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Accreditation

Its relevance for laboratories measuring radionuclides

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Abstract

Accreditation is an internationally recognised way for laboratories to demonstrate their competence. Obtaining and maintaining accreditation is, however, a costly and time-consuming procedure. The benefits of accreditation also depend on the role of the laboratory. Accreditation may be of limited relevance for a research laboratory, but essential for a laboratory associated with a national authority and e.g. issuing certificates. This report describes work done within the NKS/BOK-1.1 sub-project on introducing accreditation to Nordic laboratories measuring radionuclides. Initially the focus was on the new standard ISO/IEC 17025, which was just in a draft form at the time, but which provides now a new framework for accreditation of laboratories. Later the focus was widened to include a general introduction to accreditation and providing through seminars a forum for exchanging views on the experience laboratories have had in this field. Copies of overheads from the last such seminar are included in the appendix to this report.

Keywords

Accreditation; Radionuclides; Standard; ISO/IEC 17025; Laboratories

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Report from the NKS/BOK-1.1 project group
Laboratory Measurements and Quality Assurance

NKS

November 2001

Contents of report

The standard ISO/IEC 17025 cannot be distributed with this report, since it is copyrighted and it can be bought from the International Standards Organisation (ISO):
http://www.iso.ch/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=30239
or a reseller. A **draft version**, ISO/DIS 17025, can however at the time of writing be downloaded free of charge from the following web site:
http://www.quametec.com/ISONews.htm
(a link is also provided from the BOK-1.1 web site: http://www.gr.is/bok-1.1/). The difference between the draft version and the final version is minimal, but for defining standard requirements the official standard must be used.

Summary

In recent years there has been increased need for laboratories to be able to demonstrate the quality of their results. This is e.g. due to increased international trade and co-operation, and increased emphasis on quality control. It can also be a direct legal requirement, as is the case concerning the EU Council Directive 93/99/EEC of 29 October 1993 on additional measures concerning the official control of foodstuffs, which requires 'Official laboratories' to be accredited and to participate in appropriate proficiency testing schemes. Accreditation is the internationally recognised way for laboratories to demonstrate their competence. It has thus received increased attention amongst Nordic laboratories measuring radionuclides in the environment and foodstuffs.

In the previous NKS period, 1994-1997, accreditation was taken up as a special topic within the EKO-3.2 sub-project on quality assurance in laboratory measurements. During the current period a new draft standard on accreditation, ISO/IEC DIS 17025, generated interest, since there were claims that the new standard might offer more flexibility and/or make it easier to obtain accreditation. At least it was certain that the new standard, if accepted, would change the framework for accreditation.

The initial emphasis was thus on drawing attention to the new draft standard, and to provide a forum for discussing the possible implications for laboratories measuring radionuclides. This was e.g. done at a BOK-1.1 seminar in Skagen, Denmark, 23 August 1999; at the NSFS meeting in Skagen, 23-27 August same year and a final BOK-1.1 seminar in Oslo on 27 March 2000. Initially there were some doubts whether the standard would be accepted. The development in the final stages was however rapid and now it defines the framework for accreditation of laboratories as the approved standard ISO/IEC 17025:1999.

The new standard is structured in a similar way as other corresponding standards. It is therefore easier to work with it than the previous ones. It also combines into one document requirements for accreditation, which were previously listed in different publications. The structure of the standard is such that it can be used as a model for building up a quality manual, simply by using the same index and meeting the stated requirements one-by-one. In this report the structure of the new standard is described and a reference to where it can be bought. A reference is also given in the report to where a draft version of the standard can be downloaded from the World Wide Web.

At the final seminar in Oslo an independent consultant gave an overview over the terminology used in quality assurance and the general use of accreditation. A summary is provided in the report and copies of overheads used in his talk are given in the appendix to the report.

The report gives also an elementary introduction to accreditation and how it can be obtained. Additionally it gives reference to more detailed material that can be downloaded from the Web. The report lists also some advice concerning preparation for accreditation. A laboratory considering accreditation should contact the accreditation body in its country. There documentation can be obtained on the accreditation process and the formal requirements in the country. This report gives reference to some relevant international publications, many of which can be

downloaded from the Web. A list of accreditation bodies in the Nordic Countries and Baltic States is given in the appendix to the report, contact information is also included in each case.

Accreditation involves being able to demonstrate quality of measurements. For most laboratories this means critically reviewing own analytical procedures, and making improvements where needed. One of the often-neglected components is the assessment of uncertainty in results. It can be performed and reported in various ways. Often it is not clear what is included in stated uncertainty of a result. In intercomparisons the spread of results is often greater than can be explained by the stated uncertainties. There are now available international standards and guidelines, which describe how uncertainty should be assessed and reported. References to such material that can be downloaded from the Web are given in the report. Gamma spectrometry is often assumed to be a simple procedure, but care needs to be taken if accurate low-level results are to be obtained. The background can be variable, there can be considerable differences between parameters in nuclear libraries and for a given amount of sample material, the measurement geometry can have a big effect. A system of quality assurance measurements can help to identify problems and even to predict detector failures. These topics were discussed at the final seminar in Oslo and copies of some of the overheads presented can be found in the appendix of this report.

Another important component of accreditation is documentation and system of document control. Documentation needs to be detailed, but at the same time the information has to be accessible so it will be used and the updating process must be efficient enough not to hinder progress. In many cases computerised document systems will make this work easier.

At the final seminar representatives from the Radiation and Nuclear Safety Authority, Finland, (STUK) and the Norwegian Radiation Protection Authority (NRPA) discussed their experience of the accreditation process. The different possible strategies were discussed, e.g. whether to base the quality system on Total Quality Management, which is then applied to the institute as a whole, or to have it centred on the laboratory. Both authorities have laboratories, which have now obtained accreditation for measurements of radionuclides. The experience at STUK and NRPA has shown the procedure to be time consuming, but it has lead to a useful critical review of procedures leading to improvements, and improved documentation and reporting. This is an experience shared by many other laboratories.

In the end each laboratory needs to decide whether accreditation is worth the effort or not. The needs of a research laboratory may be different from those of a laboratory performing routine measurements for an authority. Accreditation may not be appropriate for a university research laboratory. But all laboratories can benefit from studying what steps are needed for accreditation and possibly meeting some of the requirements.

The references cited on the Web were correct at the time of writing and they were checked again before the report was published. Some may change, but it is usually possible to find the material in question again by using a Web search engine.

1. Introduction

Accreditation has received increased attention amongst Nordic laboratories measuring radionuclides in the environment and foodstuffs. The same can be said about Nordic authorities using these data. The reasons include:

- For some measurements accreditation has become a legal requirement in the EU. This can be found in the Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs, which requires 'Official Laboratories' to be accredited and to participate in appropriate proficiency testing schemes
- A laboratory may find it necessary to obtain accreditation as the number of accredited laboratories grows, just in order to get its results accepted (especially in international co-operation).
- A laboratory or institute may find accreditation useful for internal purposes, in its own quality assurance programme.

The debate on accreditation led to that it was taken up as a special topic within the EKO-3.2 sub-project in the 1994-1997 NKS project period, introduction to the process of accreditation was given and prototype quality and technical manuals written and distributed.

In the planning of the current NKS project period it was not considered necessary to take up again as a special topic a general introduction to accreditation of laboratories. A new debate started however within the current period. It was stimulated by statements that had been made by various people, indicating that a new international draft standard, the ISO International Standard Organisation) DIS (Draft International Standard) 17025, would make it easier for laboratories to obtain accreditation, while allowing more flexibility than was previously possible. This possibly new framework was judged to be relevant for Nordic laboratories and therefore it was decided to take this up as a topic within the BOK-1.1 sub-project in the current project period. The project could provide a forum for introducing to Nordic laboratories and discussing the possible effects of the new draft standard. The work has included presentation at a BOK-1.1 seminar in Skagen, Denmark, 23 August 1999; at the NSFS meeting in Skagen, 23-27 August same year (including an article in the proceedings of the meeting) and at a special BOK-1.1 seminar in Oslo on 27 March 2000. The development of the draft standard was however faster than expected. During the one year the project work spanned, the standard evolved from a draft standard to an approved standard, which now already forms the new basis for accreditation of laboratories.

It can be argued that the main value of this project work was to have drawn attention to the changing framework for accreditation of laboratories and to have provided a forum for introducing and discussing these changes while they were in the making.

Accreditation can be a legal requirement for a laboratory as well as a very useful tool for demonstrating quality of measurements. It requires, however, a lot of commitment and resources. Each laboratory must decide for itself if it should obtain accreditation. The aim with this report is to help in this decision process by summarising the dialogue on accreditation within the project during the changing status of the new ISO/IEC 17025 standard. The report is not meant as a guide on how to obtain

accreditation. References to some such sources are given and more can be found on the BOK-1.1 web site. Each laboratory considering accreditation should contact the accreditation body in its own country. Information can be obtained there about the accreditation process in general and specific national requirements (information is provided in the appendix to this report about how the accreditation bodies in the Nordic countries and the Baltic States can be contacted).

Accreditation means that factors that can affect the quality of laboratory results are kept under control in a defined way. These factors are outside the scope of a discussion on the accreditation process as such, but they are of great practical importance for laboratories preparing for accreditation. Reference is therefore included in this report to presentations on quality assurance which were given in association with the discussion on accreditation within the project (section 5.1).

The author is grateful to those who contributed to this report through discussions and comments, especially to Ágúst Þór Jónsson, a consultant on quality assurance and accreditation. All views put forward in this report are, however, the responsibility of the author.

For more information on the **NKS/BOK-1.1** sub-project on "Laboratory measurements and quality assurance", please visit the project's web site:

http://www.gr.is/bok-1.1/

For information about the **NKS** (Nordic Nuclear Safety Research), please visit the NKS web site:

http://www.nks.org/

This report is also available as a PDF file from the NKS web site and the BOK-1.1 web site as document:

http://www.gr.is/bok-1.1/accredit.pdf

The figures (e.g. in the Appendix) are there in full colour and may thus be easier to read than those in the printed version.

2. Accreditation and quantification of uncertainty

What is Accreditation?

Laboratory accreditation is a process where a third party recognises that:

- the laboratory meets requirements for developing, implementing and maintaining a quality system
- that it can demonstrate proficiency in conducting laboratory analyses

Through accreditation a laboratory can thus both demonstrate competence and that it can produce results of quality on a routine basis. The third party in the process mentioned above is the accreditation body. It evaluates the laboratory against requirements in an appropriate international standard (or standards) and laboratory specific requirements (e.g. for laboratories measuring radionuclides).

If a laboratory wants to begin the accreditation process, it must contact the accreditation body and obtain documentation. Then a baseline assessment must be conducted of what the present system of the laboratory contains and what improvements need to be made. The gaps so identified are included in an implementation plan. The system can then be evaluated before an accreditation assessment is scheduled.

Once a certificate of accreditation has been issued, the laboratory has the following obligation to the accreditation body:

- Maintenance fees must be paid
- The laboratory quality system must continue to meet requirements
- Periodic assessments or surveillances must be made on a scheduled basis
- The laboratory must respond promptly with corrective actions when needed
- The laboratory must use the logo of the accreditation body in a prescribed manner

Those interested in more information on the process of accreditation are advised to contact their national accreditation body. Information about international and national accreditation bodies can be found at the web sites sited below:

- International Laboratory Accreditation Cooperation - (ILAC)
  http://www.ilac.org/
- European Cooperation for Accreditation of Laboratories - (EAL)
  (formally WECC and WELAC)
  http://www.european-accreditation.org/
- A list of the EAL members in each country is accessible from the web site above at:
  http://www.european-accreditation.org/mla/member.html

Many documents are available for downloading from the EAL web site:
http://www.european-accreditation.org/documents.html
The following are examples of documents currently valid and that can be downloaded as PDF files:

- EA-4/02 Expressions of the Uncertainty of Measurements in Calibration (previously EAL-R2). *(Note: this is a mandatory publication, see also the reference to the EURACHEM/CITAC guide at the bottom of this page)*
- EA-4/05 Accreditation for Chemical Laboratories (with EURACHEM) (previously EAL-G4)
- EA-4/07 Traceability of Measuring and Test Equipment to National Standards (previously EAL-G12)
- EA-4/09 Accreditation for Sensory Testing Laboratories (previously EAL-G16)
- EA-4/10 Accreditation for Laboratories Performing Microbiological Testing (previously EAL G18)
- EA-4/12 Accreditation of Medical Laboratories (with ECLM) (previously EAL-G25)
- ILAC G2:1994 Traceability of Measurement

Some of the documents relating to the previous standard for accreditation of laboratories were formally withdrawn 31 December 2000. Even though the withdrawn documents have lost their formal significance, the information can still give a relevant insight into the accreditation process and the requirements. The following are examples of withdrawn documents that can be downloaded (with the exception of EA-4/06):

- EA-4/01 Requirements Concerning Certificates Issued by Accredited Calibration Laboratories (previously EAL-R1)
- EA-4/03 Requirements for the Accreditation of Laboratories and Organisations Performing Site Calibrations (previously EAL-R3)
- EA-4/04 Internal Quality Audits and Management Review for Laboratories (previously EAL-G3)
- EA-4/06 Interpretation of Accreditation Requirements in ISO/IEC Guide 25 and EN 45001 (with ECITC) (previously EAL-G5) *(Note: this document is not available for downloading)*
- EA-4/08 Accreditation for Non-Destructive Testing Laboratories (previously EAL-G15)
- EA-4/11 Calibration and Maintenance of Measuring and Test Equipment in Testing Laboratories (previously EAL-G19)
- EA-4/13 Guidance on the Application of EN 45001 and ISO/IEC Guide 25 to Electromagnetic Compatibility (EMC) Testing (previously EAL-G27)

Quantification of uncertainty

Proper quantification of uncertainty is important in quality assurance and essential for accreditation. For information on this the *ISO Guide to Expression of Uncertainty in Measurement* (ISO, Geneva, 1993) can be consulted. Another good source is the EURACHEM/CITAC guide *Quantifying Uncertainty in Analytical Measurement, The Second Edition (2000)*, which is available as a PDF file from the web site:

http://www.eurachem.bam.de/guidesanddocuments.htm

An indexed HTML version of the Guide can be obtained from the web site:

http://www.measurementuncertainty.org/

3. The new international standard ISO/IEC 17025

A new draft international standard, **ISO/IEC DIS 17025 -** ***General Requirement for the Competence of Testing and Calibration Laboratories*** had recently been issued when the project work began. This new standard was to replace the EN 45001:1989, which had been used as the basis for accreditation of laboratories in Europe. It was not clear, however, what changes might be made to the draft, how long this process might take and if the changed standard would be approved. The new draft standard had clearly various advantages over the previous one for laboratories in the process of seeking accreditation:

- The standard replaces EN 45001:1989 and ISO/IEC Guide 25:1990 and includes all the requirements of ISO 9001 and ISO 9002 that are relevant to the scope of testing and calibration services. By following this standard it becomes easier for a laboratory to set up a single quality system which meets the requirements for accreditation and certification based on the ISO 9001-2.
- The new standard is far more detailed than the EN 45001:1989. There is much less need for other documents giving advice on the implementation of the standard. The standard can actually be followed paragraph for paragraph when building up a quality handbook, using the same table of contents.
- The standard is structured in a similar way as other corresponding standards
- There are some differences in the new standard, compared with the previous one, that may make it easier for laboratories to adopt more flexible accredited procedures. Some aspects of the interpretation of the standard by the accreditation bodies will clarify as it is taken into use.

