Qualification Management of Nuclear Equipment Suppliers: Analysis of China's Unique Regime

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Abstract: In the context of climate change and energy crisis, nuclear energy, as a clean and low-carbon energy source, has embraced global development opportunities. In recent years, the nuclear power industry has witnessed rapid development, with continuous progress in nuclear power technology and an expanding scope of nuclear energy utilization, following which, the risks in the quality of nuclear facility equipment have been on the rise, and the requirements for the stability and reliability of the equipment supply chain have become more stringent. This paper summarizes the diverse regulatory approaches adopted by various countries regarding nuclear facility equipment suppliers and first sorts out four mainstream regulatory models: third-party organization assessment, quality system certification, operator internal control audit, and direct licensing by regulatory authorities. On this basis, it emphasizes the analysis of China's unique licensing system led by the National Nuclear Safety Administration (NNSA), which covers four types of activities (design, manufacturing, installation, NDT) for nuclear safety mechanical and electrical equipment. Qualifications are granted through standardized processes such as application, technical review, and multi-level decision-making, with a clear 5-year validity period and invalidation scenarios specified for the license. The analysis shows that this system can improve bidding efficiency, enhance supply chain quality and stability, and impose effective penalties. Nevertheless, it has issues such as high consumption of regulatory resources, high requirements for personnel quality, and insufficient adaptability to new technologies. This study aims to provide references for nuclear countries to optimize the management of equipment suppliers and to promote the sustainable development of the global nuclear supply chain.

Keywords: Equipment Regulation; Third-Party Organizations; Operators; Licensing Regime; Regulatory Agency

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1 Introduction

Nuclear energy is a well-established technology that has provided electricity and heat to consumers for over 50 years. In 2023, more than 410 reactors were in operation in over 30 countries, with nuclear energy providing 9% of global electricity supply. Nuclear power ranks as the second-largest source of low-emissions electricity, following hydropower, and global nuclear power generation is projected to reach an all-time high in 2025 [1]. At the 28th Conference of the Parties to the United Nations Framework Convention on Climate Change (COP28) held in 2023, many countries announced that they would accelerate the development of nuclear power generation and pledged to triple the global nuclear power generation capacity by 2050 [2].

By the end of 2024, China had 58 commercial nuclear power units in operation, with the total installed capacity

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ranking third globally. Additionally, 28 nuclear power units were under construction, the installed capacity of which had maintained the top position globally for 18 consecutive years. China's nuclear power generation has been growing steadily, and in 2024, it accounted for 4.72% of the country's total electricity generation [3]. China is on track to overtake both the United States and the European Union in terms of installed nuclear power capacity by 2030 [1].

The development of nuclear energy technology and the nuclear power industry offers hope for addressing the energy demands of modern industry. However, this relies entirely on the stable and safe operation of nuclear facilities. The quality and reliability of the systems, equipment, and components that constitute nuclear facilities serve as the foundation for ensuring their safe operation. Consequently, while nuclear power operators take overall responsibility for the nuclear safety of nuclear facilities, the nuclear supply chain and equipment suppliers shoulder corresponding nuclear safety responsibilities. The research topic of this paper focuses on the qualification requirements and management of nuclear equipment suppliers in different countries, with a particular emphasis on China's practices.

2 Overview of Nuclear Equipment Regulation

As of 2023, 31 countries had operational nuclear power units, while another 3 countries had nuclear power units under construction [4]. Given the unique nature of nuclear power and the utmost importance of nuclear safety, the International Atomic Energy Agency (IAEA) has stipulated in multiple documents and standards that countries using nuclear power should establish independent regulatory agencies [5-8]. Countries using nuclear power generally implement supervision in varying ways and to different extents throughout the entire life cycle of nuclear facilities, encompassing site selection, design, construction, commissioning, operation, and decommissioning. As for the regulation of nuclear equipment activities and equipment suppliers, a common practice is that the regulatory agencies conduct regular or irregular supervision and inspections of equipment activities in different cycles and forms. Apart from that, there are significant disparities in qualification management of equipment suppliers among countries.

The qualification management of nuclear equipment suppliers in various countries mainly falls into four categories: (1) the regulatory agency authorizes and recognizes a third-party organization, which then conducts assessments and evaluations of suppliers or their products in accordance with standards and regulations; (2) certification of quality system; (3) the operator conducts evaluations and authorizations of suppliers through its internal control; (4) the regulatory agency directly grants administrative licenses to suppliers.

