Big Science Morning – Ouality Management in Big Science

How to describe and present your quality system

- Experience and lessons learnt

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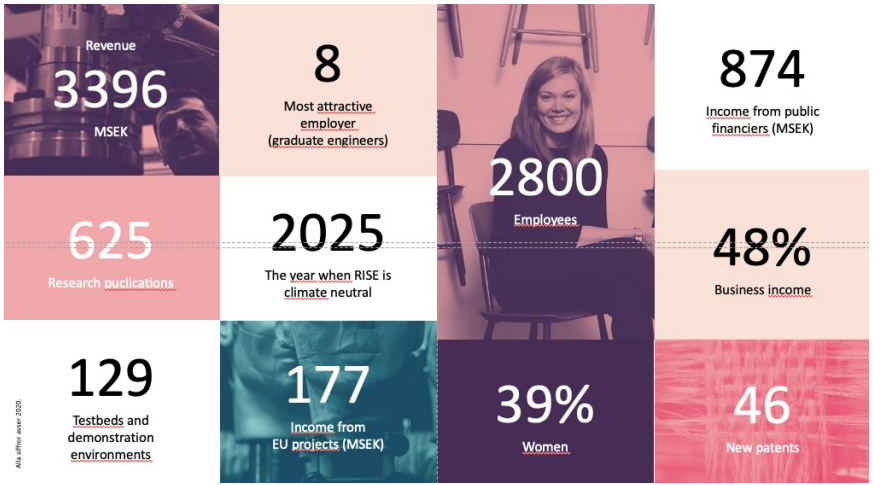
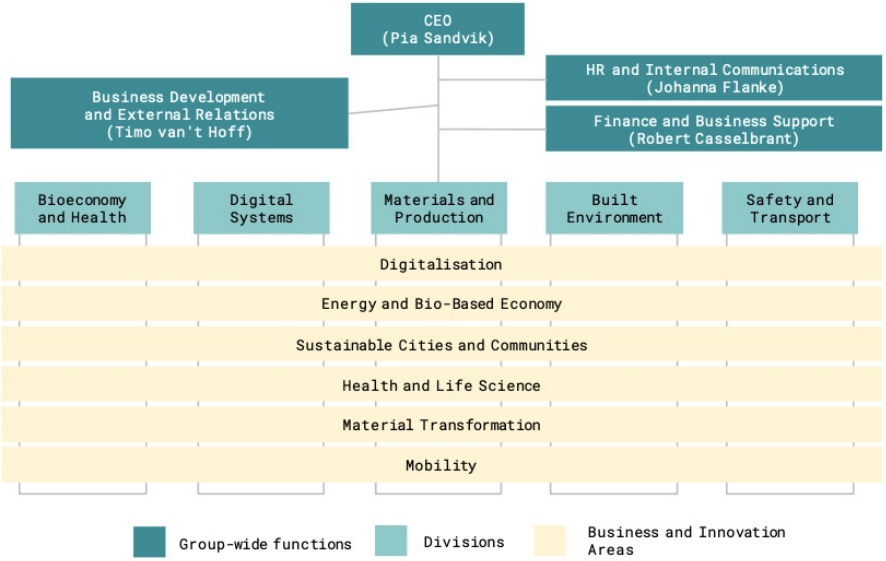
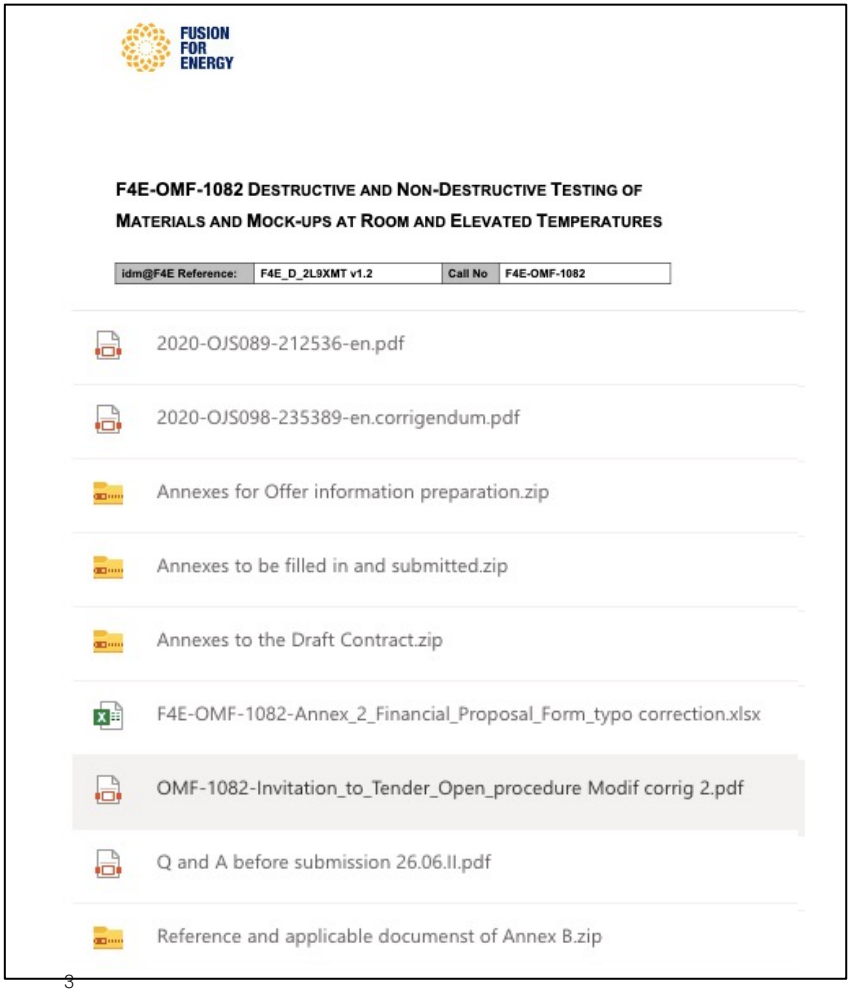
The Government's research and innovation bill states that the overarching goal for the research institutes gathered under the RISE AB umbrella is to be internationally competitive and facilitate sustainable growth in Sweden by strengthening competitiveness and innovation in the business Community.

