



# **Performance of Review and Assessment by the Regulatory Body**

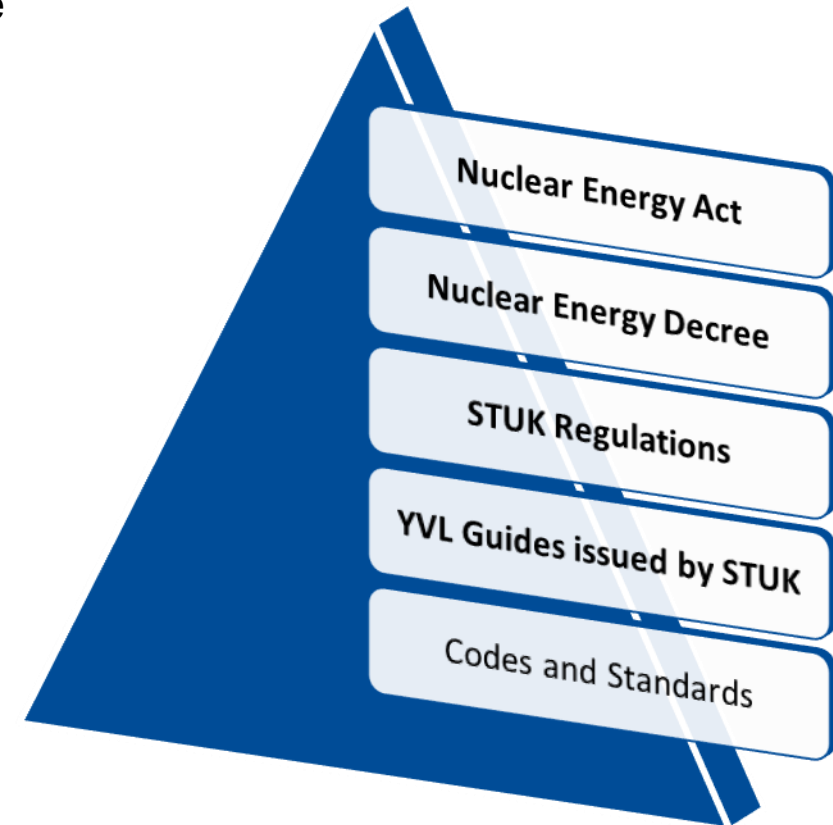
Päivi Salo

# Content R&A at CL stage

- Basis for R&A
- Scope of R&A
- Resources used in R&A
- Tools used in R&A
- Output of R&A

# Nuclear legislation and safety requirements in Finland

- Nuclear Energy Act
  - Fundamental principles like “nuclear energy utilisation shall be safe”; “licensee is responsible for safety”;
  - Covers safety, security and safeguards
  - Obligation to apply a license
  - STUK’s mandate and duties
- Nuclear Energy Decree
  - Administrative details for licensing and regulatory oversight
- STUK Regulations
  - Mandatory requirements for safety, emergency preparedness, security, nuclear waste management and safety of mining and milling
  - General principles, fundamental technical requirements
- YVL Guides
  - Detailed technical requirements, acceptable practices, guidance for licensee-STUK interaction, STUK’s oversight



# STUK regulations – basis for STUK Safety Assessment

- Five STUK regulations
  - Regulation on the Safety of Nuclear Power Plants, STUK Y/1/2018
  - Regulation on Emergency Preparedness, STUK Y/2/2018
  - Regulation on the Security in the Use of Nuclear Energy, STUK Y/3/2020
  - Regulation on the Safety of Disposal of Nuclear Waste, STUK Y/4/2018
  - Regulation on the Safety Of Mining and Enrichment Operations Aimed at Producing Uranium or Thorium, STUK Y/5/2016

# Requirements for R&A

- **STUK always performs its review and assessment prior to any decision or authorization.** Safety-related requirements for which fulfilment is evaluated via review and assessment process are presented in the legislation and regulations. Review and assessment processes are described in STUK's internal guides.
- **Mandatory requirements for safety of nuclear facilities are given in Nuclear Energy Act, N.E. Degree and STUK regulations.** More detailed requirements are given in STUK's YVL Guides. The above-mentioned requirements are also the guiding principles in the review and assessment process of STUK.
- **NEA establishes general requirements for the safe use of nuclear energy and nuclear facilities.** General requirements concerning safety are stated in Chapter 2a of NEA including, for example, "Safety as high as reasonably achievable"-principle (SAHARA), the graded approach and the defence-in-depth-principle.