Evolution of standard during project period, from draft to final form

It should be noted that during the one year that the project work spanned, the status of the standard *General requirements for the competence of testing and calibration laboratories* evolved rapidly and it developed from a draft standard to an approved standard in use. The standard thus appeared in 3 forms:

- **ISO/IEC DIS 17025** Draft standard
- **ISO/IEC FDIS 17025:1999 (E)** Final draft standard submitted for voting
- **ISO/IEC 17025:1999** The approved standard in its final form.

This rapid development must be born in mind when reading about the developments and articles. When the dialogue started the standard EN 45001 formed the basis for work on accreditation and this new proposed standard seemed a futuristic framework for some. Now it has become the basis for accreditation and those laboratories which have already obtained accreditation according to the previous standard must in just over a year's time also comply with the requirements of the new standard. The dialogue on the changing framework for accreditation seems thus to have come at an appropriate time within the NKS project work.

The **final version** of the standard can be bought from the International Standards Organisation (ISO):
http://www.iso.ch/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=30239
The **draft version**, ISO/DIS 17025, can however at the time of writing be downloaded free of charge from the following web site:

http://www.quametec.com/ISONews.htm

(a link is also provided from the BOK-1.1 web site: http://www.gr.is/bok-1.1/). The difference between the draft version and the final version is minimal, but for defining standard requirements the official standard must be used.

Why use the new standard?

Before the standard was approved one might have asked why this new standard should be used instead of the existing EN 45001:1989? The answer is simple: after it has been adopted there will be no choice, quality manuals will in time have to be revised to meet the requirements of this new standard. It made good sense, however, to start using this standard right away because the standard in its structure is more modern and better harmonised with other related international standards.

The accreditation of laboratories has been based on the standard **EN 45001:1989** ***General criteria for the operation of testing laboratories***. The actual text of the standard is 9 pages. The brief text of the standard does not cover the actual requirements set by the accreditation bodies. The gap has to be bridged by:

- guidance documents
- services of consultants

The actual text of the new standard, **ISO/IEC 17025 -** ***General Requirement for the Competence of Testing and Calibration Laboratories,*** is 22 pages. It is thus far more detailed than the old EN 45001:1989. There is much less need for guidelines and consultants and it is possible to structure a quality manual directly on the standard.

Another advantage is that the new standard replaces **EN 45001:1989** and **ISO/IEC Guide 25:1990** and includes all the requirements of **ISO 9001** and **ISO 9002** that are relevant to the scope of testing and calibration services, that is the requirements for obtaining *accreditation* and *certification* (e.g. with respect to ISO 9001).

The third advantage is that the standard allows for somewhat more flexibility and the laboratories have a chance to comment on their results. How this will be implemented in praxis remains to be seen.

The structure of the new standard is shown on the next page. The same structure can be utilised when a quality manual is being written.

Requirement to comply with the new standard

After the NSFS meeting in August 1999, the Final Draft version of the standard was published, ISO/IEC FDIS 17025. The standard was also published as a Final Draft European Standard, prEN ISO/IEC 17025. The voting on the standard began on September 16th 1999 and was terminated on November 16th 1999. The outcome was that the standard was approved and it is now in use and forms the basis for accreditation of laboratories. By early 2002 all laboratories that have been accredited according to the old standard EN 45001 will have to meet the requirements of the new standard ISO/IEC 17025.

The standard, that seemed to some to be only of a theoretical interest at the beginning of the year 1999, forms already now the framework for accreditation of laboratories.

Contents of standard
ISO/IEC 17025 – GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

Contents

4. Preparing for accreditation - General advice

Informal interviews were conducted with representatives from institutes having obtained accreditation (or in the process of obtaining it) and consultants working in this field. The main conclusions are summarised below.

Those interviewed gave the general advice to have the scope of the accreditation limited in the beginning, and then expand as needed. The laboratory is a good place to start in an institute.

The work becomes much easier if the institute as a whole has a quality system which can be referred to (e.g. concerning dealing with complaints, records of training etc.).

Consultants can be of use, but the bulk of the work will need to be done by the people involved with the measurement procedures being accredited.

Many institutes and companies have made the mistakes of writing too elaborate quality manuals, which have then become far too cumbersome to use and maintain. Many of these quality manuals are now being trimmed down.

The high level of complexity of the work performed in many laboratories (even small ones) makes it nevertheless necessary to write detailed quality manuals. The comprehensive document control needed should not be underestimated. It is one of the biggest tasks in accreditation.

Writing the quality manuals is maybe not the most difficult task. It takes a lot of resources, but while it is being done it is usually given top priority. Maintaining, updating and distributing quality documents can be a very demanding task, especially since this procedure has to be done in accordance with strict document control rules.

A computerised document system can make the tedious work of creating, revising, issuing and distributing quality documents much easier. A fully developed document control system should be used (not a “home made” application). Databases for quality documents are commercially available. First a skeleton of the quality manual can be created. Already existing documents can then be put into place and new documents written as needed. Modern computer technology means that a description can take various forms. It can include text, sound, photographs and even videos. Different types of views can then be tailored into the document database for each type of user.

But probably the most important advantage of using a computerised document control system is that many of the formal procedures for maintaining quality documents can be built into the system. The system can ensure that all the tedious formalities concerning the revision process are adhered to and it is easy to ensure that every user has access to the updated versions of the documents.

5. The NKS/BOK-1.1 seminar on accreditation, Oslo, March 2000

The BOK-1.1 dialogue on quality assurance and accreditation was concluded with a seminar, held at the Norwegian Radiation Protection Authority, Oslo, on 27 March 2000. Attending were 27 participants from all the Nordic Countries and the three Baltic States.

The seminar was divided into three main sections:

- Quality of results of laboratory measurements
- Accreditation as a tool for demonstrating quality of laboratory measurements
- Possible follow-up work in the rest of the BOK-1.1 project period (+ suggestions for the next NKS project period)

Quality of results of laboratory measurements

Presentations and topics discussed:

- Quality of laboratory measurements - are there really any problems? Results from the EKO-1 and BOK-1.1 intercomparisons of laboratory analyses (Christian L Fogh / Sven P. Nielsen)
- Problems in gamma spectrometry - possible corrective actions (Seppo Klemola, Mika Nikkinen and Sigurður Emil Pálsson)
- Problems in radiochemical analyses, beta counting and alpha spectrometry
- Discussions: status of competence, identifying needs for improvements

Intercomparison exercises, in previous NKS periods and now in the present one, have shown considerable variation in analytical results, greater than would be expected from the stated uncertainties. The results of the BOK-1.1 intercomparisons have been presented in a separate report by **Christian L. Fogh**, NKS-19 *"NKS 1999 intercomparison of measurements of radioactivity"*. Many factors can contribute to this variability and understanding these factors is very important in order to improve the situation.

Seppo Klemola and Mika Nikkinen gave presentations on some of the issues which need to be addressed in order to obtain good quality results in gamma spectrometry. Copies of their overheads are in the Appendix to this report.

Seppo Klemola focused on background evaluation, nuclear data and geometries. The background is often poorly described and it can easily change with time. Proper knowledge of the background is essential for good results, especially when dealing with low-level samples. An example was given of using background control charts as a quality assurance tool.

A nuclear library contains a lot of information about energy and probability of various gamma rays, as well as half-lives of radionuclides. Often the data in these libraries have not been updated and in some cases the differences can be large enough to affect the results in a significant manner. As an example, 6 out of 103 radionuclides investigated required a change in half-life of 2 - 5%. 22 out of 583 gamma-ray probabilities needed a correction greater than 20%. Many of the gamma lines have stated uncertainties that are often not taken into account in the gamma spectrometric analysis.
There is no single correct answer for all applications concerning optimum sample and detector geometries. It is a function of:

- amount of sample material available
- sample density
- energy of interest
- size and shape of detector

Examples of the effects of these parameters were given.

Mika Nikkinen gave a presentation on quality assurance and gamma spectrum analysis. An example was given using the network of air filter stations currently being set up by the Comprehensive Nuclear-Test-Ban Treaty Organisation (CTBTO). Filters are changed and analysed once per day in each station and the spectra are sent to the CTBTO for analysis and evaluation. A very high degree of operational reliability is requested and a strict quality assurance (QA) system is essential for being able to have confidence in the results. Examples were shown of assessments of some key parameters that affect gamma spectrometric analysis. A good QA system can help to detect not only what has gone wrong, it can even point out developments which may or will lead to failures. An example was given of how a plot of the change with time of measured peak width could predict detector failure.

Mika's conclusions were:

- Proper quality assurance measurements and analysis can prevent false interpretations of the results
- The uncertainties in the measurement systems should be known
- Data evaluation can be used to predict forthcoming problems and to ensure measurement correctness
- Test data sets should be generated to test the analysis methods (both real and synthetic), intercomparisons for data analysis are also needed
- Routine tools are needed for the data evaluation

Accreditation - Demonstrating quality of laboratory measurements

Presentations and topics discussed:

- Introduction to quality assurance and accreditation (Ágúst Þór Jónsson)
- Obtaining accreditation for a laboratory measuring radionuclides - Experience at NRPA (Anne Lene Brungot)
- Obtaining accreditation for a laboratory measuring radionuclides - Experience at STUK (Seppo Klemola)
- Obtaining and maintaining accreditation - A case story from a high dose reference laboratory (Arne Miller, Risø)
- Discussion on the present and future use of accreditation for demonstrating laboratory competence

Ágúst Þór Jónsson (independent consultant) gave an introduction to accreditation as a tool for demonstrating quality of laboratory measurements. Copies of his overheads can be found in the Appendix. He began by stressing the need for understanding, and, when appropriate, using the terminology that has developed within the field of quality assurance. Just as in radiation protection, certain terms have been given a precisely defined meaning. Using these terms like in everyday language can therefore lead to misunderstandings when communicating with experts in quality assurance. A brief explanation of the terminology was given with reference to the ISO 8402 standard

- **Accreditation**
  Formal recognition that a testing laboratory, certification body or an inspection body is competent to carry out specific tests, certifications or inspections. Accreditation is not branch orientated.
- **Test**
  Technical operation that consists of the determination of one or more characteristics of a given procedure.
- **Certification**
  Action by a third party, demonstrating that adequate confidence is provided that a duly identified product, process or service is in conformity with a specific standard or other normative document.

- **Inspection**
  Examination of a product design, product, service, process or plan, and determination of their conformity with specific requirements, or on the basis of professional judgement general requirements.

Accreditation can be useful both from the national and international point of view:

International Aspects

International trade

Tool for establishment of Mutual Recognition of Tests Inspection and Certification

National Aspects

Regulatory purposes

Assessment and establishment of competence of bodies performing technical control activities

Health care sector

A reference was made to the main standards that form the framework of quality assurance of relevance for laboratories. The criteria set in standards for the operation and competence of a testing laboratory were described, both according to the "old" EN 45001 standard and the new ISO/IEC 17025. Finally, the process of accreditation was described. It involves a number of steps:

- Information
- Application
- Examination
- Assessment
- Report
- Corrections
- Decision of accreditation
- Contacts, reports etc
- Surveillance

To the question if accreditation is a valuable tool for a laboratory, Ágúst gave two answers:

- For quality assurance in **routine testing: Yes**
  It is the only internationally recognised methodology for the assessment of competence of laboratories, based on international standards
- For quality assurance in **fundamental research**: **No**
  Fundamental research is by definition an act of innovation and not limited to predefined testing, certification or inspection.

It therefore remains the responsibility of the laboratories to define their role and needs, and to what degree quality assurance is of relevance for them. It is clear, however, that some form of quality assurance is highly relevant for every laboratory.

Seppo Klemola described the experience at STUK from obtaining accreditation for a laboratory measuring radionuclides. Copies of these overheads are in the Appendix of this report. The STUK quality system is based on Total Quality Management (TQM) and forms the basis for the laboratory manuals. The structure of the quality manual of the research department was described as well as the manual for gamma spectrometric sample measurements. Accreditation was applied for on 21 December 1998 and the certificate was obtained within a year, on 17 December 1999. Seppo summarised his current feelings on having obtained accreditation:

- the work on quality assurance is not finished, it is just starting
- a lot of useful documents have been created for workers (instructions, procedures), institute (ensure continuation) and customers (evaluation).

