Regulatory Control on Radiation Protection – Instruments for Information and Experience Exchange in a Federal System

Claudia Schmidt, Jörg Kaulard, Boris Brendebach

Gesellschaft für Anlagen und Reaktorsicherheit (GRS)mbH
Schwertnergasse 1, 50677 Köln

Abstract:
The regulatory bodies who are responsible for radiation protection have to fulfil obligations, mainly related to issuing of licences and their supervision. Hereby, the regulatory body today is facing several challenges: while the number of tasks and also the number of licences increase the number of staff members of the regulatory body decreases or at best remains constant. Thus, for each staff member the time available to focus on individual regulatory tasks is limited resulting in the need to select focal points of regulatory activities. At the same time, the technical complexity of the application of ionising radiation outside the nuclear sector increases, requiring a continuous effort to keep and improve technical qualifications, which are needed to assess licence applications and to effectively supervise licensees. Hence, a growing need inter alia to develop instruments to support the regulatory functions of regulatory bodies exists to meet these challenges and to contribute to a further increase of efficiency. Within this contribution to the EUROSAFE 2012 results of a recently completed project will be presented, which serve to improve information and experience exchange in Germany and to share approaches on regulatory licensing and supervision.

1 INTRODUCTION

Germany is a Federal Republic and licensing and supervision about licences or notifications related to ionising radiation are performed by the regulatory bodies of its 16 Federal States (so called Länder). The objective of the regulatory licensing and supervision is to control that the licensee does comply with the applicable regulations and conditions of the licence and by that to contribute to the protection of human health and environment against hazards of ionising radiation.

Related to the central obligation of licensing and supervision, the regulatory body has to fulfil further duties and obligations and has to cope with changing conditions and technical challenges. To address some of these aspects, GRS performed a project between 2008 and 2011, which was funded by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), which analysed the obligations and detailed tasks to be met by the regulatory bodies. To ensure a high practical relevance in the outcomes of the project, an intensive involvement of regulatory bodies of the Länder, which are responsible for licensing and supervision of the application of ionising radiation outside the nuclear field, was foreseen and realised. Regulatory bodies of most of the 16 Länder supported the project by sharing experiences on current obligations and duties, but also on recent challenges and provided feedback on the outcomes of the project, i. e. proposals for methodes and common approaches to support and improve related regulatory activities.

The German system on regulatory control related to the application of ionising radiation outside the nuclear field is described in section 2. In section 3, current challenges regarding the implementation of regulatory control in the German system are discussed. In section 4, the developed approaches and methods to address the challenge of information, knowledge and experience exchange are explained. Conclusions will be drawn in the final section 5.

2 REGULATORY CONTROL ON RADIATION PROTECTION IN A FEDERAL STATE

In Germany, the protection of human health and environment against hazards of ionising radiation is regulated by the provisions of the Atomic Energy Act and, in particular, the Radiation Protection Ordinance (RPO) and the X-Ray Ordinance (XRO). The application of ionising radiation in the areas of research, industry and medicine is performed on the basis licences by the RPO and on the basis of notifications and licences by the XRO.

The responsibilities of law-making and law enforcement are assigned differently to organs of the Federal Republic and the Länder, specified under the Basic Law (GG) of the Federal Republic of Germany. The Federal Republic has the exclusive legislative competence related to the use of nuclear energy for peaceful purposes, the construction and operation of facilities, which serve these purposes, protection against hazards from the release of nuclear energy or arising from ionising radiation, and the disposal of radioactive substances. BMU is assigned as the related competent regulatory body within the Federal Government.

