

The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services



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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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FOREWORD

The OECD Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) is an international committee consisting primarily of senior nuclear regulators. It was established in 1989 as a forum for the exchange of information and experience among regulatory organisations and for the review of developments which could affect nuclear regulatory requirements. The committee is responsible for the NEA programme which deals with the regulation, licensing and inspection of nuclear installations. In particular, it shares information on current regulatory practices and operating experience.

The CNRA has produced a series of reports, known as regulatory guidance booklets or “green booklets”, which examine various regulatory challenges and address the major elements and contemporary issues of a nuclear safety regime. A compilation of the first thirteen booklets was issued in 2009 under the title *Improving Nuclear Regulation* [1]. Based on the consensus of CNRA members at their December 2008 meeting, a senior-level expert group was formed to produce a report on *The Nuclear Regulator’s Role in Assessing Licensee Oversight of Vendor and Other Contracted Services*. In preparing its report, the group considered previously published proceedings and reports (see References) by the CNRA and the International Atomic Energy Agency (IAEA).

The current report focuses on nuclear power plants; however, the principles addressing the oversight of contractors have equal applicability to other types of nuclear installations. “Safety” is understood to incorporate the nuclear safety of systems, structures and components, the radiological protection of workers, the public and the environment, and the health and safety of those who might be affected by the facility throughout each phase of its lifetime. All references to contractors are intended to include the whole of the contracting and subcontracting chain, whether for the provision of goods or services to be supplied to the nuclear facility, or for the performance of activities partly or wholly at the nuclear facility. “Contractors” are thus understood to include designers, vendors, suppliers, manufacturers and any chains of subcontractors involved in the supply of items or services to the licensed site.

The audience for this report is primarily nuclear regulatory bodies, although the information and ideas are also expected to be of interest to licensees and nuclear industry organisations in general, as well as of special interest to countries looking to begin a nuclear energy programme but which have yet to develop well-established regulatory regimes. The challenges apply to all phases throughout the lifetime of the nuclear facility, including design, siting, manufacturing, construction, commissioning, operation, maintenance and decommissioning.

This report is the result of contributions from all the members of the expert group. Glenn Tracy (United States) skilfully chaired the group, with technical and secretarial assistance from Diane Jackson and Jim Furness.

The senior-level expert group consisted of the following representatives:

Mr. Pierre Barras	Belgium
Mr. Ken Lafreniere	Canada
Mr. Jouko Mononen	Finland
Dr. Jean-Christophe Niel	France
Dr. Hartmut Klönk	Germany
Mr. Atsuhiko Kosaka	Japan
Mr. Shunsuke Ogiya	Japan
Dr. Albert Frischknecht	Switzerland
Mr. Jim Furness	United Kingdom
Mr. Glenn Tracy	United States
Ms. Diane Jackson	OECD Nuclear Energy Agency

Note: Dr. Frischknecht replaced Dr. Germerdonk as the Swiss delegate following the group's first meeting in 2009.

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EXECUTIVE SUMMARY

Contracted services are an integral part of the design, construction and operation of a nuclear facility. Changes in the nuclear industry sector, including the availability of nuclear expertise, the expansion of the international supply market and the introduction of new technologies have tended to increase the licensee's use of contracted services. These changes have created challenges for licensees and regulators related to the retention of nuclear expertise, the effective management of the interfaces between the licensees and contractors, and the oversight of contractor manufacturing quality in the context of greater multinational diversity. The regulatory body must address these challenges to provide assurance that the licensee maintains its responsibility for the safety of the facility, regardless of who provides goods and services for the facility or where the activities involved in the supply chain take place. This report is intended to assist regulatory bodies in assessing their current practices for the oversight of licensees' use of contractors, and to adapt them where necessary to meet the changing situation.

Throughout any contracting process, the licensee must retain ultimate responsibility for the quality of work performed, whether by its staff or by contractors, and for maintaining the safety of the licensed facility. Effective oversight by the licensee must ensure the quality of products and services from its contractors, and any chain of subcontractors, commensurate with their safety significance. The licensee's oversight must ensure compliance with applicable codes, standards and regulatory requirements of the country in which the service or product will be used. Regulatory bodies should ensure that the licensee is retaining its core technical capabilities to be an "intelligent customer" in its contracting process and oversight; has a robust management system to ensure the required quality and to be the "controlling mind" for all activities; and maintains (or at the appropriate time takes ownership of) its safety case to be the "design authority" for the facility.

Contractor oversight challenges have equal applicability to operating facilities, as well as to new construction. The need to upgrade facilities for long-term operation and to replace components at existing facilities has led to an increased use of contractors who may be drawn from other countries.

Additionally, for the construction of the new facilities being planned in a number of countries, there will be an increase in first-of-a-kind and turn-key projects, where the dependence on contractors will be substantially greater. As such, this report provides recommendations that apply to both mature and emergent regulatory bodies.

The regulatory body's assessment of the licensee's oversight of its contractors is based on a sample of activities that should be aimed primarily at ensuring that the licensee is meeting its overall responsibility for the safety of its nuclear installation. The regulatory body's activities for assessing the adequacy of the licensee's oversight of its contractors should not be seen as duplication of the oversight of contractors, which should be exercised by the licensee. It is clear that the potential for the regulatory body to have a presence at the contractors' premises adds to the robustness of the quality and safety assurance of safety-significant equipment and activities.

