QUALITY MANAGEMENT IN A HOTLAB – CHALLENGES & SOLUTIONS

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ABSTRACT

As nuclear installation at Paul Scherrer Institute (PSI) the department HOTLAB (AHL) is obligated by the Swiss regulator to serve a management system according to the IAEA Standard GS R-3.

The Laboratory of Nuclear Materials (LNM) as well as the AHL has to fulfill the ISO 9001 standard as a major request from their customer's side (fuel industry and Swiss power plants).

As consequence AHL and LNM have set up a common quality management system (QMS) according to ISO 9001 (SN-EN-ISO-9001) and obtained their certificates in 2007. Since the starting of the QMS in the HOTLAB (first certificate 1999 with the predecessor organization) the constraints and requirements increased continuously.

After a first phase of the implementation of the QMS the predecessor organization decided to develop the management system on the basis of the commercial software IQSoft of the company IQS Ltd. in Zofingen (CH). The system was implemented in 2005 in the former Microsoft Access based program, mainly using the modules Document Management, Continuous Improvement Process, as well as the Resource Management.

In 2010 it was decided, due to the development of the software, to migrate the database on a MSSQL server. With the increased demands of the regulator body the use of the database IQSoft has been intensified. In 2013, a maintenance program including all historic data and used since 1990 was integrated into IQSoft. The IQS Ltd. itself is currently developing the application further in terms of web and app functionality. With the new mobile solutions, user-friendly presentations and applications can be realized inexpensively and effectively. This increases the acceptance of the whole management system among the employees.

This work summarizes the past development, the occurred challenges and found solutions as well as the envisaged further future developments. The Swiss regulator has commended the system as exemplary at their last inspection. The PSI HOTLAB QMS might become a successful example to others.

1. Introduction

The hot laboratory (HOTLAB) was originally built in 1961 as part of the former Swiss Federal Institute for Reactor Research (EIR) for carrying out materials science, experimental investigations to highly radioactive samples and for the preparation of diagnostically and therapeutically useful radioisotopes. The facility HOTLAB today is used for applied materials research for high-level radioactive samples, which originate mainly from core internals of nuclear power plants (NPP), research reactors, the spallation neutron source (SINQ) and the proton accelerator of Paul Scherrer Institute (PSI).

The department HOTLAB (AHL) with its infrastructure is also highly relevant for the immediate clarification of damage and corrosion cases in Swiss NPP problem situations.

The legal framework for the safe operation is given by the Nuclear Energy Act (KEG), the Radiological Protection Act (StSG) and its derived regulations, such as the Nuclear Energy Ordinance (KEV) and the Radiological Protection Ordinance (StSV).

The HOTLAB is supervised by the Swiss regulator ENSI (Eidgenössisches Nuklearsicherheitsinspektorat) and the international section of the Swiss Federal Office of Energy (SFOE) and is considered as a research facility. Universally valid are the federal, cantonal and PSI internal rules for fire protection, occupational safety, risk management, transport of radioactive material, etc. As nuclear installation at PSI the AHL is obligated by the regulator to serve a management system according to the IAEA Standard GS R-3.

The Laboratory of Nuclear Materials (LNM) is the designated Swiss center of competence in the field of material behavior and aging in nuclear power plants. With its commitment the LNM provides important

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research contributions to the sustainability of current and future nuclear power plants for electricity and heat generation. Short to medium term, research is application-oriented to scientific services, long term it is oriented towards basic research.

The LNM uses the PSI large scale research facilities and laboratories like the synchrotron or neutron source. In particular, it maintains a close collaboration with the Department HOTLAB as one of the main users of this facility.

At PSI there are several independent labs or departments which are using different quality management systems for different reasons but LNM as well as AHL have to fulfill the ISO 9001 standard as a major request from their customer's side (fuel industry and Swiss power plants).

