2. REGULATORY BODY

LEARNING OBJECTIVES FOR SECTION 2

Regulatory Body

After following the lectures, studying the printed material, performing the exercises, studying the given IAEA references and after discussing with the tutor the application of the IAEA practices at the national level, the learner will be able to describe the following:

- IAEA guidance on regulatory organization and functions;
- Some national good practices on regulatory organizations;
- Licensing of a nuclear power plant;
- Some national practices on licensing;
- Quality assurance in the regulatory body;
- Regulatory effectiveness and performance reviews;
- Professionalism and training of the regulatory staff;
- National regulatory practices in the learner’s own country;
- Comparison of the learner’s own regulatory body with international practices.

FUNDAMENTAL REFERENCES (TO BE READ THOROUGHLY)

2.1. REGULATORY INDEPENDENCE

The importance of regulatory independence is recognized in the Convention on Nuclear Safety [11] and the IAEA Safety Requirements on legal and governmental infrastructure for safety (Ref. [2] ). Both documents address the establishment of a regulatory body and the need for its separation, or independence, from the promoters of nuclear technology. The primary reason for this separation is to ensure that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety. Furthermore, the credibility of the regulatory body in the eyes of the general public depends in large part upon whether the regulatory body is regarded as being independent from the organizations it regulates, as well as independent from government agencies or industry groups that promote nuclear technologies.

It is recognized that a regulatory body cannot be absolutely independent in all respects from the rest of government: it must function within a national system of laws and budget constraints, just as other governmental and private organizations do. Nevertheless, it is important for its credibility and effectiveness that the regulatory body has effective independence in order to make the necessary decisions with respect to the safety of workers, the public and the environment.

The need for independence of the regulatory body does not imply that it needs to have an adversarial relationship with operators or any other stakeholder.

The following paragraphs provide a more detail discussion of a number of elements of regulatory independence:

**Elements Of Regulatory Independence**

*Political:* The political system shall ensure clear and effective separation of responsibilities (duties) between the regulatory body and organizations responsible for the development of nuclear technologies. In this regard, it is important to distinguish between independence and accountability. The regulatory body should not be subject to political influence or pressure in taking safety decisions. The regulatory body should however be accountable with regard to fulfilling its mission to protect workers, the public and the environment from undue radiation hazards. One way of providing this accountability is by establishing a direct reporting line from the regulatory body to the highest levels of government. In the case where a regulatory body reports to a government agency that has responsibility for exploiting or promoting nuclear technologies, there should be channels of reporting to higher authorities to resolve any conflicts of interest that may arise. This accountability should not interfere with the independence of the regulatory body in making specific safety decisions with neutrality and objectivity.

*Legislative:* In the legislative framework of a national regulatory system (e.g. atomic laws or decrees) the role, competence and independence of the regulatory body with respect to safety should be defined. The regulatory body shall have the authority to adopt or develop safety regulations that implement laws passed by the legislature. The regulatory body shall also have the authority to take decisions including enforcement actions. There should be a formal mechanism for appeal against regulatory decisions, with predefined conditions that must be met for an appeal to be considered. The regulatory body shall have the responsibility for adopting or developing safety regulations that implement laws passed by the legislature.
Financial: “The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.” (Ref. [2], Para. 2.2 (4)) While it is recognized that the regulatory body is in principle subject to the same financial controls as the rest of government, the budget of the regulatory body should not be subject to review and approval by government agencies responsible for exploiting or promoting nuclear technologies.

Competence: The regulatory body should have independent technical expertise in the areas relevant to its safety mission. The management within the regulatory body should therefore have the responsibility and authority to recruit staff with the skills and technical expertise they consider necessary to carry out the regulatory functions. In addition the regulatory body should maintain awareness of the state of the art in safety technology. In order to have access to outside technical expertise and advice that is independent of operator or industry funding/support to support its regulatory decisionmaking, “The regulatory body shall have the authority to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate” (Ref. [2], Para.2.6 (10)). In particular, the regulatory body shall have the ability to set up and fund independent advisory bodies to provide expert opinion and advice (Ref. [2], Para. 2.4, (9)) and to award contracts for research and development projects.

Information to the Public: One of the responsibilities of the regulatory body is to provide information to the public. “The regulatory body shall have the authority to communicate independently its regulatory requirements, decisions and opinions and their basis to the public.” (Ref.[2], Para. 2.6, (11)). Since the public will only have confidence in the safe use of nuclear technology if the regulatory process and decisions are transparent, government should set up a system to allow independent experts and experts from major stakeholders (for example, the industry and the workforce and the public) to provide their views. The experts’ findings should be published.

International: “The regulatory body shall have the authority to liaise with regulatory bodies of other countries and with international organizations to promote cooperation and exchange of regulatory information.” (Ref.[2], Para. 2.6, (14)).

2.2. ORGANIZATION AND FUNCTIONS OF REGULATORY BODY

2.2.1. IAEA guidance for regulatory organization [2]

The prime responsibility for safety is assigned to the operator. The primary objective of the regulatory body is to ensure that the operator fulfils this responsibility to protect human health, and the environment from possible adverse effects arising from nuclear facilities and management of radioactive waste. In order to achieve these objectives the regulatory body defines policies, safety principles and associated criteria as a basis for its regulatory actions. Table VI presents the main functions of the regulatory body.

In order to discharge its main responsibilities the regulatory body needs to:

?? Establish a process for dealing with application, e.g. issuing of an authorization;
?? Provide guidance to the operator on developing and presenting safety assessments or any other required safety related information;

---

Ensure that proprietary information is protected;

Communicate with, and provide information to, other competent governmental bodies, international organizations and the public; Ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated;

Ensure that appropriate records relating to the safety of facilities and activities are retained and retrievable;

Ensure that its regulatory principles and criteria are adequate and valid, and shall take into consideration internationally endorsed standards and recommendations;

Advise the government on matters related to the safety of facilities and activities;

Confirm the competence of personnel responsible for the safe operation of the facility or activity; and

Confirm that safety is managed adequately by the operator.

TABLE VI. FUNCTIONS OF THE REGULATORY BODY [2]

The regulatory body has the following main functions:

Establishment, promotion or adoption of regulations and guides, upon which its regulatory actions are based;

Review and assessment of submissions on safety from the operators both prior to authorization and periodically during operation as required;

Issuing, amending, suspending or revoking of authorizations;

Carrying out regulatory inspections;

Ensuring corrective actions if unsafe or potentially unsafe conditions are detected;

Taking the necessary enforcement actions in the event of safety requirements having been violated.

The regulatory body may also have additional functions such as:

Carrying out independent radiological monitoring in and around nuclear facilities;

Carrying out independent testing and quality control measurements;

Initiating, coordinating and monitoring safety research and development in support of the regulatory functions;

Providing personnel monitoring services and medical examinations;

Monitoring of nuclear nonproliferation;

Regulatory control of industrial safety.

The regulatory body needs to be structured in a manner that ensures that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The organizational structure and size of the regulatory body are influenced by many factors and it is not appropriate to recommend a single organization model. The regulatory body needs a structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it needs adequate resources to discharge its responsibilities.

The organizational structure of a regulatory body varies from country to country. The following sections provide general guidance on the organizational structure based on the functions of the regulatory body. The principal functions to be carried out are: regulations and guides, authorization, review and assessment, inspection and enforcement. The regulatory body has also the function in connection with emergency preparedness. For a large organization it is often useful to have each of these functions assigned to a discrete section or division within the regulatory body. Each of these functions need many specialized skills.
Rather than having each functional unit containing its own specialists, it is often practical and efficient to group the specialists in a matrix such that each organizational unit assigned responsibility for a function can draw on specialist skills as needed.

Development of regulations and guides requires a considerable amount of resources. If new or revised regulations and guides are required frequently it may be appropriate to have a permanent unit to deal with this. Where the need for new or revised regulations and guides is infrequent it may be sufficient to identify a mechanism whereby such resources can be drawn together when required. Regulations and guidance cannot be produced in isolation but consultation both within and outside the regulatory body is needed. In developing regulations and guides, account is taken of international standards and recommendations obligations imposed by any conventions to which the state may be party, relevant industrial standards and any advances in technology.

Review and assessment are among the main continuous functions of a regulatory body. It is therefore appropriate to assign this to a person or organizational unit within the regulatory body. This function often involves drawing together teams of specialists. Review and assessment is based on regulations and guides. The review and assessment necessitate effective communication and interaction between different units of the regulatory body. The main parameters, characteristics and results are recorded and retained, in written form, for future reference.

Inspection is another continuous function of the regulatory body and can take many forms. The inspectors may form a permanent part of the inspection unit, or may be drawn from other parts of the regulatory body as required. Project managers or supervisors should be appointed to plan and monitor the work of all inspections performed for a facility and draw the results together. An inspection may result in a requirement for additional review and assessment or for enforcement action. Therefore, there should be strong and effective links with all other parts of the regulatory body.

The use of resident inspectors may provide benefits such as improving the ability of the regulatory body to engage in onsite surveillance of systems, components, tests, process and other activities of the operator at any time. The full-time presence of inspectors can improve the ability of the regulatory body to identify and respond promptly to problems. With resident inspectors, inspection frequency and intensity at any given level of human resources can be more readily optimised, and the regulatory body may be better informed of operator schedules and hence better able to coordinate its inspection activities with key operator activities that it wishes to observe. Where resident inspectors are employed, consideration should be given to locating more than one at a particular site for mutual support. There should be adequate communication between resident inspectors and the headquarters to maintain regulatory effectiveness.

The use of non-resident inspectors may demand less in terms of human resources than the use of resident inspectors. Non-resident inspectors may inspect more than one site, which may be a more efficient use of limited resources. Alternatively a non-resident inspector may be assigned to a particular facility and may coordinate inspection activities at that facility. Furthermore, a non-resident inspector is less likely to become unduly isolated from the activities and decision making of the regulatory body.

Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. There are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator is
required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed timescale, and to take all necessary measures to prevent recurrence. The regulatory body shall ensure that the operator has effectively implemented any remedial actions. The organizational structure of the regulatory body needs to enable enforcement actions to be taken at appropriate level.

The precise role of the regulatory body in emergencies varies considerably between states, depending on how it is organized to respond to emergencies in general. In many states, the regulatory body has an advisory function for the authority responsible for emergency preparedness. It will therefore be necessary to set up procedures to draw together the necessary resources when required, and to exercise them as appropriate. The structure of the regulatory body should clearly indicate a responsible person or group in charge of coordinating the development of procedures, liaising with other organizations involved in the overall emergency preparedness and conducting the exercises.

The regulatory organization needs an administrative support that is an organizational unit dedicated to general administrative work.

A regulatory body is by its very nature engaged in activities that require professional legal support. The legal support can be provided as part of the staff of the regulatory body or provided by another governmental body or obtained through contract. The regulatory body should be structured to recognise either implicitly or explicitly the interface of legal functions with technical and management functions. Activities typically requiring professional legal participation include, e.g. development of basic legislation and regulations including compatibility with international conventions and agreements, providing legal advice and representation of the regulatory body in the case of enforcement activities and at the court of law.

If a regulatory body or its dedicated support organization does not have an adequate number of qualified personnel or the workload does not justify the recruitment of full-time staff, consultants may be used to perform selected tasks. The technical qualifications and experience of such consultants are at least at the same level as the staff of the regulatory body performing similar tasks. More generally consultants are used by the regulatory body to assist in performing tasks requiring an additional level or area of expertise which may arise occasionally, or to provide a second opinion on important issues. Since the regulatory body has to evaluate and utilize the work performed by consultants, it defines the scope of the work to be performed. The consultants are required to provide a detailed written report which includes the basis and method of evaluation, conclusions and recommendations that will assist the regulatory body in completing its evaluation.

The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body. For example, broadly based advisory committees with membership drawn from other government departments, regulatory bodies of other countries and scientific organizations can bring broad perspectives to bear on the formulation of regulatory policy and regulations. Another type of advisory committee is the technical committee composed of members with a range of technical skills needed to evaluate complex technical issues. Such committees may have a defined role in the authorization process. Alternatively, they may be ad hoc, performing a function similar to that of consultants but for which a number of different skills are needed to address complex issues. Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations.
The regulatory body encourages facility operators to carry out the research and development needed to produce adequate argumentation about safety. However, there may be situations in which the operator’s research and development are insufficient or in which the regulatory body requires independent research and development to confirm specific important findings. The regulatory body may need research and development work in support of its regulatory functions in such areas as inspection techniques, analytical methods or in developing new regulations and guides. The regulatory body’s organizational structure reflects these needs either by setting up a research unit or by having staff who can define research and development needs, initiate, coordinate and monitor the work and evaluate the results. Regardless of how it is carried out, the regulatory body ensures that the research is focused on regulatory needs, whether short or long term, and that the results are disseminated to the appropriate organizational units.

The actions and responsibilities of many organizations can interact with those of the regulatory body. Such an organization may include government departments, environmental protection authorities, other bodies with responsibilities for emergency preparedness, physical protection, water and land use planning authorities, authorities responsible for public, occupational, health and safety, fire protection authorities, etc. Where regulatory authorities overlap it may be appropriate to manage the relationship between the bodies by means of a formal agreement. This should set out each body’s responsibilities, which should lead on any aspect of overlap and how conflicting requirements should be resolved. In many cases, it may be appropriate to have regular liaison meetings.

The regulatory body is organized to provide public information regarding its activities, both on a regular basis and in relation to abnormal events. Information provided to the public is objective, reflecting the regulatory body’s independence. The regulatory body is as open as possible while complying with national legislation on confidentiality. This can best be done by individuals with expertise in the field of public information to ensure that the information presented is clear and comprehensible. In a large regulatory body, this may warrant the establishment of a specialized unit.

