Helsinki, 3 0 -11- 2011

CLARIFICATIONS 1

Open call for tender ECHA/2011/185
Quality management software as a service

Question 1.1:

1. To which degree is the requested solution supposed to support initial and collaborative compilation and issue of quality management documentation?

Answer:
The requested solution should support the control of quality management documentation as required by ISO 9001:2008. This includes the initial issuing and the subsequent revisions of the documents under version control and the review and approval process prior to issue.

Question 1.2:

Which process architecture elements are documented in the existing integrated quality management (roles, artefacts, ...)?

Answer:
The process system is under development. Process architecture is based on the hierarchical approach including process aggregates, processes, sub-processes, transactions, their sequence and interaction. Process description is also under development and includes characteristic process information such as input, output, supplier, customer, documents and records, actors, tools, information about indicators and measurement.

Question 1.3:

Are "non-conformity (NC) management, corrective actions (CA) and preventive actions (PA) management" established processes in the organization that the requested tool has to accompany and document or are these processes new to the organization?

Answer:
The processes are new to the organisation. The related procedures are defined and the requested tool should support the forthcoming implementation of the NC-CAPA processes.

Question 1.4:

Does the functionality to support "internal auditing" mean that auditors can use the system to schedule audits and plan audit content and keep records of audits conducted?

Answer:
yes