3 Regulation Through Third-Party Organization

In this regulatory model, the regulatory agency does not impose direct requirements of license on the qualification of equipment suppliers. Instead, some third-party organizations are tasked with evaluating and appraising the equipment provided by suppliers, and these third-party organizaitons must obtain the recognition or authorization of the national nuclear safety regulatory agency. This is the most widely adopted approach.

In France, the national nuclear safety regulatory agency is the French Authority for Nuclear Safety and Radiation Protection (ASNR) [9], and the regulatory legislation related to equipment is *Equipement Sous Pression Nucléaire (ESPN)*. *ESPN* defines and classifies nuclear pressure-retaining equipment based on the nature of the fluid it contains. Mechanical pressure-retaining equipment is classified into levels of N1, N2, N3 and NC. To manage equipment of different levels, the Conformity Assessment Module is employed. For N1 equipment, ASNR directly conducts the conformity assessment; for N2 and N3 equipment, some third-party organizations (commonly referred to as Agreed Notified Bodies, ANBs, or Conformity Assessment Bodies, CABs) are responsible for the conformity assessment. In addition, some welding procedure qualifications during the equipment manufacturing process require the approval of an independent third-party organization (different from ANBs, usually referred to as Independent Third Party, ITP). Both the aforementioned ANBs and ITPs should be authorized by ASNR.

The United Kingdom also adopts a similar equipment regulatory approach. The national nuclear safety regulatory agency is the Office for Nuclear Regulation (ONR). The UK does not have dedicated legislation on equipment

and generally incorporates the requirements of the ESPN legislation into contract documents.

The scope of equipment activities subject to the above-mentioned conformity assessment or third-party approval includes: design, material procurement and witnessing of manufacturing activities (such as welding procedure qualifications, hydrostatic tests, etc.).

The German government requires that all systems, structures and components used in nuclear facilities must meet the standards set by KTA (Kerntechnischer Ausschuss). The scope covers: organization and occupational health and safety, plant construction engineering, operation, electrical and instrumentation and control systems, mechanical components, reactor core and system design, and radiation protection. The German government authorizes and entrusts TUV (Technischer Überwachungsverein) as a third-party organization to conduct 100% independent inspections of the products provided by suppliers. Products that pass the inspections are marked with TUV marks.

The American Society of Mechanical Engineers (ASME) has developed a comprehensive set of codes and standards for the design, manufacture, and inspection of mechanical equipment [10], which are widely applied in the mechanical field all over the world. ASME certification belongs to the certification and accreditation by an independent third-party organizaiton, as a social professional association. It is a mandatory certification for boilers and pressure vessels exported to North American regions such as the United States and Canada. ASME certification programs related to nuclear equipment include: Boiler and Pressure Vessel (BPV), Nuclear Component (N-Type), Nuclear Quality Assurance (NQA-1), Nuclear Material Organization (QSC), Authorized Inspection Agency (AIA), Pressure Relief Device Testing Lab, and Personnel Certification. The US Nuclear Regulatory Commission (NRC), as the nuclear safety regulatory agency, recognizes the ASME codes and standards.

4 Certification of Quality System

In addition to certification of products meeting the requirements of technical standards, the certification of an enterprise's quality system is also an important qualification for enterprises engaged in nuclear equipment activities. The nuclear power standard system generally includes relevant requirements for organizational quality assurance, such as ASME NQA-1 and KTA 1401, therefore, certification according to those standards from a third-party organization may incorporate this part of certification of quality system.

Furthermore, the International Organization for Standardization (ISO) [11] develops sets of standards that have reached a consensus on an international scale, covering multiple process activities of enterprises. Among them, ISO 9000 family of standards on quality management is the most widely applied and highly recognized standard for quality management systems in industry. In countries where certification to nuclear power standards is not mandatory, most enterprises apply ISO 9000 to assess their management system. And the newly published ISO 19443: 2018 focuses on the specific requirements for the application of ISO 9001: 2015 by organizations in the nuclear energy sector's supply chain that provide products and services crucial to nuclear safety [12]. More and more countries have already incorporated or are considering incorporating ISO 19443 into their management regulations for equipment suppliers.