The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, establish arrangements for the exchange of safety-related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfill safety obligations and to promote cooperation. The involvement of the regulatory body in international cooperation, arranged by means of multilateral or bilateral agreements, could consist of exchange of information, mutual assistance in regulatory activities, staff training, regular staff meetings on specific subjects and other matters. Multilateral cooperation could be organized using different approaches; for example, regional approaches, multilateral based on design or type of facilities concerned. The regulatory body may also be involved in fulfilling national obligations under international conventions. These may require subsequent actions as appropriate.

In the following, different types of organizational arrangements are described as examples of how the above responsibilities and duties can be organized.

2.2.2. Examples of regulatory organizations [15]

2.2.2.1. Finland
STUK — Radiation and Nuclear Safety Authority acts as the regulatory body for nuclear power plants in Finland. STUK maintains jurisdiction over nuclear safety, radiation protection, pressure vessel, and nuclear material and safeguards. STUK gives detailed technical and administrative instructions relative to the design, construction, commissioning and operation of nuclear power plants in so called “YVL” guides. Organizational scheme is presented in Fig. 8. At the end of the year 2000, STUK employed 290 persons. STUK has a staff of approximately 80 inspectors for the supervision of nuclear power plants (4 units). Basic educational level of the inspectors of STUK is: approximately 20% engineers, 70% graduate engineers (diploma) or a corresponding degree, and 10% with a higher degree. There are training policies and guidelines for the training of inspectors.

FIG. 8. Finland — organization of STUK.

Total finance in 2000 was 129 million FIM (22 million Euros). The sources of funding of STUK were as follows: states funding allocations (42%); income from monitoring under public law (29%); expert services (23%); external funding for joint venture (6%), other funding (2%). Expenditure by sector in 2000 was: nuclear safety (30%); research (29%); services (21%); radiation safety (8%); environmental radiation monitoring (4%); preparedness (4%); information (4%).

Regulatory oversight including respective direct costs such as contracted research activities carried out by STUK is directly charged from the utilities. Other sources of STUK incomes are the governmental budget and some contracted services. Overhead expenses are divided to different organizations in relation of working hours carried out. Emergency preparedness, public information and international and domestic cooperation are paid from the governmental budget.

2.2.2.2. Switzerland

The legal basis for the regulation and supervision of nuclear activities are: The nuclear law (1959), the federal amendment to the nuclear law (1978) and the Federal Ordinance about
the supervision of nuclear installations (1983). According to the Ordinance the Federal Nuclear Safety Inspectorate (HSK) exercises supervision over nuclear installations in Switzerland. Its main tasks are the establishment of the safety review to be delivered to the federal government with regard to the granting of a general licence or of permits for construction, operating, etc. of nuclear installations, and the surveillance and inspection of these installations. Organizational scheme is presented in Fig. 9.

![Organizational diagram of the Swiss Federal Nuclear Safety Inspectorate](image)

FIG. 9. Swiss Federal Nuclear Safety Inspectorate organization.

The licensee has full responsibility for the safety of his plant. The regulatory body defines the safety requirements and checks for fulfilment of these requirements. Persons entrusted with the surveillance may at any time require information and have access to all documents; they have unhindered access to all installations, offices, and stores.

The inspection personnel belong to HSK as the governmental organization, and also to private organizations (e.g. for mechanical components, civil structures, and some for radiation monitoring). The HSK does not have people, who are full time inspectors. Supervision is carried out by different sections. The coordination and inspection section has the duty to coordinate inspection activities. Each site has a site inspector who is a member of this section. About 70 persons are involved overall in inspection activities of the HSK. They include some 20 persons from private organizations. Inspectors and regulators in the HSK are identical. Typical qualification is a BS or MS degree and several years of experience in nuclear or non-nuclear industries. Supplemental training in reactor technology and safety is provided in the first year.

The annual budget of the Inspectorate (HSK) is approximately 6.2 million Swiss francs (salaries and infrastructure, including the secretariat of the advisory commission (KSA), but excluding the Commission as such). In addition, some 7 million Swiss francs are budgeted for external experts and for research contracts. The expenses of HSK are mostly compensated for by specific revenue from the federal treasury. Fees have to be paid by the applicants/licensees for all licensing procedures. The operators of nuclear installations are invoiced by the federal administration for the actual costs of the supervision by the Inspectorate and its experts.

2.2.2.3. United Kingdom

Her Majesties Nuclear Safety Directorate (NSD) as part of the Health & Safety Executive (HSE) is responsible for enforcing safety and health legislation at any licensed site.
Organization of NSD is presented in Fig. 10. NSD has about 150 inspectors and 90 administrative support staff. About one third of the inspectors are engaged in site inspection duties, about one third in assessment, with the rest in project management, strategy and other related duties. There are also a number of inspectors located elsewhere in HSE providing advice on policy matters. Inspectors are all technically or professionally qualified. Typically they hold chartered engineer or equivalent status and have suitable experience in an appropriate field. Internal training programmes cover legal and other activities to ensure that an Inspector is competent to inspect and enforce legislation. NSD does not employ non-inspectorial technical or professional staff. Outside experts or specialists are rarely contracted by NSD to perform inspections but are sometimes contracted to provide assistance or advice on particular assessment issues.

Inspectors appointed by the HSE also have the power to stop unsafe acts or require improvements to be made within given time scales. Some of the conditions attached to the licence also give the HSE the power to direct the licensee to undertake a specified task (e.g. shutdown reactors) and the power to consent or approve to certain activities (e.g. items of high safety significance). These powers are carefully set out so as to not take away the absolute responsibility of the licensee for safety on the licensed site.

Neither HSE or NSD are involved in licensing of individuals at the nuclear installation, but powers in the licence conditions exist to enable the HSE to stop any appointment by the licensee of persons to key safety related posts such as control room operators. NSD’s actions are subject to internal review processes and in extreme cases can be subject to review by the United Kingdom courts of law. The Government sets the policy on siting of nuclear installations, dealing with radioactive waste and decommissioning which NSD implements through the granting of site licences and its powers under the site licence conditions. HSE sets policy in respect of work radiation exposure that is enforced by NSD on licensed nuclear installations and by other parts of HSE for other industrial and medical uses of radioactive material. NSD also enforces other safety and health regulations in relation to non-nuclear hazards at licensed nuclear sites.
The Health and Safety Commission also has a group of nuclear experts called Nuclear Safety Advisory Committee (NUSAC), which provides advice on matters which may be referred to it or it has decided to take an interest in. NSD makes presentations to NUSAC and considers its advice.

Under the Nuclear Installations Act, HSE recovers most of the running costs of NSD, together with the costs of any research thought necessary from licensees. Fines, which the United Kingdom courts of law may impose on a licensee or person, go to the courts and not NSD.

2.2.2.4. US Nuclear Regulatory Commission

The basic legal and organizational framework for nuclear regulation in the USA has already been described in 1.4.4. The following section includes a basic description of the structure and responsibilities of the US Nuclear Regulatory Commission (NRC). The Commission’s organization chart is set forth in Fig. 11.

Organizational structure of the NRC

The NRC is headed by a Commission comprising 5 members, each appointed by the President of the USA and confirmed by the US Senate. Several measures have been adopted to ensure the Commission’s independent, non-partisan character. Commissioners serve for fixed five year terms and can only be removed for legal cause (e.g. violation of law or dereliction of duty). The Chairman of the Commission is designated by the President from among the Commissioners and serves in that capacity at the discretion of the President. Although the Chairman has some special responsibilities regarding management of the agency, each Commission possesses and equal vote on policy matters. If removed as Chairman, the person may remain on the Commission for the remainder of his or her term of office. One of the commissioners’ terms expires each year, providing a regular rotation of membership. Commissioners may be reappointed. However, to avoid partisanship, no more than three of the five commissioners can be members of a single political party.

A few years ago, the NRC was somewhat restructured along the lines of a corporate business model. In particular, two new officers were designated to manage major organizational functions. A Chief Information Officer (CIO) was designated to be responsible for all information technology, communication and computing capabilities. Similarly, a Chief Financial Officer (CFO) was designated to deal with resource and budget issues. The Executive Director for Operations (EDO) continues to be the Chief Operating Officer of the Agency. The EDO maintains management supervision over all NRC’s three main operating divisions — Materials, Research and State Programmes; Reactor Programmes; and Management Services. As indicated in Fig. 8 organization chart, these three Divisions supervise the activities of the various NRC offices covering specific areas of the Agency’s responsibility. These cover all the traditional areas of regulatory supervision, including standard-setting, licensing, inspection and enforcement. A number of offices related to the Commission’s overall administrative functioning are directly supervised by the Commission itself. Such offices include: Inspector General; Congressional Affairs; Public Affairs; General Counsel; and International Programmes. The Commission’s various advisory bodies (such as the Advisory Committees on Reactor Safeguard and on Waste) also report directly to the Commission.
Consistent with the large size and geographic breadth of the US programme, the Commission has also established four regional offices (in Pennsylvania, Georgia, Illinois and Texas). These regional offices provide a direct link to state and local governments and individual installations through resident inspectors stationed at each nuclear power plant.

The role of the Office of the Inspector General should be highlighted. This office is functionally independent of the Commission, issuing reports on how the agency conducts its business from the standpoint of efficiency, ethics and effectiveness. The office has a separate budget, approved by the Congress, to avoid any suggestion that the Commission is unduly influencing its reviews so that the Commission cannot limit its resources if it does not like the kind of reporting it is getting. As mentioned, the Commission has created two independent bodies to provide technical advice to the Commission. The Advisory Committee on Nuclear Waste and the Advisory Committee on Reactor Safeguards (meaning safety) are comprised of expert scientists and engineers. Law and regulations require that the views of these bodies be considered in the licensing process.

Regulatory independence and the NRC

Although it is difficult to define regulatory independence, the regulatory framework within which the NRC functions has been structured to insulate the Commission from outside influence in its decision making on issues affecting public health, safety, security and the environment. Key features of this framework are the following:

Separation of functions: As an organization, NRC not only has no responsibility for promoting or developing nuclear energy, but— importantly — is completely separate from any other government bodies having such responsibilities.

Political influence: As already noted, no more than three of the five commissioners can come from a single political party. In a country with two dominant political parties, this helps protect against partisanship, no matter how much control one party may have on other organs of government. Commissioners also serve relatively long (5 years) fixed terms, and may also only be removed for “cause” (i.e. not because they have lost favor with the current political leadership).

Conflicts of interest: The Commission implements very strict that prohibit the commissioners or any of the NRC staff from having a financial or personal interest in entities or subject that may be subject to their regulatory decisions. Transparency is important in this regard. NRC employment regulations require annual financial disclosure reports to ensure that improper relationships are identified and eliminated.

Openness: The concept of transparency goes even further at the NRC. Several laws ensure that the commission’s decisionmaking process is conducting in public. For example, the Government in the Sunshine Act requires advance public notice of meetings, with a right of attendance by interested parties. The Freedom of Information Act requires broad public access to any materials used in the decisionmaking process.

Reporting: An important guarantee of independence is NRC’s ability to provide extensive safety-related information to the public, media, other governmental bodies, without review or clearance from any other government agency.
**Budget and finance:** The NRC covers essentially all of its budget through license fees, as authorized in an annual appropriations act by the Congress. This “full cost recovery” approach is believed to provide at least some insulation from political pressures that could result from having NRC’s resources derived entirely from tax revenues. Further, the NRC is entitled to submit its own budget to the Congress, subject only to review by the President’s Office of Management and Budget (OMB).

**Technical capabilities:** For any agency responsible for regulating a complex technology, it is important to possess adequate scientific, engineering, management, financial and legal expertise. The NRC’s large staff (almost 3000 employees) reflects high technical competence and covers a wide range of technical areas. This provides important independence from the regulated industry in terms of assessing information provided by licensees.

**Oversight mechanisms:** As final insurance against improper decision-making, the NRC system includes important oversight mechanisms. The internal— but independent— Office of Inspector General provides a scheduled review of NRC’s management. External oversight is exercised by the independent judiciary through appeals of NRC decisions to the federal courts. Congress also conducts oversight that can result in remedial action through legislation or appropriations.

The eight elements outlined above do not guarantee absolute independence, a status that is both impossible to achieve and undesirable in principle. However, these elements are important in assuring that safety judgements are not subordinated to other interests— political, economic or social. This degree of independence helps maintain public confidence in the safe uses of nuclear energy, and indispensable prerequisite for its continued use.

**NRC implementation of main regulatory functions**

In the following is described in greater detail the manner in which the NRC implements its responsibilities in the main areas of regulatory activity: standard-setting or rulemaking, licensing, inspection, enforcement, regulatory research and public information.

**Standard-setting or rulemaking**

At the NRC, regulatory standards are issued through a process called rulemaking. The process is primarily initiated by the Commission’s technical staff, although any member of the public can propose that NRC develop, change, cancel or rescind any regulation. The Commission receives many such requests from environmental organizations and local organizations. NRC rulemaking is a very open process, with public participation a keystone. NRC cannot promulgate rules without giving the public an opportunity to make comments. Before a rule is even drafted, the NRC staff often holds public meetings or workshops to solicit views on a proposed rule. The preferred approach to rulemaking is to provide advance notice of a proposed rulemaking in the Federal Register (the daily federal publication that announces significant government actions). Such an advance notice of proposed rule making is short, typically about a page long; stating that the Commission is considering adopting a new rule or changing or cancelling an old one. Some considerations may also be included, with an indication of initial factors the NRC staff is considering as a basis for the rulemaking. A period of time (usually not less than 30 days) is provided for comment by stakeholders (i.e. industry, interest groups, the public). Emergency rules or minor rules may be issued without public comment, but that is exceptional.
After receiving comments, the NRC staff develops the text of a proposed rule. This text is also placed in the Federal Register, for specific comment. Depending on the significance of the issue or on the comments received, the NRC will determine whether to conduct a public hearing on the proposed rule. After comments on the proposed rule are received and evaluated, and a hearing conducted or denied, a final rule (reflecting any changes considered appropriate) is published in the Federal Register. NRC rules are subject to challenge in the federal courts. As previously indicated, such appeals are typically based on whether the procedure followed in adopting the rule has complied with relevant legal requirements; not whether the NRC’s technical judgements are correct.