The report also includes a sample of guiding questions to consider when assessing the adequacy of the licensee's oversight of contractors. Depending on the nature of the contracted activity and the regulatory structure, the questions can be adapted as required to meet the particular circumstances faced by the regulatory body.

1. INTRODUCTION

Contractors have long been an integral part of the resources available to a licensee, particularly in relation to the design, construction, maintenance and modification of nuclear power plants. Indeed, contractors can be regarded as part of the licensee's team, bringing specialist skills and expertise, and additional manpower to particular tasks. To the regulatory body, whether work is performed by the licensee's employees or by contractors is immaterial in the assessment of safety. However, when a licensee chooses to use a contractor, the licensee's oversight of the contractor is of interest to the regulatory body. Regulatory oversight must extend to include the activities of those contractors whose work could affect safety at the licensed facility.

When assessing the licensee's oversight of contractors, the regulatory body must make rational judgements on the extent and the method of regulatory oversight that needs to be applied. The choice will depend on a range of factors including the safety significance of the goods or services being supplied, the previous experience of the licensee and the contractor in relation to the goods or services being procured, the presence of any novel or unusual features, the extent of evidence available that the appropriate quality can be demonstrated, and the national legislation that governs the regulatory body. Much of the same considerations will apply to the degree to which the licensee should be involved in the contractor's activities. All of the parties will be aware of the different sanctions that are ultimately available to the licensee and the regulator, and this will affect the relationships that each has with the contractor.

Two fundamental principles which provide a foundation for the regulatory body's role in the assessment of the licensee's oversight of contractors are the following:

The licensee shall retain primary responsibility for the safety of its licensed facility, including responsibility for those activities of contractors and subcontractors which might affect safety.

The regulatory body should, through its regulatory activities, provide assurance that the licensee meets its responsibilities for the safety of its facility. This includes assuring that the licensee provides the appropriate level of oversight of all contractors and subcontractors, commensurate with the safety significance of the activity.

These fundamental principles are an extension of the requirements in the Convention on Nuclear Safety (CNS). Although the CNS contains no specific reference to contractors, it is clear that if the licensee holds the prime responsibility for safety, the licensee has the responsibility for the activities of any contractors that it uses and for the activities in the chain of subcontractors. This concept is reinforced by international organisations and has been documented in various reports such as the IAEA GS-R-3 [2] report on management systems, and its associated guides.

It is essential that the licensee retains the capability to be:

- The “controlling mind” of those core activities for which the licence has been granted. Ceding that control to other parties would not be consistent with the principle that the licensee retains primary responsibility for safety.
- The “design authority” [3] which understands the basis of the safety case, and the significance of ensuring that all activities are designed so as to keep the facility within the boundaries of the safety case.
- An “intelligent customer” or “smart buyer” for the goods and services being procured.

2. CHALLENGES

The licensee's use of contractors presents challenges that are grouped under four categories. Important features under each of these headings are outlined in the following sections.

Challenges with the retention of nuclear expertise

The global interest in constructing nuclear facilities has led to the formation of some new licensees and contractors, not all of whom have had longstanding experience in the field of nuclear safety. The general trend, driven by economic, financial and societal influences is towards:

- The merging of companies and the formation of new partnerships and alliances between licensees and some contractors, which will bring a new mixture of employees, skills, and diversity, and potentially a new safety culture.
- The greater ability for skilled staff of licensees and contractors to move between companies, thus challenging the knowledge management of these companies.
- The increased use of contractors drawn from other countries, with whom a relationship must be established and built to work effectively at each stage of the contract.
- Licensees tending to concentrate increasingly on their core business as a means of controlling the costs of work formerly done in-house and contracting more work than in the past.

The last decade has led to some loss of skills within existing nuclear organisations. Some experienced people have retired without their knowledge being transferred to other workers. Written procedures and available documentation did not necessarily capture all the information needed to retain the lessons learned from operating history, to understand the nuances of the safety case and to train new recruits. Additionally, there was a reduction in the

intake of new students interested in the nuclear field, which now makes it more difficult to recruit individuals with the necessary qualifications.

In some countries, existing nuclear plants are entering or preparing for the long-term operation. As such, it is even more important for licensees to retain sufficient knowledge of the technical details of the original safety case, as well as understanding the need for, and safety justification of, any plant upgrades or updating to modern standards that might be required. This is more difficult where there has previously been a heavy reliance on contractors for key activities.

These issues are compounded in the case of an organisation seeking to become a licensee for the first time, possibly in a country without previous experience of nuclear power generation. In some of these countries, the regulatory body may also be newly formed. The prospective new licensee faces the challenge of creating an entirely new nuclear operating organisation, hiring and training managers and staff, and making the initial choice of reactor design and contractors for the main design, key components and for construction. In this context, the prospect of using a “turn-key” approach can be an appealing and practical option, the objective being to utilise the experience of design, manufacturing and construction consortia with previous experience of constructing a similar design in other countries.

