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KELPO – Development of the licensing and qualification processes for the systems and equipment of nuclear facilities in Finland

Final report

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Note:

Due to the cross-organisational nature of the project, the normal inspection and approval markings are not presented herein. The report has been prepared by the members of the project team, and the contents of the published report have been reviewed and approved by the steering group and project team.

Tiivistelmä

Ydinalan toimijat niin Suomessa kuin ulkomailla ovat havainneet toiminnassaan yhä enemmän haasteita: Raskaaksi koetut luvitus- ja kelpoistusprosessit tekevät ikääntyvien laitteiden ja järjestelmien modernisoinneista haasteellisia. Toimittajaverkosto harvenee ja kiinnostus toimittaa laitteita ydinlaitoksille on laskenut. Muilla teollisuudenaloilla on viime vuosikymmeninä tapahtunut huomattavaa laatukehitystä, jota ei tällä hetkellä ydinalalla riittävästi hyödynnetä.

Ydinvoiman kilpailukyky muuttuvassa toimintaympäristössä on varmistettava. Muutostöiden ja modernisointien kannattava tekeminen sekä kattava toimittajaverkosto ja laitteiden saatavuus ovat edellytyksiä ydinalan toimintaedellytysten varmistamiselle ja kokonaisturvallisuuden takaamiselle.

Vuonna 2018 toteutetun KELPO-projektin tarkoitus oli löytää keinoja luvitus- ja kelpoistusprosessien kehittämiseksi Suomessa. Tähän luvanhaltijoiden yhteiseen projektiin osallistui myös STUK. Projektin tuloksena on ehdotettu luvitus- ja kelpoistusmenettelyihin muutoksia, joilla menettelyistä tehtäisiin tarkoituksenmukaisempia. Projektissa keskityttiin erityisesti alempien turvallisuusluokkien mekaanisiin laitteisiin. Tarkastelun kohteena oli suomalainen luvitusympäristö, mutta tavoitteena on jatkossa hyödyntää tuloksia EU-tasolla vastaavissa selvityksissä. KELPO-projektin tavoitteeksi määriteltiin graded approach -periaatteen laajentaminen, standardilaitteiden hyödyntäminen sekä kattavan toimittaja-/valmistajaverkoston varmistaminen ja luvanhaltijoiden yhteistyön lisääminen.

Projektin tuloksena on esitetty vaihtoehtoisia kehitysehdotuksia, jotka korostavat luvanhaltijoiden yhteistyötä ja luvanhaltijan vastuuta sekä kohdentavat STUK:n valvontaa sinne, missä ydinturvallisuuteen voidaan eniten vaikuttaa: Ehdotettu ylätason muutos tarkastuslaajuuteen kohdentaa viranomaisvalvontaa korkeampiin turvallisuusluokkiin ja laitos- ja järjestelmätasoille ja toisaalta korostaa luvanhaltijan omaa valvontavastuuta erityisesti laitetasolla. Toisena kehitysehdotuksena esitetty menettely pyrkii poistamaan luvanhaltijoiden päällekkäistä työtä ja lisäämään luvanhaltijoiden yhteistyötä sekä tuomaan ydinalalle käyttöön kansalliset hyväksynnät. Tämä menettely olisi toteutettavissa verrattain helposti ja pienin muutoksin nykykäytäntöön nähden. Kolmas kehitysehdotus on uusi menettelytapa, joka poikkeaa nykymallista enemmän ja pyrkii viemään laitehankinnoissa käytettäviä menettelyjä kohti muiden teollisuudenalojen toimintatapoja. Tavoitteena on selkeyttää vaatimuksia toimittajan suuntaan ja hyödyntää muilla teollisuudenaloilla käytössä olevia standardeja ja menettelyjä. Ehdotetun uuden menettelyn testaamiseksi ja edelleen kehittämiseksi on suunniteltu pilottiprojektia toteutettavaksi yhteistyössä luvanhaltijoiden ja STUK:n kesken. Yllä mainittujen kehitysehdotusten lisäksi projektissa on tarkasteltu standardi-/sarjavalmisteisten laitteiden käyttöä eri tekniikanaloilla sekä näiden laitteiden mahdollisia luotettavuusdatan lähteitä.

Esitetyt kehitysehdotukset korostavat luvanhaltijoiden yhteistyötä sekä luvanhaltijan omaa vastuuta onnistuneesta ja vaatimustenmukaisesta laitehankinnasta. STUK:n valvontaa kohdennetaan sinne, missä perusteet ydinturvallisuudelle luodaan ja missä siihen eniten voidaan vaikuttaa. Vaatimuksia ja menettelyjä laitetoimittajien/-valmistajien suuntaan pyritään selkiyttämään ja hyödyntämään laitehankinnoissa muilla teollisuudenaloilla käytössä olevia menettelyjä ja standardeja, joihin toimittajat ja valmistajat ovat tottuneet. Näillä keinoin pyritään helpottamaan muutosprojektien tekemistä ja laitetoimittajien/-valmistajien osallistumista projekteihin.

KELPO-projektin jälkeen toteutettavan pilotoinnin tuloksena saadaan selville ehdotetun menettelyn heikkoudet, vahvuudet ja muutostarpeet. Ehdotettuja kehitysehdotuksia työstetään projektin jälkeen yhteistyössä luvanhaltijoiden ja STUK:n kesken niiden edelleen kehittämiseksi ja viemiseksi käytäntöön. Luvanhaltijoiden yhteistyö ja sen kehittäminen sekä yhteistyö myös STUK:n kanssa ovat avainasemassa tulevaisuuden kehitystyössä. Yhteistyötä on tulevaisuudessa tarkasteltava myös laajemmin, mm. Ruotsin kanssa ja EU-tasolla. Menettelyjen ja toimintatapojen kehittäminen on välttämätöntä ydinalan toimintaedellytysten varmistamiseksi ja kokonaisturvallisuuden takaamiseksi muuttuvassa toimintaympäristössä myös tulevaisuudessa.

Summary

The nuclear industry in Finland and abroad is facing an increasing amount of challenges. The licensing and qualification procedures are considered heavy which creates challenges in modernisation of equipment and systems. The equipment suppliers and manufacturers show declining interest in participating in nuclear projects. In other fields of industry there has in the past decades been a significant increase in quality requirements and thus improvement in quality of equipment. This development is at present not sufficiently utilized by the nuclear industry.

The competitiveness of nuclear energy in the changing market has to be secured. The viability of modification and modernisation projects as well as a comprehensive supplier network and availability of equipment are prerequisites to enable feasible operation of the nuclear industry in a changing environment and to guarantee the overall nuclear safety in the future.

The purpose of the KELPO-project carried out in 2018 was to suggest ways to develop the licensing and qualification practices in Finland. The Project was a co-operation of the Finnish license holders/licensees, to which also the Finnish nuclear authority STUK participated. As a result, changes to make the licensing and qualification practices more functional are proposed. The Project focused on mechanical equipment in lower safety classes as well as on the Finnish licensing framework. However, the goal is to utilize the results in EU-level development work later. The objectives of the Project were set as: widening the use of the graded approach principle, utilizing standard equipment and securing a comprehensive supplier network as well as increasing co-operation between license holders.

As a result, alternative ways to develop the licensing and qualification practices are proposed. The suggested measures increase the co-operation between license holders, emphasize the license holders' own responsibility and focus authority surveillance on areas where nuclear safety can be affected the most. Firstly, a high-level change to scope of supervision is proposed: authority supervision is focused on higher safety classes and on plant- and system-level, while the license holder's own responsibility is emphasized especially on equipment-level. The second suggestion is a process, which cuts the overlapping work of licence holders and increases co-operation as well as introduces national approvals in Finnish nuclear industry. This process would be relatively easy to adopt, as it requires only small changes compared to the existing practices. The third proposed change is a new method which suggests more changes compared to the existing practices and aims to change the practices closer to those used in other industries. This method aims to clarify the requirements for equipment suppliers and manufacturers as well as to utilize methods and standards similar to other fields of industry. To test the suggested method, a pilot project has been planned to be carried out by the licence holders in co-operation with STUK. In addition to the above-mentioned suggestions the use of standard/serially manufactured equipment and the potential sources of reliability data of such equipment has been studied.

The proposed development suggestions emphasize co-operation between license-holders as well as the license-holder's own responsibility for successful procurement of equipment which fulfil the requirements. Authority supervision is focused on areas where nuclear safety can be affected the most. From the equipment suppliers' and manufacturers' point of view the requirements are clarified and practices and standards familiar from other industries utilized. At the end, these means aim to facilitate implementing modernization projects at nuclear facilities as well as to make it easier and more interesting for suppliers and manufacturers to take part in these projects.

A pilot project will be carried out to identify the strengths, weaknesses and modification needs of the proposed new method. The suggestions made in this Project will be further processed in co-operation between the license-holders and STUK to develop them and bring them to practice. Co-operation among the license holders and with STUK is essential for further development work. Also wider co-operation e.g. with Sweden and on EU-level shall be considered. It is essential to develop the procedures in the nuclear industry to secure the feasibility of operating nuclear installations and to guarantee high level of overall nuclear safety also in the future.

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Abbreviations and definitions

AIO	Authorised inspection organisation
EN	European Standard
EYT	No nuclear safety classification
HP	Hold point
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
KOT	Commissioning inspection
LH	Licence holder/applicant
NDT	Non-Destructive Testing
STUK	Radiation and Nuclear Safety Authority
PED	Pressure Equipment Directive
PG	Part Group
PRA	Probabilistic Risk Assessment
E/I&C	Electrical/Instrumentation and control
SIL	Safety Integrity Level
SC	Safety Class
TP	Third Party
YVL	YVL Guide

Authorised inspection organisation

Authorised inspection organisation shall refer to an independent inspection organisation approved by the Radiation and Nuclear Safety Authority under Section 60 a of the Nuclear Energy Act to carry out inspections of the pressure equipment, steel and concrete structures and mechanical equipment of nuclear facilities in the capacity of an agency performing public administrative duties.

Graded approach

A principle according to which safety requirements and measures must be commensurate with and allocated to the level of risk and safety significance.

Hold point

A point beyond which work cannot proceed without an approved official inspection.

Notified body

Notified body shall refer to a notified body as referred to in Article 12 of the Pressure Equipment Directive (97/23/EC).