The NRC has recently taken steps to make its rulemaking process even more open and efficient. The Commission has created a website NRC Rulemaking Forum giving advance notice to the public of rule making and providing a mechanism for receiving comments electronically. The NRC rulemaking process may appear protracted and cumbersome. However, it is consistent with the country’s traditions of open and democratic traditions decision making. It has also been found useful in creating a more stable regulatory system because Commission decisions are less likely to be challenged or overturned if NRC can demonstrate that the public has been involved fully and at every stage in establishing regulatory standards.

Licensing

For some years, NRC’s reactor licensing function has not been particularly active. The Commission has not received an application for a new nuclear power plant since the late 1970s. However, the Commission has used this period to streamline and update the licensing process.

The traditional approach to licensing power reactors was a two step process, involving a separate Construction Permit (CP) and an Operating License (OL). This process is set forth in Part 50 of the Commission’s rules (in Title 10 of the Code of Federal Regulations (CFR)). Part 50 lists the extensive requirements such licenses. Extensive evaluation of the licensing process, urged by the nuclear industry and some in Congress, convinced the Commission that this two-step process was unnecessarily cumbersome and inefficient. As a result, the NRC adopted a streamlined, combined CP/OL licensing process that is set forth in Part 52 of the CFR. Under this approach, an applicant with a preapproved site and approved design can obtain a single license permitting him to operate the plant. Part 52 details the requirements for site and design approvals.

Even under the new Part 52, the reactor licensing process is lengthy and complex. The following summary identifies the major steps in the NRC process:

?? The applicant must submit a safety analysis report (SAR) covering essential factors including: design criteria and information; comprehensive site data; safety features to prevent and mitigate hypothetical accidents; an environmental report on potential impacts; and economic information for purposes of an antitrust review (analyzing possible competitive economic effects).

?? The application must also be reviewed by the Commission’s independent Advisory Commission on Reactor Safeguards (ACRS).

?? The NRC staff prepares an environmental statement that is issued for public comment.
A public hearing on the application is required before one of NRC’s atomic safety and licensing boards (ASLB). An ASLB is comprised with 3 members, two of which have technical backgrounds and one who is lawyer. Typically, an ASLB is chaired by the lawyer, who is expected to deal with legal and procedural issues.

During this process, the Commission may issue a limited work authorization (LWA) to permit certain site preparation and initial construction activities on a “reasonable assurance” that the plant will meet safety and environmental requirements.

After the public process has been completed a final safety analysis report (FSAR) is prepared, setting forth details justifying the issuance of the license.

Under the Part 52 process, the Commission may issue an early site permit (valid for 10–20 years) and a standard plant design certification (valid for 15 years). A number of sites in the USA have received early site approval. Also, several standardized plant designs have been certified. A hearing is mandatory under Part 52, after completion of the ACRS and NRC staff reviews. An important benefit of the combined Part 52 license is that issues resolved in early site permit or design certification proceedings cannot be considered at the combined license stage.

Even in the absence of applications for new nuclear power plants, the NRC has been confronted with important licensing issues. The first of these is license renewal. Nuclear plants in the USA were originally licensed for 40 years. A number of operating plants are now approaching the end of their license terms. This raises the issue of whether (and if so, for how long) they should be authorized to continue operating. With over one hundred operating reactors in the USA, the NRC anticipates a large number of requests for license renewal. The commission’s regulations in Part 54 of Title 10, Code of Federal Regulations, establish detailed safety requirements for license renewal. The NRC’s primary focus in its license renewal review is on so-called “passive” and “longlived” structures and components (e.g., reactor vessel, reactor coolant pumps, piping, steam generators, pressurizer, valve bodies and pump casings). A must demonstrate that any ageing effects will not unacceptably affect the safety of the plant. License renewal also requires another environmental review, supplementing the original review, for the purpose of assuring that extended operation will not have unacceptable impacts.

A second major licensing issue confronting the NRC is license transfer. Restructuring and deregulation of the electricity industry for economic reasons has accelerated in recent years in the USA. New companies are getting into the business of generating electricity, while other companies are leaving the business or merging into new legal entities. Where a new legal entity takes over an existing nuclear plant, continued operation will require a transfer of the current NRC operating license. For this to happen, the Commission must make a determination that the new operating organization has the technical, management and financial capabilities to operate the reactor safely.

Inspection

The third key regulatory function is inspection. NRC conducts a wide range of different types of inspections of nuclear reactors, fuel cycle facilities and other users of nuclear material. For nuclear reactors, the Commission inspection programme is primarily conducted through a system of resident inspectors. The Commission has assigned at least two
resident inspectors to each site, with additional inspectors for sites with multiple reactors. Resident inspectors continually monitor licensee activities on the site, both obtaining and transmitting early information concerning plant conditions and facility events. The resident inspectors provide direct contact between NRC management and the licensee. They also evaluate what additional inspection activities may be needed that they are not competent to conduct themselves. Many of these special inspection activities are conducted from the NRC’s four regional offices and some from the Commission headquarters. Specialist inspectors from headquarters or regional offices typically cover such as radiation protection, instrumentation and control, earth sciences and fire safety. In terms of overall inspection effort, the NRC spends an average of approximately 3250 inspection hours (about 6 person years) on each reactor annually. The NRC has also developed specific reactor inspection programmes for the major phases of nuclear power plant construction and operation, including: preconstruction activity, construction permit activity, preoperational phase, start-up phase, operations phase and decommissioning phase.

Outside the power reactor field, NRC also conducts approximately 1700 health and safety inspections of nuclear materials licensees annually.

Qualification requirements for NRC inspectors include: a college degree in engineering or physical science, experience in the nuclear industry (except for interns), onsite inspection training, qualification board and certification and periodic refresher training. The NRC provides an extensive training and certification programme for inspectors at its training center in Chattanooga, Tennessee. Much of the training is done through reactor simulators at the training center on fullscope simulators covering most major reactor designs used in the USA.

Each NRC inspection is fully documented in a formal report that includes scope of the inspection and conclusions on the effectiveness of the programme inspected, licensee management and quality assurance programme, strengths and weaknesses of the licensee, compliance with NRC requirements, findings to support conclusions and determinations on violations (generally dealt with in a separate enforcement proceeding).

Finally, with regard to inspection, it should be noted that the NRC has recently implemented a new reactor oversight process utilizing a risk-informed, performance-based approach focusing on safety issues deemed of greatest importance. This approach aims at re focusing inspection effort and reducing the burden to both regulators and operators by taking advantage of risk insights. Although it involves the entire range of regulatory activity, it is particularly relevant to the inspection and enforcement functions. This new approach is discussed in some detail in 6.3.1 — NRC’s risk-informed, performance-based assessment programme.

**Enforcement**

The fourth key regulatory function is enforcement. The importance of the enforcement function is underlined by the fact that NRC maintains an office of enforcement that is separate from organizational bodies conducting regulatory inspections. Requiring inspectors to justify the need for enforcement action by another Commission body, is not only a check on overzealous inspectors, but encourages full documentation of violations. The objectives of NRC enforcement action are to deter licensees from failing to comply with NRC regulatory requirements and to encourage licensees to promptly identify and to correct any violation of safety significance.
Three types of enforcement actions are employed by the NRC: notice of violation, civil monetary penalties and orders to modify, suspend or revoke licenses.

Violations are ranked by their significance from severity level I (most serious) to severity level IV (least serious). NRC considers four factors in determining the level of significance: actual safety consequences, the potential or future safety consequences, impact on NRC’s regulatory functions, intent of the violation (e.g. whether the licensee committed the violation deliberately or was merely careless, or did not understand the requirement).

In applying its enforcement sanction, the Commission may consider civil monetary penalties for Level III violations (these are routinely used for Level I and II violations). The Atomic Energy Act authorizes the NRC to penalize a licensee up to 120 thousand dollars per day. A more severe sanction would be to close down a facility entirely, an action the NRC is also authorized to do in cases where the public health and safety may be at risk. The amount of a civil monetary penalty will depend on several factors, including: type of licensed activity, type of licensee, severity level of the violation, whether the licensee has been the subject of significant enforcement action in the past two years or past two inspections, whether the licensee should receive credit for identifying the violation, whether the licensee has taken prompt and effective action to correct the violation, whether, in view of all the circumstances, discretion should be exercised with regard to the amount of the penalty.

In 1999, the NRC assessed over a million dollars in civil penalties. The money obtained through NRC enforcement does not come directly to the Commission, but it goes to the US Treasury. For serious violations we do have criminal prosecution penalties.

For serious, intentional or repeated violations, criminal penalties (e.g. imprisonment) may be applicable. In such cases — extremely rare — the NRC will refer the matter to the Department of Justice for further investigation and possible prosecution.

Regulatory research

NRC has a very substantial regulatory research programme. The Commission usually refers to its programme as confirmatory research to make clear that its purpose is to support its regulatory mission, not the development or promotion of nuclear energy. The programme has three main objectives: to provide independent information to support regulatory decision making, to assess the potential safety significance of technical issues, and to prepare the NRC to deal with future safety issues arising from new designs and technology.

NRC’s research budget, which had averaged about $100 million annually, has been reduced to approximately $70 million in recent years due to government deficit reduction efforts and other circumstances. With more limited resources, current NRC research activities have focused on issues of greatest significance for nuclear safety, including: emerging technologies (e.g. digital instrumentation and control systems), plant ageing issues, decommissioning, operating experience, and risk-informed regulatory approaches.

More limited resources have also encouraged the NRC to look for opportunities to conduct cooperative safety research with other nations in joint bilateral or multilateral projects. The NRC maintains a large cooperative programme with Japan, a joint project with Russia, and with other countries.
Public information

NRC considers public information one of its most important responsibilities. Public confidence in the safety of nuclear energy depends, to a great extent, on the openness and credibility of regulators. NRC maintains a separate Office of Public Affairs that reports directly to the Commission. Each of NRC’s four regional offices also maintains a public affairs office. As discussed earlier, a number of laws require the Commission (and all other US government agencies) to provide a broad range of information to the public, the legislative branch, and to the press and media. Examples of the wide-ranging materials made available by the Commission are provided in the next section of this Section—NRC regulatory guidance. The NRC’s website (www.nrc.gov) provides access to this information in electronic form.

Regulatory guidance

The system through which the NRC provides regulatory guidance is extremely wide-ranging and diverse. It should be emphasized that this guidance is not directed solely to licensees. Of course, guidance is essential in achieving an effective regulator-operator interface. However, it is also important to recognize that the regulatory guidance has many stakeholders who seek to review this guidance and to utilize it for their purposes. Such stakeholders include: local and state governments having important roles in the regulatory process; other federal agencies; interest groups (i.e. local community groups, environmental organizations); the press and media; other nations; international organizations; and members of the general public. It should not be ignored that the primary consumers of regulatory guidance are NRC’s own employees, who will be expected to conduct their responsibilities consistently with agency policies and standards.

NRC guidance ranges from highly formal documents that are strictly binding on licensees and NRC staff, to less formal guidance on general Commission policy. This guidance is also multifunctional, ranging from organization and management procedures, through standards and technical specifications, to inspection and enforcement requirements. This guidance also covers many different subjects.

An important feature of NRC’s guidance system is that virtually everything NRC produces as a guideline is publicly available, resulting in a highly transparent process. Finally, another important aspect of the NRC system is that it is a process in constant revision and reinvention. NRC guidance documents are continually reviewed, updated, changed and cancelled accordingly.

Before discussing some of the most important examples of NRC regulatory guidance, it may be useful to have a general overview of the types of documentation developed and made available by the Commission. Table VII — Survey of USNRC guidance documents provides such an overview.
TABLE VII. SURVEY OF US NRC GUIDANCE DOCUMENTS

?? Code of Federal Regulations — Title 10
?? Regulatory Guides
?? NRC Legislation
?? NRC Inspection Manual
?? ADAMS
?? Federal Register Notices
?? Standard Programme
?? Enforcement Reports
?? Inspection and Assessment Reports
?? Operational Experience Reports
?? Part 21 Reports
?? SALP Reports
?? Technical Reports
?? Administrative Letters
?? NRC Bulletins
?? Generic Letters
?? Information Notices
?? Regulatory Issue Summaries
?? Inspector General Reports
?? Commission Meeting Transcripts
?? Preliminary Notifications
?? Speeches
?? Information Digest

It would not be either possible or useful to attempt to describe all of these documents. However, they can be easily accessed through the Internet, to provide a detailed picture of NRC’s regulatory approach.

The legal pyramid of guidance documents

As in most other nations, the legal pyramid in the USA is comprised of the fundamental law or constitution at the top, regular legislative acts or laws at the next lower level, regulations at a lower level still, with technical standards and regulatory guidance at the lowest level. For the USA, the top of the pyramid is occupied by the US Code Annotated, the official compilation of laws enacted by the Congress. To the extent that these laws sometimes adopt specific requirements that must be applied by the NRC, they could be considered a form of regulatory guidance.

*Code of Federal Regulations:* However, the highest level of material that can be properly considered NRC guidance is probably the next lower level, which is occupied by the code of federal regulations (CFR). The CFR comprises the regulatory enactments of all US Federal agencies. Title 10 of the CFR contains energy-related regulations, including those promulgated by the NRC. These regulations are promulgated through formal agency
procedures, typically involving the requirement for public notice and opportunity to comment. Title 10 contains basic standards generally applicable to all NRC licensees, with a range of technical references. The Index to Title 10 is about 4 pages and lists all subjects in the CFR that pertain to the business of nuclear regulation. However, only a few parts of the CFR need special mention here. Examples of those particularly relevant to the regulation of the safety of nuclear reactors include:

Part 2 rules for licensing proceedings.
Part 20 radiation protection standards.
Part 21 reporting defects/non-compliance.
Part 25 fitness for duty reports.
Part 50 licensing of production and utilization facilities (NPPs).
Part 51 environmental protection.
Part 52 early site permits/standard designs.
Part 54 NPP license renewal.
Part 55 operators licenses.
Part 100 reactor site criteria.
Part 171 annual fees for reactor licenses.

