



Development and Management of R&A Process in Finland Regulatory Body

Päivi Salo

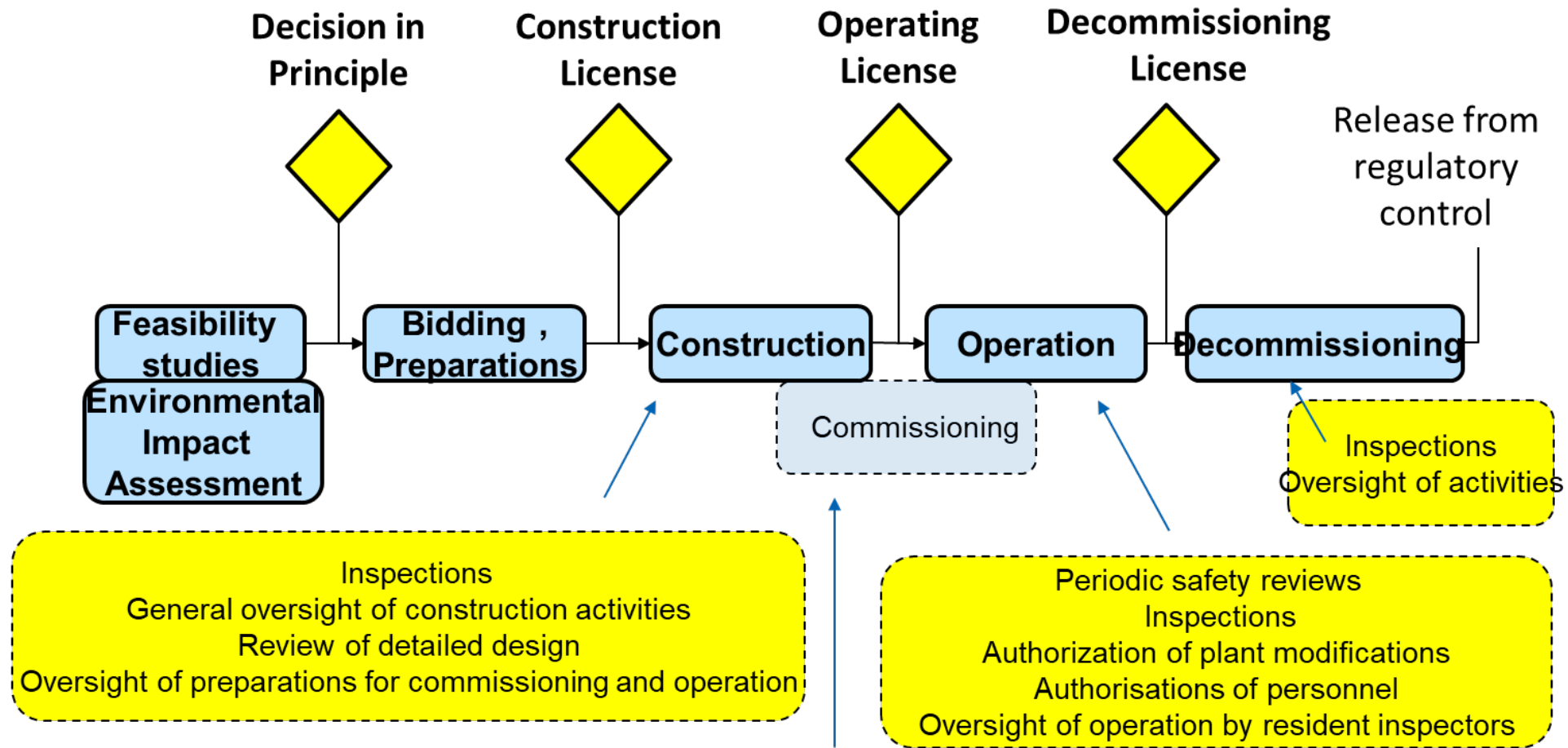
Content

- Organization of R&A for the licensing process
- Resource planning
- Documentation and records
- Application of graded approach
- Interaction with the licensee and the contractors

