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OSKARI RAITANEN
USE OF COMMERCIAL-GRADE ITEMS IN NUCLEAR FACILITIES

Master's thesis

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ABSTRACT

OSKARI RAITANEN: Use of commercial-grade items in nuclear facilities

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Nuclear facilities hold a great amount of safety classified items. Production of the items in different safety classes must adhere to the requirements set by STUK. Previously, it has been stated that commercial-grade items commonly used in industrial applications have reached or even surpassed nuclear-grade Safety Class 3 (SC 3) items in quality. A case study was conducted to investigate these statements. Metso Flow Control (MFC) compiled and provided a requirement specification followed in their Oil & Gas (OG) shut-off valve deliveries. This specification was compared qualitatively with a requirement specification of a nuclear-grade SC 3 shut-off valve. The findings showed that several requirements in the specifications are identical or similar. For example, structural design and most factory tests can be done according to same standards. Differences were identified for example in the inspection scope and in design bases requirements regarding tolerability of seismic events or radiation. Additionally, the case study attempted to compare quantitatively the failure rates of nuclear- and commercial-grade isolation valves. It was found that the failure rates are compiled in a fundamentally different way and that MFC couldn't allow access to the original failure data because of its sensible nature. Therefore the failure rates could not be compared in this study.

This study included also an interview study, where a total of nine experts from different organizations were interviewed. According to the findings, in order to accept commercial-grade items for nuclear use, the deviations from nuclear items must be identified and compensated for. This was seen as the way to confirm that the commercial-grade items meet the safety level of nuclear-grade items. The interviewees emphasized the role of cooperation in closing the gap between nuclear- and commercial-grade items. Additionally, it was found that nuclear requirements are partly perceived as unclear. Cooperation between all stakeholders was also stated to improve clarity of requirements and the public image of nuclear power. Reaching a more explicit requirement level and a better public image were said to improve the cost-effectiveness of nuclear power. The new requirement for a Requirement Specification Document (RSD) was unanimously seen as a step towards more clarity, and the interviewees agreed that the licensees could definitely cooperate when compiling the RSDs. This was said to reduce overlapping efforts.

TIIVISTELMÄ

OSKARI RAITANEN: Standardilaitteiden käyttäminen ydinlaitoksissa

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Ydinlaitoksissa on suuri määrä turvallisuusluokiteltuja laitteita. Säteilyturvakeskus määrittää Suomessa turvallisuusluokkakohdaiset vaatimukset, joita laitteiden valmistuksessa täytyy noudattaa. Aikaisemmin on esitetty väitteitä siitä, että teollisuuden yleisesti käyttämien laitteiden (standardilaite) laatu olisi saavuttanut tai jopa ylittänyt ydinalan turvallisuusluokka 3:n laitteiden laadun. Väitteiden tarkastelemiseksi toteutettiin tapaustutkimus, jossa Metso Flow Controlin (MFC:n) öljy- ja kaasuteollisuuden vaatimustasoon pohjautuvaa sulkuventtiilin vaatimusmäärittelyä verrattiin laadullisesti ydinalan turvallisuusluokka 3:n vaatimustasoon pohjautuvaan vaatimusmäärittelyyn. Tuloksista selvisi, että vaatimusmäärittelyt ovat identtisiä tai samankaltaisia useiden vaatimusten osalta. Esimerkiksi venttiilien rakenteellinen suunnittelu ja suurin osa tehdastesteistä voidaan tehdä samojen standardien mukaan. Eroja havaittiin muun muassa venttiilien tarkastuslaajuudessa ja suunnitteluperusteisiin liittyvissä vaatimuksissa, esimerkiksi ydinalan venttiilien maanjäristys- ja säteilykestoisuuden osalta. Tapaustutkimuksessa pyrittiin myös vertailemaan ydinlaitoksissa käytettävien ja MFC:n valmistamien eristysventtiilien vikaantumistaajuuksia määrällisesti, mutta venttiilien vikaantumistaajuuksia ei voitu tässä tutkimuksessa vertailla, koska vikaantumistaajuudet oli muodostettu lähtökohtaisesti eri menetelmin ja MFC:n alkuperäiseen vikaantumisdataan ei ollut pääsyä.

Tähän tutkimukseen sisältyi myös haastattelututkimus, jossa haastateltiin yhteensä yhdeksää asiantuntijaa eri organisaatioista. Haastatteluissa selvisi, että standardilaitteiden hyväksyttämiseksi ydintekniseen käyttöön täytyy niiden eroavaisuudet ydinteknisiin laitteisiin nähden määrittää ja kompensoida, jotta voidaan varmistua siitä, että laite saavuttaa ydinteknisille laitteille määritetyn turvallisuustason. Haastatellut korostivat yhteistyön merkitystä, jotta eroa standardilaitteiden ja ydinteknisten laitteiden välillä saataisiin kavennettua sekä ydinvoiman julkisuuskuvaa parannettua. Ydinalan vaatimukset koettiin osin epäselvinä ja vaatimusten yksiselitteisyyden parantaminen nähtiin tärkeänä kehityskohteenä. Näiden asioiden todettiin lisäävän ydinalan kustannustehokkuutta. Uusi vaatimus laitevaatimusmäärittelystä nähtiin askeleena kohti selkeämpää vaatimustasoa. Haastatellut olivat yhtä mieltä siitä, että suomalaiset luvanhaltijat voisivat laatia laitevaatimusmäärittelyt yhteistyössä keskenään, mikä karsisi päällekkäisen työn määrää.

FOREWORD

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Off to unbeaten paths!

In Umeå, 15.10.2017

Oskari Raitanen

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ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
BWR	Boiling Water Reactor
CDF	Core Damage Frequency
CSWG	Codes and Standards Working Group
DBC	Design Basis Condition
DEC	Design Extension Condition
DiD	Defence-In-Depth
Euratom	European Atomic Energy Community
EYT	Non-nuclear safety class
FMEDA	Failure Modes, Effect and Diagnostic Analysis
FOAK	First Of A Kind
IAEA	International Atomic Energy Agency
IO	Authorized inspection body
ITP	Inspection and Testing Plan
JRC	Joint Research Centre
MDEP	Multinational Design Evaluation Programme
MFC	Metso Flow Control
MT	Magnetic particle Testing
MTTR	Mean Time To Repair
NDT	Non-Destructive Testing
NPP	Nuclear Power Plant
NRC	United States Nuclear Regulatory Commission
OG	Oil & Gas
PFD	Probability of Failure on Demand
PIU	Proven In Use
PT	Penetrant Testing
PWR	Pressurized Water Reactor
PRA	Probabilistic Risk Assessment
QMS	Quality Management System
RI	Risk-Informed
RRF	Risk Reduction Factor
RSD	Requirement Specification Document
RQ	Research Question
RT	Radiographic Testing
SA	Severe Accident
SAHARA	Safety As High As Reasonably Achievable
SC	Safety Class
SIF	Safety Instrumented Function
SIL	Safety Integrity Level
SIS	Safety Instrumented System
SQC	Statistical Quality Control
SSC	Systems, Structures and Components
STUK	The Finnish Radiation and Nuclear Safety Authority
UT	Ultrasonic Testing
WENRA	Western European Nuclear Regulators Association
WPS	Welding Procedure Specifications

1. INTRODUCTION

Nuclear energy production is based on a nuclear reaction that produces radioactive fission products whose environmental release may cause biological damage in living organisms. Therefore, it is crucial that the producers of nuclear energy facilitate a high safety level. International agreements steer the national legislation and the Radiation and Nuclear Safety Authority (STUK) supervises the safe use of nuclear energy in Finland. The detailed requirements for the safe use of nuclear energy and radiation are presented in the YVL regulatory guides by STUK. Systems, Structures and Components (SSCs) of Nuclear Power Plants (NPPs) are grouped into four Safety Classes (SCs), 1-3 & EYT (non-nuclear safety) depending on their significance in terms of operational safety of the facility or the long-term safety of disposal (YVL B.2e, pp. 3-4). The SCs specify certain requirements the SSCs must fulfill prior to being included in nuclear facilities. The nuclear requirements are often different from those of other industries. Additionally, there is country-specific variation in the nuclear requirements.

1.1 Background

This study was funded by and mainly conducted at the premises of Teollisuuden Voima Oyj (TVO), a Finnish nuclear power company that operates two nuclear reactors that hold a combined 1760 MW of electrical power output. TVO is currently building their third reactor, Olkiluoto 3 (1600 MW), that is scheduled to start operation in late 2018 (TVO 2017a). Nuclear facilities consist of a large variety of different SSCs, including thousands of valves. High quality of the SSCs is crucial for the safe and economic generation of nuclear power. Therefore, it is essential that quality is at the core of all contributing stakeholders. Ensuring high quality involves the licensee, authorities and manufacturers, all of which contributed to this research. This research is part of a larger project within TVO. The project's one objective is to study what the nuclear industry can learn from conventional industries in order to improve safety effectively. The project includes evaluating if some of the current customs in the nuclear sector could be brought closer to the customs of conventional industries.

In order to meet the nuclear requirements, the production of nuclear-grade items often differs from that of so called "commercial-grade items" produced according to the standards of more conventional industries such as the Oil & Gas (OG) industry. The customized production process of the nuclear-grade items might require special manufacturing techniques, facilities, documentation, inspection and tests. After the nuclear construction boom of the 1970s, some of the vendors discontinued the production of nuclear-grade

items and the large quantity purchases shifted to small-volume maintenance and repair purchases (EPRI 2014, sec. 1-2). The overall quality and reliability of commercial-grade items has leaped (Wahlström & Sairanen 2001) since the adolescence of nuclear energy, which begs the question: do all of the nuclear-specific requirements in fact improve safety?

International Atomic Energy Agency (IAEA) lays out the basic guidelines for nuclear safety which individual countries use to compile their own nuclear legislations. The national legislation is further refined into more detailed and practical requirements by national authorities, which means that the detailed requirements are globally inconsistent. Deviations from standard manufacturing procedures coupled with inharmonious national safety requirements have been said (EPRI 2014; Wahlström 2003) to result in a lower number of qualified vendors and availability issues. Previous work (Wahlström & Sairanen 2001; Abbt 2017) has also suggested that the smaller production volume of customized items may cause inferior product quality at a greater price compared to using serially produced commercial-grade items. However, these statements have mostly emerged from within the nuclear community, not from peer-reviewed scientific research.

A Codes and Standards Working Group (CSWG) under OECD's Multinational Design Evaluation Programme (MDEP) studied the similarities and differences in the Codes and Standards (C&S) of pressure-boundary components in multiple countries with the help of several Standard Developing Organizations (SDOs), and concluded that:

“Regardless of the similarities and differences, the CSWG found that each pressure-boundary code has been determined by each country to result in a component with an acceptable level of quality and safety.” (MDEP 2014, “Executive Summary”)

This result is useful, but it is solely regarding nuclear standards for pressure-boundary components, which constitute only a portion of the total components in a nuclear facility. The apparent need for further research regarding the compliance of non-nuclear requirements with nuclear requirements of Safety Class 3 (SC 3) items was identified by the European nuclear community (Abbt 2016) and the European Commission's Joint Research Centre (Martin 2017) which additionally motivates this study.

Western European Nuclear Regulators Association (WENRA) develops a harmonized approach to nuclear safety and has compiled a set of safety Reference Levels (RLs) that reflect the practices that the member states are expected to follow, but do not reach the legally and technically detailed level, which in effect defines the practical requirements for manufacturing. There has been discussion (Hill 2016) on whether the future of nuclear requirements will shift towards similar requirements (convergence of C&S) or towards finding common methods for the acceptance of different standards (equivalence of C&S).

Advances in manufacturing of mechanical equipment and data acquisition techniques have introduced more reliable products and better information about their reliability. A deterministic approach steers the nuclear regulation in Europe, which means the components are required to sustain certain design basis accidents regardless of the likelihood of the accident. This leaves little room for flexibility of the requirements that cover the production and inspection of individual nuclear-grade items. Many of the production requirements are non-negotiable and thus out of the reach of many suppliers, which might hinder the availability of the related items.

In USA, the unavailability of nuclear-grade items is improved through a method called commercial-grade dedication that allows accepting commercial-grade items for use in nuclear safety-related applications. The method defines a way to verify that a commercial-grade item holds certain critical characteristics critical to its ability to perform its safety function. The dedication process includes evaluating a commercial-grade item's conformity to the critical characteristics in order to be qualified for use in nuclear safety-related applications (EPRI 2014). Additionally, USA has been a forerunner in introducing a Risk-Informed (RI) approach in their nuclear regulation (Garrrick & Christie 2002). The commercial-grade dedication method is concerned with evaluating the quality of non-nuclear items after production rather than applying prescriptive requirements that perforate the entire production process from design to final inspection. The method lends itself to the RI approach, whose fundamental objective is to allocate resources to where they are most relevant in terms of risk mitigation. In Europe, such methods are not commonplace and therefore possibilities for their introduction shall be examined.

The commercial-grade dedication method uses reliability data of the non-nuclear industries in the verification of the critical characteristics (EPRI 2014). There has been discussion in Finland (Wahlström & Sairanen 2001) about could the deterministic criteria be relaxed if a particular system was shown to be sufficiently reliable by using probabilistic data. In practice, this approach could mean that when the reliability of a commercial-grade valve can be assured to have reached an acceptable level (with verified reliability data for proof), the valve could be accepted to be used in a nuclear facility as such or with a less comprehensive set of requirements than currently. Interviews with non-nuclear suppliers and further research on using non-nuclear reliability data in accepting commercial-grade items are additionally encouraged by the nuclear community in Europe (Launay 2000; Abbt 2017; Martin 2017).

1.2 Research questions

It has been argued that the current requirements for the production of commercial-grade items might result in equal or higher quality and reliability than that of nuclear-grade items. This hypothesis shall be examined within a case study carried out in collaboration with valve manufacturer Metso Flow Control (MFC). Research Question 1 (RQ1) asks:

RQ1: Is the requirement specification followed by Metso Flow Control for their Oil & Gas shut-off valve deliveries compliant with the requirement specification for nuclear-grade Safety Class 3 shut-off valves?

The role of MFC was to provide their requirement specification followed for Oil & Gas (OG) -grade shut-off valves. The OG-specification is compared with a requirement specification for nuclear-grade Safety Class 3 (SC 3) shut-off valve.

Assessing the reliability of nuclear-grade and commercial-grade items is crucial for the evaluation of the items' operational performance. This assessment is done to answer RQ2:

RQ2: Is a nuclear-grade item more reliable than a commercial-grade item?

RQ2 is answered through a quantitative phase of the case study, where failure rates of nuclear-grade and commercial-grade valves are presented to evaluate their operational performance. Additionally, RQ2 is answered through a qualitative interview study, where the views of the nine interviewed experts relating to the items' reliabilities are inquired.

European regulators and licensees have pushed towards the harmonization of requirements within organizations like WENRA and Joint Research Center (JRC) but much of the regulation even between EU countries has remained inharmonious especially in the lower safety classes 2-3 (WENRA 2006), although countries share a common goal of acceptably safe components (MDEP 2013). The interview study seeks to answer RQ3:

RQ3: What is the current status and future of harmonization of nuclear requirements?

In USA, commercial-grade items are routinely accepted to be used in nuclear safety-related applications. The interview study is used to probe the interviewees' perspectives on the ways that commercial-grade items may be accepted in the Finnish NPPs:

RQ4: What are the ways to accept commercial-grade items for use in nuclear applications?

Interviewing is a tool to search for knowledge that is hard or even impossible to find in literature. In order to gain new information, and perhaps validation for existing knowledge, RQ5 asks:

RQ5: How to increase safety in a cost-effective way?

To conclude, while the research questions are rather exact, this project is part of TVO's research and development program that aims for constant improvement. Hence, this study might be found successful if this project provides future targets for TVO and the nuclear industry in general.

2. GENERIC FRAMEWORK

2.1 Nuclear safety

The use of nuclear power supports climate and environmental objectives, provides reliable and carbon-free base load capacity and increases the electricity independence of a nation. The risks of nuclear power are related to an increased radiation risk, which needs to be defined by careful assessments of all the significant consequences of the operations. In order to be able to reduce the risks of using nuclear power, the safety of the nuclear operations has to be assessed extensively. The fundamental safety objective of nuclear energy production is to protect people and the environment from the harmful effects of ionizing radiation. All reasonably attainable measures are to be taken in order to achieve this level of protection. The actions include controlling the radiation exposure of both people and the environment, restricting the likelihood of events that might lead to an uncontrolled release of radiation and to mitigate the consequences should an event like that occur. (IAEA 2006)

Nuclear safety principles are globally accepted and they form the basis of nuclear safety. International requirements define the fundamental concepts that national safety requirements must comply with, but practical-level requirements are typically defined by national authorities of each country. The practical-level requirements directly related to the production of components are typically based on deterministic design bases the components must withstand in their service place and in accident conditions. The design of safety-related systems shall be validated through deterministic safety analyses. Probabilistic Risk Assessment (PRA) compliments the deterministic analyses by evaluating a broad spectrum of event sequences and by indicating the most significant risks in nuclear facilities in order to reach a balanced design (YVL A.7e, p. 5).

2.1.1 General safety principles

The guideline for minimizing the radiation load of the operation to both personnel and material is called the ALARA (As Low As Reasonably Achievable) radiation safety principle. The principle ensures that the dosages during normal operation are within prescribed limits and that the radiological exposure is mitigated in emergency situations. (IAEA 1999, p. 9)

SAHARA (Safety As High As Reasonably Achievable) –principle is the guiding principle in designing and operating a nuclear power plant. It requires the safety measures to be optimized in a way that results in the highest safety level, without prohibiting the operation of the plant excessively. The optimization needs to address the relative significance of factors such as the number of exposed people, the likelihood of the exposure and the

dosage amount and radiation risks from foreseeable events. Environmental, social and economical factors should also be assessed (IAEA 2006, pp. 10-11; Nuclear Energy Act 990/1987, 7 a §). Decreasing the frequency of accidents is crucial in risk reduction and improved safety can be achieved by increasing the overall quality of systems, structures and components and the mitigation of consequences of the unlikely, but possible accidents (STUK 2015b, pp. 2-3).

The management of a nuclear organization shall support a cross-divisional and effective safety culture. The risk factors related to the operation of the organization need to be recognized and implemented into the activities according to their significance to the overall risk. The management shall define the exact safety-related tasks and responsibilities of the personnel and make sure every person is qualified for their task. Openness shall be promoted and questioning of the present practices fostered in order to achieve an ever-improving safety culture. (YVL A.3e, p. 7)

2.1.2 Nuclear safety principles

The design of a nuclear power plant is focused on reliable and failure-free operation, which is the basis for a safe and economically feasible use of the plant. The design follows certain fundamental principles that are all-inclusive and mutually redundant by nature (YVL B.1e, p. 5). The defining principle is Defence-in-Depth (DiD), which includes the principles of multiple barriers of protection, redundancy, diversity and separation.

Defence-in-Depth

DiD is a safety approach that compensates for potential technical and human failures in the nuclear power plant. It is based on successive levels of protection independent of each other and it is the primary means of preventing accidents or mitigating the consequences should a malfunction or accident appear. (IAEA 2012, p. 6)

There are five functional defence levels in the DiD concept, the first two of which are for accident prevention and the other three are for mitigating the consequences of an accident:

1. Prevention
2. Control of anticipated operational occurrences
3. Control of accidents
4. Containment of release in a severe accident
5. Mitigation of consequences

The first level is designed to prevent from deviations of normal operation and the failure of items important to safety. Conservative safety margins, quality management and proven engineering practices shall be used when designing, manufacturing, installing, commissioning, inspecting, testing and maintaining the systems, structures and components and the operation of the plant (IAEA 2012, p. 7; YVL B.1e, p. 13) This level is

directly concerned with component-level quality, which is of major importance to this study. The other levels are systemic, as the components are integrated into systems that perform certain safety functions.

The second level of defence is the control of abnormal operation. Even though the plant has been designed for failure-free operation, the goal of this level is to establish control over any failures and to prevent any malfunctions from evolving into accidents and, if needed, to bring the plant to the controlled state, which means that the reactor is shut down and that the decay heat removal is secured. (YVL B.1e, p. 13; STUK 2016a, p. 2)

At the third level, occurring accidents are controlled from developing further. The protection is achieved through reliable automatic control systems that observe malfunctions and react if needed. The objective is to protect the confinement of radioactive substances, prevent fuel failures and accidents from evolving into Severe Accidents (SAs). The third level is divided into two sublevels, 3a and 3b: at level 3a, the goal is to control a single initiating event -based event to limit the radiological release and to bring the facility to a controlled state. At level 3b, the objective is to control Design Extension Conditions (DECs) such as common cause failures in the system designed to control the event at hand, combinations of failures selected based on Probabilistic Risk Assessment (PRA) and rare external events. (YVL B.1e, p. 13)

The fourth defence level is for confining the release in severe reactor accidents. The goal is to mitigate the consequences by ensuring the integrity and the leak-tightness of the containment to meet the preset release limits for a SA. At the fifth and final level, the primary objective is to mitigate the consequences of an accident that releases considerable amounts of radioactive substances to the environment. Emergency preparedness arrangements are to be made in order to restrict the radiological dose of the population (YVL B.1e, p. 13)

Multiple barriers of protection

In addition to the defence levels, the defence-in-depth ideology consists of the principles of multiple barriers from a radioactive release, redundancy, diversity and separation (Sandberg 2004, p. 101). To protect the environment from a radioactive release, the nuclear power plant is designed to have multiple barriers between radioactive sources and the environment. In general, there are four barriers and the first barrier is the nuclear fuel rod itself. The rod holds the ceramic fuel pellet and the fuel rod cladding that is mechanically durable and gas-tight. In case of damage in the fuel rod cladding, the resulting release is held within the bulky and leak-tight steel reactor vessel and the primary cooling water circuit that form the second barrier. The third barrier is the surrounding concrete structure called the containment building, which is designed to contain the released radioactive materials if the primary circuit is damaged. The fourth and final barrier is the

reactor building, which protects the reactor from external hazards such as airplane collisions and extreme weather phenomena. The reactor building is also equipped with filters that purify possible radioactive releases prior to discharging (Sandberg 2004, p. 97). The four successive barriers are displayed in Figure 1.

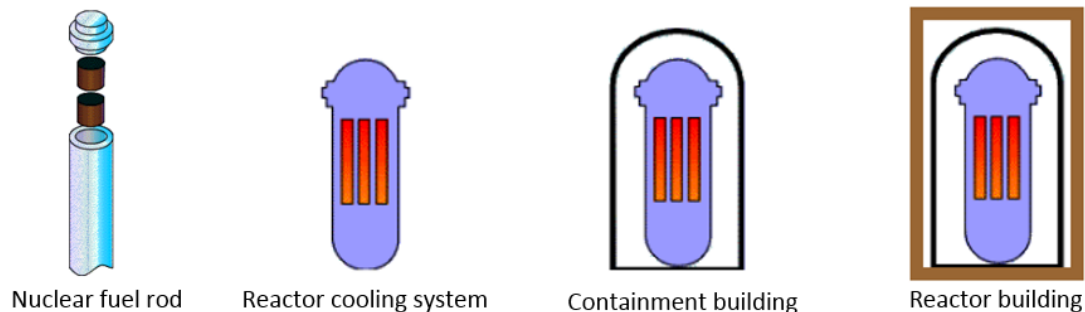


Figure 1. Four barriers that protect from a radioactive release. Adapted from (STUK 2016b).

As seen in Figure 1, the physical protection starts from the very core of the reactor and ends to the visible façade of the plant.

Redundancy, diversity, and separation

The redundancy principle is one of the cornerstones of nuclear safety design. It means that the structures, systems and components of a nuclear power plant are designed in a way that allows for a particular safety function to be performed regardless of the failure or operational state of a single item (Sandberg 2004, p. 102). This is achieved through dissecting the items that contribute to the selected safety function and implementing identical or diverse alternatives to carry out the safety function in the case of failure of a single item (YVL B.1e, p. 14). An example of applying the redundancy principle is assuring the decay heat water removal with multiple cooling system pumps that are able to cool the reactor core independent of each other.

In nuclear safety, the diversity principle means using multiple different technologies to perform a single safety function. Diversification decreases the probability of simultaneous failures, because if a particular technology is unavailable due to any reason, the backup technologies are still available to carry out the safety function (Sandberg 2004, p. 103). For example, a reactor may be shut down by a fast insertion of solid neutron absorbers (control rods) or by pumping boron liquid into the core.

The principle of separation is divided into physical separation and functional isolation. Physical separation is based on placing parallel redundant trains of safety systems in a way that reduces the probability of their simultaneous failure. It is done by leaving a sufficient distance between the trains or by building protective barriers around them. In

addition, the safety-related systems of a nuclear facility are typically placed apart from the other systems. In functional isolation, the objective is to prevent the adverse interplay of parallel or interrelated systems. Functional isolation also covers the electric isolation and isolation of the processing information between two systems. The separation principle, among other things, ensures that fires, floods or other events don't prevent the safety systems from functioning. (Sandberg 2004, pp. 102-104; YVL B.1e, p. 41)

2.1.3 Classification of safety systems

The need to classify the various systems, structures and components of a nuclear power plant according to their significance on safety was identified already in the adolescence of the nuclear industry, especially due to the rapid acceleration of the American nuclear industry in the late 1960's. In the early stages of the nuclear based power production, basic methodologies and procedures for quality assurance and safety classification were laid out, many of which stand steady even today. Some of these practices, however, have gone through a learning curve along with the development of general industrial quality assurance and important lessons have also been learned within the nuclear power industry (IAEA 2014, p. 1). This has led to updates in the classification procedures. An IAEA document (IAEA 2014) contains the global guidelines for member states to meet the obligations under general principles of international law and it is the most recent safety standard document that guides the member states' regulatory bodies in making regulations that constitute a high level of safety. While the national classification procedures vary, this chapter describes the classification basis in the Finnish regulation.

In Finland, the Radiation and Nuclear Safety Authority (STUK) supervises that the requirements for the safe use of nuclear energy are adequate and that nuclear energy producers comply with the requirements. To ensure a high level of safety, STUK supervises the production of the items. The various SSCs of a nuclear facility are performing certain safety functions and are therefore required to have sufficient quality. In the Finnish classification system, the SSCs are divided into four Safety Classes: 1, 2 and 3, and Class EYT (non-nuclear safety). The classification is done with respect to safety significance, and it is based primarily on deterministic methods, and where necessary, supplemented by a probabilistic risk assessment and expert judgment. (YVL B.2e, p. 3)

The safety classification is divided into functional and structural classification. The functional classification identifies the systems and components, considering their relevance for an example in control of initiating events, and the structural classification considers structures with regard to preventing radioactive substances from spreading (STUK 2015a, p. 3). The safety classification of systems is based on the safety functions and the role of the systems in performing these safety functions, with respect to ensuring safety by Defence-in-Depth. Structures are classified considering the strength, integrity and leak tightness required to perform their safety functions or to prevent the spreading of radioactive substances. The components of a nuclear facility are classified based on the functions

required of them to perform safety functions or to prevent the spreading of radioactive substances as well as on the structural strength, integrity and leak-tightness required of them. (YVL B.2e, p. 3)

The classification originates from the DiD concept, but there is no direct connection between the categorization of the Design Basis Conditions (DBC) and the safety classes. Figure 2 presents a simplified way of using items of different safety classification to control the progression of anticipated occurrences, postulated and severe accidents within the DiD framework.

Design Basis Conditions	Levels of Defence in Depth					
	Level 1	Level 2	Level 3a	Level 3b	Level 4	Level 5
	Prevention	Control	Control of postulated accidents	Control of DEC's	Accident management	Emergency preparedness
DBC 1 Normal operation	SC 1 •Nuclear fuel & the primary circuit ⇒ SC 2 SC 3 EYT	SC 3 •Partial emergency shutdown				
DBC 2 Anticipated operational occurrences $f > 0.01 \text{ a}^{-1}$	⇒	SC 2 •Emergency shutdown	SC 2 •Systems enabling a controlled state •Containment building			
DBC 3 (Class 1 postulated events) $0.001 \text{ a}^{-1} < f < 0.01 \text{ a}^{-1}$ DBC 4 (Class 2 postulated events) $f < 0.001 \text{ a}^{-1}$	⇒		SC 3 •Systems enabling a safe state •Systems that maintain control			
DEC Design Extension Category			⇒	SC 3 •Diverse systems enabling a controlled state		
SA Severe Accidents $f < 0.00001 \text{ a}^{-1}$				⇒	SC 3 •Systems controlling severe accidents	

Figure 2. Simplified presentation of the DiD levels, Design Basis Conditions and corresponding Safety Classes. Adapted from (STUK 2015b; YVL B.2e).

In Figure 2 the Design Basis Condition 1 (DBC 1) refers to the normal operation of the nuclear power plant, including start-up, testing, maintenance, shutdown and refuel (YVL B.3e, p. 12). At the first DiD level, the design basis condition is to support the normal operation of the plant, and the main contributors are SC 1 items like nuclear fuel and the main components and large piping of the primary circuit. SSCs of all other safety classes are also needed at the first level, depending on the characteristics of occurrences. (STUK 2015a, p. 3)

The systems at the second defence level are designed to detect any anticipated operational occurrences, which are expected to occur at least once in every hundred operational years (DBC 2), and to prevent their progression into accidents (STUK 2015a, p. 4; YVL B.3e, p. 12). These systems include SC 3 systems, which are typically of limiting nature, such as a partial emergency shutdown. Additionally, some SC 2 safety functions are needed when the SC 3 limiting functions are not sufficient. These functions include the emergency shutdown and the supply of secondary emergency feed water and backup power. (STUK 2015a, p. 4)

The defence level 3a includes SC 2 systems that mitigate the consequences of class 1 and 2 postulated accidents by bringing the facility to a controlled state and maintaining it at least for 72 hours. This level includes SC 3 systems whose function is to bring the facility to a safe state and maintain it, in addition to components that are essential for emergency control. Class 1 postulated accidents (DBC 3) are assumed to occur less than once in a hundred operating years, but at least once in a thousand operating years. Class 2 postulated accidents (DBC 4) are anticipated to occur less frequently than once every thousand operating years. (STUK 2015, p. 4; YVL B.3e, p. 12)

DEC refers to Design Extension Conditions, which are divided into three subcategories: DEC A is an accident where an anticipated operational occurrence or a DBC 3 involves a common cause failure in a system required to execute a safety function (e.g. loss of offsite power & common cause emergency diesel generator failure). DEC B refers to an accident derived from a combination of failures identified as significant based on PRA, and DEC C refers to an accident caused by a rare external event that the plant is required to sustain without a severe fuel failure. Systems of Safety Class 3 that accomplish the diversity principle safeguard the facility from the development of the DEC. (YVL B.3e, p. 13).

Severe accidents are beyond design basis accidents that have a low probability of occurrence (less than once every 10 000 years), but significant consequences that may result from degradation of the nuclear fuel. SC 3 systems mitigate the consequences of such accidents by, for an example, ensuring the leak-tightness of the containment. (YVL B.1e, p. 13)

After the classification of safety systems, the requirements for each safety class need be specified in a way that ensures the design, manufacturing, inspection, installation and operation of the SSCs is at a verified quality level, and that the inspections and testing are adequate per the safety significance of the SSCs group in a specific class. The system-specific lists of different structures and components in safety classes 1-3 and EYT shall be included in the classification document, in addition to the classification criteria and the classification requirements. The classification document is required to be submitted to STUK as part of the construction and operating license application. (YVL B.2e, p. 7)

2.1.4 Safety classification

A nuclear facility holds a range of different SSCs with unique requirements, not all of which can be included in this study because of space limitations, but the general safety class specific classification bases are presented. The safety classes are numbered in a descending order from 1 to 3 and EYT, the first class being the most significant class in terms of safety, and class EYT being the least significant.

Safety Class 1

The first safety class includes nuclear fuel and components whose failure could result in an accident compromising reactor integrity and require immediate actuation of safety functions. Additionally, SC 1 includes the reactor pressure vessel and components of the primary circuit whose failure may cause leakage of the primary circuit that cannot be compensated for by any systems related to normal plant operation (YVL B.2e, p. 5). These components are mechanical and include reactor coolant pumps, main coolant piping and the pressurizer.

Safety Class 2

Systems that are grouped in safety class 2 are designed to provide against postulated accidents and to bring the facility to a controlled state until the prerequisites for shifting to a safe state can be ensured. Structures and components in SC 2 include the main components and piping of the emergency core cooling system, structures of the core support and reactor shutdown system, primary circuit piping, decay heat removal system, the containment building and the fuel storage racks. (TVO 2014; YVL B.2e, pp. 4-5).

Safety Class 3

According to (YVL B.2e, pp. 4-5), the third safety class includes systems accomplishing safety functions that

1. are designed to bring the facility into a safe state over a long period of time
2. are designed for severe reactor accident management
3. accomplish the diversity principle and are designed to ensure the bringing of the facility into a controlled state in case of the failure of systems primarily taking care of a corresponding safety function
4. mitigate the consequences of anticipated operational occurrences unless they are assigned to a higher safety class for some other reason
5. are designed to control reactor power, pressure or make-up water (the main controllers of the nuclear power plant) provided that they, in case of their failure, directly initiate a Safety Class 2 function
6. contribute to fuel handling or lifting of heavy loads and may, in case of their failure, damage structures important to safety or cause fuel failure

7. have been installed as fixed parts of the plant contributing to the monitoring of dose rates and air activity concentration at the nuclear power plant's rooms and monitoring of radioactive substances in the systems or the monitoring of radioactive releases from the plant.
8. are designed to cool spent fuel
9. prevent the spreading of radioactive substances outside the containment
10. essential for the maintenance of control room habitability
11. are essential for the control and management of anticipated operational occurrences and accidents (measurement systems).

Additionally, SC 3 includes buildings and structures that ensure the operability and physical separation of SC 2 systems or SC 3 functions. Structures and components not assigned to higher safety classes and whose damage may cause a significant radioactive release shall be included in safety class 3. The small-diameter piping ($DN \leq 50$) connected to SC 2 piping or equipment shall also be classified into SC 3 as well as leakage control pipes ($DN \leq 20$) of the sealings of primary circuit equipment. Safety class EYT holds equipment that hold no significance in terms of nuclear safety. (YVL B.2e, p. 6)

Classification document and seismic classification

The classification document includes the different classifications of systems, structures and components of a nuclear power plant. According to the Nuclear Energy Decree (sections 35 & 36), the classification document is to be delivered to the authority as part of the construction and operation license application. The document to be updated during the operation of the nuclear plant, and all modifications have to be included. The classification document shall include the marking system for the SSCs, list of systems, system-specific lists of different SSCs in all safety classes. It shall also include flow and main diagrams, conceptual I&C diagrams, safety classification criteria, safety classes of SSCs, connections between safety classes and quality requirements, seismic classification criteria, seismic classification of the SSCs, environmental qualification of the SSCs and software and their recording equipment. (YVL B.2e, p. 7)

Seismic classification categorizes the SSCs of a nuclear power plant according to the seismic requirements set for them. The categories are S1, S2A and S2B, and the categories include certain requirements for the calculations and testing of the classified items, for instance. The categorization guidelines and requirements are explained in more detail in the YVL regulatory guide B.2. (YVL B.2e, p. 6)

2.1.5 Deterministic and probabilistic approach

A risk is either deterministic or stochastic. A deterministic risk considers the impact of a given hazard scenario and a stochastic risk takes into consideration all possible scenarios and their likelihood and associated impacts. The deterministic approach models the probability of an event as finite, and it typically uses known input values to model the output. Probabilistic Risk Assessment (PRA) assesses stochastic risks to obtain qualified estimates of a hazard's frequency and its impacts.

Deterministic approach

NPPs have been designed to sustain damages or unavailability of certain main equipment and safety systems without exceeding preset limits for radiological release. The design makes presumptions of the worst possible events and conditions that are based on expert judgement and statistical methods. The predicted conditions cause loadings, whose effects on components are assessed through computational and experimental methods, and the components are designed and manufactured to sustain these loadings, at a minimum. To carry out the design, the cause-and-effect of the predicted event shall be understood along with associated uncertainties. The acceptability of the design of safety-related components and systems is addressed through safety analyses, which can either utilize a conservative or a best estimate approach. In the conservative approach, the safety analyses are carried out in a manner that considers the uncertainties related to the calculation models and initial assumptions so that the consequences of the event analyzed would be milder than the analysis results. For example, temperature and pressure levels of anticipated accidents are overestimated. The conservative approach is supplemented with sensitivity analyses, where the results of changes in different parameters and methods in a calculation model are assessed. In the best estimate approach, the physical modeling and initial assumptions are as realistic as possible, and it is supplemented with an uncertainty analysis that is justifiable by statistical methods (Sandberg 2003, pp. 96-97 & p. 175, YVL B.3e, pp. 12-13).

The above text described the deterministic approach to nuclear safety. For example, if a pipe break is anticipated, deterministic requirements set the production of the pipe and auxiliary equipment towards manufacturing equipment that sustain 100 % of the presumed conditions during and after the pipe break.

Probabilistic approach

In the probabilistic approach, each input has an output, but neither the frequency of the input nor the resulting output are 100 % certain. For example, a pipe break is not expected to happen with 100 % but the event is assigned a probability according to physical modelling and historical data. The outcome of the situation is dependent on the pipe in question and, for example, on the successes and failures of the relevant safety systems

and operating personnel actions. The frequency and the presumed severity of the pipe break, which constitute the total risk of the occurrence, can then be used as supporting information to define the production and inspection scope of the pipe and auxiliaries. However, the requirements for the production of nuclear-grade components are mostly based on deterministic approach in Finland.

PRA is conducted to support deterministic safety analyses through assessing possible accident scenarios, their probabilities and frequencies. PRA uses historical data of hazardous events along with their ramifications as well as phenomenological models of the physical behavior of systems, structures and components should the events materialize. An important part of the modelling is inclusion of dependencies between the initiating event and the systems needed in response to such an event as well as dependencies between available systems. Additionally, the possible actions of operating personnel are typically taken into account in the modelling of the accident progression. The PRA models hold uncertainties that are associated with the historical data and models, and the uncertainty is included in the assessment results. PRA is conducted for pointing out the risk significance of specific equipment, systems and maintenance procedures, and is therefore a tool to reach balanced plant design. Nuclear facilities are included in a PRA model as an entity that consists of thousands of components in safety-related systems. Each modelled component holds a value for their unavailability, i.e. a probability for not being able to fulfil the intended safety function, which is typically derived from the historical performance of similar components. The PRA model links the components together in order to model the development of accidents, their frequencies and consequences. One of the biggest deliverables of PRA is calculating the overall Core Damage Frequency (CDF). (Sandberg 2003, pp. 126-127)

Evaluations of the performance of individual components are based on failure reports that are collected and modified into reliability data that can be utilized as component-level input in PRA. For reactors by Westinghouse Electric Company (such as Olkiluoto 1 and 2), the reliability data for components is presented in T-book (TUD Office 2010) that contains information collected during 378 reactor operating years in Sweden and Finland.

Participating nuclear facilities send component failure reports regularly to TUD database according to a protocol where information of the failure mode, service place and time of usage are implemented. In addition to usage and failure data, supporting information such as component specifications and environmental conditions is reported to TUD database. The reports are analyzed and approved by an administrator. Then, an algorithm (T-code) uses the failure reports to generate reliability data: time-related failure rates (λ_s and λ_d) and a demand-related failure probability q_0 . Finally, these quantities can be used to calculate steady state unavailability of a component (Q):

$$Q = q_0 + \lambda_s * \frac{TI}{2} + (q_t + \lambda_s * TI) * \frac{t_r}{TI} + \lambda_d * t_d + \frac{t_{FU}}{FUI}, \quad (1)$$

where

q_0 = the probability of time independent failure on demand [dimensionless]

q_t = the probability of time independent failures at tests (usually $q_t = q_0$) [dimensionless]

λ_s = failure rate in standby [failures/h]

λ_d = failure rate under operation [failures/h]

TI = test interval [h]

FUI = interval between preventive maintenance [h]

t_r = active repair time/down time/maximum time for corrective maintenance [h]

t_d = transient time/operating time/demand time [h]

t_{FU} = maximum time for preventive maintenance [h]

In the right-hand side of equation (1), the five consecutive terms stand for:

- Unavailability in standby after the latest test occasion (related to demand).
- Unavailability in standby during one test interval (time dependent).
- Unavailability due to repair.
- Unavailability in operation.
- Unavailability due to preventive maintenance. (TUD Office 2010, p. 39)

The steady state unavailability (Q) is a dimensionless probability (between 0 and 1) that can be implemented into PRA models. Bi-cycle, a program for analyzing the failure rates, allows the user to examine the component-specific failure data in more detail when necessary.

2.1.6 Hierarchy of regulation

International Atomic Energy Agency (IAEA) is an organization within the United Nations and its mission is to promote the safe, secure and peaceful use of nuclear technologies worldwide. One of its tasks is to prepare radiation and nuclear safety guidelines, which are primarily prepared as international cooperation within international committees governed by IAEA. All Member States (168 as of February 2016) have a say in the guideline drafts, and the guidelines represent a consensus of nuclear safety globally. Euratom (European Atomic Energy Community) established the Euratom Treaty, which was signed in 1957 and it lays out the fundamentals of regulatory hierarchy within the EU Members (IAEA 2016; Sandberg 2014, pp. 364-366). The hierarchy in the nuclear regulation is presented in Figure 3.



Figure 3. *General hierarchy of nuclear regulation.*

As visible in Figure 3, the IAEA's top-level guidelines are the basis of national legislation. The practical-level requirements are usually compiled by an independent authority that is different for each country. The government regulates the use of nuclear energy in Finland. The Ministry of Economic Affairs and Employment is responsible for preparing the permission decisions and proposals for the development of the legislation. It also coordinates the development and implementation of nuclear waste management. The Radiation and Nuclear Regulation Authority (STUK) operates under the Ministry of Social Affairs and Health and its mission is to ensure radiation and nuclear safety in Finland. On January 1st 2016, STUK issued regulations concerning the safety of nuclear power plants, and the regulations replace previous Government Decrees on nuclear safety. STUK has the responsibility to prepare, confirm and maintain the regulations. STUK is an independent member who also supervises that the nuclear energy producers meet the requirements set by regulation. The detailed safety requirements are presented by STUK in regulatory guides on nuclear safety (YVL guides). For instance, the YVL guides present the practical-level requirements considering the production of nuclear-grade items that are used in safety-related applications.

2.2 Quality control and quality assurance

According to American Society of Quality (ASQ 2017), quality is "the characteristics of a product or service that bear on its ability to satisfy stated or implied needs". The concept of quality is diverse and it has multiple field-specific interpretations. In the manufacturing industry, the concept of quality dates back to ancient times, but the study of quality has evolved during the last century. As the industrial revolution accelerated in the 1920s, the manufacturing responsibility of a product shifted from one worker to multiple workers with their individual manufacturing stages. Products became more complicated and jobs more specialized, and the need for Quality Control (QC) after manufacturing was apparent (Besterfield 1994, p. 3). QC has a multitude of definitions, depending on culture and location. Juran and De Feo (2010, sec. 6.3.1) define QC as follows: "quality control has as its primary purpose maintaining control. Performance is evaluated during operations, and performance is compared to targets during operations". This means that QC actions provide a feedback loop where the output of a process is evaluated by tests and compared

to the desired output, and any defects are corrected until the output is within a tolerable margin. The data provided in the QC process is primarily kept inside the organization in order to produce high-quality products.

The rapidly increased volume of military equipment during the Second World War elevated the level for quality requirements, and Statistical Quality Control (SQC) was fully utilized as a means to control the quality of mass produced items (VTT 1978, p. 10). SQC utilizes the basic data collection and data analysis by frequency distributions, Pareto principle (the 80/20 rule) and process charts, for instance (Juran & De Feo 2010, sec. 6.11.1).

Starting in the 1950s, the Japanese shook the manufacturing world by establishing quality standards the rest of the world would later emulate. In the 1950s, the concept of Quality Assurance (QA) and quality audits were established, which in turn accelerated the development of quality. QA is similar to QC, but there is a fine distinction that must be understood. According to Juran and De Feo (2010, sec. 6.3.1):

"The main purpose of quality assurance is to verify that control is being maintained. Performance is evaluated after operations, and the resulting information is provided to both the employees and others who have a need to know."

QA consists of all the systematic and planned actions necessary to provide confidence that a product or service fulfills the quality requirements. Typically, the requirements are defined internally by the management or externally by customers, regulators, certifiers or third parties (Besterfield 1994, p. 2). The notion of internal and external requirements is the largest difference in QC and QA, respectively. To sharpen the slight deviation, QC provides information for those directly responsible of their operations (e.g. mechanic), and QA for those not directly responsible for the operations but who have a need to be informed (e.g. the product manager) (Juran & De Feo 2010, sec. 1.13.20).

In the 1950s, the management of an organization took more responsibility of the quality and additional focus was driven towards organizing quality efforts and optimizing costs. The 1960s introduced the development of Total Quality Management (TQM), which is a cross-organizational set of practices aimed to continually improve the ability to deliver high-quality products. (VTT 1978, pp. 10-11)

Since the 1970s, different Quality Management Systems (QMS) were developed in order to satisfy customer needs and expectations by establishing the organizational goals, policies, processes, information and resources to implement, maintain and improve quality. This resulted in various organization-specific guidelines that has sometimes caused multiple audits between the customer and the supply chain, essentially to check compliance to equivalent requirements. This redundant auditing did not add value, which caused the development of quality management system standards, for instance the ISO 9000 standard series. A third party assesses the conformance of an organization to a specific standard

and if conformance is fully demonstrated, the third party issues a certificate to the organization and registers their quality system in a public register (Juran & De Feo 2010, sec. 16.5.1).

2.2.1 Development of nuclear quality assurance

The need for a uniform QA system was realized in the 60s as first nuclear power plants started operation in USA and multiple manufacturers entered the nuclear marketplace. The staple quality level of industrial items at the time was not seen sufficient for safe production of nuclear energy. In the United States, the Atomic Energy Commission (AEC) proposed in 1969 that QA requirements be included in the federal legislation. In 1970, these requirements were included in the amendment 10CFR50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants". The amendment included 18 safety-related criteria which touched all safety-related operations in NPPs. There was, however, misconceptions within the suppliers about what exactly was the criteria required of them, so American National Standards Institute (ANSI) published the standard N45.2 "Quality Assurance Program Requirements for Nuclear Power Plants". The standard presented the general requirements for QA program design and implementation without detailed technical requirements of proving conformance to quality. As the number of reactors increased rapidly in the 1970s, ANSI issued multiple revisions of N45.2 and AEC provided guidance for the implementation of 10 CFR 50 in their "gray book" and regulatory guides. (VTT 1978, pp. 29-30; ASME 2017)

In 1979, the ANSI committee N45 assigned the responsibility for nuclear QA standards to an ASME committee on Nuclear Quality Assurance (NQA), which published the first NQA standard, NQA-1-1979. NQA incorporates the 10CFR50 criteria and has been updated multiple times since then and the latest update is from 2015. These updates have included more demanding requirements for documentation and the introduction of performance-based criteria, for instance. NQA-1 standard is approved by United States Nuclear Regulatory Commission (NRC) and although it is binding only in the USA, it has been integrated as a valid QA standard in other countries such as Finland, where the NQA-1 qualification of a manufacturer is satisfactory to certain requirements. The concepts of NQA-1 have also been adopted into the national regulation of nuclear energy producing countries. (ASME 2017, YVL E.3e, p. 12).

The cost of implementing and maintaining the NQA-1 program is rather large and therefore some component manufacturers choose not to apply for NQA-1 certification. This may result in unavailability of NQA-1 qualified manufacturers of certain components. Components of non-qualified or foreign manufacturers may, however, be qualified for use through a gap analysis of the standard used against NQA-1 to assess equivalence. Commercial-grade dedication is another method for approving commercial-grade items for use in safety-related applications in nuclear facilities.

2.2.2 Commercial-grade dedication in USA

A method to accept commercial-grade items for use in safety-related applications is used in the American nuclear field. The method is called commercial-grade dedication and it allows using components that are not designed and manufactured in accordance with a QA program conforming to 10CFR50 Appendix B whose requirements are included in the NQA-1 Part II standard approved by NRC. The need for such method emerged from the absence of qualified manufacturers, mainly because of the decreased amount of NQA-1 qualified manufacturers in the U.S. The dedication process is defined in the requirements of 10CFR50 and ASME NQA-1 standard. (EPRI 2014; ASME 2017).

Dedicating a commercial-grade item is always conducted by the licensee through a two-stage process. The process includes technical evaluation and an acceptance process. The key elements of commercial-grade dedication are presented in Figure 4.

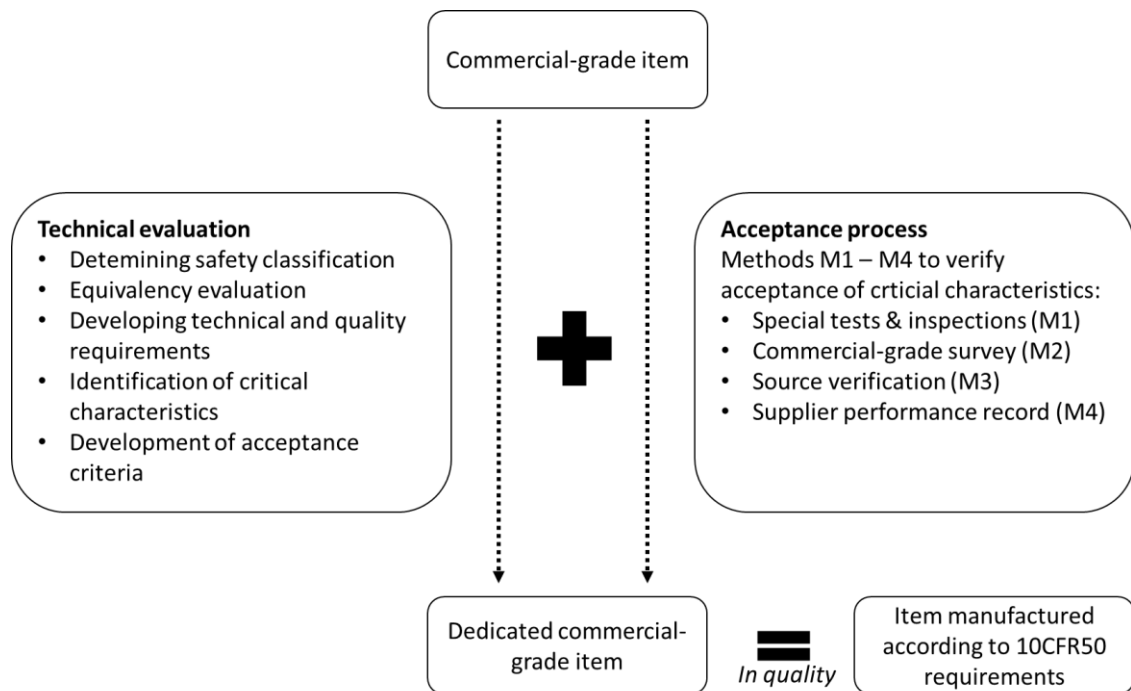


Figure 4. Overview of the commercial-grade item dedication process. Adapted from (EPRI 2014, sec. 3.3).