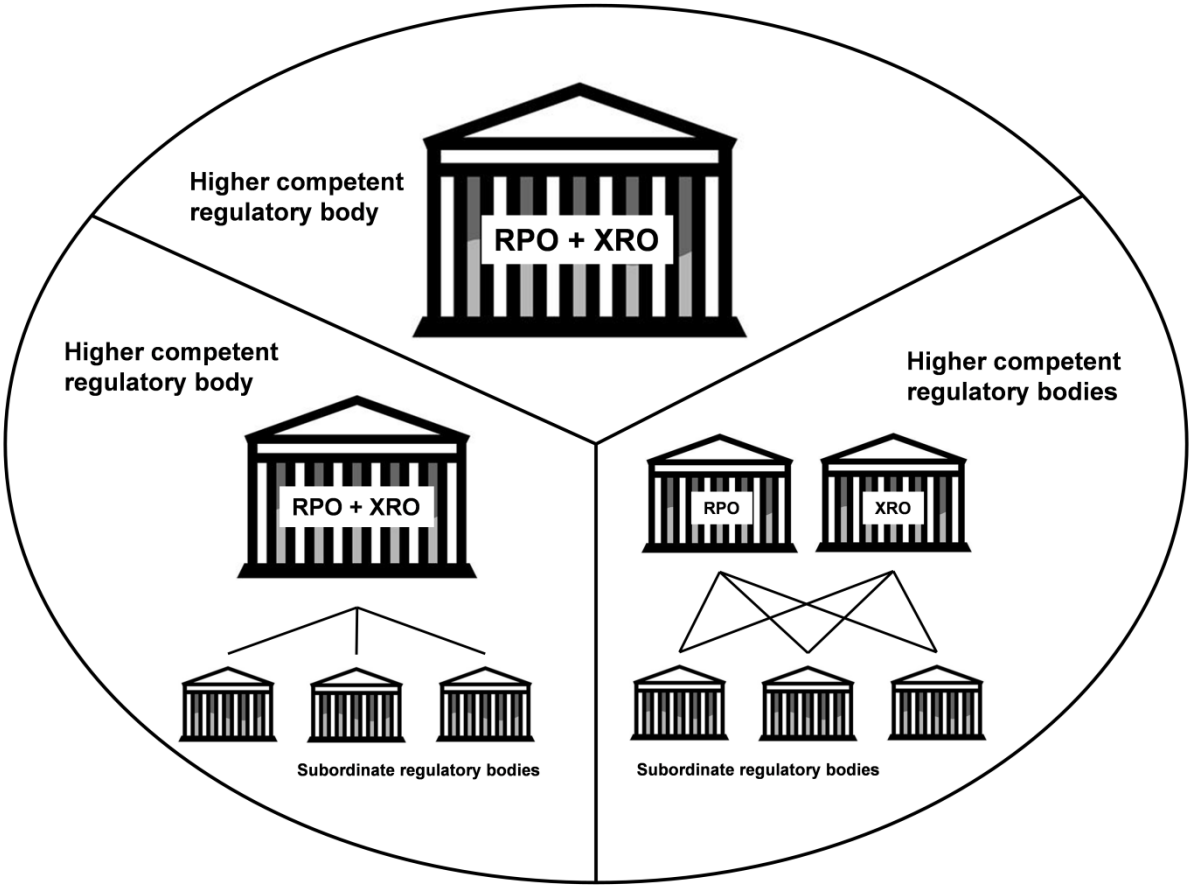

Figure 1: Organisational structures of the licensing and supervision in radiation protection implemented in the Länder

The execution of laws, regulations and general administrative regulations, i. e. licensing and supervision, is performed by the Länder on behalf of the Federal Republic according to the Atomic Energy Act. As a consequence, the Federal Republic, represented by BMU, is obliged and responsible to establish and perform a supervisory system on the legality and appropriateness of regulatory actions of the Länder.

The establishment of the individual regulatory bodies of the Länder lies within the responsibility of each Land. As a consequence, different organisational structures have evolved in the Länder to implement regulatory functions related to the application of ionising radiation. Figure 1 illustrates some possible organisational structures implemented in the Länder.

In case of the application of ionising radiation outside the nuclear field, a two-tier system exists in most Länder comprising of a higher competent regulatory body and several subordinate regulatory bodies. In most cases, the higher competent regulatory body

- is participating in national boards to discuss national and international developments,
- is responsible for implementing new regulations and guidelines of the Federal Government,
- has to fulfil the reporting commitment towards the Federal Government and
- has to guarantee the uniformity of regulatory actions among the subordinate regulatory bodies within the respective Land.

The subordinate regulatory bodies are in most cases responsible for issuing licences and conduct of supervisory actions to control that the licensee does comply with the applicable regulations and conditions of the licence. As such, the subordinate regulatory bodies are involved in the daily work including inspections.