- improved understanding of critical stages of analysis
- training, competence register has been set up
- format of reports has been standardised

Obtaining accreditation has involved much work for STUK, but clear benefits have also been obtained. Basing the quality system on TQM meant that the whole of the institute was actively involved in the process. The total work was therefore more than if just the laboratory had established a quality system. The work for the personnel of the laboratory was, however, less.

Anne Lene Brungot described the process of obtaining accreditation for measurements of radionuclides at the Norwegian Radiation Protection Authority's (NRPA) radionuclide laboratory. This process has involved much work (but also benefits) and was still ongoing at the time of the seminar. The NRPA has subsequently obtained accreditation for the laboratory (in September 2000).

Arne Miller described the experience of obtaining accreditation at the high dose reference laboratory at Risø. Many of the practical issues concerning obtaining accreditation and maintaining a quality system are the same as for laboratories measuring radionuclides.

6. Conclusions

An important part in preparing for accreditation is understanding what can go wrong in a measurement and being able to control and quantify the uncertainties. Intercomparison exercises repeatedly show that even for gamma-spectrometrical analysis laboratories report results with apparent errors which cannot be explained by the stated uncertainties. Laboratories need to get the various sources of error under control and quantify them correctly before proceeding towards accreditation. Some of these sources are well known (density and geometrical corrections), others less so (errors and uncertainties in nuclear data libraries). Some factors can become a problem under certain conditions or for some nuclides (e.g. coincidence summing, background estimation for low-level samples).

If accreditation is to be obtained, then a decision has to be made whether a quality system is to be built up around the laboratory or total quality management for the whole of the institute. Each approach has its advantages and disadvantages. Basing it on the laboratory will mean less work for the institute as a whole, but much more work for the personnel of the laboratory.

The interest in this topic has been clearly manifested amongst Nordic laboratories. Baltic laboratories have also participated in this work and stated that for them, quality assurance is very important. Accreditation is the formal way in which a laboratory working in a new field can obtain recognition.

In the end each institute/laboratory must decide for itself whether obtaining accreditation justifies the use of time and resources required. A laboratory serving an authority will no doubt feel a stronger need than a research laboratory at a university. Accreditation may not be needed for a laboratory and if it is needed, it may just be needed for a limited set of procedures. It is however clear that in many fields accreditation is increasingly being used as a measure of if results submitted by a laboratory are acceptable to others (e.g. in international co-operation). The pressure of obtaining accreditation is also growing as more and more laboratories obtain it.

It is clear that the dialogue on quality assurance must continue amongst laboratories measuring radionuclides and measures sought for improvement and demonstrating quality of measurements. NKS could have an important role in keeping this dialogue alive, whatever format is chosen.

Appendix 1. Contact information for accreditation bodies in the Nordic countries and Baltic States

This information is taken from the EAL web site listing member organisations in each country: http://www.european-accreditation.org/mla/member.html

Danish Accreditation, DANAK
attn. Vagn Andersen
Danish Agency for Trade and Industry
Dahlerups Pakhus
Langelinie Allé 17
DK-2100 COPENHAGEN
DENMARK
http://www.danak.dk
Phone +45 35 46 62 10
Fax +45 35 46 62 02
e-mail: va@efs.dk

Finnish Accreditation Service, FINAS
attn. Tuulikki Hattula
Centre for Metrology and Accreditation
P.O. Box 239
FI-00181 HELSINKI
FINLAND
http://www.mikes.fi/finas/english
Phone +358 9 616 761
Fax +358 9 616 7341

Icelandic Board for Technical Accreditation, ISAC
attn. Sigurlinni Sigurlinnason
Löggildingarstofa
P.O. Box 8240
IS-128 REYKJAVIK
ICELAND
http://www.ls.is
Phone +354 510 1100
Fax +354 510 1101
e-mail: sigurlinni@ls.is

Norwegian Accreditation, NA
attn. Gro Rodland
Justervesenet
Fetveien 99
NO-2007 KJELLER
NORWAY
http://www.justervesenet.no/na
Phone +47 64 84 84 84
Fax +47 64 84 84 85
e-mail: norsk.akkreditering@justervesenet.no

Swedish Board for Accreditation and Conformity Assessment, SWEDAC
attn. Katarina Wenell
Box 878
SE-501 15 BORÅS
SWEDEN
http://www.swedac.se
Phone +46 33-17 77 00
Fax +46 33-10 13 92
e-mail: katarina.wenell@swedac.se

Estonian Accreditation Centre, EAK
attn. Viktor Krutob
Aru 10
EE-10317 TALLINN
ESTONIA
Phone +372 602 1801
Fax +372 602 1806
e-mail: viktor@evs.ee

Latvian National Accreditation Bureau, LATAK
attn. Janis Mikelsons
157, Kr. Valdemara St.
LV-1013 RIGA
LATVIA
http://www.latak.apollo.lv
Phone +371 7 37 3051
Fax +371 7 36 2990
e-mail: mikelsons@latak.apollo.lv

Lithuanian National Accreditation Bureau, LA
attn. Irena Mikelioniene
T. Kosciuskos 30
2600 VILNIUS
LITHUANIA
Phone +370 2 23 61 38
Fax +370 2 23 61 53
e-mail: laccr.bureau@ip.lt

Appendix 2. Overheads from presentations at accreditation seminar in Oslo, 27 March 2000.

Quality in gamma-ray spectrometry (Seppo Klemola);
Quality assurance and gamma spectrum analysis (Mika Nikkinen);
Accreditation as a tool for demonstrating quality of laboratory measurements (Ágúst Þór Jónsson);
Obtaining accreditation for a laboratory measuring radionuclides - Experience at STUK (Seppo Klemola)

The material provided as overheads by the authors has been reformatted for use in this report.

Some of the figures, which were originally in colour, have been reproduced here in black and white. This report can be downloaded as a PDF file with all figures in original colours from the NKS website:

http://www.nks.org/

and currently also from the NKS/BOK-1.1 website:

http://www.gr.is/bok-1.1/

Quality in gamma-ray spectrometry

Experiences on

- Background evaluation
- Nuclear data
- Geometries

Seppo Klemola / STUK
OSLO 27.3.2000

Draft for International Standard IEC 45/430CDV:

Test methods for spectrum background in HPGe nuclear spectrometry

Uniform BG spectrum description

- all counts that do not come from the sample
- statistical uncertainty appr. 5% (1σ) at the region of 100 keV $\Rightarrow$ number of counts ≥ 400 per channel
- equations for continuum and peaks

External background can be seriously affected by:

- geographical location
- shielding materials, thicknesses and geometry
- date and time
- weather conditions
- duration of the measurement
- airborne activity
- ventilation of the counting room

- any results derived should have all of the measurement details described

BG consists of two parts:

- the smooth or non peak BG
  - major factor in the MDA
  - averaged over a region centered at the stated energy with width 5 x FWHM
  - counts / keV / 1000 s
- the full energy peaks of nuclide specific gamma rays
  - can mask the presence of these nuclides in the sample
  - calculated as gross counts in a region 3 x FWHM - baseline in the same region
  - baseline determined by below and above the peak regions (3 - 1,5 x FWHM)
  - counts/1000 at the peak energy

ANNEX A

List of common peak energies

The Components of the Background

U-238	E /keV
↓	
Th-234	63.3
	92.6
↓	112.8
Pa-234m	766.4
↓	**1001.0**
Ra-226	**186.2**
↓	
Rn-222	
↓	
Pb-214	53.2
	242.0
	295.2
	351.9
	786.0
Bi Kα_1	77.1
↓	
Bi-214	609.3
	665.5
	768.4
	806.2
	934.0
	1120.3
	1155.2
	1238.1
	1280.6
	1401.5
	1408.0
	1509.2
	1729.6
	1764.5
	1847.4
	2118.5
	2204.2
↓	2447.7
Pb-210	**46.5**

Th-232	E /keV
↓	
Ac-228	99.5
	129.1
	209.3
	328.0
	338.3
	463.0
	755.3
	772.3
	795.0
	835.7
	911.2
	964.8
	969.0
	1588.2
	1630.6
Th Kα_1	93.4
Th Kα_2	90.0
Th Kβ	105.3
↓	
Ra-224	241.0
↓	
Pb-212	238.6
	300.1
Bi Kα_1	77.1
↓	
Bi-212	727.2
↓	785.4
	1620.6
Tl-208	277.4
	583.1
	763.1
	860.5
	2614.5
Tl-208 S.E.	2103.5

The Components of the Background (cont'd)

U-235	E /keV
↓	109.2
	143.8
	163.1
	185.7
	202.1
	205.3
Th $K\alpha_1$	93.4
Th $K\alpha_2$	90.0
↓	
Th-231	25.6
	81.5
	84.2
↓	
Pa-231	27.4

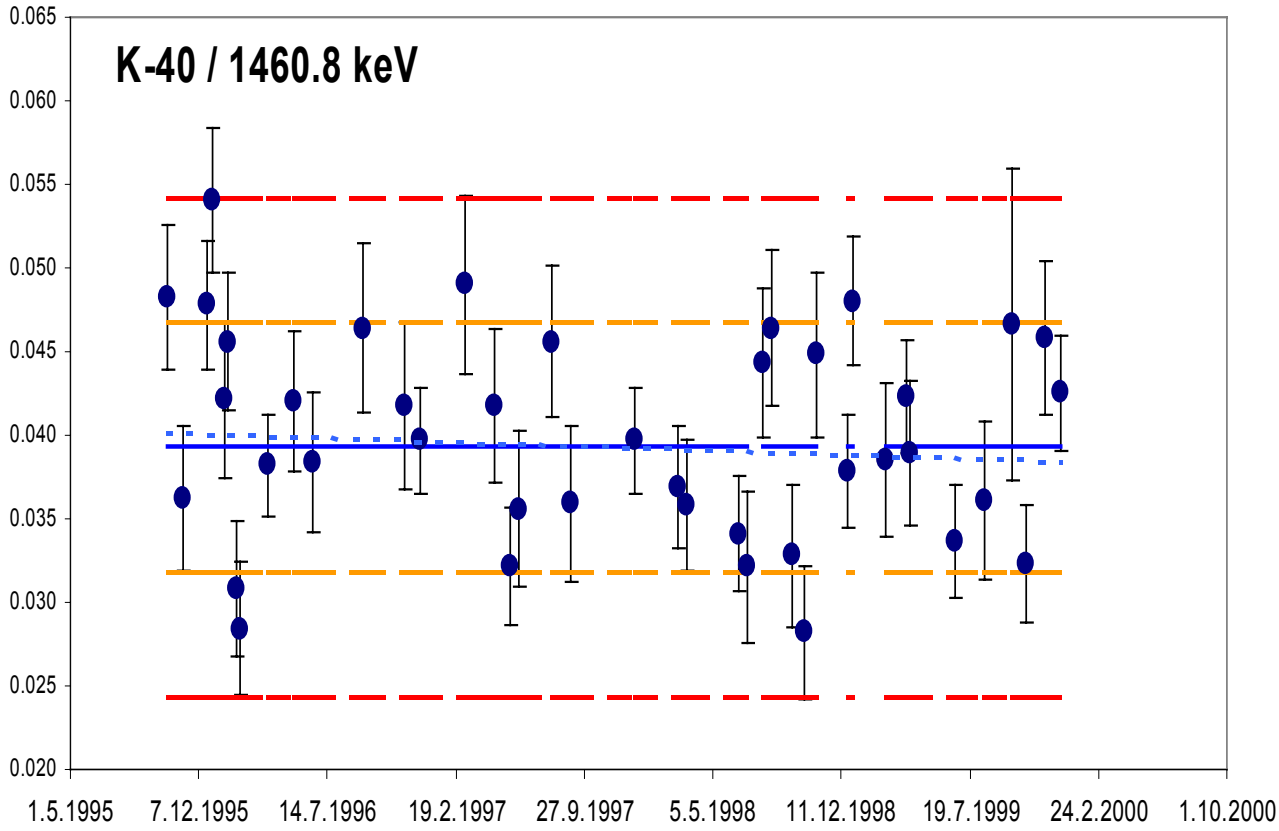
Cosmic radiation	E /keV
Cd-114* (^{113}Cd(n,γ))	558.5
Ge-71m (^{70}Ge (n,γ))	198.4
Ge-73m (^{72}Ge(n,γ))	53.4
Ge-73m (^{72}Ge(n,γ))	66.7
Ge-75m (^{74}Ge(n,γ))	139.9
Ge-77m (^{76}Ge(n,γ))	159.7
Pb-207 (Pb(n,γ))	569.7
Pb-207 (Pb(n,γ))	1063.6
Pb-206* (^{206}Pb(n,n'))	803.0

X-rays	E /keV
Pb $K\alpha_1$	75.0
Pb $K\alpha_2$	72.8
Pb $K\beta_1$	84.9
Pb $K\beta_2$	87.3

