The Swedish Radiation Safety Authority’s Regulations and General Recommendations concerning Exemptions from the Requirement for Approval of Contractors

Please note that translated versions of the Authority’s regulations lack legal force and are for information purposes only.
The Swedish Radiation Safety Authority’s Regulations concerning Exemptions from the Requirement for Approval of Contractors;¹ decided on 19 December 2008.

On the basis of Section 17 of the Ordinance (1984:14) on Nuclear Activities, the Swedish Radiation Safety Authority issues the following regulations.

Scope
Section 1 These regulations contain provisions concerning exceptions from the requirement for approval of contractors in accordance with Section 5, second paragraph, point 1 of the Act (1984:3) on Nuclear Activities.

Definitions
Section 2 The terms nuclear activities, nuclear facility, nuclear material and nuclear waste carry the same meaning in these regulations as in Sections 1 and 2 of the Act (1984:3) on Nuclear Activities.

The following terms and definitions are also used in these regulations:

licensee: the holder of a licence according to Section 5 of the Act (1984:3) on Nuclear Activities to conduct nuclear activities,

contractor: any private person or legal entity that is contracted by a licensee to take measures which, according to the Act (1984:3) on Nuclear Activities, shall be carried out by the licensee.

¹ These regulations and general recommendations were previously published in the Swedish Nuclear Power Inspectorate Regulatory Code (SKIFS 2006:1)
Exceptions from the requirement for approval

Section 3 A licensee may, after notifying the Swedish Radiation Safety Authority, without approval by the Authority, engage a contractor to take the following measures:

1. construct or assemble: buildings or structures, systems, components or devices in a nuclear facility,
2. dismantle or demolish: buildings or structures, systems, components or devices in a nuclear facility,
3. maintain and inspect or test: structures, systems, components or devices in a nuclear facility,
4. train personnel in tasks for the nuclear activities,
5. carry out qualified expert assignments which it is not reasonable for the licensee to perform with his own personnel,
6. keep such documentation as is required according to Chapter 8 of the Swedish Radiation Safety Authority’s Regulations (SSMFS 2008:1) concerning Safety in Nuclear Facilities.

The measures described in the first paragraph may, however, not pertain to all or significant portions of the measures covered by the licence according to the Act (1984:3) on Nuclear Activities. Nor may they pertain to surveillance measures or measures that entail interim storage or final disposal of nuclear materials or nuclear waste.

Provisions regarding security screening of personnel who participate in the activities at a nuclear facility are found in Section 7 of the Swedish Radiation Safety Authority’s Regulations (SSMFS 2008:12) on Physical Protection of Nuclear Facilities.

Licensee’s management

Section 4 In order for the exception according to Section 3 to be applicable, the measures must be performed under the licensee’s management and follow-up.

Provisions regarding management and follow-up of nuclear activities are found in the Swedish Radiation Safety Authority’s Regulations (SSMFS 2008:1) concerning Safety in Nuclear Facilities.

Notification of the Swedish Radiation Safety Authority

Section 5 The Swedish Radiation Safety Authority shall be notified in accordance with Section 3, first paragraph, before the assignment is begun, and the notification shall include a description of what the assignment involves as well as reasons why the licensee does not carry out the measures included in the assignment himself.

Assignments of fundamental importance

Section 6 In cases where the Swedish Radiation Safety Authority finds after notification that an assignment can be considered to be of fundamen-
Exceptions from the requirement for approval

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Assignments of fundamental importance

Section 6

In cases where the Swedish Radiation Safety Authority finds after notification that an assignment can be considered to be of fundamental or otherwise particular importance, the Swedish Radiation Safety Authority may, notwithstanding these regulations, decide that the assignment may not be given to a contractor without approval according to Section 5, second paragraph, of the Act (1984:3) on Nuclear Activities.

These regulations shall enter into force as of 1 February 2009.

SWEDISH RADIATION SAFETY AUTHORITY

ANN-LOUISE EKSBORG

Tomas Isenstam
The Swedish Radiation Safety Authority hereby issues the following general recommendations.

Section 1
On exceptions from the requirement for approval

According to Section 5, first paragraph, of the Act (1984:3) on Nuclear Activities (Nuclear Activities Act), nuclear activities may not be conducted without a licence. A permit is required for construction and a licence for ownership and operation of a nuclear facility. A licence to operate a nuclear facility is thus issued to a specific owner.