The adoption of a quality management system (QMS) fulfilling both, the GS R-3 and the ISO 9001 standards have been a strategic decision of AHL as well as LNM. By consequence AHL and LNM have set up a common QMS and obtained their certificates in 2007. Since the starting of the QMS in the HOTLAB (first certificate 1999 with the predecessor organization Laboratory for Materials Behavior (LWV)) the constraints and requirements increased continuously.

The design and implementation is manly influenced by the organizational environment as nuclear installation with its risks, the organizational structure as two independent labs of a scientific institute as well as the varying needs of the various groups of the labs with particular objectives and working results. The processes and the education and training of the employees differ between AHL and LNM but the QMS itself serves for both.

After a first phase of the implementation of the QMS, the LWV organization decided to develop the management system on the basis of the commercial software IQSoft of the company IQS Ltd. in Zofingen (CH).
The philosophy of IQS Ltd is: "IQS creates quality" and "Acting instead of reacting".
Due to its many years of experience IQS has a broad expertise and flexibility in this field. The customer orientation allows also to tackle QM systems for specific environments like a hotlab.

The todays QMS was implemented in 2005 in the former Microsoft Access based IQSoft program, mainly used for document management, continuous improvement process, as well as for the resource management.

There were different needs in the past four years, to improve the settled QM-system to be ready to manage the HOTLAB in the next decade.

2. The history of the QM-System of AHL and LNM

Right from the startup of planning the construction of the PSI HOTLAB a kind of quality management system was implemented.

2.1. System until 2010

Already in 1957 rules were established how to proceed, control, classify and archive documents and records as well as how to determine, provide and maintain the infrastructure.

In 1990 the regulator requested a database system to ensure the maintenance of the safety relevant infrastructure of the HOTLAB, especially, hot cells, glove boxes, ventilation system, waste water and the integrity of the building itself. Therefore the Swiss software named SAMA was introduced as maintenance and repair system for the infrastructure group.

Mid nineties the need for a quality management system according to the ISO 9001 standard was recognized. A large project started to document the used system according to the new ISO standard, including the introduction of a new quality management hand-book, new procedures according the use and calibration of measuring and test equipment as well as new rules for control of documents and records. The Laboratory for Materials Behavior (LWV) was firstly certified 1999 according ISO 9001:1994, followed by a recertification in the year 2002. In the following year the system was updated to the new process oriented ISO 9001:2000 and the need for a special software tool was recognized.

Due to the experiences of the Department Safety and Irradiation Protection of PSI (ASI) with the Software IQSoft, this product was also introduced in the LWV in 2005.

This software product was developed from 1993 on and consists of different program modules based on a Microsoft Access database. Depending on the needs of the users it is possible to license different modules, functions as well as in different languages (German, English & France). The LWV started using the modules for managing "documents and data", "testing and operating equipment" as well as "opportunities for improvement". The main focus was clearly on managing the documents created by the lab.

After the last recertification of LWV in the year 2006 the lab was divided into two units, the Department of HOTLAB (AHL) and the Laboratory for Nuclear Materials (LNM).

Both new units got a new certificate in the year 2007 and have been successfully recertified according to ISO 9001:2008 in the years 2009 and 2012.

Figure 1: (left) The old filing system: Log books for testing and operating equipment, literature and standard working instructions; (right) laboratory journal. All needed information was there, but not always easy to find.

