# Nuclear Legislation in OECD and NEA Countries

Regulatory and Institutional Framework for Nuclear Activities



Switzerland





## Switzerland

<b>I</b> .	General Regulatory Regime	3
1.	Introduction	3
2.	Mining Regime	4
3.	Radioactive Substances, Nuclear Fuel and Equipment	5
	a) Nuclear fuels	5
	b) Radioactive substances and equipment generating ionising radiation	6
4.	Nuclear Installations	8
	a) Licensing and inspection, including nuclear safety	8
	b) Protection of the environment against radiation effects	11
	c) Emergency response	11
5.	Trade in Nuclear Materials and Equipment	13
6.	Radiation Protection	14
7.	Radioactive Waste Management	16
	a) Legal framework	16
	b) Waste categories	17
	c) Division of responsibilities for the management of radioactive waste	17
	d) Disposal of waste, storage and waste management programme	18
	e) Search for suitable sites for deep geological repositories	19
8.	Non-Proliferation and Physical Protection	21
9.	Transport	22
10.	Nuclear Third Party Liability	23
11.	Environmental Protection	25
п.	Institutional Framework	26
1.	Regulatory and Supervisory Authorities	27
	a) Federal Council	27
	b) Federal Assembly	27
	c) Federal Department of the Environment, Transport, Energy and Communications (DETEC)	28
	d) Swiss Federal Office of Energy (SFOE)	28
	e) Swiss Federal Nuclear Safety Inspectorate (ENSI)	28
	f) Federal Department of Home Affairs (FDHA)	29
	g) Federal Office of Public Health (FOPH)	29

	h) State Secretariat for Education, Research and Innovation (SERI)	30
	i) Other authorities	31
2.	Advisory Bodies	31
	a) Swiss Federal Nuclear Safety Commission (NSC)	31
	b) Federal Commission for Radiological Protection (CPR)	33
	c) The National Emergency Operations Centre (NEOC)	. 33
3.	Public and Semi-Public Agencies	34
	a) PSI	34
	b) Fund for the decommissioning of nuclear installations	
	and for waste disposal	35
	c) National Cooperative for the Disposal of Radioactive Waste (Nagra)	36

#### I. GENERAL REGULATORY REGIME

#### 1. Introduction

In 1946 the peaceful use of nuclear energy was first regulated by the Swiss Confederation in the form of a Federal Order, dated 18 December 1946, encouraging research in the field of nuclear energy.

Given the complexity of the issues raised by the use of nuclear technology and the fact that large sums of money are required to put it into effect, Parliament authorised an amendment to the Constitution in June 1957 (currently Article 90 of the Constitution of 18 April 1999) for nuclear legislation to fall within the sole jurisdiction of the Confederation. This was approved in a referendum and by all cantons in November 1957. Cantons, therefore, are not responsible for questions related to nuclear safety but have residual jurisdiction with regard to the licensing of nuclear installations (e.g. building permits, mining legislation, fire permits, water samples and use, etc.). This division of jurisdiction between federal and cantonal authorities was sanctioned by the Federal Supreme Court in the decisions of 18 August 1973 and 23 March 1977.

In Switzerland, the development and use of nuclear energy is not a state monopoly, and a large role is left to private industry. The first commercial nuclear power plant was brought into service in 1969. Many local authorities, however, have a direct or indirect interest in the operation of nuclear installations. There are, at present, four active nuclear power reactors located on three sites, with a total net capacity of 2 960 MWe: Beznau I and Beznau II in Döttingen, Gösgen in Däniken, and Leibstadt in the village of the same name near the border with Germany. Mühleberg in Bern is in the process of being decommissioned and was taken off the grid at the end of 2019. Nuclear energy represents almost 33% of Switzerland's annual electricity production. In addition, Switzerland operates several research reactors. One of these (now decommissioned) was located at the Department of Physics of the University of Basel and another is located at the Laboratory for Reactor Physics and Systems Behaviour (LRS) at the Swiss Federal Institute of Technology Lausanne (EPFL). Two decommissioned research reactors, and a third still in the process of being decommissioned, are located at the Paul Scherrer Institute (PSI).

It should also be noted that referenda on nuclear energy were held on 22 and 23 September 1990. The Swiss population and the cantons were asked to decide on three questions of major importance for the country's energy policy: a public motion, as set out in the Constitution, calling for the progressive and definitive abandonment of nuclear energy (rejected by a 52.9% majority); a public motion calling for a 10-year moratorium on the construction of all new nuclear power plants (accepted by a 54.6% majority); and a government proposal to amend the Constitution in order to give the Confederation authority to promote energy savings (accepted by a 71% majority). The cantons unanimously accepted the constitutional article on energy, while a majority of cantons decided in favour of the moratorium and against abandonment. Following a further referendum held on 18 May 2003, the population and the cantons rejected two popular constitutional initiatives called "Moratorium Plus" (*Moratorie Plus*) and "Phase-out Nuclear" (*Sortir du nucléaire*). On the same day, the Swiss population accepted the new Nuclear

Energy Act of 21 March 2003 (Nuclear Energy Act or NEA) (SR 732.1), presented by the government as a counterproposal to the two initiatives.<sup>1</sup>

The NEA entered into force on 1 February 2005, at the same time as its implementing ordinance, thereby replacing the former 1959 Atomic Act as amended, the Federal Order of 1978 and the implementing Ordinance of 18 January 1984 amended on several occasions. The Swiss atomic legislation needed to be amended in order to centralise some elements contained in several ordinances of the Federal Council (decommissioning of nuclear installations, disposal of radioactive waste and financing of such activities) and to introduce new elements (obligations to be complied with by operators of nuclear installations, adaptation of licensing procedures and reprocessing of radioactive waste). The new Nuclear Energy Act maintained the nuclear energy option: the construction of new nuclear plants remains possible as long as the most recent technology is used. However, a decision in principle of Parliament will be necessary in respect of any new nuclear facilities, which will also be subject to an optional referendum (see general authorisation procedure under Section 4).

On 27 November 2016, a referendum was held on the withdrawal from the use of nuclear energy. The referendum called for a ban on the construction of new nuclear power plants in Switzerland and for the duration of the service life of the five then-existing Swiss nuclear power plants to be limited. The Federal Council and Parliament recommended rejection of the referendum, and the Federal Council put forward its "Energy Strategy 2050" as an indirect counterproposal. The referendum was subsequently rejected by a 54.2% majority.

Energy Strategy 2050 is a package of measures that was accepted in a national referendum held on 21 May 2017.<sup>2</sup> Against the backdrop of the planned withdrawal from the use of nuclear energy, Energy Strategy 2050 is intended to secure the long-term supply of electricity in Switzerland. It includes measures to enhance energy efficiency, reduce CO<sub>2</sub> emissions and foster the use of renewable energy. One of its objectives is to reduce Switzerland's dependency on imports of fossil energy sources. The package also includes a ban on the licensing of new nuclear power plants (NEA, Article 12a), thus the existing nuclear power plants will not be replaced after they have been decommissioned. However, there is no prohibition of nuclear technology *per se*; nuclear research will be carried out as before, will be supported by the federal government, and will not be restricted by either Energy Strategy 2050 or by Energy Perspectives 2050+.

#### 2. Mining Regime

There are no special mining regulations in Switzerland relating to nuclear ores.

Nuclear ores (uranium and thorium) are not classified as nuclear materials within the meaning of the Nuclear Energy Ordinance of 10 December 2004 (NEO) (SR 732.11) (Article 1(2)(a)).<sup>3</sup>

3. An official translation of this ordinance can be found at: www.fedlex.admin.ch/eli/cc/2005/68/en.

<sup>1.</sup> An official English translation of this act can be found at: www.fedlex.admin.ch/eli/cc/2004/723/en.

More information on Energy Strategy 2050 can be found at: www.bfe.admin.ch/bfe/en/home/policy/energy-strategy-2050.html/.

#### 3. Radioactive Substances, Nuclear Fuel and Equipment

The Nuclear Energy Act simplifies the categories of radioactive substances. In this context, "nuclear fuel" no longer exists as a distinct category. In addition to "nuclear waste", the Act identifies three sub-categories within the general category of "nuclear goods" (NEA, Article 3(h)):

- nuclear materials, which means substances that may be used to produce energy by means of nuclear fission processes;
- materials and equipment intended or required for the use of nuclear energy; and
- technology that is required for developing, manufacturing and using goods cited in the above two points.

Nuclear materials are further specified in the NEO. According to Article 1(1) of the NEO, nuclear materials are the following source materials: uranium containing a naturally occurring mixture of isotopes; depleted uranium-235; thorium; and any other material containing the foregoing substances in whatever form. In addition, the following special fissile materials are considered nuclear materials: plutonium-239; uranium-233; uranium-235; enriched uranium, meaning uranium containing isotopes 235 or 233 or both in an amount such that the abundance ratio of the sum of these isotopes is greater than the ratio of the isotope 235 to the isotopes occurring in nature; and any other material containing the foregoing substances in whatever form.

In accordance with Article 1(2) of the NEO, the following are not considered nuclear materials: uranium and thorium ores; source materials that are not used for obtaining energy by means of nuclear fission processes, in particular source materials meant for the analysis and measurement, shielding or the production of industrial products, as well as the products themselves; and special fissile materials up to a weight of 15 grams.

Radioactive substances that do not fall under the Nuclear Energy Act are governed by the Radiation Protection Act of 22 March 1991 (RPA) (SR 814.50).<sup>4</sup>

#### a) Nuclear fuels

According to Article 13 of the NEO, the handling of nuclear materials and the storage and transport of nuclear fuels are subject to licensing by the Swiss Federal Office of Energy (SFOE). According to Article 3(j) of the NEA, handling means research, development, production, storage, transport, import, export, transit and brokerage.

The SFOE grants licences based on the technical advice of the Swiss Federal Nuclear Safety Inspectorate (ENSI). ENSI also certifies that the international regulations on the transport of dangerous goods have been complied with. Any export of sensitive nuclear materials, equipment and technology is considered in light of the Nuclear Suppliers Group (NSG) guidelines on nuclear transfers, subject to the provisions relating to the transfer of nuclear technology; applications are to be submitted to the SFOE and the State Secretariat for Economic Affairs.

The handling of nuclear fuels is subject to supervision by the Confederation, to which end the Confederation or any bodies designated by it may take all necessary steps to protect

<sup>4.</sup> An official translation can be found at: www.fedlex.admin.ch/eli/cc/1994/1933\_1933\_1933/en.

humans and the environment against the risks of nuclear energy. In practice, supervision is mainly carried out by ENSI.

The Nuclear Energy Act established a 10-year moratorium on the reprocessing of spent nuclear fuel beginning on 1 July 2006. This moratorium was subsequently extended to 2020. The initial package of Energy Strategy 2050 measures definitively prohibits the reprocessing of spent nuclear fuel elements (NEA, Article 9(1)). Instead, spent fuel elements must now be safely disposed of as radioactive waste.

#### b) Radioactive substances and equipment generating ionising radiation

The Radiation Protection Ordinance of 26 April 2017 (RPO) (SR 814.501) contains provisions regulating substances, objects and waste with a level of activity, concentration, contamination, dose rate or mass in excess of the values listed in the annex.<sup>5</sup> The licensing authorities are the Federal Office of Public Health (FOPH) and, in certain cases, ENSI.

