Human Aspects of Nuclear Safety
2024

The Mutual Impact of Nuclear Regulatory Bodies and License Holders from a Safety Culture Perspective

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Specific areas of competence of the NEA include the safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

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Foreword

The NEA has vested considerable effort in recent years to improve the understanding of "human aspects of nuclear safety" – most particularly nuclear safety culture. As highlighted by previous NEA work in this area, as well as a series of Country-Specific Safety Culture Fora held in various countries, safety culture, while relatively simple in general concept, is a very complex matter that is impacted by a wide range of factors – including history, culture, policy, leadership and others that comprise the context in which regulatory staff and licensees operate. Operating history shows clearly that the root cause of safety incidents is often not technical nor the fault of a single individual, but rather originate compromised safety culture – sometimes in both the operator and the regulator.

One of the most challenging aspects of safety culture is one that I find some regulatory officials hesitate to consider – the impact the culture, approach and practices of the regulator may have on operators. It is a precept of nuclear safety that responsibility for safety lay with operators. Given that, it is then the job of regulators to provide the framework of expectations and oversight on behalf of the public to assure that operators carry out their safety responsibilities in an appropriate manner.

This is the general philosophy that has been espoused for decades. The reality is, often, more complex. Regulators hold great power over licensees and how that power is wielded can have great impact on how operators see their responsibilities. If an operator believes a new technology or methodology can improve safety and save costs, but finds it too difficult and expensive to gain regulatory approval for its use, will the operator be more hesitant to suggest improvements in the future? Is this a benefit to safety? Is it better for operators and regulators to come to common understandings about safety matters or for operators to simply wait for the regulator to decide what is best and then implement the orders without substantive question? If licensees refrain from taking any actions before seeing decisions by regulators, does that serve the cause of improved safety?

Understanding these interactions and influences is essential as we continue to strive towards higher levels of nuclear safety around the world. This report, the result of collaborative work conducted by safety culture experts in our member countries, presents a model for how the safety culture of the regulator and the licensee mutually impact each other. It substantiates with international, qualitative data the importance of *responsive regulation* and outlines how to achieve this through an *accountability-oriented, enabling* regulatory approach. The goal is for the regulator and licensee to advance towards higher safety culture maturity. The data-backed insights contained in the following pages may also help countries with stakeholder engagement activities, specifically related to the effectiveness of dialogue- and learning-based approaches over compliance-oriented regulation. Moving beyond prescription to foster the licensee's accountability for safety through a reciprocal, co-operative relationship between the regulator and the licensee is in the ultimate public interest.

I thank and congratulate the expert group that developed, implemented and completed this invaluable report. The work of regulators will only become more challenging as new technologies, new types of licensees and new operations approaches come into focus. Optimising the relationship between the regulators and the regulated serves both nuclear safety and broader public interests.

William D. Magwood, IV
Director-General
Nuclear Energy Agency

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The Nuclear Energy Agency (NEA) thanks the Committee on Nuclear Regulatory Activities (CNRA) Working Group on Leadership and Safety Culture (WGLSC) Chair, Nobuhiko Ban (Commissioner, Nuclear Regulation Authority [NRA], Japan) and the task group leader, Marc McBride (Office for Nuclear Regulation [ONR], United Kingdom), as well as all the task group members for their efforts and contributions to this report. Their respective leadership and participation in task meetings, workshops and plenary meetings have made this report possible.

The qualitative data collection and analysis upon which this report is based would not have been possible without the significant efforts of many individuals. The contributions of Cornelia Ryser (Swiss Federal Nuclear Safety Inspectorate [ENSI], Switzerland), Walter Glöckle (Ministry of the Environment, Climate Protection and the Energy Sector Baden-Württemberg, Germany) and Marta Barrientos (Spanish Nuclear Safety Council [CSN], Spain) were particularly notable. Many others assisted by conducting interviews in their countries, translating and analysing the data, and providing support, including but not limited to Hiroko Takada (NRA, Japan), Su Jin Jung (Korea Institute of Nuclear Safety [KINS], Korea), Anne Edland (Swedish Radiation Safety Authority [SSM], Sweden) and Zoltánné Bódis (Hungarian Atomic Energy Authority [HAEA], Hungary). Thanks are owed to these individuals and many more who participated over the three-year initiative to bring this report to fruition.

WGLSC Secretariat Florence Maher guided the process from start to finish and her hand touched every page. Kosuke Tobe and Minori Kato from the NEA Secretariat provided significant support for the Japanese interviews. Finally, the team would like to recognise Asli Bokesoy for her editorial support.

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List of abbreviations and acronyms

AER	Accountability-oriented, enabling regulation
CNRA	Committee on Nuclear Regulatory Activities (NEA)
FAA	Federal Aviation Authority
HOF	Human and organisational factors
HRO	High Reliability Organisation
IAEA	International Atomic Energy Agency
NEA	Nuclear Energy Agency
OECD	Organisation for Economic Co-operation and Development
WGSC	Working Group on Safety Culture (NEA)
WGLSC	Working Group on Leadership and Safety Culture (NEA)

Executive summary

Key messages

- Regulatory bodies, by their nature, deeply influence the safety culture of nuclear site licence holders. This influence is also mutual, from licensee to regulatory body.
- This study identifies the *factors and mechanisms* by which each party influences the safety culture of the other, based on the insight of senior practitioners worldwide.
- A clear picture emerges of the nature of interactions between the regulatory body and licensee that leads to a positive mutual impact on safety culture. This picture is of a reciprocal, co-operative style of interaction, characterised by respect, openness and trust, with a shared focus on safety and learning.
- Within this model, the regulatory body's approach seeks to foster the licensee's accountability for safety, enabling continuous improvement and growth of the licensee's safety culture towards higher maturity levels. This approach has been termed *accountability-oriented, enabling regulation*, which builds on the concept of performance (or outcome) based regulation, but also includes a focus on risk (or hazard), processes, and self-assessment by licensee.
- It is recognised that such an approach to regulation is not always achievable, nor appropriate. Therefore, the regulatory body also needs to be agile in its approach, moving between accountability-oriented, enabling regulation and a more prescriptive style according to the circumstances (*responsive regulation*).
- Two main factors determine the extent to which the regulatory body is able to adopt an accountability-oriented, enabling approach: the safety culture maturity of the licensee, and the safety culture maturity of the regulatory body. In both cases, the more mature the safety culture, the more an accountability-oriented, enabling regulatory approach is likely to succeed.
- Regulatory bodies and licensees are encouraged to use the information contained in this report to assess the health of their interactions and identify areas for improvement and good practices to share.
- Regulatory bodies should, where appropriate, consider how they might move their approach towards a more accountability-oriented, enabling style, developing the regulatory oversight methods and culture which support this.

Summary overview

This report presents NEA work to explore interactions between nuclear regulatory bodies and site licence holders (licensees) and how each influences the safety culture of the other.

The specific objectives of the study were to:

1. Understand how regulatory bodies impact licensees (and vice versa) from a safety culture perspective; and
2. Share good practice and learning on how regulatory bodies can ensure that this impact is positive, avoid negative impacts, and support the achievement of safety objectives.

To explore this topic, nearly 50 interviews were carried out with experienced practitioners and senior leaders in both regulatory bodies and licensees, representing 13 member countries, to gather and analyse their insights and experience. The approach was based on well-established qualitative research techniques (Bell et al, 2019), to ensure a high standard of methodological and ethical rigour.

The study identifies the principal factors which determine the influence of each party on the safety culture of the other. These include the communications, relationships and behaviours of staff at the interface between the regulatory body and licensee. In turn, these are influenced by the regulatory regime, comprising the system of legislation and standards, roles and responsibilities, regulatory approach, etc., and the capability, leadership and management of each organisation. Finally, the ability of each party to learn from their interactions, and from others, determines whether the influence on safety culture has a positive (upward) or negative (downward) trend.

From the interview data, a consistent picture emerges of the nature of interactions between the two organisations that leads to a positive mutual impact on safety culture, whether from a regulatory body or licensee perspective, and consistent despite differences in national context. This picture is of a reciprocal, co-operative style of interaction, characterised by respect, openness and trust with a shared focus on safety and learning (as shown in Figure E1). This type of interaction enhances the licensee's ability to "self-regulate" through increased self-awareness and consequential improvement action. Such interaction drives a focus on safe outcomes beyond mere compliance with regulations.

Within this model, the regulatory body's approach seeks to foster the licensee's accountability for safety, enabling continuous improvement and growth of the licensee's safety culture towards higher maturity levels. This approach is termed "accountability-oriented, enabling regulation", which builds on the concept of performance (or outcome) based regulation, but also includes a focus on risk (or hazard), processes, and self-assessment by licensee.

The need for an accountability-oriented, enabling approach is consistent with the increasing focus on organisational resilience following the Fukushima Daiichi Nuclear Power Plant accident, as well as "Safety-II"[1] thinking. These concepts place less emphasis on conventional regulatory techniques, e.g. compliance inspections, and rather more emphasis on dialogue to understand the normal functioning of organisations, including the day-to-day variability of performance and behaviour ("work-as-done") and its consistency with "work-as-imagined".

It is recognised that an accountability-oriented, enabling approach to regulation is not always achievable, nor even appropriate. Therefore, the regulatory body needs to be agile in its approach, moving between accountability-oriented, enabling regulation and a more prescriptive style according to the circumstances ("responsive regulation"). The present study has identified two main factors which influence this:

- The safety culture maturity of the licensee; and
- The safety culture maturity of the regulatory body.

As regards the licensee's safety culture, the more mature the safety culture, the more an accountability-oriented, enabling regulatory approach is likely to succeed, fostering continued innovation and growth of the licensee's capability. However, for licensees with a less mature safety culture, a prescriptive approach might be more appropriate, or even necessary, providing the needed formality of requirements and supporting enforcement mechanisms. Even in this situation, however, the regulatory body's aim should always be to influence the licensee to move towards a higher level of cultural maturity, in the long-term interests of safety.

1. Safety-II is a condition where the number of successful outcomes is as high as possible. It is the ability to succeed under varying conditions. Safety-II focuses on making sure that things go right, rather than on preventing them from going wrong (Hollnagel, 2014).

The ability of the regulatory body to adopt an accountability-oriented, enabling approach also depends on its own safety culture maturity. Such an approach places greater emphasis on the technical and behavioural competence of inspectors to interpret regulatory requirements in a particular setting and influence improvements.

Another factor which determines the extent to which the regulatory body is able to adopt an accountability-oriented, enabling approach is the expectation of, and the level of trust it enjoys from, the public[2]. The more public trust in the regulatory body, the more it is able to adopt an accountability-oriented, enabling approach with its greater emphasis on less formal styles of interaction, e.g. dialogue and influencing, as opposed to formal interactions, e.g. compliance inspections.

This report includes examples of good practices and lessons learnt which underpin the model of regulatory body-licensee interactions described above. It also sets out the common challenges for regulatory bodies and licensees identified by interviewees, including:

- Establishing a clear and predictable regulatory framework;
- Maintaining trust and respect in the relationship between the regulatory body and licensee; and
- Understanding how the regulatory body can preserve its independence while also maintaining open dialogue with the licensee.

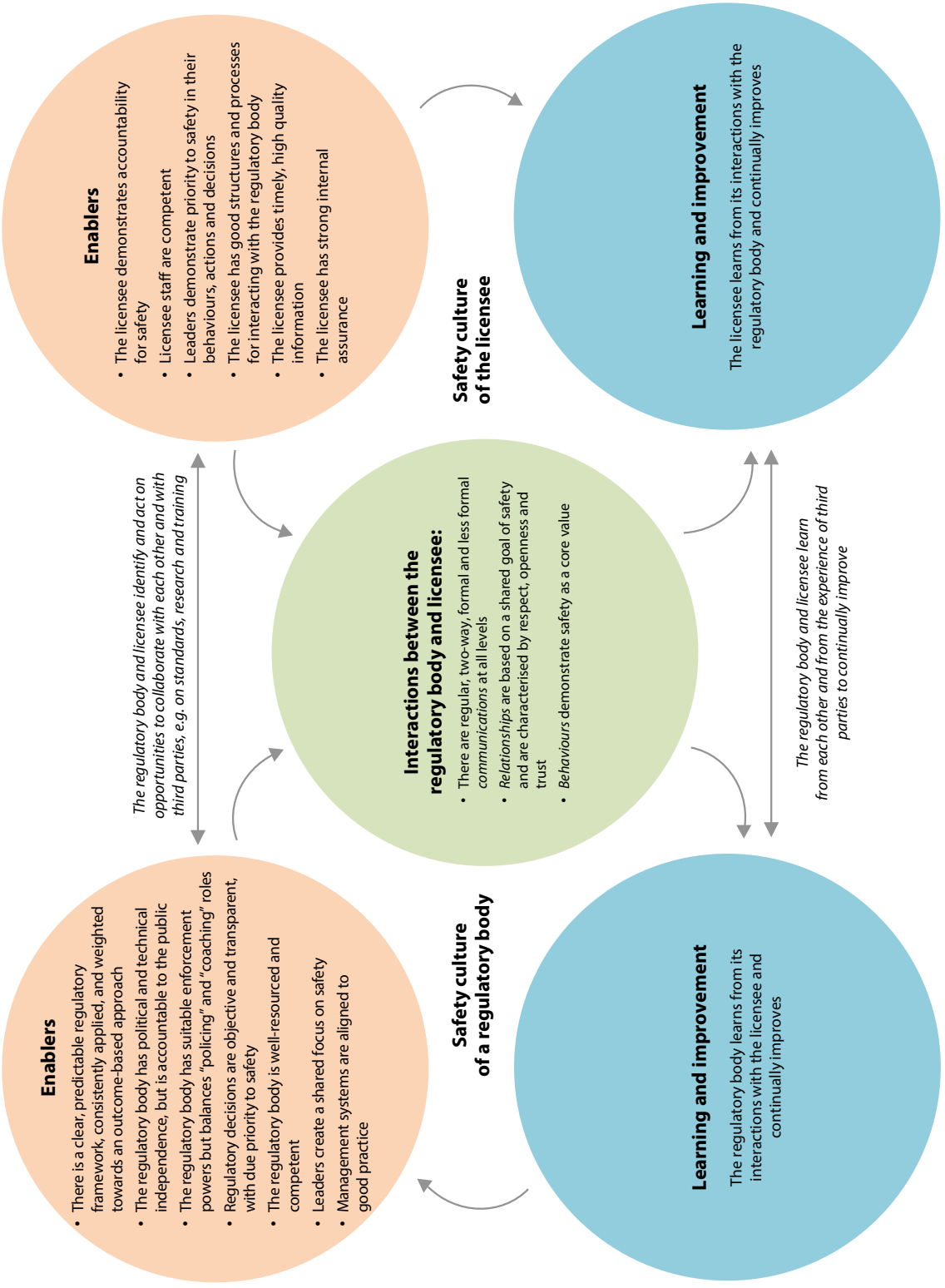
The information contained in this report can be used by both regulatory bodies and licensees to understand the health of their current working relationships, explore factors which may be undermining a mutual positive impact on safety culture, and identify good practices which can be shared with others.

The present study points to the need for further work to explore how regulatory bodies and licensees can move towards and sustain a more reciprocal, co-operative style of interaction, for example by:

- Developing guidance and tools on how to create awareness of the impact regulatory bodies and licensees have on their respective safety cultures;
- Deepening and substantiating the concepts of accountability-oriented, enabling regulation and responsive regulation and the practical implications for the nuclear industry;
- Developing guidance and tools, and exchanging experience on the development and application of accountability-oriented, enabling regulation and responsive regulation;
- Further exploring how the regulatory body achieves a balance in its regulatory approach and interactions with the licensee and the wider interconnected system of stakeholders; and
- Communicating with the public on the concepts of accountability-oriented, enabling regulation and responsive regulation, and their impact on safety and trust.

2. The topic of public trust is explored in the NEA publication *The Characteristics of a Trusted Nuclear Regulator* (NEA, forthcoming) and complements ongoing NEA work by examining the regulatory body-public axis alongside the regulatory body-licensee axis explored here.

Figure E1. **Model of effective interactions between the regulatory body and licensee: How each can positively influence the safety culture of the other *(summarised version)***



Chapter 1. Introduction

The role of the regulatory body is to provide oversight of licensees, while the accountability for the safe operation of a nuclear facility rests with the licensee. The safety culture of the regulatory body has a potentially significant impact on that of the licensee. Through its regulatory strategy, the way it carries out its daily oversight work, the type of relationship it cultivates with the licensee, the values it conveys and the importance this gives to safety (its "safety culture"), the regulatory body profoundly impacts the safety culture of the licensee and its sense of accountability for safety. This influence is also mutual, from licensee to regulatory body, and by its nature it is pervasive and may be unseen.

The NEA report *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture* (NEA, 1999) focuses on regulatory oversight of safety culture and discusses how the regulatory body could recognise and respond to early signs of declining safety performance of licensees. The NEA report also recognised that, in addition to enforcing safety regulations, the regulatory body should make sure it has a positive effect on the operator's safety culture. Another guidance report, *The Safety Culture of an Effective Nuclear Regulatory Body* (NEA, 2016) (commonly and hereafter referred to as the "2016 NEA Green Booklet"), identifies and describes five principles and their associated attributes (see Table 1.1) that underpin and support the safety culture of an effective nuclear regulatory body. The 2016 NEA Green Booklet emphasises the importance of the regulatory body taking a holistic approach to safety by working in a systematic manner. The human and organisational factors (HOF) analysis of the Fukushima Daiichi Nuclear Power Plant accident also led to recognition of the need for a systemic approach that encompasses interactions among all stakeholders involved in nuclear safety (IAEA, 2015).

Regulatory bodies oversee and regulate complex socio-technical systems that, together with the regulatory body itself, form part of a larger system made up of many stakeholders, with competing as well as common interests. All the participants in this system influence and react to each other, and there is a need for awareness and understanding of this mutual influence. Past events in the nuclear sector and more recent events in other sectors, e.g. the Boeing 737 MAX accidents, continue to emphasise the role of the regulatory body as an important component of the broader system ensuring the safety of workers and the public.

Table 1.1. **Principles and attributes of a health safety culture in regulatory bodies**

Principles	Attributes
Principle 1: Leadership for safety is to be demonstrated at all levels in the regulatory body.	• "Safety first" is a guiding principle in the regulatory body. • All leaders throughout the regulatory body demonstrate a commitment to safety in their decisions and behaviours. • Leaders create an environment for positive development of the safety culture. • Leaders clearly define individual roles, responsibilities and authority. • Leaders ensure that the necessary resources are available to meet the safety mission.

Table 1.1. **Principles and attributes of a health safety culture in regulatory bodies** *(cont'd)*

Principles	Attributes
Principle 2: All staff of the regulatory body have individual responsibility and accountability for exhibiting behaviours that set the standard for safety.	• Personal commitment to and accountability for safety from every staff member, at all levels of the organisation. • A strong sense of collaboration and co-ordination of activities across the organisation. • The need for moral courage and agility in doing the right thing.
Principle 3: The culture of the regulatory body promotes safety and facilitates co-operation and open communication.	• Openness and transparency. • Clear organisational commitment to co-operation. • A questioning attitude, and mechanisms to raise differing opinions on regulatory decisions. • Promotion of safety and associated knowledge.
Principle 4: Implementing a holistic approach to safety is ensured by working in a systematic manner.	• A healthy respect for the consequences of all actions and decisions taken by the regulatory body. • Clear awareness of roles and responsibilities in relation to licensees. • A clear regulatory framework. • Proactivity, adaptability and a holistic approach. • Recognition of the complexity of safety issues.
Principle 5: Continuous improvement, learning and self-assessment are encouraged at all levels in the organisation.	• Safety culture self-assessment and peer reviews. • Learning from experience, fostering exchanges and increasing knowledge. • Knowledge management to build a healthy safety culture. • Continuous improvement as a clear value of the regulatory body.