2.2. System development starting 2010

In 2010 it was decided to improve the use of IQSoft, due to the development of the software and new needs of the AHL. The first step was the migration of the Access database on a new MSSQL server. All documents which were stored historically on a windows file server were moved to a newly introduced open source and open standard enterprise content management system (ECM) named Alfresco. With this step we have been enabled to give access to the documents through WebDav protocol as well as with CIFS protocol for all authorized employees. Alfresco enables to manage user authorization in an easy and efficient way down to a single document.
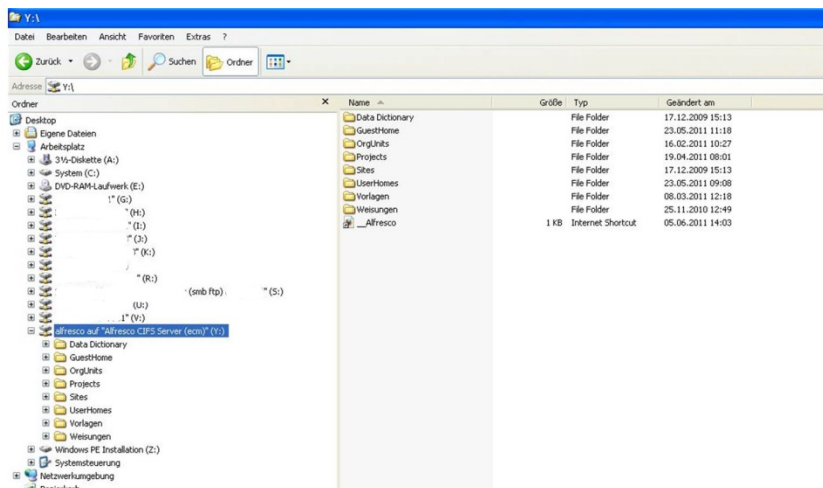

Figure 2: Alfresco tree structure look and feel like Microsoft Windows file explorer.

At the same time PSI introduced the new web management software FosWiki for developing the PSI intranet. With the possibility of the MSSQL server, the WebDav access to the documents and the newly intranet policy we have been enabled to establish several user defined web sides with direct access to the IQSoft data. This enhanced the acceptance of the QM-system at AHL and LNM significantly.

At the same time IQS Ltd. changed their strategy towards web application. HOTLABOR QM-System introduced the first versions of the web applications from the above mentioned modules ("documents and data", "testing and operating equipment", "opportunities for improvement") to be used in parallel to the well-known Access modules.

The number of modules was increased by the use of an education and training module, as well as special modules for meetings, audits and projects.

With the increased demands of the regulator body the use of the database IQSoft has been intensified. In 2013 the decision was taken to integrate the SAMA maintenance program including all historic data and used since 1990 into the IQSoft database.

This project [1] was performed together with an IT student performing a 6 month traineeship at the HOTLAB. Just the set of the historical journals includes almost 35'000 data entries.

After the migration HOTLAB started to program special queries directly on the MSSQL server to create interfaces between the IQSoft database and Microsoft office documents[1]. With this it is possible to send official documents to the regulator with different requested lists of persons, tools, equipment and further more.

The IQS Ltd recognized that web application will be the main future user interface of their product. They started to convert their web application to the .NET environment to enhance the capabilities and user friendliness of their product.

As PSI HOTLAB was one of the major customers of the last years requesting further development, the QM-System of HOTLAB became an alpha and beta testing site for new versions which let to a lot of additional input and ideas.

IQS Ltd. is currently further developing the application in terms of web and mobile app functionality. With the new mobile solutions, user-friendly presentations and applications can be realized inexpensively and effectively. This increases the acceptance of the whole management system among the employees.
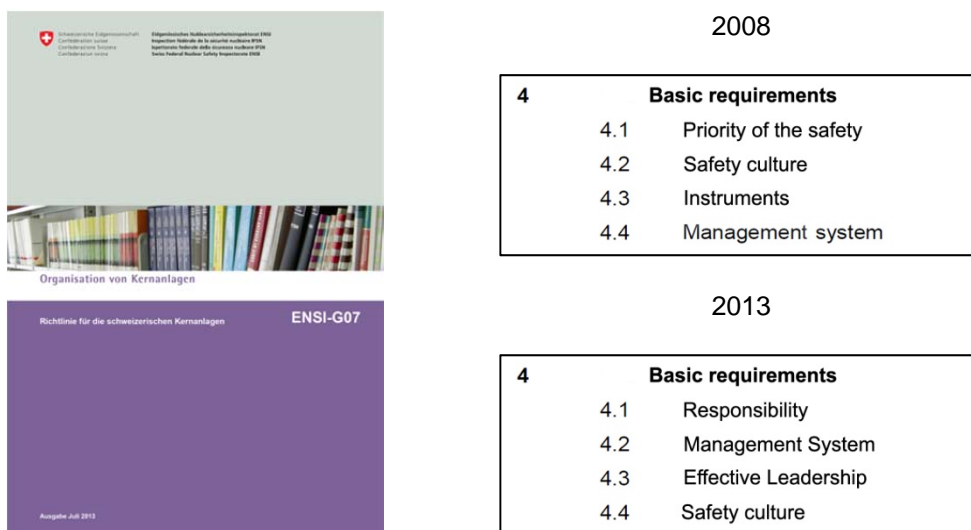

