



Working Group on Manufacturing, Construction, Commissioning and Operation

Phase 3 Report

Regulatory Considerations in Pre- Licensing Engagement for Long- Lead Item Requests

December 2023



**Regulatory Considerations in Pre-Licensing Engagement for
Long-Lead Item Requests**



The content produced by the Forum is protected by copyright. Where external parties seek to reproduce the Forum's outputs, in part or in their entirety, for their own purposes, the Forum requires the parties to seek authorization from the Scientific Secretary at: SMR-RF-Contact-Point.Team@iaea.org detailing the extent and purposes of any reproduction. Once such authorization is granted, the Forum requests any reproduction of its material in other publications to be duly credited/attributed.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
1. INTRODUCTION	3
2. WHAT ARE LONG LEAD ITEMS AND WHAT ARE THEY USED FOR?	3
3. SMRS AND REGULATORY CHALLENGES FOR LLI REQUESTS.....	6
4. CONSIDERATION OF REGULATORY APPROACHES FOR SMR LLIS	8
5. CONSIDERATIONS OF OFF THE SHELF MANUFACTURING AND FLEETWIDE MANUFACTURING	10
6. CONCLUSIONS.....	11
REFERENCES	12
LIST OF ACRONYMS AND ABBREVIATIONS	13
LIST OF CONTRIBUTORS	14

EXECUTIVE SUMMARY

There continues to be sustained global interest in small modular reactors (SMRs), which have the potential to play an important role in globally sustainable energy development as part of an optimal energy mix. In particular, SMRs may enhance energy availability and security of supply in countries expanding their nuclear energy programs and those embarking on a nuclear energy program for the first time.

As the interest in SMRs continues to grow, so does the importance of international collaboration. Given that its main purpose is to bring together experienced regulators to identify and address key SMR-related challenges, the SMR Regulators' Forum has an increasingly important role to play in making such collaboration possible.

The SMR Regulators' Forum was formed in 2014 as a regulator-to-regulator entity to consider key issues that could emerge in future SMR regulatory discussions and propose common positions regarding the way in which these could be addressed. The Forum's work is expected to help enhance safety as well as efficiency in SMR regulation, including licensing, and to enable regulators to inform changes, if necessary, to their requirements and regulatory practices. Since then, the Forum has had three phases of work. For more details about the Forum, please visit: <https://www.iaea.org/topics/small-modular-reactors/smr-regulators-forum>.

This report has been produced by the Manufacturing, Construction, Commissioning and Operation (MCCO) Working Group (WG) of the SMR Regulators' Forum during its Phase 3 of work (2021 to 2023). It considers how long lead items (LLI) for SMRs (including non-light water reactors) may differ from traditional LLIs and the foreseeable regulatory challenges introduced by these differences. The MCCO WG has compared current practices used for regulating LLIs between the SMR Regulators' Forum Member States and how the challenges presented by LLIs for SMR and advanced reactor technologies may impact on the regulatory frameworks.

This report was developed based on information, insights, and experience gained from the regulatory activities of the SMR Regulators' Forum members. It is generally consistent with existing IAEA documents but may deviate in some cases. This report is intended to provide useful information to regulators and industry in the development, deployment, and oversight of SMRs.

Common Positions for this report

Common Position 1

Although the regulatory approaches for LLIs may differ, regulators should understand the need for some important to safety/safety related components to be procured in advance to align with new build programs.

Common Position 2

There is a common understanding by the members of the SMR Regulators' Forum on the type of components and systems that are procured as LLIs across all Member States, e.g.: safety related large forgings and castings, etc.

Common Position 3

Licensees (or future licensees) placing orders for LLIs on vendors proceed 'at commercial risk' with the objective of reducing the projects' risks overall.

Common Position 4

Regulators may decide not to accept LLIs at any stage due to regulatory concerns. For instance, the LLI may not be fully compatible with the final design, or the manufacturer cannot fully meet the component specifications.

