



# The regulator-regulatee relationship embedded in a network of third parties

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Eric Marsden, Noëlle Laneyrie, Cécile Laugier  
and Olivier Chanton

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*Coordination: Eric Marsden*

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**TOPIC**

Risk management



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[www.FonCSI.org](http://www.FonCSI.org)

6 allée Émile Monso – CS 22760  
31077 Toulouse cedex 4  
France

Twitter: @TheFonCSI  
Email: [contact@FonCSI.org](mailto:contact@FonCSI.org)



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**Authors** Eric Marsden, Noëlle Laneyrie, Cécile Laugier and Olivier Chanton  
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This document concerns the **regulatory oversight** and governance of **high-hazard industrial activities**. A complex set of laws, regulations and institutions contribute to the social control of these activities, reinforcing and serving as a complement to the risk prevention mechanisms put in place by operating companies. This document focuses in particular on the relationships between regulated firms, regulatory authorities and third party intermediaries who play a role in safety oversight (certification bodies, auditors, insurers, professional associations, etc.) and the impact of the quality of these relationships on industrial safety. The scope is the prevention of major accident hazards in different industry sectors (process industry, transport, energy), in France and at an international level.

We focus our attention on different forms of “regulatory coproduction” (often called coregulation), the act of enrolling the entities concerned by regulatory measures in their elaboration and the verification of their compliance, which is believed to improve their appropriation by private actors and thereby produce better oversight than classical command-and-control regulation. We analyze in particular the partial delegation of authority, internal risk control mechanisms and the use of third party intermediaries in the oversight process. This coproduction of regulation by public and private entities is increasingly used in different industry sectors, and leads to a more collaborative and interconnected regulatory process, based on a network of actors rather than a simple regulator-regulatee duopole.

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## About the authors

This document is a product of FonCSI's strategic analysis on the regulator-regulatee relationship, a group of industry experts and researchers that met on a dozen occasions between 2020 and 2022. The document is based on discussion during the group meetings, on the contributions of group members and on the research and professional literature on these topics. The preparation of the document was coordinated by Eric Marsden, a programme manager at FonCSI. Noëlle Laneyrie (EDF), Cécile Laugier (EDF) and Olivier Chanton (IRSN), prepared the discussion of the internal control (independent oversight) mechanism in place at EDF. The automated translation from French to English was reviewed by Eric Marsden.

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# Introduction

## Context

This document focuses on the **control** and **safety governance** of industrial activities involving **major accident hazards**. A complex set of legislation, regulations and institutions help to regulate and oversee these high-hazard activities. The aim of this oversight activity is to complement and reinforce the risk management measures which are the primary responsibility of the firms that design and operate high-hazard facilities and activities.

The activities of the organizations involved in this oversight, and their relations with industrial firms, are important for several reasons:

- ▷ Adopting a systemic perspective, the regulation and oversight activity is an important (though indirect) contributor to the safety of industrial activity. History provides several examples that bear witness to the importance of these safety governance issues, such as (to take some recent cases) the catastrophic pollution generated by the accident on the Macondo oil drilling platform in the Gulf of Mexico in 2010, the Fukushima Daiichi nuclear disaster in 2011, and the Grenfell Tower fire in London in 2017.
- ▷ The safety regulator, by establishing common rules in a given “world” (an industry sector at a given moment in history), is the only organization able to move all competing parties from one “world” to another. Indeed, when higher safety requirements are – as is often the case in practice – associated with higher costs, a company that chooses, in isolation, to increase its spending on safety, becomes less competitive, and could even disappear. On the other hand, when the regulatory authority imposes a new rule on all economic players in an industry, the effect on competition is nil<sup>1</sup>. One example is English coal mines around 1850, which saw their safety levels (very low at the time) rapidly increase following the introduction of the Mines Act.
- ▷ The level of social acceptability of a risky industrial activity seems to be largely linked to the level of trust placed in the safety authority [Bronfman et al. 2009].

The relationship between the regulator, the regulated entities (dutyholders) and third parties that contribute to oversight is the subject of multiple **tensions**:

- Between **cost** and **performance**: regulation and oversight generate costs, both direct (operation of the control authority) and indirect (time spent by operating companies to respond to requests from the supervisory authority, limitations on innovation in safety) which must be weighed against its contribution to risk prevention.

This tension is not always present, and some of the most remarkable regulatory interventions (in terms of their beneficial effect on safety) are those that are least visible (for the costs they impose). Consider for example, product safety requirements for cradles which prevent infants’ heads from getting caught between the bars, and those prohibiting the use of lead in children’s play equipment.

- Between **efficiency** and **equity**: oversight to be more efficient when the regulator’s attention is focused on those entities who are assumed to present the greatest risks, but this focus on a small number of players implies unfair – or at least unequal – treatment.
- Between the role of “advisor” and that of “policeman”: the regulator can take on the role of “policeman”, based on verifying compliance with a reference system and sanctioning deviations; and in other situations adopt an advisory role, in which it will establish a dialogue with the operating company to help them better understand the regulatory requirements, point out the most important areas for improvement and suggest possible solutions to reaching compliance.

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<sup>1</sup> Except insofar as many industrial sectors are affected by international competition: there may be an effect on competitiveness of differing standards set by national safety authorities.

- Between **effectiveness** and **intrusiveness** in the case of industrial entities: a regulator will be better able to assess an operating company's risk management actions if it has access to more exhaustive information on its operations, but excessive intrusiveness can infringe on the industrialist's rights and generate risks of confusion of responsibilities. Intrusiveness can also lead to defensive reactions on the part of operating companies, which will tend to avoid documenting any concerns they might have about potential problems.
- Between the **independence** and the **competence** of the people undertaking oversight activities, both in the authority, as well as third parties carrying out oversight/auditing activities on a delegated basis: maintaining a good understanding of the factors that contribute to safety, as well as the associated threats, requires a certain proximity (physical, social, cultural) to the installations and the people who operate them on a day-to-day basis. However, this independence of the regulator and may affect his or her judgments. In addition, third parties whose inspection or certification work is remunerated by the manufacturer or operating company may find it difficult to ensure strict independence between commercial considerations and those linked to their safety assessments.

## Objectives of this document

This document focuses on governance and societal control (oversight on behalf of civil society) of high-hazard activities. In particular, it analyzes the **relationships** established between **safety authority**, **dutyholders** and **third-parties** involved in safety governance. The focus is on the prevention of major accident hazards, in various industry sectors (transport, energy, the process industries). The document is based on work and expert discussions undertaken in France, but most of the content is applicable elsewhere. We seek to clarify the contributions of these relationships to the governance of high-hazard activities and to safety.

The document is based on discussions held during the "strategic analysis" undertaken by FonCSI over the period 2020-2022. It also draws on academic literature on the subject (research in "regulation studies", a field that encompasses law, political science, economics and management), as well as the work of various expert bodies.

This document is a translation of the document originally published in French in the same collection, titled *La relation contrôleur-contrôlé au sein d'un réseau d'acteurs* [Marsden et al. 2023].

Continuing the reflections recorded in a previous Cahier entitled *La relation controller-controlled in high-risk industrial activities* [Marsden 2019] on a related theme we focus our attention on different forms of "**coproduction of control**" (also called "coregulation" in the literature) between regulator and regulated dutyholders. Involving organizations concerned by regulatory measures to participate in drawing up and monitoring their implementation, is supposed to ensure greater ownership by private players and therefore more effective control than would be the case with conventional prescriptive regulation; it also has a number of other advantages and disadvantages, which we attempt to decipher in this document. In particular, we discuss the partial delegation of authority, internal control systems within companies, and the integration of third parties in oversight activities. The co-production between public and private players is developing in many sectors, using different commitment and enrolment mechanisms. It is transforming the role of safety authorities to that of a coxswain, rather than an oarsman<sup>2</sup>. It leads to a more collaborative and collaborative and interconnected form of oversight, based on a network of players rather than a simple regulator-regulatee duopole, and based on the sharing of information on the internal operation of firms.

The co-production of oversight also recognizes the role played by indirect control mechanisms, such as civil liability mechanisms, economic incentive tools (taxes, subsidies, etc.), incentive programs based on encouraging the implementation of "good practice" and charters, peer pressure motivated by the need to maintain a sector's reputation, and label

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<sup>2</sup> "The state should steer rather than row", as [Osborne and Gaebler 1992] put it, an idea echoed in the "third way" manifesto by Tony Blair and Gerhard Schröder in 1999

programs. These tools are often used in combination to move practices in a direction deemed favorable to the common good.

## Structure of the document

Chapter 1 on **coregulation** describes the historical trend, in several sectors of co-production of control between the safety authority and the regulated dutyholders. This trend is taking place against a backdrop of decentralization — or privatization — of powers previously held exclusively by the State, in the hope of ensuring a proper distribution of safety responsibilities between the various organizations involved, and to enable the use of risk control measures better adapted to each specific context.

Chapter 2 looks at different forms of **partial delegation of authority** for the oversight of safety-related decisions, such as the delegation of authority to authorized third parties, delegation by designation, and enrolment by duty of care.

Chapter 3 examines the **internal control** mechanisms, put in place by operating companies in certain sectors of activity (in particular nuclear power) to provide a high level of assurance of the safety of their activities. It also analyzes how the internal control mechanisms interact with the oversight activities of the safety authority and accredited third parties.

Chapter 4 analyzes the role played by different categories of **third parties in the regulator-regulatee** relationship. Intermediaries such as notified or accredited bodies, insurers, professional associations and federations, extra-financial rating agencies, associations and NGOs, are increasingly involved or invited to take part in discussions between a safety authority and dutyholders, and participate in various ways in social risk control activities. This polycentric nature of safety oversight makes it more democratic and leads to greater transparency, but also raises questions about the responsibility of each of these organizations.

Appendix A provides a description of existing internal control systems in the French nuclear power sector, in particular at EDF, the main operating company. The authors provide a detailed analysis of the main benefits and costs of these internal control mechanisms and of the way in which they interact with external oversight activities.

The document features numerous illustrations of the concepts discussed, from a variety of industrial sectors (processes, energy, transport, health and safety, construction...). These examples sometimes concern problems encountered, and sometimes positive practices that might be applicable elsewhere. However, it is important to bear in mind that every regulatory instrument or practice exists in a particular **historically situated context**, that its functioning and the way it is received depend on specific characteristics of a given industry sector (in particular, some sectors pose far greater safety challenges than others) and on past decisions.

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## The progressive move towards coregulation

### 1.1 From prescription to coproduction of oversight

The control of major accident hazards was historically one of the first areas of activity in which the State has taken on the role of technical prescriber, by setting up a risk regulation regime<sup>1</sup>. In France for example, the corps of «ingénieurs des mines» was established in 1810 to develop safety regulations and inspect that they were correctly implemented in coal mines [Le Roux 2014], and thereafter to oversee the risk of explosions generated by the introduction of city gas for public lighting, then by the development of the first steam engines.

In the rule classification proposed by [Coglianese 2010], and schematically illustrated in figure 1.1, this prescriptive regulation is based on “micro/means” rules, i.e. imposing specific implementation details regarding risk prevention rather than specifying a performance target, and aimed at the micro-level of systems (a specific source of risk, such as a specific piece of equipment) rather than issues at a macroscopic level (such as the number of people killed in the workplace).

	means	ends
<b>micro</b>	micro/means technical prescriptions	micro/ends Sulphur emissions < 2T/an evacuation time < 2 minutes
<b>macro</b>	macro/means Mandatory implementation of an SMS, HACCP	macro/ends < x killed per passenger- kilometre

Figure 1.1 Classification of regulatory instruments proposed by [Coglianese 2010; NAP 2018]. The horizontal axis distinguishes between rules that impose specific means to reach the regulatory objective (for example, the installation of a specific piece of equipment or technology) and those that require a specific outcome to be attained. The vertical axis represents the point in the causal chain leading to the top event (the accident) that justifies the implementation of a regulation, distinguishing between regulatory instruments that target the micro scale of the system (specific hazard sources) from regulatory instruments that target the global risks at the macroscopic system level.

While this type of oversight is well suited to traditional, well-established industrial activities, it is less so for activities involving major technological innovation, where operators are better informed about the risks and possible control means than are the inspectorate/regulator (cf. the box below on information asymmetry between regulator and regulatee). Because of the lack of latitude in the choice of control measures, this type

<sup>1</sup> A **risk regulation regime** is a set of legal provisions, institutions public and private, practices and theories put in place to govern and regulate major accident hazards [Hood et al. 2001; Sparrow 2000; Wilpert 2008]. The interested reader will find a summary of the main regulatory regimes used with regard to safety issues in the Cahier [Marsden 2019].

of control also tends to inhibit research and development into innovative methods for controlling risk and producing safety.

Key issue

In industry sectors subject to rapid technological change, the people directly involved in the design and operation of systems generally have, through their day-to-day work in close proximity to the systems, a better understanding of the safety issues at stake in the business than that which can be obtained by an external regulator [Lindøe et al. 2013]. As a Boeing employee notes in the 737 MAX case concerning the difficulty for employees of the authority to understand all the sources of risk, “It’s impossible for someone sitting at a desk at the FAA to keep up with the technology. Once you step out, it will bypass you really fast.”

For these reasons, regulatory approaches based on technical prescriptions (micro-means in the sense of figure 1.1) have gradually been supplemented – or sometimes replaced – by regulatory approaches based on **objectives** (micro/objectives or macro/objectives), or by regulatory approaches based on **processes** (macro/means).

Regulation based on objectives entails that the regulatory authority imposes an obligation to achieve certain outcomes, rather than prescribing specific means. This obligation can pertain to a micro level of the causal link between hazard and harm, such as a maximum emissions limit for a pollutant per unit of production, or a maximum time limit for the evacuation of individuals after the detection of a hazardous situation (top right cell in figure 1.1). Alternatively, it can focus on a broader safety objective, such as a probability of death per passenger-kilometer (bottom right cell). When assessing compliance with safety objectives is challenging or costly, the regulatory authority may prefer to rely on monitoring the risk management processes implemented by operators. For example, this could involve requiring operators to establish a safety management system and evaluating the organizational framework they put in place (rather than attempting a direct assessment of the risk level).

