

INSAG-17

# Independence in regulatory decision making

## INSAG-17

A REPORT BY THE  
INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP

# INSAG



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INDEPENDENCE IN  
REGULATORY DECISION MAKING

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A report by the International Nuclear Safety Advisory Group

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REGULATORY DECISION  
MAKING

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A report by the  
International Nuclear Safety Advisory Group

INTERNATIONAL ATOMIC ENERGY AGENCY  
VIENNA, 2003

The International Nuclear Safety Advisory Group (INSAG) is an advisory group to the Director General of the International Atomic Energy Agency, whose main functions are:

- (1) To provide a forum for the exchange of information on generic nuclear safety issues of international significance;
- (2) To identify important current nuclear safety issues and to draw conclusions on the basis of the results of nuclear safety activities within the IAEA and of other information;
- (3) To give advice on nuclear safety issues in which an exchange of information and/or additional efforts may be required;
- (4) To formulate, where possible, commonly shared safety concepts.

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# **FOREWORD**

**by Mohamed ElBaradei**  
**Director General**

Regulatory bodies in the area of nuclear safety have the task of ensuring that individuals, society and the environment are properly protected against radiological hazards associated with the use of nuclear technology, without unnecessarily impairing the benefits to be gained from the use of nuclear technology.

It is widely recognized that independence of the regulatory body is needed to ensure that regulatory decisions can be made and enforcement actions taken without unwarranted interaction and attempts to influence regulatory decision making in a way that detrimental to safety.

This INSAG report defines in greater detail the independence needed in the regulatory decision making process and how to meet the potential challenges to that independence. Thus, the report identifies a number of measures that need to be implemented at different levels to promote and protect independence in the regulatory decision making process. The basic principles have to be embedded into the legal framework and followed up by systematic quality management of regulatory processes and activities.

The report is intended to promote a common understanding among legislators and other political decision makers, nuclear safety regulators and licensees of the concept of independence in regulatory decision making and how to achieve it. Other interest groups, such as non-governmental organizations and members of the public interested in the regulation of nuclear safety, may also find the report useful.

I am pleased to release this report to a wider audience. In particular, I hope that it will increase understanding of this important issue for all nuclear regulators.

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# **1. INTRODUCTION**

1. This report is intended to promote a common understanding among legislators and other political decision makers, nuclear safety regulators and licensees of the concept of independence in regulatory decision making and how to achieve it. Other interest groups, such as non-governmental organizations and members of the public interested in the regulation of nuclear safety, may also find the report useful.

2. Regulatory bodies have three basic functions: (1) to develop and enact a set of appropriate, comprehensive and sound regulations; (2) to verify compliance with such regulations; and (3) in the event of a departure from licensing conditions, malpractice or wrongdoing by those persons/organizations under regulatory oversight, to enforce the established regulations by imposing the appropriate corrective measures.

3. The performance of these functions must be entrusted to a regulatory body provided with adequate authority, competence, and financial and human resources to discharge its assigned responsibilities. Moreover, in order to ensure independence in exercising these basic regulatory functions, there must be an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy. The need for this separation of functions has long been acknowledged. Such a separation is included as an obligation for Parties to the Convention on Nuclear Safety [1] and for Parties to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [2].

4. The organizational structure of regulatory bodies differs between countries, depending on their national constitutional and legal framework. In several States, the three functions defined above are divided between more than one organization. For example, some legal instruments regulating safety may be the responsibility of ministries; the technical assessments needed to verify compliance with regulations may be performed by special technical safety organizations (TSOs); and some enforcement actions may finally be decided through the national judicial system. In the following pages, the term ‘regulatory body’ includes all organizations performing regulatory functions as defined above.

5. The primary reason for independence of the regulatory body is to ensure that regulatory decisions can be made and enforcement actions taken without

pressure from interests that may conflict with safety. Thus, in order to ensure independence in its decision making, INSAG recommends that the regulatory body should have effective independence from government departments and agencies, from industries and from interest groups that promote or oppose nuclear technologies. In particular, it must be independent of the organizations that it regulates, whether these are State owned or privately owned. The credibility of the regulatory body in the eyes of the general public, whose health and safety it is the regulatory body's responsibility to protect, depends in large part upon whether the regulatory body is considered to be independent in its decision making.

