## **IAEA-TECDOC-485**

# ANALYSIS OF REPLIES TO AN IAEA QUESTIONNAIRE ON REGULATORY PRACTICES IN MEMBER STATES WITH NUCLEAR POWER PROGRAMMES

SUMMARY REPORT PREPARED BY THE INTERNATIONAL ATOMIC ENERGY AGENCY



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#### FOREWORD

Safety of nuclear power results from the combined activities of designers, constructors, operators and regulators. The regulatory practices associated with safety of nuclear power vary from country to country, depending upon the constitutional and legal framework and the historical development of nuclear power in each Member State.

At the Special Session of the General Conference in September 1986, it was suggested that the IAEA could play a role in assisting Member States in the enhancement of their regulatory practices with the objective of giving the international community confidence in the safety of nuclear power programmes. This suggestion was discussed at the Expert Working Group on International Cooperation in Nuclear Safety and Radiation Protection held in in November 1986 and it was agreed that the IAEA should develop a programme for the survey of regulatory practices in Member States. The programme developed by the IAEA comprises an initial questionnaire to gather the relevant information, the analysis of the answers to the questionnaire to identify the main regulatory practices currently being used, and a meeting of regulatory experts to be held not later than 1988 to review the findings and discuss possible ways of propagating good regulatory practices in Member States. This approach was discussed and accepted by the IAEA Board of Governors at its meeting in February 1987.

The survey of regulatory practices by means of a questionnaire distributed to Member States with nuclear power programmes is the first stage of the programme. The questionnaire was drafted by IAEA staff members and consultants in April 1987.

The questionnaire was so structured as to correspond approximately to the structure of Code on the Safety of Nuclear Power Plants: Governmental Organization (IAEA Safety Series No. 50-C-G (Rev. 1)), with account taken of defining how the Code is reflected in the regulatory practices of Member States. The questionnaire was sent to 64 Member States on 7 July 1987. Replies received from 44 Member States were analysed by IAEA staff members with the assistance of consultants with a view to identifying the main differences in approach and the important features of regulatory practices in Member States. This report is the summary report of the analysis of the replies of Member States to the questionnaire.

## EDITORIAL NOTE

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#### **1. INTRODUCTION**

At the Special Session of the IAEA General Conference in September 1986, it was suggested that the IAEA could play a role in assisting Member States in the enhancement of their regulatory practices with the objective of giving the international community confidence in the safety of nuclear power programmes.

A survey of regulatory practices in Member States with nuclear power programmes is the first stage of the Agency's response to that suggestion. A questionnaire was drafted by IAEA staff members and consultants in April 1987. The questionnaire consisted of 120 detailed questions which were grouped into 6 parts: General; Statutory Basis; Organization of the Regulatory Body; Licensing and Regulatory Review Process; Regulatory Inspection and Enforcement, and Liaison and Consultation. The structure of the questionnaire corresponds approximately to the structure of Code on the Safety of Nuclear Power Plants: Governmental Organization (IAEA Safety Series No. 50-C-G (Rev.1)).

The questionnaire was sent to 64 Member States on 7 July 1987 and replies were received from 46 Member States. Two of these replies did not provide any of the information requested and therefore 44 replies are regarded as the effective response to the questionnaire. The Assessment of the replies is considered representative, since the response received covers about 98 % of the 417 power reactors presently in operation and about 93 % of the 120 reactors presently under construction.

Analysis of the replies from 44 Member States has been done by IAEA staff members with the assistance of two consultants. This Technical Document is the summary report of this analysis.

#### 2. OBJECTIVES OF THE SURVEY

#### 2.1. Objectives

The main objectives of the questionnaire were to determine how each Member State sets up its Regulatory Body; how this Body is organized to regulate nuclear safety, and radiation and environmental protection; how the Regulatory Body carries out review and assessement of submissions made in support of licence applications; how the Regulatory Body carries out its inspection and enforcement activities; how it consults and liaises with its applicants, licensees and other related bodies; and finally, what it considers to be the strong features of its regulatory approach.

#### 2.2. Structure of the questionnaire

The questionnaire consisted of six parts, namely: Part A - General; Part B - Statutory Basis; Part C - Organization of the Regulatory Body; Part D - Licensing and Regulatory Review Process; Part E - Regulatory Inspection and Enforcement; Part F - Liaison and Consultation.

The structure of the questionnaire corresponds approximately to the structure of Code on the Safety of Nuclear Power Plants: Governmental Organization (IAEA Safety Series No. 50-C-G (Rev.1)). (This is referred to as "the Code" hereinafter in this report.) It should be noted that Part A (General) is also set up for defining the statistical basis by surveying nuclear power programmes being operated or planned to be operated.

The full questionnaire is appended as Appendix I.

#### 2.3. Treatment of the results of the replies

The analysis of the replies to this questionnaire identifies the main differences in approach and the important features of regulatory practices in Member States. Comments are presented as appropriate. The replies to the questionnaire are treated in confidence by the IAEA and the report ensures that no information is attributable to any particular Member State.

#### 2.4. Definition of the term Regulatory Body

In this report the term Regulatory Body means a national authority or a system of authorities designated by a Member State, assisted by technical or other advisory bodies and having a legal authority for conducting the licensing process, for issuing licenses and thereby regulating nuclear energy facilities. In addition the terminology used in the questionnaire is meant to be consistent with the definitions used in the IAEA Nuclear Safety Standards (Safety Series No. 50).

### **3. ANALYSIS OF THE REPLIES**

The questionnaire was sent to 64 Member States in July 1987 and replies were received from 46 Member States. Two of the replies do not provide any of the information requested and therefore there were effectively 44 replies.

Fourteen of these 44 Member States state that they do not plan on having a nuclear power programme in the immediate future. These countries are:

(1)	Algeria	(8)	Jamaica
(2)	Australia	(9)	Liberia
(3)	Austria	(10)	Malaysia
(4)	Denmark	(11)	Norway
(5)	Greece	(12)	Portugal
(6)	Iraq	(13)	Thailand
(7)	Israel	(14)	Uruguay

The remaining 30 countries state that they are operating or planning to operate a nuclear power programme. These 30 countries are:

(1)	Belgium	(16)	Japan
(2)	Brazil	(17)	Korea, Republic of
(3)	Bulgaria	(18)	Mexico
(4)	Canada	(19)	Morocco
(5)	China	(20)	Netherlands
(6)	Czechoslovakia	(21)	Pakistan
(7)	Egypt	(22)	Poland
(8)	Finland	(23)	Spain
(9)	France	(24)	Sweden
(10	) German Democratic Republic	(25)	Switzerland
(11	) Germany, Federal Republic of	(26)	Turkey
(12	) Hungary	(27)	USSR
(13	) India	(28)	United Kingdom
(14	) Indonesia	(29)	USA
(15	) Italy	(30)	Yugoslavia.

The assessment of the replies to the IAEA questionnaire is considered representative, since the response received covers 407 of the 417 nuclear power reactors presently in operation, i.e. about 98 % of operating plants and 112 of the 120 nuclear power reactors presently under construction, i.e. about 93 %. <sup>[1]</sup>

The replies from these 30 countries have been analysed to identify the main differences in approach and the important features of regulatory practices. The results of these analyses are stated in detail in section 4.

<sup>[1]</sup> Statistics obtained from IAEA-Power Reactor Information System
(not from the questionnaire).

#### 4. RESULTS OF ANALYSIS

4.1. General (Al, A2) [2]

4.1.1. Classification

A nuclear power programme is in operation or planned in 30 of the 44 countries which answered the questionnaire.

These countries may be classified according to their nuclear power reactors as follows:

- Nuclear power reactors are in operation in 23 countries.
   (These countries are referred to as Group A countries hereinafter in this report.)
- (2) Three countries have nuclear power reactors under construction but no reactors operating. (These countries are referred to as Group B countries hereinafter in this report.)
- (3) Four countries have no nuclear power reactors in operation or under construction but plan to construct nuclear power reactors. (These countries are referred to as Group C countries hereinafter in this report.)

Three countries of Group C countries have research reactors. The remaining one country has not had any nuclear facilities and activities but gives the answer reflecting the regulatory practices such as they are envisaged in the draft legislation which is at present being put into its final form and which constitutes the basis for implementation of the nuclear power programme envisaged in the country.

<sup>[2]</sup> The number in brackets after the subtitle is the question number in the questionnaire. This usage is adopted hereinafter in this report.

#### 4.1.2. Features remarked

All the countries (26) <sup>[3]</sup> with nuclear power reactors in operation and/or under construction have research reactors, experimental reactors or critical assemblies. Distinct parts of the associated fuel cycle (e.g. fuel processing and manufacturing plants) are being operated, constructed or planned in most of the countries. Several countries (9) also have fuel reprocessing plants in operation, under construction or planned. Radioactive waste management and transport of radioactive materials should be regarded as being performed and planned in all the countries (29) with any nuclear reactor. (See Table 1.)