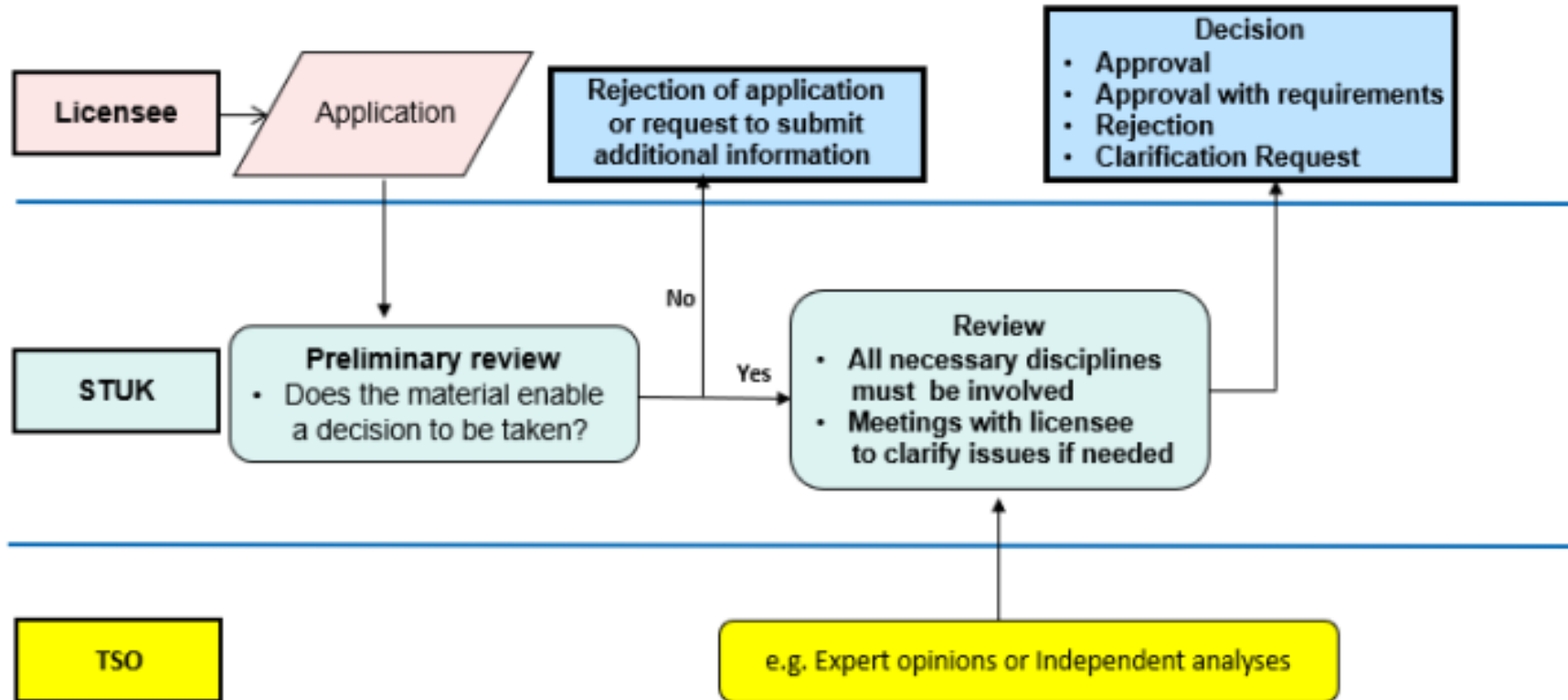


Organisation of the R&A for licensing process

Licensing of a nuclear facility-other authorizations and oversight

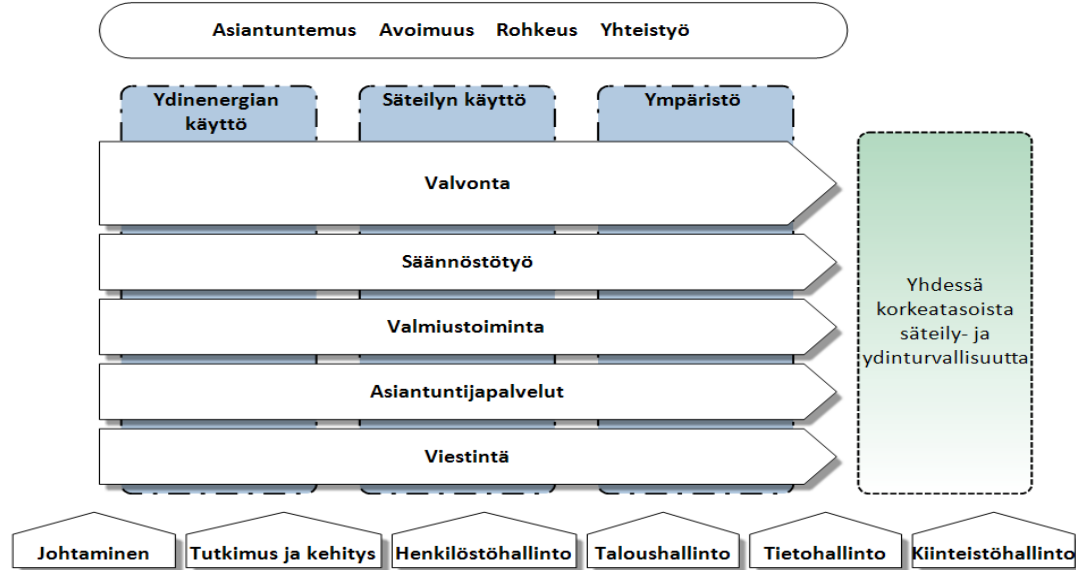


R&A process within STUK

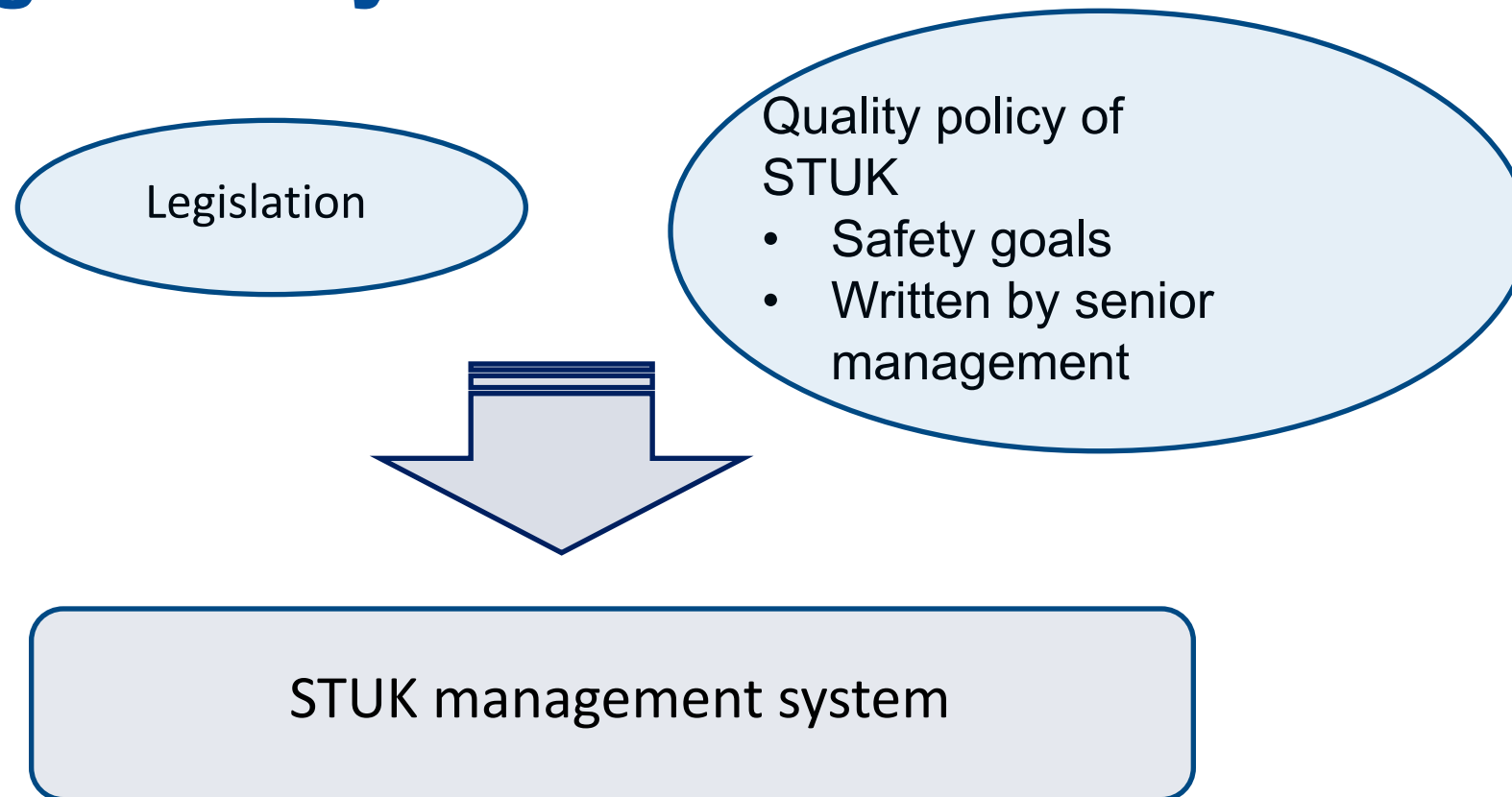


Organization for the licensing process

Basis for organizing the regulatory work is the Management System of STUK.