#### Process regulation

Example

According to [Downer 2009], the oversight exercised by authorities in the type certification process of an aircraft (civil aviation) essentially involves verifying the organizational procedures implemented by the designers-manufacturers, as well as the level of qualification and expertise of the employees, rather than objectively verifying the calculations that ensure a particular level of safety. The author describes an approach that “despite appearances to the contrary, [...] quietly assesses the people who build aeroplanes in lieu of assessing actual aeroplanes”.

These oversight approaches based on objectives or processes allow operators to select the most suitable risk management measures for each facility, thus promoting innovation in safety. They constitute a form of “co-regulation”, a term that refers to involving relevant organizations in the development and monitoring of the implementation of the regulatory measures. Co-regulation is believed to enable better engagement by private actors and, therefore, more effective control than traditional prescriptive regulations, as suggested by a [White Paper on Governance](#) issued by the European Commission in 2001. The same document indicates that co-regulation increases flexibility in the enforcement of legislation, enhances the transparency of public action, and reduces the control costs borne by taxpayers. A 2011 document describing the [European Commission’s strategy on corporate social responsibility](#) suggests that

“Public authorities should play a supporting role through a smart mix of voluntary policy measures and, where necessary, complementary regulation, for example to promote transparency, create market incentives for responsible business conduct, and ensure corporate accountability.

Co-regulation can be thought of as an intermediate form of control between, on the one hand, a traditional regulatory regime (on the left in figure 1.2), in which the definition of the regulatory framework and its enforcement are carried out by public authorities, and on the other hand, self-regulatory or non-regulated modes on the right. In other words, co-regulation can be seen as a “regulated” or directed form of self-regulation.

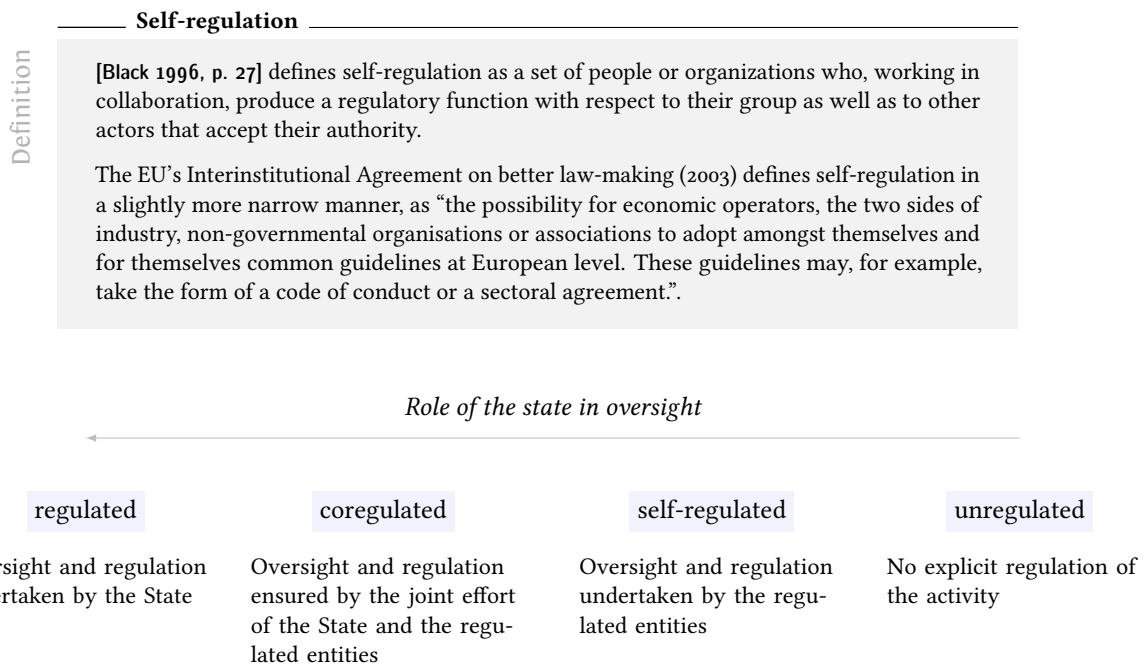


Figure 1.2 Different levels of self-regulation, based on [Bartle and Vass 2005].

In the self-regulated category, [Bartle and Vass 2005] differentiate between different levels of participation of the authority:

- **Cooperative**, in which the control activity is ensured through the co-operation of the regulator and the regulated entities.

Example: the regulation of the electricity market in the UK.

- **Delegated**, in which aspects of authority and responsibility are delegated by the authority (through regulatory means) to the regulated entities (*cf.* chapter 2).
- **Devolved**, in which the authority and responsibility are devolved to the self-regulated entities ("statutory self-regulation").

Examples: the oversight ensured for their respective professions by the Order of physicians and the Bar Association, which in European countries are generally private organizations that exercise activities in the public interest (decisions with respect to professional deontology, disciplinary committees).

- **Facilitated**, a form of self-regulation which is explicitly supported by the authority or the state, but not backed by a regulatory or statutory measure.

Example: good practice codes concerning insurance for housing loans.

- **Tacit**, almost "pure" self-regulation, in which there is little explicit support for the authority provided by the state, though the authority can use influence and play an implicit role.

Examples: the deontological code for advertising in France (published and overseen by the Autorité de régulation professionnelle de la publicité, ARPP); the Press ombudsman in France («médiateur de la presse écrite»).

Regulation is comprised of four main functions, described below [Black 2003]:

- **Standard setting and rulemaking**, which consists of identifying the problems to be resolved, the values and the objectives to be reached by the regulated entities. This function includes establishing the risk management policy (including the selection of risk treatment options), potentially after having consulted stakeholders. It also includes the framing of regulations.
- **Promoting respect** for standards and regulation, which includes the activities that encourage voluntary conformity with the expectations and obligations of the rules. This includes the provision of technical advice, training, publicity, the implementation

of economic incentives to comply and maintaining positive public opinion concerning the importance of regulatory compliance.

- **Inspections and market surveillance**, which involves collecting information on the level of conformity with the regulations, as well as on the way in which they are perceived by regulated entities.
- **Enforcement** activities, which aim to ensure that regulated entities respect the content of regulations. This function includes encouragements and obligations to conform, for example using fines or administrative closures in case of non-compliance.

The distribution of these roles among the organizations involved in oversight and safety governance (the regulatory body, regulated firms and different third parties such as industry sector bodies) varies depending on the structure of the regulatory regime, as illustrated in figure 1.3.

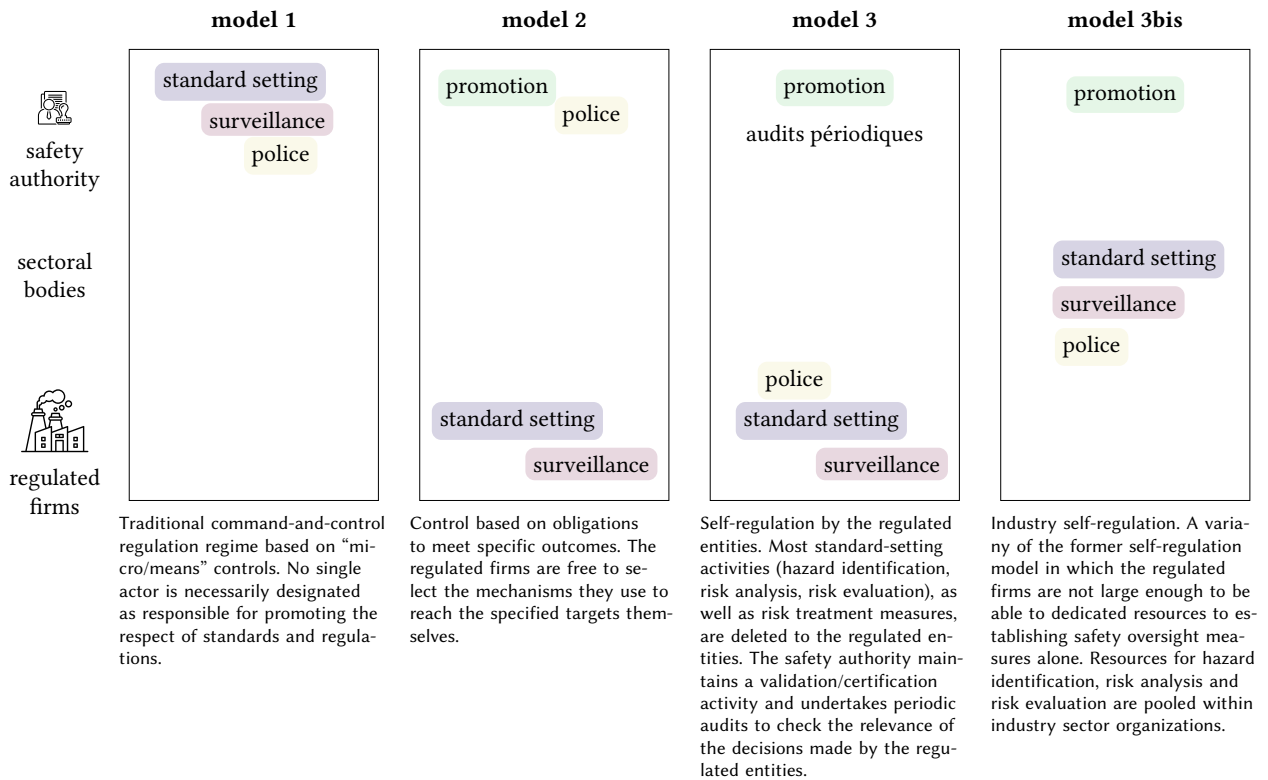


Figure 1.3 The distribution of the main functions that contribute to safety oversight between safety authority, industry sector organizations and other third parties, and regulated firms, in different regulatory regimes. Adopting the terminology used in figure 1.2, model 1 corresponds to a regulated regime, model 2 to a coregulatory arrangement, and models 3 and 3bis to self-regulatory situations.

“Lex mercatoria”, commercial law during medieval times

Example

Since the Middle Ages, there have been situations in which regulation is developed and administered by private entities, with varying degrees of state involvement. The *Lex mercatoria* was a private set of obligations governing interactions within the guilds of medieval merchants. The system aimed to establish the necessary trust for the development of long-distance trade (credit lines between merchants, goods entrusted to agents for marketing in distant lands) where purely reputation-based systems within small communities would not suffice. It relied on the sovereign’s powers to enforce compliance. Any individual who failed to deliver the expected goods or any local ruler who failed to protect foreign merchants would be excluded from the trading system.

Consequently, the system allowed for a decoupling between the entity developing the rule framework (the guilds) and the entity responsible for its enforcement (the local sovereigns). These rules gradually evolved into modern commercial law.



The coproduction of oversight by public and private actors is expanding across various sectors, utilizing different mechanisms of engagement and enlistment. This evolution shifts the role of regulatory authorities from being rowers to becoming helmsmen<sup>2</sup>. It leads to a more collaborative and interconnected form of control based on negotiation and consensus-building rather than decrees (a “new governance” approach that involves governing without government [Rhodes 1996], coordinating public action with a network of actors, varying in structure across sectors). Control is now grounded in actor networks rather than a simple regulator-regulatee dyad, relying on the sharing of information regarding the internal functioning of businesses.

The configuration of control tools (the relative weight of traditional normative instruments, objective-based control, the role of civil and criminal liability, incentives, and reputational mechanisms) has significantly evolved compared to historical regulatory approaches based on unilateral interventions and hierarchical state power.

The coproduction approach to control also acknowledges the role played by indirect control mechanisms, such as economic incentive tools (taxes, mandatory contributions, royalties, etc.), civil liability mechanisms, incentive programs based on the promotion of “good practices” and charters, peer pressure driven by the desire to maintain the reputation of an industry sector, and labeling programs. These tools can be used in combination to influence practices in a direction deemed beneficial to the common good.

## 1.2 Self-regulation and private regulation

As described in the previous section, there are various forms of co-regulation, with different degrees of responsibility assigned to private actors in the coproduction of control. The forms in which the authority plays a limited role include self-regulation (or self-control), professional regulation by a professional body, and private regulation. These mechanisms aim to achieve similar results to traditional regulation but at a lower implementation cost, and in particular, a lower cost for the taxpayer.

When an industrial sector is self-regulated, it establishes a normative framework with rules that apply to all parties involved (firms, consumers). An example is provided by development of the internet, which has been organized since the 1970s by private entities like the Internet Engineering Task Force (IETF) and the Internet Corporation for Assigned Names and Numbers (ICANN).

In a system of private regulation (or private law), the definition of the normative framework, the oversight and control mechanisms, and conflict resolution are carried out by private actors rather than by public actors with legal rights. Private regulation can be seen as a form of self-regulation in which the regulators and the regulated entities coincide.

### — The *Responsible Care* programme in the chemicals sector —

Example

The voluntary program *Responsible Care*<sup>3</sup> develops various initiatives to promote responsible management of chemical products in logistics chains (product stewardship) and to enhance employee training. The program also incorporates a common reporting system for all companies in the sector, covering issues related to process safety, occupational safety, and environmental emissions. This system combines self-declarations and mandatory audits conducted at the headquarters of participating companies and their production sites.

The program is based on a charter outlining six relatively generic guiding principles, such as “Protecting people and the environment through continuous improvement in environmental, health, safety, and security performance of facilities, processes, and technologies”, which is signed by the top management of each company participating in the program. It is managed by professional chemical associations (Cefic at the European level, and the International Council of Chemical Associations at the international level) in a federated form, allowing regional associations representing the chemical industry to adapt initiatives to local contexts.

One of the risks associated with a self-regulation mechanism based on a label, like *Responsible Care*, is the “free-riding” phenomenon: if companies are able to participate in the program without improving their performance, lower-quality companies may seek to join the initiative to gain reputational benefits without absorbing the associated costs. To address

<sup>2</sup> “The state should steer rather than row”, as written by [Osborne and Gaebler 1992], echoed in Tony Blair and Gerhard Schröder’s “Third Way” manifesto in 1999.

this risk, professional associations can decide to exclude companies that do not fulfill their commitments. However, some observers argue that informal peer pressure mechanisms<sup>4</sup> are used more frequently than this expulsion mechanism.