As seen in Figure 4, the dedication starts with technical evaluation, which ensures that the item is classified and specified correctly. The first part of the evaluation is determining the functional safety classification of the item. The classification determines the scope of the dedication process and if the item is classified as safety-related, it shall be procured as a commercial-grade item and thus dedicated for use in a safety-related application. By equivalency evaluation, the suitability of an alternative item's design is assessed through comparing design characteristics of the original item with the proposed alternative. Critical characteristics are the important design, material and performance characteristics a commercial-grade item must hold in order to provide reasonable assurance of the item's

ability to perform its intended safety function. The critical characteristics shall be identified to later evaluate their fulfilment to the acceptance criteria that shall also be compiled in the technical evaluation phase. (EPRI 2014, sec. 6.1)

In the acceptance process, the organization performing commercial-grade dedication may use one or more of the acceptance methods 1-4 (M1-M4) as presented in Figure 4. The methods are used to verify acceptance of the critical characteristics defined during technical evaluation. Special tests and inspections (M1) are performed by the dedicating organization after the item is received. Method 1 is carried out after receiving the item from the supplier and it may include dimensional checks or Non-Destructive Testing (NDT) procedures in order to assess conformity to a predefined critical characteristic. Commercial-grade survey (M2) is a performance-based supplier assessment conducted in order to determine if the supplier's QC is adequate for ensuring the critical characteristics of the item being dedicated. (EPRI 2014, sec. 4.6)

Source verification (M3) is used to verify the fulfilment of critical characteristic during manufacture through testing. The tests are witnessed by the dedicating organization and are typically related to key milestones of the production process or final testing. The dedicating organization shall define witness and hold points that define their participation in the important tests during manufacturing or final inspection. Supplier performance record (M4) is used to assess the previous performance history of the supplier and the item being dedicated. The extent of using the other acceptance methods is based on this assessment case-by-case. After one or more of methods 1-4 are used, the determination of the item's success in the acceptance process shall be determined and the results documented. If the commercial-grade item meets the acceptance criteria for its critical characteristics, it shall be accepted for use in safety-related applications. (EPRI 2014, sec. 4.6)

3. CASE STUDY FRAMEWORK

3.1 Functional safety in oil & gas industry

The concept of Functional Safety (FS) is a core concept for improving safety in industries of safety significance such as the Oil & Gas (OG) industry. Safety is defined by standard IEC/TR 61508-0 as “freedom from unacceptable risk of physical injury or of damage to health of people either directly through damage, or indirectly through damage to property or to the environment.”

Functional Safety is part of overall safety that depends on a system or equipment operating correctly in response to its inputs. FS includes the safe management of environmental changes, likely human errors and hardware and software failures (IEC/TR 61508-0). An example of functional safety is an overpressure protection device that uses a pressure sensor connected to a control device that controls a relief valve through which the pipeline pressure is lowered should a predetermined pressure condition be violated.

In the FS concept, Safety Instrumented Systems (SISs) are identified. Each SIS holds one or more Safety Instrumented Functions (SIFs). SISs are designed to mitigate or prevent unwanted events by taking a process to a safe state after certain conditions have been violated. The safe state is attained through SIF loops that hold a combination of logic solvers, sensors and final elements (e.g. valve entities). All Safety Instrumented Systems have SIFs, which in turn have a Safety Integrity Level (SIL), which is a measure of safety system performance. To see if an item is suitable for use in a particular SIL environment, the combined SIL rating of all components that contribute to performing the examined safety function must be proved through calculation. For instance, if a valve entity is considered, the calculation of SIL rating must address at least the physical valve, its actuator and a control unit. (General Monitors 2008; Metso 2015)

There are four SIL levels from 1 to 4 in an ascending importance on safety. That is, the 1st SIL level is less critical to safety than the 4th level. The performance of a SIF according to SIL levels is quantified by a Probability of Failure on Demand (PFD) value as presented in Table 1. A Risk Reduction Factor (RRF) is the inverse of PFD.

Table 1. SIL levels with related RRFs and PFDs. Adapted from (SFS-EN 61508-1).

Safety Integrity Level	RRF	PFD
SIL 4	100000 – 10000	10^{-5} - 10^{-4}
SIL 3	10000 – 1000	10^{-4} - 10^{-3}
SIL 2	1000 – 100	10^{-3} - 10^{-2}
SIL 1	100 – 10	10^{-2} - 10^{-1}

To highlight, individual components or assemblies do not hold a specific SIL ratings, but they are suitable for use in specific SIL environments. However, the SIL calculation uses data of the individual components to carry out the final SIL calculation for the assembly of components that contribute to the same SIF. The SIL ratings for specific components are determined through two methods: Failure Modes, Effect and Diagnostic Analysis (FMEDA) and Proven In Use (PIU). FMEDA assesses a component's performance by evaluating the effects of the different failure modes. The failures are divided into safe and dangerous failures, and both safe and dangerous overall failure rates are calculated. FMEDA is audited by an independent body to ensure its quality. The PIU method utilizes historical data of the components' failure rates and evidence of the manufacturers' management systems. (General Monitors 2008).

Achieving functional safety through risk management

More safety can be achieved through decreasing the risk of a given system. When a risk is defined, one must consider the likelihood and impact of an unwanted event, both of which typically hold some uncertainty. When a person experiences risk, it is always a contextual and subjective experience related to the person's risk appetite and the voluntariness and controllability of the unwanted event. For example, the risks of nuclear power are publically perceived as unknown, dread, uncontrollable, inequitable, catastrophic, and likely to affect future generations. This has caused public anxiety nuclear power, although experts perceive the risks of nuclear power as significantly milder. (Slovic 1987)

When an organization seeks to mitigate or remove risks, they must first define their risk tolerance which depends on the organization's philosophy, budget, legislation and other factors. The risk tolerance is unique for each individual and organization. Determining the tolerance level must include subjective and objective assessment that also takes the related uncertainty into consideration. A simple model for risk management is presented in Figure 5.

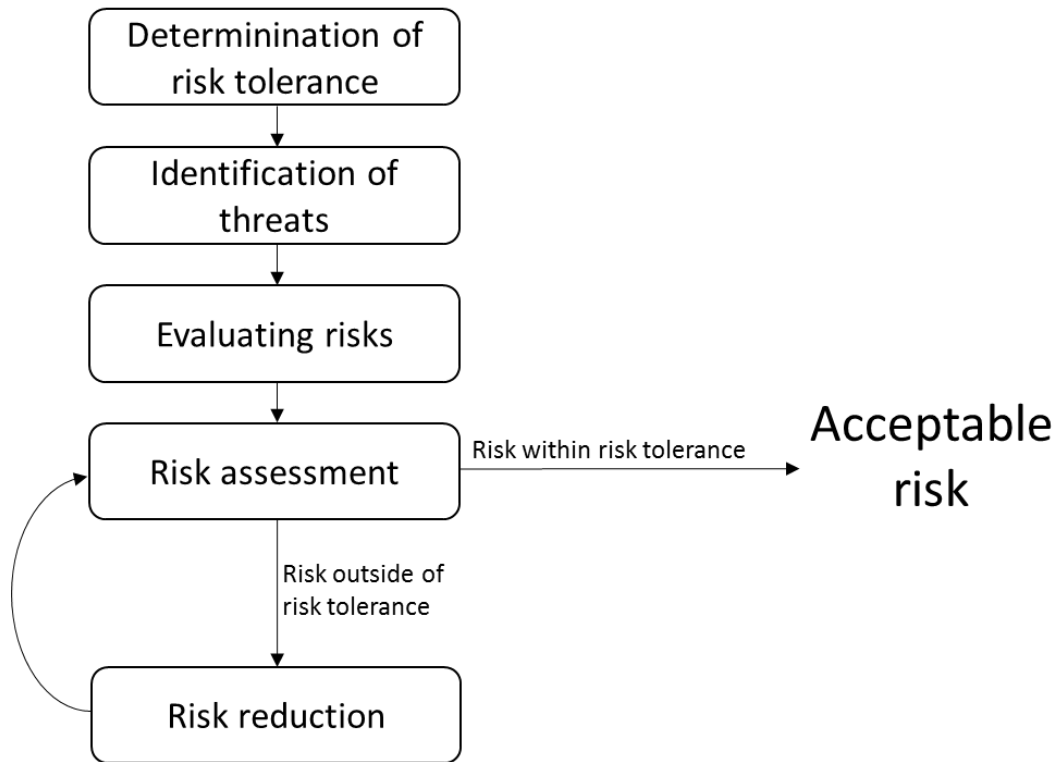


Figure 5. Risk management process.

Threats must be identified in order to evaluate the related risk, which is defined as the frequency of the occurrence of threats (e.g. failures/hour) coupled with the potential consequences of realized threats (health effect, monetary, etc.). Through risk assessment, the magnitude of the identified threats and their impacts are determined by qualitative or quantitative methods. (Kuusela & Ollikainen 2005, pp. 19-20)

Once the risk assessment is done, the risk must be weighed against the organization's risk tolerance. If the risk is within the predefined risk tolerance (e.g. monetary or legislation), the risk is accepted. If the risk assessment results in a risk that's not within risk tolerance, additional measures to reduce the risk must be carried out. Generally, risk reduction is achieved through decreasing the frequency of the threat and/or the impact of an unwanted event. Additionally, risk reduction includes reducing the related uncertainty. For example, uncertainty of a project meeting its schedule may be reduced by assigning additional time to carry out a project. On a systemic level, risks may be reduced through for example conceptual process design, where pinch-points are identified and addressed. If the risk level is still outside of risk tolerance, a SIL level for the SIF is calculated. Process industry companies typically accept SIS designs only up to SIL 2 level, and systemic re-engineering must be done to lower the intrinsic risk. Once a SIL requirement for a SIF has been calculated, the residual risk in a given system can be reduced to an acceptable level by implementing components of suitable SIL rating. Once the SIL graded equipment have

been introduced into the system, the risk assessment is repeated. This risk assessment/reduction loop is continued until the risk is within the risk tolerance and the risk is finally accepted. (General Monitors 2008)

Risks related to safety instrumented systems are mitigated through assigning production requirements that result in an acceptable SIL rating for each component, for example a valve. The oil & gas industry holds processes where valves are of great importance to safety. In the case study in Chapter 5, the requirement comparison is conducted for valves, and therefore basic valve theory is presented next.

3.2 Valve theory

Valves are mechanical devices that are designed to start, stop, direct, mix, or regulate flow, pressure or temperature of a fluid (Skousen 2011, sec. 1.1). Valves can be used in applications that involve single- or multiphase flow. Valves are common items in nuclear facilities, and they are used for many applications. They control, regulate or direct the flow of typically water, steam or air and on some occasion different gases. Valves are located in high- and low-safety systems and have certain safety functions, for example to stop the flow rapidly in order to prevent or mitigate an accident and its consequences.

Valves can be grouped into four categories according to their functionalities:

1. Control valves: flow rate regulation
2. Relief valves: protection from overpressure
3. Check valves: protection from backflow by allowing only single-direction flow
4. Shut-off valves: rapid starting or stopping of the flow.

Control valves are commonly used in applications of the processing industry for their rapid ability to change the flow characteristics towards the wanted direction. Control valve types are many: for example, butterfly, ball, segment, eccentric rotary plug or globe valves can be used as control valves. Selecting a right control valve type depends on the process conditions (e.g. medium, temperature, pressure), the related safety requirements but also largely on end user preferences. Relief valves are commonly used to lower the pressure to a tolerable level, and they are utilized for example in the reactor pressure relief system. Check valves are often included in nuclear applications where assuring a single-direction flow is wanted, for example feed water and dump lines. Shut-off valves are typically used in applications where the primary function is to rapidly close or open the flow of a medium once a predefined condition has been offended. The shut-off valve remains in its position until the condition (pressure, for instance) has returned to an acceptable level. Shut-off valves are controlled by a solenoid or a controller and their actu-

ating force may be provided pneumatically, hydraulically, electrically or by hand. In nuclear power plants, emergency shutdown valves are common and can be used e.g. to shut off steam supply. (Skousen 2011)

Pneumatic shut-off valve

A pneumatic globe valve is a linear-motion valve, where a plug is moved up- or downwards by a pneumatically powered actuator. The actuator provides the force for moving plug up and down in the flow, which affects the flowrate.

Globe valves are generally versatile and can be used in a variety of application, for example flow control and shutoff. The linear motion transfers the actuator's force directly to the regulating element. A globe valve consists of five main components that can be seen in Figure 6.

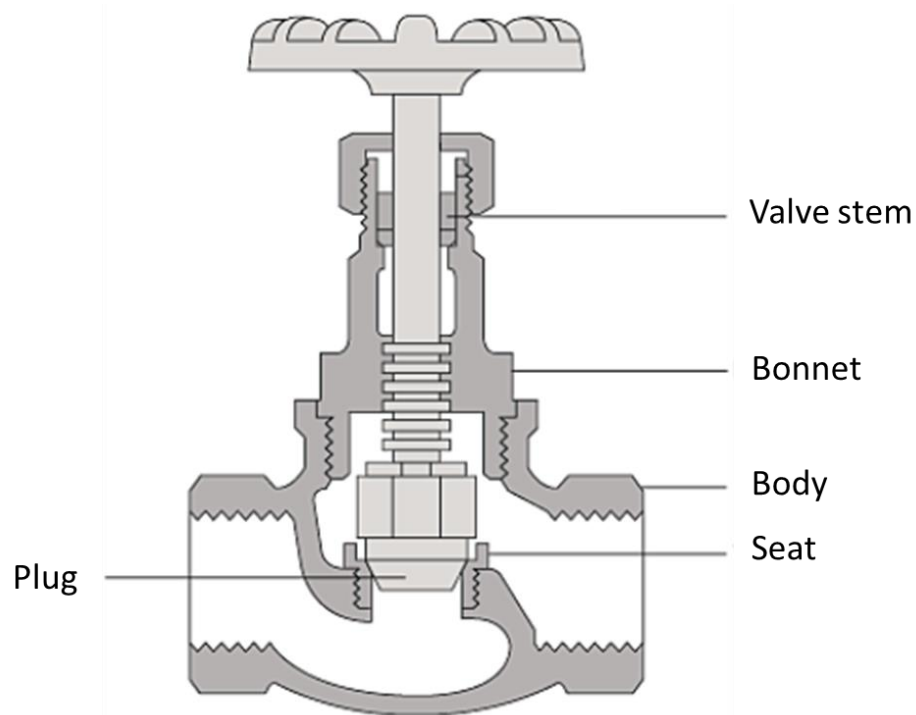


Figure 6. Illustration of a closed globe valve. Adapted from (Spirax Sarco).

A spherical valve body is the element that creates the physical characteristics of a globe valve. The body holds all of the valve's parts that are in contact with the flowing gas. A bonnet is a cover for the valve body and it contains the valve's internal parts. The bonnet can usually be detached for internal maintenance. A bonnet contains the valve body from the surrounding space. The bonnet contains a single packing, which prevents material from leaking outside of the valve. The packing material is wearable and needs to be replaced as time passes. A disc is a regulating element that is moved in a linear manner by the actuating force, which throttles the flow. A valve stem is a force-transferring member that transmits the actuator force from the actuator to the inside of the valve body. The

stem is moved by a handwheel in Figure 6. A seat is a shutoff surface against which the disc is screwed when the valve is shut.

Globe valves withstand process extremities well and can, like most valves, be designed to handle high pressures by increasing wall thickness and using heavier auxiliary parts. Globe valves are therefore applicable in nuclear facilities but they are, however, larger and heavier than a rotary valve of equal capacity, which causes problems with seismic occurrences for their height and weight might damage the pipeline or the valve itself during vibrations. (Skousen 2011, sec. 4.2)

The valve's stem is moved by an actuator. Actuators are typically powered pneumatically, hydraulically or electrically. Example of pneumatic actuator is presented in Figure 7.

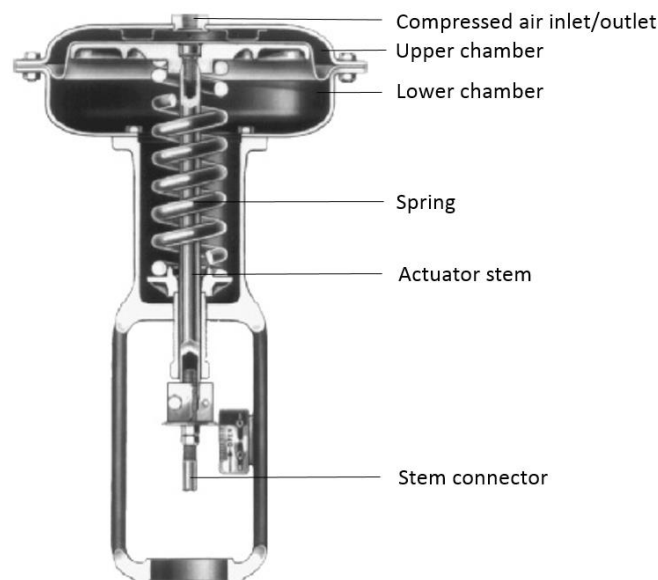


Figure 7. An illustration of a pneumatic actuator in the open position. Adapted from (Skousen 2011, sec. 5.3.2).

When a control element gets a signal that indicates the valve to be closed, compressed air is fed through the inlet to the upper chamber of the actuator casing. The actuator stem is connected to the valve stem, and thus the valve disc moves downwards along with the stems as the upper chamber fills with air, closing the valve and compressing the spring. When the control element gets a signal to open the valve, air pressure in the upper chamber is reduced and the actuator stem moves upward as the spring extends.

4. METHODS AND MATERIALS

In general, a scientific process uses deductive or inductive reasoning to reach a logical conclusion. In deductive reasoning, a predetermined hypothesis is tested against a set of data, whereas in inductive reasoning data is used to form hypotheses and theory. Both of these approaches have their individual problems. According to Ketokivi and Mantere (2010, pp. 316-318), deductive reasoning “sidesteps the question of alternative explanations and focuses instead on testing a single theory for empirical adequacy”, while inductive reasoning holds an “unavoidable logical gap between empirical data and theoretical generalizations”. Thus, the deductive approach is not suitable for drawing new conclusions from data, and therefore it is more commonly used in quantitative research. The inductive approach allows for drawing new conclusions from data, making it more suitable for qualitative research. This research holds both quantitative and qualitative elements, and therefore both of these reasoning approaches are utilized.

4.1 Case study (RQ1 & RQ2)

After introducing the theoretical framework in the previous chapters, a case study was carried out in Chapter 5 to answer Research Questions 1 and 2 (RQ1 & RQ2). RQ1 asks *“Is the requirement specification followed by MFC for their OG shut-off valve deliveries compliant with the requirement specification for nuclear-grade safety class 3 shut-off valves?”* A qualitative approach was used to seek insights for RQ1, as the requirements for the valves’ design, manufacturing and inspection were presented and compared with each other in Section 5.1. RQ2 asks *“is a nuclear-grade item more reliable than a commercial-grade item?”* Insight for this question was inquired quantitatively, where the reliability data of nuclear- and commercial-grade shutdown valves were compared quantitatively. Little previous research exists on comparing the requirements and reliabilities of nuclear- and commercial-grade items. According to Edmondson and McManus (2007, p. 1162), if “little is known, rich, detailed, and evocative data are needed to shed light on the phenomenon”. As a method, a case study allows reaching depth rather than breadth, and was therefore chosen to explore these rather unknown subjects. It was left for future research to evaluate the findings on a broader level.

Requirement comparison (RQ1)

As suggested by Abbt (2016) and Martin (2017), more research is needed to evaluate the the compliance of non-nuclear requirements with nuclear requirements of lower Safety Class (SC 2 & 3) items. To shed light on this topic, the similarities and differences of requirements for the production of nuclear (SC 3) shut-off valve were presented and compared with the production requirements for shut-off valves designated to the oil & gas

industry. This qualitative and comparative approach was selected because requirements cannot usually be assigned with a numerical or explicit value.

Selecting the examined valve began with searching for a safety class 3 valve from the data system of TVO. The primary goal was to select an individual valve manufactured by Metso Flow Control according to the requirements TVO laid out according to the most recent YVL guides (2013 update). The original motive was to compare the production-related requirements of the nuclear valve delivery with a similar delivery to the Oil & Gas (OG) industry. However, reality proved that such valves did not exist. Therefore a decision was made to select a valve type instead. The selected valve type was a shut-off valve, because such a valve (in SC 3) was just procured in 2016 by TVO, and the construction plan and other related documents (TVO 2016a, b & c) were available in TVO's data system. Having data of the requirements of an approved SC 3 valve was seen as helpful in compiling the broader requirement specification for nuclear SC 3 shut-off valves, too. Other data sources for gathering the requirement specification for nuclear shut-off valves were YVL regulatory guides, standards, and TVO's drafts for their Requirement Specification Documents (RSDs) (TVO 2017b & c). A safety class 3 valve was selected, because the majority of valves in nuclear facilities are classified in SC 3 and therefore most potential for future discussion is seen in these valves. The classification bases for SC 3 items can be found in Section 2.1.4.

In the OG industry, refineries and other facilities hold safety-critical processes that contain reactive mediums, high pressures and temperatures. These processes include additionally less critical mediums and conditions such as water or nitrogen. The main difference to the process conditions of nuclear facilities is the number of different mediums and their reactivity, and the fact that some nuclear processes contain radiation. Valve manufacturer Metso Flow Control (MFC) was cooperative during the whole research process. MFC compiled and provided their requirement specification (Metso Flow Control 2017) that is based on their best estimation of general requirements for shut-off valves in the OG industry. In the OG-requirement specification, the requirements are based on the valves' quality class according to the production method, metallurgy, service conditions and fluid. The specification presents requirements for quality class M valves, for they constitute the largest volume of total valves. It must be highlighted that the OG-requirements represent a general requirement level of MFC for shut-off valves in the OG-sector, without penetrating in the detailed or company-specific requirements. Therefore, the results under this method are not generalizable to other non-nuclear equipment or industries as such.

The rather large amount of data in these sources was reduced and transformed for analysis by the researcher during July 2017. All sources for the particular requirements in appendices B.1-B.3 are referred to in the appendices. For clarity, referring to original sources is left out from the tables included in the body text. Valves used in different applications

may hold similar constructions, but the requirements relating to their design, manufacturing and inspections vary. The requirements of the nuclear-grade and OG-grade valves were presented under three themes: design, manufacturing and inspection & testing requirements. Examples of requirements under each theme are given in Table 2.

Table 2. Example of the comparison of nuclear and OGI-grade valve requirements. (TVO 2017b & 2017c; MFC 2017.)

#	Theme	Nuclear	Oil & gas
		Description of requirement	Description of requirement
Design requirements			
1	Design life	Valve parts which cannot be changed during normal maintenance are e.g. valve body, bonnet, stem and yoke shall be designed for whole design life. Valve parts which can be replaced during normal maintenance can be excluded when replacement intervals are planned and given in valve maintenance instructions. Those spare parts shall be marked in the design documentation. Required design life is given in Valve Data Sheet (VDS). (TVO 2017b, 12)	The design shall last in operation for six years and 9000 cycles (except ISO 15848 valves). Replacement of the internal parts shall be possible.
Manufacturing requirements			
2	Material certificates	Material certificates shall be according to SFS-ISO 10204 ² (Metallic products. Types of inspection documents): Valve pressure-retaining main parts: 3.1 Pressure-retaining bolts, obturator, stem: 2.2 Other parts significant for valve integrity or operability: 2.1 (YVL E.8e, App. B)	Chemical composition of materials shall be as per EN 10213 (Steel castings for pressure purposes) or ASTM (American Society for Testing and Materials) standards. Pressure-retaining valve manufacturers conforming to EN 10213 are obligated to request appropriate inspection documentation according to EN 10204.
Inspection and testing requirements			
3	Seat tightness test (with air):	ISO 12266-1, test P12 (Seat tightness), Rate B (for soft-seated valves Rate A). Acceptance: 0.3 x DN. Or some other EN standard like EN ISO 5208.	ISO 12266-1, test P12, rate A. Acceptance: No visually detectable leakage for the duration of the test. Or rate A according to EN ISO 5208.

The actual thematic requirement tables were appended (appendices B.1-B3). For better clarity and readability, terms “nuclear-grade valve” and “OG-grade valve” are referring to a valve that has been produced according to the requirement specification for nuclear safety class 3 shut-off valves and MFC’s requirement specification for shut-off valves, respectively.

Reliability of nuclear-grade vs. commercial-grade items (RQ2)

Reliability data of commercial-grade items is as an argument to qualify non-nuclear items for use in nuclear safety-related applications in USA (EPRI 2014). Additionally, previous research over the Finnish regulation (Wahlström & Sairanen 2001) has asked “can the

deterministic criteria be relaxed if the reliability of the system can be shown to be very high?”

To evaluate the operational reliability of nuclear- and commercial-grade items, the second research question, “*is a nuclear-grade item more reliable than a commercial-grade item?*”, was set to quantitatively compare the failure rates of a commercial-grade valve type and a similar valve type that is used in the nuclear industry. The data gathering procedures and numerical failure rate data were presented. The source for nuclear valves’ failure rate data was T-Book (TUD Office 2010). The failure rates of the commercial-grade valves were calculated with Nelprof, a program by Metso Flow Control. However, the methods for constructing failure rate data were found fundamentally different. This coupled with unavailability of the original commercial-grade failure data were seen as barrier to proceed with the comparison as it appeared in the case study. Answers for RQ2 were additionally sought for qualitatively, more specifically through the interview study. This was done to allow methodological triangulation, which was been said to strengthen credibility of the analysis and findings (Edmondson & McManus, 2007, p. 1157).

4.2 Interview study (RQ2 – RQ5)

A research method should be selected based on the amount of existing knowledge on a topic. If a lot of theory exists on a topic, rigid and well-established methods are used to answer research questions that focus on elaborating or challenging an existing theory. According to Edmondson and McManus (2007, p. 1162), when no or little theory exist on a topic “the research questions are more open-ended than those used to further knowledge in mature areas of the literature”. In this case where the current views of Finnish experts from the nuclear sector are inquired, the amount of existing knowledge is low. Therefore, this part of the research uses an inductive approach, where data is gathered through a semi-structured theme interview.

Interviews provide valuable insight that may be absent or hard to find in literature, technical documents or regulation. A semi-structured theme interview was selected as the interview method, because it was seen practical for this kind of qualitative research where the end result is not as clear as in quantitative research where the questions are predetermined and the answering options are often limited. The semi-structured theme interview is guided by a thematic, topic-centered approach of themes under which the interviewer has predetermined topics to discuss. The conversation may, however, arise more topics to dwell into, and the flexibility of the semi-structured interviewing method allows for interactional dialogue between the participants (Edwards & Holland 2013, p. 3).

The interviewed persons were part of three different organizations that operate in the nuclear industry: licensee (Teollisuuden Voima Oyj, TVO), authority (STUK) and manufacturer (Metso Flow Control, MFC). This study was conducted as an assignment for the licensee (TVO) that is currently one of two operative nuclear power companies in Finland

(along with Fortum Oyj). TVO was therefore a logical participant in the interviews, as was STUK, who compiles the practical requirements nuclear-grade items must comply with. MFC is a valve manufacturing company that delivers valve to mostly conventional industries such as the oil & gas sector, but holds some experience on nuclear deliveries, and this background was the reason MFC was selected for this interview study.

The interviewer was the same person that conducted this research in its entirety. Coming from a technical field, the researcher was new to qualitative research so this study was a learning process. In addition to extensive review of methodological literature, insights for conducting the interview section were inquired from academic advisors and a social science graduate student, who holds extensive experience on qualitative research also from working life (thanks Rita). It must be noted that prior to starting this research, the researcher had worked at TVO for three months during the summer of 2016.

The interviewing process is multilateral, and therefore it was crucial to plan ahead and engage in open communication throughout the process. The interview study process is presented in Figure 8.

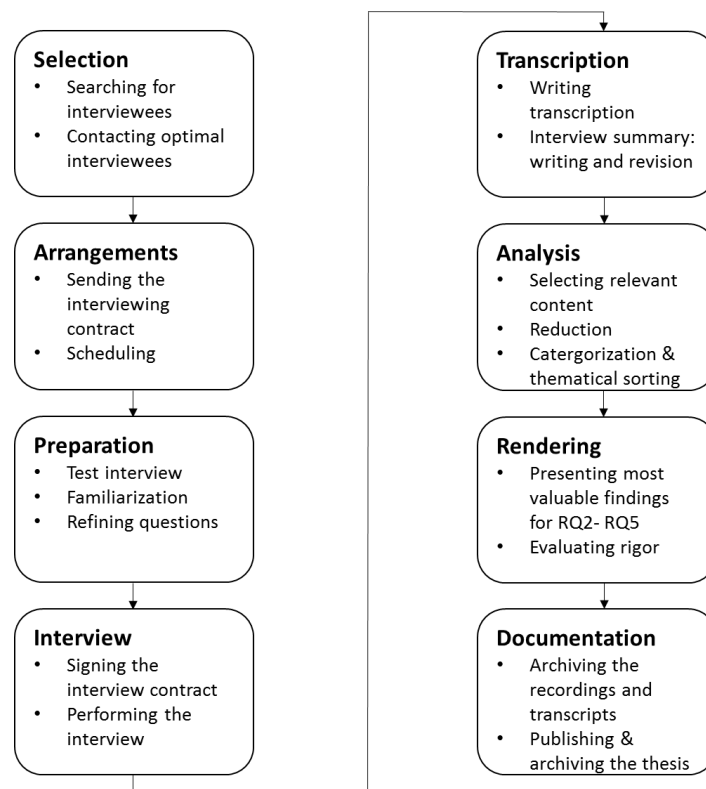


Figure 8. The interview study process.

Three persons from different branches within each organization were selected and approached through an email or a phone call, and the purpose of this interview was elaborated. After agreeing to be interviewed, the interviewees received an interview contract (Appendix C) by email, where the interview's objective and anonymity were addressed.

The exact positions of the interviewees were excluded from this study in order to preserve anonymity and promote unrestricted answers.

Before the actual interviews, a test interview was held in order to see how the interview structure works and to point out possible deficiencies. This way the interviewee gained experience of the whole interviewing process and was able to perform certain corrective maneuvers before the actual interviews. Additionally, the interviewer prepared for each individual interview in order to familiarize himself with the interviewee and his/her position. This was hoped, according to Koskinen *et al* (2005, pp. 118-120) to help present more detailed questions that experts may find more interesting and fresh than broad questions, which they have possibly already answered in previous occasions. Additionally, familiarization was hoped to produce more fruitful conversation and promote unique findings that may have been absent in previous research.

The interviews were held in-person at the workplace of each interviewee. Both the interviewee and interviewer signed the physical interview contract prior to starting the interview. Applying the safety principle of redundancy, the interviews were recorded using two recording devices should the primary recording device fail. The discussed topics were similar, but as the semi-structured interview format allows for more detailed exploration, certain topics were discussed more extensively with some interviewees. This allowed the interviewer to present more accurate questions specific to the interviewees' expertise and to present follow-up questions when needed. During the interview, the researcher tried to remain as objective as possible, yet still aware of his own preconceptions and biases. Because the interviewees were experts on different fields, all topics were not discussed with all interviewees. The recordings were transcribed into text format within 48 hours of the interviews. The transcription was done manually to protect the interviewees' anonymity from the uncertainties related to automatic transcription software. Additionally, manual transcription was used to ensure that the researcher would be familiar with the material prior to analysis.

A summary of the interviews was compiled and sent to each interviewee before starting the analysis. The summary included the most valuable interview findings, both in bullet points and in phrases. This allowed the interviewees to review the interviewer's perception of their message, and to correct any misinterpretations. Additionally, the interviewees could point out any classified information they would like to have censored from the public version of this study. This was hoped to promote unrestricted and honest answers and to increase openness between the stakeholders. Upon receiving the summary, an interviewee of the authority's organization (Authority #1) informed the researcher having not understood that the interview content may be directly quoted from word to word, and wanted the direct quotes excluded from this study. This is the reason why Authority #1's columns "*Original answer in Finnish*" and "*Translated Answer in English*" are left blank in Appendix A.1.

After receiving approval for the summary, the transcription was coded and analyzed from a realistic perspective, focusing solely on the factual content of the transcription without any interpretations of the style or tone of the answers. That is, the focus was only on what was said, not on how it was said. The analysis was done with as little subjective presumptions as possible, according to the researcher's perception of what was the most relevant content. It is good to keep in mind that the relevancy of each comment reflects the researcher's own biases, views and assumptions. Additionally, the positions of the interviewees are to be acknowledged when interpreting their answers. The coding started with selecting the most relevant phrases by highlighting the transcriptions by hand, using paper and pens. The second step was moving the selections into tables (Appendices A.1 – A.3). After that, the selected phrases were reduced for eliminating any non-relevant content and to help with categorization. The original answers and the reduced answers were translated to English, because the interviewing language was Finnish. The risk of losing valuable information in the translation phase was noted, but the benefits of using Finnish as the interviewing language to acquire in-depth material were seen to outweigh the risks of missing certain distinctions in the translation process.

In the categorization, the most relevant content of the interviewees' answers was divided first into bottom categories, which include certain keywords like "Material selection" and "Quality of production". Additionally, the bottom categories were conceptualized into top categories according to Tuomi and Sarajärvi (2002). The top categories were described by keywords like "Reliability", after which a theme was assigned for each answer. The categorization was designed to help the discussion by making it easier for the researcher to point out commonalities between the answers and thus make further analysis more straightforward. After the categorization, the selected content was thematically sorted into three major themes:

1. Reliability of commercial-grade items vs. nuclear-grade items
2. Harmonization
3. Reasons for higher costs of nuclear vs. commercial-grade items.

These themes emerged from the data itself. The aforementioned coding procedures were found helpful for filtering such a massive amount of raw data. The coding resulted in the appended tables that hold the original answers, reduced answers, categories and themes. An example of the analysis is presented in Table 3.

Table 3. An example of the interview table (Appendix A.1).

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English
Authority #2 A.1.2.5	Näkemyksen standardilaitteiden luotettavuusdata käytökelpoisuudesta turvallisuusluokiteltujen laitteiden kelpoistuksessa?	What is your view on utilizing reliability data in qualifying safety classified equipment?	<i>Tokihan sitä voi hyödyntää, et jos se tehdas on sarjavalmisteiseen tuotantolinjaan säädetty niin ei se pahaa tee se luotettavuustietokaan, mutta että kuinka paljon siihen voidaan luottaa niin se täytyy varmistaa. Laaduntuottokyvyn varmistaminen on tärkeintä. Sen kun pystyy osoittamaan ja sitten nää lisävaatimukset eivät ole niin velvoittavia kaikin puolin.</i>	<i>It [reliability data] can sure be utilized if the factory is tuned to serial production, it doesn't hurt to have reliability data, but the level to which it can be trusted must be assured.</i>
Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Laaduntuottokyky on tärkeintä. Luotettavuustieto on hyvää, mutta siihen sisältyy epävarmuutta.	The ability to produce quality is th priority. Reliability data is great, but it comes wiht uncertainty.	Quality of production Reliability data Uncertainty	Reliability	Reliability of commercial-grade items vs. nuclear-grade items

In Table 3, the columns were divided into two sublayers because of the portrait orientation of this page. The full interview tables can be found in Appendixes A.1 (Authority), A.2 (Licensee) and A.3 (Manufacturer). The appendixes have a landscape orientation for better readability. In the first column, the identifier “A.1.2.5” is there to help the reader identify the comment from the Appendixes: “A.1” is the appendix number, “.2” refers to the second interviewee of three. The “.5” is referring to the interviewee’s fifth comment of this interviewee. The phrases of each interviewee were painted with a different color for better readability and clarity. The phrases that were selected for quotation in Chapter 6 are highlighted in the appendixes with yellow color so that the reader may easier locate the phrases in the appended tables. After each interview table, a summary was included that holds information of the location and timespan of the interviews, and also the number of each interviewees’ answers. This was hoped to build a transparent viewpoint to the whole interviewing process.

5. CASE STUDY RESULTS

This chapter answers the first two research questions (RQ1 & RQ2):

- **RQ1:** Is the requirement specification followed by Metso Flow Control for their Oil & Gas shut-off valve deliveries compliant with the requirement specification for nuclear-grade Safety Class 3 shut-off valves?
- **RQ2:** Is a nuclear-grade item more reliable than a commercial-grade item?

RQ1 is answered through comparing the general production requirement specification for nuclear-grade safety class 3 shut-off valves to the requirement specification valve manufacturer, Metso Flow Control (MFC), follows for their shut-off valves deliveries for oil & gas customers. RQ2 is answered through a quantitative comparison of the failure rates of nuclear- and commercial-grade items.

5.1 RQ1: Is the requirement specification followed by MFC for their OG shut-off valve deliveries compliant with the requirement specification for nuclear-grade SC 3 shut-off valves?

The OG-valve's requirement specification (Metso Flow Control 2017) was compiled and provided by valve manufacturer Metso Flow Control (MFC) that is a part of Metso, one of the largest industrial companies in the world. In 2016, MFC accounted for 24.4 % of Metso's total sales of 2586 M€ (Metso 2017). MFC operates globally and their main customers operate in the pulp & paper and oil & gas industries. MFC provides a variety of valves and services for their customers around the world, and they were selected as a partner because they hold some experience with nuclear deliveries, although it need be stated that the nuclear sector is a minor customer for them. Their focus on the OG-sector was seen to deliver a valuable viewpoint to a non-nuclear industry. MFC was cooperative during the whole research process from February 2017 to October 2017 (8 months), and multiple emails and phone calls were exchanged during this period.

The requirements and related standards are presented thematically in order to build a frame under which the extent of the requirements may be discussed. The thematic requirement tables are appended (Appendixes B.1 – B.3). The themes are as follows:

1. Design requirements (Appendix B.1)
 - General design
 - Analysis
 - Functional and safety
 - Environmental

2. Manufacturing requirements (Appendix B.2)
 - Manufacturer
 - Special processes
 - Materials
3. Inspection and testing requirements (Appendix B.3)
 - Materials
 - Welds
 - Factory tests
 - Inspection prior to shipment

Themes two and three are weighed most heavily because benchmarking the manufacturing and inspection requirements is seen as most potential for future discussion. This comparison mostly excludes auxiliary valve components such as controllers, actuators and limit switches and it focuses on the valve's pressure-retaining parts, in order to keep the extent of this case study manageable.

5.1.1 Design requirements

General design requirements

General requirements include standards and common guidelines the valve design shall comply with. Conformity to Pressure Equipment Directive (2014/68/EU) is required of both the nuclear and the OG valve designs, although a specific PED module was not defined in the nuclear requirements. The OG-valve is designed according to PED module H (full quality assurance). The nuclear requirements, particularly guide YVL E.8e state that the structural design of SC 3 valves shall be based on a design generally applied by the valve manufacturing industry, whereas the OG-specification assigns certain standards such as ASME B16.34 (Valves – Flanged, Threaded and Welding End), ASME Boiler and Pressure Vessel Code (BPVC) (Section VIII, Div. 1) and API that shall be followed in the design. The design life for nuclear-grade SC 3 valves is based on the design basis lifetime of the valve whereas the OG-specification set a concrete time/cycle endurance goal of six years or 9000 cycles for the valve.

Design analysis requirements

Analysis requirements define the physical modelling that is needed to conform the suitability of the valve to its service place. For the nuclear valve type, a defined set of analysis requirements relating to dimensioning and stress-, fatigue-, seismic- and hazard analyses is presented. The level of a nuclear valve's design analyses must be in relation to the environmental conditions and potential accidents that are specified in the design bases that take into account the valve's location in the nuclear facility. The OG-specification

refers to analysis requirements in ASME or API standards, which do not present specific analysis requirements. Seismicity and hazard analysis (e.g. for airplane crashes) are emphasized in the nuclear requirements in service places where the design basis conditions include such threats. The OG-specification does not directly require such analyses, but paragraph UG-22 (loadings) in ASME BPVC (Sec. VIII, Div. 1) defines loadings such as dynamic reactions, impacts and seismicity the design shall consider.

Functional and safety design requirements

Functional & safety design requirements refer to the valve's design concerning its ability to fulfil the intended safety-relevant tasks. The OG-specification sets a strict rule that a shut-off valve shall sustain a temperature of 1200 °C for 30 minutes whereas the nuclear requirements emphasize the need for design basis fire tolerability. The design of both nuclear and OG-valves must allow fail-safe position. Stroke time of nuclear shut-off valves is dependent of the service place, whereas the OG-specification details specific stroke times according to the valve's nominal diameter. The pressure drop of a reduced bore is made by the licensee after receiving the pressure drop data from the manufacturer's previous products, whereas the pressure drop of OG-grade valves is more specific with a maximal allowable reduction of 0.2 bar. For nuclear-grade valves, the noise level of valves is restricted max. 85 dB during normal operation. The OG-specification does not set any requirements considering noise.

Environmental design requirements

Design requirements considering the environment cover specific environmental conditions the valves must sustain. Again, the nuclear requirements stress the importance of meeting design bases requirements. The OG-specification lays out specific environmental conditions the shut-off valves must be designed to sustain. These conditions include ambient temperatures from -40 °C to +80°C and strong winds (>40 m/s). The integrity of OG-grade safety valves in zones with fire risk must be maintained, whereas nuclear requirements do not specify detailed fire-safety requirements other than those included in the basic industrial valve design standards their design must comply with. The design of OG-grade shut-off valves in potentially explosive environments shall conform to safety requirements in Directive ATEX 2014/34/EU (equipment and protective systems intended for use in potentially explosive atmospheres), whereas nuclear-grade valves' design must consider explosion pressure effects when required in the service place. The most relevant design requirements of the scrutinized valve type are presented in Table 4.

Table 4. *Most relevant design-related requirements of nuclear and Oil & Gas –grade shut-off valves.*

Requirement theme	Nuclear (SC 3)	Oil & Gas
General design	<ul style="list-style-type: none"> • PED • Structural design according to generally applied design standards by the valve manufacturing industry 	<ul style="list-style-type: none"> • PED Module H • ASME B16.34 • ASME BPVC VIII, DIV. 1 • API standards
Analysis	<ul style="list-style-type: none"> • Specific dimensioning & analysis requirements per service place • Seismic analyses must be done if seismic classification requires 	<ul style="list-style-type: none"> • Analyses per ASME or API standards • Loadings shall be considered in the design
Functional & safety	<ul style="list-style-type: none"> • Design must meet design basis conditions • Max. 85 dB noise at 1 m 	<ul style="list-style-type: none"> • Detailed limits for fire tolerability, stroke time and pressure drop • No noise limit
Environment	Service place –specific environmental conditions must be sustained	Specified environmental conditions must be sustained

As seen in Table 4, general design for nuclear-grade valves can be done according to the OG-requirements. Specific requirements relating to the service places of nuclear valves differentiate the analysis and environmental requirements of scrutinized valve types.

5.1.2 Manufacturing requirements

Manufacturer

The Quality Management System (QMS) of nuclear valve (SC 3) manufacturers shall adhere to ISO 9001 (Quality Management Systems - Requirements) standard or equivalent standard that has been audited by a third party. The Oil & Gas –manufacturers must meet the ISO 29001 (Petroleum, petrochemical and natural gas industries. Sector-specific quality management systems. Requirements for product and service supply organizations)

standard, which fulfills ISO 9001 and includes specific requirements for equipment suppliers in the O&G industry. The QMS of subcontractors of nuclear SC 3 valves shall be assessed by the manufacturer. ISO 29001 (7.4.1) lays down similar requirements for the OG-grade valves. Both nuclear and OG specifications require that the extent of surveillance shall be determined according to the effect the subcontractors have on the product.

Special processes

This theme covers requirements for special processes used in the manufacturing. Special processes include welding, heat treatment as well as hot and cold working. Valve manufacturers that use special processes on valves' pressure retaining parts shall apply for workplace specific approval from STUK (YVL E.8e, p. 7), whereas OG valve manufacturers don't have such requirement.

Manufacturers that perform welding on nuclear SC 3 valves shall be certified for quality assurance according to SFS-EN ISO 3834-2 (Quality requirements for fusion welding of metallic materials. Part 2: Comprehensive quality requirements). If the manufacturer is authorized by ASME N-stamp, ISO 3834-2 and ISO 9001 are automatically covered. The welders shall be qualified according to SFS-EN ISO standards (such as SFS-EN ISO 9606-1) in question and certified by a third-party organization. Valve manufacturers using welding in the OG-industry shall have qualified procedures according to ISO 11970 (Specification and qualification of welding procedures for production welding of steel castings) or ASME Division IX (Welding, Brazing, and Fusing Qualifications). The welders shall have qualification according to EN 287-6 (Qualification test of welders. Fusion welding. Part 6: Cast iron), ISO 9606-1 (Qualification testing of welders. Fusion welding. Part 1: Steels) or ASME IX.

Welding repairs of nuclear-grade valves shall have equivalent strength properties with the base metal, whereas weld repairs of OG-grade valves shall use the base metal as welding material. Both nuclear and OG-specifications allow weld repairs for casted valves. Weld repairs on forged OG-valves are forbidden, but it is possible for nuclear-grade valves should STUK or an authorized inspection body (IO) approve the repair construction plan.

For nuclear SC 3 valves, standard SFS-EN ISO 17663 (Quality requirements for heat treatment in connection with welding and allied processes) shall be followed when welding is done in conjunction with heat treatment. The OG-specification stresses that the weld shall be impact tested after post-weld heat treatment to verify toughness at minimum temperature.

Materials

Material properties of nuclear-grade valves shall sustain design basis conditions and related phenomena such as fatigue, wearing, corrosion, cavitation, corrosion and radioactivity. Pressure-retaining parts of OG-valves shall be constructed of materials according to their pressure-temperature rating per ASME B16.34 Table 1. Identical materials in accordance with the ASME BPVC, Section II (Materials) may also be used for these parts.

The nuclear-grade SC 3 valves shall have material certificates according to standard SFS-ISO 10204 (Metallic products. Types of inspection documents) as follows:

- a. Valve pressure-retaining main parts: 3.1
- b. Pressure-retaining bolts, obturator, stem: 2.2
- c. Other parts significant for valve integrity or operability: 2.1

The chemical composition of casted OG-valves' materials shall be as per EN 10213 (Steel castings for pressure purposes) or ASTM (American Society for Testing and Materials) standards. Pressure-retaining valve manufacturers conforming to EN 10213 are obligated to request appropriate inspection documentation (material certificates) according to EN 10204.

Materials for both nuclear and OG valves with no direct conformance to PED shall have a Particular Material Appraisal (PMA) to demonstrate compliance with essential safety requirements of PED. PMA is a process by which the pressure equipment manufacturer ensures that each proposed material that is not in a harmonized standard or covered by a European Approval for Materials (EAM) conforms to the applicable Essential Safety Requirements (ESR) for materials.

Welding material for nuclear valves shall be approved per ASME II C (Specification for welding rods, electrodes and filler metals), or for justified reasons other classification standards shall be followed. Welding material for nuclear valves shall have certificates per EN 10204 as follows:

- a. Pressure-retaining valve welds: 3.1
- b. Welded claddings: 2.2
- c. Other welds significant for valve integrity or operability: 2.2

A corresponding standard may also be used to verify material conformity. Welding material for OG-grade valves shall comply with ASME IX.

The content of material elements that could become activated when in contact with primary circuit water (not typical in SC 3 valves) is restricted. The concentration of such elements is required to be low enough not to have any significant effect on the radiation

level of the nuclear facility. Therefore, valves having a wetted surface area (area in contact with primary circuit water) bigger than 100 cm² must hold a material certificate that includes cobalt content analysis. Such requirements are not given in the OG-specification. Table 5 presents the key requirements for the manufacturing of the scrutinized valves.

Table 5. *The most relevant requirements for the manufacturing of nuclear and OG-grade valves.*

Requirement theme	Nuclear (SC 3)	Oil & Gas
Manufacturer	Third party audited Quality Management System such as ISO 9001	ISO 29001 QMS (incl. ISO 9001 requirements)
Subcontractor	Graded subcontractor surveillance	Graded subcontractor surveillance
Welding	<ul style="list-style-type: none"> Quality Assurance: SFS-EN ISO 3834-2 or ASME N-stamp Welder approval: ISO 9606-1 	<ul style="list-style-type: none"> Welding procedures: ISO 11970 or ASME IX Welder approval: ISO 9606-1
Weld repairs	Weld repair must have equal strength properties to base metal	Weld repair material must be equivalent to base metal
Welding with heat treatment	SFS-EN ISO 17663 must be followed when combining welding and heat treatment	Impact tests shall be conducted after post-weld heat treatment to verify toughness at minimum temperature
Materials	Materials shall sustain design basis conditions	Materials shall be per the valve body's pressure-temperature rating
Material certificates	Per SFS ISO 10204	Per EN 10213 (with reference to ISO 10204)
Welding material	<ul style="list-style-type: none"> SFS EN standards ASME BPVC Section II C Material certificates as per SFS ISO 10204 	ASME IX
Materials with potential to activate	<ul style="list-style-type: none"> Cobalt content analysis if $A_{wetted} \geq 100 \text{ cm}^2$ 	Not specified

The most remarkable notion in Table 5 is the Quality Management System (QMS) requirement. In the OG-specification, the requirement is ISO 29001 that is a lot more demanding than the nuclear requirement ISO 9000. Having a demanding QMS certificate can be seen as a proof of general ability to provide quality, so this can be seen as a bonus for the oil & gas requirement specification.

5.1.3 Inspection and testing requirements

Inspection and testing requirements proved to constitute the largest volume in this requirement comparison. The nuclear and oil & gas specifications present a multitude of different inspection and testing requirements. This section presents most relevant requirements in order to present the similarities and differences in the requirement levels of these fields. The contents of this section were compiled based on the appended (Appendix B.3) inspection and testing requirement table, where also references for the requirements can be found.

Participation in inspections

The requirements for participation in the inspections differ between the nuclear and OG-fields. As a part of the construction plan, the nuclear licensee is required to provide an Inspection and Testing Plan (ITP), where hold and witness points are defined for the inspection and testing procedures. The construction plan and thus the ITP shall be approved before a construction inspection. The entities conducting the hold and witness points (licensee, STUK, IO) must be defined in the ITP. For SC 3 valves, it is typical that an inspection body authorized by STUK may conduct the inspections. The inspection and testing requirements are presented under four main themes.