5 Operator's Internal Control

Although most countries do not have administrative license requirements from the national nuclear safety regulatory level for nuclear equipment suppliers' qualifications, during the construction of nuclear facilities, nuclear power operators will have specific internal control requirements. They will review the suppliers' quality management system, production capacity and the compliance of products with standards, and authorize or certify suppliers that meet all the internal requirements. Only suppliers that have obtained authorization or certification are eligible to provide equipment for nuclear facilities.

Électricité de France (EDF) issues EDF certification to its qualified equipment suppliers, and the certification is valid for 5 years. Japanese electricity companies and some EPC companies like Mitsubishi Heavy Industries, IHI Corporation and Mitsubishi Hitachi Power System, conduct audits and approvals of suppliers, and qualified suppliers that obtain the approvals will undergo long-term regular audits. Velan SAS issues suppliers with qualification review reports. AREVA NP retains a list of qualified suppliers. ANDRITS Group conducts authorization certifications.

6 Administrative Licenses Directly from the Regulatory Agency

Countries like Russia and China have different qualification requirements for nuclear equipment suppliers compared to the third-party certificate or the operators' internal control mentioned above. Instead, the regulatory agencies directly grant administrative licenses to suppliers. The following details the licensing system of China's national nuclear safety regulatory department for equipment suppliers [13, 14].

6.1 Introduction of the Licensing Regime

The national nuclear safety regulatory department of China is the National Nuclear Safety Administration (NNSA) [15]. The administrative license granted by the regulatory agency to equipment suppliers is a qualification permitting regime, which is mandatorily required by laws and regulations. The goal of the licensing regime is to ensure the safe operation of civil nuclear facilities, prevent and respond to nuclear accidents, and thereby protect public health and the ecological environment, through the regulation of civil nuclear safety equipment. The subject of the license is the supplier, rather than a specific batch of products they produce. The application for license shall go through a set of standardized and rigorous procedures, in which the technical capabilities and operation process of the suppliers' management system are evaluated. NNSA has established a series of laws and regulations to standardize and restrict the procedures of license application, modification, renewal and so on.

6.2 Scope of Licensed Activities and Licensed Equipment

Enterprises that would provide nuclear safety equipment design, manufacturing, installation or non-destructive testing (NDT) services for nuclear facilities in China, should apply for a license in advance. Based on the scope of licensed activities, there are four types of licenses: design, manufacturing, installation and NDT.

The scope of licensed equipment is "civil nuclear safety equipment", that is, equipment performing nuclear safety functions in civil nuclear facilities, including nuclear safety mechanical equipment and nuclear safety electrical equipment, which is far beyond the scope of mechanical pressure-retaining equipment. According to the safety functions performed by the equipment, mechanical equipment is classified into nuclear safety levels 1, 2, 3 and non-safety level, and electrical equipment is classified into levels of 1E and non-1E. NNSA has issued the *Catalogue of Civil Nuclear Safety Equipment* to specifically define the categories and types of licensed equipment. For instance, in the valve category, there are isolation valves, control valves, check valves, and other types of valves.

6.3 Obtainment, Maintenance and Invalidity of License

When a supplier intends to provide equipment products or services within the scope required by the regulations mentioned above for Chinese nuclear facilities, it should apply to NNSA for corresponding license in advance. This is a necessary condition for starting production activities, and all the subsequent process of production activities should be under the supervision of NNSA.

The application materials should be fully prepared and formally submitted by the supplier, including introductions and supporting materials of the organization's technical capabilities, valid performance, quality system, safety culture construction, etc., as required by regulations, as well as the production scheme and quality plan of the mock-up. After NNSA decides to accept the application, it will entrust one to two technical supporting organizations (TSOs) to conduct technical reviews and evaluations on all the relevant materials and process, including inspections during the mock-up production.

The detailed and comprehensive evaluation reports submitted by the TSOs will be discussed by the expert committee, after which the application enters the multi-level administrative decision-making process within NNSA. Finally, the equipment supplier is granted the license and thereafter performs the activities specified in the license. The main process for obtaining a civil nuclear safety equipment activity license is shown in Figure 1.

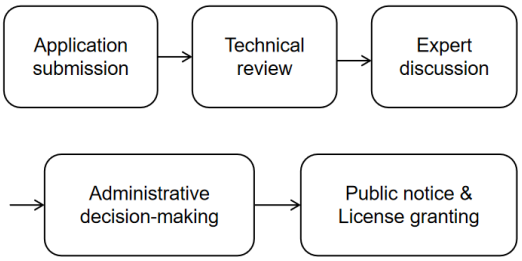

Figure 1 Main process of license acquisition

The validity period of a civil nuclear safety equipment activity license is 5 years. Suppliers that intend to continue engaging in relevant activities after the license expires should submit a renewal application to NNSA within the specified time. Factors determining whether the license can be renewed include: the maintenance of the supplier's technical capabilities during the validity period of the license, the quality and reliability of the supplied products and services, etc.