Nuclear facilities and activities concerned		Number of countries	Remarks S
(i) Nuclear power plants	(A) In operation	23	Group A countries
	(B) Initially under construction	3	Group B countries
	(C) Planned	4	Group C countries
	Subtotal	30	
(ii) Research reactors, ex and critical assemble	xperimental reactors ies	29	
(iii) Fuel processing and a	manufacturing plants	18	
(iv) Fuel reprocessing pla	ants	8	
(v) Radioactive waste man	nagement facilities	24	(a)
(vi) Transport of radioact	tive materials	26 (	(a)
(vii) Any other facility as nuclear energy	ssociated with civil	1 (	(b)

TABLE 1. NUCLEAR FACILITIES AND ACTIVITIES

(a) All countries with nuclear reactors have radioactive waste management facilities and transport nuclear materials. Therefore 24 and 26 should be taken as 29. However, some countries do not provide the information.

(b) A production facility for tritium  $(H_3)$  is mentioned in one reply.

<sup>[3]</sup> The number in parentheses is the number of countries giving some answer to the question concerned. This usage is followed hereinafter in this report.

4.2.1. Legal framework (Bl)

All countries (30) with nuclear power programmes, whether in existence or being planned, have established or plan to establish the principal laws, ordinances, decrees or other legal provisions to regulate their own nuclear power programmes. It might be inferred that all nuclear power programmes are controlled or regulated by a governmental organization.

4.2.2. Principal requirements of the fundamental legislation

4.2.2.1. The establishment of a Regulatory Body and licensing (B2, B3)

Almost all countries (27/29)<sup>[4]</sup> state that the current legislation require the establishment of a Regulatory Body with responsibility for full Governmental regulation of all aspects of nuclear power programmes related to nuclear safety, and radiation and environmental protection. Two remaining answers are not clear.

It also requires licencing of all nuclear facilities, such as those described in Table 1 in all the countries (29/29).

4.2.2.2. Issuance of safety regulations (B4)

The Regulatory bodies in many countries (26/29) are either formally "required" or at least "authorized" to issue safety regulations.

Such regulations can be of broad application (and include safety principles, criteria, guides and other standards) or attached to specific licences. Three remaining countries state that the Regulatory Body is not required to issue safety regulations.

[4] The first number in parentheses is the number of countries giving the <u>same</u> answer to the question. The second number is the <u>total</u> number of countries answering the question. This usage is followed hereinafter in this report. The population number of 29 means that the remaining country provides no information or not enough information in reply to the question concerned. This is followed hereinafter in this report.

### 4.2.2.3. Periodic reports on the safety of licensed nuclear facilities (B5, B6)

In fewer than half the countries (14/29) is the Regulatory Body required to prepare periodic reports on the safety of licensed nuclear facilities, and three of these countries make comments to the effect that periodic reports for specific areas are required. This is not required in some (12/29) of the countries. Such reports are addressed to other competent governmental organizations, to the parliament, to the congress or to other legislative assemblies. One country where periodic reports are not required states that the Regulatory Body actually prepares these reports. Three out of seven countries (Group B and C countries) with no nuclear power reactors state that it has not yet been decided whether legislation will require the Regulatory Body to prepare periodic reports on the safety of licensed nuclear facilities.

4.2.2.4. Public participation in the licensing process (B7, B8)

In more (16/29) than half the countries public participation in the licensing process is not a formally defined requirement. It is required in fewer than half the countries (13/29). It is carried out by various means such as by adjudicatory hearings, possibilities to comment on statements made by the Regulatory Body, or ad hoc discussion sessions, according to the legal and administrative measures set up in each country.

4.2.2.5. Other requirements in the legislation (B9)

The requirements on compensation under third party liability, control of nuclear materials, safeguards, physical protection, and so on, are listed by some countries as other requirements defined in the current legislation.

#### 4.2.3. Statutory responsibilities (Bl0-Bl3)

Many countries answer to the effect that the statuory responsibilities of the Regulatory Bodies are to issue safety regulations, to conduct the licensing and to control all activities related to nuclear power in order to ensure nuclear safety, and radiation and environmental protection.

The statutory responsibility of the licensees generally includes compliance with the conditions of the licences, regulations and orders issued by the Regulatory Body. Many countries answer to this effect.

The statutory responsibility of the Regulatory Body is institutionally or functionally clearly separated from that of the applicant/licensee in almost all countries (26/29). In a few countries (3/29) the relationship between the statutory responsibility of the Regulatory Body and that of the applicent/licensee is not so evident.

#### 4.2.4. Organizational framework

4.2.4.1. Independence of the promotion of nuclear power (B14, B15)

Most (22/28) of the countries state that the Regulatory Body is independent of the organizations responsible for the promotion of nuclear power. It is not independent in some countries (6/28). A few countries (3) comment to the effect that it is not independent because it also has a statutory responsibility to promote nuclear power. The relationship between the statutory responsibility of the Regulatory Body and that of the organization responsible for the promotion of nuclear power is not clear in the remaining three countries.

In any case, for regulatory practice to be together with promotional aspects is not consistent with para. 302 of the Code, which recommends that the Regulatory Body shall not be responsible for promotion of nuclear power.

#### 4.2.4.2. Organizational framework (B16, B17)

In several replies, there seems to be some confusion as to which body is the Regulatory Body. Also some countries do not provide enough information to identify whether the Regulatory Body comprises more than one organization. However, on the basis of the replies received, the number of countries with one Regulatory Body may be regarded as 11. It may be inferred that the Regulatory Body comprises more than one organization in 14 countries. Most of the countries where the Regulatory Body comprises more than one organization state that there is a distribution between these organizations of responsibilities for nuclear safety, and radiation and environmental protection. For instance, nine countries state that another

national organization or a local authority has responsibility for environmental protection. Three countries state that another national organization has responsibility for radiation protection.

4.3. Organization of the Regulatory Body

4.3.1. Structure of the Regulatory Body

4.3.1.1. General structure of the Regulatory Body (C1, C2)

The structure of a Regulatory Body varies from country to country, depending upon the constitutional or legal framework, the size of the nuclear power programme, the availability of skilled personnel, and so on. Nevertheless, it may be interpreted that the Regulatory Body, as particularly related to nuclear safety, comprises more than one organization in four countries and is one organization in 24 countries. Three of the former countries state that they have Regulatory Bodies at both the national level and the local level. One of the former countries implies that it has different regulatory organizations, depending upon the stage of development of and the purpose of the nuclear reactor.

The Regulatory Body comprises a headquarters organization and supporting outstations <sup>[5]</sup> in three countries. With respect to the relationship with a headquarters organization, two countries state that supporting outstations are responsible for the inspection of a nuclear power plant.

It is noted that, depending upon the political structure (e.g. federal or non-federal) of a country and/or its size, and the development of the nuclear power programme in its various regions, the Regulatory Body may be centralized in all its functions (i.e. setting of regulations, licensing and inspection/enforcement), or decentralized for its licensing

[5]

Several countries regard resident inspectors as being supporting organizations. The answer from these countries is not taken into account since the term supporting outstations refers to regional organizations which may carry out some regulatory functions. and inspection/enforcement functions, or decentralized for its inspection/enforcement functions only.

4.3.1.2. Determination of size and structure of the Regulatory Body (C3,C4,C5)

The optimum manpower resources of the Regulatory Body will vary in time with the type of activity and in particular will depend on whether the country is assessing, is embarking on or already has a well established nuclear power programme with its associated facilities. For instance, 20 countries regard the size of the nuclear power programme as the principal factor determining the size of the Regulatory Body and 17 countries regard the type, the volume and the distribution of work as the principal factors determining the size. In certain countries, with no nuclear power programme of a significant size, other activities (e.g. research establishments, transport) may also necessitate regulatory activities. The diversity of types and designs of nuclear power plants may also influence the required manpower resources of the Regulatory Body.

One country makes comments to the effect that a long term workload of safety activities is to be foreseen such as review of older plants, decommissioning, radioactive waste management and waste disposal.

4.3.1.3. Present number of technical/professional staff (C6)

The present number of technical/professional staff is listed in Table 2.1. The present number of technical/professional staff <u>per power</u> <u>reactor</u> in operation and/or under construction is listed in Table 2.2. These two tables seem to imply that there is, corresponding to nuclear activities, a minimum threshold of manpower resources for regulatory purposes which do not appear to be at the disposal of one out of three countries. That is to say, according to these tables, that the number of staff in more than half the countries answering the question is below the number defined in para. 415 of the Code. Nevertheless, the comparison of present numbers of staff with numbers given in the Code should be performed cautiously, as is emphasized in para. 415.

