Concepts for top-down QA

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Overview

- Top-down planning is essential to ensure that the QMS is capable of meeting the needs of the users: prime requirements to be defined by:
  - Implementer (NUMO, JNFL, JAEA)
  - Regulator (NSC, JNES)
  - R&D organisations (JAEA, RWMC, CRIEPI, …)
  - Other stakeholders (General public, universities, professional societies, media - **often forgotten**!)
- Bottom-up planning is needed in parallel to ensure all critical technical issues are addressed and the overall QA programme is suitably dimensioned: requirements & constraints defined by R&D organisations (more from Russell)
- These 2 approaches lead to iterative development of an integrated and well-balanced QMS (exercise!)

Quality goal – an operational definition

Quality = demonstrable ethical & scientific rigour

Demonstrable = clearly & openly communicated

Ethical rigour = honesty & openness

Scientific rigour = application of best practice by well-qualified and experienced staff

The QMS facilitates quality and checks to assure that levels are maintained (continual, active process)

Example: Code of Ethics for Scientists

- Rigour
  - Rigour, honesty and integrity

    Making sure you keep your own skills fresh, and encouraging others to do so, particularly if you are responsible for a team. Encouraging **strict adherence to scientific method** whatever the subject area, understanding how your results have been informed by the work of other scientists and acknowledging those factors which have influenced you. Careful and complete documentation of all work.
- Respect
  - Respect for life, the law and public good

    Ensuring that your work is lawful and justified. Minimising and justifying any adverse effect your work may have on people or the environment
- Responsibility
  - Responsible communication, listening and informing

    Communicating results and intentions honestly and accurately, and understanding that your work or its outputs will have an impact on society in its broadest sense.

QM principles (1)

- Define absolute goals only if they will be comprehensively and consistently applied – otherwise weaken-off and emphasise trade-offs in real life projects.
  - Quality management is often over-sold and represented as a top priority: although important, in real life this may need to be balanced against other requirements (e.g. operational or long-term safety).
  - Ethical goals (e.g. openness and transparency) can be presented in absolute terms, but conflict with needs for commercial confidence, personal data protection and the simple practicalities of political or economic constraints

QM principles (2)

- All QM goals must be capable of being audited / reviewed: the output of such processes must be handled positively **(openness to constructive criticism!)**
  - Application of the QMS must apply throughout an organisation – including upper hierarchical levels. Audits must be applied consistently throughout and taken to heart
  - QM review processes must be rigorously applied: a very common problem is collecting series of “autographs” rather than signatures that confirm that certain reviews have been carried out (NB feedback exercise)

QM principles (3)

- Accept that different levels of quality are needed for different applications – critical QM actions are to assess quality levels and check that they meet minimum requirements
  - Worst past QA failures have involved over-dimensioned application of QM procedures (e.g. in USA): for the applications considered here, relevance to a safety case can provide a useful measure for assessing required quality
  - All material used in a safety case must have an assigned quality level but, in some cases, it is inevitable that this will be either “low” or “undefined” – especially at early stages of the programme …illustrated in the AN

QM principles (4)

- Although it is possible to “back QA” older material, this is difficult, time consuming and may result in assigning very low quality levels: it may be cost-effective in many cases either to accept as “undefined quality” or simply to discard it
  - Problems are particularly severe if information results from an external organisation with either an incompatible or no established QMS
  - As noted previously, openly published literature cannot be automatically assumed to be of high quality, even from “quality”, peer-reviewed publications

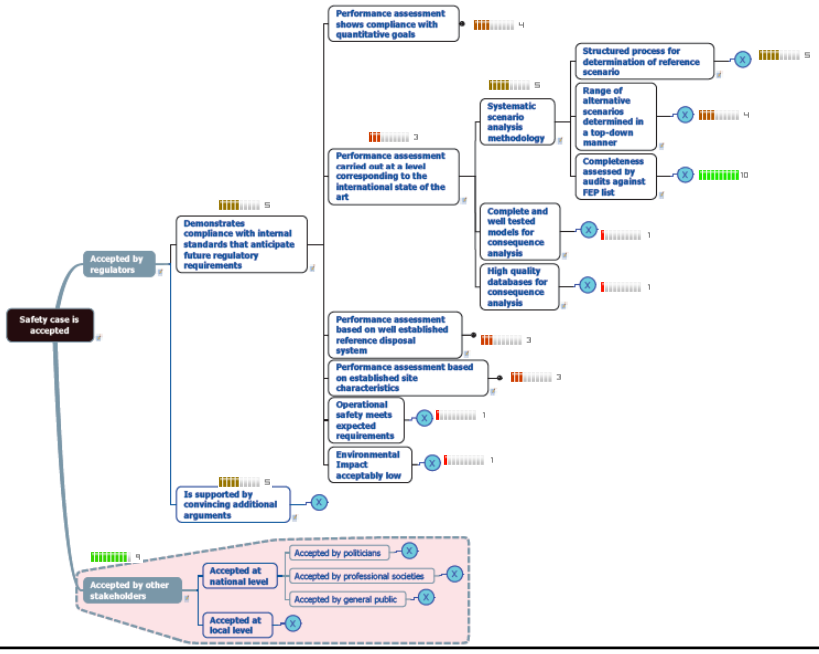
QM principles (5)