1. Inspection of materials
2. Inspection of welds
3. Factory tests
4. Inspection prior to shipment

The oil & gas requirement specification is not based on authoritative regulation, but on requirements set by large oil & gas companies. These requirements demand that the frequency and extent of inspection during and after production shall be defined by the customer, i.e. the entity placing the order. The oil & gas specification lays out a customer attendance requirement of 100% for critical or specific valves (comparable with SC 1 and 2 valves). The requirement for standard valves is 10% for each valve type (comparable with SC 3 valves). The required inspection of nuclear (SC 3) and oil & gas shut-off valves scope is presented in appendix B.3 and is referred to in the following text when relevant.

Inspection of materials

Material inspection and testing is based largely on Non-Destructive Testing (NDT) in both the nuclear and oil & gas requirements. The qualification of nuclear valve NDT examiners shall be per ISO 9712 (Non-destructive testing. Qualification and certification of NDT personnel) with minimally a Level 2 qualification or an equivalent qualification system. A Level 1 tester may perform exposure required for Radiographic Testing (RT). The same standard is used to qualify NDT examiners in the OG-field, but the requirement is less demanding: a Level 1 tester level for all NDT tests with a Level 2 tester interpreting the results.

For nuclear SC 3 valves, following NDT standards are used:

- Visual inspection: SFS-EN 13018 (Non-destructive testing. Visual testing. General principles).
- Penetrant Testing (PT): ISO 3452-2 (Non-destructive testing. Penetrant testing. Part 1: General principles).
- Magnetic particle Testing (MT) before hard facing: ISO 9934-1 (Non-destructive testing. Magnetic particle testing. Part 1: General principles). After hard facing: ISO 17638 (Non-destructive testing of welds. Magnetic particle testing). MT is conducted only for ferromagnetic materials.
- Radiographic Testing (RT): ASME Sec. V, Art. 2 (Radiographic Examination).

For oil & gas shut-off valves, following NDT standards are used:

- Visual inspection: MSS SP-55 (Manufacturers Standardization Society - Quality Standard for Steel Castings for Valves, Flanges and Fittings and Other Piping Components - Visual Method for Evaluation of Surface Irregularities).
- PT: ASTM E165 (Standard Practice for Liquid Penetrant Examination for General Industry).
- MT: ASTM E709 (Standard Guide for Magnetic Particle Testing). MT is conducted only for ferromagnetic materials.
- RT: MSS SP-54 (Radiographic Examination Method).
- Ultrasonic Testing (UT): ASTM A609 (Standard Practice for Castings, Carbon, Low-Alloy, and Martensitic Stainless Steel, Ultrasonic Examination Thereof).

The material inspection requirements are presented for castings, forgings and machined surfaces. Before hard facing of casted nuclear valve parts, visual inspection and PT shall be done for all parts. MT shall be carried out per ISO 9934-1. After hard facing of all casted valve parts, visual inspection and PT is done and MT shall be according to ISO 17638 for ferromagnetic materials. Spot-check (random) RT shall be done before and after hard facing. There's no requirement for UT.

For 100 % of casted OG-valves, visual inspection, PT and MT are required. Additionally, 100 % of valve bodies, bonnets, covers and 10 % of the body necks of the castings and are subjected to RT and UT. Microstructure examination is not required of SC 3 nuclear valves, whereas microstructure of casted OG-valves shall be tested per ASTM

A262 (Standard Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels).

Forged nuclear valves are subjected to equal inspection requirements as casted nuclear valves. 100 % of forged bodies, bonnets and covers of OG-valves are required to be visually inspected. Complete PT and MT examination is required for 10 % of each batch. The requirements for UT and RT are excluded with forged valve parts.

Machined surfaces of nuclear valves shall be subjected to equal inspection regime as castings and forgings whereas in the OG-sector, the inspections should be performed on raw parts (free of machining), except for inspections relating to seating surfaces and flange facing machining. 10 % of male-female and tongue-and-groove faces are to be subjected to a 100 % PT. Also 100 % of Ring Type Joints (RTJ) are subjected to PT.

Inspection of welds

For nuclear valves, the inspection of all weld filler materials shall comply with PED, common SFS-EN standards or ASME BPVC Section II (Specifications for Welding Rods Electrodes and Filler Metals). Their material certificates shall be per appendix B.2. The weld material tests shall include e.g. composition examination, tensile/hot tensile and impact testing. Weld materials of casted oil & gas shut-off valves shall be according to EN ISO 11970 that defines mandatory tests including:

- a. 100 % Visual inspection
- b. 100 % RT or UT
- c. Transverse tensile testing: 1 specimen per batch
- d. Impact test: 2 tests per batch

Additional tests (micro- or macrostructure, hardness, etc.) shall be done according to customer specification. For body-bonnet welds of forged valves, 5 % of each batch are subjected to RT and PT or MT. Inspection of the validity of Welding Procedure Specifications (WPS) of nuclear valves shall be according to EN ISO 15614-1. The oil & gas valve's reference standard is EN ISO 11970.

Factory tests

Factory tests of nuclear SC 3 shut-off valves include tests of pressure (hydrostatic), tightness and functionality. The tightness tests may be performed prior to the construction inspection, and the pressure and functional testing shall be conducted in conjunction with the construction inspection. Nuclear valves are not subjected to test concerning fugitive emissions, unlike OG-valves that are located in areas that hold volatile air pollutants and hazardous fluids. The factory test standards with their acceptance criteria are presented in Table 6.

Table 6. Standards and acceptance criteria for factory testing of nuclear SC 3 and oil & gas shut-off valves.

Nuclear (SC 3)		Oil & Gas	
Standard	Acceptance criteria	Standard	Acceptance criteria
Pressure test (hydrodynamic)			
ISO 12266-1 Test P10 (Shell strength)	$P_{\text{test}} = 1.5 \times P_{\text{max, RT}}$, $t_{\text{test}} (\text{DN } 100) = 3 \text{ min.}$ No visually detectable leakage from any external surface of the shell is permitted)	ASME B16.34	$P_{\text{test}} = 1.5 \times P_{\text{max, } 38^\circ\text{C}}$ $t_{\text{test}} (\text{DN } 100) = 1 \text{ min.}$ Visually detectable leakage through pressure boundary walls is not acceptable
Shell tightness test			
ISO 12266-1 Test P11	No visually detectable leakage is permitted.	ISO 12266-1 Test P11	No visually detectable leakage is permitted.
Seat tightness test			
ISO 12266-1 Test P12 ¹	Rate B (0.3 x DN)	ISO 12266-1 Test P12 ²	Rate A (No visually detectable leakage for the duration of the test)
Functional test (FAT)			
ISO 12266-2 Test F20 (Operability)	The test shall confirm: a. Ability of the assembled valve to open and close fully and, as applicable b. Correct operation of the position indicators and/or other auxiliary devices Attendees: Witness point for Licensee and IO/STUK	According to customer standard	Conforming a. Adequate opening/closing of the valve b. Travel times c. Maximal pressure differentials d. Solenoid valves and actuator checks

¹ Or some other EN standard like EN ISO 5208

² Or rate A according to EN ISO 5208

In Table 6, it is seen that most factory tests can be done according to similar standards and tests, and sometimes even according to the same acceptance criteria. However, there is some variation, for example in the functional test requirements.

Inspection prior to shipment

The final stage of inspection and testing of manufacturing is the referred to in the nuclear field as “construction inspection” and in the oil & gas field as “final inspection”. In Figure 9, the inspection and testing procedures for a nuclear and an OG-valve are presented.

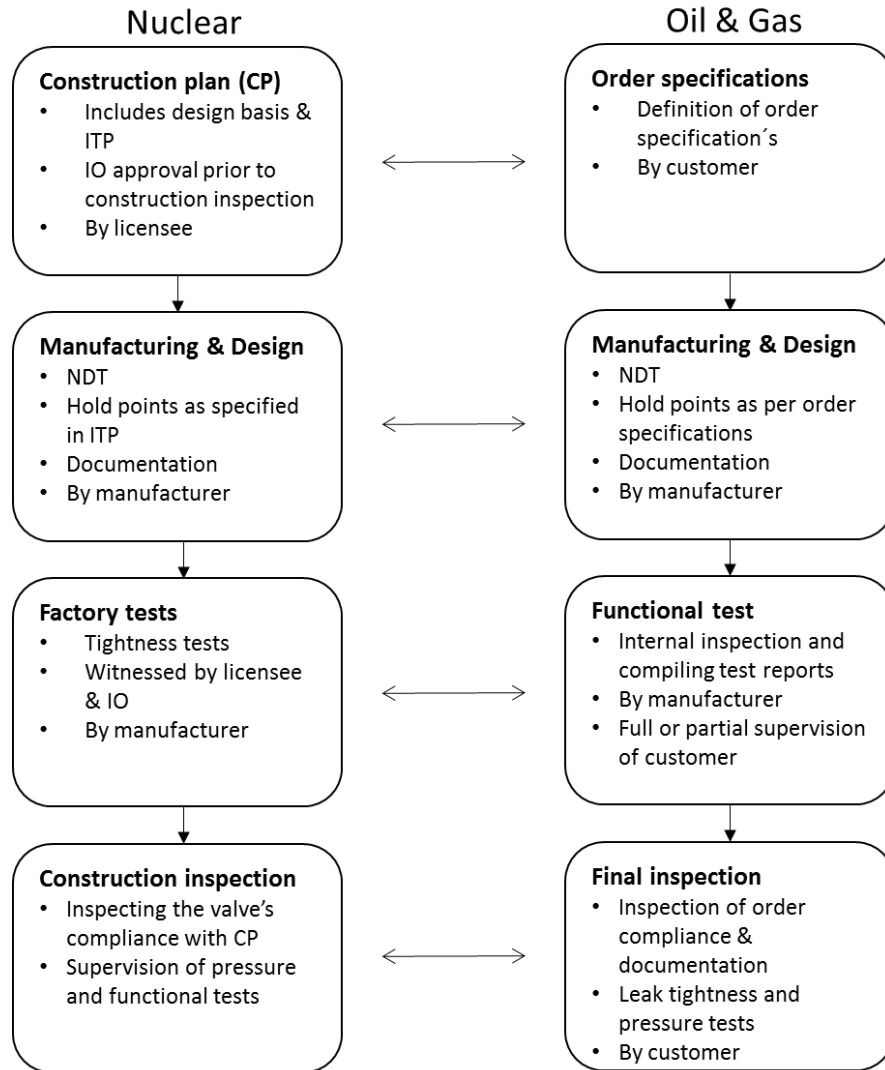


Figure 9. The inspection and testing procedures in the nuclear and oil & gas fields.

The construction inspection of SC 3 shut-off valves shall be conducted primarily at the manufacturing site by an authorized inspection body (IO) approved by STUK. The inspection includes:

- a. Assessing manufacturing documentation.
- b. Conducting visual and dimensional inspections.
- c. Witnessing factory tests or their documentation.

In the assessment of manufacturing documentation, the IO inspects the conformity of manufacturing documentation to an approved construction plan and makes sure the manufacturing tests have been done accordingly. The IO visually inspects the valves and checks that the dimensions and markings are adequate. The documented results of tests relating to tightness are inspected. Pressure and functional tests are supervised as a part of the construction inspection of SC 3 valves.

In the oil & gas field, the final inspection shall be done at the manufacturer's premises and it includes checking:

- a. Compliance with the order.
- b. Visual and dimensional inspection.
- c. Checking manufacturing documents (material conformity, NDT procedures, etc.).
- d. Conducting functional and leak tightness tests.
- e. SIL parameters and fugitive emissions certification.
- f. ATEX certification.

Table 7 presents the most relevant inspection and testing requirements for the scrutinized valve types.

Table 7. Summary of relevant inspection and testing requirements of nuclear and Oil & Gas –grade shutoff valves.

Requirement theme	Nuclear (SC 3)	Oil & Gas
Participation in inspections	Hold and witness points are defined in ITP approved by IO	Hold and witness point are per customer specification
Materials inspection	<ul style="list-style-type: none"> • Qualification of NDT examiners: ISO 9712 Level 2 • NDT after heat treatment • PT, MT, RT according to ISO and ASME standards • No UT requirements • No requirements for microstructure check • Similar testing requirements for casted and forged materials 	<ul style="list-style-type: none"> • Qualification of NDT examiners: ISO 9712 Level 1 • NDT after heat treatment • PT, MT, RT according to MSS and ASTM standards • UT requirement for casted materials • Microstructure check per ASTM A262 • More demanding testing requirements for casted than forged materials
Inspection of weld materials	SFS-EN standards or ASME BPVC Section, II C	EN ISO 11970
Welding Procedure Specification (WPS)	EN ISO 15614-1	EN ISO 11970
Pressure test	ISO 11226-1 (test P10)	ASME B16.34
Shell tightness	ISO 12266-1 (test P11)	ISO 12266-1 (test P11)
Seat tightness	ISO 12266-1 (test P12 rate B)	ISO 12266-1 (test P12, rate A)
Functional test	ISO 12266-2	According to customer standard
Inspection prior to shipment	Construction inspection <ul style="list-style-type: none"> • Conducted by IO • Assessment of documentation conformity with ITP • Visual & dimensional inspection • Witnessing factory tests 	Final inspection <ul style="list-style-type: none"> • Conducted by customer • Checking compliance to order specifications • Visual & dimensional inspection • Conducting functional and tightness tests • Checking SIL parameters • Checking fugitive emissions and ATEX certificates

As seen in Table 7, the inspection and testing requirements hold both similar and different requirements. Most significant similarities were found in factory tests and the largest differences in the scope of inspection during production. The Oil & Gas specification demands a more extensive inspection regime before shipment, but the conductor is the customer (such as Shell or Total), whereas an IO conducts the construction inspection in the nuclear field. This means the construction inspection of nuclear-grade SC 3 shut-off valves is under authoritative control.

RQ1: Summary & discussion

Answers for the first research question, “*Is the requirement specification followed by MFC for their OG shut-off valve deliveries compliant with the requirement specification for nuclear-grade SC 3 shut-off valves?*” were sought for through comparing the production requirements for a nuclear-grade safety class 3 shut-off valve with a requirement specification valve manufacturer Metso Flow Control follows for Oil & Gas (OG) shut-off valves. The overall finding was that especially the structural design requirements and most testing requirements in the OG-specification meet the nuclear requirement level, but design basis requirements diverge the production of the nuclear-grade valve from that of the OG-grade valve in some instances. Also, the scope of inspection during and after production was found dissimilar.

The OG-requirement level was found to exceed the nuclear requirements in the standard for QMS of manufacturers (ISO 29001 > ISO 9001) which is seen as a large bonus in terms of proof of quality of the OG-grade valves. Also, the level of Non-Destructive Testing (NDT) for casted valve parts was slightly more extensive in the OG-specification. Additionally, the acceptance criteria for a seat tightness test was found to be more demanding in the OG-specification. The scope of final testing for OG-grade valves proved more extensive than that of a nuclear-grade valve, although the nuclear requirements assign more testing efforts to be done during the production. The superiority of these two approaches is hard to evaluate and therefore more research is needed. For example, the number of unwanted findings per batch in both testing regimes could be compared. Additionally, different hold- and witness point requirements could be assigned according to the legitimacy and performance records of the manufacturer, much like in the commercial-grade dedication method in USA. The final inspection of an OG-valve is more extensive than the construction inspection of nuclear valves but the final inspection done by the customer. The tests in the construction inspection are supervised by an authorized inspection body approved by STUK. This means nuclear-grade valves’ testing organization must be under authoritative control, which is seen to better ensure objective tests.

The nuclear requirement level is connected to the service place and the design basis conditions of each valve. The requirements must result in a valve that sustains its integrity and/or operability in all predefined environmental and accident conditions. In the OG-field, the requirements are based on general standards and clearly defined parameters, for

example the material selection of an OG-valve is based on the pressure-temperature rating of the valve body. Examination of the possibilities to assign broader design bases for some nuclear-grade components is encouraged. This would increase the suppliers' motivation to place bids and thus promote organic market conditions.

Requirements for design and dimensioning analyses were more demanding in the nuclear requirement specification. Especially the analysis requirements for rare accident loads such as seismic events were expressed more extensively for nuclear shut-off valves. Requirements for seismic analyses are not based on the safety class of a given component, but on the seismic classification as presented in Section 2.1.4. Although seismic analyses are out of reach for some manufacturers, they are seen mandatory for certain components in nuclear facilities, and their existence shouldn't be questioned.

The requirement for NDT examiner qualification level was slightly different. For nuclear SC 3 valves, a level 2 qualified examiner (as per ISO 9712) is required for most nuclear NDT tests, while the OG-requirement is level 1. The qualification for level 2 examiners is more demanding than for level 1 examiners. For example, the nuclear requirement for a level 2 qualified NDT examiner could be fulfilled with little effort for the OG-valves' examiner must hold a level 1 qualification, but a level 2 examiner must interpret the results. This means the level 2 examiners is taking part in the testing process, and could therefore be easily utilized for the actual testing. Other "low-hanging fruit" where the nuclear requirements can be reached through slight tweaks to the OG specifications shall be explored. For example, even though pressure test standards are different (ISO 11226-1 and ASME B16.34), the procedures are similar. The test time is more demanding for the nuclear valve (3 minutes > 1 minute), but after increasing the time of OG-valves' pressure test to meet the nuclear requirement, conversations on accepting the OG-standard for the nuclear valve's pressure test are expected to be more constructive.

The oil & gas specification demands a lighter NDT examination regime for forged valve parts than casted parts. The NDT requirements for casted and forged nuclear-grade valves are similar, even though forging generally produces superior quality. This was seen as a notable distinction. The current regulation demands that the testing scope shall be according to the manufacturing method:

"The material testing methods and testing scope shall be defined by the safety class, material type and manufacturing method, operating conditions and dimensions." (YVL E.3e, p. 17)

Thus, the similar NDT requirements for forged and casted nuclear-grade valve parts were seen unjustified. Therefore, TVO's data source (RSDs and order-related documents) must hold some over-specification for forged valves. Dialogue for assigning a of a lighter NDT regime for forged valve parts is encouraged, as it is seen to be backed up by the current regulation.

Some identical requirements were identified in the requirement specifications. Ways to accept the similar requirements must be explored, but the biggest obstacle is to find means for the qualification of non-nuclear standards and methods for use in the production of nuclear-grade safety class 3 valves. This notion was further supported in the interview study in discussions of the harmonization of requirements (Section 6.2). The Finnish regulation (YVL guide E.8e, p. 7) presents the possibility to apply common design standards for use with SC 3 valves:

“The structural design and dimensioning of safety class 3 valves shall be based on a design standard generally applied by the valve manufacturing industry.”

This is seen as a mandate to propose ways to qualify non-nuclear design standards for use with SC 3 valves. For example, the requirement for welder approval (as per ISO 9606-1) and shell leak test (as per ISO 12266-1, acceptance: Rate A) were equal in both the nuclear and OG-specification. Additionally, some nuclear requirements leave the door open for accepting non-nuclear standards for the production of nuclear-grade SC 3 valves. At the same time, some design basis requirements position nuclear-grade valves out of reach of non-nuclear standards. Nuclear-specific safety requirements, such as sustaining design basis seismic events are to be respected. However, safe ways to close the gap between the nuclear and non-nuclear fields shall be explored, which is supported by previous research (Martin 2016; Abbt 2017). For example, compliance with a material strength requirement could be verified through other means than material thickness, e.g. by using alternative materials of different dimensions.

5.2 RQ2: Is a nuclear-grade item more reliable than a commercial-grade item?

The operational reliability of nuclear- and commercial-grade items was set to be evaluated through a quantitative comparison of the failure rates of nuclear- and commercial-grade valves. However, it was found that such comparison cannot be executed, because some fundamental differences were identified.

Reliability data of a nuclear valve

Reliability data for nuclear components is presented in T-book (TUD Office 2010). The data includes failure rates that are presented for specific types of equipment in general, not according to a manufacturer or service place. The failure rates are compiled based on Westinghouse’s Nordic NPPs and their operating history as described in Section 2.1.5. In the T-book, a pneumatic valve is considered to hold the following components: main control board, logic solvers, control equipment, relays, solenoid valve, pneumatic actuator and valve body

The failure rates of a nuclear valve are presented for a spring-closed pneumatic containment isolation valve. The selected failure mode is “failure to open”, because this particular component is relatively common in the included NPPs and the number of failures is higher than with most failure modes (TUD Office 2010). In Table 8, Olkiluoto 1 and 2 (OL1-2) -specific and generic failure rates (λ_s and q_0) are presented. The confidence level of the presented failure rates is 95 %, which means the actual value is smaller than the presented value with 95 % confidence. The generic values have been compiled using failure reports from a total of 14 plants and during a total of 378 reactor years. The OL1 and OL2 values have been calculated with failure report data from 27 years (1981 – 2007) (TUD Office, p. 11).

Table 8. Failure to open: failure rates for a spring-closed pneumatic isolation valve. λ_s is the time-related failure rate in standby. Adapted from (TUD Office 2010, pp. 206-209).

Facility	λ_s [failures/hour]	q_0 [failures/demand]	Mean active repair time [h]
OL1	$26.1 \cdot 10^{-7}$	$13.0 \cdot 10^{-4}$	Not specified
OL2	$58.0 \cdot 10^{-7}$	$13.3 \cdot 10^{-4}$	1
Generic	$49.6 \cdot 10^{-7}$	$14.5 \cdot 10^{-4}$	3

In addition to Table 8, the number of valves in the data material in the generic case was 725 and the number of demands was 27807. During this period, 75 failures were detected. (TUD Office 2010, p. 206). It is notable that the generic values represent a consensus of the operational history of all the plants included in the data.

Reliability data of a commercial-grade valve

Metso Flow Control (MFC) uses certifications by a certifying body such as TÜV Rheinland in the evaluation of their valves’ performance. The failure rate of the valves is represented through Probability of Failure on Demand (PFD) [failures/demand]. The PFD calculation utilizes Failure Modes, Effects and Diagnostic Analysis (FMEA) and field data that has been gathered from actual valves. To demonstrate how PFD is calculated, an example of a valve assembly manufactured by MFC is presented. The chosen valve assembly consists of a full-bore ball valve (X series) and a pneumatic actuator (BIJ series). In addition, the assembly holds an intelligent safety solenoid that allows preventive diagnostics during operation. Original number of the items and their failures are known, but were not specified for this study because the information was said to be confidential. However, an email with an MFC representative (Employee of MFC, personal communication, 11.08.2017) brought up that the rough number of valves in the X-series is in the thousands per year. The assembly’s failure rate was combined using Nelprof, a software by MFC as shown in Figure 10.

Final element setup				
Safety position	Open			
Architecture	1oo1D			
Diagnostic coverage	Valve+Actuator (open)+VG			0.77

Test intervals			
Full stroke test	TIFST [months]		24
Partial stroke test	TIPST [months]		3
Pneumatic test	TIPNEUMATIC [days]		7

Valve and Actuator		λ_D [1/h]	MTTR[Hours]	PFD
Valve	X/M-SERIES	2.04E-7	24	5.879E-4
Actuator	B1J-SERIES	2.4E-8	24	6.917E-5

Accessories		λ_D [1/h]	MTTR[Hours]	PFD
Intelligent PST	VG9000F/H	5.578E-8	4	3.056E-5
Instru 1 (None)				
Instru 2 (None)				
Instru 3 (None)				
Instru 4 (None)				
Instru 5 (None)				

Calculate

Result:

PFD total

6.876E-4

Final element is suitable for use in safety systems up to and including

SIL 3

Figure 10. Nelfprof PFD calculation for a ball valve (X-series) with a pneumatic actuator (B1J-series).

In Figure 10, the λ_D refers to the dangerous failure rate that results in the Safety Instrumented Function (SIF) being unavailable to perform the required safety function on demand. MTTR is Mean Time To Repair. The calculation presumes that a full stroke test is carried out every two years, which is comparable to the major outage period in OL1 and OL2 plants. Additionally, the valve's functioning diagnosed during operation by the intelligent solenoid (VG900F/H): it is presumed that a partial stroke test is done every three months and a pneumatic test once a week. As seen in Figure 10, the PFD is $6.876 \cdot 10^{-4}$ failures/demand, and the MTTR is 24 hours. This assembly is suitable for use in Safety Integrity Level 3 (SIL 3) environments, as referred to in Section 3.1.

RQ2: Summary & discussion

This research section was set to answer the second research question: “*Is a commercial-grade item more reliable than a nuclear-grade item?*” The reliability of nuclear-grade items was presented by introducing the failure rates of a pneumatically actuated spring-closed isolation valve. The failure rate data for nuclear-grade items is gathered from a relatively small number of items, but the material and methods used to gather the data are clear and well-documented. The material includes exact numbers of items and their failures, which are used to finally calculate failure rates. Information about the maintenance,

performance, environmental conditions and specific location of the items is also included in the material.

Reliability of commercial-grade items was set to be evaluated through a quantitative failure rate of Metso Flow Control's valve assembly. Although the number of the valves was found to be significantly higher (with at least a magnitude) than that of the nuclear valves', the material and methods through which the failure rates are achieved were found to be unclear. A large contributor to the uncertainty was the manufacturer's reluctance to give up original failure data. The reason for this was said to be securing trade secrets. This causes unavailability of information such as environmental conditions, maintenance and closing/opening profiles. Additionally, the methods used in calculating the commercial-grade valves' failure rates are different from the nuclear-grade valves' methods: FMEDA is not used when compiling the failure rates of nuclear-grade valves, and the failure rates presented in T-book (TUD Office 2010) are based solely on historical field data. A representative of Metso Flow Control also stated (Employee of MFC, personal conversation, 11.08.2017) that they do not have access to the original conditions in which a failure has occurred, which reduces the possibilities to prove comparability. While the T-book considers a nuclear-grade valve assembly to hold logic solvers, controllers, relays, actuators and the valve body, MFC's analysis tool (Nelprof) considers each of these components separately. As seen in Figure 10, Nelprof combines the failure rates and FMEDA results for only an assembly that holds a valve body, an actuator and a safety solenoid, which is a less inclusive assembly than that of the nuclear-grade valve in the T-book. Although the "accessories" column in Nelprof allows including auxiliary items, the options are limited and not as extensive as those connected to the nuclear-grade valve assembly. *These methodological deviations in compiling the valves' failure rate data were seen as fundamental barriers for a justified comparison of the failure rates.*

As T-book presents failure rates for nearly all components within nuclear facilities, it is clear that this finding is applicable also for other components than valves. To compare the reliability of nuclear-grade and commercial-grade items in the future, better access to reliability data of commercial-grade items must be achieved. Exploring ways to increase openness and dialogue with the manufacturers and non-nuclear end users is encouraged. The need for this kind of cooperation was additionally noted by previous research and dialogue (Launay 2000; Abbt 2017; Martin 2017). A concrete suggestion of such cooperation is acting together with manufacturers and large companies in safety-related industries to find ways for accessing reliability data without endangering their trade secrets or safety. Through such cooperative projects, the comparability of failure rates may be improved, which would increase possibilities for the acceptance of commercial-grade items in nuclear applications.

6. INTERVIEW STUDY RESULTS

This interview study was conducted as an essential part of this study and it sought answers to research questions RQ2 – RQ5:

- **RQ2:** Is a commercial-grade item more reliable than a nuclear-grade item?
- **RQ3:** What is the current status and future of harmonization of nuclear requirements?
- **RQ4:** What are the ways to accept commercial-grade items for use in nuclear applications?
- **RQ5:** How to increase safety in a cost-effective way?

A total of nine Finnish experts from three different organizations were interviewed during 15.5.2017 – 14.6.2017. The organizations were Teollisuuden Voima Oyj, (TVO), valve manufacturer Metso Flow Control (MFC) and the Finnish Radiation and Nuclear Safety Authority (STUK). Three interviewees were interviewed of each organization. The interviews were held in-person at the workplace of each interviewee. The length of the interviews varied from 23 to 53 minutes. The interview recordings were transcribed into text format, and the transcription was coded as explained in Section 4.2. The transcriptions constituted a total of 79 pages. In the coding phase, a total of 130 individual answers were selected, all of which can be found in the appended tables (Appendices A.1 – A.3). The original Finnish phrases were translated to English. The reduced answers, categorization and the corresponding theme can be found in the tables as well. The quoted phrases are highlighted in the appendixes for faster review, and an identifier code (e.g. A.3.1.6) is included after the quotations below. For clarity, representatives of the authority, licensee and manufacturer are referred to as the Authorities, Licensees and Manufacturers, respectively. The interviewees were asked similar, but often not equal, questions whose main contents are bolded in the following sections. All the questions or topics were not discussed with all interviewees as their expertise varied. The most valuable outcomes of the interviews considering the research questions are presented next.

6.1 **RQ2: Is a nuclear-grade item more reliable than a commercial-grade item?**

The reliability of a given safety function is fundamentally built on two cornerstones: systemic and component-level reliability that ensures the component fulfills its safety function when needed. Systemic reliability is achieved through conceptual designs that follow the nuclear safety principles, but the reliability of individual components must be built into the actual items. In addition to the quantitative comparison in Section 5.2, answers

for RQ2 were sought for through a qualitative interview with members of the authority, licensee and manufacturer. As an introductory subject, the purpose of nuclear-specific safety requirements was discussed.

The interviewees shared their opinion about the purpose of the specific safety requirements of nuclear-grade items. The Authorities placed emphasis on the design basis conditions and accidents the items must withstand, and Authority #3 made also a clear distinction between systemic and component-specific safety:

“A difference is that in conventional industries a single operation's reliability can be improved by adding redundancy by installing two redundant systems instead of one. But in nuclear facilities you can't use solely redundancies. Assuring top quality of a single system or component is important. (A.1.3.1)

The Licensees agreed that the items must tolerate design basis conditions and added that the item's safety function is also ensured through the requirements. The Manufacturers added that the purpose of nuclear-specific requirements is to ensure quality and reliability through third-party assurance of the material production and quality and the product itself.

Structural and quality control -related customization and reliability

The main discussion covered two main topics: reliability effects of requirements related to QC and structural customization. Customization starts when additional requirements for the production of a commercial-grade item are introduced. There are roughly two kinds of customization: Quality Control (QC)-related and structural customization. The former refers to additional activities that don't change the physical attributes of a nuclear-grade item from those of an original commercial-item. For example, non-destructive examination is QC-related customization. The latter, structural customization, in effect changes the item's physical attributes. For example, changing an item's original material composition or coatings is structural customization.

Discussions about the reliability effects of QC-related customization brought about some parallel arguments, but also clear philosophical distinctions. The Authorities argued consistently that additional QC does not improve quality as such, but the items' conformity to their requirements must be ensured. Authority #1 noted that the inspections have revealed defects in the items, and therefore the quality and reliability have improved, which was backed by Authority #3, who had seen false assemblies and other defects in finished or installed products. However, Manufacturer #3 stated the defects have by no means been catastrophic:

“They [post-production defects] are by no means dramatic. I dare to say that catastrophic problems like wrong materials or rips have never been seen.” (A.3.3.7)

In general, the Licensees shared their views on the fact that QC is important for defect identification, but the need for additional QC on top of conventional industries' requirements was seen low, except for Licensee #3, who stated that in especially low-volume production must be subjected to specific QC requirements:

“If it's [an item] used a lot, then these potential flaws and deficiencies in the manufacturing process are inevitably revealed. But if these are parts that are seldom made and if they are on stand-by like our emergency motors, then there's no user experience gained. And then we have to give special attention to their production and of course inspection.” (A.2.3.2)

The previous comment also noted that some nuclear-grade items are on stand-by and therefore not as much user experience is accumulated. The Manufacturers underlined that nuclear-specific QC requirements do not improve reliability if the supplier is well-established and holds an independent quality system, but unknown suppliers must be controlled.

The interviewees were asked about their opinion on how structural customization affects the reliability of items. The Authorities stated clearly that while structural customization may hinder quality, it is always done for a reason - there is always some acceptance criteria behind the specific requirements. The Licensees were supportive of this vision, but some stated that the total reliability might actually be lower because design basis requirements may differentiate the production to the extent where the benefits of customization are lost.

Manufacturers #1 and #2 agreed with the Authorities that some requirements ensure operability in design basis conditions, thus making the structurally customized valve more reliable, as Manufacturer #2 put it:

“If the calculation requirement differs from it [a standard product], it may require us to add material thickness or to use a harder material. It helps achieving safe operation even though centimeters of material would peel off.” (A.3.2.5)

Manufacturer #1 stated that the quality of manufacturing is equal in both cases, and that more reliability can be achieved through over-specification of the valves, which supports the previous quote.

Reliability of nuclear-grade items versus commercial-grade items

The Authorities noted that while it is crucial to use custom-made nuclear items in high-safety applications, it is not completely clear that the customized production results in better reliability, especially if QC has been taken care of. Also, the need for more research was noted. Authority #1 stated that in some cases the larger production volume of com-

mercial-grade items might result in better quality because the adolescence problems dissolve as user experience accumulates. The quality effect of standardization was backed up by Authority #3:

“Standardization in the production adds quality.” (A.1.3.3)

The Licensees supported the Authorities’ notion of the reliability of high-volume production. Licensee #2 even stated that the quality of commercial-grade items is sometimes superior to the nuclear-grade quality:

“Nowadays the quality of even above SC 3 nuclear-grade items is inferior to the industrial quality because of the introduction of the PED in the 90s [partly censored to retain anonymity]. I have seen the evolution of the quality and the disappearance of problems and reclamations. The nuclear sector has not fully understood the extent of this quality leap.” (A.2.2.2)

Licensee #2 underscored above that quality leaped in the 90s mostly because of the Pressure Equipment Directive (PED), which is the basis for the quality systems of European pressure equipment manufacturers. Again, Licensee #3 highlighted the need for QC in the case of low-volume production. The Manufacturers saw the reliability in both cases close to equal, at least if the manufacturers hold a credible quality system.

Suitability of using reliability data to accept commercial-grade items for nuclear use

As discussed in the case study, commercial-grade items hold much reliability data, but it is collected from multiple processes whereas nuclear-grade items hold less data that is collected from a very well-known set of processes. This means that the acquired reliability data material is different in both cases.

The Authorities noted that while commercial reliability data may be useful, its comparability need be verified so that it can be utilized for the acceptance of commercial-grade items, as Authority #1 concluded:

“It [reliability data] can sure be utilized if the factory is tuned to serial production, it doesn't hurt to have reliability data, but the level to which it can be trusted must be verified.” (A.1.2.5)

At the same time, assuring the supplier’s ability to produce quality was seen as the most important thing, and all evidence of reliable end products can be seen as a bonus. On the other hand, Authority #3 doubted the Manufacturers’ willingness to give up such data:

“Sure it could be used, but I feel like a common obstacle is the reluctance of manufacturers to give up such data.” (A.1.3.5).

For example, Authority #3 referred to some situations where a manufacturer had claimed to have great operating experiences of a programmable device, but upon asking for evidence, it had not been in their interest to provide such data. The qualification process that followed had hundredfold the price. This notion proved right in the case study (Section 5.2), where it was evident that giving up the exact numbers of failures and auxiliary information is not indeed in the interest of a particular manufacturer.

Two of the Licensees agreed with the fact that the comparability of reliability data must be proven in order to qualify commercial-grade items in nuclear-specific service places. However, Licensee #2 saw that the biggest advantage of using commercial-grade items is the very fact that the reliability data is collected from multiple processes:

“NPPs too have multiple service places and a variety of operational conditions. I'd say that this is the maximal added value - to have the maximum amount of users and conditions.” (A.2.2.5)

Manufacturer #2 commented that using the reliability data would require having sufficient information of both processes, because for example the flowing medium greatly affects abrasive wear and might skew the reliability data. In general, the Manufacturers saw that process conditions in the nuclear applications are milder and less aggressive than those of the oil & gas industry, for example:

“I almost could say that OG-processes are more demanding [than those of processes of nuclear facilities]” ... “OG-processes contain really aggressive mediums, frequently cycling valves and other stuff like particles etc.” (A.3.1.8)

This is an interesting notion that shall be appreciated when the reliability data collected from oil & gas processes is evaluated.

RQ2: Summary & discussion

This interview section was aimed to provide insight of the interviewees' outlook on the reliability of nuclear-grade versus commercial-grade items (RQ2). The Authorities made a clear point that although repetitive production improves quality, commercial-grade items are not sufficient in all service places as such, because the design bases set boundary values for the acceptance criteria the items must comply with. The Authorities also noted that while QC does not necessarily improve quality, compliance with requirements must be ensured. This is seen as encouragement to further investigate the justification of the current QC requirements – after all the requirements should result in a product whose operational performance is ensured, and operational performance can be achieved also through other means than compliance with the requirements.

The Licensees saw the need for custom production and inspection in high-safety items, but concluded that the reliability gains of repetitive production outweigh the reliability

improvements that are sought for with nuclear-specific requirements. This hypothesis must be further examined through studying the failure rates of nuclear-grade and commercial-grade items as encouraged in Section 5.2 and literature (Abbt 2017; Launay 2000; Martin 2017). The most important findings are presented in Figure 11. The italicized text outside the rectangles represent a common position.

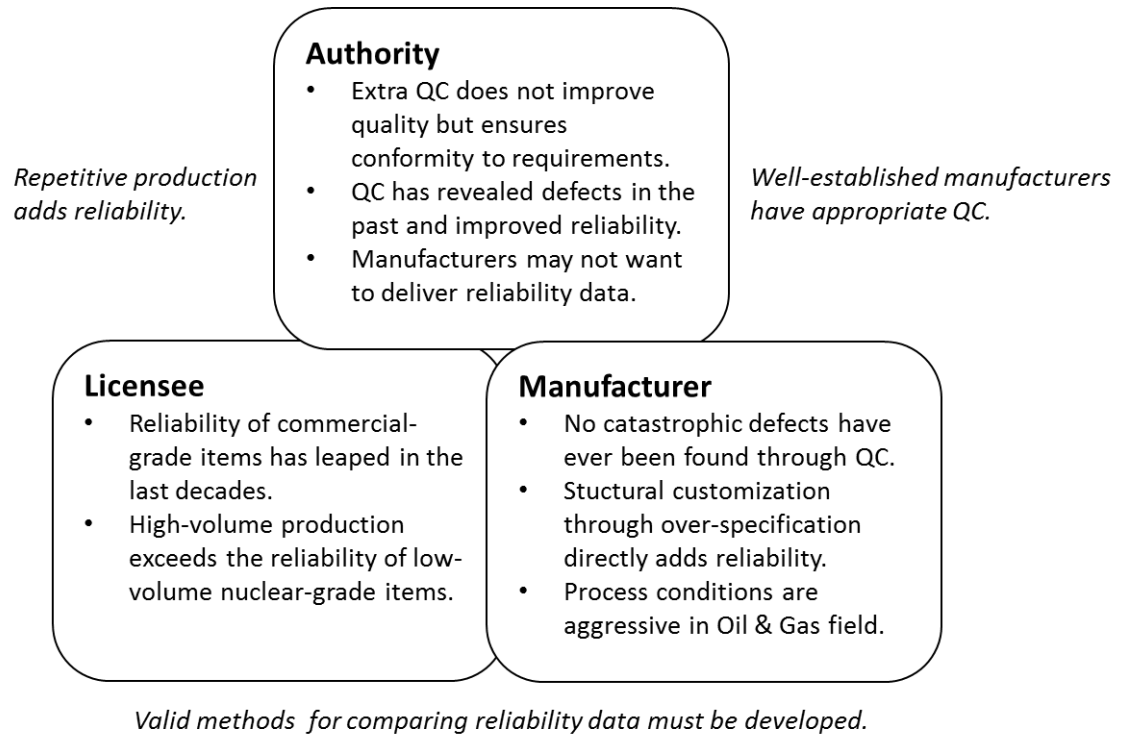


Figure 11. The most relevant interview findings to RQ2.

QC measures safeguard that a manufactured item meets its design criteria. As seen in Figure 11, the Manufacturers stated that conservative design margins of nuclear-grade items improve safety, but that additional QC requirements do not add reliability at least with credible manufacturers, which was agreed by most interviewees. According to current regulation, the impacts of activities on the safety significance are to be accounted for when defining the requirements:

“The impact of products and activities on nuclear and radiation safety shall be identified and taken into account in defining the requirements set to them.” (YVL E.3e, p. 8)

However, the interviews revealed that currently the practical requirement level does not correlate with the trust in a particular manufacturer. In the Risk Informed (RI) approach, resources are allocated to where they are most relevant in terms of risk mitigation, and it is utilized in the commercial-grade dedication method in USA. Reviewing and further discussing the possibilities of using the RI approach in defining the requirements are encouraged for decreasing ineffective inspection of credible manufacturers. Additionally,

consideration of the effectivity of QC measures is encouraged to evaluate their true effect on a product's operational reliability.

The interviewees agreed that in order to further discuss using commercial-grade items in nuclear safety-related applications, the comparability of the items' reliability data must be verified. Although many industrial processes have demanding conditions, nuclear facilities hold specific design basis accident conditions and radiation that the items must withstand. Additionally, different flowing mediums and process conditions need be taken into account. The current regulation does not allow extensive use of reliability data in qualification, but one particular requirement (YVL E.8e, p. 10) allows reductions in the calculation requirements when operating experience feedback can be used to demonstrate conformity:

“In safety classes 2 and 3, the construction plan's calculations can be replaced by the operating experience feedback or type test data of a valve having an equivalent construction and design values if the valve's conformity can be equally demonstrated by this data.”

These findings coupled with the difficulties in the comparison of nuclear and commercial reliability data (as seen in Section 5.2) make it easy to encourage further research in order to reach better comparability of reliability data.

6.2 RQ3: What is the current status and future of harmonization of nuclear requirements?

Although nuclear applications are similar globally, the regulations is unique for virtually each country that produces nuclear energy. IAEA compiles the fundamental safety guidelines that represent a global consensus, but national legislation steers the practical-level requirements that are related to the manufacturing of nuclear-grade items, for instance. Efforts to make the requirements more uniform have been made, but much of the regulation remains inharmonious between nations even today. This part of the interview study was to examine the interviewees' outlook of the current status of harmonization, effects of more harmonized requirements and of the future of harmonization. The main contributors to this theme were the Authorities and Licensees, as the Manufacturers operate mostly in the non-nuclear sector.

Current status of harmonization of nuclear requirements

The Authorities and Licensees concluded that while top-level organizations – for example Western European Nuclear Regulators Association (WENRA) – have compiled fundamental requirements, national legislation and regulation steer the practical-level requirements, which was viewed as problematic. Authority #3 had doubts about WENRA's willingness to compile more specific requirements:

”They [WENRA] have presented reference levels for operational and new plants, then Fukushima of course messed up everything and I feel like going to details is not in their [WENRA’s] best interest.” (A.1.3.8)

Authority #3 also stated that national differences in designs don't necessarily emerge of regulative requirements but of the specific customs of power companies and local culture. Authority #1 stated that here should not be an issue to qualify a standard that has already been used somewhere in the nuclear sector, which was backed by the Licensees who saw that nuclear-specific standards (e.g. RCC-M and ASME) are easy to deal with as they are similar, but the problems lay in the acceptance of non-nuclear standards.

Effects of increased harmonization

The Authorities concluded that their overall load would be lighter in the presence of a more uniform requirement level, but it would shift responsibility of towards the Licensees. Authority #2 highlighted that harmonized requirements would have to conform to the Finnish regulation:

“If we could gain good confidence that harmonized methods reach conformity to requirements also against Finnish YVL guides, it would decrease the specificity of inspections.” (A.1.2.10)

Additionally, Authority #3 noted that more harmonization would make the nuclear industry more attractive for suppliers and that today it is viewed neither safe nor sexy, which decreases market competition.

More volume, faster delivery time and lower costs were seen the main effects of harmonization by the Licensees. Licensee #3 saw that the autonomy of the authority would decrease, making it more of a supervisory member who would oversee the items’ conformity to the requirements. Manufacturer #2 summed up the Manufacturers’ perspective on the matter:

“I think the benefits [of more uniformity] are quite obvious. Awareness would grow and the whole process would become clearer. It’s confusing that even though we provide for the same application, our product is not valid in all countries as it is.” (A.3.2.11)

The Manufacturers saw also that increased harmonization would speed up deliveries and cut prices because it would decrease the huge amount of bidding documentation and allow working with more subcontractors. Currently, the specific requirements cause unavailability issues:

“Firstly, it’s hard to find the suppliers because if we buy something like standard steel in the kilometers, it’s readily available. But when we have a requirement for

maximal cobalt content, it's a whole different conversation. It has to be searched for.” (A.3.3.11)

Future of harmonization

The Authorities stated that harmonization will evolve but with its own problems, and not least because of non-uniform interests between stakeholders. Authority #2 pointed out that even though STUK is part of MDEP's Vendor Inspection Co-operation Working Group that aims to maximize results obtained from regulators' efforts in inspecting vendors (OECD 2017), it cannot take any responsibility off of the licensees:

“If the authority audits a supplier, it might gain responsibility of the component's safety. That is not the role of the authority - we have to ensure that the licensee does their thing accordingly.” (A.1.2.12)

Additionally, Authority #3 underlined that they are reluctant to see a central authority in Europe:

“We don't want an EU-level central authority that sets common requirements.” (A.1.3.8)

Licensee #3 noted that there is certain protectionism in the nuclear domain, which complicates the situation:

“These large countries where the nuclear industry is statist: France, China, Russia. The projects are so big - we're talking billions [of euros] - and the autonomy is wanted to maintain.” (A .2.3.10)

The Authorities concluded that the goal should be the equivalence of Codes and Standards (C&S) and without it they will diverge even more. To the contrary, the Licensees saw that standards will converge towards a single standard that is utilized globally. Licensee #2 saw increasing harmonization as a mutual interest for the nuclear sector:

“I think that it [harmonization] should be a shared interest in the nuclear sector today as the world is united after all. The manufacturing and ownership can be located anywhere and - the days of protecting the production in Europe are gone.” (A.2.2.15)

RQ3: Summary & discussion

The interviewees' outlook about the harmonization of nuclear requirements was discussed. The overall impression was that there is a clear need for pushing harmonization forward. The current state of harmonization was uniformly seen as vague with organizations like WENRA conducting top-level harmonization, but not moving to the practical level or presenting acceptance methods for non-nuclear standards, which prevents non-nuclear suppliers from entering the nuclear marketplace. Directing more resources towards unifying of the ground-level requirements is encouraged since it is the only way to enable more suppliers to operate in the nuclear sector. Figure 12 presents the most important findings under RQ3. The italicized sentences outside the rectangles represent a common position.

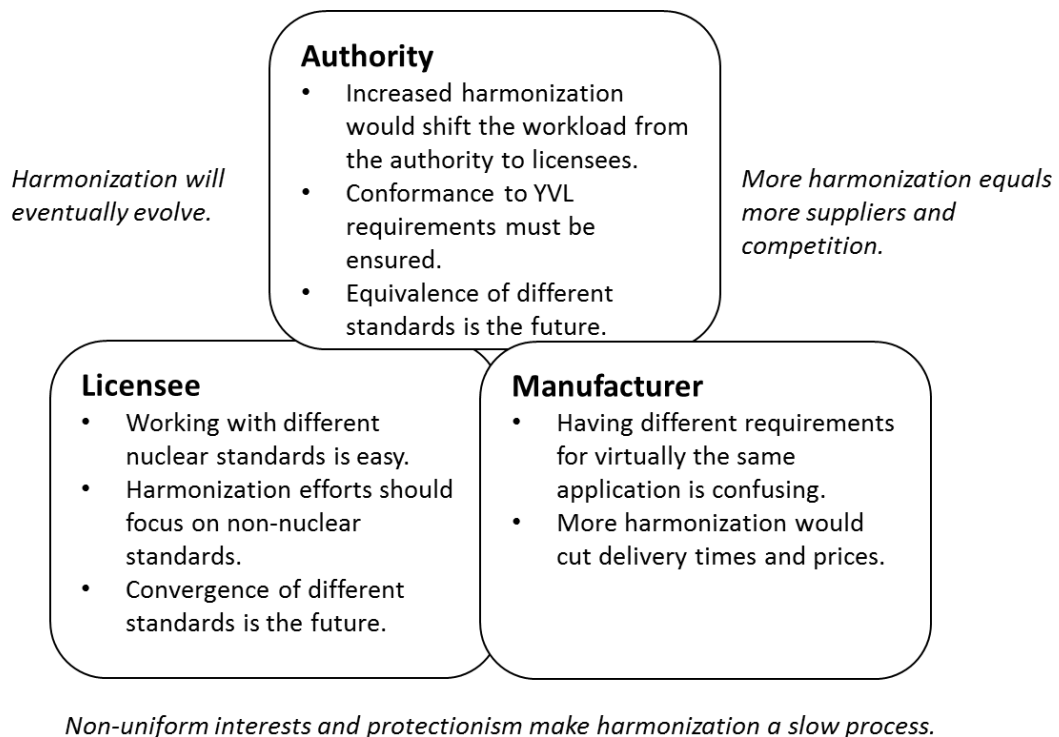


Figure 12. *The central findings for RQ3.*

The Authorities saw that increased harmonization would streamline their work and probably cut costs, but the harmonization would have to result in conforming to the YVL guides' requirements and the current legislative framework. The Licensees and Manufacturers concluded that harmonization would open up the market which would allow faster delivery times and lower costs. Negative effects of harmonization were not brought up, but harmonization efforts must be careful enough not to endanger safety in any way, for example through neglecting geographical differences in design basis requirements for sustaining seismic loadings.

The interviewees saw that the biggest barriers to harmonization are the non-uniform interests between stakeholders, which leads to protectionism. Protectionism exists in all organizations, but it slows down development. Licensee #2 noted that the days of local nuclear ownership are over and therefore the current culture of protectionism is fading in the future. A degree of protectionism is useful in order to for example protect the sovereignty of the authority, but ways to tackle purely monetary-based sheltering shall be explored as it is not contributing to safety. These efforts may include challenging the current regulation, market situation and manufacturing procedures.

The development of harmonization was seen inevitable, but slow. The Authorities concluded that the trend should be towards finding ways to accept different standards to be used, which is seen counterintuitive to the Authorities' earlier statements saying that harmonized requirements should conform to the YVL guides. The Licensees opposed to the Authorities' notion by predicting that in the future standards will converge towards a uniform standard. This view was not supported by previous research and it is seen as a less likely scenario than the equivalence of different standards. Reaching equivalence means finding ways to accept different standards and products – whether nuclear or non-nuclear – to be accepted for use in a given nuclear application.

6.3 RQ4: What are the ways to accept commercial-grade items for use in nuclear applications?

If the nuclear sector seeks to utilize more commercial-grade items in their facilities, assessing the suitability of non-nuclear items for nuclear applications is critical. To find answers for RQ4, the interviewees were asked about their views on how the qualification and production of commercial-grade items should be arranged in their view. The Licensees and Authorities were most vocal, but also the Manufacturers shared their views on how to ensure the production of reliable products.