STUK Management system



STUK management system

- Objective is to ensure the quality and productivity of the operations.
 - The employees know the work flows in processes and also the tools and documents in these processes.
 - The Management system describes the tasks and responsibilities of all organizational units and persons, as well as management practices and internal communication at all levels.
- The effectiveness on Management System is evaluated and improvement actions are taking place when needed. The evaluation includes self assessments, independent assessments, internal audits, external audits, management reviews.

STUK Management System – Manual of Nuclear Reactor Regulation department

- The manual of the Nuclear Reactor Regulation department includes instructions for the day-to-day work.
- Related to organisation of the work (not exhaustive)
 - Nuclear Reactor Regulation Department Organisation and tasks
 - Planning, follow-up and development of operations of nuclear reactor regulation department
 - Competence management
 - IT-tools
 - Use of Technical support organisations
 - Indicators
 - Document handling
 - Administrative handling of application, assigning responsible person, his/her duties, process in case of disagreement, templates for decisions
 - Archives and their maintenance
 - Oversight projects

STUK Management System – Manual of Nuclear Reactor Regulation department

- Related to oversight in general (not exhaustive):
 - Applying graded approach
 - Enforcement of Regulatory Decisions
 - Oversight of safety in the use of nuclear energy
 - Overall safety assessment of a nuclear facility
 - Safety statements concerning decision in principle and main licenses
 - Process for approval of personnel
 - Process for approval of manufacturers
 - Process for approval of testing organisations
 - Process for approval of inspection organisations

STUK Management System – Manual of Nuclear Reactor Regulation department

- Guides related to review, assessment and oversight (not exhaustive)
 - Design, analyses (deterministic analyses, PRA, strength analyses, failure analyses..), Operational limits and conditions, plant modifications
 - Outages, fire safety, security, radiation protection, waste management, operational experience...
 - Organisations, resources, safety culture, licensee's management system...
 - Safeguards, transportation of nuclear material
- Guides related to inspections
 - Inspection program for unit under construction
 - Inspection program for unit in operation
 - Inspections of mechanical components
 - Inspections related to nuclear materials

Organisation of the licensing process

- Major review and assessment tasks are coordinated as projects
 - New build projects
 - Operating license renewals and periodic safety reviews
 - Extensive plant modifications involving
 - several technical areas
 - high safety significance
 - long time schedules (several years)
 - large resource need (several person-months of oversight work).
- Continuous oversight of operating units is coordinated and carried out by the line organisation
- The projects use the resources of the line organisation.

Construction License (CL) Documents

- Documentation submitted to STUK (Nuclear Energy Decree § 35)
 - Preliminary Safety Analysis Report
 - Probabilistic Risk Analysis
 - Safety Classification
 - Quality Management
 - Preliminary plan for physical protection
 - Preliminary plan for emergencies
 - Plan for safeguards control
 - STUK's oversight possibilities
 - Other documents
 - License applicant's safety assessment
 - Assessment on the compliance with regulations
 - An applicant for a licence shall also provide the Radiation and Nuclear Safety Authority with any other reports that the STUK considers necessary.

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.

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.*”
- Fennovoima proposed:
 - Approvals related to main components of the reactor coolant system
 - According to the current plan Fennovoima will request for approval on the basis of 55 §(i.e. permit to start manufacturing before CLG) only for the RPV, the SGs and the pressurizer.
 - Other Components to be submitted for the review of STUK before CLG
 - There are components for which Fennovoima plans to apply for manufacturer approval and to submit a Construction Plan before CLG (Bubbler, Core catcher, Main personnel hatch for containment entry, Emergency personnel hatch, Material transport hatch, etc.)
 - FH1 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, Fennovoima will submit to STUK a justification of its position 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 (ref. slide 6) 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 Fennovoima Hanhikivi 1 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.

- **B.1 606.** *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.*

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

Cont...

B.1 608. 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.**

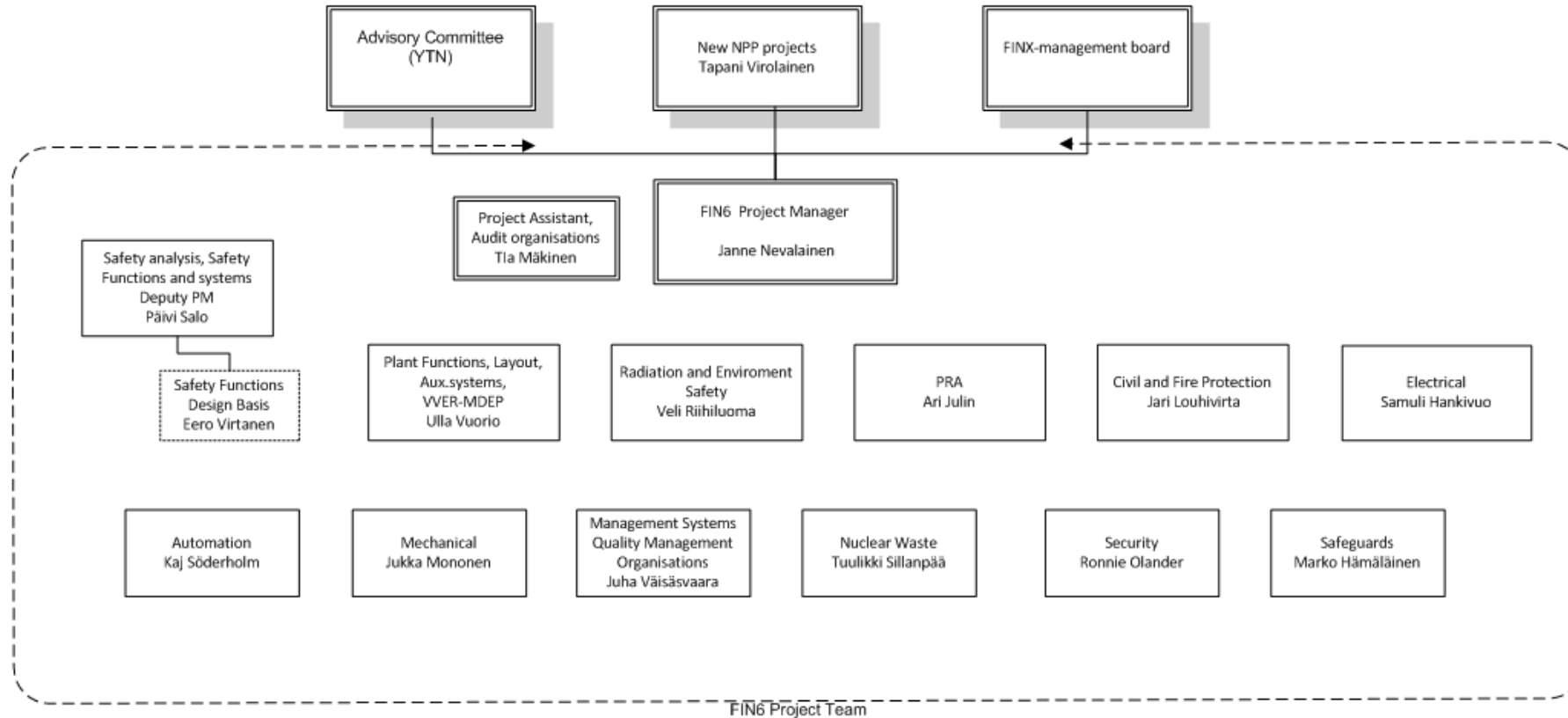
- Confidence to STUK review and assessment work. Focusing to effective and risk-informed and open regulatory oversight.
- Public confidence will be achieved with open and clear communication