In accordance with Article 11(2) of the RPO, ENSI is responsible for granting licences for the following: activities at nuclear installations which are not subject to mandatory licensing or a decommissioning order under the NEA; experiments involving radioactive substances in connection with geological investigations as specified in Article 35 of the NEA; the import and export of radioactive substances for or from nuclear installations; the transport of radioactive substances from and to nuclear installations; the discharge of radioactive waste from nuclear installations to the environment; and the decay storage of radioactive waste from nuclear installations and all related activities.

The FOPH is the competent licensing authority in all other cases (RPO, Article(11)(1)).

A licence is required for the handling of radioactive material or of equipment or objects containing such material, for the manufacture, distribution or use of installations or equipment capable of emitting ionising radiation and for the application of radiation or radioactive material to the human body (RPA, Article 28).

In addition to the activities specified in Article 28 of the RPA, or by way of clarification thereof, the following activities are subject to mandatory licensing according to Article 9 of the RPO:

- handling of material whose specific activity exceeds the clearance level and whose absolute activity exceeds the licensing limit;
- handling of contained gaseous material whose absolute activity exceeds the licensing limit;
- discharge to the environment of material whose specific activity exceeds the clearance limit and whose absolute activity is greater than the activity of 1 kilogram of a material whose specific activity is equal to the clearance limit;
- distribution of material whose specific activity exceeds the clearance limit and whose absolute activity is greater than the activity of 1 kilogram of a material whose specific activity is equal to the clearance limit;
- use of radionuclides in the human body;

<sup>5.</sup> An official translation can be found at: www.fedlex.admin.ch/eli/cc/2017/502/en.

- deployment of occupationally exposed persons at one's own or at another company in Switzerland or abroad;
- performance of quality assurance measures on radiation generators, nuclear medicine imaging equipment and activity meters, or image receptor and display systems used in medical diagnostics;
- further use of radiological legacies;
- activities involving the handling of NORM; and
- decay storage of radioactive waste from nuclear installations outside nuclear installations.

In accordance with Article 10 of the RPO, the following activities are exempt from mandatory licensing:

- transport of radioactive material which does not exceed the activity concentration limits for exempt material or the activity limits for exempt consignments specified in Annex A of the European Agreement of 1957 and in the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) in accordance with Appendix C;
- transport of radioactive substances as excepted packages;
- transport of radioactive substances by air (UN numbers 2908, 2909, 2910, 2911, 2912, 2913, 2915, 2916, 2978, 3321, 3322, 3332 and 3507);
- distribution, use, storage and transport, as well as the import, export and transit, of finished timepieces containing radioactive sources, provided that they comply with ISO standards 315714 and 416815, and comprise no more than 1 000 timepiece components with radioactive tritium-based luminous paint;
- handling of stray radiation sources, where:
  - 1. the electron acceleration voltage does not exceed 30 kV; and
  - 2. the ambient dose rate at a distance of 10 cm from the surface does not exceed 1  $\mu\text{Sv}$  per hour;
- handling of mineral and rock collections with a specific activity below the NORM clearance limits, or if they contain less than 10 grams of natural thorium or 100 grams of natural uranium;
- handling of radiation sources, with the exception of distribution, for which a type licence has been granted;
- activities and radiation sources which are subject to mandatory licensing or a decommissioning order under the NEA; and
- deployment of occupationally exposed aircrew by aircraft operators.

In the case of radiation sources with a particularly low hazard potential for humans and the environment, the FOPH may grant a type licence (RPO, Article 15), in particular if:

- they are designed or measures are taken so as to prevent inadmissible exposure or contamination of persons; and
- it is assured that, if necessary, they will be delivered to the federal collection centre as radioactive waste at the end of their useful life.

Applications must be submitted, along with the necessary documentation, to the relevant licensing authority. The authority issuing the licence (for a maximum period of 10 years) communicates its decision to the canton concerned and to the supervisory authority.

The Nuclear Energy Act establishes a licensing regime for persons handling nuclear materials. The licensing authority and the licensing procedure are set out by the Federal Council. The licence is limited in time and is subject to licensing conditions (Arts. 6 ff. NEA). In particular, the competent authority checks whether the required financial cover for nuclear third party liability is provided.

Licence holders are subject to certain obligations. In particular, they are obliged to notify the supervisory authorities of activities or special occurrences which could endanger nuclear security or safety. They are also required to check stock and keep accounts (NEA, Article 11). The Nuclear Energy Act provides for criminal provisions which, generally speaking, are applicable to persons who intentionally infringe provisions laid down in the field of nuclear energy (NEA, Articles 88(ff)). This includes breaches of security and safety measures, offences relating to nuclear materials or radioactive waste, breach of the obligations imposed by a nuclear installation licence, breach of confidentiality, relinquishing possession of nuclear materials or radioactive waste.

#### 4. Nuclear Installations

#### a) Licensing and inspection, including nuclear safety

The Nuclear Energy Act establishes a licensing process for nuclear power plants consisting of three stages: the general authorisation (decision in principle) procedure, the construction authorisation and the operating authorisation procedure. As to Swiss legislation, the concerns of the cantons and the entities and persons concerned are considered in the decision-making process at all three stages. However, the authorisation of the canton in which a nuclear site is to be located is not required. The Confederation is the sole entity responsible for granting licences.

At the international level, Switzerland ratified the 1994 Convention on Nuclear Safety on 12 September 1996.

#### *i)* Granting of general licences

The Federal Council is the body which decides upon applications for general licences (NEA, Article 12). The application is sent to the SFOE, which is responsible for leading the general licence procedure. As a first step, the ENSI prepares a technical expert report as regards to the application, relating in particular to the protection of humans and the environment and the disposal of radioactive waste. After having invited the cantons and specialised services of the Confederation to give their opinions regarding the application and the expert report, a public enquiry must be opened and published, in which everybody is entitled to submit comments. The cantons, specialised services and authors of the expert report are then given an opportunity to state their view on these comments. Finally, the Federal Council takes its decision on the application. The decision is then submitted to the Federal Assembly for approval (NEA, Article 48(2)). Resolutions by the Federal Assembly concerning the approval of general licences are subject to optional referendum (NEA, Article 48(4)). The Swiss electorate has the final say.

According to Article 44 of the Nuclear Energy Act, the canton in which the installation is to be located, as well as the cantons in the immediate proximity will be particularly involved in preparing the general licence decision of the Federal Council.

General licences are granted provided the following conditions are met:

- the protection of humans and the environment can be ensured;
- there are no other grounds for refusal under federal legislation, in particular as regards environmental protection;
- there is a plan for decommissioning or for an observation phase and a plan for closing the installation;
- radioactive waste produced will be disposed of;
- Switzerland's external security is not affected;
- there is nothing in any international undertaking by Switzerland to oppose it; and
- as regards deep geological repositories, geological studies confirm that the site is a suitable one.

The general licence specifies the site to be selected for installation, the licence holder, the purpose of the installation, a brief outline of the project, the maximum permissible exposure to radiation for people in the vicinity of the installation, and, in the case of deep geological repositories, the criteria for deciding that a proposed site is unsuitable, and a provisional protection area (NEA, Article 14(1)).

*ii) Granting of construction and operating licences* 

Under Articles 15 and 19 of the Nuclear Energy Act, these licences are granted by the Federal Department of the Environment, Transport, Energy and Communications (DETEC).

Applications considered by the SFOE are forwarded to the cantons concerned for their opinion (NEA, Article 53). The construction and operating licence procedure also includes publication of the application, with the possibility for those concerned to oppose the application. The decision can be appealed before the Federal Administrative Court and at a later stage before the Federal Supreme Court.

If DETEC issues a licence contrary to the opinion of the canton in which the installation is to be located, the latter shall have a right of appeal against this decision; however, a cantonal licence is not required (NEA, Article 49(3)). The Nuclear Energy Act thus differs from the former Act of 23 December 1959 on the Peaceful Uses of Atomic Energy and Protection against Radiation, which provides that the cantonal authorities are competent for granting licences in relation to the regulations of installation construction, fire brigade (fire-fighting) and water police (use of cooling water) (Article 4(3)).

The applicant shall have a right of expropriation in order to construct, operate and decommission a nuclear installation requiring a general licence, as well as to proceed with geological studies which require a licence, construct the service facilities and prepare sites for the storage or recycling of digging, excavation or demolition materials which are directly related to the installation project (NEA, Article 51).

#### *iii)* Technical advisory and supervisory bodies

The SFOE is responsible for implementing licensing procedures for nuclear installations. Based on the documentation supplied with the application for a licence, in particular the safety analysis report, the ENSI delivers a comprehensive safety assessment report. The Federal Nuclear Safety Commission (NSC) can give its opinion on the safety assessment report (NEA, Article 71, as amended and the provisions of its related Ordinance regarding the Federal Nuclear Safety Commission). On the basis of these documents, among other criteria, the Federal Council takes a decision on the licence.

Nuclear installations are supervised by the Confederation (NEA, Article 70). To this end, the Federal Council and the bodies designated by it establish measures and monitor the implementation of such measures in order to protect humans and the environment and to ensure nuclear safety and security. In practice, it is ENSI which carries out most technical inspections of installations, although ENSI may also call on experts from outside the Federal Administration.

#### *iv)* Collection of fees

Under Chapter 8 of the Nuclear Energy Act, the operator bears all fees and expenses for the granting, transfer, amendment or withdrawal of licences, as well as for preparing an expert report, supervisory activities and controls.

#### v) Decommissioning of nuclear installations and management of radioactive waste

According to Article 31 of the Nuclear Energy Act, the producers of radioactive waste are required to cover the costs of managing their wastes. Current expenditure arising while the nuclear power plants are still in operation, including the costs of conditioning operational waste at the power plants, reprocessing of spent fuel, operating centralised waste treatment facilities, research carried out by Nagra and constructing interim storage facilities, are covered directly by the producers on an annual basis.

To meet the expenses of the decommissioning and dismantling of nuclear installations which are no longer in operation and of the disposal of the resulting waste, a fund for the decommissioning of nuclear installations was set up on 5 December 1983 under the responsibility of the Federal Council (Ordinance of 5 December 1983, Article 1, replaced and supplemented by the Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund), to collect the necessary payments from the operators of nuclear installations. Chapter 7 of the Nuclear Energy Act contains more detailed provisions on the topic: the decommissioning fund ensures the financing of the disposal of the waste produced thereby (decommissioning costs), whereas the waste disposal fund ensures the financing waste and spent fuel assemblies, after withdrawal from service of nuclear installations (disposal costs).

The waste disposal fund was set up on 6 March 2000 under the responsibility of the Federal Council (Ordinance of March 2000, Article 1, supplemented by the Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund). This fund was established to collect the contributions from the operators of nuclear installations for the payments of costs arising after the decommissioning of the nuclear plants. The fund provides provisions to cover costs of the disposal of radioactive waste after the decommissioning, the construction of the necessary repositories to store the waste

(including the deep geological disposals), 50 years' monitoring after the closure of the deep geological disposals, transport, insurance and administration.

Each fund has legal personality and is managed by an administrative board acting as the directing body (NEA, Article 81). A board establishes the amount of the contributions paid by each contributor to the fund it manages, and the amount of the payments made by the latter. Operators pay annual contributions, the amount of which is fixed in accordance with the anticipated cost of decommissioning and dismantling the installation. On 1 February 2008, the Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund entered into force. This outlines a new theoretical duration (50 years) for the exploitation of nuclear plants. This duration influences the calculation of the contributions that the operators of nuclear plants have to pay.

