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Labquality Days 10–11 February 2011 in the Helsinki Fair Centre
S. 22
Labquality celebrates forty years of operations

Forecasting is difficult, that is clear. Nevertheless, weather forecasts for the next few days are starting to be reliable, thanks to developments in meteorological technology. Forecasts for even a week ahead are quite accurate. But as weeks become months, and months become years, the vision becomes indistinct. What do we say now about the forecasts made a few years ago that because of global warming, there would no longer be any skiing in Helsinki and traffic need not take precautions against heavy snowfalls? The main headline in the Finnish newspaper Helsingin Sanomat on 20th December aroused mixed feelings: “Blizzard changes into biting cold freeze – over 20 centimetres of snow fell in Helsinki – European air traffic disrupted.”

Forecasting is difficult in other fields of life too, not just meteorology. Despite budgeting and action plans, there will always be uncertainty in forecasts for business operations. Since an annual budget will often be already out of date as soon as it is created, it may be more appropriate to focus on developing dynamic and flexible objectives, and means of monitoring them and taking action. One often needs a vision of the future that takes into account rapid changes in the business environment.

Labquality will be celebrating its 40th birthday in 2011. This will be apparent through, among other things, the new colours and visual features of our logo. The year’s first issue of Labquality News has information about the operations of Labquality and its subsidiaries Bioclin and Qualitor, and the importance of the operations of international EQA organizations to our organization. In looking back on our history, we are also envisioning the future and the challenges it will bring.

The sincere amazement of the people who founded Labquality at the extent of its current operations is heart warming. They could not have anticipated this when they organized the first national quality assessment schemes. The open-minded, dynamic and flexible development of operations through cooperation by enthusiastic people has in the intervening years brought us to where we are now. If we can keep the same spirit in our organization in the coming decades, we can look forward to achievements that we cannot even foresee today.

As I write this, it is frosty and snowing, but when you read it, the weather may have changed. It is better to avoid forecasting too precisely, instead prepare for changing weather conditions.

Labquality is well placed provided we can adapt ourselves flexibly to customer needs and satisfy them, and among our personnel, experts and customers we have open-minded people who will create a successful future.
Quality and patient safety ever more important on the agenda

MAURI KEINÄNEN

It is said that forecasting the future is difficult, especially without knowing history. Labquality’s history dates back over forty years already, and even longer if one takes into account EQA research and development by laboratories before the organization was founded. In that time, through the addition of the two subsidiaries Bioclin and Qualitor the company has grown from Labquality Oy into the Labquality Group. However, the objectives have not changed over these decades: quality and patient safety remain at the heart of the Labquality Group’s current operations, although now in an even more diverse way.

Internal and external quality control are an essential part of clinical laboratory analysis. Photo: Mauri Ratilainen
Labquality was founded in the 1960s when it was resolved that clinical laboratories’ should be assessed to achieve uniform and reliable standards of testing. Operations started to be developed by a group of open-minded pioneers in the field rich with ideas. Changes in Finnish legislation and stipulations set by Finland’s National Board of Health required Hospital Districts to organize quality management of laboratory tests. To achieve this, Klinisten Laboratoriotutkimusten Laaduntarkkailu Oy, now called Labquality Oy, was established with strong support from, among others, Sairaalanliitto representing hospitals.

Timely action with the help of experts

Reasons why the company has been successful include its timely establishment and the contributions of a large number of experts who have developed EQA and the international expansion of operations. The framework and mode of operations have developed in these forty years from initially national projects to an organization providing international services with majority of clients outside Finland. Operations have always been oriented towards public service obligations with the objective of improving quality and patient safety. It has been noticed, that international cooperation has helped to achieve also national requirements.

In 2009, in response to the expansion of operations and the customer base, the Articles of Association and mode of operations of the company were updated, especially to take into account international growth. At the same time, Labquality Oy and its subsidiaries Bioclin Oy and Qualitor Oy were grouped under the name Labquality Group. Bioclin was founded in 1990 and Qualitor in 2008. The operations of the subsidiaries are closely associated with the parent company’s mission: improving patient safety through quality improvement. Bioclin sells control materials for clinical laboratories in Finland and abroad. Qualitor’s core expertise is certification and auditing for developing and improving quality in Finnish social and health care organizations.

Aim is to become a key player in European EQA

Labquality’s core operation and therefore main field is External Quality Assessment (EQA). The company’s vision is to become a key player and one of the leading provider of EQA for health care in vitro diagnostics in Europe.

Prerequisites for achieving these very demanding objectives and competing successfully are flexible, cost-efficient and, most important of all, customer-oriented expert services that clearly benefit and add value to clients’ own business operations. Achieving these objectives will require diversification and focusing on essentials. It will also require linking operations to work on patient safety in healthcare. In recent years the company has expanded its clientele beyond clinical laboratories under the slogan “Health Quality from Labquality.”

EQA markets in the Nordic countries and Western Europe are nowadays considered mature, but markets have been growing in new EU countries such as Poland, Romania and the Baltic States, where legislation is putting pressure to organize such services. Projects related to quality and patient safety in the Nordic countries also have a tailwind, so new quality management services will become available for use in health care.
Relevance of schemes must be considered in development work

Labquality has decided to offer a wide range of products and services so that the services will cover almost all fields of laboratory medicine. This may not be the most efficient way to operate, but we believe it is in the best interests of our clients, so we may maintain this policy in coming years too.

The company’s EQA product range includes about 150 different EQA surveys covering all fields of laboratory medicine. For high quality and competitiveness, the aim is to use high quality samples that are as authentic as possible. Comments by experts are also a significant part of the service.

However, the purpose of each scheme or service must be borne in mind in developing EQA schemes. For example, the maximum use of reference method values in defining target values would certainly increase accuracy, but sometimes costs would then outweigh benefits. The best alternative as regards quality is “Fit for Purpose”. In certain circumstances, even in EQA schemes, every possible and available refinement is required, but schemes and services intended for widespread use must be tailored to what clients actually need. A challenge for Labquality is to find the best balance to meet these different client needs.

Benefits to key stakeholders

Objectives, values and performance can be evaluated by three key reference groups: clients, employees and owners. If all these three groups are satisfied with the performance, the long-term prospects for operations and success are good.

- For the client reliability, impartiality and client-focused solutions are prerequisites for Labquality’s operations to establish good cooperation with clients.
- For the employees, experts and decision-making bodies professionalism, openness-mindedness and cooperation skills are needed to create the basis for an effective expert organization.
- For the owners financial solidity and sufficient profitability enable the basic operations, development and provision of good services for society.

Continuous work essential to maintain quality

The prospects for the organization are good. Even though competition in the sector is intensifying and becoming more international, there is increasing demand and social pressure for, among other things, EQA services in social and health care, quality systems development and systems for reporting adverse events.

Our services for improvement of quality and patient safety can be compared to maintaining standards of hospital equipment and hygiene. Continuing work is needed even by an organization that has achieved high standards. Although a deficiency may not necessarily be detected in the short term, in the long term it will lead to deterioration in quality and the safety of a hospital’s basic operations.

Keys to success for the Labquality Group in the next few years will be a sufficient range of services and number of customers, international services and service chain, price competitiveness enhanced by efficiency, utilization of IT solutions and “authorization” through official accreditation status so it can act as an approved EQA organizer.