However, additional challenges may arise from this approach. Reactor designs, particularly at the start of a new design generation, are far from static. A licensee who chooses a previously untried design must weigh the commercial risks. The regulatory body works to prevent such situations from having a detrimental effect on nuclear safety, but in these circumstances it should be expected that there will be major challenges for the regulatory body, and the strains in terms of the nuclear expertise available to both the licensee and the regulatory body can be very significant.

Challenges with the interfaces between the licensee and the contractors

A licensee’s relationship to any contractor is primarily of a commercial nature, based on a purchased service or work in return for a negotiated payment, but it will also include carefully defined safety and quality requirements. All contracts between licensee and contractors are therefore expected to be governed primarily by commercial objectives. Challenges at the interface between licensee and contractors arise when the contract requirements for less tangible aspects such as quality assurance, quality management, quality of safety cases, ways in which regulatory requirements can be satisfied, the

adequacy of the qualification of personnel have to be interpreted during the course of the contract.

Normally, contractors working at a licensed facility are under the direct supervision of the contractor's managerial personnel, but at the same time will have to comply with the relevant safety provisions and instructions set by the licensee. It is the licensee's responsibility to check the contractor's compliance with the relevant safety requirements at all stages of the supply chain and regardless of the location of the activity.

Licensees must take control of the drawings, design codes and documentation which describe the basis for licensing the construction, commissioning and operation of the nuclear facility in order to maintain design configuration control. Obtaining all of this detailed documentation from contractors can potentially give rise to tensions between the licensee's need to take over as the design authority, and the contractor's wish to retain what it sees as proprietary information. However, the licensee must have this information so that it can be preserved throughout the life of the facility, and in case the information is no longer available from its original source.

The regulatory body, through its programme of sampling inspection, tries to ensure that the licensee does not put into service any purchased component that does not meet the required specification. However, the regulatory body needs to make judgements on how far back up the procurement chain it is practicable to exercise its regulatory oversight. The general spirit of the IAEA GS-R-3 is to encourage regulators to examine the management systems of the licensee with the intention of reducing the precursor factors which could lead to a degradation of nuclear safety. In the case of contracting, the management systems for procurement form part of the licensee's overall management system, and weaknesses here could well have the potential to affect the nuclear safety of the facility. This report therefore recommends that regulatory bodies should consider the licensee's procurement arrangements within its list of candidate areas for regulatory oversight.

Challenges with multinational contracting and manufacturing

The variety of challenges that arise when dealing with projects involving multinational contracting and manufacturing range from differing levels of understanding among the participating organisations of the relevant regulatory requirements, to addressing the issues of cultural and linguistic diversity inherent in a global supply chain.

Licensees face the challenge of ensuring the quality of the thousands of parts and materials manufactured across the world that are used in their nuclear power plants. This challenge increases in complexity with more contractors and subcontractors within the supply chain, and differences in regulatory requirements, codes and standards in the various countries that may be involved. This expanded supply chain also increases the possibility, and challenges associated with preventing the entry of counterfeit, fraudulent or substandard parts.

Differences in regulatory requirements, nuclear codes, standards and safety goals among countries using nuclear power continue to be a challenge for regulators, licensees and the industry. The regulatory body and the licensee in the country where the components will be used might each impose requirements that differ from the specification that would be normal for the country in which the component is manufactured. It is important to ensure that the applicable regulatory requirements are known and understood by all those within the supply chain.

Contracts may be placed with contractors who are not completely familiar with the culture language and terminology of the country in which the equipment will be used. Licensees must ensure that contractors are familiar with the working practices and expectations regarding safety and security at the licensed site. Licensees also need to ensure that all of the information supplied by the design contractors is sufficiently clear and explicit to convey all the relevant requirements to the contractors chosen to manufacture, install and commission the equipment.

It is important that the safety culture and safety awareness of contractors along the whole of the supply chain is no less effective than that of the licensee in terms of assuring the future safety of the facility for which the component or service is being supplied. All contractors need to be fully aware of the safety significance of what they have been contracted to supply, and to demonstrate the same “questioning attitude” if any aspect of the work specified seems unusual or is not fully understood, or if any situation occurs during the course of the supply that could affect the quality of the finished component or service.

Translating technical drawings and construction-related documents into other languages can be a significant problem: some recent large construction sites have experienced workforce diversity resulting in more than five languages being spoken by contractors on site. The accurate translation of engineering documents requires the services of specialist translators with specific experience of the subject-matter if the licensee’s quality and safety management expectations are to be communicated effectively to those carrying out the work.

In those cases where the design and safety case documents for the facility originate from a country that uses a different convention, such as for measurements, drawings or materials, the conversion from one system to another may be considerably more complicated than simply applying the appropriate conversion factors. Materials made to mathematically “converted” dimensions may not be available in the country where the manufacturing takes place, and the use of the nearest equivalent “standard” size may significantly alter the originally-designed properties of significant structures. An example of this kind of challenge would be the different sizes of steel reinforcing bars and rolled steel structural sections that are standard in different regions of the world. Licensees should ensure that designers take full account of these issues if the country of the licensee or of the key equipment manufacturers uses different systems for the measurement of dimensions, material properties, pressures, temperatures and other parameters relevant to the design, manufacturing, construction, commissioning and operating processes. Regulatory oversight should review the adequacy of the licensee’s arrangements for dealing with the additional problems that can arise in such a situation.