How would you personally approach accepting a commercial-grade item for a nuclear service place that holds safety significance?

The Authorities stated consistently that the conformity of commercial-grade items to the requirements should be assessed through inspections and testing, for example by using a vibration table to prove tolerance of seismic events. Authority #3 noted that the extent of the item's conformity to the nuclear regulation need be examined, after which alternative ways to achieve safety should be explored:

“First, I would like to know that what is the delta. Our requirements in YVL-guides, they are one way to achieve the required safety level. There can, however, be an alternative way too, and the licensee is free to present it. We need factual evidence of what is missing and then some reflection on how to compensate for it.” (A.1.3.7)

Also the Manufacturers saw the need for conducting gap analyses of non-nuclear standards against the nuclear standards in order to assess the level of compliance and to discuss ways to fill the gap. Licensee #3 agreed with the Authorities about the need for a primary assessment of the item's conformity to the requirements. The other Licensees were certain that if the production adheres to EN-standards and PED, no extra inspections or material certificates would be needed for SC 3 items. Additionally, Licensee #2 noted that USA's commercial-grade dedication methodology may be used to accept non-nuclear items in Finnish nuclear facilities.

How would you organize the production to ensure that a nuclear-grade valve holds sufficient reliability?

This valve-specific topic was discussed with the Manufacturers who concluded that for reliability, ensuring subcontractor and material quality is of primary importance. The Manufacturers uniformly claimed that these matters are thoroughly assessed in their organization. They stated that the actual production process should follow standard production to benefit from repetitive and well-known practices. After the valve is finished, a third-party inspection of documentation and testing would take place to prove quality. Manufacturer #3 strongly emphasized that the current nuclear regulation focuses too much on inspections that happen during production, whereas OG-requirements allows them to manufacture the product in their own way after which the orderer assesses the product:

“After that [ensuring material compliance] I would very well trust the standard processes until the assembly is completely ready. And there [after manufacturing] we would have a combinational inspection [testing & documentation inspection] like in petrochemistry: do whatever you do, but we [the orderer] will make sure it's how it should be at the end.” (A.3.3.7)

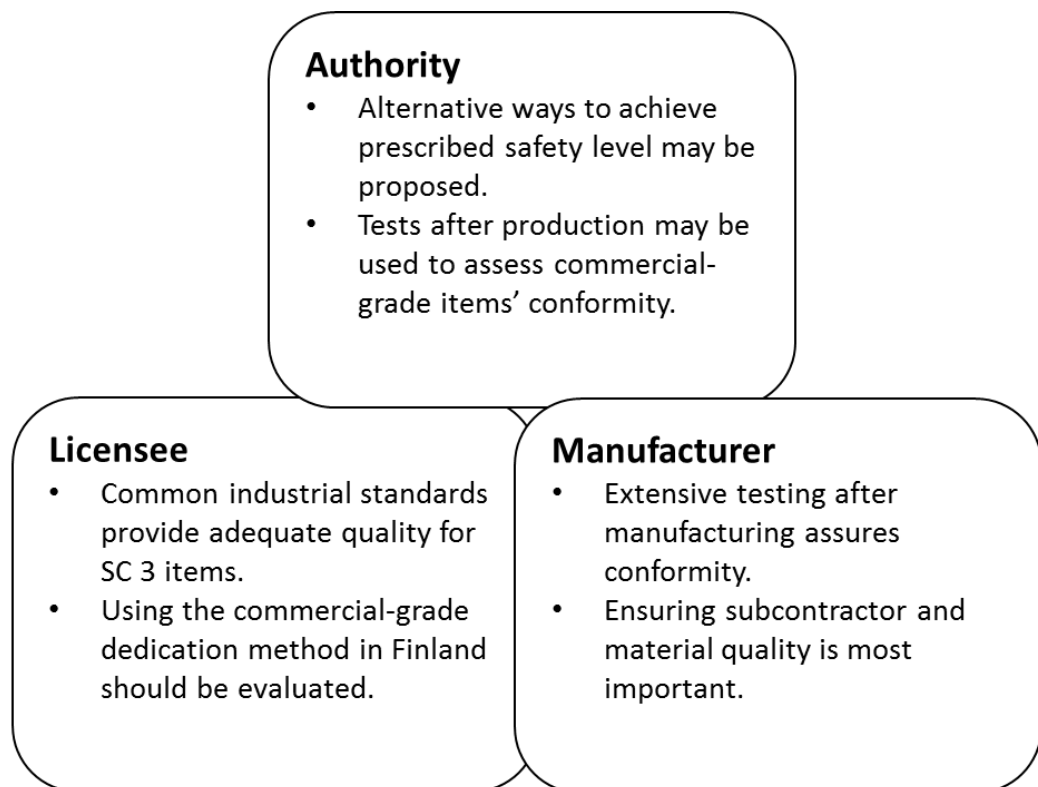
Manufacturer #3 supported this argument by claiming there has not been any dramatic findings, like wrong material, seen in this kind of end testing. However, this view was challenged by Licensee #3 and Authority #2, who stated earlier in the interview that previous experience has brought up misassembled and invalid parts.

RQ4: Summary & discussion

The interviewees highlighted that for accepting commercial-grade items for use in nuclear safety-related applications, there should be an assessment of the item's conformity to requirements, after which fulfilling the remaining “delta” should be examined. The Authorities suggested that alternative ways to show conformity may be examined. This is further emphasized in the current legislation, and according to section 7 r(3) of the Nuclear Energy Act, the safety requirements of STUK are binding on the licensee, but the licensee has a right to propose an alternative procedure or solution to that presented in the regula-

tions. If the licensee can convincingly demonstrate that the proposed procedure or solution will implement safety standards in accordance with the Nuclear Energy Act, STUK may approve a procedure or solution by which the prescribed safety level is achieved.

Most Licensees stated that SC 3 items should not be subjected to additional requirements, because the current standards and directives provide sufficient quality. This is a rather vague statement that needs more evidence for backup. Additional research about the quality of commercial-grade items and credible comparison of reliability data is encouraged. The commercial-grade dedication method in USA is seen a strong initiative towards the acceptance of commercial-grade items, and utilizing elements of this method also in the Finnish nuclear sector should definitely be discussed. The most important findings on RQ4 is presented in Figure 13. The sentence outside the rectangles represents a common position.



Compliance of commercial-grade items and ways to fill the gap shall be assessed.

Figure 13. *The most important findings under RQ4.*

The Manufacturers saw that assuring subcontractor and material quality is the key for achieving trust that commercial-grade items are reliable also in nuclear appliances. In their view, the production itself should not be touched by nuclear-specific requirements: the post-production inspection and testing used in the oil & gas industry were seen adequate. The inspection and testing requirement comparison in Section 5.1.3 presented the

scope of inspections in both the nuclear and oil & gas field, and this fundamental difference in the inspections was noted. However, it must be highlighted that factory tests in the final inspection in the oil & gas industry are conducted by the orderer, whereas an authorized inspection body (IO) supervises pressure and functional tests that are done by the manufacturer. An IO is approved by STUK, whereas the manufacturer in the oil & gas field is not under authoritative control, and its plausibility is not seen as high as that of an IO. It must also be pointed out that the Manufacturers are looking at this subject from their own perspective, as are the Licensees and Authorities, and thus possible vested interests must be kept in mind.

6.4 RQ5: How to increase safety in a cost-effective way?

This part of the interview study was introduced to find practical suggestions for development. The discussion uncovered important areas for development, such as the reputation of nuclear power, clarity of the requirements and benchmarking requirements of different industries.

Most and least effective requirements in ensuring reliability

Requirements relating to verifying material compliance and material characteristics (e.g. chemical composition, strength) were seen most important across all interviewees. The Manufacturers emphasized the role of post-production testing in ensuring quality, operability and integrity:

“Safety wise, if conformity of material is assured, then we have pressure tests to show that the valve doesn’t develop any deformations under stress and that no leaks are detected.” ... “Then we have product quality tests to show the product functions as planned: operational and integrity tests.” (A.3.3.3)

Licensee #2 noted that requirements relating to operability and integrity should be differentiated:

“It should be based on demand and safety function and if it's solely an integrity requirement, then the requirements are clearly different than when there is operability requirements and then the security measures are targeted to the specific operation.” (A.2.2.3)

Licensee #2 also claimed that sufficient integrity is presently achieved in commercial-grade items. The Authorities failed to name any specific low importance requirements, but Authority #2 stated that machining is not subjected to specific requirements for it is a well-known process and it does not change material characteristics at least macroscopically. Licensees #1 and #2 saw the requirement for 3.2 material certificates as excessive

burden in most cases, along with requirements for annual re-audits of suppliers and inspectors. The Manufacturers saw documentation and irrelevant standard tests as wasteful activities. Manufacturer #3 felt that inspections during production are not effective:

“Intra-production inspection is given excessive attention, because the post-production testing cycle is already quite demanding.” (A.3.3.4)

Reasons for the price gap between nuclear- and commercial-grade items

The Licensees saw that some nuclear-specific requirements such as having a certain type of management system has limited the number of potential suppliers, which was said to shift the market towards a monopoly setting. Licensee #3 made a clear point that being associated with the nuclear industry is seen as a liability by some suppliers. Authority #3 strongly supported this notion:

“It [a more uniform requirement level] would probably have effects such as the nuclear industry would become more attractive. Nowadays vendors don't want to supply anything for it's so hard in their view. It's not sexy and it's a bit risky because being identified as a nuclear power plant supplier might hurt your reputation. More business would make it [the nuclear sector] more attractive to the vendors.” (A.1.3.11)

Sometimes the nuclear requirements demand using conservative design margins, which was said to raise raw material and production prices. Manufacturer #3 also noted the amount of required documentation:

“Well first there is documentation. Someone has to create the documentation, which increases the price definitely. Another thing is using structures that are beyond safe. There can be conservative safety margins. It means more expensive coatings and materials. They all correlate to the price directly.” (A.3.1.14)

Additionally, the Manufacturers viewed that the low volume of nuclear-grade items increases the price. The Manufacturers and Licensees stated in unity that third party inspection during production accumulates the price, and Manufacturer #2 put a price tag on the matter:

“Then the third-party attendance requirement – it costs easily 1000 € per day just for us. And how it cumulates even further down the chain increases the price.” (A.3.3.8)

Licensee #2 noted that suppliers might not be familiar with the requirements, which is visible as a risk premium added to the price:

“And at the same time, we differ from the manufacturer's normal product, so the manufacturer adds some uncertainty-based risk marginal in the price for they don't know if their product is acceptable.” (A.2.2.9)

All Manufacturers didn't underscore this point to that extreme, but Manufacturer #1 found that unambiguous clarification of requirements would make everything easier and decrease the price.

Bridging the price gap without compromising safety

Under this topic, safe ways to decrease the price gap between nuclear- and commercial-grade items were discussed. The Licensees saw that the requirements should be presented more clearly in order to mitigate order-related uncertainty perceived by the suppliers:

“These requirements should be articulated to the manufacturers: what do they really mean and what has been agreed upon with STUK about the YVL guides. To show that the requirements are not as bad as first look might imply. To prevent from stage fright.” (A.2.1.9)

This articulation of requirements was seen to be improving along with the introduction of the Requirement Specification Document (RSD) in the Finnish regulation. Licensee #2 stated that the nuclear industry has a lot to gain from conventional industries, aviation in particular:

“I've been both in the conventional and nuclear field and I see a huge potential if we understood the manufacturers' knowhow, experience and would make use of all their references and networks.” ... “The aviation industry is good at producing quality, and the products are well specified. The supply chain works well. There's something to learn from.” (A.2.2.11)

The Manufacturers pointed out the aforementioned more unambiguous defining of requirements as a way to cut costs, along with benchmarking requirement levels of customers in the oil & gas industry, as Manufacturer #2 put it:

“If the nuclear requirements would be compared against a well-established oil & gas standard like Shell or Total to see to which extent they meet the nuclear requirement level.” (A.3.2.9)

Manufacturer #2 stated that small tweaks to a standard product might meet many nuclear valve requirements, which would bring the customized product closer to their standard production:

“We could do a little customization to a standard product and still show conformity.” (A.3.2.10)

According to Manufacturer #2, conformity to requirements concerning material characteristics might be assured through alternative ways, for example certain material strength might be achieved through different coatings or materials and not solely by adding material thickness as per the requirement. Manufacturer #3 stated that the extent of supplier auditing and verification should be weighed against the supplier's track record. This procedure reflective of the Risk Informed (RI) approach was proposed to be viable also for different production methods:

“And it [the extent of inspections] could be determined over the production method, for example if it's something like sand-casting.” (A.3.3.9)

The Authorities were understandably less vocal what comes to the cost aspect, but Authority #3 noted that the cost structure of the licensees would decrease as uniform requirements would promote market rivalry. Authority #3 also noticed that less costly equipment may promote quicker updates:

“I personally have nothing against the fact of using commercial-grade items for they usually are less expensive. It might result in quicker update cycles at the facility.” (A.1.3.5)

Increasing cooperation between the licensees was seen as a common way to bridge the price gap between nuclear and commercial-grade items, and the interviewees uniformly stated that increased cooperation between licensees would be positive. Authority #1 saw cooperation with compiling the Requirement Specification Documents (RSDs) as a really viable idea because more uniform requirements would allow STUK to use authorized inspection bodies more effectively as there would be less room for interpretations. Authority #2 noted that cooperation with RSDs would be good, given that plant-specific differences are taken into account:

“I guess it [cooperation between licensees in compiling RSDs] is good. The plants and service places are different, so the plant specific things need be taken into account. But I see it as a great idea to have more cooperation between the licensees [in drafting the RSDs] to harmonize them to some extent.” (A.1.2.14)

Licensee #2 disagreed slightly with Authority #2 about the plant specificity of RSDs:

“It [the item] doesn't know whether it's in a PWR (Pressurized Water Reactor) or a BWR (Boiling Water Reactor). Some equipment are plant specific, of course.” (A.2.2.18)

The Licensees saw the introduction of RSDs in the regulation as a positive thing. Cooperation between licensees in the drafting of RSDs was seen a way to cut costs. Manufacturer #2 was clear on the point that only one RSD is needed in a country like Finland:

“I think that one set of RSDs would suffice for one country because we have the same supervising authority.” (A.2.2.17)

Aside from the RSDs, Authority #3 saw that the licensees could cooperate in auditing suppliers, for example:

“If it were done so that fundamentally both [licensees] would take part in it [supplier audit]. The audit would be performed with a set of requirements that suits the needs of both parties. Then there would be synergy of a larger customer.” (A.1.3.15)

This notion was supported by Licensee #1 who claimed that cooperation would decrease costs and workload. Licensee #2 demanded cooperation on a broad scale:

“Cooperation in everything. Combined orders, agreeing on policies, storage. I hope the authority would allow a shared warehouse between licensees. We could reduce the stock value because we won't have the same situation [equipment failure] at once.” (A.2.2.19)

Licensee #2 noted that this kind of cooperation would increase the number of capable manufacturers and quality as batch size would grow. Manufacturer #2 stated that the true meaning of specific requirements might not always be clear for them, and thus more discussion between licensees would help finding the sufficient level of design. Manufacturer #3 pointed out that updating and referring to the right standards is something to develop.

RQ5: Summary & discussion

Through this section of the interview study suggestions for developing the current requirements in a safe and cost-effective way were inquired. The interviewees unambiguously stated that the requirements relating to material characteristics are the most important in securing the reliability of items. The Manufacturers saw the amount of required documentation and testing during production as excessive, and that standard integrity and operability tests after production ensure adequate reliability. This claim must be further examined for evaluating the superiority of end testing vs. testing during production. The most important findings are presented in Figure 14. The italicized sentences outside the rectangles represent a common position.

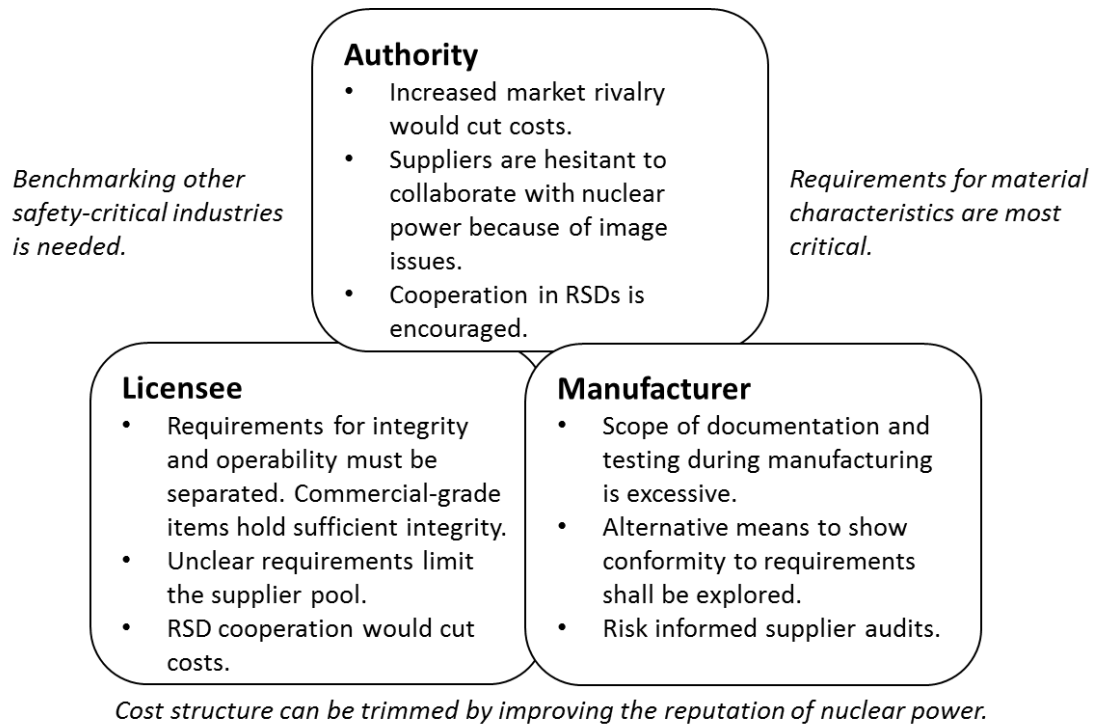


Figure 14. The central findings for RQ5.

Licensees strongly emphasized that requirements relating to operability and integrity of items should be more clearly separated. Presently, the Finnish regulation assigns different classification criteria according to a system's safety function and the structural resistance, integrity and leak tightness of structures and components. Further discussion on assigning the requirements according to an individual item's operability and integrity is encouraged. This prevents from designing items beyond or below safe. Additionally, The Manufacturers saw conservative design margins as directly correlating with the price. Licensee #2 stated that commercial-grade items hold sufficient integrity. This hypothesis needs more evidence, for example through comparing pressure and tightness test results of nuclear- and commercial-grade valves and their failure history.

As pointed out in the interviews, suppliers may fear their image is negatively affected if they are providing for the nuclear industry. The supplier pool was said be limited because the negative associations with nuclear power make suppliers reluctant to place bids. To reach better price competitiveness safely, the nuclear field should focus on improving their public image. Improving the reputation of nuclear power would make more suppliers willing to collaborate, which would increase market rivalry. Building a stronger image for nuclear power is a slow process that requires effort of from the entire nuclear industry globally. A large part of the process is, of course, the safe uninterrupted production of nuclear power. Safe disposal of nuclear waste is also central to reaching public acceptance for new plants, which in term would increase the attractiveness of the nuclear field. Confusing articulation of requirements was seen as another cause for the high price-level of nuclear-grade items. This confusion may cause uncertainty that is visible in the prices. To

tackle the related uncertainty, presenting requirements more explicitly and exploring ways to reach more uniformity in the requirements globally are encouraged. The interviews also brought up the need to assign the extent supplier auditing in relation to the supplier's previous performance, which would cut costs of especially well-established suppliers.

The Manufacturers pointed out that alternative ways to show conformity to certain requirements (e.g. material strength) should be searched for cutting unnecessary costs safely. For instance, if a valve shell's strength is required to be achieved through using certain material, it automatically leads to a given thickness. An alternative route to reach equivalent strength could be, however, found by using a stronger material of smaller thickness. Exact material composition requirements were seen by the Manufacturers as large contributors to the price, so exploring these kinds of alternative means to show compliance with requirements is seen worthwhile.

To safely bridge the price gap between nuclear- and commercial-grade items, benchmarking requirement specifications and standards of other safety-critical industries, such as the aviation and oil & gas industry, are encouraged. Benchmarking is seen as a way to point out the most significant similarities and differences in the requirement regimes. Authority #3 saw this as an important step when discussing the qualification of non-nuclear items for nuclear applications:

“We need factual evidence of what is missing and then some reflection on how to compensate for it.” (A.1.3.7)

This kind of “gap analysis” is practiced the American nuclear sector, where the NQA-1 standard allows for assessing the equivalence of non-qualified or foreign manufacturers. Further investigation of non-nuclear specifications is strongly encouraged in the literature (Abbt 2016; Martin 2017). Benchmarking the requirements of an oil & gas –grade shut-off valve was done in the case study.

The requirement for Requirement Specification Documents (RSDs) was introduced in the latest YVL guide updates in 2013, and as of now, the Finnish licensees have been compiling their individual RSDs. The Authorities felt strongly that cooperation of the Finnish licensees when compiling the RSDs would be useful, given that plant specific differences are taken into account. The cooperation was said to allow more agile use of authorized inspection bodies and to increase requirement uniformity within Finland. The Licensees were also in favor of this kind of RSD cooperation as it would cut costs. The Finnish licensees could also collaborate in supplier audits, which would cut overlapping efforts.

7. DISCUSSION

7.1 Evaluating the qualitative rigor of this study

According to Thomas and Magilvy (2011, p. 151), qualitative rigor is “a way to establish trust or confidence in the findings or results of a research study”. The evaluation of the qualitative rigor of this study follows an article by Thomas and Magilvy (2011) which addresses four components of trustworthiness: credibility, transferability, dependability and confirmability. These components were originally presented by Lincoln and Guba (1985). The rigor of this study is evaluated in the light of achieving these components.

Credibility

Credibility, also known as truth value is “achieved by checking for the representativeness of the data as a whole” (Thomas & Magilvy 2011, p. 152). Credibility can be achieved through reflexivity, informant feedback, and peer examination. Throughout this research, the researcher openly reflected on how his position in the organization of a nuclear power company, along with the interviewees’ positions in other organizations, may cause biases. The researcher also noted that the interview situation and content analysis are always reflective of the researcher’s subjective assumptions and views. In the requirement comparison stage of this study, the appended requirement tables (Appendixes B.1-B.3) were sent for Metso Flow Control’s (MFC) review by email, as the original Oil & Gas requirement level was received from MFC, and rendered into the tables by the researcher. MFC was involved throughout this study and the requirement comparison was iteratively planned and discussed with their valve experts prior and during the analysis. Additionally, to verify the different way reliability data is compiled for commercial-grade valves by MFC, multiple phone calls and emails were exchanged with MFC. For data verification in the interview study, the researcher compiled a summary of the interviews’ most relevant content and sent the summary to each informant for review. Thus, the researcher built self-corrective elements into the study already during the data gathering process. Additionally, the use of both quantitative and qualitative methods for between-method triangulation for RQ2 was intended to strengthen the credibility of findings (Edmondson & McManus 2007, p. 1157).

To familiarize himself with the interviewing situation and material, the researcher conducted a preliminary test interview and opted to transcribe all interviews manually. In addition, the translated original quotes of the interviewees’ phrases were brought up in the actual body text. These choices were said (Thomas & Magilvy 2011, p. 153) to strengthen the credibility of a qualitative study. The researcher admitted being new to qualitative research. As wished to have been clearly presented in this study, the researcher discussed the qualitative research process with his advisors and a social science graduate

student. This was hoped to show sufficient maturity and humility needed to admit one's weaknesses and push for constant improvement. In the light of this consideration, it is seen that the researcher showed sufficient effort to show credibility in his study.

Transferability

Transferability, also known as generalizability, refers to the ability to transfer findings or methods inter-contextually. That is, how relevant these findings are outside of this study's environment? Given the qualitative nature of this inquiry, it is natural that the data is collected from a narrow segment. It is evident that this narrowness causes problems with generalizing the results. However, according to Thomas and Magilvy (2011, p. 152), the purpose of qualitative research "is not to generalize to other subjects, but to explore deeply a specific phenomenon or experience on which to build further knowledge".

Objective of the requirement comparison (RQ1) was to shed more light on the compliance of non-nuclear requirements with nuclear requirements of lower Safety Class 3 (SC 3) items in Finland. This segment was de-generalized even further by selecting a specific valve type whose requirements in the Finnish nuclear field (in SC 3) were presented. These requirements were compared against the requirement specification MFC follows for their oil & gas shut-off valves. Although the scrutiny covered an extremely narrow segment, detailed description of the research context and data gathering techniques was hoped to increase possibilities for transferring the findings to a broader setting, or at least to build motivation for conducting similar inquiry on a larger scale. An example of a more general inquiry may be comparative studies of nuclear- and non-nuclear design standards.

Both quantitative and qualitative methods were used to evaluate the reliability of nuclear- and commercial-grade items (RQ2). After a rather unsuccessful quantitative inquiry of failure rates, paradoxically the qualitative interview findings supported the findings of the quantitative inquiry by concluding that comparing nuclear- and commercial-grade items' reliability data is hard. Between-method triangulation was hoped to improve transferability by strengthening the finding. The researcher gave apparent reasons for the impossibility of the numerical comparison of the scrutinized valve types' failure rates. This was hoped to build an understanding of the researcher's critical attitude, and also of the fact that this finding embraces a fundamental difference that is applicable also for other equipment beyond valves.

The methodology and execution of the semi-structured theme interview was explained in detail. Additionally, the background of the interviewer, interviewees and the organizational context were elaborated. One can justly argue that the interviewees come from the same country and reflect their individual thoughts and values that are a manifestation of both their personal backgrounds and organizational culture. This is arguably true for explorative interviews in general, and hence being transparent throughout this study was

hoped to build transferability. At least in the nuclear industry, the positions of the interviewees can be seen as geographically transferable between the licensees, authorities and manufacturers, as their organizational roles are supposedly similarly interrelated in each country. Statements of interviewees within same organizations were aligned, and therefore it can be assumed that the common views of the interviewed organizations (TVO, STUK, MFC) were reflected well in this study. However, it is clear that additional interviews with multiple stakeholders are needed for better transferability.

Dependability

According to Thomas and Magilvy (2011, p. 153), dependability occurs when “another researcher can follow the decision trail used by the researcher”. Laying out the background and specific research questions for this study was intended to give the reader a purpose for this study. Also, the selection process of the collaborating stakeholders (MFC and interviewees) was elaborated. The data gathering process was explained thoroughly, and also the possible deficiencies related to using multiple different and classified data sources were addressed. It is seen as justified to question the consistency of especially the data for the case study. However, the researcher has, at least in his view, been transparent and honest about the data sources and the reasons why such data were selected, including classified materials. Additionally, the reduction and analysis processes of the data were presented, although more concisely in the interview study than the case study.

The method selection for this study were discussed with peers in order to reduce the risk of using false methodology. Additionally, the data gathering process included iterative elements where validation of the reduced data was asked of the data sources. Quantitative and qualitative research methodologies and the criteria for choosing a method were explained, and thus the grounds for evaluating the researcher’s choice of research methods were hoped to be clear for the reader. Questioning the method for the case study’s requirement comparison is seen as justified, and having a predefined methodological framework for future comparison would help greatly. Although this study was not replicated, it is seen that the researcher has provided sufficient proof of dependability of his findings, especially with the interview study.

Confirmability

Confirmability, according to Thomas and Magilvy (2011, p. 154), occurs when “credibility, transferability and dependability have been established”. Lincoln and Guba (1985) described in 1985 confirmability as “the extent to which the data and interpretations of the study are grounded in the events rather inquirer’s personal constructions”. Previously in this chapter, the credibility, transferability and dependability of this study have been evaluated. Efforts to achieve credibility were seen sufficient, as the researcher promoted

transparency throughout the whole research process by being reflective of his own position, worldview and possible biases. The researcher showed that he had been hands-on familiar with his data, and presented his methods for iterative data source verification.

Adequate justifications for the use of chosen methods were presented, and between-method triangulation were introduced to reduce the researcher's own biases over the findings. Additionally, transferability was built into this study through clear and transparent description of the context, methods and data sources. However, it is evident that the findings are gathered from a niche segment, and no large generalizations can be made. However, this study is found successful if future targets for development for TVO and the nuclear industry in general are identified. As it was seen that most insights of this study provide guidance and motivation on the preferable way forward, this study has achieved a degree of transferability. An interview is always situational, and cannot be identically replicated. Still, the interview study was seen to hold extensive proof of dependability, for the researcher engaged in peer debriefing his methods and in verifying his findings with collaborators and interviewees. For the case study, the data sources were scattered, but the researcher showed transparency when describing the sources. However, it is apparent that a more refined methodology for this kind of comparative inquiry must be in place for increased dependability.

To conclude, the researcher built trustworthiness into this study's findings. Most findings were achieved through the interview study, and these findings are seen especially trustworthy. The criteria for reaching confirmability the findings, to the extent of a master's thesis, were met and justified.

7.2 Scientific contributions

Most requirements for the production of shut-off valves are similar in the Oil & Gas and nuclear (in SC 3) fields

This study generated further knowledge on top of previous studies and inquiries. MDEP (2014) evaluated the equivalence of different nuclear Codes and Standards (C&S) of pressure-boundary components and noted that the requirements of different nuclear codes result in an acceptable component. Subsequent dialogue (Abbt 2016; Martin 2017) encouraged further inquiry about the equivalency of non-nuclear and nuclear requirements for Safety Class 3 (SC 3) components. This research contributed for the scientific community through a qualitative case study, where requirements followed by Metso Flow Control's for their oil & gas shut-off valve deliveries were compared with the Finnish requirements assigned for a similar nuclear-grade valve in SC 3. It must be again highlighted that this inquiry was very specific and strongly tied to the requirement specification compiled and provided by a single manufacturer.

It was found that most design and testing requirements of the scrutinized valve types are equivalent or of similar nature. The current nuclear regulation allows using general structural design standards applied by the valve manufacturing industry. For example, both valves' shell tightness test was found to be according to an equivalent test procedure and equal acceptance criteria (ISO 12266-1, test P11). ISO 12266-1 is also used for the seat tightness test, but the acceptance criteria was found to be more demanding in the OG-specification (rate A) than the nuclear specification (rate B). The qualification of NDT examiners in both cases was according to ISO 9712, but in the OG-specification the requirement was level 1, and in the nuclear requirement was level 2, which is more demanding. The Quality Management System (QMS) followed by most petrochemical manufacturers is ISO 29001, and it holds and exceeds the requirements in ISO 9001 certification that nuclear SC 3 valves' manufacturers are required to have. Additionally, the welder approval was found to be equivalent in both requirement specifications (as per ISO 9606-1).

Although there are major equivalences and similarities as described, some nuclear-specific requirements, such as the construction inspection regime and requirements related to sustaining design bases conditions, form a gap in the requirement levels. It is evident that this research was only a preliminary inquiry of a very narrow section, and is thus not transferable as such, but it is seen that these results add motivation for further inquiry. In following research, novel procedures for more exact comparison of nuclear and non-nuclear requirements and standards must be developed in order to rigidly evaluate the compliance of non-nuclear procedures on a broader level.

Acceptance of commercial-grade items for nuclear applications

Commercial-grade dedication is a method utilized in USA to accept commercial-grade items for use in nuclear safety-related applications. A similar systematic approach to accept commercial-grade for nuclear use is unseen in Europe, and especially the European nuclear community (Abbt, 2017) has motivated to explore such procedures. This study looked to elaborate on this subject through an interview study. An overall finding was that in Finland, the acceptance process should start from evaluating a commercial-grade item's conformity to the nuclear requirements, after which ways to reach the required level shall be examined. This finding further motivates exploring and developing rigid methods for the evaluation and acceptance of commercial-grade standards and practices.

Operational reliability of nuclear- and commercial-grade items

In order to shed light on the reliability of nuclear- and commercial-grade items, this study combined qualitative and quantitative methods. In the qualitative interview study, the interviewees were found to disagree on the reliability of the items. Most Licensees stated that the reliability of First Of A Kind (FOAK) designs is inferior to items that are serially

produced, while the Manufacturers saw that although extended QC does not add reliability, the conservative design margins commonly applied for nuclear-grade items directly increase reliability. The Authorities stated that it is uncertain whether or not the nuclear-grade items hold superior reliability, but that previous QC measures have revealed non-conformances. This view was opposed by the Manufacturers, who stated that no dramatic defects have been identified through QC. This is seen as an area for further research: for instance, the type and numbers of QC occurrences may be compared in the nuclear and commercial-grade items' production.

Most interviewees concluded that legitimate ways to compare the reliability data of nuclear- and commercial-grade items shall be explored. To provide for this need also motivated previously by Abbt (2016) and Martin (2017), the operational performance of nuclear- and commercial-grade valves was set to be quantitatively compared. However, as it turned out during this study, the legitimate comparison of the valves' failure rates as such is not possible. Procedures used for the construction of their failure rates are remarkably different. The nuclear-grade valves' failure rates are based solely on accurate historical field data with precise numbers of failures and components included. The failure rates of commercial-grade valves are compiled through theoretical FMEDA analyses and field data. The collaborating manufacturer didn't provide original failure data, pleading to securing trade secrets. In addition, information of the valves' operation, environment and maintenance were not accessible. These distinctions were seen to cause uncertainty that prevents from comparing the failure rates. However, a huge potential is seen in utilizing the large database of commercial-grade items' failure rates. More research on ways to reach comparability of the failure rates or other manifestations of operational performance is encouraged. This research should include developing a uniform method for the construction of failure rates across industries. The oil & gas industry holds a large volume of components whose failures are documented according to a uniform procedure. The nuclear field would benefit from more uniform procedures for collecting and analyzing failure data, because the application of nuclear power is fairly similar globally. Accessing more data within the industry would increase knowledge of the items' performance.

Harmonization of nuclear requirements in an ongoing but slow process

The fundamental goal of each country that produces nuclear energy is to ensure safety. The top-level requirements represent a global consensus, but the practical ground-level requirements are rather dissimilar. Efforts have been made in order to harmonize the requirements, but the research is just starting off. Previous research (Hill 2016) proposes that requirements will either converge towards a similar set of global standards and requirements, or reach equivalence which means that multiple different procedures and requirements and standards are qualified and accepted globally. One of the objectives of this study was to inquire most likely future path of the uniformity of nuclear requirements through interviews. The interviewed Licensees stated that the requirements will converge towards a single requirement level, while the Authorities viewed that equivalence is the

future. Although the interviews didn't provide a consistent finding, in the light of this entire study, it is apparent that the future holds more elements of requirement equivalence than convergence. As it emerged during the interviews, cultural and legislative differences are deeply anchored in the nuclear industry, along with protectionism and vested interest of different stakeholders. This is seen to make it extremely hard to agree upon abandoning most existing regulation and practices and choosing one path that is followed by all. Therefore, reaching a consensus over the practical-level requirements is seen close to impossible, and hence the path of requirement equivalence is viewed as most likely.

Nuclear market is unattractive and confusing to non-nuclear suppliers

The exclusivity of nuclear requirements has been stated (Wahlström 2003; EPRI 2014; Abbt 2017) to produce items of higher price and lower reliability in comparison to commercial-grade items. Wahlström and Sairanen (2001) noted that safe production can be achieved only when the financial situation of a nuclear facility is sound. As the price of electricity has gone down, it is apparent that the reasons behind the rather high nuclear price level must be identified and evaluated. Some interviewees saw that the requirements are not presented clearly enough for non-nuclear suppliers, who therefore add a risk-premium on top of their price. This was also emphasized strongly by Abbt (2016) who stated that half of the added price of nuclear-grade items may be accounted for by this uncertainty. This hypothesis was supported by the interviewed Manufacturers and Licensees. Another fundamental issue was brought up: non-nuclear suppliers might not want to be associated with nuclear power in the first place because it was seen as bad for their other business. This was viewed to decrease the supplier pool, which in effectively decreases market rivalry. This notion was not brought up to this extent in previous research.

7.3 Practical contributions

This study was conducted as an assignment for Teollisuuden Voima Oyj (TVO), and it was a part of a larger project whose one objective is to study what the nuclear industry can learn from conventional industries to maintain and improve safety cost-effectively. This study hoped to deliver practical suggestions for future development that would be useful for both TVO and the whole nuclear community. Both the case study and the interview study were used to gather data for the research questions. Three areas for practical development were distilled from the data, and refined by the researcher's rationale that developed iteratively during the research process.

1. Qualification through equivalency analysis and supplementary measures

Nuclear regulation and the practical-level requirements were stated to be different between countries producing nuclear power. Current deviations of different nuclear standards were not seen as the issue by the interviewees or previous research (MDEP 2014), but the problems were seen to lie in the difference of non-nuclear and nuclear standards.

Although most interviewees disagreed on the future path of requirement uniformity, in the light of this research the most recommended way forward is promoting ways to accept non-nuclear procedures to be used in the nuclear domain. Hence, to pursue equivalence in the future, it is suggested that TVO and the nuclear community engage in activities that aim to accept non-nuclear requirements and standards for use in nuclear applications.

The interviewed authorities noted that although QC requirements don't necessarily add reliability of items, compliance with the requirements must be ensured. However, compliance with the requirements does not necessarily ensure the item's safe operational performance, which should be the objective of all nuclear facilities. Hence nuclear and non-nuclear QC procedures must be compared to evaluate their effects, for example by analyzing unwanted findings per examined batch. This kind of evaluation is seen a way the acceptance of non-nuclear items may be discussed. As this study showed, many requirements related to design and inspection in nuclear and non-nuclear fields are equivalent or similar, but some fundamental differences exist. Welder qualification, structural design and factory test requirements were found equivalent or closely related, but the definition of hold/witness points and the end testing regime were found different. To increase the resolution of these findings, further investigation on the compliance of non-nuclear requirements is needed. To start off from a higher baseline, equivalency analyses of the requirements and standards of other safety-critical industries such as the oil & gas and aviation industries are encouraged.

Rigid methods for evaluating the equivalence of non-nuclear procedures must be constructed. During this study, it was notable that not having well-established methods for comparing the nuclear- and OG-specifications increased the workload and added uncertainty of the relevance of findings. Such methods shall be developed in close cooperation with the authorities, because without authoritative acceptance, it is highly unlikely that the methods or proposed findings will lead to concrete actions. As brought up by the interviewees, once such methods have been established, the equivalency analysis shall be executed. After the analysis, supplementary measures to fill the remaining gap must be designed, validated and executed. Supplementary measures may include post-production testing and evaluation of supplier performance and reference records: the interviews brought up that the level of trust in a particular supplier does not correlate with the assigned QC and QA regime. These supplementary measures are part of the commercial-grade dedication method in USA, where safety has increased and costs have decreased after accepting commercial-grade items for nuclear applications. Further exploring the possibilities of this method in the Finnish nuclear sector is strongly encouraged, as also brought up in the interviews.

QC of nuclear-grade items was said to have revealed defects by the Authorities, while the Manufacturers claimed not to have seen any dramatic defects in their commercial-grade

QC. The Licensees saw that there's no need for additional QC on top of standard industrial practices. To validate these statements, comparison of revealed defects in the production of nuclear- and commercial-grade items is advised.

It is clear that some nuclear-specific requirements, such as requirements regarding seismicity, must be satisfied. However, alternative measures to reach certain characteristics shall be examined. The Finnish legislation (Nuclear Energy Act, section 7r (3)) supports this view, and the interviewed authorities suggested exploring alternative ways to show conformity. For example, compliance to a strength requirement may be shown by using another material and dimensions than prescribed in the nuclear standard.

2. Improving comparability of nuclear- and commercial-grade reliability data

A qualitative inquiry was set to compare failure rates of similar nuclear- and commercial-grade isolation valves. However, reality proved that the failure rates were constructed in fundamentally different ways. This, coupled with the reluctance of a collaborating valve manufacturer to give up original failure data because of its sensitive nature, prevented from proceeding with the comparison. This is seen a valuable insight that was additionally supported by the interview findings. Throughout this study, a clear need for safe access to commercial-grade failure data was identified. To help accept commercial-grade items for use in nuclear applications, rigid evidence of their operational performance must be presented. Access to reliability data is seen a prerequisite for reaching comparability of the items' failure rates. The nuclear field is very cooperative internally, but external cooperation with non-nuclear stakeholders must be increased. Cooperation between all stakeholders shall be increased for finding safe ways to access commercial-grade items' reliability data without endangering trade secrets. The suggested cooperation is seen to help promote an open atmosphere and facilitate information sharing.

In the interviews, reliability effects of structural customization (e.g. abnormal material selection) were seen differently. The Authorities stated clearly that while a requirement might diverge the production from repetitive practices, it is always assigned for a reason - there is always some acceptance criterion behind a specific requirement. The Licensees were supportive of this vision, but some stated that the total reliability might actually be lower because design basis requirements may differentiate the production to the extent where the benefits of structural customization are lost. The Manufacturers stated that structural over-specification, for example a using harder material, directly adds reliability. These findings further motivate the comparison of nuclear- and commercial-grade items' reliability data.

3. Safety and cost-effectiveness through improved reputation and cooperation

It is evident that the nuclear industry must seek ways to improve cost-effectiveness in a rapidly evolving electricity market. The search cannot, however, by any means endanger safety that is the core value of nuclear energy production. Most interviewees saw that the

current bad reputation of nuclear power is driving the prices up, as some suppliers are not willing to collaborate with the nuclear industry in the first place. Suppliers may feel that the risks of being associated with nuclear power outweigh the benefits of collaboration. Active work is needed to promote public acceptance, even though changing the public opinion on nuclear power is a slow and demanding process. The Fukushima accident in 2011 reminded that maintaining safety is of great importance for the global acceptance and future of nuclear power. Improving the reputation of nuclear power is a shared goal for the nuclear industry, and benefits of such development may be seen on a broader level beyond cost savings.

The interviews brought up that a more uniform requirement level in the nuclear industry would open up the market and decrease prices through rivalry. This may be achieved by improving the uniformity of nuclear requirements globally and by accepting non-nuclear procedures for use in the nuclear industry. Additionally, some non-nuclear suppliers might see the requirements related to their nuclear deliveries as unclear, which may cause “stage freight” as one interviewee put it. A more explicit and clear articulation of requirements is seen to help the non-nuclear suppliers understand better what exactly is required. Therefore, dialogue between the licensees, regulators, and the suppliers is encouraged. The Requirement Specification Documents (RSDs) were seen a step towards a clearer requirement regime. The interviewees unanimously stated that the Finnish licensees could collaborate in compiling the RSDs. This kind of development would not only promote a more uniform requirement specification, but allow for intelligent use of resources and prevent from overlapping efforts. Also, benchmarking the procedures of other safety-critical industries such as the aviation and oil & gas industries was recommended in the interviews.

8. CONCLUSIONS

Systems of nuclear facilities include individual items whose quality is of great importance for ensuring a safe and uninterrupted operation. Production of an item follows requirements that are assigned according to its safety significance. However, these requirements sometimes differentiate nuclear-grade items from commercial-grade items that are used in large volumes by many industries. The production of commercial-grade items benefits from repetitive and well-developed manufacturing practices. It has been stated that commercial-grade items meet the quality and reliability required of nuclear-grade Safety Class 3 (SC 3) items.

These statements were assessed in a case study, where the requirements and reliabilities of nuclear- and commercial-grade valves were compared. Valve manufacturer Metso Flow Control (MFC) delivered their general requirement specification they follow for their shut-off valve deliveries to the Oil & Gas (OG) industry. To answer Research Question 1 (RQ1), this specification was compared with a requirement specification for nuclear-grade shut-off valves in SC 3. It was found that most structural design and testing requirements are equivalent or similar. For example, a test procedure for shell tightness was equal (ISO 12266-1, test P11) in both specifications. In addition, the valves' structural design and welder approval can be done according to same standards. The largest differences were found in certain requirements related to design basis conditions whose tolerance the nuclear valves' production must ensure, for example tolerance of environmental conditions such as seismic events or radiation. Additionally, the findings indicate that the scope and definition of hold/witness points and the end testing regime are different. Certain production phases and end tests of nuclear SC 3 valves shall be supervised by an authorized inspection body that is approved by STUK. However, the OG-specification holds a less extensive third-party inspection regime during manufacturing, but a more demanding end testing regime that is done by the customer. To conclude, the findings show that although some nuclear-specific requirements are unique, majority of the requirements are of similar nature.

The operational reliability of nuclear- and commercial-grade items was evaluated quantitatively in the case study, where the failure rates of nuclear- and commercial-grade isolation valves were set to be compared (RQ2). However, it was found that the failure rates of these valves are compiled differently: failure rates of nuclear valves are based on accurate historical data collected from nuclear facilities, and failure rates of the scrutinized commercial-grade valves are based on FMEDA analyses and data collected from different types of facilities. Additionally, it turned out that the original commercial-grade failure

data is not accessible due to its commercially sensitive nature. As it turned out, a trustworthy comparison of failure rates is not possible, and the quantitative comparison was not executed.

An interview study was conducted to inquire knowledge for research questions 2-5. Nine experts from three different organizations in the Finnish nuclear sector were selected and interviewed. RQ2 was discussed also in the interview study, but the focus was on items and not just valves. As the findings show, the repetitive production of commercial-grade items is seen to increase their quality and reliability. However, the Authorities stated that while some nuclear-specific Quality Control (QC) requirements do not necessarily improve reliability, they must be conducted to ensure compliance with the requirements. It was also stated that previous QC efforts have revealed defects in nuclear-grade items. Licensees and Manufacturers saw that additional QC requirements on top of industrial standards do not increase reliability at least with credible suppliers, and that dramatic defects have not been found. However, the Manufacturers saw that structural customization (e.g. over-specification of material characteristics) directly increases the reliability of nuclear-grade items. The Licensees disagreed and stated that structural customization prevents benefiting from repetitive production which results in lower reliability. In addition, the results show that for using reliability data to accept commercial-grade items for nuclear applications, its comparability with nuclear-grade data must be ensured. This finding is strengthened by the difficulties of comparing reliability data as shown in the case study.

In the interview study, also the current state and future of nuclear requirement harmonization (RQ3) was discussed. As the results show, top-level nuclear requirements were seen as uniform globally, but the practical level as inconsistent between countries. This was found to emerge from nationally different legislation and culture but also from vested interests of different stakeholders. Non-uniformity of requirements was stated to limit the number of capable suppliers as it prevents them from using similar nuclear specifications for multiple customers. While no consensus was found among the interviewees about whether the future is towards convergence or equivalence of requirements, in the light of this study, the future path of harmonization is towards equivalency. Reaching the equivalency of requirements means that ways to accept different standards and procedures are developed and adopted.

Differences in nuclear-specific standards were not seen as a major obstacle, unlike the differences of nuclear and non-nuclear requirements and procedures. In USA, commercial-grade dedication is a method used to accept commercial-grade items for use in nuclear safety-related applications. Such methods are not commonplace in Europe, and ways to accept commercial-grade items for use in nuclear applications (RQ4) were discussed in the interviews. The findings indicate that in order to accept commercial-grade items, their compliance with the nuclear requirements should first be assessed. After the

assessment, alternative measures to fill the remaining “gap” should be designed and executed. The Manufacturers underscored that assuring subcontractor quality and conducting extensive post-production inspection and testing are enough to ensure that commercial-grade items function reliably also in nuclear applications.

Cost-effective ways to increase safety were discussed in the interviews (RQ5). The Manufacturers and Licensees suggested that practices of other safety-critical industries should be benchmarked. The Manufacturers emphasized the importance of end testing, and that the current QC efforts during production are wasting resources. Also, the Licensees stated that current QC requirements included in industrial standards and PED are sufficient for SC 3 item. It was additionally found that the current negative reputation of nuclear power makes some suppliers reluctant to collaborate with the nuclear sector. Some interviewees suggested that the public image of nuclear power should be promoted in order to attract more suppliers and to increase supply. Authority #3 summed up the current issues:

“It [a more uniform requirement level] would probably have effects such as the nuclear industry would become more attractive. Nowadays vendors don't want to supply anything for it's so hard in their view. It's not sexy and it's a bit risky because being identified as a nuclear power plant supplier might hurt your reputation. More business would make it [the nuclear sector] more attractive to the vendors.” (A.1.3.11)

As the previous quote and other interview findings indicate, non-nuclear suppliers may perceive the nuclear requirements as confusing or hard. This was said to increase prices. Hence, a clearer articulation of nuclear requirements was encouraged by most interviewees. Cooperation between licensees in drafting the requirement specification documents was seen as a way to clarify the Finnish nuclear requirements, reduce overlapping efforts and to ensure the safety of items. Finally, it was found that improving the uniformity of nuclear requirements would lower the bar for the suppliers to collaborate with the nuclear sector. This was seen to promote healthy market conditions.

Data used to arrive at these conclusions was gathered and analyzed according to justified and transparent procedures. However, these findings clearly represent an extremely narrow segment, and cannot as such be transferred to other environments. It must be noted that especially qualitative interviews hold biases that reflect the subjective views and positions of the researcher and interviewees. Although this study succeeded in providing the nuclear industry future targets for development, more research is needed to improve the trustworthiness of these findings. It is clear commercial-grade items cannot be used as such in the place of safety-related nuclear-grade items. Therefore, it is recommended that rigid methods for evaluating compliance of the items and for filling the “gap” are developed. Such methods could include using reliability data, if the comparability of nuclear- and commercial-grade items' reliability data is improved.