Source: NEA (2016).

The NEA Working Group on Safety Culture (WGSC) was formed in 2017 to foster discussion and exchange information and experience in practical approaches to developing and sustaining a healthy safety culture within the regulatory body and the wider interconnected system. The first report published by the WGSC, *Methods for Assessing and Strengthening the Safety Culture of the Regulatory Body* (NEA, 2021a) provides both an overview and practical information regarding the methods and approaches performed by regulatory bodies to build safety culture competence and awareness and to assess their own safety culture. The work presented here is a follow-on to the 2021 report.

In 2021, WGSC members established subgroups to work on two main tasks. One task addressed the impact of regulatory bodies on the organisations they oversee (and vice versa) from a safety culture perspective. The other task identified effective characteristics, competencies, values and how these are exhibited in the behaviour of leaders in a regulatory body which has a healthy safety culture. Both tasks were in close alignment with the challenges identified in the 2016 NEA Green Booklet.

Due to the important influence leadership has on the effectiveness of the regulatory body, the WGSC was subsequently restructured as the Working Group on Leadership and Safety Culture (WGLSC) in January 2023. The aim of the WGLSC is to exchange information and experiences at a senior regulatory level and to provide practical, innovative products to

support the leadership and safety culture of the regulatory body and wider interconnected system. The WGLSC's work is focused on leadership and safety culture as they relate to regulatory activities, while appreciating the mutual impact of the licensee and other stakeholders within the wider interconnected system to ensure safety. The WGLSC collects and analyses information to identify and capture best practices on how the leadership, human aspects and safety culture of the regulatory body affects the regulated entity's safety culture, and vice versa[1].

This document reports on the first task of the WGLSC (begun by the WGSC in 2021), to investigate interactions between the regulatory body and licensee and how each influences the safety culture of the other. This report is intended to gather and analyse the knowledge and experience of regulatory bodies and licensees on how regulatory strategies and approaches, including relationships between regulatory bodies and licensees, influence safety culture. The second report in the series, *Practices for Enhancing Leadership for Safety in Nuclear Regulatory Bodies* (NEA, forthcoming), is a guidance document that identifies elements of effective leadership for safety characteristics, competencies and values. Specifically, the report identifies how these are best exhibited in the behaviour of regulatory body leaders in order to maintain a healthy safety culture.

This present document provides both an overview of mechanisms by which the regulatory body and licensee influence their respective safety cultures, and associated good practices, lessons learnt and challenges. The remainder of this report is divided into five chapters. Chapter 2 sets out the purpose and scope of the report. Chapter 3 provides a summary of the literature review and the methodology for data collection and analysis. Chapter 4 then summarises the data analysis results, including mechanisms of influence, good practices, lessons learnt and challenges. It also proposes a model for effective interactions between the regulatory body and licensee. The discussion and conclusions, along with recommendations for future NEA work, are presented in Chapter 5. Annexes catalogue the literature reviewed (Annex A), the questions used in the data collection interviews (Annex B), examples of good practices and lessons learnt (Annex C), and features of ineffective interactions between the regulatory body and licensee (Annex D).

1. Current information about the WGLSC's work can be found at www.oecd-nea.org/WGLSC.

Chapter 2. **Purpose and scope**

The regulatory body interacts with the licensee through its regulatory activities. The purpose of this study is to explore this interaction in more detail in the context of safety culture. This will facilitate building and maintaining a healthy relationship between the two organisations in the interests of safety.

Past events in the nuclear sector, e.g. the Fukushima Daiichi accident, and more recent events in other sectors, e.g. the Boeing 737 MAX accidents, continue to emphasise the role of the regulatory body as an important component of the broader system ensuring the safety of workers and the public. Prior to the Fukushima Daiichi Nuclear Power Plant accident, "…the regulatory bodies lacked an organisational culture that prioritised public safety over their own institutional wellbeing, and the correct mindset necessary for governance and oversight" (National Diet of Japan, 2012: 44). Further, investigators into the Boeing 737 MAX accidents noted that, "The [Federal Aviation Authority's] waning safety culture stands as a significant barrier to its capacity to learn lessons from the MAX tragedies and make fundamental organisational improvements" (U.S. House Committee on Transportation and Infrastructure, 2020: 234).

More specifically, the objectives of this study are to:

- Understand how regulatory bodies impact licensees (and vice versa) from a safety culture perspective; and
- Share good practice and learning on how regulatory bodies can ensure that this impact is positive, avoid negative impacts, and support the achievement of safety objectives.

Thus, the report will explore how regulatory bodies positively and negatively affect the organisations they oversee (and vice versa) from a safety culture perspective. It gathers and analyses the knowledge, insights and experience of regulatory bodies and licensees worldwide in how regulatory strategies and approaches, including relationships between regulatory bodies and licensees, influence the safety culture of each organisation.

This report focuses particularly on fourth principle of the 2016 NEA Green Booklet: "Implementing a holistic approach to safety is ensured by working in a systematic manner" (NEA, 2016) (see Table 1.1). The present report builds on the attributes of this principle, e.g. a healthy respect for the consequences of all actions and decisions taken by the regulatory body, and a clear awareness of roles and responsibilities in relation to licensees.

This report also addresses three of the key challenges identified in the 2016 NEA Green Booklet, namely:

- Maintaining the focus on safety by avoiding complacency and sustaining institutional memory;
- Addressing external pressures on the regulatory body by protecting against undue influence and avoiding "regulatory capture"; and
- Building, maintaining and adapting a regulatory system by evolving and adapting to changes in government policy and the industry landscape to maintain a healthy safety culture.

Gaining a deeper awareness of these elements is important for regulatory bodies, considering their potential influence on the safety culture of licensees. Furthermore, it is also important to be aware of how the licensees' safety culture influences the regulatory body.

This report is intended primarily for staff in the regulatory body and their licensees. This includes managers at all levels, and staff members who are responsible for, or involved in, regulatory strategies, activities and interactions to strengthen the safety culture of the regulatory body as well as that of the licensee. However, it is also intended for staff in other functions, e.g. training, human resources, self-assessment and safety culture specialists. Furthermore, other potential readers might be interested stakeholders in the wider system, e.g. government, international bodies and the public. Widespread engagement of stakeholders in this report's findings provides an opportunity to develop awareness of the regulatory body and licensee's relative strengths and weaknesses and their impact on each other's safety culture.

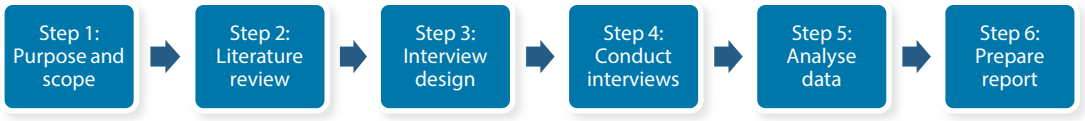
The report captures the knowledge and experience of 12 NEA member countries and the United Arab Emirates in regulatory strategy, practice and relationships, which serve to sustain and enhance the safety culture and safety performance of the regulated organisations. While there will inevitably be nuances in the regulatory approach taken by each country according to the national culture and context, the report draws out insights and good practices from which all countries can learn. This report also aims to contribute to nuclear safety by capturing key success factors with the aim of avoiding repetition of past regulatory failure and promoting good practice internationally.

The NEA encourages regulatory bodies and licensees to use this report as a reference for reviewing and improving their activities to foster and enhance a healthy safety culture. This aim is to help in raising awareness of the impact regulatory bodies and licensees have on each other's safety cultures. More specifically, this report can encourage regulatory bodies and licensees to undertake self-reflection, self-assessment and improvement activities. Together with the companion publication *Practices for Enhancing Leadership for Safety in Nuclear Regulatory Bodies* (NEA, forthcoming), this report can be used to enhance training, development and guidance of staff.

Chapter 3. Methodology

The methodology used in this report was derived from well-established, qualitative research techniques (Bell et al., 2019). The main steps (Figure 3.1) comprised a literature review to understand the maturity of knowledge in the field of regulatory safety culture, followed by a data collection and analysis phase. The main method of data collection was semi-structured interviews with senior practitioners in regulatory bodies and licensee organisations worldwide. Section 3.1 summarises the outcome of the literature review. Section 3.2 then details the approach to data collection and analysis.

Figure 3.1. **Research methodology**



3.1. Summary of literature review

The literature review examined 24 items of literature ranging from academic publications, to work by international bodies, assessments of regulatory oversight culture, and authoritative investigations and reviews of the role of the regulatory body in major accidents in the nuclear and other sectors. The items of literature reviewed are listed in Annex A together with a summary of the main items considered relevant to the present study.

The main findings of the literature review were that:

- There have been no published, large-scale studies in the nuclear sector examining how the regulatory body influences the safety culture of the licensee, and very little work on the influence of the licensee on the regulatory body.
- The studies that have been undertaken to explore the traits and attributes of healthy regulatory safety culture have several common elements, e.g. leadership and continuous improvement. These provide a useful reference point for the present study.
- Investigations into the Fukushima Daiichi Nuclear Power Plant accident, as well as others, have highlighted the crucial role of the regulatory body in providing competent, independent, effective oversight of the industry, and the continuing challenges in achieving this.
- Studies in the nuclear and other sectors indicate that no single approach is optimal in terms of the regulatory body delivering its purpose of assuring safety on behalf of the public. Rather, a flexible approach is needed that depends on the safety culture maturity of the duty holder as well as of the regulatory body itself. Nevertheless, the aim of any regulatory approach should be to foster the accountability of the regulated organisations and their growth towards higher cultural maturity levels.

The literature review was used to design the next phase of the study – specifically the design of the semi-structured interviews and the development of a set of categories or "codes" around which to organise the data collected through the interviews.

3.2. Methodology for data collection and analysis

3.2.1. *Data collection*

The main method chosen for the data collection phase of the study was semi-structured interviews with senior practitioners in regulatory bodies and licensee organisations worldwide. The reason for choosing semi-structured interviews is that they allow rich discussion based on a core set of mandatory questions while allowing the interviewer to add further questions to seek clarification and further insights. The individuals interviewed were directors, managers, inspectors and safety culture specialists within regulatory bodies and licensee organisations, including recently retired staff, all with significant experience of working at the interface between the regulatory body and licensee.

In total, 49 interviews, including focus group interviews, were conducted by members of the WGLSC during 2022, encompassing 60 individuals in 13 member countries. Each interview lasted approximately 90-120 minutes. An initial pilot of the interview and data analysis process was undertaken to validate the approach and inform the remainder of the interviews. The pilot phase comprised 17 of the 49 interviews.

Most of the interviews were recorded and transcribed, or extensive notes taken, to provide the basis for detailed textual analysis while mitigating the introduction of unintentional bias. The interviews were primarily conducted in the native language of the interviewee to ensure clarity of communication, given the nature of the matters being discussed. Members of the WGLSC also participated in each other's interviews to promote learning and consistency of approach. Table 3.1 summarises the interviews conducted.

Table 3.1. **Interviews conducted by WGLSC members**

Country	Number of interviews		Total
	Regulatory body	Licensee	
Australia	2	1	3
Canada	3	1	4
Finland	2	0	2
Germany	1	2	3
Hungary	2	2	4
Japan	2	11[1]	13
Korea	2	1	3
Slovak Republic	0	1	1
Spain	2	2	4
Switzerland	1	3	4
United Arab Emirates	1	0	1
United Kingdom	2	2	4
United States	2	1	3
Total	**22**	**27**	**49**

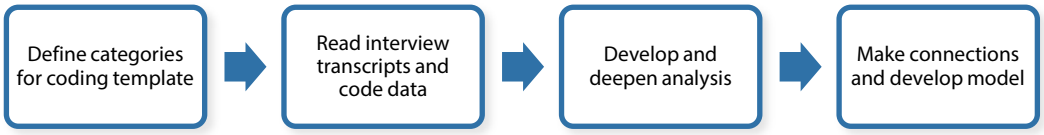
1. Interviews were conducted with all the licensees in Japan to provide an additional layer of protection for the anonymity of the data. However, no additional weight was given to the views expressed in these interviews compared to other countries.

The interviews were conducted in accordance with an ethical framework to protect the anonymity and confidentiality of the interviewees and the information provided. Participants were provided with an information sheet in advance detailing the safeguarding provisions, the questions to be asked and seeking their consent to participate in the study. Annex B lists the questions forming the core of the semi-structured interviews, which align with the main objectives of the study. Interviewers reported that the interviews were open and engaging, and that participants provided high quality information and insights.

3.2.2. *Data analysis*

The method chosen for analysis of the data from the interviews was thematic data analysis (Bell et al., 2019). In this method a pre-specified coding template, drawing on existing knowledge, is used to organise the interview data, but the codes can be refined in the course of the analysis. In this case, the literature review provided the source material for the development of the initial coding template. The codes were then modified in response to the themes that arose from the interview data.

Figure 3.2. **Methodology for data analysis**



Each interviewer carried out the initial analysis of their interview data; the completed coding templates were then translated into English. A core group of WGLSC members then performed the next level of data analysis to distil key themes and make comparisons and connections in order to provide an explanation and interpretation of the data. Finally, the outputs of this analysis were reviewed and refined in data analysis workshops in which all WGLSC members participated.

The interview data provided rich information on:

- The mechanisms by which the regulatory body influences the safety culture of the licensee (and vice versa); and
- Good practices, lessons learnt and challenges in effective interactions between the regulatory body and licensee.

The information was used to develop a model for effective interactions between the regulatory body and licensee in which each party has a positive impact on the safety culture of the other, as detailed in Chapter 4).

Chapter 4. Results of data analysis

This chapter presents the results of the data analysis derived from the interviews with senior practitioners in regulatory bodies and licensee organisations on how each party influences the safety culture of the other. Sections 4.1. and 4.2 of the chapter describe the mechanisms of influence, with examples of positive and negative impacts. These sections also include illustrative quotations from the interviews and present both a descriptive and normative analysis, referring to the key items of literature in Section 3.1 and Annex A. Section 4.3 covers good practices and lessons learnt for interactions between regulatory bodies and licensees. Section 4.4 then analyses the challenges facing regulatory bodies and licensees in ensuring that their interactions are effective and positively influence each other's safety culture. Finally, Section 4.5 discusses the main findings of the data analysis and presents a proposed model for effective interactions between the regulatory body and licensee, drawing together the insights provided by the interviews.

In analysing the interview data, consideration was given to whether there were any significant differences in the opinions expressed by representatives of regulatory bodies versus those of licensees, or among the different countries participating in the study. No such differences were found and indeed the interview data gives a consistent picture of the mechanisms of influence of each party on the safety culture of the other, and what constitutes an effective interaction between a regulatory body and licensee. This may in part relate to the strong international networks which exist in the nuclear sector.

4.1. Mechanisms of influence of the regulatory body on the safety culture of the licensee

4.1.1. *Overview*

The literature review (Section 3.1 above and Annex A) identified a provisional set of factors relevant to the influence that the regulatory body has on the safety culture of the licensee (and vice versa). The analysis of the interview data has provided significant additional insight into these factors. In the case of the influence of the regulatory body on the safety culture of the licensee, the following factors emerge from the interview data. These are presented in Table 4.1 below as the "main factors," each of which has several "sub-elements".

Table 4.1. **Factors that determine the regulatory body's influence on the safety culture of the licensee**

Main factors	Sub-elements
1. The regulatory regime	1.1 The regulatory framework: its design, development and implementation 1.2 The roles, responsibilities, accountabilities and authorities allocated to the regulatory body, licensee and other players 1.3 The regulatory body's degree of independence 1.4 The regulatory body's priorities 1.5 The regulatory body's decision-making processes 1.6 The regulatory body's methods and tools

Table 4.1. **Factors that determine the regulatory body's influence on the safety culture of the licensee** *(cont'd)*

Main factors	Sub-elements
2. The capability of the regulatory body	2.1 The competence of staff in the regulatory body 2.2 The resourcing of the regulatory body 2.3 The ability of the regulatory body to access independent sources of technical expertise 2.4 The knowledge management practices of the regulatory body
3. The leadership and management of the regulatory body	3.1 The capabilities and practice of leaders in the regulatory body 3.2 The regulatory body's management system and practices
4. The regulatory body's communications	4.1 The structure and format of communications between the regulatory body and licensee 4.2 The content of communications between the regulatory body and licensee 4.3 The communications between the regulatory body and the public
5. The regulatory body's relationships with the licensee and other stakeholders	5.1 The characteristics of the relationship between the regulatory body and licensee 5.2 The development and maintenance of the relationship between the regulatory body and licensee 5.3 The relationships between the regulatory body and other stakeholders
6. The behaviour of the staff of the regulatory body	6.1 The behaviour of the regulatory body's staff in promoting safety 6.2 The visibility of the regulatory body's staff in the licensee 6.3 The compliance of the regulatory body's staff with the licensee's safety arrangements
7. The ability of the regulatory body to learn and improve	7.1 The ability of the regulatory body to learn and improve from its own experience 7.2 The ability of the regulatory body to learn and improve from the experience of the licensee 7.3 The ability of the regulatory body to learn and improve from the experience of others

The following sections describe how the above factors combine and influence the safety culture of the licensee. These are the "mechanisms of influence" identified in this study.

4.1.2. *Influence of the regulatory regime*

The regulatory body influences the safety culture of the licensee, firstly, by the way in which the **regulatory framework** (the system of legislation, standards and guidance) is designed, developed and implemented. It is important that the regulatory framework is clear, comprehensive and predictable, aligned with regulatory objectives and values, and developed in consultation with licensees. It should then be consistently explained, interpreted and applied. These sub-elements together will promote effective working relationships between the regulatory body and licensee, generate mutual understanding and a motivation to comply. By contrast, a regulatory framework that lacks clarity, or is inconsistently applied, can lead to confusion, poor safety outcomes and wasted effort.

> *"Participation in the development of regulations, the possibility of considering both the regulatory body and licensee's views, and full understanding of the meaning of the regulations, helps compliance and conviction on the need and benefits of the regulations. It sets the steps in building a culture of improving, not merely fulfilling prescription." – Interviewee*

> *"If the values and norms promoted by the regulatory body are inconsistent with the actual regulations, it will be difficult to give a positive message to the operator no matter how the regulatory body emphasises safety culture." – Interviewee*

The insight provided by the interviewees indicates that the emphasis in the regulatory regime should be towards an outcome-based or goal-setting approach (see Box 4.1 in Section 4.5 for a definition) rather than a prescriptive approach. By focussing more on the outcome, and less on the detail of how the outcome is to be achieved, the regulatory body

promotes the licensee's sense of accountability for safety, allows flexibility for varying circumstances, and supports innovation. Other important features of the design of the regulatory framework that were identified:

- A holistic approach to safety, considering human, technology and organisation;
- A graded approach to safety, i.e. stringency of controls commensurate with level of risk;
- Systematic consideration of safety across national boundaries; and
- The provision of a suitable range of regulatory enforcement powers.

Often there is more than one regulatory body involved in regulating related activities within an operating organisation. A key lesson from past accidents (IAEA, 2015) is that regulatory bodies co-ordinate their efforts to clarify expectations and promote optimal outcomes.