6. At the same time, it is recognized that a regulatory body cannot be absolutely independent in all respects of the rest of government: it must function within a national system of laws and under budget constraints, just as other governmental organizations do. However, the necessary political guidance and oversight must be clearly defined and limited in the appropriate legal instruments in order to ensure a high degree of professional independence in the way the regulatory body operates its regulatory decision making. In this respect, a regulatory body should more resemble the judicial branch (the courts of law) than the executive branch of government. Thus, 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 and the public and the protection of the environment.

7. The principles concerning the independence of regulatory organizations are developed and discussed in publications in the IAEA's Safety Standards Series [3, 4]. Although the principles relating to protecting the independence of the regulatory body provide the necessary basis for independence in regulatory decision making, there are additional factors and features that require attention to ensure independence in the decision making by the regulatory body. This INSAG report highlights and discusses a number of such factors and features.

## **2. INDEPENDENCE IN REGULATORY DECISION MAKING: KEY FEATURES AND CHALLENGES**

8. Key features of independence in regulatory decision making in the area of nuclear safety include:

- Insusceptibility to unwarranted external influences, but the existence of appropriate mechanisms for external professional dialogue and consultation, with both licensees and independent experts, along with appropriate mechanisms for dialogue with the public;
- Decisions taken on the basis of science and proven technology and relevant experience, accompanied by clear explanations of the reasoning underpinning the decisions;
- Consistency and predictability, in relation to clear safety objectives and related legal and technical criteria;
- Transparency and traceability.

9. To achieve these features, the regulatory body must have the legal and organizational means to protect itself against various challenges to independence in its decision making. Moreover, clear and consistent procedures need to be followed in judging regulatory issues and making regulatory decisions. As decisions are prepared and taken by human beings, there is also a need for democratic and ethical attitudes on the part of the decision makers and their legal, scientific and technical advisers.

10. *External challenges* may include unwarranted interaction and attempts to influence regulatory decision making by individual politicians and political groups, by licensees and vendors, and by interest groups such as non-governmental organizations. The qualification ‘unwarranted’ is an important one. As discussed further in the following section, each of the groups mentioned has legitimate types of interaction with the regulatory body, as legislators, as parties in a professional dialogue and in monitoring the quality of the regulatory work. However, some stakeholders may seek other ways than the legitimate types of interaction to influence regulatory decision making and regulatory decision makers in order to further various political and economic interests, thereby challenging independence in regulatory decision making and the integrity of the decision makers.

11. There may also be *internal challenges* to achieving the key features of independent regulatory decision making. Such challenges relating to the internal characteristics of the regulatory body may include:

- A lack of clearly defined safety objectives and criteria, which renders it more difficult to achieve consistency and predictability in regulatory decision making and, at the same time, makes the decision making process more susceptible to unwarranted external influence.

- Insufficient competence to ensure that regulatory decisions are firmly based on science and proven technology and relevant experience. Again, this makes regulatory decision making more susceptible to unwarranted external influence.
- Too great a dependence on a few individuals as decision makers and their individual approaches to preparing for and taking decisions. Although the personal integrity and ethics of individual decision makers are highly important, the quality and independence in regulatory decision making should not be susceptible to changes in a few positions in senior regulatory management.
- A lack of clearly defined procedures and criteria for the appointment (by selection or promotion) of staff to managerial and decision making positions in the regulatory body. Deficiencies in this respect can make the regulatory body susceptible to unwarranted external influence in the appointment of senior staff. Moreover, such deficiencies may depress staff morale, and highly competent staff members may decide to leave the regulatory body if it seems that promotion is based on factors other than professional competence and performance.