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APPENDIX A.1 - Interview table - Representatives of the Authority

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Authority #1 A.1.1.1	Mikä on ydinlaitoksissa käytettävien turvallisuusluokiteltujen laitteiden laatuun liittyvien erityisvaatimusten tavoite?	What is the goal of the specific quality requirements of safety classified equipment?	VIRANOMAINEN #1:N ALKUPERÄISET VASTAUKSET ON SENSUROITU HAASTATETAVAN OMASTA PYNNÖSTÄ.	ORIGINAL ANSWERS OF AUTHORITY #1 HAVE BEEN CENSORED FROM THE INTERVIEWEES OWN REQUEST	Suunnitteluperusteisesti varaudutaan tiettyihin käyttötilanteisiin ja onnettomuuksiin, joiden pohjalta asetetaan tietyt hyväksymiskriteerit.	Design bases define certain acceptance criteria the equipment need sustain during normal operation and occurrences.	Compliance with design bases	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.1			Tietenkin pyrkii siihen et se laite on turvallinen. Sillä tavalla [laatuvaatimuksilla] saadaan varmistettua et nää [laitteet] on vaatimustenmukaisia ja että ne tarkastukset on tehty riittävällä tarkkuudella jos on korkeen turvallisuus- tai laatu luokan komponentti, jota otetaan jonkin järjestelmän käyttöön.	Of course the goal is to have safe equipment. [Quality requirements] that way gives assurance that these [equipment] are in conformance with the requirements and that the inspections are done with adequate precision, if we have a high safety or quality class component that's commissioned in some system.	Turvallisuus on laatuvaatimusten tavoite. Laitteen laatuvaatimukset antavat varmuutta vaatimuksenmukaisuudesta turvallisuusmerkityksellisten komponenttien osalta.	Safety is the fundamental goal of quality requirements. Quality Control gives assurance of conformity to requirements in safety significant components.	Fundamental safety Assurance of conformity	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Authority #3 A.1.3.1			Et kyl se mun mielestä on sen luotettavuuden parantaminen siinä lopputuotteessa ja sit etenkin kun mennään automaatioon ja ohjelmoitavaan automaatioon, ettei sinne jää mitään piilo-ominaisuuksia ohjelmistoon.	In my opinion it's the improvement of reliability in the end product, especially what comes to programmable automation, for there not to be any hidden attributes in the programs.	Luotettavuus on vaatimusten tavoite. Ohjelmoitavassa automaatiossa on varmistuttava siitä ettei mitään ominaisuuksia jää piiloon.	Reliability is the goal of the requirements. Assurance of programmable automation systems' features need be gained.	Reliability Programmable automation	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
			ehkä yks ero konventionaalseen puoleen, et siel esimerkiksi sä voit tavallaan toiminnon luotettavuutta parantaa lisäämällä tätä rinnakkaisuutta et laitat yhden sijasta kaks rinnakaista tekemään samaa juttua, niin täällä tavallaan sä et voi sitä neljää rinnakkaisuutta syödä sillä - se ei oo tarkoitettu siihen vaan on ajateltu, että se yksin on jo hyvin laadukas.	a difference is that in conventional industries a single operation's reliability can be improved by adding redundancy by installing two redundant systems instead of one. But in nuclear facilities you can't use solely redundancies. Assuring top quality of a single system or component is important.	Konventionaalisessa teollisuudessa redundanttisia toiminnallisia kerroksia voidaan lisätä parantamaan luotettavuutta, mutta ydin alalla rinnakkaisuus ei riitä vaan on keskityttävä yksittäisen tuotteen laatuun.	In convetional industry, a single operation's reliability can be assured by adding redundant layers, but in nuclear facilities, only redundancy is not sufficient. Special attention must be given to the quality of a single equipment.	Conventional vs. nuclear industry Redundancy Reliability	Commercial-grade items Safety systems	Reliability of commercial-grade items vs. nuclear-grade items
Authority #1 A.1.1.2	Miten Suomen nykyiset laitososien laadunvalvontaa koskevat erityisvaatimukset vaikuttavat turvallisuusluokiteltujen laitteiden luotettavuuteen ydinlaitoksissa?	How do the current Finnish Quality Control related requirements affect the reliability of safety classified equipment in nuclear facilities?			Tarkastus ei paranna laatua, mutta suunnitelmien vaatimuksenmukaisuudesta on varmistuttava. Tarkastuksissa on tullut myös hylkäystapauksia.	Quality is not improved by testing, but conformance need be assured. Nonconformances have been detected in inspections.	Role of inspection in QC	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.2			Kun kaikki menee niin kuin on ennalta suunniteltu niin silloin on luottamus siihen, että kaikki huomioitavat asiat tulee otetuks huomioon, ettei mitään jää pois. Semmonen ennakotarkastusmenettely mikä meillä on, on aika hyvä työkalu siihen että saadaan YVL-ohjeiden mukainen menettely.	When everything goes according to the plan, we can trust that all considerable matters are considered and nothing is left out. The pre-inspection procedure we have is a great tool to assure accordance with YVL Guides.	Kun edetään tarkastussuunnitelman mukaan, voidaan varmistua siitä että kaikki asiat on huomioitu ja saadaan YVL-ohjeita noudattava menettely.	When the inspection plan is followed, we may trust that everything in the YVL-guides is accounted for and nothing is left out.	Role of plans on QC	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Authority #3 A.1.3.2			kyl siin on haluttu varmuutta siihen et se mikä esimerkiksi tulostodokumentaatiossa esitetään pitää paikkaansa. Tällaista riippumatonta arviointia siitä vaatimustenmukaisuudesta.	it's to gain assurance of conformity for example to the result documentation's arguments. This kind of independent review of conformity to requirements.	Laadunvalvonnan tarkoitus on saada riippumatonta valmistusta vaatimustenmukaisuudesta.	The goal of QC is to gain assurance to the requirements by independent members.	Role of inspection in QC	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Authority #1 A.1.1.3	Miten standardilaitteiden luotettavuus suhtautuu ydin alaan vaatimusten mukaisesti räätälöidyn laitteen luotettavuuteen?	How does the reliability of commercial-grade equipment position against customized equipment in compliance with nuclear requirements?			Jos laadusta huolehditaan asianmukaisesti, standardilaitteen luotettavuudessa ei ole merkittävää eroa TL 3:n vaatimusten mukaisesti valmistettuun laitteeseen verrattuna. Joissain tapauksissa standardilaitteen luotettavuus on parempi, koska lastentaudit ovat karsituneet ajan myötä ja on saatu palautetta kentältä.	If quality is taken care of, there is no significant difference in the reliability between SC 3 equipment. Sometimes serial production produces better quality through learning.	Serial production	Commercial-grade items	Reliability of commercial-grade items vs. nuclear-grade items

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Authority #2 A.1.2.3	Miten standardilaitteiden luotettavuus suhtautuu ydinalan vaatimusten mukaisesti räätälöidyn laitteen luotettavuuteen?	How does the reliability of commercial-grade equipment position against customized equipment in compliance with nuclear requirements?	<i>Täytyy olla joku korvaava menettelytapa tälle normaalille menettelylle [standardikomponenttien tuotanto], koska ei ole riittävää korkeassa turvaluokassa että vaikka kuinka luotettaisi siihen sarjavalmistuksen laaduntutokkyyn niin se täytyy pystyä myös todentaa jossakin.</i> <i>Siinä [standardilaitteiden kelpoistamisessa] täytyy varmistaa ensinnäkin se, että se tuotantolinja tai tehdas joka niitä valmistaa on vaatimustenmukainen, eli siellä täytyy olla varmuus siitä että se tekee laatua, systemaattisesti joko hyvää tai huonoa jos nyt karrikoidaan. Ja täytyy varmistaa niinkun laadunhallinnan kautta et se on kohdalleen säädetty se tehdas, jos niin sanotaan. Silloin voi olla mahdollista käyttää näitä standardikomponentteja vaativammassakin kohteessa.</i>	There must be some alternative procedure to the normal procedure [standard component production], because it's just not enough that we trust in the ability to make quality products as serial production in a high safety class. It must be verified somewhere. By using that [qualifying commercial-grade items] we must verify firstly that the manufacturer conforms to the requirements, which means they must assure they're producing quality, systematically either good or bad quality. The factory's functioning in a proper manner must be validated through quality management. Then commercial-grade items may be utilized even in more challenging applications.	Korkeissa turvallisuusluokissa ei voida käyttää sarjavalmistaisia komponentteja sellaisenaan vaan lisävarmuutta on haettava jostain. Standardilaitteiden kelpoistamisessa on varmistuttava tehtaan laaduntutokkyvystä laadunhallinnan menetelmillä. Se mahdollistaa standardilaitteiden käytön jopa korkean turvallisuusmerkityksen kohteissa.	In high safety classes it's not possible to use serially produced components as such. We have to seek additional assurance. In qualifying commercial-grade items we must get assurance of the factory's ability to produce quality. It's done through quality management measures. It allows to use commercial-grade items even in high safety applications.	Serial production Assurance Commercial-grade dedication Assurance	Commercial-grade items Commercial-grade items	Reliability of commercial-grade items vs. nuclear-grade items
Authority #3 A.1.3.3			<i>No se on hyvä kysymys. En mä pysty antaan suuntaan enkä toiseen mitään evidenssiä. En mä oo niin kun nähnyt." ... "Se [evidenssi] olis mielenkiintoinen just nähdä.</i> <i>tietysti omatkin kokemukset vaikka tosta kolmosen projektistakin on vähän sellaset et ei täs tällasessa uniikkituotannossa, ei siinä mitään hienoo oo. Kyl siinä voi mennä niin kun paljon asioita pieleenkin. Et kylhän se standardisointi siinä valmistuksessaakin sitä laatuun tuo.</i>	Well that is a good question. I can't show any evidence for either case. It would be interesting to see. of course my own experience with for example the OL3 project says that this kind of unique production is not anything great by itself. I mean that a lot can go wrong in the process. Standardisation in the production adds quality.	On todella hankalaa sanoa kumpi laite olisi luotettavampi, koska tutkimustietoa ei ole. Lisätutkimusta tarvitaan. Kokemus sanoo, että räätälöity tuotanto ei aina johda korkeaan laatuun vaan voi aiheuttaa myös paljon ongelmia. Standardoidumpi valmistustapa lisää laatua.	It's impossible to speculate which one of the equipment is more reliable. More research is needed. Experience says that customization doesn't always result in high quality - it may cause a lot of troubles. A more standardised manufacturing process results in better quality.	Reliability difference Quality difference	Commercial-grade items Nuclear-grade items	Reliability of commercial-grade items vs. nuclear-grade items
Authority #1 A.1.1.4	Miten näet että tuotantoprosessin rakenteellinen eriytyminen vaikuttaa tuotteen luotavuuteen?	How do you see the reliability effect of structural differentiation?			Räätälöinti heikentää laatua, mutta räätälöinnille on aina syynsä.	Custom production impairs quality but there's reason for the customization to be used.	Compliance with Design bases. Serial production	Commercial-grade items	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.4			<i>No siinä on riskkejä siinä sarjatuotantovalintoedossa että spesifiset vaatimukset, jotka kohteeseen edellytetään sen normaalin laadun lisäksi, eivät täyttisi välttämättä. Verrattuna siihen konventionaaliseen menettelytapaan, jossa tehdään rakennesuunnitelma ja rakennetarkastus. Sillä täytyy olla jotain varmentavia toimenpiteitä että vaatimukset täyttyy, jos turvallisuusluokka niin edellyttää.</i>	Well there is risk that the service place specific requirements would not be fulfilled in the serial produced alternative. In comparison with the conventional way that includes the construction plan and inspection.	Sarjatuotanto ei välttämättä täytä laitospaikkakohtaisia vaatimuksia verrattuna konventionaaliseen menettelytapaan.	Serial production won't necessarily fulfill the service place specific requirements like the conventional way does.	Serial production Specific requirements Construction plan	Commercial-grade items Conventional procedure	Reliability of commercial-grade items vs. nuclear-grade items
Authority #3 A.1.3.4			<i>Jos käytännössä tulis tällanen keissi esiin niin jonkunhan sit pitäis analysoida et varmaan sen toimittajan pitäisi osoittaa ostajalle, että tällä ei oo mitään negatiivista vaikutusta. Ja tota, joo. Useinhan nää on tosiaan aika edullisia asia et periaatteessahan niitä voi vaikka rikkoa ja kattoo et miten se käyttäytyy.</i>	if we had a case like this in practice, someone would have to analyze, probably the supplier would have to show that the customization has no negative effect. And uh, it's common that these parts are cheap so DT may be used to show its behaviour.	Valmistajan täytyisi tällaisessa tapauksessa todistaa luvanhaltijalle, ettei eriytymisestä aiheutunut negatiivista vaikutusta luotettavuudelle, esimerkiksi rikkovan testauksen avulla.	The supplier has to show that the customization didn't result in negative effects for the reliability by for example DT.	Conformance of reliability Alternative procedures to assure safety Destructive Testing (DT)	Reliability	Reliability of commercial-grade items vs. nuclear-grade items

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Authority #1 A.1.1.5	Näkemys standardilaitteiden luotettavuusdatan käyttökelpoisuudesta turvallisuusluokiteltujen laitteiden kelpoistuksessa?	What is your view on utilizing reliability data of commercial-grade items in accepting safety classified equipment?			Luotettavuustieto on hyvä asia, mutta se on usein kerätty olosuhteista, jotka eivät vastaa ydinvoimalan olosuhteita.	It's great to have a lot of reliability data but another thing is to have data that is gathered in NPP conditions.	Reliability data Operational experience	Qualification	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.5	Näkemys standardilaitteiden luotettavuusdatan käyttökelpoisuudesta turvallisuusluokiteltujen laitteiden kelpoistuksessa?	What is your view on utilizing reliability data of commercial-grade items in accepting safety classified equipment?	<i>Tokihan sitä voi hyödyntää, et jos se tehdas on sarjavalmistukseen tuotantolinjaan säädetty niin ei se pahaa tee se luotettavuustietokaan, mut että kuinka paljon siihen voidaan luottaa niin se täytyy varmistaa. Laaduntutokkyyn varmistaminen on tärkeintä. Sen kun pystyy osoittamaan ja sitten nää lisävaatimukset eivät ole niin velvoittavia kaikin puolin.</i>	<i>It [reliability data] can sure be utilized if the factory is tuned to serial production, it doesn't hurt to have reliability data, but the level to which it can be trusted must be verified.</i>	Laaduntutokky on tärkeintä. Luotettavuustieto on hyvästä, mutta siihen sisältyy epävarmuutta.	The ability to produce quality is th priority. Reliability data is great, but it comes with uncertainty.	Quality of production Reliability data Uncertainty	Reliability	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.6			<i>Jos on hyvä luottamuksia siitä, että tuote tulee laadukkaaksi niin se on hyvä asia. Ja onhan YVL-ohjeissakin aina mahdollisuus, vaikka ne vaatimukset on velvoittavia, niin esittää vaihtoehtoinen toimintatapa, jolla saavutetaan sama turvallisuustaso.</i> <i>Noin yleisesti voidaan kuitenkin ajatella, että jos on varmuus ja näyttö siitä että tuotantolinja tuottaa hyvää laatua niin kyllä se tietysti luokitellaan tulevaisuudessa.</i>	<i>It's great if we can trust that the process will produce quality products. The YVL Guides give the opportunity to present an alternative procedure that reaches the same safety level.</i> <i>In general we can think that if we have confidence and evidence of good quality of a production line, it's of course credible information.</i>	YVL-ohjeet antavat mahdollisuuden esittää vaihtoehtoisia toimintatapoja ja tuotteiden luotettavuustieto tukee tällaisten menettelytapojen turvallisuuden varmistamista.	The YVL guides allow for alternative ways to ensure adequate safety, and reliability data is a way to bring more assurance of the safety.	Alternative procedures to assure safety Reliability data YVL guide	Reliability	
Authority #3 A.1.3.5	Näkemys standardilaitteiden luotettavuusdatan käyttökelpoisuudesta turvallisuusluokiteltujen laitteiden kelpoistuksessa?	What is your view on utilizing reliability data of commercial-grade items in accepting safety classified equipment?	<i>En mä siinä niinkun näkis, teollisuusympäristö kuin teollisuusympäristö. Niin kauan kun ei nyt puhuta mistään säteilystä eikä tällasesta eikä ympäristöolosuhteisiin kelpoistamisesta. Lämpöä, tärinää ja tällastahan teollisuudesta kaikkialta löytyy.</i> <i>Tota kyl sitä niin kun käyttää vois, mutta musta tuntuu et se usein tyssä tähän et sä et niin kun, se ei oo niin kun valmistajan intressissä antaa sellasia tietoja.</i> <i>Ja sit toinen kysymys siinä on se et onks se saatu käyttökokeistietoa relevanttia, koska valmistaja tekee kuitenkin muutoksia siihen koko ajan.</i> <i>Tosi ongelmallisiin tilanteisiin välillä ajaututaan, et sulla on joku 20 euron osa missä on pätkä jotain koodia ja valmistaja sanoo et tästä on hyvät käyttökokeukset. Sit kun sulle sanoo et no osalta se - no ei olekaan intressiä osoittaa ja ei nyt 20 euron osan takia ruveta mitään osoittamaan. No kelpoista se. Okei, kelpoistetaan, mut se maksaa 2000 € sen jälkeen.</i> <i>Mulla ei ainakaan oo henkilökohtaisesti mitään sitä ajatusta vastaan että oikeesti käytettäisiin näitä tällaisia standardilaitteita, koska ne on yleensä edullisempia hankkia. Se voisi johtaa nopeampaan päivityssykliin laitteilla.</i>	<i>xi don't see any differences what comes to industrial environments as long as we're not talking about things like radiation or qualification to special environmental conditions. Heat, vibrations and other phenomena are found in all industries.</i> <i>Sure it could be used, but I feel like a common obstacle is the reluctance of manufacturers to give up such data.</i> <i>Another question is that is the operational data relevant for the manufacturer is modifying their product constantly.</i> <i>Sometimes we're faced with really problematic situations like when you have a 20 € part that has some code in it. The manufacturer says it has good operational experience. When you ask them for proof, it's not in their interest to prove it for a 20 € part. Well qualify it. Okay, it's qualified and the price is 2000 € after that.</i> <i>I personally have nothing against the fact of using commercial-grade items for they usually are less expensive. It might result in quicker update cycles at the facility.</i>	Muista teollisuusprosesseista kerätty luotettavuustieto on validia, kunhan sitä ei käytetä erikoisiin ympäristöolosuhteisiin (esim. säteily) kelpoistukseen. Luotettavuustietoa ei ole helposti saatavilla valmistajilta Luotettavuustieto ei välttämättä ole relevanttia esimerkiksi laitemuutosten takia. Tiedonsaannin hankaluus aiheuttaa joskus kustannuksia, koska etenkin ohjelmistojen kelpoistus maksaa paljon.	Reliability data collected of other industrial processes is valid when it's not used to qualify items to nuclear-specific service places. Reliability data is not easily available from the manufacturers. Reliability data may not be relevant because product modifications Difficulties in getting reliability data may cause extensive cost, mostly because of qualification of programming.	Reliability data Industrial processes Obstacles of reliability data usage Commercial secret Obstacles of reliability data usage Modifications Obstacles of reliability data usage Qualification of programming More costs Benefits of commercial-grade items Less costs	Reliability Economics Commercial-grade items Economics	Reliability of commercial-grade items vs. nuclear-grade items Reliability of commercial-grade items vs. nuclear-grade items

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Authority #3 A.1.3.6	Reaaliaikaisen kunnonvalvonnan mahdollisuudet valmistusvaatimuksista keskusteltaessa?	Possibilities of real-time condition monitoring in discussing manufacturing requirements?	<i>okei, sä valvot, mut mitä sä valvot? Onks se kaikki siitä laitteista? Verrattuna vaikka perinteiseen kunnonvalvontaan kun sä kuuntelet sitä ja kattelet ja teet sille värähtelymittaukset, niin päin pois. Et se laajuus on tietysti.</i> <i>Kun mennään tarpeeks korkeelle turvallisuusluokituksessa niin siinä ollaan aika ehdottomiakin [vaatimuksia] välillä et vaik sä kuin pystyisit osoittaan et se on yksisuuntaista liikennettä. Sen takia siihen suhtaudutaan negatiivisesti.</i>	Okay, you inspect but what? Is it all of the equipment? In comparison with traditional condition monitoring when you listen, watch and perform vibration measurements, etc. The extent is one thing. When we go high enough in safety classification, there are some quite implicit [requirements], it doesn't matter how well you could assure one-way data traffic. Therefore we have quite a negative outlook.	Reaaliaikaisen kunnonvalvonnan laajuus ei välttämättä ole tarpeeksi läpileikkaavaa. Ydinvoimalaitosten turvallisuuden kannalta keskeisten järjestelmien tietoliikenne pidettävä täysin salattuna.	Real-time condition monitoring may not be extensive enough. The safety of nuclear facilities demand that the data traffic of safety intensive systems is completely secret.	Downsides of real-time condition monitoring Cyber security	Real-time conditioning monitoring	Reliability of commercial-grade items vs. nuclear-grade items
Authority #1 A.1.1.6	Mitkä ovat mekaanisen komponentin valmistuksen tärkeimpiä vaiheita?	What are the most important production phases of mechanical components?			Materiaal ominaisuuksia muuttavat valmistusvaiheet ovat mekaanisten komponentin valmistuksen tärkeimpiä vaiheita.	Methods that alter the material characteristics are most important for the manufacturing of mechanical components.	Welding Heat treatment Molding	Manufacturing methods	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.7			<i>Ainakin ne valmistusprosessit, jotka muuttaa materiaall ominaisuuksia: hitsaus, muokkaus, lämpökäsittely.</i>	The manufacturing processes that change the material characteristics: welding, molding and heat treatment.	Materiaal ominaisuuksia muuttavat valmistusvaiheet ovat mekaanisten komponentin valmistuksen tärkeimpiä vaiheita.	Methods that alter the material characteristics are most important for the manufacturing of mechanical components.	Welding Heat treatment Molding	Manufacturing methods	Reliability of commercial-grade items vs. nuclear-grade items
Authority #1 A.1.1.7	Miten lähestyisit turvallisuusluokitellun laitteen kelpoistusta, jos valmistajat eivät kykenisi valmistamaan laitetta vaatimusten mukaisella tavalla?	How would you address the qualification of safety classified equipment if suppliers were unable to manufacture the equipment in conformance with the requirements?			Testausta laitepaikan olosuhteissa tarvitaan vaatimusten mukaisuuden osoittamisessa.	Testing in the circumstances of the service place is needed to prove conformity to requirements.	Conformity to requirements	Qualification	Reliability of commercial-grade items vs. nuclear-grade items
Authority #2 A.1.2.8			<i>Sarjasta otetaan joitakin kappaleita joillakin valintakriteerillä ja osoitetaan että ne on vaatimusten mukaisia. Siten voidaan riittävästi luottaa että se koko sarja on vaatimusten mukainen.</i> <i>Sekään ei vielä riitä, koska sitten tota venttiili kun menee laitospaikalle niin sen täytyy varmistaa et se kestää niitä prosessin parametrejä.</i>	Some items are picked according to some criteria and their conformity is displayed. Then we can gain adequate trust that the whole series conforms to the requirements. It's not enough though and the valve must be assured to withstand the process parameters.	Valmistuserän vaatimusten mukaisuus osoitetaan, minkä jälkeen yksittäinen laite testataan laitepaikan prosessiolosuhteissa.	The conformance to requirements of a manufacturing batch is displayed and the equipment's suitability to the process parameters is tested.	Conformity to requirements Manufacturing batch Testing	Qualification	Reliability of commercial-grade items vs. nuclear-grade items
Authority #3 A.1.3.7			<i>Kyl mä niinkun ensin haluaisin tietää mikä se delta siinä on. Kuten meidän vaatimuksetkin, nyt puhutaan YVL-ohjeista, niin nehan on niin kun yksi tapa päästä siihen turvallisuustasoon mitä me vaaditaan. Et voi olla jokin toinenkin tapa ja sen voi luvanhaltija meille aina esittää. Ja kyl se pitäis ekana lyödä faktat pöytään et mitä jää puuttumaan ja sit miettiä miten se voidaan kompensoida.</i>	<i>First, I would like to know that what is the delta. Our requirements in YVL Guides, they are one way to achieve the required safety level. There can, however, be an alternative way too, and the licensee is free to present it. We need factual evidence of what is missing and then some reflection on how to compensate for it.</i>	Aluksi täytyisi tutkia, miltä osin standardilaitte täyttää ydinalan laitteen vaatimukset ja sen jälkeen katsoa, millä vaihtoehtoisella tavalla vaadittuun turvallisuustasoon päästään.	The extent of conformity to the nuclear regulation need be examined and after that the alternative ways to achieve safety must be explored.	Conformity to requirements Delta Alternative ways of assurance	Qualification	Reliability of commercial-grade items vs. nuclear-grade items
Authority #1 A.1.1.8	Millaisena näet vaatimusten kansainvälisen harmonisoinnin nykytilan?	How do you view the current state of international requirement harmonization?			Katto-organisaatiot ovat harmonisoinneet yleiset periaatteet, mutta käytännön tason harmonisaatio uupuu. Lähes kaikki mekaaniset standardit viittaavat ASMEen ja ainakin eheysasiat ovat joko senkin harmonisoitu.	The top organizations have harmonized the guiding principles, but the grass-level harmonization is lacking. Neatly all mechanical standards refer to ASME. The level of harmonization is high what comes to integrity.	Problems with grass-level harmonization Already harmonized aspects	Harmonization issues Existing harmonization	Harmonization

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Authority #2 A.1.2.9	Millaisena näet vaatimusten kansainvälisen harmonisoinnin nykytilan?	How do you view the current state of international requirement harmonization?	<i>No siis lähtökohtaisesti tää on aika monimutkainen mihin tää vaatimusmaailma on mennyt. Aina vaan monimutkaisemmaks ja tota myöskin nää viranomaismääräykset on maakohtaisesti omakohtaisia syystä että joka maassa on oma ydinturvallisuuslainsäädäntö, joka velvoittaa tietyllä tavalla. Sen pohjalta on lähdetty joka maassa miettimään sitten ehkä vähän eri, tai onkin lähdetty, miettiin eri tavalla miten ne vaatimukset täytetään ja tulee erilaisia viranomaisvaatimuksia - tää on se yks puoli. Mut niissä pitäis viitata sitten teknisiin standardeihin, jonka perusteella ne komponentit hyväksytetään sitten teknisesti sitten. Molemmilla puolella esiintyy aikamoista vaihtelua, se on niinkun se ongelma.</i>	To start with, this requirement scheme is complicated and it's getting more and more complex. Additionally, these regulative requirements are unique for each country because they have their national legislations for nuclear safety that's binding in a certain way. Based on the legislation, every country has thought individually about how the legislation is filled and this resulted in multiple regulatory requirements - this is one aspect to it. But the requirements should refer to technical standards, based on which the components are qualified technically. Both sides include large variance, which is the problem.	Vaatimusmaailma on mennyt aina vain monimutkaisemmaksi. Maakohtainen ydinenergialakki velvoittaa maata laatimaan tietyt vaatimukset, jotka viranomainen laatii tulkitsemallaan tavalla. Vaatimuksissa viitataan teknisiin standardeihin, joilla komponentit hyväksytetään. Lainsäädännössä, viranomaisvaatimuksissa ja standardeissa on isoa vaihtelua - se on se ongelma.	The requirement scheme is complicated for the many related aspects: there is unique national legislation that steerts the regulative requirements into a certain direction. The requirements refer to different technical standards that are used in the acceptance of components. There's large variance in these aspects- that is the problem.	Divergence of requirements National differences Legislation Regulative requirements Different standards	Harmonization issues	Harmonization
Authority #3 A.1.3.8	Millaisen näet vaatimusten kansainvälisen harmonisoinnin nykytilan?	How do you view the current state of international requirement harmonization?	<i>Kun se ydinturvallisuuden varmistaminen on jätetty kunkin maan viranomaisen kontolle, se ei esimerkiksi EU:ssa ole mitenkään harmonisoitu homma. Ensimmäisiä askeleita jonkun näköiseen harmonisointiin ollaan vasta ottamassa kun on tää ydinturvallisuusdirektiivi tullut, mut sekään ei niin kuin konkreettisesti tasolla vielä juuri mitään harmonisoi.</i> <i>Ettei niin kun halutakaan mitään tällasta esimerkiksi EU:sta mitään tällasta keskusviranomaista, millä ois niin kuin yhteiset vaatimukset.</i> <i>Nehän [WENRA] on nyt niin kun esittäneet referenssitasoja käyville ja uusille laitoksille, sit Fukushima sotki tietysti kaiken ja jotenkin mulla on sellanen olo et se ei oo sen porukan [WENRA:n] intressi mennä kauheen detskuhiin.</i> <i>[MDEP:ssä] ollaan kysytty sitä miks eri maihin tarvittavissa laitoksissa on näin paljon suunnittelueroja? Niin ei se syy oo välttämättä aina viranomaismääräykset vaan siellä on tullut sitten voimayhtiöiden vaatimuksii tai käytäntöi kun joissain maissa on tehty. Välillä oikeastaan ei oo edes mitään syytä et jossain on valittu toisenlainen tekninen ratkaisu kuin jossain toisaalla.</i>	Because assuring nuclear safety is left for the authorities of each country, it's not at all harmonized in the EU for example. First steps towards harmonization are being taken with the nuclear energy directive, but it doesn't harmonize anything on a concrete level. We don't want an EU-level central authority that sets common requirements. They [WENRA] have presented reference levels for operational and new plants, then Fukushima of course messed up everything and I feel like going to details is not in their [WENRA's] best interest. We have asked [in MDEP] that why there are so many differences of the designs of the same facility that's going to different countries? The reason is not automatically the regulatory requirements, but there have been requirements by power companies or country-specific customs. Sometimes there's no clear reason for the technical differences between locations.	Kunkin maan viranomainen vastaa ydinturvallisuuden varmistamisesta ja vaikka esimerkiksi EU-tasolla on otettu askelia ylätasoon harmonisointiin, on harmonisointi vielä kaukana konkreetiasta. Viranomainen ei halua monikansallista keskusviranomaista. WENRA tekee ylätasoon työtä eikä sen intresseissä ole ottaa kantaa ruohonjuuritason vaatimuksiin. MDEPissä on huomattu, että suunnitteluerot eri maihin toimitettavien laitosten osalta eivät välttämättä johdukaan viranomaismääräyksistä vaan maakohtaisista voimayhtiökäytännöistä ja selittämättömistä eroista.	National authorities are responsible of assuring nuclear safety. Some minor effort has been made towards harmonization but it remains out of concrete measures. The Authority does not want a multinational central authority. WENRA operates at a higher requirement level without an interest to go into grass-roots level detail. MDEP has identified that design deviations don't necessarily emerge of regulative requirements but of power company, location specific customs. Sometimes the root cause is unidentifiable.	National differences Nuclear energy directive Lack of concrete harmonization National requirement independency WENRA Top down requirements MDEP National differences Cultural differences	Harmonization issues Existing harmonization	Harmonization
Authority #1 A.1.1.9	Miten luulisit että laajempi harmonisointi vaikuttaisi viranomaisen toimintaan? Miten luulisit että laajempi harmonisointi vaikuttaisi luvanhaltijan toimintaan?	How do you think that more extensive harmonization of requirements would affect the Authority? How do you think that more extensive harmonization of requirements would affect the licensee?			Yhteen standardiin viittaaminen olisi hyvä asia. Vaatimusten taakka kevenisi kun olisi maidenvälisesti yhtenäistetty vaatimustaso, joka olisi helposti ymmärrettävissä.	Referring to a single standard would be great. The load would be lighter in the presence of a nationally uniform and comprehensive requirement level.	Convergence of standards Convergence of standards	Benefits of harmonization	Harmonization

APPENDIX A.1 - Interview table - Representatives of the Authority

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Authority #2 A.1.2.10	Miten luulisit että laajempi harmonisointi vaikuttaisi viranomaisen toimintaan?	How do you think that more extensive harmonization of requirements would affect the Authority?	<i>Jos se [harmonisation] menestyksellisesti lisääntyis, se virtaviivaistais kyllä toimintaa täälläkin [viranomaisellakin] varmaan. Jos pystyttäis saamaan hyvä luottamus siihen, että harmonisoiduilla menetelmillä saavutetaan hyvä vaatimustenmukaisuus myöskin suomalaisia YVL-ohjeita vasten, se vähentäisi tarkastusten yksityiskohtaisuuden tarvetta.</i>	If it [harmonization] would become successfully widespread, I guess it would streamline our work. If we could gain good confidence that harmonized methods reach conformity to requirements also against Finnish YVL guides, it would decrease the specificity of inspections.	Harmonisoinnin yleistäminen tavalla, joka antaisi varmuuden sen YVL-ohjeiden vaatimusten mukaisuudesta, virtaviivaistaisi STUKin työtä ja vähentäisi tarkastusten resoluutiota.	More proper harmonization would lower the resolution need of inspections and streamline STUK's processes. The harmonization must conform to the YVL Guides' requirements.	Harmonization and streamlining	Benefits of harmonization	Harmonization
	Miten luulisit että laajempi harmonisointi vaikuttaisi luvanhaltijan toimintaan?	How do you think that more extensive harmonization of requirements would affect the licensee?	<i>No luvanhaltijalla säilyy se kokonaisvastuu. Täytyis perustella STUKille jos niitä tarkistuksia vähennettäisiin se todistustaakka säilyy kyllä luvanhaltijalla aika vahvasti. Pitäis pystyä osoittamaan että se harmonisoitu prosessi, jos siinä on vielä sarjatuotanto takana, tuottaa vaatimustenmukaisen tuloksen.</i>	The total responsibility remains on the licensee. They would have to argue to STUK if inspections were made less frequent. The licensee would have to prove that the harmonized process, if it's serially manufactured, will result in a product that conforms to the requirements.	Todistustaakka harmonisoidunkin menettelytavan vaatimustenmukaisuudesta säilyy luvanhaltijalla.	Proving conformity to the requirements is solely the responsibility of the licensee in the case of a harmonized standard.	Nuclear responsibility	Liability of harmonization	
Authority #3 A.1.3.9	Miten luulisit että laajempi harmonisointi vaikuttaisi viranomaisen toimintaan?	How do you think that more extensive harmonization of requirements would affect the Authority?	<i>Jos sä ajattelet et harmonisointi ois äärimmilleen viety niin silloinhan se voisi päästä loppujen lopuksi siihen tilanteeseen et kun joku viranomainen jossain arvioi jonkun ratkaisun, laitteen tai laitetyypin niin sä voisit saman arvion tuloksia sellaisenaan käyttää.</i>	If harmonization would be taken to the extreme, we would end up using the evaluation results of another country's authority as such.	Ääritapauksessa minkä tahansa maan viranomaisen arvioimaa ja hyväksymää suunnitteluratkaisua voitaisiin käyttää sellaisenaan missä tahansa muussa maassa.	Taken to the extreme, harmonization would allow for global acceptance of evaluation results.	Global evaluation	Benefits of harmonization	Harmonization
Authority #3 A.1.3.10	Miten luulisit että laajempi harmonisointi vaikuttaisi luvanhaltijan toimintaan?	How do you think that more extensive harmonization of requirements would affect the licensee?	<i>siinä joskus voitais joutuu miettiä sitä et voidaanko me ihan oikeesti luottaa jossain kaukana kaukana tehtyyn arvioon jostain laitteesta vai pitäiskö tää oikeesti nyt jotenkin katsoa ltte.</i>	[If this would be the case,]We might have to consider that can the evaluation done far away be trusted or should we look into it.	Tällöin pitäisi kuitenkin harkita, pitäisikö joissain tapauksissa arvioida suunnitteluratkaisu itse, etenkin jos alkuperäinen arvio on tehty kaukana Suomesta. Luvanhaltijan kulumat kevenisi kun toimittajakentän kilpailutilanteen helpottuessa	In globally accepted evaluation we must ask if all results can be trusted.	Global evaluation	Harmonization issues	
	Miten luulisit että laajempi harmonisointi vaikuttaisi laitevalmistajien toimintaan?	How do you think that more extensive harmonization of requirements would affect the manufacturer?	<i>Ja varmaanhan se [harmonisoituminen] sitten luvanhaltijoiden suuntaan laskis hintaa, tarjousvaihtoehtoja.</i>	It [harmonization] would probably lower the costs and increase supplier possibilities.	Laajempi harmonisointi lisäisi alan houkuttelevuutta myös laitevalmistajien silmissä. Nykyään ydinalan kanssa toimimista ei nähdä seksikkäänä tai turvallisenä.	The cost structure of the licensee would be lower as the market rivalry would increase.	Less costs	Benefits of harmonization	Harmonization
Authority #3 A.1.3.11	Miten luulisit että laajempi harmonisointi vaikuttaisi laitevalmistajien toimintaan?	How do you think that more extensive harmonization of requirements would affect the manufacturer?	<i>Kyl se [harmonisoinnin lisääntyminen] tota varmaan sillein positiivisesti vaikuttaisi niin kun että tota, ensinnäkin alasta tulisi taas kiinnostavampi kun eihän ydinvoima-alalle enää laitevalmistajat halua toimittaa mitään kun se on heidän mielestä niin vaikeeta, ei oo kauheen tällasta seksikästä ja vähän riskialtistakin et menee maine viel kun toimitat ydinvoimalaitoksiin jotain. Kun siinä ois niin kun isompi bisnes niin kylhän se [ydinala] ois taas niille paljon kiinnostavampi.</i>	It [a more uniform requirement level] would probably have effects such as the nuclear industry would become more attractive. Nowadays vendors don't want to supply anything for it's so hard in their view. It's not sexy and it's a bit risky because being identified as a nuclear power plant supplier might hurt your reputation. More business would make it [the nuclear sector] more attractive to the vendors.	Laajempi harmonisointi lisäisi alan houkuttelevuutta myös laitevalmistajien silmissä. Nykyään ydinalan kanssa toimimista ei nähdä seksikkäänä tai turvallisenä.	More harmonization would make the nuclear industry more attractive for vendors. Today it's viewed neither safe nor sexy.	Market conditions	Economics	
Authority #1 A.1.1.10	Miten näet harmonisoinnin tulevaisuuden?	What is your view on the future of harmonization?			Harmonisointi menee eteenpäin ajan kuluessa, mutta oman edun ajaminen on suuri haaste harmonisoinnin tehokkuudelle.	Harmonization will evolve but with its own problems, not least because non-uniform interests between stakeholders.	Future of harmonization	Harmonization issues	Harmonization
					Vaatimusten ekvivalenssi tulee olemaan tuleva suuntaus.	The equivalence of requirements is the way of the future.	Qualification of standards	Qualification	
					Jos standardia on käytetty ydinvoimateollisuudessa, sen hyväksynnälle ei pitäisi olla ongelmaa.	There should not be an issue to qualify a standard that's been used in the nuclear industry			

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Authority #2 A.1.1.11	Miten näet harmonisoinnin tulevaisuuden?	What is your view on the future of harmonization?	<i>Se [eri standardien hyväksyttäminen] on varmaan tässä tavoite. Jos tähän ei kiinnitetä huomiota niin ne [standardit ja koodit] rupee hajaamaan toisistaan vielä enemmän ja sitä koitetaan tulla. Käytännön tasolla ne ne [standardit ja koodit] on kuitenkin vielä edelleen aika erilaisia. Tietysti tää aiheuttaa haittaa, riippuen mikä ydintekninen koodi valitaan/hyväksytetään suunnittelukoodiksi niin miten se istuu siihen valmistusprosessiin. Siellä on kuitenkin sit erilaisia vaatimuksia testauksella ja tarkastuksella että. ASME ja RCC-M on aika erilaisia ja niin edelleen. Se harmonisointi on vaikeaa.</i>	That [acceptance of different standards] is the goal. If this is not taken into consideration, the codes will diverge even more which should be avoided. In practice they [codes & standards] are quite different. Of course this is a problem depending on the chosen nuclear code for design code, how it fits the given manufacturing process. They do have different requirements for testing and inspection. ASME and RCC-M are quite different and so on. Harmonizing is difficult.	Standardien ekvivalenssi on tavoitteena. Ilman sitä koodit ja standardit hajaantuvat vielä enemmän toisistaan. Käytännössä ne ovat melko erilaisia (esim. ASME ja RCC-M), mikä aiheuttaa mm. valmistusteknisiä haastoja prosessista riippuen.	The goal is to reach equivalence of standards - without it the codes will diverge even more. The current codes (ASME, RCC-M, etc.) are quite dissimilar, which causes issues in manufacturing.	Acceptance of multiple standards ASME RCC-M Divergence	Equivalence of codes & standards	Harmonization
Authority #3 A.1.3.12			<i>Niin mä hiukan suhtaudun siihen skeptisesti et tulis tämmöstä niin kun globaaliympä standardisointia yhtään mihinkään.</i>	I'm slightly sceptical of widespread global standardization.	Standardisointi tulee tuskin etenemään globaalilla tasolla.	Global standardization won't likely push through.	Future of harmonization	Harmonization issues	Harmonization
Authority #2 A.1.2.12	(Keskutella eri maiden eri käytännöistä viranomaistarkastusten suhteen)	(Relevant conversation about inspection by authorities)	<i>Me ollaan oltu niissä yhteistarkastuksissa [liittyen MDEPin Vendor Inspection Cooperation -projektiin] katsomassa miten viranomaiskollegat tekee, me ollaan itekin mukana. Mutta se on niinkun lisätietoa tai lisäärvoo meille kun me nähään joku valmistaja et se suoriutuu hyvin tällaisessa yhteisauditissa.</i> <i>Luvanhaltija auditoi sen kuitenkin et se ei korvaa sitä mitenkään, koska luvanhaltijalla on päävastuu näistä asioista Suomessa ja tietysti muuallakin, mut me korostetaan sitä vähän eri tavalla.</i> <i>Viranomainen kun lähtee tekeen audittia niin silloinhan on vaara että viranomainen ottaa vastuuta siitä komponentin turvallisuudesta. Se ei oo viranomaisen rooli vaan meidän pitää varmistaa että luvanhaltija hoitaa hommansa asianmukaisesti.</i>	We have been in these common inspections [relating to MDEP's Vendor Inspection Cooperation Working Group] to see how authority colleagues perform [these inspections], but it's only extra bits of knowledge for us to see how a supplier performs in a common audit. The licensee audits it after all, the common inspection is not replacing it in any way since the licensee has the main responsibility in these issues in Finland and elsewhere too, but we stress it a little differently. If the authority audits a supplier, it might gain responsibility of the component's safety. That is not the role of the authority - we have to ensure that the licensee does their thing accordingly.	Kansainvälinen viranomaisyhteistyö auditointien osalta on hyvä lisä, mutta STUK ei ottaa vastuuta komponentin turvallisuudesta suorittamalla auditointeja vaikka joidenkin maiden käytännöt ovat erilaisia.	International inspection cooperation within authorities is useful, but STUK cannot take any accountability of the licensees' nuclear responsibility. In some countries there are nuances that allow for different auditing possibilities for authorities.	Harmonization of authority audits Authority Nuclear responsibility	Harmonization issues	Harmonization
Authority #3 A.1.3.13	Mikä on laitevaatimusmäärittelyn tarkoitus?	What is the purpose of the requirement specification document (RSD)	<i>[Laitos/laitevalmistajalle voidaan esittää suuntaan] tommonen dokumentti [laitevaatimusmäärittely] ja sit ton lisäksi tässä on tämmönen muutama erityisvaatimus. Sit kun se on tapeltu viranomaisen kanssa etukäteen niin sit sun ei tarvi siinä hankintatilanteessa alkaa vääntää.</i> <i>YVL-päivitystä tullaan muuttamaan siten et meil ei sitä EYT-puolel pitäis olla enää tällasta roolia.</i>	[The suppliers] can be presented a document [RSD] and additionally we have a couple specific requirements. It's been fought over with the authority beforehand and you don't have to twist anything in procurement. The YVL-guide will be updated to change the role of STUK in the EYT Safety Class.	Laitevaatimusmäärittely helpottaa määräysten tulkintaa etenkin hankinnassa. EYT tullaan poistamaan laitevaatimusmäärittelyn piiristä.	The RSD helps interpret the requirements especially in procurement. The inclusion of EYT class in the RSD will be eliminated.	National harmonization Requirement specification document benefits EYT	Requirement specification document	Harmonization
Authority #1 A.1.1.11	Miten uutena YVL-ohjevaatimuksen tulleen luvanhaltijoiden laitevaatimusmäärittelyjen laadinta on sujunut?	How has the drafting of the requirement specification documents been going on?			Ensivaikutelmalta on hyvä. Sen pitäisi olla luvanhaltijan oma standardi, joka määrittää vaaditun suunnittelu- ja laadunvalvonnan tason. Se helpottaa myös tarkastuslaitosten työtä.	The requirement specification drafts look good. It's supposed to be the licensee's own standard that defines the level of design and QC. It also helps with IO's work.	Requirement specification document draft Streamlining	Requirement specification document	Harmonization

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Authority #2 A.1.2.13	Miten uutena YVL-ohjevaatimuksen tulleen luvanhaltijoiden laitevaatimusmäärittelyjen laadinta on sujunut?	How has the drafting of the requirement specification documents been going on?	<i>No siinä on tietysti [ongelmia] kun on uusi prosessi. Kyllä niitä on tullut ja mun ymmärtääkseni on siellä aika hyviäkin tehty. Se niinkun menee oikeille urilleen se homma pikku hiljaa. Kun tulee joku uusi prosessi niin se vie aikaa.</i> <i>(Keskustelua perusteluyhteenvedosta)</i> Kyl luvanhaltijan pitäis enemmän perustella sitä et miks se [rakennesuunnitelma] on hyväksyttävä. Sillain me voidaan luottaa siihen enemmän ja päästään siinäkin vähän harmonisoidumpaan prosessiin. Ei tarte tehdä niin paljon joka ainoan asian kanssa töitä että jos syntyy luottamus siihen että luvanhaltija on tarkastanut sen niin meidän ei tarvitse ihan niin tarkkaan kattoo.	Well of course there's [problems] because the process is new. We have received some drafts and I guess some of them are quite good. It will find its form with time. It always takes time to excel a new process. (related conversation of the summary of justification document) The licensee should more effectively argue why it [the construction plan] is acceptable. Then we could trust the plan more and we shift towards harmonization in that aspect as well. We don't have to put so much effort into every matter when we have more confidence.	Laitevaatimusmäärittelyn menestyksessä laadinnassa menee oma aikansa, kuten aina uusissa prosesseissa. Osa tähänastisia luonnoksista ovat olleet hyviä. Rakennesuunnitelman perusteluyhteenvedo lisää luottamusta siihen, että luvanhaltija tietää mitä tekee. Perusteluyhteenvedolla saadaan harmonisoitua eteenpäin kun STUKin ei tarvitse suorittaa niin yksityiskohtaista tarkastusta.	It always takes time to excel in new processes like the requirement specification document. The summary of justifications improves STUK's confidence that the licensee is on top of things. This pushes things to a more harmonized direction as STUK can alleviate the specificity of its inspection.	Requirement specification document draft Summary of justification in harmonization	Requirement specification document Summary of justification document	Harmonization
Authority #1 A.1.1.12	Näkisitkö, että suomalaiset luvanhaltijat voisivat tehdä yhteistyötä laitevaatimusmäärittelyjen laadinnassa? Minkä takia?	Do you think that Finnish licensees could cooperate in the drafting of requirement specification documents (RSDs)? Why would that be?			Yhteistyö laitevaatimusmäärittelyjen luonnissa luvanhaltijoiden välillä olisi todella hyvä asia. Selkeämmät vaatimukset mahdollistaisivat paremman tarkastuslaitosten käytön ja vähentäisivät tulkinnallisuutta.	Cooperation in drafting the requirement specification documents would be seen as a remarkable thing. Clearer requirements [of a shared RSD] would allow for more effective use of IOs as there would be less room for interpretations.	Requirement specification document cooperation Effectiveness of cooperation	Requirement specification document Requirement specification document	Harmonization
Authority #2 A.1.2.14	Näkisitkö, että suomalaiset luvanhaltijat voisivat tehdä yhteistyötä laitevaatimusmäärittelyjen laadinnassa? Minkä takia?	Do you think that Finnish licensees could cooperate in the drafting of requirement specification documents (RSDs)? Why would that be?	<i>Kyllä se varmaan tietysti hyvä on. Laitokset on erilaisia ja käyttökohteet on erilaisia, eli täytyy siinä ottaa laitospkohtaiset spesialiteetit ja erityisvaatimukset huomioon. Mutta kyllä mä näkisin, et se olis hyvä ajatus että luvanhaltijat vois tehdä yhteistyötä siinä, että niitakin voidaan harmonisoida tiettyyn määrään asti.</i> <i>Siitä tulis semmonen vakiintunut käytäntö ja ei nyt ihan standardimenetelly, mutta kuitenkin menettely, joka olis entistä helpompi tarkastaa sillain, että kaikki asiat tulee huomioon otetuksi.</i>	<i>I guess it [cooperation between licensees in compiling RSDs] is good. The plants and service places are different, so the plant specific things need be taken into account. But I see it as a great idea to have more cooperation between the licensees [in drafting the RSDs] to harmonize them to some extent.</i> It [RSD] would be an established procedure, and if not totally standardized, a procedure that's ever more easier to inspect in an all-encompassing way.	Laitevaatimusmäärittelyjen luvanhaltijayhteistyö on hyvä asia, jolla päästäisiin harmonisoinnissa eteenpäin. Yhteistyö laitevaatimusmäärittelyjen osalta parantaisi tarkastuksen kokonaisvaltaisuutta kun olisi yeyxysi vakintunut tarkastuskäytäntö.	Harmonization would be pushed further if the RSDs could be drafted with more cooperation. The cooperation would result in a common procedure that would make inspection easier.	Requirement specification document cooperation Streamlining inspection	Requirement specification document Requirement specification document	Harmonization
Authority #3 A.1.3.14	Näkisitkö, että suomalaiset luvanhaltijat voisivat tehdä yhteistyötä laitevaatimusmäärittelyjen laadinnassa? Minkä takia?	Do you think that Finnish licensees could cooperate in the drafting of requirement specification documents (RSDs)? Why would that be?	<i>No mikäs sitä estää. Laitokset on tietysti vähän erilaisii et sitä pitää vähän punnita et meneeks se liian yleiselle tasolle, jos sä teet vaikka kiehanille ja painevesilaitokselle yhteisen. Mut jos se on mahdollista niin miksei?</i>	Why not. The plants are slightly different and it need be weighed if it's on a too general level, if you make a shared RSD for BWR and PWR. But if it's possible, why not?	Luvanhaltijoiden väliselle yhteistyölle laitevaatimusmäärittelyjen laadinnassa ei ole esteitä kunhan laitostyyppikohtaiset eroavaisuudet huomioidaan.	There's no barriers to cooperation of licensees in conducting the RSD's as long as the plant-specific requirements are accounted for.	Requirement specification document cooperation National harmonization Plant specificity	Requirement specification document Requirement specification document	Harmonization
Authority #3 A.1.3.15	Mitä muuta luvanhaltijat voisivat tehdä yhteistyössä keskenään?	In what else could the licensees do cooperation?	<i>Kaikkee mitä sä ulkopuolella teetät mikä on tämmöstä ydinvoimaspesifistä niin mikset sä vois hankkia sitä yhdessäkin. Siinä vois olla joku kolmannen osapuolen arviot esimerkiksi.</i> <i>Jos sen tekisin niin et niin kun lähtökohtaisesti molemmat lähtis siihen [toimittajien auditointiin]. Auditointi tehtäis sit sellaisella vaatimussetillä et se tydyttäis molempien tarpeet - sillainhin siinä tulis sellaisen isomman ostajan synergiaakin siihen.</i>	Everything that's nuclear-specific and that's commissioned from outside - why couldn't you team up in the procurement. Maybe third party assessments for an example. If it were done so that fundamentally both [licensees] would take part in it [supplier audit]. The audit would be performed with a set of requirements that suits the needs of both parties. Then there would be synergy of a larger customer.	Ydinvoimaspesifit, luvanhaltijoiden ulkopuolella teetetyt asiat voitaisiin hankkia yhteistyössä. Esimerkiksi kolmannen osapuolen arvioinnit. Toimittajien auditoinnissa voisi hyvin tehdä yhteistyötä siten, että auditoinnissa käytettävät vaatimukset olisivat yhteiset. Kun toimittaja olisi auditoitu yhteisiä vaatimuksia vasten, luvanhaltijat pääsisivät hyötymään myös ostajan mittakaavaedusta.	External, nuclear-specific manners could be procured in a cooperation. E.g. third party assessments. In supplier audits, the cooperation would be well viable if the requirement criteria were common. If the supplier was audited against the common requirements, the licensees would benefit from the buyers' scale of economics.	Licensee cooperation Assessment cooperation Audit cooperation Less costs Scale of economics	Cooperation Cooperation Economics	Harmonization

APPENDIX A.1 - Interview table - Representatives of the Authority

Interviews held during 15.5.2017 – 29.5.2017 in Helsinki, Finland.