# General principles of R&A

- A major legal principle in the Finnish framework is the **licensee's ultimate responsibility** for nuclear and radiation safety. It is essential that the licensee/licence applicant presents its safety assessment and statement on acceptability of design, plans and activities.
- Another major principle is the **use of a graded approach**. In addition to the safety classification of systems, structures and components, possible factors in grading reviews and assessments include safety significance, whether the component, system, etc. is the first of its kind or already known, and the level of quality displayed by the licensee's safety assessment. Safety significance refers to how the failure of a piece of equipment or system impacts the safety function, or other possible consequences. Probabilistic Risk Assessment (PRA) is also used in safety significance determination. However, the graded approach is not limited to these factors in the review and assessment process.
- STUK's review and **assessment is targeted in particular at matters with actual safety significance**. In practice, it is carried out using the aforementioned graded approach principle. Additionally, internal YTV guides determine the scope and target of each individual review and assessment process.

# Construction licence R&A

- When applying for a construction licence, **the documents for R&A listed in section 35 of Nuclear Energy Degree (NED)**, and other reports considered necessary by STUK under subsection 2 of section 35 of NED shall be submitted to STUK for review and assessment.
- STUK issues a statement about the construction licence application only after having approved the essential parts of **each of these documents by a separate decision**

# CLA content NED Section 35 (732/2008) 1/2

When applying for a construction licence, the applicant shall submit the following to the Radiation and Nuclear Safety Authority:

- 1) the preliminary safety analysis report, which shall include the general design and safety principles of the nuclear facility, a detailed description of the site and the nuclear facility, a description of the operation of the facility, a description of the behaviour of the facility during accidents, a detailed description of the effects that the operation of the facility has on the environment, and any other information considered necessary by the authorities;
- 2) a probabilistic risk assessment of the design stage;
- 3) a proposal for a classification document, which shows the classification of structures, systems and components important to the safety of the nuclear facility on the basis of their significance with respect to safety;

## CLA content NED Section 35 (732/2008) 2/2

- 4) a description of quality management during the construction of the nuclear facility, showing the systematic measures applied by the organisations that take part in the design and construction of the nuclear facility in their operations affecting quality;
- 5) a guideline plan for periodic inspections; (755/2013)
- 6) preliminary plans for security and emergency response arrangements; (755/2013)
- 7) a plan for arranging the safeguards necessary to prevent the proliferation of nuclear weapons; (755/2013)
- 8) a description of the arrangements referred to in section 19, paragraph 7 of the Nuclear Energy Act; (755/2013)
- 9) a programme for investigating the baseline condition of the nuclear facility's surroundings; (755/2013)
- 10) a plan for the decommissioning of the nuclear facility. (755/2013)
- 11) An applicant for a licence shall also provide the Radiation and Nuclear Safety Authority with any other reports that the Authority considers necessary.

# Specific Regulatory Guidance: Licensing plan

## Guide YVL A.5 5.1 Oversight of design

- The general principle is that STUK approves plant and system design for a new nuclear facility in connection with the review of the plant's construction and operating licence applications in accordance with Chapter 7 of Guide [YVL B.1](#). In terms of plant modifications, the corresponding inspection points are the review of conceptual design plans of the modifications and the pre-inspection documents of systems. The licensee shall in connection with the licensing plan for a construction or plant modification project present in detail how the fulfilment of nuclear and radiation safety requirements is demonstrated during the various phases of a construction or plant modification project. **The licensing plan shall be submitted to STUK for information as part of the construction licence application** or in connection with the conceptual design plan for a plant modification.*