Licence holder

Licence holder shall refer to the holder of a licence entitling to the use of nuclear energy. In this report, licence holder also refers to licence applicant, where applicable.

Licensing and qualification

Procedures for having a system or product approved for use at the nuclear facility.

Low-energy

In safety class 2, ‘low-energy’ refers to equipment with a design pressure of up to 20 bar(g) and a design temperature of up to 120 °C and to which the design, dimensioning and quality-control requirements of corresponding equipment from safety class 3 can be applied without causing a risk of the equipment losing operability.

Construction inspection

An inspection carried out when accepting equipment to ensure that the equipment and its manufacture, testing, inspection and documentation have been carried out as laid down in the specified requirements.

Serially-manufactured equipment

Serially-manufactured equipment shall refer to equipment that is not designed or manufactured for the location of use specially according to the client’s requirements. Typically, the equipment is manufactured in large batches and is also suited to other applications. The structure, dimensions and materials of the equipment and the methods and quality of manufacture does not essentially differ within or across manufacturing batches.

Standard equipment

The manufacture, testing, inspection and documentation of standard equipment is based on the standards and procedures normally used by the manufacturer.

Type approval

Type approval shall refer to a nationally or internationally recognised procedure whereby the accredited certification body granting the approval verifies that the product and its implementation meet the applicable technical requirements.

1 Introduction

Power companies and other nuclear industry organisations have noted in their daily work that there is a great deal of development potential in procedures connected to licensing and qualification. By developing these procedures to make them more appropriate, we can better facilitate modifications and lower the threshold for organisations to participate in nuclear projects and thereby improve the overall safety of facilities as well as promote the comprehensiveness of the supplier network, for example.

At present, carrying out modifications to improve overall safety and plant usability is considered difficult, expensive and laborious, particularly due to the large amount of documentation and the high number of time-consuming licensing phases required. The deviations from manufacturers' normal practices and processes due to the special requirements in the nuclear sector also lead to difficulties. The heavy licensing process complicates the maintenance and modernisation of ageing equipment and systems and does not sufficiently support the implementation of safety-improving actions using modern, reliable and commonly available technology. In the nuclear sector, it must be possible to also leverage quality developments achieved in other fields of industry which improve the usability and reliability of equipment. According to Section 7 a of the Nuclear Energy Act, "for the further development of safety, measures shall be implemented that can be considered justified considering ... advances in science and technology", and licensing and qualification procedures must support this principle [1].

Carrying out modifications is also considered difficult for individual pieces of equipment replaced for maintenance purposes. If the original manufacturer has left the market, the equipment must be replaced with an equivalent equipment from another manufacturer, and the cumbersome manufacturer approval process must start again. This can lead to a situation where, instead of procuring new equipment, it is more cost-effective to "wear out" the existing equipment, which in turn leads to additional shutdowns and longer repair outages. On the other hand, the large amount of approval documentation needed has reduced the interest of equipment suppliers and manufacturers to supply nuclear facilities. The dwindling supplier network hikes up prices further, makes it more difficult to carry out modifications and limits the availability of equipment for nuclear facilities. Nuclear facilities are unable to select the best possible equipment because the best suppliers are not willing to participate in projects that they find cumbersome.

Cost-effective modifications and modernisations, the availability and utilisation of high-quality equipment and the best technology as well as ensuring a comprehensive supplier network are all vital for ensuring the operational feasibility of the nuclear sector and guaranteeing the overall safety of nuclear facilities. The nuclear sector must continue to be able to operate cost-effectively in the changing operating environment.

Based on this need, the KELPO Project was launched with the purpose of developing the licensing and qualification processes for the systems and equipment of nuclear facilities by proposing more practical processes and concrete improvements to procedures and requirements without the proposed changes having a negative impact on nuclear safety. In this context, licensing and qualification processes refer to the procedures for having a system or product approved for use at a nuclear facility. The need for the project was also recognised in a preliminary study commissioned by STUK, "Ydinlaitosten luvitusmallien kehittäminen (Luvike)" ("Development of licensing models for nuclear facilities") [2[.

The proposals for procedure improvements developed in this project can be utilised in modification projects of operating nuclear facilities and in the construction projects of new facilities. The project has also investigated and sought to promote cooperation between licence applicants and licence holders in licensing and qualification processes.

This report presents the proposals for improving licensing and qualification processes developed as a result of the KELPO Project. The plan is to further improve and advance the development proposals after the project in collaboration between the licence holders/applicants and STUK. Thus, the development work will continue after the project.

2 Project description

This section provides a brief description of the KELPO Project. The project team consisted of representatives of licence holders and licence applicants as well as the project manager: Project team members included representatives from Fortum (Lauri Pajunen, Henrik Jokineva, Joonas Pöytäniemi), TVO (Kirsi Hassinen) and Fennovoima (Jouko Tuominen) as well as a project manager from ÅF-Consult (Maria Palo). In addition, STUK (Petri Vuorio) participated in the work of the project team so that the regulatory authority’s viewpoint could also be considered in the proposals. Furthermore, other persons from the aforementioned organisations contributed to the work as needed. The development work was mainly carried out from the perspectives and starting points of licence holders/applicants, and STUK participated in the work at a later stage by commenting on proposals. The development proposals of the project are based on the experience and insight of the project team as well as the potential development needs they have observed in their practical work.

In the project, equipment procurement and the associated procedures in other industries were analysed based on the experience of the project team members, knowledge gathered from the companies represented in the project team and interviews of individual companies and equipment suppliers. However, the project did not feature comprehensive interviews of organisations from other industries or equipment suppliers/manufacturers.

In the main, the project focused on mechanical equipment and equipment assemblies in safety class 3 and 2. The system level was also analysed because pieces of equipment are parts of a system and, for example, requirements for equipment derive from systems. In some respects, other fields of engineering were also examined.

Goals set for the project:

- Expansion of the graded approach principle
    - Developing the licensing procedures so that the requirements and procedures are truly lighter in case of, for example, standard equipment, parts of equipment or equipment assemblies which are less significant for nuclear safety, or something in the lower safety classes.
- Utilisation of standard equipment
    - Analysing the feasibility of nuclear facilities utilising equipment that has not been manufactured in accordance with nuclear-power specific standards and requirements, and the availability of reliability data on the equipment in question
- Ensuring a comprehensive supplier/manufacturer network
    - Finding ways to make the nuclear sector more attractive to suppliers
    - Finding ways to further improve the cooperation between licence applicants/holders.

The purpose of the project was to present alternative proposals for improving the licensing and qualification procedures such that these proposals will be processed further in collaboration between the licence holders and STUK after the project. The current regulations and operating principles were analysed constructively in the project, striving to find ways to lighten and simplify the procedures in a way that would result in improved nuclear safety. The aim is to improve overall safety, for example by facilitating easier modernisation and a comprehensive supplier network as well as by managing to persuade the best and most experienced suppliers to also supply nuclear facilities.

The project focused on the Finnish licensing environment, though the aim is to utilise the results in similar analyses at the EU level in future.

3 Other projects on the topic

Some of the challenges described in this report have also been observed in the nuclear sector outside Finland, and many in Finland and abroad have awakened to the developments needed in order to ensure the operational feasibility of the nuclear sector.

At the EU level, there is an ongoing project titled Modernisation & Optimisation of European Nuclear Supply Chain, which deals with the same topic as the KELPO Project described in this report. Nuclear operators from several EU countries are participating in the project. In Sweden, the topic was discussed at a national level and a report on the use of standard equipment at nuclear facilities was published [3].

In addition, theses have been and are currently being written on the use of standard equipment at nuclear facilities. In 2017, TVO commissioned a diploma thesis connected to the topic, examining the use of standard equipment at nuclear facilities and comparing the requirements and procedures of the nuclear sector with the oil and gas industry in safety class 3 using case studies [4]. Fortum has an ongoing thesis examining the use of standard equipment and its qualification for nuclear power plants, including how the use of standard equipment improves nuclear safety and the cost savings it can bring [5].

4 Development focuses and limitations of the project

In accordance with the project plan, the project focused on the key development areas recognised based on the experiences of the project team, which are briefly outlined in this section. These development areas are not separate from one another; on the contrary, they are closely connected.

The leading idea behind the development proposals is that the safety of nuclear facilities is created through, for example, plant-level and system-level design bases, defence-in-depth levels, diverse and redundant systems as well as common-cause and single-failure tolerance, and thus the equipment level could, in some cases, be processed with lighter procedures than is the current practice, especially in safety class 3, but also in safety class 2.

Focus areas of the project as specified in the project plan:

- Change at the upper level of the scope of inspection:
    - A new perspective to the scope of inspection, where control is targeted differently from the current practice, is proposed for the upper level. This is described in more detail in Section 5.1.
- Shared approvals:
    - The project reviewed how to also utilise approvals for other organisations and avoid overlapping work when a company has obtained approval for a manufacturer or equipment, for example.
    - Shared approvals as well as cooperation between licence holders and suggestions in connection to them are discussed in more detail in sections 5.2.3 and 7.
- Use of alternative standards:
    - The project looked into introducing alternative standards, which are used in other industries, alongside nuclear-power specific standards as well as the effects and advantages of this and the availability of reliability data on standard equipment.
    - On the whole, the procedures and development proposals presented in the project serve the use of standard equipment, and the topic is discussed in more detail in Section 5.3. Reliability data is dealt with in Section 5.4
- Modification project analysis:

  - The project examined the life cycle of a modification project of safety-classified equipment, described the current state of licensing and presented a vision for the future (through procedures and documentation).
  - The current status and development proposals are described in Section 5.2.
- Pilot:
  - A modernisation project was selected which is proposed to be piloted together with STUK, and the implementation of the pilor project was planned. The pilot is described in Section 6.

The procedures presented in this report are applicable to new nuclear facilities as well as replacement spare parts and modification projects at operating nuclear facilities.

5 Results

5.1 Scope of inspection at the upper level

This section introduces and gives reasons for the proposed change in the scope of inspection at the upper level and discusses the changes and advantages it brings compared to the current situation.