Interviewee	Number of answers
Authority #1	12
Authority #2	14
Authority #3	15
TOTAL	41

APPENDIX A.2 - Interview table - Representatives of the Licensee

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Licensee #1 A.2.1.1	Mikä on ydinlaitoksissa käytettävien turvallisuusluokiteltujen laitteiden laatuun liittyvien erityisvaatimusten tavoite?	What is the goal of the specific quality requirements of safety classified equipment?	<i>Se on tietysti turvallisuuden lisääminen totta kai, mutta kaikoin toinen puoli on olemassa, et jos on kovinkin erikoisia vaatimuksia, joihin nää valmistajat ei oo tottuneet niin saattaa jopa mennä toiseen suuntaan se turvallisuus.</i>	It's [the goal is] increasing safety of course, but the flipside is that if there's really specific requirements that are strange for the manufacturers, safety might go the other direction.	Laatuvaatimusten tavoite on turvallisuuden parantaminen, mutta joskus erikoiset vaatimukset saattavat huonontaa turvallisuutta.	The goal of QC requirements is increasing safety, but sometimes specific requirements may decrease safety.	Safety Customized production	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #2 A.2.2.1			<i>Täällähän on tietysti se et ydinvoima-alalla on tarkoituksena varmistaa se, että kaikki suunnitteluperusteiset ja turvallisuuteen, turvatoimintoon liittyvät edellytykset täyttyvät. Eli se, mitä muualla teollisuudessa perustuu pitkälti kokemukseen ja siihen tavallaan oikeisiin valintoihin, niin täällä on lisäksi se varmistus et valvotaan sekä viranomaisen toimesta ja luvanhaltijan toimesta siinä niinkun sivussa. Et tää tekee siitä niinkun erilaisen ja raskaamman.</i>	It's of course in the nuclear sector to assure that all prerequisites for safety function and design basis related are met. What in other industries is built on largely experience-based choices, here [in the nuclear sector] we have the assurance that the authority and the licensee oversee the process. This makes it different and more burdensome.	Tarkoituksena on varmistaa, että kaikki laitteen suunnitteluperusteiset ja turvatoimintoon liittyvät edellytykset täyttyvät. Siihen liittyvä valvonta eriyttää valmistusprosessia.	The goal of QC requirements is to assure all design basis and safety related requirements are met. The related monitoring differentiates the process.	Design basis requirements Safety requirements Customized production	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #3 A.2.3.1			<i>Se, mitä haetaan tavoitetta on se, että laite toimii niissä olosuhteissa, joissa sen pitää toimia.</i>	What we want is to have the equipment function in its intended environmental conditions.	Laitteen täytyy toimia niissä olosuhteissa, joissa sen pitäisi toimia.	The equipment must function in its intended service place's conditions.	Service conditions	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #1 A.2.1.2	Miten Suomen nykyiset laitososien laadunvalvontaa koskevat erityisvaatimukset vaikuttavat turvallisuusluokiteltujen laitteiden luotettavuuteen ydinlaitoksissa?	How do the current Finnish Quality Control related requirements affect the reliability of safety classified equipment in nuclear facilities?	<i>Sanotaan näin et jos on tosi erikoista valmistusta niinkun reaktoripuolen ja primääripiirin komponenteissa niin siellä mä ymmärrän et ne puolustaa paikkaansa. Mutta turvallisuusluokissa 3 ja sitä alemmissa niin mä en nää niinkun niiltä kovin tarpeellisina. Meillä on nykyään, jos me tehdään laitteita PEDin ja EN-standardien mukaan, joihin valmistajat on tottuneet niin kyllä ne on aivan yhtä hyviä. Siihen voi lisätä erikoisvaatimuksia niin tuskin laatu paljon paranee.</i>	Let's say that the requirements are justified in components of the reactor side and primary circuit, but in Safety Class 3 and lower I don't view them that necessary. Nowadays PED and EN-standards produce equivalent products: if you add extra requirements the quality won't improve much.	Reaktoripuolen ja primääripiirin komponenteissa erityisvaatimukset puolustavat paikkaansa, mutta TL3:ssa ja alemmissa turvallisuusluokissa vaatimukset eivät ole kovinkaan tarpeellisia, koska nykyään PEDin ja EN-standardia noudattava valmistus on valmistajille tuttu tapa valmistaa korkealaatuisia tuotteita.	In the reactor and primary circuit side, the requirements are valid, but in SC3 and lower they do not elevate quality that PED and EN standards already produce.	Primary circuit Safety Class 3 PED EN Standard quality	Reliability effects of Quality Control Standards	Reliability of commercial-grade items vs. nuclear-grade items
			<i>Jos meillä on valmistaja, joka on tehnyt paljon joitakin tuotteita ja on kokemusta paljon miten ne tehdään niin se laatu on parempaa kun jos se joutuu poikkeamaan normaaliroituineistaan ja tekemään jotain mitä hyvin harvoin tehdään.</i>	A manufacturer with strong experience on making a certain product in a certain way produces better quality than when it has to shift from its normal routines by doing something that's very rarely done.	Jos valmistaja on tehnyt jotain tuotetta isoja määriä, valmistuskokemuksia kertyy ja laatu on parempaa kuin silloin kun jotain tuotetta valmistetaan pieni määrä.	A manufacturer has produced something in volume, user experience accumulates and the quality is better than when something is produced in small volumes.	Customized production	Quality effects of Quality Control	
Licensee #2 A.2.2.2			<i>tietenkin valvomalla pystytään tekemään tiettyyn tasoon saakka varmistamaan, että joka yksilön jokainen osa tulee tehtyä tämän halutun vaatimuksen mukaan. Mut se ei varmistu sen toimivuutta välttämättä, koska me ajaudutaan helposti siihen et se tuote poikkeaa siitä isosta massasta et miten se valmistaja alun perin on ajatellut sen tehtävän.</i>	<i>of course by controlling one can to a certain level assure that every part of every item is manufactured according to a specific requirement. However, this does not necessarily assure the operability of the item because it tends to cause differentiation from the originally intended mass production.</i>	Laadunvalvonnan tarkoitus on varmistua vaatimustenmukaisuudesta, mutta valvontavaatimukset voivat johtaa tuotteen eriytymiseen normaali tuotannosta.	The objective of QC is to assure conformity to requirements, but the control requirements might cause the manufacturing to differentiate from normal production.	Conformity to requirements Customized production	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
			<i>Ja mä näkisin tänä päivänä et jos verrataan ydinvoima-alan eri turvallisuusluokan tuotteita niin jopa yli TL3:n vaatimusten nousi tämä [teollisuuslaatu painelatelidirektiivin myötä] [vastauksen keskiosa poistettu anonymitettiin säilymiseksi]... ja itte oon ollut silloin [90-luvulla] näkemässä sen miten se laatu saatiin nousemaan ja reklamaatioiden, kaikkien ongelmien määrä putosi ihan murto-osaan. Ja tätä ei oo ihan tiedostettu ydinvoima-alalla, mikä se laadun nousu on ollut.</i>	<i>Nowadays the quality of even above SC 3 nuclear-grade items is inferior to the industrial quality because of the introduction of the PED in the 90s [partly censored to retain anonymity] I have seen the evolution of the quality and the disappearance of problems and reclamations. The nuclear sector has not fully understood the extent of this quality leap.</i>	Nykypäivänä laatuvaatimusten ero on pieni, ja joskus standardilaitteiden laatu jopa ylittää ydinalan osilta vaaditun laadun. Laatuharppausta ei ole ydinalalla noteerattu tarpeeksi.	Today the quality requirements are similar, but sometimes the standard quality surpasses the quality of nuclear-grade items. The quality leap is not fully understood.	Quality leap Quality differences		
Licensee #3 A.2.3.2			<i>kyl mä siellä nään et on tämmösiä kokemuksia, et on koottu väärin, on väärä asia. Ja on koottu väärin, sitten on epäpuhtauksia joutunut laitteisiin. On tärkeää.</i>	I have seen false assemblies with wrong parts and inpurities inside equipment. [Quality Control] is important.	Ydintekniseen erityiskäyttöön tulevien laitteiden laadunvalvonta on hyvin tärkeää puutteiden havaitsemiseksi.	Quality Control of nuclear-grade items is important to identify deficiencies.	Deficiency detection	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
			<i>Ei sitä nyt jos se on normaali, sitä on paljon käytössä. Sitten tämmöset mahdolliset viat, puutteet siinä valmistusprosessissa tulee väistämättä näkyviin. Mut jos ne on osia, joita tehdään harvoin ja sit ne on vielä tämmösiä kun meilläkin nyt hätämoottorit standby-laitteita niin ei tule sitä käyttökokemusta. Ja silloin on kiinnitettävä erityistä huomiota sitten valmistukseen ja tietysti tarkastukseen.</i>	<i>If it's [an item] used a lot, then these potential flaws and deficiencies in the manufacturing process are inevitably revealed. But if these are parts that are seldom made and if they are on standby like our emergency motors, then there's no user experience gained. And then we have to give special attention</i>	Suurissa valmistuserissä lastentautien paljastuminen on väistämätöntä, mutta pienen valmistuserien kohdalla on toisin ja lisävalvontaa tarvitaan.	In mass production, teething problems are revealed, but small volume production is different and extra control is needed.			

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Licensee #1 A.2.1.3	Mitkä ovat sellaisia vaatimuksia, joilla on vähäinen turvallisuusmerkitys suhteessa niiden vaatimiin resursseihin?	What are requirements that have low significance to safety when compared to the resources needed?	<i>nää materiaalitodistukset. Et aika herkästi vaaditaan sellasta 3.2-tason todistusta, jossa on kolmannen osapuolen taho läsnä kun testejä tehdään. Mun mielestä nää menee monta kertaa yli nää tällaset, et normaaleille ei-painetta kantaville osille pitäis riittää ihan laatuvaruutus, sanotaan näin.</i> <i>Näähän on nää aika erikoisia nää valmistajan/tarkastajan vuosittaiset hyväksynnät, jotka pitää raportoida. Mun mielestä tällaset EN:n mukaiset pätevyyydet ja niiden voimassaolo voisi riittää</i>	to their production and of course inspection. these material certificates. Quite often a 3.2 certificate is required, which means a third party must be present in testing. I think this is often excessive. A quality insurance should suffice for normal non-pressure retaining parts. The reporting of annual supplier/inspector inspections is quite unusual. I think a valid EN proficiency should suffice.	3.2-materiaalitodistuksia vaaditaan liiaka. Laatuvaruutuksen pitäisi riittää painetta kantamattomille osille. Jokavuotinen valmistajien/tarkastajien raportointivaatimus on melko epätavallinen. Voimassaoleva EN-kelpoistodistus pitäisi riittää.	3.2 material certificates are required too easily. Quality insurance for non-pressure retaining parts is enough. Annual reporting requirement of manufacturers/inspectors is unusual and a valid EN proficient should suffice.	3.2 material certificate Quality insurance	Inefficient requirements Material certificate	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #2 A.2.2.3			<i>Laitteiden kohdalla se et mennään 3.2 todistuksiin vielä 3.1 todistuksista niin ei välttämättä anna enää lisäarvoa.</i> <i>Näis pitäis olla selkeemmin vielä se et se tulee tarpeen mukaan ja turvatoiminnan mukaan et jos se laitevaatimus on pelkkä eheysvaatimus niin silloin [vaatimukset] on selkeästi erilaiset kuin sillä millä on joku operatiivinen vaatimus ja silloin kohdistetaan silloinkin laitteessa ne turvatoiminnot vain niihin mitä se oikeesti tekee.</i>	<i>In equipment, going to 3.2 [material] certificates does not necessarily add value.</i> It should be based on demand and safety function and if it's solely an integrity requirement, then the requirements are clearly different than when there is operability requirements and then the security measures are targeted to the specific operation	3.2-materiaalitodistus on usein turha. Laitteiden rakenteelliset ja toiminnalliset vaatimukset pitäisi pystyä erottamaan paremmin toisistaan ja kohdentamaan vaatimukset sen mukaisesti.	A 3.2 material certificate is oftentimes not needed. The structural and operability-related requirements should be separated better and to allocate the requirements accordingly.	3.2 material certificate Structural vs. operability requirements	Inefficient requirements Material certificate Improving the requirements	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #3 A.2.3.3			<i>Niin tällainen ohjelmistokelpoistus, jos meillä on venttiileitä ja laitteita, joissa on tällainen itsenäinen järjestelmä eli black box. Jos niitä tehdään kymmeniä tuhansia vuodessa, niin se käyttökokemus on olemassa. Ja sit meidän pitäis tehdä räätälöity versio ydinvoimatekniikkaan niin sen mä nään resurssien tuhlausena.</i>	Qualification of programming, if we have valves or equipment with a self sustaining system i.e. black box. If they're manufactured in the ten thousands annually, the user experience is there. And if we need to still customize it for nuclear technology, I find it wasting resources.	Ohjelmiston kelpoistus on resurssien tuhlausta tapauksissa, joissa käyttökelpoisesta teknologiasta on mittavasti käyttökokemustietoa. Räätälöinti johtaa uniikkiin tuotteeseen.	Qualification of programming is wasted resources if we have a lot of user experience of usable technology. Customization leads to a unique product.	Program qualification Customized production User experience	Inefficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #1 A.2.1.4	Jos laittaisit siihen lisää testejä niin mitä ne testit olis jotka on sun mielestä kaikkein tärkeimpiä?	If you were to add more tests, what would the most important tests look like?	<i>No, tietysti nää kuumavetokokeethan on perinteisesti, niitä on jonkun verran kai jätetty pois nykyisesti. Niiden poisjättäminen pitäisi harkita vähän tarkemmin.</i>	Well, of course these hot tensile tests because they have been supposedly left out as of recently. Leaving them out should be weighed more carefully.	Kuumavetokokeet. Niiden poisjättämistä tulisi harkita.	Hot tensile tests. Leaving them out should be considered.	Hot tensile tests	Efficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #2 A.2.2.4			<i>Silloin [kun ei ole operatiivisia vaatimuksia] tää integrity pystytään hoitaa ihan konventionaalisella ja silloin tärkein kysymys on se luotettavuus. Eli meillä on pitkät käyttökokemukset, meil on valmistaja osoittanut et sillä on laatuja järjestelmä ja se tekee suuria sarjoja niin tällä pystytään TL3:n toimittamaan samaa laatu luokkaa vähintään mitä YVL-ohjeen TL3:n mukaan vaatimuksiin tehdään</i>	Then [when there's no operability requirements] this integrity can be dealt with in the conventional way and the biggest question is reliability. We have extensive user experience and the manufacturer has proved its quality system and it's producing big volume - then we can achieve equal quality class that the YVL Guide demands as SC3.	Luotettavuuden varmistaminen, koska TL3:ssa on harvoin turvatoimintona muita kuin eheystoiminto, joka osataan konventionaalisessa valmistuksessa hoitaa siten, että luottamus laatuun on suuri.	Assurance of reliability for there seldom is any other safety function than integrity in SC3, and integrity is mastered in conventional manufacturing in a reliable way. Structural vs. operability requirements	Integrity Assurance of reliability	Efficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #1 A.2.1.5	Räätälöidyn laitteen tuotantoprosessi eriytyy valmistajan sarjatuotannosta. Miten näet että tuotantoprosessin eriytyminen vaikuttaa tuotteen laatuun?	The production of a customized product differentiates its production from serial production. How do you see the quality effect of the differentiation?	<i>Se [luotettavuus] ei välttämättä ainakaan parane, se on tietysti vähän case by case, mutta ei se välttämättä pääsääntöisesti juurikaan parane.</i> <i>EN:n mukaisesti testatut laitteet on aika hyviä, se taso riittää hyvinkin tonne normaalkäyttöön.</i>	It [reliability] does not necessarily improve, it's a little case-by-case of course, but it doesn't improve as a rule. Equipment that have been tested according to EN [standards] are quite good and the level is sufficient for normal use.	Räätälöity valmistusprosessi ei aina paranna luotettavuutta. Luotettavuus ei parane, koska EN-standardien mukaisen laitteiden laatu on jo korkealla tasolla.	Customized production doesn't always improve reliability. Reliability is not improved for the EN-standards constitute high quality.	Customized production Reliability effects of requirements	Reliability Inefficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #1 A.2.1.6	Näkemys standardilaitteiden luotettavuusdataa käyttökelpoisuudesta turvallisuusluokiteltujen laitteiden kelpoistuksessa?	What is your view on utilizing reliability data of commercial-grade items in accepting safety classified equipment?	<i>Se standardilaitteen käyttökokemus on aina huomattavasti laajempi kuin erikoislaitteesta, se on joka paikassa näin. ... No pitää se tietysti vähän katsoa et minkälaisista olosuhteista ne on. Pitää nää muut [standardilaitteet] tietysti olla hyvin lähellä sitä mitä meilläkin on, sitten se käyttökokemus on relevantti.</i>	The operational experience of a commercial-grade item is notably more comprehensive than that of a customized product. ... Well the conditions from which the data was collected must be looked at. The commercial-grade items must be close to what we have to make the operational experience relevant.	Standardilaitteen osalta luotettavuusdataa on tarjolla paljon enemmän ja sitä voitaisiin käyttää kelpoistuksessa, kunhan huolehditaan siitä että standardilaitteen käyttökokemus on hankittu riittävän samankaltaisista käyttöolosuhteista.	Commercial-grade items offer much more reliability data that could be used in qualification as long as the similarity of the ambient conditions is taken care of.	Reliability data for qualification Similarity of conditions	Reliability data	Reliability of commercial-grade items vs. nuclear-grade items

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Licentsee #2 A.2.2.5	Näkemyks standardilaitteiden luotettavuusdatan käyttökelpoisuudesta turvallisuusluokiteltujen laitteiden kelpoistuksessa?	What is your view on utilizing reliability data of commercial-grade items in accepting safety classified equipment?	ydinvoimalaitoksessakin on se et täällä on monta eri kohdetta ja käyttöolosuhteissakin on hirveen iso ero mitä tehdään. Et tän mä näkisin et se [standardilaitteiden luotettavuusdatan kattavuus] on se suurin lisäarvo mitä saadaan, et se on suurin mahdollinen se käyttäjäkunta ja käyttöolosuhteet	NPPs too have multiple service places and a variety of operational conditions. I'd say that this [the variety of commercial-grade items' reliability data sources] is the maximal added value - to have the maximum amount of users and conditions.	Juuri luotettavuusdatan kattavuus mahdollistaa luottamuksen siihen, että laitetta voidaan käyttää luotettavasti myös ydinvoimalaitoksen käyttöolosuhteissa.	It's exactly the coverage of the reliability data of commercial-grade items that enables the trust in that the equipment may be reliably used in also NPP conditions.	Reliability data for qualification Dissimilarity of conditions	Reliability data	Reliability of commercial-grade items vs. nuclear-grade items
Licentsee #3 A.2.3.4			Se ei riitä että meillä on standardikomponentti, joka on osoitettu että se toimii luotettavasti vaan on katsottava että se toimii ympäristöolosuhteissa. ... Se riippuu missä olosuhteissa ne on toiminut. Siinä pitää katsoa mitkä ovat olleet toimintaympäristöt jos haetaan luotettavuusdataa. Jos ne [olosuhteet] vastaa toisiaan niin silloin pitäis olla mahdollista käyttää näitä normaalejakin teollisuuskomponentteja. Et jos on varavomadiesel niin se on varavomadiesel riippumatta siitä et se et potentiaalinen riski on ydinvoimalaitoksella suurempi mut toiminnalliset vaatimukset tälle varavomadieseleille on kuitenkin samat.	It's not sufficient to have a standard component that is proven to function reliably - we have to see that it functions in the ambient conditions. ... It depends on where it has functioned. The ambient surroundings must be looked at when reliability data is sought for. If they [the conditions] are equal, the usage of normal industrial components should be fine. If you have a emergency Diesel Generator (EDG), it's an EDG even though the potential risk is higher at a NPP but the functional requirements are equal [compared to the conventional side].	Luotettavuusdataa käytettäessä täytyy varmistua olosuhteiden vastaavuudesta. Teollisuuskomponentteja voidaan käyttää, jos olosuhteet vastaavat toisiaan ja laitteen toiminnalliset vaatimukset ovat samat.	Ambient conditions must meet if reliability data is applied. Industrial components may be utilized if the conditions and functional requirements are equal.	Reliability data for qualification Similarity of conditions	Reliability data	Reliability of commercial-grade items vs. nuclear-grade items
Licentsee #1 A.2.1.7	Miten lähestyisit turvallisuusluokitellun laitteen kelpoistusta, jos valmistajat eivät kykenisi valmistamaan laitetta vaatimustenmukaisella tavalla?	How would you address the qualification of safety classified equipment if suppliers were unable to manufacture the equipment in conformance with the requirements?	sanotaan näin et jos meillä on EN:n mukaiset materiaalit ja EN:n mukainen valmistus ja PED voimassa niin mun mielestä sen pitäis riittää TL3:ssa. Ei mitään ylimääräisiä materiaalitodistuksia tai ylimääräisiä tarkastusvaatimuksia, ei siihen välttämättä tarvii sitten.	Let's say that if the manufacturing and materials are according to EN ja PED is valid, I think that it should be sufficient in SC3. No additional material certificates or additional inspection requirements are necessarily needed.	Jos valmistus noudattaa EN-standardeja ja PED:iä, niin välttämättä mitään ylimääräisiä (standardit ylittäviä) tarkastuksia tai materiaalitodistuksia ei tarvittaisi.	If manufacturing adheres to EN and PED, no extra inspections or material certificates are needed.	Standard production SC3 EN PED	Accordance to standards	Reliability of commercial-grade items vs. nuclear-grade items
Licentsee #2 A.2.2.6			Mä pistäisin siihen tiettyjä lisävaatimuksia siihen valmistajan hyväksynnälle ensinnäkin et se valmistaja tunnetaan. Tässä on tärkeää se että se ketju tiedetään: referenssit ja toimitukset on tehty samanlaisella niin kuin valmistajakonseptilla. Nykyään on vaan ongelmia se et monet yritykset on ostettu moneen kertaan, yhdistetty, muutettu. Ja yritetään vielä mennä vanhoilla tyyppilyhyksynnillä tai vanhoilla referensseillä. Se on tärkeä et tunnetaan se toimittaja ja tunnetaan sen tuotteet että se on valmistanut niitä tuolla tehtaalla näin ja näin. Jos se toteutuu niin se on se suurin asia. Eli tää commercial-grade dedication, missä siel on nää neljä eri tapaa mitä lisätään, niin mahdollisesti joku lisä.	I would introduce certain additional requirements for the manufacturer approval to make sure the manufacturer is a known player. The key is to know the chain: references and that the deliveries have been done according to a similar concept. The problem is nowadays that many companies have been bought, fused and changed. And still we try to manage with the same old type approvals or references. Knowing the supplier's production is the critical key. This commercial-grade dedication [ASME methodology for the acceptance of commercial-grade items], where they have four different ways, possibly some extra [requirement].	Tutustumalla valmistajan toimintaan tunnetaan referenssit ja valmistuksen historia. Kun laatuajärjestelmää ja reklaamaatiota yms. pystytään tarkastelemaan niin voidaan varmistua toimittajan laaduntouottokyvystä. Myös ASME-puolen Commercial-grade dedication -metodologian piirteitä voitaisiin käyttää standardilaitteiden kelpoistuksessa turvallisuusluokiteltuihin käyttöpaikkoihin.	Assurance of the manufacturer's ability to produce quality can be reached by knowing the references and the history of manufacturing. Also features of AMSE's methodology, commercial-grade dedication could be used to qualify standard equipment to safety classified service places.	Familiarity with standard production Supplier references	Additional requirements Type tests References	Reliability of commercial-grade items vs. nuclear-grade items
Licentsee #3 A.2.3.5			Sit ainakin katsotaan se et mitä teollisuusstandardeja siinä on käytetty. Eli täyttääkö se tämmöiset normaalit teollisuusstandardit. ... Et jos siinä noudatetaan tämmösiä, silloin jo normaalisti tullut jo turvallisuusvaatimuksia, on nää SIL-luokat. Sit katsotaan et ovatko ne jo riittäviä, et niillä pystyis osoittan sen turvallisen käytön.	We would see which industrial standards it adheres to, does it meet regular industrial standards. If these are already adhered to, then there's normally already been safety requirements. We have these SIL-levels. Then their sufficiency would be evaluated to prove adequate safety.	Pitäisi katsoa, mitä normaaleja teollisuusstandardeja laite täyttää, koska silloin myös tietyt turvallisuusvaatimukset täyttyvät.	The equipment's conformity to normal industrial standards should be evaluated to see the level of adherence to safety requirements.	Standard production Industrial standards	Conformance to requirements	Reliability of commercial-grade items vs. nuclear-grade items
Licentsee #2 A.2.2.7	Reaaliaikaisen kunnonvalvonnan mahdollisuudet valmistusvaatimuksista keskusteltaessa?	Possibilities of real-time condition monitoring (RTCM) in discussing manufacturing requirements?	Tämä tarkoittaa sitä, se isoin asia sillä on jo se et ensin, sillähän poistetaan noin 90 % asennuksen virheistä, eli varmistetaan et säädöt, kaikki asennuksen kiristykset on mennä oikein eli suunnitelman mukaan. Eli tavallaan se kunnonvalvonta on se viimeinen millä voitaisi jo ajatella että varmistetaan sen oikeat kasaamisesta jo oikeat säädöt ja kaikki.	This means effectively that circa 90% of installation failures are removed - it [RTCM] assures that all adjustments and tightenings are according to the plans. So RTCM would be the final stage of assuring conformance.	Reaaliaikaisen kunnonvalvonnan avulla n. 90% asennusvirheistä voidaan poistaa.	RTCM allows for the removal of circa 90% of installation defects.	Upsides of real-time condition monitoring Installation defect Failure detection	Real-time condition monitoring	Reliability of commercial-grade items vs. nuclear-grade items

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Licensee #2 A.2.2.8	Reaaliaikaisen kunnonvalvonnan mahdollisuudet valmistusvaatimuksista keskusteltaessa?	Possibilities of real-time condition monitoring (RTCM) in discussing manufacturing requirements?	<p><i>Se kenellä se on [reaaliaikainen kunnonvalvonta] käytössä, se pystyy analysoimaan missä sillä on muita laitteita ja se toimittaja pääsee kiinni kuinka pitkälle ne on päässeet ne tuotteet missä sattuu olemaan se erä tätä. Ettei se oo välttämättä se et se toimii vaan se on se jäljitettävyyys myös et saadaan kerättyä muilta pois ne tuotteet ja vikaantuminen.</i></p> <p><i>Kunnonvalvonnan osalta niin sillähän nähdään koko ajan et miten se lähtee kehittymään nää kaikki asia ja mä näkisin et sillain kun kunnonvalvonta tulee ja jos siinä luvanhaltija oikeesti käsittelee tiedon ja viranomaisen jos se on mukana siinä niin sen jälkeen meidän ei tarvii valvoo sitä toimitusta enää siellä sillä tasolla mitä tänä päivänä ainakaan.</i></p>	<p>That who uses it [real-time condition monitoring] can analyze all the locations that have the same equipment. So it's not necessarily just how the equipment works but it's the traceability to show and collect failed items.</p> <p>RTCM allows to see transients in equipments' functions and if the licensee and authority cooperate in analyzing the RTCM data, the delivery itself would require less monitoring.</p>	<p>Reaaliaikaisessa kunnonvalvonnessa on kaksi hyötynäkökulmaa: ensiksi kunnonvalvonta, eli nähdään toimilko laite oikein. Toiseksi se, että käyttäjä tai toimittaja pystyy analysoimaan vikaantuneet tuotteet ja paikantamaan ja poistamaan vaaralliset tuotteet järjestelmistään tai toimituksistaan.</p> <p>Reaaliaikainen kunnonvalvonta mahdollistaa mahdollisten vikaantumisten kehittymisen, minkä vuoksi valmistusvalvontaa voitaisiin vähentää.</p>	<p>Real-time condition monitoring offers two upsides: 1) To see if the equipment functions properly. 2) Detecting failures allows for detection and elimination of dangerous equipment.</p> <p>RTCM allows for failure development detection and therefor quality control may be reduced.</p>	User feedback Failure detection	Real-time condition monitoring	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #3 A.2.3.6			<p><i>Kun ne toimitaolosuhteet onnettomuuksissa poikkeaa niin paljon normaaliolosuhteista niin turvallisuusjärjestelmät on periaatteessa stand-by laitteita ei ne edes toimi normaalisti. Niin ei se auta mitään kun nähdään et se laite on hajoamassa.</i></p>	The operational conditions during accidents vary so much from normal conditions and safety systems are fundamentally stand-by systems so they're not operational normally. There's no use to know whether or not the equipment is breaking down.	Reaaliaikainen kunnonvalvonta ei ole hyvä asia, koska laitteen täytyy toimia myös onnettomuuksien aikana, jotka on suunnitteluperusteisesti määrätty. Ei auta mitään, vaikka laitteen kuntoa monitoroidaan jos laite hajoaa.	RTCM is no good because also the stand-by safety system equipment must perform in the special conditions during design basis accidents. It's not useful to know if something is breaking.	Downsides of real-time condition monitoring Accident conditions	Real-time condition monitoring	Reliability of commercial-grade items vs. nuclear-grade items
Licensee #1 A.2.1.8	Mitkä seikat vaikuttavat siihen, että ydinlaitoksen vaatimuksiin räätälöidysti valmistetun osan hinta on standardilaitteiden hintaa korkeampi?	Which factors cause the nuclear-grade item to be more expensive than the commercial-grade item?	<p><i>Hyvin herkästihän se nostaa hintaa jos on erittäin vähän tarjoojia niin monopoliasemassa oleva toimittaja kun huomaa vahvan asemansa niin yleensä tuppaa nousemaan hinta sitä kautta.</i></p> <p><i>tietysti tää vaatimus tästä johtamisjärjestelmästä, laatujärjestelmä tietysti pitää valmistajilla olla mut sitten tämä YVL:n mukainen johtamisjärjestelmä niin se on mun mielestä aika vieras, et se on yks esimerkki tällaisista erikoisvaatimuksista joka tuo vaikeuksia.</i></p> <p><i>Kyllä, se rajoittaa kilpailua selväsi. Monet niinkin näkee tän vaatimuksen niin ne kieltäytyy tarjoamasta, tällasii on tullut vastaan aika paljonkin.</i></p> <p><i>joskus sit nää erikoisvaatimukset tulee yllätyksenä siinä vaiheessa kun ruvetaan valmistamaan ja lopputarkastamaan tuotetta ja katotaan papereita niin huomataan että jaaha, tällainenkin todistus pitäisi olla.</i></p>	<p>Having less bidders is likely to cause an elevated market price level: so once a supplier find itself in a monopoly situation it tends to raise prices.</p> <p>of course this requirement of the management system, quality control is a prerequisite for the manufacturers, but this management system according to the YVL Guide is quite strange. It's an example of these special requirements that bring about trouble.</p> <p>Yes, it [management system requirement] clearly restricts rivalry. Many [suppliers] decline from bidding upon seeing this requirement [management system requirement]. This has been seen quite a few times.</p> <p>sometimes these special requirements come as a surprise when we start to manufacture and inspect the product. We notice that: oh yeah, this kind of certification is also needed.</p>	<p>Valmistajien aseman monopolisoituminen puolestaan nostaa hintaa.</p> <p>Tietyt YVL-ohjeiden erikoisvaatimukset, esimerkiksi johtamisjärjestelmään liittyvät vaatimukset ovat valmistajan näkökulmasta vieraita.</p> <p>YVL-vaatimus valmistajan johtamisjärjestelmästä saa jotkin valmistajat perääntymään tarjouksen jättämisestä.</p> <p>Tilauksen vaatimuksiin liittyvä epävarmuus nostaa hintaa.</p>	<p>Monopolisation of the supplier positions in term raises the price.</p> <p>The Finnish requirements for management systems are viewed as strange in the eyes of manufacturers.</p> <p>The YVL-requirement of the management system may prevent some vendors from bidding.</p> <p>Uncertainty of the requirement raises the price.</p>	More costs Monopoly Market conditions Unclear requirement Management system	Economics Risks perceived by the supplier	Price of nuclear vs. commercial grade items
Licensee #2 A.2.2.9			<p><i>Kun ajatellaan YVL-ohjeen vaatimuksia niin TL3:ssakin tehdään hirveen paljon näitä kolmannen osapuolen tarkastuksia ja käydään pitkiä matkoja, niistä kaikista kertyy sitä ylimääräistä kulu.</i></p> <p><i>Ja samaan aikaan kun me poiketaan valmistajan normaali tuotteesta niin valmistaja lisää siihen omaa epävarmuutta ja sitä riskiä kun se ei tiedä varmaks sitä et onks se hyväksyttävä niin se laittaa siihen marginaalin.</i></p> <p><i>Näillä konventionaalisilla toimittajalla on ihan aito kilpailutilanne. Tänä päivänä ydinvoimatoimittajia on rajallinen määrä - niillä on niin paljon ollut vaatimuksia</i></p>	<p>In the YVL Guides' requirements, in SC3 there is an awful lot of third party inspections that are done far away - these accumulate the price.</p> <p>And at the same time we differ from the manufacturer's normal product, so the manufacturer adds some uncertainty-based risk marginal in the price for they don't know if their product is acceptable.</p> <p>The conventional suppliers have a genuine rivalry situation. These days nuclear suppliers are rare - they've had so</p>	<p>Kaikki ulkopuolisen osapuolen tekemät tarkastukset lisäävät kokonaishintaa.</p> <p>Toimittaja lisää tilaukseen epävarmuudesta johtuvan riskimarginaalin.</p> <p>Konventionaalisella puolella on olemassa aito kilpailutilanne toimittajien välillä, kun taas</p>	<p>Third party inspections accumulate the total price.</p> <p>The supplier adds an uncertainty-based risk marginal to their price.</p> <p>Nuclear suppliers don't operate in a genuinely rivaled market that still exists in the conventional market.</p>	More costs Uncertainty of acceptability	Economics Risks perceived by the supplier	Price of nuclear vs. commercial grade items

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Licensee #2 A.2.2.10	Mitkä seikat vaikuttavat siihen, että ydinlaitoksen vaatimuksiin räätälöidysti valmistetun osan hinta on standardilaitteiden hintaa korkeampi?	Which factors cause the nuclear-grade item to be more expensive than the commercial-grade item?	<i>et silloin kun ne tietää et ne täyttää niitä niin ne voi hinnoitella hyvin vapaasti.</i> <i>Ydinvoima-alan angelma on tänä päivänä se et sähköän hinta on niin alhainen, että meillä ei oo enää tätä erityisalaa, et voidaan maksaa mitä vaan.</i>	many requirements so if they still conform to hose requirements they may price very freely. The problem of nuclear sector is the current low market price of electricity. We're no longer a special field that can sustain all kind of payments.	ydinalan toimittajien osalta tilanne on jokskeenkin monopolisoitunut. Sähkön markkinahinta on heikentänyt ydinvoima-alan maksuvalmiutta.	Low price of electricity has weakened the liquidity of the nuclear field.	Low price of electricity	Economics	Price of nuclear vs. commercial grade items
Licensee #3 A.2.3.7			<i>Se on vaan lisätyötä ja silloin jos se lisätyö hinnoitellaan sen mukaan niin tämähän sen nostaa. Ei se ole liiketoimintaa, se on täysin sen muun toiminnan ulkopuolella.</i> <i>Pikemminkin ydinvoimaa toiset katsoo et se on pelkästään haitaksi, jos on ydinvoiman kanssa tekemisissä, ei he halua olla missään tekemisissä ydinvoiman kanssa.</i>	It's just extra work and it's thus priced in accordingly, which raises the price. It's not business at all, it's completely outside of the other operation. Some [suppliers] see rather that collaborating with the nuclear sector is a liability and therefor don't want anything to do with nuclear power.	Valmistajat näkevät sarjatuoannosta poikkeavan tuotannon taakkana, mikä nostaa kuluja. Ydinalan toimittajaksi leimautumisen vaara voi vähentää kykenevien valmistajien määrää, mikä nostaa hintaa.	Manufacturers view atypical production as a burden, which raises expenses. Being labeled as a nuclear supplier may affect the amount of capable manufacturers, which raises prices.	Customized production More costs Bad reputation	Economics Risks perceived by the supplier	Price of nuclear vs. commercial grade items
Licensee #1 A.2.1.9	Miten räätälöidyn ja standardilaitteen hintaeroa saataisiin kavennettua?	How could we bridge the price gap of nuclear and commercial-grade items?	<i>Näitä vaatimuksia pitäisi kertoa valmistajille: mitä nää vaatimukset tosissaan pitää sisältään, ehkä näitä tulkintoja et mitä on näistä YVL-ohjeista STUKin kanssa sovittu niin niitä pitäisi tietyt kertoa ettei ne niin pahoja ole kuin miltä ne äkkiseltään näyttää. Ettei tämmöstä rimakauhua niin sanotusti tulisi.</i>	<i>These requirements should be articulated to the manufacturers: what do they really mean and what has been agreed upon with STUK about the YVL Guides. To show that the requirements are not as bad as first look might imply, to prevent from stage fright.</i>	Valmistajille pitäisi avata vaatimusten todellista merkitystä, jotta niihin liittyvää epävarmuutta saataisiin vähennettyä.	The true meaning of the requirements should be elaborated to decrease the related uncertainty.	Uncertainty of requirements	Ways to lower costs	Price of nuclear vs. commercial grade items
Licensee #2 A.2.2.11			<i>Uudet YVL-ohjeet vaatii luvanhaltijaa tekemään laitevaatimusmäärittelyt: geneeriset ja oikeesti menemään hyvinkin tarkaks kaikkien vaatimusten tavallaan kirjaamiseen, että se tulee toimittajan kanssa kommunikoitua ja heti alusta.</i> <i>oon ollut konventionaalisella puolella ja täällä nuclear-puolella ja oon molempii puoli tutkinu ja näkis hirveen potentiaalin sillä että täällä ymmärrettäis se valmistajien osaaminen, kokemus ja yritettäis ihan ääripäähän asti hyödyntää ne referenssit ja se tavallaan se kaikki toimittajaverkostot ja kaikki siinä. ... Niillä [lentokoneteollisuudella] on vaan tää laaduntuottokyky hyvä ja se et ne on speksattu hyvin ja ne valmistajat on ammattilaisia, se toimitusketju toimii hyvin. Et täs on ydinvoima-alalla opettelemista.</i> <i>Ainoastaan jos me ostetaan uusi tuote niin silloin me voidaan ottaa se jostain muualta, mut tänä päivänä niitä toimittajia on aika rajallinen määrä ja ne on helposti tietävinään sen tason, koska ei ne kauheesti poikkea ne hinnat.</i>	The new YVL guides require the licensee to compile requirement specification documents: generic and more specific ones. They help with communicating the requirements to the supplier already in the beginning. <i>I've been both in the conventional and nuclear field and I see a huge potential if we understood the manufacturers' knowhow, experience and would make use of all their references and networks. ... The aviation industry is good at producing quality, and the products are well specified. The supply chain works well. There's something to learn from.</i> Only if we're buying a new product, we can buy it from elsewhere, but these days the amount of suppliers is limited and they tend to know the current market price.	Kustannussäästöihin voitaisiin päästä määrittämällä toimittajille tilauksiin liittyvät ehdot tarkemmin. Myös uudet laitevaatimusmäärittelyt selkeyttävät vaatimuksia toimittajille, mikä vähentää epävarmuutta. Hintaeron kaventamisessa on paljon potentiaalia ja opittavaa on etenkin lentokoneteollisuudesta. Jos kyseessä on uusi tuote niin hankinta voidaan kilpailuttaa, mutta usein toimittajien ra-jallinen määrä rajoittaa hintakilpailua.	Cost savings may be achieved if the terms and conditions were articulated more precisely. Also the RSDs clarify the requirements, which lowers the uncertainty perceived by suppliers. Bridging the price gap has a lot of potential from the conventional side, particularly aviation. The bids of new products can be shopped around but the low supplier amount causes stable prices.	Uncertainty of requirements Requirement specification document Benchmarking Aviation industry Bidding Market conditions	Ways to lower costs Economics	Price of nuclear vs. commercial grade items
Licensee #3 A.2.3.8			<i>toimittajan ei tarvitse sisällyttää sitä [lisensointi]riskiä siihen hintaan vaan silloin se voi niinkun tehdä ja sitten jos tulee lisäkustannuksia niin ne tietää kelle tulee. Et se ei johda silloin valmistajan tappioon.</i>	the supplier doesn't have to include the [licensing] risk in the price. The contract needs to state that it doesn't result in the loss of the manufacturer if there's extra costs.	Hintaeroa voitaisiin kuroa ottamalla itse enemmän vastuuta toimituksesta. Jos valmistuksessa tarvitseekin tehdä lisätyötä, ei siitä koituisi kuluja toimittajalle vaan TVO hoitaisi maksun. TVO toimisi tavallaan laitevalmistajana ja toimittaja alihankkijana.	The price gap could be bridged by taking more responsibility of the order. TVO would take care of the cost of potential extra work. TVO would act as the "manufacturer" and the supplier would be the "subcontractor" in a contractual sense.	Adding contractual responsibility Uncertainty of requirements	Ways to lower costs	Price of nuclear vs. commercial grade items
Licensee #1 A.2.1.10	Millaisena näet vaatimusten kansainvälisen harmonisoinnin nykytilan?	How do you view the current state of international requirement harmonization?	<i>ISO/EN:t on varmaan aika hyvin harmonisoitu ja aika hyvin hallinnassa kaikissa eurooppalaisissa maissa, mut jos mennään EU:n ulkopuolelle niin sit voi olla vähän niin ja näin. Sit varmaan EN:n lisäksi noissa reaktoripuolen asioissa tää ranskalainen RCC-M on varmaan aika hyvä, joka on itse asiassa kopio amerikkalaisesta ASME:sta, kyllä se on varmaan ihan riittävä.</i>	ISO/EN standards are supposedly well harmonized in European countries but outside the EU its a little so-so. Additionally in the reactor side of things the French RCC-M is quite good I guess. In fact it's a copy of the American ASME standard, I guess it's sufficient.	ISO/EN-standardit on aika pitkälle harmonisoitu EU:n sisällä, mutta ulkopuolella on enemmän varianssia. Reaktoripuolen standardeissa ranskalainen RCC-M on hyvä ja yleisesti käytetty standardi, ja se onkin kopio amerikkalaisesta ASME:sta.	ISO and EN standards are well harmonized within the EU but other countries have more variance. RCC-M is a good standard in the reactor field.	Harmonized standards ISO EN RCC-M	Harmonization issues Existing harmonization	Harmonization

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Licensee #2 A.2.2.12	Millaisena näet vaatimusten kansainvälisen harmonisoinnin nykytilan?	How do you view the current state of international requirement harmonization?	<i>mut jos euronormit ja RCC-M:t ja ASME-maailma niin mä näkisin siinäkin et EN-normien kanssa toimiminen on ainakin henkilökohtaisesti toiminut tosi hyvin</i>	Euro norms, RCC-Ms and the ASME world, I would see that EN-norms have personally been easy to work with	EN-normien, RCC-M:n ja ASME-maailman kanssa työskentely toimii hyvin.	EN, RCC-M and ASME are easy to deal with.	Harmonized standards EN ASME & RCC-M	Harmonization issues Existing harmonization	Harmonization
Licensee #3 A.2.3.9			<i>On tää WENRA, siinä on ne vaatimukset mut nekin on vielä yleisellä tasolla. Periaatteet ja sitten kun lähdetään sanoo mitä tää periaatteet tarkoittaa, niin siitä on poikkeamia.</i>	WENRA sets some requirements but they remain an a general level. Fundaments, but the practicality of the requirements contain anomalies.	Esimerkiksi WENRA määrittelee yleisen tason vaatimusperiaatteet, mutta kun periaatteita lähdetään avaamaan maakohtaisesti, ilmenee poikkeamia.	WENRA sets the general requirement principles, but the national interpretations of the principles cause anomalies.	Harmonized standards WENRA	Existing harmonization	Harmonization
Licensee #2 A.2.2.13	Mitkä ovat nykyisiä esteitä harmonisoinnin leviämislle?	What are the current barriers with improving harmonization?	<i>on ollut ongelma kun sitä [EN-standarddeja] ei oo tavallaan turvatuokassa 2 ja tääl ylemmis turvatuokissa hirveesti käytetty ja meil on ollut nyt omissa ajatuksissa sille turvatuokassa 2 matalaenergiselle puolelle saakka mennä ihan näillä [EN-standarddeilla].</i>	the problem has been its [EN-standards'] nonexistence in SC2 and higher. Our own interest is now to go until the low energy side of SC2 with these [EN-standards].	Engelmana on lähinnä matalaenergisin TL2:n komponentteihin liitetyt koodit ja standardit ja niiden hyväksyttäminen Suomessa.	The problem is qualifying C&S of low energy components of SC2 in Finland.	SC2 low energy components	Harmonization issues	Harmonization
Licensee #3 A.2.3.10			<i>Kun on nää isot maat niin siellä on kuitenkin ydinvoimateollisuus on valtiojohtoisia: Ranska, Kiina, Venäjä. Niin mä en tiedä mut siinä on tämmönen kansallinen itsemääräämisoikeus että koska se on kuitenkin projekteja halutaan viedä eteenpäin ja säilyttää se itsemääräämisoikeus ja sit on kysymys kuitenkin miljardiluokan hankkeista aina. se mitä omassa maassa tehdään niin se katsotaan riittäväksi niin siihen ei haluta että ulkopuoliset vaikutta.</i>	These large countries where the nuclear industry is statist: France, China, Russia. The projects are so big - we're talking billions [of euros]- and the autonomy is wanted to maintain. What is done in each country is considered sufficient and outside influence is not wanted.	Ydinvoima on etenkin isoissa maissa valtiojohtoisia, jolloin kansallinen itsemääräämisoikeus johtaa erilaisiin vaatimuskäytäntöihin. Eri viranomaiset näkevät omat määräyksensä riittävänä ja pitävät niistä kiinni.	Nuclear power is statist in large countries, and different national requirements are formed. Authorities see their national requirements good as they are defined.	Autonomy of requirements	Harmonization issues	Harmonization
Licensee #1 A.2.1.11	Miten luulisit että laajempi harmonisointi vaikuttaisi viranomaisen toimintaan?	How do you think that more extensive harmonization of requirements would affect the Authority?	<i>Se varmaan yksinkertaistais sitä tarkastusprosessia kun olis yhdenmukaiset standardit olemassa mitä vasten verrataan.</i>	I think it probably would simplify the inspection process to have uniform standard to compare with.	Harmonisoinnin yksi vaikutus olisi myös viranomaisen tarkastusprosessin yksinkertaistuminen.	One harmonization effect would be the simplification of authorities' inspection process.	Simplified inspection	Harmonization benefits Economics	Harmonization
	Miten luulisit että laajempi harmonisointi vaikuttaisi valmistajan toimintaan?	How do you think that more extensive harmonization of requirements would affect the manufacturers?	<i>Se [harmonisoinnin lisääntyminen] lisäis tietenkin toimittajien ja valmistajien määrää ja parantais tiettyä laatuakin sitä kautta. Ja vois alentaa hintaa kun tulis lisää kilpailua.</i>	It [more harmonization] would of course increase amount of suppliers and manufacturers and it would thus improve quality. And prices might drop as market rivalry increases.	Toimittajien määrä kasvaisi, laatu paranisi ja luultavasti samalla saataisiin kustannussäästöjä.	More harmonization would mean more manufacturers, better quality and probably cost cuts.	Manufacturer pool Less costs Quality improvements	Quality Ways to lower costs	Harmonization
Licensee #2 A.2.2.14	Miten luulisit että laajempi harmonisointi vaikuttaisi luvanhaltijan toimintaan?	How do you think that more extensive harmonization of requirements would affect the licensee?	<i>Kyl se varmaan meitäkin helpottaa pidemmässä juoksussa et tota, se selkeyttäis. Tää on vähän ollut semmosta sekasta kun meilläkin on ollut täällä, nyt saarellaikin, on EN-normien ja RCC-M:n ja ASMEn mukaista tavaraa. Kyl se helpottais ja etenkin silloin kun tulee uusi henkilöitä, se kaikki oppiminen ja käytännöt yhtenäistyis kaikissa.</i>	I guess it would help us to clarify things in the long run. It's confusing when we have material that adheres to EN norms, RCC-M and ASME. It would help especially in training of new staff.	Luvanhaltijan toiminta virtaviivaistuisi koodien yhtenäistessä.	The licensee's operation would be streamlined along with better harmonization of codes.	Streamlining Codes & Standards	Harmonization benefits	Harmonization
	Miten luulisit että laajempi harmonisointi vaikuttaisi viranomaisen toimintaan?	How do you think that more extensive harmonization of requirements would affect the Authority?	<i>Ehkä se olis se et viranomaisten ei taitte olla koko ajan kaikkien muutosten ja koda ajan kerätä kaikist niitä ja käydä läpi kaikkee vaan se riittäis jos olis mukana vain yhdessä kooditoimituksessa.</i>	Perhaps it would be that the authority wouldn't have to deal with changing codes & standards - It would suffice to participate in a single code.	Viranomaisen työtaakka kevenisi määräysten yhtenäistessä.	Workload of the authority would be lower if the C&S Sunify more.			
	Miten luulisit että laajempi harmonisointi vaikuttaisi valmistajan toimintaan?	How do you think that more extensive harmonization of requirements would affect the manufacturers?	<i>Jos toimittajaverkostoa ajatellaan niin olis paljon helpompia kun niitten ei tarvii hakee kaikkia sertifiointeja ja hyväksyntöjä ja tarkastusmerkintöjä eri standardien kautta. Se on hirveä kulu myös toimittajalle. Ja jos olis yks niin toimittajat pystyis toimittamaan ympäri maailmaa, jolloin niillä olis isommat massat samalla ja standardisoidut tuotteet. "</i>	If the supplier chain is concerned, they would benefit a lot for not having to apply multiple verifications, acceptations, ja inspection marks through multiple standars. It's a large cost also for the supplier. If there would be one [standard], the suppliers could ship globally at a larger volume.	Toimittajat hyötyisivät harmonisoinnista kun heidän akkreditointitaakka pienenis, mikä pudottais hintaa. Myös markkina avautuisi ja valmistuserät kasvaisivat.	The suppliers would simplify their accreditation process, which would cut costs. They would operate on a larger market with more volume.	Simplified accreditation Less costs More volume		
Licensee #3 A.2.3.11	Miten luulisit että laajempi harmonisointi vaikuttaisi viranomaisen toimintaan?	How do you think that more extensive	<i>Se poistais kyllä viranomaisen itsenäisyyttä sillain et silloin tulis tämmönen valvova elin, joka katsois et täytyäkö se ne vaatimukset mitkä on</i>	It would decrease the autonomy of the authority and it would change it to be a	Viranomaisen itsenäisyys vähenisi, mikä muuttaisi viranomaisen roolia	Authority's autonomy would decrease.	Authority autonomy	Authority power	Harmonization