### **3. MEETING CHALLENGES TO INDEPENDENCE IN REGULATORY DECISION MAKING**

12. A number of measures can be taken in order to ensure that the regulatory body is well equipped to meet the challenges to independence in regulatory decision making in matters of nuclear safety which were discussed in the previous section. Some of these measures need to be taken by the relevant political decision makers (government and parliament). Others are the responsibility of the senior management of the regulatory body. These measures can be grouped into three tiers:

- The establishment of the legal framework governing regulatory activities and their associated objectives, principles and values, including the legal basis for adequate and stable financing of regulatory activities;
- The establishment and implementation of clearly defined processes for regulatory decision making;
- The establishment and implementation of a clearly defined competence management programme for the regulatory body which includes an internal management programme for human resources and provides the necessary means to secure independent scientific and technical support

for the regulatory activities, with international co-operation as an important component.

13. These measures, which are discussed below, may be regarded as fundamental components of a regulatory quality management system (Fig. 1) aimed at ensuring the key features of independent regulatory decision making discussed in Section 2 and the overall quality of regulatory activities.

### 3.1. THE LEGAL FRAMEWORK AND ASSOCIATED OBJECTIVES, PRINCIPLES AND VALUES

#### 3.1.1. Legal status and powers of the regulatory body

14. All laws reflect certain objectives, principles and values that legislators have decided shall govern activities covered by the specific law. Legislation on nuclear safety is no exception. The overriding objectives, principles and values

#### CHALLENGES TO INDEPENDENCE IN REGULATORY DECISION MAKING

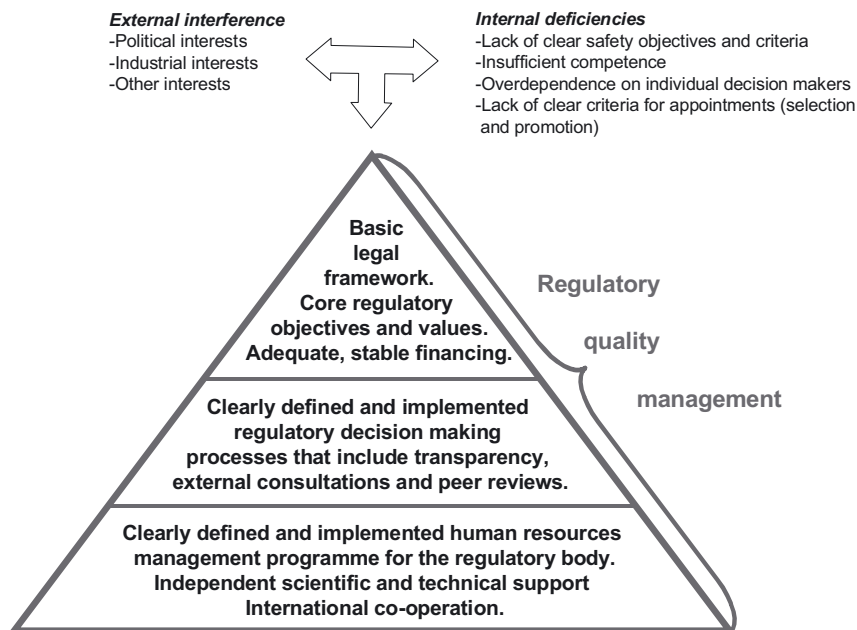


FIG. 1. Components of a system for quality management to ensure independence in regulatory decision making.

which should be clearly reflected in the national legal framework related to nuclear safety are stated in the Convention on Nuclear Safety and in the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Thus, the independent legal status and decision making powers of the regulatory body (or bodies) have to be clearly defined in national legal instruments (laws or decrees) enacted at the highest political level (government and parliament). In particular, the regulatory body must have the authority to adopt or develop safety regulations so as to implement laws passed by the legislature. The regulatory body must also have the authority to take decisions, including decisions on enforcement actions.

15. Furthermore, the legal framework defining the decision making powers of the regulatory body needs to provide legal barriers to protect the independence in regulatory decision making from external interference in decisions on specific safety issues. Such barriers may include legal provisions with regard to certain elements in the decision making process, for example, appropriate procedures that are open to public scrutiny for eliciting opinions from licensees and other stakeholders, and procedures for the documentation of regulatory decisions and their legal and technical justification.