Figure 3: (left) The ENSI guidelines for Swiss nuclear facilities; (right) chapter four, changing of the priority concerning a management system.

2.3. System today

The QM system of the HOTLAB is based on a process model according to the requirements of ISO 9001:2008. The technical implementation of the system is realized by the database IQSoft and additional tools like Alfresco, Foswiki, as mentioned in the chapters above.

All employees are provided with the appropriate level of the application-based QMS online at their working place.

The today's system integrates not only the quality process model but also processes for special measures for third parties and research. External requirements concerning handling and transportation of radioactive materials, regarding occupational safety, fire protection, technical inspections of facilities and equipment, and maintenance are also supported by the QM system.

The QM system defines workflows and makes them transparent to the customers. The organization aims to enable all processes to continuously improve. In addition, the formalization helps to avoid errors or - in case

of errors - fix them systematically. The administrative processes are regularly reviewed by the line and in internal and external audits.

The system is designed in a kind, that in addition to the requirements of the ISO 9001:2008, international and national regulations for handling radioactive materials and special requirements of PSI are naturally integrated. The QM system is as such binding for all employees of the AHL and LNM.

Figure 4: (left) The AHL certificate; (right) The LNM Certificate

3. Used IQSoft Modules

IQSoft used by more than thousand different customers is a proven management tool. For us it is the tool for measurable and sustainable improvement of the quality in our work environment. IQSoft documents processes, associated information, presenting them clearly and integrates a wide variety of standard requirements. It simplifies internal processes, reduces errors and therefor lowers costs. The main used modules are:

3.1. Documents and data

With this module the QM-System provides our employees all the documents such as manuals, process descriptions, forms, checklists, instructions, etc. directly on the computer screen. This eliminates a large number of manuals in printed form. In addition to textual and graphical documents all forms of multimedia (image, movie, sound) can be integrated via hyperlinks.

External internet documents such as standards and laws can be linked to the corresponding web address.

We grouped our employees into distribution groups, such as "member of LNM" or "quality management team" etc. Each document introduced into the QM-system can have multiple distribution groups assigned. When introducing a new document or revision an existing one, the concerned users are informed selectively by e-mail from the system, that a new document is available for them. IQSoft logs those changes automatically in a document history database, which shows for each document how often and for what reasons it has been changed. The control of timeliness of the documents is automated.

3.2. Testing and operating equipment

All test, measurement and operating equipment is managed with all relevant data in IQSoft. The tests, repairs, status changes, etc. are logged directly for the concerned areas and the corresponding data is tracked independently. The system reduces the necessary calibrations of measurement equipment to a minimum.