Requirements connected to the safety design of nuclear facilities are based on the defence-in-depth principle: plant design must be carried out with several successive, independent and redundant structures and systems. The redundancy, diversity and separation principles are also applied in design to ensure the operability of the safety functions even in the event of a failure. The overall safety of a nuclear facility is created through plant- and system-level design bases, defence-in-depth levels, diverse and redundant systems as well as common-cause and single-failure tolerance. Systems are designed such as to ensure that the failure of any single piece of safety-classified equipment cannot result in the loss of a safety function.

The regulatory control and inspections of nuclear facilities should focus on areas that are essential to nuclear safety. According to the principle presented and approved in the project plan (see Table 1), STUK's regulatory control should focus on the plant level and system level, in particular, from which the specified requirements and design bases for the lower levels originate. On the other hand, the higher the safety class, the more regulatory control should focus on the system level and equipment level. In the proposal, STUK's regulatory control is allocated according to the graded approach principle by shifting control activities in the lower safety classes to authorised inspection organisations (AIO) and to the licence holder's independent person/organisation or in-house inspection (licence holder) or other independent assessment. In safety class 3, procedures commonly used in industry must, as a rule, be considered sufficient to ensure equipment quality and conformity to requirements.

Back when the procedures used in the nuclear sector were drawn up, the requirements in other industries, and thereby the quality and reliability of the normal products of manufacturers, were much lower than today. At the time, the procedures to obtain high-quality equipment for nuclear facilities were necessary and justified. Today, customers in other industries demand that equipment be reliable, due to which the procedures of equipment manufacturers and quality of products have improved significantly in recent decades. The application of the procurement and quality assurance procedures normally used in other industries as well as the manufacture, inspection and testing practices leads to a high-quality end product that conforms to requirements.

Table 1. Upper-level proposal for a new scope of inspection and allocation of control activities.

	SC1	SC2	SC3
Plant level	**STUK**	**STUK**	**STUK**
System level	**STUK**	**STUK/Licence holder***	**STUK/Licence holder***
Plant level **	**STUK**	**AIO/Licence holder *** **	**Licence holder/ Third party Notified body ******

*) STUK approves the final safety analysis report. After that, changes are assessed against it: small changes are processed by the licence holder, while larger changes are submitted to STUK for approval.

**) At equipment level, STUK approves the general requirement specifications for equipment and materials along with inspection plans.

***) Low-energy serially-manufactured equipment in SC2: Third party/Notified body.

****) Procedures commonly used in industry equipment procurement. Notified body when PED is applied.

As presented in Annex A to Guide YVL E.1, STUK currently plays a key role at equipment-level in safety classes 2 and 3, and only some of the regulatory control falls within an authorised inspection organisation's purview [7]. The proposed change in the scope of inspection promotes the implementation of the graded approach principle. At present, the workload is largely focused on the bottom right corner of the table, at the equipment level of lower safety classes, even though control should focus where the foundation for safety is created, meaning the upper levels and higher safety classes. Modifications are the most numerous in the lower safety classes, which contain a large number of systems and equipment, due to which their control and inspection consumes a considerable amount of time and resources. For overall safety and to optimise the activities of the licence holder/applicant and the authority, it makes sense to allocate the work according to the table hereinabove. It must be noted that the other parties that carry out regulatory control (AIO, licence holder) will continue to carry out the work and control in accordance with the procedures specified for each area even after the change. The new approach does not mean decreased control, but rather its allocation to different phases and a different body than currently. The proposed change also supports STUK's new strategy, which states that the philosophy of STUK's regulatory control will change and, in the future, STUK will steer regulatory control based on safety benefits. In conjunction with its strategy reform, STUK also emphasises that safety is not created through regulatory control but rather as the result of the good work of a responsible operator, emphasising the operator's responsibility [8].

When planning a change, the licence holder must ensure that any equipment change or system change essentially complies with the safety requirements and design bases specified for the original system. If a system change in safety class 2/3 is significant, the change must be submitted to STUK for approval. Minor changes that do not affect the system-level design bases are processed through the licence holder's in-house control. The licence holder must also assess the risks associated with common-cause failures and the necessity of the equipment's common-cause failure tolerance as well as ensure common-cause failure tolerance.

The reliable and safe operation of a nuclear facility is of primary importance from the perspective of the licence holder/applicant. It can be partly guaranteed by ensuring that the equipment acquired for nuclear facilities is high-quality and reliable. When low-quality and unreliable equipment fails, it may cause extra outages and thereby affect the facility's production and profitability. Therefore, the procurement of high-quality and reliable equipment for nuclear facilities is to the licence holder's/applicant's advantage. That aim is also promoted by other factors, not only by the official requirements and approvals required.

The reform and clarification of the procedures in the lower safety classes will also increase the inclination of equipment suppliers and manufacturers to supply nuclear facilities, especially if procedures commonly used in industry can, in broad outline, be applied in safety class 3. At present, the heavy documentation, inspection and testing requirements that differ from other industries make the nuclear sector confusing and uninteresting for equipment suppliers and manufacturers. The best suppliers prefer to choose customers that do not require procedures and documents that deviate from its normal operation. On the other hand, the best end product is often achieved when the manufacturer follows its established practices and procedures. Changes to these procedures mean some deviation from the normal manufacture and supply process, which may reduce the quality of the end product. This viewpoint also recommends adjustment of the procedures connected to nuclear-sector equipment procurements in the lower safety classes to be closer to the procedures used in other industries.

The proposed change in the scope of inspection will change the role of STUK, the AIO and the licence holder. Any change must be carried out and followed through between all interested parties, and the roles of all operators and the associated operating principles must be considered and developed together. With the proposed change, STUK inspections will focus on the upper level and the higher safety classes, and in other areas STUK will occupy a more distant regulatory control role. However, it must be noted that, even though regulatory control will undergo a change, documents will be sent to STUK for information in the appropriate scope, enabling STUK to supervise matters more closely to the extent it considers necessary. The role of the AIO will also change. At present, the AIO does not have creative authority in its regulatory control or the possibility to apply requirements at its discretion. In the future, this must be developed so that the use of an AIO does not lead to stricter and more inflexible requirements and procedures than would be the case with STUK's processing. The development work must be done in cooperation between STUK, the AIOs and licence holders. With the change, the role and responsibility of the licence holder will be emphasised, and licence holders must improve their procedures to correspond with this role in cooperation with the other organisations.

In order to change the scope of inspection as proposed, it must be reviewed what changes to existing legislation are required (e.g. Nuclear Energy Act, Section 60a [1]). The necessary changes could be carried out in conjunction with the upcoming total reform of nuclear energy legislation.

5.2 Modification projects: phases, procedures and documentation

5.2.1 Description of the principle

The project analysed the modification project of a safety-classified piece of equipment and the associated licensing and qualification phases. Potential development needs were sought by analysing these phases. The analysis focused on procedures connected to standard and serially-manufactured equipment.

This section presents, for comparison, the current state of licensing and qualification procedures (5.2.2), a procedure for eliminating overlapping work of licence holders (5.2.3) and a future procedure proposing more changes from the current state (5.2.4). This means that there are two development proposals connected to the procedures of a modification project: The procedure for eliminating overlapping work of licence holders presented in Section 5.2.3 can be implemented and its advantages achieved with relatively minor changes. As the licensing and qualification procedures are worked on and developed towards more practical future procedures, the first phase proposes an increase in cooperation between licence holders, elimination of overlapping work and updating requirements and regulations to make such cooperation possible. This work must be started and the results applied in practice on a quick schedule. In the future, greater changes to the procedures will be proposed in accordance with the new procedure presented in Section 5.2.4. The project team recognised that the practical application of this procedure will require more changes and time.

In the proposed changes, the regulatory body is as proposed in Section 5.1, depending on the level and safety class of the subject.

5.2.2 Current status

The diagram in Appendix 1 depicts the licensing and qualification phases and procedures of a safety-classified piece of equipment in the current situation. The proposed procedure covers all safety classes. The diagram shows how three licence holders each send similar or even the same documents to the regulatory authority and separately apply for approvals, for the same manufacturer or inspection organisation for example, even if they are about to acquire the exact same equipment. This requires additional work from licence holders, which separately produce identical documents, and from the authority, which processes these identical documents individually.

The diagram also presents the hold points, beyond which work cannot proceed without an approved inspection of the phases. They cause delays in work progress and lead to modification projects being long and time-consuming. However, it must be noted that some of the hold points presented in the diagram can be combined and can thus be carried out concurrently. Some of the phases presented, such as the general equipment requirement specification and manufacturer approval, are not carried out separately for each modification project; often, they already exist. However, this must always be separately confirmed.

5.2.3 Procedure for eliminating licence holders’ overlapping work

Appendix 2 (A and B) presents how, by utilising shared approvals, harmonising licence holders’ activities and increasing cooperation, time-consuming licensing phases and the associated work can be reduced even if the phases themselves remain quite close to their current form. The subjects recognised and the related practices and procedures proposed are described in this section. This proposed procedure can be utilised in all safety classes and, particularly in safety classes 2 and 3, it can help achieve significant advantages in terms of reduced workloads, expenses and the time required for the modification project, because these safety classes contain a large number of applications where similar, standard/serially-manufactured equipment can be used at nuclear facilities. The simplification of modification projects will also lead to improved nuclear safety when equipment reaching the end of its service life can be replaced more easily with modern equipment.

The number of hold points, beyond which work cannot proceed without an approved inspection of the phases, will decrease with the new procedure; after approval of the manufacture construction plan, the next hold point is approval of the installation construction plan. The phases during manufacture and during the acceptance of the product can be carried out smoothly, and the result documentation can be reviewed during the installation construction plan review, at the latest. The operability analysis of E/I&C equipment will be done at the same juncture, analysing the compatibility and cooperativity of an E/I&C equipment and a mechanical component.

Licence holders will work to create shared documents and obtain shared approvals. On the other hand, when licence holders’ shared documents and approvals are introduced, the licence holder must be able to refer in its documents to materials submitted previously by another licence holder and existing approvals. It must not be required that each licence holder separately re-submit the same documents to the regulatory body.

By increasing cooperation and combining overlapping documentation, roughly speaking slightly over one-third of the separate actions/documents connected to licensing and qualification can be avoided. Furthermore, shifting hold points from the manufacture phase to the installation construction plan review will reduce the time consumed by a modification project. When the cooperation between licence holders and the work already done by other licence holders can be utilised efficiently, thus reducing the time and resources required for an individual modification project, the threshold for procuring new equipment and carrying out modernisations will be lower. This will result in the improvement of overall safety as the maintenance of safety-classified systems using modern equipment becomes easier.