**NRC regulatory guides:** An important category of NRC guidance is regulatory guides (see Table IV, number 2). These are designed to provide guidance to licensees and applicants on implementing specific NRC regulations. They explain the methodologies and techniques used by the staff in evaluating certain problems or accidents. They also provide specific data needed by the NRC staff in reviewing permits or licenses. They inform a licensee what he has to submit for the purpose of obtaining authorization to conduct a licensed activity. The regulatory guides fall within 10 divisions, as follows:

?? Power reactors.
?? Research and test reactors.
?? Fuels and materials facilities.
?? Environment and siting.
?? Materials and plant protection.
?? Products.
?? Transportation.
?? Occupational health.
?? Antitrust and financial protection.
?? General.

**NRC inspection manual:** Very important document is the NRC inspection manual that is primarily intended to guide NRC inspection staff in regulatory activity. However, it also provides guidance to licensees and public on how NRC conducts its work including procedural and organizational matters. The manual is an internal document, it is not subject to the level of outside review or public participation like the Code of Federal Regulations.

**NUREG Documents:** Somewhat below the regulations and regulatory guides there are reports in a numbered series designed NUREG Documents. The series was begun very early in the history of the Atomic Energy Commission. NUREG Documents are technical reports on subject of broad interest. They are not regulations, nor even mandatory documents, but they provide important on technical subjects of broad interests. They also include directories, manuals, procedural guides for internal NRC use, as well as the proceedings of meetings or conferences on technical subjects. International agreements are also set forth in NUREG
Documents. Generic environmental impact reports, which are general statements about the impact of certain kinds of nuclear activities on the environment that are used in the licensing process are also included in this series. Reports about contracts the NRC has negotiated with other organizations are a final category of NUREG.

Generic communications: Because they do not fit in any other category, NRC has included a number of documents in a series called ‘Generic Communications’. The category can include administrative letters to licensees about aspects of their work that are concerned to the Commission. The series also includes bulletins on technical or administrative matters, circulars, generic letters and similar documents (for example, those relating to a common mode problem in a reactor system). Information notices and regulatory issues summaries are also circulated to the public. These concise summaries describe the handling for regulatory issues of particular interest.

Inspector General reports: The Inspector General issues annual and semi-annual reports on specific topics providing the reports of his investigations on NRC management practices to ensure efficiency, effectiveness and integrity. This is the important mechanism of the NRC’s internal quality assurance process. The Inspector General may also report on conduct by licensees where that conduct affect NRC regulatory programmes. Inspector General reports are read very carefully on the subject of great interest.

Accessing NRC regulatory guidance documents: The first stopping point for anyone seeking a particular NRC guidance document is the agency’s website at www.nrc.gov. The site is a user-friendly clearinghouse for the complete range of NRC documentation. In addition to the NRC website, another avenue for research into the Commission’s guidance documents has recently been developed. ADAMS is the acronym for NRC’s new automated data acquisition and management system, an information technology engine that puts every piece of paper in the NRC system into an electronic form that can be accessed by authorized persons. ADAMS will permit rapid access to every aspect of the NRC regulatory guidance system, enabling the Commission to communicate with its licensees, the public and other people.
FIG. 11. US Nuclear Regulatory Commission — organization.
2.3. LICENSING OF A NUCLEAR POWER PLANT

2.3.1. IAEA approach to licensing

The Convention on Nuclear Safety presents in its Article 7 that the legislative and regulatory framework shall provide for a system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a license. The license means any authorization granted by the regulatory body to the applicant to have the overall responsibility for the siting, design, construction, commissioning or operation of a nuclear installation.

The licence is an official document that authorizes a specified activity or set of activities in connection with nuclear installations and establishes requirements and conditions governing the performance of these activities. Such sets of activities are often: siting, construction, commissioning, operation and decommissioning. Further details concerning licences are given in 5.1.2.5.

In this respect, the licence and its set of conditions fulfils several functions: the licence may be the appropriate (and best) means to develop, interpret and complete the legislation/regulation when the latter follows non-prescriptive approach, and it will make mandatory appropriate parts of guides and standards, as well as specific proposals made by the applicant (this is usually the case in a non-prescriptive approach, where the choice of methods or solutions will be based on such proposals and submitted to the regulatory body for approval). The licence could thus fulfil a part of the functions attached to regulations in the case where appropriate regulations are not available.

The licence is the final result of evaluation (review and assessment) of the application and formulates the conclusions and decision(s) of the regulatory body relative to it and, as such, it gives the applicant the formal authorization to proceed within the limits set, on the one hand, by the legislation and, on the other hand, by the conditions included in the licence. Licence conditions are always mandatory and have the force of law. They have to be included in the licence either explicitly or by reference or attachment. Licences may include (parts of) legislation/regulation and other relevant documents by quoting, by reference or by attachment.

In the licensing process, the licence is at the key-point of starting a new set of activities of the “applicant” and where the “applicant” becomes a “licensee”.

The licence with its conditions is a living document: it can be adapted (sometimes it has to be adapted) to a changing situation (e.g. modification of the plant; experience feedback; new knowledge brought by research); it can also be suspended or revoked. Only the regulatory body has the legal power to modify, suspend or revoke a licence. The licensee may request a modification of its licence, but it has to do so through a new application.

More detailed guidance on the format and content of licence document is given in 5.1.2.5.
2.3.2. Examples of licensing practices

2.3.2.1. USA

The current trends in the USA in the licensing and re-licensing of nuclear power plants are presented in 2.1.2.4.

2.3.2.2. United Kingdom

In the UK, the NSD as regulatory body grants only one licence at the creation of the nuclear facility. At each new stage in the life of the facility, that means also at each stage of the licensing process, the initial licence will be amended and the set of licence conditions will be adapted to the new stage. The British licence contains a standard set of 35 licence conditions. The NSD can modify a licence condition without delay and without a possibility of appeal. Each nuclear site licence has conditions attached that have the force of law and which place either absolute requirements or require the making of adequate arrangements and compliance with those arrangements. A fundamental feature of one condition is the requirement for the licensee to demonstrate the safety of the proposed operation in a document known as the “safety case”, prior to the start of that operation. Breach of any law, regulation or licence condition is a criminal offence and the offender may be prosecuted in the United Kingdom courts of law.

2.3.2.3. Switzerland

In Switzerland, the licence is a general authorization usually for a whole set of activities involving one nuclear facility (nuclear power plant or other nuclear facility including associated radiological aspects) or for a single step in the case of a „small“ project such as a radiochemical laboratory with only aspects of radiological protection. In the case of the nuclear facility, it is the government itself (Federal Council) that has the exclusive competence to grant the licence. A modification of a licence condition needs re-issuing the licence along the licensing procedure, i.e. including consultation and possibility of appeal. However, in case of urgency, the Swiss safety authority (HSK), has the power to issue an order to modify a particular licence condition or even to suspend the licence, but this has to be eventually confirmed by the licensing authority.

Within the frame of a valid licence, the HSK defines sets of the licensee’s activities for which its approval is necessary prior to starting specified activities. Upon its approval, the Inspectorate has the competency to give the corresponding authorizations directly to the licensee and does it in the form of issuing “execution permits”. This gives to the Inspectorate a practical and efficient means of controlling the licensing process (e.g. selected parts of construction work; manufacture of important components; assembling and wiring on site; sets of commissioning tests; start up after refuelling or after modification or repair; etc.).

2.3.2.4. Licensing and commissioning of nuclear power plants in Finland [16]

In Finland, licensing procedures are presented in the Nuclear Energy Act and Decree. Licensing documents are handled in more detail in Section 4. Applications are sent to the Council of State and the administrative body handling the applications is the Ministry of Trade and Industry. According to the law STUK is the expert body to review the nuclear
safety aspects. STUK gives its statement including its stand on nuclear safety and safety assessment report to the Ministry.

The siting and construction of a nuclear power plant requires the decision in principle of the council of state stating it is in line with the overall good of society. According to the Nuclear Energy Act, the decision in principle shall be given to parliament for review so that parliament may reverse the decision in principle as such or may decide that it remains in force as given. In the application, one or several plant site and plant type options may be given on which a decision will be made later. In accordance with Nuclear Energy Act, STUK makes a preliminary safety assessment of the application. When preparing the safety assessment, STUK invites comments on the assessment from the advisory committee on nuclear safety and, where necessary, also from other expert organizations.

A nuclear power plant construction licence as well as an operating licence is applied for from the council of state. STUK issues statements on the applications for a construction licence as well as for operating licence. The statements are supplemented with safety assessments. When preparing the safety assessments, STUK invites statements on them from the advisory committee on nuclear safety and, where necessary, also from other expert organizations. The prerequisites for granting a construction and operating licence are prescribed in the Nuclear Energy Act. In its safety assessment STUK takes a stand on the fulfilment of statutory requirements as regards the issues to be reviewed by STUK.

According to the Nuclear Energy Decree, the various phases of nuclear facility construction may be started only after STUK is satisfied for each phase. STUK exercises detailed control over the construction of the facility. This control aims to ensure that the conditions of the construction licence, the regulations which apply to pressure vessels and the approved plans are complied with and that the nuclear facility is built, also in other respects, in accordance with the regulations issued by virtue of the Nuclear Energy Act. During construction, control is focused on the working methods in particular to guarantee high quality. The licensee shall appoint a responsible manager and his deputy for the construction of a nuclear facility who have approval from STUK for this job. The qualifications required of the responsible manager are presented in the Nuclear Energy Decree.

Pursuant to the Nuclear Energy Decree, STUK ensures that the operating organization is adequate and appropriate and that the individuals participating in the use of nuclear energy meet the qualifications required and that proper training is arranged for them. According to the Nuclear Energy Decree, the licensee shall appoint a responsible manager and his deputy for the operation of a nuclear power plant who shall have approval from STUK for this job. Pursuant to the Nuclear Energy Decree, the operator of the facility systems in the main control room of a nuclear facility must have STUK's approval for the job.

A trial run is an essential part of a nuclear power plant's commissioning. It serves to demonstrate that the plant is built and operates according to design. The trial run is divided into the following main parts: systems tests, fuel loading and pre-criticality tests of reactor systems, reactor criticality and tests at low power, and tests at various power levels. STUK controls nuclear power plant trial run by reviewing the overall trial run plans and programmes, by witnessing the tests conducted at the power plant and by inspecting the trial run result reports.

Nuclear power plant operation is considered to begin when the loading of nuclear fuel into the reactor is started. At this stage, to ensure that the plant conforms to the regulations that
apply to it, STUK makes a specific inspection to ensure that the plant and the operating organization are ready for the operation. Reactor loading may be started when STUK has approved the loading application and the reactor and fuel behaviour reports for the first fuel cycle. The reactor may be made critical and brought to a higher power level in conformity with STUK's decisions.

When the trial run has ended, the licensee and STUK will carry out an overall assessment of the results. Based on the results of the trial run, also the technical specifications are reassessed. Based on the assessment, the licensee makes any necessary changes which are then approved by STUK.

2.3.2.5. Licensing in Germany: principal parties involved [17]

Licensing authorities

In Germany there is no central licensing authority like in most countries. The implementation of the nuclear licensing procedure is within the competence of the supreme authorities of the Länder but the Federal Government retains the ultimate legal power and the right to overrule local decisions, if necessary. Thus, the construction and operating licence for a nuclear facility will be granted by the respective Land authority acting as the nuclear licensing authority. There is co-operation between federal supervisory authorities and nuclear licensing authorities.

The Supreme Land authorities (ministries), appointed by the Land governments, are responsible for licences and interim decisions in accordance with the Atomic Energy Act as well as their withdrawal and revocation. In general, these authorities are the respective ministries for the environment or economic affairs of the Länder. These authorities also supervise facilities according to the Atomic Energy Act and the use of nuclear fuels outside the facilities. In individual cases, they may appoint subordinate authorities to carry out this task.

Federal offices and advisory committees

The Federal Office For Radiation Protection (BfS) was established as the sovereign supreme federal authority in Salzgitter in the portfolio of the Federal Minister For The Environment, Nature Conservation and Reactor Safety (BMU). This Federal Office performs administrative tasks in the fields of radiation protection, nuclear safety and the transportation of radioactive substances and radioactive wastes. It supports the BMU in technical and scientific matters and also does research in fulfilment of its tasks.

Among other things, the Federal Office for radiation protection is responsible for:

- State custody of nuclear fuels;
- Construction and operation of plants of the federal government to secure and permanently store radioactive wastes;
- The transportation licence for nuclear fuels and large sources, as well as its withdrawal and revocation;
- The licence for storage of nuclear fuels outside of state custody.
In addition, the Federal Office is the Federal Government Centre for the monitoring of environmental radioactivity and keeps the radiation protection register. The radiation protection register includes data on the radiation exposure of persons exposed to radiation due to their profession. In order to keep watch over the values of the maximum permissible dose as well as data on compliance with the principles of radiation protection. The Federal Export Agency and the customs authorities of the Federal Minister of Finance, respectively, are responsible for licensing the import and export of nuclear fuels.

The following advisory commissions and one co-ordination panel (Federal Government/Länder) are available to the BMU for the purpose of federal supervision of the Länder:

- Reactor Safety Commission (RSK).
- Commission on Radiation Protection (SSK).
- Länder Committee for Nuclear Energy.

RSK and SSK prepare recommendations for the BMU concerning special safety-related matters in general or on a particular nuclear power plant.