Common Position 5

Vendors and would-be licensees should consider the regulatory challenges for SMR LLIs detailed in this report and address them within their design and business models prior to approaching regulators for approval.

Common Position 6

There is a common understanding by the members of the SMR Regulators' Forum on the key differences and potential challenges presented by SMR LLIs. How regulators address these challenges may vary across the Member States.

Common Position 7

Member State regulators treat SMR LLIs consistently with conventional nuclear power stations in terms of the level of regulatory oversight, proportionate to the safety significance of the items.

Common Position 8

Member States likely to, or already embarking, on SMR projects should share experience in the regulation of SMR LLIs and continue to learn from other Member States.

Common Position 9

The concept of "off the shelf" manufacturing and fleet wide manufacturing for long lead items are not considered to be one in the same.

Recommendations for IAEA

The IAEA should develop guidelines which Member State regulators can use to establish their principles and regimes for the regulatory oversight of SMR LLIs. This report provides points for consideration when compiling the guidance from the regulators' perspective.

The IAEA should establish a mechanism to facilitate the sharing of regulatory experience with regards to the oversight of SMR LLIs (both good practice and issues).

1. INTRODUCTION

Regulatory bodies are faced with an evolving regulatory activities/process for the regulation of SMRs that are different than the historical large light water reactor reviews. In some Member States organizations are asking governments and regulators for pre-application reviews.

Some organizations may be in the process of procuring LLIs and seeking regulatory assurance to reduce long lead time risks to their projects.

The traditional expectations of regulators, when approached by a Licensee (or future licensee) aiming to procure a familiar piece of equipment from a vendor with an established pedigree in the nuclear industry, are being challenged due to the nature and novelty of SMRs.

This report considers how LLIs for SMRs (including non-light water reactors) may differ from traditional LLIs, and the foreseeable regulatory challenges introduced by these differences. The MCCO WG has compared current practices used for regulating LLIs between the SMR Regulators' Forum Member States and how the challenges presented by LLIs for SMRs may impact on the regulatory regimes of Member States.

2. WHAT ARE LONG LEAD ITEMS AND WHAT ARE THEY USED FOR?

The members of the SMR Regulators' Forum came to a common position, i.e. agreed unanimously, on the following statements:

Common Position 1

Although the regulatory approaches for LLIs may differ, regulators should understand the need for some safety related components to be procured in advance to align with new build programs.

Common Position 2

There is a common understanding by the members of the SMR Regulators' Forum on the type of components and systems that are procured as LLIs across all Member States, e.g.: safety related large forgings and castings, etc.

Common Position 3

Licensees (or future licensees) placing orders for LLIs on vendors proceed 'at commercial risk' with the objective of reducing the projects' risks overall.

Common Position 4

Regulator may decide not to accept LLIs at any stage due to regulatory concerns. For instance, the LLI may not be fully compatible with the final design, or the manufacturer cannot fully meet the component specifications.

This section details the nature of LLIs and how the Member States represented in the SMR Regulators' Forum regulate LLIs currently.

The regulatory regimes developed and deployed differ from country to country. In some Member States there may only be a single, well-established Licensee, whereas other states may have multiple Licensees and multiple requesting bodies seeking to licence and build new nuclear power plants. In some Member States, the regulator approves safety-related components and may also approve manufacturers in accordance with established codes, whilst other state regulators rely on Licensees (or future licensees) to justify the design and manufacturing of safety-related components. Although the regulatory approaches may differ, all regulators accept the need for some safety-related components to be procured in advance to align with, and reduce risk, to new build programs.

The rest of this section details a broadly generalised description of the regulatory regimes which have developed for LLIs.

A long lead item refers to a product specifically ordered by a Licensee with specific design, functional and project timeline requirements. The quantities are low and for a specific project. The manufacturing of the product, typically, may need to commence around the time of the submission of a design safety case to ensure that the project timelines are met.