Numl sta:	ber of te ff (N)	chnical/professional	Number of countries
1.		N ≥1000	1
2.	1000 >	N ≥ 500	1
3.	500 >	N ≥ 100	6
4.	(100 >	$N \geqslant 80$ <sup>(a)</sup>	1
5.	80 >	$N \ge 50$	4
6.	50 >	N ≥ 25	7
7.	25 >	N ≥ 10	4
8.	10 >	N	1

(a) These numbers (100 > N  $\geqslant$  80) are referred to in para. 415 of the Code.

TABLE 2.2. NUMBERS OF TECHNICAL/PROFESSIONAL STAFF IN THE REGULATORY BODY PER POWER REACTOR

Number staff	of technic per power r	al/professional eactor (N/R)	Number of countries
		N/R > 25	3
2	25 >	$N/R \ge 10$	7
з.	10 >	$N/R \ge 5$	6
ł.	5 >	$N/R \ge 2.5$	2
5.	2.5 >	N/R	3

Table 2.3 shows the distribution of staff by the following four areas in seven countries where the number of staff in these areas is specifically given:

- (i) the preparation of regulations and guides;
- (ii) review and assessment;
- (iii) inspection and enforcement;
- (iv) legal matters.

Country		Percentage by	y area	
	(i) Preparation of regulations	(ii) Review and	(iii) Inspection and	(iv) Legal matters
	and guides	assessment	enforcement	
	2 R0 8 100 mil			
a	6	71	13	10
b	23	48	23	6
с	16	43	40	1
đ	14	53	32	1
e	6	34	56	4
£	21	21	47	11
g	25	12	38	25

TABLE 2.3. PERCENTAGE OF STAFF IN THE REGULATORY BODY BY PRINCIPAL FUNCTIONAL AREA IN SOME COUNTRIES

Also Table 2.4 shows the ratios in 13 countries of the number of staff for review and assessment and for inspection and enforcement to the number of staff for preparation of regulations and guides and for legal matters.

It may also be noted that in all cases except for one the bulk of the regulatory staff's activities lies in review and assessment and inspections and enforcement rather than in the preparation of regulations and guides and in legal matters, which seems appropriate.

TABLE 2.4. RATIO OF THE NUMBER OF STAFF IN THE REGULATORY BODY RESPONSIBLE FOR REVIEW AND INSPECTION TO THE NUMBER OF STAFF RESPONSIBLE FOR REGULATIONS AND LEGAL MATTERS IN SOME COUNTRIES.

	Percentage of staff responsible for	Percentage of staff responsible for
Country	<ul> <li>(i) preparation of regulations</li> <li>and guides and</li> <li>(iv) legal matters and</li> <li>enforcement</li> </ul>	(ii) review and assessment and (iii)inspection
a	16	84
b	29	71
С	17	83
đ	15	85
e	10	90
f	32	68
g	50	50
h	26	74
i	10	90
j	14	86
k	26	74
1	16	84
m	6	94

4.3.2. Recruitment, qualification and training of Regulatory Body staff

#### 4.3.2.1. Qualification of the staff (C7)

A regulatory body has broad and significant responsibility and authority for regulating nuclear safety, and radiation and environmental protection. It is therefore essential that all regulatory staff should have appropriate academic qualifications combined with a broad background in one or more of the disciplines specified and the experience concerned. In general, graduates of university or engineering colleges or persons with equivalent diplomas from other institutions should be preferred and work experience should be considered as one of the most important items when appointing staff.

All the countries seem to reply more or less in line with this, which is consistent with the terms of Section 3 of IAEA Safety Guide No. 50-SG-G1.

In more specific terms, some countries with relatively small nuclear power programmes or at the first stage of nuclear power programmes tend to answer that at least a bachelor's degree is required or desirable as a qualification for staff engaged in the various functions of the Regulatory Body. Some countries with relatively large nuclear power programmes answer that the qualifications are invariably job specific, even, though the possession of a university degree, technical college degree or equivalent degree from another institution is desirable.

4.3.2.2. Grades of technical/professional staff (C8)

It is normal that the grades of technical/professional staff of the Regulatory Body increase with their level of responsibilities and that grading clarifies the distribution of responsibilities and enhances the various functions of the Regulatory Body.

Approximately half the countries reply more or less along this line, which may be interpreted that in the Regulatory Body in these countries, the grades are set up and vary according to levels of responsibility. Ten countries supply the specific levels of grades of technical/professional staff.

#### 4.3.2.3. Sources of Recruitment (C9-C12)

Depending on the degree of development and the type of nuclear activities, the regulatory body may recruit its staff from universities or scientific or research institutions, and it may at a certain stage benefit from the experience which exists within organizations responsible for the design, manufacture and operation of nuclear facilities. The latter may materialize either through staff mobility (taking the necessary precautions with regard to conflicts of interest) or through training programmes that ensure that Regulatory Bodies and vendors and operators of nuclear plants/installations have a reciprocal exchange of knowledge and experience and show the right frame of mind.

Almost all countries answer that staff of the Regulatory Body are usually recruited from all sources relating to nuclear safety, such as universities, scientific institutes, research institutes, the nuclear industry or other related organizations.

In this connection, alsmost all the countries (24/28) answer that there are functions where previous experience of the nuclear industry is of particular importance. A few (4) of these countries comment that previous nuclear experience is useful for inspection functions.

With respect to the question as to what importance is attached to previous experience, many countries answer to the effect that all relevant experience required to perform the duties of the position to be filled is considered in determining the grade of staff. This experience must provide the staff with the knowledge and abilities for the scope, and responsibilities of the positions concerned. Almost all countries (23/24) state that previous nuclear industry experience determines the grade of the officer. Some (9) of these countries comment that it determines the grade of the officer in some cases or to a certain extent. One country states that it does not.

Many countries (22/27) state that technical/professional staff are recruited from organizations responsible for the design, manufacture and operation of nuclear facilities. A few (5) of these countries comment that this practice is restricted to a few cases or is to a limited extent. On the other hand, a few countries (5/27) state that technical/professional staff are not recruited from these organizations.

#### 4.3.2.4. Training (Cl3)

The means of training depend on the degree of development and the nuclear power facilities in the various countries and are therefore also influenced by possible interactions in this respect between the regulatory body and vendors and operators.

In all the countries at least some training is given to technical/professional staff in the Regulatory Body and various training is conducted by means of the Body's own training programmes, participation in training courses organized by other organizations, on-the-job training or some combination of these. Eleven countries comment that the Regulatory Body requires the staff to participate in interregional training courses organized by the IAEA as part of their training programmes. Six countries comment that staff are trained on the job.

4.3.3. Regulatory Body advice and consultation

4.3.3.1. Nature of Advisory Committees (Cl4, Cl5, Cl6)

In 22 countries the Regulatory Body has Advisory Committees and receives advice from them on regulatory activities, and one additional country plans to make the same arrangment. Five countries do not have Advisory Committees and one country of these five comments that such a committee may be established if necessary.

As regards the legal nature of the Advisory Committees, they are legal requirements in 13 countries and ad-hoc advisory organs in nine countries. One country has both types of Advisory Committees.

The Advisory Committees are standing committees in 16 countries and ad hoc in four countries. Three countries comment that they have some standing Advisory Committees and other ad hoc Advisory Committees.

4.3.3.2. The Scope of the Advisory Committee ( C17)

The scope of each Advisory Committee varies from country to country. Nevertheless, it may be stated that the scope of each Advisory Committee is to give the Regulatory Body advice on nuclear safety and on radiological and environmental protection aspects, from specific matters to generic matters such as matters related to licensing, issuing of regulations and guides, research activities, generic nuclear safety issues and other matters concerned.

#### 4.3.3.3. The Composition of Advisory Committees (C18)

The composition of each Advisory Committee, i.e. the technical background required of members, varies from country to country and also varies according to their functions. It may be stated in general that the Advisory Committee consists of experts or members with specific knowledge in depth in relevant fields in many countries.

4.3.3.4. The Appointment of the Advisory Committees (C19, C20)

It may be concluded that the Regulatory Body or the organization supervising the Regulatory Body has the power in many countries to appoint the members of the Advisory Committee.

It should be noted that the members of the high level Advisory Committees of some countries are appointed by the Minister or the Director General as the highest authority of the Regulatory Body or the organization supervising the Regulatory Body.

The members of the Advisory Committees are appointed individually in nine countries and they are appointed to represent organizations in two countries. Nine countries comment that some of the members are appointed individually and the others are appointed to represent organizations.

4.3.3.5. The written guidelines of the Advisory Committees (C21, C22, C23)

In eight countries the Advisory Committees have written guidelines to facilitate their discussions, and one country comments that only some of the Advisory Committees have written guidelines. Another country makes the comment that the Advisory Committees have written guidelines for specific areas.

The scope of these written guidelines varies from country to country, and also according to the scope of the Advisory Committees.