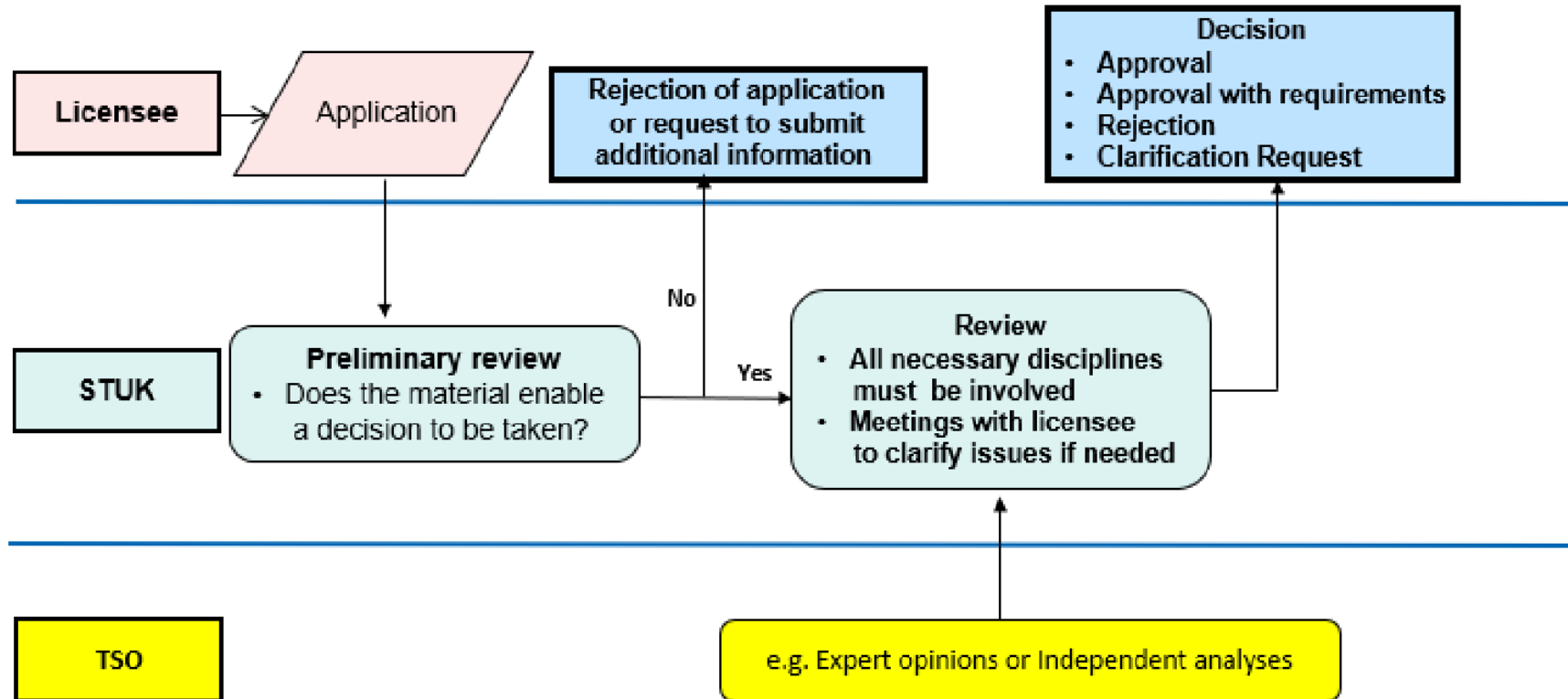
# Content of safety analyses at different licensing steps (case FH1) 1/2

- Decision in Principle phase
  - Information on analysis (including assumptions, acceptance criteria, methodology and validation of used methods and codes) carried out
  - demonstration that the organisation performing the analyses has adequate competence
- Construction permit phase
  - Preliminary deterministic accident analysis (see [YVL B.3](#));
    - description on methodology
    - calculation models and validation of used codes
    - used assumptions and acceptance criteria
  - Preliminary failure tolerance analysis (fulfilment of failure criterion)
  - Preliminary CCF (Common Cause failure) analysis
  - design-stage probabilistic risk assessment (PRA) levels 1 and 2 Including computerised PRA model
    - Preliminary plant and system level FMEA (Failure Mode and Effect Analysis, dependences between different safety classes, systems, etc)
  - analyses of internal and external hazards/events

# Content of safety analyses at different licensing steps (Case FH1) 2/2

- Operating license phase
  - Deterministic accident analysis
    - description on methodology
    - validation of used codes
    - used assumptions and acceptance criteria
    - final analysis based on detailed design of the plant
  - probabilistic risk assessment (PRA) levels 1 and 2 Including computerised PRA model
    - Final system and plan level FMEA
  - Final failure tolerance analysis (fulfilment of failure criterion)
  - Final CCF (Common Cause failure) analysis
  - Analyses of internal and external hazards/events

# R&A process within STUK



# STUK's review and assessment process roles and responsibilities

## Receiving the application in STUK

### Register office

- Recording the application in STUK's document management system

### Coordinator

- Defines the responsible person for review
- Defines target date for review
- Checks confidentiality

### Responsible person

- Preliminary review (quality and completeness of the application)
- Defines needed experts
- Arranges kick-off meeting if necessary

