



Accreditation of the GHEP-ISFG proficiency test: One step forward to assure and improve quality



K. Fernández*, J. Gómez, J. García-Hirschfeld, E. Cubillo, C. Sánchez de la Torre, G. Vallejo

National Institute of Toxicology and Forensic Sciences (INTCF), Ministry of Justice, Madrid, Spain

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ABSTRACT

Since 1992, it has been organized annually in Spain, a Forensic Intercomparison Exercise coordinated by the Madrid Department of the National Institute of Toxicology and Forensic Sciences (INTCFM) and organized by the Spanish and Portuguese Speaking Working Group of the International Society for Forensic Genetics (GHEP-ISFG). The need to improve and assure the quality of our services as well as to demonstrate our competence, led us to accredit this Exercise under ISO/IEC 17043. This International Standard ensures quality of proficiency testing providers regarding technical and management requirements. In this work, we present the step-wise process we began in 2011 focused on upgrading the Basic level of the Intercomparison Exercise towards its accreditation, which was successfully achieved in December 2014. All adjustments made are described. From the early structural changes, since the Exercise had to be divided in two levels, passing through the definition of the scope, to the technical improvements made and management policy implementation.

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1. Introduction

It is essential that forensic laboratories establish quality assurance programs in order to monitor and demonstrate the quality and reproducibility of their analyses. Use of internal quality controls, periodical supervision of the staff, audits or most notably participation in proficiency test, among others, shall be included in these programs.

Participation in proficiency tests can report many advantages to forensic laboratories. It represents an important tool to assess and monitor the quality performance of the laboratory for a specific test; it provides a mean to compare laboratory work with other laboratories of the same field. Externally it affords additional confidence on laboratory performance and moreover it can encourage a self-improvement attitude, identifying problems and needs.

For a proficiency testing program to be fully utilized as a quality assurance tool it is necessary that it meets basically the following characteristics: it should be suitable for the specific tests performed in the laboratory (adequate items and analyses) relevant: the relevancy is measured by the number of participants, the higher number the more statistical validity and confident and reliable: it

should possess a proven quality as a proficiency test, and preferably be accredited by the adequate International Standard.

The International Standard that specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes is the ISO/IEC 17043: 2010 Conformity assessment. General requirements for proficiency testing [1].

2. GHEP-ISFG proficiency test: a bit of history

In 1992, the Spanish and Portuguese working group of the ISFH (what is now known as, the Spanish and Portuguese-Speaking Working Group of the International Society for Forensic Genetics (GHEP-ISFG)), under the coordination of the Quality Assurance Service of the INTCF in Madrid (INTCFM), started issuing a collaborative exercise on DNA profiling, in order to exchange knowledge and standardize the incoming techniques in this field. In 1995, the Exercise turned into a Proficiency testing program. Year after year the program evolved gradually being introduced different changes regarding the DNA polymorphisms assessed and the kind of samples to be analyzed [2].

Different systems have been assessed along the Exercise, from the early SLPS, DQA1 and VNTR (from 1992 to 2003) or Polimarker (from 1994 to 2003) to the autosomal STRs introduced in 1993, or the Y chromosome STR markers and mitochondrial DNA assessed since 1998 to the latest polymorphism incorporated in 2006

* Corresponding author.

E-mail address: coro.fernandez@justicia.es (K. Fernández).

(X chromosome STR markers) being all of them the current DNA polymorphisms utilized in this program.

Although it included originally testing of blood samples, later other different samples (saliva, semen) were included for genetic analyses and body fluid identification. In 2000 it was introduced the analysis of hair. Regarding theoretical studies, in 1996 it was implemented the statistical resolution of kinship cases, further on data for solving forensic studies were also added to the Exercise (2007).

But the most notorious change was carried out in 2011 when the Exercise was divided in two levels: Basic and Advanced.

3. Stepwise process towards accreditation

The need to improve and assure the quality of our services as well as to demonstrate our competence, led us to accredit the Basic Level of this Exercise under ISO/IEC 17043. The prospect of going through an accreditation process began to take shape in 2008, when the Spanish Royal Decree RD 1977/2008 November 28th was approved regulating the composition and functions of the National Commission for the Forensic Use of DNA (CNUFADN). As the Exercise constituted a regulatory requirement for the Commission to evaluate the performance of the Spanish Forensic laboratories, it was considered that its suitability and quality should be proven by means of accreditation. From the Quality Assurance Service of the INTCFM several reports were issued exposing and valuing the necessary changes to be carried out in the Quality system and the implications of accrediting the Exercise. In 2010 the ISO/IEC 17043 was approved and a first draft of the Quality System Manual including this ISO was issued.

4. Early changes

It was in 2011, when effective changes began to be implemented in the proficiency test for the accreditation process. First all of it was the division of the Exercise in two levels: Basic and Advanced. The Basic level was structured as an Intercomparison Program with more standardized criteria, including a practical study with both kinship and forensic samples and theoretical studies for kinship and forensic modules. Meanwhile the Advanced level remained as a collaborative program in order to provide the opportunity to include new genetic systems, analyze complex forensic samples and solve theoretical challenges (kinship and forensic) that would help laboratories to compare their results.