The current common understanding of the need for and nature of LLIs is detailed in the ‘Blue Box’ below:

Traditional Meaning of Long Lead Items (LLI)

Equipment, products, systems and, in some cases, control software programs and technical information:

- That are important to safety in the construction and operation of a nuclear power plant.
- That have long lead times which necessitate their procurement early enough to align with the scheduling of works on an existing facility or new build project.
- Procurement often commences before the start or completion of regulatory design assessment and licensing process for the new build project the LLI is intended for.
- Consequently, the future Licensee accepts the liability that the LLI does not have binding regulatory assurance that the LLI will be accepted.
- Often requires some form of regulatory feedback to gain sufficient confidence that the LLI will not present undue barriers in the licensing/authorization process for the new build project (i.e., developers are mitigating risk of early sourced items not being wholly acceptable in terms of the final design, customer requirements or regulatory expectations).

Examples of traditional LLIs for Nuclear Power Plant (NPP) projects have included but were not limited to:

- Large forgings, large castings, design specific control hardware platforms and control software.
- Training and certification programs for specific staff with safety functions critical to the facility’s safety case (authorized nuclear operators, maintenance staff).
- Safety analysis methodologies.

In common with other industries, nuclear Licensees procure long lead items to ensure that such items are delivered within their project timescales. Typically, LLIs have been components and equipment such as large forgings and castings for nuclear islands along with their associated preliminary design assessments. Control software has also been developed and assessed as LLIs.

Licensees often order such items many years in advance of installation work commencing due to the limited manufacturing windows available. Generally, regulators have sufficient capability to assess LLIs, these often being based on familiar light water reactor technology and its associated design and manufacturing codes and standards.

Contracts for LLIs have often been placed before designs have been finalised and sometimes before site licenses have been granted. Licensees (or future licensees) placing orders for LLIs on vendors proceed ‘at commercial risk’ with the objective of reducing the projects’ risks overall.

In most States Licensees engage with the state nuclear regulator at an early stage to understand its expectations. The regulator appraises LLIs and their design and manufacturing standards at this early stage based on assumed design configurations to reduce the risk of a regulatory rejection later in the project. That said, the regulator may still reject the LLI at any stage. For instance, the LLI may not be fully compatible with the final design, or the manufacturer cannot fully meet the component specifications. This is the commercial risk that the Licensees accept.

For nuclear build projects the regulatory work associated with LLIs is usually carried out in parallel with the overall project along with design assessment and site licensing work. Consequently, the regulator is usually ‘well sighted’ on the safety significance of LLIs within the overall design and site considerations. This is advantageous for the regulator as it has early involvement with the LLIs and the evolving design, making for more effective and efficient use of the regulator’s limited resources.

Recent examples of Traditional Long Lead Items for Light Water Reactors, and Lead Times Needed for Procurement and Delivery to the Project	
Major Pressure Boundary Components (incl. large forgings)	5-10 years prior to installation (depending on supplier backlog and component type)
Operations Training Program and Facilities (incl. simulator)	3-5 years prior in readiness for commissioning and operation activities
I&C Architecture/Platforms Important to Safety	1-3 years. Varies with novelty of platform design
Others may exist depending on regulatory processes in each Member State (e.g.: manufacturing licences/ approved quality programs for suppliers, or approvals for project organizational arrangements/partnerships)	

3. SMRS AND REGULATORY CHALLENGES FOR LLI REQUESTS

Common Position 5

Vendors should consider the regulatory challenges for SMR LLIs detailed in this report and address them within their design and business models prior to approaching regulators for approval.

Common Position 6

There is a common understanding by the members of the SMR Regulators' Forum on the key differences and potential challenges presented by SMR LLIs. How regulators address these challenges may vary across the Member States.

Regulators in some Member States which have embarked on SMRs programmes have started to engage with vendors directly in the absence of Licensees or future licensee organizations. These regulators may have no formal regulatory authority over vendors but are engaging at an early stage with the vendors on a pragmatic basis.