"In recent years the company has expanded its clientele beyond clinical laboratories under the slogan “Health Quality from Labquality.”"
International cooperation strengthens company’s expertise

MINNA LOIKKANEN

Labquality is approaching a good middle age. Next summer 40 years will have passed since Labquality was founded. During these years this national organization has undergone some name changes, finally becoming Labquality. At the same time its functions have increased and expanded over borders, mainly to Northern Europe.

Looking at this middle-aged Labquality, we see a strong, internationally active organization. The Finnish pioneers of external quality assessment started Nordic cooperation in the 1980s with Danish (DEKS), Norwegian (NKK, NOKLUS), Icelandic (KLLÍ) and Swedish (EQUALIS) national EQA organizations. Close and fruitful relationships were initiated. Nowadays, these Nordic sister EQA organizations cooperate under EQAnord, their umbrella organization.

Strong Nordic cooperation in surveys

International information and knowledge are shared in Nordic meetings. EQAnord has already been recognized by international organizations such as NFKK, EQALM and ECLM. The aim of this cooperation is to enhance external quality assessment activities by organizing EQA surveys that might otherwise be difficult for any one of these organizations to arrange alone.
Many interference studies in general clinical chemistry were undertaken in the 1990s. The survey of interference by heterophilic antibodies in 2009 is the latest study. In this study the participating laboratories received two sera, one with an artificially elevated amount of polyclonal sheep anti-mouse immunoglobulin and the other normal human serum as a reference. The serum materials were produced by a group at the Norwegian Radium Hospital. Altogether 141 Nordic laboratories participated in the study. The cost of the analysis was paid by the participants, and the national EQA providers paid the rest. Relevant experts, suitable special materials, result processing and reporting are needed to enable a study like this. Publication of the study results is in preparation.

**Internationally recognized health care expertise**

Lately the mode of operation and focus of EQAnord have changed. Statistical experiments and problem solving seminars have been arranged for coordinators as educational activities. Peer review and harmonization procedures are seen as very important, especially in the accreditation processes. The international standard ISO 17043 for the accreditation of EQA schemes was officially adopted in February 2010.

There is an obvious need for peer group meetings or a forum for coordinators from different organizations.

Labquality’s own Nordic technical committee and international meetings have actively advanced cooperation with many experts in different specialties. External quality assessment has become an educational tool for laboratory professionals in improving the quality of analyses. International cooperation and quality work in health care have borne fruit in recent years. Nordic health care has gained a reputation for quality in Europe and further afield.

**Expanding into Eastern Europe and beyond**

Participation in our programmes in the Baltic States and Poland rapidly increased towards the end of the last millennium. At the end of 2010 there were 4,600 laboratories in 48 countries participating in Labquality programmes. International activities naturally put demands on the operations of the provider and the expertise of its staff. The diversity and number of schemes and surveys have rapidly increased from year to year.

As foreign participation has expanded, logistics have been developed and constantly improved. Courier services are used to many countries. The average time till participants receive their samples varies from three to four days after shipment. However, globalization of EQA is still restricted by the availability and stability of
the sample materials, logistics and customs regulations in different countries. Uniform coding is needed for EQA samples to improve and increase international cooperation. Labquality operates internationally and seeks solutions with different partners to improve the quality of patients’ test results and health care.

Valuable feedback and exchange of ideas

Labquality has over a hundred experts with different specialities, who are mainly distinguished Finnish laboratory professionals. Some foreign experts give comments in their own native language, which makes their precise meaning clearer. Working groups in different specialities gather each year to work on the challenges of the sample materials and scheme designs. Participants are actively encouraged to suggest improvements. Their feedback is registered and documented in the quality system.

The experts are active and have positions not only in Labquality, but also in other international organizations through their everyday professions and expertise.

The staff of Labquality are also active in international professional forums, such as EQALM and EurachemPT. EQALM provides a forum for cooperation and exchange of information about quality-related matters, especially with regard to external quality assessment and assurance programmes Laboratory Medicine in Europe. It has working groups on Microbiology, Hematology, Hemostasis, Nomenclature, Virtual Microscopy and Frequency. The Hemostasis working group has been especially active and organized many international studies. EQALM and EurachemPT both represent European core and top expertise in external quality assessments.

Labquality Days arranged by Labquality, a notable educational event in external quality assessment for laboratory personnel especially in Finland but also in Europe, attracts around a thousand participants each year. The topics include Microbiology, Haematology, Pathology, Clinical Chemistry and Point-Of-Care testing. At Labquality educational input and professional implementation of the schemes are strongly appreciated in scheme design.

The author is the Quality and Production Manager of Labquality.

Abbreviations

- ECLM, European Confederation for Laboratory Medicine
- EQA, External Quality Assessment
- EQALM, European Organization for External Quality Assurance Programmes in Laboratory Medicine
- EQAnord, External Quality Assurance of Laboratory Medicine in the Nordic Countries
- EQUALIS, External Quality Assurance in Laboratory Medicine in Sweden
- EurachemPT, Eurachem’s Proficiency Testing Working Group
- LKKÍ, Icelandic Society for Clinical Biochemistry and Laboratory Medicine
- NFKK, Scandinavian Society of Clinical Chemistry
- NKK, Norwegian EQA Program for Medical Biochemistry
- NOKLUS, Norwegian Quality Improvement of Primary Care Laboratories
Pioneering quality improvement work in Finnish social and health care services

MARJA POKKA-VUENTO

Qualitor, which provides services related to quality improvement in social and health care, was established as a part of the Labquality Group only in 2008, but its services and expertise date back nearly twenty years. Since 1993 its experts working with a wide network of auditors in social and health care have helped to improve quality in Finnish social and health care organizations.

The means currently used for quality improvement, including quality systems, did not arise by chance, they are the result of step by step development. The field of quality management has changed as awareness of matters has increased and technologies have been developed to support operations. Means of improving quality are still relatively new, as they have arisen mainly in the industrial era. They were introduced into manufacturing early on to minimize wastage of time and materials, among other things. Utilization of quality improvement methods in other sectors and different countries has progressed at its own variable pace in each case.

Increasing need to introduce quality systems

The USA and Canada have been notable trailblazers in quality improvement in social and health care. In the USA, improvement of quality criteria dates back to 1917. In the USA and Canada the first comprehensive auditing and accredi-
tation programmes in health care were launched in the early 1950s.

In Finland there was little systematic monitoring and assessment of quality in social and health care services until the end of the 1980s. Types of monitoring included control measures taken by authorities and infection registers kept by them, monitoring and guidance by a close superior, and complaints made by clients and patients. Quality assurance measures to anticipate and prevent errors were introduced in some activities, such as laboratories.

Systematic quality management measures covering an entire organization were introduced in social and health care in the early 1990s. Independent decision-making powers of municipalities to organize social and health care services were also increased in the early 1990s when state subsidies were reformed. Freedom of choice for clients stimulated demand for quality management measures. It became more common for organizations providing social and health care services to build up and utilize quality systems when developing their operations. The health care sector in particular was advanced in introducing quality systems and has taken a lead in adopting ISO 9000 standards and in certification.