An important feature of the regulatory regime is the allocation of **roles, responsibilities, accountabilities and authorities** to the regulatory body, licensee and other players. The regulatory body should have authority to carry out its functions and clear accountability to the public, while accountability for safety should rest with the licensee. An important influence on the safety culture of the licensee is how the regulatory body interprets and exercises its role, e.g. as a "police officer" or "coach". Too much of an emphasis on its policing role and formal enforcement, for example, can diminish the licensee's sense of accountability for safety. On the other hand, too much of an emphasis on the coaching role can undermine the independence and public accountability of the regulatory body. This is similar to the findings of Reiman and Norros (2002), who identified three roles the regulatory body performs ("expert", "authority" and "public") and the trade-offs between them.

> *"My experience is that enforcement can sometimes be very positive for culture. It can also be very difficult sometimes, in a formal interaction, when trying to understand the background and the reasons for a particular course of action or decision. A blend between informal support, early advice, that helps the licensee understand the direction of travel, before getting into the realms of enforcement, is really helpful." – Interviewee*

The **independence of the regulatory body** from both a technical and a political perspective is a key feature of the regulatory regime. However, this independence should not be at the expense of the regulatory body becoming isolated from other stakeholders, e.g. licensees, government and other regulatory bodies, which may limit its ability to influence.

Many interviewees noted that **the way in which the regulatory body prioritises** its activities has an important influence on the safety culture of the licensee. This can have a positive impact when the regulatory body prioritises its attention on key risks and performance shortfalls. Conversely, it can have a negative impact when the regulatory body focuses on irrelevant or insignificant matters.

> *"The regulatory approaches must pay attention to risks, operational performance and outcomes, and the oversight activities should be targeted in the areas with the largest safety significance. The regulatory approaches and activities must be justifiable and fair." – Interviewee*

Similarly, the **regulatory body's decision-making** is an important manifestation of its culture and can also have a positive or negative effect on the licensee. Decisions that are objective, fair, predictable, transparent, suitably informed, and with due priority to safety, foster trust and respect with the licensee. By contrast, decisions that are biased, ill-informed, or unreasonable, create mistrust and can adversely influence the safety culture of the licensee.

Finally, the **methods and tools** used by the regulatory body are another way in which it can influence the safety culture of the licensee. At the heart of this is the balance the regulatory body strikes between the use of formal methods, e.g. inspections and assessments, and less formal methods, e.g. dialogue. The former support the public accountability of the regulatory body, while the latter can generate a stronger, positive influence on safety culture by promoting the licensee's self-awareness and sense of accountability for safety. Other important characteristics of the regulatory approach are the use of announced as well as

unannounced inspections (to counteract undue "pre-positioning" by the licensee) and the integration of regulatory intelligence to generate an overall view of the licensee's safety performance against regulatory standards. The latter can promote self-reflection and benchmarking among licensees on respective strengths and weaknesses.

The mechanisms of influence identified above are consistent with those identified by the NEA (2014 and 2016) and IAEA (2016a). They underline the importance of the regulatory regime in promoting a healthy safety culture, within both the regulatory body and licensee, and positive safety outcomes. They also reflect learning from past experience in the nuclear and other sectors, for example the Grenfell high-rise building fire in the United Kingdom (Hackitt, 2018) in which "…inadequate regulatory oversight and enforcement tools… had helped to create a cultural issue across the sector, which can be described as a 'race to the bottom…'" These elements can be considered, among other factors, as a self-reinforcing negative feedback loop.

4.1.3. *Influence of the regulatory body's capability*

Staff in the regulatory body influence the licensee, firstly, by their **technical ability**, comprising technical and regulatory knowledge, skills and experience. This supports good regulatory decision-making and creates credibility and respect for the regulatory body in the eyes of the licensee. By contrast, staff lacking technical competence can engender mistrust within the licensee, and inexperienced staff may be unduly prescriptive or overzealous in their approach.

> *"The only chance to be taken seriously by the licensee is to be technically competent. It is ineffective to act as a bureaucrat who only checks off formal aspects." – Interviewee*

The second important aspect of competence are the "**soft skills**" of regulatory staff, e.g. communications skills and emotional intelligence. These enable professional, respectful working relationships between staff in the regulatory body and licensee and support resolution of difficult problems, enabling a positive influence on safety culture.

Other important aspects of staff competence in the regulatory body are their knowledge and situational awareness of the context and challenges of the licensee, and their understanding of the practical implications of implementing regulatory expectations. As above, these can help build credibility and respect, and motivate the licensee to respond positively to the regulatory body's expectations.

> *"When you see what a regulatory requirement can trigger, that it can have massive repercussions, then the regulatory body must be aware of its responsibility and ask itself 'What are we triggering in the plant?' Every requirement costs money and binds resources, in the regulatory body as well as the licensee. You have to think about where to put the resources in the interests of risk management." – Interviewee*

In addition to competence, the other dimension of capability is **resources**. It is important that there is alignment between the regulatory body's priorities and the resources available to put them into effect. Furthermore, the regulatory body should balance reliance on its own resources with access to **independent sources of expertise**. This ensures that the regulatory body maintains its technical independence, while being open to new developments in knowledge. In turn, this means that the regulatory body can scrutinise the licensee's proposals authoritatively and efficiently.

The final aspect of capability that is important is the regulatory body's **knowledge management** practices. By sharing good practice and learning both internally and externally, the regulatory body can maximise its ability to positively influence safety culture within licensees. Similarly, the regulatory body's willingness to engage in collaborative research, at a national and international level, enhances both its own knowledge and that of the licensee.

The importance of regulatory capability is reflected in the work of Bradley (2017), who identified a "*commitment to technical excellence*" as a cultural strength of regulatory bodies. It also aligns with one of the key findings of the official investigation into the Macondo oil spill, namely that the regulator's "*…ability to regulate safety is contingent upon adequate numbers of staff*

with multifaceted competencies in not only technical disciplines, but human and organisational factors, communication and interpersonal skills such as negotiation, persuasion and advocacy" (U.S. Chemical Safety and Hazard Investigation Board, 2016). The previous report in this series (NEA, 2021a) identifies the methods by which regulatory bodies can build knowledge and awareness of safety culture – both as a matter of regulatory oversight and self-reflection.

4.1.4. *Influence of the regulatory body's leadership and management*

Staff at all levels in the regulatory body influence the safety culture of the licensee not only by what they say, but by what they do, e.g. their decisions, actions, priorities and behaviours, and the degree of alignment between the two. It is imperative that managers in the regulatory body recognise the influence that the regulatory body has on the safety culture of the licensee and set clear expectations for the regulatory approach and behaviours of staff. They should **lead by example**, support staff, recognise good behaviour and correct poor behaviour where appropriate. The prioritisation and timely resolution of issues raised by inspectors, following a graded approach, is an important characteristic of managers in the regulatory body and supports a positive safety culture. Underpinning their credibility, managers should be competent in their role but also recognise the limits of their competence and when to draw on expertise elsewhere in the organisation.

> *"Leaders in the regulatory body need to create a positive work environment with a clear, shared focus on safety, where there is trust, respect and open dialogue helping to enhance safety culture. Dialogue must be maintained at all levels before decision-making, while understanding each other's role and the decision-making lines and responsibilities. This also creates a perception of trustworthiness in the regulatory body and impacts the licensee's behaviour. When the regulatory body is perceived as dysfunctional, the impact on the licensees can be negative." – Interviewee*

The fundamental role that leaders play in creating and shaping culture was highlighted in the official investigation into the Boeing 737 MAX crashes. That report noted a key takeaway from a safety culture survey conducted by the U.S. Federal Aviation Authority (FAA) that "[FAA] *senior leadership's response to and management of industry pressure is at the heart of the organisation's core safety culture challenges: lack of trust, inconsistent accountability, FAA role confusion, and the perception that…[FAA] is moving further away from its safety mission"* (U.S. House Committee on Transportation and Infrastructure, 2020: 241) The NEA, in *Practices for Enhancing Leadership for Safety in Nuclear Regulatory Bodies* (NEA, forthcoming) sets out in more detail the characteristics, competencies, values and behaviour of leaders in a regulatory body which has a healthy safety culture (NEA, forthcoming).

Management systems and safety culture have a mutual dependence in any organisation (IAEA, 2016b; IAEA, 2019). Therefore, by following a systematic, graded approach to its regulatory activities, aligned to relevant good practice, the regulatory body will enhance its own safety culture and in turn have a positive impact on the safety culture of the licensee. Conversely, a dysfunctional regulatory body sets a poor example and will have a negative impact on the licensee. As part of its management arrangements, it is important that the regulatory body plans its work realistically, aligned to its regulatory strategy and priorities, taking due account of uncertainties. This provides the basis for constructive engagement with licensees, including managing expectations and mitigating undue time pressure on staff in either organisation.

> *"It's essential that the regulatory body has consistency in the implementation of its policies and practices, and that it does things according to an integrated management system, which is the backbone of its work." – Interviewee*

> *"When the licensee asks the regulatory body 'What do you do?', the regulatory body has to show that it is also making its own effort, e.g. by developing and implementing a mission statement or a management system." – Interviewee*

4.1.5. *Influence of the regulatory body's communications*

The **structure and format of communications** between the regulatory body and licensee have an important influence on safety culture (see also Section 4.1.8 concerning the regulatory body's ability to learn and improve). Regular, two-way communications at all levels between the regulatory body and licensee promote a consistent approach, allow expectations to be promulgated by management and issues to be addressed at the most appropriate level (strategic or technical). Lack of such a structure risks inconsistency, inefficiency, and ineffectiveness in the relationship between the regulatory body and licensee. Additionally, escalation of issues without proper dialogue first between those accountable can create mistrust.

> *"I believe that one main element of a good safety culture influence from the regulatory body is that the licensee trusts, respects, and understands the regulator. That's why we need to have frequent dialogue." – Interviewee*

Similar to the point made above (see Section 4.1.2, "Influence of the regulatory regime"), it is important that the regulatory body strikes a balance in its approach between formal communications with the licensee, e.g. meetings with the licensee that are open to the public, formal reports, decisions and letters to the licensee that are publicly available etc., and less formal communications, e.g. "closed door" meetings with the licensee (not open to the public) and informal e-mail exchanges. Formal communications support the regulatory body's transparency and accountability to the public, but do not necessarily encourage open and frank exchange of information between the two organisations. This can lead to the gradual distancing of relationships and "ratcheting" of regulatory action. This is particularly the case in some countries where discussions between the regulatory body and licensee are broadcast live, which can impact psychological safety and the effectiveness of interactions. By contrast, less formal communications allow issues to be aired by both parties, in turn generating better understanding and a greater chance of the issues being resolved, ultimately leading to a more trustful relationship. However, excessive use of such informal interactions risks undermining the independence of the regulatory body and may cut across each organisation's formal processes.

> *"The most effective safety culture interaction is that informal conversation when the regulatory body is not there to carry out a stated inspection against a particular standard. What I welcome from our regulatory bodies is actually more frequent, less formal interactions. The formal processes, great, but I think its impact on safety culture is actually less." – Interviewee*

Early engagement between the regulatory body and licensee is particularly beneficial in authorisation activities, e.g. licensing and certification. Such engagement helps clarify regulatory expectations and enables assumptions or misconceptions on both sides to be unravelled.

Aside from structure and format, the **content of communications** is equally important. By consistently and regularly communicating its requirements, decisions, plans and priorities, together with the supporting rationale (the "what" and "why"), the regulatory body promotes understanding of its approach among licensees and other stakeholders and can address queries and challenges. Without the "why" element in particular, the licensee may perceive arbitrariness or irrationality in the regulatory body's approach, making it more resistant to regulatory findings and weakening trust.

> *"If the regulatory body wants and requires something, it is important that it communicate clearly. Open communication helps, with clear goals. If the licensee also understands it, the acceptance is there. 'Because the regulator wants it' is not a good explanation. The regulatory body has to explain why it wants something." – Interviewee*

In addition to communications between the regulatory body and licensee, **communications between the regulatory body and the public** are also relevant in this context. By publishing the outcomes of its activities in a clear, accessible format, the regulatory body promotes transparency and greater public understanding of its activities and decisions. Clarity is key, and a focus on only the technical rationale may generate misunderstanding or suspicion. Several interviewees spoke of the benefits of the regulatory body engaging in broader communications with the public on its activities and impacts in the industry. The licensee benefits from the public being assured of the independent scrutiny applied by the regulatory body.

"In the public and political sphere, having the supervisory authority also helps us. It gives us a safety net. We are not directly exposed to the wind. We can say we are monitored. It shields us to some extent. It fosters trust, the knowledge that there is an independent supervisory authority watching our backs." – Interviewee

Open and candid communication between the regulatory body and industry, as well as other stakeholders, is among the attributes identified by Bradley (2017) as contributing to a learning culture between the respective organisations. The current findings are also mirrored in the study by Durbin (2013) that identifies the regulatory body's communications as a factor significantly impacting its effectiveness, irrespective of the particular regulatory approach used (outcome-based, prescriptive, etc.).

4.1.6. *Influence of the regulatory body's relationships with the licensee and other stakeholders*

Interviewees explained that having a common understanding and shared goal on safety is fundamental to an effective working relationship between the regulatory body and licensees. The interviewees were also consistent in identifying the main **characteristics of an effective working relationship** between the regulatory body and licensee as follows:

- Trust;
- Professionalism;
- Fairness;
- Mutual respect;
- Openness, honesty and transparency;
- A questioning attitude; and
- Self-reflection and learning.

Trust was described by interviewees as two-way. The licensee must be able to trust the regulatory body's decision making, e.g. that it responds proportionately to a reported non-compliance. The regulatory body must in turn be able to trust that the licensee responds "in the right way" to its expectations, i.e. in a way that is sustainable and strengthens safety culture, not merely fulfilling requirements. However, too much trust can be problematic for the regulatory body, which must retain its independence of view and questioning attitude to satisfy its accountability to the public.

"It is important to trust each other. If a staff member of a regulatory agency thinks that a certain person at a business is trustworthy, the discussion will be more active, and the conversation will be more engaging. The question is how to build a relationship of trust." – Interviewee

The characteristics set out above promote constructive, co-operative working relationships between the regulatory body and licensee, enabling difficult issues to be addressed in the interests of continuously improving safety culture and safety performance. By contrast, suspicion, arrogance or defensiveness in the relationship have a detrimental impact. Positive personal relationships between staff in each organisation are desirable but should not stray into inappropriate fraternisation ("*friendly but not friends*", as described by one interviewee).

"It's about creating a respectful work environment, which includes trust in each other, as one is not a 'robber' and the other not a 'cop', but professionals who can speak objectively about technical issues." – Interviewee

"Regulators must respect that licensees are knowledgeable in their field … intimidation and table-pounding are not good. It sets up an adversarial position. We are the regulator and need to be independent, but we also need to be respectful." – Interviewee

If relationships are important, then taking the **time to build and maintain these relationships** is also important. Again, the regulatory body needs to strike a balance in its approach. Inspectors in the regulatory body need time to build relationships before they

become fully effective, but equally too long a time in a particular role can lead to "regulatory capture," in which the inspector begins to lose objectivity.

Alongside effective working relationships with licensees, the regulatory body needs to maintain **effective working relationships with a range of other stakeholders**, e.g. unions and non-governmental organisations. This demonstrates openness, invites challenge and ultimately builds confidence in the regulatory approach.

The nature of the relationship between regulatory bodies and duty holders is a feature of the literature reviewed for this study (Annex A). Black (2014) reviews several events in which the regulatory body, in seeking a co-operative relationship with the duty holder, was "*insufficiently interrogative of information*", "*slow to take action,*" and in one case "*simply too trusting*". The need for the regulatory body to balance its independence and openness towards the licensee is identified as one of the challenges in the NEA's ten-year report on the Fukushima Daiichi Nuclear Power Plant accident, which proposes that

> …such [a] balance can and should be achieved through multilateral and bilateral, public and non-public engagement between the regulator and external stakeholders, including nuclear industry representatives; care must be taken to conduct bilateral engagements with any stakeholder in a manner that avoids or minimises the perception of bias or compromise. (NEA, 2021b: 56)

4.1.7. *Influence of the behaviour of the regulatory body's staff*

The **behaviour of staff in the regulatory body** represents one of the most direct means by which the regulatory body influences the safety culture of the licensee. Staff whose behaviours consistently espouse the value of safety have a correspondingly positive effect on the licensee. Likewise, staff who promote the licensee's sense of self-awareness, e.g. by asking about internal oversight and self-correction activities, promote the licensee's sense of accountability for safety, in turn reinforcing its legal obligations and minimising dependence on the regulatory body.

> *"It is foundational that licensees themselves find the minor event and its causes at the site and correct it by themselves. At the nuclear power plant, there were cases where the inspector identified such events. When I exchanged opinions with the power plant manager, I was told that he was remorseful about why the licensees could not find such events themselves, and that he would like to consider the cause and respond. I think that the awareness from inspectors, and giving new awareness through such an approach, leads to improvement in a positive direction." – Interviewee*

As discussed above (see Section 4.1.2, "Influence of the regulatory regime"), by focussing more on outcomes and less on the detail of how the outcome is to be achieved, the regulatory body enables innovation in the licensee and new paths to compliance. Conversely, seeking to impose detailed requirements stifles innovation and may be unhelpful or ineffective. Interviewees emphasised that a regulatory body that highlights good practices as well as identifying deficiencies is likely to be more effective in positively influencing safety culture in the licensee. Similarly, when shortfalls are found, a regulatory body that encourages the licensee to address root causes and similar conditions elsewhere in its organisation, beyond merely complying with the letter of the law, promotes a culture of "*doing the right thing*".

> *"There is a positive impact of the regulatory body in reinforcing what the licensee does well, including innovation or going beyond the requirements. It even helps to understand and contextualise the regulatory body's role when identifying negative aspects." – Interviewee*

Interviewees highlighted that the mere existence of the regulatory body and its presence on nuclear sites – in other words, what it says and does and what it does not say and do – has an influence on the safety culture of the licensee. Regulatory staff who maintain **visibility** throughout a licensee organisation (at a senior level and at the working levels), encouraging safe behaviour as well as checking compliance, are more likely to have a positive impact.

"Regulatory body staff influence licensee staff by being in and around the station, e.g., by being out and about, in meetings with licensee staff, and attending training with licensee staff. The regulatory body's presence can result in the licensee adjusting their 'safety glasses'." – Interviewee

"The regulatory body should talk to the licensee in terms of safety, not in terms of regulations. Dialogue should be based on observations or inspections that have a nexus to safety, not just that you violated a regulation." – Interviewee

Finally, a fundamental way for regulatory body staff to positively influence the licensee's safety culture is to take the time to understand and **comply with the licensee's own safety arrangements** – as well as those of the regulatory body – questioning and challenging where necessary.

4.1.8. *Influence of the regulatory body's ability to learn and continuously improve*

The final factor determining the regulatory body's influence on the safety culture of the licensee is its **ability to learn** from its own experience and that of the licensee and others and continuously improve. By implementing systematic arrangements within its own organisation to identify and act on learning opportunities, and expecting the same of licensees, the regulatory body promotes a culture of continuous improvement in safety. It is important that the regulatory body regularly reflects on and assesses its own culture, including its impact on the safety culture of the licensee and the regulatory body's effectiveness in delivering its objectives and priorities. In so doing, it should gather feedback from within its own organisation as well as from licensees and other stakeholders in the system.

The methods by which the regulatory body can carry out safety culture self-reflection and self-assessment activities were the subject of the NEA's 2021 report, which provides an overview and practical examples of such methods (NEA, 2021a). These include key features and lessons learnt in their application. By cultivating an ability to learn, the regulatory body can detect signs where its influence on the safety culture of the licensee may be negative and take appropriate corrective action.