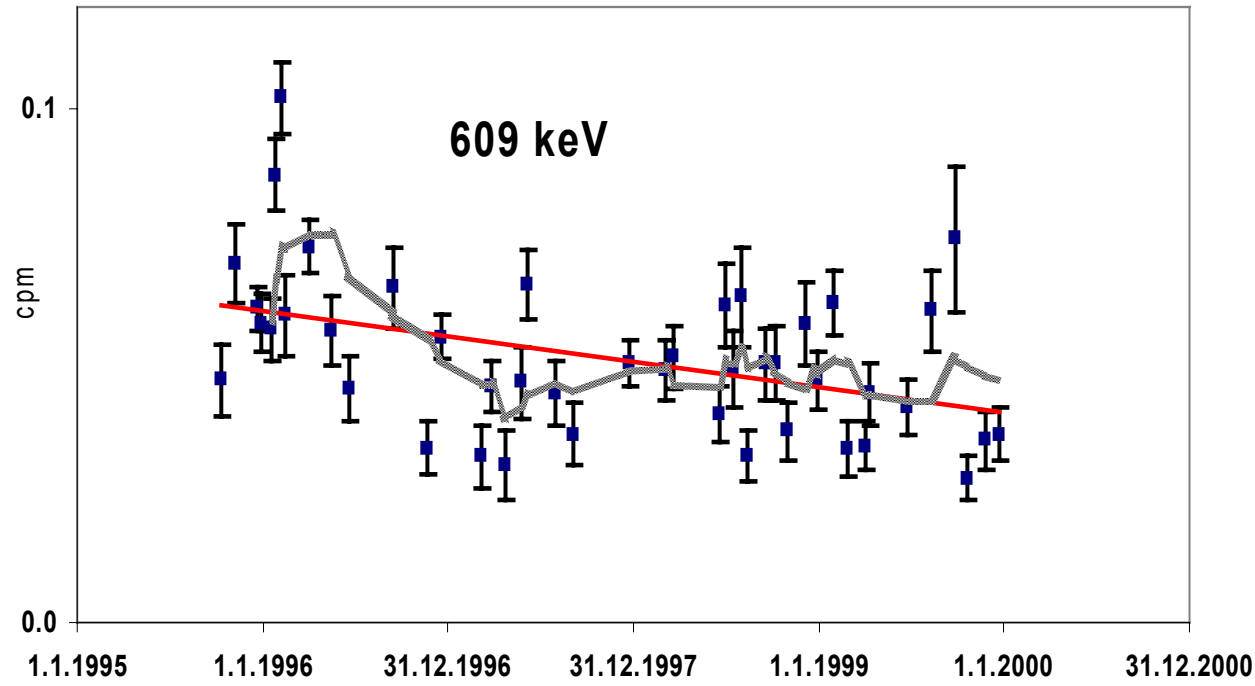
K-40		1460.8
Annihilation		511.0
Contamination		
	Cs-137	661.7
	Co-60	1173.2
		1332.5

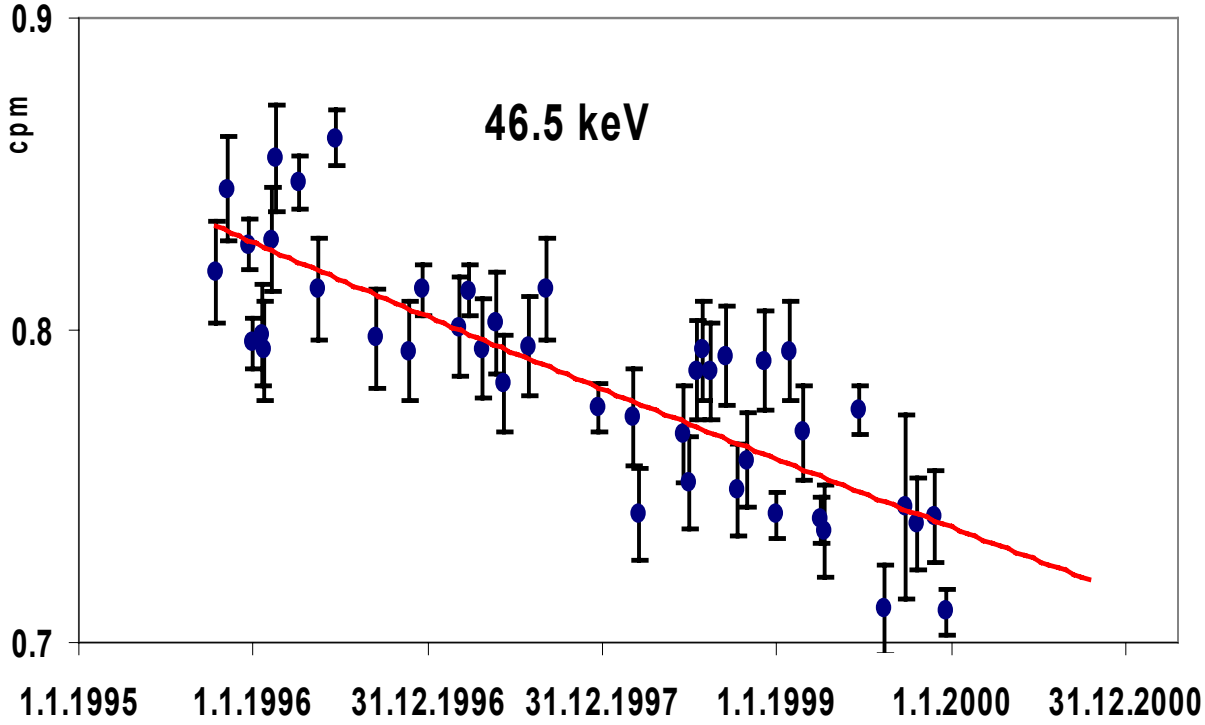
BACKGROUND CONTROL CHARTS

- Application of action limits (2-3σ)
- Different behaviour of various BG components
  - considered as stable
  - variable: monotonous, cyclic, irregular
- Separate update frequency



Examples of BG charts





Nuclear Data –
Experiences on updating a nuclide library

- Library:
  - 103 nuclides
  - 583 gamma energies
  - 'age' ~15 years
- Updated to Table of Isotopes, 8th ed., 1996
- Change in half-live 2 - 5%: 6 out of 103
  - e.g. ^{109}Cd: 453 d $\rightarrow$ 463 d
- Change in gamma ray probability
  - > 5%: 106 out of 583
  - > 10%: 47
  - > 20%: 22
  - e.g. ^{140}Ba 537keV 19.9 $\rightarrow$ 24.4

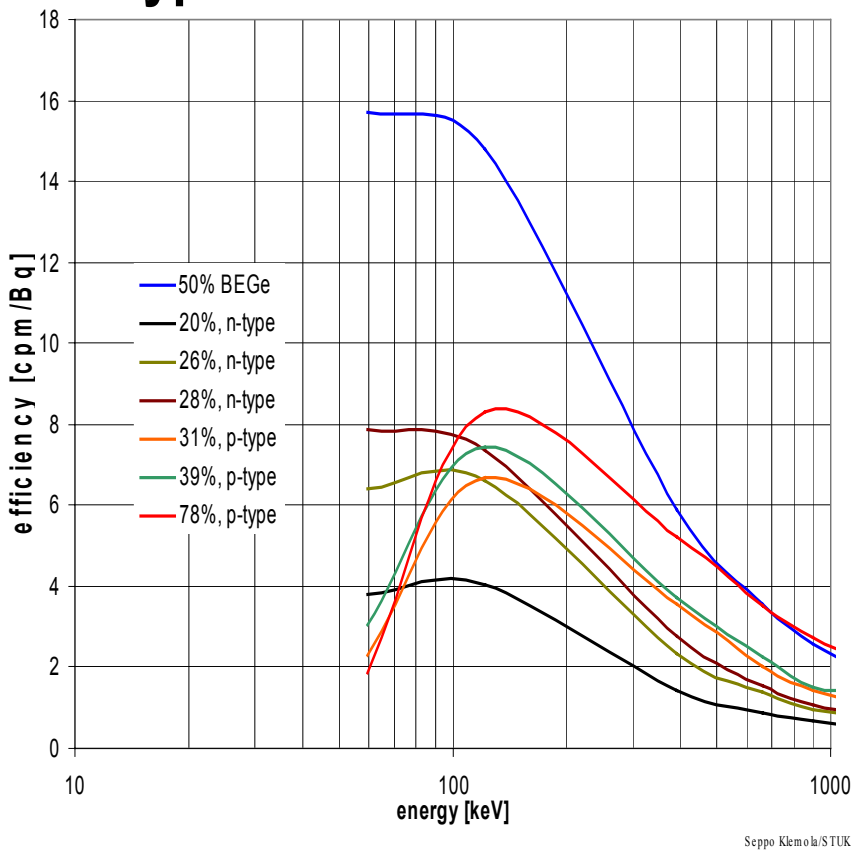
UNCERTAINTIES OF GAMMA- RAY EMISSION PROBABILITIES

Uncertainty	> 5 %	113 out of 698
	> 10%	38 -"-
	> 20%	9
e.g.:		
^{59}Fe		2.5 - 2.7%
^{109}Cd	88 keV	2.5%
^{131}I	average	1.1%
^{132}I	"	8.2%
^{133}I	"	2.4%
^{134}I	"	4.5%
^{135}I	"	2.1%

OPTIMUM SAMPLE AND DETECTOR GEOMETRIES

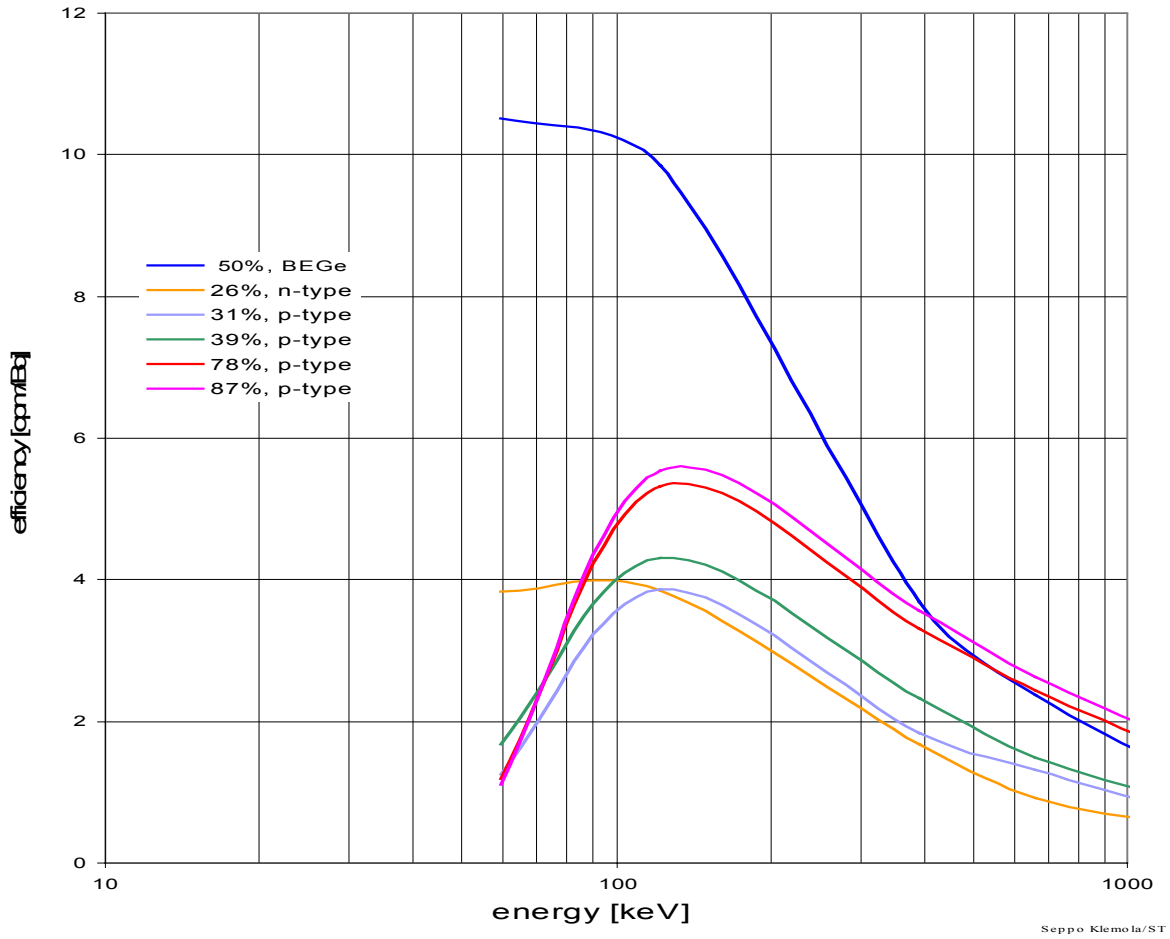
- No single correct answer for all applications
- Function of
  - amount of sample material available
  - sample density
  - the energy of interest
  - **the size and shape of the detector**
    - relative efficiency is poor measure of detector's performance
      - 1332 keV
      - point source at 25 cm
    - BG ~ volume of a det. crystal
    - MDA ~ √BG

Full peak efficiencies of detectors of different type and size

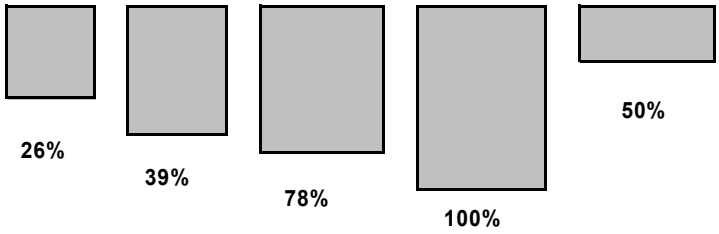


sample: diam. 42 mm, height 12 mm, on top of the detector end cap

Full peak efficiencies of detectors of different type and size



sample: diam. 74 mm, hgt 19 mm, on top of the detector end cap



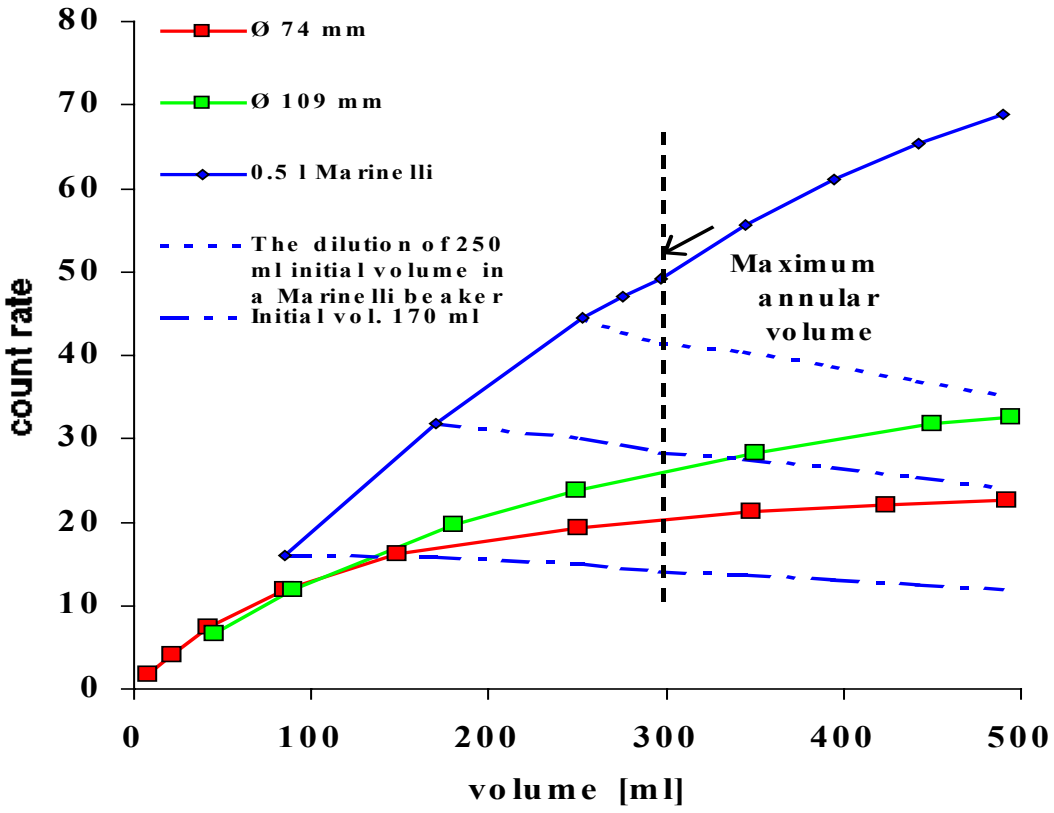
Efficiency vs. count rate

Efficiency as cnts/γ decreases as sample

- diameter increases
- thickness increases
- density increases

but efficiency as cnts/(γ/g) <u>increases</u> until it reaches a constant or near-constant value