Development work and audits in social and health care under the Social and Health Quality Service (SHQS) programme based on international accreditation started in 1993 in the first health care organizations. The SHQS programme, previously called the King’s Fund quality programme, came to Finland from England, where audits were already being undertaken in the late 1980s in over 200 health care organizations, and they had been awarded accreditation status.

"Freedom of choice for clients stimulated demand for quality management measures.

Aim to improve client’s status

At national level, quality management recommendations have been mainly guidance through providing information. The targets and best practices presented in quality recommendation documents aim to steer operations in the desired direction. Finland’s first recommendations for organizing quality management in social and health care were published in 1995 by the National Institute for Health and Welfare (Stakes). The basic outlines were focused on improving the status of the client, guidance through information, initiating quality improvement work in cooperation with many different health care professionals, and freedom to choose the means and approaches for own quality management.

The new quality recommendations published in 1999

of hospitals were involved in quality improvement projects. In social care, 63% of the people interviewed in social care management reported projects that in general terms could be considered quality improvement projects and 24% reported projects that were of more specifically quality management character. There was therefore a lot of scope for further development.
The quality recommendations were intended to increase the emphasis on the importance of including clients as part of quality management and promotion of client-oriented operations.

by the Finnish Ministry of Social Affairs and Health, Stakes and the Association of Finnish Local and Regional Authorities were a response to the quality management challenges of the 2000s. The quality recommendations were intended to increase the emphasis on the importance of including clients as part of quality management and promotion of client-oriented operations. The recommendations were also intended to describe how quality management supports good services and promotes initiatives to start quality improvement and development in social and health care.

This included the idea that operations by local authorities could be made more efficient through quality recommendations. Service-specific quality recommendations followed the introduction of national quality recommendations. Quality recommendations were also included in the national target and action plan for 2000–2003 covering the whole sector (National Target and Action Plan for Social and Health Care, 1999). This included the idea that operations by local authorities could be made more efficient through quality recommendations. Some service-specific quality recommendations could be specified for certain client or population groups, such as the quality recommendation concerning care and services for elderly people introduced in 2001. Some of the recommendations cover a wider group or the entire population, such as the Quality Recommendation for Health Promotion introduced in 2006. The challenge and also the aim for the next generation of quality recommendations is to include indicators for comparison in the recommendations.

Systematic progress in adopting quality management

A survey by Stakes and the Association of Finnish Local and Regional Authorities in 2004 concerning the state of quality management in social and health care revealed that the number of organizations in social and health care that used various quality improvement models and criteria had increased between 1999 and 2004. There were no systematic differences in quality management between social care and health care in 2004. However, there were big differences within each of these sectors.

Hospital Districts in health care and rehabilitation centres in social care, including rehabilitation centres for war veterans, were ahead of others in quality management. Progress had been made in nearly all social and health care sectors, especially as regards systematic quality management, documentation and formulation of operating instructions. Nearly nine out of ten health care organizations had adopted criteria for quality improvement, and six out of ten social care organizations had adopted quality management models or criteria. Integrating measures of evidence-based operations and systematic risk management posed new challenges in quality management. Some organizations were adopting evidence-based operations, more so in health care than social care. Evidence Based Management (EBM) guidelines were first drafted in 1994. The Finnish Medical Society Duodecim has been responsible for writing them. The guidelines are based on scientific evidence and aim to provide
national health care guidelines and provide a basis for planning regional care programmes and care chains. There are currently nearly a hundred in use.

Quality monitoring required by legislation and norms

Clinical audits that started in Finland in 2002 under the Radiation Act are norm-based quality management. Clinical auditing is a requirement for operations of entities stipulated under the Radiation Act, which is based on the EU Directive on health protection of individuals against the dangers of ionizing radiation due to medical exposure, under which clinical audits must be carried out in accordance with national procedures. The applicable national procedure in Finland is described in the Ministry of Social Affairs and Health’s Decree on the Medical Use of Radiation 423/2000. Clinical audits are undertaken at five-year intervals, so now the second round is in progress. Qualitor is one of the leading providers of radiation safety audits in Finland. An impartial clinical audit expert panel coordinates and develops audits with representation from the Radiation and Nuclear Safety Authority Finland, the Ministry of Social Affairs and Health, the Finnish Accreditation Service FINAS and university hospitals.

The so-called care guarantee introduced in 2005 takes the form of a norm-based directive. The Primary Health Care Act and the Act on Specialized Medical Care were revised so they stipulate the maximum waiting time for a patient to access non-emergency medical care. This was expected to improve patients’ access to non-emergency medical care significantly. In general terms, the care guarantee has improved access to medical care, but still there are problems in adopting it. The most important factor hindering the effectiveness of the care guarantee has been shortage of staff, especially experts in certain special fields.

“The most important factor hindering the effectiveness of the care guarantee has been shortage of staff, especially experts in certain special fields.”

In 2010 about 250 professionals working in the social and health care sector participated in courses arranged by Qualitor. Photo: Olli Salo
Patient safety increasingly important

Patient safety is one priority in EU health care policy. The national patient safety strategy for 2009 - 2013 in Finland was published in January 2009 at the first national patient safety conference. The patient safety strategy aims to provide guidance on harmonizing patient safety culture in Finnish social and health care and promote its implementation. Finland participated in a network project for 2008 - 2010 that was created to promote patient safety in EU countries. The national patient safety network is a forum for discussion and providing information, and a contact point for the EU’s patient safety network EUNetPas. OECD and Nordic Council of Ministers committees for quality improvement are developing indicators for monitoring patient safety.

Reform of Finnish Health Care Act in progress

The new Health Care bill aims at improving the status of clients and also the quality of services and care. This is to be achieved by giving clients freedom to choose their place of care, by guaranteeing equal access to services and by improving the quality of care and patient safety. The bill stipulates that health care units must draw up a plan for quality management and implementation of patient safety.

The decree supporting the act will promote adoption of the Health Care Act and work relating to quality management and implementation of patient safety. The decree of the Ministry of Social Affairs and Health stipulates the matters that must be agreed in the plan for quality management and implementation of patient safety. The decree will support nationally drawing up a harmonized plan for different health care units. It is proposed that the decree will enter into force at the same time as the new Health Care Act on 1 May 2011.

Finnish social and health care faces an interesting future that offers a wide range of new prospects and challenges, for instance relating to population structure and social and health care service structure. In Qualitor we aim to continue to offer high quality services to meet social and health care needs, and means to improve client satisfaction and safety. They are always crucial when considering quality and quality improvement, irrespective of which aspect of quality is considered. Quality management methods have been developed to achieve customer satisfaction. The ways to achieve customer satisfaction change in accordance with the spirit of the time.

The author works as a Lead Auditor in Qualitor.

Qualitor Oy

- Qualitor is part of the Labquality Group. The Finnish certification and quality assessment operations of Qualisan and SHQuality Oy were merged to form Qualitor Oy in October 2008.
- Personnel: four employees and about 250 contracted auditors
- Turnover: about € 700,000 in 2010
- Clients: social and health care organizations in Finland
- Services: certification of quality management systems to ISO 9001:2008 standard, SHQS quality programme, pathology quality recognition, radiation safety auditing (clinical auditing), personal certification and training of clinical researchers
Bioclin, active subsidiary of Labquality

MAURI KEINÄNEN

Bioclin Oy was established in 1990 to improve the performance of clinical laboratories through importing, exporting and trading quality control products and means of research and development relating to the sector. This followed the decision to transfer sales and development of controls, calibrators and reference materials, which had been part of parent company Labquality’s EQA operations, into a separate subsidiary.

