International perspective on QA

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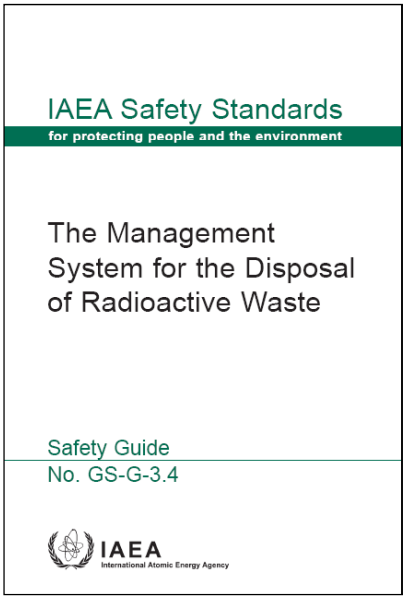
Overview

- There is general international acceptance on the need for a well-established QA system
- This is especially critical for licensing but, as “back QA” of existing information is very tricky, a suitable QMS should be introduced as soon as possible
- There is, however, no international consensus on what is required in a repository QA programme and experience to date has been mixed in national programmes
- A good international overview is included in the record of ITAC 5 (www.numo.or.jp)

IAEA Safety Guide

- 1.2. This Safety Guide uses the term ‘management system’ instead of ‘quality assurance’. The term management system reflects and includes the evolution in the approach from the initial concept of ‘quality control’ (controlling the quality of products) through ‘quality assurance’ (the system to ensure the quality of products) and ‘quality management’ (the system to manage quality).
- …process-oriented with little consideration of assuring quality of technical content



Starting point – ISO certification

- The ISO standard (ISO 9001, 14001, etc.) certification process provides a useful introduction to QM methodology and approaches
- Such standards may be required in the future by regulators as a minimum demonstration of implemented quality management
- Experience in national programmes is mixed: even when certification is regularly audited, the established processes are often bypassed (e.g. YMP scandal)
- Certification tends only to control processes and not content of technical projects

ISO certification: pros

- Forces recognition of QA throughout an organisation
- Provides traceable documentation trails for decisions and supporting analyses and databases
- Allows early identification of some kinds of problem via quality audits
- Can provide consistent process quality levels in diverse organisations
- Allows a clearly specified standard to be referred to in regulatory guidelines

ISO certification: cons

- If poorly applied, can require extensive work that is perceived to have little benefit and hence demotivate staff (especially at a working level)
- Can cause complacency: the simple existence of an audited ISO certificate may lead staff to assume QA is “done”
- Cannot be applied to all aspects of a national disposal programme: the places where such system fails (interpretation of data, development and interpretation of models, etc.) are some of the most important components of a Safety Case

Insider information – QA failures

- Despite ISO certification:
  - Process for acquiring field data incomplete or incorrect
  - Data synthesis QA incomplete or completeness impossible to check due to huge volume of documentation
  - Integrated PA documentation review incomplete or not consistent with established QA processes
  - Misrepresentation of concept feasibility
  - Hidden process for changes in national policy

…these examples are based on personal experience: problems are almost certainly similar in all national programmes

Where can the system fail? (1)

- Data production level:
  - Rejection of QA system by researchers, especially academics (effort too high, benefits negligible or not evident)
  - Incomplete understanding or application of rigorous scientific methodology (international problem: poorly addressed by most educational systems)
  - Lack of either internal or external review at a programme / planning level
  - Poor or no understanding of specialist work in a general context (work inappropriate or poorly focused)
  - Assumption that peer review for technical publications is sufficient (general quality poor to miserable)

Examples

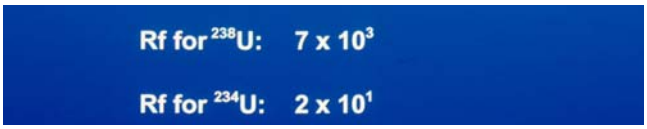
- …use of Oklo analogue information to support proposal that HLW (SF) is disposed of in bitumen

Nature **354**, 472 - 475 (12 December 1991);

Organic matter and containment of uranium and fissiogenic isotopes at the Oklo natural reactors

Bartholomew Nagy*, F. Gauthier-Lafaye†, P. Holliger‡, D. W. Davis§, David J. Mossman, Joel S. Leventhal¶, Mark J. Rigali* & John Parnell£

- …publication of clearly nonsensical "in-situ Kd" values for different U and Th isotopes (Radiochimica Acta)



Background in - Mc Kinley, I.G., Alexander, W.R., On the incorrect derivation and use of in-situ retardation factors from natural isotope profiles, Radiochim. Acta, 74, 263-267, (1996).

Where can the system fail? (2)

- Data synthesis level:
  - Rejection of QA system by specialists (effort too high, application unclear, benefits negligible or not evident)
  - Lack of (or insufficient input from) generalists with an overview of the integration of / checks of consistency between individual disciplines
  - Lack of review at a programme / planning level or lack of independent generalists capable of such work
  - Huge volumes of specialist documentation that swamps review capacity (information explosion)
  - Poor interface / lack of dialogue between data producers and users of output of data synthesis

Example

- …YMP license application is based on a volume of documentation that cannot possibly be overviewed or checked for completeness / consistency (…they don't even know the total number of pages included!)