"We need to have an ongoing discussion with licensees about how they see the effectiveness of our oversight work – and what areas of our oversight work are viewed as the most effective." – Interviewee

"Getting examples out there of where the regulator has taken some learning from experience and changed how it does things. It's useful to get that out there to the license holders. The more that the regulator can show that it's receptive to challenge and, when there's an opportunity to change something because it's the right thing to do, it does it. I think that's a good thing to do." – Interviewee

Interviewees identified that it is important for the regulatory body to have in place methods by which anyone can raise concerns about safety, or the conduct of the regulatory body, and for those concerns to be properly addressed. This is an essential feature of public bodies in many countries and provides an important source of intelligence for the regulatory body in carrying out its functions, including positively influencing safety culture in the licensee, over and above the reporting systems that licensees themselves should have in place.

Finally, it is important that the regulatory body is open to learning through participation in national and international activities such as the development of standards, research, benchmarking and peer review. This will enhance the safety practices of both the regulatory body and licensee.

"What I experienced was the activity of a consultative body (a learning and research council). It is used as a venue for active information exchange between the regulatory body and operator. As a result, it can be said that it has a positive effect on safety culture by exchanging information about safety issues actively and transparently."

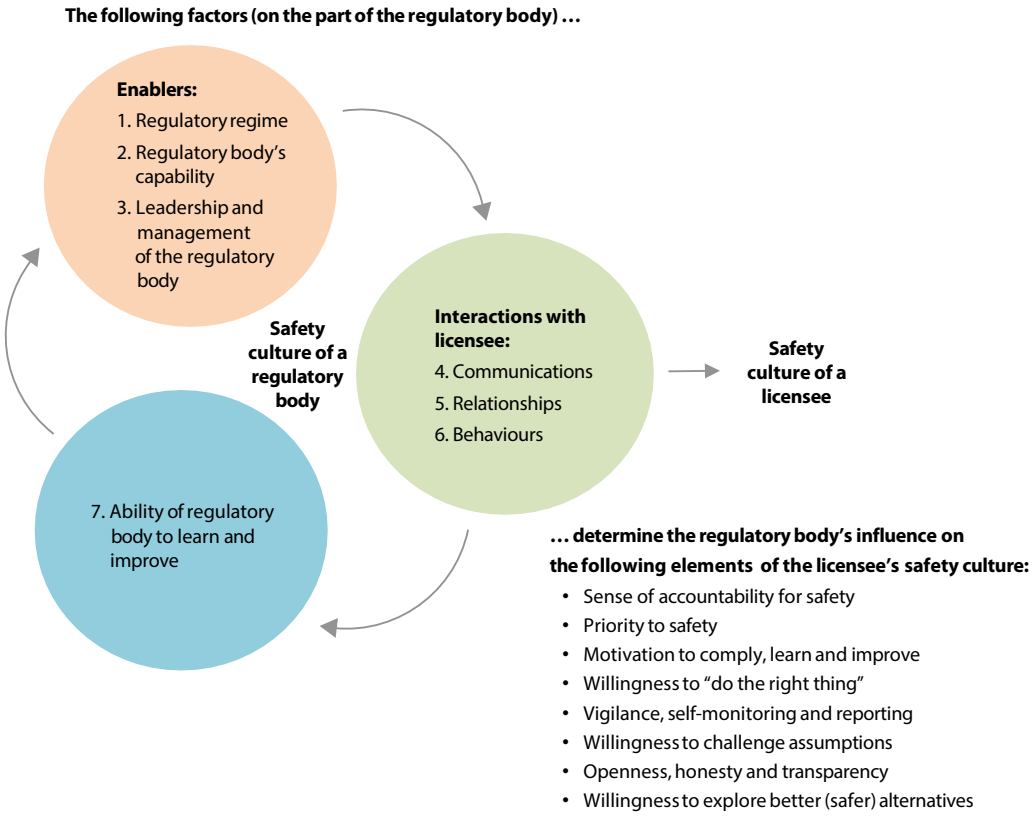
The ability of the regulatory body to learn and improve is a common feature of existing frameworks for regulatory safety culture. For example, Bradley's (2017) research indicates the need for the regulatory body to both gather and leverage data and intelligence from external stakeholders, e.g. industry members, associations and other regulators, and share data and intelligence with the same stakeholders.

4.1.9. *Summary*

This section has identified seven principal factors that determine the regulatory body's influence on the safety culture of the licensee. These factors are consistent with the traits and attributes of a healthy safety culture for the regulatory body (NEA, 2016) and for licensee organisations (IAEA, 2006; IAEA, 2020) and extend further by explaining how the former influences the latter, based on the experience of senior practitioners in nuclear regulatory bodies and licensee organisations worldwide.

The interview data indicates that there is a relationship between the factors identified. Factors 1, 2 and 3 (respectively, the regulatory regime; the regulatory body's capability; and the leadership and management of the regulatory body) are enablers of factors 4, 5 and 6 (respectively, the communications, relationships, and behaviours that characterise the interactions between a regulatory body and licensee), while factor 7 (the regulatory body's ability to learn and improve), in affecting factors 1, 2 and 3, determines whether there is a positive (upward) or negative (downward) spiral in the influence that takes place. These factors combine to influence the safety culture of the licensee. In particular, these factors influence the licensee's sense of accountability for and priority given to safety, and its motivation to comply, learn and improve. This is summarised in Figure 4.1 below.

Figure 4.1. **Summary of the mechanisms of influence of the regulatory body on the safety culture of the licensee**



4.2. Mechanisms of influence of the licensee on the safety culture of the regulatory body

4.2.1. *Overview*

The nuclear regulatory body influences the safety of the installations and the licensee's safety culture. This is a matter of course, and the interviewees were able to illustrate this influence with many examples. In contrast, the influence that the licensee exerts on the regulatory body's safety culture is not as obvious and presumably also more subtle. Nevertheless, investigations of major events like the Fukushima Daiichi and the Boing 737 MAX accidents showed such influences.

The interviewees often stated that they had not thought in depth about how licensees influence the safety culture of the regulatory body. Some interviewees from the licensee's side pointed out that they did not know the regulatory body and its organisational culture well enough to be able to make a statement about it.

In addition, the regulatory body has the formal power to influence the licensee's actions. A licensee has no such formal power over the regulatory authority. Its influence is therefore informal and stems more from its actions. Thus, a licensee mainly influences the regulatory body's safety culture by the way it communicates and reacts to the regulatory body's actions.

The licensee often has a direct effect on the way that the regulatory body performs its tasks like rulemaking, communication and oversight. The interviewees gave some examples of this. In contrast, they gave fewer examples of how licensees perceive their influence on the regulatory body's safety culture. For them, it was easier and more tangible to talk about the influence on action than about the influence on structures, values, or assumptions.

As shown in Section 4.1, analysis of the interview data has provided significant insight on how the regulatory body influences the safety culture of the licensee, with an overview in Table 4.1. The main factors which determine the licensee's influence on the safety culture of the regulatory body are similar and are listed in Table 4.2. However, the identified sub-elements of those main factors are fewer in number and slightly different because of the reasons mentioned above.

Table 4.2. **The factors which determine the licensee's influence on the safety culture of the regulatory body**

Main factors	Sub-elements
1. The regulatory regime	1.1 The regulatory framework: its design, development and implementation 1.2 The roles, responsibilities, accountabilities and authorities allocated to the regulatory body and licensee 1.3 The impact on the independence of regulatory body
2. The licensee's capability	2.1 The competence of the licensee's staff
3. The licensee's leadership and management	3.1 The capabilities and practice of the licensee's leaders 3.2 The licensee's structures and processes
4. The licensee's communications	4.1 The structure and format of the communications between the regulatory body and the licensee 4.2 The feedback provided by the licensee

Table 4.2. **The factors which determine the licensee's influence on the safety culture of the regulatory body** *(cont'd)*

Main factors	Sub-elements
5. The licensee's relationship with the regulatory body	5.1 The relationship building between the regulatory body and licensee 5.2 The characteristics of the relationship 5.3 The collaboration between the licensee and the regulatory body
6. The behaviour of the licensee's staff	6.1 The behaviour of the licensee's staff 6.2 The licensee's response to the regulatory body's oversight methods and tools
7. The ability of the licensee to learn and improve	7.1 The ability of the licensee to learn and improve from its own experience 7.2 The ability of the licensee to improve its interaction with the regulatory body

The interviews highlighted how the above factors are related and how they influence the safety culture of the regulatory body. These "mechanisms of influence" identified in this study are described in the following Sections 4.2.1 to 4.2.8. In Section 4.2.9, the effects of the seven factors are summarised by emphasising in which respect the safety culture of the regulatory body is affected.

4.2.2. *Influence of the regulatory regime*

The **regulatory regime** is established mainly by the regulatory body and as shown in Section 4.1, it influences the safety culture of the licensee. An influence in the reverse direction on the safety culture of the regulatory body is provided through joint development or commenting on regulations. In this way, the licensee can contribute to a clear and predictable regulatory regime.

The priorities of the regulatory body were also identified above as an influencing factor on the licensee's safety culture. Again, this is not one-way. The behaviour and safety performance of the licensee also feed back into the prioritisation of the regulator. Furthermore, determining the right balance between a prescriptive and a goal-setting approach is influenced by the behaviour of the licensee. The regulatory body adapts the regulatory regime to the licensee's behaviour and performance. Significant events may even lead the regulatory body to fundamentally adjust the regulatory regime.

> *"In the case of the Fukushima Daiichi accident, for example, there were many aspects that the licensee got wrong in decision making, design change, and response. It has influenced not only Japan, but also the world, and has had a great influence on our country as well. Looking at it like that, I think that licensees' decisions and such things have a huge impact on the regulatory organisation of course." – Interviewee*

As stated above, the **allocation of roles, responsibilities, accountabilities and authorities** between the regulatory body and the licensee is an important feature of the regulatory regime. The accountability for safety should rest with the licensee. The interviews showed that this fundamental distinction between accountability for safety on the side of the licensee and the task to oversee if and how the accountability is discharged is well understood. However, in practice licensees may seek to shift accountability, e.g. by saying that they do things in a certain way because the regulatory body required it. They may influence the role perception of the regulatory body by discussing issues in order to get advice, or by adopting a reserved attitude in order to receive strict instructions.

> *"We [the supervised organisations] can make life easier or harder for you [regulatory body]. We could absolutely just always do the minimum and delegate the responsibility. That would cause you to watch very closely. If the authority sees that we are proactive, trying to achieve higher standards out of our own motivation, it is easier for the authority." – Interviewee*

By knowing and accepting the different regulatory roles, a licensee can support the discharging of them in a positive sense, e.g. supporting the public communication role by providing adequate information in due time. On the other hand, unjustified reference to confidentiality obligations can impair the communication role of the regulatory body. The interviewees gave several examples of how, in a given situation, the actions of a licensee and its interactions with the regulatory body trigger which roles the regulatory body considers important and how it fulfils its responsibilities. By flexible adaptation to the licensee's behaviour, the regulatory body can adjust its oversight of each licensee. The different roles of the regulatory body may cause ambiguities or misunderstandings, e.g. whether it communicates advice or a requirement. Through knowledge and understanding of the regulatory body's roles and responsibilities, a licensee can articulate ambiguities and consequently create clarity on the side of the regulatory body. Thus, in sum, a licensee can positively influence the regulatory body's safety culture in the way that the regulatory body adapts its regulation and ensures role clarity.

The **independence of the regulatory body** and its strict focus on safety is a central component of the regulatory body's safety culture. Licensees benefit from having an independent regulatory body. For example, this creates public confidence and protects the licensees from unjustified accusations. However, licensees can also impair the regulatory body's independence in different ways. Emphasising financial conditions and economic goals can distract the regulatory body from safety issues. Its decision-making can be put under pressure by unreasonable deadlines. Engagement in social activity between staff in the licensee and the regulatory body may impair an independent evaluation of inspection findings. A licensee may put pressure on the regulatory body's staff by threating to complain to the government that the regulatory body hinders business activities, thus causing political pressure on the regulatory body. The importance of the regulatory body's independence, stability and reliability is reflected in the work of Bradley (2017). External pressure or relations impairing these aspects may increase the politicised mission of the regulatory body, which is a vulnerability for its safety culture.

4.2.3. *Influence of the licensee's capability*

The licensee's staff strongly influences the regulatory body through their **knowledge and experience**. They can help the regulatory body to better understand the safety issues and inform its activities, priorities, or decision making. Licensees may help the regulatory body to understand new upcoming technologies. Inspectors taking training offered by the licensee learn much about the technology of the nuclear plant and the plant-specific operating procedures.

> *"Resident inspectors take a lot of training offered by the licensee and understand their processes and human performance tools and you learn a lot about safety from the licensee. And that rubs off on how we do our own work." – Interviewee*

Additionally, a high level of competence on the part of the licensee generates appreciation, respect, and trust on the part of the regulatory body. For example, documents from organisational units that are known as competent are more easily accepted by the regulatory body. Thus, the depth and intensity of regulatory oversight is affected by the licensee's competence.

Interviewees from regulatory bodies acknowledged that licensee personnel naturally have more plant-specific knowledge and experience. Nevertheless, they considered that the regulatory body should not merely trust, but should ask questions until fully understanding the issue. Overall, competently conveyed information from the licensee promotes the regulatory body's understanding and improves its capabilities and activities. It supports the common goal to resolve conflicts on the basis of sound technical arguments and not in legal proceedings.

> *"We want to talk to each other directly and on a technical level, not via lawyers." – Interviewee*

In sum, high competence on the part of the licensee can foster the regulatory body's technical excellence – a cultural strength according to Bradley (2017). However, it also brings the risk of reducing the regulatory body's critical questioning attitude.

4.2.4. *Influence of the licensee's leadership and management*

Leadership behaviour and management processes are crucial to developing and sustaining a healthy safety culture. Therefore, regulatory bodies include such aspects in the framework of their oversight activities. In doing so, the regulatory body recognises good and negative practices of the licensee and can transfer them to itself. Notably, the contacts between leaders from the regulatory body and licensee can influence their respective leadership behaviour and organisational cultures.

Events in the nuclear industry as well as in other high-risk sectors (see Section 3.1) have demonstrated the importance of safety-oriented **structures and processes** and of safety culture. This has led to increased oversight in those areas. Regulatory bodies have increased resources for oversight on safety management and safety culture, which has also enhanced the self-reflection within their own organisation and the capability to improve their own safety culture. In this way, the analysis of events and the oversight of the licensee's leadership and management feeds back to the regulatory body's safety culture. The regulatory body recognises the need to reflect its influence and to enhance its own safety culture.

> *"In order to conduct regulatory oversight on the safety culture of operators, it is necessary not only to input the corresponding regulatory resources, but also to enhance the safety culture within the regulatory body." – Interviewee*

In addition, good structures or processes in the licensee to interact with the regulatory body support the regulatory body's safety culture, e.g. a strong focus by the licensee on safety causes inspectors to pay amplified attention to safety as well. The regulatory body's management and staff develop knowledge of different licensees and learn from examples of good processes for their own organisation.

Finally, strong safety assurance processes in the licensee affect the depth and intensity of the regulatory body's oversight and its regulatory approach, as is illustrated in the following observation:

> *"If licensees have really strong peer review processes, internal assurance processes, nuclear safety committees etc. – internal governance is very safety focused, robust and you can see it works well – this really does have an impact on us [the regulatory body] because it enables us to almost step back a little in some areas." – Interviewee*

4.2.5. *Influence of the licensee's communications*

Many interviewees pointed out the high importance of trustful communication between the licensee and the regulatory body. All opportunities should be used for open exchange of information and opinions. Discussions at different hierarchical levels are helpful. However, care should be taken to ensure that the information is also passed on within the respective organisations.

> *"By talking with various inspectors, we can understand each other's thoughts. It is important to express the operator's thoughts to the regulator in this process." – Interviewee*

> *"When they [the licensee] influence the regulatory body at the high-level management and bypass the staff of the regulatory body it can also influence the safety culture negatively in the regulatory body." – Interviewee*

An **open dialogue** helps to better understand and support the mutual perspectives, roles and accountability of the regulatory body and licensee. The licensee recognises the information needs of the regulatory body and can provide appropriate data. Submitting plans and priority lists from the licensee helps the regulatory body with its workload and in its way

of working. Exchange of expectations and boundary conditions help to avoid undue time pressure and a negative influence on safety. A mature, trustful relationship supports early and proactive provision of relevant background information (e.g. from licensee's internal discussions) and helps to cope with difficult developments, e.g. organisational changes in connection with decommissioning and dismantling.

> *"The more the licensee talks openly and has open discussions with the regulator, it will have a more positive impact on the regulator's understanding of safety culture as it pertains to operating plants, and it just adds to a healthier relationship between the regulator and the licensee." – Interviewee*

The licensee's feedback concerning regulatory approaches and practices stimulates improvements and fosters the regulatory body's safety culture. Such feedback indicates whether the messages of the regulatory body are understood, helps to adjust the oversight, and enables effective regulation. In the same way that the regulatory body influences the safety culture of a licensee, a licensee can encourage the regulatory body's learning and improvement by giving feedback, asking questions, promoting good practices, and being an example.

> *"The best way they [licensees] can influence us [the regulatory body] is feedback on how they have been regulated." – Interviewee*

> *"It could have a positive impact on the regulatory body if the licensee asks questions […] eager to understand [the decisions of] the regulator." – Interviewee*

The statements made in the interviews highlighted that frank discussion and communication promote understanding, familiarity and trust. An atmosphere of open exchange enables the licensee to give constructive feedback to the regulator. Such feedback helps the regulatory body to adapt and improve the regulatory regime and methods. In doing so, the licensee can foster the learning culture of the regulatory body. By contrast, inappropriate information or dominant and demanding communication by the licensee impairs the openness and trust of the regulatory body. Such behaviour by a licensee may lead to a formal, compliance-oriented approach by the regulatory body.

4.2.6. *Influence of the licensee's relationships with the regulatory body*

Through frequent contacts in meetings as well as during inspections, openness and trust can grow between the people involved. Such **relationship building** needs time and space in meetings or less formal conversation during inspections. Trust built between individuals radiates out to their colleagues and organisations, and thus contributes to trustful co-operation between the regulatory body and the licensee that even outlasts the individuals' terms of service. However, caution and clarity are also necessary so that a good relationship is not confused with fraternisation.

> *"Where there's a good relationship between two people, one in the regulator and one in the licence holder, you tend to find that there's a more open and trustworthy dialogue happening. And as a result of that, there is opportunity to work with each other and help shape outcomes. But still doing it in a safe and secure way." – Interviewee*

Openness and trust on the side of the licensee leads to openness and trust on the side of the regulatory body, and vice versa. On the other hand, an arrogant, criticising, or overconfident attitude by the licensee causes rejecting or distancing behaviour on the part of the regulator. A licensee withholding information or limiting it to what is explicitly requested creates mistrust and an increasingly formalistic approach from the regulatory body. Thus, both sides must pay attention to the relationship so that it is positively strengthened and does not become a vicious circle of mistrust.

> *"For our safety culture, it is important that we have a trustful regulatory body that respects our responsibility for safety. We can foster this trustful relationship by open and timely communication and by believing in our strength, i.e. that we are good and have nothing to disguise." – Interviewee*

A special kind of relationship building is achieved through **collaboration** in joint efforts. Interactions between regulatory body and licensee personnel in common activities like training events, symposia, committees for technical regulations or joint disaster drills increase knowledge and promote mutual understanding. Thus, collaboration is a means by which the licensee influences the regulatory body's safety culture via improving the competence and the quality of its activities. Through questions and in-depth discussion, the regulatory body's staff can expand their own knowledge while maintaining a detached, critical approach in accordance with their oversight function.