Bioclin sells, markets and develops third-party, independent controls, calibrators and reference materials for internal quality control by customers such as clinical laboratories, research institutes and pharmaceutical and diagnostic companies. Control materials such as these that are not manufactured and optimized specifically for a particular device and analytical method provide more reliable data on the performance of a test device for internal quality assessment than using only the manufacturer’s own controls.

Clients benefit from cooperation with parent company

The company supplies its own range of control materials under the Bioclin name as well as a wide range of products from Finnish and foreign control product manufacturers for various fields of laboratory medicine. Initially, the aim was to meet the need for control materials to improve the quality of testing in Finland, but Bioclin’s products are now used in laboratories abroad, too. Close cooperation with the parent company facilitates development and expansion of operations and benefits customers. Labquality’s external quality assessment services and Bioclin’s control materials for internal quality assessment, and information on how to use them, are available under the same roof.

In 2010 the company’s turnover reached about € 570,000. The company directly employs two persons and indirectly employs many experts. A significant additional resource available to the company is support services purchased from the parent company.

In 2001 Bioclin obtained ISO 9001 Quality Management System certification covering the planning, production, sales and marketing of reference materials.

Product Manager Anita Latvala (on the right) and Sales and Marketing Assistant Riikka Menna of Bioclin Oy.
“Identifying the requirements and wishes of a client is the first step in writing a brief history,” says Project Assistant Anne Korhonen, M.Pol. Sc., of Viestintätoimisto Bränn & Bränn Oy. The book on Labquality’s history will be published in the second half of 2011.

Projects start with a brainstorming meeting with the client that will provide the basis for the researcher’s work. This meeting identifies the client’s wishes concerning the structure and appearance of the book, and its target readers, among other things. The person responsible for research and writing then drafts a research plan.

Initially, the plan is not carved in the stone, but acts as a chart to guide the progress of the project. The research plan includes a work schedule, and the type of reference material and literature to be used. At the start of the project we must also establish an editorial team with the client. This team will supervise the project, and we will present our research results and texts to it. The role of the editorial team is to comment and discuss matters actively.

A crucial part of the project is archive material, because the book will be based on it. Research is the cornerstone of a work on history. According to Korhonen, the aim in book projects is always to obtain the archive material to be used as soon as possible so that the researcher can start going through it folder by folder, make notes and outline the history of the organization.

“Because Labquality is a Limited Company, I started by reading the minutes of Annual General Meetings and minutes of the meetings of the Board of Directors. The main events and storyline are often to be found in such records about operations.”

Depending on the researcher and working methods, the research work may then move on
to further reference material. Currently, Korhonen is working on Moodi magazines.

“Published abstracts of lectures at Labquality Days have turned out to be a good source. For example, opening speeches outline what was then happening in the clinical laboratory field, regulation and society.”

Turning small items into a narrative

Anne Korhonen thinks the chronological approach is the best way of starting the work. She goes through one type of reference material at a time. She divides a huge mass of chronological material into themes. However, in its final form the book may not necessarily be strictly chronological, it may evolve and change along the way.

“I start writing at an early stage, because research can best be set out by writing your thoughts down. Turning ideas into words is the best way to construct the story.”

The publication about Labquality is challenging in that the subject is not part of general knowledge, but advanced medicine.

“However, it is all about work by people. When one delves deeply enough into the history with a healthy curiosity, even a difficult matter comes alive. A researcher also starts getting interested in people and what has happened. A capacity to put one’s heart and soul into history and the ability to see the world through people and actions from the past are required from the researcher.”

Wrong emphases may make the work more challenging.

“When it happened, something may have seemed important and been recorded in the minutes of meetings, for instance, but later it may become clear that over a forty-year perspective, it was not significant. When the editorial team is working most efficiently, the client will be attuned and notice the emphasis and tone of the text. A two-way dialogue and feedback are really vital.”

A good history interprets the truth

The client is asked to consider and define what in its opinion constitutes a good historical narrative. However, one general rule always applies: the basic information and text must be scientifically of high standard and valid. Naturally, there is no conclusive truth, only interpretations valid at that time.

“The book must be based on what really happened. The emphasis of the events described in the book and how it interprets the past are the overall results of the interaction between us and the client,” says Bränn & Bränn Managing Director Torra Bränn.

The ultimate appearance of the historical record depends on many factors.

“There are over a hundred different paper grades, and illustrations are crucial to the book, especially if it is to be used to promote the company externally,” Bränn points out.

“All the illustrations do not have to be photographs. A classic example is a picture of an organization’s founding charter. A picture of this possibly faded document adds the quintessence of history to the book,” Korhonen notes.

The pictures for the book are collected during the research and writing of the book. However, deciding the visual appearance of the cover is a long process, if not the longest in creating the book.

“All the illustrations do not have to be photographs. A classic example is a picture of an organization’s founding charter. A picture of this possibly faded document adds the quintessence of history to the book,” Korhonen notes.

The cover is crucial as it should generally reflect the content of the book and will create mental images of it,” says Bränn.

Researcher looking into the past

According to Korhonen, a researcher’s work gives a perspective on different areas of the operation.

“Through it one can delve deep into the subject of the research. Sometimes it feels as if I am getting deeper into it than anyone who has been working for the company for a while. Memories in an organization are sometimes very short. All influential
persons in different periods consider their own actions highly significant, but a researcher may conclude that the valuable contribution by one person may against the timescale of decades seem rather insignificant. There have been innovators in the past and more will come after them."

In the next meeting of the Labquality editorial team, Anne Korhonen will present the latest research results and preliminary ideas on the chronological breakdown of the book. Then she will actively start the writing work, which will be presented to the editorial team during 2011.

The book on Labquality’s history produced by Bränn & Bränn will be published in the second half of 2011.

Labquality Group milestones

8.6.1971 Memorandum of Association of Kliinisten Laboratoriotutkimusten Laaduntarkkailu Oy signed at Meilahti Hospital in Helsinki.

1972 First meeting for users arranged. (Training event later known as Laaduntarkkailupäivät and Labquality Days.)

1977 First issue of news magazine Moodi published.

1990 Subsidiary Bioclin Oy established for sales of products.

1994 First presentation of Laaduntarkkailupalkinnot (EQA Awards), which were subsequently called Laadunedistämisspalkinnot (Quality Promotion Awards).

1996 General Meeting of Shareholders resolved to change company’s official name to Labquality Oy.

1996 First issue of Labquality News magazine published.

2007 Company purchases Qualisan’s certification and quality assessment operations and also in the same sector SHQuality Oy to support the new product range within the Group.

2008 Certification and quality assessment operations of Qualisan and SHQuality merged under the name Qualitor Oy, a new subsidiary.

2009 First Raimo Tenhunen Award presented at Labquality Days.

Viestintätoimisto Bränn & Bränn Oy
(Finnish for Communications Agency Bränn & Bränn Ltd.)

■ Tora Bränn, Diploma in Marketing (MKT) and Vocational Qualification in Business and Administration, with expertise in the commercial side of the business, sales and administration, and her sister, historian Michaela Bränn, M.A., responsible for content and implementation, joined forces to establish this company in 2002.

