Experience in applying QA in project management and documentation control - Sweden

Johan Andersson JA Streamflow AB, 27 June, 2003

The SKB QA and management system was certified according to ISO 9001:1994 and ISO 14001:1996 in June 2001. There are two aspects of Quality in Project Management “doing the things right” and ”doing the right things”. The SKB project model is described in the “Project handbook” and outlines the structure for project organisation, project decisions, project plans, activity plan, quality plans, audit and control. Ensuring “the right things” primarily stems from the skill and experience of staff and consultants and is handled though extensive internal discussions, production of various planning reports, and through Internal and External Review. SKB has a well-defined documentation system ranging from the publicly available TR, R and P-series down to internal memos and protocols. All reports and documents are numbered and filed. This system works very well. QA in the ongoing Site Characterisation work is essential. In concerns predefined procedures, characterisation plans, method descriptions, model methodology reports, data management and databases, data freezes with connected model version as well as internal and external review. However, while QA is necessary condition it is not sufficient and overly ambitious systems can be very tedious. Procedures and protocols cannot replace thought, technical skill and scientific understanding – especially in the continuous learning process of the Repository programmes.

Apart from being required by authorities, the specific value of the QMS in relation to nuclear waste disposal is that it is a safeguard for avoiding errors and mistakes in data, procedures, published reports and other documents. Creating an accountable information handling with traceable records of the origin of data and other information is particularly important given the long time span of the nuclear waste project and the associated change of staff over time. QMS is thus a necessary component for appropriate design and siting decisions and a safeguard against potential reviewers accusations of errors etc. in documents during the licensing process.

FINNISH EXPERIENCE IN APPLYING QA IN PROJECT MANAGEMENT AND DOCUMENTATION CONTROL OF A NUCLEAR WASTE MANAGEMENT ORGANISATION

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Posiva Oy

Abstract

Early QA practices for the research, development and technical design (RTD) work on nuclear waste disposal were based on rules and requirements of the nuclear power companies. In 1996 a specific nuclear waste management organisation, Posiva, was established, and at the same time the work was started to create a quality system tailored to the specific needs of Posiva. The development of the system was based on the ISO 9001 standard. The QA system was to cover all the activities of Posiva, but the focus was laid on management of RTD projects and, in special, on guidance of the field work related to the site investigation programme. The QA documentation includes a quality handbook, a number of procedures for administrative activities and the work instructions for all those RTD activities in which Posiva's own staff was directly involved. Much effort was paid to the establishment of QA procedures for the use of contractors.

The QA system also defines the procedures for the review and acceptance of all documents, including the RTD reports. All research and investigations reports are in the open domain and single copies are distributed free of charge on request.

The system is now being revised to conform to the ISO 9001:2000 version of the standard and extended to environmental management according to ISO 14001. The revision also takes into account the new requirements arising from the start of construction of the first underground access way, ONKALO in 2004. Since the ONKALO may become a part of the actual repository, the special instructions from the IAEA safety guides will be acknowledged. Pursuant to the recommendations from the regulatory authority, STUK, the new developments aim at creating a good safety culture at Posiva.

National experience in applying QA

Project management and document control

Bernard FAUCHER Andra DG/AI

ITAC meeting n°5

Background :
Historically, Andra had an internal QA system (elaborated in the years 80) as it is a regulatory compliance.
Following a reorganisation and review of QA system, Andra decided in 1998 to be certified as per ISO and set up an action plan to reach this objective.
ISO 14001 was added to the initial objective ISO 9001 (i) as the additional effort was considered as limited (since anyway the environmental monitoring is a regulatory compliance) and (ii) as it was considered beneficial for the "environmental" image
Andra obtained ISO 9001 and 14001 certification in March 2001 (valid for 3 years)

Andra obtained the 2000 update of the ISO 9001 certification in April 2003 (since the previous version ISO 9001 V1994 becomes obsolete by end 2003).