STATUS of STUK preparations for CLA review and assessment

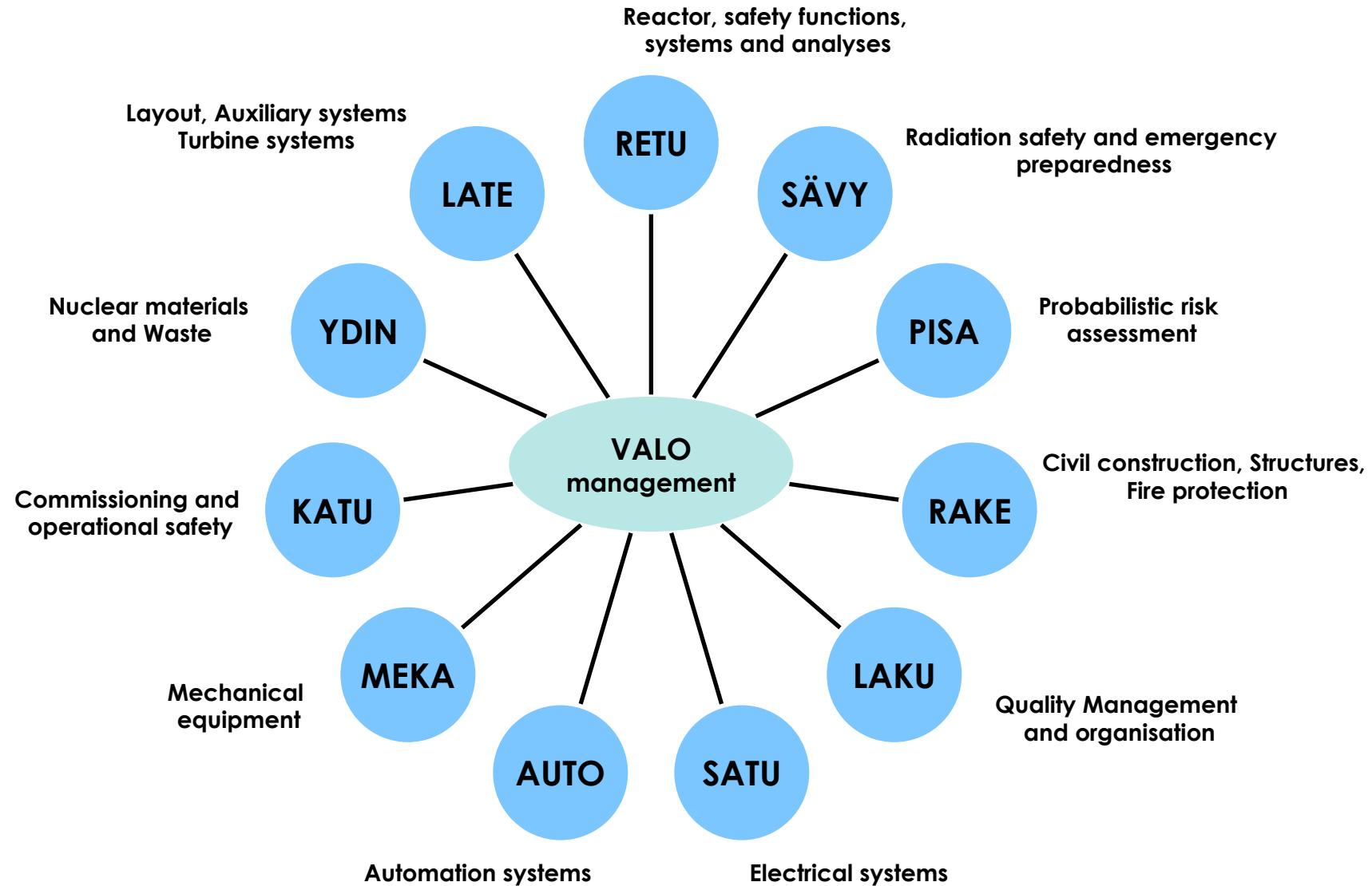
- STUK own project plan and project organisation (please see separate slide)
- STUK allocated YVL requirements to CLA PSAR chapters and other documents for review and assessment work by using requirement management tool (Polarion)
- STUK review of the Licensing plan
- STUK performed a pre-inspection 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