■ Bränn & Bränn Oy provides marketing communication, cultural history research and writing services. Since 2006 Bränn & Bränn has been expanding its services into providing expertise in a wide range of information management and ArkivePRO® archive services.

■ The company produces books in Finnish and Swedish. Publications are based on archive material and research work, from which each publication is produced to meet the client’s wishes.

■ Vision for the future: reflect the spirit of each period and offer the best for the client.

Tora Bränn and Anne Korhonen work on histories.
EQALM, the European Committee for External Quality Assurance Programmes in Laboratory Medicine, is a group of organizations involved in external quality assessment of laboratory medicine services. The members, which are EQA organizers, have a meeting at least once a year. This year it was held in Lisbon, Portugal, on 11–12 October 2010.

Production Manager Minna Loikkanen, Client Relations Manager Juha Wahlstedt and EQA Coordinator Jonna Pelanti represented Labquality at the meeting. Minna Loikkanen has been a member of the EQALM Board since 2008.
Lisbon greeted us with heavy rain and darkness when we finally arrived late on Sunday evening. The taxi queues were long and winding, but the arrangements went well and soon we found ourselves in our hotel a little outside the city centre. The restaurant recommended by our hotel was not ‘easy to find’ or ‘very close’, and we would not have found it at all had we not had the luck of running into a friendly girl offering to lead us there. However, the food turned out to be delicious, so it was well worth the trouble.

Effect of frequency on testing

Monday morning was bright and clear. Some of the symposium participants walked the few miles to Instituto Nacional de Saúde Dr. Ricardo Jorge, while others took a taxi. EQALM has the following working groups (WG): WG on Hemostasis, WG on Hematology, WG on Nomenclature, WG on Microbiology, WG on Virtual Microscopy and WG on Frequency. First in order was the WG on Frequency, where we had a good discussion about how often to evaluate using external quality assessment and what kind of effect frequency has on the results. Labquality offered to assess retrospectively what kind of effect taking part in fewer EQA schemes has on the quality of a laboratory. After next year, Labquality will also have material that could be used to assess whether participating in a scheme more times per year improves the quality of the laboratory. In the other working groups there were good discussions and ideas about new ways to examine and assess quality.

“...It was very interesting to see how many ways there are of evaluating and presenting similar results.

Learning about pre-pre-analytics and post-post analytics

This symposium session started at noon. There were more than 70 participants from 22 different countries. We heard presentations from different representatives on how they evaluate long-term quantitative EQA results. It was very interesting to see how many ways there are of evaluating and presenting similar results. From Labquality’s point of view, this was a very appropriate time to see different reports and ways of presenting results, since we are in the midst of a large IT project in which we are renewing our whole system of gathering, processing and presenting our results.

We also had the opportunity to learn different ways of solving problems related to external quality assessment schemes. We learned that there are not only pre- and post-analytics, but also pre-pre- (what happens within the patient) and post-post-analytics (how the results are interpreted and used after leaving the laboratory). Our host, Portugal’s own Maria Adelina Gomes, also gave us a comprehensive look back on Portugal’s 32-year-long history of external quality assessment.

For the past two years, the ‘Adam Ulldal’ lecture as it is called has been given during the EQALM symposium. Adam Ulldal from Denmark was one of the founders of European quality assessment cooperation. To honour him and his work, an established and prominent person in the EQA world is invited to give a lecture relating to current issues within EQA. This year Gunnar Nordin from EQUALIS in Sweden received this honour. He took us back a year to the 2009 EQALM symposium and reflected on the role of EQA in analytical quality assurance.

Beautiful Lisbon and its fascinating culture

After a long and exiting day, a bus was waiting for us outside the Instituto Nacional de Saúde Dr. Ricardo Jorge, and we were taken via a sightseeing tour to a Portuguese evening of food and fado. It seemed that we were trying to navigate through the nar-
row alleys during the rush hours, since there were so many cars everywhere. We were bussed past a bull fighting arena, several churches and finally high up on a hill from where we could see the whole city centre of Lisbon. We drove past the only house that survived the terrible earthquake of 1755. We saw the Christo Rei statue (Lisbon’s copy of the Rio de Janeiro statue of Jesus) and the Vasco da Gama bridge, Europe’s longest bridge until the Öresund bridge was built. We passed the presidential residence, the old marketplace and lots of museums in the darkening evening.

After two hours of sightseeing we came to the Museum of Pharmacy in the Bairro Alto part of the city. Large, round tables were waiting for us after a champagne toast. We sat at an almost entirely Nordic table, our group of ten people comprising Nordic colleagues plus participants from Wales, Germany and Spain. We enjoyed Portuguese appetizers (pre-pre-food) followed by starters (pre-food). Our main course comprised beautiful seafood skewers and beef wellingtons.

After the feast we were indulged with beautiful fado singing. A young girl with a lovely voice accompanied by Portuguese guitar and traditional guitar players gave us an insight into fado. We were allowed to join in and ‘cantu fado’ (sing fado) every time the gorgeous singer raised her finger. After this culinary and cultural evening, we all fell sound asleep awaiting the next day.

**Future and challenges of EQA**

On Tuesday we looked more carefully into post-analytics and learned ways of assessing it by EQA. Different choices such as Internet surveys and e-learning tools were presented. We also heard of the value of commenting on laboratory results either manually or partially automated.

Current challenges in microbiology EQA were dealt with and presentations on healthcare-acquired infections, reference testing and accreditation were discussed. At the end of the seminar the topics that emerged in the working groups were reviewed, after which the EQALM general assembly took place. In the assembly next year’s symposium host was revealed and the venue will be Szeged in Hungary in October 2011.

Overall, the seminar was excellent. During two days we had the opportunity to hear how EQA is provided and how the results are processed, reported and used in different countries. It was also inspiring to meet people working with EQA in Europe and all over the world.

*The author works as an EQA Coordinator in Labquality.*

*The presentations are published at www.eqalm.org.*
Labquality Days again bring laboratory professionals together

For the 38th time, Labquality Days arranged annually by Labquality Oy will bring professionals from clinical laboratories and point-of-care testing together under one roof. In 2010 nearly a thousand people attended the two-day congress and exhibition. This year the event will be held for the first time in the Helsinki Fair Centre, which is renowned for its first-class fair and congress facilities and excellent transport connections.

The Labquality Days congress is one of most important in Finland in the sector, including a wide range of lectures related to different aspects of clinical laboratory medicine. The themes highlighted this year will include haematology, bacteriology and mycology, continuous improvement, immunology, immunochemistry, physiology, virology and parasitology, bioanalyst’s work, pathology and basic analysis. There will be a total of 80 lectures focusing on dealing with analytical problems and solutions, medical background relating to surveys, new technology, external quality assessment and total quality management.

Most of the lectures will be in Finnish, but on both days of 10-11 February 2011, part of the programme of the congress will be in English. The topics this year will include European water and air quality, using EQA for quality improvement in the USA, preanalytical errors and their cost, and the future of external quality assurance programmes for medical laboratories. On the following pages are some abstracts from this year’s programme of lectures for readers of Labquality News. Further material on lectures will be available after Labquality Days from www.labqualitydays.fi
Goals in monitoring air quality

VUOKKO KARLSSON

National air quality legislation in Finland is based on Directives 2004/107/EC and 2008/50 of the European Parliament and Council. The objectives are to reduce air pollution to levels that minimize harmful effects on human health (paying particular attention to sensitive populations), ecosystems, vegetation, materials and the ozone layer, and to prevent formation of air pollution. Other targets are to improve the monitoring and assessment of air quality, including the deposition of pollutants, and to provide information to the general public.