The nature of, and approaches to, the regulation of LLIs for SMRs may differ from one Member State to another. It is likely that some vendors will approach the regulator for LLI assurance before a capable Licensee has been identified or established. Other Member States' laws and regulations do not currently permit changes or flexibilities to regulatory approaches with respect of pre-licensing activities. Some of the foreseeable differences which present challenges to the existing regulatory arrangements are listed in the 'Blue Box' below.

Vendors are approaching regulators for advice and assurance for many different SMRs designs, some of which are based on novel technology. The advent of SMRs means that regulators may have to reconsider aspects of their regulatory regimes for design considerations and licensing. It follows that for Member States which are likely to build SMRs, the existing regulatory arrangements and protocols for LLIs may also have to be reconsidered for the regulators to have sufficient regulatory assurance.

The short timescales for the build and construction of SMRs, and the limited individual regulatory resources, can challenge the existing regulatory arrangements for assessing LLIs (e.g.: to approve manufacturers, assess out of code items, pragmatically engaging with vendors and future licensees, etc.). Regulators, vendors and would-be licensees should consider this report and the identified regulatory challenges associated with LLIs for SMRs, to enable regulators to gain adequate assurance of the safety integrity of the LLIs. It is recommended that Member States consider the best prioritization for review of proposed LLIs for SMRs based on each state's resources, legal framework, and priorities (i.e., experience, safety significance, etc.,).

Key differences for SMR LLIs

The MCCO identified the following key differences for LLIs supplied for SMRs compared to the traditional LLIs associated with new gigawatt size NPPs:

- LLIs are likely to be procured by vendors and not Licensees.
- Materials for components (i.e., pressure vessels) could be novel for SMRs (light water reactors vs High Temperature Gas Cooled reactors etc.) and there could be challenges in evaluation of those materials.
- SMRs may be designed and manufactured by vendors for Licensees who are not sufficiently developed to perform the roles of Design Authority and Intelligent Customer. The end user Licensee(s) may not be known when the vendor asks the regulator to assess the manufacture of LLIs.
- With the advent of modular design and construction, whole safety system modules may be manufactured as LLIs. In some instances, the entire SMR plant may be delivered as a single package.
- Some manufacturers of 'micro' SMRs wish to deliver reactors which are already fueled.
- LLIs may be manufactured as part of an extended production run where the destination of individual safety components and modules may not be known at the time of manufacture. Shorter construction and installation schedules proposed for some SMRs could be more susceptible to supply chain disruptions, with potential adverse impacts on quality.
- Some SMRs using advanced nuclear technology will require LLIs which are not covered by existing design codes (e.g.: ASME, RCCM, IAEA Standards and Guides, Regulator Guides, etc.).
- Access for regulators to the Vendors' manufacturing facilities (potentially in other jurisdictions) may be necessary for regulatory manufacturing oversight, and for witnessing in factory commissioning.
- Vendor supply chains for novel technology may not be familiar with regulatory expectations nor regulators be familiar with the technology.
- Some states are embarking on collaborative agreements to share and recognize each other's design assessments. It is likely that there will be similar expectations from vendors and governments to recognize and accept LLIs manufactured in accordance with arrangements approved by other regulators.

4. CONSIDERATION OF REGULATORY APPROACHES FOR SMR LLIS

Common Position 7

Member State regulators treat SMR LLIs consistent with conventional nuclear power stations in terms of the level of regulatory oversight, proportionate to the safety significance of the items.

Common Position 8

Member States likely to, or already embarking, on SMR projects should share experience in the regulation of SMR LLIs and continue to learn from other Member States.