4.2.7. *Influence of the behaviour of the licensee's staff*

In Section 4.1, it was shown that the behaviour of the regulatory body's staff exerts a major influence on the safety culture of the licensee. Conversely, the **behaviour of the licensee's staff** also has an impact on the safety culture of the regulatory body. A questioning attitude, focus on safety, learning from best practices, and conservative decision making by the licensee impact the regulatory body's response and attitudes towards the licensee. Free access for the inspector and the possibility to speak to everyone in the plant improves communication in a positive way. Openly presenting and not hiding issues and informing the regulatory body about internal discussions and processes increases the regulatory body's confidence and trust and allows it to reduce its oversight intensity.

By contrast, a licensee's poor work and outcomes lead to unnecessary effort or time pressure on staff in the regulatory body. A rude, obstructive, or aggressive attitude on the part of the licensee's staff may lead to a more prescriptive response. When licensee staff repeatedly undercut requirements, the regulatory body loses faith in them and acts more strictly.

> *"Secrecy and hiding of problems on the licensee side promotes lack of confidence and suspicion on the part of the regulatory body, leading to a more prescriptive approach, and creating in the regulatory body a culture of mistrust and antagonism between organisations." – Interviewee*

The way in which licensee staff **respond to the regulatory body's oversight methods and tools** impacts directly on the regulatory body's staff. It may increase trust and reduce the oversight intensity and approach, or it may cause the regulatory body to act more formally and strictly. Thus, the licensee's response provides feedback and learning potential for improving regulatory practices. In reflecting on its regulation and oversight approach, the regulatory body should make sure that single negative cases are not overestimated. In the case of poor licensee behaviour, the regulatory body may tend towards a more prescriptive approach. This may cause licensee behaviour that itself is oriented towards solely fulfilling prescription instead of striving to improving safety. Therefore, a special challenge is to avoid entering a prescriptive compliance spiral, but rather instead to enable the licensee to become a learning organisation.

4.2.8. *Influence of the licensee's ability to learn and continuously improve*

The ability to learn and continuously improve is a key characteristic of a healthy safety culture. Developments and changes on the licensee's side challenge and support learning in the regulatory body in order to stay up to date. The methods of self-reflection and self-assessment to cultivate and improve a questioning attitude, focus on safety, learning from best practices, conservative decision making, etc., of the licensee form a role model for the regulatory body. Both the regulatory body and licensee can learn from the practices and experiences of each other.

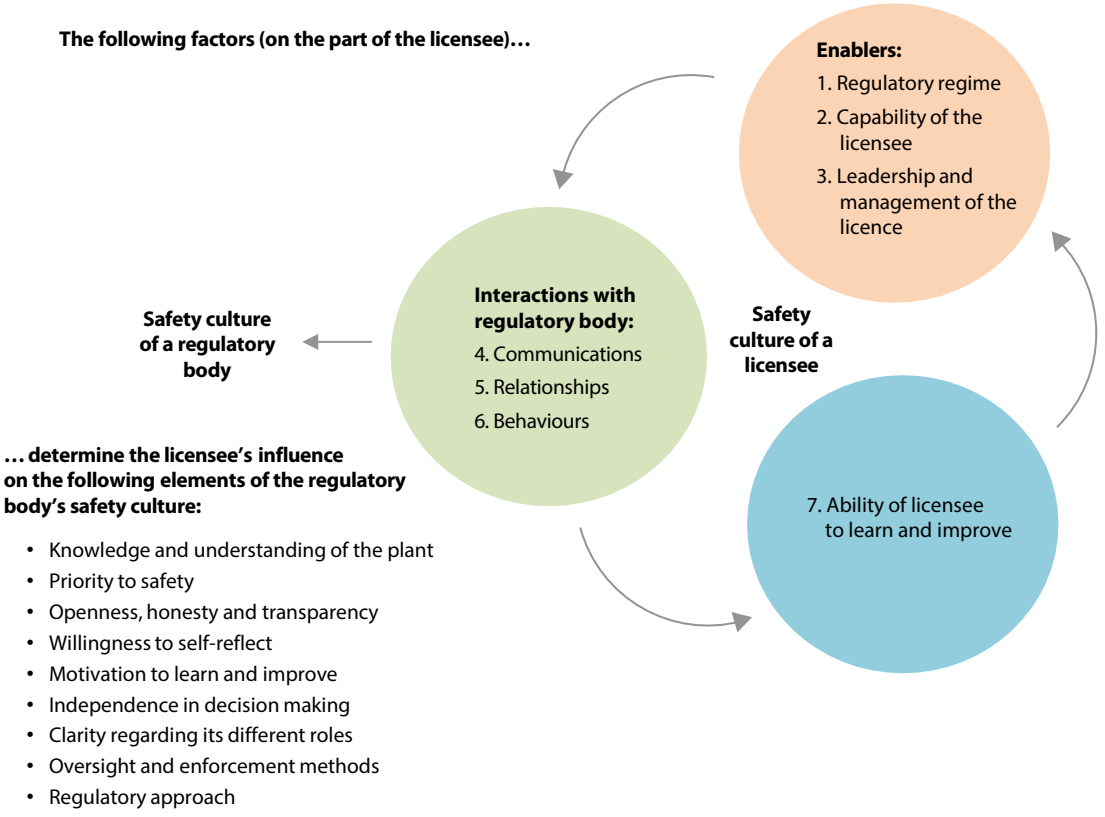
> *"If we create a system to praise and share each other's good practices regarding safety culture, I think it will contribute to the nuclear safety culture." – Interviewee*

With its arrangements to learn and continuously improve, the licensee uses insights from its interactions with the regulatory body to improve its structures, capabilities and processes. The licensee recognises ways in which to influence the regulatory body's safety culture, e.g. by giving feedback, asking questions, and promoting good practices.

4.2.9. *Summary*

In this Section 4.2, the ways in which the licensee influences the safety culture of the regulatory body were described. The information from the interviews was structured according to the same factors as in Section 4.1. The main influences identified were the communications, relationships and behaviours between the licensee and the regulatory body. These have an immediate and direct effect on the regulatory body's staff, and they affect the regulatory body's safety culture as well. Of course, it is not only the effect of a single interaction, but rather the totality of interactions with many individuals from various licensees that exerts a formative influence on the regulatory body's safety culture. The licensee's capability, its leadership and management, and its contributions to the regulatory regime build the framework and support the licensee's interactions with the regulatory body. They act as enablers of effective and transparent communications, relationships and behaviours between the licensee and regulatory body. Furthermore, the licensee's ability to learn from such interactions determines whether there is a spiral of continuous improvement in the way that it positively affects the safety culture of the regulatory body (Figure 4.2).

Figure 4.2. **Summary of the mechanisms of influence of the licensee on the safety culture of the regulatory body**



The description of factors and sub-elements above showed how they affect the regulatory body's safety culture. These factors affect the depth of the regulatory body's knowledge and understanding of the nuclear installation. Furthermore, they inform priority setting and assigning the necessary attention to safety. They determine the openness, honesty and transparency of the regulatory body's interactions and willingness to self-reflect. The motivation of the regulatory body's staff to assume accountability and to learn and improve is also impacted by these factors. In addition, they affect the independence of the regulatory

body and the clarity regarding its different roles. The influence of these factors on regulatory oversight and enforcement actions, methods, and approaches is particularly important. This influence affects how the regulatory body acts in specific situations, the choice of oversight methods, and the general regulatory approach. The licensee's influence on the safety culture of the regulatory body should not be ignored, but instead recognised and addressed so that it enhances and does not degrade the safety culture of the regulatory body. Such a reflected approach to the mutual influence is a significant component of a system of responsive regulation that is elaborated in Chapter 5.

4.3. Good practices and lessons learnt in the interactions between the regulatory body and licensee

As part of the interviews conducted with senior practitioners in regulatory bodies and licensee organisations, interviewees identified good practices (existing or proposed) and lessons learnt in effective interactions between their respective organisations. These provide practical examples and suggestions for how to conduct such interactions to have a positive mutual influence on safety culture, and in turn to enhance the effectiveness of the regulatory body and the safety performance of the licensee.

Annex C presents these good practices and lessons learnt according to the themes below, focussing on examples of how the regulatory body and licensee can work collaboratively, in their mutual interest, while respecting each other's duties and obligations:

- Regulatory regime;
- Capability;
- Leadership and management;
- Communications;
- Relationships;
- Behaviours; and
- Learning and continuous improvement.

Specific examples of good practices and lessons learnt are as follows:

Lesson learnt – An enabling approach to regulation. At a fuel cycle facility, progress with legacy hazard reduction had slowed, in part due a regulatory approach that was too bureaucratic and conservative. The regulatory body changed to an "enabling" approach by:

(i) Forming a group of senior stakeholder representatives to identify a common safety goal;

(ii) Removing unnecessary bureaucracy and giving ownership of risk to the licensee; and

(iii) Encouraging innovative, fit-for-purpose solutions to achieve the agreed goal.

The effect of the above was that tangible hazard reduction began at several facilities, with significantly accelerated work programmes in others.

Good practice – Guidance and examples to promote understanding of regulations. The regulatory body published a document providing commentary and examples to promote understanding of the safety regulations. The document covers event reporting and disclosure rules in nuclear power and related facilities. There are many differences of opinion on this subject, but through the commentary and examples provided, the difference in understanding between the regulatory body and the operator has been reduced and resolved.

Good practice – The role of the resident inspector. Resident inspectors have their own inspection modules and required activities, but they observe a great deal simply by being on-site. This information can be very valuable to the licensee's leadership if the two parties take advantage of the proximity and talk to each other. It is the daily, routine observation and full view of the station by the resident inspector that makes their perspective particularly important.

Good practice – Dialogue between the regulatory body and licensee to reflect on their relationship. The regulatory body and licensee engage in dialogue to reflect on their relationship: (i) regularly, as part of formal interactions, and (ii) sporadically, as part of project work or event follow-up. The regulatory body and licensee can discuss for example:

- How each party deals with the other and their respective experiences of the relationship;
- How the relationship helps or how it hinders either party;
- What each party values about the other; and
- What works well, or not so well, from the licensee's perspective.

4.4. Challenges in effective interactions between the regulatory body and licensee

Regulatory body and licensee relationships are subject to a number of challenges that impact their ability to effectively work together and interact in a way that supports safety culture in both organisations and that guarantees a positive impact on one another, as discussed in the previous sections. These challenges can derive from the regulatory regime itself; they might be imposed from the surrounding environment; or they might relate to the regulatory body's ability to effectively achieve the right balance in its regulatory role and approach. The particular challenge has been identified by such researchers as Reiman and Norros (2002), Bradley (2017), and in the final report of the Ten-Year Investigation Commission on the Fukushima Nuclear Accident (2021).

The interviews have identified challenges that have been grouped into the three categories set out below. The first group relates to the characteristics of the regulatory system and the regulatory body and licensee themselves and their interaction ("internal"). The second group of challenges derives from the external environment ("external"). A third group has been added, referring to a special type of challenges related to the ability to reach a virtuous balance between different approaches, forces, or roles (both internal or external) that a regulatory body faces and to which the solution is not always clear or unipolar ("Challenges of balance in the regulatory approach").

4.4.1. *Internal challenges*

One of the main challenges to a successful interaction between the regulatory body and the licensee is for the regulatory body to build a **clear and predictable regulatory framework** (that would include rulemaking, an enforcement and sanctions system, expectations, event notification and reporting rules, among other aspects). The application of the regulatory framework should take into account the risk and safety significance of issues, as demonstrated in the regulatory body's priorities and resource allocation.

The regulatory body's public role implies a mediation with society on the desired level of safety. The regulatory body provides independent scrutiny, on behalf of the public, to ensure that the industry achieves high standards of safety. To accomplish this, it needs to set the rules by which such standards are fulfilled. In order to achieve this goal, the **involvement of licensees** and their perspective in the rulemaking is crucial and will help ensure the achievability of the requirements and the willingness and accountability of the licensees to comply with the rules.

"Regarding regulations, there are some matters that I believe are not clearly stated. Therefore, the strength of the regulations can change depending on the interpretation of the person in charge. As operators, we will not be able to trust them very much." – Interviewee

"There is a benefit in understanding the basis for regulatory body decisions and requirements, that helps compliance and willingness to comply. The prescriptive approach can be balanced with the expert role." – Interviewee

The relationship between the regulatory body and the licensees needs to be built on the foundation of **mutual trust and respect**, enabling adequate communication and fostering the licensee's accountability and compliance through understanding and involvement. The starting point to build such a relationship is a basic positive assumption of the counterpart's good intentions and accountability. Attention must be paid to the fact that trust takes time to be built, but can be easily destroyed, impairing future communication.

"[The most significant challenge to effective interactions between regulatory bodies and licensees] is having a relationship and establishing trust. When the relationships and trust work well, amazing things can happen." – Interviewee

"Bad experiences and reputation are also easily preserved for a longer period of time because the events of history stay alive and in the memories of people, and therefore trust can be lost or weakened for a longer period of time." – Interviewee

Interactions between the regulatory body and the licensees are challenged by the need to maintain and differentiate each other's role and to ensure independence in decision making, while also keeping open channels (in the exercise of the expert role, as stated by Reiman and Norros [2002]). There is also the challenge for the regulatory body to **understand the impact** that its chosen oversight methods and type of interactions have on licensees and the capability to use these impacts as tools to strengthen desired behaviours and activities while avoiding the negative impacts (as stated in previous sections) and encouraging accountability.

"If the oversight approach turns too prescriptive and intrusive, the licensee can diminish the responsibility for safety that is part of its role, impacting culture: the licensee tries to merely comply with requirements, and initiative (and even questioning attitude) is reduced." – Interviewee

Leadership is recognised as a pillar in building culture in the organisation of the licensee and the regulatory body, and as seen in the previous sections, is also key in the impact of each organisation in the safety culture of the other. Thus, building such leadership in each organisation is a significant challenge for both parties. This aspect is addressed in depth in the NEA report *Practices for Enhancing Leadership for Safety in Nuclear Regulatory Bodies* (NEA, forthcoming). Moreover, the regulatory body should be able to set the conditions for the licensee to develop their own leadership for safety and to foster their own accountability for safety.

4.4.2. *External challenges*

One of the main challenges facing both the regulatory body and licensee is adapting to deal with an **uncertain and changing environment**. Examples include announced nuclear power plant shutdowns, electrical supply challenges, energy policies and priorities, new technologies, increasing focus on waste management, decommissioning, or even challenges imposed by the global COVID-19 pandemic and its effects. Thus, the common challenge is to build a resilient environment to deal effectively with uncertainty and changes, and this may require new regulatory approaches. Success will necessarily entail a space for collaboration and learning from each other.

"The regulatory body can support the development of a mutual understanding concerning external challenges and changes (phase-out, decommissioning with differences in structures, persons, routines, and priorities) by demanding clear, timely actions, the submission of concepts (e.g. relocation of staff from operation to dismantling not too fast, counteracting the increasing importance of non-safety-related goals), and by checking the plausibility of these concepts." – Interviewee

"Where the licensees might be able to help too is technology foresight. So, as other technologies are coming to the forefront, it might well be that there's more dialogue that can happen there in terms of making sure that the regulator has the right level of understanding as to what these technologies are and where some of the challenges could come in." – Interviewee

Specifically, there is a need for both parties to prepare for and mitigate the **impact of staff turnover** due to ageing workforces and changing interest in the nuclear field in some countries in order to avoid the loss of knowledge and experience. In the process, generational change and associated cultural differences must be taken into account to maintain competence and effective work relationships. Also, it must be noted that recruitment and workforce morale might be affected by the energy policy and phase-out decisions in some countries, and measures to counteract this must be set in place.

4.4.3. *Challenges of balance in the regulatory approach*

Interactions between the regulatory body and licensee must balance opposing forces and tendencies in order to be effective. They must facilitate open communication and trust building, even while independence is maintained and each other's role is differentiated. Ultimately, the interactions must ensure that the licensee has the chance to develop its primary accountability for plant safety.

The issue of balancing opposed requirements or approaches is discussed in the literature reviewed for this report. It is considered especially relevant in the work by Bradley (2017), Reiman and Norros (2002), and in the report of the Ten-Year Investigation Commission on the Fukushima Nuclear Accident (2021).

Some of the opposing forces and tendencies that interviewees mentioned are listed below:

- ***Prescriptive norms vs. licensee's accountability***

  As stated above, the regulatory body's selected methods and approaches to oversight have an impact on the licensee response and set the basis for particular cultural traits in the licensee. Safety requirements with a certain degree of prescriptiveness are needed to lay the foundation and establish a stable framework with predictable consequences, as stated in the Section 4.4.1. Rules must be clear and broad enough to ground the framework, but at the same time allow room for the licensee to exert its own role. They should avoid unnecessary burdens and unjustified conservatism.

  In addition, an "intrusive" regulatory body that over-regulates or oversteps in its technical decisions and makes decisions that would more properly belong to the licensee can discourage the licensee's sense of accountability for safety. Here again, the regulatory body should balance its authority role and expert role in order to be effective.

  "If the oversight approach turns too prescriptive and intrusive, the licensee can diminish the responsibility for safety that is part of its role, impacting culture: the licensee tries to merely comply with requirements, and initiative (and even questioning attitude) is reduced." – Interviewee

- ***Public transparency vs. open communication with the licensee***

  The transparency and public communication policy of the regulatory body must be set in a way that does not jeopardise open communication with the licensee. It should allow for a technical exchange of viewpoints, respect for confidential issues, and trust.

  "Particular transparency laws that require disclosure of (almost) all findings and documents by the regulatory body, although important for public trust building, can also be an obstacle for open communication between the regulatory bodies and the licensees." – Interviewee

- ***Open dialogue with the licensee vs. regulatory body independence***

  A balance must be sought to allow for an open dialogue between the regulatory body and the licensee, while maintaining independence and differentiating each other's role in safety. In this endeavour, attention must be paid to the channels used (including the

level of formality), and the purposes and occasions when each one is used (as stated in Section 4.1.2).

Creating an environment of trust and respect that enables effective communication and relationships between the regulatory body and the licensee is a challenge itself, as stated earlier. When doing so, it is necessary to avoid the risk of regulatory capture, maintaining independence and a clear focus on each party's role.

"From a regulator's point of view, to have too cosy relationship with anybody is not perceived to be a good thing. On the operator's side, there's a concern about, well, if I ask the question, do I reveal that maybe I don't know as much as I should. How do we get to the situation where we recognise that sharing knowledge and asking questions is a good thing?" – Interviewee

"From the standpoint of regulatory independence, the social atmosphere is shifting toward reducing the act of meeting with operators and/or stakeholders." – Interviewee

- ***Independence from external forces vs. co-operation and co-ordination***

  The need to preserve the independence of the regulatory body and licensee from external actors (political, commercial, etc.) should not prevent healthy interaction and communication with other stakeholders, facilitating adequate co-ordination and mutual learning. Independence is a challenge regarding the many factors that can impact – or create the impression of impacting – the regulatory body's independence. In any case, the regulatory body must seek an appropriate balance to maintain independence without strangling communication channels with the various actors. It must avoid isolation and enable dialogue, thereby staying in contact with the frontline realities.