The Reactor Safety Commission advises the BMU on all safety-related matters related to nuclear reactors and nuclear fuel cycles. In general, the RSK consists of 18 members who represent the different technical areas of nuclear engineering, as e.g. constructional engineering, measurement and control engineering, reactor physics, systems control engineering and the science of materials. As a general rule, membership is limited to three years and constitutes a personal honorary function without allowing substitution. The members are appointed by the BMU. They are independent and not bound by directives.

The Commission on Radiation Protection has the task of advising the BMU in all matters related to the protection against the hazards resulting from ionising radiation. In general, the SSK consists of 17 members who need to have special knowledge of one of the following main areas: biophysics, radiochemistry, radiology and nuclear medicine, radioecology, radiobiology, non-ionising radiation, radiation genetics, radiation protection medicine, radiation measurements technique and radiation protection technique. As with RSK, the SSK-membership constitutes a personal honorary function. As a general rule, the members are appointed by the BMU for a period of three years. They are independent and not bound by directives.

The Committee for Nuclear Energy debates and co-ordinates questions related to the application and interpretation of statutes and ordinances pursuant to nuclear law and radiation protection law. With a BMU-representative in the chair, it consists of referees from the other Federal ministries as well as the department heads/functional department referees of the Länder ministries. As an Advisory and Co-ordination body of the Federal government, its decisions are only recommendations, in practice, however the Committee for Nuclear Energy plays an important role.

According to the Atomic Energy Act, the construction, operation and possession of nuclear installations are subject to continuous supervision. The supreme authorities of the Länder are responsible for exercising supervisory and control functions, which they may delegate to subordinate agencies, in individual cases. In general, independent experts or expert organizations, namely the technical inspection agencies (TÜV) are involved. In addition,
import, export other professional handling and transportation of radioactive material, as well as construction and operation of final repositories for radioactive waste are subject to governmental licensing and supervision.

**Länder authorities and technical support organizations (TÜVs)**

Within the regulatory body of a state (Land) approximately 5 to 10 person-years per nuclear power plant unit and year are spent for inspection and supervision. Typically one to three inspectors are in charge of inspections regarding nuclear safety of one nuclear power plant unit. Inspection regarding e.g. radiation protection, often is delegated to subordinate governmental agencies. In addition, supervision for industrial safety and environmental matters, as legally required for all types of industrial activities is carried out by other competent agencies.

In general, for all supervisory and inspection programmes independent experts are assigned by the Länder authorities for examination of reports, reported events, calculations, technical specifications, safety assessments for modifications and for conducting or assessing in-service inspections. In most cases, Technische Überwachungsvereine (TÜVs) are assigned as expert organizations. There are several TÜV-Organizations in Germany, historically assigned to and working mainly in the individual Federal Länder. Recent developments go for the formation of larger organizations (holdings, Ltd., Corporate) serving the needs of several Länder. Including non-nuclear inspection programmes (e.g. for cranes, fire protection, pressure vessels), which are also carried out by TÜV-personnel, a total manpower of approximately 30 to 40 man years per nuclear power plant unit each year is spent for inspection by experts. This does not, however, include safety assessments and expertise for major modifications, for which a licence is required.

During refuelling outages, the presence of regulatory inspection personnel and experts at the plant is increased. On average, about 30 experts performing inspections and recurrent tests are constantly present at the site during the outage. The inspectors of the regulatory body are in possession of a university degree e.g. engineering, physics, chemical engineering) and have several years of practical experience in industry, research centres, with technical expert organizations or in licensing bodies. Personnel of technical expert organizations (TÜV), who are contracted as experts hold university degrees in technical fields or technical engineering degrees. For special inspections, e.g. pressure vessel inspection according to the pressure vessel regulation ordinance, state authorized and licensed inspectors are assigned, also within the TÜV organizations. The inspectors are trained in professional courses, symposia, workshops, simulator training courses and, as guests, during actual operation of nuclear facilities, and by exchange of experience. The inspectors authorized by the supervisory authorities, as well as experts consulted by them, have access to the nuclear installations, and may carry out necessary examinations and request pertinent information.

To implement their respective tasks, the staff of the federal ministries and agencies and of the Länder authorities as well as their material expenses are budgeted within the Federal and the Länder governmental annual budgets. There are also budgets for research on nuclear safety and radiation protection.

According to the basic principles of the administration cost act, fees are levied for all administrative actions in favour of individual persons or private companies. In the case of licensing and supervision of nuclear installations, the Atomic Energy Act provides the
regulation for the charging of costs, including fees and expenses, to the applicant or the licensee. Details on the respective fees are laid down in the atomic energy act cost ordinance. For example, the fee for granting a construction licence for a nuclear power plant is set to 2/1000 of the construction costs of the nuclear licensed part of the plant. For other licensing decisions, fees may range from 1000 to 1 Million DM. In addition, fees for conducting inspections and measurements are fixed. These fees shall be based on the actual expenses and will be invoiced to the licensee.

The licensing as well as the inspection authorities may contract experts and expert organizations (TÜV’s) for expertise and conduct of inspections, provided these expenses are justified according to the technical needs and difficulties. The expenses for the experts are reimbursed to the regulatory body by the licensee.

Experts

In the licensing and supervisory procedure pursuant to the Atomic Energy Act or Radiological Protection Ordinance, the respective authorities may consult experts. Such consultation by the Länder authorities is normal practice. There are either experts organizations (e.g. Technical Inspection Agencies such as GRS) or individual experts. The selection criteria is: technical knowledge, experience, objectiveness, impartiality, neutrality and reliability. The experts are merely “helpers to the authorities” in establishing the facts of the case. They do not have any authority to make decisions. Their opinions are subject to the free evaluation of the evidence by nuclear licensing and supervisory authorities who make the final decisions.

The essential questions of the examination in the licensing procedure are: (1) Which requirements are to be fulfilled by systems and components? (2) Can these requirements be fulfilled according to best practices?

The Atomic Energy Act, the decrees, the general administrative rules and the so-called technical-scientific regulatory work (as e.g. guidelines, RSK/SSK-recommendations, safety standards of the nuclear standards committee (KTA-Regeln), German industrial standards (DIN-Norms) are the measuring instruments for decision-making.

Applicant

In Germany, applicants for the construction of nuclear facilities are in general independent companies that go on to operate the facility after licensing, i.e. applicant and operator are one and the same. An exception to this relates to the storage of plutonium and the treatment and final storage of radioactive substances. In this case, the Federal Office for Radiation Protection is the applicant and operator.

The manufacturer or supplier of the nuclear facilities, for which the application is made, supports the applicant in drawing up the application documents.

Involvement of the public

If the licensing authority states that the application, the safety report and the brief description contain all the necessary information for the citizens, the project can be made public. The planned project will be made public by official printed announcement. Usually,
this is the official gazette for the Land. However, this measure alone is not sufficient, since the average citizen seldom reads these gazettes. Therefore, it is prescribed by law that the project has to be announced locally by the press published in the area of the facility concerned.

After public announcement, the most important part of public participation begins. The application, safety report and brief description are made available for public inspection at the licensing authority and a suitable location near the project site. During the so-called presentation period, written objections can be raised. The term “objection” means any kind of opposition and arguments against the planned project. Thus, there are no formal limitations. The objections, however, have to be confined to the subject of the procedure. If sufficient objections are raised within the set period, a hearing will be scheduled.

The Hearing constitutes the conclusion of public participation. This Hearing serves several purposes. On the one hand, the objections raised within the permitted time are discussed to clarify the concerns of those objecting. On the other hand, those objecting shall be granted the right of audience by being given the opportunity to specify their written objections orally. Further, those objecting shall receive information on other, in many cases also contrary, opinions.

The Hearing is conducted by a representative of the licensing authority. This person has to arrange the procedure formally in such a way that all aspects are considered. None of the objections may remain non-discussed. Therefore, the leader of the Hearing stipulates the order of the subjects to be discussed at the beginning of the hearing.

The licensing authority has to examine all of the aspects presented and must make a decision at the end of the licensing procedure. This is a difficult task because of the often conflicting positions of the different persons involved.

2.3.2.6. Licensing in Germany: legal aspects and procedures of assessment [17]

Objective and reason for an assessment

According to the Atomic Energy Act a licence may only be granted if the licensing prerequisites are given. This is to be examined by the respective licensing authority which can either carry out the examinations itself or consult experts. Generally, experts are consulted to show whether or not protective provisions have been made against damage due to the construction and operation of the plant in accordance with best engineering practices and if protection against interference and other impacts by third persons can be ensured.

If a nuclear facility is built, a separate experts opinion is ordered for each partial licence, as a general rule. Partial licences have to be applied for by the applicant separately according to the Nuclear Licensing Procedures Ordinance. Thus, the applicant determines the number of partial licences, as far as there is a legitimate interest in doing so.

Appointment of experts by the authority

Pursuant to the Atomic Energy Act, the responsible authorities are entitled to consult experts. In general, these experts come from experts organizations. Foremost among these are Technical Inspection Agencies and GRS. The law, however, also permits consultation with
independent individual experts. There are no stipulations regarding special qualification prerequisites by ordinance, but primarily each expert has to possess technical knowledge and must be impartial and reliable.

Due to the wide range of technical issues to be clarified when assessing a nuclear facility, the experts consulted may, upon agreement with the authority, confer sub-contracts on additional experts, as e.g. GRS. In this respect, the principles on the allocation of sub-contracts by experts of the Länder Committee for Nuclear Energy are to be observed.

*Documents to be submitted*

According to the requirements of the nuclear licensing procedures ordinance, a safety report, among other things, has to be attached to the application for nuclear licensing, describing the hazards connected with the plant and the safety measures provided. In 1976 the Home Secretary (the minister responsible for reactor safety at that time) published “advice giving outline criteria for a standardized safety report for nuclear power plants equipped with pressurised water reactor or boiling water reactor”. The publication of the Home Secretary contains guidance for each section of the outline which should be considered when drawing up a safety report. A further list, which is the "collection of information necessary for the examination in the nuclear licensing and supervisory procedures (ZPI), comprises the documents required for the experts opinion, in addition to the safety report, and which also are necessary for the accompanying control. The requisition of documents is stated in thematic order and structured according to submission dates within each subject.

The requisition of documents is subdivided into two categories. Documents of category “A” are to be submitted for examination of the licensing prerequisites, and documents belonging to category “B” are related to the fulfilment of constructional requirements or the accompanying control. The ZPI-list comprises about 50 pages and was developed from the experiences gained from previous licensing procedures. In particular cases, deviations from it are possible by non-requisition of single documents stated in the ZPI, or requisition of additional documents. As a general rule, the required documents are to be submitted by the applicants.

*Assessment criteria*

The criteria relevant for an assessment can be ordered hierarchically according to their obligatory character. As a matter of course, the Atomic Energy Act and ordinances belonging to it, as e.g. the radiological protection ordinance, are to be observed as binding.

For nuclear power plants, safety criteria and safety-related guidelines are also to be observed. The safety criteria include principles on safety-related requirements to ensure accident prevention according to the Atomic Energy Act. Incidents are listed in the safety-related guidelines. If an applicant has based the plant design on this, a licensing authority may regard the accident prevention requirements as fulfilled.

All directives inferior to ordinances are not legally binding. In general, however, they represent the “modern most up-to-date science and technology” quoted in the Atomic Energy Act. An expert has to examine this before their implementation. If need be, he has to consider the latest operating experiences or latest research results.
The Reactor Safety Commission, the Advisory Body of the Federal Minister for the Environment, Nature Conservation and Reactor Safety, drafted guidelines for pressurized water reactors and boiling water reactors as a basis for their advisory activities. As the Reactor Safety Commission debates all significant licensing decisions and makes recommendations on the respective facts of the case, the RSK guidelines usually also are regarded as assessment criteria.

In some areas, e.g. over pressure protection for pressure vessels and steam generators, there are no special nuclear regulations. In this respect, the requirements in accordance with regulations for conventional engineering are to be adapted to nuclear requirements, taking into account e.g. aspects of radiation protection.

The nuclear regulatory work is subject to change. It is amended and modified. The safety standards of the nuclear standards committee (KTA-Regeln) for example are examined with regard to their relevance to the current situation every five years. The Technical Inspection Agencies issue loose-leaf summaries for internal use on the nuclear regulatory work entitled TÜVIS (TÜV information systems) to ensure the application of the latest regulations. At present, this loose-leaf collection consists of 18 files and is being revised continuously.

An important tool for assessing the safety of nuclear facilities is the application of probabilistic methods. It is recommended in the safety criteria for nuclear power plants under “Principles on Safety Provisions” to determine the reliability of essential safety-related systems and plant components with the aid of probabilistic methods, as a supplement to the deterministic overall safety assessment of nuclear power plants. Currently, these are often applied.

Form and contents of the assessment

It is the objective of the expert organizations to proceed according to uniform rules regarding the kind and scope of the assessment. For this purpose, when the technical inspections agencies became associated, the head office for nuclear engineering of the technical inspection agency (TÜV-Leitstelle Kerntechnik) decided on a standard outline and a directive for safety assessment requirements for nuclear power plants with pressurized water reactors and boiling water reactors. Further, there is the “General Guideline on the preparation of experts opinions in nuclear administrative procedures” of the Home Secretary issued in 1983.

The outline of an experts opinion corresponds to the outline of a standard safety report. According to the guidelines mentioned above, the introduction of the opinion embodies the task and assignment of duties. This is followed by a description of the facts of the case to be examined, all of which are solely based on the application documents.

The assessment criteria for the layout of the respective safety equipment put up by the manufacturer are stated in the section “assessment criteria” and are examined with regard to completeness and applicability.

The inspections carried out by the expert for the advisory assessment of the facts of the case are stated in the section “description of the inspections”. In the simplest case, it is a matter of comparison with the regulation requirements. Calculations are also carried out by
the applicant, sometimes with diverse computer programmes, e.g. in the field of failure
analysis, strength, probabilistic or physical design. In many cases, conservative estimates are
sufficient to substantiate the experts opinions.

The examination of the completeness of supporting material submitted is an important
part of the activities of the experts. It has to be examined, for example, whether or not all
postulated incidents and the resulting loads have been taken into account.