## During the review

### Coordinator

- Follows progress of the review
- Helps to solve problems (e.g. lack of resources, disagreements)

### Responsible person

- Keeps the coordinator informed about progress
- Arranges meetings if necessary (internal or with the applicant)
- After the experts have completed their review, drafts the decision

### Experts

- Perform the review
- Record their findings and conclusions in the document management system
- Inform coordinator, responsible person and their superiors immediately in case of significant findings

## After completing the review

### Coordinator

- Checks the draft decision (content, quality, formalities)

### Responsible person

- Finalises the decision based on the comments from coordinator and decision-maker
  - Signs the decision letter

### Decision-maker

- Checks the draft decision (content, quality, formalities)
- Signs the decision letter

### Register office

- Sending the decision to the applicant
- Archiving all related documents in appropriate manner

# Specific Regulatory guidance: STUK inspections during the R&A

- *In addition to reviewing the end results of design, STUK oversees the licensee's activities to assess, guide and approve the design performance impacting nuclear or radiation safety. Before the construction licence application is submitted, this involves an assessment by STUK of the safety-related sections of the invitation for tenders in accordance with section 3.2 of Guide [YVL A.1](#) and regular monitoring of the project's progress. **After the construction licence application has been submitted, STUK assesses the functionality of the licensee's management system and the adequacy of the procedures as part of the inspections relating to the review of the construction licence application.***

# Specific Regulatory guidance: STUK tasks during the CLA review and assessment

- The licensee is responsible for the adequate supervision of design functions and designers. **STUK can, as it deems necessary, examine the licensee's supply control plans pertaining to the suppliers at the site and participate in inspections and audits on the licensee's design organisations.** In assessing the need to participate, STUK takes into account a design object's safety significance, technical exactingness and earlier experiences of the designer and of licensee procedures for assessing design functions.
- **STUK can focus its own inspections directly on organisations responsible for the nuclear facility's design. In such cases, the inspection item is significant for safety, e.g. the design functions of the company supplying the nuclear island.** The inspections assess the functionality of the organisation's management system and the adequacy of the procedures. STUK's regulatory control is described in more detail in the field-specific and technology-specific YVL Guides.

# Example: Fennovoima approach to the Construction licensing: -> Batchwise submittal of CLA documents – at the beginning

| 2015                                                                                  |    |    |    | 2016 |    |    |    | 2017 |    |    |    | 2018     |
|---------------------------------------------------------------------------------------|----|----|----|------|----|----|----|------|----|----|----|----------|
| Q1                                                                                    | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1       |
| Batch 1 - Licensing Plan and Site Licensing                                           |    |    |    |      |    |    |    |      |    |    |    | 30-06-15 |
| Batch 2 - Quality Management of Plant and Architecture Level Design                   |    |    |    |      |    |    |    |      |    |    |    | 30-10-15 |
| Batch 3 - Plant Safety Design and Functional Architecture                             |    |    |    |      |    |    |    |      |    |    |    | 31-12-15 |
| Batch 4 - Analysis Specifications and Tools                                           |    |    |    |      |    |    |    |      |    |    |    | 31-12-15 |
| Batch 5 - Preliminary Safety Analyses                                                 |    |    |    |      |    |    |    |      |    |    |    | 02-05-16 |
| Batch 6 - Technical Architectures and Quality Management of System Level Design       |    |    |    |      |    |    |    |      |    |    |    | 31-05-16 |
| Batch 7 - Verification and Validation Concept for Technical Architectures             |    |    |    |      |    |    |    |      |    |    |    | 31-05-16 |
| Batch 8 - Verification and Validation for Technical Architectures                     |    |    |    |      |    |    |    |      |    |    |    | 05-08-16 |
| Batch 9a - Process and Electrical Systems                                             |    |    |    |      |    |    |    |      |    |    |    | 31-08-16 |
| Batch 9b - I&C System Requirement Specifications                                      |    |    |    |      |    |    |    |      |    |    |    | 31-08-16 |
| Batch 9c - I&C System Specifications and Safety Classification                        |    |    |    |      |    |    |    |      |    |    |    | 24-02-17 |
| Batch 10 - Reverification of Plant and Architecture Level Verification and Validation |    |    |    |      |    |    |    |      |    |    |    | 31-03-17 |
| Batch 11 - Final Deliveries                                                           |    |    |    |      |    |    |    |      |    |    |    | 31-05-17 |
| STUK Safety Assessment Finalization ("Quiet Time")                                    |    |    |    |      |    |    |    |      |    |    |    | 28-11-17 |
| MEE CL Finalization                                                                   |    |    |    |      |    |    |    |      |    |    |    | 29-12-17 |

