

# **Working Group on Manufacturing, Construction, Commissioning and Operation**

## **Phase 4 Report**

# **Manufacturing without an Owner/Licensee**

**March 2026**



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## 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 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 regulatory bodies to identify and address key SMR-related challenges, the SMR Regulators' Forum (SMR RF) has an increasingly important role to play in making such collaboration possible.

The SMR RF 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 regulatory bodies to inform changes, if necessary, to their requirements and regulatory practices. Since then, the Forum has completed three phases of work. For more details about the Forum, please visit: <https://gnssn.iaea.org/regnet/SMR-Forum/Pages/default.aspx>

This report has been produced by the Manufacturing, Construction, Commissioning and Operation Working Group ((MCCO WG) of the SMR RF during its Phase 4 of work (2024 to 2026). It explores the innovative concept of off-the-shelf manufacturing for SMR components and modules in scenarios without a designated owner or licensee. This approach is recognized for its potential to streamline deployment and reduce costs, and this report aims to unravel the complex challenges and opportunities that it presents.

This report was developed based on information, insights, and experience gained from the regulatory activities of the SMR RF Members. While it is generally aligned with existing IAEA documents, deviations may occur in some cases. This report aims to provide useful information to regulatory bodies and industry involved in the development, deployment and oversight of SMRs.

The text presents 'common positions' – that is, statements relevant to the topic under discussion that are unanimously agreed upon by the Forum Members – on issues such as off-the-shelf manufacturing, maintenance once on the shelf, and Counterfeit, Fraudulent and Suspect Items (CFSI). It is important to note that these common positions reflect the views of the Forum's experts and do not represent a formal consensus of all IAEA Member States.

While this report contains no specific recommendation for the IAEA, the common positions agreed upon by the MCCO WG are presented below.

## **COMMON POSITIONS FOR THIS REPORT**

### **Common Position 1**

All parties, including vendors, manufacturers and licensee (as soon as possible), should be involved throughout the design, manufacturing, storage and transport process. Regulatory bodies should also be involved in review of the process, where possible, based on regulatory framework and jurisdictional requirements.

### **Common Position 2**

Each Member State has their own set of regulations and associated industry codes and standards for manufacturing of nuclear structures, systems and components (SSCs). The differences need to be considered by SMR vendors as they design SSCs for use in multiple Member States.

### **Common Position 3**

Regulatory bodies set broad safety objectives in their regulatory frameworks. This allows them to use a graded approach in achieving the safety objectives for SMR business models. However, this approach is expected to be tested in the future in relation to different SMR models, and especially in relation to the concept of manufacturing components in accordance with a code without an owner being identified or established.

### **Common Position 4**

SMR vendors/designers and licensees, once identified, are responsible for the development and maintenance of the nuclear supply chain. The licensee is accountable under the license, but SMR vendors/designers have a contractual responsibility. The SMR vendors/designers and licensees should drive standardization in the nuclear supply chain.

### **Common Position 5**

Industry (manufacturers, vendors/designers, licensee) should work together and develop standardized components for their designs. Industry should consider developing a standard catalogue.

### **Common Position 6**

For the First-of-a-Kind (FOAK) SMRs, a licensee should be identified and involved at the earliest stage possible, to facilitate the manufacturing oversight.

### **Common Position 7**

If vendors choose to proceed without a prospective licensee/owner, they should evaluate available options for minimizing commercial risks associated with

modularization and factory-based manufacture. This can include options such as pre-licensing engagement with the regulatory body (e.g. Generic Design Assessment (GDA), vendor Design Review (VDR)).

#### **Common Position 8**

The vendor will need documented evidence that the component, module, or SMR available for purchase can meet all regulatory requirements for the regulatory jurisdiction where the SMR will be located. The prospective licensee should be aware that there may be a need for further testing following the storage of such components.

#### **Common Position 9**

For the licensee, as early as practical or feasible, the verification of manufacturer production process and implementation of their management system process should be reviewed to assess quality. This can also be a good practice for regulatory bodies for independent verification.

#### **Common Position 10**

Most Member States do not have regulatory authority over non-licensees, such as manufacturers of components. Early engagement with the regulatory authority by a prospective licensee would be necessary to ensure that components that were manufactured without the oversight of the prospective licensee could be utilized.

#### **Common Position 11**

From the regulatory body's perspective, the quality of manufacturing and assembly of modules and independent oversight of the process will play a role in SMR modules in the absence of the licensee.

#### **Common Position 12**

Most Member States could recommend to potential licensees/vendors the use of third-party oversight, in addition to the oversight required by regulations and/or Codes and Standards to address manufacturing of components in the absence of licensee.

#### **Common Position 13**

It would be a good practice for potential licensees/vendors to use the third-party oversight for construction of modules.

#### **Common Position 14**

One of the keys to success for SMRs and its supply chain will be to take a step-wise approach to modularization in systems where it makes sense and not just for the sake of modularization. A step-wise approach is likely to be the key to success, instead of being too ambitious, especially for the first few projects.

### **Common Position 15**

Manufacturers, vendors and designers should work together to develop codes and standards related to storage and maintenance of modules. The IAEA safety standards *Equipment Qualification for Nuclear Installations*, SSG-69 [1] and The *Management System for Nuclear Installations* (GS-G-3.5) [2] can be used as reference as it pertains to preservation/storage of components.

### **Common Position 16**

Maintaining records of condition monitoring in storage will also be very important and should be maintained for the life of the component/module. These records should be transferred to the licensee if the component/module is used in their facility.

### **Common Position 17**

Similarly to the existing fleets, non-safety components/modules should be maintained consistent with their quality requirements to ensure that there is no impact on safety-related components/modules.

### **Common Position 18**

A future licensee should be able to retrospectively verify that vendors/manufacturers have had robust CFSI detection processes and methods in place at the time of production of a given structure, system and component (SSC).