The appropriate objectives set for ambient air quality take into account relevant WHO standards, guidelines and programmes. When assessing ambient air quality, account is taken of the size of the population (reflecting population density) and ecosystems exposed to air pollution. Air quality measurements are also used in verifying air chemistry models, in detecting long-term changes in air quality and in following the effects of international emission reduction agreements.

Local measuring organizations produce data

In order to ensure that the measured air quality data are sufficiently representative and comparable across the whole European Community, the Directives give common criteria for the number and location (macroscale and microscale siting) of measuring stations. The data quality objectives of the measurements of different air pollutants, such as measurement uncertainty, data capture, time coverage, quality assurance, data validation and traceability are given. The Directives also

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<th>The pollutants to be measured are:</th>
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<tr>
<td><strong>Gases</strong></td>
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<tr>
<td>SO2, NO2, NOx, CO,</td>
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<tr>
<td>O3, benzene, VOC (ozone precursors), Hg</td>
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<td><strong>PM10</strong></td>
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<tr>
<td>mass concentration,</td>
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<td>B(a)P and six other PAH compounds, Pb, As, Cd, Ni</td>
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<tr>
<td><strong>PM2.5</strong></td>
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<td>mass concentration,</td>
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<td>particles (SO42-, NO3-, Cl-, NH4+,</td>
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<td>Na+, K+, Ca2+, Mg2+, elemental carbon, organic carbon)</td>
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<td><strong>Rainwater</strong></td>
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<td>Hg, Pb, As, Cd, Ni, B(a)P and six other PAH compounds</td>
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define the reference method to be used for each relevant pollutant. In Finland the responsibilities are handled by a decentralized system, so it is the responsibility of municipal authorities to be aware of the air quality situation in their territory and arrange air quality measurements when necessary. In 2010 there were about 35 different measuring organizations (local networks) in Finland producing air quality data at about 110 measurement stations. The Finnish Meteorological Institute (FMI) is responsible for measurements on background areas for the European Commission and different international environmental monitoring programmes (WMO-GAW, EMEP, HELCOM, AMAP). The Institute also collects all air quality data measured by the local networks for further dissemination and reporting.

Participation in interlaboratory comparisons is extensive

The Finnish Meteorological Institute is an expert institute in air quality issues under the national Environmental Protection Act. FMI maintains the National Reference Laboratory (NRL) and is accredited for the required reference methods. The tasks of NRL are inter alia to maintain traceable calibrations, to organize intercomparisons and training of the local networks and to perform field audits. NRL participates in international intercomparisons organized by the European Reference Laboratory for Air Pollution (JRC/ERLAP), International Bureau of Weights and Measures (BIPM) and European Collaboration and Measurement Standards (EUROMET). FMI’s Calibration Laboratory (K043) participates in international intercomparisons for O3, NO, NO2, SO2, CO and benzene using automatic analysers. FMI’s Testing Laboratory (T097) participates regularly in international intercomparisons of analytical methods for inorganic pollutants organized by WMO and EMEP since 1977. In the field of organic air pollutants, the laboratory participates in PAH intercomparisons organized by JRC (Joint Research Centre of the European Commission) and in testing of promising reference materials for PAH compounds and heavy metals in airborne particulate matter. Additionally, WMO performs field audits on the Finnish field site of the worldwide GAW monitoring network.

Real time and historical data available to the general public

The National Air Quality Portal (http://www.ilmanlaatu.fi/) is maintained by FMI for fulfilling the EU requirements concerning dissemination of environmental information to the general public. The portal is a free public web service and data management system containing all available real time and historical air quality information for Finland. FMI takes care of ozone alerts to the general public and air quality data reporting to the EC and various environmental data banks.
The European Drinking Water Directive (DWD, 1998) is the harmonized legal basis for drinking water quality and monitoring throughout Europe. It is the primary goal of the DWD to protect human health and ensure that drinking water is wholesome and clean at the consumer’s tap. Following technical and scientific progress, the European Commission is currently preparing a revision of the DWD.


No political decisions have been taken and revision is still under lively discussion. However, we would like to highlight the following alterations that have been agreed by the technical working groups in Brussels.

### Water Safety Plan (WSP)

The WSP comprises the general principles of system-specific hazard identification and risk assessment. The key elements are system assessment, operational monitoring and management arrangements along the whole water supply chain from capture to tap. The principles correspond to the well known HACCP approaches in the food industry.

Experience of implementing WSP for German water suppliers will be given.

### Monitoring and sampling

For the strategy of drinking water surveillance monitoring, two groups of parameters were suggested:
**Group 1:** Parameters considered most important to a potential health impact or in relation to customer acceptability and optimum treatment. These parameters must be monitored unless it is demonstrated by risk assessment that they are not present or present at consistently low concentrations in the raw or drinking water.

**Group 2:** Parameters generally occurring only under specific circumstances. The need to monitor these parameters routinely is determined by risk assessment (WSP).

There is a general distinction proposed between operational monitoring and compliance monitoring. For both monitoring procedures, the application of good sampling practice is required.

**Standards for products in contact with drinking water conform to Article 10 of DWD**

The European Acceptance Scheme for construction products (EAS, 2004) is an approach for the mutual acceptance of products in contact with drinking water. As the EAS has not been implemented so far, on a voluntary basis, a proposal for a harmonized procedure for the acceptance of metallic materials was issued recently by four member states (“±MS approach”). The objective of this initiative is convergence of the approval schemes in the respective countries (UK, F, NL and DE) and development of a proposal that can serve as a template for other member states and the Commission.

**Health aspects**

The system of setting limits for drinking water is based on two principles. The dominant approach is based on the relevant toxicological aspects of the parameters and takes into account that drinking water must be safe and healthy over a life period.

The second approach applies to the limit values for pesticides and metabolites that may have a practical or political dimension in their derivation and are mainly not based on health.

Examples will be given, for example endocrine disruptors and emerging contaminants.

**Quality assurance**

The DWD follows a fitness-for-purpose approach. This means that no specific methods are prescribed (with the exception of methods for microbiological parameters), but the methods applied must fulfil performance requirements for precision, trueness and limit of detection (LOD).

In the frame of laboratory accreditation according to EN ISO 17025, the most important tool of external quality assurance is successful participation in performance tests (PT, “interlab trials”) according to ISO 17043. Examples on the state of play will be given.
Using EQA for Quality Improvement in the USA

SHARON S. EHRMEYER

In 1988 the United States Congress passed Public Law 100-578 to implement the Clinical Laboratory Improvement Amendments (CLIA). CLIA mandates for the first time minimal standards for all clinical laboratories to ensure accuracy, reliability and timeliness of patient test results.

External quality assessment (EQA), which is known as proficiency testing (PT) in the USA, is a CLIA mandate to assess a laboratory’s ability to produce the right answer. CLIA identifies 80 “regulated” analytes for mandatory PT, details “rules” that must be followed, and states acceptable performance limits for each of the analytes. Acceptable performance for one event of five samples per analyte is none or one wrong (>80% correct); more than one incorrect result is failure for that analyte in that event.