However the structure of the regulatory body in the individual Länder is, the regulatory activities of all regulatory bodies (including subordinate regulatory bodies) are based on the respective German laws and ordinances, some of them mentioned previously. These laws and ordinances define a frame, in which regulatory activities are performed. But due to the nature of the laws and ordinances, there is still sufficient space for interpretation and specific design of regulatory actions when applying them on the individual case. To harmonise the interpretation between different Länder, so called BMU regulations exist, which are based on laws and ordinances but belong to the sublegal German regulatory system (ref. figure 2). They are jointly developed by BMU and the Länder and are applied by the regulatory bodies of the Länder.

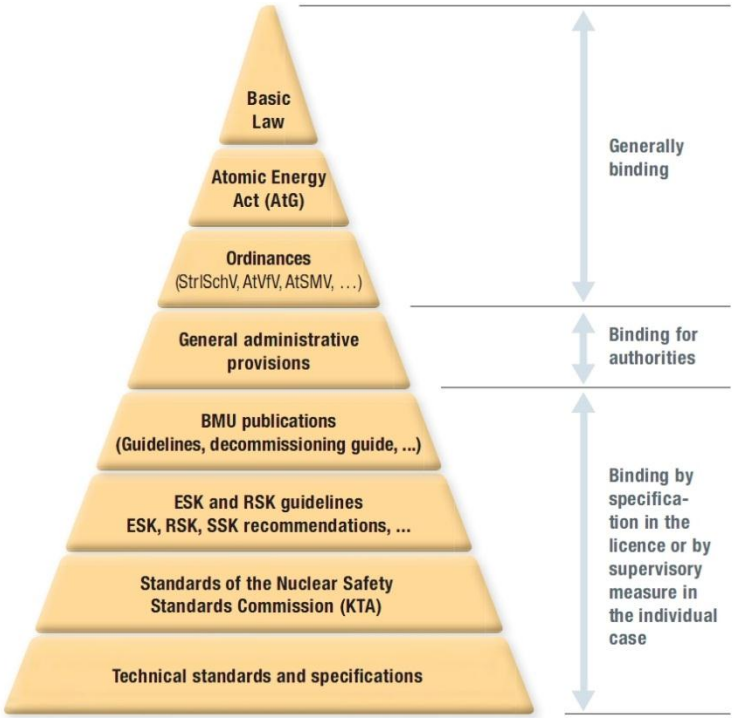

Figure 2: Overview of the German legal and sublegal regulatory system

As these BMU regulations cannot address all aspects significant for all regulatory activities, there was and is still significant need to develop relevant interpretations and work instruments. Work done in the past and to be done in the future offer opportunities for improvements inter alia to avoid that concepts are developed twice or more often in different Länder.

3 CHALLENGES FOR THE REGULATORY CONTROL ON RADIATION PROTECTION

The regulatory body responsible for radiation protection faces a number of challenges not only related to the process of issuing licences and supervising compliance with the regulations adopted but also going beyond these. Some basic challenges are related to the requirement of transparency and uniformity of regulatory activities.

In the frame of the above mentioned GRS project, GRS analysed challenges specific to the situation of a federal state with several regulatory bodies involved in radiation protection. After discussion with staff members of regulatory bodies of the Länder during various meetings and a workshop in June 2011, GRS focussed on four topics, which can be regarded as major challenges to the regulatory control (ref. figure 3):

- The first issue is related to inspections; with the increase of licensees the number of inspections increases.
- The second issue is related to an effective organisation of data and information to effectively support the administrative processes and the conservation and improvement of competences.
- The third issue is related to the exchange of information, knowledge and experience.
- The forth issue is related to the communication with the public, which needs to consider not only today information technologies but also the increasing demand for real-time information, especially in case of radiological relevant events.