### **3.1.2. General safety objectives**

16. The legislation on nuclear safety or other types of legal instruments endorsed by government or parliament need to specify in general terms the safety objectives to be fulfilled by the licensees under regulatory oversight. Such general safety objectives may in fact protect the regulatory body from undue external influence on its operational decision making by various pressure groups, including the industry under its oversight. Such general safety objectives should be consistent with widely endorsed international safety principles like those stated in the IAEA Safety Fundamentals publications. Any departures from such safety principles need to be discussed and justified, with relevant information made publicly available.

### **3.1.3. Appeal mechanisms**

17. Independence in regulatory decision making does not obviate the need for an appeal process under which the licensees and other stakeholders are given the legal right to challenge regulatory decisions by means of appropriate legal procedures. There needs to be a specific legal mechanism for appeal against regulatory decisions, with predefined conditions that must be met for an appeal to be considered.

### **3.1.4. Accountability**

18. Independence in regulatory decision making does not obviate the need for accountability. Although the regulatory body must not be subject to political influence or pressure in taking specific safety decisions, it must be accountable to government and parliament as well as to the general public with regard to effectively and efficiently fulfilling its mission to protect workers, the public and the environment from radiation hazards. There are several ways to provide this accountability, for example, through regular, public reporting to government and parliament and through professionally recognized audit and peer review procedures, as discussed below. Should such audit and peer review procedures demonstrate substandard professional performance on the part of the regulatory body, government and parliament have the responsibility and authority to ensure that the appropriate corrective actions are taken.

### **3.1.5. Financing**

19. Adequate and stable financing for all regulatory activities and their scientific and technical support is fundamental to independence in regulatory decision making. Funding affects the ability to recruit, train and keep qualified staff in the regulatory body as well as its ability to elicit the opinions of independent scientific and technical experts.

20. The financing mechanism should be clearly defined in the legal framework. If the costs of regulatory activities are to be recovered from the licensees, the financing mechanism needs to be designed to prevent its misuse by licensees as a means to reduce regulatory independence. The budget for the regulatory body should not be decided by or be subject to the approval of those parts of the government which are responsible for exploiting or promoting nuclear technologies, nor should it depend on fines collected from licensees. Moreover, the budgetary process should be designed in such a way that the legitimate financial needs of the regulatory body and the consequences of inadequate funding are brought to the attention of the political decision makers at the highest level.

21. Within the limit on its total budget, the regulatory body needs to have a high degree of independence in deciding how the budget is to be distributed between its various regulatory activities for the greatest effectiveness and efficiency. The performance of the regulatory body and its proper use of funds then needs to be evaluated by means of appropriate independent audit and review mechanisms.

## 3.2. THE REGULATORY BODY'S DECISION MAKING PROCESSES

22. There are many types of regulatory decision to be made, such as decisions on the issuing of regulations and licences, the approval of design changes and enforcement actions. Each of these types of decision is prepared by means of regulatory activities of various kinds, such as reviews, assessments and inspections. Even if an inspection is found not to give grounds for any enforcement action, this conclusion is in itself a regulatory decision.

23. To achieve independence in regulatory decision making and to ward off any challenge to independence as described in Section 2, there needs to be a clear, well documented and carefully implemented process by means of which regulatory decisions of each type are prepared and taken. As already indicated, some elements of the regulatory decision making process should be prescribed in the legal framework, as decided by government and parliament. However, starting from these elements, and in accordance with the principle of regulatory independence, most of the descriptions of decision processes should be part of the internal regulations of the regulatory body, preferably as part of its quality assurance (QA) system, and should be decided by the senior management of the regulatory body. The details of the decision processes would depend largely on the type of regulatory decision to be taken. Nevertheless, they should have certain features in common to ensure independence and quality in regulatory decision making. These features are briefly discussed below.

### 3.2.1. Clear fundamental objectives, principles and criteria

24. The fundamental objectives, principles and criteria that govern regulatory decisions of each type need to be specified. They include not only safety objectives and requirements but also the ethical principles and codes of conduct that are to be applied in the decision making process, for example with regard to interactions with licensees and other stakeholders.

### 3.2.2. Completeness of information

25. The process description needs to provide reasonable assurance that the information used as a basis for a regulatory decision is relevant and sufficiently complete for each type of decision. Several mechanisms to achieve this have to be considered, such as internal consultations, consultation of external scientific and technical experts and advisory bodies, and eliciting additional information from licensees and other stakeholders.



