



Continuous standardisation through accreditation. Application in the case of a Radioactivity Measurements Laboratory.

> ERRICCA-2 Athens Meeting 14-15 October, 2002, Athens G.N. Papadakos Ntua, Greece





What is accreditation?

"Accreditation:

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks."

[Source: ISO/IEC Guide 2:1996 (E/F/R)]

"Accreditation delivers confidence in certificates and reports by implementing widely accepted criteria set by the European (CEN) or International (ISO) standardisation bodies. The standards address issues such as impartiality, competence and reliability; leading to confidence in the comparability of certificates and reports across national borders. Governments have confidence in testing and certification in support of regulatory functions."

[Source: http://www.european-accreditation.org]

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Laboratory Accreditation benefits

Laboratory accreditation

- provides a means of determining the competence of laboratories to perform specific types of testing, measurement and calibration,
- enables people who want a product, material or instrument to be checked or calibrated to find a reliable testing or calibration service able to meet their needs,
- provides feedback to laboratories as to whether they are performing their work in accordance with international criteria for technical competence,
- assists manufacturing organisations to enhance the testing of their products by their own in-house laboratories, thus decreasing the load of governmental testing laboratories,
- provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and access reliable testing and calibration services.





Standardisation

"Activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context."

[Source: ISO/IEC Guide 2:1996 (E/F/R)]



Accreditation Organisations (1)		
International		
ILAC	httn•//www ilac org	
International Laboratory Accreditation Cooperation		
IAF	http://www.iof.nu	
International Accreditation Forum		
Regional		
EA	http://www.european-	
European Cooperation for Accreditation	accreditation.org	
National		
Beltest OBE/BKO		
Belgian Organisation for Accreditation and Conformity Assessment (Belgium)	http://beltest.fgov.be	
DANAK	http://www.dopole.dk	
Dansk Akkreditering (Denmark)	http://www.danak.dk	

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FINAS Finnish Accreditation Service (Finland)	http://www.finas.fi
COFRAC Comité Francais d' Accreditation (France)	http://www.cofrac.fr
DACH Deutsche Akkreditierungsstelle Chemie (Germany)	http://www.dach-gmbh.de
DAP Deutsches Akkreditierungssystem Prüfwesen (Germany)	http://www.dap.de
DAR Deutscher Akkreditierungs Rat (Germany)	http://www.dar.bam.de
DASMIN Deutsche Akkreditierungsstelle Mineralöl (Germany)	http://www.dasmin.de



DATech Deutche Akkreditierungsstelle Technik (Germany)	http://www.datech.de
DKD Deutscher Kalibrierdienst (Germany)	http://www.dkd.ptb.de
ESYD Hellenic Accreditation Council (Greece)	http://www.quality.ypan. gr/ESYDsite
NAB National Accreditation Board (Ireland)	http://www.forfas.ie/nab
SINAL Sistema Nazionale per L' Accreditamento di Laboratori (Italy)	http://www.sinal.it
SIT Servizio di Taratura in Italia (Italy)	http://sit.imgc.to.cnr.it



Accreditation Organisations (4)

RvA Raad voor Accreditatie (Netherlands)	http://www.rva.nl
NA Norsk Akkreditering (Norway)	http://www.justervesenet. no/na
IPQ Instituto Português da Qualidade (Portugal)	http://www.ipq.pt
ENAC Entitad Nacional de Accreditación (Spain)	http://www.enac.es
Swedish Board for Accreditation and Conformity Assessment (Sweden)	http://www.swedac.se
UKAS United Kingdom Accreditation Service (United Kingdom)	http://www.ukas.com

Accreditation Organisations (5) ERRICCA-2

SAS Schweizerischen Akkreditierungstelle (Switzerland)	http://www.sas.ch
PCA Polskie Centrum Akredytacji (Poland)	http://www.pca.gov.pl
CAI Czech Accreditation Intitute (Czech Republic)	http://www.cai.cz
NAT Nemzeti Akkreditáló Testület (Hungary)	http://www.nat.hu
SA Slovenska Akreditacija (Slovenia)	http://www.gov.si/sa
RENAR Romanian Association for Accreditation (Romania)	Phone: +40 1 310 2270 FAX: +40 1 310 1390





Standards for accreditation in the conformity assessment scheme (1)

Application field	European Standard	Corresponding International Standard	Present situation or future trends	Comments
Laboratories EN ISO/IEC 17025	ISO/IEC 17025	Recently replaced JSO Guide 25 and JEN 45001	Aligned with ISO 9001:1994	
	17025	150/1EC 17025	Expected: Minimal alignment with ISO 9001:2000	
Accreditation bodies for laboratories	EN 45003 (1995)	ISO/IEC Guide 58:1993	Drafting of the International standard ISO/IEC 17011	"One standard for
Certification bodies	EN 45010 (1998)	ISO/IEC Guide 61:1996		Accreditatio n of All Conformity
Inspection bodies		ISO/IEC TR 17010		Assessment"

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Standards for accreditation in the conformity assessment scheme (2)

