Short record of the JAEA QA workshop

Tokyo, 28 – 29th January 2009

Short glossary of abbreviations used in the text:

H3, H12	First and Second Progress Reports on the Research and Development for Geological Disposal of HLW in Japan
H22	JAEA mid-term report: "The Knowledge Base supporting safety cases for deep geological disposal"
ISO	International Organization for Standardization
KM	Knowledge management
KMS	Knowledge management system
PA	Performance assessment
QA	Quality assurance
QM	Quality management
QMS	Quality management system
RMS	Requirements management system
RN	Radionuclide
SA	Safety assessment
SC	Safety case
SKB	Swedish Nuclear Fuel and Waste Management Company (Swedish implementing organisation)
TDB	Thermodynamic database
URL	Underground research laboratory

This is a short note which captures some of the discussion and outcomes of the two day workshop. It is meant only as a supplement to the presentations given by the speakers, which are appended. The outcomes from the feedback exercise and the team working exercise are also captured in overheads (appended). Finally, the output from the workshop is summarised in a short set of overheads 'Summary of the workshop output' which is also appended.

Participants: see list appended.

Wednesday 28th

Block 1 (Japanese)

Introduction and aims *K. Hioki*

Background to the KMS and plans for H22 *H. Umeki*

QA – a regulatory perspective *S. Masuda*

QA – concept and implementation *T. Miwa*

QA – perspective of the knowledge producer *M. Yui & K. Ota*

There was some discussion of the error propagation in Yui-san's presentation, which subsequently led to extensive exchanges on uncertainty analysis within thermodynamic databases.

Block 2 (English)

International perspective on QA *I McKinley*

Critical review: Japanese data production *R. Alexander*

Question from Umeki-san: With respect to Category 1 – 5 critical indicators for quality, Category 3 is the lowest quality for hydrogeological modelling and categories 1 & 2 for redox. Is this specific to the SKB site and concept (spent fuel)? For use in Japan, we need to include site-specific criteria but we can use the SKB system as the basis. Also SKB take water samples specifically for testing whereas, in Horonobe, samples are taken during drilling and hydrotesting, not specifically for hydrogeochemistry.

Question from Yui-san – Propagation of errors is specific for each measurement. The problem is going to PA from academic data - how do we show that data for performance assessment have a suitable level of confidence? This was discussed further in the top-down QA presentation.

Critical review: Japanese modelling and PA *I. McKinley*

Feedback exercise

All participants were asked to complete, anonymously, a short exercise dealing with interpretation of results and errors. The answers were presented followed by a summary of the numbers of correct responses (included in the summary of the workshop output). There was some concern that the participants generally fared quite badly on some exercises – particularly with respect to assessing the implications of uncertainty on a measurement and taking account of background. However, the questions on assessing compliance were answered correctly by the majority.

Concepts for top-down QA *I McKinley*

Concepts for bottom-up QA *R. Alexander*

Yui-san – Sampling is expensive in the field so we want to make as much use as possible of obtained data. What correction methods can be used to take account of effects which cause lowering of quality of the samples?

The emphasis is on taking good samples, rather than modelling to correct results from poor samples; this saves money and increases credibility. Preliminary work has been on ensuring quality of sampling and then extending the processes to ensure quality in data analysis and interpretation. But the same underlying approach is used with the emphasis on increasing quality to reduce uncertainty and save money.

Thursday 29th

Presentation of group output

The notes below are based on the presentations as given. A clearer idea of the teams' output may be gained (for Japanese readers) from the overheads used to present the teams' ideas, which are appended to this record.

Group 1 – Regulator (Safety case review team). Makino-san presented the output.

Definition of starting points

- Requirement for the regulator – trust of the public as well as the implementer

- Strong emphasis on the competences of regulator

A table was presented (see appended overheads) showing activities and requirements of implementer, regulator and other stakeholders and interactions between them. Stakeholders must accept that the regulator has the ability to rigorously assess the safety case.