The actual impact of these voluntary programs on pollution levels and safety is a subject of debate. Empirical studies tend to demonstrate that participation in the *Responsible Care* program did not reduce pollution [Morgenstern and Pizer 2007; King and Lenox 2000; Gamper-Rabindran and Finger 2013], but it seems to be associated with a reduction in the number of workplace accidents (around 70%) and process accidents (an 80% decrease) [Finger and Gamper-Rabindran 2013]. The introduction of the requirement for certification by a third-party organization in 2005 had no observable effect on the number of accidents in U.S. companies participating in the program [Li et al. 2018].

### Private regulation of food safety

Example

[Havinga 2006] illustrates a case in the Netherlands, where supermarkets impose private standards concerning food safety on their suppliers. These private standards include requirements that go beyond the constraints set by regulations. All supermarket chains in the country have agreed upon a uniform standard. Compliance audits are conducted by third-party companies, and the control costs are borne by the suppliers.

Self-control mechanisms are a useful way to leverage the positive motivations of firms to comply with regulatory objectives, but they are often criticized for the latitude they afford controlled entities to engage in fraud. For instance, in 2022 in France, there were public reactions of outrage following incidents of contamination in pizzas and chocolates from major agri-food brands in a sector that is heavily reliant on self-control for food safety. Certification or labeling initiatives for self-control mechanisms are sometimes criticized for perceived insincerity, with accusations of “greenwashing” concerning their environmental impact claims [Marquis et al. 2016] or “safewashing” regarding safety indicators [O’Neill et al. 2016].

### Failure of a self-regulatory system: the Grenfell Tower case

Example

The Grenfell Tower fire in London in 2017, in which the fire rapidly spread throughout the residential building due to a flammable insulation cladding installed during recent renovation work, resulted in 79 fatalities. The insulation panels used were not fire-resistant and should not have been used for a high-rise building.

The regulation of fire safety issues had been significantly weakened in the decades leading up to the fire, with a shift towards self-control concerning research on the safety of new construction materials, establishment of standards, and compliance inspections. The control system was criticized by the accident investigation:

“the whole system of regulation, covering what is written down and the way in which it is enacted in practice, is not fit for purpose, leaving room for those who want to take shortcuts to do so.

– Judith Hackitt, interim report on Grenfell Tower

The gradual move towards deregulation in the sector has been strongly condemned by the professional firefighters’ federation.

The recognition of the failure of self-regulation in the industry led to the expansion of the mandate of the Health and Safety Executive, the authority responsible for workplace and process safety, to include the control of construction safety.

<sup>3</sup> The *Responsible Care* program is described at [icca-chem.org/responsible-care/](https://icca-chem.org/responsible-care/).

<sup>4</sup> The report of the National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling, analyzing the interest of relying more on self-regulation mechanisms in the oil extraction sector, indicates that “Executives from leading firms pressure their non-compliant counterparts at industry meetings to adopt and adhere to the industrial codes” [USNC 2011, p. 233].

A study conducted in the USA on companies' commitments to reduce air pollution [Short and Toffel 2010] found that certain factors related to the legal context and oversight activities have a significant impact on the **effectiveness** of these **voluntary commitments**. Companies are more likely to adhere to their commitments when they are closely monitored by oversight authorities and when they undertake these commitments freely, without the threat of sanctions. The study also revealed that companies with a history of significant pollution were much more likely to fail to meet their commitments in the future, suggesting that self-control is an ineffective strategy for companies known for not complying with legal obligations.

[Coglianese and Mendelson 2010], based on an analysis of the functioning of the Responsible Care program and the INPO<sup>5</sup>, suggest that self-control works best when the regulated industry consists of a small number of relatively homogeneous and interconnected entities, and when there is an implicit "threat" of external regulation if self-control were to fail<sup>6</sup>.



The next chapter describes one of the main institutional mechanisms that enable coregulation: the partial delegation of authority for safety oversight activities to the industrial players concerned.

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<sup>5</sup> INPO is an association of operators in the nuclear energy sector in the USA, founded in 1979 after the Three Mile Island accident to promote excellence in safety and reliability. The organization produces professional standards, facilitates knowledge sharing among operators, and develops performance indicators to assess nuclear power plants along various dimensions. The performance indicators are used by insurers to determine the amount of insurance premiums paid by operators and have an impact on the operators' stock prices. Mechanisms of peer pressure encourage operators of plants with identified weaknesses to improve their practices [Rees 1994]. Further details on the historical functioning of INPO can be found in an IAEA bulletin from 1986.

<sup>6</sup> [Verbruggen 2013] uses the analogy of a "gorilla in the closet" that could be wielded by a non-sanctioning control actor to express concerns to an authority.



## Partial delegation of safety oversight

In some industry sectors, certain categories of decisions concerning safety, along with the associated responsibility, are delegated to the industry players that operate the high-hazard activities. This partial delegation of authority encompasses both the validation of design options (decisions related to certification) and the monitoring of operations (inspections, site visits, etc.). This delegation narrows the informational gap between the regulator and the regulatee, while also ensuring the presence of incentives to limit the cost of safety oversight. However, it raises questions regarding the structural and cultural independence of the people responsible for oversight with respect to production and performance pressure. What are the benefits and challenges faced by different industry sectors in this evolution?

The delegation can encompass various components of safety governance and oversight activity:

- Rulemaking and standard setting, which entail drafting legislation and regulation, as well as preparing standards;
- Verification of compliance with the regulatory framework, for instance through inspection and audit mechanisms or by measuring emissions;
- The resolution of conflicts related to compliance judgments, typically overseen by an administrative justice system.
- The implementation of coercive measures to ensure compliance, such as issuing fines or shutting down the activities of an industrial facility which is non-compliant.

The most commonly delegated activity is compliance verification (in particular, using third-party auditors), but certain institutional situations also lead to the delegation of the activity of drafting normative frameworks or best practice codes used by a profession<sup>1</sup>.

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<sup>1</sup> Several examples can be cited where third parties define standards or codes of practices that are approved, or at least used as reference, by a regulatory authority: (1) The OPPBTP is a French organization managed jointly by labor unions and employers' organizations in the construction sector, overseen by the Ministry of Labor. It produces standards aimed at improving safety in this sector. (2) Regulations related to oil exploration and production activities often refer to "recommended practices" described in standards developed by the [American Petroleum Institute](#), a private entity funded by the oil industry in the USA. Its recommendations are incorporated into regulations in the USA, as well as in many other countries. This example illustrates a partial delegation of certain regulatory development activities ("standard setting" and "rulemaking") to the regulated industry. (3) In the financial sector in the UK, the UK Financial Markets Standards Board (FMSB) is a self-regulatory organization managed by participants in the financial markets. It establishes standards and codes of best practice aimed at bridging the "regulatory gap" that exists between high-level principles and low-level operational rules. The creation of the FMSB was recommended by the [Fair and Effective Markets Review](#), following financial scandals such as the manipulation of the LIBOR exchange rate.

The **advantages of delegating authority**, as stated by [Michael 1995], include the following:

- Enhance the quality of regulatory frameworks and standards by involving actors with the best knowledge of the activity in their drafting.
- Expedite the updating of prescribed frameworks to incorporate the possibilities and risks associated with technological advancements and new societal expectations.

However, it's important to note that a certain stability in the tools used to assess the level of safety is necessary. For instance, the French nuclear sector has been engaged in a debate for several years regarding a shift from a deterministic approach for safety demonstration toward a more probabilistic (risk-informed) approach, allowing the use of economic arguments to assess design choices, such as cost-benefit analyses.

- Improve oversight **efficiency**: budgetary constraints often mean that regulators and inspectorates lack the resources necessary to ensure that all operating companies comply with safety regulations [Kolstad et al. 1990]. Authorities need to possess and maintain a high level of expertise to assess the safety of company activities and design choices, particularly concerning the prevention of major accident hazards, where the risk analyses and safety practices are generally more challenging to assess than for workplace safety. This expertise is typically better rewarded in the private sector than in the public sector.
- Reduce the cost of oversight: the cost to taxpayers is diminished because a portion of the oversight activity cost is borne by the regulated entities. These private actors thus have a direct incentive to ensure the economic effectiveness of oversight activities<sup>2</sup>.
- Enhance firms' compliance with regulatory obligations, because voluntarily adopted constraints are more readily accepted than externally imposed ones (see the box below on the crowding-out of intrinsic motivation, one explanation for this observation), and the regulations are perceived as being better informed by industrial concerns;
- Foster pluralism in regulation and oversight, which constitutes a source of legitimacy<sup>3</sup>.

#### Crowding-out of intrinsic motivation by external incentives

Definition

Research in behavioral economics and social psychology<sup>4</sup> suggests that external motivations aimed at increasing precautionary behaviour (such as fines or monetary incentives) can, under certain circumstances, crowd out intrinsic motivation (stemming from factors like morality, a sense of duty, legitimacy, fairness, or loyalty) to adopt prudent behavior.

For instance, regulations imposing fines for environmental damages sometimes have the effect of increasing the propensity to pollute, as if individuals react to the external motivation by reducing their efforts to fulfill their duty. The fine produces a "crowding-out" effect of the intrinsic motivation not to pollute by associating rule violation with a psychologically acceptable cost. A survey of Swiss citizens residing in cantons where the government was considering the possibility of installing a nuclear waste storage facility found that the proportion of people supporting the project in their canton was halved when a monetary compensation (whose existence was publicized) was offered. The acceptance rate dropped from 51% to 25%, and the level of financial compensation had no effect on the project's acceptance level [Frey and Oberholzer-Gee 1997]. A similar effect was observed in Nevada (USA) concerning the impact of tax incentives on accepting the location of a nuclear waste storage project [Kunreuther and Easterling 1990]. The most well-known study on these crowding-out effects involves an experiment conducted by a nursery in Israel that put in place fines to discourage parents from picking up their children after closing time. After an adjustment period, the number of parents arriving late increased significantly. This observation is compatible with the theory that imposing a financial penalty magnifies the

<sup>2</sup> Regulatory authorities must carry out inspections and audits of regulated facilities. This activity is costly, and the costs are borne by society. Economists offer various criticisms regarding the cost of regulation and oversight, including the fact that its costs for society can sometimes outweigh its benefits for society [Coase 1960], that it reduces market efficiency, and that it can impede economic growth.

<sup>3</sup> Pluralism, in the context of political science, doesn't necessarily imply aiming for broad public participation, but rather involving those people and organizations most directly affected or best informed about the issues in the decision-making process. This type of process encourages constructive debate and helps limit biases that may arise when regulations and oversight decisions are made within restricted decision-making circles [Dahl 1961].

perceived importance of a commercial relationship between parents and staff, crowding out parents' intrinsic motivation to respect staff working hours by introducing the notion that they are now compensated for the inconvenience [Gneezy and Rustichini 2000].

In contrast, the use of delegation of authority presents several **disadvantages**:

- It increases the risk that rules and oversight measures are designed more to accommodate the interests of the regulated industry than the public interest.
- It suffers from **lack of acceptability** by the public, particularly related to perceived legitimacy<sup>5</sup>.

Key issue

The **legitimacy** of institutions and decision-making processes is a significant subject of analysis in political science. A useful model for analyzing legitimacy involves adopting a systemic approach to the issue, distinguishing [Scharpf 1999; Schmidt and Wood 2019]:

- **Input legitimacy**, obtained through elections, which pertains to the ability to understand citizens' expectations and involve them in the decision-making process (governance *by* the people, to echo a portion of Abraham Lincoln's famous phrase);
- **Output legitimacy**, assessed based on the content of adopted policies and their ability to promote the common good and the values expressed by citizens (governance *for* the people);
- **Quality of processes** implemented (the process between inputs and outputs), which involves evaluating the level of transparency, inclusivity, accountability, performance, and absence of corruption.

## 2.1 Forms of partial delegation of authority

Figure 2.1 illustrates several types of delegation of authority for the societal oversight of safety issues:

- Elected representatives (who derive their democratic legitimacy from the electorate) and the government can delegate the safety oversight of an activity sector or a risk category to an agency or an independent administrative authority (①, *cf.* § 2.1.1).
- Elected representatives can *enroll* (②) industrial actors in the oversight of safety issues by making their responsibilities explicit (the "duty of care" notion); *cf.* § 2.1.2.
- Agencies and independent authorities can delegate some of their activities to approved private organizations (③), for example using public tendering mechanisms (*cf.* § 2.1.3).
- Agencies and authorities can allow designated industrial firms to take certain decisions related to safety oversight themselves (④) (*cf.* § 2.1.4).

We describe these forms of partial delegation of authority in the following sections.

<sup>4</sup> This theory is most well known under the term **motivation crowding theory** [Frey 1992; Frey and Jegen 2001; Fehr and Rockenbach 2003].

<sup>5</sup> A classical hypothesis concerning acceptability is that citizens believe in the principles of democracy and will accept decisions when they are established through democratic processes. However, a recent study on citizens' preferred decision mechanisms (parliamentary votes, referendums, or technocratic delegation to an agency) regarding socially sensitive topics (nuclear energy, immigration, and cannabis legalization) in three European countries showed that citizens are mainly guided by their anticipation of whether a decision mode will lead to the outcome they desire, rather than having a stable preference for a particular decision mode [Beiser-McGrath et al. 2022].

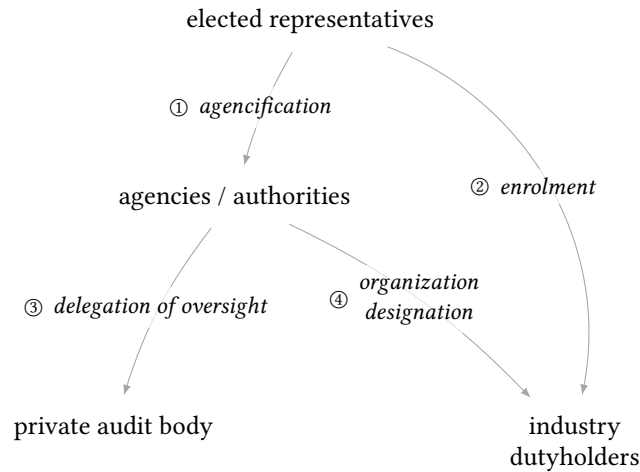


Figure 2.1 Forms of partial delegation of authority in the oversight of safety. The figure shows the sources of legitimacy to exercise oversight authority, but does not represent the oversight and inspection actions themselves. The reverse forces representing the different mechanisms through which regulated entities influence the framework of their oversight are not represented.

