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BACKGROUND PAPER ON THE IMPLEMENTER-REGULATOR DIALOGUE

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IMPLEMENTER-REGULATOR DIALOGUE

1. Introduction

A step-wise process, involving various stakeholders, is considered as a responsible approach to planning for disposal development and implementation, including final closure.

It is broadly recognised that a stepwise decision-making process with discrete and easily evaluated steps facilitates the traceability of decisions, allows input and feedback from stakeholders and the public and promotes public and political confidence in a safe approach to long-term waste management. The decision-making process in radioactive waste management and disposal should be seen in the context of a well structured dialogue/interaction between implementer, regulator, political decision maker and the general public. A necessary condition for a successful process is that institutions and decision makers gain and merit recognition as trustworthy and accountable.

Dialogue between regulators and implementers is important in any licensing process, and in the case of a stepwise decision making process it is crucial that this dialogue starts in the early phases of the process, and continues all along the process. It must be managed so that the independence between regulator and implementer is clearly maintained while ensuring that information which could affect subsequent decisions is communicated early enough in the process to avoid either party taking actions that would imperil the ability to take necessary decisions at later stages.

The importance of the process of interaction between regulator and implementer has been recurrently pointed out by the NEA RWM since the Cordoba Workshop (1997). In the recent past the RWM Regulators Forum launched the “Long term Safety Criteria” (LTSC) initiative and has organised international discussions on long-term safety criteria for geological disposal of radioactive waste, with the Paris November 2006 and Tokyo January 2009 workshops ([1] and [2]). The overall objective was to explore diverse perspectives and expectations and come to a common understanding of the main objectives and bases of the long-term safety criteria for disposal of the long-lived, high level waste.

Discussions, e.g. on optimisation of protection and on the development of the regulatory framework and guidance’s in the context of a stepwise decision making process, pointed to the importance of a process of interaction between the regulatory authorit(y)(ies) and the party responsible for the development and implementation of a disposal facility (regulator – implementer dialogue). Since many years, such processes actually take place in national programmes.

2. Aim of the document

While some of the main principles, objectives and requirements of the regulator implementer interaction are identified in international recommendations (IAEA, ICRP, NEA), an in-depth international analysis and discussion of the actual implementation on the national level of these principles, objectives and requirements has never taken place. National experiences and lesson’s learned are available, but an overall appreciation of concrete achievements, difficulties and challenges, and ways forward is missing.

This document aims at providing a starting point for discussing the usefulness of launching an international discussion and reflection on the basic elements, the concrete experiences and the challenges of the regulator – implementer dialogue in the process of developing a (geological) disposal facility.

3. The development of disposal facilities: step-wise, multidimensional, many actors involved

Waste disposal facility development is characterised by a long-lasting, stepwise approach, generally involving the following major steps:

- Generic R&D and concept development
- Site(s) selection and characterization
- System design for selected site
- Construction
- Operation
- Closure
- Post-closure

Stepwise decision making is implemented, with at each decision point the involvement of various actors with different responsibilities. The decision-making process should be seen in the context of a well structured dialogue/interaction between the various actors involved: implementer, nuclear safety regulator, political decision-maker, the general public, ... A necessary condition for a successful process is that institutions and decision-makers gain and merit recognition as trustworthy and accountable. Roles and expectations of all actors have evolved in the last decade. The evolving roles and practices do not always supplant traditional activities, but usually complement them.

The main objective of geological disposal facilities, i.e. providing intrinsic safety over very long time-frames, poses a unique challenge of regulating and assessing system safety. But not only technical safety & protection decisions are required. A broader decisional framework integrating dimensions of safety, society, economics, technology, ethics... is needed.

4. Regulator and implementer: responsibilities in the step-wise process

Disposal facilities are nuclear facilities requiring both policy decisions at the governmental level and technical regulatory decisions at the level of (a) technical regulatory bod(y)(ies) (nuclear regulator or nuclear safety authority, and environmental protection authorit(y)(ies)).

Policy decisions often define the overall stepwise decisional process for disposal and the policy framework for developing disposal solutions, e.g. the type(s) of disposal facility(y)(ies) to be developed. Once policy decisions been taken, major responsibilities and competences can shift to the level of technical regulatory bod(y)(ies) as defined in the national framework (institutional, legal, organisational).