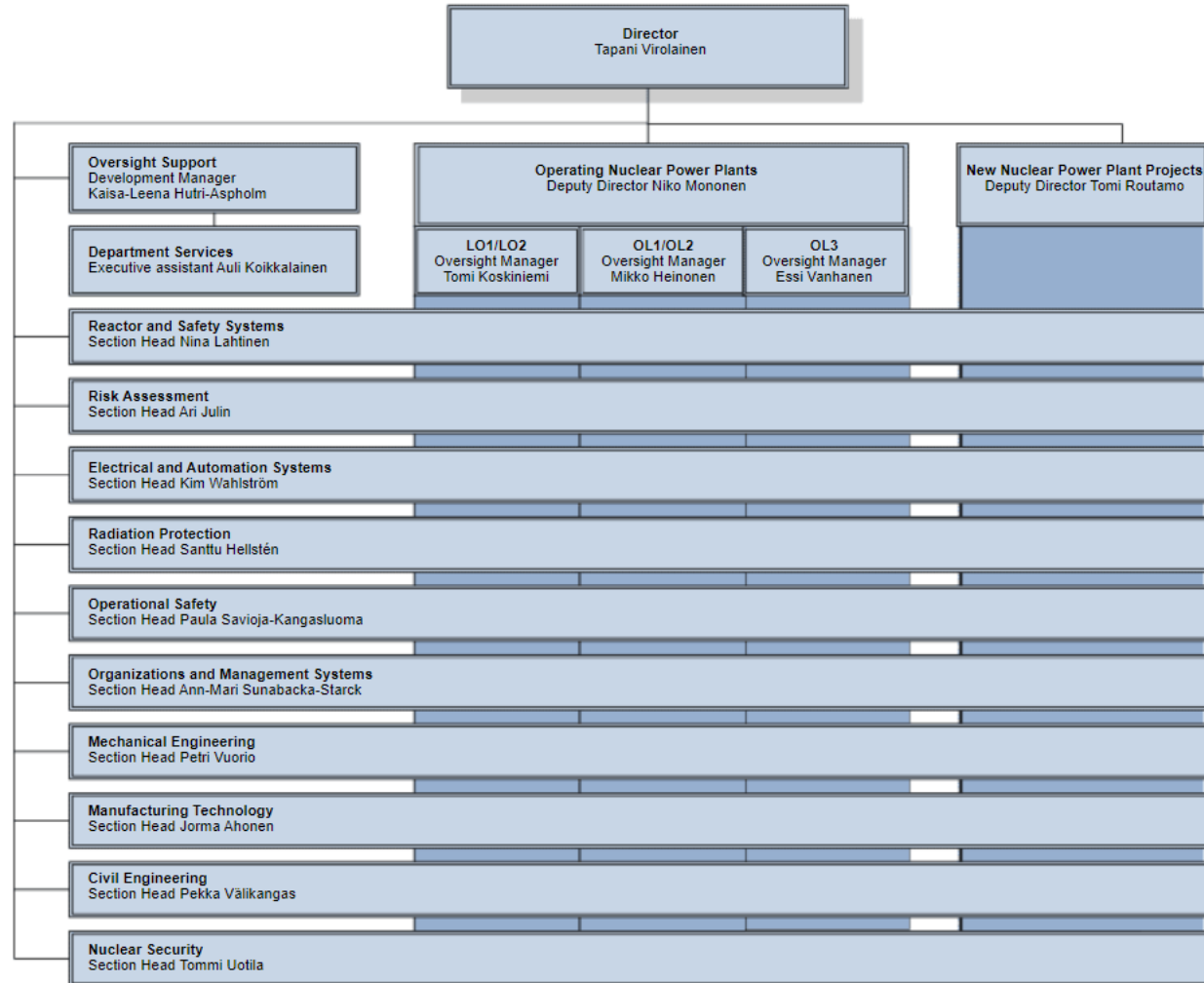
Acc. Project Plan #1563953, v13, 30.4.2015



Project Group in STUK for licensing of OL3



NRR organization 1.11.2023



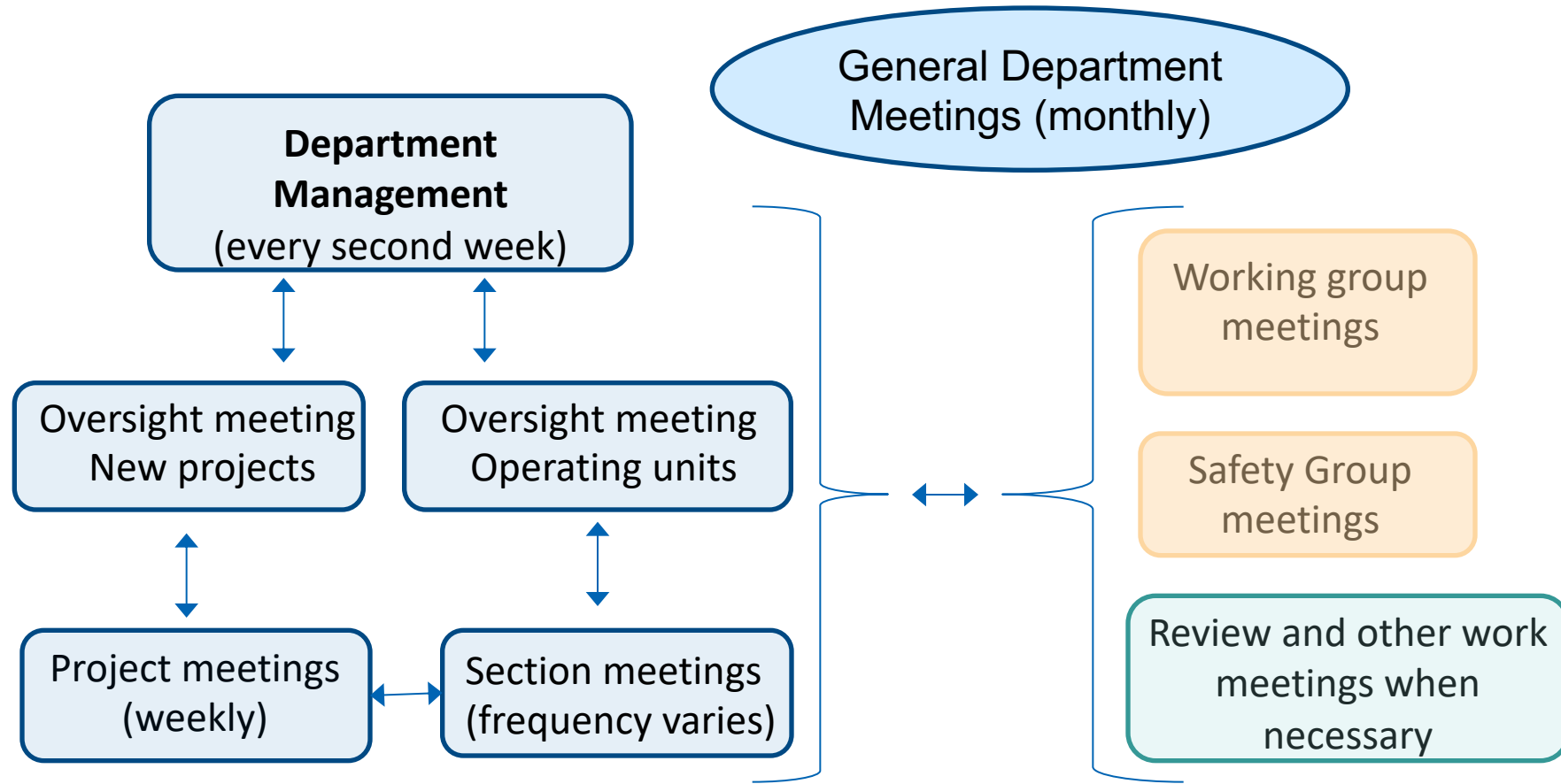
Project in STUK for licensing OL3

- Established some time before construction license application was submitted
 - In Decision in Principle phase STUK's workload is low, and can be managed without organising the work as a project
- Project plan was drafted in the beginning for the whole duration of the project (until start of commercial operation of the unit)
 - The later phases (commissioning, operating license review) were in the beginning planned only in very general level
 - The project plan is kept up-to-date all the time, and a detailed oversight plan is drafted every autumn for the next year
- Project managers have been persons with technical background and with experience of regulatory work and also with project work. Training on project management has been arranged.
- Project owner is Director of Nuclear Reactor Regulation Department

Project duties (OL3)