### 2.1.1 Agencification

Agencies are a form of administrative organization whose utilization for implementing public policies has developed, particularly since the 1990s. This process of “agencification” [Hood 1991] has led to the establishment of a significant number of semi-autonomous public entities to which varying degrees of regulatory authority are delegated<sup>6</sup>. Agencies possess distinct legal personality, have a specific domain of competence, and enjoy a certain level of operational independence. The growing reliance on agencies is explained by several factors:

- The desire to employ independent scientific experts more effectively;
- The aim to produce decisions less susceptible to political pressures, thereby enhancing the credibility of adopted public policies;
- The dissemination of the “New Public Management” doctrine (see the box below);
- In Europe, a desire to harmonize standards among member states to promote the development of the European Economic Area.

#### “New Public Management”

Definition

The “New Public Management” doctrine, which emerged in the 1980s in the United Kingdom and subsequently spread to other countries, aimed to enhance the efficiency of public administration and the quality of services provided to the public by applying strategies borrowed from the private sector. It is characterized by the separation of functions such as strategy, management, and oversight (reserved for central administrations) from operational functions (which are delegated to agencies or authorities). It also involves an increased use of market mechanisms, the implementation of outcome-based management, and the development of performance indicators.

For an illustration of how the New Public Management approach was introduced in the regulation of Seveso facilities in France, mainly by extending the existing management framework, refer to [Bonnaud and Martinais 2018].

<sup>6</sup> The development of agencies occurred at different times in various countries. In the USA, their development dates back to Roosevelt’s New Deal, with the creation of entities like the Securities and Exchange Commission (SEC) in 1934 to restore investor confidence in the stock market, the Federal Communications Commission in 1934, and the Civil Aeronautics Authority (later becoming the Federal Aviation Administration) in 1938. In France, “offices” responsible for implementing public policies with a high degree of autonomy were established in the early 20th century, followed by “agencies” (« agences ») in the 1960s, eventually reaching 103 entities by 2012, according to a study by the Council of State [Richard and Cytermann 2012].



In Europe, various types of agencies have been established since the 1970s, with significant growth particularly in the 1990s. The political context is complicated by the supranational status of these agencies, which gradually assume regulatory powers that were previously held by member states<sup>7</sup>. Three categories of European agencies can be distinguished based on their regulatory authority<sup>8</sup>:

- Agencies with rulemaking powers, such as EASA and ECHA (chemicals).
- Agencies with a role in providing technical or scientific advice (“pre-decisionmaking”), providing the Commission with non-binding opinions, although these opinions are often practically adopted as they are, such as EFSA (food safety), EMSA (maritime safety), ERA (railways).
- Agencies with a “regular” role in coordinating a network of actors or disseminating information, such as EU-OSHA (occupational safety and health) and the EEA (European Environment Agency).

### 2.1.2 Enrolment through the duty of care obligation

The authority can “enroll”<sup>9</sup> industrial actors by establishing obligations such as “vigilance plans”, which carry legal and reputational consequences for companies failing to meet these obligations.

Several examples will illustrate this mechanism:

- Obligations of “vigilance” related to the duty of care have been imposed in France on major contractors by Article L. 225-102-4 of the Commercial Code, following the outcry caused by the collapse of the Rana Plaza building in Bangladesh in 2013. These large companies are required to establish, ensure effective implementation of, and publish “reasonable” vigilance measures designed to “identify and prevent risks and serious infringements of human rights and fundamental freedoms, health and safety of individuals, as well as the environment” throughout their value chain.
- Financial institutions must implement “know your customer” mechanisms to verify the identity and monitor the activities of their customers to contribute to the prevention of tax evasion and money laundering.
- Major players in the chemical industry are encouraged to implement safe chemical management programs with their business partners (“product stewardship”).

The emergence — and controversial nature — of the notion of vigilance (which is closely related to the “due diligence” concept as applied to corporate directors, especially in the United States) in French law can be analyzed as a recognition by public authorities that traditional legal standards do not adequately control the adherence of large corporations to all citizen expectations (particularly for activities conducted in other countries). It can also be interpreted as a way to transfer a portion of the burden and cost of oversight related to corporate social responsibility to economic actors themselves.

<sup>7</sup> For instance, in the aviation sector, the EASA has progressively absorbed certification activities that were previously managed by national authorities such as DGAC in France. However, other sectors like telecommunications and energy have seen the development of exchange networks among national authorities, without the creation of a supranational entity [Levi-Faur 2011].

<sup>8</sup> We adopt here a classification and terminology proposed by [Griller and Orator 2010].

<sup>9</sup> The term “enrollment” is used by the sociologist of science M. Callon in his actor-network theory to describe one of the phases in a process of “translation”, in the sense of negotiations and actions through which a set of initially isolated actors organize into a “community” sharing a common way of framing the problem and ready to collaborate on its resolution. These phases are problematization (formulating a problem based on observations affecting several actors), *interessement* (stabilizing the network of actors interested in the problem), enrollment (defining and coordinating the roles and tasks of each actor), and finally, mobilization (actors align to make a proposal credible).

### 2.1.3 Delegation to a regulatory third party

Several control activities are carried out by private actors operating under a regulatory delegation of authority, which could be characterized as second-level control or partial privatization of control activities. Several examples are mentioned below.

- **Notified bodies** are private companies that provide conformity assessment services for products and services within the European Economic Area, thereby contributing to the regulation of safety-related issues<sup>10</sup> Their services are paid for by companies that produce or import goods or services.

#### The “New Approach” to Technical Harmonization in Europe

Definition

The development of the role of notified bodies is a component of the “New Approach” to technical harmonization and standardization, initiated by the European Commission since the 1980s to foster the common market by removing technical barriers to trade and equipment interoperability [Borraz 2007; Galland 2013]. Key points of the New Approach include:

- \* Regulation based on a requirement for results with respect to essential performance, functionality, and safety standards, rather than the prescription of specific means;
- \* Detailed technical specifications through harmonized European standards, rather than national regulations;
- \* Use of independent private law bodies authorized by Member States (notified bodies) to conduct compliance assessments, rather than public control authorities.

Key issue

While the mechanism of notified bodies seems to function satisfactorily for controlling “standard” risks (long-identified risks for which a consensus on treatment methods has been reached), this mechanism appears less suitable for the safety control of complex systems. In such systems, a contradictory or dialogic approach, based on rigorous technical debate, appears to be a better method for ensuring the effectiveness of risk management activities<sup>11</sup>.

- In the maritime sector, **classification societies** are private companies that provide technical inspection services for ships. They perform a dual role, serving both as private *classifiers* on behalf of shipowners and insurers (verifying the ship’s compliance with a classification standard) and as public *statutory certifiers* on behalf of flag states [Mansell 2009]. Classification societies also conduct audits of the ship’s safety management system in accordance with the International Safety Management (ISM) Code.

Historically, classification societies represent one of the earliest examples of private companies playing a role in risk assessment. The establishment of the *Lloyd’s Registry of Ships* dates back to 1764 in London, where insurers, investors, and sailors desired an independent and objective evaluation of the safety status of ships. They hired retired captains to conduct inspections of ships. This activity gradually evolved, giving rise to renowned risk management experts such as Lloyd’s Register (London, 1760), Bureau Veritas (originally established in Antwerp under the name *Bureau de renseignements pour les assurances maritimes* in 1828), and Det Norske Veritas (founded in Oslo in 1864).

<sup>10</sup> Notified bodies, for instance, conduct compliance assessments for non-food products in the context of CE marking, as well as safety-related checks under the Machinery Directive, Pressure Equipment Directive (2014/68/EU), Equipment for Explosive Atmospheres Directive (2014/34/EU), and Medical Devices Regulation (2017/745/EU).

<sup>11</sup> This opinion is based on Jean-Pierre Galland’s contribution to the academic seminar on the controller-controlled relationship organized by the FonCSI strategic analysis group on this theme in late 2021 [Galland 2023], as well as discussions within the group.

**Risk of a “race to the bottom”**

Classification societies provide an early example of the “race to the bottom” phenomenon that can impact the performance of private certification systems. This phenomenon occurs when certifiers perceived as more lenient with their clients attract a larger client base. In 1873, the secretary of the Lloyd’s Register wrote [Martin 1876, p. 353]:

“Up to within five or six years, we classed nearly the whole of the ships that were built in the colonies; but the Bureau Veritas stepped in, and when they found that we made concessions, they gave further concessions; for instance, if we gave a vessel an eight years’ class, they would give it nine; and if we gave it ten, they would give it eleven. That goes on till it brings into existence an inferior class of ships to what would otherwise be produced.

The work of statutory classification and certification, especially when carried out by classification societies that are not members of the professional association **IACS**, is sometimes deemed insufficient to ensure a satisfactory level of navigability. States provide a second level of vessel control in their territorial waters through **port inspections** conducted by authorized officials. When defects are identified on a vessel, it may be detained in the port until the issues are rectified, resulting in significant costs for shipowners.

This example illustrates a situation of **mutual reinforcement** between a state-controlled mechanism and one managed by private actors [Fulconis and Lissillour 2021].

- The inspection of **pressure equipment** (gas cylinders, tanks, pipelines, compressors, boilers, etc.), historically carried out in France by Seveso inspectors (the **DRIRE**), has been delegated to notified bodies since 1997 under the framework of the European “New Approach” (European Directive 97/23/CE). While the primary objective of the new approach was to reduce technical barriers to trade within the common market, another reason for modifying the control method of these equipment types was that the historical control approach, based on a set of gradually enriched technical prescriptions from a century of experience, allowed little room for the use of more efficient new control techniques, such as non-destructive testing.

Control of certain pressure equipment designed for **nuclear installations (ESPN)** has been **delegated** by the Nuclear Safety Authority to approved private organizations since 2005<sup>12</sup>. Additionally, **since 2022**, certain associated metallurgical analyses must be carried out in a certified laboratory. A number of other controls related to radiological risks, governed by standards and to be carried out on a large scale, are delegated to private organizations, such as the control of sources and devices emitting ionizing radiation.

- In Spain, inspections to verify compliance with the requirements of the **Seveso III** regulations (process industries) are conducted by conformity assessment bodies, private companies whose work is controlled by the regulatory authority. This work is carried out by a public regulatory authority in other European states. Moreover, critical assessments of hazard studies<sup>13</sup> are conducted by private consultants, working on behalf of the regulatory authority, but funded by the operators [Versluis 2003].
- **OSAC** is a subsidiary of the Apave Group authorized by ministerial decree to carry out missions of **civil aviation technical inspection** in France (see the box below).

<sup>12</sup> Only the less critical equipment is entrusted to these organizations. The most critical equipment, such as the reactor vessel or the steam generators, falls under the responsibility of the Pressure Equipment Directorate of the ASN.

<sup>13</sup> Installations covered by Seveso III regulations must prepare a hazard study, an analysis document demonstrating that the technological risk level generated by the site is reduced to an acceptable level.

- The **technical inspection of vehicles** is undertaken by private firms and paid for by the vehicle owner. Inspections are performed at centers by certified technical inspectors approved by the prefects of the departments in France. The inspection standards are established and updated by a central technical organization, **UTAC OTC**, a private organization mandated by the Ministry of Transport. To prevent conflicts of interest, these centers are not allowed to engage in any other activities related to automobile repair or trade.

#### Role of OSAC in civil aviation technical inspection

Example

As part of the French Civil Aviation Authority, OSAC issues, monitors, suspends, or withdraws approvals for production, maintenance, airworthiness management, and maintenance training organizations, as well as airworthiness documents for aircraft and aircraft mechanic licenses. OSAC performs its inspection missions:

- As part of the competent authority for activities governed by European regulations that oversee the role of the European Aviation Safety Agency EASA (e.g., issuing certificates of conformity on behalf of the authority);
- By delegation from the minister in charge of civil aviation, as part of the national civil aviation authority, for activities governed by national regulations;
- As a subcontractor of the Directorate of Civil Aviation Security (DSAC) when DSAC acts on behalf of a third party. The conditions for carrying out these missions are defined in a subcontracting contract between OSAC and DSAC;
- Under international agreements, as part of the authority defined in said agreements.

The designation of OSAC for the periods 2017-2022 and 2023-2028 was decided through competitive bidding. OSAC is remunerated through fees corresponding to the issuance of authorizations. With the agreement of DGAC, it also provides paid inspection and support services to civil and military authorities, certification services to private companies, as well as paid training activities for inspectors and investigators from various public organizations.

The work of OSAC is monitored by DSAC, which implements oversight through sampling and audits.

#### 2.1.4 Delegation to the regulated dutyholders through an designation mechanism

A regulatory authority may delegate some decisions related to equipment design or compliance verification during operation to the industrial entity that designs or operates the system. Generally, the authority verifies, using an approval and **designation mechanism**, that the industrial entity possesses both the necessary expertise and an internal organization that separates safety-related decisions from production-related pressures.

This situation of partially delegated control is not equivalent to a self-regulatory configuration (as discussed in chapter 1), because the authority oversees and monitors how this delegated oversight is undertaken and retains responsibility for the overall functioning of the oversight system. The partial delegation of oversight to the regulated entities is also distinct from goal-based regulation, in which the regulatory authority specifies the goals to be achieved and leaves the choice of means to the regulated entities, even though this latter form of oversight involves delegating the responsibility for selecting the means of attaining compliance to the industrial actors.

Let's mention a few examples of this type of delegation by designation:

- The *Organization Designation Authorization* (ODA) program implemented by the U.S. Federal Aviation Administration (FAA) allows partial delegation of **safety assessment for design** activities (type certification, certification of parts, for instance) to aircraft manufacturers (see the box below). Authorizations can also be obtained for maintenance activities. This program allows designers to make certain "routine" decisions themselves without direct FAA approval. The authority monitors the operations of organizations holding an ODA and ensures that the certificates they issue meet normative and regulatory requirements.
- The *Design Organization Approval* (DOA) program by the European Aviation Safety Agency (EASA), which shares many similarities with the ODA partial delegation mech-

anism of the FAA. However, the oversight by EASA focuses less on the competence of individuals within the delegated organization (an essential point in the ODA mechanism) and more on the separation and independence of the delegated organization from the product organizations within manufacturers, the robustness and design of their internal processes, the clarity of responsibilities, the availability of appropriate resources, and the ability to provide a satisfactory level of critical distance on design decisions<sup>14</sup>.