#### b) Protection of the environment against radiation effects

The FOPH is responsible for the constant monitoring of ionising radiation and radioactivity in the environment (air, precipitation, water, soil and plants). The FOPH collaborates with the cantons on the survey of radioactivity in the food chain. Every year, the FOPH establishes a sampling and measuring programme in collaboration with other federal authorities (ENSI, NEOC, Suva) and the cantons. All laboratories and authorities which participate in the monitoring programme deliver the results they obtained in this frame to the FOPH. On the basis of these results, the FOPH establishes and publishes a report each year on the environmental radioactivity and on the radiation doses to which the Swiss population is exposed. The Federal Council is regularly informed of the monitoring results.

#### c) Emergency response

On 17 October 2007, the Federal Council adopted the Ordinance relating to the Federal Emergency Organisation on Radioactivity (EOR), which replaced the previous Ordinance of 15 April 1987. The 2007 Ordinance determines the competent authorities for such an emergency response, as well as their responsibilities, and describes the tasks to be performed in the event of a hazard caused by a nuclear installation (Art. 1). The situation in Europe resulting from the Chernobyl accident highlighted the need to set up an organisation in Switzerland to co-ordinate the measures to be taken by the different public services concerned so as to achieve optimum results. Accordingly, the ordinance lists a number of bodies in which these services are represented, lays down the conditions for their involvement and provides for a co-ordinated network to allow for an appropriate response to an increase in radioactivity (Arts.5 to 16).

The EOR was replaced on 1 January 2011 by the Ordinance on the Organisation of Deployment in the Event of Emergencies and Natural Hazards (ABCN Intervention Ordinance). This Ordinance regulates the activities of the federal government to deal with incidents of national importance that endanger or otherwise impact the population, fauna and the environment as a consequence of increased levels of radioactivity, biological or chemical accidents and natural hazards (ABCN emergencies) (Art. 1).

In 2018 the ABCN Intervention Ordinance was subsequently replaced by the Ordinance on the Emergency Organisation for the Protection of the Population (SR 520.17). With this new Ordinance, the range of operations which had previously been limited to ABCN scenarios was extended to include all events of relevance to civil protection. At the same time, the federal unit responsible was renamed the Federal Civil Protection Crisis Management Board (CCMB).

In addition, the Ordinance of 14 November 2018 on Emergency Protection in the Vicinity of Nuclear Power Plants (Emergency Protection Ordinance or EmPO) (SR 732.33) is also applicable. This Ordinance entered into force on 1 January 2019 and replaced the previous Emergency Protection Ordinance of 20 October 2010.

In the event of an anticipated or existing increase in the level of radioactivity, the National Alarm Centre is responsible for various tasks, including the implementation of immediate measures until the relevant federal organisation is ready for deployment: in the event of impending danger it warns the relevant federal, cantonal and Liechtenstein authorities, as well as the operators of critical infrastructure. If necessary, it also warns and informs the population and circulates recommendations for taking action. In the event of a disaster it orders the warning of the population of Switzerland and Liechtenstein, circulates information and issues instructions for taking action (Art. 7(2) Ordinance on Civil Protection) (SR 520.12).

In the event of a major incident, two emergency protection zones are set up around each nuclear facility (Art. 3 EmPO). Zone 1 encompasses the section in which immediate measures have to be taken if the incident represents a threat to the population (radius of 3 to 5 kilometres around the facility). Zone 2 is adjacent to Zone 1 and encompasses the section in which protective measures have to be taken if the incident represents a threat to the population (radius of approximately 20 kilometres around a nuclear facility). It is divided into threat sectors (Annex 2). Specific zones may also be defined as the basis for the planning and preparation of protective measures (Annex 4). Within these planning zones, specific protective measures have to be implemented in the event of an incident.

The distribution of iodine tablets to the population is provided for in an Ordinance of 1 July 1992 that was revised on 22 January 2014 (Ordinance on the Distribution of Iodine Tablets) (SR 814.52). This Ordinance regulates the supply of iodine tablets to the population in the event of an incident that could represent a threat due to radioactive iodine.

The Armed Forces Pharmacy is responsible for ensuring that iodine tablets are procured for the entire population, the necessary quantity of iodine tablets is at the disposal of the relevant authorities for precautionary distribution and storage, and sufficient reserves of iodine tablets are permanently available (Art. 2).

In communes located in a radius of 50 kilometres around a Swiss nuclear power plant, iodine tablets must, as a precautionary measure, be distributed to everyone who spends time there on a regular basis (Art. 3(1)). Alongside the precautionary distribution in accordance with Article 3, the Armed Forces Pharmacy is also responsible for ensuring the additional storage of iodine tablets in pharmacies and drugstores in the communes in accordance with the Annex, in order to secure distribution in accordance with the pick-up principle in the event of an incident (Art. 4). In regions of Switzerland outside the radius of 50 kilometres around a Swiss nuclear power plant, the cantons are responsible for the decentralised storage of a sufficient quantity of iodine tablets at a suitable location in standardised childproof packaging, in order to supply the entire population in the event of an incident. They are required to prepare the distribution of iodine tablets so that they can be provided to the population within 12 hours from the time of issue of the official order in accordance with Article 8 (Art. 5(1 & 2)). Operators of nuclear installations participate with the federal government in financing the costs generated by these operations (Art. 10).

At the international level, Switzerland ratified both the 1986 Convention on Early Notification of a Nuclear Accident<sup>6</sup> and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency<sup>7</sup> on 31 May 1988.

#### 5. Trade in Nuclear Materials and Equipment

The Swiss Confederation has committed itself internationally to co-operate in the fight against the proliferation of nuclear weapons. It ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT)<sup>8</sup> on 9 March 1977, and in the same year, became a member of the Nuclear Suppliers Group (NSG), a group of the main states involved in the export of nuclear items. The Ordinance of 25 June 1997 (control of goods) includes the trigger list and the list of dual use goods as specified in the NSG Guidelines (IAEA Document INFCIRC/254) and requires export licences for nuclear material, equipment and technology according to the same guidelines. Switzerland is also a member, since its establishment, of the Zangger Committee, a group of states involved in the technical definition of Article III of the NPT. Switzerland follows procedures contained in the Zangger Committee's guidelines (IAEA Document INFCIRC/209).

The granting of licences for the export of sensitive nuclear equipment and materials is assessed by the competent federal authorities in light of the NSG Guidelines and of internal legislation. The non-proliferation of nuclear weapons is one of the licensing criteria laid down by the Act (partial revision of 9 October 1986 of the Act of 23 December 1959, Article 5.1).

The Nuclear Energy Act provides that, notwithstanding the licensing regime, the Federal Council or the authority designated by it may prohibit or impose conditions on the import, export, transit or brokerage of nuclear goods to ensure non-proliferation of nuclear weapons. Likewise, the Federal Council may provide that no licence shall be granted in relation to certain states or groups of states (Article 8).

In accordance with the Control of Goods Ordinance of 3 June 2016, the export of nuclear material, equipment and technology is to be authorised by the Trade Division of the Federal Department of Economy (DFE). At the same time, the SFOE has to authorise the use, trade, transport, import and export of nuclear material. The export and trade of nuclear technology also requires SFOE authorisation.

Switzerland has legal instruments to implement UN and other international sanctions to third parties.

Switzerland has concluded bilateral agreements with Canada, China, France, Russia, Sweden and the USA in the realm of co-operation in the peaceful uses of nuclear energy.

<sup>6.</sup> Convention on Early Notification of a Nuclear Accident (1986), IAEA Doc. INFCIRC/335, 1439 UNTS 276, entered into force 27 Oct. 1986 (Early Notification Convention).

Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1986), IAEA Doc. INFCIRC/336, 1457 UNTS 134, entered into force 26 Feb. 1987 (Assistance Convention).

Treaty on the Non-Proliferation of Nuclear Weapons (1968), IAEA Doc. INFCIRC/140, 729 UNTS 169, entered into force 5 Mar. 1970 (NPT).

Swiss nuclear legislation does not include any regulation dealing specifically with nuclear industrial property. Accordingly, the ordinary law on patents applies in the nuclear field.

#### 6. Radiation Protection

Radiation protection measures taken by the federal government are based on the recommendations of the International Commission on Radiological Protection (ICRP) and on the joint standards of international bodies (IAEA, EC, FAO, ILO, OECD/NEA, PAHO, UNEP, WHO).

The RPA is a framework act designed to protect human beings and the environment against the dangers arising from ionising radiation.<sup>9</sup> It applies to all activities, installations, events and situations which could present a radiation hazard and in particular to the use of radioactive substances and equipment, installations, and objects containing such substances or capable of emitting ionising radiation. The RPA defines the broad principles of protection against radiation and grants the Federal Council the power to promulgate detailed implementing regulations, which can thus be adapted rapidly to keep pace with scientific and technological progress. The comprehensive revision of the Radiation Protection Ordinance is an example of such adaptation.

The new RPO is based largely on the recommendations of the ICRP, on the International Basic Safety Standards (GSR Part 3)<sup>10</sup> as well as on Directive 2013/59/EURATOM<sup>11</sup>. The RPO has been restructured according to the new system of radiation protection based on three exposure situations (planned, emergency and existing), which cover all situations of exposure, whether artificial or natural.

Licensing and supervision are consistent with the concept of graded approach. For low-risk applications, e.g. the use of an X-ray system in dental practices, the licensing procedure is simplified. For high-activity, sealed radioactive sources, radiological safety and security have been reinforced.

Clearance limits for low-level radioactive materials were adapted to international standards in order to optimise the protection of the public when disposing of waste and discharges into the environment, and to facilitate the cross-border export or import of materials, e.g. for recycling.

The new RPO aims to improve the protection of workers. In order to prevent cataracts, the dose limit to the lens of the eye has been lowered. This measure mainly concerns healthcare professionals exposed to X-rays during radiological procedures. In addition, natural radiation sources to which workers might be exposed are now more effectively taken into account. This applies to workplaces exposed to radon and industries using

<sup>9.</sup> An official translation is available at: www.fedlex.admin.ch/eli/cc/1994/1933\_1933\_1933/en.

<sup>10.</sup> IAEA (2014), Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series, General Safety Requirements, No. GSR Part 3, Vienna.

Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal of the European Union (OJ) L 13 (17 Jan. 2014) (Euratom Basic Safety Standards).

natural radioactive materials. Furthermore, flight crews are now considered as occupationally exposed persons, so that annual doses are assessed individually.

The new RPO introduces clinical audits in hospitals and radiological institutes in order to better protect patients from unnecessary exposure to radiation. The aim of this measure is to avoid unjustified examinations and treatments. These peer review audits are carried out in collaboration with medical professional associations.

The reference level for radon in dwellings has been reduced to 300 Becquerel per cubic metre. This means that radon exposure has to be more effectively taken into account in the construction of buildings throughout Switzerland. In addition, new provisions apply to radiological legacies. These include the measurement and, if necessary, the remediation of the buildings concerned. In Switzerland, such a situation applies to radium contamination due to past activities of the watch industry.

Reference levels have been introduced to protect the population, and persons with special duties, in emergency exposure situations during the emergency phase. The RPO also specifies the responsibilities of the competent bodies to manage these situations.