Based on a comparison of the examination results with the safety assessment standards
an experts assessment of the facts of the case is carried out. For this purpose, the positive and
negative results of the examinations are discussed in detail. Should the occasion arise that a
positive overall result can only be achieved by fulfilment of later requirements by the
applicant, these requirements have to be worked out carefully in accordance with the results
of the experts opinion. These requirements, however, must be feasible.

The expert has to sign his opinion personally with the following statement: " hereby
declare to have delivered this opinion impartially according to the best of my knowledge and
belief and free of pre-decided results'.

Licensing steps

The nuclear licensing authority not only has to examine the formal and material
nuclear licensing prerequisites, but also has to observe other regulations under public law.

Even though the authority states that the applicant of the project has fulfilled all
nuclear licensing prerequisites as well as all other regulations under public law, and even if
the result of the environmental impact assessment was positive for the applicant, the nuclear
licence does not necessarily have to be granted. Now, the authority may use its discretion, as
the authority is vested with the so-called rejection discretion according to the German Atomic
Energy Act. This means that the authority may reject the application even if all licensing
prerequisites have been met. Nevertheless, the discretionary considerations have to be
reasonable and, in particular, correspond to the specific appropriation in accordance with the
Atomic Energy Act. Thus, an arbitrary decision will not be allowed. A “discretion” is only
possible if aspects concerning single nuclear licensing prerequisites and other regulations
under public law could not have been examined up till then.

In general, many aspects and partly contrary points of view are being brought together
through the involvement of citizens and authorities. The licensing authority has to consider
decision alternatives thoroughly on the basis of these aspects.

Rejection of the project application

If the licensing prerequisites have not been fulfilled and fulfilment cannot be ensured
by additional conditions, the application for construction and operation has to be rejected.

Preliminary decision

It is possible that the applicant applied for a preliminary decision instead of a licence.
It is permitted by law to issue a preliminary decision on special subjects if the granting of a
nuclear licence depends on a positive response to special items. Thus, only questions at the
preliminary stage of a later licensing procedure will be clarified. By this, the preliminary decision anticipates statements of the later construction or operating licence. It is not prescribed by law which items can be clarified in advance by a preliminary decision. Only the preliminary decision on the plant location is expressly stated.

**Full licence**

The full licence for construction and operation of a nuclear facility is the guiding principle of the law. In general, however, such a project is so complex that it cannot be coped with by a single official decision. Therefore, it is common practice with major projects to divide the entire licensing procedure into several steps. The procedure subdivided into several sections, each of them ending with a decision-in-part of the authorities, i.e. the partial licence.

**Partial licences**

The stepwise procedure has several advantages. By subdividing the information material into several sections the procedure becomes more transparent. The work can be planned efficiently, thus saving time and costs. Moreover, applicant and licensing authority can each react more flexible in case of particular, small procedural steps. Above all, this manner of proceeding respects the principle of best possible danger prevention and risk precautions as each partial licence must correspond to the state of the art. First of all, an application by the operator for a decision by the authority on partial licensing procedures is required according to the law. For this purpose, the applicant has to demonstrate a legitimate interest in partial licences. The legitimate interest of the applicant consists generally of securing stepwise his considerable investment. The investment risk can be reduced by the granting of partial licences.

Legal security is provided insofar as the licensing authority is bound by the licensing decision made. If the facts of the case do not change and the legal situation does not change to the disadvantage of the applicant, the applicant can count on the continued validity of the partial licence issued. The discretionary rejection becomes increasingly limited with each additional partial licence granted until, finally, the applicant has a legal right to the granting of the last partial licence, which is normally the operating licence.

Just as with a full licence, the partial licence is a beneficial administrative act. It permits specified actions to be taken such as excavation, construction of the reactor building or installation of vital operational or safety systems etc. Usually, a partial licence involves various conditions and referrals.

The partial licence differs from the full licence only by its limited regulatory content. In contrast to a full licence, the partial licence does not permit the complete construction and operation of a plant, but only parts of it. This implies that the nuclear licensing authority has carried out definitively an examination of and judgement on the licensing prerequisites for each partial licence.

**Preliminary positive overall decision**

In the end, the total of all partial licences shall be equivalent to the full licence, but this can only be achieved, if the parts fit together. Therefore, the partial licences must be related to each other. The alignment can only be made if the total project as planned by the applicant is
kept in view. If, for example, the foundation of the reactor building is licensed by the first partial licence, it is necessary to know the loads on and floor plan of the building. This, on the other hand, requires an adequate knowledge of the components, systems and machines which are to be located in the building. Therefore, a licence for a plant component can only be granted if the licensing authority has clarified the requirements of the total project at the outset. This implies a decision on the basic approval of the whole project. The preliminary positive overall decision represents the necessary linking between the licensed plant component and the entire plant as planned.

Announcement of the decisions

The nuclear licensing procedure ends with an announcement of the decision of the authority. The authority has to promulgate its decision and the grounds for it in writing, and, of course, deliver it also to the applicant. In addition, the decision has to be delivered to the objectors as well.

Further, the decision will be announced to the public in the official publication gazette and the local newspapers in the area of the plant. If more than 300 persons raised objections, the individual serving of the decision will be replaced by a public announcement.

As only the decision together with the instructions for legal remedy will be published, and not the grounds for the decision, every citizen has the right to inspect the entire decision within two weeks beginning with the public announcement at the licensing authority or another office near the nuclear power plant. Upon request, those who object can obtain the decision in writing from the licensing authority. For this purpose, important partial licences — as e.g. the first partial licence or the first operating licence — usually are printed in book form.

Additional licences

Further to licensing pursuant to the Atomic Energy Act, a series of licences is additionally necessary due to parallel laws.

Regional planning procedure

The regional planning procedure serves the purpose of examining if and, where applicable, under which conditions the planned nuclear power plant meets the requirements of regional planning.

Construction licence procedure

All facilities to be built at a nuclear power plant require a licence according to building laws just as for conventional construction projects. In general, several partial construction licences will be granted. The first partial construction licence may not be granted before the first nuclear partial licence has been granted. In some Länder, the nuclear licensing according to the Atomic Energy Act includes the construction licence.

Licensing procedure according to Emission Control Act
A licence according to the Federal Emission Control Act is required for cooling towers, conventional boiler systems and start-up boilers.

Permission procedures according to water law

The lowering of the ground water level, the treatment and drawing off of surface water during construction as well as the tapping and discharge of cooling water later during operation, all require permissions according to the water law.

Industrial law procedures

Reactor pressure vessels, steam generators and all other pressure vessels have to be licensed according to the industrial law, particularly with regard to maintaining industrial health and safety standards.

Plan approval procedure

According to the Atomic Energy Act, the Länder have to establish land collecting points for the interim storage of radioactive waste produced in their territories and the federal government has to establish facilities for safe custody and final storage of radioactive wastes. The construction and operation of these federal facilities as well as all major modifications of such facilities or their operation are subject to plan approval. The procedure for it is stipulated in the administrative procedure law.

An important difference between plan approval procedure and licensing is the placement of all licences and similar official documents under one authority, i.e. the plan approval authority, unless otherwise stipulated by law. Only the regulations of mining and deep-storage law are not subject to plan approval.

The plan approval represents an official function with regard to the facility plan. On the basis of a particularly formal procedure, the admissibility of specified facilities with regard to all public interests affected shall be determined. Further, all relationships related to public law between the operator and the persons affected by the plan shall be regulated finally in such a way that the required licences and similar documents subject to other legislative provisions are replaced by the decision of the plan approval authority. The incontestability of the legal continuity of the licence under public law shall be guaranteed by this decision.

The procedure ends with the plan approval decision comprising all licences under the respective laws regarding areas of speciality. In contrast to the licensing procedure for nuclear power plants, partial licences are not provided for in the plan approval procedure.

A particular regulation with regard to the mining law is stipulated in the Atomic Energy Act. The plan approval does not cover the admissibility of final storage according to the mining and deep-storage law. The decision on admissibility is a matter for the responsible mining authority.

In contrast to the plan approval procedure, the mining law procedure is a continuous procedure which is carried out parallel to mine operation. It ends with the shutdown of the mine and, if necessary, the re-cultivation of the premises.
2.4. QUALITY ASSURANCE, PERFORMANCE REVIEWS AND SELF-ASSESSMENT IN THE REGULATORY BODY

2.4.1. Quality assurance

2.4.1.1. IAEA criteria for quality assurance

Quality assurance plays an important role in regulatory activities. Quality assurance programmes within utilities and their subcontractors and especially the implementation of these programmes is of vital importance to nuclear safety. Simultaneously, the quality assurance programme of the regulatory body itself and implementation of the programme are of great importance. When studying the QA viewpoint of activities of regulatory body the same criteria as presented for nuclear industries is a good starting point.

Article 13 of the Convention on Nuclear Safety [11] concerns quality assurance and requires: “Each contracting party shall take the appropriate steps to ensure that quality assurance programmes are established and implemented with a view to providing confidence that specified requirements for all activities important to nuclear safety are satisfied throughout the life of a nuclear installation.”

Basic objectives, concepts and principles to ensure the safety of nuclear facilities are presented in the IAEA “Safety Fundamentals” [8]. The Safety Fundamentals document forms a top level publication in the hierarchy of the IAEA Safety Series. Some of those issues concern quality assurance like:

“Quality assurance practices are an essential part of good management and are to be applied to all activities affecting the quality of items, processes and services important to safety. Inherent in the achievement of quality is the adoption of a quality assurance programme, which includes the planned and systematic actions necessary to provide adequate confidence that specified requirements are satisfied. Implementation of the quality assurance programme involves managers, performers of tasks, and those responsible for verification and assessment of the effectiveness of the programme. It is not a sole domain of a single group. However, management has the key responsibility to ensure that the programme functions properly and to establish and cultivate principles that integrate quality assurance practices with daily work activities.” and

“Quality needs to be verified by a disciplined approach. Thus, quality assurance practices include:

?? A detailed analysis of the objectives to be achieved;
?? An analysis of the tasks to be performed;
?? The identification of skills required;
?? The selection and training of personnel;
?? The use of appropriate equipment and procedures;
?? The use of document control and record systems;
?? The creation of a satisfactory working environment; and
?? A recognition of individual responsibilities.
The extent and type of quality verification need to reflect the safety significance and nature of the individual tasks. Such verification methods include audits, checks and examinations to ensure that each task has been satisfactorily performed or that any necessary actions have been taken. However, the basic responsibility for achieving quality remains with the performer of the task, not the verifier.”

The other QA related criteria presented in the Safety Fundamentals Document are as follows:

?? Organizations engaged in activities important to safety shall establish policies that give safety matters the highest priority, and shall ensure that these policies are implemented within the managerial structure having clear divisions of responsibility and clear lines of communication.

?? Organizations engaged in activities important to safety shall establish and implement appropriate quality assurance programmes that extend throughout the life of the installation, from siting and design through to decommissioning.

?? Organizations engaged in activities important to safety shall ensure that there are sufficient numbers of adequately trained and authorized staff working in accordance with approved and validated procedures.

?? The capabilities and limitations of human performance shall be taken into account at all stages in the life of the installation.

In accordance with the Safety Fundamentals document the quality assurance principles shall be applied in all organizations engaged in activities important to nuclear safety.

More detailed IAEA Requirements are presented in [6]. The Requirements document presents basic requirements and principles that in the light of experience and the current state of technology must be satisfied to ensure adequate safety. The main objective is to place emphasis on work results, recognising the responsibilities and contributions of managers, workers and those who assess the quality of work. The purpose of this kind of performance-based approach to quality assurance is to prioritise programme implementation and effectiveness, rather than programme development and documentation.

Plenty of other regulations exist for quality assurance programmes (quality systems). A series of ISO 9000 documents is a generally approved and largely used foundation. Further, the regulatory bodies have their own requirements defined in national regulations and safety guides.

2.4.1.2. Quality assurance programmes

The quality assurance programme is a component of good management and is essential to the achievement and assessment of high quality of products, services and work processes. To ensure a proper implementation it is important that the quality assurance programme is tailored to an organization by taking into account existing routines and specific features of the organization. The requirements constitute the foundation of a comprehensive quality assurance programme.

These basic requirements are divided into three functional categories:


2.4.2. Performance reviews — IAEA IRRT services

2.4.2.1. Purpose

The International Regulatory Review Team (IRRT) service provides advice and assistance to member states to strengthen and enhance the effectiveness of their nuclear safety regulatory body [18].

2.4.2.2. Objective

The key objective of an IRRT mission is to enhance nuclear safety by:

?? Providing the host country (regulatory body and governmental authorities) with an objective review of their nuclear regulatory practices with respect to international guidelines;
?? Providing the host regulatory body with recommendations and suggestions for improvement in areas where their organization or performance can be improved or falls short of internationally accepted practices;
?? Providing key staff at the host regulatory body with an opportunity to discuss their practices with experts who have experience of other practices in the same field;
?? Providing all member states with information regarding good practices identified in the course of the review; and
?? Providing experts from member states and the IAEA staff with opportunities to broaden their experience and knowledge of their own field.

2.4.2.3. Scope

An IRRT mission can review following topics:

?? Legislative and governmental responsibilities;
?? Authority, responsibilities and functions of the regulatory body;
?? Organization of the regulatory body;
?? Authorization process;
?? Review and assessment;
?? Inspection and enforcement;
?? Development of regulations and guides;
?? Emergency preparedness;
?? Radioactive waste management and decommissioning;
?? Radiation protection, and
?? Transport safety.

2.4.2.4. Experience
The IRRT service was inaugurated in 1989 and four missions were completed in the period to 1994. Since 1997 there has been a much greater demand for the service and during this period missions to Bulgaria, Romania, Slovakia, Ukraine, Switzerland, Slovenia, Czech Republic, Finland, Hungary and China were completed. Pre-IRRT missions to Viet Nam and Indonesia have also been completed. There is now a very high demand for the service. Although the service started with a focus on regulations for NPPs, most missions now include reviews of regulations in the areas of radiation, radioactive waste and transport safety.