The control of this procedure will take place as presented in Section 5.1, and the party implementing control activities will depend on the level and safety class of the subject. Methods for cooperation between licence holders are discussed in Section 7.

5.2.3.1 General equipment requirement specifications and material requirement specifications

Currently, each licence holder/applicant creates its own documents for equipment requirement specifications and material requirement specifications. Each licence holder prepares and maintains its own documents, which STUK must also separately approve for each licence holder. To the equipment supplier/manufacturer too, these documents, prepared separately by each licence holder, can easily appear unclear and confusing as the licence holders present requirements based on the same requirements, each in its own, divergent way and in a different scope. By improving the cooperation between licence holders, these documents can be shared, which will avoid overlapping work connected to preparing and maintaining documents, also reducing the number of separate documents from the perspective of the authority processing them (STUK). Furthermore, harmonised requirement specifications where the requirements are presented clearly will make it easier for equipment suppliers/manufacturers to participate in nuclear projects.

Shared equipment requirement specifications and material requirement specifications of licence holders/applicants are already possible in light of the current regulations. During the project, STUK also expressed that such documents could be common to all licence holders. In future, it must also be possible to process them only once at STUK, and for STUK to approve them simultaneously for the use of all licence holders. On the other hand, if STUK has already once approved the documents submitted by one licence holder, it will not be necessary for another licence holder to submit the same documents to STUK for approval. Instead, the licence holder can refer to the decision with which the documents were previously approved in the documentation it sends to STUK.

The contents and format of requirement specifications need to be developed so that the contents are clear and directly usable during the procurement phase when requirements are presented to the equipment supplier. Joint requirement specifications and a clear and appropriate format for their contents are discussed in more detail in Section 5.2.5.

5.2.3.2 Approval of manufacturers, inspection organisations and testing organisations

At present, the approval of a new manufacturer is a heavy and time-consuming process, causing work for the licence holder/applicant as well as for the manufacturer being approved. For this reason, nuclear facilities prefer to use products from manufacturers who have already been approved once in order to avoid the heavy and time-consuming approval process for a new manufacturer. In some cases, the original manufacturer of the equipment to be replaced has left the market, and the original equipment is no longer available and the manufacturer no longer exists. In such cases, the modification may even be left undone due to the massive amount of work needed to have a new manufacturer approved. From the licence holder’s perspective, it is more cost-effective to “wear out” the existing equipment than to replace it with new equipment when the need arises.

Currently, each licence holder/applicant applies for approvals of equipment suppliers separately, as needed. This means that, in order to have a manufacturer approved, each licence holder separately submits documents on the same supplier. This creates unnecessary, overlapping work for manufacturers, licence holders and the regulatory authority.

In order to avoid overlapping work, licence holders/applicants must cooperate by applying for approval for manufacturers jointly all at once. Licence holders must also be able to utilise existing manufacturer approvals applied for by another licence holder. Once a manufacturer has been approved to supply a certain type of product to a Finnish nuclear facility, the manufacturer must be able to also supply these products to other nuclear facilities based on the same approval. From the perspective of the authority, it must be sufficient that the manufacturer has already been approved to supply products to nuclear facilities, regardless of which licence holder applied for the approval. Other licence holders can, in their documentation, refer to a manufacturer approval that has already been processed once, thus avoiding overlapping work.

Correspondingly, the approvals of inspection organisations and testing organisations must be processed as shared and such that another licence holder does not need to separately apply for the approval of an organisation that has already been approved once. Instead, the organisation can be considered approved based on an approval applied for by one licence holder.

The approval of manufacturers and qualification of special processes must also be done with joint approvals. In the future, requirements connected to these must be based on standards, where applicable, with no other approvals or qualifications required.

5.2.3.3 Manufacture construction plan

At present, a manufacture construction plan has a great deal of content that can be created jointly by licence holders when acquiring the same equipment from the same supplier. In the future, the construction plan must be shared, where applicable. The joint manufacture construction plan will be supplemented with plant-unit specific requirements and design values such that plant-unit specific requirements are presented separately and location-specific data is not presented in the manufacture construction plan but rather with the installation construction plan, where the suitability of the equipment and its design values for the location will be reviewed.

5.2.3.4 Preliminary and final suitability assessment of E/I&C equipment

The preliminary and final suitability assessments of E/I&C equipment can be carried out jointly by licence holders such that they may share the same general section. Location-specific data and cooperativity with a mechanical component will be discussed in the operability analysis. In other respects, an E/I&C equipment will be dimensioned for the location during normal modification planning.

5.2.3.5 Analyses and tests

Licence holders may jointly carry out the necessary analyses, or have them carried out, for example to ensure the seismic resistance of equipment or equipment assemblies. Once analyses and tests have been conducted for a specific piece of equipment, it will be unnecessary for another licence holder to have them carried out separately (presuming that the requirements and design values used as the basis of the analyses match).

5.2.3.6 National approvals of safety-classified equipment

Once standard/serially-manufactured equipment has been approved for use at a nuclear facility in Finland, the same equipment can, based on this approval, also be used at another Finnish nuclear facility in a similar operational location. In its documentation, a licence holder may refer to existing approvals and the work carried out by another licence holder. Location-specific suitability will be analysed before installation.

5.2.4 Proposal for the new procedure

Modification project phases and procedures under the proposed new procedure are outlined in the diagram in Appendix 3 which, in addition to the modification project phases, also presents the documentation to be submitted to the party implementing control activities during each phase and the approvals required from the party implementing control activities . This proposed procedure is suitable for standard/serially-manufactured mechanical equipment in safety classes 2 and 3.

The proposal for the new procedure emphasises the licence holder’s own responsibility for changes and the approval of their acceptability as well as the licence holder’s responsibility for successful equipment procurement that conforms to requirements. Some of the regulatory control measures required from the authority in the current practice will transfer for the licence holder to perform, and the focus of regulatory control will shift to installation and inspections that prepare for commissioning. In the final phases of a modification project, the control measures during inspections connected to commissioning will remain unchanged, and an operating licence issued by the regulatory body will be a precondition for adopting the modification into operation. The licence holder’s failure in its own operations will reflect directly in delays in commissioning, but it will not affect nuclear safety.

The concentration of regulatory control and inspections in the final stretch of the project will make it possible to carry out the earlier phases efficiently and smoothly without delays caused by the consecutive processing of several documents. This will make it easier to introduce changes as the total time required for the process becomes shorter. A change can be carried out at the right time in terms of the plant’s operation and availability as well as with full utilisation of data received from condition monitoring. In the best-case scenario, this will prevent an unplanned shutdown of the plant due to failure, which will further improve the plant’s overall safety compared to the current practice.

Phases connected to actual equipment procurement, which are described in Section 5.2.4.2 (shown on green background in the diagram in Appendix 3), can be carried out separately from the modification project, and the necessary equipment can be procured in advance and placed in storage. This way, when the time comes for the modification, the other steps can be followed in accordance with the diagram, except that the equipment purchased in advance is taken from storage and its suitability for the intended location is verified. Phases connected to equipment procurement could also have potential for further improvement of the procedures and methods towards uniform and joint procurement by licence holders.

Clarification of the procurement process, especially for the equipment supplier/manufacturer, and bringing it closer to the procedures used in other industries will make the process clearer for suppliers and will make it easier for them to participate in nuclear projects. It will help demonstrate to equipment suppliers and manufacturers that supplying equipment to nuclear facilities can be sensible business, making it possible to choose the best suppliers for nuclear projects too, from a wide range of suppliers instead of being forced to buy from a small and increasingly smaller group of suppliers that currently agree to supply nuclear facilities.

It must be noted that the times proposed for documentation submission in the procedure are the submission deadlines. If the documentation is available earlier, it is naturally sensible and advantageous for all parties to provide and process the documentation as soon as possible.

Appendix 4 presents a comparison between the current procedure and the proposed new procedure in safety class 3. The control measures under the current procedure during different phases are presented based on the currently valid versions of the E series of YVL Guides (E.3, E.8 and E.9). The requirements of E.1 and E.12 regarding inspection and testing organisations are also touched on. [9]

The control of this procedure will take place as presented in Section 5.1, and the party implementing control activities will depend on the level and safety class of the subject.

5.2.4.1 Modification planning and assessment

During modification planning, the licence holder must assess the effects of the equipment/system modification. Particular attention must be paid to the following considerations:

- After the modification, will the system essentially meet the safety requirements and design bases set for the original system?
- Assessment of the necessity of common-cause failure tolerance and ensuring common-cause failure tolerance.

If the modification essentially meets the safety requirements and design bases set for the original system, the licence holder's own processing of the change will suffice. If the licence holder judges that the modification does not meet the safety requirements or design bases set for the original system, the modification will be submitted to STUK for approval in advance using procedures under the current practice.

The licence holder will describe the modification and its effects with justifications in a licence holder's summary of justifications on the modification, or in a similar document, and prepare a safety assessment of the modification. As presented above, when assessing a modification, the licence holder must pay special attention to whether the system is required to tolerate common-cause failures. If the system must tolerate common-cause failures, its common-cause failure tolerance will be confirmed, for example by acquiring equipment from different suppliers or using another method that keeps the risk of common-cause failure as low as possible. The documentation produced during this phase will be submitted to the party implementing control activities for approval, at the latest before installation:

- Modification description
- Modification safety assessment
- Justifications for a system modification.

5.2.4.2 Equipment procurement, design and manufacture

For equipment procurement, the licence holder must have the following in advance:

- Detailed and traceable procurement procedures and practices as well as methods for maintaining them
- General requirement specifications approved by STUK for equipment and materials.

The role, proposed format and contents of the general requirement specifications for equipment and materials and procurement procedures are described in more details in Section 5.2.5.1. In the proposed procedure, these documents are shared by licence holders, supplemented with location-specific requirements and design values.

For equipment procurement, the licence holder must:

- Define the requirements and design bases for material and equipment design imposed by the system and environment as well as required of the use of the equipment.
- Define the equipment and material manufacture such that it will be carried out in accordance with the applicable requirement specifications approved in advance by STUK for equipment and materials, including general inspection requirements, and in accordance with the licence holder's own procurement procedures.
- Define the equipment delivery and the associated inspections, tests, spare parts and final documentation to be carried out in accordance with the other principles presented in the specifications and procedures.