The Federal Department of Home Affairs (FDHA) and the Federal Department of the Environment, Transport, Energy and Communications (DETEC) are responsible for implementing regulations in the field of radiation protection. They concentrate particularly on the protection of persons, and thus are concerned with health risks, which may affect certain groups of people – workers or patients – or the population as a whole, when exposed to ionising radiation. Those who, in their work, handle radioactive substances or use radiation-producing equipment are required to follow adequate radiation protection training and education. According to the new RPO, continuing education in radiation protection is now mandatory for all of them.

The Federal Commission for Radiological Protection (CPR) advises the Federal Council, the FDHA, DETEC, the Federal Department of Defence, Civil Protection and Sport, the FOPH, ENSI, interested services and Swiss National Accident Insurance Fund (Suva) on matters concerning radiation protection.

This CPR gives its opinion, inter alia, on:

- the interpretation and evaluation of international recommendations concerning radiation protection with a view to their application in Switzerland and
- the preparation and development of standard principles for applying radiation protection requirements.

The relevant authorities for granting licences for the use of ionising radiation are the FOPH and, for activities carried on in nuclear installations, tests involving radioactive substances in the framework of preparatory measures within the meaning of Article 35 of the Nuclear Energy Act and the import, export and transport from and to nuclear facilities of radioactive material, ENSI.

The FOPH, Suva and ENSI are responsible for supervising the protection of humans and the environment against ionising radiation. The FOPH exercises control over companies in which the primary concern is to protect the public, in particular medical companies as well as research and training institutes in higher education establishments. Suva exercises control over firms in which the primary concern is the protection of workers, in particular, industrial companies and small businesses. ENSI supervises nuclear installations and the transport of nuclear goods as well as preparatory measures within the meaning of Article 35 of the Nuclear Energy Act.

#### 7. Radioactive Waste Management

#### a) Legal framework

The NEA and the NEO provide comprehensive regulation on all aspects of radioactive waste management. They entered into force on 1 February 2005, replacing the Atomic Act of 23 December 1959. Those who operate or decommission a nuclear installation are responsible, at their own cost, for the safe disposal of radioactive waste arising from the installation (NEA, Article 31). This duty of disposal is fulfilled according to Article 31, paragraph 2, when the waste has been emplaced in a geological repository and the financial means are secured for a monitoring phase and subsequent closure of the facility or when the waste has been emplaced in a foreign disposal facility.

The Nuclear Energy Act stipulates that the radioactive waste produced in Switzerland must be disposed of within Switzerland. The import and export of radioactive waste are authorised if the transaction occurs between states which have permitted the import or export of such waste. In both cases, the receiving facility must comply with the state-ofthe-art science and technology at the international level.

Waste producers are also required to prepare a waste management programme. This is reviewed by the federal authorities and approved by the Federal Council. Waste producers have to provide information on the radioactive waste for disposal, the required geological repositories and their design concepts, the allocation of waste to the repositories, the time plan for implementing the repositories and the financing of waste management activities.

The Nuclear Energy Act also regulates the licensing procedure. Licences for geological investigations in potential siting regions, a general licence, and licences for construction, operation and closure of the repositories are required.

The Nuclear Energy Act does not specify the procedure to be followed for selecting sites for geological repositories. According to Article 5 of the NEO, the federal government has to specify the objectives and requirements applying to the disposal of waste in geological repositories in a sectoral plan. This includes, in particular, the site selection process for repositories for all waste categories. The site selection process represents an important basis for the waste management programme; the programme depends to a large extent on the configuration of the selection process as specified in the sectoral plan and, according to the NEA, has to be modified periodically to meet changing conditions. The ordinance contains a list of the fundamental safety requirements to be met by a deep geological repository, e.g. sufficient volume of suitable host rock, favourable hydrological conditions, long-term geological stability. The monitoring and recoverability of stored radioactive waste must be guaranteed until the repository has been definitively sealed.

The main aspects of financing the decommissioning of nuclear installations and the disposal of radioactive waste and spent fuel are regulated in the Nuclear Energy Act, with the details being contained in the Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund. These two independent funds are fed by annual contributions from the facility operators. The decommissioning fund was established in 1984 and, at the end of 2020, the accumulated fund capital was CHF 2 822 million. The waste disposal fund

was established in 2001 and had an accumulated capital of CHF 6 030 million at the end of 2020.

It is relevant to note that, at the international level, Switzerland has ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.<sup>12</sup>

#### b) Waste categories

The NEO defines three waste categories:

- high-level waste comprises fission products from nuclear power plants;
- alphatoxic waste refers to waste material with a high content of alpha emitters; and
- low and intermediate-level waste comprises operational waste material from nuclear power plants (e.g. protective clothing, machines, rinsing water), waste arising from the decommissioning of nuclear power plants, and waste from the healthcare sector, industry and research (including the dismantling and decommissioning of research facilities).

The Nuclear Energy Act stipulates that the use of radioactive matter must result in as little waste material as possible. All waste material that is produced despite this minimisation requirement first has to be conditioned (i.e. brought into a stable state) and packed in suitable receptacles (concrete containers, steel safety tanks), and then has to be transferred to interim storage facilities until such time as deep geological repositories are available.

The management (handling and storage) of radioactive waste is governed by the provisions of the NEA and the NEO both of which entered into force on 1 February 2005. Further, the management of radioactive waste originating from medicine, industry and research is governed by the Radiological Protection Act and the Radiological Protection Ordinance both of which came into effect on 1 October 2004.

#### c) Division of responsibilities for the management of radioactive waste

The federal government is responsible for providing the legal framework, and its supervisory authorities are responsible for the supervision of nuclear power plants and the disposal of radioactive waste.

The SFOE participates in the organisation and implementation of the various licensing procedures and prepares decision-making bases for DETEC and the Federal Council.

The FOPH, which forms part of the Swiss Federal Department of Home Affairs (FDHA), is responsible for waste produced from the healthcare sector, industry and research. It issues the necessary licences and permits, supervises the involved facilities and ensures compliance with radiation protection regulations. It is also responsible for measuring levels of radioactivity in the environment.

Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (1997), IAEA Doc. INFCIRC/546, 2153 UNTS 357, entered into force 18 June 2001 (Joint Convention).

The Nuclear Energy Act explicitly states that the supervisory authorities are independent of technical directives and requests formal independence of the licensing authorities. With the Federal Nuclear Safety Inspectorate Act the Swiss supervisory authorities (HSK and the nuclear security section of SFOE) were separated from SFOE and converted into an institution under public law, the ENSI. The new Act became effective on 1 January 2009. Along with this transition, the former Federal Commission for the Safety of Nuclear Installations was replaced by the Federal Nuclear Safety Commission (NSC). The tasks of this new, more streamlined commission focus on fundamental issues of nuclear safety.

The NSC examines fundamental issues relating to nuclear safety and may submit statements of position to the Federal Council and the DETEC concerning safety assessments of ENSI.

In 1978, the Federal Council set up the Swiss Federal Workgroup for Nuclear Waste Disposal. On behalf of the Federal Council, it monitors the general developments in the field of waste disposal, formulates statements of position and deals with issues relating to waste disposal. It also co-ordinates the independent research on nuclear waste disposal carried out by Nagra. In addition, it monitors the status of implementation of the recommendations of the Federal Nuclear Safety Commission. The workgroup comprises representatives from the supervisory (Swiss Federal Nuclear Safety Inspectorate), licensing (Swiss Federal Office of Energy), public health (Federal Office of Public Health), environmental protection (Federal Office for the Environment) and area planning (Federal Office for Spatial Development) authorities. In addition, the Federal Office of Topography (swisstopo) and energy research institute PSI hold a seat in the workgroup. Representatives of Nagra are also called on as specialists on a case-by-case basis. Each year the workgroup submits a report to DETEC on its activities.

The parties who produce radioactive waste are required to provide a safe means of its disposal and to bear the associated costs. For this purpose, in 1972, the producers of radioactive waste, including the Confederation, formed a private company – the National Corporative for the Disposal of Radioactive Waste (Nagra) – which has the task of managing the radioactive waste for which waste producers are responsible.

As a federal government body specialising in geology, the Commission for Radioactive Waste Disposal (CRW) advises the SFOE and ENSI on geological aspects of radioactive waste disposal and comments on scientific reports of Nagra. This commission was replaced in 2012 by the Expert Group for Nuclear Waste Disposal.

#### *d)* Disposal of waste, storage and waste management programme

Concerning radioactive waste disposal, the long-term safety of human beings and protection of the environment are of highest priority. All radioactive waste is to be disposed in repositories located in suitable geological formations. Near-surface disposal is not allowed. Either a combined repository or two repositories are foreseen, one for mostly short-lived low and intermediate-level waste (L/ILW) and the other for high-level waste and spent fuel as well as long-lived intermediate-level waste (HLW) mainly from reprocessing. The site selection process has to observe a "sectoral plan" procedure within the framework of the spatial planning legislation. Stringent requirements in terms of geological stability, host rock barrier performance and local geological conditions (depth, thickness and lateral extent of host rock are therefore a decisive factor in the site selection procedure. In addition to safety criteria, the site selection procedure additionally has to take account of socioeconomic and spatial planning aspects. These vary from region to region and can only be developed with the participation of the involved regions.

Since no repository is yet available, all radioactive waste is currently stored in interim storage facilities. Each nuclear power plant has the interim storage capacity for its own operational waste. The radioactive waste from medicine, industry and research is stored at the Federal Storage Facility. Radioactive waste returning from reprocessing abroad is stored at the Central Storage Facility (ZZL).

To comply with the legislation, the waste producers must submit a waste management programme to the federal government and update it every five years. On 2 April 2008 the Federal Council announced that the waste management programme had to be submitted together with the proposals for siting areas for deep geological repositories. The waste management programme was thus submitted to DETEC on 17 October 2008. It entails information on the radioactive waste for disposal, the required geological repositories and their design concepts, the allocation of waste to the repositories, the time plan for implementing the repositories and the financing of waste management activities.

#### e) Search for suitable sites for deep geological repositories

The NEA does not specify the procedure to be followed for selecting sites for geological repositories. According to Article 5 of the NEO, the federal government must specify the objectives and requirements applying to disposal of waste in geological repositories in a sectoral plan.

The Federal Council adopted the Conceptual Part of the Sectoral Plan for Deep Geological Repositories in April 2008, thus initiating a three-stage procedure that will result in the designation of suitable sites for deep geological repositories. The procedure is led by the SFOE, whereas the National Cooperative for the Disposal of Radioactive Waste (Nagra) acts as the implementer. ENSI is the safety authority. An overview of milestones and decisions in the Swiss programme is presented below.

Stage 1 (2008-2011)

Stage 1 focused on the identification of suitable siting regions based on safety and geological criteria. In October 2008, Nagra proposed potential geological siting regions on the basis of safety criteria (see chapter 3.2):

- Südranden (canton of Schaffhausen) with host rock Opalinus clay and its confining units.
- Zürich Nordost (cantons of Zürich and Thurgau) with host rocks Opalinus clay and the claystone sequence Brauner Dogger with their confining units.
- Nördlich Lägern (cantons of Zürich and Aargau) with host rocks Opalinus clay and the claystone sequence Brauner Dogger with their confining units.
- Jura Ost (canton of Aargau) with host rock Opalinus clay and its confining units.
- Jura-Südfuss (cantons of Solothurn and Aargau) with host rocks Opalinus clay and its confining units, and the Effingen Beds.
- Wellenberg (cantons of Nidwalden and Obwalden) with host rock marl formations of the Helveticum.