- ***Notification of events vs. counting events***

  The notification of events and the goal of learning from operating experience should not be jeopardised by a formalistic focus on event statistics. The emphasis should be on learning from events rather than counting them. The latter approach could lead to a tendency by the licensees to focus on statistics and to minimise the number of reported events, rather than on continuous improvement and prevention of causal factors.

  "Counting reportable events sometimes leads to unnecessary (counterproductive) measures on the part of the licensee in order to avoid reportable events." – Interviewee

  As seen in the previous sections and in the above statements, each one of the "forces" that a regulator needs to balance in its performance is interrelated and affected by the others. Finding the right balance is therefore not a "two factor" equation. Instead, there are multiple, interacting factors that must be addressed. When considering open communication and collaboration, for example, it appears that the regulatory body needs to engage the licensees in order to ensure a clear regulatory framework and to encourage accountability. At the same time, the regulatory body needs to maintain an appropriate distance to differentiate roles, avoid interference in decision making and also to ensure the licensee's accountability for safety. In so doing, the regulatory body must be able to explain to the public that its independence is maintained, thus avoiding a loss of trust on the part of the public.

  When examining regulatory approaches, similar interrelations and balances arise. Fewer prescriptive norms allow room for dialogue and licensee accountability in its methods for achieving safety, but can also lead to an unclear framework. Overly prescriptive frameworks, for their part, can reduce the licensee's perception of their own accountability. There is no rule of thumb for setting the level and appropriate balance between the different factors and their impact. Each should be analysed case-by-case, taking into account each country's unique context and culture; the safety culture maturity of both the regulatory body and licensee; and the requirements imposed by the legislative framework and the public. At the same time, the framework should allow for open dialogue and collaboration.

4.5. Summary of findings

4.5.1. *Main findings – descriptive view*

The preceding sections have identified the principal factors and mechanisms by which the regulatory body and licensee influence each other's safety cultures. These form the "descriptive" view of this report's findings – i.e. without a judgement on whether the influence is a positive or negative one – and are presented in Figure 4.3. At the heart of this model are the communications, relationships and behaviours that characterise the interactions between the two entities. These provide the means by which each organisation influences the safety culture of the other.

In turn, the interactions between the two entities are influenced by the regulatory regime (comprising the system of legislation and standards, roles and responsibilities, regulatory approach etc.) and the capability, leadership and management of each organisation. Finally, the ability of each organisation to learn and improve from their interactions acts as a "shaping" factor, determining whether the influence on safety culture has a positive (upward) or negative (downward) trend (the "normative" view as explained in Section 4.5.2). Figure 4.3 provides further detail about the elements that make up each of these factors.

The text boxes below illustrate some of the specific mechanisms of influence as an indication of the different "paths" through Figure 4.3:

The influence of the regulatory body's decision making on the safety culture of the licensee

The objectivity, predictability, transparency, and timeliness of the regulatory body's decision-making influence the level of openness, trust, and respect of the licensee towards the regulatory body. This in turn influences the licensee's commitment to making safety improvements.

The influence of the regulatory framework, specifically the balance of outcome-based and prescriptive elements, on the safety culture of the licensee

The way in which the regulatory body balances the outcome-based and prescriptive elements of its approach influences the nature of the dialogue between the two entities, the licensee's sense of accountability for safety, and ultimately its safety culture. On the one hand, the regulatory body's need to ensure explicit requirements and a consistent approach lends itself towards a prescriptive approach. On the other hand, freedom for the licensee to explore alternative means of achieving the same, or higher, levels of safety would tend the regulatory body towards outcome-based approach.

The influence of the licensee's capability on the safety culture of the regulatory body

The licensee's level of knowledge and experience influences the regulatory body's understanding of the licensee's technology and associated safety issues. This in turn influences the regulatory body's activities, priorities, and decision making. The licensee's competence also influences the regulatory body's level of respect and trust in the licensee and the depth and intensity of its oversight.

The influence of the licensee's provision of information on the regulatory body's safety culture

The quality and timeliness of the information provided by the licensee influences the regulatory body's workload, way of working, and the level of trust in the relationship. This may in turn influence the quality of safety decision making by the regulatory body and the ability of both entities to work through difficult situations.

4.5.2. *Main findings – normative view*

From the interviews conducted in this study, a consistent picture emerges of what constitutes an effective interaction between the regulatory body and licensee and results in a positive influence on each organisation's safety culture. This forms the "normative" view of this report's findings – i.e. "what good looks like" – and is shown in Figure 4.4 below. It reflects a consistent view given by interviewees from both regulatory bodies and licensee organisations, and across the 13 participating countries.

The picture that emerges is of a reciprocal, co-operative style of interaction, characterised by respect, openness, and trust, with a shared focus on safety and learning. This promotes the licensee's sense of accountability for safety and willingness to "self-regulate" through enhanced self-awareness and corresponding improvement action. It drives a focus on safe outcomes, e.g. safe operation, technical improvements, and staff competence, beyond mere compliance with regulations. Within this model, the regulatory body's approach seeks to foster the licensee's accountability for safety, enabling continuous improvement and growth of the licensee's safety culture towards higher maturity levels. This approach has been termed **"accountability-oriented, enabling regulation" (AER)**. It builds on the concept of performance (or outcome) based regulation, but also includes a focus on risk (or hazard), processes, and self-assessment by the licensee (see Box 4.1 below). However, the regulatory body retains the ability to adapt its approach towards a more prescriptive style according to the circumstances.

The interview data also points to approaches that clearly contribute to ineffective interactions between the regulatory body and licensee. These are shown in an equivalent figure in Annex D. Factors such as inadequate clarity or consistency in applying the regulatory framework, or insufficient preparedness by the licensee for interactions with the regulatory body can lead to mistrust and a lack of openness in the relationship. This may be compounded by the inability of each party to learn from their interactions and may lead to a downward spiral in the safety culture of both organisations.

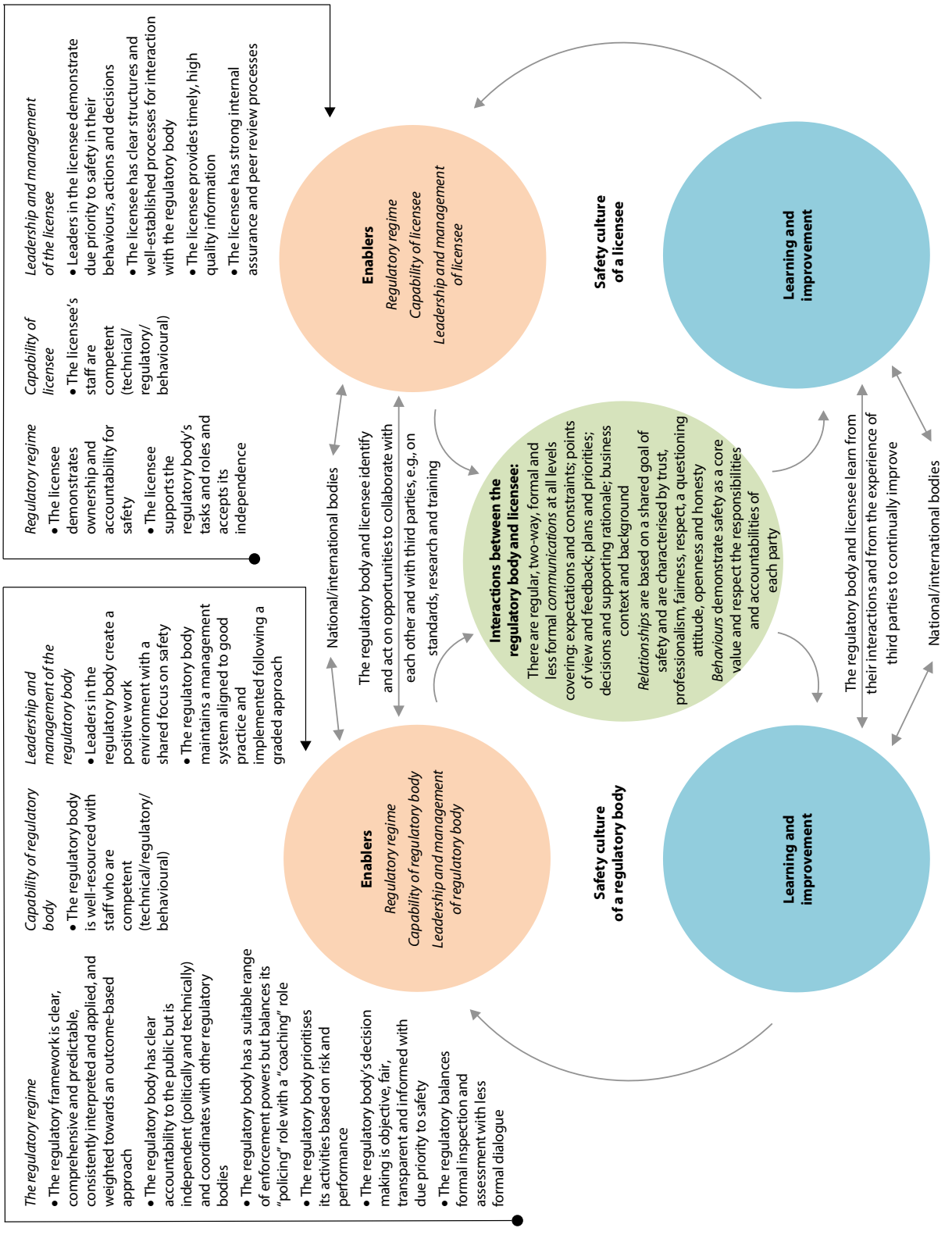
Compared to studies carried out in other sectors (Bradley, 2017), the model (see Figure 4.3) that emerges from this study has a stronger focus on the communications, relationships and behaviours between the regulatory body and licensee. This is not surprising given the rigorous licensing, inspection and authorisation regime that operates in the nuclear sector worldwide, which necessitates a close working relationship between the regulatory body and licensee and numerous contacts between their respective staff. In such circumstances, one organisation will as a matter of course have an influence on the culture of the other.

4.5.3. *Good practices and lessons learnt*

The interview data highlighted several good practices and lessons learnt that underpin the model set out in Figure 4.4. For instance, several examples were given of the means by which regulatory bodies can collaborate with licensees in areas of mutual interest such as training, standards, research, and emergency preparedness. These enhance the relationships and trust between the two organisations, contributing to effective interactions on core regulatory matters. Another example of a lesson learnt that emerged from one interview concerned the implementation of an "enabling" approach to regulation. This places accountability firmly with the licensee and focuses on fit-for-purpose solutions to deliver priority outcomes.

Figure 4.3. **The factors and mechanisms by which regulatory bodies and licensees influence their respective safety cultures**

Figure 4.4. **A model of effective interactions between the regulatory body and licensee: How each can positively influence the safety culture of the other**



4.5.4. *Challenges*

The interview data illuminated common challenges to achieving effective interactions between the regulatory body and licensee. The regulatory body and licensee both face the issue of maintaining a relationship based on mutual trust and respect. Other challenges include achieving a clear and predictable regulatory framework, and fulfilling short- and long-term term needs with existing scarce personnel resources. There are also specific issues for the regulatory body to address. These include, for example, preserving its independence on the one hand, while also maintaining openness with the licensee (and other stakeholders) on the other and in balancing prescriptive and outcome-based approaches in its regulatory framework. In sum, these challenges taken together highlight that there is further work to do if regulatory bodies and licensees are to move towards and sustain a co-operative style of interaction, based on accountability-oriented, enabling regulation.

Box 4.1. **Accountability-oriented, enabling regulation (AER)**

An **"accountability-oriented, enabling"** regulatory approach (in contrast to a "prescriptive" approach) as advocated in this report is an approach to regulation that respects the prime responsibility, or accountability,[1] of the licensee. It aims to strengthen its motivation and ability to act and operate its nuclear installations according to this accountability, thereby enabling continuous improvement and growth of the licensee's safety culture towards higher maturity levels (e.g. SM ICG, 2019). The term "accountability" is used to make clear that it is not merely a matter of the licensee formally assuming its legal responsibility, but that the regulatory body acts in a way that enables the licensee to demonstrate its accountability for safety.

In the literature and in the policies and practices of some regulatory bodies, a "performance-based" regulatory approach is often advocated when seeking ways that are better suited to foster the accountability of regulated organisations than a prescriptive approach (e.g. Wilpert, 2008). The term "performance-oriented/based" is usually used as a synonym for "goal" or "outcome" based. This means that the regulatory body formulates its expectations and requirements in the form of goals or expected outcomes and assesses the "performance" of the licensee in fulfilling them, leaving the approach and methods used to reach the goals within the responsibility of the licensee (see IAEA, 2020a; Wilpert, 2008). In the taxonomy of regulatory approaches found in two studies commissioned by the Swedish nuclear regulatory body (Melber & Durbin, 2005; Durbin, 2013; cf. also NEA, 2014), this understanding corresponds to the "**outcome-based**" strategy that "(e)stablishes specific performance goals or outcomes for licensees to attain but does not specify how they shall be attained. Licensees determine how they will conduct their work activities" (Durbin, 2013:127).

One difficulty of such an approach to oversight, however, is to define suitable goals and outcomes as well as suitable indicators to assess their achievement (see Melber et al., 2005; Durbin, 2013; Dandy, 2019). For instance, it is important that the fulfilment of the goals is not only assessed in a reactive manner, waiting until something (usually undesirable) has happened (see Melber et al., 2005) (using "lagging indicators"), but also in a proactive way, identifying precursors and trends at an early stage as well as necessary capabilities and skills (using "leading indicators"). On the other hand, the fact that goals have been successfully achieved in terms of outcomes does not necessarily imply that the way they have been achieved can be judged as safe and as demonstrating a healthy safety culture on the part of the licensee. Often, flawed processes and practices do not translate immediately into corresponding negative outcomes. For example, a deterioration in training and qualifications of staff is not necessarily directly visible in terms of safety-related outcomes. Instead, it can take a quite long time before the "safety performance" of the installation and the organisation starts to decline and negative results become visible (see Melber et al., 2005).

1. Prime responsibility for safety is the term often used in international standards, e.g. NEA (2016) and IAEA (2016c). In this report, accountability is used as a synonym for prime responsibility, emphasising that the licensee is answerable for the desired outcome (safety), not just for compliance with the law.

For this reason, in a regulatory approach oriented towards strengthening the accountability of the regulated organisations, outcome-based regulation needs to be complemented by "**process-based"** regulation, defined in the Swedish study as a regulatory strategy that "identifies specific key processes that lead to safe performance and requires licensees to establish and implement these processes effectively" (Durbin, 2013: 127). The term "performance" in its strictest sense primarily refers to the act of doing something or to how well an activity is done (OED, 2005) rather than to the result of the activity. This means that the regulatory body in its oversight activities should also focus on how (well) the licensees manage safety, i.e. on the processes they establish (including their implementation in daily practice, "work-as-done") in order to ensure the safe operation of their nuclear installations and to continuously improve safety and foster their safety culture. Yet in doing so, the regulatory body should avoid taking over the accountability from the licensee by dictating the details of the processes and their implementation in a prescriptive manner. Rather, the regulatory body should take care to maintain the spirit of the accountability-oriented, enabling approach in terms of supporting and fostering the licensee's accountability by formulating its expectations and requirements in a non-prescriptive manner.

A further regulatory approach identified by the Swedish studies (Melber et al, 2005; Durbin, 2013) is one characterised by strengthening the licensee's accountability for safety, namely the "**self-assessment based**" approach that "identifies both good practices and problem areas needing improvement, internal reviews and follow up. The regulator evaluates the licensee self-assessment programme, reviews the result of the licensee assessments, and selectively inspects the licensees' follow up on self-assessment results" (Durbin, 2013: 127). This approach appears to be well-aligned with an accountability-oriented, enabling regulatory strategy.

Finally, an accountability-oriented, enabling regulatory approach also implies a focus on risks and hazards and a risk consciousness by the regulatory body. This is in contract to the compliance or checklist mentality associated with a primarily prescriptive approach (see Brandley, 2017). When directing its attention and deploying its resources in oversight activities and requirements addressed to the licensee, the regulatory body's focus and priorities in turn directly impact the focus and deployment of resources on the side of the licensee as well as its attitude towards risk management (Bradley, 2017). As an element of an accountability-oriented, enabling regulatory approach, licensees need to "demonstrate an understanding of their risks and the regulator should be investigating how they know this intelligence is accurate, how the (licensee) deals with these risks, and how the (licensee) ensures those efforts are effective" (Bradley, 2017: 50). Therefore, the "**risk/hazard-based approach**" as described in the Swedish studies (Melber et al., 2005, Durbin, 2013) can be considered an element of an accountability-oriented, enabling approach. It is also important to remain sensitive to the danger that neither the licensee nor the regulatory body may pay enough attention to some issues if the focus is only on quantifiable risks. Therefore, "risks" should be considered as only one of several important perspectives that inform oversight (Melber et al., 2005, Durbin, 2013).

In summary, an accountability-oriented, enabling regulatory approach can be defined as a combination of various regulatory approaches. In the terminology of Melber et al. (2005), Durbin (2013), and the NEA (2014), this combination includes the "outcome-based", "process-based", and "self-assessment-based" approaches. AER also encompasses elements of the "risk/hazard-based" approach. It aims primarily at strengthening the licensee's accountability for safety and enabling the latter to continuously improve safety and to further develop its safety culture according to its own initiative and motivation. The AER regulatory approach is characterised by a low degree of prescriptiveness in regulations and oversight activities. It is built on effective relationships between the regulatory body and licensee, which are in turn based on constructive co-operation, dialogue, and trust, as well as on mutual respect and acknowledgement of the respective roles and responsibilities of each entity.

Chapter 5. **Discussion**

The objective of the study discussed in this report is (1) to understand how regulatory bodies impact the organisations they oversee (and vice versa) from a safety culture perspective; and (2) to share good practice and learning on how regulators can ensure that these impacts are positive, avoid negative impacts, and support the achievement of safety objectives (See Chapter 2). As is stated in *The Safety Culture of an Effective Nuclear Regulatory Body* (NEA, 2016) and *Methods for Assessing and Strengthening the Safety Culture of the Regulatory Body* (NEA, 2021), the regulatory bodies, by nature of their role, deeply influence the safety culture and the safety of the organisations they regulate and oversee. Based on their regulatory strategy, the way they carry out their daily oversight work, the type of relationship they cultivate with licensees, the values they convey, and the importance they give to safety, regulatory bodies profoundly impact the licensees' safety culture, their sense of accountability for safety and, by extension, the safety of their installations. Although this assumption might seem obvious and confirmed by the daily experience of the staff of regulatory bodies, not much literature and research are available addressing this topic in general, let alone in the nuclear industry (see Section 3.1). Even less corroborated knowledge is available on the way the licensees for their part impact the safety culture of the regulatory body.

The NEA, through its Working Group on Leadership and Safety Culture (WGLSC), therefore decided to conduct a study to help fill this gap in order to better understand the nature of this impact, i.e. through which mechanisms the regulatory body influences the safety culture of the organisations it oversees and vice versa, and what the findings entail for the improvement and further development of regulatory strategies and methods to ensure that the safety culture of both licensees and regulatory bodies and hence the safety of nuclear installations can be further improved. In the following sections, the findings of the study are discussed and conclusions are drawn.