How regulatory challenges manifest themselves will depend on the particular SMR programme, and the vendors' intentions and business models. For instance:

- In some Member States which have started SMR projects, the regulators are considering their protocols for the procurement of LLIs and, pragmatically, are applying them to the vendor, pending the identification of capable licensee(s). In other states the established protocols of engaging with the Licensee(s) – and not the vendor - still apply.
- Where a vendor approaches a regulator with the intention of manufacturing a SMR in that state and works with the regulator from an early stage to seek approval of the design and manufacturing methods, then the existing regulatory protocols for the procurement of LLIs may be applied pragmatically to the vendor pending the identification of the Licensee(s).
- Conversely, should a licensee or vendor approach the state regulator with the intention of installing a SMR in the state, and the state regulator has had no prior involvement with the design and methods, then the regulator would be faced with addressing the challenges associated with the differences for SMRs' LLIs listed in the 'Blue Box' in section 4.

Some Member States have embarked on SMR projects where the regulators have had to accommodate extensive challenging requests and engagements. This paper captures useful experience on the effectiveness of approaches adopted by these states. This paper highlights the desirability that Member States continue to learn from other Member State regulators' experience.

For Member States likely to embark on SMR programmes, which the Member State government may require, or be advocating, the regulator should:

- Start considering the implications of a request for LLI review should one be made, i.e., regulators should evaluate their regulatory framework for technology neutrality to prepare for a potential application.
- Consider what changes to the regulatory framework and existing protocols could be made, for instance:
 - The extent of manufacturing assurance which could be derived from another state regulator's prior engagements with the vendor. For example: the Organization for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA) Committee on Nuclear Regulatory Activities (CNRA) working group supply

chain routinely performs multinational vendor inspections to promote the sharing of oversight activities.

- The burden of achieving sufficient manufacturing assurance of LLIs at several suppliers may be excessive for a single regulator. Regulators could derive manufacturing assurance from, for instance:
 - The extent and nature of manufacturing assurance required for LLIs already manufactured and the nature of the LLIs (i.e., single components, competed modules, etc.).
 - Leveraging of manufacturing assurance activities carried out by other state regulators. Bilateral agreements may be needed or renewed to achieve total recognition of another state regulators oversight activities. IAEA Nuclear Harmonization and Standardization Initiative (NHSI) is working on developing a process to leverage regulators reviews.
 - Collaboration with other state regulators in assessing manufacturers.
 - A willingness to accept modular LLIs manufactured under the oversight of reputable third-party inspection agencies, or similar arrangements.

5. CONSIDERATIONS OF OFF THE SHELF MANUFACTURING AND FLEETWIDE MANUFACTURING

Common Position 9

The concept of “off the shelf” manufacturing and fleetwide manufacturing for long lead items are not considered to be one in the same.

As discussed above a long lead item refers to product specifically ordered by a licensee with a specific design, functional and project timeline requirements.

“Off the shelf” manufacturing implies manufacturing without a specific licensee and typically involves manufacturing high quantities (depending on demand) with a standard process. The products are manufactured according to the vendor’s design specifications and the functional requirements are generic. The product is placed “on the shelf” once manufacturing is completed and allows for the user to purchase as and when needed. The section 1.2 ‘Manufacturability’ of the Phase 2 report [1] provides common positions related to manufacturing of components.

Fleetwide concept is a broad concept and could apply to different stages of SMR lifecycles. For the purpose of manufacturing the concept can be described as follows: a FOAK design is taken and is used to create a fleet of the same design. This can reduce the times for long lead items related to manufacturing and assessments and could result in on the shelf inventory so that it is no longer a long lead item. The regulator should consider that there might be cases, where not all fleetwide products will have a licensee or a location where they will be installed at the time of manufacture (in which case it becomes off the shelf). This concept should be explored in further detail in a future paper. How the site characteristics will impact fleet manufacturing should also be considered. For example, will the sites be adapted to the manufactured components or will the site characteristics affect the fleet manufacturing?

This paper discusses the differences in the regulatory frameworks of the Member States for LLIs and the common position on how they can be adapted for SMRs. The off-the-shelf concept is different from LLIs and thus may require a separate paper.