### **Common Position 19**

Tier 1 vendors (direct vendor to the licensee) should perform activities to prevent CFSI at their sub-tier suppliers. Tier 1 vendor's continuous efforts for those activities need to be made over a lengthy period of time.

## 1. INTRODUCTION

### Common Position 1

All parties including vendors, manufacturers and licensee (as soon as possible) should be involved throughout the design, manufacturing, storage and transport process. Regulatory bodies should also be involved in review of the process where possible based on regulatory framework and jurisdictional requirements.

This report explores the innovative concept of off-the-shelf manufacturing for SMR components and modules in scenarios without a designated owner or licensee. This approach is recognized for its potential to streamline deployment and reduce costs, and this report aims to unravel the complex challenges and opportunities that it presents.

All the options proposed in this report are suggestions for potential licensees as risk reduction for them that can possibly be beneficial to them during their procurement process. The ultimate responsibility for all components/modules is on the licensee to ensure that components/modules meet the regulatory requirements.

Detailed discussions on the feasibility and implications of off-the-shelf manufacturing span multiple sections, addressing its applicability and the stringent quality assurance required across various regulatory frameworks. Emphasis is placed on the essential collaborative framework involving vendors, manufacturers, licensees, and regulatory bodies. The critical roles of phased approaches, international regulatory harmonization, and proactive communication strategies for navigating towards successful implementation are highlighted.

Further, the interaction between broad safety objectives set by regulatory frameworks and the detailed, prescriptive nature of codes and standards is analysed. This report delves into the technical nuances that distinguish regulatory approaches and their operational implications for the SMR industry, emphasizing the need for a balanced application of robust solutions and regulatory flexibility.

Standardization in the manufacturing process is another focal point, addressing how it can simplify the supply chain and reduce complexities by establishing common standards for components. The discussion extends to how these practices can be harmonized across jurisdictions to enhance regulatory processes and operational efficiency.

Additionally, the report considers the manufacturing of SMRs in the absence of a licensee. In this scenario, the responsibility for, and the ownership of, the safety-related items will have to be with the vendor. This is because the regulatory bodies will not be involved during the manufacturing process. In addition, when the licensee is eventually in place, there will be extensive reliance of reconciliation/acceptance process during the procurement, which can pose significant commercial risks. The report discusses potential commercial risk mitigation strategies and the importance of integrating licensees early in the manufacturing process to ensure oversight and compliance particularly for the FOAK with regulatory standards.

The report concludes by offering insights into the broader impacts of such manufacturing practices, including design modularization, maintenance of manufactured components, and the implications for fleet-wide deployment strategies. These considerations are crucial for understanding the logistical, operational, and regulatory challenges that could influence the trajectory of nuclear energy development.

Through its comprehensive analysis, the report provides common positions for addressing the regulatory challenges associated with off-the-shelf manufacturing in the SMR industry.

### 1.1. IAEA CONTEXT

At the highest level, the IAEA *Fundamental Safety Principles* [3] specify in section 3.4 that “[a]uthorization to operate a facility or conduct an activity may be granted to an operating organization or to an individual, known as the licensee.”

Further, the IAEA safety standard *Governmental, legal and Regulatory Framework for Safety* [4], requirement 23, states that “[a]uthorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.” Section 4.29 of this document states that “[d]ifferent types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes.”

The IAEA safety standard *Leadership and Management for Safety* [5], requirement 11, states that “[t]he organization shall put in place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply to it of items, products and services that may influence safety”. Section 4.34 of this document states that “[t]he organization shall have a clear understanding and knowledge of the product or service being supplied. The organization shall itself retain the competence to specify the scope and standard of a required product or service, and subsequently to assess whether the product or service supplied meets the applicable safety requirements”. Section 4.36 states that “[t]he organization shall make arrangements for ensuring that suppliers of items, products and services important to safety adhere to safety requirements and meet the organization’s expectations of safe conduct in their delivery”.

More specific guidance for licensing is found in the IAEA safety standard *Licensing Process for Nuclear Installations* [6]. The following guidance is helpful in understanding the issues associated with manufacturing without an owner:

The regulatory body holds the licensee responsible for safety regardless of commercial arrangements. The licensee must have the capability to demonstrate effective oversight and control of the activities being carried out under the license.

The applicant or licensee need to be able to demonstrate that contractual arrangements do not compromise the independence or safety of its decision making and effective oversight processes.

In addition, section 6.13 of the IAEA safety standard *Safety of Nuclear Power Plants: Commissioning and Operation* [7] states:

“[t]he operating organization shall be responsible for ensuring that construction activities are of appropriate quality and that completion data on commissioning activities and comprehensive baseline data, documentation or information are provided. The operating organization shall also be responsible for ensuring that the equipment supplied is manufactured under a quality assurance programme that includes inspection for proper fabrication, cleanliness, calibration and verification of operability”.

Safety Report No.123 [8] points to gaps in regulatory oversight and supply chain oversight in GSR-Part 1 [4], GSR-Part 2 [5], GSG-13 [9], SSG-12 [6], SSG-38 [10] and GS-G-3.1 [11] in case of SMR foreign manufacturing, off-the-shelf manufacturing and when components are produced before a licensee is identified. Some of these issues will be addressed, at a high level, in the revised version of SSG-12 under preparation [12]. However, additional information would be helpful to support Member States in considering new SMR deployment models. The discussion of the feasibility and implications of off-the-shelf manufacturing, including the commercial risks and the necessity of the manufacturer maintaining components and modules, are helpful to regulatory bodies and licensees.

## 2. CODES AND STANDARDS

### Common Position 2

Each Member State has their own set of regulations and associated industry codes and standards for manufacturing of nuclear structures, systems and components (SSCs). The differences need to be considered by SMR vendors as they design SSCs for use in multiple Member States.