A second CLIA performance rule looks at all analyte results tested by a laboratory in a particular specialty or subspecialty. Acceptable performance is >80% correct responses. Except for laboratories performing minimal testing, this rule is very difficult to violate. Failure in a single event has no consequence other than requiring the laboratory to take the necessary corrective actions to resolve the problem and then document these actions.

The government uses “unsuccessful” when referring to cumulative failures -- failing the same analyte in two of three consecutive events. Unless patients are in jeopardy, “unsuccessful” laboratories generally are allowed to continue to provide results for the failed analyte(s), provided a plan of correction is created and followed. However, the government can and does implement a range of sanctions that culminate in mandatory suspension of testing. Despite the many limitations of the PT process, it is a valuable quality assessment by participants, regulators/accreditation bodies and manufacturers.

The government in its recent CLIA Proficiency Testing Brochure reiterates the importance of PT as a laboratory tool for verification of the accuracy and reliability of testing. However, there are concerns in that no comprehensive studies clearly establish PT as an effective quality indicator. This became more obvious with the Maryland General Hospital Scandal of 2004, where for 14 months, questionable HIV and hepatitis tests were reported when quality control indicators showed the results might NOT be accurate. The Government Accountability Office (GAO) and the Centers for Disease Control and Prevention (CDC) investigated. For the PT process, GAO stated, Comprehensive analysis of the proficiency testing database is [would be] particularly valuable because it provides a uniform way to assess the quality of lab testing across survey organizations....

The 2008 CDC report lists 21 recommendations to improve PT. Stay tuned!
Dr. Sharon S. Ehrmeyer

PhD, MT (ASP), is Professor of Pathology and Laboratory Medicine and Director of the Medical Technology Program at the University of Wisconsin in Madison, USA. She is active among others at the National Committee for Clinical Laboratory Standards, where she serves on the Board of Directors. She has concentrated in her research in the areas of clinical laboratory quality and the impact of government regulations on laboratory practices.

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The European Federation of Clinical Chemistry and Laboratory Medicine (EFCC) was founded in 2007 as the European branch of IFCC through the merger of the much older FESCC and EC4. One of its main goals is “to improve patient outcomes and the quality and safety of patient care through the highest standards in laboratory medicine”.

EFCC has six committees related to public and professional relations, science, quality management, education and training, profession (European register), and finance. To achieve specific goals formulated by the board but reflecting priorities given by national societies, Working Groups are set up with a specific objective and most of them have a restricted period of existence. Many Working Groups on quality aspects have been set up by the Science Committee, for instance on standardization, guidelines and test evaluation. The focus of this presentation is on the activities of the Quality Management Committee.

Guidance on application of EU IVD Directive

The recently set up working group on IVD (in vitro diagnostics) focuses on interpretation and harmonization of the application of the EU IVD Directive. It has steered the EFCC reaction on the public consultation about the present Directive, for instance about “in-house developed tests”, and validation and traceability required for tests with EC recognition. It will also provide guidance for installation and preventive maintenance of equipment needed according to existing regulations. The European Diagnostic Manufacturers Association (EDMA) is represented on this working group.

Third edition of ISO 15189 is progressing

The longstanding working group on Accreditation and ISO/CEN standards is active on both aspects. It has made representations on ISO TC 212 and CEN TC140 contributing on standards related to the medical laboratory field. It is concerned with ISO 22870 Point-of-care-testing (POCT) – Requirements on Quality and Competence, and especially ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence.

One item that leads to a lot of discussion is uncertainty. For the Working Group it is important that it contributes to our service to physicians, and that it is accepted by laboratory professionals. We agree with the way this is handled by Australian colleagues. The work on the third edition of ISO 15189 is certainly progressing, and
one of its main advantages is that it is easier to understand. A clear differentiation is made between validation and the more restricted verification.

Harmonizing accreditation practice

In the area of accreditation we are well represented in the EA (European cooperation on Accreditation) Health Care Committee. EFCC has recently been accepted as a Recognized Stakeholder of EA. We have influenced the discussion about flexible scope as accepted in the guideline EA4-17 “EA position paper on the description of scope of medical laboratories”. It states clearly that the majority of tests should be included and that consultation forms an integral part of the accreditation process. This is in line with the position of IFCC. Many differences still exist between the way accreditation is performed in different European countries. Within this Committee and in our Working Group we try to harmonize the accreditation practice. Involvement of laboratory professionals in all these activities is important.

Wim Huisman

is a clinical biochemist and head of the Laboratory of Clinical Chemistry and Haematology of the Medical Center Haaglanden in Den Haag, The Netherlands. He has been active in the field of quality systems and accreditation since 1987, first in the Quality Committee of the Nederland Society of Clinical Chemistry and Laboratory Medicine, and later in the Working Group on Accreditation of EC4. Presently he is chairing the Working Group on Accreditation and ISO/CEN standards of the EFCC.
As rightly stated in ISO 15189, the main purpose of laboratory tests is to contribute to patient care, so EQA should focus on correct interpretation of analytical results into clinically correct and useful information for the requester.

EQA can also be used for continuing education and quality improvement. Laboratories can be familiarized with emerging parasitological and viral diseases through EQA challenges. The EQA material may be used for interpersonal tuning.

Item 5.6.4 of ISO 15189 (4) states the following:

The laboratory shall participate in interlaboratory comparisons such as those organized by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled. Interlaboratory comparison shall be in substantial agreement with ISO/IEC Guide 43-1.

External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

Our examples of new EQA approaches for the preanalytical, analytical and postanalytical process according to the requirements of ISO 15189 are discussed below.

Preanalytical process

Examples of the preanalytical process are:

- Paper challenge with a given clinical context. Participants receive a clinical history for which they are expected to propose the most appropriate tests to be performed or a decision tree with a sequence of tests to be performed.
- Evaluation of sample appropriateness. In these schemes, participants receive EQAP samples demonstrating one or other deficiency, such as wrong sample type for the requested tests, expired tube or swab, or too long time since sampling. They are expected to detect sample deficiencies, refuse analysis or report conditionally.
- Evaluation of appropriateness of mailing conditions. Participants are expected to send a sample under their usual mailing conditions to the organizer (inverse EQA).

Analytical process

Here we distinguish participant performance evaluation and method performance evaluation. The scheme design and sample material will be chosen to suit the intended purpose. New types of sample material will be used, such as movies on DVD for sperm motility evalu-
Postanalytical evaluations

Here we can consider the use of correct reference values and the conversion of analytical results into appropriate clinical information.

In the last part of the lecture at Labquality Days, 10 – 11 February 2011, we will give an example of what an EQA survey might be like in the near future. The haematology example given will include all the aspects discussed, and especially the postanalytical process.

In conclusion, EQA schemes organized by professionals can play an important role in surveillance of the laboratory's contribution to patient care.
Health care institutions are under tremendous cost pressure and looking for ways to reduce costs and work more efficiently. Erroneous laboratory results can have severe and expensive consequences not only on the efficiency of the hospital, but also on the patient treatment and outcomes. These consequences include not only the rejection of the sample, but also the subsequent impact of that rejection or perhaps undiscovered error through delaying the appropriate therapy or conducting unnecessary clinical actions, possibly leading to life-threatening complications. Studies have shown that the majority of laboratory errors occur during the preanalytical phase with its many interrelated steps and stakeholders, outside the control of the highly standardized laboratory.