Application field	European Standard	Corresponding International Standard	Present situation or future trends	Comments
Evaluation of Laboratories	EN 45002			
Inspection bodies	EN 45004 (1995)	ISO/IEC 17020	Application of ISO 17020 in a world-wide base	
Quality system certification bodies	EN 45012 (1997)	→ISO/IEC Guide 62:1996 →ISO/IEC Guide 66:1999	Publication of ISO/IEC 17021	
Product certification bodies	EN 45011 (1997)	ISO/IEC Guide 65:1996	ISO/IEC Guide 67	Additional to Guide 65

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Standards for accreditation in the conformity assessment scheme (3)

Application field	European Standard	Corresponding International Standard	Present situation or future trends	Comments
Personnel certification bodies	EN 45013 (1989)		Draft International Standard ISO/IEC 17024	
Suppliers declaration of conformity	EN 45014 (1989)	ISO/IEC Guide 22	Draft International Standards →ISO/IEC 17050, →ISO/IEC 17049 and →ISO/IEC 17051	
Interlabor. comparisons		ISO/IEC Guide 43:1997		

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Case study:

Hypothetical case of accreditation by the Hellenic Accreditation Council (ESYD) of NES-NTUA for portable Radon-in-air concentration measuring device calibration, using the Laboratory' s stainless steel airtight chamber.

Accreditation procedure (1)

- 1. Application stage. Submission of Application Form, two copies of the Quality Manual and the relative documentation (to be prepared by the applicant) and payment of application fees.
- 2. Establishment of the Assessors' Team (By ESYD's Supporting Unit and Technical Committee)
- 3. Pre-Assessment (If necessary ESYD's decision)
- 4. Assessment schedule preparation (If the applicant agrees with the designed schedule by ESYD, he pays the 70% of the total fees)
- 5. Initiation of the Assessment procedure

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Accreditation procedure (2)

- 6. Assessment procedure (Includes inspection-in-action of the Laboratory' s quality system)
- 7. Assessment results:
 - Necessary changes and re-assesment or
 - Assessment completion
- 8. Final check (By ESYD' s Technical Committee, due to the suggestions of the assessors' team)
- 9. Decision for accreditation by ESYD (The applicant pays, after he is informed properly, the rest of the fees)
- 10. Surveillance and re-assessment visits, or extension of accreditation to other procedures.

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- The Certificate validation time is 4 years
- The first re-assessment takes place about 6 months after the Certificate issue. It is repeated in each one of the next 3 years.
- The accreditation procedure will be automatically initiated:
 - by the end of the 4-year accreditation period or
 - within the 4-year period, in case of significant changes in the accredited procedures.

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Accreditation Fees

Year	Cost (in EURO)*
1st	8000
2nd	6000
3rd	6000
4th	6000

* Pre-assessment; One Assessor for one day

Assessment; One Assessor and one expert for two days

NTUA-NES personnel involved; 8 members of the NES-NTUA





Potential problems during the accreditation procedure

- 1. The technical field under consideration can not be accredited yet by ESYD.
- 2. There is no cooperation between ESYD and an assessor expertised in the field of Radon-in-air concentration measurements.
- 3. Incomplete description of not standardised technical sub-procedures in the Quality Manual.
- 4. Need for change in the Laboratorie's administrative procedures and minimization of the necessary paperwork.



Critical substances of the Quality Manual

- 1. Accurate description of the authorised personel's responsibilities for the maintenance of the Quality System.
- 2. Application of the national and international Radiation Protection Regulations.
- 3. Preparation of the Laboratory's Instalation ergonomical report.
- 4. Expression of the Uncertainty and the traceability of measurements.
- 5. Design of the official printed or electronic documents file for use in the Accredited Quality System of the Laboratory.
- 6. Installation of the appropriate records for keeping the above official documents.





Uncertainty of measurements (1) Recommendation INC-1 (1980)

Expression of experimental uncertainties

"The uncertainty in the result of a measurement generally consists of several components which may be grouped into two categories according to the way in which their numerical value is estimated:

A. Those which are evaluated by statistical methods,

B. those which are evaluated by the use of other means

[Source: "GUIDE TO THE EXPRESSION OF UNCERTAINTY IN MEASUREMENT" (GUM)]

Uncertainty of measurements (2)

There is not always a simple correspondence between the classification into categories A or B and the previously used classification into "random" and "systematic" uncertainties. The term "systematic uncertainty" can be misleading and should be avoided.

Any detailed report of the uncertainty should consist of a complete list of the components, specifying for each the method used to obtain its numerical value."

[Source: "GUIDE TO THE EXPRESSION OF UNCERTAINTY IN MEASUREMENT" (GUM)]





Traceability of measurements

"Calibration means determining and documenting the deviation of the indication of a measurement instrument (or the stated value of a material measure) from the conventional "true" value of the measurand.

The term *traceability* means a process whereby the indication of a measuring instrument (or a material measure) can be compared with a national standard for the measurand in question in one or more stages."

[Source: ILAC-G2:1994 "Traceability of measurements"]





But...

The best you can do before anything else is to Search by yourself!