The next step was upgrading all the technical and management competences of the Basic level. Although the Exercise had already a long established background as proficiency test, and both skills were settled, they needed to be reviewed, adjusted or implemented to meet the requirements of the ISO.

During 2011 the first management implementations were related to the Quality System of the INTCFM. The ISO/IEC 17043 was incorporated into the Quality Policy and in the Quality Manual of the Department. It was also established an annual review of the proficiency testing management system covering all the requirements set out in the ISO to be used as a tool for introducing any necessary changes or improvements. Regarding technical personnel, an advisory group (staff from the INTCFM) was constituted to help and advice the coordinator.

5. Development of SOPs and first internal audit

Although procedures regarding Exercise general program, preparation, handling storage and delivery of items or data processing systems were already established, they had to be defined in Standard Operating Procedures (SOPs).

In order to evaluate to which extent we still needed to adjust our skills to the ISO, we underwent an internal audit carried out by an external Consultancy Service in 2012. As a result of this audit, the following technical changes were performed:

- All date records of competence, training, skills and experience of all technical personnel was up to date and the planning and design of the proficiency testing was documented including the information provided in the ISO.
- The information provided to the participants was reviewed and improved with more clear and complete instructions.
- A confidentiality agreement document for obligatory compliance was implemented for all personnel involved in the Exercise.

6. Other technical improvements and management implementations

Following the observations made by the Consultancy Service the year before, in 2013, an annual internal audit of the Exercise was included in the general audit program policy of the INTCFM. In the same year, an internal audit was carried out by the Quality Assurance Service of the INTCFM. The aim of the audits is to ensure the effectiveness of the proficiency testing procedures implemented and the detection of possible deviations from the requirements of the Standard.

Although items were prepared following the necessary procedures to maintain homogeneity and avoid contamination during their preparation, it was necessary to assess and document the homogeneity and integrity of the forensic items before their delivery by analyzing a representative group of them.

Following the policy of constant improvement in the communication with participants, they were established better procedures to deal with and resolve complaints and appeals. It was also enabled a complaint form on the website of the GHEP-ISFG group.

As the Exercise is organized by the GHEP-ISFG group and coordinated by the INTCFM since its origins it was necessary to describe and document the functions of both, the GHEP-ISFG committee and the proficiency test provider (INTCFM).

7. Defining the scope of accreditation

Prior to apply for accreditation we defined a clear scope of accreditation [3], which is an establishment of the specific tests (items, parameters to be analyzed and determination of assigned value) which will be covered by the accreditation. Taking into account the structure of the Exercise the scope was defined as follows.

Items. Kinship module: stains of one component blood and/or saliva. Forensic module: stains of one component or two components of blood, saliva or semen. Hair. For both modules set of data to solve a theoretical study.

Parameters to be analyzed (they differ depending on the type of item): STRs (autosomal, Y-chromosome, X-chromosome) and mitochondrial DNA haplotypes. Body fluid identification. Statistical calculations.

Assigned values: Consensus values among participants or known values are applied depending on the test.

In July 2014 an external assessment was carried out by the Spanish National Accreditation Body (ENAC). The assessment report concluded that there were still some aspects that would require to be examined.

The most relevant were related to the data analysis and evaluation, the preparation of items and the reports issued.

As the Exercise was originally collaborative and there were a small number of participants the criteria for achieving consensus

was established with a minimum of 5 participants. Nowadays this criteria was no longer statistically reliable so we reviewed it and consequently new assigned values were established.

New measures were introduced to update the monitorization of possible contamination such as the analysis of the substrates used as negative controls or the genetic analysis of the Kinship items before delivery which would be also useful to assess their homogeneity.

Another deviation detected was the issuance of reports. Initially 3 reports were issued in this Exercise, but in order to meet the requirements of the ISO they were merged into a single one final report which included complete information.

Finally, when all deviations were suitably rectified, in December, 4th 2014, ENAC conferred the accreditation under ISO/IEC 17043 to the INTCFM as proficiency test provider.

8. Goal achievement

Today we can assert that the accreditation of the Basic level of the Exercise has completely fulfilled all the initial established goals.

- The skills of the Exercise have been improved by means of implementing a better management system and standardizing all the procedures, facilitating its functioning.

- The quality of our services has been reassured and consequently the confidence and reliability of this proficiency test to participants have been enhanced.
- Demonstration of our competence is proven, as accreditation officially recognizes our technical competence and provides the international recognition of our services.

9. Future goals

Our next goals are to maintain and improve the effectiveness of the technical and management testing schemes acquired with the process of accreditation, through periodical reviews and audits or feedback from participants among other actions.

References

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- [3] <http://ghep-isfg.org/en/proficiency/>.