### Common Position 3

Regulatory bodies set broad safety objectives in their regulatory framework. This allows them to use a graded approach to achieving safety objectives for different SMR business models. However, this approach is expected to be tested in the future in relation to different SMR models, and especially in relation to the concept of manufacturing components in accordance with a code without an owner being identified or established.

Each Member State has different codes and standards related to the manufacture of components, which may have been incorporated into the regulatory framework and licensees' requirements. The intent of this report is not to provide standardization or harmonization for these codes and standards, but rather to provide a basis for the framework for the concept of manufacturing without an owner/licensee, where the owner/licensee would traditionally be responsible for the oversight and assurance of these components during the design and manufacturing stages. This framework covers components within the pressure boundary only.

While both nuclear regulations and codes and standards play crucial roles in ensuring the safety and security of nuclear installations, their approaches and complexities differ significantly. Regulations typically set broad safety objectives (regulatory framework), allowing a graded approach in achieving them. On the other hand, codes and standards provide intricate technical details and prescriptive requirements for various aspects like design, manufacturing, construction, and operation.

This inherent difference in detail leads to increased complexity in codes and standards. They often incorporate specific engineering principles, technical nuances related to material properties and performance parameters and can originate from diverse organizations applying different methodologies. This adds another layer of complexity due to potential incompatibilities and the need for harmonization efforts.

Furthermore, the bases for regulations and codes/standards differ. Regulations focus on achieving safety objectives through diverse means, while codes and standards specify methods and approaches. While regulations may implement graded approach, that is applying requirements proportionally to the safety significance of each activity, codes and standards emphasize robust solutions regardless of specific risk profiles. Both regulations and codes and standards can exhibit national variations due to differing technical/cultural traditions.

Standards Development Organizations (SDOs), such as the American Society of Mechanical Engineers (ASME), French Association (AFCEN) that creates Design and Construction Rules for the Mechanical Components of PWR Nuclear Islands (RCC-M), Korea Electric Association that develops Korea Electric Power Industry Code (KEPIC) and Japan Society of Mechanical Engineers (JSME), typically have requirements for an owner defined as entity that is licensed by the regulatory authority. In most Member States, an owner could be an entity that is having pre-licensing engagements with the regulatory body. In other countries, the owner may be the state itself. In this case, the installation may be operated by another entity that is licensed to do so.

SDOs are developing code cases that can potentially address the issue of manufacturing without an owner/licensee. However, these may have to be accepted by regulatory authority having jurisdiction. Changes in the Member State's regulatory framework may be necessary to address manufacturing code components without an owner.

### 3. STANDARDIZATION

#### Common Position 4

SMR vendors/designers and licensees, once identified, are responsible for the development and maintenance of the nuclear supply chain. The licensee is accountable under the license, but SMR vendors/designers have a contractual responsibility. The SMR vendors/designers and licensees should drive standardization in the nuclear supply chain.

#### Common Position 5

Industry (manufacturers, vendors/designers, licensee) should work together and develop standardized components for their designs. Industry should consider developing a standard catalogue.

Standardization plays a crucial role in off-the-shelf manufacturing by streamlining processes, ensuring consistency, and enhancing efficiency. Regulatory bodies view standardization as a form of assurance and risk reduction for vendors manufacturing safety-related components without a licensee being involved. Standardization has been successfully employed in other industries. Currently, the IAEA Advanced Reactor Information System [13] contains over 90 SMR designs worldwide. With many of these SMRs, their designers and vendors are interested in the global supply chain to have their reactors deployed in multiple countries. Most of these companies are focused on design, vendor assembly and storage solutions to achieve their goals. Industry could simplify their supply chain by focusing on standardization of specifications/components. This will result in requiring a reduced number of manufacturers needing certification for pressure boundary or other specific requirements of the Member States.

It is also important to mention that the nuclear industry used to, and still tends to, localize the production of components. As a strategic sector of countries, the nuclear industry has at least strived for its own operational and maintenance competencies while meeting local standards. But in many places, it has also sought to maximize local industry production. Demands for a high proportion of local supply can also be observed in current construction and ongoing tenders (e.g. Czech Republic<sup>1</sup>, People's Republic of China, France, Poland, Russian Federation). A question remains whether this factor will also significantly affect the production and construction of SMRs.

As briefly discussed in Common Position 10 of its Phase 3 report [14], the MCCO WG highlighted an opportunity for harmonization and standardization in all levels of organizations in light of the SMR business models.

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<sup>1</sup> Member State's experience: <https://mpo.gov.cz/en/energy/nuclear-energy-and-new-nuclear-builds/participation-of-the-czech-industry-in-nuclear-projects/participation-of-the-czech-industry-in-nuclear-projects--232008/>

Standardization at the local level (i.e. state, country, region or continent), occurs frequently to improve cost effectiveness, but global standardization of manufacturing components has not been achieved. Individual supply chains are artifacts of the existing fleet of operating reactors. The blue box below provides some background information regarding the importance of standardization [15]<sup>2</sup>.

**Why is standardization in manufacturing of components important?**

**Interchangeability:** Standardization ensures that components, parts, and products are consistent in their specifications and dimensions. This allows for easy interchangeability, meaning components from different batches or suppliers can be used interchangeably without the need for adjustments or modifications. This significantly simplifies manufacturing processes and reduces downtime.

**Supply Chain Efficiency:** With standardized components, manufacturers can rely on a stable supply chain. They can source parts from various suppliers knowing that they will fit seamlessly into their production processes. This reduces the risk of delays caused by incompatible parts or sudden changes in specifications.

**Cost Reduction:** Standardization often leads to economies of volume. By producing standardized components or products in large quantities, manufacturers can benefit from lower production costs per unit. Additionally, it reduces the need for custom tooling or equipment, further reducing manufacturing expenses.