Challenges with new technology and processes

Among the most notable changes related to nuclear power plants is the incorporation of modern technology into the design, including safety-related systems and components, and the implementation of innovative construction techniques for several recent designs. There have been several examples of design contractors from other countries proposing the use of novel design features with which the licensees and regulatory bodies have had no previous experience. New nuclear power plants, even though they share the same basic technical principles with their predecessors, make increasing use of new technologies, particularly in relation to software and digital instrumentation and control (I&C). Additionally, the increasing use of prefabrication, preassembly, and modularisation means an increase in the size and complexity of the modules being installed, from building elements or components to sub-systems or systems, ranging in some cases up to entire plant structures. This potentially increases project vulnerabilities in the event that regulatory requirements require changes to the design.

Some new approaches involve the pre-manufacture and storage of parts and components before specific customers have been identified. For example, to reduce costs and shorten delivery times, contractors may choose to manufacture a batch of components sufficient for several reactors, and store the batch, sometimes for a long time, for use in future projects. Some licensees have used components originally made for other plants (sometimes from a different country), and have faced problems in demonstrating that such components meet

the specific quality requirements for their particular country, given what could have been a long time in storage.

The acceptance of innovative structural design and manufacturing techniques, such as steel concrete composites and self-consolidating concrete, poses new challenges that have not been fully analysed. Innovative techniques, whilst offering potential benefits, may raise new issues due to the limited experience and confidence in their use, the limited availability of relevant standards that provide specific requirements regarding structural strength, and the need for additional samples, tests and analysis to justify their use in safety-related applications.

The use of digital I&C technology for process and control systems is another challenge faced by regulatory authorities as well as licensees. Demonstrating how software design, architecture, qualification and testing meet the regulatory requirements for separation, redundancy, diversity and the separation of control and protection functions is a particular problem. The growing use of digital technologies also increases the need to protect both control and safety systems against malicious attacks. New technologies in the area of human system interfaces, e.g., computer controlled systems and touch screens, may need new regulatory requirements to be defined, as well as new and additional competences, e.g., human and organisational factors engineering skills on the part of the licensee.

For long-term operation, the need for plant upgrades in existing facilities may be driven by such factors as the obsolescence of the original components, the non-availability of nuclear grade replacements, or the developments in safety standards. The regulatory body may need to consider proposals by the licensee for significant modifications to the facility in these circumstances, with correspondingly significant revisions to the original safety case. Changes to the I&C systems because of obsolescence is a typical example.

3. ELEMENTS OF REGULATORY ASSESSMENT OF THE LICENSEE'S OVERSIGHT

When assessing the licensee's method and extent of oversight needed for each product or service, the regulatory body must consider the safety significance of the product or service, and the evidence that will be needed to demonstrate that it meets the required quality. The licensee must provide appropriate oversight of contractors, especially those whose work is crucial to the safety of the facility, regardless if this work is performed at the licensee's facility, contractor's facility, or other locations.

The regulatory body should be able to make a judgement on the effectiveness of the licensee's programme for contract management to provide adequate assurance that the required quality levels have been achieved in the products or services from contractors.

The licensee's approach to the oversight of contractors

This section and the associated guidance questions highlight elements that a regulatory body should expect in a robust general contracting process. The regulatory body can structure its regulatory oversight based on some of the activities discussed here.

The licensee's oversight ensures that the expected product or service is delivered, and that the contractual requirements have been met, particularly with regard to safety and quality. Licensees should conduct all of their operations in accordance with suitable management systems that have a strong emphasis on safety and quality.

As part of its management system, each licensee should have a policy on the use of the contractors. The policy should include:

- the type of products and services that may be sourced from contractors, as well as when and how such sourcing may be performed;
- a definition of the core competencies and functions which must be retained within the licensee's organisation; and

- a logical justification for the subcontracting of any activity which is important to the safety of the plant.

All contracts between the licensee and any contractors, and through to any chains of subcontractors, should make it clear that the contractor's work will potentially be subject to oversight by the nuclear regulatory body of the country where the component or service will eventually be used, as well as by the licensee. Contract documents should therefore include the requirement for the regulatory body and the licensee to have rights of access for the purposes of oversight to the contractors' premises, which could be in another country and to any documents or information that might be relevant to quality or safety. Contractors and subcontractors will be expected to co-operate with the regulatory body and the licensee to facilitate this oversight in an effective and efficient manner. When the regulatory oversight takes place in another country, it is usual, as a matter of courtesy, to inform the regulatory body in that country so that it can observe the process if it wishes.

The licensee should have a process for the assessment or qualification of potential contractors, in which each contractor's capability to achieve the required levels of safety and quality is assessed prior to letting the contract. An assessment of the contractor's trustworthiness should be a part of the assessment process, and should include all staff within the contractor's organisation whose deliberate acts or omissions could affect the safety of the contracted work, or the licensed facility. The licensee's staff responsible for awarding qualifications to potential contractors must themselves possess the necessary competencies to make the assessment. Ongoing discussions with contractors enable the experience of contractors to be judged. The licensee may also use these discussions to advance its own knowledge in order to act as a better "intelligent customer" or "smart buyer". In some countries, the contractor assessment may result in the award of a formal qualification as a potential supplier for the items or services to be contracted, and only contractors holding the formal qualification might be invited to bid for the work.

