral Fertilizing Materials			SEPTEMBER		Grouped 15/24/45
25- Flour : farinograph			OCTOBER		Grouped 01/02/04/25/41
26- Amino-acids			FEBRUARY		
27- Fruit juices			JANUARY		
28- Patuline determination		NOVEMBER		NOVEMBER	Grouped 28/31
31- Mycotoxins					
32- Trace elements		FEBRUARY		FEBRUARY	
34- Feed water : chemicals analysis		MARCH		MARCH	Grouped 34/38/52
35- Waters : microbiological analysis		APRIL		APRIL	Grouped 35/50/54
36- Ciders		JANUARY		JANUARY	
37- Feed water : micropollutants		MARCH		MARCH	Grouped 37/48/53
38- Activéed sludge & sediments		MARCH		MARCH	Grouped 34/38/52
39- Liqueur wines			JUNE		
40- Detection & quantification of GMOs			DECEMBER		
41- Flour : rhéofermentometer			OCTOBER		Grouped 01/02/04/25/41
42- Premix			NOVEMBER		Grouped 13/42
44- PCB/HAP (in agro food)			MAY		
45- Organical Fertilizing Materials			SEPTEMBER		Grouped 15/24/45
46- Honeys			DECEMBER		
47- French Traditional Bread		DECEMBER		DECEMBER	Grouped 03/47
48- AOX - hydrocarbons		MARCH		MARCH	Grouped 37/48/53
50- Waters : Légionella		APRIL		APRIL	Grouped 35/50/54
51- Microbiological analysis in food stuffs		MAY	Experimental PTS 2006-2007		
52- Waste water : chemicals analysis		MARCH		MARCH	Grouped 34/38/52
53- Waste water : micropollutants		MARCH		MARCH	Grouped 37/48/53
54- Waters : salmonella		APRIL	Experimental PTS 2006-2007		
55- contaminants in wines		MAY	Experimental PTS 2006-2007		
56- Sanitary quality of flours		JUNE	Experimental PTS 2006-2007		

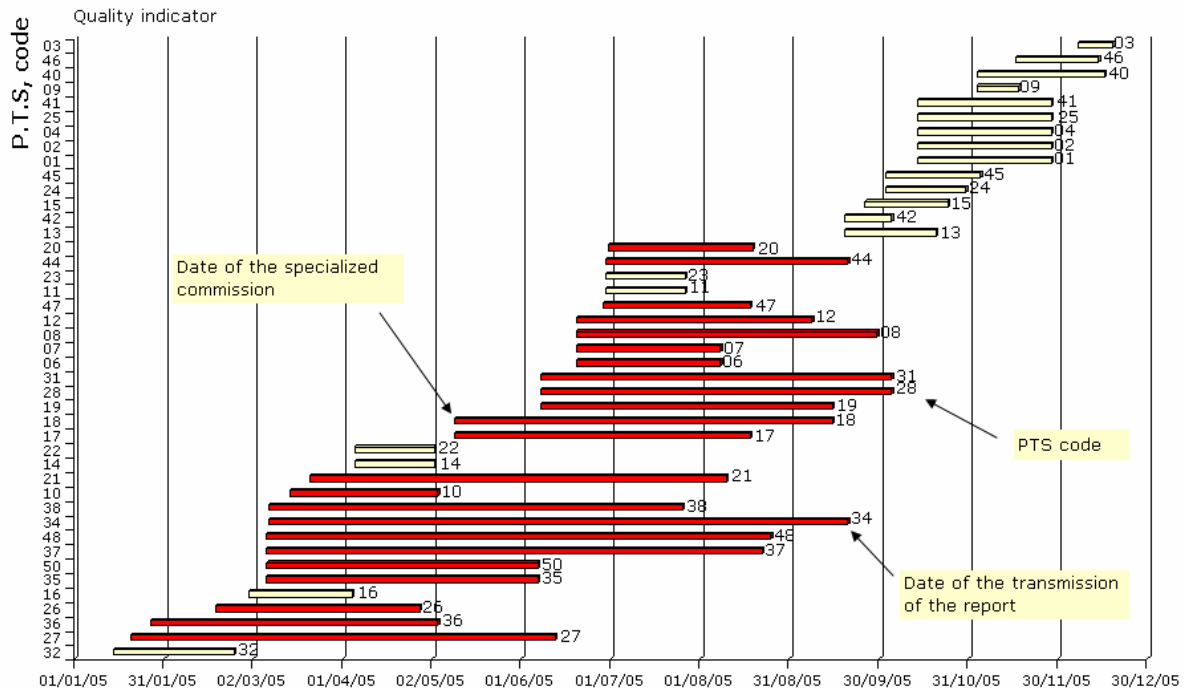


Time of publication of the specialized committee reports in Bipea

Within our Quality step , the maximum time to publish the report of the specialized committee(s) has been fixed to 45 days after the committee(s).

On these two graphs, the red studs represent the P.T. Schemes where this time is exceeded. As you can note it, Bipea attempted to solve over the year 2006 structural difficulties which were encountered in 2005 and which had an impact on this Quality indicator, but also on the member satisfaction.

Year 2005



YEAR 2006