The delegation of authority has sparked controversies in 2022 during the trial for the crash of flight AF 447 between Rio and Paris, which resulted in 228 fatalities in 2009. The responsibility of EASA as the regulatory authority (which had recently taken over aircraft certification activities previously carried out by national authorities, including the DGAC in France) as well as its independence from design-builders has been questioned by the victims' attorneys, who asked the director of EASA at the time, who was questioned during the trial, whether the agency had the means to do anything other than a "documentary check" of the data provided by Airbus during certification. The director indicated that the certification department of the authority had fewer than 200 employees, compared to thousands of engineers at the designer-manufacturer, and that it is "too complex to perform the calculations on their behalf".

- ▷ Regarding the **inspection of pressurized equipment** (one of the industrial activities with the longest-standing safety regulation), some member states of the European Union allow approved companies to inspect their own equipment without requiring inspection by the regulatory authority. This is known as "second-party control". In France, for example, for in-service inspections, several companies have a *Recognized Inspection Service* (RIS) approved by the regulatory authority of the process sector, the DREAL. Some have a *User Inspection Body* competent for equipment design control. The DREAL regularly conducts comprehensive surveillance visits to ensure the proper functioning of recognized inspection services. The control reference framework is partly established by operators using professional guides, which can be specific to an operator or a sector of activity<sup>15</sup>. Operators with an RIS may benefit from wider inspection intervals, allowing their facilities to operate longer between major maintenance shutdowns. This leads to significant economic benefits for installations such as refineries, granting these services a certain level of organizational influence.

#### The US FAA's *Organization Designation Authorization* programme

Example

The *Organization Designation Authorization* (ODA) program established<sup>16</sup> by the FAA allows for partial delegation of safety evaluation activities to aircraft designers. This enables designer-manufacturers to make certain "routine" decisions themselves, without direct approval from the FAA. Designers designate specific employees (Designated Engineering Representatives, DER, or Designated Airworthiness Representatives, DAR) to be responsible for certification decisions (verifying that the considered design options comply with airworthiness standards). At Boeing, 900 employees were responsible for this delegated control activity, overseen by 40 FAA agents. The employees must possess a specific qualification for this task, and their appointments need individual approval from the local FAA office. Personnel from the FAA typically review all decisions made by the designated employees (DER/DAR). However, it's noteworthy that non-FAA employees performed over 90% of certification tasks, according to an [official estimate from 2013](#), and even 96% in 2018, as stated in [certain testimonies](#).

<sup>14</sup> This commentary on the differences between the ODA and DOA mechanisms is based on our interpretation of oral comments made by the director of EASA during a seminar organized in 2021 by FonCSI, as well as on the report *Aircraft Certification: Comparison of U.S. and European Processes for Approving New Designs of Commercial Transport Airplanes* from the US Government Accountability Office, June 2022.

<sup>15</sup> As an example, the company Storengy (underground natural gas storage) has a professional guide for the development of recognized inspection plans, and the use of France Chimie and the Union française des industries pétrolières (French Chemistry and Petroleum Industry Union) DT 32 guide is recognized in establishments of the oil and chemical industry.

<sup>16</sup> This delegation mechanism is quite old, dating back to 1927 for the involvement of specialized physicians and 1938 for aircraft certification activities. The scope of control activities that can be delegated to designers has gradually expanded, often at the industry's request, as it felt that the process of evaluating new aircraft was too slow and hindered the competitiveness of the American industry. New directives to increase delegation in certification were issued by the U.S. Congress in 2012 and 2018.

The ODA program, particularly its role in the “type certification” process (approval of a new aircraft design), has been subject to numerous criticisms, especially following the accidents involving the Boeing 787 Dreamliner (battery fires) and the two Boeing 737 MAX crashes in 2018 and 2019 [DOTIG 2021; Nunn 2020; Robison 2021]. The criticisms primarily revolve around the level of independence of the designated employees (DER/DAR) in relation to commercial pressures within the design companies. Post-incident investigations indicate that these engineers did not feel they had a sufficient level of authority to challenge design decisions made by Boeing, where they believed the balance between profitability and safety was not upheld<sup>17</sup>. Despite these criticisms, the general principle of delegation of authority is not fundamentally challenged by investigations into these accidents<sup>18</sup>.

The Boeing 737 MAX certification case provides an illustration of the delicate balance of a partially delegated control activity. Some commentators suggest that the tipping point towards inadequate independence of Boeing employees designated as FAA representatives under the ODA mechanism occurred in 2005, when the managers of these designated employees (DER/DAR) became Boeing employees rather than FAA employees. As a result, the designated employees no longer directly reported to FAA technical teams, but rather to their Boeing managers (*cf.* Figure 2.2, adapted from an article by the *Seattle Times*, a media outlet highly engaged in this issue, whose three journalists were awarded the Pulitzer Prize in 2020).

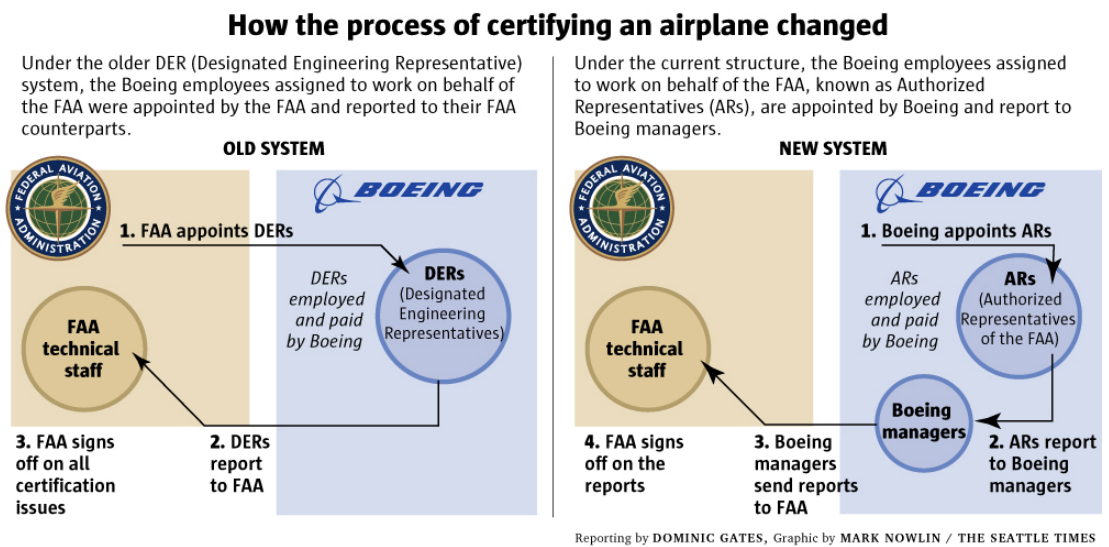


Figure 2.2 Evolution of the management hierarchy for individuals designated as representing the FAA within Boeing. Graphics from the *Seattle Times* (article dated May 5th 2019 by Dominic Gates and Mike Baker). This graphic is not included in our Creative Commons licence.

<sup>17</sup> During the design of the 737 MAX, Boeing engineers faced significant pressure to expedite the project to mitigate market share losses against the competitor Airbus A320neo. Additionally, substantial commercial pressure incentivized them to design and certify the aircraft by minimizing differences from previous 737 generations, so as to avoid requiring pilots to undergo specific training for the new generation (a costly measure for airlines, which had specified this requirement when placing orders with Boeing). These constraints led to unsafe decisions concerning the information provided to pilots about the Maneuvering Characteristics Augmentation System (MCAS).

<sup>18</sup> For example, the official report of the special committee analyzing the FAA’s certification activities in response to these accidents states (p. 49) that “The use of delegation in certification has been consistently endorsed by the agency, industry, and Congress as a means of ensuring safety and efficiency in the certification process while leveraging industry expertise”. Furthermore, the notion that certification decisions involve a balance between safety and economic considerations is widely acknowledged by the FAA: for instance, its 2017 *Blueprint for AIR Transformation* strategy document states that the FAA “balances the business needs of entities seeking certification approval (applicants) with the public’s expectations for safety”. The financial impacts of potential reinternalization of delegated activities are substantial: an FAA administrator testified before the Senate in 2019 that reinternalization would require hiring an additional 10,000 employees at the FAA and an annual increase of 1.8 billion USD in the certification activities budget.

### 2.1.5 Self-regulation without a designation mechanism

In some cases, a safety authority may delegate certain decisions related to the safety of an activity to the industrial players involved, without putting in place a formal approval mechanism designating them as being responsible. For example, food safety in Europe is partially based on the food risk management plans and auto-control mechanisms put in place by agroindustrial firms, alongside inspections undertaken by different government authorities.

Example

#### Autosurveillance of environmental emissions

Operators of polluting industrial sites in France (Seveso facilities which may have an impact on aquatic or air environments) are required to establish an emissions monitoring system to ensure compliance with emission limit values stipulated in their authorization decrees. This self-monitoring obligation aims to hold the operators of classified facilities accountable for the environmental impacts of their activities.

The measurements must be tele-declared to an information system managed by the French Ministry responsible for the environment. The measurements taken are periodically verified by third parties acting on behalf of the Regional Directorates for the Environment, Planning and Housing (DREAL).

## 2.2 Success factors for the delegation of authority

Multiple factors have been identified as being important to the success of “collaborative implementation” (by an authority and by the regulated entities, often referred to as a coregulatory mechanism) of regulatory mechanisms [Michael 1996; Balleisen and Eisner 2009]:

1. Standards and regulations are drafted in a way that allows room for interpretation in implementation methods, and the controlled entities possess the necessary expertise to enable such interpretation.
2. There exist economic incentives (reputational effects<sup>19</sup>, fear of legal sanctions in case of accidents) that drive actions towards safety, offsetting the costs for the controlled entities.
3. The regulated entities have an internal organization (such as an internal audit group, or internal inspection team) with the necessary resources and sufficient autonomy to assess their level of compliance. The results of this assessment are made public.
4. The authority actively monitors the delegated oversight program, maintaining a residual traditional oversight activity<sup>20</sup>.
5. The control process operates with a satisfactory degree of transparency.
6. Accountability issues (particularly important when an accident occurs) are taken on board seriously [Bamberger 2006].

Consider several **emblematic accidents** where a faulty implementation of partial delegation of safety oversight is assumed to have contributed to the accident:

- ▷ The crashes of the Boeing 737 MAX in 2018 and 2019, discussed above;
- ▷ The Poly Implant Prothèses (PIP) breast implant scandal in 2010 (*cf.* example 2.2 below);
- ▷ The Erika oil tanker accident in 1999 (*cf.* example 2.2).

<sup>19</sup> For instance, some commentators suggest that the public acceptance of the principle of control delegation in aviation is linked to the fact that elites – including families of major manufacturers’ leaders and regulatory authorities – are extensively exposed to risk, as they often travel by air, inherently motivating them to ensure safety. This phenomenon of risk exposure among powerful actor groups is less prominent in sectors like coal mining which have much poorer safety performance, as noted by [Perrow 1984].

<sup>20</sup> For example, one of the factors contributing to the operational conditions that led to the Deepwater Horizon accident in 2010 was a deficiency in the level of expertise and the reality of control actions by the offshore drilling regulatory authority in the USA [Mills and Koliba 2015].

**The Poly Implant Prothèses (PIP) Breast Implant Scandal**

Example

The Poly Implant Prothèses (PIP) scandal, dating back to 2010, involved a French manufacturer of breast implants that used non-compliant gels in their products, violating regulations regarding medical devices. These cheaper gels subsequently caused harm to patients. Safety and performance control of medical devices in Europe is delegated to notified bodies. The PIP implants were certified as compliant with requirements of the European Directive on Medical Devices by the notified body TÜV Rheinland, which delegated this task to its French subsidiary (despite the subsidiary lacking specialized medical personnel, unlike the parent company). The control framework for medical devices is established by the European Committee for Standardization (CEN), working on behalf of the European Union. TÜV relied on a *documentary* analysis of the manufacturer’s work (a verification mode allowed by the control framework<sup>21</sup>), without conducting technical checks of the products [Galland 2013; Verbruggen and Van Leeuwen 2018].

Figure 2.3 schematically represents the relationships among the key actors and third-party bodies involved in the PIP case control.

Since this scandal, European legislation mandates stricter controls by certification bodies, requiring them to employ personnel qualified in the medical field and perform random – and unannounced – inspections of manufacturing industries. Additionally, the French Agency for Health Safety of Health Products (Afssaps), which had a role of overall surveillance of sector actors, was replaced by the National Agency for Medicines and Health Products Safety (ANSM).

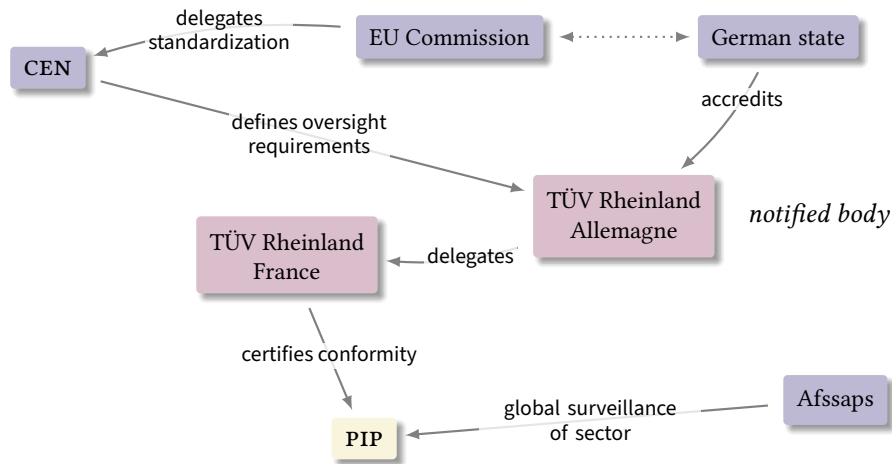


Figure 2.3 Relations between the main organizations playing an oversight role in the PIP case. Note that the institutional landscape is very different from a simple relationship between a regulator and a regulated dutyholder.