There are no written guidelines in ten countries. However, three of these countries answer to the effect that they have instructions which have the purpose of facilitating the discussion of the Advisory Committee. Also, it seems from a few answers that the Advisory Committees conduct their discussion on the basis of their own expert judgement or experience.

4.3.3.6. The recipients and the nature of advice (C24, C25)

In all the countries (21/21) the Advisory Committees advise the Regulatory Body itself or its related organizations.

As regards the nature of the advice, it is not binding in any countries (20/20).

4.3.3.7. Report of the Advisory Committees (C26)

Reports of the Advisory Committees are published in six countries and in 13 countries they are not. One country comments that they may be published depending upon their content.

4.3.3.8. Liaison or consultation with other authorities (C27)

As regards liaison and consultation between the Regulatory Body and governmental or other bodies, any necessary and effective liaison and consultation with governmental or other bodies seems to be conducted at all levels. They extend from the informal, e.g. telephone conversations between staff members/personnel, to the formal, e.g. a joint regulatory process where a number of parties combine their input to determine the terms and conditions of a licence, such as the consent of other authorities for each of the following:

- (1) emergency planning;
- (2) water resources;
- (3) land used planning;
- (4) public health;
- (5) any other areas as appropriate.

#### 4.4. Licensing and regulatory review process

#### 4.4.1. Licensing process

4.4.1.1. Licensing body and licence prerequisites (D1, D2, D10)

The type of licensing body varies from country to country depending on the constitutional and legal framework of the Member State (see paras 401-403 of the Code). However, some types of licensing bodies can be characterized as follows:

- An autonomous single organization with full responsibility for the complete licensing process (ten countries);
- (2) A single ministry or department which is normally assisted by technical organizations (twelve countries);
- (3) More than one ministry with an inter-ministerial committee (four countries);
- (4) An organization in a local government which is supervised by the federal government or a federal committee (four countries)

Two Member States reported that the parliamentary approval follows the granting of a licence by the governmental authority.

The licence is granted on the basis of an application which is backed up by adequate information showing that the nuclear power plant is constructed and would be operated without undue risk to public health and safety or to the environment, in accordance with government regulations (see Section 1.3 of IAEA Safety Series No. 50-SG-G2). All replies showed that the principal prerequisite for granting a licence is in this form. The responses to the question on the main requirements of licences to operate nuclear power plants are generally the same as the previous responses on the subject of principal prerequisites.

#### 4.4.1.2. Licensing stages (D3, D4, D5)

The number of licences to be issued varies among Member States. All except three countries issue multistage licences, as follows:

 Three stages (siting, construction, operation) are dominant in thirteen countries;

- (2) Two stages (construction, operation) are dominant in four countries;
- (3) Five stages (siting, construction, commissioning, operation and decommissioning) and four stages (the same without decommissioning) each occur in two countries only.

Three countries have adopted an approach by which a single site licence is granted and conditions attached to the licence require the consent of the Regulatory Body before various stages in construction, commissioning and operation may commence.

4.4.1.3. Time-scale for licence granting and public consultation (D6, D7)

The typical time-scale from the official receipt of an application for a licence to its granting varies widely by country and facility. The minimum time-scale reported is 5-60 days while the maximum is four years. A time-scale of less than one year was the response of 11 countries, with a further nine countries reporting times of between one and three years.

Public hearings are held by law or practice in 12 countries. The typical times allowed for public consultation range from two weeks to six months, but one country reported two years.

4.4.1.4. Other features and effects of a public hearing (D8, D9)

When no public hearing is conducted, public opinion is consulted through the local government or by a meeting held by the relevant interested ministries (three countries). The findings of public hearings are legally binding on the licensing in five countries. In six other countries, the findings do not directly affect the licensing process, and recommendations, where they may concern safety, are considered by the Regulatory Bodies and may be enforced through licence conditions as appropriate. One country reported that all hearings are adjudicatory and anyone whose interest may be affected by the proceedings may intervene and become a party to the proceedings.

#### 4.4.2. Nature and scope of licences

#### 4.4.2.1. Facility/site Licence (D11, D12)

A licence can be issued for a specific facility or for a site with more than one facility. In Member States, a facility specific licence is dominant (22 countries), while a site specific licence is rare (four countries). Three countries have a combined practice. In this case, one construction licence is issued for all facilities on one site and then individual operating licences are issued to each operating unit of the facilities.

The licence contains a time limit in 20 countries and does not in six other countries. One country cited as a justification for giving no time limit in the licence that a time limit was considered unnecessary for providing flexibility in the licensing system because the Regulatory Body has the statutory power to attach conditions to, to vary or to revoke the licence at any time at short notice.

4.4.2.2. Restrictions and duties conferred by the licence (D13, D14)

The Regulatory Body shall place restrictions upon the licensee whenever it is necessary to protect public safety and health. Six countries replied explicitly in this sense. There are no indications that other countries are not in compliance with this objective.

Even the duties which are placed upon the licensee by the licence differ from country to country in the replies; the duties are interpreted from the replies of Member States as being compliance with the regulations and conditions attached to the licence.

4.4.2.3. Shutdown for inspection and maintenance (D15-D17)

The operational reasons for periodically shutting down nuclear power plants are different depending on the reactor type and fuel cycle management mode (e.g. whether refuelling is in the on-line or batch mode). Approximately half the cases (13 countries) reported that periodic shutdown for maintenance and inspection is a regulatory requirement in the licence.

For the other cases, shutdown is a result of either the practical operations mode for the reactor and its fuel cycle (eight countries) or the Technical Specification requirement (four countries), or of an order from the Regulatory Body (two countries).

The typical interval for shutdown is one year, except for a few cases. Three countries reported one to one-and-a-half years and one reported two years.

#### 4.4.2.4. Licensing for plant personnel (D18, D19)

In most cases reactor operators and plant supervisors are licensed by the Regulatory Body itself (19 countries) or by a combined commission from the Regulatory Body and the plant operating organization (four countries). There are six countries in which no operator licence is required. In this case the Regulatory Body generally audits the programme for the training and qualification of plant personnel applied by the operating organizations to ensure safe operations. For other types of plant personnel (e.g. for maintenance or chemical control), licensing is usually not required, but their qualifications and training are normally ensured by the operating organization. No Member State has mentioned licensing or qualification requirements for upper level management of the operating organization. This may be due to the lack of a specific question in the questionnaire on the subject, but it may also reflect the fact that no regulatory control has been established over the qualification of the operating organization's managers.

#### 4.4.2.5. Licence challenge in the courts (D20, D21)

From the responses given, it appears that a licence granted by the Regulatory Body can be challenged in the courts in more than half the responding countries (17). In these cases any party/person whose interests are affected by the licence has the right to challenge it. Two countries permit court appeals from the licensees only against penalties.

#### 4.4.2.6. Appeal against licence conditions (D22, D23)

Almost two-thirds (18) of the countries replying allow appeals against licence conditions. The appeals go to the Regulatory Bodies, higher administrative organizations or the courts (either judicial or

administrative). Some information is provided from the replies to indicate that court appeals have hardly ever occurred in practice because differences of view have been resolved in advance between the Regulatory Body and the licensee.

#### 4.4.3. Safety principles and criteria (D24-D26)

The Regulatory Body produces safety principles, criteria, guides or other standards in most Member States (24). Among these, nine countries use the internationally developed standards and/or the vendor country's standards in addition to their own standards. Six countries which are in the early stages of nuclear power programmes reported that they use the internationally developed standards and/or the vendor country's standards exclusively.

Safety principles and criteria for licensing activities are intended for use mostly by the licensees, but several countries replied that they are applied to all related organizations (e.g. regulators, designers, vendors and constructors). There are two cases in which safety principles are basically addressed to the Regulatory Body itself and the licensee is required to produce its own safety criteria, which are assessed by the Regulatory Body against its safety principles.

#### 4.4.4. Licensing documentation and review

#### 4.4.4.1. Safety documentation (D27)

Necessary information should be submitted to the Regulatory Body by the applicant/licensee in support of licensing applications at each major stage of the licensing process. On the basis of the responses given, the basic elements of information appear to be present in broad terms. However, the answer did not provide details that could demonstrate conformity with IAEA Safety Series No. 50-SG-G2, entitled "Information to be Submitted in Support of Licensing Applications for Nuclear Power Plants", which is recommended as good practice. This item is one of the major areas to be explored in the future through further communications with Member States.

## 4.4.4.2. Management of spent fuel/radioactive waste and decommissioning (D28 - D31)

The responses to the questionnaire suggest that all countries require the safety document to include information on the management of spent fuel and radioactive waste. However, information required for the radioactive waste management is mostly related to the control of discharges and the temporary storage of solid waste.