**Quality Control:** Standardization facilitates quality control processes by providing clear criteria for evaluating products. With standardized specifications, manufacturers can establish consistent quality standards and easily identify deviations or defects in the manufacturing process. This helps maintain product quality and reliability.

**Market Accessibility:** Standardized products are often more marketable and accessible to a wider range of customers. Consumers can confidently purchase off-the-shelf products knowing that they meet industry standards and specifications. This broadens the market reach of manufacturers and increases their competitiveness.

**Regulatory Compliance:** Many industries have regulations and standards for products to ensure safety, compatibility, and performance. Standardization helps manufacturers comply with these requirements more easily, as they can design and produce products that already meet established standards.

In essence, standardization in off-the-shelf manufacturing can serve as a backbone for efficiency, quality, and market competitiveness, allowing manufacturers to produce reliable products at lower costs while meeting customer expectations and regulatory requirements.

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<sup>2</sup> International Organization for Standardization (ISO) – Standards <https://www.iso.org/standards.html>

It may provide regulatory bodies some assurance that components made without owners meet the regulatory requirements.

## **4. MANUFACTURING AND DEPLOYMENT**

### **Common Position 6**

For the First-of-a-Kind (FOAK) SMRs, a licensee should be identified and involved at the earliest stage possible, to facilitate the manufacturing oversight.

### **Common Position 7**

If vendors choose to proceed without a prospective licensee/owner, they should evaluate available options for minimizing commercial risks associated with modularization and factory-based manufacture. This can include options such as pre-licensing engagement with the regulatory body (e.g. Generic Design Assessment (GDA), Vendor Design Review (VDR)).

### **Common Position 8**

The vendor will need documented evidence that the component, module, or SMR available for purchase can meet all regulatory requirements for the regulatory jurisdiction where the SMR will be located. The prospective licensee should be aware that there may be a need for further testing following the storage of such components.

### **Common Position 9**

For the licensee, as early as practical or feasible, the verification of manufacturer production process and implementation of their management system process should be reviewed to assess quality. This can also be a good practice for regulatory bodies for independent verification.

### **Common Position 10**

Most Member States do not have regulatory authority over non-licensees, such as manufacturers of components. Early engagement with the regulatory authority by a prospective licensee would be necessary to ensure that the use of components that were manufactured without the oversight of the prospective licensee could be utilized.

In the case of SMRs, the potential commercial risks to vendors and prospective licensees presented by the early manufacture of components and modules by the supply chain in advance of a licensee being either identified or being granted a licence are significant. These risks are explored below, and possible risk mitigation strategies and alternative approaches are examined.

#### **4.1. MANUFACTURERS' COMMERCIAL RISKS IN THE ABSENCE OF A LICENSEE**

Traditionally, for Gigawatt electric (GWe) scale reactor projects, a prospective licensee was identified before any manufacturing of major components or modules would take place.

There have, however, been situations in at least one Member State where some long lead items (LLI) had to be ordered and manufactured in advance of the prospective licensee actually receiving their licence, and, in such cases, prospective licensees have utilized several mitigation strategies, such as Deeds<sup>3</sup> and third-party accredited bodies to provide quality assurance for these LLIs. In these situations, some prospective licensees have provided a Deed to the effect that they will behave as if they were already a licensee and agree to provide access for the regulatory body to their suppliers through their normal contractual arrangements with their supply chain. Prospective licensees have also utilized the services of a third-party accredited body to assess their quality arrangements and their quality and contractual documentation. These measures do not guarantee that a particular item will be acceptable once the quality documentation and records are formally submitted and assessed by a regulatory body, but they do provide a level of assurance and risk reduction to the prospective licensee.

In the case of SMRs, the degree of modularization and factory-based manufacture presents an increase in the commercial risk for vendors. First, the manufacture of items may not be limited to single components or systems but will likely include the assembly of complex modules and, possibly, even entire reactors in a factory with these modules later delivered to the operator's site. When coupled with a potential absence of a licensee or even a prospective licensee, the commercial risks to the vendor and even for the future licensee are potentially significantly greater than those experienced to date in GWe scale projects.

A key reason for this is the degree of modularization. This is expected to be significantly higher for SMRs compared to GWe scale. For a large complex module (that could be an entire reactor), where there is a potential that these modules cannot be disassembled in the future, the documentation needs to be relied upon, along with testing of the module after it is manufactured (i.e. blackbox). This potentially requires a large amount of quality documentation to justify the design of the module and its assembly.

Vendors will need to evaluate their options for minimizing these commercial risks; however, this is up to the industry to manage and is not something regulatory bodies need to address.

If the vendors decide to begin manufacturing and factory assembly of modules in the absence of a prospective licensee/owner, then they will have to ensure that their design meets the regulatory requirements of the particular jurisdiction, and the manufacturing supply chain is appropriately qualified to meet those requirements. This can be complicated if the vendor design is being sold to multiple jurisdictions. The amount and complexity of the quality documentation/records required to be assembled during manufacture and assembly will be significant. Vendors will need to ensure that the quality records will, when ultimately submitted to a regulatory body, be adequate when assessed. It is clear that the penalties for vendors where modules manufactured and placed 'on the

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<sup>3</sup> A Deed in this context is a legally binding contract between the prospective licensee and the regulatory body in respect to the prospective licensee's arrangements for the purchase of LLIs that could impact on safety, and the inspection of those arrangements, their implementation and inspection of such LLI during their manufacture.

shelf' for a future licensee do not eventually meet the requirements of a regulatory body in a particular jurisdiction when submitted could be commercially challenging.

## 4.2. OFF-THE-SHELF MANUFACTURING

### Common Position 11

From the regulatory body's perspective, quality of manufacturing and assembly of modules and independent oversight of the process will play a role in SMR modules in the absence of the licensee.