**The sinking of the Erika in 1999**

Example

In 1999, the oil tanker Erika encountered adverse weather conditions and sank off the coast of Brittany, France, resulting in significant environmental impacts. The vessel was flying the Maltese flag, a flag of convenience that offers low taxation levels on income from ships and lenient safety requirements.

The 25-year-old ship had been inspected three weeks before in sank and certified as being in a satisfactory navigable condition (although defects were identified) by the Italian classification society Rina. It had also undergone a vetting inspection<sup>22</sup> by the company Total SA, which had chartered the ship through a Panama-based company. Merchant vessels are periodically inspected by a classification society to verify their structural integrity. The classification societies had been affected by a race to the bottom, increasing the risk that their commercial interests affect their assessment of the safety requirements of their clients’ vessels [Braithwaite and Drahos 2000].

<sup>21</sup> A 2017 judgment of the European Court of Justice indicates that the notified body is not generally required to perform unannounced inspections, device checks, or review the manufacturer’s commercial documents, but in the presence of indications suggesting that a medical device is likely to be non-compliant with the requirements of Directive 93/42, the body must take all necessary measures to fulfill its obligations under the medical devices directive.



### 2.3 Questions raised by the delegation of authority

The delegation of authority for certain decisions concerning major accident hazard prevention raises a certain number of questions:

- ▷ Are the success factors identified in § 2.2 sufficient for preventing the different types of adverse trends that can affect these mechanisms (insufficient independence with respect to production pressures, “race-to-the-bottom” effects)?
- ▷ What is the degree of **perceived legitimacy** of these mechanisms, and which factors influence this perception?

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<sup>22</sup> In maritime commerce, vetting is a voluntary process by a charterer aimed at verifying a ship’s compliance with the transportation tasks it may be assigned. The process developed from the 1980s, with the disengagement of major international oil companies from the unprofitable crude oil shipping activities. Vetting processes were gradually established by oil companies following emblematic accidents such as the Amoco Cadiz and Exxon Valdez.



## Independent internal oversight of safety issues

Internal safety oversight is a process implemented by the management of an organization, aimed at providing reasonable assurance of a satisfactory level of safety. It consists of assessing the control of the activity, the safety performance and the level of compliance with relevant laws and regulations within the organization, using processes that are relevant, objective, and independent, producing results intended for the top management. The results of this function must be able to challenge and influence the improvement of safety performance and operational excellence at all levels of the organization<sup>1</sup>.

### 3.1 Position of internal control in the overall oversight architecture

As shown in figure 3.1, several layers of control can exist within organizations, particularly for critical safety aspects:

- ▷ A first level of front-line control by operational teams (peer review, self-verification);
- ▷ A level of functional or technical control<sup>2</sup>, carried out by, for example, managers or the safety department;
- ▷ The level of internal oversight by an body which is independent vis-à-vis operational teams (for example, an “inspector general”);
- ▷ The external oversight ensured by the regulatory authority.

Several **justifications** can be cited for the multiplicity of control levels:

- ▷ The principle of **defense in depth** (multiple successive and independent “barriers” or lines of defense, based on different individuals and varied mechanisms, reduce the probability of a common-mode failure), indicates that this redundancy limits the risk that an anomaly might not be detected by any of the control levels.
- ▷ The principle of **complementarity**: an internal actor, due to their position within the organization and their **privileged access to information**, is better positioned than an external controller to assess the relevance and potential risks associated with different decisions and ways of working. They are also better placed to devise appropriate corrective measures and ensure their effective implementation.

<sup>1</sup> Our definition draws inspiration from the one proposed by the World Association of Nuclear Operators (WANO) [WANO 2018], as well as the definition used by the French Financial Markets Authority: “Internal control is a company’s system, defined and implemented under its responsibility. It encompasses a set of means, behaviors, procedures, and actions adapted to the specific characteristics of each company, which contributes to the control of its activities, the efficiency of its operations, and the efficient use of its resources, and must allow it to appropriately consider significant risks, whether operational, financial, or compliance-related.”

<sup>2</sup> As an example, the 2022 report from the Inspection Générale Nucléaire (Nuclear General Inspection) of CEA, a French nuclear operator, explains the rationale behind independent technical control as follows (p. 10): “The basic principle of nuclear safety is that what is most important for safety (activities important for the protection of interests) must be carried out correctly. However, errors are inevitable, and a mistake in carrying out these activities that are particularly important for safety can have significant consequences. Therefore, technical control of the execution of these activities is required to identify these errors and allow for their treatment. At the end of the technical control, the defined requirements are thus, in principle, met.”

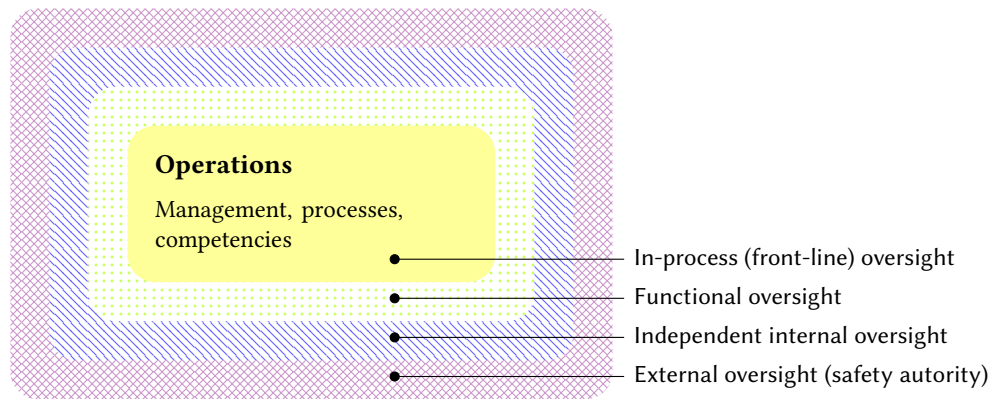


Figure 3.1 Different layers of oversight, based on [WANO 2018].

- ▷ Strengthening the **safety culture**: Internal oversight bodies and their auditing of normative commitments towards safety (procedures, company safety management system, codes of good practice, etc.) contribute, in the long run, to individuals working within the regulated entities **internalizing<sup>3</sup> the prevention objective**, rather than responding to an obligation perceived as coming from the outside [Gunningham and Rees 1997, p. 364].

### 3.2 Articulation between internal and external oversight

The reciprocal relationships between internal control activity and that provided by the external regulatory authority (or a mandated third-party organization) are interesting to study. Practices vary considerably depending on the industry sector:

- ▷ One extreme approach is to strive for a high degree of separation between the two activities in order to preserve the independence and credibility of each. This stance arises from a concern that actors in internal control might anticipate an excessively “harsh” use of their criticisms by external regulators, potentially leading them to reduce the rigor of their analyses. Such apprehension could result in censoring candid and demanding discussions about potential risks, out of fear that they might be subsequently “misused” by the regulatory authority. Conversely, sharing can lead external controllers to overly rely on analyses carried out by internal actors, without seeking to develop independent critical analyses.
- ▷ The opposite extreme involves representatives of the external authority adopting an audit approach [Power 1997], primarily relying on anomalies and criticisms developed by internal controllers (who possess privileged access to operational information), without conducting an independent critical analysis. This is the case, for example, in the banking sector, where external control explicitly and significantly relies on internal control.

This tendency aligns with a legal dynamic that employs *compliance* programs<sup>4</sup> as regulatory tools [Gaudemet 2016], and in certain respects resembles a partial delegation of authority to the controlled entity.

<sup>3</sup> In a classic work on corporate social responsibility and regulatory compliance behaviors, [Stone 1975] argues that legal sanctions are not sufficient to prevent harmful firm behaviors and promote regulatory compliance. He suggests that the most effective mechanism to allow regulation to modify firm decisions is to generate normative commitments through internal control mechanisms. Along the same lines, [Bardach and Kagan 1982, p. 123] write, “legalistic enforcement cannot encompass in formal, enforceable rules the sheer diversity of the causes of harm that arise in a large, technologically dynamic economy. The inspector who walks through a factory and faithfully enforces each regulation may not detect or do anything about more serious sources of risk that happen to lie outside the rulebook; at the same time, he alienates the regulated enterprise and encourages non-cooperative attitudes. In light of these developments, one might expect regulatory agencies to evolve enforcement strategies designed to persuade the regulated enterprise to do more than is strictly required by law. An agency’s goal would not be merely to secure compliance with rules *per se*, but to mobilize available resources to solve particular social problems in the most efficient and least disruptive way. Its mission would be to affect the consciousness, organization, or culture of the regulated enterprise in order to make it sensitive to serious sources of harm.”

<sup>4</sup> In this sense, compliance refers to the ensemble of processes that ensure a company, its managers, and its employees conform to applicable legal and ethical norms.

- ▷ An intermediate situation involves the authority prescribing a certain number of requirements concerning the controls that controlled entities must implement (different mandatory elements of an SGS, categorization of events that must be reported and internally tracked, a list of events that must be reported to the authority, for instance). This requires operators to “create auditable materials”, with the authority primarily scrutinizing the outcomes of this internal control activity. The authority supplements this activity with more or less extensive “direct” control through sampling, possibly focusing attention on companies with less effective internal control systems.

The regulatory authority can encourage operators to develop effective internal oversight mechanisms by deciding that penalties for detected non-compliance will be lower when an effective compliance program is in place<sup>5</sup>.

Thus, the regulatory authority partially relies on operators’ internal control systems and may carry out a smaller number of “direct” inspections/audits.

The use of **audit approaches** in which external oversight is conceived as a second-level control that relies on the internal oversight performed by the controlled entity presents several **disadvantages** or undesirable side effects [Power 1994]:

- ▷ It may encourage practices of “notarial safety” based on checklists and a focus on easily assessable/auditable risks, at the expense of attention to more complex and difficult-to-quantify risks.
- ▷ The development of standardization in performance evaluation tends to diminish the significance of expert judgment and thereby the autonomy and authority of professionals [Power 2021]. It tends to delegitimize and weaken specialized security expertise (specific to the field) [Almklov and Antonsen 2014], in favor of generic and standardized expertise upheld by risk management experts<sup>6</sup>. This can also be described as the infantilization of front-line actors<sup>7</sup>.
- ▷ It entails additional work to document the activity as well as translation work between the localized and situated task context on one side, and the generic boxes prescribed by the traceability system on the other. The dimensions of work that operational personnel consider most important often occur in the “shadow” of the auditability mechanism.

A description of how the articulation between internal and external control was carefully designed – as evidenced by several detailed historical analyses [Foasso 2003; Mangeon 2018] – in the French nuclear energy sector is provided in the article *Les relations entre l’autorité de sûreté et les exploitants d’installations nucléaires* [Lavérie and Flandrin 1989], where the authors write (our translation from the French original):

“*The French experience leads the safety authority to pay special attention to the competence and responsibilities of a nuclear operator. In this context, excessive regulation and control do not seem likely to enhance safety. On the contrary, excessive regulatory oversight carries the risk of “deresponsibilization” of the operator. It is the responsibility of public authorities to set safety objectives, for the operator to define practical means to achieve them, and to convince the authority of the validity of these methods, as well as to properly implement these practices, and finally, for public authorities to verify the quality of this implementation through sampling. Each of these two partners, each in their role and exercising their responsibility, must remain vigilant. These*

<sup>5</sup> For instance, the *Guidelines Manual* of the US Sentencing Commission outlines reduced criminal penalties for companies that have established an “effective compliance and ethics program”, with specific characteristics detailed in the guide.

<sup>6</sup> For instance, in a study conducted in the maritime sector, [Almklov et al. 2014] gathered the following testimony: “You know, good seamanship, it is tragic, it is about to disappear completely. That expression, ‘good seamanship,’ it doesn’t exist anymore, because everything that is to be done, has to be written on a list. You are not supposed to use good seamanship and common sense, you are supposed to use checklists, procedures and maintenance lists. That’s what it’s all about. And I know this is a source of great annoyance to the guys on the deck.”

<sup>7</sup> In a study conducted in the maritime sector, where safety control heavily relies on compliance audit approaches with reference to standards described in an SGS, [Størkersen et al. 2020] collected testimonies from experienced sailors such as “You give apples to the teacher/auditor, but it doesn’t make your work safer” and “We answer what we want our ‘parents’ to hear.”

various actions require ongoing technical dialogue that is not contradictory to the exercise of rigorous regulatory control.

### 3.3 Practices in different industry sectors

Notable differences are observed among industries concerning the extent of reliance on internal control. For instance, there is a significant proportion of direct inspections by Seveso inspectors, whereas the aviation sector heavily relies on surveillance based on internal control provisions.

Furthermore, certain industries incorporate some principles of internal control within their security framework, albeit not necessarily using this terminology. For instance, actors within the security framework of the railway and aviation sectors are often organizationally independent from operational entities. A separation between various layers of control is ensured (front-line control, functional control by hierarchical lines, independent verification of compliance with the control framework by the security framework, using audit approaches, for instance). Conversely, and although generalization may be challenging in this regard, safety framework actors are more often perceived as driving the security process (contributing to event analysis, generating indicators, continuously contemplating vulnerabilities) rather than merely forming a control framework.

Example

#### The Independent Safety Framework at EDF

This internal control system's role is to verify actions and decisions taken by teams responsible for operating installations and their impact on nuclear safety. It comprises three levels:

- ▷ The Inspector General for Nuclear Safety, reporting to the company's president and assisted by an inspector team. This position is entirely independent of the operators' hierarchical line, and it produces an annual report (publicly released) presenting its assessment of safety and radiation protection within the company.
- ▷ The Deputy Director for Safety of the Nuclear Production Division, assisted by an independent team of operational experts called the Nuclear Inspection. The Deputy Director for Safety reports directly to the Director of the Nuclear Park.
- ▷ Within various engineering divisions (Nuclear Park and Environment Engineering Division, Engineering and New Nuclear Projects Directorate), the Design Authority<sup>8</sup> studies and validates the design of new installations and modifications to existing designs, independently of the engineers performing the design (within the "design organization").
- ▷ At each power plant, the Safety and Quality Mission Leader and safety engineers conduct independent checks and audits on safety, environmental, or radiation protection-related themes. They are independent of the operational hierarchical line and report directly to the plant director. They regularly compare their assessments with those of the operating teams. Within the engineering and projects directorate, an audit and evaluation mission oversees safety in design activities.