In this document the “regulator” refers to the technical regulatory bod(y)(ies), with responsibilities for regulatory compliance & licensing decisions (often to be ratified at the governmental level and/or by legal instruments) and for issuing regulatory guidance’s. Generally speaking, a nuclear safety regulator’s mandated responsibility is (i) to define nuclear safety, radiation protection (ii) to issue guidance on safety assessment methodology and documentation; (iii) to review the implementer’s safety analysis as a basis for licensing of waste management and disposal activities and facilities; (iv) to inspect and review construction, operation and closure of nuclear facilities to ensure compliance with licensing conditions; and (v) to provide information to political authorities, the public and others as needed.

The “implementer” is the actor responsible for developing and implementing a disposal facility / system (site, design, waste). He develops the safety cases on which basis decisions are taken to move from the conceptual design phase (RD&D) to the implementation phases (construction operation, closure, oversight). This actor can also have responsibilities related to radioactive waste management in general (waste management agency); he can be or become license holder of the disposal facility or can delegate operational competences to an operator of the disposal facility.

5. The regulator – implementer dialogue: some common elements

The international safety standards of IAEA (e.g. IAEA General Safety Requirements part 1, 2010 and [3]) define a series of basic principles and requirements that are of direct importance for the regulator – implementer dialogue. The way these principles and requirements are applied at the national level can differ, but some general observations can be made.

- The dialogue between “regulator” and “implementer” is **part of a national decisional process for disposal**.
 - The national framework (institutional, legal and organisational framework) is the overall framework for the dialogue.
 - National policy decisions define the main goals and principles that are the boundary conditions for disposal facility / system development and implementation.
 - Policy decisions often define the stepwise process for disposal development and implementation in terms of the main decisional milestones and involved competent actors.
 - The licensing steps are defined by legal procedures.
 - The siting process is an *ad hoc* sub-process, defined by policy decisions and/or specific legal elements.
- **Transparency and fairness** of the overall decisional process, including the “dialogue regulator – implementer”, is an essential requirement for all parties involved (stakeholders). The role of regulator and implementer for all decisional milestones has to be well defined and understood by all parties. Transparency would demand that the “rules” of the dialogue process are published, and the main outputs of the dialogue recorded and made publicly available. The openness with which the implementer and regulator conduct their dialogue will also have a major influence on confidence. Ideally, a fluent dialogue and a fair interaction between the regulator, the implementer and other concerned parties will be best-suited and also be a sufficient platform to achieve the common objective of a safe disposal.
- The regulatory body evaluates at a given milestone the available documentation (e.g. in the form of safety case) and **he decides w.r.t. the legal and regulatory basis** (regulatory requirements, regulatory guidance’s) in a way transparent to all parties involved. Beforehand, he informs the implementer in a documented manner about his expectations w.r.t. the information required in order to be able to take an informed decision at a given milestone. This relates to the judgement that the disposal programme has reached sufficient maturity and that the remaining uncertainties do not require postponement of decision.
- The implementer has the **prime responsibility for the safety** of the disposal facility / system being developed or implemented. The regulator verifies in an independent manner through the dialogue and through the licensing procedures the safety of the disposal facility.
- Dialogue has to be organised in a way that ensures **independency of the regulator** from the implementer throughout the stepwise process. Transparency of dialogue enables all stakeholders to observe the independency of regulator. Defining the rules of engagement in a public available document may contribute to preserve both the actual and perceived independence of the regulator.
- **An evolving dialogue: from policy decisions to licensing procedures**

The dialogue between regulator and implementer takes different forms and has different objectives throughout the stepwise decisional process.

When **policy decisions** have to be taken, implementer and regulator can independently from one another provide advice to Government as a basis for policy decisions. If and how they interact in this phase of the process depends on the national process and framework.

Siting decisions are taken on the basis of both technical (site stability, isolation and containment capacity, safety, environmental protection, land use, infrastructures, ...) and non-technical (societal acceptance, ...) factors in an *ad hoc* process, mostly piloted at governmental level. Siting decisions require interactions with local and regional authorities and population. The regulator can be involved in siting decisions in various ways, in line with his competences for technical and non-technical siting matters; however, regulatory involvement in siting must not detract from regulatory independence in future reviews and decisions.