Implementation of ISO QA system :
In order to obtain the certification, implementation and maintenance phases are to be considered :

- Implementation phase of about 2 years with a very strong commitment by Andra upper management. :
- Maintenance phase with regulatory audits (every 6 months) to review and check the QA system

The structure of the QA systems considers 2 types of processes :
1° Production process :

- Concepts of waste management and design of facilities (including modifications and upgrades during or after construction)
- Waste disposal in facilities (acceptance, inventory & localisation in the facility)
- Public information and communication
- Data acquisition (including programme modification with background) & modelling
- Safety & environment

2° Support & logistics process

- Human resources
- Administration (finances, purchase, etc)
- Information system, which is the very important logistical backbone of the system

As per ISO standards, the customers considered in the very specific case of waste management are the following :

- 1° Ministries and authorities in charge of supervising Andra :
- 2° Waste generators
- 3° Public at general

Why a QA system (ISO or not ISO) for waste management organisation aiming at siting a repository?

- in all cases (formal QA system or not), a minimum set of notes and procedures *is always necessary in order to rule the structure of the organisation* (who report to whom ?, who decides on what ?etc).
- in the particular case of a waste management organisation aiming at siting, the following points are essential:
  - consistent decisions and at the right level (procedures)
  - selection of site data, with the same rule whatever the working team and site considered (documentation and data)
  - update of site data and decisions with tracability of inputs and modifications
- it does prepare to the disposal operation as for instance : waste specification and characterisation, waste inventory and localisation in the repository

Conclusion :

- QA system is a heavy necessary investment, which needs preparation and motivation, and to be maintained
- ISO standards provide an excellent frame and a well known reference.
- The ISO 14001 reference, added to ISO 9001 is not a heavy investment and provides definitely a “environmental” image to the certified organisation.
- “No QA system” option can end up in a very expensive exercise.
- The sooner the process is started, the cheaper it is.

Quality Management in German Radioactive Waste Disposal

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Abstract

According to the German Atomic Act, the Federal Government is responsible for radioactive waste disposal. Within the Government, this responsibility lies with BMU (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit = Federal Ministry for the Environment, Nature Conservation and Nuclear Safety). BMU has delegated the task of radioactive waste disposal to the Federal Office BfS (Bundesamt für Strahlenschutz = Federal Office for Radiation Protection). All geoscientific aspects of radioactive waste disposal are covered and handled by BGR (Bundesanstalt für Geowissenschaften und Rohstoffe = Federal Geological Survey). For the task of waste disposal, both institutions are linked by a cooperation contract. On the other hand, DBE (Deutsche Gesellschaft zum Bau und Betrieb von Endlagern für Abfallstoffe = German Company for the Construction and Operation of Waste Repositories) is the main contractor of BfS for the three repository projects Gorleben, Konrad, and Morsleben.

All three institutions BfS, BGR, and DBE, are applying a Quality Management System (QMS) according to DIN EN ISO 9001 “Quality Management Systems” and to the regulations of the Kerntechnischer Ausschuß KTA 1401 “General Requirements for Quality Assurance”. These rules include certification as well as internal and external audits.

General principles of QMS are:

- High quality standards of products according to requirements of customer
- Avoiding faults in all units of organization
- Quality assurance through all employees

A complete set of QM-Manuals defines the demands (what, why), whereas another set of QM-Manuals (like e.g. guidelines, instructions, specifications, check list directives) specifies the respective fulfilment (how, which, when, where). A very important objective of QMS is documentation, especially for license application and for communication with the licensing authority.

QA in Projects and Documentation Control: Experience in Canada

Keith Nuttall

(Abstract for NUMO ITAC 5 Meeting. 2003 July 29-31)

The principles and practice of quality assurance have evolved considerably in Canada, and worldwide, over the past decade. It is now imperative, from a business and regulatory perspective, to demonstrate that products and services meet high quality standards through the implementation of a Quality Management System (QMS) that is compliant with and, preferably, certified to a national or international quality standard. This has become necessary to meet the growing expectations of regulators, the consumer and to compete for business.

This increasing emphasis on quality assurance is evident in the Canadian nuclear industry, the regulator for which is the Canadian Nuclear Safety Commission (CNSC). The quality standard used is the Canadian Standards Association CSA-N286 series, applicable to all life-cycle phases of CANDU power plants, research reactors and nuclear facilities. Consequently, QA manuals and plans used by the nuclear industry (e.g., AECL, Ontario Power Generation) for such facilities must be compliant with this standard. The CNSC has increased its level of scrutiny of the industry to ensure compliance. This is achieved through review and acceptance of documents (manuals, procedures, project plans, annual operational reports) and audits. The industry is also adopting a more proactive approach in dealing with regulation and quality.