- Coordinate the review of the main license (construction, operating) applications and prepare the safety statements
- Coordinate review of all other application related to licensing of OL3
- Plan the work, both the tasks and needed resources
- Communicate with the licensee, arrange necessary meetings
- Share information within STUK (reporting to project management group, to (deputy)director, regular progress reports, in intranet, in meetings..)
- Share information with public and media in cooperation with the Public Relations unit
- Participate in international cooperation
 - Bilateral cooperation with ASN (the RB of the country of origin)
 - Participate in MDEP work (Multinational Design Evaluation Program)
 - EPR group = group of RBs of countries licensing or interested in licensing EPR

Meetings of Nuclear Reactor Regulation Department



All protocols are available in STUK intranet

Resource planning



Resource planning

- Resource planning
 - Long-term HR-plan (5 years)
 - Updated annually – statistical data on personnel, predictable retirements, needs for new resources (competence areas).
 - Annual HR-plan
 - Done every autumn
 - Section heads draft of list of tasks for next year and estimate the amount of resources and type of competence needed for carrying them out
 - Not only oversight tasks, but also development of regulations, participation in trainings (either as a pupil or a lecturer) etc.
 - The estimation is compared with the existing resources and competences.
 - In case of a gap, it is considered whether new persons are hired or is the use of support organisations or consultants possible (especially if the need of the resource or competence is only temporary)
 - No special tools are used (excel is used for listing the tasks and calculating the needed man days)).

Resource planning – Example of used excel table

Commissioning and operation, resource plan for 2015																		
Task / section	JOH	KÄY	OJO	REA	SAJ	RIS	SÄT	MEK	VAL	RAK	YTS	YMA	YJL	YJT	Outside resources	Sum	Quarter of the year	
sum of person days	11	69	5	196	75	2	11	12	11	7	10	0	4	0	0	413		
Review of commissioning test programs																0		
Nuclear commissioning																0		
Plant level tests				16	3		3									223,4		
System commissioning programs																0		
electrical systems					6											63,4		
I&C					40						10					503,4		
safety systems				40				5	5							503,4		
HVAC				35												353,4		
other				7	3		1	2	2							153,4		
General procedures				1	6			1								81,2		
																0		
Oversight of test performance and review of results		3		5												81,2		
Oversight of tests on site		10		15	4		2	2	2							351,4		
Review of result reports				20				2	2							243,4		
																0		
OLCs	4	15		35	4	2	5	0	0	2			4			711,2		
																0		
HMI (MCR and simulator)																0		
Validation plans		3		1												43,4		
Observation of MCR validation																0		
Simulator validation		5		5												103,4		
																0		
Operating procedures																0		
Validation plans		2	1	4												73,4		
																0		
																0		
Meetings and inspections																0		
HMI meetings		6		2	2											101,4		
commissioning meetings	5	15		5	5											301,2,3,4		
Inspections	2	10	4	5	2					5						282,4		
																0		
Task for support organisations																0		
expert opinion on emergency operating procedures																0		
evaluation of training simulator																0		

Resource planning - Challenges

- Especially in new-build projects, the tasks for next year are not always known exactly (even by the licensee).
 - **Example:** In Olkiluoto 3 project, the licensee was unable to confirm when they will submit the operating license application. The amount of work for reviewing the application is considerable (rough estimate 30 man years).
 - Problems in manufacturing or installation can easily increase the regulatory work load (increased number of inspections due to remanufacturing and re-installations).
 - Poor quality of documentation increases the regulatory work load.
 - Unexpected work – incidents at operating units, new safety related information (e.g. counterfeit, fraudulent, and suspect Items) major incident at any NPP
- some uncertainty always exists in the resource planning.

Resource planning – use on support organizations

- STUK utilizes Technical support organizations (TSOs) in
 - Areas, where STUK does not have resources
 - Independent accident analyses (comparison analyses)
 - Experimental verification of safety system solutions
 - Some specific areas (extreme weather, earthquakes).
 - Areas of new technology / knowledge.
 - Additional resources supporting STUK review.
- The organisation selected must have experience (references) on similar tasks
 - The organisation must have experience of the plant type
 - The organisation must be independent of the licensee and plant vendor
 - Validated methods shall be used
 - The analysis methods (codes) must be independent of the licensee or vendor methods.

Example: Olkiluoto 3 Construction license

- Main areas
 - Airplane crashes (new requirements)
 - Severe accidents (melt retention in core catcher)
 - Digital I&C (using of software based systems)
 - Primary system materials and components, LBB.
 - Independent accident analyses to verify the results of licensee's analyses
- Volume (costs) ~2 M euros during construction license review.

Example Safety oversight of the Olkiluoto 3 project

- **2000–2003: Design of a nuclear power plant unit**
 - **2001:** STUKs preliminary safety assessment
 - **2002:** Government adopts a DiP, which is confirmed by Parliament
- **2004–2005: Construction licence**
 - **2005:** STUK issues a statement and a safety assessment. The Government grants CL
- **2006–2018: Construction period**
- **2016–2019: Operating licence**
 - **2019:** STUK safety assessment. The Government grants the operating licence
- **2020–2023: Nuclear commissioning**
 - **2023:** The trial phase ends and regular electricity production starts on 16 April 2023.
- **Regulatory oversight by STUK**
- 468 person-years
- More than 100 experts
- Several thousand factory inspections in around 30 countries
- More than 10 000 on-site inspections
- More than 20 000 applications

Documentation and records



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Documents and records

- All documents are stored in a document management system (called SAHA):
 - Applications from the licensee's and related regulatory decisions
 - Protocols of meetings
 - STUK management system documents
 - Regulations and safety guides
 - Travel reports, annual reports etc.
- The applications and decisions are only in electrical format. Paper copies are submitted only if
 - The regulatory body needs the document during emergency situation
 - If the material includes large drawings which are difficult to read from computer screen
- Only paper copies are submitted for security related applications.
- Signing of the decisions is done by an electrical signature.

Documents and records

- Documents received and produced in reviewing an application
 - Application documents (covering letter explaining the question and presenting licensee's position and documents describing the actual matter).
 - STUK's decision and related memorandum. The memorandum explains the justification of the decision.
 - Possible emails between licensee and STUK related to the application
 - Deadlines for possible additional requirements are recorded and followed in the document management system (SAHA).
- Information concerning the processing of the application in STUK is stored in the system (SAHA) and can be retrieved later on, e.g.
 - responsible person
 - persons involved in the review, their comments
 - starting date of the review and target date for the completing the review
 - dates for completing different stages of the review (completeness check, "review completed" date from each individual reviewer)
- It is possible to get a list of all open requirements (not yet answered by the licensee) from the system.

Application of graded approach



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Application of graded approach

- In the law (Nuclear Energy Act) it is stated that
The requirements and the measures to ensure safety shall be scaled and allocated according to the risk related to the use of nuclear energy.
- Important tool in applying graded approach is safety classification of systems, structures and component. The safety class determines the requirements and oversight.
- STUK management system has a procedure “Applying graded approach”. The procedure gives guidance how to apply graded approach in everyday work.
- For each new application from the licensee, when deciding on the needed review, a template to evaluate the safety significance of the application is used to support the decision.