Almost half of all countries responding require that information on decommissioning is addressed in safety documentation. The required information is not uniform in Member States but the following information is generally necessary;

- The level and the nature of radioactivity at the end of plant operation;
- (2) Procedures and methods applied in decommissioning;
- (3) Description of the final stage of the plant;
- (4) Safety evaluation of the decommissioning;
- (5) Monitoring programme for the facility and the environment in the final stage of decommissioning.

The other half did not mention information on decommissioning but may require it when necessary.

## 4.4.4.3. R & D and independent analysis by the Regulatory Body (D32, D33, D35)

The responses indicate that all countries carry out research and development (R&D) to support the review and assessment of licence applications. These are done either by the Regulatory Bodies themselves (in 16 countries) or by other institutions on their behalf through contracts/national subsidiary organizations (in 13 countries). From the answers it is not clear how much R&D is performed entirely for the purpose of regulation in Member States.

Independent analyses (e.g. computer code calculations) are carried out by the Regulatory Bodies in most (24) countries to verify significant transients or accident behaviour of plants. It is normal practice that independent analyses are done to a limited extent with the assistance of external consultants.

#### 4.4.4.4. Review and assessment programme (D34, D36)

There are many areas to be reviewed and assessed at each stage in the licensing process. It is recommended that the Regulatory Body prepare an adequate review and assessment programme to check each point of safety without disrupting the licensee's schedule (see para. 804 of the Code).

Most countries did not give any details of the review programmes in their replies but there are a few countries which had review programmes. One country uses the IAEA Safety Guides and two countries have developed their own domestic methods/handbook for this purpose.

4.4.4.5. Periodic safety review during operation (D37, D38)

During the operation of a nuclear power plant, further reviews, assessments and authorizations by the Regulatory Body are required in all countries. The reviews are made in the light of design changes, operating experience (e.g. malfunctions/transients), safety research or ageing of the plant. Sixteen countries replied that the Regulatory Body requires periodic safety reviews. Of these, six countries annually review safety to justify reload during the refuelling outage. Four countries do it every ten years and the review method is similar to the method applied before the reactor is commissioned for the first time. There are a few countries which have special review procedures. In one country, the first review is done after two years in operation and then subsequent reviews follow every four years. In another of these countries old nuclear power plants are also required to undergo an extensive long term safety review after 20 years of operation to justify continued operation, in addition to the annual reviews after each periodic shutdown. Twelve countries replied that safety reviews are required whenever necessary.

#### 4.4.4.6. Use of external consultants (D39, D40)

In all countries the Regulatory Body has the right to use external consultants to obtain assistance in its review and analysis of applicant/licensee submissions. It seems to be general practice that this is done as necessary or to a limited extent because the Regulatory Body may not be entirely self-sufficient in all technical areas.

#### 4.4.4.7. Probabilistic safety assessment (D41)

Probabilistic safety assessment (PSA), although not usually a formal licensing requirement, has been used to various degrees in Member States. Half of the replies state that the Regulatory Body carries out some PSA in support of safety reviews. The degree of effective involvement of the Regulatory Body is not clear from the answers. However, it is apparent that the Regulatory Bodies themselves only employ the method to a limited extent in some countries. In other cases Regulatory Bodies review results and conclusions of PSAs conducted by the licensees or outside contractors. Several Regulatory Bodies are considering the adoption of PSA methods in the licensing process.

#### 4.4.5. Emergency preparedness

#### 4.4.5.1. Regulatory Body's responsibilities (D42)

As the national authority for regulating the safe operation of nuclear power plants, the Regulatory Body shall ensure that an adequate updated Overall Emergency Plan exists, and that emergency preparedness is maintained (see Section 3.2 of IAEA Safety Series No. 50-SG-G6).

The on-site emergency plan is developed by the operating organization (licensee). The on-site emergency plan is approved by the Regulatory Body in seven countries but by the public authorities in the majority of countries (21). In these cases, the Regulatory Body makes the main contribution in providing technical assistance on the emergency plan for the public authorities.

The responsibilities under the off-site emergency plan rest with the public authorities in all countries except in two cases, in which the Regulatory Body has full responsibility for national emergency planning.

4.4.5.2. Regulatory Body's function in the national or state emergency plan (D43)

The function of the Regulatory Body in the national or state emergency plan is: (see Section 3.2 of IAEA Safety Series No. 50-SG-G6)

- to assist the public authorities in developing their emergency plan during the planning stage;
- to act as the principal adviser to the public authorities
   during an emergency situation; and
- to review follow-up activities designed to protect the public from contamination and to minimize radiation exposures after termination of an emergency.

In six countries the Regulatory Body acts as key organization in the national or state emergency plan. In other countries the Regulatory Body carries out its roles to a limited extent on the basis of its expertise and authority.

4.4.5.3. Regulatory Body's own plan and exercises (D44)

In 20 countries the Regulatory Body has its own emergency plans. Seven countries indicate that they have no such provisions. This might be due to the limited responsibilities of the Regulatory Bodies in the national emergency planning organization, in which other public authorities might be more actively engaged. Most countries did not answer clearly about the practice of the Regulatory Body's exercises in accordance with their own emergency plan. One country gave an explicit explanation that its Regulatory Body has exercises approximately six times per year at headquarters level and communication network is tested daily with licensee event reports by the use of emergency response facility.

4.4.5.4. Observation of and participation in emergency exercises (D45, D46)

All countries commented that the Regulatory Body observes the licensee's on-site emergency exercise. The extent of participation in off-site emergency exercises is not clear from the answers supplied. 4.5. Regulatory inspection and enforcement

#### 4.5.1. Regulatory inspection

4.5.1.1. Inspection functions and objectives (E1, E2, E3)

Basically all the countries share the main objectives and functions of inspection, i.e. to verify that the licensee is constructing and operating its facility or using nuclear material in accordance with the conditions attached to the licences and the legal requirements.

The more detailed functions and objectives such as mentioned under paras 1005 and 1006 of the Code are formulated differently from country to country and therefore a more detailed survey is necessary to compare inspection practices of each country with the Code. However, their basic concept seems to be well recognized.

4.5.1.2. Written procedures for inspection (E4, E5)

About half the countries (16/26) state that the Regulatory Body has written procedures for regulatory inspection so that inspectors would have accurate guidance to accomplish their functions. A few (2/16) of these countries state that the Regulatory Body has some written procedures for specific areas.

In those countries (8/26) where such written procedures do not formally exist, guidance is given to inspectors by providing general methodological handbooks, by training programmes, through on-the-job training, etc.

Written procedures have not been prepared yet in three of the Group C countries.

In any case having no written procedures is not consistent with Section 4.4 of IAEA Safety Series No.50-SG-G4.

#### 4.5.1.3. Special inspections (E6, E7)

It is important that the Regulatory Body carries out special inspections, e.g. safety audits, in response to findings of routine inspections or to abnormal occurrences. Findings by special inspections may serve as important inputs for reviewing and identifying the root causes of any events and eventually may provide measures for ensuring nuclear safety. Therefore the Regulatory Body carries out special inspections in all except one country (27/28). This exceptional country comments that special inspections are included in routine inspections. The matter of special inspection has not been clarified yet in two of Group C countries.

Special inspections are carried out in various forms at various times in each country, depending upon the significance of each case. This may indicate that special inspections are not standardized easily, and this is why they differ from routine inspections.

4.5.1.4. Resident inspectors and designated site inspectors (E8)

Resident inspectors are used in 14 countries and are not used in 11 countries. The utilization of resident inspectors and designated site inspectors has not been clarified yet in any of the four Group C countries. However, all the Group B countries (3) state that the Regulatory Body makes use of resident inspectors.

The advantages and disadvantages of resident inspectors are discussed in Section 4.2.3 of IAEA Safety Series 50-SG-G4. The answers given confirm that there is still much difference of opinion between the various countries on this matter, with practice ranging from extensive use at virtually all stages to no use of resident inspectors at all.

However, most regulatory bodies make use of "designated" site inspectors for inspection of construction, commissioning or maintenance.

#### 4.5.1.5. External inspection agencies (E9)

In the inspection process, use of external agencies or experts is sometimes made for the inspection of special facilities, structures or components (e.g. pressure components); this is a usual practice in many

countries that varies according to the purposes and forms of utilization of such agencies or experts. This is indicated by the fact that external inspection agencies are made use of in 23 countries, and most of these countries comment that the Regulatory Body makes use of them for special cases or to a limited extent. Two countries state that the Regulatory Body does not make use of other external inspection agencies and/or experts.

All the Group C countries (4) comment that the utilization of external inspection agencies has not been clarified yet. On the other hand, all the Group B countries (3) state that the Regulatory Body makes use of them.

4.5.2. Enforcement

4.5.2.1. Enforcement powers (E10)

The Regulatory Body has powers of enforcement to ensure compliance with the licence or other regulations in all countries. The answers may be summarized as follows: The Regulatory Body may issue warning letters, curtail activities, suspend or revoke a licence, or take legal action against (e.g. penalize) a licensee under the relevant laws, depending upon the extent of failure to comply with licence conditions or other regulatory conditions.