After the siting decisions, the process enters the phase of site-specific disposal project and of preparing the license application. Before the formal licensing process is launched, a **pre-licensing dialogue** between regulator and implementer is organised, aiming at (1) the implementer informing the regulator about the final design and safety assessments that will be presented in the safety case for the license application, and at (2) the regulator informing the implementer about his expectations for the safety case. Independency of the regulator and transparency of the process remain crucial. In the pre-licensing phase the regulator issues the regulatory guidance that forms the basis for his subsequent licensing decisions. Pre-licensing is a formal process requiring well documented interactions between both parties, transparent to all stakeholders.

At the moment the license application is introduced the process enters the phase of the **licensing procedures**. Dialogue between regulators and implementers remains important in any licensing process.

Acceptance by **societal stakeholders** in the decisional process requires clarity and transparency of the compliance requirements (quantitative and qualitative) and how they will be judged.

- **Early involvement of regulator**

Because the development process of geological repositories prior to the first formal licensing step may take decades, regulatory involvement during that process is necessary in order to contribute to an effective and goal-orientated development progress, even if national legislation may give little guidance on how this interaction should be organised.

Management of knowledge and expertise in such a long process is a challenge. The implementer is in first instance the actor generating the knowledge and information for developing the disposal facility through his RD&D program. The regulator has to acquire the knowledge basis for making assessments and taking decisions through the dialogue with the implementer, through his own RD&D activities and through international collaborations.

Early involvement gives the regulator the opportunity to acquire knowledge at the pace of the progress of the RD&D programme, and the possibility to formulate regulatory review methods and guidance early in the process. It gives the regulator the time to develop the regulatory framework in a stepwise manner, which follows the progress of the programme.

Early involvement is also a challenge: the regulator should act independently and without taking responsibility for disposal development and should be able to interact with the implementer over many years in a broadly coherent manner. The regulatory guidance's and the documented dialogue, as well as continuity in staff, can be important elements for ensuring coherent judgements, assessments and decisions by the regulator.

▪ **Regulatory compliance, system development and optimisation**

The way the regulator will judge the disposal system and the safety argumentation during the licensing procedure and the role it will play is very much specific to the national legislative and regulatory culture, which can vary importantly from country to country. Formalization of discussions of issues such as: how much is good enough, is difficult in any setting and all final judgment will be influenced by societal factors and affected by a degree of subjectivity. The ICRP-103 notes for instance that “*All aspects of optimisation cannot be codified; rather, there should be a commitment by all parties to the optimisation process. Where optimisation becomes a matter for the regulatory authority, the focus should not be on specific outcomes for a particular situation, but rather on processes, procedures and judgements*”. See e.g. ICRP 103 [4] and ICRP 122 [5]

The meaning of “regulatory compliance” is thus a complex questions that could be developed further in the international arena. ICRP shows the way by suggesting that processes and procedures are important for a regulatory judgement, and this could be examined further.

6. Proposed way forward

The dialogue between regulator – implementer is part of a national decision process for developing and implementing a geological disposal system, in which other technical and non-technical stakeholders are involved.

The proposal to launch an international discussion and reflection on the basic elements, the concrete experiences and the challenges of this regulator – implementer dialogue in the process of developing a (geological) disposal facility, could be beneficial for all national programs by focussing both on basic (international) principles and on practical national experiences.

As a general approach for this international discussion three main steps can be distinguished:

1. creation of a pilot group that will ensure the preparation and coordination of all the work;
2. a first phase of gathering all the existing information on this topic by looking at (1) all the relevant international recommendations, guidance’s and outcomes from past discussions that are related to the regulator-implementer dialogue, and (2) the characteristics, the experience and the challenges of the regulator-implementer dialogue in national programmes.

This first phase of the work could be prepared with the support of a consultant and a questionnaire addressed at the national programmes.

The deliverable from this first phase is a status report synthetizing the international basic elements and the national situations.

3. A second phase could take the form of an international workshop to present and discuss the basic elements identified in the first phase. The working group will be responsible for preparing the workshop from an organisational and programmatic point of view, as well as for the production of the workshop outcomes.

The involvement of the other national stakeholders in this international discussion, e.g. in the preparation and during the workshop, could certainly add an important broader dimension to the discussions and reflections.

References

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- [5] ICRP (2013 “Radiological Protection in Geological Disposal of Long-Lived Solid Radioactive Waste” ICRP Publication 122, Annals of the ICRP Vol. 42(3).