Off-the-shelf manufacturing may not be applicable for FOAK reactors. It can be expected that increasing demand for SMRs will drive the supply chain to an 'off-the-shelf manufacturing model.' This model will have several manufacturers and designers/vendors working together in the absence of a licensee to manufacture and assemble reactor components and modules according to the vendor's design specifications and store them on the shelf at an appropriately environmentally controlled facility. This type of model typically involves manufacturing high quantities (depending on demand) with a standard process. These components and modules can then be procured by a future licensee right off the shelf and delivered to a site for final assembly.

To minimize the risk, manufacturers may choose to establish a facility in jurisdictions where the legal framework does provide some limited regulatory oversight of manufacturing. It is expected that this could be done if the vendor had some assurance that another regulatory body would accept the assessment of the host regulatory body.

If the quality requirements of the modules are met, stockpiling of modules can be an attractive option for vendors looking to have their designs accepted and projects built within short timelines at multiple locations in one or multiple jurisdictions.

A high level of quality assurance (QA) is essential, with requirements varying for different safety-related components. To facilitate deployment in multiple countries, QA should be standardized, although this is resource-intensive for regulatory bodies.

Quality control (QC) can be more easily standardized than QA, drawing on practices from the aviation industry, which could be adapted for the nuclear sector. This approach could streamline the QC process across borders, making it more efficient and less resource-heavy for regulatory bodies.

The importance of robust manufacturing quality management for SSC important to safety is established in IAEA Safety Standards (GSR Part 2 [5]; SSR-2/1 Rev.1 [16]) and ASME NQA-1 *Quality Assurance Requirements for Nuclear Facility Applications* [17]. Please refer to Focus Area on Quality of Manufactured Components and Modules (blue box below) for further discussion on quality in manufacturing.

**Focus Area: Quality of Manufactured Components and Modules**

Quality of manufactured components/modules dictates if the component/module can perform its design function for the designed life. Quality is especially vital for SSC important to safety; therefore, robust manufacturing processes are essential. Thorough testing regimes should be in place to ensure SSC components/modules are thoroughly tested to demonstrate design compliance and any failures/defects are identified. Testing processes should drive improvements to manufacturing process. Robust QA/QC processes will ensure that manufactured components/modules meet design requirements and minimize potential issues related to CFSI.

**Examples of Quality Issues in Manufacturing**

- Design changes are not well controlled;
- Manufacturing defects;
- Lack or substandard quality controls and quality assurance in a manufacturing facility;
- Substandard quality of raw material;
- Inadequate receipt inspection;
- Inadequate testing and inspection techniques;
- Poor record keeping/documentation control issues;
- Nonadherence to customer requirement;
- Human factors and poor safety culture.

**Examples of Good Quality Techniques in Manufacturing**

- Use of proven/qualified manufacturing techniques;
- A good testing program;
- Low level of non-conformances;
- Strong data management (document control and record keeping process);
- Quality management system/QA programs.

Section 1.2 'Manufacturability' of the MCCO WG Phase 2 report [18] provides common positions related to manufacturing of components. An example of quality activities in a related industry is discussed below.

**Focus Area: Quality Management Issues in Comparable Industries**

The aviation industry, as exemplified by recent operational challenges faced by Boeing, underscores the critical importance of robust quality management systems, especially under the pressures of accelerated production schedules. Boeing's experiences have revealed significant risks associated with the drive to rapidly increase output without sufficient time to ensure thorough quality control. This scenario mirrors potential challenges within the nuclear sector, particularly as it explores fleet-wide approaches to deploying SMRs. Like aviation, the nuclear industry is characterized by its extremely rigorous safety standards and the absolute necessity for precise compliance with regulatory requirements. The push for a fleet-wide deployment model for SMRs could similarly strain existing quality assurance frameworks, potentially leading to compromises unless adequate measures are implemented. The parallel with Boeing not only highlights the need for the nuclear industry to develop enhanced oversight mechanisms and adaptive quality management systems that can accommodate increased production demands while maintaining the highest levels of safety and regulatory conformity but also points to the risks of scaling up production of a large volume of SMRs by potentially inexperienced vendors without an established licensee. This approach is crucial as the sector moves towards more standardized and serialized production models, similar to those in the aviation industry, to meet growing global energy demands efficiently and securely.

**4.2.1. OPTIONS FOR CONFORMITY `ASSESSMENT OF COMPONENTS****Common Position 12**

Most Member States could recommend to potential licensees/vendors the use of third-party oversight, in addition to the oversight required by regulations and/or Codes and Standards to address manufacturing of components in the absence of licensee.

**Common Position 13**

It would be a good practice for potential licensees/vendors to use the third-party oversight for construction of modules.

In the current operating fleet, licensees are typically involved during the purchase and manufacturing of safety components (it is required by code for pressure boundary components) and therefore can ensure there is independent oversight (third-party oversight (inspection bodies and/or testing laboratories)) of the key manufacturing and testing steps (welding, hydrostatic/pressure tests and so on). However, in the manufacturing with no licensee scenario, there will be no independent oversight representing the licensee (owner), which can lead to potential manufacturing defects or CFSI- related items making their way to licensee sites and even installed in the system. Having a certification by a third-party or some sort of independent oversight will reduce this risk and provide licensee and regulatory bodies assurance that safety components and modules were built with appropriate quality.

An accredited third-party assessment in addition to the code requirement in the absence of a licensee is not a requirement in most Member States. Use of an accredited third-party body could provide the vendor with a risk reduction measure for the prospective licensee. Accredited third-party body reviews of the quality of manufacturing and the associated reports would become part of the final documentation package. Regulatory bodies potentially could consider this third-party conformity assessment documentation when a licensee submits all the documentation to regulatory body review for a component/module. Some Member States can authorize third-party entities in their current regulatory framework; however, third-party accredited bodies<sup>4</sup> can also be used. Ultimately it will be up to each regulatory body and their framework to decide whether a third-party and their assessments can be acknowledged.