'massemetric efficiency calibration'



Quality assurance and gamma spectrum analysis

Mika Nikkinen
Finland

Quality assurance and gamma spectra analysis

- Definition of quality is not unequivocal
- International standards (ISO9000, 17025) and certification bodies are used to harmonize the results, but they are not touching the core of the analysis
- The highest possible accuracy is not good enough, if the result is not **traceable** or **repeatable**
- Measurement of the quality: evaluation **metrics**
- Need for **tools** to ensure the quality on day to day operations

General problems with gammaspectrometry

- The measurement is not understood, significant factors like accuracy of the sampling, sample geometry, calibration or summation corrections are often forgotten
- There is a lack of routine tools to verify these factors
- Analysis method itself can be causing unclear uncertainties

Calibrations and QA metrics

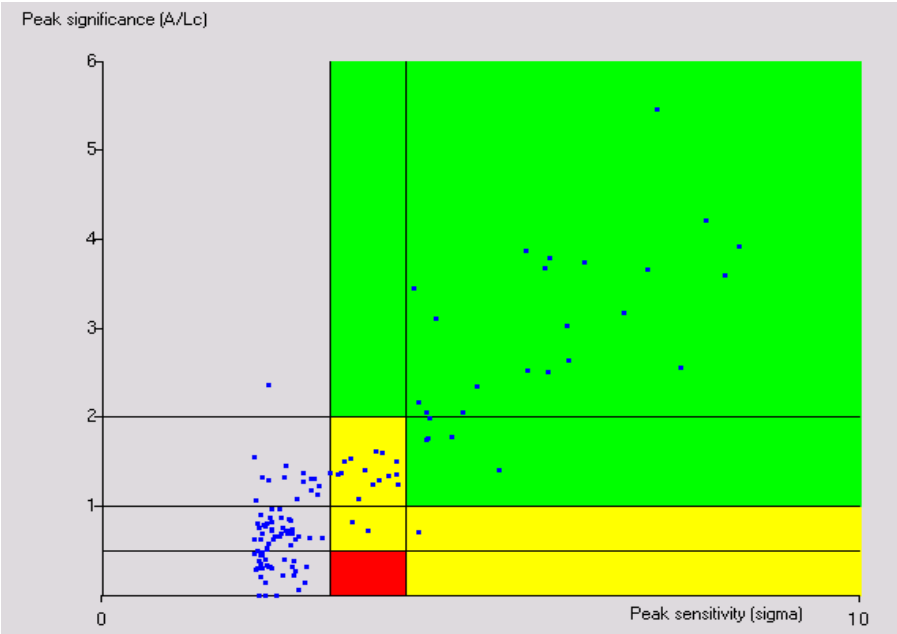
- **Daily measurement cycle of a laboratory:**
  - QA measurement with std. Calibration source, (5-15 min)
  - Sample measurement 3h
  - Sample change
  - Sample measurement 3h
  - Sample change
  - Overnight measurement
- **QA measurement:**
  - Energy calibration, measure the shift of the peak locations
  - Peak FWHM calibrations, measure the peak width changes
  - Peak Efficiency calibrations, the assumed calibration nuclide activity vs. the measured one; measure the co-incidence correction factors and see the correlation of the multi-line gamma emitter peaks vs. the actual calibration

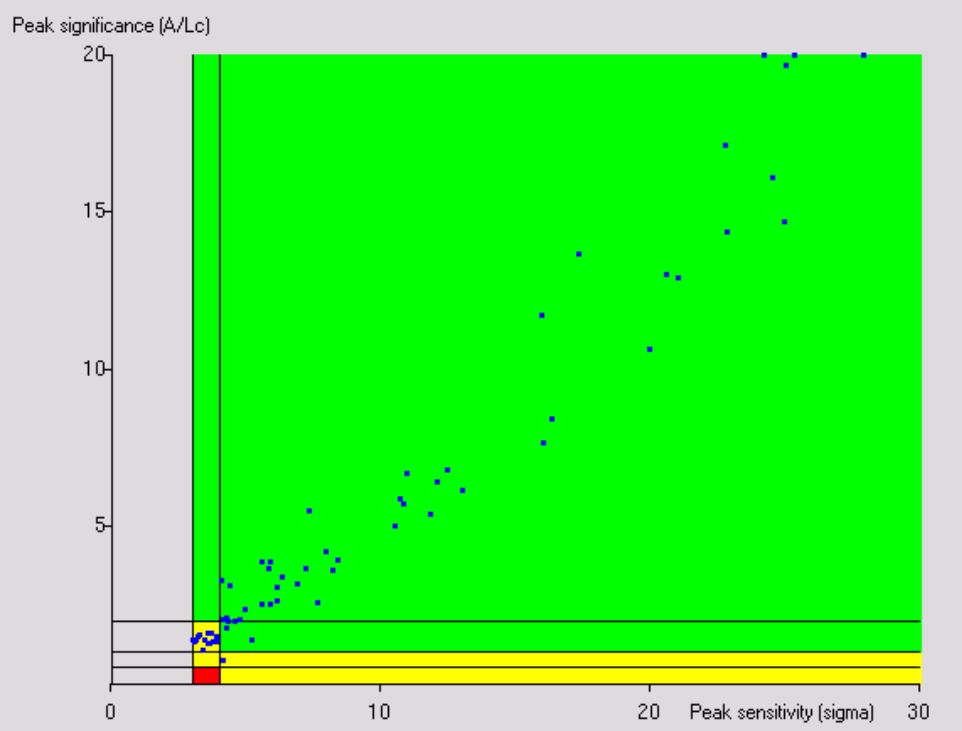
An example on QA measurement report, Cs-137 source was changed to show the difference (NaI detector)

```
SAMPO, 1999 PA,MN,JR.          Version 4.05
2000-Mar-22     14:58:18

*** Q U A L I T Y    A S S U R A N C E    R E P O R T ***
Spectrum               NAI-QA
Start of counting      2000-Mar-22     14:32:31
End of counting        2000-Mar-22     14:37:31
Live time (s)          299.7
Real time (s)          300.0
Dead time (%)          0.1
Search thr. (sigma)    4.0


********** PEAK ENERGY CALIBRATION ***********
Nuclide  Energy        Peak Difference    Estimation
Cs-137    661.6      661.92     0.32      OK
Co-60    1173.2     1171.97     1.23      OK
Co-60    1332.5     1333.46     0.96      OK


********** PEAK EFFICIENCY CALIBRATION **********
Nuclide  Energy   Efficiency              Estimation
Cs-137    661.6      125.00              FAIL
Co-60    1173.2       96.46              OK
Co-60    1332.5       97.16              OK


********** PEAK SHAPE CALIBRATION **********
Nuclide  Energy        FWHM  Measured     Estimation
Cs-137    661.6       64.49     66.53     OK
Co-60    1173.2       64.73     68.32     OK
Co-60    1332.5       65.73     65.64     OK
```

How small sign in a spectrum is a signature of a radionuclide?

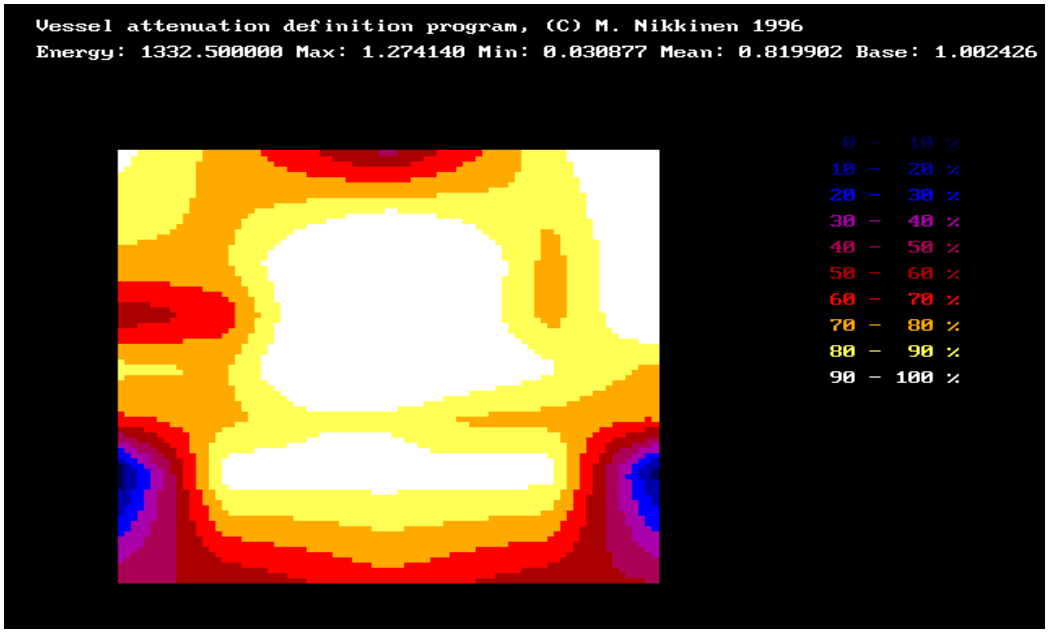
- MDA calculations required
- Some of the peaks are still spurious
- Significance vs. sensitivity: example on 2.0 and 3.0 sigma peak search sensitivity:

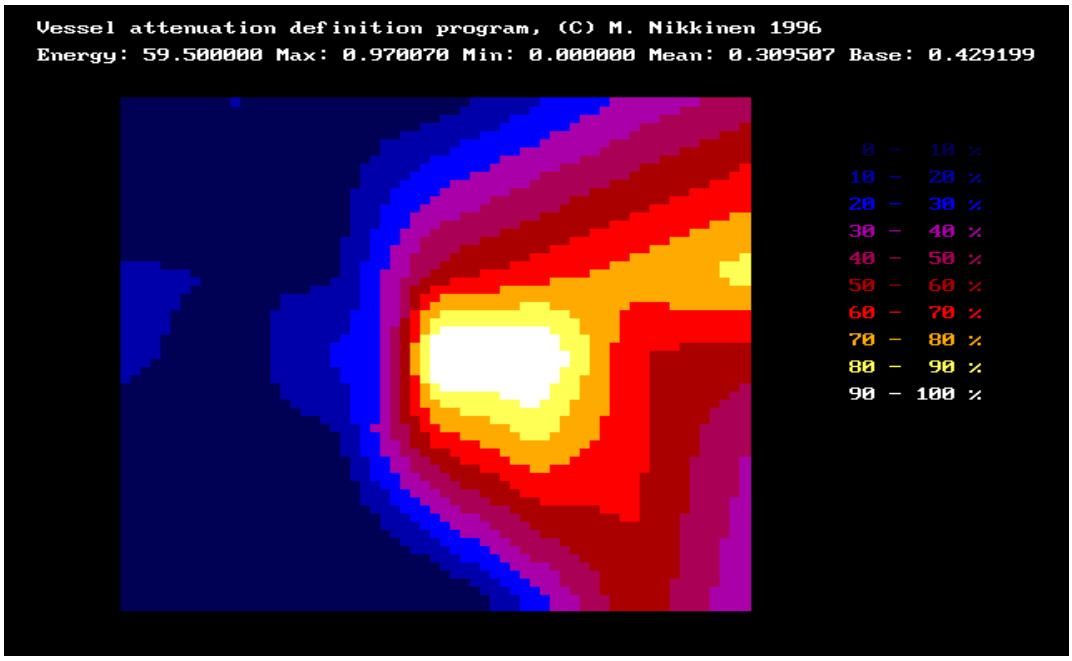




Sample geometry

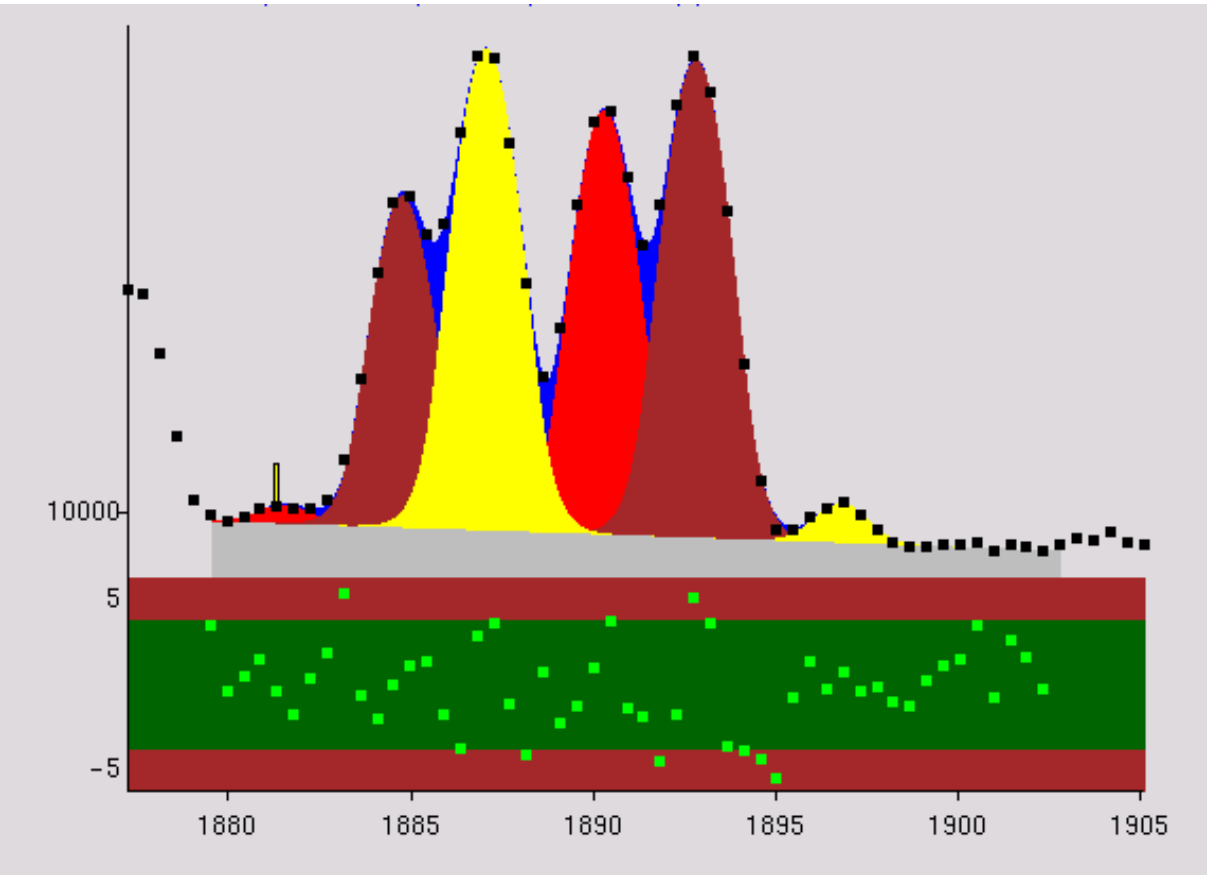
- Uncertainties have to be known
- Sample should be as homogenous as possible
- Sometimes the measurements has to be performed with difficult geometries, in that case the uncertainties should be measured:





Accurate methods including correct error estimates

- Peak location
- Peak area quantification
- Nuclide Identification
- Activity calculation
- Test the methods using both synthetic and real spectra

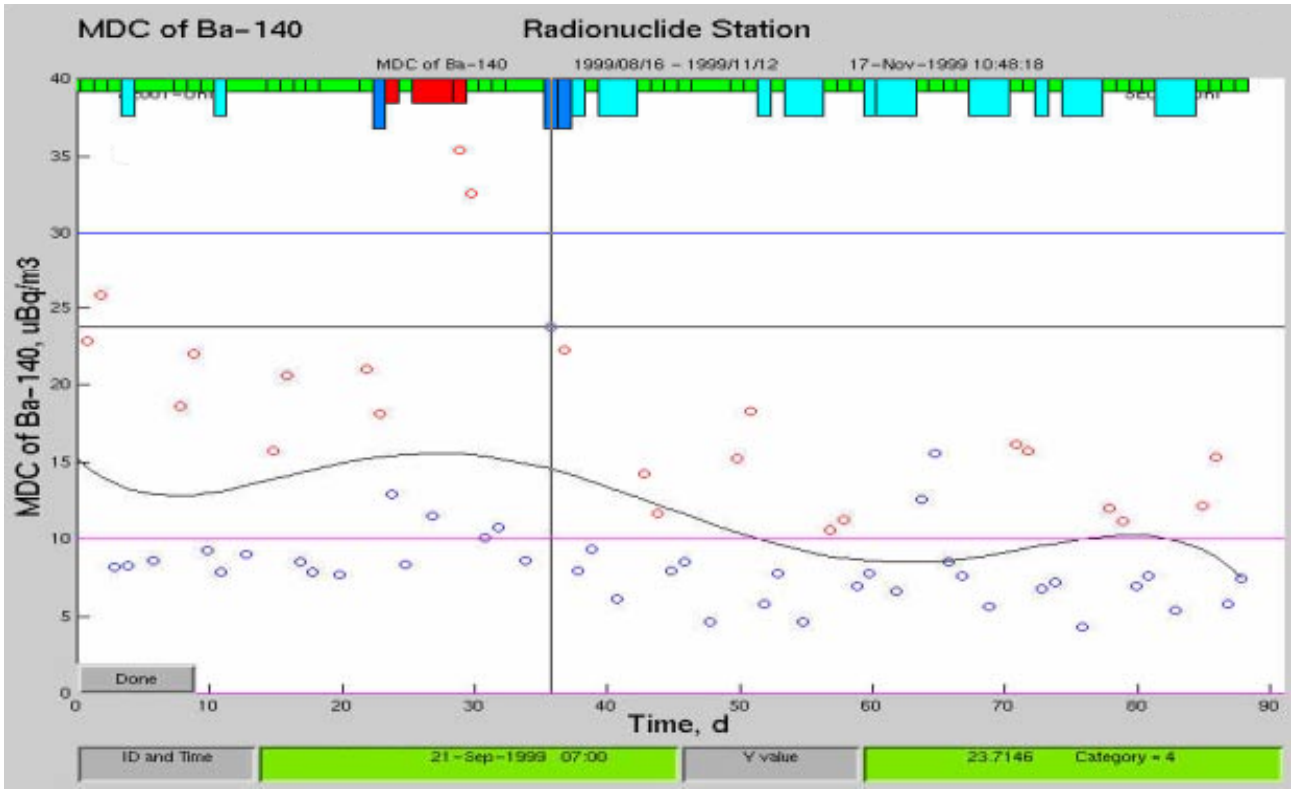


A Chernobyl sample analysed with UniSAMPO

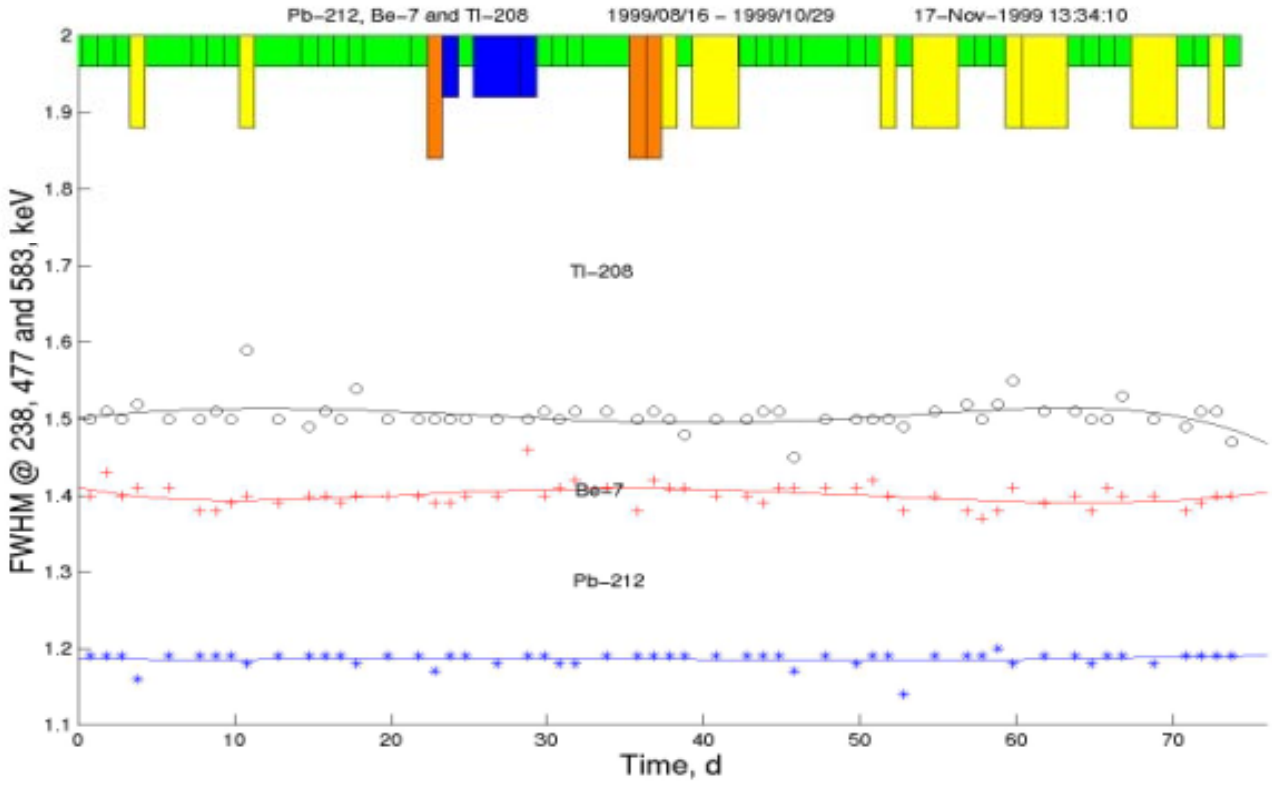
Experience with CTBT spectra

- Comprehensive Nuclear-Test-Ban-Treaty
- 80 air-filter sampling stations and 16 laboratories, the data was open for everybody to the end of February 2000.
- Daily operations, ~24h measurement + QA
- Data centrally collected and analyzed
- Evaluation of the data with Eeva (Harri Toivonen, CTBTO)
- National Data Centre evaluation