2.4.2.5. Recent developments

The experience gained during the completed missions and the new Safety Requirements Document on Legal and Governmental Infrastructure have been used to revise and update the IRRT guidelines. Recent work has concentrated on developing the guidelines for the review of radiation safety, radioactive waste management and the interface between the regulatory body and the operator. Follow-up visits are envisaged in the future.

2.4.3. Quality assurance and self-assessment in the regulatory body — an example

The basic elements of the quality assurance programme presented in 2.4.1.2. For the internal QA programme of the regulatory body are reflected in the following country specific example STUK (Finland).

2.4.3.1. Management

Nuclear Energy and Radiation Protection Acts and Decrees as well as the Decree on STUK define the regulatory framework in Finland. They also set our objectives and basic duties in the legislation. General safety requirements are given in the Decisions by the State Council (i.e. Cabinet of Ministers). Detailed technical and administrative instruction relative to the design, construction, commissioning and operation of nuclear power plants are given in the YVL guides published by STUK. These guides form a practical basis for the regulatory work. Through the YVL guides STUK transfers the legislative requirements to the practical control and inspection related requirements. In addition to the YVL guides STUK has internal guides which define administrative and inspection related practices.

The quality assurance programme of Radiation and Nuclear Safety Authority (STUK) consists of many duties and work processes which are defined in several STUK manuals and in the department specific YTV manual. In addition to the legislation and YVL guides work practices are defined in the manuals as follows:

- STUK quality manual;
- Administration manual;
- Financial administration manual;
- Emergency preparedness manual;
- Communications manual.

All of these manuals were established by examining legislation, and considering the expectations and needs of main counterparts. Co-operation modes, requirements for the nuclear facility and obligations of the utilities and their subcontractors are determined in the series of YVL guides. The YTV quality manual and the emergency preparedness manual are the main
internal documents which regulate actions of regulatory control within the department of nuclear reactor regulation. The organizational structure and individual job descriptions of the nuclear safety control are included in the YTV quality manual.

Training and qualification

There are training procedures in the YTV quality manual and training manager position in the organization. The inspector training programme has been developed and implemented. Necessary knowledge and skills for performing the duties have been identified. Staff selection methods exists [19].

Document control and records

All information exchanged between the regulatory body, other governmental bodies, the operator, its contractors, advisory committees and the regulatory body's consultants and as appropriate, members of the public should be formally recorded upon receipt and stored in a manner that allows for easy retrieval. It is particularly important that documents related to enforcement action can be accessed when required.

There is an act controlling archives of governmental organizations. This act requires that each organization must have an archive rule defining necessary activities in registration. It is a folder containing the rule and following appendixes: structure of the register, list of documents which are not registered, registration, detailed structure of the register, handling of secret documents, borrowing of a document from the register, organization, job descriptions, fees of copies, protection of documents, destroying of documents. Concerning nuclear power plants there is a separate substructure for each NPP containing the following headings: NPP administrative control, licensing document control, NPP systems, components and structures according to a system list, trial tests, control of operations of NPP (reports etc.), nuclear fuel, nuclear material, nuclear waste. All these materials are kept permanently, NPP procedures are kept when they are still valid. After the decommissioning of NPP these documents will be sent to the national archives for research purposes. There are some documents which are kept until decommissioning and then 5% of the annual documentation will be sent to national archives.

2.4.3.2. Performance

The YTV quality manual includes also procedures to define safety performance objectives as well as annual performance objectives as part of longer term strategy. Working methods which stress quality and satisfactory working environment as well as relationships with the customer groups are also included.

When applied to the operating NPP’s, regulatory control contains assessment and inspections which can be divided in three categories as follows:

?? Periodic inspections as specified by STUK in plant specific programmes;
?? Topical inspections to be requested by a plant owner on a basis of YVL guides;
?? Safety re-assessment.

The inspections contained in the periodic inspection programme are focused at safety significant functions and processes applied by the utility. The control aims to ensure compliance with the regulations and the plans and programmes approved by STUK, and to assess the appropriateness of the utility activities.
Nuclear power plant operation includes activities which can be implemented only after STUK’s approval of the activity has been granted. The approvals are tied to preceding inspections. It is also verified afterwards that the implementation complies with the plans and meets possible regulatory conditions. Requirements and obligations which apply to inspections of different topics are presented in the YVL guides.

The important inspections which the operating organization is obliged to request are the inspections of repairs and modifications. For all the repairs of failed safety significant components, as well as for all modifications of the safety systems the operating organization has to present their plans in advance for STUK approval. The plan has to include technical documentation as needed to verify the acceptability of the functional features, structure, and materials of the repaired or new equipment. Also the repair or installation method, quality control, and tests after the work have to be presented. When the work has been completed, the operating organization has to ask for construction and/or commissioning inspections.

The safety level of the nuclear power plant is re-assessed after any abnormal event, and the need for corrective measures is considered. To ensure a systematic analysis of the event and its causes, an investigation team by STUK is nominated. The team has to find out root causes of equipment failures and human errors and weaknesses in the performance of the operating organization as a whole. At the end the team has to present a report including recommendations for corrective actions, intended to prevent re-occurrence of similar events. A similar parallel activity is required from the operating organization, and it has to submit its special report for regulatory approval. A thorough evaluation of the situation at the Finnish plants is also done if an event reported from a foreign nuclear power plant is suspected to be of such a nature that it might as well occur in our country.

Besides feedback from the operating experience, safety re-assessment is done on the basis of PSA studies and in view of new information gained from safety research programmes. Periodic safety reviews are also carried out, e.g. when operating licences of NPP’s are renewed.

In addition to the regulatory control of nuclear power plant operation, STUK maintains its preparedness to act in plant emergencies. In an emergency, STUK is the authority controlling accident management and an expert body providing assistance to the authorities in charge of the rescue services.

2.4.3.3. Assessment

The regulatory body should have a system to audit, review and monitor all aspects of its activities such as inspection and enforcement activities to ensure that they are being carried out in a suitable manner and that changes to them that are needed, due to improvements in techniques or otherwise, are implemented. This system should consider among other matters, in the case of inspection and enforcement:

?? Inspection guidance and inspection methods;
?? Inspection resource allocation;
?? Procedures within the regulatory body in relation to inspection activities e.g. planning of inspections;
Procedures for co-ordination of inspection activities with the review and assessment process;
Procedures for involving consultants in inspection activities;
Recording of documentation;
Procedures related to enforcement actions.

Effectiveness of the regulatory activities is assessed through normal everyday supervision and through periodical self-assessment reviews where management, organization, work methods, quality of work, communication, human aspects etc. are handled through some systematic review method and where there is a possibility to get feedback internally or from other organizations. Some outside organizations can be used also for independent assessment such as IAEA IRRT services to review regulatory activities.

For example in STUK self-assessment project was carried out in 1995–1997. The criteria set for the Finnish quality award (see Table VIII) were used as model in this assessment and via this process strengths and weaknesses of our working methods were identified and relationships with our customer groups were also handled. Topics included leadership, management and analysis of information and data, strategic planning, human resource development, process management, results of performance, customer focus and satisfaction, society and environment related influence. The method is mainly intended for commercial companies but can be used also in analysing governmental organizations. This project provided good information for future development. Also work environment evaluations carried out by external companies as well as communication training sessions have been organized for improving working conditions and atmosphere.

The periodic inspection programme is reviewed annually through feedback gained during the previous year. The organizational units and individuals are reviewed through performance appraisals annually or more frequently. Guides and procedures are reviewed once in four years and then new developments and work methods can be written in the new revisions.

The IAEA IRRT mission was carried out in STUK in March 2000. The resulting report is provided through STUK Internet home pages.

2.5. PROFESSIONALISM AND TRAINING OF REGULATORY BODY STAFF

What is meant by professionalism in an inspector’s work? How can professionalism be developed? These are the key questions for this Section. Inspectors are proud of their profession. To develop professionalism it is essential to realize the essence of the job. For supervisors and training co-ordinators this is particularly important because they transmit their own performance and behaviour through the training they offer to newcomers.

What is professionalism? It is clear that professionalism means competence in terms of knowledge and skills, education and experience. But this is not enough. Inspection and assessment must be conducted in an independent and objective manner. Inspectors are not power company people, nor are they opponents of nuclear power. They perform independent inspection work according to the guidelines, procedures and criteria in an objective manner. They communicate in a business-like manner, which means that communication is pertinent and systematic. Because they are inspectors they have a questioning attitude. They do not
assume too much, they ask for explanation and clarification from licensees and their representatives. They know this phrase “questioning attitude” also from the safety culture discussions, and they can help to promote safety culture through their questioning attitude. Last but not least their appearance, fitness and behaviour is in accordance with the expected behaviour norms. They have learnt that unsuitable appearance and behaviour may ruin their chance of reaching their goals. This applies also to their inspection work. They affect their counterparts through their appearance and behaviour and may improve their possibilities to carry out inspection and to get better response to their findings.

The inspector understands his/her role and duties and knows his/her rights, obligations and responsibilities. The inspector knows his/her powers in inspection work. The inspector has his/her priorities in the right order where nuclear safety is concerned.

TABLE VIII. SELF-ASSESSMENT OF STUK ACTIVITIES. THE CRITERIA OF THE FINNISH QUALITY AWARD COVER THE FOLLOWING ELEMENTS:

<table>
<thead>
<tr>
<th>Results of performance</th>
<th>Strategic planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>? Product and service quality results;</td>
<td>? Strategy development;</td>
</tr>
<tr>
<td>? Company operational and financial results;</td>
<td>? Strategies and action plans.</td>
</tr>
<tr>
<td>? Supplier performance results.</td>
<td></td>
</tr>
<tr>
<td><strong>Customer focus and satisfaction</strong></td>
<td><strong>Human resource development and management</strong></td>
</tr>
<tr>
<td>? Customer and market knowledge;</td>
<td>? Human resource planning and evaluation;</td>
</tr>
<tr>
<td>? Customer relationship management;</td>
<td>? High performance work systems;</td>
</tr>
<tr>
<td>? Customer satisfaction determination;</td>
<td>? Employee education, training and development;</td>
</tr>
<tr>
<td>? Customer satisfaction results;</td>
<td>? Employee well-being and satisfaction;</td>
</tr>
<tr>
<td>? Customer satisfaction comparison.</td>
<td>? Results of employee development and management.</td>
</tr>
</tbody>
</table>

**Leadership**

? Personal leadership of top management;
? Leadership system and organization.

**Management of information and analysis**

? Management of information and data;
? Competitive comparisons and benchmarking;
? Analysis and use of company level information and data.

**Process management**

? Design and introduction of products and services;
? Product and service production and delivery;
? Support services;
? Management of supplier performance;

**Society and environment related influence**

? Responsibility for the society;
? Management of environmental issues;
? Results of environmental management.

2.5.1. Regulatory role and duties

In the following the Radiation and Nuclear Safety Authority (STUK) is used as an example to clarify the matter. In different countries there are different governmental practices that must be taken into account if applying the ideas. The philosophy of governmental regulatory body (STUK in Finland) is as follows:
The use of radiation and nuclear energy are useful but potentially dangerous activities;
The government needs to find out the acceptability of the activity from the point of view of the society and to ensure safety as well as to control the activity;
For this, the parliament passed the law establishing the STUK and giving the rights and necessary sanctions to the STUK;
Then the STUK decides what is right on the basis of powers received from the parliament.

An inspector’s role and duties in STUK in Finland are as follows:
The inspector is a civil servant of the Finnish government;
The legislation (Nuclear Energy Act) defines the specific role of the Inspectorate, e.g. the Inspectorate defines safety requirements and the inspectors verify by inspections the fulfilment of safety requirements;
The Inspectorate also has a specific role in emergency preparedness.

Other laws like pressure vessel and radiation protection laws increase the role of the STUK compared to some other western regulatory bodies.

The Nuclear Energy Act defines specific duties of the Inspectorate:

Handling of permit applications;
Control of conditions of permits and specification of detailed requirements;
Set safety requirements;
Control of fulfilment of safety requirements;
Set conditions for the persons involved in the use of nuclear power and study the fulfilment of the conditions;
Give expert assistance to other authorities;
Perform necessary research and participate in the international co-operation;
Refer to decisions and give statements on the base of control.

STUK publishes the regulatory requirements in the form of regulatory guides called YVL guides. The guide YVL 1.1 “STUK as the regulatory authority for the use of nuclear energy” [16] presents the forms of control and inspections made by the STUK. For a specific inspector the duties are defined in the job description.

2.5.2. Rights

According to the Nuclear Energy Act the inspector has the following rights:

He/she has access to the place of inspection;
The inspector can inspect, measure and get samples;
He/she gets necessary information and documents, plans and agreements;
He/she can give orders, require settlements and reports and have research made.

2.5.3. Obligations

In his/her work the inspector must note the following obligations:

Principle of law. In regulatory work we must follow the law; we know the law and the subject matter; we know how to act and what kind of rights we have; we act without delay in an open, correct and honest way.
Principle of equality. All citizens and organizations must be dealt with equally. In similar cases there should be similar solutions. This means that we know possible solutions and the solutions already used. The YVL guides define in many cases the main guidelines. Supervisors must ensure that these are followed. We are open and honest.

Principle of correct aims. When considering a solution it is not acceptable to promote other goals than what is the case.

Principle of proportional sanctions. Sanctions must be in right relationship to an offence. Seriousness of an offence is considered on the base of safety importance: we do not shoot a fly with a gun.

Principle of objectivity. The regulator must be objective and correct. If one is disqualified he must pass the matter to another person. Independence is necessary in regulatory work. A published general attitude may affect the believing on one’s objectivity.

Principle of effectiveness. The taxpayers pay the final bill. We must be careful when using public money; we must work with important matters and our actions must not consume too much time.