Investigating the financial impact

We have used a cost model that for the first time enables investigation of the financial impact of repeated blood collections. The central measure is the extended length of patient stay or the delay in hospital processes due to preanalytical errors. In an evaluation of the model conducted in other hospitals, health economists Frost & Sullivan revealed that the cost associated with preanalytical errors can be as much as € 347,000 (0.2% to 0.3% of hospital operating cost). The model highlights the substantial cost and time savings that can be achieved by reducing errors in this phase.

Diagnosing areas for improvement

However, with patient safety at risk, the focus should be not only on the cost associated with these errors but also on reducing sample rejections due to poor sample quality and thereby improving patient outcomes. The preanalytical review is a method of diagnosing areas for improvement. With the right tools to address the identified areas, this approach has the potential for significant reduction of preanalytical errors.

The review provides valuable information on the processes between sample collection and analysis, and the way errors affect sample quality. This in turn helps to prioritize improvement activities and plan resources effectively. These activities often include the need to train people involved in the preanalytical phase, however it is important to focus the training to maximize its effectiveness with health care workers who may have many conflicting priorities and time demands.

At the University Hospital Greifswald we have utilized both of these tools to evaluate, monitor and improve our preanalytical phase. We will present the results of this work and discuss their implication and applicability for other hospital institutions.

Astrid Petersmann

Dr. Med. Dipl. Biol., works as a senior physician at the University Hospital of Greifswald in the Institute of Clinical Chemistry and Laboratory Medicine in Greifswald, Germany. By training, she is a physician as well as a biologist. The laboratory serves both hospital and ambulatory care facilities. She works on POCT concepts, among others things.
Training day for scheme experts generated ideas and discussion

MINNA NÄRHILÄ

On Tuesday 30th November 2010 Labquality held an External Quality Management Training day for its scheme experts. The 27 experts who gathered in response to our invitation first heard news about development of the company’s operations and the outlook for the future, and then discussed the ISO 17043 standard and accreditation of schemes. The event was held at the training facilities of Restaurant Limone.

“Labquality’s organizational structure is currently in an interesting phase of change,” said Managing Director Mauri Keinänen, summarizing the company’s development last year. The company has grown strongly as an organization in recent years and at the same time it is looking outwards to growth markets abroad. The number of employees in the company has grown from 18
in 2000 to 36 currently. While striving to retain the flexibility and efficiency of a small company, the organizational structure has been modernized to meet current and future challenges.

Media of today and the future

Social media expert Neil Fenton of 10Duke Software Ltd began his lecture to the participants with challenging questions: “How many of your children use Facebook? How many of you are on Facebook?” The difference between the generations was clear and caused amusement as only a few hands rose in answer to the latter question.

Fenton challenged those present to think how social media could be utilized in an expert organization, what alternative social media are available and how the experts and company could benefit from the system. The lecture on social media acted like a starting pistol for group discussions.

Accreditation of schemes

The lecture part of the training day ended with concise information from Production Manager Minna Loikkanen about accreditation of certain Labquality schemes and the ISO 17043 standard. Labquality has been certified to ISO 9001:2008 standard since 1995. Now Labquality has decided to seek accreditation of certain schemes in accordance with the requirements of ISO 17043. It was said that the final choice on which schemes to put forward had not been taken, but one main aim is that the schemes chosen should represent Labquality’s strongest expertise and be the schemes for which accreditation would be of the greatest benefit to clients.

ISO 17043 is challenging and the accreditation process will require a lot of work and expertise from Labquality and input from experts. Loikkanen’s lecture, which was followed by a lively discussion, concluded the lecture part of the training day. The participants spent the rest of the day divided into groups to discuss development of cooperation between experts and Labquality.
Meet us at the spring exhibitions in Berlin and in Milan!

Labquality will take part in the major Clinical Chemistry Exhibition in Berlin and Microbiology Congress in Milan. Come and meet our personnel and hear about Labquality’s latest services and products. Looking forward to meeting you at:

- **IFCC WorldLab and EuroMedLab**
  Berlin, Germany, 15 – 19 May 2011

- **21st ECCMID/27th ICC**
  Milan, Italy, 7-10 May 2011

Further information on the exhibitions from info@labquality.fi

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Key to valid results is a clean laboratory environment

One of the most important principles in laboratory testing is a clean environment, clean instruments and a clean laboratory dish. This means not only clean from sample residues, but also clean from detergent residues. In 2011 Labquality will continue its **new Residues of detergents and disinfectants, detection (8210) scheme**. Participants will be able to register to receive samples six times per year.

The scheme is planned to detect residues of detergents and disinfectants in rinsing water and on surfaces using a test which is based on light emission of bacteria *Vibrio fischeri*. Further information on the scheme is available from either info@labquality.fi or jonna.pelanti@labquality.fi
New guideline
How to interpret Labquality EQA reports

The EQA report guideline is available for Labquality's customers in the Participant Services channel on the Internet at www.labquality.fi. The first part of the instructions (Genetics to Clinical Chemistry) is now ready. The latter part (Microbiology to Pathology) will be published in January 2011.

The guideline helps users to get the significant information from Labquality EQA reports. With the reports you can follow up your performance from survey to survey and see whether your method copes with low and high concentrations in EQA samples. For further information, please contact our Client Services Office at info@labquality.fi.

Labquality data processing system to be renewed

A comprehensive IT project is in progress at Labquality to create a modern and efficient data processing system for the company. The project includes comprehensive and varied extranet services for our clients. The aim of the new system is to enable easy and efficient receipt of clients' method data changes, results and orders, and production of reports and comprehensive information for our clients and Labquality. The entire IT project is expected to take several years. For more information, contact jonna.pelanti@labquality.fi.
Labquality Group’s input on international operations acknowledged

The major Finnish financial newspaper Kauppalehti and its research and analysis department Balance Consulting rank Labquality Group as the eleventh most successful Finnish company in international markets on the basis of its financial performance.

According to the the Menestyjä certificate (Menestyjä refers to the most successful company in Finnish) the company has well-established operations, steady growth, good financial results and profitability, a strong financial structure and liquidity that secures continuing operations. Labquality Group was compared with other companies that derived at least 30 percent of their turnover from exports. The ranking was based on year-end data in Financial Statements for 2009.

New colours refresh company image

Labquality’s logo and letterheads have an extra new colour following a makeover of the company’s image by advertising agency Mainososasto Lahti. The form of Labquality’s logo is unchanged but now red has been added as an extra colour to the blue and white. The blue-red-white colouring will appear in, for example, brochures and as the company’s exhibition stand colouring, as well as the logo.

The colouring in Labquality’s letterheads and the autumn 2011 Programme will be changed, too. Labquality’s 40th anniversary logo has the same colouring.

“The idea for the colours emerged from sample tubes, as many different coloured sample tubes were presented as we selected the depiction. We also sought a colour code to distinguish special fields from each other,” explains Art Director Ari Kiuru of Mainososasto Lahti. The outcome of this work can be seen in the letterheads already in use and in the Programme to be published at the latest by the autumn.