The provisions in Section 5, second paragraph, of the Nuclear Activities Act regarding the requirement for approval before a licensee engages a contractor to carry out a measure that is covered by the licence under the Act follow from the Act's requirement for a permit/licence to construct, own or operate a nuclear facility.

Section 5, fourth paragraph, of the Nuclear Activities Act provides a possibility to except certain assignments from the requirement for approval. If the task is suitable and the licensee controls its content and execution, the requirement for approval can be replaced by notification of the Swedish Radiation Protection Agency. According to the travaux préparatoires, the provision is intended for e.g. recurrent qualified expert assignments that are limited in time and that the licensee cannot reasonably be required to perform. Another example is assignments involving measures that are uncomplicated from a nuclear viewpoint but that require special professional knowledge. Note that assignments that come from someone other than the licensee cannot be excepted from the requirement for approval. 

1 Cf. Section 1, second paragraph, of the Act (1984:3) on Nuclear Activities (Nuclear Activities Act).

The Swedish Radiation Safety Authority’s General Recommendations concerning the Application of the Regulations concerning Exceptions from the Requirement for Approval of Contractors;

decided on 19 December 2008.

The Swedish Radiation Safety Authority hereby issues the following general recommendations.

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According to Section 5, first paragraph, of the Act (1984:3) on Nuclear Activities (Nuclear Activities Act), nuclear activities may not be conducted without a licence. A permit is required for construction and a licence for ownership and operation of a nuclear facility. A licence to operate a nuclear facility is thus issued to a specific owner.

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With the support of the authorization in Section 5, fourth paragraph, of the Nuclear Activities Act, the Government has delegated to the Swedish Radiation Safety Authority the power to define the conditions for exceptions from the requirement for approval of contractors. Of importance in this context are the implications of the concepts “nuclear activities”, “construction of a nuclear facility” and “operation of a nuclear facility” according to the Nuclear Activities Act.

The concept “nuclear activities”

The Nuclear Activities Act applies to nuclear activities. The concept “nuclear activities” is of central importance for the systematics and scope of the Act. It is particularly important since nuclear activities require a licence and special approval before an assignment can be given to a contractor.

By “nuclear activities” is meant:

- the construction, possession or operation of a nuclear facility,
- the decommissioning and dismantling of a nuclear facility,
- the acquisition, possession, transfer, handling, treatment, transport of or other dealings with nuclear material or nuclear waste,
- the import into Sweden of nuclear material or nuclear waste,
- the export from Sweden of nuclear waste.

The concept “nuclear activities” does not include design or manufacture of goods or products such as pumps, valves, pipe fittings, concrete or other items that are required for the nuclear activity. The manufacture of a steam generator for a pressurized water reactor is another example of a measure that is not included in the concept “nuclear activities”.

It is only when the pump, valve or steam generator is installed in the nuclear facility or when the concrete is poured into its forms or the pipe fittings are assembled that they can be said to constitute nuclear activities. The specified requirements on properties, performance and function that apply according to the Nuclear Activities Act, SSM’s regulations or the licence conditions for the facility will then be applicable. The licensee must be able to show that the installed products or devices possess the required durability and reliability. The same applies to the analyses that are made of the facility’s barriers and defence-in-depth. It is only when these analyses are entered into the facility’s safety analysis report (SAR) that the requirements under the Nuclear Activities Act, SSM’s regulations or the licence conditions for the facility become applicable.

Anyone who, for example, applies for a permit to construct a new nuclear facility should, however, perform certain checks or take other measures...
during the design or manufacturing stage of a product to ensure that the installed products or devices possess the required durability and reliability.

Implications of the concept “construction of a nuclear facility”

There is no explicit definition in the Nuclear Activities Act of what construction of a nuclear facility entails, but it follows from the concept as such that it applies to new facilities. It is further evident that the concept pertains to all the measures with a bearing on safety that are taken to construct a nuclear facility on a given site after a permit has been issued.

The implications of the concept “operation of a nuclear facility”

Of central importance in this context are the implications of the concept “operation of a nuclear facility”. In order for it to be possible for a nuclear facility to be operated in a safe manner, a variety of different tasks must be performed in addition to the purely technical handling of the facility. Operation involves organizational, administrative and manpower-related tasks.