With complex modules being proposed for SMRs, there will be a need of third-party oversight to verify modules are assembled without any potential damages and impedances to their operability. See section 4.2.2. below for details on modules.

An alternative approach to using third-party oversight could involve the certification of suppliers by an appropriate industry body. This would require the establishment of a nuclear industry body which leads on the oversight and assurance of the supply chain on behalf of licensees. This approach would support the development of consistent oversight and assurance standards across the industry and potential efficiencies where suppliers are common across the industry and could reduce regulatory effort on supply chain management. Establishing an industry certification body would be more difficult on an international basis than on a purely national basis but given that many SMR vendors are seeking to deploy across several jurisdictions an international certification body would be preferred. Another option could be licensing of the supply chain (see section 4.4. for details).

### 4.2.2. MODULARIZATION

#### Common Position 14

One of the keys to success for SMR and its supply chain will be to take a step-wise approach to modularization in systems where it makes sense and not just for the sake of modularization. A step-wise approach is likely the key to success instead of being too ambitious specially for the first few projects.

SMR designs focus to a great extent on modularity during manufacturing and on assembling systems and components at the factory location. There are code and standard requirements for manufacturing of components; however, there are no code and standard

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<sup>4</sup> The “third-party accredited bodies” refers to independent conformity assessment or inspection bodies accredited by a recognized national accreditation authority (e.g., ISO/IEC 17020 or 17021), and not to other regulatory bodies. These entities do not act under delegated regulatory authority but may provide independent assessments that support the Licensee’s documentation.

requirements on assembly of modules. Modularization enables performing preassembly work in parallel to site preparation to meet short project schedules and timelines.

Modular construction has been discussed previously in MCCO WG Phase 2 report [18].

It is recognized that the concept of modularization is a very attractive model to the nuclear industry and is one that has been proven in other industries, such as ship building and the automotive industry. One of the primary advantages of modularization is performing the work in a factory where the quality control of work is traditionally better, and the work environment can be controlled.

Taking a step-wise approach to modularization, by starting with a few modules in the initial design, can be recommended. Modelling, testing, transporting, and analysing the installation on the licensee's site for fit/interaction represent actions that can be done ahead of time. Improving the modules and all the processes involved before installation and commissioning would improve industry processes and construction efficiency.

The use of digital twins can greatly improve the overall designing and manufacturing process. However, these techniques are only as good as the data that are provided. As the modules are fabricated and installed on different sites, the data collected can provide an important feedback loop to the design and manufacturing process. As the experience in manufacturing of modules increases over time, the quality of each one would also increase from learning of previous modules' development processes.

#### **Focus Area: Digital Twin**

According to Ref. [19], the U.S. NRC defines:

"[a] digital twin (DT), as part of a DT system, is a virtual representation of an entity, process, or system, synchronized at a frequency and fidelity sufficient to maintain state concurrence. A DT leverages various types of models, data, and frameworks to produce knowledge/insights about the represented entity, process, or system to fulfil an intended purpose."

Digital twins are linked to real-world data sources, so they update in real time to reflect the original version.

Digital twins can be used to:

- **Monitor performance:** Oversee the performance of an asset and identify potential faults;
- **Improve design:** Identify inefficiencies and design solutions to improve the physical object;
- **Make better decisions:** Make better-informed decisions about maintenance and lifecycle;
- **Optimize simulations:** Create a digital environment that replicates and connects every aspect of an organization.

A step-wise approach and the use of proven advanced modelling techniques throughout the process will help ensure that Nth-of-a-Kind (NOAK) SMR can be efficiently modularized and effectively support the off-the-shelf manufacturing model. This process could provide confidence that off-the-shelf manufacturing processes are reliable, and modules are built to appropriate quality standards that meet the design requirements.

#### 4.3. MAINTENANCE ONCE ON THE SHELF

##### Common Position 15

Manufacturers, vendors and designers should work together to develop codes and standards related to storage and maintenance of modules. The IAEA safety standards *Equipment Qualification for Nuclear Installations* (SSG-69) [1] and *The Management System for Nuclear Installations* (GS-G-3.5) [2] can be used as reference as it pertains to preservation/storage of components.

Recognizing that different regulatory jurisdictions may have different storage requirements; a vendor should consider the acceptability of existing codes and standards to meet quality requirements for storage and maintenance and address any potential differences/gaps if they exist. This can be related to both components and modules.

##### Common Position 16

Maintaining records of condition monitoring in storage will also be very important and should be maintained for the life of the component/module. These records should be transferred to the licensee if the component/module is used in their facility.

##### Common Position 17

Similarly to the existing fleets, non-safety components/modules should be maintained consistent with the quality requirements to ensure that there is no impact on safety-related components/modules.

Once mass manufacturing of safety related components and modules becomes common, it will be accompanied by storage of these items in the factory or a storage location until they are sold to a customer (licensee). Although not a new issue for SMRs, storage conditions and periodic inspection/maintenance plans of these components and modules will be very important, as they can impact the performance/life of these items when in operational use.

When planning on storing safety related components and modules in a storage facility, the owner (vendor, licensee) will have to ensure that external influences are minimized and the conditions of these components and modules are monitored and maintained in accordance with applicable codes and standards.

Based on experience detailed in the MCCO WG Phase 2 Report [18], the owner (vendor, licensee) will need to perform functional testing to demonstrate the operational life, when retrieving components/modules meet the design specifications. It is expected that, if

storage conditions are not optimal, they will negatively impact these items, including reduced functionality and potentially reduced operational life. For example, a vessel stored in an uncontrolled environment (high humidity, high temperature, air instead of inert gas blanket, etc.) can cause it to rust and corrode, which can lead to a decrease in the thickness of the vessel in certain locations and therefore would result in reduction in its operational life and it not meeting its design requirements

**Focus Area: Storage of SMR components/modules**

The storage of SMR components/modules should be similar to current operating fleet. However, below are some of the considerations that will be important for the owner (vendor, licensee) to consider and implement:

- **Controlled environment:**  
Having an appropriately controlled storage environment will have a direct impact on stored components/modules and therefore should be one of the main considerations. It will not only impact one component/modules, but all the items stored in that location. Harsh environments can lead to faster degradation of equipment through rusting, embrittlement, stress cracking and other mechanisms.