We do this by:

- Increasing our own and our customer's international presence and competitiveness.
- Strengthening regional business communities and industrial clusters.
- Creating a robust infrastructure for innovation for the benefit of industry and society.
- Contributing to innovative, sustainable solutions to social challenges.
- Supporting small and medium-sized businesses nationwide.







Engagement at RISE

Project group of four people was established

Technical involvment

- Two divisions
- Five departements
- Three sub contractors

F4E support documentation and process was good but extensive

Under estimated the time effort – in particular regarding description of the quality plan

Example from Studsvik Nuclear AB

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Q SYSTEM COMPLIANCE

This Quality Plan describes the quality system to be implemented by Studsvik throughout the progress of the work to ensure that the contract requirements are met and that evidence of such compliance is maintained. Our quality management system is described in our internal manual xxx, which is based on the guidelines in ISO 10005 (quality plans) and ISO 10006 (management of quality).

Studsvik is certified according to quality management system (ISO 9001:2015), environmental management system (ISO 14001:2015) and occupational health and management system (OHSAS 18001:2007). Studsvik is also certified by SWEDAC for Surveillance tests according to the standard ISO/IEC 17025:2005. These certificates are attached in Appendix 1 of this draft QA plan. Management regarding safety, environment, quality and working environment are summarized in an internal management document, xxx, called xxx. The master and detailed documentation used in the management system of Studsvik Nuclear AB is shown in Figure 1, the organizational structure of Studsvik Nuclear AB is shown in Figure 2 and the proposed organizational structure of the project is shown in Figure 3.

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In addition to the above, Studsvik Nuclear AB is, as are all nuclear facilities in Sweden, subjected to the Swedish The Act on Nuclear Activities, SFS 1984:3, Lagen om kärnteknisk verksamhet, and the revisions in SFS 1992:1536 and SFS 2018:1415, which together regulates the activities performed at all nuclear facilities in Sweden. The governmental agency that supervises this is The Swedish Radiation Safety Authority, Strålsäkerhetsmyndigheten.

Example from RISE in progress

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RISE Quality management system compliance

RISE is accredited for ISO 17020 (Inspection), ISO 17021 (certification of management systems), ISO 17024 (certification of personnel), ISO 17025 (testing and calibration) and ISO 17065 (product certification). RISE is also the Swedish National Metrology Institute which secures traceability of measurements and is appointed as Technical Service and Notified Body.

RISE and RISE management system are regularly audited by SWEDAC, the Swedish Accreditation board.

The management system is processed based and includes control of documents and several supporting systems and databases such as database for competences, equipment, methods, chemicals, non-conformities and project information.

Referring to supporting systems as:

- Project document platform, time and economy
- RISE Project model
- Equipment and its status, like traceability and calibration
- Nonconformities and deviation procedures
- Monitoring of environment in labs
- Competence of involved personell

ESS TEMPLATE FOR PROJECT QUALITY PLAN

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Experience and lessons learnt

- Procurement documentation might be extensive
- Be aware of questions and answers during the time after publication
- Quality is something you must have within the organisation and documented
- Third party certification or accreditation v s self declaration ?

- Time effort for an offer will easily be under estimated but once experienced it will be easier and faster in coming procurements