U.S. Department of Energy Certifies Its Document Collection for Yucca Mountain License Application

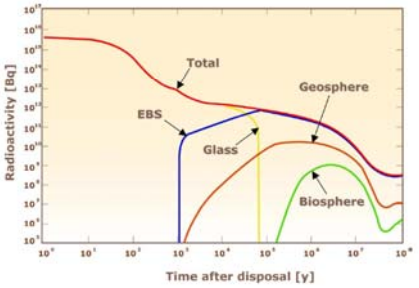
Las Vegas, NV – The U.S. Department of Energy (DOE) today certified its document collection for the Nuclear Regulatory Commission's (NRC) electronic Licensing Support Network (LSN), further advancing the Yucca Mountain repository licensing process. DOE has made electronically available on the NRC LSN over 3.5 million documents, estimated to exceed 30 million pages. DOE is required to certify its LSN document collection prior to submitting its license application to the NRC for authorization to construct the Yucca Mountain repository.

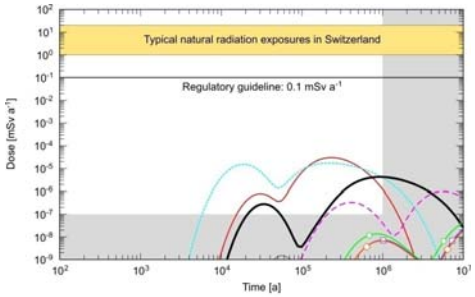
Where can the system fail? (3)

- Modelling / PA level:
  - Rejection of QA system by modellers (effort too high, application unclear, benefits negligible or not evident)
  - Incomplete understanding of simplifications introduced during conceptual model development (lack of contact between modellers and "real world")
  - Lack of either internal or external review at a programme / planning level: emphasis on short-term production of tools rather than long-term programme needs
  - Poor or no understanding of need for rigorous verification and validation of both models and databases

Example

- …report presenting modelling data for the chemical evolution of a LLW repository with a timescale (discussed in the text) extending to 10^{12} years
- …common practice of PA results extending to 10^{8} years or more without clear identification of the limitations involved





Where can the system fail? (4)

- Executive / planning level:
  - Assumption that QA system does not apply to upper-level decision making
  - Incomplete understanding of history of decision making, programme constraints and limitations of input from technical levels
  - Failure (or absence) of review process (especially if constrained by management hierarchy)
  - Poor or no open documentation of upper-level decisions
  - Ineffective internal “policing” of problems due to plagiarism, selective reporting of data, focus on “hobby” projects, …
  - Extensive use of “tacit” constraints (e.g. cost) that may be politically sensitive or, indeed, politically motivated

Example

The main findings of the review are:

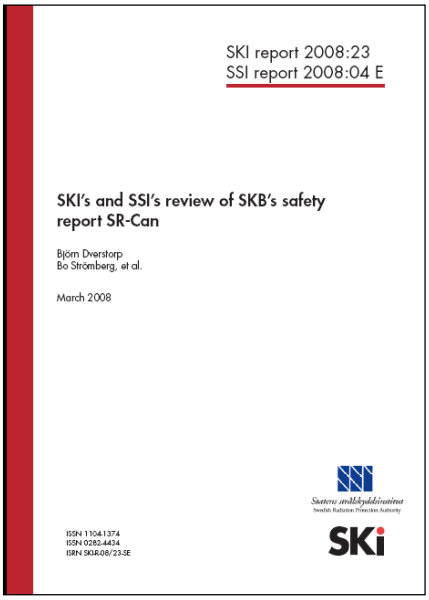
…

SKB's quality assurance of SR-Can is not sufficient for a licence application.

…

The link between assumed initial properties of repository components and quality routines of manufacturing, testing and operation need to be strengthened before the licence application.

…

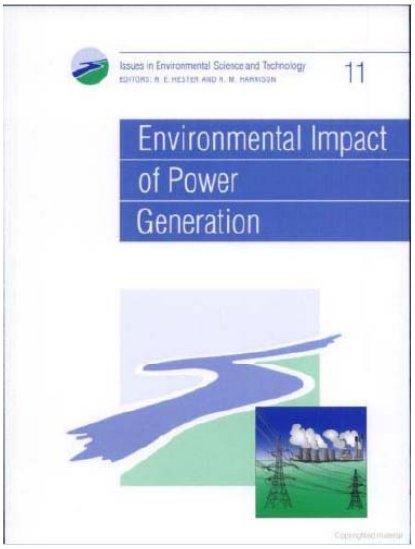


Where does the system fail (5)

- Funding / government overview level:
  - Lack experience in, and hence appreciation of, limitations of systems such as ISO
  - Limited understanding of the scientific basis of a repository safety case and the limitations of scientific peer review
  - Over-interpretation of positive experience from other national programmes and failure to access sources that record negative experience
  - Uncritical acceptance of interference by politicians, unqualified academics, etc. or inappropriate use of public consultation
  - Failure to adequately budget for required QA measures or assure resources of suitably experienced staff are available for system-level quality audits (distinct from ISO audits!)

Example

- …the history of nuclear waste management policies in the UK has been dominated by their piecemeal and changeable character…
- …it was evident …sites were chosen almost entirely because of their presumed acceptability to public opinion and hardly at all on grounds of geological acceptability



Lessons learned

- To ensure application, reduce the extent of the QMS to the minimum required: unnecessary QA is inefficient and encourages bypassing of the system (at both lower and upper levels!)
- Avoid “standard industrial” solutions: tailor the QMS to the needs of the implementer and guidelines of the regulator
- Ensure focus on the safety case for licensing: accept that key components cannot be QA’d by ISO standard procedures and hence alternative (additional) approaches will be needed (e.g. within an innovative KMS system)