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Licensee #3 A.2.3.12	Miten luulisit että laajempi harmonisointi vaikuttaisi valmistajan toimintaan?	harmonization of requirements would affect the Authority? How do you think that more extensive harmonization of requirements would affect the manufacturers?	<i>Siten, että laitostoimittaja tietäis et kun se näin tekee niin se pystytään tekemään, se poistais tätä lisensiointiriskiä</i> Haastattelija: Miten se taas vaikuttaisi? <i>Haastateltava: No aikatauluihin.</i>	supervisory member who would supervise if it [product] meets its requirements. In a way that the plant supplier would know what is required of them, it would decrease the licensing risk Interviewer: And how would that affect? Interviewee: Faster schedules.	enemmän valvovan elimen suuntaan. Valmistajat voisivat toimittaa laitteita aiempaa nopeammin, kun lisensiointiriskiä ei tarvitsisi vaatimusten yhdenmukaistuttua enää sisällyttää sopimuksiin aiemmassa mittakaavassa.	The manufacturers could ship faster when the licensing risk wouldn't have to be included in the contracts.	Faster delivery Less licensing risk	Ways to lower costs	Harmonization
Licensee #1 A.2.1.12	Miten näet harmonisoinnin tulevaisuuden?	What is your view on the future of harmonization?	<i>Vaikee sanoa miten tulee käymään. Tietysti trendi pitäis olla siihen suuntaan et käytetään samoja standardeja. Mut mä pahoin pelkään et nää tietyt erityisvaatimukset siilti on mukana vielä jonkun aikaa.</i>	It's hard to say how it's going to be. Of course the trend should be in the way of using same standards. But I'm afraid certain special requirements are still going to be present for some time.	Vaikka suunnan pitäisi olla kohti yhtenäisempiä standardeja, on tulevaa hankalaa ennustaa, mutta luultavasti erityisvaatimukset ovat mukana.	The future should look like a more unified standard, but some specific requirements are going to be present.	Convergence of standards Specific requirements	Future of harmonization	Harmonization
Licensee #2 A.2.2.15	Miten näet harmonisoinnin tulevaisuuden?	What is your view on the future of harmonization?	<i>Kyl mä näkisin et nois standardeis on varmaan aika koettuu ja hyviä puolia, niitä pitäis hiukan yhdistellä et tota täl hetkellä siel on tiettyjä jotka on toisessa paremmin kuin toisessa.</i> <i>Kyl mä näkisin et sen [harmonisaation] pitäis olla ydinvoimamaailman yks tavoite tänä päivänä kun maailma on kuitenkin yhtenäistynyt. Valmistus ja omistuksii voi olla missä vaan, et ei oo enää sillain et meil on euroopassakin hirveesti näitä, ajatellaan et tuotetaan Euroopassa ja yritetään suojella sitä mut omistaja on kuitenkin amerikkalainen. Esimerkiks Nuclearilla on paljon amerikkalaista omistusta. Vaikka kuin suojellaan sitä niin rahat menee kuitenkin Amerikkaan.</i> <i>Mun mielestä vaan isomman pöydän ympärille ja käymään läpi oikeesti niitä vaatimuksia ja kategorioita ne taas niiden turvatoimintojen mukaan vielä eikä vaan turvaluokkakohteisesti.</i>	The way I see it is that these standards have quite approved and good characteristics, which should be combined. <i>I think that it [harmonization] should be a shared interest in the nuclear sector today as the world is united after all. The manufacturing and ownership can be located anywhere and the days of protecting the production in Europe are gone</i> because the owner is American in the end. For example Nuclear has a lot of American ownership. No matter how it's protected, the money still goes to America. I think all parties should meet and really go through the requirements and categorize them also according to the safety functions and not just according to the safety class.	Standardit tulevat liukumaan enemmän kohti yhtä yleistä standardia, jota useampi tekijä käyttää globaallilla tasolla. Ydinlaan liittyvä sääntely on paikallista, mutta omistus kansainvälistä, joten lopulta nykyinen suojelun kulttuuri ei lopulta puolusta paikkaansa. Olisi koko ydinalan jaettu intressi saada harmonisointia eteenpäin. Standardien vaatimukset pitäisi läpikäydä isolla porukalla ja kategorisoida turvatoiminnollain pelkän turvallisuusluokakohtaisen tarkastelun sijaan.	<i>The standards will slide towards a single standard that is utilized by more organizations globally</i> Nuclear regulation is local, but the ownership is global. The current protectionism is not useful in the end. Harmonizing more would be a shared interest. The included requirements of standards should be discussed with all stakeholders and categorize them per safety functions, not just per safety class.	Convergence of standards Global ownership Protectionism Requirement review Structural vs. operability requirements	Future of harmonization Market conditions Cooperation	Harmonization
Licensee #3 A.2.3.13			<i>Yhtä yleistä. ... Ja meillä on neljä kertaa tänä aikana yltäosan määrökset muuttuneet. Siinä on vähän liikaa muutosta.</i>	Towards a common [standard]. ... And the top level requirements have already changed four times [during OL3 project]. It's too much change.	Vaatimusten pitäisi mennä kohti yhtä yleistä standardia. Lainsäädäntö ja paikalliset määräykset muuttuvat liian usein.	The requirements should be unified- Legislation and local requirements change too often.	Convergence of standards	Future of harmonization	Harmonization
Licensee #1 A.2.1.13	Mitä hyötyä on laitevaatimusmäärittelystä?	What are the benefits of the requirement specification document (RSD)	<i>Joo, se on aika uus asia. Kyl siinä on hyvätkin puolensa jos se tehdään juurta jaksaa ja hyvin. Se on tietysti työläs luvanhaltijalle.</i>	Yes, it's quite new. It has its upsides if done thoroughly. Granted that it's laborious for the licensee.	LVM on suuritöinen, mutta sillä on hyvät puolensa, jos se tehdään hyvin.	The GSD is a lot of work but it's useful if done correctly.	GSD workload	Requirement specification document	Harmonization
Licensee #2 A.2.2.16			<i>Se on aika haasteellinen tehdä. Mut siihen kun lyödään kaikki nämä tavallaan valmistajaa, laitetta, materiaali, laskentaa, käyttöolosuhteita ja elinkaareen liittyvät vaatimukset, se on aika iso paketti. Toisaalta se selkeyttää sitä ja vaatimukset tulee läpikäytyä toimittajan kanssa.</i>	It's quite challenging to do. It's really a big package when you include all the manufacturer, equipment, material, calculations, conditions and life cycle related requirements. On the other hand it clarifies it and the requirements are explained to the supplier.	Työ on haastava ja laaja, kun mennään detaljitasolle ja sisällytetään kaikki vaatimukset, eikä kuitenkaan haluta säikäyttää toimittajia turhilla asioilla. Toisaalta se selkeyttää toimittajalta vaadittuja asioita.	It's challenging to do, when you have to enter the detailed level and include all the requirements and at the same time you don't want to scare the suppliers with pointless matters. On the other hand it clarifies things required from the supplier.	GSD workload Clarification of requirements	Requirement specification document	Harmonization
Licensee #1 A.2.1.14			<i>Siinä kannattais harrastaa yhteistyötä. Meillä on jonkun verran ollut näitä yhteistyöelimiä olemassa, et niitä pitäis niillä fuorumella käsitellä.</i> <i>Kyl se on se selvä kustannussäästö. Ja ei turvallisuus ainakaan huonone sitä kautta.</i>	Cooperation [of licensees with RSDs] would be great. We have certain cooperative bodies, and RSDs should be handled there. It's a clear cost reduction. And safety wouldn't be compromised.	Luvanhaltijoiden välinen yhteistyö laitevaatimusmäärittelyjen laadinassa olisi todella suotavaa. Yhteistyöllä voitaisiin saavuttaa kustannussäästöjä turvallisuuden kärsimättä.	Cooperation of licensees in drafting RSDs would be great. Cooperation would cut costs - not safety.	Requirement specification document cooperation Less costs	Requirement specification document Ways to lower costs	Harmonization

APPENDIX A.2 - Interview table - Representatives of the Licensee

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated Answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Licensee #2 A.2.2.17			<i>Joo. Ilman muuta. Siis mun mielipide on että yhteen maahan riittäis yhdet [laitevaatimusmäärittelyt], koska meillä on sama valvova viranomainen täällä kuka valvoo tänne ydinvoima-alueelle tuotavia tuotteita niin kaikille pitäis olla laki samanlainen ja yhteiset [laitevaatimusmäärittelyt].</i>	<i>I think that one set of RSDs would suffice for one country because we have the same supervising authority</i>	Luvanhaltijoiden välinen yhteistyö olisi hyvä asia laitevaatimusmäärittelyiden laadinnassa.	Cross-licensee cooperation is beneficial.	Requirement specification document cooperation	Requirement specification document	Harmonization
Licensee #2 A.2.2.18	Mitä hyötyä on laitevaatimusmäärittelystä?	What are the benefits of the requirement specification document (RSD)	<i>Meilläkin on täällä [Olkiluodossa] erilaisii laitoksii. Meillä on aikomuksii tehdä yhteinen laitevaatimusmäärittely venttiileille, pumpuille, kaikille. Ei se tee eroa, ei se tunne sitä onks se painevesilaitoksessa tai kiehutuslaitoksessa. Jotkut erityislaitteet on sit tietyt laitospesifisiä.</i>	We too here in Olkiluoto have different kind of plants. We have plans to make a general RSD for valves, pumps, everything. It [the item] doesn't know whether it's in a PWR or a BWR. Some equipment are plant specific, of course.	RSDs can be shared eventhough the plants are different. Plant specific differences are to be accounted for.	General RSDs can be done for many types of plants.	Requirement specification document cooperation	Requirement specification document	Harmonization
Licensee #1 A.2.1.15	Mitä muuta luvanhaltijat voisivat tehdä yhteistyössä?	In what else could the licensees cooperate in?	<i>Ehkä tämmösiä valmistajien hyväksyntään liittyviä auditointeja, joita aina silloin tällöin joudutaan tekemään ... Se ois hyvä jos sitä tulis enemmänkin, se on vielä vähän rajoitettua tiettyihin paikkoihin. Mun mielestä se on hyvä menettely tämmösessä pienessä maassa kuin Suomi. Varmasti hyödyllinen.</i>	Auditing related to the approval of manufacturers that need be done every now and then ... It would be good to have more of, now it's somewhat restricted. I think in a small country like Finland it's useful.	Säästöihin päästäisiin, koska työtaakka kevenisi ja valmistajien hyväksyntään liittyviä auditointeja voitaisiin tehdä aiempaa enemmän yhteistyönä.	It would cut costs and workload if the licensees would cooperate in manufacturer audits.	Manufacturer audits	Cooperation between licensees	Harmonization
Licensee #2 A.2.2.19			<i>Yhteistyötä kaiken rintamalla. Mun mielestä vois myös näitä yhteistilauksia, et voitais hankkia myös kaikki ja voitais paljonkin sopia näistä linjauksista, jopa varastoinnista. Toivoisin myöskin että viranomaiset hyväksyis sen et meillä ois yhteinen varasto. Me voitais pienentää varaston arvoa, ei meillä kaikilla tuu samaan aikaan sitä tilannetta [vikaantumista].</i> <i>Joo, ja saatais nostettua ehkä sitä määrää ja valmistuserien kokoa ja sitä kautta saatais lisää [valmistajia]</i>	<i>Cooperation in everything. Combined orders, agreeing on policies, storage, I hope the authority would allow a shared warehouse between licensees. We could reduce the stock value because we won't have the same situation [equipment failure] at once.</i> Yes, and we could grow the manufacturing batch size and also the number [of suppliers].	Laajaa yhteistyötä: esimerkiksi yhteistilausten ja yhteisen varaston muodossa. Yhteisvarasto pienentäisi varaston arvoa, se ei vaikuttaisi turvallisuuteen. Yhteistyöllä saataisiin lisää valmistajia ja parempaa laatua tuotantomäärän kasvaessa.	A lot of cooperation is needed, e.g. in combined orders and storing. A shared warehouse would lower only stock value, not safety. Cooperating would increase the manufacturer amount and quality as batch size goes up.	Stock value reduction Increased batch size More manufacturers	Cooperation between licensees	Harmonization

Interviews held during 22.5.2017 – 23.5.2017 in Eurajoki, Finland.

Interviewee	Number of answers
Licensee #1	15
Licensee #2	19
Licensee #3	13
TOTAL	47

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Manufacturer #1 A.3.1.1	Mikä on ydinlaitoksissa käytettävien laitteiden erityisvaatimusten tavoite?	What is the goal of the specific requirements for nuclear equipment?	<i>koska on niin kriittiset prosessit kyseessä niin kyl varmaan halutaan varmistaa et kaikki menee juuri täydellisesti oikein eikä mikään jää sattuman varaan. Se dokumentaation ja varmistamisen määrä on todella huikaa verrattuna melkein mihinkään muuhun prosessiteollisuuteen. Paperityötä ja tarkastuksia tulee todella iso määrä.</i>	<i>because the processes are so critical, perfection must be ensured so that nothing is left to chance. The amount of documentation and assuring is astounding compared to almost any other application within the process industry. There is a lot of paper work and inspections.</i>	Koska prosessit ovat niin kriittisiä, halutaan varmistaa että kaikki on täydellistä. Tämä johtaa valtavaan dokumentaation ja varmistuksen määrään.	Perfection must be ensured for the processes are so critical. This leads to a huge amount of documentation and assurance.	Critical processes Documentation	Objective of Quality Control Quality Assurance	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #2 A.3.2.1			<i>Tämä [PED-in noudattaminen] takaa lainsäätäjän vaatiman alhaisen riskitason, jota edelleen voidaan alentaa asiakas- tai alakohtaisilla vaatimuksilla ja niihin liittyvillä tarkastuksilla."</i>	<i>This [following PED] ensures the low risk level demanded by the lawmaker, which can be further lowered by customer or field specific requirements and related inspections.</i>	PED määrittää vaatimusten perustason, jossa varmistutaan siitä että riski merkitys jää alhaiseksi muun muassa kolmansien osapuolten tarkastuksilla. Asiakaskohteisilla vaatimuksilla riskitasoa voidaan alentaa entisestään.	PED defines the basic risk level, which ensures the associated risk is low, which is achieved through e.g. third party inspections. The risk level can be lowered further by customer specific requirements.	PED Risk level Customer specific requirements Third party inspections	Objective of Quality Control Inspections	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #3 A.3.3.1			<i>sillä [erityisvaatimuksilla] monesti haetaan kolmannen osapuolen varmistusta hyvin moneen asiaan. Ja se liittyy sitten nähdäkseen materiaalivalmistukseen, tuotelaatuun ja dokumentaatioon.</i>	<i>the reason [of the specific requirements] is many times to gain third party assurance to multiple things. And it's related to production of materials, product quality and documentation.</i>	Erityisvaatimusten tavoitteena on saada kolmansien osapuolten varmistus esimerkiksi materiaalivalmistuksen, tuotteen ja dokumentaation laadusta:	The goal of specific requirements is to gain third party assurance on the quality of material production, documentation and the product itself.	Third party assurance Material production Documentation	Objective of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.2	Miten ydinalan erityisvaatimukset vaikuttavat laitteiden luotettavuuteen?	How do the nuclear specific requirements affect the reliability of equipment?	<i>No osahan siitä on varmaan sellasta et tehdään dokumentaatioo dokumentaation vuoksi, mut kyl siinä sit on myös ihan järki et varmistetaan kaikkea niin kuin materiaalien soveltuvuus, varmistetaan työn laatu - totta kai kaikilla isoilla valmistajilla on kaikki mahdolliset laatuodokumentit ja isot järjestelmät ja muuta.</i> <i>jos siellä pystytään vahtimaan valmistajaa että se on luotettava valmistaja, iso toimija, jolla on omat laatu järjestelmät niin ei niiden pitäis tuoda mitään lisäarvoa.</i> <i>se [vaatimusten luotettavuus] etu tulee jos käytetään sellasi valmistajii joiden laadusta ja suorituskyyvystä ei olla niin varmoja, niin silloinhan saadaan niitä tuotannon virheitä näkyviin.</i>	<i>It's partly documentation for its own sake, but there is a logic behind it to assure things like material suitability, quality of work. Of course every large manufacturer has things like quality documents and systems etc.</i> <i>If the manufacturer can be seen as a reliable and big party with independent quality systems, then they [additional requirements] should not add any value.</i> <i>The benefit [of the QC requirements] comes from using manufacturers whose capability can't be confirmed, then the production faults come to surface.</i>	Yhtäältä tehdään dokumentaatiota dokumentaation vuoksi, mutta toisaalta materiaalin soveltuvuuden, työn laadun ja valmistajien pätevyyden tarkastukset puolustavat paikkaansa. Ylimääräisistä laadunvalvontatoimista ei ole merkitystä luotettavuudelle, jos valmistaja on iso ja luotettava toimija, jonka laatu järjestelmä on kunnossa. Tuntemattomien valmistajien kohdalla laadunvalvonnalla saadaan virheitä esiin.	On the other hand the documentation is a burden, but then again it's good to inspect the suitability of materials, competency of manufacturers and the quality of work. Additional QC measures don't add reliability if the manufacturer is known to be reliable and has a good quality system. QC may reveal occurrences in the production of more unknown manufacturers.	Documentation Material suitability Quality of work Quality Control Quality System Familiar manufacturer Unfamiliar manufacturer	Objective of Quality Control Inspections Quality Assurance Reliability effect of Quality Control Manufacturer status	Reliability of commercial-grade items vs. nuclear-grade items

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Manufacturer #3 A.3.3.2	Miten ydinalan erityisvaatimukset vaikuttavat laitteiden luotettavuuteen?	How do the nuclear specific requirements affect the reliability of equipment?	<i>No mun täytyy sanoa, että mä en ihan hirveesti näe että se [kolmansien osapuolten tarkastus] jalostaa [luotettavuutta]. Meidän toimitukset on aika tarkkaan mietittyjä, ja se on vielä vähän sellainen understatement, että ne on tarkkaan mietittyjä oikeesti.</i>	<i>I have to say that [third party inspection] does not remarkably improve it [reliability]. Our supply chain is thoroughly designed and that is an understatement.</i>	Kolmansien osapuolten tarkastuksilla ei ole suurta merkitystä luotettavuudelle, koska toimitukset ovat jo hyvin tarkasti suunniteltuja.	Third party inspections don't play a big part in reliability because the supply chain is thorough.	Third part inspection Supply chain design	Reliability effect of Quality Control	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.3	Mitkä ovat sellaisia vaatimuksia, joilla on korkea turvallisuusmerkitys?	What are requirements that have a high significance to safety?	<i>Kyl se [tärkein asia] varmaan on ne materiaalit, et pitää olla tietyt materiaalit.</i>	<i>The most important thing is probably to ensure the right materials.</i>	Käytettyjen materiaalien tarkastuksen varmentaminen on tärkeää, koska materiaalin täytyy olla tarkasti sitä mitä on vaadittu.	Ensuring that the material used is important for the material must be exactly what is required.	Material selection	Efficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #2 A.3.2.2			<i>kaikki tietyt lähtee siitä että pystytään laadukkaasti tekemään se, eli meillä pitää olla osaaminen lähtee tekemään sitä. Nykypäivänä simulointi on tullut hyvin vahvasti meillä tekemiseen, että me simuloimalla testataan jo asiat ennen kuin me viedään se labratestaukseen. Sit mennäänkin toimittajan ja omaan laadunvarmistamiseen että saadaan sellasia komponentteja miten sen designin periaatteessa pitäis toimia että se saadaan myöskin toimin sit käytännössä.</i>	<i>everything is based on the fact that we can produce quality, after which simulation is a great tool to test the design before it's taken to the lab. Then it's about going to the supplier and our own quality assurance to see that the components conform to the design to make it work also in practice.</i>	Suunnittelulla varmistetaan vaatimustenmukaisuudesta, jota varmistetaan simuloinnin ohella myös fyysisen testauksen avulla. Myös oma ja alihankkijoiden laatu varmistetaan.	Design assures conformity to requirements that is also ensured through simulation and physical tests. Supplier quality is assured along with our own quality.	Design Conformity to requirements Supplier quality	Efficient requirements Quality Assurance	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #3 A.3.3.3			<i>Turvallisuuden nimissä, jos lähdetään siitä että materiaali on sitä mitä pitää olla niin siellä tulee tietenkin nää koeponnistukset, eli koerasitukset. Ja siinä me erotellaan tavallaan se, että se painekuori niin siinä on kaksi testauksia. Et se kestää, siinä ei tuu mitään deformaatioita eli muodonmuutoksia ja toinen että se ei vuoda mihinkään suuntaan. Sit on tietenkin se tuotelaatu [testaus], että se venttiili toimii niin kuin sen pitää – siellä on operointikokeita, tiiviystestejä.</i>	<i>Safety wise, if conformity of material is assured, then we have pressure tests to show that the valve doesn't develop any deformations under stress and that no leaks are detected. Then we have product quality tests to show the product functions as planned; operational and integrity tests.</i>	Jos materiaalin vaatimuksenmukaisuudesta on varmistuttu, koerasitustestit ovat tärkeimpiä. Niillä varmistetaan, että valmiissa venttiilissä 1) ei tapahdu muodonmuutoksia ja 2) ei tule vuotoja. Myös tuotteen laadusta varmistetaan toiminnallisten ja eheystestien avulla.	If the material is what it's planned to be, pressure tests are most important to ensure a leakproof valve that keeps its form. Product quality is also ensured through operational and integrity testing.	Pressure test Deformation Leaktightness Integrity	Efficient requirements Testing	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.4	Mitkä ovat sellaisia vaatimuksia, joilla on vähäinen turvallisuusmerkitys?	What are requirements that have a low significance to safety?	<i>Kyl se [dokumentaatio] pitää tehdä, mut sit toisaalta niin korreloiks se käytännön prosesseihin, saadanko sillä lisättyä turvallisuutta niin ei välttämättä työmäärään verrattuna tuo sitä lisäturvaa siihen.</i>	<i>It [the documentation] must be done, but the amount of documentation and safety does not necessarily correlate at least with the workload.</i>	Lisädokumentaatiolla ei välttämättä enää päästä luotettavampaan tuotteeseen.	Extra documentation doesn't necessarily bring extra safety.	Documentation Relation of documentation and safety	Efficient requirements	Reliability of commercial-grade items vs. nuclear-grade items

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Manufacturer #2 A.3.2.3	Mitkä ovat sellaisia vaatimuksia, joilla on vähäinen turvallisuusmerkitys?	What are requirements that have a low significance to safety?	Hyvin helppo on nimetä tilanteita joissa on joku tiiveysstandardi, joka hyvin selkeästi sanoo että esimerkiksi vaikka kaasulla mitataan läpivuoto. Laitetaan paine-ero vaikka 3,5 bar ja sitten läpivuotoa mitataan kaasulla - sillä ei välttämättä ole minkäänlaista todellista yhteyttä siihen asiakkaan todelliseen prosessiin. Voi olla et sen venttiilin läpi ei tule koskaan menemään kaasua vaan se on nestemäistä ja paineet on ihan eri luokkaa.	It's easy to name situations where a leaktightness standard states clearly that gas is used in testing of emissions. Let's say the pressure gradient is 3,5 bar and emission is measured with gas – gas might not have anything to do with the client's real process. The valve may very well not be subjected to gas ever again, but to liquid with all different pressure values.	Jotkut standardit vaativat testejä, joiden olosuhteilla ei ole mitään tekemistä asiakkaan todellisten prosessiolosuhteiden kanssa. Esimerkiksi tiiveysstandardin mukainen läpivuototesti, jonka reputtaminen aiheuttaa korjaavia toimenpiteitä, joista ei välttämättä ole mitään hyötyä venttiilin luotettavuudelle sen käyttöpaikalla.	Some standards require tests, whose parameters may not be relevant to the client's real process. For example failing a leaktightness test causes correctional effort that may not cause any improvements to the valve's reliability.	Standard tests Leaktightness Gas emissions	Inefficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #3 A.3.3.4			Niin niille [valmistuksen aikaiselle valvonnalle] annetaan monesti kohtuuttoman suuri painoarvo, koska se kuitenkin menee aika tiukkaan testaussykliin sitten loppujen lopuksi.	Intra-production inspection is given excessive attention, because the post-production testing cycle is already quite demanding.	Sisäisen tekemisen tarkkailu, eli tuotteen valmistuksen aikainen valvonta, on liiallista.	Inspecting the production's internal affairs is excessive.	Intra-production inspection Post-production testing	Inefficient requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.5	Miten ydinvoima-alan vaatimukset eroavat konventionaalisesta teollisuuden vaatimuksista?	How do the nuclear requirements differ from the requirements of conventional industry?	[Ydinolalla] lähdetään ihan materiaalin kemiallisia koostumuksia pilkkuleen kattamaan, kyl se viedään mun kokemuksen mukaan todella paljon pidemmälle kuin missään muualla.	The nuclear industry looks at the chemical composition of material in detail, and I think it's taken way further than in any other field.	Ydinolalla materiaalin soveltuvuuden varmistaminen on viety reilusti pidemmälle kuin muilla teollisuudenaloilla.	Assuring material suitability is taken a lot further in the nuclear industry than in any other industry.	Nuclear vs. conventional requirements	Extent of the requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #2 A.3.2.4			Näissä ydinvoimaventtiileissä nää laskelmat tuntuu olevan usein aika merkittävässä asemassa.	The nuclear valves tend to emphasize calculations quite remarkably.	Ydinvoima-alan toimituksilla laskelmavaatimukset ovat usein kattavia.	Calculation requirements in the nuclear deliveries are extensive.	Calculation requirements Nuclear vs. conventional requirements	Design requirements Extent of the requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #3 A.3.3.5			Kyl se tää ydinvoimabiznes on ihan kirkkaasti vaativin, mut se on määrällisesti niin pientä et se hukkuu sit suurempaan massaan. Ja se suuri massa tulee öljy- ja kaasuteollisuudesta. Meillä on sitten hyvin vaativaa asiakaskuntaa, nimenomaan tota petrokemiaa sekä pumppaamo- että jalostusbisneksistä. [Öljy- ja kaasuteollisuuden] vaatimukset päivitytty ja joskus niitä vähän ihmetellään mut monesti siellä voi olla joku huono kokemus asiakkaalla, tai sit voi olla ihan teknisesti perusteltavissa olevia uuden näkemyksen tuomia asioita. Esimerkiksi mikrorakennetutkimus on sellainen, että siitä on tullut aika iso juttu meille tässä muutaman vuoden aikana.	The nuclear business is by far the most demanding [requirement wise], but the volumes are so low that it drowns in a bigger mass. And the big mass comes from the oil and gas industry. We have really demanding clientele, particularly petrochemical and pumping and refining business. The oil & gas requirements are up-dated, and while sometimes the updates are marveled at, they are based on experiences or are based on technical improvements. For example microstructure research has become quite a big deal for us in the past few years.	Ydinvoimassa vaaditaan kirkkaasti eniten asioita, mutta volyymi on hyvin pientä verrattuna muihin teollisuudenaloihin. Petrokemian alalla vaatimukset ovat myös hyvin kattavia, mutta ne päivityttyvät usein. Päivitykset ovat yleensä hyvin perusteltuja, koska ne pohjautuvat asiakaskokemuksiin tai teknologian kehittymiseen, esimerkiksi mikrorakennetutkimus.	The nuclear industry has the most strict requirements but the volume is low. In petrochemistry the requirements are extensive, but updated regularly. The updated are based on customer experiences or technological leaps.	Nuclear vs. conventional requirements Requirement updates Development of technology	Extent of the requirements	Reliability of commercial-grade items vs. nuclear-grade items

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Manufacturer #1 A.3.1.6	Miten näet öljy- ja kaasuteollisuuden vaatimustason suhteessa ydinvoima-alan vaatimustasoon?	How do you view the nuclear requirement level if compared to the Oil & Gas sector?	<i>On ja osien vastaanottotarkastus ja sit on venttiilien osalta niin että venttiilin kokooja ei saa tarkastaa sitä vaan on sit toinen kaveri joka tekee koeponnistukset ja muut.</i> <i>on myös alihankkijoiden, koneistamoiden, valmoiden laadunvarmistus ja se on kans ihan yhtä tärkeitä et me seurataan systemaattisesti meidän alihankkijoiden laatua.</i>	<i>We already have an arrival inspection. Additionally, the assembler cannot inspect it, but another person does the pressure tests etc. There is also quality assurance of subsuppliers, machine shops foundries. And systematic following of sub-supplier quality is equally important.</i>	Vastaanottotarkastuksessa kokoonpanoon kuulumatonta henkilö tarkastaa ja koeponnistaa venttiili. Myös alihankkijoita valvotaan huolella, jotta heidän alihankittujen osien laadusta voidaan varmistua jo ennen oman valmistuksen aloittamista.	A person not related to assembly inspects and pressure tests the valves. Subsuppliers are also monitored with care in order to be certain of the parts before assembly.	Inspection Pressure testing Subsupplier monitoring Standard production	Extent of the requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #3 A.3.3.6			Kyllä mä uskaltaisain sanoa, että siinä öljy- ja kaasubisnessä ollaan hyvin järkevällä tasolla. Siellä on huomattavasti vähemmän sitä kolmannen osapuolen valvontaa. Perinteinen keissi on tällainen, että kolmas osapuoli tulee katsomaan nimenomaan sen testauksen. Ja siellä katsotaan se lopputuote ja dokumentaatio. Mä ymmärrän sen hyvin. Mut sieltä puuttuu nimenomaan nämä ettei tarvita kolmansien osapuolten valvomaa materiaaliveikistystä, prosessin aikaisia tarkastuksia ynnä muuta.	<i>I dare to say that the OG business is on a reasonable [requirement] level. They have significantly less of third party inspection. A traditional case is that a third party comes to oversee testing. And the end product and documentation is looked at. I get it perfectly. But it lacks the third party inspected material production and intra-process inspection etc.</i>	Öljy- ja kaasupuolen vaatimukset ovat järkevällä tasolla, koska vaatimukset valmistuksen jälkeisiin kolmansien osapuolten tekemiin testauksiin. Materiaalivalmistusta tai tuotantoprosessia ei valvota toisin kuin ydinvoima-alalla.	OG requirements are reasonable, for they focus more on post-production third party testing. Material production and the production process is not inspected unlike in the nuclear industry.	Nuclear vs. conventional requirements Post-production inspection Material production	Extent of the requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.7	Miten näet että valmistuksen eriytyminen sarjatuotannosta vaikuttaa venttiilin luotettavuuteen?	How is the reliability affected when a valve is not subjected to serial production but it's customized?	<i>Mä sanoisin et luotettavuus on sama. Kyl sen venttiili pitää toimia missä tahansa prosessissa. Valmistus ja valmistuksen laatu on kyllä sama. Sitä turvallisuutta voidaan hakea muualta, ehkä ylispekataan venttiilillä ydinalalla.</i> <i>Sillä [eriytyneellä tuotannolla] ei saa olla mitään vaikutusta laatuun. Se tulee kyllä ihan samoilla laatuvaatimuksilla. Tai ydinvoimakäytössä ehkä jopa tiukempien laatuvaatimusten mukaan. Muutokset mitä on niin ne on jollain tavalla tunnettuja kuitenkin. Ei me yleensä lähdetä testaamaan mitään mitä ei oo aikasemmin jollain tavalla todettu.</i>	<i>I'd say that reliability is the same. The valve must function in any given process. Manufacturing quality is equal. Safety can be achieved otherwise, perhaps through overspecification of nuclear valves.</i> <i>It [customization] can't have any effect on quality. It's [the customized valve] is made with equal quality requirements. Or maybe even according to more strict quality requirements. Changes that are made are known to some capacity – we don't commonly test anything that's not verified in some way earlier.</i>	Luotettavuus on molemmissa tapauksissa samaa luokkaa valmistuksen osalta. Jos halutaan lisää turvallisuutta, sitä haetaan ylispektaamisen kautta. Muutokset eivät ole yleisesti koettelematonta tekniikkaa vaan niiden vaikutukset täytyy tuntea. Laatu ei saa kärsiä, eikä kärsi. Ydinalan tapauksessa luotettavuus voi olla jopa parempi korkeamman vaatimustason vuoksi.	Manufacturing reliability is of the same category. If more safety is wanted, it's sought through overspecification. The changes made are generally not unapproved technology with unfamiliar effects. Quality is not decreased. The more stringent nuclear requirements may even elevate the reliability.	Reliability effect of customization Overspecification Quality effect of customization Better quality of nuclear-grade items	Specification Extent of the requirements	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #2 A.3.2.5			<i>Sit jos on vähän siitä [vakiotuotteesta] poikkeava laskentavaatimus niin se voi tuoda tuloksen, mikä vaatii et meidän pitää lisätä materiaalipaksuutta esimerkiksi tai sitten siirrytään lujempaan materiaaliin. Se et mitä sillä lujudella haetaan, et siellä tulee jotain</i>	<i>If the calculation requirement differs from it [a standard product], it may require us to add material thickness or to use a harder material. It helps achieving safe operation even though centimeters of material would peel off.</i>	Jos eriytyminen lopputuloksesta on vahvempi materiaali, saadaan lisää varmuutta siitä että venttiili säilyttää eheytyensä ja tiiveytensä.	If the customization leads to a stronger material, confidence over the valve's integrity and leak-tightness.	Customization Calculation requirements Hardness	Material properties Accident conditions	Reliability of commercial-grade items vs. nuclear-grade items

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			<i>olosuhteita, jossa on jotain eroosiovaraa et ikään kuin sen pitää toimia turvallisesti vaikka sieltä senttikaupalla lähtee tavaraa.</i>						
Manufacturer #2 A.3.2.6	Voiko konventionaalisen puolen venttiiliin ja ydinalan venttiiliin luotettavuustietoja verrata keskenään?	Can then reliability data of conventional side valves be compared with the nuclear valves' reliability data?	<i>Se vaatisi sen että meidän pitäisi saada ikään kuin molemmista käyttötilanteista mahdollisimman paljon dataa analysoitavaks. Se johtuu hirveesti väliaineesta mitä siellä menee.</i>	<i>It would require us to have as much of data to analyze from both operating situations. It's greatly related to the flowing medium.</i>	<i>Dataa pitäisi saada kattavasti molemmista prosesseista. Esimerkiksi kulumisilmiöt ovat erittäin riippuvaisia väliaineesta, joten prosessiominaisuudet voivat vaikuttaa luotettavuustietoon.</i>	<i>Extensive data should be acquired from both processes. For example abrasion phenomena are greatly depended on the medium, so the process conditions may affect the reliability data.</i>	Comparison of nuclear and conventional reliability data Dissimilar processes	Reliability data Process conditions	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.8	Mikä on näkemyksesi esimerkiksi öljy- ja kaasuteollisuuden prosessiolosuhteiden luotettavuudesta suhteessa ydinvoimaproessiin?	What is your view on the demands of oil and gas processes when compared to nuclear processes?	<i>Melkein voisin sanoa että öljy- ja kaasupuolella on vaikeampia prosesseja. Ydinvoimassa aika pitkälle puhutaan höyry- ja vesiprosesseista, jotka sinänsä on vaativia. Öljy- ja kaasupuolella on tosi aggressiivisia väliaineita, tosi tiuhaan sykkäviä venttiileitä ja kaikkee muuta, partikkeleja ja muuta vastaavaa. Et kyl ne tosi vaativia prosesseja on.</i>	<i>I almost could say that OGI-processes are more demanding. Nuclear processes consist mostly of steam and water, that by themselves are demanding. OGI-processes contain really aggressive mediums, frequently cycling valves and other stuff like particles etc. They are really demanding processes.</i>	<i>Öljy- ja kaasupuolen prosessit ovat haastavampia, koska väliaineet ovat reaktiivisia ja venttiilien liikesykli ovat tiheämpiä.</i>	<i>OG processes are more demanding than nuclear processes, for they contain reactive mediums and the valves cycle more often.</i>	Comparison of nuclear and OG processes Reactive medium Valve cycling	Process conditions	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.9	Miten käsittelette vikaantumisraportteja ja kuinka niistä muodostetaan vikaantumistajuuksaineisto?	How do you handle the failure reports and how is the reliability data derived of them?	<i>me arvioidaan jokainen vika erikseen et mistä se johtuu. se otetaan siinä TÜV'in arvioissa mukaan et he käyttä sitä claim-dataa yksi yhteen vaan ne arvioi et kuinka monta prosenttia vikaantumista tulisi valmistajalle tietoon. me ei voida olla ihan 100 %:sesti varmoja siitä milloin sitä on alettu käyttämään, joten tällä hetkellä käyttöaika lasketaan toimitusajan perusteella.</i>	<i>We evaluate each failure to see what caused it. a percentage of non-reported claim data is taken into account in the TÜV Rheinland evaluation. We cannot accurately know when it [the valve] was commissioned, so at the moment the operating time is calculated according to the time of delivery.</i>	<i>Valmistaja arvioi jokaisen vikaraportin ja TÜV lisää tietyt prosentin vikaantumistapauksia, koska kaikkia vikaantumisia ei ilmoiteta. Koska käyttöaikaa ei voida tarkasti tietää, käytetään toimitusajan ja vikaantumisen välistä aikaa arviona käyttöajasta.</i>	<i>The manufacturer evaluates each failure. TÜV adds a certain percentage to the failure events as all failures aren't reported. The operating time is calculated according to the delivery time.</i>	Failure reports Reliability data formation	Conventional failure rate calculation	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.10	SIL-luokitus ja sen mahdollisuudet ydinvoimalalla?	What is the SIL-classification and what are its possibilities in the nuclear sector?	<i>No siis SIL tulee turvallisuuden eheystasosta. Ja se on öljy- ja kaasupuolelta. Jalostamoissa ja muissa kun on turvapiiri niin sen turvallisuuden eheystaso pyritään laskemaan tän SIL-luokituksen kautta. Mitä kriittisempi paikka niin sitä korkeempi SIL-taso pitää olla. Ne menee ykkösestä neloseen.</i>	<i>Well SIL comes from Safety Integrity Level and it's from the oil and gas sector. In refineries and other places that have a safety circuit, the SIL is used to calculate through SIL-classification. The more critical the place is, the higher SIL-level. It ranges from one to four.</i>	<i>SIL tarkoittaa turvallisuuden eheystasoa. Esimerkiksi jos jalostamossa on turvapiiri, niin sen turvallisuuden eheystaso pyritään laskemaan SIL-luokituksen avulla.</i>	<i>SIL equals Safety Integrity Level. If for example a refinery has a safety circuit, the SIL its safety integrity level is calculated through SIL-classification.</i>	Safety Integrity Level in the nuclear sector Oil & Gas sector Criticality	Reliability modeling	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.11	SIL-luokitus ja sen mahdollisuudet ydinvoimalalla?	What is the SIL-classification and what are its possibilities in the nuclear sector?	<i>Jokaisen valmistajan jotka tekee näin kriittisiä laitteita niin pitää olla ihan päivänselvä asia tää SIL-luokitus. Voisin jopa kuvitella et tulevaisuudessa tulee olemaan isommassa roolissa ydinvoimatoimituksissa.</i>	<i>Every manufacturer who makes equipment of this criticality level must be familiar with SIL-classification. I could even imagine that in the future, it [SIL] will gain ground in nuclear deliveries.</i>	<i>Turvakriittisten komponenttien valmistajille laitteiden SIL-luokituksen pitäisi olla päivänselvä. SIL voisi olla käyttökelpoinen myös ydinvoimatoimituksissa tulevaisuudessa.</i>	<i>For manufacturers of safety critical components, the SIL-classification should be crystal clear. SIL could be utilized in nuclear deliveries in the future.</i>	SIL classification	Reliability modeling	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.12	Onko osaiskuteistissä aina kaksisuuntaista tiedonvaihtoa?	Does the Partial Stroke Test (PST) always include two-way data exchange?	<i>Se [osaiskuteisti] periaatteessa voidaan tehdä ihan point-to-point-connectionilla et</i>	<i>In [PST] can in theory be performed through point-to-point connection</i>	<i>Osaiskuteisti voidaan tehdä ilman kaksisuuntaista tiedonvaihtoa, mutta</i>	<i>PST can be done without two-way data exchange</i>	Partial Stroke Test in the nuclear industry	Real-time condition monitoring (RTCM)	Reliability of commercial-grade items vs. nuclear-grade items

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			<i>laitetaan lappini meidän laitteisiin kiinni ja tehdään testi. Käytännössä se ajetaan jonkun protokollan kautta.</i>	<i>by attaching a laptop to our equipment and performing the test. In practice it's pushed through some protocol.</i>	käytännössä se tehdään tietyn protokollan mukaisesti.	but in practice it's done according to a protocol.	Failure detection Two-way data exchange	Cyber Safety	
Manufacturer #1 A.3.1.13	Miten varmistaisit, että ydinvoimalaitokseen toimitettavan venttiilin luotettavuus on vaadittavan korkealla tasolla?	How would you ensure that the reliability of a valve going to a NPP is on a required level?	<i>Mä yrittäisin tuoda sitä spekkiä mahdollisimman lähelle normaalia käytäntöä.</i> <i>Pyrkisin tietenkin käyttämään mahdollisimman normaaleja materiaalivalintoja, koska silloin saadaan sitä tuotannon toistuvuutta siihen.</i> <i>Sit tietenkin jos halutaan niin laadunvarmistuspisteitä tai muita laadunvarmistustoimenpiteitä, ne on ihan OK. Ei niistä mitään haittaa ole, mä en kyllä usko et ne tuo mitään lisääkään luotettavuutta.</i>	<i>I would try to bring the spec as close to normal practice.</i> <i>Of course I would use material selection as close to normal as possible, because we get the repetitive production in there.</i> <i>Then of course if it's wanted, quality or other assurance measures are be OK. I think that they don't affect the reliability though.</i>	Vaativuuden ja käytettyjen materiaalien pitäisi olla mahdollisimman lähellä normaalia toimitusta, koska käyttämällä koeteltuja materiaaleja ja menetelmiä päästään hyödyntämään tuotannon toistuvuudesta tulevaa kokemusta. Normaalituotannon ylittävistä laadunvarmistustoimenpiteistä ei ole haittaa, muttei hyötyäkään.	All operations should go according to regular practices to ensure reliability, because that would utilize experience gained through repetition. Additionally, QA measures may be taken but their reliability effect is questionable.	Ensuring reliability Regular practices	Reliability of regular production Learning curve	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #2 A.3.2.7			<i>Ehkä olisi realismia, jos sitä kaupallisesti halutaan tehdä et siinä ois alihankkijaverkostoa ja muuta mukana, mut siinä on niin kuin uskottava ja luotettava laadunvarmistus</i> <i>Niille [valitulle satunnaisotannalle] tehtäis sitten kattava testaus ja ne sais sen testin läpäistyään sertifiointiin joka kattais sen tuotesarjan, jonka jälkeen se tuote olisi hyväksytty mun ydinvoimalaani.</i> <i>Jokaisella toimitettavalla laitteella pitäis olla joku kevyemmän muotoinen testi, joka varmentaa sen että se yksittäiskappale ei ole susi niin sanoitusti ja voidaan olettaa että se toimii niin kuin se on siinä sertifiointissa toiminut.</i>	<i>It would be realistic for commercial applications to have a subsupplier survey to ensure a reliable and credible Quality Assurance.</i> <i>They [random selection] would undergo a rather extensive testing procedure and should they pass, the series in question would get a certificate of conformance.</i> <i>Every shipped product must undergo a lighter test, that ensures that the single item is not unfit, or that we can assume it functions according to its certificate.</i>	Ensinnäkin olisi varmistettava toimittajaverkoston laadusta. Toiseksi venttiilisarjasta valittavalle satunnaisotannalle tehtäisiin kattavan spekin mukainen testaus, jonka läpäistyään kyseinen venttiilisarja olisi sertifioitu. Tämän jälkeen sarjan yksittäisille venttiileille olisi kevyempi testausmenettely, jonka avulla voitaisiin varmistua siitä että jokainen venttiili on sertifiointiin mukainen.	Firstly, supplier network quality must be ensured. Secondly, a random selection would be subjected to an extensive test, and after passing a certificate for the whole series would be granted. Each valve of the series would be also subjected to a lighter test plan, to ensure quality of an individual valve.	Supplier survey Random selection testing Post-production testing Series certification Conformity to requirements	Ensuring reliability Testing	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #3 A.3.3.7			<i>Voisin ottaa sinne keskusteluun, että mikä on se materiaalin valmistusmenetelmä. Meilläähän pitkälti on teräsvaluja. Se ois yksi kohta, johon mä mielelläni pysähtyisin. Mä miettiisin että okei, otetaanko takeita tai muokattua terästä: levyä, tankoa ja jos se olis valu niin mä ottaisin valuille jonkin verran tarkastuksia, sinne vois tulla radiografinen tarkastus, joku pintatarkastus. Mut jos se olis muokattua terästä niin mä uskaltaisn sanoa et ei niissä oo mitään oikeesti.</i>	<i>I would discuss the manufacturing method of material. We have steel casting mostly. That is a place where I'd stop gladly, I would think that okay, do we take forgings, processed steel: plate, bar. And If it would be casted, some radiological inspection could be included, maybe some surface inspection. But if the steel would be processed, there would be nothing [no defects].</i>	Materiaalin valmistusmenetelmä on valittava huolella, ja jos valitaan valos niin jotain materiaalitarkastuksia on tehtävä. Jos taas valittaisiin muokattua terästä niin materiaalitarkastuksia ei tarvittaisi, koska muokatun teräksen laatu on hyvin korkealla.	Great care must be put into selection of material. Castings must be inspected, but processed steel is of high quality.	Material selection Castings Processed steel	Material quality Steel type	Reliability of commercial-grade items vs. nuclear-grade items

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Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Manufacturer #3 A.3.3.7	Miten varmistaisit, että ydinvoimalaitokseen toimitettavan venttiilin luotettavuus on vaadittavan korkealla tasolla?	How would you ensure that the safety of a valve going to a NPP is on a required level?	<i>Sen jälkeen lähtisin hyvinkin luottamaan meidän normaaleihin vakioprosesseihin, kunnes ollaan siinä vaiheessa että se on valmis aivan toimitettavaksi asti. Ja siellä tulee sitten se yhdistelmä tarkastus – mistä oli just puhetta et petrokemia, öljy- ja kaasubisneksen vejareista – niin siellä monesti lähdetään siitä että tehdää mitä teette mut me tullaan lopulta kattoon et se on just kuten pitää.</i> <i>Et ne [tuotannon jälkeisessä tarkastuksessa ilmenevät virheet] ei ole missään nimessä dramaattisia. Uskallan sanoa, että sieltä ei koskaan löydy että esimerkiksi materiaali ois väärää tai ratkeamia – täämösä ihan katastrofaalisia ongelmia.</i>	<i>After that [ensuring material compliance] I would very well trust the standard processes until the assembly is completely ready. And there we would have a combination inspection [testing & documentation inspection] like in petro-chemistry: do whatever you do, but we will make sure it's how it should be at the end.</i> <i>They [post-production defects] are by no means dramatic. I dare to say that catastrophic problems like wrong materials or rips have never been seen.</i>	Materiaaliladusta varmistuttua seurattaisiin tehtaan normaalia valmistusprosessia, kunnes päästään siihen vaiheeseen että kokoonpano on valmis. Tämän jälkeen tehdään yhdistelmä tarkastus, jossa varmennetaan kolmannen osapuolen toimesta venttiilin toimivuus ja tarkastetaan dokumentaatio. Aiemman kokemuksen pohjalta voidaan todeta, että testauksissa ja tarkastuksissa ei olla havaittu merkittäviä puutteita, kuten väärää materiaaleja.	After having confirmed high quality material, the manufacturing would follow the plant's standard process until the assembly is ready. Then the valve would be subjected to a combined inspection where the valve's operability and documentation would be inspected. According to experience, no dramatic defects have been encountered in the pos-production inspection or tests.	Regular practices Post-production testing	Testing	Reliability of commercial-grade items vs. nuclear-grade items
Manufacturer #1 A.3.1.14	Mitkä seikat vaikuttavat siihen, että ydinlaitoksen vaatimuksiin räätälöidysti valmistetun osan hinta on standardilaitteiden hintaa korkeampi?	Which factors cause the nuclear-grade item to be more expensive than the commercial-grade item?	<i>No ensin on se dokumentointi. Että dokumentoinninkin joku joutuu tekemään niin siitä tulee ihan varmasti hintaa. Toinen on sitten jos käytetään täämösä rakenteita, jotka spekataan turvallisen päälle. Siellä voi olla turvakertoimet kovempia kuin normaalisti. Mennään kalliimpiin pinnotteisiin, kalliimpiin materiaaleihin. Ne kaikki korreloi suoraan hintaan.</i> <i>Yks voi olla myös et tota komponenttien hankinta jos on rajoitettu jotenkin, et meidän on rajoitettu hankkimaan jostain tietystä lähteestä komponentit niin se voi tuoda sitä hintaa yllättävänkin paljon.</i>	<i>Well first there is documentation. Someone has to create the documentation, which increases the price definitely. Another thing is using structures that are beyond safe. There can be conservative safety margins. It means more expensive coatings and materials. They all correlate to the price directly.</i> <i>Sometimes, when the component procurement is somehow restricted to a certain source, it can bring a surprisingly big increase in the price.</i>	Lisähintaa tuovat 1) Iso dokumentoinnin määrä, 2) konservatiivisten varmuuskerrointen käyttö 3) Tarkastusvaatimukset 4) Komponenttien hankintakanavien rajoittaminen	The additional price originates from 1) Extensive documentation 2) Using conservative safety margins 3) Inspection requirements 4) Restricting component sources	More costs Documentation Conservative safety margins Inspection requirements Source restriction Market Conditions	Economics	Price of nuclear vs. commercial grade items
Manufacturer #2 A.3.2.8			<i>Varmasti isoimpana tekijänä on se, että jos meillä on lähtökohtaisesti eri tuote ydinlaitokseen [kuin konventionaaliselle puolelle] niin silloin sitä kyseistä designia, mitä komponentteja se vaatii niin ne volyymit on ihan toista luokkaa. Huomattavasti alhaisemmat kuin ns. massatuotteissa niin se hintaero tulee tietysti sieltä.</i> <i>Silloin [jos tilaus on lähellä vakiotarjontaa] just minkä se asiakas sattuu haluamaan niin se sattuu olemaan meillä</i>	<i>The biggest factor must be that if we have a different product for the nuclear facility [than for the conventional facility], then the volume of that design is significantly lower, which results in a different price.</i> <i>Then [if the order is close to the regular offering], the customer gets a</i>	Suurin hintaa nostava tekijä on se, että räätälöidyn tuotteen valmistukseen tarvittavat komponentit eivät ole sarjajalmitseisia. Konventionaalisien puolen tilauksen spesifikaatiot osuvat ydinalan tilaustaa todennäköisemmin sellaiseen	Customized production doesn't utilize serially produced components, which raises the price most. Conventional orders' specifications are more likely that of a well-known product variant.	Customized vs. serial production More costs Product variants Delivery time	Economics Availability	Price of nuclear vs. commercial grade items