**Focus Area: Storage of SMR components/modules (cont.)**

- Condition monitoring in storage:  
While components/modules are in storage, vendor/licensee should have a method of monitoring their condition, similar to live or periodic online monitoring. vendor/licensee can take advantage of new technologies such as digital twins to identify any early degradations and address them on time. Maintaining records of condition monitoring in storage will also be very important and should be maintained for the life of the component/module.
- Periodic maintenance and specialized tooling:  
vendor/licensee should develop periodic maintenance plans for component and module for the storage facilities similar to the recommended online periodic maintenance. vendor/licensee should also consider developing specialised tooling for maintenance of complex modules to ensure all components are adequately maintained.
- Shelf-life vs operational life:  
A measure of shelf-life vs operational life of components/modules should be maintained following a proven and quantifiable approach. This can include taking inputs from condition monitoring and periodic maintenance activities while in storage. The shelf-life vs operational life should be recorded and easily accessible and made available to licensee and regulatory bodies upon request.
- Codes and standards:  
Currently there are codes and standards for safety related component storage. However, it is highly recommended that industry works together to develop codes and standards for storage of safety related modules to ensure consistent approach in how they are stored. There is a lot of OPEX available related to industrial items and their storage (i.e. airlines and shipbuilding industry) that can be considered when developing new code and standards. IAEA SSG-69 [1] can also be used as reference as it pertains to preservation/storage of components.
- Records management:  
Records management of components/modules during storage related to condition monitoring, periodic inspections, testing, and shelf-life vs operational life will be vital for the life of these items. These records should be regularly updated, easily accessible, securely stored and transferred to the buyer (licensee) when these items are sold.

- Design obsolescence in storage:  
The vendor/licensee will have to consider situations related design obsolescence (technical obsolescence) during a long-term storage, it may include, for example, safety-related design concept and equipment that no longer meet the updated safety standards or advanced technology, and spare parts may no longer be available, or technical support may no longer be available from their supplier. It should be considered to find out how to detect design obsolescence (technical obsolescence) that need to be addressed during storage. For example, supply chain issues such as spare parts and technical support could be included in the storage plan.

#### 4.4. LICENSING OF FIRST-TIER MANUFACTURER

**Common Position:** None

Currently, some Member States license the manufacturers of safety components/modules. This allows for direct oversight of the supply chain by the regulatory body. This approach could provide a solution to the early oversight and absence of a licensee. It may, however, transfer the risk from the licensee to the regulatory body, and would therefore require that a regulatory body have significantly more resources to undertake this additional role. For most Member States, the licensing of the manufacturers is not possible within the current legal framework. For example, in the UK the licensing process can only license a specific corporate body for a specific nuclear site for the construction, installation, commissioning and operation of a nuclear fission reactor or an installation of a prescribed type (such as reprocessing plant and fuel facility manufacturing)<sup>5</sup>. In this example, the licence covers all phases of the lifecycle of the facility (cradle to grave). In contrast, other jurisdictions can issue licences for specific phases of the lifecycle (e.g. for construction or for operation of the facility). Under these models, the oversight of the manufacturers is the responsibility of the licensee, and the regulatory body provides oversight of the licensee's arrangements for quality and manufacturer management and the implementation of those arrangements.

Some Member States utilize early design review processes that allow for direct engagement with the vendor to assess a reactor design at an early stage, including quality and supply chain management. Such processes provide confidence that the design will be able to meet the regulatory design requirements in a particular jurisdiction. However, these processes are not mandatory (in contrast to the legal Licensing Process). Examples of these processes include the UK GDA process and the Canadian VDR.

In most Member States, vendors are not licensees, and it is the licensing process that provides the legal framework for regulation of the licensee with respect to its oversight and

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<sup>5</sup> <https://www.onr.org.uk/licensing-nuclear-installations.pdf>

quality management of its supply chain. There are alternate oversight mechanisms (such as discussed in section 4.1. regarding Deeds and third-party certification) that have been used by prospective licensees to reduce the risks when ordering and manufacturing LLIs. It may be possible to utilize similar mechanisms with vendors for them to reduce the risks of early manufacturing of systems and modules. For example, a vendor could put in place commercial arrangements with their supply chain that could provide access to its suppliers by the regulatory body. Similarly, a vendor could put in place the services of a third-party accreditation organization to assess their supply chain quality arrangements. It should be noted that, in the case of SMRs, the extent of upfront manufacturing and off-the-shelf provision of modules could be far more extensive than in the case of LLIs for GWe-scale reactor projects, and hence the potential risks could be significantly higher. It is debatable if this approach would be sufficient to mitigate the higher risks in the case of SMRs.

#### **4.5. COUNTERFEIT FRAUDULENT SUSPECT ITEM WITHOUT A LICENSEE**

##### **Common Position 18**

A future licensee should be able to retrospectively verify that vendors/manufacturers have had robust CFSI detection processes and methods in place at the time of production of a given structure, system and component (SSC).

##### **Common Position 19**

Tier 1 vendors (direct vendor to the licensee) should perform activities to prevent CFSI at their sub-tier suppliers. Tier 1 vendor's continuous efforts for those activities need to be made over a lengthy period of time.

CFSI have been an object of increasing attention within the nuclear industry for a long time. Several high-profile cases of fraudulent activity have been discovered, some of them reaching decades into the past [20]. Mostly these cases have been about document falsification and material misrepresentation. For manufacturing components/modules without a licensee, the potential of CFSI is higher because of the potential absence of oversight. Further, the potential for CFSI could be higher for SMRs due to the large number of them expected to be built, the quantity of components to support the new builds, and the increased number of manufacturers of the same components. Vigilance by the manufacturers/potential licensees to prevent CFSI will be required.