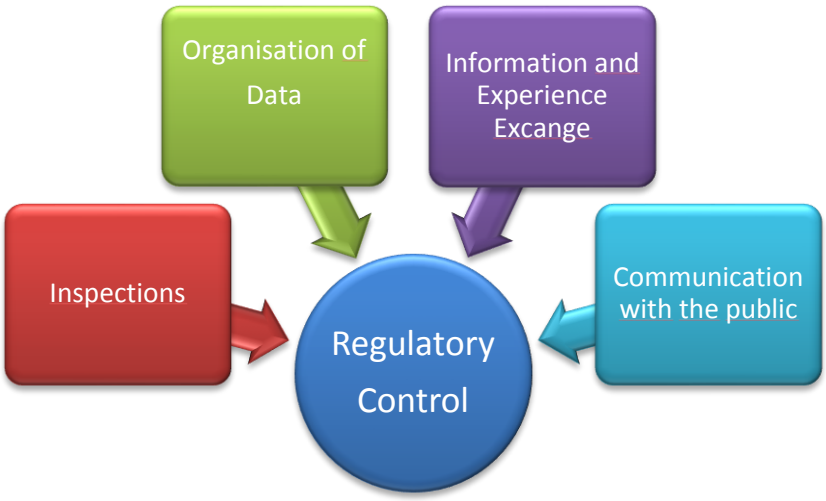

Figure 3: Identified major challenges for the regulatory control /GRS 11/

Especially with respect to the need of an exchange of information, knowledge and experiences of current influencing aspects need due consideration: The number of staff members of the competent regulatory bodies is reduced or at the best remains constant with time although the number of developments in the field of applications of ionising radiation increases, and so due licence applications. At the same time the number of administrative actions and other tasks, such as statistical analysis, increase. This situation leaves the individual staff member less and less time to fulfill a single task. Moreover, in addition to the processing of the tasks assigned, the staff member needs to keep up with evolving new techniques and the respective necessary know-how, to participate in the development and implementation of new information according to the state of science and technology and introduce this knowledge into the daily work, especially as technological advances occur at ever shorter intervals. So instruments are needed which can help in coping with the challenges to ensure proper licensing and supervision in the field of application of ionising radiation and which may contribute to the efficiency of each staff member. These instruments shall make available the necessary data and information and guarantee the preservation and sharing of knowledge and experiences among the staff members. This is of major importance, as it must be ensured for a licensee that independently of the staff member

working on a licence, the outcome of the review is the same. Therefore it is essential that practical knowledge and insights on the state of science and technology as well as information about the licensing and supervision process be exchanged quickly and freely between the competent regulatory body and the licensee.

These challenges of information and experience exchange and building up competency among the staff members of regulatory bodies are also addressed in international regulations and guidance documents. According to the International Atomic Energy Agency (IAEA) the regulatory body has to employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions /IAEA 04/:

> *"6.7. Another aspect of the requirement for having a broad capability for radiation safety and project management among the regulatory staff is that radiation source technologies change, particularly those used in medicine. The regulatory body, therefore, should have sufficient technical and project management capability to identify new safety issues that may stem from technological developments and to bring specialized technical skills to bear in addressing problem areas. […]*
>
> *6.21. In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training program ensure that this should training staff are aware of technological developments and new safety principles and concepts."*

Central to a successful knowledge management is to promote knowledge exchange between staff members of one organisational unit, i. e. a regulatory body. But in order to guarantee state-wide uniformity of the administrative actions, knowledge and experience exchange between the different regulatory bodies in the Federal Republic and in the Länder, higher and subordinate, is needed.

4 INSTRUMENTS FOR INFORMATION, KNOWLEDGE AND EXPERIENCE EXCANGE

The main requirement for the regulatory control in a federal state is to guarantee the uniformity of the administrative actions in the Länder. As described in section 2, the application of regulation functions in the field of radiation protection is within the responsibility of the different Länder and can be organised differently within each Land. This means that due to the high number of involved bodies the exchange of information and experience have a main importance for the uniformity.
As an outcome of the GRS project, three instruments for strengthening the information and experience exchange between the staff members of regulatory bodies (i. e. of the regulatory bodies of a single Land, of the regulatory bodies of different Länder and of the regulatory body of the Federal Republic) are described below.