The siting regions for HLW or a combined repository area are:

• Zürich Nordost

- Nördlich Lägern
- Jura Ost

ENSI, their experts and the Federal Nuclear Safety Commission reviewed safety-related aspects of the proposed sites. In 2010, they both confirmed that Nagra's analysis of the geological information was technically justified, comprehensive and transparent and therefore agreed to the six proposed siting regions. The proposals by Nagra were also reviewed by a cantonal expert group (AG SiKa/KES) and a German expert group (ESchT). In their review reports, both also agreed with Nagra's proposed siting regions. A broad public consultation took place from September to November 2010. The SFOE received and compiled 3 700 statements. The Federal Council approved the proposed geological siting regions in November 2011 and incorporated them into the Sectoral Plan.

With regional participation being an important component of the site selection procedure, regional conferences were set up in all six siting regions in order to guarantee that their interests and needs can be taken into account. These bodies comprise representatives from the involved communes, organisations and the population. This regional participation process, which was set up and managed by the SFOE, provides the siting regions with the opportunity to represent their region and express their concerns within the process.

#### Stage 2 (2011-2018)

Stage 2 aimed at selecting at least two sites each for the L/ILW and the HLW repository. In 2015, Nagra proposed Jura Ost and Zürich Nordost as geological siting regions in which one repository for each category of radioactive waste, or a combined repository, would be feasible. Following its detailed study, ENSI came to the conclusion that, in addition to the two proposed geological siting areas, Nördlich Lägern should also be further examined. This view was shared by the Federal Nuclear Safety Commission. In addition to narrowing down the number of geological siting regions, Nagra collaborated with the regional conferences in the proposed siting regions to identify and designate locations for the placement of the surface facilities. For each siting region, at least one area was designated. Additionally, the siting regions were evaluated on the basis of socioeconomic and ecological criteria. The findings were summarised in a socioeconomic and ecological impacts study. Following a public consultation in 2017, stage 2 was concluded with the decision by the Federal Council in November 2018. The results were incorporated into the Sectoral Plan.

Stage 3 (2018-ca. 2029)

The goal of stage 3 is site selection. The findings relating to the site-specific geological conditions will be supplemented by geological studies in the three remaining siting regions. The surface infrastructure will be finalised in co-operation with the three remaining regional conferences and the social and economic impacts of the repositories will be examined in greater detail. Around 2024, Nagra will submit general licence applications for the construction of a combined repository or two separate repositories. These applications will be reviewed by the relevant authorities. Towards the end of the 2020s, the Federal Council will decide on the applications for general licences, and its decision will have to be approved by Parliament. Parliamentary resolutions are subject to optional national referenda. If a referendum is initiated, the Swiss electorate will decide on the award of the general licence, most likely in the early 2030s. Only once this entire process is concluded will the sites for the deep geological repositories be definitive.

After the construction and operation of facilities for underground geological investigations, applications for a construction licence and ultimately for an operating licence for each repository must be submitted, both of which will need to be reviewed and granted by the relevant federal authority. According to the current schedule, the L/ILW repository should be operational by around 2050 and the HLW repository by approximately 2060. The SFOE is managing this procedure which is to lead in approximately 10 years to the designation of sites for each waste category. The procedure facilitates the co-ordination of a broad range of players and is divided into three stages. With respect to this site selection process for deep geological repositories, on 17 October 2008 Nagra submitted its proposals for suitable geological siting regions for the repositories for HLW and L/ILW to the SFOE. ENSI reviewed Nagra's entire documentation and concluded that the procedure followed by Nagra in preparing the proposals for the geological siting regions was transparent and reproducible.

#### 8. Non-Proliferation and Physical Protection

There is no legislation dealing specifically with nuclear security in Switzerland. However, special provisions have been included in the Nuclear Energy Act of 21 March 2003.

General licences for nuclear installations and licences to handle nuclear materials will be granted provided they are not in breach of any international commitment and that Switzerland's external security is not affected (NEA, Article 7(E) and Article 13(1)(e-f)).

According to Article 13(2) of the NEA, only a company limited by shares, a co-operative or public law entity can apply for a general licence. If the applicant is a foreign company, it must have a branch registered in the commercial register in Switzerland. The Federal Council may refuse to grant a general licence to a company formed in accordance with the laws of a foreign country if the country in which the company concerned is domiciled does not grant reciprocal rights, insofar as the decision of the Federal Council does not conflict with any existing international commitments.

The licensing procedure for a new nuclear installation consists of two further stages, the construction and operating licence procedure. According to Article 16(2) and Article 20(1)(b) of the NEA, the requirements set out for the general licence procedures, including those mentioned above, must be met in order to obtain a construction or operating licence.

Furthermore, according to Article 106(3) of the NEA, the same criteria (including those in Article 13(2)) apply in case of a transfer of an operating licence for an existing nuclear power plant to a foreign company.

The Nuclear Energy Act grants wide powers of investigation to the nuclear supervisory authorities (Articles 72 *et seq.*). They inform the public of the state of nuclear installations and of the situation relating to nuclear materials and radioactive waste; in addition, they may not process personal sensitive data (Articles 74 *et seq.*).

Generally speaking, all licences required by the Nuclear Energy Act are granted provided the protection of human and the environment is ensured (Articles 7, 13, 16 and 20). Moreover, a licence to handle nuclear materials is granted provided that there are no grounds for refusing it relating to the non-proliferation of nuclear weapons, in particular international control measures supported by Switzerland, even if not formally binding in international law. At the international level, Switzerland ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons<sup>13</sup> on 9 March 1977, the 1996 Comprehensive Nuclear Test Ban Treaty<sup>14</sup> on 1 October 1999 and the 1980 Convention on the Physical Protection of Nuclear Materials<sup>15</sup>.

Switzerland ratified the comprehensive safeguards agreement with the IAEA (entry into force on 6 September 1978) and its additional protocol (entry into force on 1 February 2005). The enforcement of this agreement is to be regulated internally via the Safeguards Ordinance of 4 June 2021 (SR 732.12).

Switzerland has also joined several initiatives and conventions regarding security and physical protection of nuclear material and equipment.

Switzerland joined the Global Initiative to Combat Nuclear Terrorism in 2007. This adhesion complemented a number of steps that Switzerland has taken in recent years to combat terrorism.

Switzerland has signed all the 16 UN conventions and protocols related to counterterrorism, among them, the International Convention for the Suppression of Acts of Nuclear Terrorism<sup>16</sup> and the Amendments to the Convention on the Physical Protection of Nuclear Material<sup>17</sup>.

More recently a number of new national measures have been implemented to improve the protection of the population against the threat from weapons of mass destruction (WMD).

#### 9. Transport

The transport of radioactive or fissile materials in Switzerland is governed by a number of different regulations, each dealing with a particular form of transport. In general, these instruments implement the international regulations in this field in Switzerland.

Thus, for road transport, the applicable regulation is the Ordinance of 29 November 2002 (as of 1 January 2021) on the Carriage of Dangerous Goods by Road (SDR) (SR 741.621). This Ordinance regulates the carriage of dangerous substances and objects (dangerous goods) by motor vehicles and their trailers or by other forms of transport on public roads (Article 1). For the carriage of dangerous goods by road, the provisions of the European Agreement of 30 September 1957 concerning the International Carriage of Dangerous Goods by Road (ADR) (SR 0.741.621) also apply in Switzerland. The aim of the latter

Treaty on the Non-Proliferation of Nuclear Weapons (1968), IAEA Doc. INFCIRC/140, 729 UNTS 169, entered into force 5 Mar. 1970 (NPT).

<sup>14.</sup> Comprehensive Nuclear-Test-Ban Treaty (1996) (not yet entered into force), available at: www.ctbto.org/fileadmin/content/treaty/treaty\_text.pdf (Nuclear Test Ban Treaty).

<sup>15.</sup> Convention on the Physical Protection of Nuclear Material, (1980), IAEA Doc. INFCIRC/274 Rev. 1, 1456 UNTS 125, entered into force 8 Feb. 1987 (CPPNM).

<sup>16.</sup> International Convention for the Suppression of Acts of Nuclear Terrorism (2005), 2445 UNTS 137, entered into force 7 July 2007 (Nuclear Terrorism Convention).

<sup>17.</sup> Amendment to the Convention on the Physical Protection of Nuclear Material (2005), IAEA Doc. INFCIRC/274/Rev.1/Mod.1, entered into force 8 May 2016 (ACPPNM).

Agreement is to enhance the safety of the carriage of dangerous goods in international road transport.

For transport by rail and cableway, the applicable regulations are stipulated in the Ordinance of 31 October 2012 on the Carriage of Dangerous Substances by Railway or Cableway (RSD) (SR 742.412). This Ordinance primarily declares the Regulation concerning the International Carriage of Dangerous Goods by Rail (RID) as binding for traffic within Switzerland. These regulations and the Convention concerning International Carriage by Rail (COTIF) have already entered into force for cross-border transport. The RID is based on the recommendations of the United Nations concerning the carriage of dangerous goods, referred to as the "Orange Book" (UN model regulations).

The transport of radioactive or fissile materials on the rhine (downstream from the central Rhine bridge in Basel) is subject to the European Agreement of 26 May 2000 concerning the International Carriage of Dangerous Goods by Inland Waterways (I). Article 75 of the Inland Waterway Transport Ordinance (SR 747.201.1) prohibits the transport of water-endangering goods on Swiss bodies of water. Some exceptions apply, however. The cantons involved are responsible for enforcement of this Ordinance.

The Ordinance of 17 August 2005 on Air Transport (ATO) (SR 748.411) applies to every domestic and international carriage by air of passengers, baggage and goods, unless the flight is subject to the 1999 Montreal Convention for the Unification of Certain Rules for International Carriage by Air (SR 0.748.411). Article 10 of the Nuclear Energy Act prohibits the transport of nuclear materials containing plutonium in Swiss air space.

DETEC deals with infrastructure and environmental matters. Modern transport routes, communication networks and the power grid all fall under its remit. However, DETEC also deals with issues relating to the environment and health and safety. DETEC, along with the other bodies concerned, draws up regulations in the field of the transport of nuclear materials, radioactive or fissile materials. In the case of air transport, the FOCA may impose additional requirements to be observed during transport operations, as long as these do not contradict the regulations laid down in this field by IATA Dangerous Goods Regulations, DGR Edition 2022. As for sea transport, the relevant international regulations (International Maritime Dangerous Goods Code (IMDG Code) 2020 Edition) are applied directly.

#### **10.** Nuclear Third Party Liability

Provisions relating to nuclear third party liability were originally contained in the Federal Act of 23 December 1959. They were replaced by the Nuclear Third Party Liability Act of 18 March 1983 and its associated Ordinance of 5 December 1983. The Act is based on the principles of strict and (now) unlimited liability, channelling of liability to the operator of a nuclear installation, and minimum amount of coverage. In 1983 the amount of coverage was CHF 300 million, and this figure was subsequently increased in several increments to CHF 1 billion. Switzerland did not conclude any international nuclear third party liability agreements.