### **3.2.3. Documentation**

26. Records, preferably written documentation, must be kept of all relevant information actually used in making a regulatory decision. Thus, it is necessary that the regulatory body keep records of all relevant information and opinions elicited from external scientific and technical experts and advisory bodies, licensees and other stakeholders, whether provided in oral or in written form. The decision itself and its legal and technical justification — that is, the regulatory evaluation of the information used as a basis for the decision — has to be properly documented.

### **3.2.4. Transparency**

27. Transparency is a means to promote independence in regulatory decision making and to demonstrate such independence to politicians, licensees and other stakeholders, as well as the general public. The regulatory body needs to have the authority and the obligation not only to communicate its regulatory decisions and their underpinning documentation to the licensee(s) concerned, but also to make this information available as far as possible to the public.<sup>1</sup> By means of such public access to information, the independence in regulatory decision making can be open to public scrutiny. At the same time, this serves to fulfil the requirement for the regulatory body to be accountable to the public, whose health and safety it is responsible for protecting.

### **3.2.5. Regulatory response to changes in the industry regulated and in society**

28. Preserving independence in decision making by the regulatory body requires that at an early stage it can identify structural changes in the industry it regulates and in society that have possible safety implications<sup>2</sup> and, if necessary, respond to them by modifying its regulatory activities. Such an ‘outlook’ function to identify changes and to decide on the proper regulatory response to them should be clearly defined as an internal decision making

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<sup>1</sup> For example, parts of the detailed technical information may need to be protected for commercial reasons or for the physical protection of nuclear material and installations.

<sup>2</sup> Recent examples include the deregulation of the electricity market in many States, as well as the decrease in financial support by governments and universities for long term research and development in nuclear science and technology.

process of the regulatory body. The regulatory body should make proper use of the review mechanisms described below.

### **3.2.6. Reviews and audits of regulatory performance**

29. A systematic programme for professional reviews and audits of regulatory performance is a useful tool to promote independence in decision making by the regulatory body as well as the quality of its performance in general. Such a systematic programme is therefore an important element of a regulatory QA system. Components of such a systematic programme would include:

- Participation in various types of international professional co-operation and intercomparison exercises, providing checks that the methods, models and data used in various regulatory activities are in line with internationally recognized practices. Co-operation with regulatory bodies in States in which there are reactors of the same design and manufacture is particularly important for sharing competence and experience.
- Systematic and prescribed use of external and independent scientific and technical advice and review, particularly in the preparation of the more important regulatory decisions. For such purposes, use of standing scientific and technical advisory committees by the regulatory body is considered a good practice.
- Formal, internal quality audits and self-assessments at regular intervals.
- External peer reviews, either of a specific regulatory activity or issue or of the performance of the regulatory body as a whole. The IAEA offers a range of such review services, performed at the request of the regulatory body or the government. Governments or parliaments may also choose to set up their own review activities, in line with established national legal procedures for the review of the activities of national authorities.

30. It is important that the findings, conclusions and recommendations of such reviews and audits, as well as the response of the regulatory body, are made public. For Parties to the Convention on Nuclear Safety and for Parties to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management such national peer reviews and audits will also provide valuable input to the review process under the respective conventions, and should be duly reflected in the national reports to be submitted under the conventions [5–8].

### 3.3. REGULATORY COMPETENCE MANAGEMENT INCLUDING HUMAN RESOURCES MANAGEMENT AND RESEARCH SUPPORT

31. In order to achieve independence in decision making, it is of great importance that the regulatory body has access to the necessary competence and expertise, independently of the licensees and other stakeholders. This can only be ensured by means of long term competence management programmes covering the regulatory body itself, organizations specifically assigned to assist the regulatory body with in-depth technical safety analyses and reviews (a so-called technical support (or safety) organization (TSO)), and organizations performing scientific and technical research and development in relevant areas. As the end user, the regulatory body needs to have the responsibility and authority to influence and co-ordinate the development and maintenance of competence in all these organizations, for example by means of appropriate funding mechanisms.