Some QA concerns raised by CNSC in the past few years relate to the relatively large number of QA Manuals within an organization, understanding their hierarchy and interrelationship, and the responsibility and accountability of the management structure. Correcting actions and findings from QA audits in a timely manner is a further concern.

The QMS requirements of ISO 9001:2000 are highlighted, together with a case history and lessons learned from implementing a QMS to meet ISO 9001. The importance of procedures for the control of documents is discussed and some considerations for NUMO in developing a QMS are presented.

ITAC5 Meeting
Abstract
"WIPP QA : Suggestions for NUMO"
Erik Webb
Sandia National Laboratories
July 29, 2003

The US has two large waste management programs. One of these, the Waste Isolation Pilot Plant (WIPP) is a repository located in a deep layer of salt below the southeast corner of New Mexico, USA. WIPP's QA Program was well established in the early 1990's as part of preparation for the original regulatory certification which was submitted in 1996. The details of this program cannot be fully described in a short 15 minute presentation so I have identified a small number of critical points relevant to NUMO's activities.

Primary messages to NUMO are:

- NUMO has the opportunity to build a quality management program as a part of their initial efforts and we encourage them to integrate these quality management aspects into all aspects of the program.
- The most important aspect of building a QA program is defining the REQUIREMENTS or goals. The program should think about "how will the information gathered through the QA program be used in the future?" In the US program these are derived primarily from regulatory requirements. However, NUMO has the opportunity to take a broader view and define their QA requirements and procedures in a way that helps them address three objectives: 1) guide program decisions, 2) prepare for license scrutiny, and 3) optimize operations.
- All programs must develop a rigorous structure for implementing the quality management program and documenting the program for others.
- Most nuclear waste programs have experience where their programs evolve in terms of issues, types of work, interactions with regulators and others and the QA system needs to adapt to this evolution. A "graded" approach to defining the QA requirements for a specific activity should be considered.
- There are many subcomponents of the US QA programs that are valuable and should be considered by NUMO for inclusion into their plans.
- Keep the QA system, associated documents and the descriptive language within the documents as simple as possible in order to facilitate implementation.
- The primary organization and the sub-contractors need to have well integrated QA systems.
- Assessment and audits are critical steps for ensuring quality but they should be viewed as ways to continuously improve the program.

Quality Assurance Program for the Yucca Mountain Project

Quality Assurance (QA) requirements for the Yucca Mountain Project (YMP), within the US Department of Energy's (USDOE) Office of Civilian Radioactive Waste Management (OCRWM), are defined in "Quality Assurance Requirements and Description", DOE/ RW-0333 Revision 4 (2003). As noted by Dr. Margaret Chu, Director of OCRWM, in her cover letter to this QA document, "Successful implementation of OCRWM's Quality Assurance (QA) Program is essential for OCRWM to carry out its mission. Central to our mission is the protection of the health and safety of the public and workers, the quality of the environment, and meeting the regulatory basis for the licensing of a Monitored Geologic Repository."

These OCRWM QA requirements are based on three types of documents:

Regulatory documents
These documents define the requirements necessary for obtaining licenses issued by the US Nuclear Regulatory Commission (USNRC).
Commitment documents
These commitments are imposed by OCRWM as necessary for the development and implementation of an effective QA program.
Guidance documents
These documented provide additional information useful in developing a QA program.

USDOE/ OCRWM's QA requirements are basically the same as the ones in 10 CFR 50, Appendix B and NQA-1 that have assured the safety of US public through many decades of licensing and operation of nuclear facilities. A basic intent of QA is to provide a traceable record of all information, data, assumptions and decisions that support a license application. This traceable record is not only for the license applicant, but also for all concerned stakeholders including regulators, impacted States, and local communities.

The USDOE/ OCRWM's QA requirements for the YMP are relatively prescriptive, but the US nuclear industry and the USNRC have found that this level of prescriptiveness useful. The requirements rely on

- redundant activities (i.e. - multiple sign-offs, in-depth checking of activities by independent audits),
- a QA organization reporting to the highest levels of the applicant, and
- a high level of documentation so that records and activities can be reconstituted if it ever becomes necessary.