Examples how to apply graded approach

- Component related inspections:
 - Making only spot check inspections (e.g. if a known manufacturer with a good record)
 - use of inspection organisations if safety significance of the component is low (but the inspections is mandatory due to pressure vessel law)
- Inspections to licensee's performance
 - Inspecting established processes with longer intervals, if licensee's performance has been on a good level for a long period of time
 - Focusing inspections on new processes and on areas with indications of problems

Interaction with the licensee



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Interaction with the licensee and contractors

- For oversight, it is essential to have good communication channels with the licensee, both formal and informal.
- In STUK
 - Established, formal channels exists for submitting applications, for regulatory decisions, for inspections and for informing STUK immediately (24 hours a day) about any major incidents.
 - Informal communication (email, phone calls) when necessary (in practice continuously).
 - Interaction with the contractors is always through the licensee.
 - Regular meetings between STUK's and licensee's management are held.
 - Regular meetings with the licensee in the new-build projects.
 - Other meetings arranged when necessary or useful, typical meetings are for example
 - The licensee's come to STUK to present the annual outages (schedule, main works, arrangements...).
 - Discussions about large plant modifications

Meetings with licensee

- in STUK review and assessment process
 - Presentation meeting e.g. plant modifications
 - Project meetings
 - Topical meetings when needed e.g. YVL guide interpretations
- Project specific meeting structures case by case
 - Meeting structure is mutually agreed with parties
 - Updated if needed
 - Often licensing phase specific
 - Purpose, participants, intervals, chair, meeting records etc.

Meetings with the licensee in Olkiluoto 3 -project

- E.g when the unit was approaching operation and last pre-operational commissioning tests were under way.
- Regular meetings
 - Management technical meeting (every second month)
 - Commissioning meeting (every second month)
 - Fuel loading preparations
 - Operating license meeting (four times a year)
 - Commissioning progress meeting (every week - teleconference)
 - I&C meeting (every week – teleconference)
 - Project management meeting (four times a year)
- Other meetings when necessary to discuss matters in more detail.
- The structure and content of the meetings has changed according to project stage; during construction different disciplines had regular meetings (safety, mechanical engineering, civil engineering, I&C, electrical engineering...)
- STUK does not make authorization decisions in the meetings.

Hanhikivi project - Interaction between parties

- THREEPARTY MEETINGS

Development of meeting procedures with Utility and Vendor – with STUK comments given



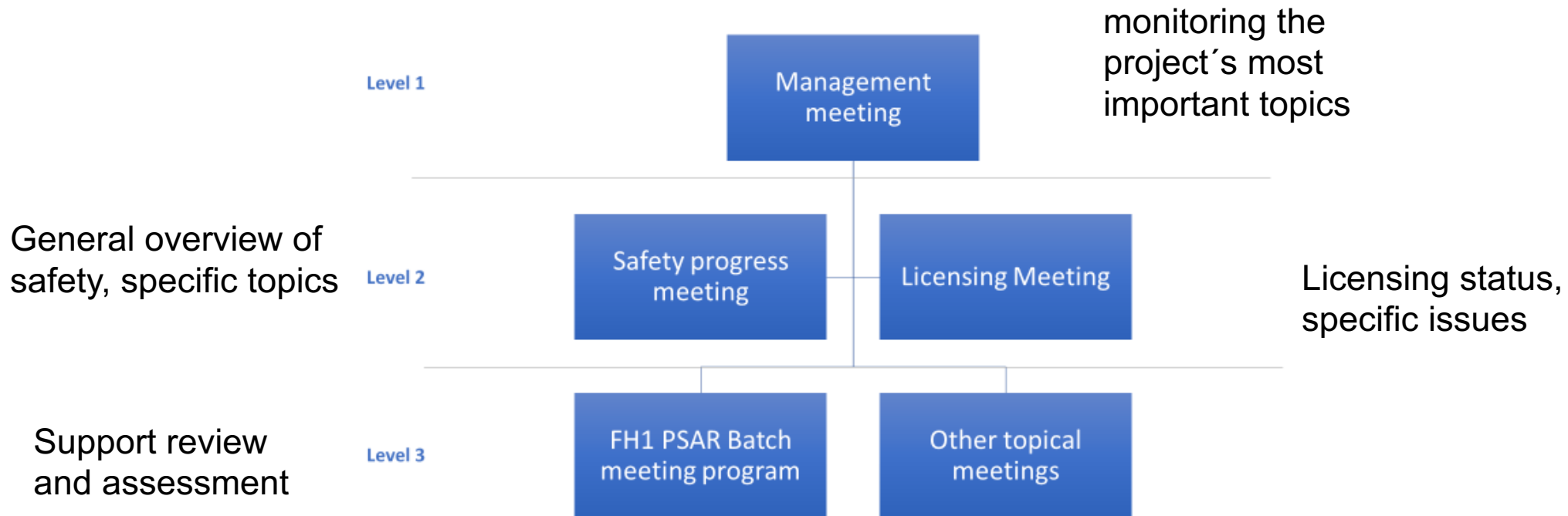
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[Esitys, Esittäjän nimi]

General meeting procedures

- Meeting agenda and materials, questions etc. to STUK at least one week before meeting
- STUK may give comments and preliminary unofficial guidelines in the meeting, but official decisions are not made in meetings
- Minutes of meeting shall be held and sent to STUK for comments