4.5.2.2. Methods of enforcement (Ell)

The answers on methods of enforcement may include all or some of the following methods, which are defined in paras 1010 through 1015 of the Code, in all the countries:

- (1) Warning letters or directives;
- (2) Order to curtail activities such as stopping construction work, reducing the operating level, reactor shutdown, etc.;
- (3) Suspension or revocation of a licence;
- (4) Penalty.

A few countries comment that the Regulatory Body utilizes informal methods such as oral advice to encourage the licensee to undertake a preferred course of conduct.

## 4.5.2.3. Avenues of appeal against Regulatory Body decisions (E12, E13)

The licensee has no avenues to appeal against Regulatory Body decisions in some countries (6/27). One of these countries comments that the licensee has no avenues except for appeals against monetary penalties. One country comments that avenues of appeal vary depending on the areas of Regulatory Body decisions.

All the other countries (20/27) have avenues of appeal against decisions of the Regulatory Body. Methods of appeal vary from country to country. Nevertheless, it may be summarized for most of these countries that the licensee may appeal against Regulatory Body decisions to the Regulatory Body itself or to the organizations which control it, and when differences of view exist even after these appeal procedures, the licensee may appeal to the court for resolution.

4.5.2.4. Conditions to direct a plant to be shut down (El4)

It is normal that nuclear power plants should be shut down whenever nuclear safety is jeopardized due to any significant events or violations of regulations or conditions attached to the licence, as given under paras 1012 and 1013 of the Code. All the countries answer to the effect that the Regulatory Body is authorized to direct shutdown of licenced facilities, effective immediately if warranted, to protect the health and safety of the public and site personnel, in the event of any significant events or of violation of regulations or conditions attached to the licence.

4.5.3. Reporting Procedures

## 4.5.3.1. Regulatory inspections reports and their recipients (E15, E16)

Actual and specific methods of reporting routine regulatory inspection actions vary from country to country, depending upon the inspection frameworks, the structure of the Regulatory Body etc. Nevertheless, it may be summarized as follows; Routine regulatory inspection actions are reported in a timely and effective manner, by inspection reports, at least to the Regulatory Body or the competent authorities which are responsible for supervising the entire activities of nuclear facilities. Significant matters are reported by using fastest means such as telephone, telefax etc. with written reports follow-up. These inspection actions are reported to specified staffs of the Regulatory Body in all countries and they are reported also to the licensee in some countries (13/29). They may be freely available in a few countries (3/29).

4.5.3.2. Analysis of regulatory inspection reports (E17)

The kinds of analysis of regulatory inspection reports are mainly dependent upon inspection findings, and analysis of various kinds is performed in each country depending on its importance, its necessity based upon the ability of those analysing regulatory inspection reports. Therefore, the practice of analysis varies from country to country. Nevertheless, the answers may be summarized more or less as follows:

Stress in the different kinds of analysis is placed on ensuring compliance with the legal requirements, including technical specifications or conditions attached to the licence, and on proposals for necessary measures to eliminate the shortcomings in all aspects of nuclear safety and radiological protection.

Analysis is performed by a special team, or by the competent staff of the Regulatory Body, with specialists if necessary or without. The forms of analysis have not been clearly defined yet in three Group C countries.

4.5.3.3. Procedure for incident reporting by licensees (E18)

It is self-evident and important that incidents should be reported to the Regulatory Body effectively and immediately by appropriate means such as telephone, facsimile, telex, etc., and afterwards this should be supplemented with written reports within the required time, depending upon the significance of the incidents. Many countries reply more or less to this effect.

Some countries (8/27) state that the procedure for incident reporting is specified in the regulations, the technical specifications or the directives. Three countries state that the procedure follows IAEA Safety Guides. The procedures for incidents have not been clearly defined yet in three Group C countries.

4.5.3.4. Procedure for investigating incidents (E19)

The procedure for investigating incidents varies from country to country, depending upon the legal framework, the structure of the Regulatory Body, the licensing process, etc., of each country.

Nevertheless, the basic procedure for investigating incidents is more or less the same in all the countries. Failures and incidents are primarily investigated at the level of the operating organization or resident inspector, or sometimes the staff of the headquarters of the Regulatory Body. The headquarters of the Regulatory Body serves more in investigating the incidents as their significance increases. A few answers imply that the headquarters of the Regulatory Body investigates the more significant incidents in co-operation with the other organizations concerned (e.g. the Advisory Committees, research institutes, designers, manufacturers, etc.) if necessary.

One country comments that the procedure for investigating incidents is as specified for ASSET <sup>[6]</sup> by the IAEA.

4.5.3.5. Procedure for evaluating incidents (E20)

The procedure for evaluating incidents is the final stage of the whole process to deal with them, which consists of two stages of investigating and evaluating the incident. The process of evaluating

[6] ASSET, for Assessment of Safety Significant Events Teams, is a new programme initiated by the IAEA in order to provide operating organizations and regulatory authorities with an independent opinion on the causes of events significant for safety, the appropriateness of corrective actions implemented, and additional corrective actions which might help to prevent the occurrence of similar events.

the incident consists of two main processes, namely, identifying the causes of the incident and then setting up effective measures to eliminate the causes and to prevent the recurrence of similar incidents, and furthermore to find any potential generic concerns to be applied to generic nuclear safety.

All the countries seem to give answers more or less in line with this concept.

In comparison with the procedure for investigating incidents, more broad, technical and special knowledge in depth is needed for evaluating incidents. The observable tendency appears in a few answers that the Regulatory Body or the organizations concerned (e.g. research institutes, etc.) with higher and broader levels of knowledge serve in evaluating incidents more than in investigating them.

Also, it is generally stated, as would be expected, that the procedure for evaluating incidents varies according to their significance, with the Regulatory Body serving more in evaluating more significant incidents. This tendency may be observed in a few answers.

One country comments that the procedures for evaluating incidents is as specified in ASSET by the IAEA.

4.5.3.6. Recipients for the findings of evaluations (E21)

It is self-evident and important that the findings of evaluations of incidents should be made available primarily to personnel or staff directly concerned with nuclear safety activities in order for them to learn the lessons of the incidents and to enhance the safety of nuclear facilities. The necessary corrective actions, such as modification of design, manufacture, inspection, etc., will be made or implemented by the responsible personnel or organizations on this basis. Therefore all the answers state more or less that they should be made available to the Regulatory Body, other concerned organizations and the licensees concerned.

Besides this, a few countries comment that the findings are reported to higher authorities and made available to the public if needed.

#### 4.5.3.7. Utilization of the findings of evaluation (E22)

It is also self-evident that the final goal of utilization of the findings of evaluation is to encourage the Regulatory Body and the licensees to ensure the safety of nuclear facilities. The Regulatory Body is able to make comments, suggestions, instructions or orders to the licensees to take the necessary measures to comply with the requirements or to prevent the occurrence of similar accidents in order to ensure the safety of nuclear facilities, by making use of the findings of the evaluation. Also, the Regulatory Body itself can take the necessary measures. These include development or amendment of the regulations concerned, modifying licence conditions or adding new ones, improving inspections, and input for feedback to safety operation, research or general nuclear safety matters, reflecting the finding of the evaluation. All the countries answer more or less to this effect.

#### 4.6. Liaison and consultation

4.6.1. The nature of the contacts between the Regulatory Body and the licensee (F1)

It is important at the level of practice that the Regulatory Body has timely and necessary contacts with the licensees to ensure prompt and effective resolution of safety issues in order to take the necessary actions or procedures for ultimately ensuring public health and safety as given under para. 428 of the Code. The nature of the contacts is to encourage excellence to co-operate to improve safety, to demand compliance with regulations, and to conduct prompt and effective enforcement when warranted. All the answers include part or all of this statement.

## 4.6.2. The form of the contacts between the Regulatory Body and the licensee (F2)

Contacts are made as the need arises to consult, discuss or resolve safety issues, scheduling, issuing of guidance, application for permission, and inspection or enforcement actions at all the necessary levels in order to ensure prompt and effective measures for nuclear safety. All the answers include part or all of this statement.

#### 4.6.3. International contacts (F3)

In general, the Regulatory Body conducts its international contacts in any forms in the field of nuclear safety, and in radiation and environmental protection in all the countries with nuclear power programmes, in order to enhance nuclear safety activities by incorporating useful information.

(1) The Government or the Regulatory Body has contacts for exchange of information not only with other countries in any form (e.g. specialist staff level, high ranking staff level, etc.), mainly under bilateral agreements, but also with international organizations, in all the countries.

It should be interpreted that all the countries (30/30) have contacts with the IAEA and that all the countries (23)<sup>[7]</sup> with nuclear power plants in operation participate in the Incident Reporting System of the IAEA, either directly or through OECD/NEA, even though all the countries concerned do not necessarily give these answers.