The award of a formal qualification, or the decision to include a contractor on a list of potential contractors, should be based on the determination that the contractor can meet the technical, quality and safety requirements of the product or service to be supplied. The contractor's qualification should be granted for a specified time period. Feedback on the contractor's performance can be used as input to assess the contractor's continuing suitability to remain a qualified contractor. The award of a qualification may be conditional upon the contractor having addressed earlier comments or corrective actions which the licensee has identified. All concerns should either be resolved, or be part of an agreed programme for improvement, prior to (further) orders being placed with the

contractor. The licensee should maintain and regularly update a database containing all relevant information regarding the list of qualified contractors, which may assist in demonstrating regulatory compliance.

Where subcontracting is allowed by the terms of the contract between the licensee and the contractor, the contract should be clear on what parts of the work may be subcontracted, and whether the prior agreement or notification of the licensee is required. Such notification would, for example, enable the licensee to judge the suitability of the proposed subcontractor and put in place arrangements for the appropriate oversight of the subcontractor's work. The contractor should provide oversight of the subcontractor and maintain appropriate records; however, the primary responsibility remains with the licensee.

Some licensees use independent inspection agencies to assist in the oversight of contractors. The use of an independent third party inspection agency can add further robustness to the oversight process. Such inspection agencies can also provide the specialised knowledge needed to verify that the appropriate quality levels have been achieved. However, independent inspection agencies are themselves contractors acting on behalf of the licensee. As such, the scope of any independent inspection oversight needs to be defined by the licensee just as carefully as the work that is being contracted, and the work of the inspection organisation should also be overseen by the licensee.

Some countries have had previous experience of “turn-key” projects for the design and construction of new reactors, and this looks likely to be an increasing trend, particularly as a way for countries with limited previous nuclear experience to start or to expand their nuclear programmes. There have been a number of different approaches to the licensing of these turn-key projects in their early phases, and experiences have been mixed. At some stage, the licensee who is to be the eventual operator of the nuclear plant needs to take over as the “design authority” for the facility. Regardless of the choice of timing for the handover of the design authority responsibility from the original reactor design organisation to the licensee, there are a number of advantages in the eventual licensee being closely involved in the construction and commissioning of their facilities, even if the initial design phase may have already been completed. The licensee can use this involvement as a means of gaining the experience needed to take over as the design authority. Regulatory bodies also need to think very carefully about the questions of who is the “controlling mind” through each of these early phases – whether this is the reactor designer or vendor, the organisation responsible for construction and/or commissioning, the eventual licensee who will operate the facility, or possibly combinations of these organisations which may change over time.

The following are considered key elements in the licensee's oversight of contractors:

Within the contract document, the licensee should:

- Make clear the importance to safety of the quality of the goods or services to be supplied.
- State the need for a proper quality plan and management system within any contractor or subcontractor to ensure that the quality requirements, on which the plant's safety case is based, can be achieved. The quality plan should summarise the planned manufacturing stages, the quality and inspection checks planned to be carried out by the contractor at each stage of the process and who will sign off each of these checks, and the records which are to be retained and provided to the licensee.
- Include the information from the safety case that is relevant to the performance of the component or service during its lifetime.
- Identify relevant regulatory requirements that apply in the country where the equipment will be used, and specify clearly whether any drawings and/or specifications will need to be modified to fully reflect the national regulatory requirements where the equipment will be used.
- Identify all relevant security-related information requirements.
- Specify the requirements for the security clearance of contractor's staff who may have access to sensitive equipment or locations, whether on or off the licensed facility.
- Explain the system that will be used to monitor the contract as it progresses, identifying any predefined hold-points and the possibility of random checks.
- Include terms of agreements and the definition of applicable personnel requirements, including any special qualifications or training for the contractor's staff, special measures (such as site induction training, personal protective equipment, and fitness for duty) that may be applicable, delivery schedule, documentation requirements, etc.

- Establish formal lines of communication between the licensee and the contractor, including any consortium of architect/engineers, nuclear designers, and balance of plant designers – along with a clear definition of roles and responsibilities.
- Identify access rights for the licensee and regulatory body to the contractor's and any subcontractor's premises, and to any documentation relevant to the quality or safety of the items or services being supplied.
- Identify the system that will be used to update or change the contract after it has been awarded.
- Ensure the orderly hand-over of all design and safety case information to the licensee.

The licensee's management of the contractor oversight process should include:

- A confirmatory check that any decision to contract a service is in accordance with the licensee's overall policy on the use of contractors.
- A verification that work is only placed with contractors who are fully qualified to perform the work. This means that the contractor should possess both the necessary technical capability and the appropriate quality assurance qualification for the work being contracted.
- The periodic re-assessment of the contractor's qualification for the work.
- An expectation that contractors will continue to assure the trustworthiness of their staff throughout the course of the work.
- A system to maintain records of all oversight activities, including records of any subsequent repairs, re-work or re-testing.
- A process for identifying any non-conformances from contractors and their resolution.
- A means to collect feedback on the contractor's performance in areas such as technical competency, safety culture, reporting of non-conformities, and resolution of issues.
- A process to assess the contractor's oversight of subcontractors.