The aforementioned items must be recorded in the equipment's procurement documentation. Special attention must be paid to ensuring that the manufacturer receives sufficient and relevant information for the delivery, so requirements based on requirement specifications for equipment and materials as well as the licence holder's own procurement procedures must be presented clearly and concisely. The requirements presented must be carefully limited to only those requirements that apply to the delivery in question. This is to ensure that the requirements for the equipment delivery are clear and comprehensible from the manufacturer's perspective.

Before concluding a procurement agreement, the licence holder must ensure that:

- The manufacturer's quality system has been certified (ISO 9001 [15] or equivalent).
- The manufacturer is capable of the delivery, considering its operating experience and operating history data as well as using prior experience.
- A manufacturer that uses special processes has access to an independent third party and its use has been agreed in accordance with the requirement specifications for equipment and materials.

The licence holder's assessment of the above items regarding the manufacturer and related justifications must be recorded in the licence holder's summary of justifications on the equipment and manufacture. Cooperation between the licence holders and collectively gathered experiences (such as a shared manufacturer database) will be utilised in the assessment of manufacturers and manufacturer approval by licence holders.

For a manufacturer of equipment in safety class 3, a normal quality system certification, which is also used in other industries, must be sufficient, and nuclear-power specific certifications, for example in accordance with the new ISO 19443, must not be required [16]. Requiring quality system certification that differs from other industries would further reduce manufacturers' willingness to supply equipment to nuclear facilities, which would limit the selection of available equipment and suppliers and make it necessary to order equipment from a supplier willing to obtain such a nuclear-power specific certification.

As regards electrical and I&C equipment, the licence holder will prepare a procurement suitability assessment during the procurement phase, assessing the equipment's general suitability and conformity to requirements.

The manufacture, testing and inspections of materials and equipment will be carried out in accordance with the requirements presented in the specifications, typically based on a standard and the PED. During manufacture, the licence holder may carry out inspections and tests, or have them carried out, according to the principles presented in the requirement specifications for materials and equipment and the procurement procedures, depending on which procedures need to be applied to the equipment delivery in order to ensure the quality of the end product. Inspection of the design and manufacture of equipment is mainly carried out by a notified body (when the equipment is governed by the PED). Quality and conformity assurance and approval of the equipment by the licence holder are carried out during the equipment's acceptance inspection and the associated construction inspection, which ensures that the equipment and its manufacture, testing, inspection and documentation have been carried out in accordance with the specified requirements. Particular attention will be paid to confirming that:

- The product's type plate information is correct and conforms to requirements, and the final documentation is marked with the corresponding code.
- The product has been manufactured, inspected and tested in accordance with the requirement specifications for equipment and materials.
- The result documentation of the equipment's manufacture and other prefabrication, installation data and operation manuals have been delivered, comply with the result documentation and are acceptable.
- Conformity certificates have been signed and delivered, and the design values specified therein correspond with the requirements set for the equipment.

The licence holder will prepare records of the acceptance and construction inspections, containing assessments/findings connected to the aforementioned considerations. The licence holder will record its assessment of the compliance of the equipment, its testing and manufacture in the summary of justifications on manufacture.

If necessary, the licence holder may, during acceptance, carry out further inspections or analyses of the equipment, or have them carried out, in order to ensure fulfilment of the requirements. However, these additional inspections must only be done when it is necessary to ensure the product's quality and conformity to requirements.

5.2.4.3 Planning and carrying out installation

Before the delivery of equipment for installation, the licence holder must ensure that:

- The prefabricated products and equipment to be installed have undergone acceptance and construction inspections and can be approved for use in installation on the design basis in the locations in question, also considering the design-basis environmental conditions.
- The equipment has appropriate location markings.

For installation, the licence holder must prepare and submit the following to the regulatory body for approval:

- Installation construction plan
- Installation summary of justifications
- System modification pressure test plan
- Commissioning and testing plans

In connection with electrical and I&C equipment, the licence holder will prepare:

- A suitability assessment for the installation of E/I&C equipment, reviewing the equipment's suitability for the location in question,
- An operability analysis reviewing the cooperativity and compatibility of the E/I&C equipment and mechanical equipment.

Before installation, the licence holder must submit to the party implementing control activities for approval a summary of justifications on the installation, an installation construction plan and a system modification pressure test plan. The licence holder will also ensure and monitor the appropriateness, validity and maintenance of method qualifications and personal qualifications. Furthermore, commissioning and testing plans will be submitted for approval during this phase. The documentation produced during the modification planning phase will also be submitted during this phase at the latest.

Installation may begin once the party implementing control activities has approved the modification and issued a work permit. During installation, the licence holder will monitor the installation in accordance with the inspection plan agreed in the installation construction plan. The system modification pressure test may be carried out when the regulatory body has approved the plan for it.

During installation, the licence holder will compile the installation final documentation, including an approved structural pressure test report and installation inspection reports and, during this phase at the latest, prepare the piping flexibility and support analyses. The aforementioned documents must be submitted to the regulatory body for approval. After that, the regulatory body will be requested to carry out the KOT I inspection.

5.2.4.4 Commissioning

During the KOT I inspection, the regulatory body approves the installation and its result documentation, carries out any registrations of pressure equipment (STUK/AIO) and gives permission for commissioning testing. The purpose of KOT I is to confirm readiness for test operation. The contents of this phase will remain unchanged, and essential changes are not proposed.

During the second phase of the commissioning inspection (KOT II), readiness for operation is noted and a commissioning inspection record is prepared, based on which the regulatory body grants the operating licence. Substantial changes are not proposed for the KOT II phase, either.

After the operating licence is granted, the modification and equipment will be in operation.

5.2.5 Documentation connected to the new procedure

5.2.5.1 Licence holders' requirement specifications

Licence holders issue requirements connected to manufacture and manufacturers through different types of requirement specifications. The idea is that an individual manufacturer will not need to read the YVL Guides separately, but instead the licence holder's requirement specifications clearly impose on the supplier the exact requirements that must be followed with the delivery in question. On the other hand, harmonising the practices between licence holders will clarify the presentation of requirements, and manufacturers will learn very quickly what is expected of them.

In order to simplify the use of standard/serially-manufactured equipment, mitigations from the current procedure are being sought in regard to requirement specifications and the associated inspection and testing plans. The manufacture, inspection and testing of equipment and materials will be specified as much as possible so as to align with commonly known standards that are also used in other industries, and additional requirements deviating from them will only be imposed when it is necessary in order to guarantee the suitability and quality of the end product.

STUK will approve equipment requirement specifications in advance, and the licence holder will carry out equipment procurement based on these specifications approved in advance by STUK.

The licence holders' requirement specifications will be shared and supplemented with plant-unit specific requirements and design values. The licence holders' shared requirement specifications play a key role in terms of the development proposals presented because they embody many of the development proposals presented in the project, such as the use of standards commonly used in industry, utilisation of the PED and cooperation between licence holders.

General equipment requirement specifications

Requirements connected to the equipment type, delivery and the required manufacture documentation and final documentation will be presented in equipment-type specific requirement specifications shared by all licence holders, grouped by safety class. Equipment requirement specifications will be divided into different requirement specifications based on the safety class, equipment group, equipment type and, for example, installation area. Equipment such a valves will need to be divided into separate equipment requirement specifications based on closure type or function. Similarly, equipment requirement specifications will be used to divide equipment between different installation areas (containment, other buildings, outdoor area) or into different material groups based on content.

Equipment requirement specifications must be such that they can be provided to the equipment supplier/manufacturer. For this reason, they must be clear and only include the requirements that are relevant to the supplier. It must be possible to, for example, filter requirements in the database so that the only requirements left are those that apply to the equipment group in question.

A proposal for the structure of these general equipment requirement specifications common to all licence holders and the list of items to be presented in the documents is presented in Appendix 5. The equipment requirement specifications will:

- Clearly describe the equipment that can be manufactured with the requirement specification in question
- Lay out the design bases of the equipment insofar as they are the same for all equipment, explain the purpose of the data sheet (changing design bases) and present a data sheet template
- State the design standards and manufacturing standards that are required or which have been approved for use, or other ways for approving design
- Set requirements for manufacturer approval as well as inspection and testing organisation approval, and set requirements for design qualification and design documentation as a part of the delivery's final documentation
- Explain the purpose of the manufacture inspection plan and itemise what will be reported in the equipment's final documentation
- Also describe other terms of the client, where applicable, such as the required service life, warranty terms, spare parts, and describe how an acceptance inspection is carried out
- Describe the different parts of the equipment and their division based on quality
- Potentially set requirements for the equipment's inspectability and testing
- Specify that suitable material requirement specifications and part classifications must be used in the equipment's manufacture.

The general or location-specific design bases and required (minimum) design values during different operating states are presented in a data sheet appended to the equipment requirement specification. The data sheet specifies, for example, the following:

- Design pressure, design temperature, designed radiation resistance limit, designed environmental conditions
- Functional requirements during and after various operational events, design conditions imposed by the environment during various short- and long-term operational situations
- Functional requirement during various operational and load events as well as the required minimum service life
- The equipment requirement and material requirement specifications to be used in manufacture
- The additional testing required for the delivery
- The safety class, seismic class and (potentially) quality class as well as the leakage class permitted under the standard
- Medium data, pressures, temperatures, possible radiation level and flow volumes
- Connection method, for example to piping.

During equipment manufacture, the general inspection requirements and inspection reporting requirements are presented in the general inspection plan, which is also appended to the equipment requirement specification. This section mainly follows the requirements imposed in the annexes to YVL E.3, E.8. and E.9 [9].

Material requirement specifications

The general requirements for materials, plant-unit specific additional requirements and plant-unit specific restrictions are presented in the material requirement specifications.

In terms of contents, material requirement specifications are very similar to equipment requirement specifications, but the requirements imposed are connected to the manufacture and manufacturer of the material. Depending on the plant unit and installation location, very different requirements are imposed on materials. The use of certain materials in certain locations can also be prohibited, restricted or additional testing requirements may be imposed on materials, in which case that is also specified in the equipment- or order-specific data sheet supplied with the order.