In addition to the usual inputs such as tools, machinery, experimental equipment etc. the main IT infrastructure as well as IQSoft itself is managed in the module. All configuration changes, extensions and support services are documented. Thus, we always have an accurate overview of available devices and also know the status of especially licensed and installed software at AHL and LNM. Repetitive maintenance activities, especially safety relevant ones, are also systematically planned and managed by the program. With the possibility to know in which system what equipment is installed we could easily fulfill some special requirements of the Swiss regulator.
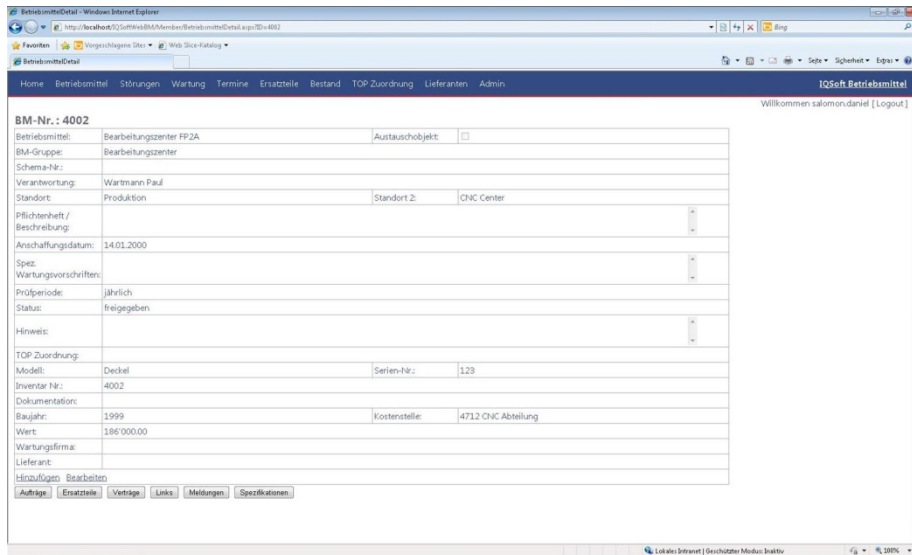
Figure 5:   Example of records in the Web based module „testing and operating equipment".

3.3. Opportunities for improvement

With this module we manage the continuous improvement process (CIP), especially customer complaints or supplier problems, internal failures or suggestions for improvement, work safety problems, audit weaknesses and training needs. Especially we use this tool to monitor all INES (International Nuclear Event Scale) events and take if necessary our counter measures.

The module itself easily allows implementing electronic documents or digital photos via hyperlink with the CIP messages, which allows accessing them at any time and without search. Measures for the further processing of messages can be delegated to individual employees, locations or decision-making bodies (meetings) and the status can be monitored.

CIP in IQSoft is an integrated information system. There is complete transparency for the users (e.g. applicants of proposals for improvement, auditors, and process owners) as well as the management of the QM-System. They can inform themselves about the current state of a CIP via the intranet at any time.

Figure 6:   Web module "Opportunities for improvement"

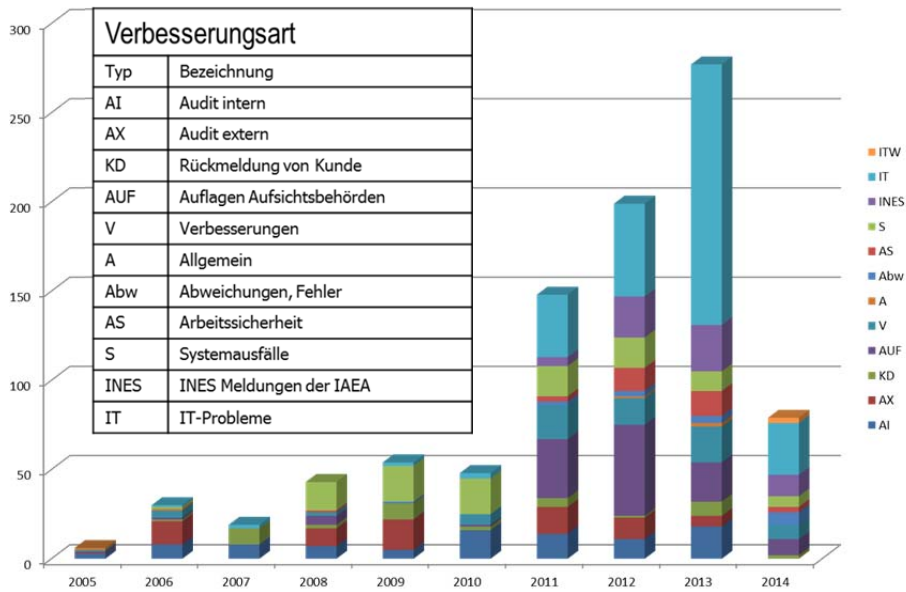| Verbesserungsart	
Typ	Bezeichnung
AI	Audit intern
AX	Audit extern
KD	Rückmeldung von Kunde
AUF	Auflagen Aufsichtsbehörden
V	Verbesserungen
A	Allgemein
Abw	Abweichungen, Fehler
AS	Arbeitssicherheit
S	Systemausfälle
INES	INES Meldungen der IAEA
IT	IT-Probleme