#### **3.3.1. Management of human resources in the regulatory body**

32. The independence in the regulatory body's decision making depends heavily on the competence of its staff. Three types of competence are needed:

- Competence in applying the regulatory processes with their underpinning legal framework, ethical principles and codes of conduct.
- Competence with regard to the installations, organizations and activities of the licensees.
- Competence in the relevant scientific and technological areas. The need for specific scientific and technical competence in the regulatory body will depend on the availability of support from TSOs. As a minimum, the staff of the regulatory body must have sufficient scientific and technical competence to carry out an effective information exchange with outside experts having in-depth competence in specific areas.

33. The balance between these three types of competence may vary between individual staff members, but the total competence and capacity of the staff in terms of qualifications and numbers should be adequately balanced with regard to the regulatory functions to be performed. Moreover, attention needs to be given to succession planning to ensure that there is a cadre of people who have the capability to serve in senior decision making positions. To achieve all this, it is necessary for the regulatory body needs to have a clearly defined and

well implemented management programme for human resources, covering (among other things):

- recruitment;
- development of the competence of individuals by means of training, retraining and other means;
- career development and promotion.

34. The salary scale of the regulatory body needs to be such that it can recruit and retain the necessary highly qualified staff in competition with other employers in industry and elsewhere.

35. Specific, well implemented policies for career development and promotion are especially important for quality and independence in regulatory decision making. Thus, procedures for the selection for and promotion to managerial positions should be clearly defined, documented and communicated to the staff. Professional competence and performance, including managerial skills and demonstrated commitment to the ethical principles and codes of conduct to be applied in the regulatory body's decision making processes, must be the deciding factors. Appointments to managerial positions for limited times with the possibility of reappointment on the basis of a performance evaluation should be considered.

36. Holders of posts at the highest managerial level in the regulatory body, whether as director general or as commissioners, are typically appointed by the government, in some States with the involvement of parliament. In general, the same type of criteria for competence must apply, duly adjusted for the demands of the position. In line with the principle of independence of the regulatory body, its senior management should have the authority to decide on appointments to all other positions in the regulatory body.

37. Competence development programmes for regulatory body staff should include participation, as appropriate, in activities for international co-operation, such as those organized by the IAEA and other international organizations. In addition, bilateral co-operation of various types, such as the exchange of inspectors, could be used to develop competence.

### **3.3.2. Access to independent external expertise and research support**

38. For in-depth assessments and reviews of scientifically and technically complicated safety issues, the regulatory body typically needs access to

independent external experts with specialized competence in the relevant scientific and technical areas. This is also the case when the regulatory body itself has considerable scientific and technical competence. In some States, the task to provide such in-depth scientific and technical support has been assigned to a special organization, a so-called TSO. National laboratories, university institutions and consultants are also used for such scientific and technical support. In some cases, such support may need to be obtained from expert organizations in other States.

39. Adequate and stable financing of such scientific and technical support functions, largely according to the same principles as the financing of the regulatory body itself, is essential to ensuring the availability and independence of these support functions. The regulatory body needs to be able to influence appropriately the long term development and maintenance of competence in scientific and technical support functions. This can be achieved, for example, by financing such support functions by a suitable mix of short term assessment and review contracts from the regulatory body and longer term research and development contracts financed from a special budget for regulatory related safety research.

40. It is important that principles and tools similar to those discussed above for ensuring independence in regulatory decision making should also be applied to ensure the independence and quality of the scientific and technical advice provided by such regulatory support functions, with due adjustment for the special features of their scientific and technical work.

## **4. SUMMARY**

41. In matters of nuclear safety, independence in regulatory decision making needs to be ensured and can be ensured by implementing a number of measures. Some of these measures are the responsibility of the relevant political decision makers (government and parliament). Others are the responsibility of the senior management of the regulatory body. The measures are aimed mainly at ensuring that a number of aspects of the quality of regulatory decision making processes are achieved, including the quality of the scientific and technical information used in making decisions, as well as the independence and competence of the decision makers. It is evident that there is a close relationship between the independence in decision making by the

regulatory body and other aspects of the quality of regulatory activities. Measures for ensuring the independence in regulatory decision making are to be included as part of a quality management system covering all aspects of the quality of regulatory activities.

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