Material testing and inspection requirements are divided according to part group in the general and shared material testing instructions. The requirements for control of material manufacture and testing are imposed in the general inspection plans for material manufacture.

The material testing requirements are divided into test modules based on safety class, material group (black, clear, rubbers, plastics, etc.) as well as into the parts specified in equipment requirement specifications and the different quality requirements set for them:

- Pressure-retaining parts, force-transmitting parts, parts important to functionality and other parts.
- Depending on the safety class and the type of certificate required in Annex B of Guides YVL E.3, E.8 and E.9, different levels of tests are carried out and reported for different parts.

5.2.5.2 Procurement procedures

Procurement procedures are licence-holder specific and present the procedures and requirements that the licence holder follows in its procurement. Procurement procedures help ensure that procurement is done with high quality and that the associated quality control and delivery control is at a sufficient level to guarantee equipment quality. Procurement procedures must describe those procedures and requirements connected to procurement and delivery that are not relevant to the equipment supplier and are thus excluded from the equipment requirement specifications. Procurement procedures must describe at least the following:

- The requirement specifications connected to procurements and during which phase they are delivered and to which party
- Assessment and approval of the equipment supplier and manufacturer
- Control and audits of manufacture and delivery
- Equipment acceptance and the associated construction inspection (insofar as it is not described in the equipment requirement specifications)
- Reporting and processing of deviations
- Procedures connected to prevention of counterfeit products.

Procurement procedures must also take into account the cooperation between licence holders, particularly in connection with manufacturer assessment, approval and deviation reporting.

Although procurement procedures are licence-holder specific, they need to be harmonised so that procurements appear the same to the supplier regardless of which licence holder is making the procurement. There are also good and high-quality procurement procedures in other industries, and these practices from other industries should be used as references in licence holders’ procurement procedures. Procedures must not needlessly deviate from those used in other industries and, thus, from what equipment suppliers and manufacturers are used to.

5.2.5.3 The licence holder’s/applicant’s summary of justifications

During different phases of a modification project, the licence holder prepares the licence holder’s summary of justifications for the phase. The summary of justifications refers to a document that presents how the modification, equipment procured or installation meets the requirements set for it, and how the licence holder has established its conformity to requirements. The summary of justifications also presents deviations and their effects. The summary of justifications is prepared for:

- A planned change, including the safety assessment for the change (system change justifications)
- The equipment and its manufacture/manufacturer
- The installation.

These documents may be prepared concurrently, especially if equipment from storage procured in advance is used.

5.2.5.4 Documents on the equipment and on its delivery

The documents prepared for and supplied with each equipment delivery will be based on the scope presented by the licence holder in the requirement specifications for equipment and materials and agreed mutually on their basis during the procurement. The documentation that the supplier usually provides with its deliveries will be used as far as possible. An example of the required documents is presented in Appendix 5.

5.2.6 Relationship between the proposed procedure and draft YVL Guides

The draft YVL Guides currently being prepared (YVL E.3, YVL E.8 and YVL E.9) present mitigations in the use of serially-manufactured equipment, and they take procedures in the same direction as this proposal of the KELPO Project for the new procedure [10][11][12]. The changes proposed in the draft YVL Guides are also in the right direction from the perspective of the KELPO Project, and it is excellent for the further development of the procedures that licence holders’ and authorities’ vision, along with their understanding of the procedure development needs, are thus aligned. The most significant differences between the procedures presented in the new draft YVL Guides and this procedure proposed in the KELPO Project are described below. The KELPO Project procedure will:

- Emphasise the licence holder’s role more and give the licence holder more responsibility for the inspection and control of phases. Regulatory control will focus on the inspections that prepare for commissioning. The licence holder will carry out the preceding phases based on requirement specifications approved by STUK.
- The construction plan will be replaced with requirement specifications and plant-unit specific design values.
- Manufacturer selection and approval will be based on the licence holder’s own assessment, the licence holders’ shared manufacturer database, previous experiences and possession of a certified quality system. No official approval for the manufacturer.
- Manufacture, inspection and tests will be mainly based on standards commonly used in other industries.
- Design and manufacture will be inspected by a notified body (in accordance with the PED). The licence holder may also carry out inspections, but mainly the licence holder will ensure product quality and conformity to requirements during acceptance while inspecting the product and the associated documentation (construction inspection).
- The licence holder will perform the construction inspection during acceptance; that is to say, there will be no STUK's or AIO’s construction inspection, before installation.
- The approval of, for example, requirement specifications, the manufacturer and equipment will be national; based on one approval, the documentation/manufacturer/equipment can also be used by other licence holders in similar applications.

5.3 Use of standard/serially-manufactured equipment

5.3.1 Use of standard/serially-manufactured equipment and its impact

This section focuses on the utilisation of standard and serially-manufactured equipment at nuclear facilities. One key aim of the KELPO Project is to find ways for facilitating wider utilisation of standard/serially-manufactured equipment at nuclear facilities. It must also be possible to utilise modern equipment in safety-classified applications at nuclear facilities while basing the manufacture, testing, inspection and documentation on the standards and procedures normally used by the manufacturer. Products procured, manufactured, inspected, tested and delivered in accordance with these standards could be utilised at nuclear facilities as they are. For safety, it is essential to be able to choose from a sufficient selection the product that is the most suitable for the process and correctly dimensioned. The development proposals presented in this report all promote the use of standard/serially-manufactured equipment at nuclear facilities. The proposed procedures bring the equipment procurement of nuclear facilities in the lower safety classes closer to the procedures used in other industries.

The effect of the safety class on the reliability of equipment (stop valves and fans) was examined at the Loviisa power plant, and it was found that there are no significant differences between safety-classified and class EYT equipment in terms of failure frequency [13]. The minor differences found can be ascribed to, for example, the different maintenance practices specified for the equipment. This supports the view that today's standard/serially-manufactured equipment is also of high quality and reliable in nuclear applications and that special nuclear-power specific additional requirements regarding the manufacturer, manufacture, inspection and testing do not unequivocally lead to better quality. Based on the experiences of both Finnish and foreign licence holders and the views of equipment manufacturers, the effect may even be the opposite: When requirements deviating from normal and customary practices break the existing manufacturing process, the quality of the end product may even decrease even though the underlying purpose of the additional requirements was surely exactly the opposite. On the other hand, standard/serially-manufactured equipment has undergone several reproductions and development phases, thereby weeding out defects and weak points. When individual pieces of equipment are manufactured in a manner that deviates from customary practices, they often manifest defects and deficiencies that have been eliminated from standard/serially-manufactured equipment. The large volume of standard/serially-manufactured equipment also means a great deal of experience and associated improvements, which helps achieve high quality and reliability for the equipment.

Even if the equipment itself is standard/serially-manufactured, it does not currently qualify as safety-classified equipment for a nuclear facility as it is. Instead, it must be supported with many documents that are not required in other industries. This does not affect equipment quality or reliability but does create a lot of work, which complicates equipment procurement, significantly increases procurement prices and makes the nuclear industry confusing and unappealing to equipment suppliers.

In other fields of industry, procurement is usually subject to procurement procedures specified within the company or project, which are intended to ensure successful procurements in terms of technology and overall economy. Procurement procedures specify, for example, the actions and responsibilities during different phases of the procurement and the documentation principles. Procurements are carried out using supplier registers based on previous experiences, which are used to select potential suppliers known to be reliable and high-quality. Suppliers are also audited, especially if there is no previous experience or if auditing is considered necessary for other reasons, such as changes in the organisation or ownership or emerging deviations. In other industries, equipment is typically procured based on applicable and well-known standards selected based on the equipment or equipment assembly. Compliance with standards is the easiest way to demonstrate a product's conformity to requirements, and it makes it easier to conclude an agreement between the client and the supplier as well as resolve any disputes. Sometimes, the requirement level set by standards is not sufficient for the prevailing process conditions and stricter requirements must be set for materials, manufacture and inspections. Such situations are typical in oil refining, where standard equipment is often not sufficient as it is.

At nuclear facilities, environmental conditions and requirements deviating from other industries, for example in connection with radiation and earthquakes, must be taken into account, and their fulfilment must be demonstrated, if necessary. However, this should be done in a way that allows licence holders to demonstrate fulfilment of these requirements with various analyses or tests and such that the associated documentation does not create unnecessary extra work for the manufacturer or necessitate the breaking of a functioning manufacturing process. Licence holders may also carry out tests, or have them carried out, for several pieces of equipment at a time and engage in cooperation connected to them, which also makes economic sense. On the other hand, seismic requirements and the associated analyses and tests, for example, are not new to equipment suppliers that supply equipment for the needs of industries such as forestry or the oil refining industry in earthquake zones. Justified, clear and predictable technical requirements are unlikely to cause problems for equipment suppliers even if they differ from the normal requirements used in industry.

The use of standard/serially-manufactured equipment makes it possible to use modern, tried and tested technology instead of procuring products unique for nuclear facilities involving higher-than-normal quality hazards due to the unique nature of the product and manufacturing process. The following sections deal with the proposed procedures and applicable standards for utilising standard/serially-manufactured equipment in various fields of technology. The analysis focuses primarily on mechanical and I&C equipment, but it can also be utilised for equipment assemblies.

5.3.2 Mechanical equipment

The use of standard/serially-manufactured mechanical equipment will be made easier by bringing the necessary changes to the requirement specifications for equipment and materials and to the associated inspection and testing plans. As much as possible, the manufacture, inspection and testing of equipment and materials will be specified to be carried out in accordance with the standards used in other fields of industry. Primarily, the control of equipment design and manufacture will be carried out by a notified body in accordance with the PED. Even with special processes, the standards applicable to these will be used, thus making separate approvals and qualifications unnecessary. Manufacturer approvals will be simplified, trusting proven, reliable manufacturers with normal certificates that are also used in other industries, for example for the quality system and special processes.