From this starting point, the team identified items for QA based on the safety case (assumption for discussion) – assessment basis, evidence, analysis and synthesis. This lead to two key points:

→ Maintenance and improvement of competency - emphasises training of staff, including education in statistical methods for results, treatment of uncertainties etc. as well as understanding the history of work carried out.

→ Review of output from implementer.

Comment from Prof. Tochiyama – The regulator should not determine the development of the requirements for the safety strategy. The safety case is determined by the implementer.

Masuda-san: However, the regulator must give guidance for safety case boundary conditions, regulatory criteria and time cut-offs (time frame for quantitative results v. qualitative arguments etc.). It is an iterative process – the regulator can't give guidelines without some initial input (e.g. H3 and H12)

Alexander: for purposes of transparency, it is good for QA to have a defined procedure for issue resolution between regulator and implementer – this will help to ensure the trust of stakeholders.

Group 2 – Implementer (Safety case production team). Suzuki-san presented the output

Slide 2: Stepwise approach to maintain flexibility – some key points:

- RMS for the QA process – developed from early stage of programme and used to exchange information with other institutions for QA.

- Requirements of local stakeholders should be included in system.

- Future issues must be identified for maintaining quality.

- Promotion of dialogue with regulator and stakeholders

- Classification levels for QA: for items important in safety case (SC), quality level will be high. Level depends on importance in SC and also the stage of implementation. Need to preserve information which is involved in decision making

Slide 3: The SC provides the basis for discussions with regulator. The implementer needs to understand the point of view of the regulator to facilitate dialogue. Dialogues and workshops can be used to increase the experience and understanding of the implementer's staff. Argumentation networks can be used to explain safety case arguments to regulators.

Slide 4: Communication with research institutes – this is a central issue for quality in the SC. QA on knowledge for building the SC – the implementer needs to clarify the process of judging quality. The primary checkpoint is a simple internal review. The second checkpoint is publications in journals (peer-reviewed, high quality). The implementer needs to know the QA system of knowledge producers and needs also to be able to clarify whether it is suitable for specific applications. The final decision on sufficient quality for the knowledge base must be balanced by cost, stage of the implementation process etc.

Slide 5: Outsourcing – a major part of building the SC is outsourced to contractor companies and institutes. These organisations don't necessarily need ISO certification, as more important is the quality of knowledge produced by the outsource organisation. Many contracts are only 1 year, which is too short to build good quality system and is short even for the R&D to be carried out competently. How can we review the outcome from the outsource organisations? NUMO staff are only generalists, how can they check all the data in detail? There needs to be review by specialists with the outcomes open to the public. Implementers must improve confidence in their activities.

Slide 6: Other aspects

Maturation of QA aspects in implementers – we need to promote understanding of transparency & traceability in all staff. Temporary staff from any outsource organisations need to maintain a neutral attitude.

The implementer should provide infrastructure for QA – don't require ISO for outsource organisation,s but the implementer should get certification for its own confidence building. QA is usually considered boring – it needs to be incorporated into normal work rather than isolated in a special QA division.

Information security is important for confidence building.

Communication is also important.

Slide 7: Education of staff

Exchange with other institutes, URLs, universities, etc. for training of staff. The implementer needs to train staff to be generalists. Integration of knowledge to build a SC is very multi-disciplinary and best learned "on the job". Funding to universities is important, as they will be teaching the next generation of scientists, engineers, etc. Universities are also out-sources of knowledge production (contracting organisations). A reward system to promote acceptance and use of QA system may be useful. Headhunting of new staff who can add skills to the organisation may also be another approach.

Question from Masuda-san: Why do you not need a QA dept? Conventionally there is a very negative image of QA as something imposed on other staff (the QA staff are 'the enemy'). QA should be backbone of the work. Integrating QA into normal work – this is very new and ambitious. To develop a QA culture, there is a need to get away from 'everyone's responsibility is no one's responsibility' attitude. How can you balance the two perspectives? How will this run with the regulator and other stakeholders?