Many of the requirements have evolved over time and have been modified by lessons learned from licensing and sustained safe operations of nuclear facilities. USDOE/ OCRWM's QA program assures that all activities are performed in a consistent and reproducible manner using documented procedures, allowing traceability of data and decisions.

There are multiple QA programs implemented in a consistent manner under USDOE/ OCRWM's QA requirements, including those of the Management and Operations contractors, various US national laboratories, the US Geological Survey and other contractors. Thus, each person within the Yucca Mountain Project contributes to maintaining OCRWM's successful QA program.

QUALITY MANAGEMENT IN NAGRA

Nagra considers it important to maintain appropriately high levels of performance in the areas of project quality, punctuality of work and budget control; Quality Management is thus an obligation for all Nagra staff. The QM policy is based on the following principles (from the QM handbook):

a) In order to achieve our objectives, we operate a quality management system which meets our needs as well as those of our principals (clients / partners) and supervisory authorities.

b) The description of our organisational structure and procedures determines who is responsible for particular tasks, and when and how these responsibilities have to be exercised.

c) As a project management organisation, we ensure that contract requirements are fulfilled through targeted inquiries into the expectations of our principals and systematic handling and processing of sub-contracts.

d) By providing suitable know-how and careful selection and support of contractors, we ensure that the necessary quality of services is provided in an optimum manner and according to schedule.

e) We attach great significance to meeting deadlines, both those of our principals and those which are imposed internally.

f) We promote the quality awareness of our employees through information and education. We encourage our employees to be aware of both quality and costs in their work.

g) We are convinced that the working methods of every employee have a direct impact on project quality. Personal awareness and careful working methods help to avoid mistakes, or to recognise them at an early stage and eliminate them.

h) Responsibility for quality lies clearly with the **persons performing the work**. In this way we aim to minimise review and monitoring requirements.

i) Assistance in assuring appropriate quality is provided by a series of tools, including a QM handbook, guidelines, checklists, etc.

j) We place the emphasis of our quality assurance efforts on avoiding mistakes rather than on recognising mistakes through subsequent checking.

k) Through periodic checking of our QM system, we ensure that it is observed, that it remains effective and takes account of necessary changes in boundary conditions.

Nagra chose to develop a "bespoke" QM system focused on its specific needs rather than to concentrate on obtaining a more generic ISO certificate. Nevertheless, ISO certification will probably be implemented to meet the expectations of specific Stakeholders (general public, collaboration partners). In any case, it has been recognised that the effort to implement a QM system is well invested and that developing a robust repository project without such a system would be impossible (and unacceptable to regulators).

Development of QA System for Technical Documentation

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Science and Technology Department
NUMO

1. Importance of QA system

NUMO has decided to proceed with repository siting based entirely on an "open solicitation procedure" (a call for volunteer host municipalities). This novel approach reflects the international experience that public acceptance is a key constraint on developing successful repository projects. In the decision-making process by stakeholders or general public, their trust in NUMO is essential. Such trust is founded on NUMO's technical credibility. For this reason, it is essential to establish a rigorous quality management system at this early stage of the siting process. At the first step of the siting process for selection of the Preliminary Investigation Areas (PIAs), the main work of the Science and Technology Department is production of qualified documentation. The development of the QA system is therefore initially focused on technical documentation production. A more comprehensive QA system will be introduced in due course.

2. Scope of application

At present, the following open technical documents are considered:

- Publications resulting from the literature survey for selection of the PIAs:
  - literature list for the survey of volunteer sites
  - reports on investigation status
  - reports on literature survey results for volunteer sites
  - report on the selection of PIAs
- NUMO Technical Reports
- Papers for conferences or scientific journals
- Material for the ITAC/DTAC and other formal meetings

3. Basic philosophy for QA management

Emphasis is placed on ensuring "T2R3" (Traceability, Transparency, Review, Reproducibility, Retrievability) of technical documents.

4. Development of the QA system

- The QA system should be developed and tailored to NUMO's capabilities / requirements with feed-back to provide improvement based on "learning by doing".
- 3 layers of hierarchy for QA management documents: QA basic plan, Guidelines, and Manuals

5. QA management documents

- Quality assurance basic plan
  - Document control Guideline
    - Document preparation manual
    - Document review manual
    - Document publication manual
    - Reference material management manual
    - Technical report preparation: Contractor manual