The standards and procedures proposed to be used with different equipment/component groups are presented below:

- Materials:
    - Prefabricated standard piping parts and serially-manufactured pressure vessels (excluding heat exchangers and filters) in accordance with the pressure equipment material list and/or type testing used in the country of manufacture of the pressure equipment, as long as the essential requirements meet the requirements set for EN materials (the licence holder assesses when ordering and confirms during acceptance). No nuclear-specific requirements for the material manufacturer.
    - The serially-manufactured materials of SC3 and SC2 low-energy pumps and valves according to the commonly known material standard. Material manufacturer approvals not required as long as the agreed material requirement specifications are followed.
- Design:

    - SC2 serially-manufactured, SC3 and EYT piping mechanical parts (excluding heat exchangers and filters) as well as serially-manufactured pressure vessels in accordance with SFS-EN 13445-3, unless they are pressure vessels subject to registration [17].
    - SC3 and serially-manufactured SC2 valves and pumps according to the EN design standards commonly used in these fields of industry. No nuclear-specific requirements in addition to these.
- Manufacture:
    - Nuclear-specific procedures and requirements connected to the approval of manufacturers of SC3 and SC2 serially-manufactured valves, pumps and piping parts will be abandoned. The manufacturer must have a certified quality system (such as ISO 9001).
    - Serially-manufactured piping parts (materials) SC3 and low-energy SC2 (excluding heat exchangers and filters) according to SFS-EN 13445 without nuclear-specific additional requirements connected to manufacturer approval, calculations and method qualifications, etc. Required to follow the material requirement specification, equipment requirement specification and standard.
    - Testing of pressure vessel and piping parts according to the standard/type testing, same for fatigue analysis.
    - Piping analyses SFS-EN 13480-3
    - Manufacture and control of valves and pumps according to type testing and the applicable standard
    - Testing and inspections of pressure vessels and piping with inspections according to type testing or, if there is no type testing, inspection according to the standards.
    - For valves and pumps, a certificate of conformity to requirements/type testing compliance is sufficient. A factory test is done if one is needed to assess conformity to requirements.
    - Qualifications of the NDT inspector, welders and other personnel according to the certified quality system
    - Subcontracts according to the quality system
    - All material certificates according to SFS-EN 10204
    - Result documentation according to the equipment requirement specification
    - Construction inspection (licence holder) at the waiting warehouse at the plant site before storage; results presented to the regulatory body before installation.

The PED can be used in connection with heat exchangers and filters [6].

5.3.3 I&C equipment and software

For I&C equipment, it is proposed that, as an alternative procedure in safety class 3, the use of SIL-compatible equipment in accordance with IEC 61511 without following any other requirements that are normally specific to nuclear power be accepted[18]. This procedure should cover the entire subsystem or equipment assembly performing the function. In the example case, the PRA would set a reliability target for the realisation of the function, after which the designer of the equipment assembly or subsystem would ensure the achievement of the target as in other industries in the case of safety automation. The target is achieved through good planning and right choice of equipment.

It is also suggested for consideration that individual pieces of equipment/equipment assemblies that form an independent entity and contain programmed but not re-programmable technology without data communication connections to other systems be processed as analogue devices. This means that software qualification would not be needed; any software errors would be included in the failure history of the equipment/equipment assembly. This would be especially useful in cases where the software is not customised in any way or developed for a specific delivery, and instead manufacturing numbers are large and operating experience is available for the equipment (including software). These might include:

- protection relays
- temperature and pressure transmitters
- measure converters
- amplifiers
- galvanic isolators
- rectifiers
- thermostat-controlled air conditioning

The requirements are developed in the right direction in paragraph 602a of draft Guide YVL E.7 [14]: *"602a. The design and implementation of software in safety class 3 shall adhere to applicable nuclear industry standards firstly or, secondarily, standards intended for the design of safety-critical software."* It is proposed to eliminate the words *firstly* and *secondarily* from the draft text. Furthermore, an example of the acceptability of the SIL certificate should be given in order to avoid straying into time-consuming, case-specific discussions about its acceptability.

5.3.4 Electrical equipment

The use of standard equipment in terms of electrical equipment was discussed during the project, and it was discovered that, in this field of technology, it is not possible to achieve sufficient development potential through the use of standard equipment to make it worth focusing on at this stage. The new draft YVL Guide already contains mitigations connected to this, and electrical equipment is also fairly standardised in other respects. Therefore, this report does not deal with the use of standard equipment in terms of electrical equipment in more detail.

5.3.5 Other equipment and equipment assemblies

The procedures presented at equipment level also serve equipment assemblies, such as lifting equipment and diesel generators. Although these are not dealt with separately, the results of the project can also be utilised for such equipment assemblies. The development proposals presented in this report are directly applicable to the processing of auxiliary equipment associated with equipment assemblies.

Other equipment groups, such as air-conditioning and ventilation equipment, have also been omitted from the analysis. A new YVL Guide on air-conditioning and ventilation equipment (E.13) is being prepared. The current practice, where the equipment of air-conditioning systems is processed under the E series YVL Guide applicable to each equipment group, is too heavy, and improvements are anticipated on this issue.

The Machinery Directive can be utilised for requirements connected to the basic design, manufacture and materials of lifting equipment [19]. However, in case of safety-classified lifting equipment, it is also necessary to set additional requirements required for nuclear safety, for example in connection to clash detection, brakes and redundant ropes.

5.4 Assessment and monitoring of equipment reliability

Equipment reliability is an important factor for the safety and cost-efficiency of a nuclear facility, so the project must also deal with the assessment and monitoring of equipment reliability. The project examined the potential sources from which reliability data on standard and serially-manufactured equipment might be available.

In the processing industry and energy sector, the reliable functioning of all equipment essential for production and safety is vitally important. Equipment failure can cause significant production interruptions or safety hazards. Sometimes, the hazard may even threaten the existence of the production plant. In such cases, there is a strong interest in choosing reliable and high-quality equipment. This is emphasised in, for example, the oil refining industry, where the plant is not stopped even once a year and hazards must be carefully controlled due to high pressures or temperatures and a flammable process material. Extra repair trips to isolated locations, such as offshore oil rigs, are also expensive.

In the oil refining industry, data about equipment reliability has been compiled in, for example, the following works:

- OREDA (Offshore and Onshore Reliability Data) Handbook, 2009 and 2015 versions [20]
    - Among other issues, the handbook deals with equipment types, failure data and maintenance history (preventive and corrective maintenance). The equipment types include compressors, gas turbines, pumps, combustion engines, steam turbines, electric generators, electric motors, batteries and UPS systems, heat exchangers, containers, heaters and steam generators, gas and flame detectors, valves and control systems etc.
- Exida Safety Equipment Reliability Handbook (2015 version) [21]
    - The handbook discusses the reliability of components that contribute to a safety function: sensors, automatics and actuators. The handbook can be used as a reference for confirming the SIL rating of a safety system. The values given in the handbook are conservative to begin with.

Safety systems commonly use SIL-rated equipment, for which certification is granted only if the manufacturer systematically collects reliability data. This data is presented in the safety manual (such as the Metso Safety Manuals [22]). For SIL-certified equipment, the certificate can also be used as a demonstration of sufficient equipment quality/reliability even if a SIL-certificate is not actually required for the location.

It is also possible to gather in-house operating experience about equipment reliability, depending on how many production plants the licence holder or applicant has. Operating experience can be obtained from, for example:

- the nuclear facility’s EYT equipment and systems
- the equipment and systems of other hydroelectric or thermoelectric or heating plants.

At the moment, the strictest practices for failure and reliability monitoring are the ones used at nuclear facilities. Other plants also monitor failures and equipment reliability. If necessary, the recording practices can be harmonised and specified in some areas in order to obtain more detailed data on interesting components and equipment.

Equipment manufacturers’ in-house quality systems usually also require the collection of data on operating experience and reliability on products, so equipment manufacturers possess reliability data connected to their equipment.

5.5 Probabilistic risk assessment (PRA)

Probabilistic risk assessment (PRA) is a key part of the safety management and assessment of a nuclear facility. The use of PRA is specified in Guide YVL A.7 [23]. Every licence holder and licence applicant has more detailed in-house procedures in connection with PRA. Under requirement 403 of Guide YVL A.7, the following sources must be used in reliability assessment:

- operating experiences gathered at similar plants or corresponding applications,
- plant-specific reliability data; or
- reliability data obtained from other similar plants or corresponding applications; or
- generic reliability data; or
- for the design-phase PRA, expert assessments and experiences from similar applications in corresponding operating environments.

No actual changes to current practices are proposed in regard to PRA.

When using standard equipment commonly used in industry, reliability data about the equipment make and model will be better available than in the current situation, when using equipment manufactured and designed especially for nuclear facilities. Operating experience will accumulate more quickly than in case of a special order with a small manufacturing batch (or "prototype"). Data about the reliability of standard equipment can be obtained from, for example, other plants of the licence holder or licence applicant, literature, the safety manuals of SIL-compatible equipment and in-house operating experiences. The oil refining industry, for example, has collected data on equipment reliability, and using it more widely in the PRA would make sense and fulfil the requirements for the PRA set in the current YVL Guide.

In case of new equipment or systems, reliability will be assessed based on the reliability data or operating experiences of equipment judged to be similar. The assessment can be based on, for example, NRC (United States Nuclear Regulatory Commission) databases, T-Book [24], ICDE database (NEA International Common-cause Failure Data Exchange Project [25]), in-house operating experiences, other literature or previous historical data from the same location. After that, reliability will be monitored regularly, which may also allow further definition of the first estimated value. Similarly, adjusting the frequency of in-service inspections, periodic testing and preventive maintenance is one way to affect the reliability and, thereby, level of risk of equipment.

Let it be stated that, alongside to the procedures presented in this report, the PRA will continue to be able to guarantee reliable assessment of the reliability of equipment and systems, perhaps even better than before.

6 Pilot

6.1 Purpose and goals

The purpose of the pilot is to test the procedure presented in Section 5.2.4 through a practical example. It also starts the cooperation between licence holders to prepare shared documents as presented in the procedure.

The procedure presented in the pilot will be tested in practice, and the goal is to:

- Find the strengths and weaknesses of the method as well as the changes and improvements required to the procedure
- Assess readiness for national approvals of mechanical components
- Acquire experience in complying with international industrial standards and their suitability for the nuclear industry
- Prepare the licence holders' shared requirement specification for the piloted equipment group and have it approved by the authority
- Have the piloted equipment approved for use by any licence holder in Finland.

The piloting will also demonstrate to the authority how the new proposed procedure will work in practice when a greater share of the control falls within the licence holder's responsibility.

After the pilot, the lessons learned, the development needs noted and the piloted procedure will be assessed and further actions to improve the procedure and introduce it in practice will be agreed.