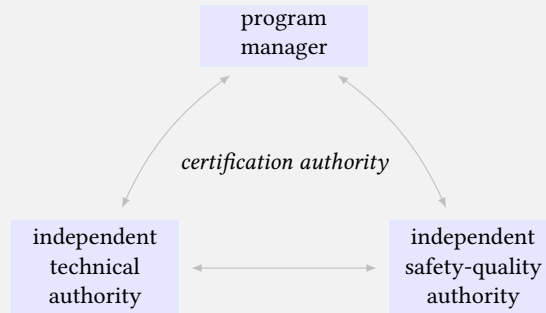
The internal safety control system in place at EDF, along with its interaction with external control, is thoroughly analyzed in Appendix A.

<sup>8</sup> According to INSAG 19 published by the IAEA, the Design Authority is the entity "responsible for ensuring that the knowledge base is established, has been preserved and is expanded with experience".

Example

### The independent safety-quality authority in the U.S. Navy

Following the loss of the nuclear submarine *Thresher* during a test in 1963, the U.S. Navy established the SUBSAFE quality assurance program. One component of this program is the separation of powers among three pillars: program managers (responsible for costs, deadlines, and the quality of the vessels under their charge), independent technical authority (responsible for ensuring technical standards adherence and availability of technical skills), and independent safety-quality assurance authority (responsible for ensuring that work conducted under the program manager's responsibility complies with the requirements of the technical authority). Each of these entities is organizationally independent and possesses the authority to withhold vessel certification until identified difficulties are resolved.



Example

### “Compliance” activities in the banking sector

The activities of “compliance” (control and prevention of non-compliance risk) have been gaining increasing importance in the banking sector over the past two decades, particularly in France since the regulation 97-02 of the Committee of Banking and Financial Regulation regarding internal control (1997). Banks have established a “compliance function” responsible for monitoring the work of operational actors in relation to various risks, such as financial risks (ensuring that financial institutions have sufficient capital to “cover” market risks) and the fight against money laundering and terrorism (know your customer obligations). Financial institutions typically have three internal levels of control:

1. Risk management by operational personnel, who are the primary responsible parties for risks generated by their activities;
2. The compliance function, which continuously monitors first-level activities and assesses financial risks at the organizational level;
3. An audit department reporting to top management, conducting occasional surveys while remaining organizationally independent of the other two levels.

The *Consultative Document on the Compliance Function in Banks* by the Basel Committee (a forum for exchange among central bank governors from around fifty countries) stipulates that the compliance function should be independent of operational teams, provide advice and report to the executive body on non-compliance risks. The banking regulator should be informed of changes in the head of this function, and the personnel assigned should possess the skills, experience, and professional and personal qualities necessary to assume this function.

## 3.4 Questions raised by the internal oversight of safety issues

Internal oversight of safety issues raises certain questions:

- ▷ Regarding the design of internal control in relation to various tensions mentioned in the introductory chapter, such as the balance between cost and performance, and between advisory and punitive measures. Internal control can be approached with a focus primarily on compliance with internal standards, or alternatively aim for a broader consideration of the system's quality and its impact on industrial security. This approach would be based on dialogue and aimed at appreciating the complexity of each local situation.
- ▷ On their **effectiveness** in controlling security issues: internal control is often more demanding than external control would be (to safeguard the legitimacy of involved stakeholders and to mitigate the fear of internal decisions being challenged by external audits).

- ▷ On the degree of **independence** from production pressures and their capacity to provide peer critiques. What mechanisms are implemented by operators to ensure the independence of the internal oversight system?

Internal oversight structures also encounter some of the same challenges faced by external regulatory authorities. How can the expertise of involved individuals be maintained while allowing them to maintain a sufficient social distance from the operational sector? What career management processes are in place, possibly involving transitions between the internal control sector and operational roles?

- ▷ Concerning **clarity of roles** and the **definition of responsibilities** among frontline actors, those in the operational hierarchy, and those in the internal control hierarchy. Illustrating these difficulties, the [2022 report](#) from the Nuclear General Inspection of CEA (a French nuclear operator) indicates that (our translation):

“ Regarding second-level oversight, I observe that its implementation varies greatly depending on the units or the theme (safety or security). It is sometimes confused with the monitoring of outsourced activities or even deployed in a routine manner, without explicit connection to risk analysis and decoupled from actual operations. Additionally, the effective distribution of various controls among actors often deviates from regulatory texts, leading to confusion. These situations weaken the effectiveness of conducted controls and squander resources instead of allocating them to more critical activities.

- ▷ How can the proper functioning of an internal security control mechanism be evaluated? For example, an indicator used by French nuclear operator EDF concerning the independent safety sector is the proportion of their remarks or recommendations that are followed by the operational sector. This follows the daily assessment of reactor safety conditions (evaluation of reactor operation parameters and conditions) conducted between the independent safety sector and the operational sector.



## The role of regulatory third parties

This chapter analyzes the role played by different categories of third parties in the regulator-regulatee relationship. Intermediaries such as notified or accredited bodies, auditors, insurers, professional associations and federations, extra-financial rating agencies, associations, and NGOs are increasingly associated or involved in exchanges between a safety authority and dutyholder, and they participate in various ways in the social control of risks [Gunningham et al. 1999; Grabosky 2013]. This trend occurs within a context of decentralization, fragmentation, and privatization of powers that were previously exclusively held by the State. The academic literature uses terms such as “tripartism” [Ayres and Braithwaite 1991], “pluralist governance”, “polycentric governance” [Black 2001], and “regulatory intermediaries” [Abbott et al. 2017].

The most frequently cited **motivations** for the use of regulatory third parties in the management of major accident hazards are listed below:

- ▷ The use of third parties, who are remunerated by the regulated firms, reduces the costs that must be borne by the public regulator and thus by the taxpayer<sup>1</sup>.
- ▷ Regulatory authorities often aim to focus their efforts on the most significant risks (an approach known as “risk-based oversight”; *cf.* the sidebar below). Thus, more traditional or easily controlled risks are addressed by third parties, using various mandatory or incentive-based mechanisms.
- ▷ Involving a larger number of more diverse actors in the regulatory process results in a greater diversity of information and values considered in decisions. This mode of regulation acknowledges that in complex systems, knowledge about risks is fragmented, and the meaning of safety (which is partly socially constructed, rather than a fully rational construct) can vary based on the positions and histories of involved stakeholders.

### Managing safety issues during football matches

Example

To illustrate the importance of involving stakeholders in regulatory activities, [Elliott and Fischbacher-Smith 2006] analyze why the football (soccer) industry in the United Kingdom underestimated the importance of safety issues during matches for many decades, despite numerous accidents since 1946 resulting in many deaths (Bolton, Bradford, Hillsborough). The clubs and authorities had long considered hooliganism to be the primary safety concern, allocating few resources to stadium design to prevent crowd crushes and control fire risks. Only external pressure from the public and the media was able to change these attitudes, which were based on a nostalgic view of the sport, ensuring that these safety issues were – albeit belatedly – taken seriously.

<sup>1</sup> Several quantitative elements illustrate the limits of the regulatory authority’s direct inspection capacity. As indicated in an evaluation report on environmental policing by the French General Council for the Environment and Sustainable Development dated 2015 (our translation), “The regulatory authority’s control capacity for classified installations is relatively low when compared to the number of installations: based on 1,230 full-time equivalent inspectors (FTEs) and an objective set by the finance law of 25 inspections per inspector per year, the theoretical control capacity is approximately 30,000 inspections per year, while the number of regulated installations is around 500,000. On average, an installation would be inspected once every 17 years, resulting in limited control pressure for an operator. The relatively low frequency is not an exception, neither in the environmental domain nor in other activities regulated by public authorities. Some of these activities are subject to even lower average control pressures.”

- ▷ By incorporating actors with different roles, tasks, and jurisdictions, regulatory processes can expand the range of options available to resolve encountered problems (this is compatible with the principle of “responsive regulation”, which emphasizes the regulator’s ability to choose an action across the spectrum of persuasion-punishment based on the perceived attitude of the controlled entity) [Van de Walle and Raaphorst 2019].
- ▷ The increased democratic transparency resulting from the involvement of third parties facilitates high-quality dialogue and helps achieve compromises that are acceptable by all parties. It also reduces the risks of the regulator being “captured” by the regulated industry.

#### Risk-based oversight, or “smart enforcement”

Definition

Risk-based oversight, also known as “smart enforcement”, involves focusing regulatory efforts on situations where violations are more likely or where the impact of non-compliance would be highest. Inspections are then prioritized for certain categories of installations or establishments historically known for low compliance levels or weak internal control systems. Decisions regarding actions to be taken upon identifying non-compliance are also proportionate to the risks associated with these violations.

While it is challenging empirically to assess the contribution of this control approach, some authors suggest that health and safety regulation in the United Kingdom, which relies on a risk-based approach, yields far superior outcomes compared to the control of similar risks in Germany, where risk-based targeting of inspections is less utilized, despite having significantly fewer inspectors per employee in the UK [Blanc and Faure 2020].

Among the criticisms directed at this form of oversight, concerns are raised regarding (1) the principle of equitable treatment of regulated firms and (2) the possibility that activities that individually pose low risks might, when aggregated across multiple establishments, lead to a significant cumulative risk.

### 4.1 Categories of regulatory third parties

We discuss below a number of examples third parties that play a regulatory role concerning industrial safety.

- ▷ Various types of **accredited organizations**, such as:
  - Conformity assessment bodies, like notified bodies in the context of various missions related to European regulations (*cf.* Section 2.1.3);
  - Maritime classification societies (*cf.* discussion on page 18);
  - Third-party experts (« tiers experts ») which participate in the oversight of Seveso installations in France, by undertaking critical reviews of safety cases on behalf of the regulator.

#### Tripartite Standardization Regime

Definition

The term “tripartite standardization regime” or “tripartite regulation” is used to describe regulatory systems based on the standardization-certification-accreditation triad, in which accredited third parties play a significant role. In these systems, schematically illustrated in figure 4.1, certification bodies verify that products and operations of industrial actors comply with a normative reference, such as an international standard or a label. This standard/norm is developed by a standardization organization with input from industrial actors, certification bodies, and accreditation bodies. Accreditation bodies verify and attest to the competence of certification bodies in evaluating conformity of products and operations [Fouilleux and Loconto 2017].

Experience indicates that these regimes require clear principles governing the relationships among the three categories of actors, as well as their interactions, for instance, to allow certification bodies to participate in standard development.

The industry sector known as *Testing, Inspection and Certification* (TIC) has experienced significant growth in recent years, as depicted in figure 4.2. It represented a financial volume of 217 billion USD in 2022, with 74 billion USD in Europe, projecting an annual growth rate of 7% by 2030. These activities, predominantly represented by companies

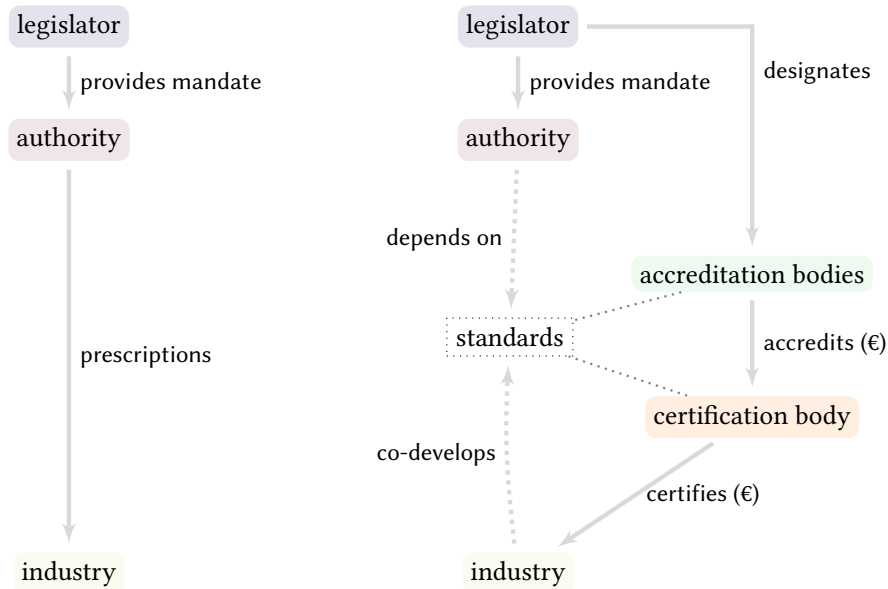


Figure 4.1 On the left, a simplified representation of a regulatory system in which the safety authority imposes, through the use of regulatory prescriptions, obligations that the relevant industry players must respect. On the right, a tripartite standardization regime in which certification bodies (accredited third parties) play an important role.

established in the 19<sup>th</sup> century in Europe, such as Bureau Veritas, Lloyd's Register, Intertek, DNV GL, TÜV, and SGS, thus constitute a **substantial commercial concern**.

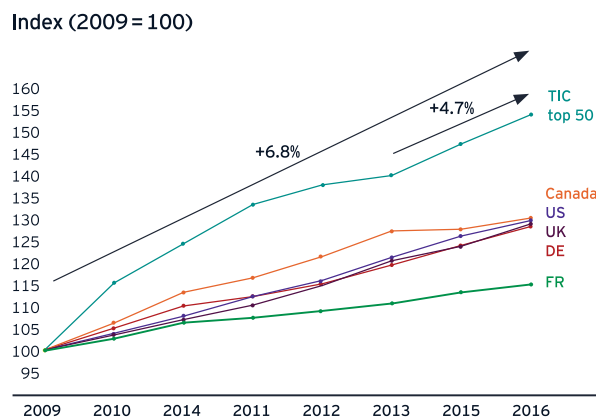


Figure 4.2 Evolution of the annual growth of the 50 largest companies in the test, inspection and certification (TIC) sector since 2009, compared with the growth of GDP of large economies over the same time period. Source: EY-Parthenon GmbH report "A steeper ascent: Growth in the testing, inspection and certification (TIC) industry", 2020.