- A means to inform the regulatory body of relevant information on its use of contractors and how this has, or might, affect the safety of the plant.
- A process to assess and ensure that contractors understand the relevant safety requirements and have a safety-conscious working environment.
- The assessment of the contractor's management system, especially those processes and control/surveillance steps that may have an influence on the quality and the future safety implications of the provided products/services. The contractor's quality system may have been recognised as meeting known national or international quality standards, in addition to other standards which are applicable to the activities being subcontracted.
- The contractor's safety culture as demonstrated through training, corrective action programmes, and its prior experience of supply to the nuclear sector or other safety critical applications.
- The contractor's policies related to occupational health safety, radiation protection and environment.
- Other commercial and socio-economical aspects. Given the potential adverse effect on safety, consideration should be given to the contractor's financial stability and human resource management policies.

Regulatory assessment of the licensee's oversight

The basic regulatory approach for assessing the use of contractors by the licensee is designed to provide assurance that:

- Contracts are fulfilled in a manner that will not adversely affect the safety of the facilities.
- The quality of work and services supplied is commensurate with the safety significance of the activities.
- The licensee has made and implemented procedures that will detect non-conformances in contracted activities and prevent them from affecting the safety of the facility.

The manner in which regulatory oversight is implemented will depend upon the legislative framework, status of the national nuclear programme and the culture in each country. Whether requirements for the regulatory oversight of licensee's contractors have been defined within the national legislation or not, it is clear that the regulatory body should include within its regulatory system appropriate mechanisms that can provide assurance that the appropriate oversight of contractors is implemented by the licensee.

The regulatory approach should be based on the requirement that competence, quality standards and safety levels are never compromised. The regulatory body should verify that the competency for judging the quality of all safety-related work resides within the licensee's organisation, regardless of whether the work is carried out by the licensee's own staff or by contractors.

If the licensee uses an independent inspection agency to assist its oversight of contractors, the regulatory body should consider the suitability of the chosen agency, the scope of the oversight that the licensee has contracted the inspection agency to undertake on its behalf, and how the licensee is overseeing the work of the agency.

The regulatory body should verify that the licensee maintains processes in its management system for the use of contractors that provide oversight for the technical work and quality assurance systems of its contractors which is appropriate to the safety significance of the contracted work. The regulatory body should use its regulatory tools, such as inspections, audits and assessment to verify the licensee's oversight of contractors. These tools may need to be modified when the regulatory oversight involves locations other than licensed facilities, or takes place in other countries. The regulatory body can use the quality plan to identify points to witness an activity or perform an audit.

The regulatory body should assure that the licensee carries out the proper and comprehensive assessment of the work of its contractors, using documented procedures fit for this purpose. The regulatory assessment should include the licensee's oversight of the training, competence and experience of the contractor's staff, as well as the suitability of the contractor's facilities for the various stages involved in the manufacture, inspection and testing of the manufactured items. It is desirable for the regulatory body to produce guidance, providing the reasoning behind the regulatory requirements for the licensees' use of contractors.

The regulatory body needs to focus on the measures that will provide reasonable assurance that the specification for any goods or services, which forms a part of the basis of the plant's safety case, has been met. The regulatory

body also needs to verify that the licensee ensures that contractors have sufficient training, particularly in the areas where the contracted service can affect the safety case, so that the contractor is fully aware of the importance and link to safety of the quality of the item being made. Regulatory bodies must also assure that licensees maintain full traceability of components, robust evidence of their quality and compliance with country-specific requirements.

The following are considered key elements in the regulatory body's role in assessing the licensee's oversight of vendors and other contracted services.

Regulatory management

- The regulatory body should have sufficient expertise on management systems (with special emphasis on quality and safety), as well as on contract and procurement management.
- The regulatory body should develop a strategy for the assessment of the licensee's use of contractors, which could take the form of rules, standards, requirements or other guidance, depending on the legislative regime. The regulatory body should make the strategy known to the licensees, and apply the strategy in a consistent manner.

Process for regulatory inspection/assessment

- The regulatory body should verify that the licensee establishes and implements a contracting process which provides reasonable assurance that all procured items and services meet the required levels of quality and safety.
- The regulatory body should consider whether the licensee's documented procurement processes include an effective evaluation and selection process for potential contractors, and whether the licensee effectively implements this process.
- The regulatory body should confirm that the licensee verifies the performance of the contractor's processes to assure quality and safety.
- The regulatory body should inspect/assess the licensee's arrangements for ensuring that it has sufficient human and technical resources to oversee the contractor's work.
- The regulatory body needs to be aware of circumstances when the licensee is likely to make increasing use of contractors. The regulatory

body should also be aware if the licensee experiences increased difficulties in knowledge management as the result of an increased reliance of contractors.

- The regulatory body may review the licensee's analysis of the trend of the contractor's non-conformance reports in order to evaluate the impact on safety.
- The regulatory body should develop techniques to evaluate how safety and quality are achieved by the processes of both the licensee's and the contractor's management systems.
- The regulatory body should verify that the licensee authorises only suitably qualified and experienced staff to supervise the work of contractors.
- The regulatory body should check that the licensee, and where appropriate, the contractor's staff know how to contact the regulatory body in order to raise any safety concerns.
- The regulatory body should encourage the licensee to improve the awareness of contractors of their responsibility for safe working and effective management of their staff at all times, promoting a positive safety culture.