There are multiple scenarios related to modularization that could exacerbate CFSI events:

1. globalization of supply chain can make it more vulnerable to bad actors and therefore CFSI;
2. lack of rigor or proper documentation during manufacturing and assembly process;
3. component is contained within a sealed module making it difficult to identify and remove just the suspect component;
4. other potential threats such as cyber security or

### 5. unknown embedded devices<sup>6</sup>.

Based on IAEA report *Managing Counterfeit and Fraudulent Items in the Nuclear Industry* [21], there are preventive measures that are usually divided into the following categories:

- Management responsibility;
- Training;
- Engineering involvement;
- Supplier selection and oversight;
- Procurement management;
- Quality;
- Zero tolerance policy on CFSI.

All these high-level principles also apply to SMR SSCs manufactured without a licensee. As SMRs are more likely to be acquired by smaller and less experienced companies than those that acquired traditional nuclear reactors, supply chain and procurement management are increasingly important, as licensees rely on external companies for technical support, etc.

Sharing experience among the prospective licensees/vendors and supply chains at all tier levels on best practices and events related to CFSI should reduce repeat occurrences and drive better detection and avoidance techniques. Section 2.7 of the MCCO WG Phase 2 report [18] elaborates on sharing experience and best practices.

Ordering components/modules from manufacturers that have processes in place, such as third-party inspections, accredited certified laboratories and sufficiently comprehensive manufacturing documentation, minimizes the potential for CFSI. However, the risk potentially increases if the licensee accepts components/modules while their manufacturer has gone out of business and the above processes could not be verified. This, again, underlines the importance of credible certified third-party inspections, accredited certified laboratories and sufficiently comprehensive manufacturing documentation.

In the absence of a licensee, a vendor's direct suppliers should incorporate practices that are currently in place for large NPPs supply chain. These current practices include best practices for Tier 1 vendors, as they could have a large number of qualified nuclear suppliers and should establish the QMS requirements for nuclear suppliers, including with respect to safety culture, prevention of CFSI, quality record requirements, design change control, documented requirements for sub-tiers, related code requirements, etc. Tier 1 vendors should also establish a method of qualification (and its renewal) and then develop a survey/audit check sheet based on their QMS requirements for nuclear suppliers when conducting audits.

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<sup>6</sup> Embedded devices: it is a computer system that is built into a larger device or a product to perform a specific task and often relatively invisible to end user.

To effectively conduct deterrence activities in response to CFSI in the supply chain, it is essential for Tier 1 vendors to have intensive and frequent engagement with their sub-tier suppliers. The continuous efforts may include:

- to hold an annual interaction meeting with suppliers for the latest information sharing and safety culture improvement;
- to develop a periodic questionnaire to identify and analyse the partner's comments or requests for reflecting in the improvement on Tier 1 activities;
- to strengthen the audits focusing on activities related to CFSI;
- to have direct communications by visiting to key partners, such as newcomers, doing a lot of business, conducting important process, nonconformity occurs, etc. to communicate closely and build trusting relationship;
- to provide support materials for reminding/alerting for CFSI, fostering the safety culture, etc. based on the lessons learned from the past CFSI issues.

## 5. CONCLUSION

All the options proposed in this report are suggestions for potential licensees and vendors to reduce risk during their procurement process. The ultimate responsibility for all components/modules lies on the licensee to ensure that components/modules meet the regulatory requirements.

This report addresses the emerging challenge of manufacturing SMR components and modules in the absence of a designated owner or licensee, a scenario increasingly relevant as SMR deployment accelerates globally. The absence of a licensee during early manufacturing stages introduces significant regulatory, commercial, and quality assurance risks, particularly for safety-related components and modules intended for off-the-shelf deployment.

To mitigate these risks, the report proposes a collaborative framework involving vendors, manufacturers, and regulatory bodies, emphasizing early engagement, standardization, and the use of third-party oversight. Key strategies include:

- Developing standardized components and catalogues to streamline supply chains
- Implementing robust quality assurance and control practices, drawing lessons from industries like aviation
- Maintaining comprehensive documentation and condition monitoring during storage
- Encouraging pre-licensing engagement and conformity assessment mechanisms to ensure regulatory compliance across jurisdictions

The report outlines 19 common positions on the best practices and risk mitigation strategies. It is hoped that the common positions will be helpful to regulatory bodies and the industry involved in the development, deployment and oversight of SMRs.

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## ABBREVIATIONS

|        |                                                                                    |
|--------|------------------------------------------------------------------------------------|
| ASME   | American Society of Mechanical Engineers                                           |
| CFSI   | Counterfeit, Fraudulent and Suspect Items                                          |
| FOAK   | First-Of-A-Kind                                                                    |
| GDA    | Generic Design Assessment                                                          |
| GWe    | Gigawatt electric                                                                  |
| JSME   | Japan Society of Mechanical Engineers                                              |
| KEPIC  | Korea Electric Power Industry Code                                                 |
| LLI    | Long Lead Items                                                                    |
| MCCO   | Manufacturing, Construction, Commissioning and Operation                           |
| NOAK   | Nth-Of-A-Kind                                                                      |
| QA     | Quality Assurance                                                                  |
| QC     | Quality Control                                                                    |
| RCC-M  | Design and Construction Rules for the Mechanical Components of PWR Nuclear Islands |
| SDO    | Standards Development Organization                                                 |
| SMR    | Small Modular Reactor                                                              |
| SMR RF | Small Modular Reactor Regulators' Forum                                            |
| SSC    | Structure, System and Component                                                    |
| VDR    | Vendor Design Review                                                               |
| WG     | Working Group                                                                      |

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