Principle of publicity. Generally matters are public. The regulator must be open if the law does not say otherwise. Openness means speed in publishing and correct content. Keeping something secret presumes a decision. Documents under preparation are non-public and STUK may consider if it gives information. There are three reasons for secrecy of documents: threat of illegal activity (terrorism), trade secret and protection of privacy.

2.5.4. Responsibilities

In law the inspector has the following responsibilities:

Disciplinary responsibility. The inspector must act according to his/her duties. In the case of failure there are sanctions as warning, dismissal for max. six months or final dismissal;

Responsibility of criminal legislation. Criminal law mentions e.g. the following responsibilities that concern government officials: bribe offence, offence against secrecy of documents and misuse of one’s office;

Responsibility for compensation of loss. If the inspector causes economic loss to the counterpart because of failure in one’s duties caused by purpose or by grave error or by neglect of duties the employer carries the responsibility in the first place but the responsibility may apply to the inspector later. There is also a principle of moderation to be applied in this kind of cases. As an example a serious case in this respect may be if the regulatory body (representative) orders the plant to be shut down without reasonable safety importance.

2.5.5. Relationships with the power company
Relationships with the licensee should be clear. An atmosphere of confidence and respect should prevail between the two parties. One should remember that a plant manager has full responsibility for the plant safety. The regulator ensures that operator fulfils this responsibility. Therefore the inspector gets all the information and documents needed for assessment and has right to inspect. It is always good to give an operator a chance to comment and propose a solution for the problem.

If needed the regulator has tools for enforcement. E.g. STUK has strong tools at its disposal. However, the strong enforcement tools have not been used in practice. We think that for achievement of a high safety level it is better to motivate people to do good work, rather than to threaten them by fines or other penalties. Especially we want to avoid charges against individuals who have committed errors by mistake or due to shortcomings in training and information provided to them. It is also recognised that the use of legal or monetary penalties does not resolve the structural root causes of the problems. Experience has shown that a very effective way of enforcement is public information about abnormal events at the nuclear power plants.

2.5.6. Professional behaviour

How should a professional inspector behave? The inspector conducts inspection and assessment independently and in an objective manner. One listens to licensee representatives carefully so that he/she understands information properly. The inspector communicates in a pertinent and systematic manner. He/she uses moderate language in oral and written communication and avoids extreme expressions. One knows how to handle proprietary information. The inspector avoids negative attitudes and he/she tries to promote safety culture with positive attitudes.

2.5.7. Inspection/auditing techniques

Inspection/auditing techniques are a special skill the inspector must have if he/she is going to perform inspections successfully. In the following some key ideas are presented to stimulate your imagination. A suitable technique depends on the type of inspection. Your successful ideas and techniques should be discussed with your colleagues because through experience we learn these things.

There are several methods for acquiring information: review of written material, interviews with personnel, direct observation of performance, status and activities, independent testing. Before inspection one must decide what written information to read before going to the plant and what during the inspection/audit. At the beginning of inspection the inspector establishes a good communication with the licensee representative and gives the general overview on the inspection. The inspector takes control of inspection activities: is well prepared; does not assume but asks questions, takes detailed notes, and adheres to plant rules. When performing the inspection one pays attention to detail and gets to the root cause of problems; one verifies and evaluates findings and searches for objective evidence; one should take bigger sample if he/she is unsure of problem scope or existence.

When interviewing people one asks open questions avoiding “yes” or “no” answers, e.g. by using words how, who, what, when, why, show me and he/she listens the answers carefully. The inspector does not reveal his/her opinion of the answer and does not compare different organizations. One does not disagree between the team members during the
interview and one admits if his/her question is beyond the level of his/her knowledge. The inspector is objective and shows rather positive attitudes than negative and arguing attitudes. If the inspector finds deficiencies he/she gets admission from the licensee representative.

Professional attitude in inspection is that the inspector tries to find problems and areas for improvement but leaves finding of solutions to the power company.

2.5.8. Inspection philosophy

It is important for the regulatory body to define inspection philosophy — to formulate some kind of inspection programme. In Finland the nature of the inspection programme has been defined in the YVL-guide 1.1. In different countries the inspection philosophy varies somewhat. What functions well in a small country may not be applicable in a big country and vice versa. Therefore it is useful for the inspector to exchange information with colleagues from other countries to get new ideas for developing inspection practices in one’s own country. E.g. there is a working group of inspection practices (WGIP) of the OECD/NEA/CNRA for this kind of information exchange among OECD countries and it has published some useful documents in this respect e.g. presenting the inspection philosophy, organization and practices in different countries [15].

Inspectors should also have some tools to prioritise inspection work. A safety classification document is a useful tool in this respect. Use of PSA is also used increasingly to prioritise inspections. We are nuclear safety inspectors. Therefore the most important viewpoint in inspection for us is nuclear safety viewpoint. From a philosophical point of view the application of basic principles of defence-in-depth concept are central. Inspectors should know the concept so well that he/she even by instinct covers the key points in his/her inspection work. Application of the concept is a good sign of the right safety culture attitudes.

Starting from the basic principles of “defence-in-depth” thinking, we should concentrate on the following three lines of defence in our inspection work:

?? Prevention of failures.
?? Monitoring or detection of failures.
?? Making sure that failures cannot recur and mitigation of consequences of failures.

Specifically, when operations, maintenance and technical support of NPPs are concerned. Each of these topics leads to more detailed sub-items depending on the topic such as:

?? For prevention: are there proper procedures and are they used, preventive maintenance programmes, tools and working conditions, briefing and training, QA etc.;

?? For monitoring and detection: are there proper alarms and alarm procedures, surveillance programmes, testing procedures and criteria, testing lines and measuring devices etc.;

?? For experience feedback and mitigation: are there proper operational feedback systems and methods, component repair and reliability histories, reactor protection system response, incident procedures, accident management procedures, etc.?
When the organizational and safety culture aspects are considered the following key items should be considered:

?? Policy level commitment.
?? Managers’ commitment.
?? Individuals’ commitment.

Also in this case each of these topics leads to more detailed subitems to be considered such as: is there a proper safety policy statement, where are the safety topics handled in the documentation (policy level, QA manual, Tech. Specs, respective procedures); what is management and individuals’ opinion on the subject matter: what have they done to minimise the risk, do they support the finding, what are they going to do to improve the situation, why it was possible that the inspector made the finding before they realised the unsafe situation, how often unsafe situations appear, how often inspectors make these findings etc.

Our questions and review should be directed in such a way that these aspects will be covered if they are applicable in the inspection in question. If our work reflects these aspects systematically we have good opportunities to promote nuclear safety and safety culture through our work.

**2.5.9. Maintaining competence**

How does a professional inspector maintain competence. One follows the development in his/her technical field of speciality. One keeps up to date with changes in regulatory policy and practices. One develops his/her skills in inspection and assessment to the highest level for being able to develop practices and not only to perform routine work.

If this is your goal how do you organize the matter?

**2.5.10. Training of inspectors**

One of the central prerequisites for professionalism is competence i.e. knowledge, skills and attitudes needed for the job in question. The IAEA Requirements for Governmental Organization say that a regulatory body shall ensure that its staff members participate in well-defined training programmes. Continuing training is also required. For well-defined training programmes the regulatory body needs training administration as well as initial and continuing training. Table IX shows the basic elements of regulatory training programme [19].

Organization of training depends on the size and resources of the regulatory body. A small and inexperienced regulatory body needs external international support. A large and experienced organization may be self-sufficient. In any case international information exchange is needed for continuing training to get fresh and new ideas for further development. Examples of regulatory competencies and training activities in a regulatory body are given in [20].

**TABLE IX. ELEMENTS OF REGULATORY TRAINING PROGRAMME**

<table>
<thead>
<tr>
<th>Basic knowledge</th>
<th>Communication and management skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>?? Familiarization with the law and radiation and industrial safety;</td>
<td>?? Effective writing skills;</td>
</tr>
<tr>
<td>?? Nuclear safety principles and safety culture;</td>
<td>?? Interviewing skills;</td>
</tr>
<tr>
<td></td>
<td>?? Negotiation skills;</td>
</tr>
</tbody>
</table>
?? Plant and systems knowledge;
?? Accident analysis and emergency planning;
?? QA and organizational matters.

Professional knowledge
?? Regulatory control;
?? Assessment skills;
?? Inspection skills;
?? Job specific training courses;
On-the-job training.

?? Leadership and team work skills.

Continuing training
?? Refresher training;
?? Further personal development;
?? Information exchange and international co-operation.

For the well-defined training administration training manager/coordinator as well as training policy and necessary training procedures are needed. Job descriptions are needed for preparing systematic, job specific and individual training programmes. Furthermore training courses, facilities and training materials should be established. In addition to training courses, a systematic approach by using individual on-the-job training guidelines is needed. A good model is provided by the OECD/NEA/CNRA/WGIP through its inspector qualification guidelines [21].
CONTROL QUESTIONS TO SECTION 2

The objective of the control questions is to assist the learner to remember better the key issues of Section 2 and to provide self-assessment of learning. Please write your answers on the empty spaces reserved for the purpose. If agreed, your personal tutor can check your answers. The right answers are found from the respective parts of textbook handling the topic. If you do not know the answer read the text carefully again.

1. List 5 main functions of the regulatory body.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

2. List 6 important authorities/ rights regulatory body needs for performing its functions.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

3. List 5 support functions or organizations which are necessary for the regulatory body.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
4. Draft an ideal organizational chart of the regulatory body which illustrates main regulatory functions and also some technical disciplines. Compare your result with organizations presented in Section 2.

5. What do we mean with the word “license”. Do we need a license for a NPP?

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

6. What is the role of regulatory body in licensing? Look at the examples and explain what kind of licensing practices there are in different countries.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________
7. Review the paragraph describing IAEA guidance on quality assurance and conclude what is necessary for the regulatory body.

8. In quality assurance, what are the 3 functional categories?
9. List 5 important assessment topics or methods which can be used by the regulatory body in its internal development.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

10. What does an IAEA IRRT mission do?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

11. Professionalism. Describe some features of the relationship between regulatory body and NPP.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
12. Describe 5 important features of professional behaviour when inspector communicates with the licensee representatives.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

13. What is important when interviewing a licensee representative?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

14. How is nuclear safety best reflected in your inspection work?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

15. How can you maintain your professional competence?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
SPECIFIC TASKS TO BE CARRIED OUT INDIVIDUALLY

The objective of the following tasks is to assist the learner to use Internet for finding useful information for comparison, to assist the learner to apply the knowledge and to study his/her own national, respective regulatory arrangements and to compare them with international practices. Please write your answers on the empty spaces reserved for the purpose. If agreed, your personal tutor can check your answers. The key issues are found from the respective parts of textbook handling the topic.

16. Go to the OECD/NEA website www.nea.fr, open the report the name status report on inspection philosophy, organization and practices and study regulatory organizations in different OECD countries, e.g. organizational charts are collected in Appendix. List the most interesting topics you found (3–5 topics) and print your favourite regulatory body’s organization from which you find something useful and interesting to you.

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

17. Go to the OECD/NEA website www.nea.fr, open the report the name status report on inspection philosophy, organization and practices and study regulatory organizations in different OECD countries. Look the Appendix presenting staff sizes. Calculate how many professional staff members there are per reactor in different regulatory bodies. Can you conclude something concerning your own organization?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
18. Go to the USNRC website www.nrc.gov, look what kind of regulatory information there exist, click About NRC, study mission and organization, study organization chart and NRC functional descriptions and specifically office of nuclear reactor regulation — list their sub units. Study also NRC strategic plan and list 2–3 performance goals. Study also NRC annual report and budget information.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

19. Go to the Finnish regulatory body’s (STUK) website www.stuk.fi, click in English, (1) Find the quality policy from the text and read it, write down the two first sentences in the section “Conduct of Work”. 2. Click the publications and find the regulatory guide YVL 1.1 and study the regulatory duties presented there. Click also the annual report and study it.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________
20. Find your National Report written for the Convention on Nuclear Safety and study what has been presented on regulatory body. Print/copy sections concerning regulatory body and legislation and regulations. List some important findings you can make on the basis of your previous studies.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

21. Compare the organizational chart of your own regulatory body with the IAEA practices and organizational charts presented in Section 2. Explain your conclusions.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________
22. Compare the regulatory functions and arrangements in your regulatory body with the IAEA practices and examples presented in Section 2 including authorization, development of regulatory guides, review and assessment, inspection and enforcement, and emergency preparedness. How are these functions organized? Explain your conclusions.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

23. Explain how administrative activities are carried out in your regulatory body including internal quality assurance arrangements, strategies, performance goals, financing, administrative manuals and internal guidance. Specifically consider regulatory effectiveness and self-assessment and peer reviews.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________
24. Study the contents of the IAEA IRRT review service which can be used as an external peer review of regulatory activities, see 2.3.2. Study also one example of IRRT report presented in www.stuk.fi, click in English and find the IRRT report on STUK. Find also the IRRT report on your own regulatory organization. What can you conclude?
GROUP ACTIVITIES

In a group of 3–6 people from different regulatory bodies discuss and compare practices in your countries concerning the following issues:

25. Compare the regulatory organizations in your countries in respect of the regulatory functions and organizational arrangements. Discuss how the main regulatory functions have been organized in your countries. Specifically consider the staff size, use of consultants, and advisory bodies. Explain what kind of differences and similarities you find.

26. Compare the regulatory practices in your countries for carrying out the main (IAEA) functions such as authorization, development of regulatory guides, review and assessment, inspection and enforcement, and emergency preparedness. How are these functions organized? Explain what kind of differences and similarities you find.

27. Compare administrative activities and regulatory effectiveness in your regulatory bodies. Specifically consider the internal quality assurance arrangements, strategies, performance goals, financing, administrative manuals and internal guidance, self-assessment and peer reviews. Explain the differences and similarities you find.