Information/knowledge and experience for the regulatory role

- The regulatory body should have access to all information and all places of work, including those of contractors, where it is relevant to the current and future safety of the licensed facility.
- The regulatory body should have access to procurement contracts and documents which may help the regulatory body to identify which activities to oversee. National policy in some countries may make it appropriate for price and cost information to be redacted prior to the copies of the documents being passed to the regulator. However, even in these countries, there may be particular circumstances in which it is necessary for the regulatory body to see the original non-redacted versions.
- The regulatory body should keep itself informed on the licensee's use of contractors and contractors' activities, and use this information in

developing its regulatory strategy and in focusing inspections, audits or assessments.

- The regulatory body should encourage the licensee to share information and experience regarding contractors with others in the licensees' communities.
- The regulatory body should encourage the licensee and its contractors to share information, knowledge, and lessons learnt from safety-significant events which might, in part, be due to inadequacies in its oversight of contractors.
- The regulatory body should ensure that the licensee and contractors have an effective corrective action process so that they can understand and correct deficiencies in order to prevent re-occurrence of quality- or safety-significant events.
- The regulatory body should protect all proprietary information, as well as considering sensitive information in inspections and assessments, by establishing processes and procedures for the exchange of this information with any technical support organisations (TSOs) that it may use. When selecting TSOs, the regulatory body should ensure that any potential conflicts of interest are declared and understood.

Communication

- Depending on the regulatory regime in each country, the regulatory body should discuss its regulatory strategy with stakeholders, and explain the regulatory system and the safety goals using meetings, workshops or conferences to which licensees and contractors are invited.
- Routine senior level meetings should be held between the regulatory body and the licensees, at which the discussion should include any organisational changes proposed by the licensee, including an increased use of contractors.
- Regulatory bodies should share among themselves information, knowledge and lessons learnt from deficiencies in contractor performance which might, in part, be due to inadequacies in the licensee's oversight of contractors.

Procurement oversight

- The regulatory body should be alert to the introduction by the licensee of cost management measures that could affect the safety of nuclear facilities. In relation to procurement, the regulatory body should make sure that the licensee recognises that the “best” tender does not necessarily mean the lowest price.
- The regulatory body should be aware that the mechanisms for placing contracts between suppliers and buyers have changed dramatically since the arrival of the Internet. The use of some procurement mechanisms, e.g., electronic reversed auctions (ERAs), may not be appropriate for the procurement of safety-significant equipment and services.
- The regulatory body should try to be alert to any practice that could distort the objectivity, fairness and transparency of the procurement process, as these may have an adverse effect on the nuclear safety of the facility. Because the nuclear regulatory body is likely to have a greater presence than any other government authority, if it has suspicions of any lack of integrity in the procurement process, it should draw these suspicions to the attention of the relevant government authority.

4. CONCLUSIONS

The regulatory approach for assessing the licensee's performance in its use of contractors is to provide reasonable assurance that contracts are fulfilled in a manner that will not adversely affect the safety of the facilities, and that the quality of work and services supplied is commensurate with the safety significance of the activities. The manner in which regulatory oversight is implemented will depend upon the legislative framework, the status of the national nuclear power programme and the culture in each country.

This report has described in detail some key elements for a regulatory body to consider when developing or verifying the effectiveness of its regulatory programme to meet the challenges of an environment in which licensees are making increasing use of contractors. Additionally, it has identified the important elements of a robust licensee oversight programme in order to help the regulatory body when planning its assessment of the effectiveness of the licensee's oversight programmes. The key elements include procurement and contract development, contract implementation throughout the supply chain, contractor quality management, access to documentation and facilities, communications and safety culture.

As contracted services change and licensees modify their oversight and procurement practices, regulatory bodies must also continually adapt to maintain their effectiveness in the assessment of the licensees' contracting practices in an increasingly international supply market. Such improvements in the oversight process will facilitate the ongoing multinational work to evaluate and eventually increase harmonisation in designs, regulations, standards and quality requirements that is now being supported by many of the regulatory bodies and by industry. Continued and increased international co-ordination and co-operation among regulatory bodies through the collection and dissemination of inspection findings, operating and construction experience, lessons learnt, and information related to substandard contractor products and services, including the timely identification and communication of information on counterfeit, fraudulent and substandard parts, is paramount. These efforts enhance regulatory effectiveness and efficiency in all countries without diminishing regulatory independence.

Gaining insights from the rules and practices of regulatory authorities of other countries greatly strengthens the effectiveness of regulatory activities. Enhanced co-operative agreements among regulatory bodies around the world should be aimed at developing common approaches towards addressing safety-significant issues and harmonising safety approaches, codes and standards, and inspection practices. Greater harmonisation would enhance confidence in meeting regulatory requirements in all countries. Such efforts would also assist in the development of more consistent nuclear regulatory policies in emerging nuclear countries.

APPENDIX: GUIDANCE QUESTIONS

These guidance questions are intended to be used as tools that the regulatory body can use when assessing the licensee’s oversight of vendor and other contracted services. Depending on the nature of the contracted activity and regulatory structure, further questions can be added, as necessary by the particular circumstances. They should be taken as examples that can be adapted to fit into each country’s legal framework and regulatory approach.