# Regulatory approvals based on Nuclear Energy Act para. 55

- According to NEA 55 §” *The Radiation and Nuclear Safety Authority (STUK) may, upon request by anyone planning to use nuclear energy, check the plan drawn up by them and issue preliminary instructions on what should be taken into account with respect to safety, physical protection and emergency planning.*”
  - Case FH
    - proposal for approvals related to main components of the reactor coolant system
      - According to the plan approval on the basis of 55 § (i.e. permit to start manufacturing before CLG) is requested for the RPV, the SGs and the pressurizer.
    - Other Components to be submitted for the review of STUK before CLG
      - plan to apply for manufacturer approval and to submit a Construction Plan before CLG (Bubbler, Core catcher, etc.)
      - safety analyses will be available for Design Basis
    - Approvals of Documentation and Plans related to Structures
      - To ensure the timely progress of the construction project, a justification that the levelling concrete to be cast on the bedrock underneath the base slabs of the buildings is not considered as a safety classified structure.

# STUK Regulatory Oversight Project FIN6 scope (1/2)

- CLA Safety assessment (Governmental Degrees requirements ) and regulatory review (YVL-Guideline requirements),
- STUK safety statement according to NEA, NED and YVL-Guides
- STUK regulatory decisions on NED 35 § documents and report to the Ministry (MEE) according to the Ministry request for Statement.
- Statements from other authorities according to NEA and other relevant statement needed for review and assessment as statement on security arrangements.
- STUK has to enclose Nuclear Safety Advisory Committee Statement to it's statement.
- As well as list the possible open items, which can be closed during the construction of the facility

# STUK Regulatory Oversight Project FIN6 scope (2/2)

- Regulatory treatment of Long Lead Items according to NEA paragraph 55 and Site preparation observation,
- Co-ordinate domestic and international co-operation.
- Interface with the Licensee organization and observing Licensee Audit Program.
- Regulatory Inspection Program planning and execution
- Not included to the scope of FIN6 Project:
  - Tasks mentioned on the YVL-guidelines, which are not part of CLA review and assessment, as the Nuclear Safeguards licensing and permitting.

# Objectives for the FIN6 review and assessment project (1/2)

- The NPP fulfills the Finnish safety requirements. The basic design of the plant has to be mature for regulatory requirement verification. (Plant and systems level maturity stated in YVL B.1)
- With regard to plant design, STUK will review and assess the design basis of the plant, the requirement specifications, the analyses substantiating the fulfilment of safety criteria, the implementation of defence-in-depth concept in the design as well as the implementation of redundancy, physical separation, functional isolation and diversity principles in the design and implementation of safety functions.
- The information enclosed with the application for a construction licence shall provide STUK with sufficient grounds for preparing the safety assessment. Information shall be provided on the safety functions and the systems performing safety functions to such a level of accuracy that the operation of the plant in anticipated operational occurrences and accidents in all operational states can be analysed and the PRA can be reviewed. The information may be presented to the required level of accuracy in the preliminary safety analysis report or, alternatively, summarised in the preliminary safety analysis report and specified in more detail in separate topical reports supplementing it. (YVL B.1 606. )