5.1. **Factors and mechanisms of influence**

A very broad and differentiated set of factors and mechanisms of influence emerges from the study, showing that there is no easy and simple answer to the question of how the regulatory bodies and licensees impact each other from a safety culture perspective. The following mechanisms were identified (See Figure 4.3) by which the regulatory body and licensee influence safety culture, comprising:

- *Enablers* – the regulatory regime and the capability, leadership, and management of each party;

which influence

- the nature of *interactions* between the two organisations, i.e. the quality of communications, relationships, and behaviours;

and in turn are shaped by

- each party's ability to *learn and improve* from their interactions.

By these means, the regulatory body influences, for example, the licensee's sense of accountability for and priority placed on safety. In turn, the licensee influences, for example, the regulatory body's knowledge and understanding of the licensee's activities and its regulatory approach and priorities. The identified factors and mechanisms of influence were

substantiated by the interviewees with concrete examples from their experience and understanding. Thus, the descriptive model (Figure 4.3) also resulted in a normative model of effective interactions between the regulatory body and licensee, depicting how each can positively influence the safety culture of the other (Figure 4.4).

5.2. The mutual nature of the impact of the regulatory body and licensee on each other's safety cultures and the need for a systemic view

While the factors and mechanisms by which the regulatory body influences the safety culture of the licensees were relatively easily recognised and described by the interviewees, the identification of the factors of influence of the licensees on the safety culture of the regulatory body turned out to be more challenging. Nevertheless, a number of factors emerged from the interviews that are based on the same basic mechanisms of influence identified for the regulatory body (see Section 4.2). These show that the issue of the impact on safety culture is by no means unidirectional from the regulatory bodies to the licensees, but that a systemic view considering the mutual impact of the regulatory body and the licensee must be applied.

The data from the study show that the influence of the licensee on the safety culture of the regulatory body happens in both direct and indirect ways. This is one possible reason for the difficulty experienced by the interviewees in identifying the factors and mechanisms of influence by the licensees on the regulatory body. On the one hand, the licensees directly influence the regulatory body in a relatively easily recognisable way as their performance impacts the regulatory body's oversight approach and its priorities. There is also a subtler and less visible influence, based on the "informal power" that the licensee can exert on the regulatory body. Examples include the licensee's ability to control to some extent its degree of openness and transparency and its proactive or restrictive information practice vis-à-vis the regulatory body.

On the other hand, the licensees can have an indirect impact on the safety culture of the regulatory body via third parties. Indeed, as is posited by Bradley (2017) and supported by the data of the present study, the performance of the licensees also has an impact on external stakeholders, e.g. governments, media, non-governmental organisations etc. These actors in turn can have an impact on the regulatory body, e.g. via funding, public or media pressure, etc. Bradley (2017) concludes that

> …collectively, industry and other external parties affect the nature and character of the regulator by their actions (or inaction). The regulator seeks legitimacy and resourcing within this environment and adapts, as it deems appropriate, to maintain institutional credibility" (Bradley, 2017: 98).

She identified specific attributes of the regulatory body and its approach, such as the selected regulatory approach (prescriptive or performance-based), the type of oversight instruments typically applied, the enforcement approach, the degree of political independence, the degree of technical competence, etc. "These aspects are in fact outputs of the broader institutional environment and regulatory system, but they become regulatory inputs into the regulator's safety (oversight) culture" (Bradley, 2017: 98). The data collected for the present study supports these findings that not only the regulatory body impacts the licensees' safety culture, but also that its own safety culture is for its part impacted by the licensees and the wider interconnected system, as was postulated in *The Safety Culture of an Effective Nuclear Regulatory Body* (NEA, 2016).

As a consequence, it is important that regulatory bodies are aware of this complex web of interrelationships and mutual impact in the wider interconnected system. Regulatory bodies should therefore adapt their methods and regulatory approaches accordingly.

5.3. The need to move towards an accountability-oriented, enabling regulatory approach

As was explained above, a remarkable consensus can be seen in the views of the interviewees from all over the world towards the need to develop regulatory approaches and interactions that are more accountability-oriented, enabling, and co-operative (as opposed to prescriptive), or at least an integration of more accountability-oriented and enabling elements into the overall regulatory approach. This implies a regulatory approach that aims to support the licensee's accountability and to enable the licensee to act and operate its nuclear installations according to this accountability. This would thereby promote continuous improvement and growth of the licensee's safety culture towards higher maturity levels (SM ICG, 2019) (see Box 4.1). This need to develop further regulatory approaches towards accountability-oriented, enabling approaches advocated by the interviewees is consistent with the shift that has been observed in the last decades in the regulatory approaches in different industries (see Leistikow & Bal, 2020; Rorie, 2015) and on recent developments of new models of regulation that situate co-operation between stakeholders at their core (e.g. outcome-based co-operative regulation, see Hodges, 2022, 2023).

Similarly, in recent years increasing focus has been laid on the concept and principles of "high reliability organisations" (HRO) (e.g. Weick & Sutcliffe, 2015) and the need to foster resilience in organisations that deal with high risks and hazards. For example, this entails enhancing their ability to cope with and to (proactively) adapt to changing environments and boundary conditions as well as to respond flexibly and competently to occurring events while maintaining control of the situation; or swiftly regaining temporarily reduced control by adjusting performance to the conditions as they arise and change (see e.g. Hollnagel, 2018).

The idea of organisational resilience itself has evolved over time as well, towards a more integrative understanding of the concept. Resilience does not focus only on the "negative", i.e. on unwanted events and situations, but also includes the "positive", i.e. the organisation's ability to seize and adapt to opportunities and allow for improvement and innovation (e.g. Macrae & Wiig, 2019). Such an encompassing concept of resilience is based on an understanding of safety that in the safety sciences is often referred to as "Safety-II", as opposed to the traditional understanding of "Safety-I" (see Hollnagel, 2014; ENSI, 2021)[1]. Accordingly, regulatory bodies need oversight approaches that foster resilience and "Safety-II"-oriented approaches to safety management in licensee organisations.

The literature on resilience and "Safety-II" (e.g. ENSI, 2021 for an overview) stresses the need for regulatory approaches going beyond mere compliance-driven oversight to an approach based on dialogue and trust. This also entails an understanding of the way that licensee organisations function on a day-to-day basis, and of the situational and contextual factors that influence daily operations. In sum, the characteristics of a suitable regulatory approach that fosters resilience and the "Safety-II" perspective that are discussed in the literature are consistent with the accountability-oriented, enabling regulatory approach as described in this report[2].

1. Stated in simple terms, Safety-I focuses on things that go wrong and on "work-as-imagined", i.e. on assumptions and expectations about how work should be carried out as stated, for example, in work plans, procedures and processes in the management system, and aims at strengthening compliance. Safety-II, on the other hand, focuses also on things that go right and on "work-as-done", i.e. on the way in which work is actually carried out under the conditions and circumstances of the real situation, and aims at strengthening resilience (cf. Leistikow & Bal, 2020).

2. Several further conceptualisations can be found in the literature. They all describe similar regulatory approaches with similar aims and methodologies, albeit each with a somehow different focus and wording. For example, besides the above-mentioned organisational resilience and "Safety-II", these might include complex systems and drift into failure, trustworthiness, and co-operation. These can be applied to the conceptualisation of accountability-oriented, enabling regulation as discussed in this report (e.g. Bradley, 2017; Leistikow & Bal, 2020; Wiig, Aase & Bal, 2019; COFSOH, 2019; Dekker, 2011; Hodges, 2022); for an overview on different conceptualisations also see ENSI (2021).

5.4. The need for specific oversight methods to support accountability-oriented, enabling regulation

Implementing an accountability-oriented, enabling regulatory approach that strengthens the accountability and adaptability of the licensees calls for a co-operative relationship between the regulatory body and the licensee organisations based on dialogue and trust. It requires developing and using specific oversight methods that aim at both ascertaining that the licensees are effectively upholding their accountability and at the same time at fostering their sense of accountability. Such methods differ from traditional methods, such as formalised inspections in which the regulatory body focuses on searching for deviations and non-compliances on the side of the licensee. Instead, accountability-oriented, enabling methods concentrate on an open, respectful and trustful relationship and intensive dialogue between the regulatory body and the licensee. They aim to foster self-reflection within the licensee organisation. The licensees thereby need to demonstrate to the regulatory body that they "do the right thing", i.e. that they are "trustworthy" (Hodges, 2022).

Such an approach and the corresponding methods place high demands on the staff of the regulatory body. In particular, a high degree of technical and social competence and the ability for self-reflection and learning on the side of regulatory staff are paramount (e.g. COFSOH, 2019).

5.5. The need to balance different regulatory goals and approaches while maintaining the trust of the public

The present study clearly demonstrates the need for regulatory bodies to balance different goals and approaches in their oversight of licensees and in their interactions with them as well as with the other stakeholders towards whom they are accountable (e.g. the public). For example, the regulatory body needs to strike a balance between prescriptive and accountability-oriented, enabling regulation, between formal (e.g. inspection) and less formal (e.g. dialogue-based) methods, between its different roles, e.g. the "policing" and the "coaching" role, and between open dialogue with the licensee and maintaining independence of the regulatory body. Such balances are necessary for different reasons. On the one hand, the regulatory body not only interacts with the licensees in its daily activities but is also accountable to the public in its "public" role. The results of the study suggest that many of the interviewees assume that the "policing role", based on a prescriptive approach, can generate greater public trust in the regulatory body's work due to the greater visibility of regulatory outputs and ultimately greater public trust in the safety of nuclear installations.

On the other hand, the study supports the view that an accountability-oriented, enabling approach produces better safety outcomes compared to a primarily prescriptive approach. In particular, the former fosters the licensee's accountability for the safety of its installations, while the latter tends to transfer accountability to the regulatory body. The accountability-oriented, enabling approach is also more suited to the complex environment that characterises the nuclear sector, i.e. complex combinations of technology, people, and organisations in a complex environment where cause and effect are difficult to predict, and the development of organisational resilience is imperative. It seems therefore of crucial importance for regulatory bodies to engage in and find ways to explain to the public the benefits of such accountability-oriented, enabling oversight approaches for safety and safety culture so that both public trust and safety can be enhanced. This would obviate the need for a prescriptive regulatory approach by the regulatory body to demonstrate its effectiveness towards the public.

5.6. The need to adapt the regulatory approach based on the licensee's performance and safety culture maturity level

The option to use prescriptive oversight methods and measures remains important for the regulatory body despite a need and tendency to develop further their approaches towards more accountability-oriented, enabling oversight. In fact, regulatory bodies need to be able to

adapt their oversight approach depending on the situation at hand (e.g. safety performance of a licensee, incidents, developments in the markets, etc.). This may include using different oversight approaches for different licensees. This would be based on the licensees' demonstrated capability and willingness to effectively carry their accountability and to act in a self-reliant and trustworthy way to comply with the safety requirements, i.e. based on the maturity level of their safety culture (e.g. Hudson, 2007; SM ICG, 2019).

For example, a licensee might demonstrate a lower level of safety culture maturity by acting only in a reactive manner to external inputs such as measures resulting from incidents, formal requirements from the regulatory body, or the rules from the regulatory framework. In such a case, an accountability-oriented, enabling approach by the regulatory body requiring a high degree of proactivity and a general sense of accountability by the licensee might not (yet) be appropriate. Instead, the situation might require a more prescriptive oversight approach. On the contrary, if a licensee demonstrates a high level of cultural maturity and trustworthiness, then an accountability-oriented, enabling approach is best suited and even necessary. In this case, prescriptive oversight may inhibit the licensee's sense of accountability and impair its motivation to further strive for continuous improvement (see SM ICG, 2019).

5.7. The need for a high level of safety culture maturity in the regulatory body

Notwithstanding the possibly different maturity levels of licensees, the aim of the regulatory body should always be to foster the growth of the licensees towards higher cultural maturity levels (SM ICG, 2019) that allow for continuous safety improvement in the nuclear industry. This endeavour has in itself important implications for the regulatory bodies as well, as it requires them to demonstrate high levels of cultural maturity themselves. A regulatory body with a low level of safety culture maturity will more likely practice a traditional, prescriptive oversight approach, eventually hindering the further development of the safety culture in the entire nuclear industry of its country.

Therefore, the regulatory body must itself be highly reflexive (see Rutz, 2017). This means, for example, that it must be able to accept and deal with uncertainty and to adapt its oversight methods accordingly. It must also be willing to continuously learn through a "…continuous process of self-observation and self-critique" (Rutz, 2017: 151). In Reiman and Norros' model of balancing the different roles of regulatory bodies, this requires a strong "expert role", which is characterised by dialogue, co-operation, self-criticism. and reflectivity (Reiman & Norros, 2002). In this "expert role", the regulatory body sets high expectations concerning the technical and regulatory competence of its own staff.

5.8. The need for responsive regulation

The present study has identified the necessity for the regulatory body to advance its oversight approaches towards a more accountability-oriented, enabling oversight while at the same time preserving the option and ability to adapt its regulatory approach to unfolding situations and to the safety culture level of licensees. This agility is at the core of the concept of "responsive regulation" (e.g. van der Heijden, 2020; Healy & Braithwaite, 2006). "Responsive regulation" implies that there is no one specific approach to oversight that fits all licensees at all times and in all situations, but rather that oversight needs to be adapted over time depending on the performance and the culture of a specific licensee.

Responsive regulation is generally illustrated in the form of an escalation pyramid (often called the "enforcement pyramid" or "regulation pyramid") (e.g. Wood, et. al., 2010; Wood et al, 2015; Ivec & Braithwaite, 2015). At the bottom of the pyramid is the oversight approach based on self-regulation, persuasion, and voluntary compliance (i.e. an accountability-oriented, enabling approach). The pyramid ladders upwards through different escalation levels. Strong sanctions and a strictly prescriptive approach appear at the top of the pyramid as "ultima ratio", should all the milder and less intrusive regulatory actions in the lower levels of the

escalation ladder be ineffective (Ivec & Braithwaite, 2015). Moreover, de-escalation down the pyramid should be sought at first opportunity (Ivec & Braithwaite, 2015).

The concept of responsive regulation appears to be well suited to integrate the insights that emerged from the present study and to serve as a foundation upon which to develop further the nuclear industry's oversight approaches. It seems therefore sensible to explore to a greater extent if and how a responsive regulation pyramid could be developed for the nuclear industry. Any such model should be accompanied by methods and tools for regulatory bodies to help them advance their oversight towards more accountability-oriented, enabling approaches while at the same time enabling them to find and sustain the right balance between different requirements such as the safety performance or the cultural maturity level of licensees, the specificities of different countries' regulatory frameworks[3], the level of confidence and the expectations of stakeholders in the regulatory body, as well as the national cultural context.

3. E.g. the IAEA in *Functions and Processes of the Regulatory Body for Safety* argue that "The degree to which the regulations are performance based or prescriptive, and the level of detail in the associated guidance, will depend on the national approach; however, this should not reduce the authorised party's prime responsibility for safety" (IAEA, 2018: 11).

Chapter 6. **Conclusions**

The current study explores interactions between the regulatory body and licensee and identified the factors and mechanisms by which each organisation influences the safety culture of the other. The main factors are the communications, relationships, and behaviours of staff at the interface between the two organisations. These influence on the one hand the licensee's sense of accountability for safety, and on the other the regulatory body's approach and priorities. The communications, relationships, and behaviours of staff in the two organisations are in turn influenced by the regulatory regime, i.e. the regulatory framework, roles and responsibilities, regulatory approach, etc., and the capability, leadership, and management of each organisation. Finally, each organisation's ability to learn from its interactions and from others determines whether the influence on safety culture has a positive (upward) or negative (downward) trend.

A clear picture emerges from the study of the nature of the interaction between the regulatory body and licensee that produces a positive effect on each organisation's safety culture. This is a reciprocal, co-operative style of interaction, characterised by respect, openness, and trust, with a shared focus on safety and learning. This promotes the licensee's sense of accountability for safety and willingness to "self-regulate" through enhanced self-awareness and corresponding improvement action. It drives a focus on safe outcomes, beyond mere compliance with regulations. Within this model the regulatory body adopts an accountability-oriented, enabling approach to regulation, but with the ability to adapt its approach towards a more prescriptive style according to the circumstances ("responsive regulation").

It is recognised that not all interactions between the regulatory body and licensee may always achieve the characteristics set out above. Two main factors determine this: the safety culture maturity of the licensee, and the safety culture maturity of the regulatory body. A low safety culture maturity of the licensee may mean that it is more appropriate for the regulatory body to adopt a prescriptive style of regulation. Similarly, the regulatory body's ability to move towards an accountability-oriented, enabling approach depends on its own safety culture maturity; for example, the technical and behavioural competence of staff to interpret regulatory requirements in a particular setting and influence improvements. The current study therefore indicates the need for the regulatory body to be responsive in its regulatory approach, although always with the goal of fostering the growth of the licensee towards higher levels of safety culture maturity in the long-term interests of safety.

It is also apparent from the study that the ability of the regulatory body to follow an accountability-oriented, enabling regulatory approach, with its increased emphasis on a less formal, more dialogue-based style of interaction, depends on the expectations of – and the level of trust it enjoys from – the public. This important relationship is further explored in *The Characteristics of a Trusted Nuclear Regulator* (NEA, forthcoming). It underlines the need for a systemic approach, considering the interactions between all stakeholders in the system – regulatory body, licensee, public and other stakeholders – and their mutual impact on safety culture.

The current study builds on the five principles set out in *The Safety Culture of an Effective Nuclear Regulatory Body* (2016). The NEA encourages regulatory bodies and licensees to use the information contained in this report to examine the health of their own interactions, and to identify areas for improvement and good practices to share.

Specifically, regulatory bodies are encouraged to:

- Recognise the systemic nature of the influence on safety culture, from regulatory body to licensee and vice versa, and extending to other stakeholders in the system;
- Consider how they can evolve their approach towards more accountability-oriented, enabling regulation;
- Develop regulatory oversight methods based on dialogue and aimed at fostering self-reflection that support an accountability-oriented, enabling regulatory approach;
- Balance regulatory goals and approaches, e.g. balancing "policing" vs "coaching" styles and formal vs less formal interactions, to maximise their influence on safety improvements by the licensee, while maintaining the trust of the public;
- Adapt their regulatory approaches according to the performance and safety culture maturity of the licensee;
- Enhance their own safety culture to support development towards accountability-oriented, enabling regulation; and
- Practice a responsive style of regulation, according to the cultural maturity of the licensee, although always with the aim of promoting growth of the licensee's safety culture towards higher maturity levels.

To support regulatory bodies in implementing these recommendations, the NEA will continue to work on the insights gained and the challenges identified in this report. For instance, it has identified the following further areas of potential investigation:

- Developing guidance and tools on how to create awareness of the mutual impact of regulatory bodies and licensees based on the model of the factors and mechanisms of impact that resulted from the current study;
- Deepening and substantiating the concepts of accountability-oriented, enabling regulation and responsive regulation and the practical implications for the nuclear industry, including developing a responsive regulation "pyramid" for the nuclear sector to understand the escalation / de-escalation mechanisms;
- Developing guidance and tools to help regulatory bodies to move towards more accountability-oriented, enabling regulatory approaches and towards responsive regulation;
- Providing platforms and spaces for regulatory bodies to exchange experience with the development and implementation of accountability-oriented, enabling regulatory approaches and responsive regulation;
- Further exploring how the regulatory body achieves a balance in its regulatory approach and interactions with the licensee and the wider interconnected system of stakeholders; and
- Exploring ways to communicate with the public about regulatory approaches and their impact on safety and trust.