However, Switzerland continued to follow with great interest international developments in the field of nuclear third party liability and participated in the discussions carried out in this field. On 12 February 2004, Switzerland signed the 2004 Protocols to amend the Paris

Convention<sup>18</sup> and the Brussels Supplementary Convention<sup>19</sup>. On 13 June 2008, both Conventions as well as the Joint Convention and the revised Nuclear Energy Liability Act were approved by the Swiss Parliament, with reservations concerning Articles 8(f) and Article 9 of the Paris Convention and the Joint Convention on reciprocity.

Switzerland is a party to:

- the Paris Convention on Nuclear Third Party Liability as amended by the 2004 Protocols (Paris Convention or PC) (SR 0.732.44);
- the Brussels Supplementary Convention as amended by the 2004 Protocols (BSC) (SR 0.732.440); and
- the Joint Convention (Joint Convention) (SR 0.732.441).

On 1 January 2022 the new Nuclear Energy Liability Act of 13 June 2008 (NELA) (SR 732.44) and Nuclear Energy Liability Ordinance (NELO) (SR 732.441) entered into force. Articles 1 to 15 of the Paris Convention are directly applicable ("self-executing") under Swiss law.

The principles of Switzerland's nuclear liability obligation are as follows:

- For nuclear damage, the operator of a nuclear facility is liable for the full amount.
- Operators of nuclear facilities are also liable even if they are not directly at fault (strict liability). This also applies even if nuclear damage should be caused by acts of terrorism or war.
- The operator is solely liable (channelling).
- The operator must have and maintain liability insurance or other financial security. The amount of coverage is EUR 1.2 billion (plus 10% for interest and court-awarded costs). Of the total amount of coverage (EUR 1.2 billion), at least CHF 1 billion must be covered by a insurer authorised to do business in Switzerland or another cover provider. The Federal Council is obliged under this Act to increase the minimum amount covered by private insurance once the insurance market offers higher cover on acceptable terms.<sup>20</sup> Insurers may fully or partially exclude certain risks from coverage (e.g. extreme weather events or acts of war). The Federation covers damages up to the amount of EUR 1.2 billion that are not covered by private

<sup>18.</sup> Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960, as amended by the Additional Protocol of 28 January 1964, by the Protocol of 16 November 1982, and by the Protocol of 12 February 2004, entered into force 1 Jan. 2022, unofficial consolidated text available at: NEA (2017), "Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960, as amended by the Additional Protocol of 28 January 1964, by the Protocol of 16 November 1982 and by the Protocol of 12 February 2004", NEA Doc. NEA/NLC/DOC(2017)5/FINAL (Revised Paris Convention).

<sup>19.</sup> Convention of 31 January 1963 Supplementary to the Paris Convention of 29 July 1960, as amended by the Additional Protocol of 28 January 1964, by the Protocol of 16 November 1982 and by the Protocol of 12 February 2004, entered into force 1 Jan. 2022, unofficial consolidated text available at: NEA (2017), "Convention of 31 January 1963 Supplementary to the Paris Convention of 29 July 1960, as amended by the Additional Protocol of 28 January 1964, by the Protocol of 16 November 1982 and by the Protocol of 16 November 1982 and by the Protocol of 12 February 2004", NEA Doc. NEA/NLC/DOC(2017)6/FINAL (Revised Brussels Supplementary Convention).

<sup>20</sup> Private cover has been increased to EUR 1.2 billion since 1 January 2023.

insurance. Operators pay a premium for this. These premiums are calculated and billed annually by the Swiss Federal Office of Energy. This is carried out in accordance with insurance principles and taking into account the respective risk of the installation or the transport. The calculation formulas are cited in the Appendices to the NELO. The premiums are paid into the Federal Nuclear Damage Fund, which is not a separate legal entity but is financially independent.

- The amount of coverage for nuclear research facilities, for the federal interim storage facility, for decay storage facilities and for nuclear installations in decommissioning, when there are no more fuel elements on the site, is EUR 70 million (plus 10% for interest and court-awarded costs).
- Transports of nuclear material must be insured separately from the nuclear installation. Depending on the transported nuclear material, the amount of insurance cover is EUR 1.2 billion (transport of spent fuel elements) or EUR 80 million (in each case, plus 10% for interest and court-awarded costs).
- In the event of damage, the insurance cover of EUR 1.2 billion is supplemented by an amount of EUR 300 million, which is paid by the contracting parties to the Brussels Supplementary Convention. Thus, a total of EUR 1.5 billion is available to cover nuclear damage.
- If the amount of liability insurance should not suffice to cover the damage, the available financial resources of the operator with unlimited liability will be used. Should these financial resources also not be sufficient, a situation of large-scale damage is declared. This also applies if it is not possible to conduct ordinary proceedings due to the large number of damaged parties. In this case, Parliament may specify a compensation plan for the just distribution of the available funds and, if necessary, stipulate that the federal government may award additional contributions to compensate uncovered damage.
- For compensation claims following a nuclear accident, one single court has jurisdiction over claims for compensation, regardless of the place of residence or nationality of the injured party.
- Where damage is caused by a deep geological repository which is no longer subject to nuclear energy legislation, the Federation is to cover nuclear damage from the nuclear damage fund and up to EUR 1.2 billion.
- When a person suffering from nuclear damage incurred in Switzerland for which the operator of a nuclear installation located in another country is liable cannot obtain adequate compensation, the Federation compensates for this nuclear damage from general funds up to the corresponding amounts mentioned in the Brussels Supplementary Convention.
- The relative prescription period for nuclear damage is three years, while the absolute prescription period is 30 years. Upon the expiry of the 30-year period, no further nuclear damage claims may be made against the operator. Damage after expiry of this period (so-called long-term damage) is covered by the federal government from the Federal Nuclear Damage Fund.

#### **11. Environmental Protection**

The main purpose of the Nuclear Energy Act is to protect humans and the environment against the risks of nuclear energy (Article 1). When using nuclear energy, humans and the environment must be protected against the danger due to ionising radiation (NEA, Article 4(1)). Therefore, there are several regulations which attend to environmental

protection within the framework of the appropriate legislation: A licence may only be issued if the protection of humans and the environment is assured (NEA, Article 7(a); Article 13(1)(a); Article 16(1)(a) and Article 20(1)(c)). Among other terms, the general licence shall specify the maximum permissible exposure to radiation for people in the vicinity of the installation (NEA, Article 14(1)(e)). The operating licence shall specify notably the measures for environmental surveillance (NEA, Article 21(1)(d)). Radioactive waste must be managed in such a manner as to ensure the permanent protection of humans and the environment (NEA, Article 30(3)).

According to these principles, the application procedure stipulates that the federal office in particular shall obtain the necessary expert reports on protection of humans and the environment (NEA, Article 43(1)(a)). Before taking any decision on the planning, construction or modification of installations, an authority must assess their impact on the environment at the earliest possible stage (Swiss Environmental Protection Act (EPA), Article 10(a)(1). Therefore, anyone who wishes to plan, construct or modify an installation must submit an environmental impact report to the competent authority (EPA, Article 10(b)(1). In order to prepare for the report, a preliminary investigation is carried out (EPA, Article 10(b)(3)). The environmental protection agencies assess the preliminary investigation and the report and propose the measures required to the competent decisionmaking authority (EPA, Article 10(c)). As Switzerland has signed and ratified the Espoo Convention on Environmental Impact Assessment in a Transboundary Context, the regulation of this convention is, where appropriate, also applicable.<sup>21</sup> Furthermore, Switzerland has also signed the Aarhus Convention on Access Io Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.<sup>22</sup> Ratification process of this convention is still ongoing.

#### **II. INSTITUTIONAL FRAMEWORK**

Since 24 November 1957, when Article 24 (now Article 90 of the amended Swiss Constitution which entered into force on 18 April 1999) was added to the Swiss Constitution, nuclear energy has been the responsibility of the federal legislature. Thus, the Confederation is responsible for granting licences for nuclear transport and nuclear facilities. It also supervises all nuclear activities (EA, Article 72). The Confederation also plays an important role in the field of research and the training of nuclear specialists (NEA, Article 86).

The Federal Council has the necessary regulatory and administrative powers to adopt the regulations required for the development of the use of nuclear energy and for radiation protection. The Federal Department of the Environment, Transport, Energy and Communications (DETEC), and the Federal Department of Home Affairs (FDHA) are responsible for implementing the provisions adopted by the Federal Council in the field of the use of atomic energy and the field of protection against ionising radiation, respectively. The ENSI is the supervisory authority for nuclear safety and security.

<sup>21.</sup> Convention on Environmental Impact Assessment in a Transboundary Context (1991), 1989 UNTS 310, entered into force 10 Sept. 1997 (Espoo Convention).

<sup>22.</sup> Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (1998), 2161 UNTS 450, entered into force 30 Oct. 2001 (Aarhus Convention).

Apart from the federal departments and the specialised services of the Confederation, the public sector is also represented by a public scientific research centre, PSI.

#### **1.** Regulatory and Supervisory Authorities

#### a) Federal Council

The Federal Council, which represents the executive branch of government in Switzerland at federal level, plays an important role in the nuclear institutional framework.

First, the Federal Council assists in the development of regulations in the atomic energy field and ensures their implementation (NEA, Article 101). The Federal Council sets up the necessary administrative bodies and the commissions responsible for questions relating to the use of nuclear energy and to radiation protection (NEA, Articles 6, 24, 32, 70, 71 and 81). More specifically, the Federal Council has the power to broaden the category of activities for which a preliminary licence is required (NEA, Article 6). The Federal Council or the authority designated by it may make exceptions to the licensing regime by taking special measures against specific destination states. It may waive the rules on licences (NEA, Article 8). Furthermore, the Federal Council lays down the minimum requirements which specialised staff of nuclear installations and the surveillance team have to meet (NEA, Articles 22 and 23). It also lays down the criteria applicable to protection zones (NEA, Article 40).

At an administrative level, the Federal Council is responsible for examining and deciding upon applications for preliminary general licences for nuclear installations, prior to construction and operating licences (NEA, Article 12). Since the entry into force of the Nuclear Energy Act, the Federal Council is no longer the competent authority for granting construction and operating licences. According to Articles 15 and 19 of the Nuclear Energy Act, the Federal Department for the Environment, Transport, Energy and Communications (DETEC) is now in charge of decision-making in this regard. DETEC is also the competent licensing authority for taking preparatory steps for the setting up of a radioactive waste repository (Art. 35). However, the Act provides that the Federal Council may exclude from the licensing regime studies which involve only minor prejudice.

The Federal Council may order the precautionary shutdown of nuclear power plants in extraordinary situations (NEA, Article 25). Extraordinary situations mean cases of threat of war or other power-political threat.

The Federal Council may promote applied research regarding the peaceful use of nuclear energy. It may also contribute to international organisations and participate in international projects in connection with the peaceful use of nuclear energy (NEA, Articles 86 and 87).

#### b) Federal Assembly

The Federal Assembly, Switzerland's Parliament, is involved in the nuclear field by approving the Federal Council's decisions as to general licences for nuclear installations (NEA, Articles 48 and 67). The Nuclear Energy Act provides that, if the Federal Council refuses to grant a general licence and the Federal Assembly does not approve this decision, it shall instruct the Federal Council to grant the general licence with any requirements decided by it and to submit to it a new decision for approval. The decision of the Federal Assembly regarding the approval of a general licence is subject to referendum (NEA, Article 48).