Handbook on licensing and supervision in radiation protection

A tool that could contribute to the knowledge and experience exchange and that could promote synergies between the competent regulatory bodies in a single Land and between the Länder, is a handbook on licensing and supervision in radiation protection. Such a kind of handbook already exists in other fields of occupational health and safety and seems to be a suitable format to organise documents in the sense of a collection of instructions, rules and checklists. As the organisational structure of regulatory control in the Länder differs, a modular design for such a handbook seems reasonable. A general module may include basic topics in terms of licensing and supervision, which are the same for every Land. This concerns, for example, legal principles, definitions and explanations, relevant federal agencies and contacts. A module "Land" of the handbook can be tailored to the individual needs of a respective Land. Such an approach would make it possible to use basically the

same structural design for the handbook in all Länder, supplemented by the respective special interests of a Land and its competent regulatory bodies.
The implementation of such a handbook should be done on a digital basis. The handbook should be accessible via a shared server, as use and updating of the modules would benefit from such an approach - the regulatory bodies maintain the content, which is of their special interest, update documents on a timely basis and then upload them to a shared server. In an analogous manner the general module, for example, could be maintained by the regulatory body of the Federal Republic.

Seminar series on issues of licensing and supervision in radiation protection

For staff members of the BMU and higher regulatory bodies of the Länder, some meetings are held to discuss recent topics in the field application of radiation protection during the year. Because of shortness of time and the multitude of issues to be addressed, very little time for exchange of experience remains during these meetings. In addition, most of the topics address superior aspects of radiation protection but not issues of the daily regulatory work, especially of the subordinate regulatory bodies.
Especially to compensate the later deficiency but also to allow a larger number of staff members to participate in the information and experience exchange, some individual Länder already today perform internal training courses on radiation protection issues for their staff members on a regular basis. But a platform on which staff members of the subordinate regulatory bodies can participate in a cross-Länder exchange of experiences is lacking. Such a possibility could be created by a new seminar series with participants from all Länder with the focus on issues of daily regulatory work related to licensing and supervisor in radiation protection. Such a series of seminars will aid in creating the necessary knowledge and serve to promote the exchange of experience in the field of radiation protection.

Internet-based communication platforms

In addition to exchange of experience in the form of seminars, establishing an internet-based communication platform could aid in the exchange of information and experiences between staff members of the regulatory bodies.
Such an internet-based communications platform could be used, for example, to share information on new developments and techniques in the field of application of ionising radiation, to make available experiences and findings gained during inspections. Standardised licences or checklists can be exchanged on this platform. In addition, the establishment of forums to discuss emerging questions and challenges would be conceivable. Access to this platform would only be granted for staff members of the regulatory bodies. In summary, such a platform of information and experiences exchange could promote and thus could create the opportunity to efficiently and collectively meet the challenges of the regulatory control in the field of radiation protection.

5 CONCLUSION

In a project, funded by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, GRS analysed current challenges for regulatory bodies involved in the licensing and supervision of the application of ionizing radiation outside the nuclear field in Germany. Four major topics were identified: inspections, organisations of data, communication with the public and information, knowledge and experience exchange.

As one outcome of the GRS project, a need has been identified for instruments to support and improve the exchange of information and experiences. Central elements within such an instrument are

- use of a handbook on licensing and supervision by the regulatory bodies of all Länder,
- seminar series to address aspects of daily regulatory activities with special focus on the needs of different levels of regulatory staff and

- technical means, especially a communication platform, to allow a real-time exchange of information, working documents etc. related to the regulatory functions.

Due to the high importance and benefit of such an instrument a new project is proposed by GRS to implement such an instrument. Already today, a very strong interest of the regulatory bodies of the Länder exists in the conduct of the project and especially in the establishment of a communication platform to jointly share already existing tools available at the individual Länder. Furthermore, high interest is already indicated for a seminar series dedicated to the individual (and different) needs of higher regulatory bodies and their subordinate regulatory bodies.
All these instruments could help to cope with the requirement on uniformity in regulatory action as well as building and maintain competences of the regulators bodies

Even if the project performed by GRS in the past and the proposed new project address the needs of regulatory bodies responsible for radiation protection outside the nuclear field, some of the outcomes could be further elaborated to the situation of European countries. Especially, a European wide experience and information exchange could contribute to further improvements of regulatory activities to ensure radiation protection.

6 REFERENCE

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