Glossary

Accountability-oriented, enabling regulation (AER)	A regulatory approach which seeks to foster the licensee's accountability for safety, enabling continuous improvement and growth of the licensee's safety culture towards higher maturity levels. This regulatory approach is characterised by a low degree of prescriptiveness in regulations and oversight activities and is built on effective relationships between the regulatory body and licensee, in turn based on constructive co-operation, dialogue and trust, as well as mutual respect and acknowledgement of the respective roles and responsibilities of each organisation.
Accountable	Required or expected to justify actions or decisions. (OED, 2005)
Prescriptive regulation	A regulatory approach which "establishes very detailed requirements for technical solutions and conducting specific activities. Safety is assured because the regulator has established that its requirements provide for the safe conduct of these activities". (Durbin, 2013)
Responsible	Having an obligation to do something, or having control over or care for someone, as part of one's job or role. (OED, 2005)
Responsive regulation	A regulatory concept which implies that there is not one specific approach to oversight which fits all licensees at all times and in all situations, but rather that oversight needs to be adapted over time depending on the performance and the culture of a licensee. Responsive regulation is generally illustrated in the form of a pyramid ("enforcement pyramid", "regulation pyramid") which represents an escalation from an oversight approach based on self-regulation, persuasion, voluntary compliance at the bottom of the pyramid, upwards through different escalation levels, with strong sanctions and a strictly prescriptive approach at the top of the pyramid as "ultima ratio", should all the milder and less intrusive regulatory actions in the lower levels of the escalation ladder be ineffective. Moreover, de-escalation down the pyramid should be sought at the first opportunity.
Safety culture of a licensee	The assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance. (IAEA, 2022)
Safety culture of a regulatory body	The regulatory body's strategy, the way it carries out its daily oversight[1] work, the type of relationship it cultivates with licensees, the values it conveys and the importance it gives to safety. (NEA, 2016)

1. In this report the term "oversight" is used to mean the specific activities the regulatory body undertakes to give effect to the regulations and ensure the compliance of licensees, e.g. inspection, assessment, authorisation, monitoring and dialogue, while the term "regulation" is used to mean all the functions of the regulatory body, including rulemaking, stakeholder consultation.

Safety leadership	The use of an individual's capabilities and competences to give direction to individuals and groups and to influence their commitment to achieving the fundamental safety objective and to applying the fundamental safety principles, by means of shared goals, values and behaviour. (IAEA, 2016c)
Safety management	A formal, authorised function for ensuring that an organisation operates efficiently and that work is completed in accordance with requirements, plans and resources. Managers at all levels need to be leaders for safety. (IAEA, 2016c)

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Annex A. **Literature review**

A.1. **List of literature reviewed**

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A.2. **Summary of main items of literature relevant to the study**

- *Regulatory Culture: Balancing the Different Demands of Regulatory Practice in the Nuclear Industry*, Reiman and Norros (2002)

  Reiman and Norros investigated the organisational culture of the Finnish nuclear regulatory body and proposed a model for the core task of a nuclear inspector with three, occasionally conflicting, roles: an authority role (leading to effectiveness), an expert role (leading to competence) and a public role (leading to credibility).

- *Regulatory Safety (Oversight) Culture: How a Regulator's Culture Influences Safety Outcomes in High Hazard Industries*, Bradley (2017)

  Bradley's research in the oil and gas sector in Canada proposed a framework for regulatory safety culture and its influence on industry safety culture and performance. The framework has six dimensions: leadership and political independence (vs politicised mission); learning culture (vs punitive culture); innovation (vs bureaucratic inertia); technical excellence (vs tolerance of inadequate capacity and competency); risk consciousness (vs compliance mentality); and systems thinking (vs preoccupation with active failures).

- *Regulator Safety Culture: A Conceptual Framework for Ensuring Safety in the Nuclear Industry,* Fleming and Bowers (2016)

  Fleming and Bower's study drew on interviews with experts across a range of industry sectors to develop a framework for regulatory safety culture with five dimensions: leadership commitment to creating a positive safety culture; a proactive, risk informed and flexible approach; continuous learning and self-improvement; unwavering ethical standards; and transparency through communication.

- *Safety Culture Practices for the Regulatory Body*, IAEA (2020)

  The IAEA's report identifies six practices that promote safety culture in the regulatory body as well as regulatory oversight of the safety culture of licensees: leadership and commitment; individuals' awareness of safety culture, and their roles and responsibilities; individual behaviours that place proper value on safety; decision making; continual improvement and learning; and the management system.

- *Fukushima Daiichi Nuclear Power Plant Accident, Ten Years On: Progress, Lessons and Challenges* (NEA, 2021) and the Ten-Year Investigation Commission on the Fukushima Nuclear Accident, 2021)

  These reviews have identified significant improvements that have been made in the regulatory approach in Japan since the Fukushima Daiichi accident, e.g. the technical capability and independence of the regulatory body. The reviews also identify continuing challenges, e.g. balancing regulatory independence and openness with licensees, and the regulatory approach (prescriptive vs goal setting).

- *Organisational Culture Self-Assessment Tool and Guidance for Regulatory Authorities*, Safety Management International Collaboration Group (2019)

  This report explores how regulatory bodies in the aviation community impact duty holders through their organisational culture. It suggests that regulatory bodies should be flexible in their approach according to the safety culture maturity of the duty holder. For duty holders at the less mature, reactive end of the spectrum, a regulatory approach based on prescription and compliance might be appropriate, or even necessary, although it entails the risk of hindering or hampering the development of the duty holder towards higher levels of cultural maturity. However, for duty holders at the more mature, proactive level, a performance-based approach should be applied. An objective of the regulatory body should be to support the growth of the safety culture of the duty holder towards more mature levels. The ability of the regulatory body to operate in this flexible way depends on its own cultural maturity.

Annex B. Question set for semi-structured interviews

Section	Mandatory questions in roman text. *Supplementary questions in italics.*
1. Introduction	Introduce purpose of interview and give opportunity to interviewee to ask any questions.
2. Main questions	Q1. Based on your experience, how do the practices and behaviour of the regulatory body influence the safety culture of the licensee (positively or negatively)? What are the most important mechanisms of influence? - *Can you give examples of positive and negative influences?* Q2. Based on your experience, how do the practices and behaviour of the licensee influence the safety culture of the regulatory body (positively or negatively)? What are the most important mechanisms of influence? - *Can you give examples of positive and negative influences?* Q3. (Refer to the most important mechanisms of influence identified by the interviewee in Q1 and Q2). How can regulatory bodies and licensees ensure that they have a positive influence on each other's safety cultures? - *What good practices have you seen?* - *What are the conditions which enable this?* - *What lessons have been learnt?* Q4. Based on your experience, what are the most significant challenges to effective interactions between regulatory bodies and licensees and how can they be overcome?
3. Closing question	Is there anything else that we have not covered so far that you would like to mention? Do you have any questions for us?

Annex C. Good practices and lessons learnt for effective interactions between the regulatory body and licensee

Table C1. Good practices and lessons learnt for effective interactions between the regulatory body and licensee

(a) Regulatory regime

Good practices	Lessons learnt
Methods by which the regulatory body can promote the licensee's sense of accountability for safety The regulatory body can use its oversight methods to promote the licensee's sense of accountability for safety, in particular to strengthen: • The voice of those within the licensee who can bring forward safety optimisations; • The value the licensee attaches to its own rules and processes (by evaluating compliance with these rules); • The licensee's internal oversight and inspection methods, e.g. by evaluating peer reviews and self-assessments; • The alignment of 'work-as-done' versus 'work-as-imagined', by repeatedly inspecting actual working practice; • The licensee's willingness to do more, beyond compliance actions, in the interests of safety; and • Mutual understanding of the impact of external challenges and changes, e.g. plant life cycle changes. **Comprehensive inspections encompassing higher-level management in the licensee** The regulatory body has found that comprehensive inspections involving higher-level management in the licensee have a positive impact on the safety culture because: • Lower-level staff can see that higher management are also subject to inspection; • The inspections add value by stimulating thinking on safety culture at senior management level; and • The inspections provide the opportunity to impart specialist knowledge on safety culture to the licensee. **Guidance and examples to promote understanding of regulations** The regulatory body has published a document providing commentary and examples to promote understanding of the safety regulations. The document covers event reporting and disclosure rules in nuclear power and related facilities. There are many differences of opinion on this subject, but through the commentary and examples provided, the difference in understanding between the regulatory body and the operator has been reduced and resolved. **The role of the resident inspector** Resident inspectors have their different inspection modules and things that they have to do, but they see a lot by acting as a 'fly on the wall'. This information can be very valuable to the licensee's leadership if they just listen and talk to each other. It's the day in, day out, full view of the station that comes from the resident inspector that makes them particularly important.	**An enabling approach to regulation** At a large fuel cycle facility, progress with legacy hazard reduction had slowed, in part due a regulatory approach which was too bureaucratic, and at times, overly conservative and risk averse. The regulatory body changed to an "enabling" approach by: • Forming a group of senior stakeholder representatives to identify a common goal, the barriers to achieving hazard reduction and how the barriers would be overcome; • Removing unnecessary bureaucracy in the regulation of the facility and giving ownership of risk to the licensee; and • Encouraging innovative, fit for purpose and legally compliant solutions, focused on the priority outcome. The effect of the above was that tangible hazard reduction began at several legacy facilities, with significantly accelerated work programmes in others. The success of the enabling approach depends on mature self-regulation by the licensee.

(b) Capability

Good practices	Lessons learnt
Use of staff secondments between the regulatory body and licensee Use of staff secondments between the regulatory body and the licensee has been found to enhance understanding of: • Each other's role; and • What influences how the role is carried out.	**Training of inspectors in soft skills** It should not be assumed that all inspectors have the high level of communications skills needed to influence safety culture and safety improvements in the licensee. They may not be able to make themselves fully understood, or fully understand the licensee's staff. There is a need therefore for training of inspectors in communications skills to eliminate variation in this competence.

(c) Leadership and management

Good practices	Lessons learnt
Targeted, holistic regulatory oversight programmes The regulatory body has developed regulatory oversight programmes that support a targeted, holistic approach to safety, by: • Utilising a range of regulatory tools – dialogue, inspection etc.; • Covering all safety areas over a specific cycle; • Providing a basic oversight programme to which further activities can be added according to whether the licensee takes responsibility and demonstrates their ability and competence; • Developing and maintaining an overall picture of licensee safety performance; and • Reflecting discussion with licensees on their view of the effectiveness of regulatory oversight activities. **Joint planning between regulatory body and licensee** *(proposed good practice)* Agreement on a roadmap or long-term safety programme by the licensee and regulatory body to support allocation of resources.	**Flexibility and agility in the application of the regulatory regime** The accelerated approval of Covid-19 vaccines provides useful learning for nuclear regulatory bodies in enabling innovation while demonstrating leadership for safety. In one country the accelerated time for the approval of the new vaccines was attributed to: • adopting a regulatory process of "rolling review" of data on a vaccine's safety, quality and effectiveness, considering data as and when it became available; and • the flexibility and agility of clinicians and scientists in the regulatory body. The above approach was underpinned by the existing expertise, rigour and independence of the regulatory bodies.

(d) Communications

Good practices	Lessons learnt
Regular communications between regulatory body and licensee It is important to hold regular meetings and build up communication as a way to achieve both transparency and frank discussions between regulatory bodies and operators. **Use of different channels of communication between the regulatory body, licensee and public** The regulatory body uses various communication channels to engage the licensee, including: • Public meetings, held to give everyone access to information and to provide open, honest discussion on working together; and • "Drop-ins" or private, closed-door meetings with management of the regulatory body at which the licensee can discuss issues privately. These are intended to be listening sessions, no approvals of requests are given.	

(e) Relationships

Good practices	Lessons learnt
Development of regulatory body capability in advanced nuclear technologies and early engagement with vendors The regulatory body has established a capability to support and regulate advanced nuclear technologies. This includes: • Familiarisation exercises and training to identify key safety and security considerations, and close knowledge gaps; • Engagement with industry via seminars and workshops to enhance the regulatory body's understanding of design developments and communicate its expectations; • Engagement with other national nuclear regulators; and • Review and update of regulatory process and guidance to ensure that they are fit for purpose.	

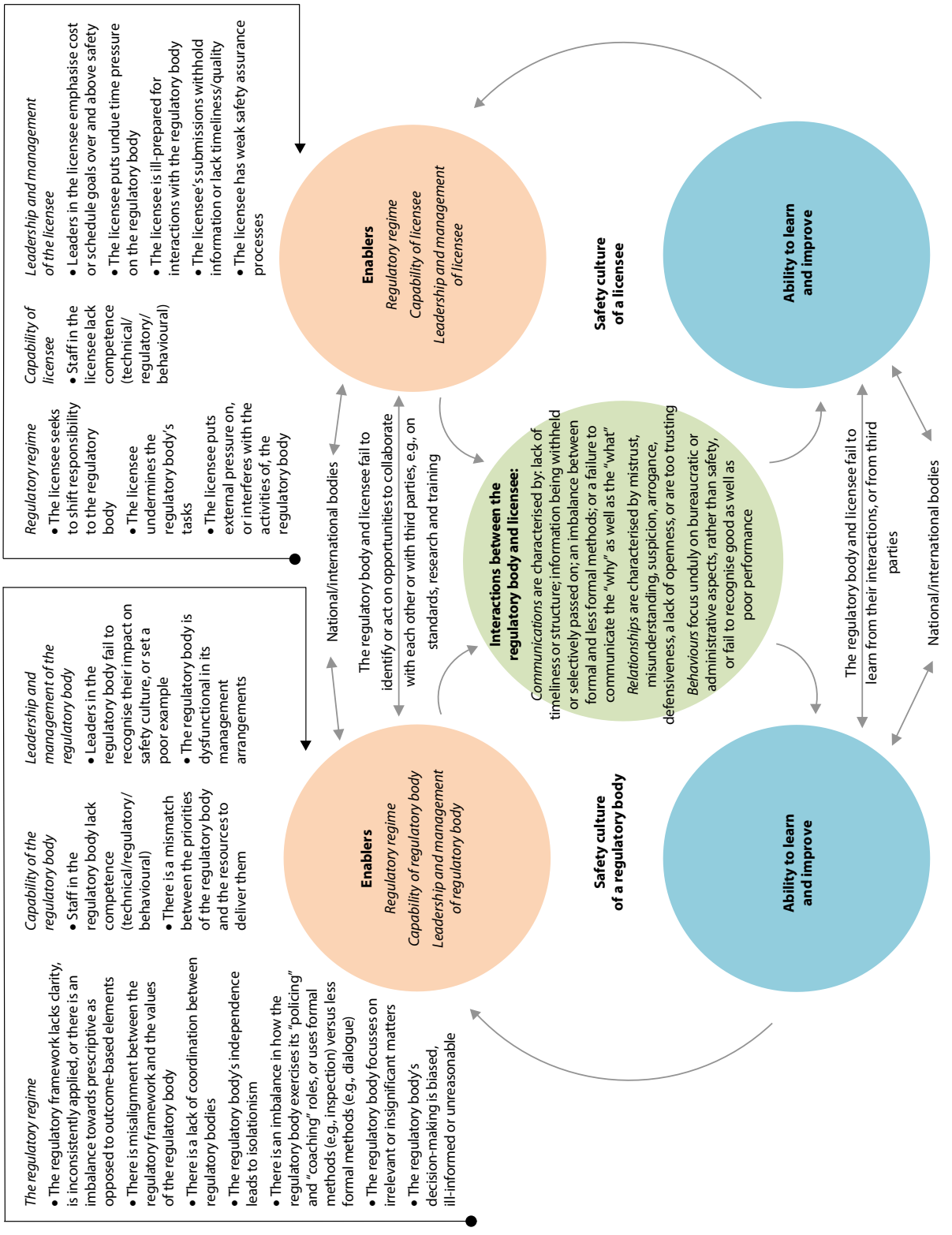
(f) Behaviours

Good practices	Lessons learnt
Presence of regulatory body senior management on the licensee's site. The regulatory body has found that periodic visits by the regulatory body's senior management, in particular decision-makers, to the licensee's site is beneficial. It helps broaden the experience of managers, generates better understanding of issues and leads to better decision making.	**Monitoring the effectiveness of interactions between the regulatory body and licensee** Senior management in the regulatory body were unaware that relationships between the regulatory body and one licensee had deteriorated. The regulatory body and industry therefore agreed a set of values and behaviours which can be used to monitor the health of their everyday interactions: • The agreed values and behaviours fall under four categories: - Responsive, well-informed and innovative; - Balanced and proportionate; - Consistent and transparent; and - Timely. • At the end of a meeting or inspection, the regulatory body and licensee take a few minutes to ask each other whether: - The objectives of the interaction were agreed; - The objectives were met; and - There were any good practices or areas for improvement against the agreed behaviours. Any immediate actions are agreed and the feedback from the meetings is reviewed periodically for common themes.

(g) Learning and continuous improvement

Good practices	Lessons learnt
Use of a professional association for employee concerns The regulatory body and licensees make use of a professional association for employee concerns to talk about cases openly so that they can learn from each other's experiences without fear of regulatory action. **Dialogue between the regulatory body and licensee to reflect on their relationship** *(proposed good practice)* The regulatory body and licensee engage in dialogue to reflect on their relationship: (i) regularly, as part of formal interactions, and (ii) sporadically, as part of project work or event follow-up The regulatory body and licensee discuss e.g.: • How each party deals with the other and their respective experiences of the relationship; • How the relationship helps or how it hinders either party; • What each party values about the other; and • What works well, or not so well, from the licensee's perspective.	**Self-critical reflection by the regulatory body on its work and impact** The regulatory body should adopt a self-critical questioning attitude to its work and make improvements, e.g. in the event that: • Approval of a plant modification is delayed; • The licensee implements requirements set by the regulatory body even though it doesn't see any sense in them, in order to avoid a conflict with the regulatory body; • Different disciplines within the regulatory body have different opinions, attitudes or values on the meaning of oversight work. **Learning for the nuclear regulatory body from other industry sectors** A regulatory body in the civil aviation sector was facing a challenge with the pace of technology advances coming forward. Its response was to set up a dedicated Innovation Hub with the purpose of: • Making it easier for innovators to access regulatory body expertise and viewpoints; • Helping innovators maximise regulatory readiness for the demonstration of their systems; and • Accelerating development of new policies and regulations. The nuclear regulatory body in the same country has used the aviation regulator's experience to develop its own approach to innovation.

Annex D. **Features of ineffective interactions between the regulatory body and licensee leading to a downward spiral in safety culture**



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The Mutual Impact of Nuclear Regulatory Bodies and License Holders from a Safety Culture Perspective

Most safety incidents are often not due to a technical fault or the actions of a single individual, but rather originate in a compromised safety culture – the collection of the beliefs, perceptions and values that employees share in relation to risks within an organisation, such as a workplace or a community.

Regulatory bodies, by their very nature, have a deep influence on the safety culture of nuclear site licence holders. But this influence can also flow in the other direction, from licensee to regulatory body. Based on the insights from senior practitioners worldwide, this report examines the factors and mechanisms by which nuclear regulatory bodies and site license holders influence the safety culture of the other. It presents a model, *accountability-oriented, enabling regulation*, for a regulatory body's approach to foster a licensee's accountability for safety. This approach builds on the concept of performance (or outcome) based regulation, but also includes a focus on risk (or hazard), processes, and licensee self-assessment. Two main factors determine the extent to which a regulatory body is able to adopt an accountability-oriented, enabling approach: the maturity of the safety culture at the licensee and in the regulatory body. In both cases, the more mature the safety culture, the more an accountability-oriented, enabling regulatory approach is likely to succeed.

Regulatory bodies and licensees are encouraged to use this report to assess the health of their interactions and identify areas for improvement and good practices to share.

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