The basic provisions of Nuclear Activities Act, together with the general obligations of the licensees, provide an adequate definition of what is included in the concept “operation of a nuclear facility”. According to these provisions, the licensee shall, in connection with the operation of a nuclear facility, take the measures that are required:

- to prevent faults in or malfunction of equipment, improper handling or anything else that can lead to a radiological accident,
- to safely manage and dispose of spent nuclear fuel and nuclear waste arising in the activities,
- to decommission the nuclear facilities in which activities are no longer to be conducted,
- to prevent unlawful dealings with nuclear material or nuclear waste, and
- to ensure compliance with the obligations that follow from Sweden’s agreements for the purpose of preventing nuclear detonations and proliferation of nuclear weapons.

Section 3, first paragraph

The measures that a licensee may engage a contractor to perform, with exception from the requirement for approval according to Section 5, second paragraph, of the Nuclear Activities Act, are mentioned in this section.

Points 1 and 2 refer to measures taken at the nuclear facility or the building site.

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7 Cf. Sections 3 and 4 of the Nuclear Activities Act.
8 Cf. Sections 10 – 14 of the Nuclear Activities Act.
Point 3 refers for example to measures specified in the Swedish Radiation Safety’s Regulations (SSMFS 2008:13) concerning Mechanical Devices in Certain Nuclear Facilities. It may also refer to maintenance and service work that requires special equipment or special expert knowledge. It also applies to service work that is uncomplicated from a nuclear viewpoint, even if it requires professional knowledge from other viewpoints, such as service on various IT systems. Decontamination of radioactive parts may also be included.

Point 4 refers for example to measures for basic training and retraining for a position in accordance with the Swedish Radiation Safety’s Regulations (SSMFS 2008:32) concerning the Competence of Operations Personnel at Reactor Facilities.

Point 5 refers for example to measures in response to temporary work loads or measures of such a special kind that the licensee cannot reasonably be required to hire personnel with the equivalent expert competence.

Section 3, second paragraph

The second paragraph stipulates restrictions in the right to engage a contractor to take measures without approval. Approval is, for example, required when the licensee, instead of hiring his own personnel, engages one or more contractors to take measures that pertain to all or significant portions of the construction – for example a general contract – or operation of a nuclear facility.

An example of a case where significant portions of the operation of a nuclear facility have been contracted out is when a licensee wants to engage one or more contractors to take all or the majority of the service measures that are required for the operation of the facility.

In the procurement of contracts it should be clearly indicated in the tendering documents that the assignment may require approval under the Nuclear Activities Act.

Section 4 §

The fact that measures are performed under the licensee’s management and follow-up entails that the licensee should:

- formulate concrete goals and guidelines regarding how the contractor is to perform the work with regard to safety in the nuclear activity,
- ensure that the contractor has sufficient manpower and competence to carry out the assignment in a safe manner,
- ensure that the contractor has the necessary equipment for executing the assignment and that the contractor employs adequate methods and processes where applicable,
- ensure that the contractor employs management and quality systems that provide full control over safety in conjunction with the assignment and that manufactured and assembled structures, systems, components and devices meet stipulated safety requirements,
— continuously supervise the contractor’s activities to ensure that all regulatory requirements and licence conditions are satisfied, along with the goals and guidelines for the activity to which the assignment pertains,
— continuously follow up the contractor’s evaluation and reporting to the licensee of events and ensure that appropriate safety-related measures are taken,
— when necessary, instruct the contractor to take suitable measures, or take such measures himself if the contractor does not adhere to the goals and guidelines established for the assignment.

Section 5 §
Notification should be made in as good time as is possible and reasonable with a view to the nature of the assignment.

Section 6 §
According to Section 17 of the Ordinance (1984:14) on Nuclear Activities, the Swedish Radiation Safety Authority shall hand over, along with its own opinion, a matter concerning approval of a contractor to the Government for a ruling in cases where the matter is of fundamental or otherwise particular importance. In cases where the Swedish Radiation Safety Authority finds, in conjunction with its review of the notification according to Section 5, that a licensee has, pursuant to the regulations, engaged a contractor to take measures which can, according to the Authority, be considered to be of fundamental or otherwise particular importance, the Swedish Radiation Safety Authority may, pursuant to this section, decide that the matter is to be ruled on by the Government.

These general recommendations apply as of 1 February 2009.

SWEDISH RADIATION SAFETY AUTHORITY

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