- **The most fundamental constraint on QMS application is the commitment and capability of the workforce**
  - Commitment must be assured by explanation of benefits, design and provision of tools to minimise additional work and **examples from upper hierarchical levels**
  - Staff capability must be assured by structured programme of training (both conventional and by structured accumulation of practical experience)
  - Fundamentally, this involves knowledge management and hence would logically be coupled with – or integrated within – a KMS

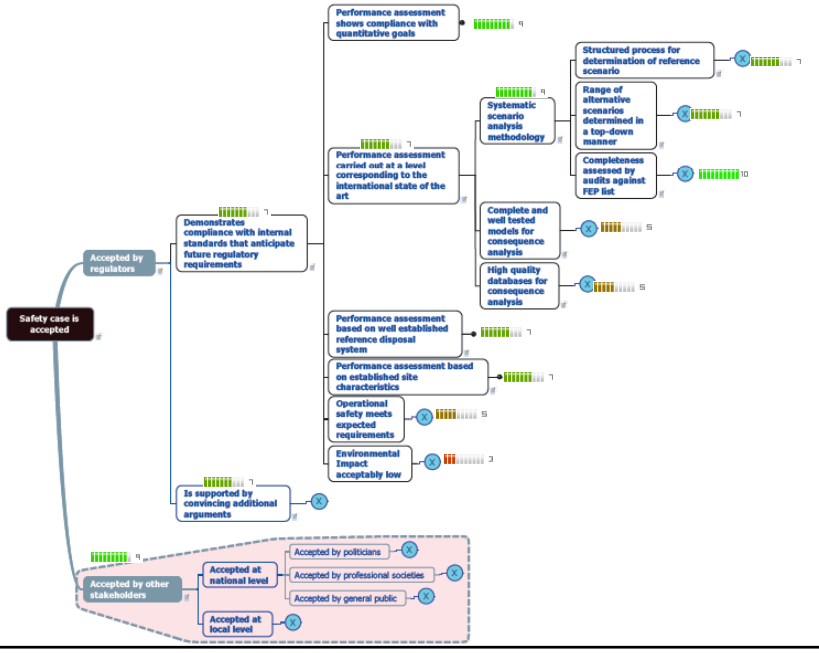
KM tools to focus QM on a safety case

- Base on argumentation network of technical basis of specific safety case
  - Set desired quality goals – NB hierarchy: in general lower level arguments will have the same or lower quality requirements than the upper level arguments that they support
  - Assess existing quality level and flag any areas where improvement is needed
  - Hyperlink all relevant Q-documentation
- Eases development and review of quality requirements by all stakeholders

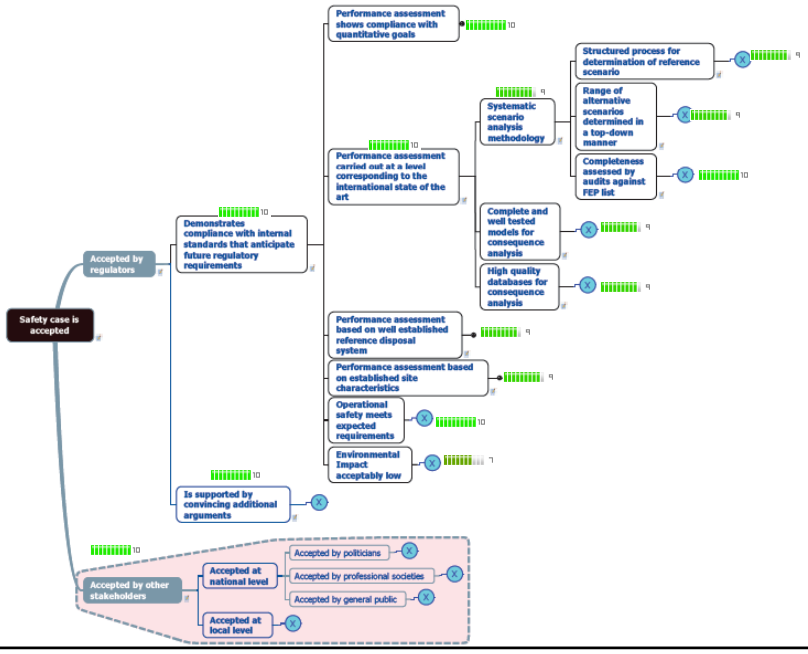
Implementation example – PI selection



Implementation example – DI selection



Implementation example – Licensing



Coolrep QA

…demonstration

Conclusions

- Problems experienced elsewhere provide guidance on how an optimised QMS can be designed and implemented
- Top-down conceptual planning has to be coupled to bottom-up input from the working level to ensure that all critical issues are identified and the system is appropriately dimensioned
- The JAEA KMS provides a valuable set of tools that will facilitate implementation of a QMS – but the components of this system have yet to be defined (work for tomorrow!)