The Assembly is also competent in respect of third party liability and insurance (Article 29 of the Nuclear Third Party Liability Act of 18 March 1983). Thus, in the case of large-scale damage, the Federal Assembly is empowered to draw up indemnification rules determining the general principles of compensation for victims. A special independent body may be set up by the Federal Assembly to ensure that these principles are applied.

The Nuclear Energy Act requires that the Federal Council regularly informs the Federal Assembly of the progress of the programme prepared by the persons responsible for disposing of radioactive waste (Article 32).

### c) Federal Department of the Environment, Transport, Energy and Communications (DETEC)

The general task of the DETEC is to prepare legislation related to the use of nuclear energy.

DETEC is also the competent authority to grant construction and operating licences (NEA, Articles 15 and 19), as well as licences for geological studies carried out in a possible location in order to gather information about the feasibility of constructing a deep geological repository (NEA, Article 35). The licences granted by DETEC can be revoked at any time if the prerequisites for granting are not or are no longer fulfilled (NEA, Article 67).

#### d) Swiss Federal Office of Energy (SFOE)

According to Article 9 of Ordinance on the Organisation of the DETEC of 6 December 1999 (OrgO-DETEC) (SR 172.217.1), the SFOE is the specialised service for the security of energy supply and the use of energy. Regarding the use of nuclear energy, the office is engaged in ensuring high-security standards. The SFOE supports DETEC in preparing the national legislation in the field of nuclear energy as well as, in conjunction with the Federal Department of Foreign Affairs, international nuclear treaties, and in ensuring that national and international regulations are properly implemented. The SFOE also prepares the decisions taken by the Federal Council and DETEC regarding nuclear energy. For example, applications for a general licence are sent to the SFOE, which checks the application file and decides whether an expert report is necessary (NEA, Articles 42 and 43). It is also the competent authority for licensing the transport of nuclear materials and radioactive waste (NEO, Articles 13 and 14).

#### e) Swiss Federal Nuclear Safety Inspectorate (ENSI)

The ENSI is the supervisory authority for nuclear safety and security. ENSI emerged from the former principal nuclear safety division (DSN) of the SFOE. With the Federal Act of 22 June 2007 on the Swiss Federal Nuclear Safety Inspectorate Act (ENSIA) (SR 732.2), the DSN was separated from the SFOE and transformed into an institution under public law endowed with its own legal personality. ENSI is administratively attached to DETEC (OrgO-DETEC, Article 14a). However, it is vested with operational, institutional and financial independence (ENSIA, Articles 1 and 18). The creation of an independent supervisory authority brings Switzerland *de facto* and *de jure* in full compliance with the Convention on Nuclear Safety (Article 8(2)) and the Swiss Nuclear Energy Act (NEA, Article 70(2)). ENSI management, consisting of the director and the division heads, is responsible for current operations. It reports to the ENSI Board, a strategic management board, which is elected by the Federal Council. The ENSI Board is accountable to the Federal Council, to whom it must submit an annual report. ENSI is the competent authority for supervising nuclear facilities with respect to radiation protection and nuclear safety at all stages of the life cycle. Since 2008, ENSI is also the competent authority with regard to physical protection. ENSI has three main functions:

- specifies the detailed safety requirements in regulatory guidelines;
- reviews licence applications; and
- supervises the nuclear facilities, the preparations for the disposal of radioactive waste and the transport of radioactive material from and to nuclear facilities.

ENSI also has certain licensing powers according to the radiation protection legislation; in addition, it grants permits for modifications that do not significantly deviate from a construction or operating licence.

#### f) Federal Department of Home Affairs (FDHA)

With respect to radiological issues, the Federal Department of Home Affairs (FDHA) has been granted regulatory and administrative powers in the area of radiation protection.

Regarding its regulatory powers, the FDHA has a general responsibility for radiation protection issues. It has the task of specifying the necessary rules for applying measures enacted by the Federal Council for protection against ionising radiation. In particular, with the assistance of DETEC, and upon consultation with the relevant supervisory bodies, it regulates the implementation of the radiation protection and the corresponding supervisory activities to be carried out.

In addition, the FDHA specifies measures to be adopted for the protection of persons exposed to radiation for medical purposes. With regard to foodstuffs, the FDHA determines the maximum concentrations of radionuclides which may be incorporated in food products.

Moreover, the FDHA has issued regulations governing the training programme, examination method and rights in relation to training and further education courses in the field of radiation protection. Courses offered by private institutions must first be recognised by the relevant supervisory body. In any tasks involving the use of radioactive materials or equipment generating ionising radiation in a professional context, it is necessary to have completed education and training recognised by the FDHA or the relevant supervisory body.

The FDHA also has the power to impose any necessary measures with regard to the medical supervision of persons exposed to ionising radiation at their workplace.

In the field of radioactive waste management, the FDHA ensures the disposal by PSI of radioactive waste, excepting that originating from electricity-producing nuclear installations and facilities for the reprocessing of spent fuel elements.

#### g) Federal Office of Public Health (FOPH)

Through its Radiation Protection Division, the FOPH enjoys wide administrative and supervisory powers in the field of protection against radiation.

#### *i)* Administrative powers

The FOPH is the competent authority for issuing licences for the production, use, possession, disposal, import and export of radioactive material, including their authorised

radioactive discharges to the environment and for radiological equipment, whether used for industrial, scientific, medical or agricultural purposes, with the exception of nuclear installations and nuclear fuel elements. The Swiss National Accident Insurance Fund (Suva) advises the FOPH when an application for a new licence is submitted in the industry sector. Anyone who manufactures or trades in radioactive material or equipment emitting ionising radiation, and which falls under the licence regime, must submit an annual report to the FOPH on their activities. The FOPH may allow certain types of radioactive material and equipment emitting ionising radiation or containing radioactive substances to be used generally or for specific purposes without a licence for the users if certain criteria are met and a type licence is issued. The FOPH grants the necessary licence for the use of material and equipment and receives the declarations of persons possessing substances or equipment available for general use, unless it waives such formalities.

In consultation with a panel of experts, the FOPH may also advise the relevant authority or the ethics commission on protection against radioactive substances intended to be used for medical purposes (radiopharmaceuticals). The FOPH must authorise any work involving unsealed radioactive sources and application to human beings, which a company or hospital wishes to carry out.

#### *ii)* Supervisory powers

The FOPH supervises companies in which the primary concern is protection of the public, i.e. mainly for medicine and research applications, while Suva supervises those in which the primary concern is the protection of workers, i.e. for industrial applications.

Meanwhile, ENSI is responsible for inspecting the safety of nuclear installations. The FOPH and the SFOE, each in their own sphere, control the transport, import and export of radioactive substances as well as equipment and objects containing such substances.

#### *iii)* Other powers

The FOPH is responsible for the monitoring of ionising radiation and radioactivity in the environment in Switzerland. ENSI additionally monitors ionising radiation and radioactivity in the vicinity of nuclear facilities. The results of environmental monitoring are published in the annual report of the FOPH.

The FOPH is also responsible for the collection of radioactive waste from industrial, research and medical activities. The FOPH works together with PSI with respect to the collection and conditioning of this waste. The FOPH acts as the central administration responsible for collecting radioactive waste other than that from nuclear installations.

The FOPH is also the authority which recognises training and further education courses offered by Swiss institutions, as well as education in radiation protection in the medical, industrial and research sectors, and the education of individuals carried out abroad when a person wants to qualify as a radiation protection expert in Switzerland.

#### *h)* State Secretariat for Education, Research and Innovation (SERI)

The State Secretariat for Education, Research and Innovation (SERI) is part of the FDHA. SERI co-ordinates research activities carried out in university circles, the private sector and by government authorities. It represents the government in bodies carrying out fundamental and applied research. It also deals with research into thermal nuclear fusion and high and medium-energy nuclear physics.

#### *i)* Other authorities

Other federal departments are called on to regulate questions falling within the nuclear energy field and in particular: the Federal Department of Justice and Police, for the transport by road of dangerous goods, and the Federal Department of Foreign Affairs, for public protection measures; the Federal Department of Economic Affairs, Education and Research for the export of nuclear materials of particular significance; the Department of Defence, Civil Protection and Sport for radiation protection on behalf of the army; and the Federal Department of Finance with respect to legislation on nuclear measurement units.

#### 2. Advisory Bodies

#### a) Swiss Federal Nuclear Safety Commission (NSC)

In the context of the reorganisation of the nuclear regulatory body, Article 71 of the Nuclear Energy Act was also amended to replace the former Federal Commission for the Safety of Nuclear Installations with the new Swiss Federal Nuclear Safety Commission (NSC) by 1 January 2008.

In its bill for restructuring the nuclear regulatory body, the Federal Council referred to the completely independent organisational structure of the new ENSI, including its supervisory board (ENSI Board). The Federal Council had therefore proposed to do without an independent advisory body and eliminate Article 71 of the Nuclear Energy Act. In the parliamentary legislation process, however, Article 71 of the Nuclear Energy Act was reintroduced and amended to provide for an independent advisory body with a reduced number of members and a reduced scope of duties.

#### *i)* Legal status

The Swiss Federal Nuclear Safety Commission is stipulated in Article 71 of the Nuclear Energy Act, as amended on 22 June 2007 and entered into force on 1 January 2008. The obligations and the organisation of the NSC are further detailed in the Ordinance on the Swiss Federal Nuclear Safety Commission of 12 November 2008, which entered into force on 1 January 2009.

The NSC acts as an advisory body to the Federal Council, DETEC and ENSI, and delivers an annual report to DETEC.

#### *ii)* Responsibilities

The functions of the NSC are outlined in the Nuclear Energy Act. According to Article 71 of the NEA, the NSC studies fundamental nuclear safety issues and supports legislative work in the context of nuclear safety. It can give the Federal Council or DETEC an opinion on the safety assessment reports by the regulatory body. The NSC also gives its opinion on safety issues, as requested by the Federal Council, DETEC or the SFOE.

The duties of the NSC are further detailed in the Ordinance of 12 November 2008:

• State-of-the-art and research (Article 2):

The NSC keeps track of the state-of-the-art of science and technology, in particular in the field of nuclear safety. It can propose relevant research that could be carried out in Switzerland or recommend participation in foreign or international research projects. • Basic nuclear safety issues (Article 3):

The NSC deals with basic nuclear safety issues, in particular in the fields of the technical safety of installations, the impact of organisational and human factors on nuclear safety, the disposal of radioactive waste, the assessment of nuclear safety as well as the regulation and surveillance of nuclear installations. The NSC may recommend measures to enhance nuclear safety. It may also give its opinion on specific issues raised by ENSI.

• Rule-making (Article 4):

The NSC is involved in the drafting of acts and ordinances in the field of nuclear safety. It may comment on the directives of the regulatory bodies. The NSC may recommend adopting or amending regulations for Swiss nuclear installations.

• Opinions (Article. 5):

The NSC may give its opinion on the safety assessment reports by the regulatory body in the licensing procedures for a general licence, construction licence or operating licence; it may also give its opinion on other safety assessments by the regulatory body. In doing so, the NSC may cover only selected aspects of safety; it includes, however, a statement on the adequacy of the measures taken to protect humans and the environment.

The NSC does not cover security issues. Radiation protection issues are assigned to the Federal Commission for Radiological Protection.