6.2 Description of the pilot project

The pilot project presented in this section mainly deals with the first phase of the pilot, which involves piloting an equipment procurement. This first phase does not involve system modifications. During the first phase of the pilot, TVO will acquire a (SC3) valve in accordance with the new proposed procedure based on an equipment requirement specification prepared jointly by licence holders.

The valve's installation at the location will be piloted separately once the equipment procurement has been piloted successfully. At a later date, Fortum could use the further developed procedure as a basis to carry out a second pilot project including a small system modification.

6.3 Organisation and implementation method

A project team will be established for the pilot, featuring two people from each organisation, the licence holders/applicants and STUK. Each person will serve as a contact person for their organisation. Other persons from the organisations may participate in the work, if necessary for the phase in question.

The shared materials of the pilot project must be available to the entire project team in a browser-based document management system. The documents and pilot phases will always be reviewed by the entire project team together before submitting documents or moving to the next phase.

6.4 Pilot phases, schedule and costs

The pilot project will include the following phases:

Phase	Month
Appointment of the project team	Dec 2018
Submission of applications for deviating from normal procedure to STUK (TVO and Fortum)	Jan 2019
Preparation and approval of a shared equipment requirement specification between the licence holders/applicants	Jan–Feb 2019
Approval of the equipment requirement specification at STUK	Mar 2019
Pilot equipment approval and procurement	Apr–Nov 2019
Gathering of experiences and definition of further action	Dec 2019
Piloting of (pilot equipment) installation (next phase)	2020

The pilot project and the experiences and development needs gained from it will be documented in a final thesis commissioned by TVO, which is to be completed during 2019.

Each organisation participating in the pilot will commit to the jointly agreed schedule and, based on it, reserve the necessary resources for the piloting. It is of vital importance that all organisations commit to the pilot and to further developing the procedure together.

Each organisation participating in the pilot will be responsible for its own costs.

6.5 End results

As a result of the pilot:

- The licence holders' first shared equipment requirement specification will be completed and approved (for the pilot).
- The equipment qualified will be available for use at any Finnish nuclear facility.
- The final thesis on the pilot will be ready.
- The development needs of the proposed procedure will be known.
- The procedure will be ready for adoption after consideration of the development needs.

7 The licence holders'/applicants' cooperation model

7.1 Implementation method and financing of the cooperation

For the practical implementation of the cooperation between the licence holders/applicants, a cooperation body must be established to coordinate shared activities and work, collect and maintain the necessary data as well as prepare and maintain shared documents. The cooperation body will also coordinate the shared work carried out by the licence holders.

The cooperation body may be a work group to which responsible persons from each organisation are appointed. When the cooperation first starts, each organisation should be responsible for its own costs but, at a later stage, each organisation could pay a specific annual sum to finance the activities of the cooperation body, and licence holders could bill the cooperation body for the work they do.

A web-based environment to which all parties have access is needed for the management of the shared documents and knowledge. This could be, for example, a SharePoint-based environment, or an existing system of one of the organisations could be used as a basis for building a shared environment.

Duties of the cooperation body will include:

- Maintenance of manufacturer approvals and the manufacturer database
- Recording and maintenance of the reference data of all decisions applying to everyone (such as the numbers of STUK letters on manufacturer approvals, decision numbers and approval scope, etc.)
- Maintenance of shared documents.

7.2 Future development potential

In the future, during phases connected to equipment procurement of the procedure in Appendix 3, the cooperation between the licence holders could be developed further to increase and expand the cooperation in equipment procurements. For example, equipment could be procured jointly in advance and placed in storage, from which each licence holder could purchase the equipment they need for their modification projects. Any analysis of the cooperation between the licence holders in procurements must take into account the potential restrictions and boundary conditions imposed by legislation.

On the other hand, the duties of the licence holders' cooperation body listed in the previous section could, in the future, be the responsibility of some separate organisation from which the licence holders would purchase the service connected to equipment procurements. This organisation would be responsible for procurement procedures, among other things, serving as an interface with equipment suppliers/manufacturers.

In the future, the cooperation between the licence holders can also be developed to cross Finnish borders, first with Swedish nuclear organisations and later at the EU level.

8 Summary, further actions and the future

The development proposals presented herein emphasise cooperation between the licence holders and the licence holder's own responsibility for successful equipment procurement that conforms to requirements. STUK's regulatory control will be allocated where the foundations of nuclear safety are created and where it can be influenced the most. Control at equipment level in the lower safety classes will be processed in a new way, increasing the role of the licence holder. The proposed change supports and complies with STUK's strategy, emphasising the licence holder's own responsibility.

Procedures connected to equipment procurement and how a procurement appears to the equipment supplier/manufacturer, in particular, will be brought closer to the procedures used in other industries, which will make it easier to participate in nuclear projects and help ensure a comprehensive and high-quality supplier network in the future. When the procedures for the equipment supplier/manufacturer are clear and resemble the procedures of other industries, and when equipment procurements utilise standards and procedures used in other industries, it will also facilitate the utilisation of modern, high-quality standard equipment and serially-manufactured equipment at nuclear facilities, reducing the need for unique one-off products. This will reduce not only the costs and time consumed by projects but also the quality risks associated with customised products.

The piloting of the proposed procedure is an important first step in advancing the development proposals and developing the procedures further. It is of vital importance that all organisations commit to the pilot and to further developing the procedure during it. The pilot project must be launched immediately, and the necessary resources must be reserved for it.

The licence holders' shared requirement specifications and their development will play a key role in the further development and practical implementation of the procedures. The development proposals, such as the use of standards commonly used in industry, utilisation of the PED and cooperation between licence holders, are embodied right there in the equipment requirement specifications. This makes it extremely important to prepare the pilot project's equipment requirement specifications carefully in cooperation between the licence holders and STUK.

Cooperation between the licence holders must be developed further. After this project, cooperation must be launched and developed. Later, cooperation must be analysed more extensively, first between Finland and Sweden, and after that also at the EU level. From the perspective of manufacturers, it is clearer and more appealing if a greater volume of products is procured based on similar requirements, specifications and procedures. Phases connected to equipment procurement could also have potential for further improvement of the procedures and methods towards uniform and joint procurement by the licence holders.

Some areas that also have significant development potential and should thus be examined more closely were excluded from the scope of this project. A closer examination of the procedures connected to instrumentation and control systems and equipment would likely yield potential development needs. The same applies to electrical systems and equipment even though they were not analysed more closely in the context of this project. There is also development potential in the procedures connected to the processing of air-conditioning and ventilation systems and related equipment. These and other areas must also receive attention in the future as the licensing and qualification procedures are developed.

In the future, it would also be advisable to examine whether STUK's role as the authority on pressure equipment for nuclear facilities is still appropriate in the current situation or whether a practice for the regulatory control of pressure equipment that is consistent with other industries might be a better future solution.

The development of procedures and adjusting them to be more appropriate is essential for ensuring the operational feasibility of the nuclear industry in the future. It is vital to develop the procedures further in cooperation with STUK, the licence holders and other organisations, and for all parties to commit to the changes. It was observed during the project that the YVL Guides currently being updated contain changes similar to those proposed in this project. This means that visions for the development of licensing and qualification are aligned. Openness to change, an interactive atmosphere and cooperation are important for achieving common goals and ensuring the operational feasibility and overall safety of the nuclear industry also in the future.

References

1. Nuclear Energy Act (990/1987)
2. Ydinlaitosten luvitusmallien kehittäminen, Esiselvitys (Development of the licensing models of nuclear facilities, Preliminary Study). R. Rintamaa/Clenercon Oy, K. Törrönen/EnergyWave Oy, 2017
3. KSKG Position Paper – Application of Standard Equipment
4. Raitanen Oskari, Use of commercial-grade items in nuclear facilities, Master's Thesis, 2017.
5. Pöytäniemi Joonas, The use of standard equipment in safety-important nuclear applications, Final Thesis (being written, preliminary title, estimated completion date May 2019).
6. Pressure Equipment Directive 97/23/EC
7. Guide YVL E.1, Authorised inspection body and the licensee's in-house inspection organisation, 15.11.2013, STUK.
8. Säteilyuutiset 1/2018, STUK: STUK Strategy 2018—22 https://www.stuk.fi/ajankohtaista/uutiskirjeet/sateilyuutiset-uutiskirjeet/sateilyuutiset-1-2018/stukin-strategia-2018-22-avainsana-muutos-
9. YVL Guides, https://www.stuklex.fi/fi/ls#ydinturvallisuusohjeet
10. Guide YVL E.3 Pressure vessels and piping of a nuclear facility, Draft 19.10.2018, STUK.
11. Guide YVL E.8 Valves of a nuclear facility, Draft 23.10.2018, STUK.
12. Guide YVL E.9 Pumps of a nuclear facility, Draft 23.10.2018, STUK.
13. Kattainen Matti, Preliminary findings: Safety class effect on equipment reliability parameters – Loviisa NPP, Presentation on 11 October 2017
14. YVL E.7 Electrical and instrumentation and control equipment of a nuclear facility, DRAFT 9 April 2017, STUK.
15. SFS-EN ISO 9001:2015. Quality management systems. Requirements. Published: 23 October 2015
16. SFS-ISO 19443:2018. Quality management systems. Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety. Published: 12 June 2018
17. SFS-EN 13445-3, Unfired pressure vessels. Part 3: Design
18. IEC 61511:2018, Functional safety – Safety instrumented systems for the process industry sector
19. Directive 2006/42/EC of the European Parliament and of the Council
20. OREDA, Onshore and offshore reliability data, http://www.oreda.com/
21. Exida, Safety Equipment Reliability Handbook, 2015, https://www.exida.com/Books/Safety-Equipment-Reliability-Handbook-4th-Edition
22. Safety Manuals, Metso Valves http://valveproducts.metso.com/catalog/1166/Safety_Manuals_ENG1.html
23. Guide YVL A.7 Probabilistic risk assessment and risk management of a nuclear power plant, 15.11.2013, STUK
24. T-Book, Reliability Data of Components in Nordic Nuclear Power Plants, The TUD Office, 2010. ISBN 978-91-633-61449.

25. NEA International Common-cause Failure Data Exchange (ICDE) Project
https://www.oecd-nea.org/jointproj/icde.html