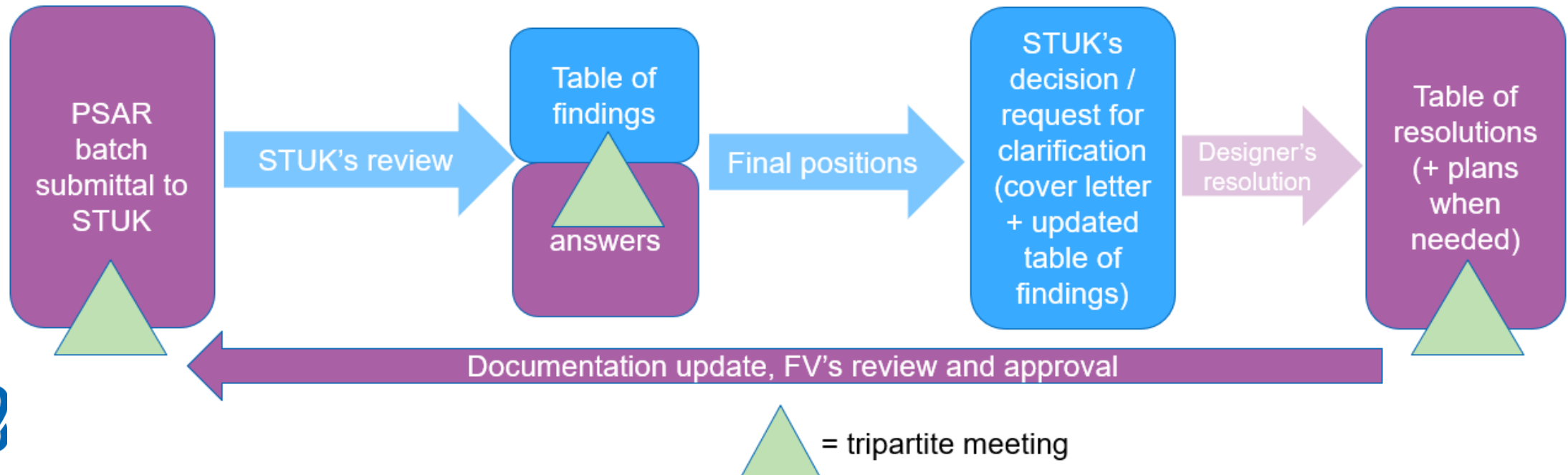
Meeting Structure case Fennovoima



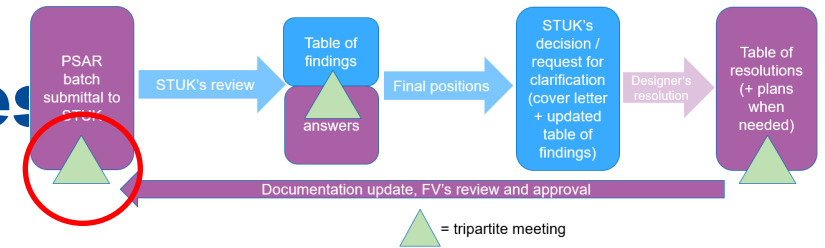
FV STUK and other authority meeting instruction rev. 7 10/2021

PSAR batch meetings – overview

- Meetings to be held only when meeting preconditions are fulfilled, and all organizations are ready for the meeting
- Weekly time slot reserved for the meetings
- Meeting participants shall include the relevant experts contributing to the discussions

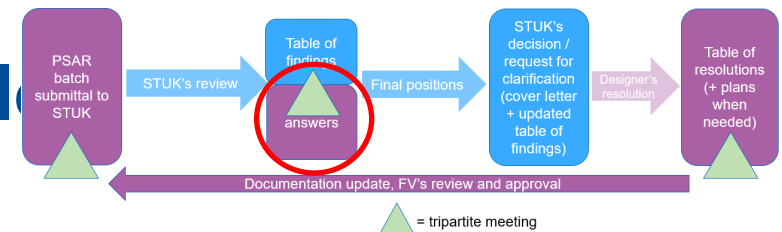


Presentation meeting – principles



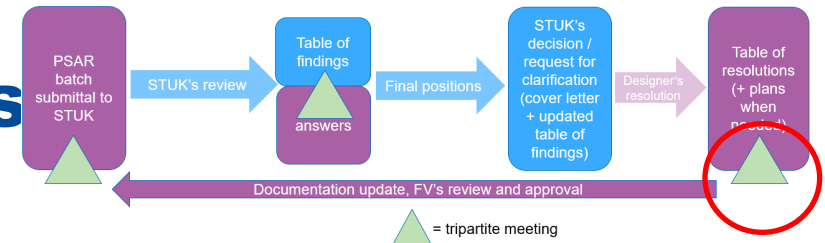
- Purpose: to support STUK's review by introducing batch contents and by providing answers to STUK's initial questions
- Timing: when batch submitted to STUK (± 2 weeks)
- Roles:
 - **FV presents and chairs** - safety responsible and/or system system responsible gives the presentation and chairs the meeting
 - **Supplier supports** - provides answers and clarifications to possible questions
 - **STUK listens and asking clarifying questions-** mainly listening role, but asking clarifications
- Meeting preconditions and preparations: batch ready to be submitted to STUK and presentation materials prepared by FV and sent to STUK 2-3 days before the meeting
- Meeting memorandum: FV prepares short memo including participants, presentation material and main discussion points (if any), memo will be sent for comments to all participants after the meeting

Pre-clarification meeting - principle



- Purpose: to discuss STUK's findings, **provide clarifications AND design solutions** and support STUK in preparing the decision Timing: roughly 3 weeks after receiving STUK's preliminary findings
- Responsibilities:
 - **FV presents/supports and chairs** - safety responsible (supported by others) chairs the meeting, presents the responses together with the Supplier and updates the excel table
 - **Supplier presents/supports** – presents clarifications to the design solutions
 - **STUK presents STUK's view** – STUK provides opinion whether the responses and proposed actions are acceptable
- Meeting preparations and preconditions:
 - STUK's preliminary findings sent to FV in excel table **with categorisation**
 - Supplier provides clarifications to each finding (within one week)
 - FV and Supplier discuss and agree the common responses to each finding (within one week)
 - Meeting agenda and responses (one common response agreed between FV and Supplier) sent to STUK one week before the meeting
 - The responses mainly focus on **providing design solutions** clarifications and justifications to findings related to plant design solutions related to the current batch, the responses shall be brief (possible longer explanations to be given in separate background material)
 - STUK checks the responses before the meeting in order to provide STUK's **preliminary** opinion regarding the responses – so that the meeting can focus on the unclear items
- Meeting memorandum: excel table including STUK's view is updated and (and thus no need to send the excel for comments after the meeting)

Clarification meeting – principles



- Purpose: to present **and discuss and agree** the action plans for STUK's requirements (to ensure common **understanding** opinion regarding the actions needed to continue the FH1 licensing)
- Timing: some weeks after receiving STUK's decision (when meeting preconditions are fulfilled)
- Responsibilities:
 - **FV presents and chairs** - (safety responsible supported by others) mainly presents the responses (action plans)
 - **Supplier supports** - provides support and clarifications when needed
 - **STUK presents STUK's view** – STUK provides opinion whether the responses and proposed actions **are inline with STUK expectations**
- Meeting preparations and preconditions:
 - FV's internal allocation of requirements to responsible persons and PSAR chapters
 - Meeting agenda and one common response agreed between FV and Supplier and sent to STUK one week before the meeting
 - STUK checks the responses before the meeting in order to provide STUK's opinion regarding the responses – so that the meeting can focus on the unclear items
 - The response shall present a clear plan and actions how the requirement will be considered and what are the impacts on the documentation or design, the responses shall be brief (possible longer explanations to be given in separate background material). **To be delivered to STUK.**
 - FV also categorizes the requirements based on the requirement importance before the meeting
 - If the requirements impact the plant design, the possible impacts shall be discussed and agreed internally within FV (Safety and Engineering) and within the Supplier (PLP and AP's design organization)
- Meeting memorandum: excel table including STUK's view on the action plans is updated and commonly agreed during the meeting (and thus no need to send the excel for comments after the meeting)

Questions?