Figure 7: The development of the quantity of the reports from continuous improvement process (CIP), Opportunities for improvement Module
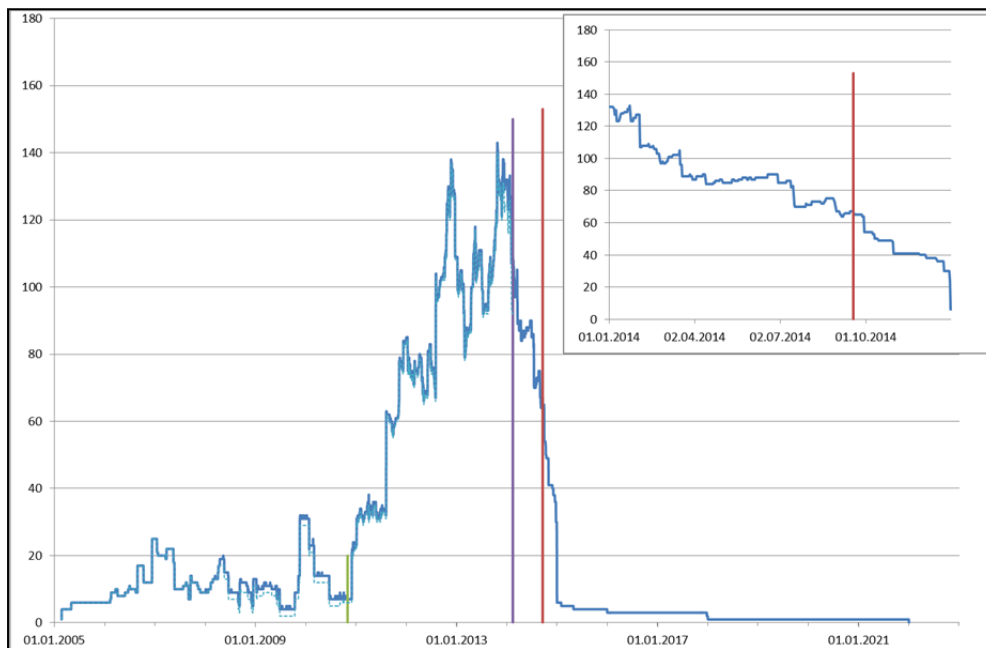

Figure 8: Number of open ,cases in Opportunities for improvement

3.4. Meeting management

The meeting management module is an important part of the CIP. The necessary urgent measures of CIP are manly executed by the affected employees, their supervisors or by the process owner. The corrective and preventive measures, however, are in the responsibility of a decision-making body, called in our case QM team. Analysis or decision-making measures from the CIP are allocated directly to meetings of the QM team, so that they will automatically appear in the appropriate agenda. Decisions are logged directly in the CIP database.

3.5. Audits

The audit module is used in our case for planning, preparation, accomplishment and documentation of all internal audits. In addition we document all inspections from the regulator with this module.

All audit questions are linked in the database with processes, documents, organizational units or standards. The creation of necessary checklists and audit plans are thereby done with minimal effort. The audit invitation for the appropriate location, as well as the checklist of evaluation criteria for the auditor and the involved persons are issued automatically by IQSoft. Found issues during the audit are directly put into the system as CIP.

3.6. Education and training

The education and training of our staff is documented and optimized with the "Educ" module of IQSoft. We manage training profiles for individual employees, course reviews and certificates.

Internal training programs and courses are planned, performed and documented directly with this module. The staff conducted training sessions are recorded and tracked as well.