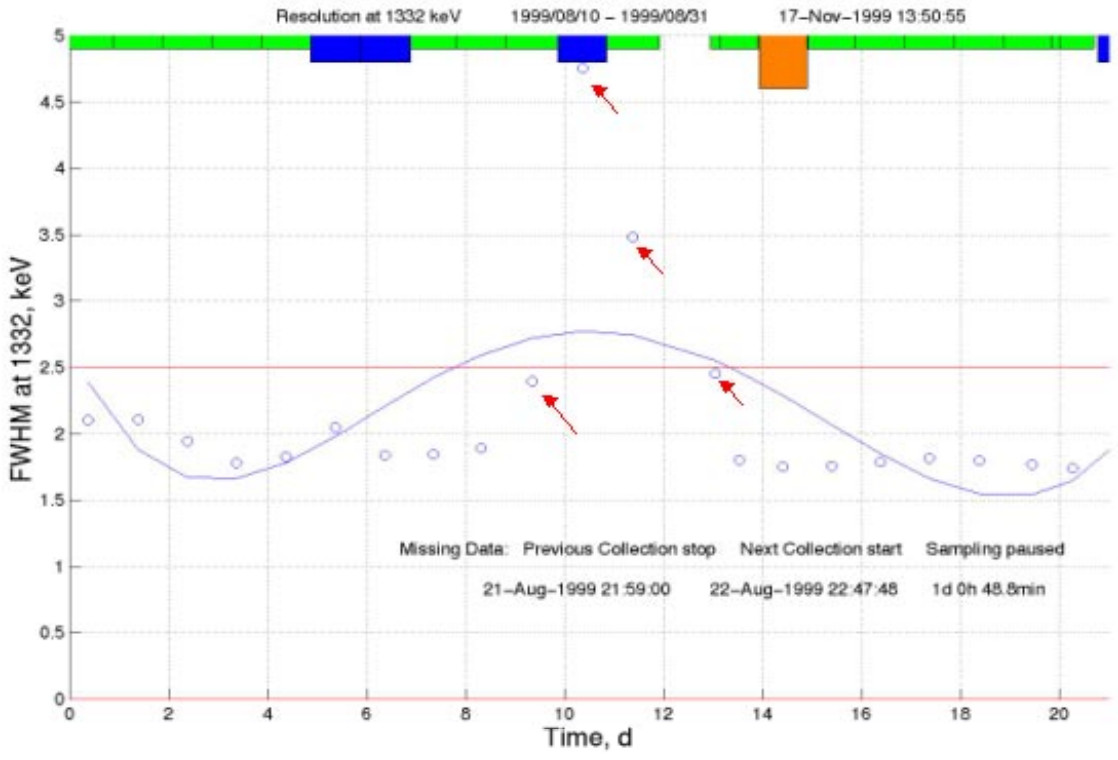
Detection capability plot



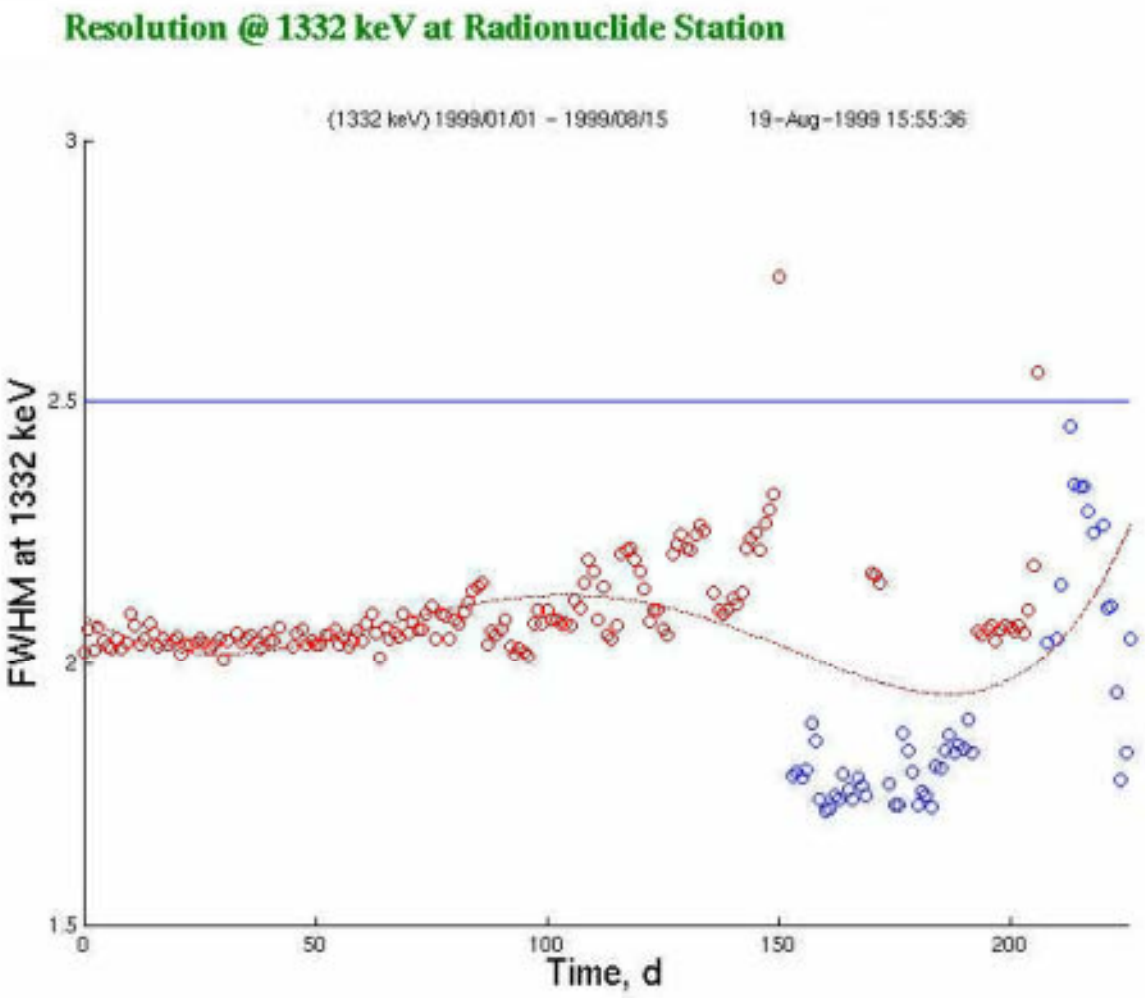
FWHM plots



Resolution plot /w problems



FWHM plot predicting detector failure



Conclusions

- Proper QA measurement and analysis can prevent false interpretations of the results
- The uncertainties in the measurement systems should be known
- Data evaluation can be used to predict forthcoming problems and to ensure measurement correctness
- Test data sets should be generated to test the analysis methods (both real and synthetic), intercomparisons for data analysis is also needed
- Routine tools are needed for the data evaluation

Accreditation as a tool for demonstrating quality of laboratory measurements

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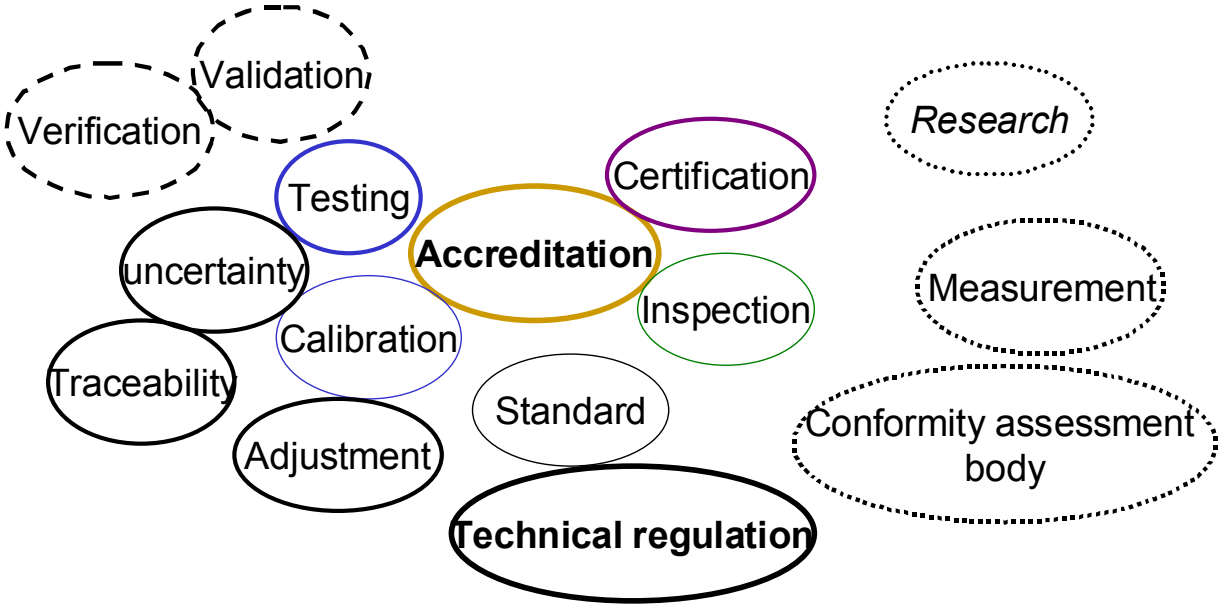
Tel: +46 70 322 8027

Definitions



Definitions (ISO 8402)

Accreditation

Formal recognition that a testing laboratory, certification body or an inspection body is competent to carry out specific tests, certifications or inspections. Accreditation is not branch orientated.

Test

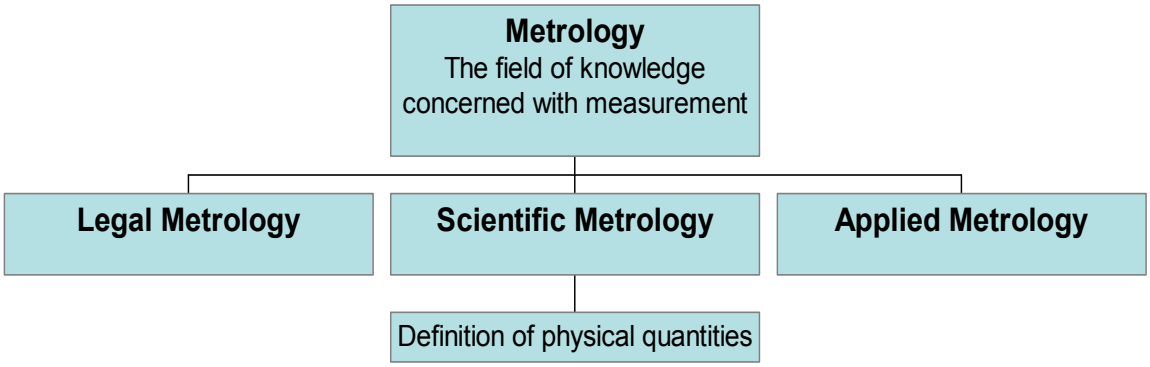
Technical operation that consists of the determination of one or more characteristics of a given procedure.

Certification

Action by a third party, demonstrating that adequate confidence is provided that a duly identified product, process or service is in conformity with a specific standard or other normative document.

Inspection

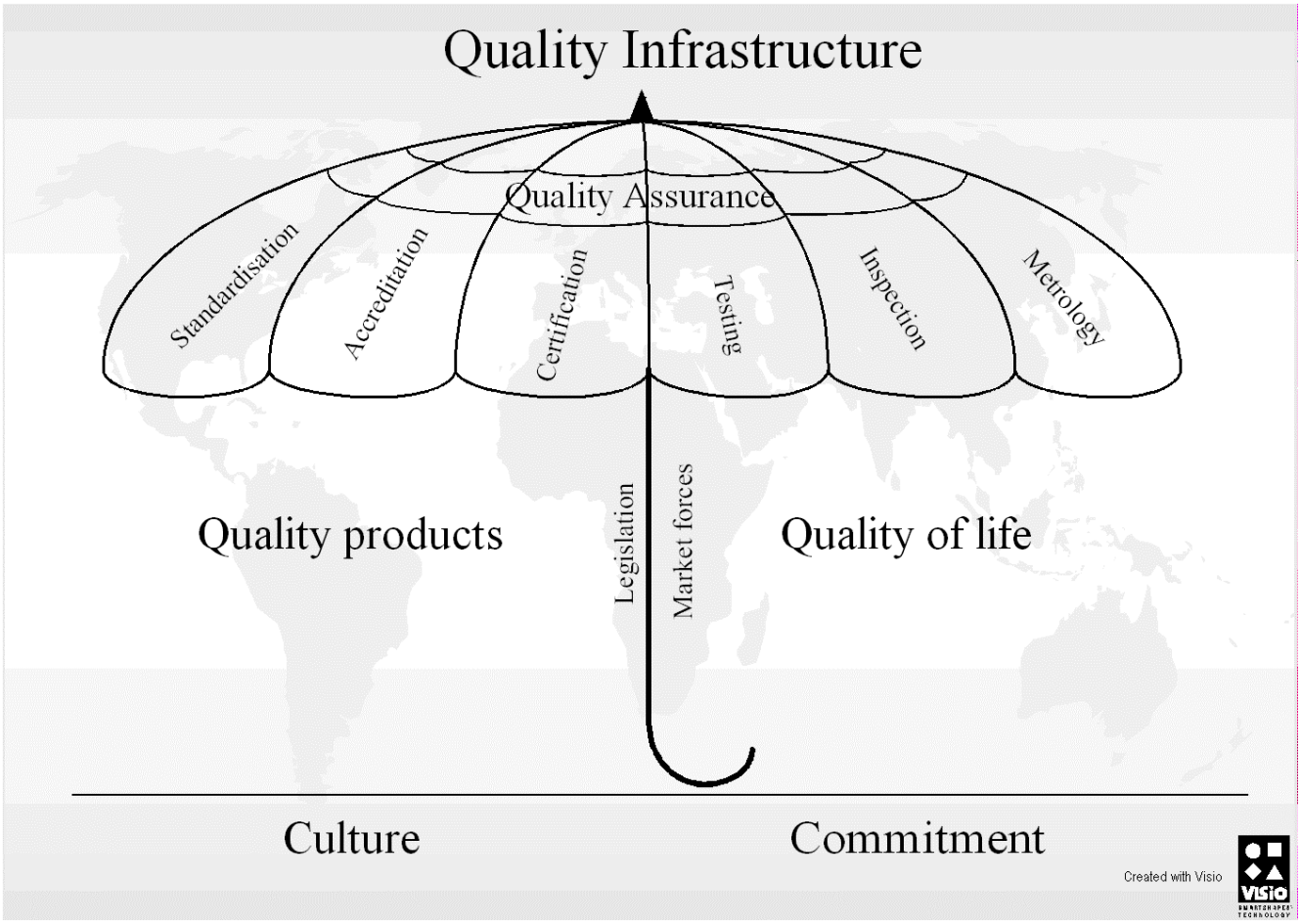
Examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements, or –on the basis of professional judgment-general requirements.



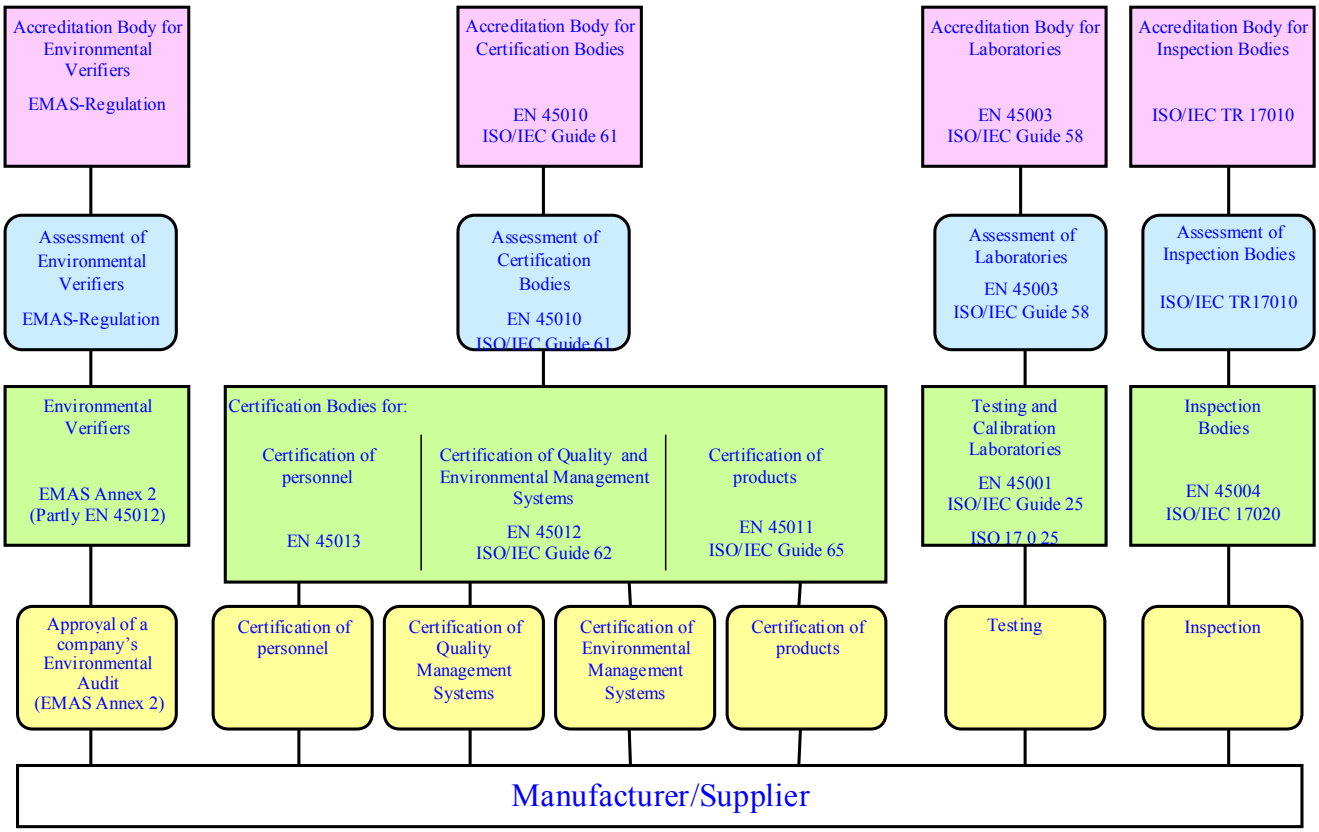
Measurement: set of operations having the object of determining a value of quantity