(2) With respect to notification of incidents or abnormal occurrences, most (8) of the European countries state that they have formal agreements with neighbouring countries or other countries concerned for notificating of incidents or abnormal occurrences.

It should be interpreted that the Government or the Regulatory Body participates in the activities of the Incident Reporting System of the IAEA in 23 countries. Also, it is the case that the Government participates in or has already signed to participate in the Convention on Early Notification of a Nuclear Accident in 28 of 30 countries answering the questionnaire, even though not all of the countries necessarily make these comments.

<sup>[7]</sup> One of the 24 countries participating directly or through OECD/NEA in the Incident Reporting System of the IAEA did not reply to the questionnaire.

(3) With respect to mutual assistance in the case of nuclear accidents, most (8) of the European countries state that the Government has the formal agreements with neighboring countries or with other countries concerned.

It should be interpreted that the Government participates in or has already signed to participate in the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency in 27 of 30 countries answering the questionnaire, even though not all of the countries concerned necessarily make these comments.

4.6.4. The form of international contacts (F4, F5)

(1) In general, the Regulatory Body's international contacts in the field of nuclear safety, and radiation and environmental protection are based upon formal exchange agreements, mainly because they are activities between nations.

All the countries (25/25) state that these international contacts are mainly based upon formal agreements. However, the forms of international contacts are dependent upon the importance, the promptness or the priority of the contacts. Some countries (7/25) comment that some international contacts are on an ad hoc basis, although they are mainly based upon formal exchange agreements.

(2) Also, these international contacts are made mostly at high levels such as the Government level because of their international nature. Nevertheless, it is clear that they vary as to the purpose, the function and the particularity of contacts and they are also made at the executive level or working level. Many countries answer to this effect.

4.6.5. Participation in international organizations (F6)

The Regulatory Bodies of all the countries participate in the activities of the IAEA. Some of the countries state that they participate in the activities of CMEA besides the IAEA. Some of the countries participate in OECD/NEA and/or CEC. Some countries state that they participate in other international organizations such as WHO, FAO, etc.

#### 5. CONCLUSIONS

The analysis of the replies to the questionnaire has identified some deficiencies in the formulation of the questions. The expressions or the contents of the replies vary from country to country and are not necessarily uniform and comprehensive. All kinds of questionnaires have more or less similar limitations for surveying or analysing facts.

Nevertheless, the replies provide much significant information on regulatory practices in Member States, and the analysis of the replies allows preliminary conclusions on the status and practices of the Regulatory Bodies in Member States. The views provided in various sections are at this stage preliminary because it has not been possible to hold discussions with Member States in order to clarify their replies.

Taking the above into consideration, the main conclusions of the analysis are:

- (1) The basic concepts, purposes and functions of the Regulatory Body seem to be well recognized in all Member States having nuclear power programmes which responded to the questionnaire. These seem to be generally in accordance with the recommendations of the Code.
- (2) Some regulatory practices, however, vary widely in the international community, according to national factors such as the history of nuclear development, the governmental structure of the country and the size of the nuclear programme. Therefore, it is not easy to correlate actual practices with the Code and to identify what could be considered good practices by means of the questionnaire survey alone.
- (3) Some of the countries with a nuclear power plant under plan have not yet set up regulatory rules for regulatory inspection techniques and methods, and for investigating and evaluating incidents.

The analysis has highlighted a number of areas where practices vary. The international nuclear community and the IAEA should focus attention on them as important areas in which standards might be necessary in order to make them more uniform, to define and propagate good practices with the objective of reducing the likelihood of another nuclear accident.

Among these areas one could mention:

- Necessary documentation requiring review and assessment at various stages of licensing.
- (2) Regulatory inspection methods, including use of resident inspectors.
- (3) Procedures for analysis of routine inspection reports in order to identify potential deterioration of safety.
- (4) Requirements for periodical reassessment of safety of plants during operation.
- (5) Use of probabilistic safety assessment in regulatory decisions.

There exists also the need to establish methods of evaluating the effectiveness of the regulatory process itself, in order to give the international community confidence in the safety of nucelar power programmes.

In this last aspect, it has been suggested that the IAEA could play a major role. With these objectives possible future IAEA activities have been suggested, including the following proposals:

- (1) A more detailed survey may be initiated for the specific areas where significant variations in regulatory practices have been identified. Later analysis of this survey may lead to the identification of the reasons for differences and eventually lead to a clarification of what could be considered good practices.
- (2) Specialists meetings may be set up to take place regularly (e.g. annually) with a view to exchanging information and discussing regulatory practices in Member States.

- (3) Regulatory review missions could be organized by the IAEA with the support of outside experts in order to visit Regulatory Bodies in Member States and to evaluate their practices in the light of the recommendations of the Code. The mission would prepare a confidential evaluation report to the Member State's Government, presenting the recommendations.
- (4) Under IAEA co-ordination, a small group of Member States with similar nuclear power programmes (e.g. similar types of reactor, similar political organization, importing their power plants from similar vendors) could be organized into a mutual evaluation group. High level regulatos from these Member States could perform a series of exchange visits in order to inform themselves regarding regulatory practices in other countries and to prepare a final document enumerating common practices and evaluating differences.

Any of these proposals could be implemented by the IAEA according to responses from Member States.

#### Appendix I

### IAEA QUESTIONNAIRE ON REGULATORY PRACTICES IN MEMBER STATES WITH NUCLEAR POWER PROGRAMMES

PART A : GENERAL

- A l. Is your country operating or planning to operate a nuclear power programme ?
- A 2. If the answer to A l is yes, specify the numbers and types of facilities and/or activities in the following areas:
  - (i) Nuclear power plants;
  - (ii) Research reactors, experimental reactors and critical assemblies;
  - (iii) Fuel processing and manufacturing plants;
  - (iv) Fuel reprocessing plants;
  - (v) Radioactive waste management facilities;
  - (vi) Transportation of radioactive materials;
  - (vii) Any other facility associated with civil nuclear energy.
- A 3. If the answer to A l is no, return this questionnaire to IAEA without further comment.

#### Legal Framework

B 1. Specify the principal laws, ordinances, decrees or other legal provisions used to regulate your nuclear power programmes. Note: these provisions should include nuclear safety, and radiation and environmental protection.

#### Principal Requirements of the Fundamental Legislation

- B 2. Does the current legislation require the establishment of a Regulatory Body with responsibility for full Governmental regulation of all aspects of nuclear power programmes relating to nuclear safety, and radiation and environmental protection ?
- B 3. Does the current legislation require licensing of all nuclear facilities, such as those described in Question A 2 ?
- B 4. Does the current legislation require the Regulatory Body to issue safety regulations ?
- B 5. Does the current legislation require the Regulatory Body to prepare periodic reports on safety of licenced nuclear facilities ?
- B 6. If the answer to B 5. is yes, to whom are these reports addressed ?
- B 7. Does the current legislation require public participation in the licensing process ?
- B 8. If the answer to B 7 is yes, what form of public participation is required ?
- B 9. What other requirements are defined in current legislation ?

#### Statutory Responsibilities

- B 10. What are the statutory responsibilities of the Regulatory Body ?
- B 11. What are the statutory responsibilities of licensees ?
- B 12. Is the statutory responsibility of the Regulatory Body institutionally separate from that of the applicant/licensee ?
- B 13. If the answer to B 12 is no, what is the relationship ?

#### Organisational Framework

- B 14. Is the Regulatory body independent of the organisation responsible for the promotion of nuclear power ?
- B 15. If the answer to B 14 is no, explain the relationship.
- B 16. If the Regulatory Body comprises more than one organisation, (e.g. National and State Bodies) what is the relationship between these bodies having responsibility for nuclear safety, radiation and environmental protection ?
- B 17. Provide a diagram showing the Governmental organisation(s) for the regulation of nuclear power, making clear the reporting lines of the various bodies within the legislative framework. It would be helpful to distinguish between direct lines of control and lines which show where advice is given and or received. (An example of such a diagram is presented in attachment 1).

PART C : ORGANISATION OF THE REGULATORY BODY

#### Regulatory Body Structure

- C 1. Provide a diagram showing the structure of the Regulatory Body. Where the Regulatory Body comprises more than one organisation, provide a diagram for each. The organisation chart should show the management structure, the fields of activity covered by the Regulatory Body and the numbers of staff involved in each area. (An example of such a diagram is presented in attachment 2)
- C 2. Where the Regulatory Body comprises a headquarters organisation and supporting outstations, what is the relationship between each and how are responsibilities shared ?
- C 3. What were the principal reasons used to determine the size and structure of the Regulatory Body ?
- C 4. Is the size of the nuclear industry a factor in determining the size of the Regulatory Body ?
- C 5. What other criteria are used to determine the size of the Regulatory Body ?
- C 6. What is the present number of technical/professional staff employed ? It would be useful to divide these into those involved in:
  - (i) preparation of regulations and guides
  - (ii) review and assessment
  - (iii) inspection and enforcement
  - (iv) legal matters

#### Regulatory Body Staff Recruitment, Qualification and Training

- C 7. What qualifications are required for staff engaged in the various Regulatory Body functions ?
- C 8. What grades of technical/professional staff are employed? State the levels of responsibility attached to each grade.