4. Lessons learned

❖ During the setup of the QM-System of AHL and LNM it was recognized that it is only worth if there is a basic acceptance from all employees and a clear benefit to the work result. In case of a scientific institute or lab like ours, we have learned that scientific persons often don't like to deal with an unpopular management process, called quality management. Therefor try to take them on board by evaluating their needs and implement them, if it is possible, in the QM-system.

4.1. To set up a system just to get a certificate will create additional work with no benefit than to have a certificate. One has to live it. The QM System has to mirror the reality. If it describes a kind of wanted perfect processes which do not exist in reality, one will get major difficulties during the next audit.

4.2. To reach additional value from the system it is of absolute importance to have an open ear for the colleagues and their criticism on the QM System and to deal with their problems seriously. It is almost not possible to push a QM System against the employees. Always try to involve the staff. Therefore the module "opportunities for improvement" is a simple but brilliant instrument. This module is also a good tool to communicate with the technicians from IQSoft to have constant improvement of the modules.

4.3. It is a good idea to find some QM system friendly people among the employees. With them one is able to build up an efficient QM team and they do also work as mediators between the QM manager and the colleagues. You need anyway people for internal audits. Send the QM team members to external courses to become an internal auditor. It increases the understanding of living QM and helps the QM people to find the weak points and setting priorities.

4.4. The requirements for example made by the Swiss regulator ENSI are permanently increasing. One has to try to implement them in a practicable and transparent way. This causes quit often a lot of programming work at the beginning, but it will result in a comfortable PC work environment for the users.

4.5. A powerful data base and fast server are a must. An intelligent back-up system is also essential. Do not try to save money.

4.6. Maintenance and surveillance on the SQL server are easier, if you have the control.

4.7. Use "talking numbers" to label equipment or parts.

5. Conclusions

This paper addresses the need and introduction of a vital and constantly improving QM system in AHL and LNM. It was shown, that with the right persons at the right places and a clever strategy, it was possible to implement a QM System in an environment affected by scientific people.

The implementation of the SAMA System was done successfully and is great help for the infrastructure people.

The change from Microsoft Access based Modules to Web based ones was important in many ways. Maintenance and surveillance on the SQL server are easier. The access via intranet is simple and that is one of the crucial things for the acceptance in the staff.

Because of our transparent and complete documentation we could convince the Swiss Regulators ENSI from the quality of our QM System, which is really necessary for the future operating permit.

Educating the employees, in how to use the QM System and why it could be helpful is important to keep it alive and to reduce possible restraints to work with it. Also important are refresh lessons and to present improvements and changes.

A QM System will never be complete; it is an ongoing process.

6. Outlook

6.1. A next step is, beside the continuous improvements, to build up an effective WLAN (Wireless Local Area Network) in the HOTLAB and to equip the responsible employees with tablet computers. With the tablets and a QR Code (Quick Response Code) reading App it will be possible to identify labelled testing and operating equipment and report dysfunctions immediately via WLAN to the QM System.
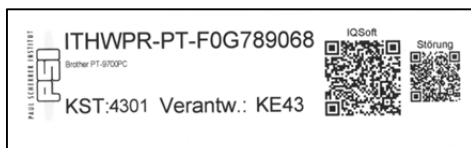

Figure 9: (left) Example of a printed machine label;
(right) Tablet for scanning QR Code on labels

6.2. Together with IQSoft we are building an integral management system including the former KBuch (fissile material management) and Probenverwaltung (own developed Microsoft Acces based management system for active and activated samples). With the consolidation of the two old systems we are able solve some historical program bugs and to generate many synergies. See also "Integrated Management system in a modern HOTLAB" from Marco Streit [1].

6.3. The third Laboratory with activities in the HOTLAB is the LES (Laboratory for Waste Management); it also has the need to be certified according to ISO 9001. Therefore they will adopt the QM System of AHL and LNM. This will save money and time.

7. Acknowledgement

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8. References

[1] M. Streit, R. Zubler, C.Kost, M. Kiel; „Integrated Management System in a modern HOTLAB";
HOTLAB 2014, Baden (CH), 2014