# Objectives for the FIN6 review and assessment project (2/2)

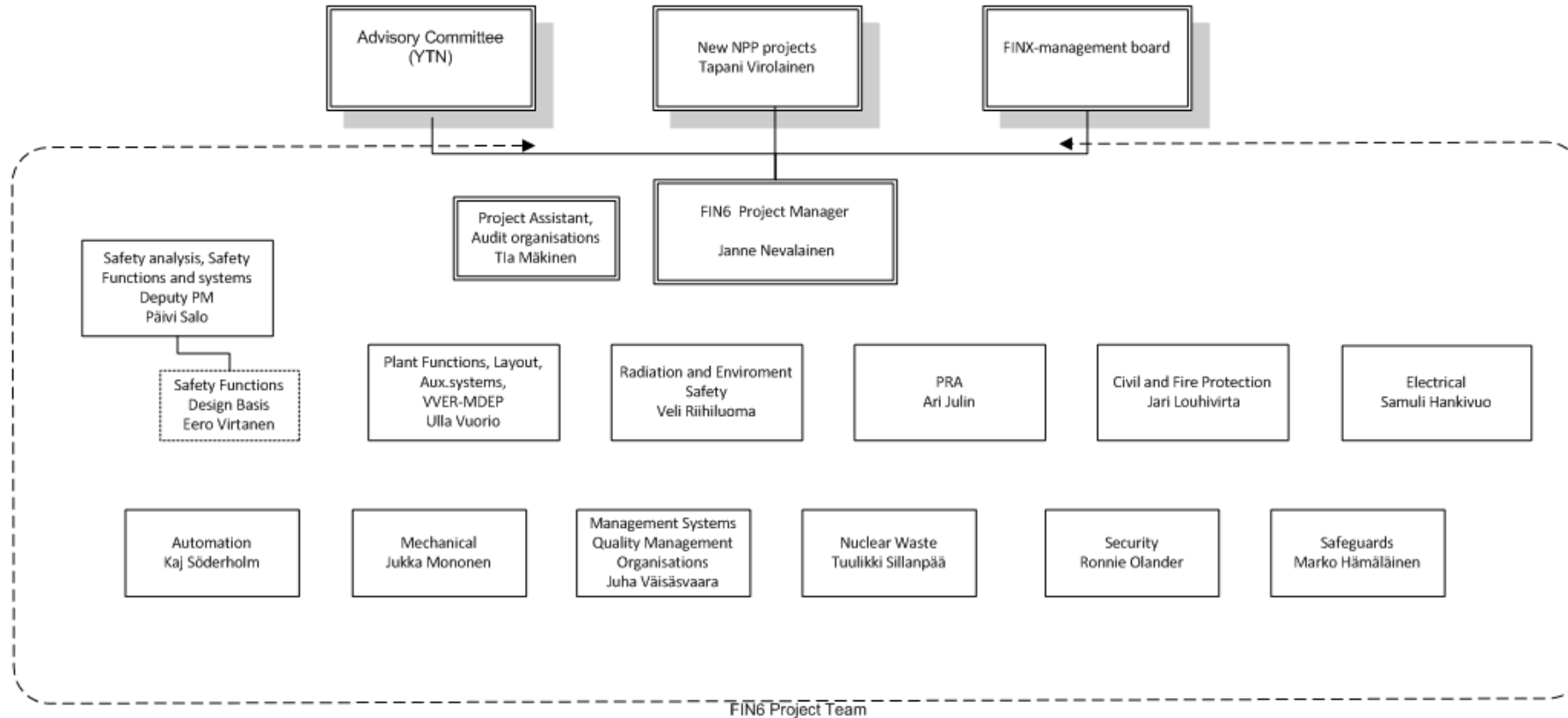
- The preliminary safety analysis report shall provide an overview of the plant-wide design principles and the technical implementation of each safety-classified system and its relationship with the overall plant complex. When an application for a construction licence is filed, **the systems' design shall have been frozen to the extent that the detailed design will not necessitate any substantial changes to the information pertaining to the layout design of the plant, the location of main system components, or the systems listed in para. 609, and that the requirement specifications can be made for the purpose of procuring components and structures.** (YVL B.1 608)
- Confidence to STUK review and assessment work. Focusing to effective and risk-informed and open regulatory oversight.
- Public confidence will be achieved with open and clear communication

# STUK preparations for CLA review and assessment

- STUK own project plan and project organisation (please see separate slide)
- STUK allocated YVL requirements to CLA Safety Assessment and PSAR chapters and other documents for review and assessment work by using requirement management tool (Polarion)
- STUK reviewed the Licensing plan and its updates
- STUK performed a pre-inspection on the documents to ascertain that the form and content of the document are in compliance with the requirements set out in the YVL guides.
- STUK started the review and assessment of first batch as the Ministry sent 8.9.15 the request of Statement of Safety and STUK also started TSO work package procurement

# FIN6 - CLA Oversight Project For Fennovoima FH1 CLA

Acc. Project Plan #1563953, v13, 30.4.2015



# Tools for review and assessment

- Control of the documentation and assessment process for nuclear facilities is done through the **electronic document management system SAHA**, which covers, for example, the selection of a coordinator, recording and archiving submissions, task distribution, specification of intermediate actions, on-line monitoring of the review status, recording the STUK review/inspection reports and the justification of decisions made.
- **The Polarion requirements management tool** is used for several purposes for nuclear facilities: the planning of review and other regulatory activities, follow-up of activities, **overall safety assessment of facilities**, management of regulation including follow-up fulfilment of regulatory requirements, operating experience feedback, and the collection and analysis of observations made concerning licensees' activities.
- **STUK does not operate any experimental facilities.** The necessary experimental results can be obtained through the national research programmes or by contracting dedicated experiments to other organizations for regulatory support.