Section	Guidance questions
1.	General process for contracting
1.1	Does the licensee have a clear policy governing what activities or services may be contracted and what should remain in-house?
1.2	Does the licensee have formal processes and procedures for contracting?
1.3	Do the licensee’s policies include the requirement to retain the core competencies needed to remain the “controlling mind” for the licensed facility?
1.4	Does the licensee’s staff have the necessary qualifications to ensure it is an “intelligent customer” or “smart buyer” for the contracted goods or services? This includes the ability to: <ul style="list-style-type: none"> - draft an invitation to tender, including the accompanying technical specification for the work? - carry out the process of evaluating potential contractors, including their safety culture, know-how and previous experience? - judge between several tenders for work? - ensure effective oversight of the contract during its execution phase?
1.5	Does the licensee have a management system that ensures contracted goods or services conform to specified purchase requirements?
1.6	Does the licensee’s management system include provisions that the type and level of oversight applied to the contractor and the procurement of goods and services recognises their related safety significance?

Section	Guidance questions
2.	Procurement
2.1	Does the licensee ensure that all relevant information for the safety case is included in the procurement documentation?
2.2	Does the licensee ensure that all relevant legislative and regulatory requirements are either included or referenced in the procurement documentation?
2.3	Does the licensee include within the procurement documentation the requirement for those contractor’s staff who could, by their deliberate acts or omissions, degrade the safety of the licensed facility to hold a suitable security clearance?
2.4	Does the licensee have standard conditions of contract that provide rights of access for the staff of the licensee, and of the regulatory body which has jurisdiction in the licensee’s country to the contractor’s premises and to any subcontractors, and to documentation relevant to the contract? Do these rights include the ability to have unannounced access?
2.5	Does the licensee establish contractual requirements that the contractor notifies it of any product or service non-conformances and establish a system for the communication of these non-conformances?
2.6	Does the licensee define in the contract a means for resolving disputes between the licensee and the contractor, when these relate to the quality of work that affects safety?
2.7	Does the licensee have in mind that the “best” tender does not necessarily mean the lowest price? Does the licensee ensure that the contractor applies a similar approach to any subcontracts?
2.8	Does the licensee verify that potential contractors have the relevant quality assurance or quality management qualifications?
2.9	Does the licensee assess organisational matters, such as the financial stability of potential contractors, their industrial relations policies, and the pattern of staff turnover, as these pertain to safety?
2.10	Does the licensee maintain an up-to-date list of qualified and certified contractors?
2.11	Does the licensee’s system ensure that the contractor delivers all relevant documentation to the required level of quality and in a timely manner?

Section	Guidance questions
3.	Contract implementation and oversight
3.1	Does the licensee include a requirement in the contract, when necessary, for the contractor to supply a quality plan? Does the quality plan include the checks that are necessary to demonstrate that the required quality will be delivered in the finished product or service?
3.2	Do contracts include a requirement for the relevant training and qualification of contractor's staff that will be involved in the contracted activity?
3.3	Does the licensee stipulate whether contractors may or may not use subcontractors?
3.4	Does the licensee's staff have the appropriate expertise to monitor the quality of the work during the contract?
3.5	Does the licensee adequately document its oversight activities, including the oversight by independent inspection agencies?
3.6	Does the licensee assess the contractor's performance, including any subcontractors, in accordance with the safety significance of the contracted service and use feedback from this assessment to refine its oversight of the contractor's work?
3.7	Does the licensee have defined hold points at which it formally inspects the delivered service?
3.8	Does the licensee have a system to effectively document and address non-conformances from the contractor in accordance with their safety significance?
3.9	Does the licensee's system ensure that any such non-conformance reports are raised to the appropriate level in the licensee's organisation, depending on their safety significance?
3.10	Is there a clear path and sufficient organisational freedom for licensee staff, contractors and subcontractors to raise and document safety and quality concerns and issues without fear of retaliation?
3.11	Does the licensee communicate the importance of a good safety culture to the contractor?
3.12	Does the licensee's management system include a means to address issues which can be caused by multinational contracting and workforce cultural and linguistic diversity?
3.13	Does the licensee communicate the final acceptance of the work to the regulatory body?

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Additional reading material related to the subject of this report:

NEA/CNRA/R(2007)1 WGIP: Proceedings of the 8th International Nuclear Regulatory Inspection Workshop on how international nuclear regulatory inspections can promote, or not promote, good safety culture, inspection of interactions between the licensee and its contractors and future challenges for inspectors (e.g. new techniques, developing competence, etc.), held on 1–3 May 2006 in Toronto, Canada.

Proceedings: www.nea.fr/nsd/docs/2007/cnra-r-2007-1.pdf.

Appendix: www.nea.fr/nsd/docs/2007/cnra-r-2007-2.pdf.

NEA/CNRA/R(2003)4 WGIP: “Nuclear Regulatory Inspection of Contracted Work Survey Results”, www.nea.fr/nsd/docs/2003/cnra-r-2003-4.pdf.

IAEA Peer Discussion Report, “Regulatory Control of the Use of Contractors by Operating Organisations”, PDRP-5, 2000, www-pub.iaea.org/MTCD/publications/PDF/pdrp_005_prn.pdf.

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