In addition to failure to renew the license on time when it expires, serious violations, counterfeiting, or capacity degradation during the validity period of the license may lead to the invalidation of the supplier's license. Once the license becomes invalid, any equipment supplier engaging in the corresponding activities or supplying products or services ill be acting illegal.

7 Analysis of Pros and Cons of China's Unique Licensing Regime to Equipment Suppliers

The NNSA's grant of activity licenses to equipment suppliers is a comprehensive evaluation. It is not, as described in Part 2 of this paper, an evaluation of a certain type or batch of products, but an assessment of the overall capabilities of the enterprise, considering both technical and management aspects, i.e., the enterprise's current hardware conditions, the compliance of past performance with standards and specifications, and its operation quality, the operation of the quality system, and the ability to produce mock-ups to verify the production process of products within a specific parameter range in the future.

The direct licensing regime from the regulatory agency has the following advantages:

(1) License is a legally mandatory requirement, which sets the first threshold for enterprises entering the market competition of nuclear power equipment. Holding a license proves that an enterprise has sufficient production capabilities and a valid quality system, which is a unified necessary condition in equipment bidding, improving the efficiency and fairness of the bidding process.

(2) Many guidelines or recommended provisions in nuclear power industry have become mandatory requirements for license applications and renewals, such as the promotion of safety culture, the construction of anti-CFSIs system, and the operation of experience feedback system. In fact, the threshold requirements for suppliers to enter nuclear power industry are higher, which is beneficial to the overall quality awareness and reliability level of the supply chain.

(3) Since the process of applying for and obtaining a license is strict and complex, involving technical reviews, administrative decision-making and mock-up of simulations within a complete set of qualification tests if necessary, once a supplier is granted a license, it has a high degree of dependence on the nuclear power industry. The supplier will also invest sufficient resources to maintain its license qualification. Therefore, the stability of suppliers in the nuclear power market is strong.

(4) NNSA has a "zero-tolerance" attitude towards violations and falsification of equipment suppliers. There are clear penalty provisions such as suspension of activities, revocation of licenses and fines in laws and regulations, which provide a direct legal basis for addressing widely concerned issues as CFSIs. The penalties under the licensing regime are forceful, efficient and effective.

However, this qualification licensing regime also has the following issues worthy of attention:

(1) As of February 28, 2025, a total of 230 domestic Chinese enterprises hold licenses of civil nuclear safety equipment activities, and 155 overseas enterprises have been registered for that. Reviewing and managing the qualifications of these enterprises require a large number of technical personnel and administrative resources. It is necessary to ensure the intensity of regulation as well as to improve regulation efficiency.

(2) As mentioned above, the granting of license qualifications takes both of technical and management aspects into consideration, which requires the regulatory personnel not only to have a deep understanding of standards and specifications of nuclear equipment, but also to constantly reflect and improve management methods to adapt to the development of advanced nuclear power technology. In other words, the comprehensive quality requirements for regulatory personnel are high.

(3) Currently, nuclear power technology is developing rapidly, and the direct and detailed regulation of equipment suppliers may not be efficient in com-

mercial processes and unavoidably incompatible with new technologies. For example, many new types of equipment different from traditional reactors have emerged in various new research reactors and other small-scale reactors, and new processes and new methods emerging during the design and manufacturing process are beyond the original scope of regulation. All those prompt the regulation means and requirements to progress accordingly.

8 Conclusions

Equipment is the basic unit constituting nuclear facilities. The reliable quality of each piece of equipment jointly guarantees the safety of nuclear facilities. Different countries adopt different management methods and regimes for nuclear equipment. In some of them, equipment and suppliers are evaluated and approved by third-party organizations, and in some other of them, qualifications of suppliers are controlled by operators respectively. China, on the other hand, adopts a licensing regime of directly authorizing qualification to suppliers by the regulatory agency. In the context of the vigorous development of nuclear power construction, although this regime has certain limitations, it also plays an important role in guaranteeing nuclear safety and improving the overall level of equipment manufacturing industry.

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