# Electronic document management system with workflow

The screenshot displays the CGI VIRTÄ web application. The top navigation bar includes 'ASIAIT', 'TIEDONOHJAUS', and 'RAPORTIT'. The main content area is titled 'KÄSITTELY' and shows a list of tasks and documents. The 'Työnkulun tehtävät' section at the bottom lists tasks with columns for 'TEHTÄVÄ', 'SUORITTAJA', 'SAATE/KOMMENTIT', 'LUOTU', and 'KUTITTU'.

| TEHTÄVÄ | TEHTÄVÄN SUORITTAJA     | SAATE/KOMMENTIT | LUOTU      | KUTITTU |
|---------|-------------------------|-----------------|------------|---------|
| Kultaus | Tuomainen Minna (STUK)  | Käsitteli       | 17.08.2022 |         |
| Kultaus | Tiippana Petteri (STUK) | Käsitteli       | 17.08.2022 |         |
| Kultaus | Nevalainen Janne (STUK) | Käsitteli       | 17.08.2022 |         |
| Kultaus | Valkeapää Aleksi (STUK) | Käsitteli       | 17.08.2022 |         |
| Kultaus | Leino Jaakko (STUK)     | Käsitteli       | 19.08.2022 |         |
| Kultaus | Tanskanen Aapo (STUK)   | Koordinoi       | 14.06.2022 |         |
| Kultaus | Hämäläinen Marko (STUK) | Käsitteli       | 23.08.2022 |         |

# R&A Safety Assessment done in data base requirement management tool

Requirements library NEA, NEA, STUK Regulations selected for Assessment

Req. Data base

Req ID

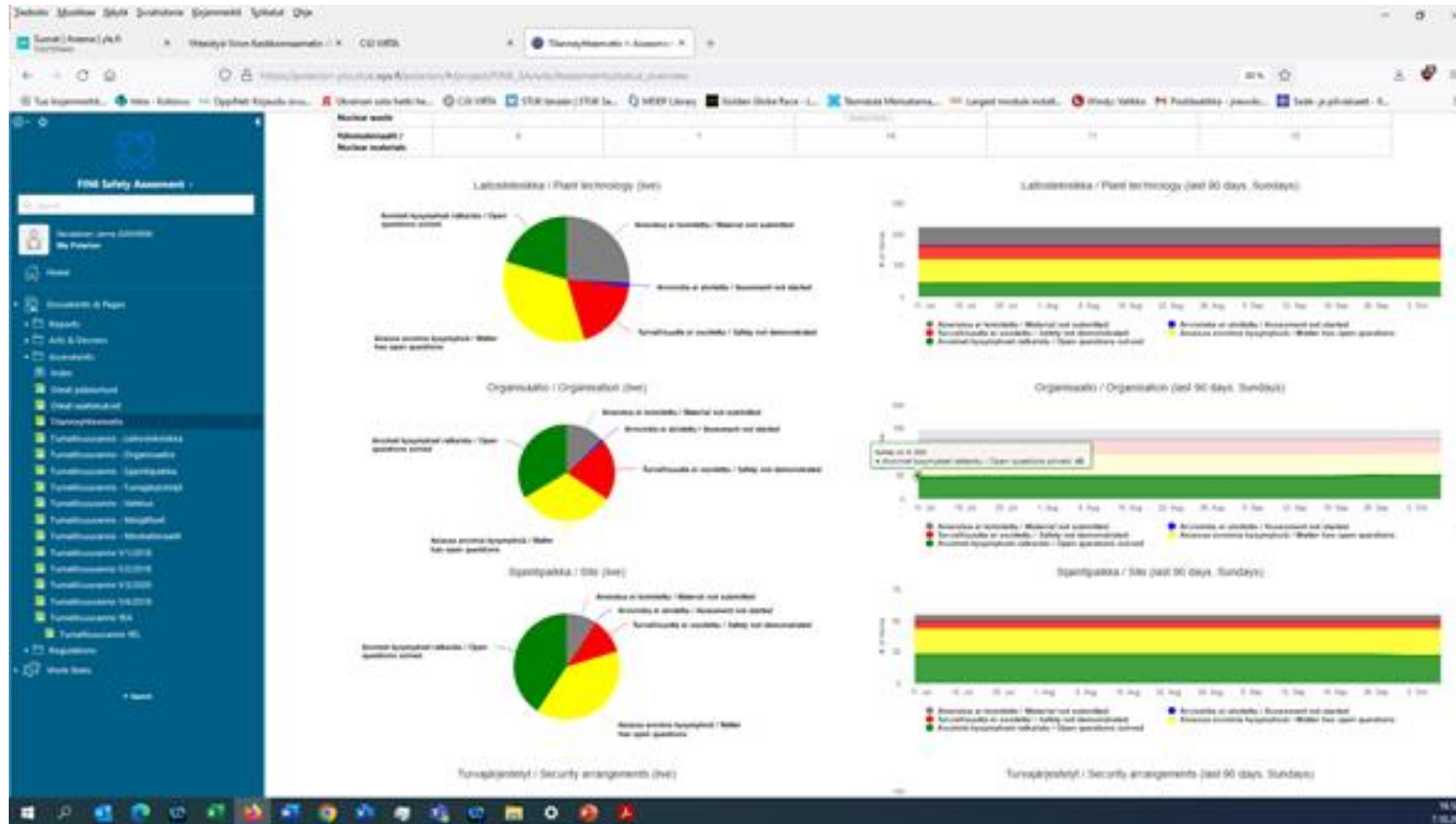
Attributes: site, techonolgy, organisation,,