The NSC is required to submit on an annual basis a work plan and a report on its activities to DETEC. The annual report is published. All statements in the context of licensing or rule-making procedures are published on the NSC website.

iii) Structure

The Swiss Federal Nuclear Safety Commission is comprised of five to nine members. Members of the NSC have expert knowledge in relevant fields of science and technology. Candidates for members, including the chairperson, are nominated by DETEC and appointed by the Federal Council. The NSC can submit proposals for candidates to DETEC.

The NSC and its members act without a mandate. Members carry out their tasks personally and not as members of an organisation or company. A comprehensive neutrality requirement applies to all members. This means they may not belong to any authority that deals with the enforcement of nuclear energy legislation, nor to any company that operates a Swiss nuclear power plant or is involved in the planning of a deep geological repository.

If necessary, the NSC may, with permission of the SFOE, call in external experts (Article 10 of the Ordinance of 12 November 2008). Also, specific issues may be dealt with in temporary expert committees to prepare for decision-making in the NSC.

Necessary information is provided to the NSC by the regulatory bodies. Should the information not be available to them, the NSC is entitled to collect such information directly from the holder of, or applicant for, a licence. The NSC's work is confidential, and an obligation of professional secrecy is imposed on experts. If anyone is directly involved in a subject matter or is associated with a party involved in a subject matter beyond their assignment in the NSC, they are required to abstain.

The NSC can take decisions in meetings on a simple majority basis (with casting vote by the chairperson), if at least two-thirds of its members are present. Alternatively, decisions

can be taken via correspondence on a qualified majority basis of at least two-thirds of the members.

The NSC is supported by a secretariat. The NSC and its secretariat are administratively attached to the SFOE.

#### b) Federal Commission for Radiological Protection (CPR)

The Federal Commission for Radiological Protection (CPR) is attached to the FDHA.

#### *i) Responsibilities*

The CPR is responsible for giving general advice on matters concerning radiation protection to the Federal Council, the FDHA, DETEC, the Federal Department of Defence, Civil Protection and Sport, the FOPH, ENSI, interested services and Suva (see Section 6).

#### *ii) Structure*

Members of the CPR come from academic, industrial and medical circles and from public administration.

#### c) The National Emergency Operations Centre (NEOC)

The National Emergency Operations Centre (NEOC) is the federal authority responsible for dealing with emergency incidents. It also serves as national reporting and situation centre and as the staff unit of the Federal Civil Protection Crisis Management Board. The NEOC is a division of the Federal Office for Civil Protection (FOCP) within the Federal Department of Defence, Civil Protection and Sport (DDPS). The NEOC is the federal centre of expertise for incidents involving suspected or increased radioactivity that presents or could present a risk to the population and the environment. The spectrum of events is therefore very large, ranging from radiological industrial and transport accidents to incidents in Swiss and foreign nuclear power plants to nuclear explosions or accidents. More recently, the NEOC has had to focus increasingly on nuclear terrorism in all its different forms.

In the event of such an accident, the NEOC provides the authorities with early warnings and alerts the population. Furthermore, in its role as competent authority, the NEOC is responsible for assessing radiological emergencies and deciding on the necessary protective measures. In cases of extreme urgency, it is also authorised to issue instructions.

The NEOC is the permanent core of a larger organisation, the Federal Emergency Organisation. It has access to a wide range of measuring equipment belonging to federal and cantonal partner organisations. Should an incident occur, the NEOC can deploy this equipment to assess the radiological situation.

The NEOC is also the contact point and competent authority for foreign organisations, such as the International Atomic Energy Agency (IAEA). They keep the NEOC up-to-date with incidents abroad. Conversely, it must report incidents in Switzerland that could have an impact on other countries.

Given that the Hazmat Suisse database contains information of radioactive nuclides, its maintenance is part of the NEOC's routine radiation protection activities.

#### 3. Public and Semi-Public Agencies

#### a) PSI

PSI is a multi-disciplinary research centre for natural sciences and technology. It collaborates with national and international universities, other research institutions and industry in the areas of solid-state research and materials sciences, particle physics, life sciences, energy research and energy-related environmental research. PSI employs about 2 100 people, and is thus the largest national research institution, as well as the only one of its kind within Switzerland.

#### *i)* Legal status

PSI is part of the ETH Domain, which covers the two Swiss federal institutes of technology run by the Confederation, ETH Zürich and EPFL, and four national research institutes, one of them being PSI. PSI is a federal research establishment governed by public law.

#### *ii)* Responsibilities

PSI is entrusted with research activities in the following fields:

- physics of condensed matter and materials sciences;
- radiochemistry, structural biology and radiation medicine;
- elementary particle physics;
- nuclear energy (especially relating to nuclear safety and radioactive waste disposal); and
- non-nuclear energy and energy-related environmental sciences.

PSI is one of the world's leading user laboratories for the national and international scientific community. It develops, builds and operates complex large-scale research facilities that imposes particularly high requirements in terms of knowledge, experience and professionalism. PSI also plays an important role in education and training. About 320 PhD students are working on a doctoral thesis at PSI and about 200 PSI scientists currently teach at Swiss universities, ETH Zürich, EPFL or one of the universities of applied sciences.

PSI also provides various services to the government and to other public bodies and the industry, also in the fields of nuclear safety, radioactive waste disposal and environmental protection in relation to energy use. PSI advises federal bodies, in particular the Swiss nuclear safety authorities, and carries out research on their behalf. It also provides support to the Swiss authorities responsible for radiation protection.

Lastly, PSI collaborates with the international scientific community in preparing joint research and development programmes.

iii) Structure

PSI belongs to the domain of the Swiss federal institutes of technology (ETH Domain), which consists of the two technical universities ETH Zürich and ETHL and four national research centres, the largest of them being PSI. PSI operates large scientific research facilities, such as the Swiss Light Source (SLS), the free-electron X-ray laser (SwissFEL),

the SINQ neutron source, the S $\mu$ S muon source and the Swiss research infrastructure for particle physics (CHRISP). In addition to its research activities, it operates Switzerland's sole facility for the treatment of specific malignant tumours using protons.

The ETH Board is the strategic management and supervisory body of the ETH Domain. It defines the strategy of the domain, sets boundary conditions and formulates the performance agreements for the six ETH institutions. The ETH Domain receives an annual global budget, which is distributed to the institutions of the domain, taking account of strategic issues, national duties and the performance of the six institutions in past years.

#### iv) Financing

PSI is about 70% government funded (by the annual global budget; approximately CHF 300 million in 2020). The remaining 30% comes from third party contributions (research contracts with industry, funding organisations, donations and sponsoring). Scientific services are charged at full cost.

#### b) Fund for the decommissioning of nuclear installations and for waste disposal

#### i) Legal status

Provisions were made in the former Federal Order of 6 October 1978 on the Atomic Energy Act for the setting up of a fund to finance the decommissioning and dismantling of nuclear installations no longer in service. This fund was established on 1 January 1984 and is managed under the supervision of the Federal Council. It has its own legal personality and has its headquarters in Bern.

Chapter 7 of the Nuclear Energy Act contains more specific provisions: it separates the decommissioning fund from the waste disposal fund, both of which still report to the Federal Council and have legal personality.

The Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund defines costs the funds have to cover, the requirements concerning the payments, the investments politic, the currency, the accountability, the provisions before the decommissioning of the nuclear power plants, the organisation and the monitoring of the funds.

#### ii) Responsibilities

The fund for financing the decommissioning and dismantling of nuclear installations no longer in service was set up to cover costs arising from the decommissioning and dismantling of nuclear installations no longer in use and from the management of the waste produced.

The decommissioning fund established by the Nuclear Energy Act ensures the financing of the decommissioning and dismantling of nuclear installations withdrawn from service, and that of the disposal of the waste produced thereby (decommissioning costs). The waste disposal fund ensures the financing of the disposal of radioactive operating waste and of spent fuel assemblies, after withdrawal from service of nuclear installations, disposal costs (NEA, Article 77).

#### iii) Structure

Each fund established by the Nuclear Energy Act must be administered by a board acting as a directing body and nominated by the Federal Council (NEA, Article 81).

The Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund defines the structure of the funds. This structure outlines a board, a secretariat and an auditing body. With effect from 1 January 2022, the structure also encompasses the administrative committee board, the investment committee and the finance committee. The members of the commission and of the auditing body are nominated by the Federal Council. The funds are administered by a Commission with a maximum of 11 members. Nuclear power plant operators are entitled to a maximum of one-third of the seats of the Commission, committees and workgroups.

#### iv) Financing

The resources of the fund for financing the decommissioning and dismantling of nuclear installations no longer in service are constituted by the contributions paid by the owners of nuclear installations subject to the Ordinance of 7 December 2007 on the Decommissioning Fund and the Waste Disposal Fund. Every five years, the Commission of the fund fixes the annual amount due by each owner.

The boards administering the funds established by the Nuclear Energy Act set the amount of contributions to be paid by each contributor to the funds.

#### c) National Cooperative for the Disposal of Radioactive Waste (Nagra)

#### i) Legal status

The National Cooperative for the Disposal of Radioactive Waste (Nagra) is a private cooperative company set up in 1972 by the radioactive waste producers (the Confederation and five electricity companies) to undertake, at national level, the planning and implementation of final disposal solutions for the various categories of radioactive waste.

#### *ii)* Responsibilities

Nagra is responsible for the disposal of all types of radioactive waste. This includes, in particular, the preparation of proposals and licence applications (within the framework of the sectoral plan "deep geological repositories" and in accordance with the NEA) as well as the construction, operation and closure of the repositories. Its tasks include the following:

- characterisation and ongoing inventorying of radioactive wastes as a basis for planning disposal projects;
- checking waste specifications as part of the waste disposal certification procedures and as a service to the members of Nagra;
- acquisition and evaluation of geological data required for site selection, safety assessment and disposal projects;
- project studies providing input for designing repository installations and engineered barriers, and for planning operating procedures;
- ongoing analysis of results and data within the context of performance assessment and evaluation of information with a view to licensing procedure requirements;

- development of databases and fine-tuning of the methods used to evaluate disposal system behaviour, verification and validation of the data and models used in performance assessment;
- active participation in international collaborative projects, with the aim of coordinating and optimising planning and development activities as well as maintaining contact with similar organisations in foreign countries;
- fulfilling responsibilities in terms of communication and information requirements, in particular, keeping the public informed on the current status of disposal programmes and proposals for management solutions; and
- providing expert services to third parties.

Every five years, Nagra has to compile the waste management programme on behalf of the waste producers as stipulated by nuclear energy legislation. Nagra also periodically updates the cost estimates for final disposal that serve as a basis for the annual contributions paid by the nuclear power plant operators to the waste management and decommissioning fund.

#### iii) Structure

All Swiss producers of waste of nuclear origin, including the Confederation, are members of Nagra. The Confederation participates on two counts: first, as a producer of waste from research reactors and from the processing of radioactive materials, and secondly, as the collector of waste produced in the fields of industry, research, medicine and education.

The Board of Directors of Nagra is composed of persons from industry circles concerned with the disposal of radioactive waste as well as representatives of the Federal Administration. Particular responsibility for studying the technical and safety aspects of waste processing has been given to a technical commission made up of specialists in the nuclear energy field. To accomplish its task, the commission may call upon external experts.

iv) Financing

Nagra is a non-profit co-operative organisation. Expenses are paid by the members. The cost of radioactive waste disposal is borne entirely by the producers of the waste concerned.