C 9. Where are staff recruited from ?

- C 10. Are there functions where previous nuclear industry experience is of particular importance ?
- C 11. What importance is attached to previous experience and does this determine the grade of the officer ?
- C 12. Are technical/professional staff recruited from the organisations responsible for the design, manufacture and operation of nuclear facilities ?
- C 13. What training is given to technical/professional staff in the Regulatory Body ?

### Regulatory Body Advise and Consultation

- C 14. Does the Regulatory Body receive advice from Advisory Committees ?
- C 15. Are Advisory Committees a legal requirement ?
- C 16. Are these Advisory Committees standing or ad-hoc ?
- C 17. What is the scope of each Advisory Committee ?
- C 18. What is the composition of each Advisory Committee, i.e. technical background required by Members ?
- C 19. Who appoints the Advisory Committees ?
- C 20. Are members appointed individually or are they appointed to represent organisations ?
- C 21. Do the Advisory Committees have written guidelines to facilitate their discussions ?

C 22. If the answer to C 21 is yes, specify the scope of such guidelines.

- C 23. If the answer to C 21 is no, specify the basis on which recommendations are made.
- C 24. To whom do the Advisory Committees give advice ?
- C 25. How binding upon the Regulatory Body is the advice given ?
- C 26. Are reports of the Advisory Committees published ?
- C 27. How does the Regulatory Body liaise or consult with Governmental or other bodies having responsibility for each of the following ?
  - (i) emergency planning
  - (ii) water resources
  - (iii) land used planning
  - (iv) public health
  - (v) any other areas as appropriate

### Licensing Process

- D 1. Which Body or Bodies grant licences ?
- D 2. What are the principal prerequisites for granting a licence ?
- D 3. Is the licensing process single stage or multistage ?
- D 4. If single stage, what information is the licence applicant required to submit ?
- D 5. If multistage, what are the stages and what information is the applicant/licensee required to submit at each stage ?
- D 6. What is the typical timescale from the official receipt of the licence application for a particular facility to the grant of the licence to enable construction to start ?
- D 7. Is there any time allowed for public consultation ? If so, what is typical time ?
- D 8. Are there any other special features which have a bearing on the licensing process, e.g.
  - (i) Is there a requirement for a public inquiry or public hearing into an application ?
  - (ii) What, if any, form do these take ?
  - (iii) Is the public consulted in any other way ?
- D 9. How are the findings of any public inquiry/hearing likely to affect the licensing process ?

- D 10. What are the main requirements of a licence for each type of facility or activity described in A 2 ?
- D ll. Is a licence specific to one facility or can it apply to a site with more than one facility on it ?
- D 12. Do licences contain time limits, if not, explain the reason for not having such limits ?
- D 13. What restrictions can be placed upon the licensee by the licence ?
- D 14. What duties are placed upon the licensee by the licence ?
- D 15. Do licences require licensees to shut down plants at regular intervals for inspection and maintenance ?
- D 16. If the answer to D 15 is yes, what is a typical interval ?
- D 17. If the answer to D 15 is no, please comment on how these activities are performed.
- D 18. Do licences require plant personnel to be licenced, if so by whom ?
- D 19. If the answer to D 18 is no, what procedures are used to ensure that plant personnel have adequate qualifications, training and experience ?
- D 20. Can a licence be challenged in the courts ?
- D 21. If the Answer to D 20 is yes, who has the right to challenge it ?
- D 22. Does the licensee have the right to appeal against conditions applied to him for the licence ?
- D 23. If the answer to question D 22 is yes, to whom can he appeal and how are differences of view resolved ?

#### Safety Principles and Criteria

- D 24. Does the Regulatory Body produce safety principles, criteria, guides or other standards ?
- D 25. If the answer to D 24 is yes, specify their present status and for whom are they intended.
- D 26. If the Regulatory Body does not produce its own nuclear safety principles, criteria etc, what safety standards does it use ?

#### Licensing Documentation and Review

- D 27. What safety documentation is the applicant/licensee required to supply to the Regulatory Body during the major stages of the licensing process ?
- D 28. Does the required safety documentation include information on the management of spent fuel and radioactive waste ?
- D 29. If the answer to D 28 is yes, what information is required at each stage ?
- D 30. Does the required safety documentation include information on decommissioning ?
- D 31. If the answer to D 30 is yes, what information is required at each stage ?
- D 32. Does the Regulatory Body carry out Research and Development to support its review and assessment programme ?
- D 33. If the answer to D 32 is no, who is responsible for such activities ?
- D 34. What programme of review and assessment is carried out by the Regulatory Body prior to grant of a licence for the commencement of construction ?

- D 35. Does the Regulatory Body carry out independent analyses (e.g. computer code calculations) ?
- D 36. What programme of review and assessment is carried out by the Regulatory Body during construction and commissioning of a nuclear facilities ?
- D 37. Does the Regulatory Body require periodic safety reviews during the operation of the plant ?
- D 38. If the answer to D 37 is yes, what period of time is allowed between reviews ?
- D 39. Has the Regulatory Body the right to use external consultants to assist it in its review and analysis of applicant/licensee submissions ?
- D 40. Is it general practice to use external consultants ?
- D 41. Does the Regulatory Body carry out probabilistic safety assessments ?

#### Emergency Preparedness

- D 42. What are the Regulatory Body's responsibilities for emergency planning ?
- D 43. What role does the Regulatory Body have in relation to the National or State emergency plan ?
- D 44. Does the Regulatory Body have its own emergency plan and how is it exercised ?
- D 45. Does the Regulatory Body observe the licensees emergency exercises ?
- D 46. To what extent does the Regulatory Body participate in emergency exercises ?

#### Regulatory Inspection

- E 1. What are the inspection functions of the Regulatory Body ?
- E 2. How does the Regulatory Body carry out its inspection function ?
- E 3. What are the objectives of regulatory inspection ?
- E 4. Does the Regulatory Body provide written procedures for regulatory inspections ?
- E 5. If the answer to E 4 is no, how is guidance given to inspectors ?
- E 6. Does the Regulatory Body carry out special inspections, e.g. safety audits, in response to findings of routine inspection or abnormal occurrences ?
- E 7. If the answer to E 6 is yes, what form do these special inspections take ?
- E 8. To what extent does the Regulatory Body make use of resident inspectors, designated site inspectors from headquarters ?
- E 9. To what extent does the Regulatory Body make use of other external inspection agencies and/or experts ?

#### Enforcement

- E 10. What powers of enforcement does the Regulatory Body have to ensure compliance with the licence or other regulations ?
- E 11. What methods of enforcement (e.g. warning letters, order to curtail activities, monetary penalties) are available to the Regulatory Body ?
- E 12. Does the licensee have avenues of appeal against Regulatory Body
   decisions ?

- E 13. If the answer to Question E 12 is yes, what are they and how are differences of views resolved ?
- E 14. Under what conditions does the Regulatory Body have the power to direct a plant to be shut down ?

#### Reporting Procedures

- E 15. How are routine regulatory inspection actions reported ?
- E 16. To whom are routine regulatory inspection reports available ?
- E 17. What kind of analysis is performed on regulatory inspection reports and by whom ?
- E 18. What is the procedure for incident reporting by licensees ?
- E 19. What is the procedure for investigating incidents ?
- E 20. What is the procedure for evaluating incidents ?
- E 21. To whom are the findings of such evaluations made available ?
- E 22. In what way does the Regulatory Body make use of these findings ?

#### PART F LIAISON AND CONSULTATION

- F 1. Specify the nature of the contacts between the Regulatory Body and the licensee.
- F 2. How often do these contacts take place, at which level and for what purpose ?
- F 3. Specify the Regulatory Body's international contacts in the fields of nuclear safety and radiation and environmental protection with respect to:
  - (i) Exchange of information
  - (ii) Notification of incidents or abnormal occurrences
  - (iii) Mutual assistance in the case of nuclear accidents
- F 4. Are these contacts based upon formal exchange agreements or are they on an ad-hoc basis ?
- F 5. At what levels are international contacts made ?
- F 6. Specify the Regulatory Body's participation in the activities of international organisations.

#### Attachment 1





#### Attachment 2

#### ORGANIZATION OF THE DIRECTORATE GENERAL RS IN THE FEDERAL MINISTRY FOR THE ENVIRONMENT, NATURE CONSERVATION AND NUCLEAR SAFETY



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