Requirement text

Status of Review

Safety assessment

# R&A Metrix – online status of safety assessment



# Documents produced by STUK in the main licensing steps

- STUK does not make decisions about the main licenses (Decision-in-Principle, Construction, Operating and Decommissioning Licenses) – the main licenses are Government decisions
- STUK prepares for the Government



**Statement on Safety -**  
STUK's view on whether  
Finnish safety requirement  
are fulfilled or not



**Safety Assessment Report** –Gives justification  
to the Statement on Safety. Includes evaluation  
of each requirement given in the relevant  
Regulations

- Example: Olkiluoto 3 operating licence granted on 7 March 2019
  - [STUK's statement](#)
  - [STUK's safety assessment](#)

# Licensing Process - License conditions

- Nuclear Energy Act:

*The licence shall include the conditions that are necessary in order to implement the general principles referred to in chapter 2.*

*When amending the licence conditions, the same procedure shall be complied with, where applicable, as when granting a licence.*

## Examples of Principles in Chapter 2:

The use of nuclear energy must be safe and it shall not cause harm to people or damage to the environment or property.

Nuclear waste generated in connection with or as a result of the use of nuclear energy elsewhere than in Finland, shall be handled, stored or permanently disposed of in Finland.

The safety of nuclear energy use shall be maintained at as high a level as practically possible.

# R&A results output -> Use of license conditions in Finland

- Requirements already laid out in the legislation are not repeated as license conditions.
- In Finland, use of license conditions is rather limited and mainly concerns:
  - ✓ Deadline for submitting the results of the next Periodic Safety Review
  - ✓ Maximum allowed amount of spent fuel or other radioactive waste on the unit/storage/site
  - ✓ Maximum thermal power of a reactor
- STUK issues a statement about the construction licence application only after having approved the essential parts of **each of NED 35 § (licencing basis) documents by a separate decision.**
- STUK issues a statement about the operating licence application only after having approved the essential parts of **each of NED 36 § (licencing basis) documents by a separate decision**

# Continuous Public Communication 3/year public report on STUK web-pages on R&A progress with following infograph





## Tiedonohjaussuunnitelma

## 0 YLEISHALLINTO

## 1 HENKILÖSTÖHALLINTO

## 2 TALOUSHALLINTO

## 3 SÄTEILYN KÄYTÖN TURVALLISUUS (Laki Säteilyturvakeskuksesta 1164/2022 2 §)

## 4 YDINTURVALLISUUS (Laki Säteilyturvakeskuksesta 1164/2022 2 §)

## A Ydinturvallisuus Loviisa I

## A41 Ydinlaitosten yleiset asiat

## A42 YEA:n 35§ ja 36§ mukaiset ja laitostason asiat

## A422 I Ydinlaitoksen lupa-asiat

## A42213 Käyttölupa-asiat

## A42214 Ydinjäte- ja ydinmateriaalilupa-asiat (toiminta-, vienti-, tuonti- ym. luvat)

## A42215 Määräaikainen turvallisuusarvio

## A42217 Turvajärjestelyt (salaiset)