6. CONCLUSIONS

The SMR Regulators' Forum has considered the implication of SMR LLIs and highlighted the key regulatory challenges that should be considered and addressed by the Member States. As an overriding principle, regulators should treat SMR LLIs consistent with conventional nuclear power stations in that the level of regulatory oversight is proportionate to the safety significance of the items.

The report details the common positions of the SMR Regulators' Forum for LLIs both in terms of conventional nuclear new builds and for SMRs.

The overall adjustments to regulatory regimes which Member States are making for regulating SMRs are ongoing. However, the IAEA should proceed to develop Guidelines which regulators can use to establish their principles and regimes for the oversight of SMR LLIs. This report provides points for consideration when compiling the guidance from the regulators' perspective.

As different Member States are moving at differing paces with regards to the building of SMRs, it is important that channels for sharing and learning from other regulators should remain open and active. Therefore, the IAEA and Member State regulators should facilitate the sharing of regulatory experience with regards to the oversight of SMR LLIs (both good practice and issues).

REFERENCES

- [1] SMALL MODULAR REACTORS REGULATORS' FORUM, Working Group on Manufacturing, Construction, Commissioning and Operation, Phase 2 Report (2021).

LIST OF ACRONYMS AND ABBREVIATIONS

ASME	American Society of Mechanical Engineers
FOAK	First of a kind
I&C	Instrumentation and Control
LLI	long lead item
MCCO	Manufacturing, Construction, Commissioning and Operations
NHSI	Nuclear Harmonization and Standardization Initiative
NPP	nuclear power plant
PWR	pressurized water reactor
RCCM	<i>Règles de conception et de construction des matériels mécaniques des îlots nucléaires des réacteurs à eau pressurisée</i> (Design and construction rules for mechanical components of PWR nuclear islands)
SMR	Small Modular Reactor
WG	working group

LIST OF CONTRIBUTORS

This report was produced and/or reviewed by the following volunteer representatives from the IAEA Member States who are also members of the MCCO WG of the SMR Regulators' Forum and was subsequently approved by the Steering Committee:

Contributor	Country	Institution
Sarah Eaton	Canada	Canadian Nuclear Safety Commission (CNSC)
Arslan Baig	Canada	Canadian Nuclear Safety Commission (CNSC)
Rui Liu	China	National Nuclear Safety Administration (NNSA)
Daniel VLČEK	Czech Republic	State Office for Nuclear Safety (SÚJB)
Jiří Ondruška	Czech Republic	Ministry of Industry and Trade (MPO)
Lukas Novotny	Czech Republic	Ministry of Industry and Trade (MPO)
Ville Raunio	Finland	Radiation and Nuclear Safety Authority (STUK)
Tarja Nuoranne	Finland	Radiation and Nuclear Safety Authority (STUK)
Joachim Miss	France	Institut de Radioprotection et de Sûreté Nucléaire (IRSN)
Tatsuya Fujita	Japan	Nuclear Regulatory Authority Japan (NRAJ)
Yusuke Kasagawa	Japan	Nuclear Regulatory Authority Japan (NRAJ)
Dmitry Polyakov	Russian Federation	Federal Environmental, Industrial and Nuclear Supervision Service of Russia (Rostekhnadzor)
Nonyane Dorcas	South Afrika	National Nuclear Regulator (NNR)
Paul Murphy	United Kingdom	Office for Nuclear Regulation (ONR)
Kerri Kavanagh (Chair)	United States of America	U.S. Nuclear Regulatory Commission (USNRC)
Paula Calle Vives	IAEA	International Atomic Energy Agency (IAEA)
Volha Piotukh	IAEA	International Atomic Energy Agency (IAEA)
Mario Alves dos Santos	IAEA	International Atomic Energy Agency (IAEA)
Izaias Jose Botelho	IAEA	International Atomic Energy Agency (IAEA)