Comment: McKinley: With respect to the boundary conditions for contractors, a real problem is annual renewal of contracts. This may make it impossible to ensuring quality, especially in a field programme. In this case, the influence of METI is too strong and causes real problems, as everything is under artificially-generated time pressure. In other countries, implementers have their own budget and can make decisions about the balance between quality requirements and cost. In Japan, it may need a government culture change to allow NUMO its own budget control and ability to award multi-year contracts that run in a continuous manner.

Agreements are needed between the implementer and the regulator on how much quality is required on any information at each stage. There needs to be dialogue to make sure these decisions are agreed on both side.

Generalists and other experts are needed through the whole program, not just by the implementer.

<u>Group 3 – Data producer. Sugiyama-san presented the output.</u>

Slide 1: Individuals acquiring the data are responsible for the evaluation of uncertainty and must also think about how data will be used.

Slide 2: Countermeasures to address issues:

Uncertainty – it is a problem of personal responsibility/dependability and the solution must be to ensure transparency & traceability.

Keep records of discussions about the confidence level of the data, so that any qualifications are recorded.

Representativeness of the samples: there must be defined procedures and standardised methods for sampling.

Precision & Accuracy: For example, how data such as solubilities are affected by changes in groundwater – perhaps these should be better explained so the PA people don't try to use the data where they are no longer appropriate.

Procedures for methods should be standardised, so that data can be compared or combined without problems.

Impact on other organisations:

- Data should be provided with confidence limits to both implementers and regulators.

Impact from other organisations:

- Consider the balance between the requirements of the requesting organisations (implementer and regulator) and those of data providers.

How can a balance be achieved between the requirements of the data users for high quality data and restrictions on the data providers (and academic freedom of the researchers) – the implementer/regulator shouldn't put too great a burden on the data producers or it will de-motivate them. Emphasis on formal quality control only when it is necessary.

The competence of the scientists should be high enough to judge the quality of the data produced.

Everyone needs to have confidence in the data – personnel in all areas have to know about uncertainties and how this impacts on how the data are used. Staff need to understand the fundamental limitations of the methods and data, e.g. the quality level of the sample will influence the quality of the eventual data.

The implementer can provide guidelines for data producers. e.g. solubilities for elements – solubility is critical for only a few elements (RNs), so a large effort is not required for many other elements. But the implementer needs to make this clear to the data producer. What solubilities, under what conditions, are the key values and which are of secondary importance for which lower quality is acceptable?

Brainstorming on QA guidelines for the JAEA KMS

Differences in quality level can arise between different data producers, therefore the QA system applied in KMS must be open and applied throughout, irrespective of source of data:

- It is necessary to make clear what quality level is required – this may be different for different purposes (e.g. TDB compared to solubilities in safety case);
- If university data is being used, it is necessary to make sure that the university workers can assess the quality of their data;
- The basic level of quality must be based on defined methods and procedures, so that all data will meet some minimum standard and higher quality data are required only where necessary;
- The quality of the JAEA KM system is the responsibility of JAEA - this is a different issue from the quality of the individual data collected;
- In the development of the RMS, there are likely to be similar problems with ensuring quality at each level; this system is feeding into decision-making, which may also require high quality level to ensure well founded decisions;

- Use of software tools is recommended as, once these are assured, it allows greater control over modelling and analysis;
- There may be a conflict of requirements between quality professionals and spreading the QA efforts through the whole organisation;
- Maintenance of the KM system may require specific, identified responsibilities;
- How do you consider the use of tacit knowledge (expert knowledge), as it is difficult to assign a quality level? It is difficult to be rigorous, but the most important issue may be how this knowledge is used;
- It is proposed to have a hybrid system of expert systems + tacit knowledge. Over time, decisions will be recorded in the expert system control shell, so that this information becomes part of the expert system;
- Tacit knowledge may be more important for communicating with general public (and other stakeholders) rather than detailed scientific knowledge;
- Long-term maintenance of the KM system. The KMS could support the development of specialists in the future;
- How to extract data from KMS? An e-learning system could be a component of the KMS (especially for treatment of errors).