Bodies involved in accreditation and conformity assessment

Regulatory Authorities
Accreditation bodies
Certification bodies
Inspection bodies
and
Laboratories



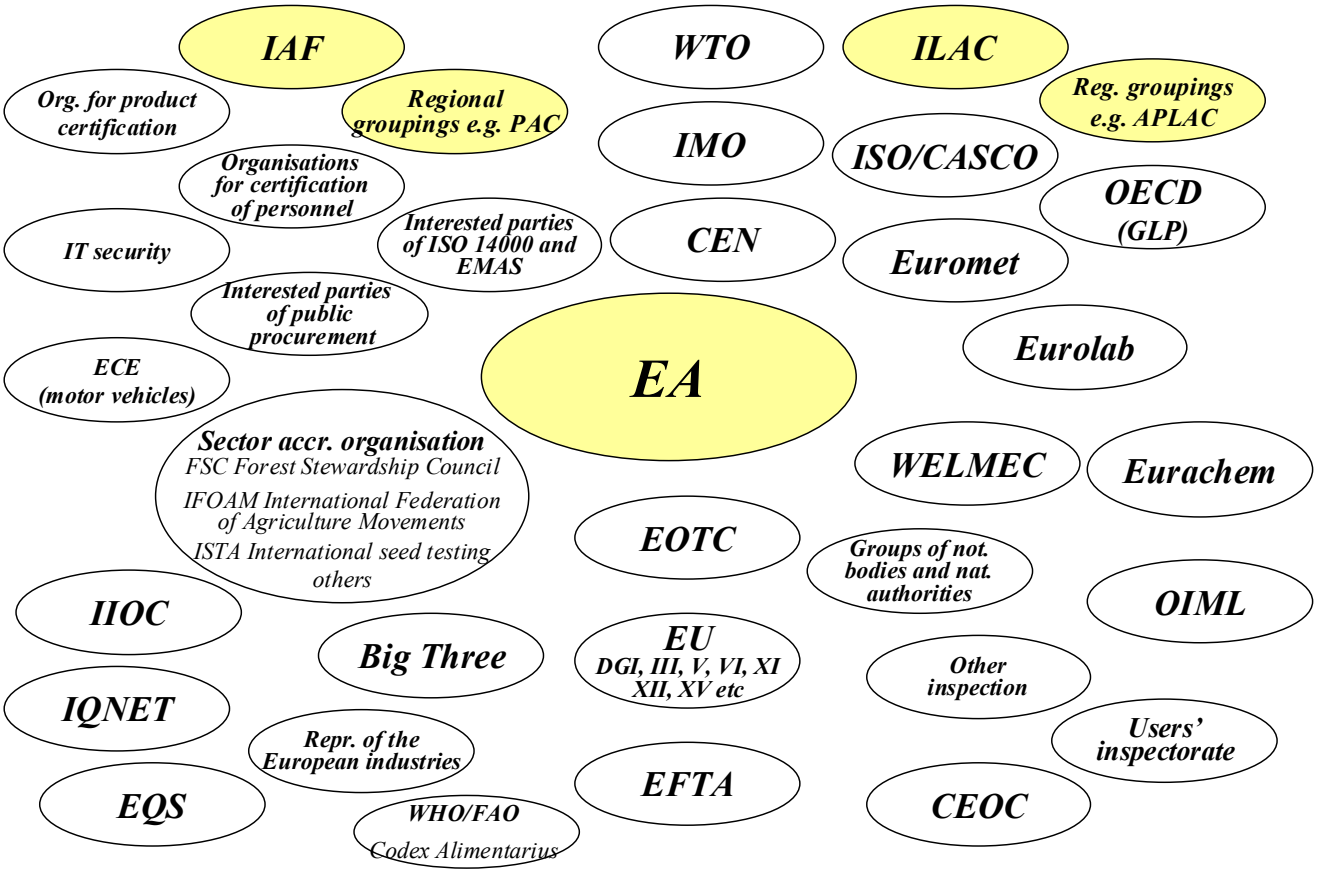
Conformity assessment standards, overview



Use of Accreditation

- **International Aspects**
  - International trade
  - Tool for establishment of Mutual Recognition of Tests Inspection and Certification
- **National Aspects**
  - Regulatory purposes
  - Assessment and establishment of competence of bodies performing technical control activities
  - Health care sector

Some international bodies related to conformity assessment



Co-operation of accreditation bodies

- **ILAC**
  - *International Laboratory Accreditation Conference*
- **IAF**
  - *International Accreditation Forum*
- **EA**
  - *European co-operation for Accreditation*
- **APLAC, PAC, IACC** etc. in other parts of the world

Which standards are applicable for laboratories performing measurements of radioactivity? (surveillance?)

- EN 45 001, Laboratories (ISO/ DIS 17025)
- EN 45 004, Inspection bodies (ISO/DIS17020)

General criteria for the operation of testing laboratories (EN 45 001)

1 Object and field of application
2 Definitions
3 Legal identity
4 Impartiality, independence and integrity
5 Technical competence
- 5.1 Management and organisation
- 5.2 Personnel
- 5.3 Premises and environment
  - Availability
  - Premises and environment
  - Subcontracting
- 5.4 Working procedures
  - Methods
  - Quality system
  - Reports
  - Records
  - Handling of test samples and items
  - Confidentiality and security
  - Sub-contracting

6 Co-operation
7 Duties resulting from the use of accreditation

General requirements for the competence of calibration and testing laboratories

”New” ISO/IEC Guide 25 = ISO/DIS 17025

1 Scope
2 Normative references
3 Terms and definitions
4 Management requirements (see below)
5 Technical requirements (see below)
Appendices
A Cross-reference to ISO 9001 and 9002
B Guidelines for competence

4 Management requirements
- 4.1 Organisation and management
- 4.2 Quality system
- 4.3 Document control
- 4.4 Request, tender and contract review
- 4.5 Sub-contracting of test and calibration
- 4.6 Purchasing services and supplies
- 4.7 Service to the client
- 4.8 Complaints
- 4.9 Control of non-conforming T/C work
- 4.10 Corrective action
- 4.11 Preventive action
- 4.12 Records
- 4.13 Internal audits
- 4.14 Management reviews

5 Technical requirements
- 5.1 General
- 5.2 Personnel
- 5.3 Accommodation and env. conditions
- 5.4 T/C methods incl. sampling
- 5.5 Equipment
- 5.6 Measurement traceability
- 5.7 Sampling
- 5.8 Handling and transportation of items
- 5.9 Assuring the quality of T/C results
- 5.10 Reporting the results

Routine of Accreditation

Information
∇
Application
∇
Examination
∇
Assessment
∇
Report
∇
Corrections
∇
Decision of accreditation
∇
Contacts, reports etc
∇
Surveillance

"Is *accreditation* a tool for current and future use in quality assurance?"

Answer: **Yes / No** - It depends

Case 1: **Quality Assurance in Routine Testing**
Answer: **Yes**

Why?

- Accreditation is the only internationally recognised methodology for the assessment and establishment of competence of laboratories, certification bodies and inspection bodies based on international standards
- Accreditation is a part of the establishment of the new International Trade Regime
- Accreditation supports the new principles for open government and transparent regulatory activities
- Accreditation is an integrated part of the international systems for the establishment of mutual trust in conformity assessment.
  The other systems are:
  International Standardisation
  Internationally Traceable Metrology Systems
- Accreditation is a tool for one-stop approach for regulatory activities based on quality assurance

Case 2: **Quality Assurance in fundamental research**
Answer: **No**

Why?

- Fundamental research is by definition an act of innovation and not limited to pre- defined testing, certification or inspection

OBTAINING ACCREDITATION FOR A LABORATORY MEASURING RADIONUCLIDES - EXPERIENCE AT STUK

Seppo Klemola OSLO 27.3.2000

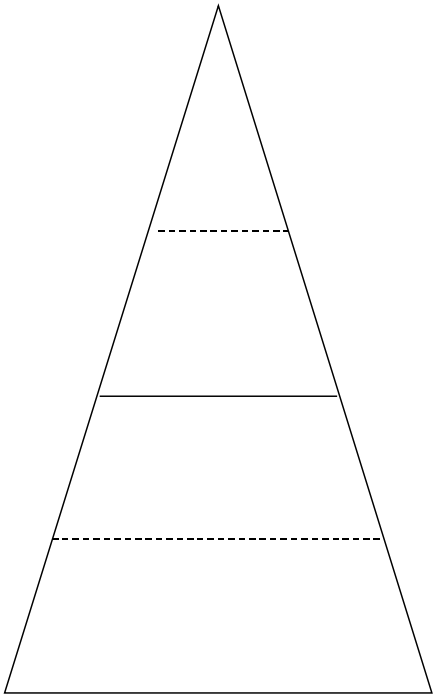
Timetable:

- 1995 - motivation
  - EU directive
  - visit to NRBP

- 1996 - start
  - gamma spectrometry as a pilot project at STUK
  - first draft of a quality manual

- 1997 - STUK quality system
  - based on TQM
  - basis for laboratory manuals

STUK QUALITY SYSTEM



- **Quality policy**
- **STUK Quality Manual**
- **Manuals regarding to different functions at STUK level**
- **Department-specific**
- **quality manuals**
- **Instructions, manuals etc.**

Bases
- STUK's practices, guides etc.
- ISO 9000 -standards, SFS-EN 45001
- Self assessment - quality criteria

1998: Quality Manual for the Research Department

- *QUALITY SYSTEM*
- *ORGANISATION AND MANAGEMENT*
  - *Organisation and management*
  - *Equipment*
  - *Measurement traceability and calibration*
  - *Laboratory accommodation and environment, site security*
  - *Handling of complaints*
  - *Pricing of tests and analyses*
- *GUIDES FOR ACTIVITIES AS A TESTING LABORATORY*
- *SUPPORTING ACTIVITIES*
  - *training*
  - *emergency preparedness*
- *STAFF*
  - *competence*

List of activities aiming for accreditation

- Sampling
- Pre-treatment
- Gamma spectrometric analysis
- Tritium analysis
- Strontium analysis
- Plutonium, americium and curium analysis
- Gammaspectrometric whole body analysis
- Airborne radon concentration
- Radon concentration in water
- Uranium, lead and polonium in water
- Biological assessment of radiation dose

16.12.1998

Title		Identification
Gammaspectrometric sample measurements		**Guide TKO 3.1.3**
Prepared by: Seppo Klemola Date	Reviewed by: Raimo Mustonen Date	Approved by: Sisko Salomaa Date
Distribution: TKO-laatukäsikirjan jakelu	Valid from:	Guide replaced:

Contents

THE CONTENTS OF THE STUK GAMMA MANUAL

1. General
2. Gamma laboratories
3. Equipment and Accessories
4. Computer Programs and Files
5. Calibrations
6. Measurements and Spectrum Processing
7. Spectrum Analysis
8. Quality Assurance

THE PROCESS OF OBTAINING ACCREDITATION

- 1998-1999 - Preparation of the laboratory manuals + THE GAMMA MANUAL
- 21.12.1998 - Application for accreditation
- Preparatory meeting 22.3.1999
- Assessment 28.5.1999
- Corrective actions - 31.8.1999
- Proficiency tests Oct./1999

- **CERTIFICATE 17.12.1999**

’Current feelings ’

- **<u>not finished anything - just started</u>**
  - continual improvement of quality
  - annual internal & external audits
- created a lot of documentation -necessary from the viewpoints of
  - workers
    - instructions, procedures, etc.
  - institute
    - continuation
  - customers
    - evaluation
- improved understanding of critical stages of analysis
- training, competence register
- format of reports

Bibliographic Data Sheet **NKS-47**

Title	Accreditation. Its relevance for laboratories measuring radionuclides
Author(s)	Sigurður Emil Pálsson
Affiliation(s)	Geislavarnir ríkisins (Icelandic Radiation Protection Institute)
ISBN	87-7893-100-2
Date	November 2001
Project	NKS/BOK-1.1
No. of pages	57
No. of tables	-
No. of illustrations	21
No. of references	-
Abstract	Accreditation is an internationally recognised way for laboratories to demonstrate their competence. Obtaining and maintaining accreditation is, however, a costly and time-consuming procedure. The benefits of accreditation also depend on the role of the laboratory. Accreditation may be of limited relevance for a research laboratory, but essential for a laboratory associated with a national authority and e.g. issuing certificates. This report describes work done within the NKS/BOK-1.1 sub-project on introducing accreditation to Nordic laboratories measuring radionuclides. Initially the focus was on the new standard ISO/IEC 17025, which was just in a draft form at the time, but which provides now a new framework for accreditation of laboratories. Later the focus was widened to include a general introduction to accreditation and providing through seminars a forum for exchanging views on the experience laboratories have had in this field. Copies of overheads from the last such seminar are included in the appendix to this report.
Key words	Accreditation; Radionuclides; Standard; ISO/IEC 17025; Laboratories

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