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
			<i>vakiotarjonnassa, niin sillä on vakioitoimitusaika ja vakiohintaa.</i>	<i>product that has a standard delivery time and price.</i>	<i>tuoteyhdistelmään, jonka valmistuksesta on kokemusta. Tällöin ollaan lähempänä vakiotuotantoa ja voidaan varmistaa nopeasta toimitusajasta ja hinnasta.</i>	<i>Then we're reaching standard production and can be assured of price and rapid delivery.</i>			
Manufacturer #3 A.3.3.8	Mitkä seikat vaikuttavat siihen, että ydinlaitoksen vaatimuksiin räätälöidysti valmistetun osan hinta on standardilaitteiden hintaa korkeampi?	Which factors cause the nuclear-grade item to be more expensive than the commercial-grade item?	<i>Siellä on muutamia vaatimuksia, jotka aiheuttaa sen että meidän alihankkijalla ei ole hyllyssä kyseistä materiaalia. Siellä voi olla tällasia [vaatimuksia] että esimerkiksi kobalttipitoisuutta on rajoitettu, mikä on pelkästään ydinvoima-alan applikaatioissa tullut vastaan ja se voi olla validi tai olla olematta validi, mut se aiheuttaa sen että [materiaalia] täytyy sitten lähteä etsimään kissojen ja koirien kanssa ja kuinka ollakaan niin taas tulee 8 viikkoa lisää toimitusaikaa ja maksaa.</i> <i>sitten on tää kolmannen osapuolen läsnäolovaatimus, se on helposti 1000 euroa per päivä karkeasti sanottuna ihan meidän kustannusta. Miten se kumuloi tuukaan piikertomella ja näinpäin pois siitä sitten. Siinä tulee kanssa kovasti hintaa.</i>	<i>There are some requirements that lead to our suppliers not having the material in question in stock. There may be requirements that restrict cobalt content - which can be valid or not - but they make it harder to locate the right material, which costs 8 weeks in delivery time plus money.</i> <i>then the third party attendance requirement - it costs easily 1000 € per day just for us. And how it cumulates even further down the chain increases the price.</i>	<i>Materiaaliominaisuuksiin liittyvät vaatimukset aiheuttavat sen, että alihankkijoiden tarjonnasta ei löydy vakiona haluttua materiaalia. Lisäksi alihankkijat myyvät materiaaleja suurimääräisesti ja räätälöityyn tuotteeseen tarvitaan vain pieni määrä.</i> <i>Myös kolmansien osapuolten läsnäolo nostaa hintaa reilusti.</i>	<i>Requirements concerning material characteristics cause unavailability of materials in the supply chain. Additionally the suppliers sell materials in volume and customized production demands very little material.</i> <i>Third party attendance raises the price vastly.</i>	More costs Material requirements Low volume of custom materials Third party inspections	Economics	Price of nuclear vs. commercial grade items
Manufacturer #1 A.3.1.15	Miten räätälöidyn ja standardilaitteen hintaeroa saataisiin kavennettua?	How could we bridge the price gap of nuclear and commercial-grade items?	<i>Ehkä se yksiselitteisyys on se avainsana. Jos ne on niin selkeästi että kaikki tietää miten toimia niin sit sen pitäis olla kyllä helpompaa.</i>	<i>I'd say unambiguity is key. If everything [all requirements are presented] is so plain and simple that everyone knows how to act, it should be easier.</i>	<i>Yksiselitteinen vaatimusten selvittäminen tekee asiasta helpompaa ja leikkaa hintaa.</i>	<i>Unambiguous clarification of requirements makes everything easier and cuts the price.</i>	Uncertainty of requirements Unambiguity	Ways to lower costs	Price of nuclear vs. commercial grade items
Manufacturer #2 A.3.2.9			<i>No jos ottais tällasen vaikka Shellin [standardin], joka on varmaan sieltä kovimmasta päästä tuolla öljy- ja kaasupuolella viemässä vaatimuksia eteenpäin. On varmaan jonkunlainen benchmark omalla spekillään tai Total tai muut vastaavat isot toimijat. Se että kuinka paljon ne jo vaatii ja kuinka paljon ydinvoimayhtiöt vaatii enemmän tai mentäiskö jo ikään kuin riittävälle tasolle.</i>	<i>If the nuclear requirements would be compared against a well established oil & gas standard like Shell or Total to see to which extent they meet the nuclear requirement level and that are they sufficient.</i>	<i>Ydinalan vaatimuksia voisi verrata esimerkiksi öljy- ja kaasuteollisuuden vaatimuksiin, jotta voitaisiin osoittaa yhteneväisyydet ja eroavaisuudet sekä pohtia olisiko öljy- ja kaasuteollisuuden standardit jo riittäviä myös ydinalalla.</i>	<i>Nuclear requirements could be compared with oil & gas requirements and to show similarities and dissimilarities and to evaluate could the oil & gas standards be sufficient in the nuclear industry.</i>	Comparison of conventional and nuclear requirements Oil & Gas requirements	Ways to lower costs Acceptance of conventional standards	Price of nuclear vs. commercial grade items
Manufacturer #2 A.3.2.10			<i>voisko ratkaisu ollakin sit semmonen että meillä löytyis sieltä lähempänä vakiotuotetta, ehkä pienellä räätälöinnillä, ratkaisu.</i> <i>Jos nyt on niin että ydinvoimalassa vaan vaaditaan paksummat seinämävahvuudet niin voi olla että siinä tietyssä venttiilissä kaikki muut</i>	<i>we could do a little customization to a standard product and still show conformity.</i> <i>if there's a requirement for thicker walls, then all other components but the shell could be standard components, and the shell could be looked at</i>	<i>Pienellä vakiotuotteen räätälöinnillä voitaisiin mahdollisesti täyttää iso osa ydinalan venttiilien vaatimuksista ja päästäisiin kauemmas täysin räätälöidystä erillistuotteesta. Ratkaisuna voisi olla esimerkiksi materiaalilujuuden varmistaminen erilaisilla pinnoitetekniikoilla tai</i>	<i>Small tweaks to a standard product might meet many nuclear valve requirements, which would bring the customized product closer to standard production. A solution might be to ensure material strength through different coatings or materials and not</i>	Tweaking standard production where needed Alternative ways to show conformity	Ways to lower costs Acceptance of conventional standards	

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
			<i>komponentit vois olla vakiokamaa, mut sit siinä tullaan erikoiskoteloituihin, joka on sitten materiaalipaksuudeltaan suurempi tai sitten toisaalta siihen on materiaalivalintoihin liittyviä vaihtoehtoja, et onks ne pelkästään senttimetreit tai millimetreit mitkä ratkaisee vai löydettäiskö se ratkaisu materiaalia vaihtamalla.</i>	<i>differently: if it would be possible to find other solutions than just the wall thickness to ensure conformity.</i>	materiaalia vaihtamalla eikä ainoastaan materiaalipaksuutta kasvattamalla.	solely by adding material thickness.			
Manufacturer #3 A.3.3.9	Miten räätilöidyn ja standardilaitteen hintaeroa saataisiin kavennettua?	How could we bridge the price gap of nuclear and commercial-grade items?	<i>No mä oisin kyllä sitä mieltä, että nimenomaan niistä kolmannen osapuolen läsnäolovaatimuksista niin tietenkä se on nyt helppo sanoa ja paukuttaa omaa tehdasta, mutta mä en nää niille ihan kovinkaan suurta arvoa. Toki se saadaan se varmistus, mutta se aiheuttaa aina hintaa ja toimitusaikaa.</i> <i>Ja se [Ulkopuolisten tarkastusten laajuus] vois olla nimenomaan riippuen aina siitä valmistusmenetelmästä, et onko se just joiain hiekkavalua.</i>	<i>Well I think that it's the attendance of third parties, of course it's easy to say that your plant is great, but I don't see much value in their attendance. Of course it helps with assurance, but it increases price and delivery time.</i> <i>And it [the extent for inspections] could be determined over the production method, for example (if it's something like sand-casting).</i>	Kolmannen osapuolen läsnäolovaatimuksia voisi kyseenalaistaa, koska niiden arvo on hankalaa nähdä, vaikka niiden myötä saadaan varmuutta. Jos esimerkiksi teräsmateriaalille on vaatimus ulkopuoliseen tarkastukseen lähettämisestä, niin tarkastusvaatimusta voitaisiin harkita tapauskohtaisesti esimerkiksi materiaalin alkuperän ja valmistusmenetelmän perusteella.	Third party inspections could be questioned. If steel material needs to be sent to outside inspection, the requirement could be assessed case by case for example according to the origin or manufacturing method of the material.	Third party inspections	Ways to lower costs	Price of nuclear vs. commercial grade items
Manufacturer #3 A.3.3.10	Miten kuvailisit ydinalan tilauksiin liittyvien spesifikaatioiden yhdenmukaisuutta?	How would you describe the uniformity of nuclear orders' specifications?	<i>Meillä paljon [tilauksia] esimerkiksi tulee Ruotsista. Me toimitetaan sinne varaosia muutamaankin laitokseen. Niiden kanssa on simpellä, mut se johtuu varmaan siitä et sitä ollaan hierottu kymmenien vuosien ajan. Jos sieltä tulee päivityksiä niin Ruotsin myynnin kanssa on sit aika hyvät diskuteerausvälit, että voidaan kattoo se.</i>	<i>We have a lot [of orders] from Sweden. We provide spare parts to a few plants over there. It's simple to work with them but it's probably because of having dealt with them for tens of years. We have great discussing relations with their sales teams and we can cope with updates.</i>	Ruotsin toimitusten osalta on helppoa varmistua toimitusten vaatimustenmukaisuudesta, mutta se johtunee pitkistä toimitushistoriasta.	With Swedish deliveries it's easy to ensure conformity, but it's probably because of the long history with them.	International specifications Ensuring conformity	Existing harmonization	Harmonization
Manufacturer #1 A.3.1.16	Miten luulisit että yhdenmukaisempi vaatimustaso vaikuttaisi valmistajan toimintaan?	How do you think that more uniform harmonization of requirements would affect the manufacturers?	<i>Se ois itse asiassa aika hyvä asia, koska nyt jos ne [vaatimukset] on erilaisia niin me joudutaan joka paikkaan valmistamaan joiain eri tavalla tai spekkamaan eri tavalla.</i> <i>Ensinnäkin tarjoaminen olis todella paljon nopeampaa, ei tarvisi käydä joka kerta uusiksi sitä järjetöntä määrää - tuhansia sivuja - sitä tarjousdokumentaatiota. Siinä säästää aikaa itse asiassa todella paljon.</i>	<i>In fact, it would be a good thing since now that they [the requirements] are different, we have to manufacture or spec differently.</i> <i>Firstly, bidding would be really much faster as you wouldn't have to go through the senselessly big amount - thousands of pages - of bidding documentation. It's a real time-saver in fact.</i>	Vaatimusten yhdenmukaistaminen olisi hyvä asia. Tarjousten jättäminen olisi nopeampaa kun ei tarvitsisi läpikäydä tuhansia sivuja tarjousdokumentaatiota.	More uniformity of the requirements would be great. Bidding would be a lot faster when you wouldn't need to go through thousands of pages of bidding documentation.	Nonuniform requirements Individual specifications Extensive documentation Faster delivery	Current state of harmonization Ways to lower costs	Harmonization
Manufacturer #1 A.3.1.17	Miten luulisit että yhdenmukaisempi vaatimustaso vaikuttaisi valmistajan toimintaan?	How do you think that more uniform harmonization of requirements would affect the manufacturers?	<i>kyl se varmaan korrelois jollain tavalla hinnankin kanssa että pystyttäis sanomaan että tää on se ratkaisu, ei tarvii alkaa joka kerta laskemaan alusta asti et paljon tää on. Et ois semmonen hyvä tuntuma et se</i>	<i>probably it [more uniform requirements] would somehow correlate with the price because we could say that this is the solution, and there would not be a need to calculate all over</i>	Myös hinta tulisi alaspäin, koska tiedettäisiin tarkemmin mitkä ratkaisut toimivat ja mitä ne maksavat.	The price would also drop since we would know which solutions work and how much they cost.	Ensuring conformity Faster delivery	Current state of harmonization Ways to lower costs	Harmonization

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
			<i>on tässä. Ja lasketaan tarkalleen jossain vaiheessa.</i>	<i>again the whole price. To have a gut feeling of the price. And it would be further calculated in some step.</i>					
Manufacturer #2 A.3.2.11	Miten luulisit että yhdenmukaisempi vaatimustaso vaikuttaisi valmistajan toimintaan?	How do you think that more uniform harmonization of requirements would affect the manufacturers?	Kyl mun mielestä [yhdenmukaistamisen] hyödyt on aika ilmeiset. Tietoisuus paranisi siten, että tulee selkeyttä koko prosessin tekemiseen että kyllähän se hämmentää jos ikään kuin samaan sovellukseen toimitetaan, mutta eri maahan niin sitten se sama ei kelpaakaan.	<i>I think the benefits [of more uniformity] are quite obvious. Awareness would grow and the whole process would become clearer. It's confusing that even though we provide for the same application, our product is not valid in all countries as it is.</i>	Koko prosessi selkeytyisi, koska nykyinen käytäntö hämmentää: vaatimukset ovat erilaiset, vaikka sovellutus on efektiivisesti sama.	The whole process would be clearer since now the system is confusing: there are different requirements for effectively the same application.	Confusing requirements Clarification of requirements	Harmonization benefits	Harmonization
Manufacturer #3 A.3.3.11			Mä uskaltaisn sanoa, että toimitusajat olisivat huomattavasti kohtuullisempia. Hinnasta oon hirveen huono sanomaan, mutta vaikea nähdä että se ainakaan kalliimmaks menisi, et kyllä sieltä varmaan tulisi ihan halvempia vaihtoehtoja. Ensinnäkin sen toimittajan etsiminen, koska jokaisesta tukkuri, jos me nyt jotain vakioterästä ostetaan ihan kilometrikaupalla. Sitä löytyy. Mut sit kun sinne hyppää sellainen [vaatimus] kuin maksimikobalttipitoisuus niin se on heti eri keskustelu. Sitä lähetään etsimään että löytyykö, eikö löydy.	<i>I'd dare to say that the delivery times would be significantly more reasonable. I'm not so qualified to say anything of the price, but it's hard to see the price increasing. I guess there would be cheaper options. Firstly, it's hard to find the suppliers because if we buy something like standard steel in the kilometers, it's readily available. But when we have a requirement for maximal cobalt content, it's a whole different conversation. It has to be searched for.</i>	Toimitusajat lyhenisivät ja luultavasti myös hinta laskisi. Ydinalan erikoisvaatimukset, kuten koboltin maksimipitoisuus, vaikuttavat välittömästi tilanteeseen ja oikeaa toimittajaa täytyy etsiä.	Delivery times would drop and also the price would probably decrease. Nuclear specific requirements like maximal cobalt content make it harder to find suitable suppliers.	Quicker delivery Less costs Nuclear specific requirements Cobalt content	Harmonization benefits	Harmonization
Manufacturer #1 A.3.1.18	Mitä luvanhaltijat voisivat tehdä, jotta laitevalmistajien toiminta helpottuisi?	What can the licensees do in order to make the work of manufacturers easier?	<i>en mä kyllä usko et me päästään koskaan ydinvoimassa sarjatuotantoon mut niin kun päästäis ees jonkunnäköiseen toistettavuuteen niin sekin tietienkin helpottaa valmistamista.</i>	<i>I don't think that we will ever get to serial production in nuclear power, but it would of course help if we could get to even some kind of repetitive manufacturing.</i>	Usko ydinalan vaatimusten harmonisoitumiseen ei ole korkealla, mutta valmistajaa helpottaisi pienikin yhtenäistyminen.	Confidence to more harmonization is not high, but even a little more uniformity would help the manufacturer.	Uniformity of requirements	Harmonization benefits Future of harmonization	Harmonization
Manufacturer #2 A.3.2.12			Kuinka me se [tarkoituserä] täytetään niin silloin päästäis sille oikealle tasolle, et ei ainakaan ylisuunnittelais tai alisuunnittelais Standarditekstit ja vaatimukset - vaikka niissä ei pitäisi olla tulkinnan varaa - mutta sitten kun niitä ruvetaan lukemaan niin että tarkoittoa tää nyt sitä tai tätä. Kuinka varmennat sen [suunnittelun] ja kuinka se on riittävä? Niin varmasti sellasissa tulis hyötyä, että tulis sellasesta keskustelua.	<i>How do we fulfill it [the requirement], it would help us reach the required level without over or under designing. When standard text and requirements – even though they should not be open to interpretations – are being read whether they mean this or that. How do you ensure it [the design] and is it enough? There would definitely be benefits to have such discussion.</i>	Yksityiskohtaisten vaatimusten todellisen merkityksen tulkinta ei aina ole yksiselitteistä, joten etenkin tulkintaerojen ehkäisemiseksi vuoropuhelua tarvittaisiin lisää. Se auttaisi myös riittävän suunnittelutason löytämisessä.	The true meaning of specific requirements might not always be clear, so especially more discussion would be beneficial. It would help to find the sufficient level of designing.	Clarification of requirements Level of designing	Harmonization benefits	Harmonization

APPENDIX A.3 – Interview table – Representatives of the Manufacturer

Interviewee Identifier	Question in Finnish	Translated question in English	Original answer in Finnish	Translated answer in English	Reduced answer in Finnish	Reduced answer in English	Bottom category	Top category	Theme
Manufacturer #3 A.3.3.12	Mitä luvanhaltijat voisivat tehdä, jotta laitevalmistajien toiminta helpottuisi?	What can the licensees do in order to make the work of manufacturers easier?	<i>Et ei mentäis sillä vanhalla tutulla standardiavuutuksella tai toimintatapavaihtauksella vaan se olis päivitetty.</i> <i>se ajatusmalli vanhoissa standardeissa on niin erilainen, jos nyt puhutaan vaikka ihan tarkastusstandardeista jotka antaa hyväksymiskriteereitä eri tarkastusmenetelmille niin se filosofia tuntuu olevan hyvin erilainen kuin mitä se on tänä päivänä. Se on vaan sitten aika kova työmaa lähteä vertaileen että hetkenen, jossa on appelsiineja ja omenoita niin miten tää menee sit yhteen.</i>	<i>Not to go with the same old standard reference but to have it updated.</i> <i>the thought process is so different between old and new standards, if we're talking about e.g. inspection standards that lay acceptance criteria for different inspection methods, the philosophy seems remarkably different than today. It's a hard job to compare the standards, because one is apples and the other one is oranges.</i>	Standardien päivittäminen ja oikeisiin standardeihin viittaaminen on yksi kehityskohde. Edelleen viitataan ikivanhoihin standardeihin, jotka ovat filosofialtaan hyvin erilaisia nykyaikaisten standardien kanssa. Standardien päivittämien tai yhdenmukaistaminen on kuitenkin hyvin suurikokoinen projekti.	Updating the standards and referring to right standards is something to develop. There's references to ancient standards, and the philosophy in them is really different compared to the modern standards. Updating standards or unifying them is a huge task.	Standard updates DIN Modern vs. old standards Standard philosophy	Harmonization benefits Challenges of harmonization	Harmonization

Interviews held during 5.6.2017 – 14.6.2017 in Vantaa, Finland.

Interviewee	Number of answers
Manufacturer #1	18
Manufacturer #2	12
Manufacturer #3	12
TOTAL	42

APPENDIX B.1 – Design requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
1	General design	<p>Pressure Equipment Directive (PED) 2014/68/EU must be followed (module not specified.)</p> <p>EN 13445-3 (Unfired pressure vessels. Part 3: Design) shall be followed as a general design standard.</p> <p>The structural design of SC 3 valves shall be based on a design standard generally applied by the valve manufacturing industry. (YVL E.8e, p. 7)</p>	<p>PED Module H (Full Quality Assurance)</p> <p>ASME B16.34 (Valves - Flanged, Threaded and Welding End) shall be followed as a basic design standard.</p> <p>ASME Boiler and Pressure Vessel Code (Section VIII: Pressure Vessels, Division 1) shall be followed according to pressure rating for valve body joint, bonnet and cover. This covers also the calculation analysis requirements.</p> <p>Valve design must comply with a valid API (American Petroleum Institute) standard like API 6D (Specification for Pipeline Valves).</p>
1.1	Design life	Valve parts which cannot be changed during normal maintenance are e.g. valve body, bonnet, stem and yoke shall be designed for whole design life. Valve parts which can be replaced during normal maintenance can be excluded when replacement intervals are planned and given in valve maintenance instructions. Those spare parts shall be marked in the design documentation. Required design life is given in Valve Data Sheet (VDS). (TVO 2017b, 12)	<p>The design shall last in operation for six years and 9000 cycles (except ISO 15848 valves).</p> <p>Replacement of the internal parts shall be possible.</p>
2.	Analysis	Analysis shall be made according to commonly used standards in the nuclear industry.	Analysis methods from ASME or API standards are to be used to prove a valve's suitability for its service place.
2.1	Strength dimensioning and stress analysis	<p>Strength dimensioning shall be conducted for</p> <ul style="list-style-type: none"> a. valve's main pressure retaining parts and connections (e.g. casing and nozzles) b. other pressure retaining parts and connections c. parts in load transfer chain in valves DN > 50 d. other load bearing parts DN > 50 <p>Stress analysis shall be performed if the strength cannot be verified according to simplified methods of the chosen design code. Stress analysis can be made e.g. using finite element method. (TVO 2017c, p. 19)</p>	Per ASME or API standards
2.2	Fatigue analysis	Fatigue analysis shall be conducted for valves > DN 100 and normal operation temperature T > 100°C. (TVO 2017b, p. 19)	Per ASME or API standards

APPENDIX B.1 – Design requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
2.3	Seismic analysis	Seismic analyses shall be conducted to verify seismic resistance of valves in seismic classes S1 and S2A. Analytical methods may be used. If necessary they may be supported or replaced by experimental analysis. (TVO 2017b, 20; YVL E.8e, 10)	There are no requirements for emergency shut-down (ESD) valve concerning seismicity. However, seismic events are included in ASME BPVC VIII design code, see below.
2.4	Hazard analysis	Effects of design bases hazards such as airplane crashes and pipe breaks shall be modelled by analyzing the dynamical behavior of the valve. The objective is to prove the maintenance of integrity and operability under loadings. (TVO 2017c, p. 20)	ASME BPVC, Division 1: UG-22 (Loadings) defines conditions to which a pressure vessel shall be designed. These conditions include, but are not limited to: <ul style="list-style-type: none"> a. internal or external pressure b. cyclic or dynamic reactions due to pressure or temperature variations c. wind, snow, seismicity and impact reactions.
2.5	Actuator dimensioning	The dimensioning must include all forces and torques required to operate the valve in different loading conditions. (TVO 2017c, p. 19) SC 3 valves providing for severe accident management shall have calculations for maximum torque resulting from friction forces exerted by the valve disc, stem seals and other parts vs. the minimum torque generated by the actuator. (YVL E8e, Appendix C)	The torque of the actuators shall be at least 1.5 times the maximum torque required by the valve in safety service. The stem and all other components shall be able to withstand the maximum torque generated by the actuator.
3	Function and safety	Valve units shall fulfil the functional and safety requirements specified by the licensee and related standards. (TVO 2017b, p. 13)	An emergency shutdown valve shall provide safety function on demand.
3.1	Fire-safety	A valve shall be designed to sustain any design basis fires.	Safety valves, located in a zone with potential fire risk, shall during and after a fire maintain safety position. Safety valve, its actuator limit switches and connection tubes and cables located in a fire zone shall be protected. The protection shall enable the valve assembly to operate normally at a temperature of 1200 °C for 30 minutes.
3.2	Fail safe position	The design must allow a fail safe position according to the service place and design basis conditions.	A safety valve shall be fail safe in loss of external energy.
3.3	Stroke time	Manufacturer shall determine the stroke time and it shall be added to VDS. Possible requirements for valve stroke time are given in VDS. (TVO 2017b, p. 17)	Stroke time of a safety valve shall be as follows: <ul style="list-style-type: none"> a. <DN80, 3 seconds b. DN80-DN250, 1 second per 25mm c. >DN250, 10 seconds

APPENDIX B.1 – Design requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
3.4	Pressure drop	Final decision of valve bore will be made by the licensee after receiving pressure drop data. (TVO 2017b, p. 15)	For reduce-bore ESD valves, the pressure drop shall not exceed 0.2 bar.
3.5	Noise	The design of the valve shall be such that their sound pressure level does not exceed 85 dB (A), measured without insulation at a distance of 1 m during normal operation of plant. (TVO 2017b, p. 14)	There are no requirements for emergency shut-down (ESD) valve concerning noise.
4	Environment	Integrity, leak tightness and operability requirements shall be fulfilled in each design condition as required in Valve Data Sheet (VDS). (TVO 2017b, p. 12)	Safety valve design shall meet the following environmental conditions: <ul style="list-style-type: none"> a. Ambient temperatures must cover -40...+80°C b. Temperate zone solar radiation c. Very strong winds (>41m/s) d. Relative humidity 20...100% e. Ice, hailstones: 5..8mm f. Rainfall, 100 mm/day g. Saline environment in proximity to the sea h. Winds carrying particles (80kg/h with sand) i. Presence of insects
4.1	Fire tolerance	There are no nuclear-specific fire tolerability requirements for valves in SC 3, but the rules of general design standards apply.	Safety valves, located in a zone with potential fire risk, shall during and after a fire maintain their seat tightness and external tightness to the outside.
4.2	Explosions	Explosion pressure effects shall be considered in design when required in VDS and/or loading specification. (TVO 2017b, p. 17)	Valve design shall conform to safety requirements in Directive ATEX 2014/34/EU when ATEX is required or valve design is intended for use in potentially explosive atmospheres.
4.3	Corrosion	Material properties with their manufacturing tolerances shall fulfil the requirements of design condition corrosion.	The corrosion allowance for safety valves is 1.55 mm, 3 mm or 6 mm.

APPENDIX B.2 – Manufacturing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
1	Manufacturer		
1.1	Quality Management System (QMS)	<p>(Covers also material manufacturer)</p> <p>ISO 9001 (Quality Management Systems- Requirements) or other appropriate certified or equivalent management system that has been independently evaluated by a third party. (YVL E.8, p. 6)</p> <p>An audit of the manufacturer's QMS is not a prerequisite and it can be evidenced by documentation. Manufacturer approval of STUK is needed prior to the construction inspection. (TVO 2017c, p. 14)</p>	<p>QMS shall comply with requirements specified in PED (see details above).</p> <p>Metso Flow Control Inc.'s Vantaa Plant follows ISO 29001¹ (Petroleum, petrochemical and natural gas industries. Sector-specific quality management systems. Requirements for product and service supply organizations) which is required by big O&G-companies. ISO 29001¹ is based on ISO 9000 but includes requirements for equipment suppliers in the O&G industry.</p>
1.2	Subcontractor surveillance	<p>The manufacturer shall have in place systematic and documented procedures for the assessment, selection and supervision of its subcontractors. (YVL E.3e, p. 12)</p> <p>The manufacturer shall evaluate the effectiveness of the subcontractor's quality management system and ascertain that the subcontractor has the prerequisites for delivering products or services that satisfy all requirements.</p> <p>The licensee shall evaluate the extent of surveillance based on e.g. the criticality of the manufacturing phase and previous experience of the supplier. (STUK 2015a)</p>	<p>The manufacturing organization shall establish documented methods and criteria to control the purchasing process and supplier selection and achieve conformity to the requirements. (ISO 29001, 7.4.1)</p> <p>The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. (ISO 29001, 7.4.1)</p>
2	Special processes		
2.1	Welding	<p>Manufacturers performing welding shall be certified for quality assurance according to the requirements of SFS-EN ISO 3834-2 (Quality requirements for fusion welding of metallic materials. Part 2: Comprehensive quality requirements). ASME N-stamp Manufacturer authorizing by ASME meets both ISO 3834-2 and ISO 9001 requirements. (TVO 2017c, p. 13)</p> <p>Qualification of welders and welding operators shall be performed according SFS-EN ISO standards such as SFS-EN ISO 9606-1. (TVO 2017c)</p> <p>Welding procedures shall be subjected to witness point by the licensee.</p>	<p>Welding procedures for steel castings shall be qualified in accordance with ISO 11970 (Specification and qualification of welding procedures for production welding of steel castings) or ASME IX (Welding, Brazing, and Fusing Qualifications).</p> <p>Welders shall be qualified in accordance with EN 287-6 (Qualification test of welders. Fusion welding. Part 6: Cast iron), ISO 9606-1 (Qualification testing of welders. Fusion welding. Part 1: Steels) or ASME Division IX.</p> <p>The welding procedure qualification shall include impact tests in order to verify that required toughness values at the specified minimum temperature are guaranteed.</p>

APPENDIX B.2 – Manufacturing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
2.2	Welding repairs	<p>Material Manufacturer is permitted to carry out weld repairs to steel castings according to material standard and their QMS. Areas repaired by welding have to fulfil requirements as strength properties equal to parent material. (TVO 2017c, p. 18)</p> <p>Repair of all other than casted parent metal is forbidden by welding without written approval of the repair construction plan. STUK or an authorized inspection body reviews the valve repair plan submitted by the licensee and issues a decision on it. (TVO 2017c, 18; YVL E.8e, p. 19)</p>	<p>The repairs shall be carried out using a filler metal identical to the base metal.</p> <p>Any repairs by welding on forged valves are prohibited.</p>
2.3	Welding in conjunction with heat treatment	In case that manufacturing includes heat treatment in connection with welding and allied processes on this equipment quality management system shall meet also the requirements of standard SFS-EN ISO 17663 (Quality requirements for heat treatment in connection with welding and allied processes). (TVO 2017b, p. 13)	The weld shall be impact tested after post-weld heat treatment to verify toughness at minimum temperature.
3	Materials		
3.1	General material requirements	Material properties with their manufacturing tolerances shall fulfil the requirements of design conditions and related phenomena such as fatigue, wearing, corrosion, cavitation and radioactivity of medium, transient loads and site conditions. (TVO 2017b, p. 16)	<p>Selection of material for all valve parts subjected to pressure loading shall be consistent with the valve body's pressure-temperature rating. (ASME B16.34, B-1.2)</p> <p>The body, bonnet, cover and bolting of those shall be constructed of materials as listed in ASME B16.34 Table 1. Identical materials in accordance with the ASME Boiler and Pressure Vessel Code, Section II (Materials) may also be used for these parts. (ASME B16.34, 5.1)</p>
3.2	Material certificates	<p>Material certificates shall be according to SFS-ISO 10204² (Metallic products. Types of inspection documents):</p> <p>Valve pressure-retaining main parts: 3.1 Pressure-retaining bolts, obturator, stem: 2.2 Other parts significant for valve integrity or operability: 2.1 (YVL E.8e, App. B)</p>	<p>Chemical composition of materials shall be as per EN 10213 (Steel castings for pressure purposes) or ASTM (American Society for Testing and Materials) standards.</p> <p>Pressure-retaining valve manufacturers conforming to EN 10213 are obligated to request appropriate inspection documentation according to EN 10204.</p>
3.2.1	Particular Material Appraisal (PMA) ³	In demonstrating the acceptability of nationally standardized pressure equipment materials and materials standardized under factory standards, the manufacturer of the pressure equipment may utilize a PMA, if such an appraisal has been drawn up for the materials in question. (YVL E.3e, p. 18)	Materials conforming to an ASME standard shall have a PMA in order to show compliance with essential safety requirements of PED.
3.2.2	Approval of welding material	SFS EN standards, ASME Boiler and Pressure Vessel Code Section II C (Specification for welding rods, electrodes and filler metals), or for justified reasons other classification standards shall be followed. (YVL E.3, p. 19)	Welding consumables must comply with ASME IX.

APPENDIX B.2 – Manufacturing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
3.2.3	Material certificates of welding material	<p>Welding material certificates shall be according to SFS ISO 10204:</p> <p>Pressure-retaining valve welds: 3.1</p> <p>Welded claddings & Other welds significant for valve integrity or operability: 2.2 (YVL E.8e, App. B)</p> <p>A corresponding standard may also be used to verify material conformity (YVL E.3e, p. 20).</p>	Welding consumables must comply with ASME IX.
3.2.4	Materials with potential to activate	Materials containing elements that could become activated shall be avoided in any such surfaces of valves are coming into contact with primary circuit water (Mostly SC 1 & SC 2 valves). Material certificate including cobalt contents analysis is required for valves having a wetted surface area $\geq 100 \text{ cm}^2$. Wetted surface area means in this context the surface area which is in contact with primary circuit. (TVO 2017b, p. 17)	No specific requirements considering activity are given for O&G-grade valves.

¹ **ISO29001** is based on ISO9001 but includes specific requirements for equipment suppliers in the O&G industry. It incorporates supplementary requirements emphasizing defect prevention and the reduction of variation and waste from service providers.

² **SFS ISO 10204** (Metallic products. Types of inspection documents).

- 3.1 (Inspection certificate 3.1): Statement of compliance with the requirements of the order, with indication of test results. The document shall be validated by the manufacturer's authorized inspection representative independent of the manufacturing department.
- 2.2 (Test report): Statement of compliance with the order, with indication of results of nonspecific inspection. The document shall be validated by the manufacturer.
- 2.1 (Declaration of compliance with the order): Document in which the manufacturer declares that the products supplied are in compliance with the requirements of the order, without inclusion of test results. The document shall be validated by the manufacturer.

³ **A Particular Material Appraisal (PMA)** is a process by which the pressure equipment manufacturer ensures that each proposed material that is not in a harmonized standard or covered by a European Approval for Materials (EAM) conforms to the applicable Essential Safety Requirements (ESR) for materials.

APPENDIX B.3 – Inspection and testing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
0	Participation in inspections	Hold Points ¹ (HP) and Witness Points ² (WP) shall be defined in the licensee's Inspection and Testing Plan (ITP) that is to be included in the construction plan.	It is the responsibility of the entity placing the order to define the frequency of its participation (or of its representative's) in inspections, tests and document reviews. The usual rules are to attend inspection of: a. 100% of critical or specific valves (comparable with SC1 and 2 valves). b. 10% of standard valves and each type (comparable with SC 3 valves).
1	Materials		
1.1	Qualification of Non-Destructive Testing ³ (NDT) examiners	ISO 9712 (Non-destructive testing. Qualification and certification of NDT personnel): At least Level 2 qualification (or an equivalent qualification system for the method used in testing.) A level 1 tester may perform exposure required for Radiographic Testing (RT). (YVL E.12e, p. 9)	ISO 9712 Primarily, all tests shall be performed by level 1 certified personnel, and interpreted by level 2 certified personnel.
1.2	NDT	For all casted parts	
1.2.1	Castings	<u>Before hard facing</u> Visual inspection: SFS-EN 13018 (Non-destructive testing. Visual testing. General principles) Penetrant Testing (PT): ISO 3452-1 (Non-destructive testing (NDT). Penetrant testing. Part 1: General principles). Acceptance criteria ³ . And for ferromagnetic materials: Magnetic particle inspection (MT): ISO 9934-1 (Non-destructive testing. Magnetic particle testing. Part 1: General principles). Acceptance criteria ⁴ . Spot-check RT inspection according to ASME V, Art. 2 (Radiographic Examination) (TVO 2015). <u>After hard facing</u> Visual inspection PT: ISO 3452-1. Acceptance criteria ⁴ . MT: ISO 17638 (Non-destructive testing of welds. Magnetic particle testing) for ferromagnetic materials. Acceptance criteria ⁴ . Spot-check RT inspection for Class 3 components according to ASME V, Art. 2. No requirements for microstructure evaluation in SC 3 (only in SC 1).	NDT shall be conducted after heat treatment is completed. For 100 % of casted external and internal surfaces for all parts: Visual inspection: MSS SP-55 (Manufacturers Standardization Society - Quality Standard for Steel Castings for Valves, Flanges and Fittings and Other Piping Components - Visual Method for Evaluation of Surface Irregularities) PT: ASTM E165 (Standard Practice for Liquid Penetrant Examination for General Industry) MT: ASTM E709 (Standard Guide for Magnetic Particle Testing). MT is conducted only for ferromagnetic materials.) For ferromagnetic materials. For 100 % of the bodies, bonnets and covers and for 10 % of the body neck of the castings of each batch with a minimum of 1 casting per batch: RT: MSS SP-54 (Radiographic Examination Method) Ultrasonic Testing (UT): ASTM A609 (Standard Practice for Castings, Carbon, Low-Alloy, and Martensitic Stainless Steel, Ultrasonic Examination Thereof). Microstructure check for stainless steels as per ASTM A262 (Standard Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels)

APPENDIX B.3 – Inspection and testing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
1.2.2	Forgings	For all forged parts: Equivalent requirements with casted valves both before and after hard facing.	Visual inspection: For 100 % of external and internal surfaces of valve bodies, bonnets and covers. PT and MT (for ferromagnetic materials): 100% of internal and external surfaces on 10% of parts from each batch. No UT required. RT for 5 % of body-bonnet welds
1.3.3	Machined surfaces	Visual inspection. PT: ISO 3452-1. For ferromagnetic materials: MT: ISO 9934-1. Acceptance criteria ⁶ .	Inspections should be performed on raw parts (free of machining), except for inspections relating to seating surfaces and flange facing machining*. * Flange facing machining: a 100% dye-penetrant test of male-female and tongue-and-groove faces shall be performed on 10% per item. 100 % PT for all Ring Type Joint (RTJ) faces on all parts. The hardness of RTJ flange faces shall be inspected on 10% of the parts from each batch.
2	Welds		
2.1	Inspection of welding filler material	The materials shall be classified according to: SFS-EN standards. Or ASME Boiler and Pressure Vessel Code Section II C (Specifications for Welding Rods Electrodes and Filler Metals). Other classification standards may also be used for justified reasons. Tests shall include e.g. <ul style="list-style-type: none"> - Analysis of the weld metal (incl. ferrite content) - Tensile strength - Hot tensile strength - Impact toughness - Holding time and temperature transients of heat treatment of weld metal (YVL E.3e, p. 19) 	Per EN ISO 11970 (Specification and qualification of welding procedures for production welding of steel castings): <ol style="list-style-type: none"> 100 % Visual inspection 100 % RT or UT Transverse tensile testing: 1 specimen Impact test: 2 tests per batch + Additional tests if required by customer specification. Or ASME BPVC Division IX (Welding, brazing, and fusing qualifications). <i>For body-bonnet weld:</i> MT or PT of the entire weld on 5% of valves for each item. RT of the entire weld on 5% of valves for each item. Impact tests shall be included in the qualification in order to guarantee the required toughness values at the specified minimum temperature.
2.2	Inspection of the validity of WPSs	EN ISO 15614-1 (Specification and qualification of welding procedures for metallic materials. Welding Procedure Specifications (WPSs))	EN ISO 11970 (Specification and qualification of welding procedures for production welding of steel castings)
2.3	Inspection of the welder qualification	ISO 9606-1 (Qualification test of welders. Fusion welding. Part 1: Steels)	ISO 9606-1 (Qualification test of welders. Fusion welding. Part 1: Steels) or ASME Division IX

APPENDIX B.3 – Inspection and testing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
3	Factory tests	(Primarily in conjunction with construction inspection.)	(Functional test prior to and leak tightness and pressure tests during final inspection.)
3.1	Hydrostatic pressure test with water.	<p>ISO 12266-11 (Industrial valves. Testing of metallic valves. Part 1: pressure tests, test procedures and acceptance criteria. Mandatory requirements), test P10 (Shell strength). Performed by manufacturer, supervised by IO.</p> <p>$p_{test} = 1.5 \times p_{max, \text{ room temperature,}}$</p> <p>$t_{test} \text{ (DN 100) } = 3 \text{ min}$</p> <p>Acceptance: No visually detectable leakage from any external surface of the shell is permitted</p>	<p>ASME B16.34 (Valves—Flanged, Threaded, and Welding End), Chapter 7 (Pressure testing).</p> <p>$p_{test} = 1.5 \times p_{max, 38^\circ\text{C}}$</p> <p>$t_{test} \text{ (DN 100) } = 1 \text{ min}$</p> <p>Acceptance: Visually detectable leakage through pressure boundary walls is not acceptable.</p>
3.2	Shell leak tightness test	<p>ISO 12266-1, test P11 (Shell tightness).</p> <p>Acceptance: No visually detectable leakage is permitted</p>	<p>ISO 12266-1, test P11 (Shell tightness).</p> <p>Acceptance: No visually detectable leakage is permitted.</p> <p>Or according to ISO 5208 (Industrial valves. Pressure testing of metallic valves)</p>
3.3	Seat tightness test (with air):	<p>ISO 12266-1, test P12 (Seat tightness), Rate B (for soft-seated valves Rate A).</p> <p>Acceptance: $0.3 \times \text{DN}$ (or some other EN standard like EN ISO 5208).</p>	<p>ISO 12266-1, test P12, rate A.</p> <p>Acceptance:</p> <p>No visually detectable leakage for the duration of the test.</p> <p>(Or rate A according to EN ISO 5208.)</p>
3.4	Fugitive emissions test	Not specified	<p>ISO 15848-1⁶ (Industrial valves. Measurement, test and qualification procedures for fugitive emissions. Part 1: classification system and qualification procedures for type testing of valves)</p> <p>Acceptance criteria⁷.</p>

APPENDIX B.3 – Inspection and testing requirements

#	Theme	Nuclear	Oil & Gas
		Description of requirement	Description of requirement (as per Metso Flow Control 2017 unless stated otherwise)
3.5	Functional test (FAT)	<p>ISO 12266-2 (Industrial valves. Testing of metallic valves. Part 2: Tests, test procedures and acceptance criteria. Supplementary requirements), test F20 (Operability). This test is conducted after final assembly and leak testing.</p> <p>The test shall confirm:</p> <ul style="list-style-type: none"> c. The ability of the assembled valve to open and close fully and, as applicable, d. The correct operation of the position indicators and/or other auxiliary devices. <p>Attendees: Witness point for Licensee and IO/STUK</p>	<p>Functional tests shall include:</p> <ul style="list-style-type: none"> a. Operating test on the control panel and valve assembly. b. Check on the complete opening/closing and closing/opening travel time. c. Check of the valve opening or closure, with the maximum differential pressure applied on the seat, at minimum control air pressure. d. Checking the minimum control air pressure applicable to the actuator with maximum differential pressure applied on the seat. e. If there is an air reserve included in the supply, check on the number of manoeuvres. f. Operating check on the solenoid valve or actuator and on the test device. g. Check on the limit switch settings. <p>Attendees: conducted by manufacturer but are partly supervised by customer or their representatives.</p>
4	<p>Inspection before shipment</p> <p>(Is referred to in different terms in the nuclear and OG-fields)</p>	<p><u>Construction inspection</u></p> <p>Conducted for every valve* primarily at the manufacturing site by an authorized inspection body (IO) to demonstrate that the materials, manufacturing, construction and operation of the valves are as described in the construction plan. The construction inspection includes the following steps:</p> <ul style="list-style-type: none"> a. Assessing manufacturing documentation. b. Conducting visual and dimensional inspections. c. Witnessing factory tests or their documentation. (YVL E.8e, p. 13) <p>Construction inspection is primarily organized at the manufacturer's facility.</p> <p>At least 1 of identical valves shall be visually inspected after factory tests.</p> <p>* For serially manufactured valves, the licensee can apply for a reduced inspection scope, where the inspector selects the valves to be inspected of the delivery batch. If any shortcomings essential for operability are revealed, the construction inspection shall be conducted for the entire delivery batch. (YVL E.8e, p. 13)</p>	<p><u>Final inspection</u></p> <p>Conducted by customer or their representative in the manufacturer's premises or the supplier's premises before shipment.</p> <p>The inspection includes following checks:</p> <ul style="list-style-type: none"> a. Compliance with order. b. Quantities. c. Specifications. d. 100% appearance and dimension inspection. e. Material (by PMI certificates or sampling). f. Operation and leak tightness. g. Manufacturer file. h. Direction of the valve safety position. i. SIL parameters and fugitive emission certification with the supply of the measurement instruments calibration certificate. j. ATEX certification of the assembly. k. Marking.

APPENDIX B.3 – Inspection and testing requirements

¹ **Hold point** shall refer to an inspection for which advance invitations have been sent to the parties defined in the inspection plan and whose supervision is a condition for proceeding with the work unless the parties have given written permission to proceed without their presence.

² **Witness point** shall refer to an inspection for which advance invitations have been sent to the parties defined in the inspection plan but whose supervision is not a condition for proceeding with the work. Having received the invitation, the invited parties may, however, separately require that they be present in order for the work to be continued.

³ **NDT** shall refer to inspections that do not essentially alter the geometry and size of the item inspected. (YVL A.1e, p. 24)

⁴ **PT Acceptance criteria per ISO 23277**: PT: acceptance level 1 for wall thickness ≤ 15 mm. For wall thickness > 15 mm acceptance level 2X shall apply.

The following indications

are not acceptable:

1. Linear indications with length exceeding 2 mm.
2. Non-linear indications with major axis dimension exceeding 3,2 mm ($t \leq 15$ mm) or 6 mm ($t > 15$ mm). (Requirement is not according EN standard)

⁵ **MT Acceptance criteria per ISO 23278**, acceptance level 1 for wall thickness ≤ 15 mm. For wall thickness > 15 mm acceptance level 2X shall apply.

The following indications are not acceptable:

1. Linear indications with length exceeding 1,5 mm.
2. Non-linear indications with major axis dimension exceeding 2 mm ($t \leq 15$ mm) or 3 mm ($t > 15$ mm).

⁶ **Acceptance criteria for machined surfaces**: For finished machined seal surfaces the above mentioned requirements (per ISO 23277 and ISO 23278) apply with the exception that acceptance level for non-linear indications is 1,5 mm.

⁷ **ISO 15848-1** specifies testing procedures for evaluation of external leakage of valve stem seals (or shaft) and body joints of isolating valves and control valves intended for application in volatile air pollutants and hazardous fluids.

⁷ **Fugitive emissions acceptance criteria**: (evaluation of external leakage of valve stem seals (or shaft) and body joints of isolating valves and control valves intended for application in volatile air pollutants and hazardous fluids.)

- a. ISO FE BH CO1 SSA1 T (-196°C, 200°C) for valves in cryogenic service.
 - b. ISO FE BH CO1 SSA1 T (-46°C, 400°C) for valves in low temperature service (low-temperature carbon steel).
 - c. ISO FE BH CO1 SSA1 T (Room temperature, 400°C) for other valves.
-

Haastattelusopimus

Olen Oskari Raitanen, energia- ja biojalostustekniikan pääaineopiskelija Tampereen teknillisestä yliopistosta ja teen diplomityötäni Teollisuuden Voima Oyj:ssä. Tutkin diplomityössäni standardilaitteiden käytön laajennuksen turvallisuusvaikutuksia ydinlaitoksissa. Työtä ohjaavat professori Jouni Kivistö-Rahnasto ja tutkijatohtori Henrik Tolvanen. Osana tutkimustani suoritan haastattelututkimuksen, jossa haastattelen ydinvoima-alan asiantuntijoita luvanhaltijan, laitevalmistajan ja viranomaisen organisaatioista.

Haastattelututkimuksen päätarkoituksena on selvittää asiantuntijoiden näkemyksiä siitä, millainen on Suomen turvallisuusluokitteluperusteisten vaatimusten mukaisesti valmistettujen laitteiden luotettavuustaso verrattuna teollisuuden laajalti käyttämien standardilaitteiden luotettavuuteen. Haastattelun toinen tarkoitus on tarkastella sitä, miten haastateltavat näkevät vaatimusten kansainvälisen harmonisoinnin nykytilan ja kehitystarpeen.

Yksi haastattelu kestää 40–60 minuuttia. Haastattelu äänitetään kahdella nauhurilla ja äänitiedosto litteroidaan tekstimuotoon. Haastattelutallenne ja litteroitu aineisto ovat luottamuksellisia, mutta sanottuihin asioihin voidaan tehdä viittauksia työssä. Haastateltavalle toimitetaan kuitenkin haastattelun jälkeen haastatteluyhteenveto, jossa haastattelun pääkohdat on kirjattu ylös. Haastateltava voi siis tarkastaa ja korjata, jos haastattelija on väärinymmärtänyt jonkun asian tai jos jokin haastatteluaineiston osa ei sovellu diplomityön julkiseen versioon. Haastateltavien nimet tai muut henkilötiedot eivät tule missään vaiheessa tutkimusta näkyviin. Haastateltavat tunnistetaan analyysissä käyttämällä ilmaisuja ”viranomaisen edustaja”, ”laitevalmistajan edustaja” ja ”luvanhaltijan edustaja”.

Haastateltavien on mahdollisuus ottaa yhteyttä minuun missä tahansa tutkimuksen tekovaiheessa puhelimitse 0456720041 tai sähköpostitse oskari.raitanen@tvo.fi.

Haastattelijan allekirjoitus ja nimenselvennys

Päivämäärä ja paikka

Olen saanut yllä olevat haastatteluun liittyvät tiedot ja suostun haastatteluun.

Haastateltavan allekirjoitus ja nimenselvennys

Päivämäärä ja paikka