- ▷ Self-regulatory organizations, whose role has particularly developed in the financial sector, are worth mentioning. These are private entities designated by the government or a regulatory authority to oversee an industry sector or market. Notable examples include [FINRA](#) in the USA, a private association designated by Congress to monitor brokerage firms' activities; stock exchanges in financial markets that undertake regulator-like activities to prevent fraud and ensure investor information; and professional associations responsible for self-regulating advertising in several countries (such as the [Advertising Regulatory Authority](#) in France).
- ▷ Professional federations and associations associated with specific industry sectors, such as the International Association of Oil & Gas Producers ([IOGP](#)) and the [American Petroleum](#)

Institute (API) for the offshore sector, WANO for nuclear power plant operators, and the International Air Transport Association (IATA) for aviation. These structures are increasingly used<sup>2</sup> as flexible coordination platforms between entities sharing common interests, for example, to establish industry standards or best practice guidelines. They can establish “soft law” and reference frameworks that serve as standards for all actors within a sector (for instance, API standards are often “referenced” in national regulations for oil exploration and production activities), which can turn into international standards [Brunsson et al. 2012; Olsen et al. 2019]. This interaction between public regulatory approaches and initiatives driven by private actors is occasionally criticized for potential violations of certain democratic principles (for example, access to private standards – even when incorporated by reference into public regulations – often requires payment, which is incompatible with the principle of equality before the law) [Baram and Bieder 2022].

Voluntary standards are also used by the judiciary in cases related to product safety or operator negligence, when assessing whether the prevention measures taken met the duty of care standard. A manufacturer or operator deviating from commonly used standards within an industry often needs to justify the reasons for such deviation.

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#### The SQAS Warehousing Standard for Logistics Safety

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Example

The European Chemical Industry Council (Cefic), an association of chemical industry manufacturers in Europe, manages a reference framework for assessing the quality, safety, and environmental performance of logistics providers and distributors of chemical products, called the *Safety & Quality Assessment for Sustainability (SQAS)*. Assessments are conducted by third parties trained and accredited by Cefic. The evaluation results are used by chemical industry companies to select their logistics service providers.

Following the Lubrizol/NL Logistique fire in Rouen (France) in 2019, France Chimie, a professional association of chemical companies in France, launched a campaign to promote the widespread use of this reference framework among service providers engaged in the storage and transport of hazardous materials in the French chemical industry.

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#### OCIMF, International Coalition of Major Oil Producers

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Example

The Oil Companies International Marine Forum (OCIMF) is an association that brings together major oil producers. It operates a tanker inspection program (“vetting”) for vessels transporting crude oil (Ship Inspection Report Program, SIRE), based on sharing audit reports conducted by private auditors. This program is significantly more demanding than international maritime regulations in the oil shipping sector, which rely on the requirements of the flag state where the ships are registered (often open registries with relatively lenient technical ship standards) and on occasional inspections conducted by port authorities. SIRE audit reports are shared with maritime authorities in different countries as well as with port authorities.

Accident analysis studies show positive effects of this mechanism on the safety of the vessels involved [Knapp and van de Velden 2011], in an industry where economic competition severely limits national regulatory authorities’ ability to impose binding regulations [Størkersen 2015].

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<sup>2</sup> There is interesting academic literature on *meta-organizations*, which refers to organizations composed of other organizations (not individuals) [Gulati et al. 2012; Berkowitz et al. 2022]. These entities blur the boundaries of traditional organizations, allowing the establishment of complex networks of exchanges among actors with sometimes diverse interests, particularly in fields where the cross-border nature of issues makes relying on traditional regulation difficult.

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**Safety audit programs organized by IATA**


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Example

The **International Air Transport Association (IATA)** represents major international airlines. IATA establishes safety standards based on International Civil Aviation Organization (ICAO) regulations and industry best practices and verifies compliance of its member airlines through audits. IATA has developed and promoted labels such as **IOSA** (IATA Operational Safety Audit for airlines) and **ISAGO** (IATA Safety Audit for Ground Operations for ground handling service providers), allowing for the mutualization of audits under the “duty of care”. These audits are particularly relevant in codeshare situations between airlines or for member airlines within the same alliance. Audits are conducted by auditors trained and authorized by IATA and have international scope.

These two programs can be useful complements to national regulatory oversight activities [Mills 2016], where IOSA audits, for instance, can be made mandatory components of an airline’s safety management system, a form of hybridization of public and private oversight.

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**The Center for Offshore Safety in the USA**


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Example

After the Macondo accident (Deepwater Horizon platform) in 2010, which resulted in significant environmental damage, the offshore industry in the USA organized itself by establishing the *Center for Offshore Safety* (COS) within the professional association API. The COS assists operators by developing standardized audit procedures, accreditation mechanisms for auditors, and information-sharing mechanisms [TRB 2016, p. 118].

- ▷ **Supranational agencies and organizations** that play a role in harmonizing practices and jointly developing reference frameworks used at an international level. These include international organizations in the United Nations framework, such as the International Civil Aviation Organization (ICAO) that develops standards used by various national aviation authorities, the International Atomic Energy Agency (IAEA) that focuses on the safe use of nuclear technology, the International Maritime Organization (IMO) that develops standards for maritime transport safety, and the International Union of Railways (UIC).
- ▷ **Auditors** who certify compliance with private normative frameworks, such as ISO 14001 for environmental management systems or audits associated with the voluntary *Responsible Care* program in the chemical industry. Over the past decade, with the rise of socially responsible investing and increased interest in environmental, social, and governance (ESG) criteria, auditors assess companies’ **non-financial performance** concerning various criteria, including some related to HSE issues, such as environmental impacts and physical and psychological risks to employees (the social dimension of ESG). These assessments affect companies’ borrowing capacity and their stock prices. French law<sup>3</sup> mandates that the compliance and accuracy of such statements (for large companies) be verified by an “independent third-party organization” (OTI) accredited by Cofrac. The OTI’s assessment must be communicated to the company’s shareholders.
- ▷ **Insurers** and their expertise organizations, which can provide advice to companies on how to manage their industrial risks<sup>4</sup>. Insurers play a particularly important role in fire risk, and standards from the US *National Fire Protection Association*, an association funded by major insurers, serve as a reference for fire risk prevention and mitigation.

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<sup>3</sup> The regulatory framework regarding corporate non-financial reporting has been gradually evolving for the past decade. The European Directive 2014/95 (“NFRD”) was transposed into French law in 2017, requiring large companies to prepare an annual non-financial performance statement. The European Directive 2022/2464 *Corporate Sustainability Reporting Directive* (CSRD) expands reporting obligations to more companies and strengthens and standardizes reporting requirements by using the “European taxonomy”.

<sup>4</sup> The role of insurers dates back to the birth of industry, with the *Great Fire* in London in 1666, caused by a bakery oven. From the 18th century onwards, inspectors and fire brigades were the primary drivers of fire risk prevention [Le Roux 2014]. In contemporary times, insurers and reinsurers such as Marsh, FM Global, Allianz, and Swiss Re have established specialized teams for high-hazard industrial activities.

The Lubrizol/NL Logistique fire in Rouen (France) in 2019, which caused significant concerns about the health impacts of the generated pollution, provides an interesting illustration of the work carried out by insurers regarding the assessment and improvement of technological risk control. The operating company's insurer, FM Global, produced a report containing several recommendations to enhance fire risk management, which were not known to the regulator, the DREAL<sup>5</sup>.

#### The American Society for Mechanical Engineering (ASME)

Example

The ASME is a non-profit, independent organization founded in the USA that develops standards for pressure equipment, elevators, and transport pipelines. The organization was established in 1880 in response to numerous deadly steam boiler explosions, a novel equipment type that was rapidly developing at the time, for which there was little established knowledge of safe fabrication practices. Insurers rely on compliance audits with standards established by ASME to ensure their clients follow industry best practices in equipment design, operation, and maintenance.

#### Insurance Institute for Highway Safety in the USA

Example

In the USA, the *Insurance Institute for Highway Safety* (IIHS) is a non-profit organization funded by vehicle insurers. One of its main missions is to conduct vehicle crash resistance tests. These tests are often more demanding than those conducted by the governmental authority NHTSA, including non-frontal collisions, for instance. The results published by this organization influence some consumers' purchasing choices and thus impact vehicle design.

- ▷ **Safety consultants** who sometimes play an important role in risk analysis, such as in preparing hazard studies for facilities in the process industries [Owen 2021; Størkersen et al. 2023].
- ▷ **Associations and NGOs**, especially those concerned with environmental issues or representing the residents near certain installations. Notably, recent forms of activism have used legal means to influence the environmental policies of large companies<sup>6</sup>.

#### The dismantling of the Brent Spar oil platform

Example

In 1995, a highly publicized disagreement regarding the decommissioning of the offshore Brent Spar platform in the North Sea arose between the NGO Greenpeace and the oil company Shell, the platform's owner [Löfstedt and Renn 1997]. Believing that the usual end-of-life treatment for these installations, dismantling on land, would be risky due to the platform's configuration and structural condition, Shell **planned** (with the agreement of the UK government) to clean the platform of its oil residues and sink it in deep sea waters.

Greenpeace contended that this sinking operation would release significant amounts of oil into the sea and launched a media campaign to advocate for a land-based dismantling solution. Activists occupied the platform, and the NGO organized a boycott of the company's gas stations. Shell eventually changed its strategy and decided to dismantle the platform on land.

An independent audit of the platform later revealed that it contained one hundred times less oil than Greenpeace claimed, prompting the NGO to issue an apology letter to Shell.

<sup>5</sup> The insurer's report specifically mentioned (our translation) that "During a fire, intermediate bulk containers (IBCs) made of plastic would melt rapidly, and the combustible and/or flammable liquid would spread on the ground, causing a large pool fire", a situation that indeed occurred. Regulation has evolved since this incident to allow inspectors of classified facilities to access such reports, and the decree of September 24, 2020 now stipulates that "The elements of risk assessment reports that concern findings and recommendations resulting from the insurer's risk analysis conducted within the establishment shall also be made available to the inspection of classified installations".

<sup>6</sup> For instance, following a lawsuit by several environmental NGOs, a Dutch court ruled in 2021 that Royal Dutch Shell was not fulfilling its duty of care in addressing climate change and should accelerate its reduction of "scope 3" carbon emissions by 45% by 2030 compared to 2019 levels. Moreover, a small activist investment fund, Engine 1, launched a campaign to transform ExxonMobil's sustainability policy. Backed by major index funds BlackRock and Vanguard, it gained three seats on the company's board, despite owning only 0.02% of the shares.

Certain NGOs even play a role in overseeing the power of states: for instance, Transparency International aims to reduce corruption in national governments and international institutions, and Amnesty International highlights human rights violations. Although these entities lack formal mandates for oversight and coercive power, their ability to mobilize public opinion grants them regulator-like influence over state actors' activities [Scott 2002].

- ▷ **Independent researchers and laboratories** that can carry out verifications and checks independently of those conducted by the regulatory authority and the operator, in order to identify points that warrant further analysis. They can play the role of an **external whistleblower**.

#### Emissions test fraud: the “Dieselgate” scandal

Example

The Dieselgate scandal involving emissions test fraud by various diesel vehicle manufacturers (including Volkswagen, Volvo, and Renault) was detected in 2015 by a team of researchers from the University of West Virginia (USA), working on behalf of the *International Council on Clean Transportation*, a US-based NGO. The regulatory compliance tests implemented by the regulatory authorities in the USA and Europe were conducted under standardized laboratory conditions, allowing a “defeat device” (software installed in the vehicle engine controller) to detect when a test was underway and consequently lower pollution levels produced. In contrast, the measurements taken by the researchers were conducted under real driving conditions, which revealed nitrogen oxide emissions levels more than 20 times higher than permitted.

Key issue

This example also illustrates the phenomenon of *regulatory capture*, whereby the industry being regulated gains influence over the regulatory authority: the widening gap between pollution measurements obtained during vehicle approval tests (allowing their commercialization in Europe and the USA) and emissions under real driving conditions was known to national authorities and the European Commission, but an implicit “don’t shake the boat” agreement existed between the authorities and the industry, due to the commercial and industrial challenges that would arise from strict emissions control [Aggeri and Saussois 2017].

- ▷ The **justice system**, as a counterpower with the ability to sanction a regulatory authority whose work is deemed incompatible with the law, or as an authority that can enforce the law when approached by a complainant. The phenomenon of **judicialization** (the expanding role of judges in monitoring compliance with regulation and criminalizing actions that precede accidents) is having an increasing impact on the practices of stakeholders, notably due to:
  - the growing trend of people (associations, NGOs, and even local governments) challenging industrial activities through legal action;
  - regulatory developments like the duty of care for major contractors<sup>7</sup> in France, and the rapid rise of securities fraud actions in the USA [Strauss 2020].
- ▷ **Consultation bodies** play a role in the regulator-regulatee relationship. For instance, in the field of nuclear energy in France, representatives of CLI<sup>8</sup> occasionally participate as observers in inspections conducted by the ASN. This participation as observers requires,

<sup>7</sup> The duty of care for parent companies and major contractors was introduced in France in 2017 by Law No. 2017-399, amending Article L.225-102-4 of the Commercial Code, following a contentious legislative process (and many challenges from large firms).

<sup>8</sup> Local information commissions (CLI) are dialogue tools established around basic nuclear installations in France. They have a mission of monitoring, providing information, and facilitating consultation on nuclear safety, radiation protection, and the impact of nuclear activities on people and the environment. They are required to be consulted during certain projects involving changes to installations. Marie Kerveillant’s doctoral thesis analyzes their operations, the impact of their increasing institutionalization (Transparency and Nuclear Safety Law of 2006, followed by the Energy Transition for Green Growth Law of 2015, which reinforce the official role of CLI) on the work of ASN inspectors, their perception of their role in control, and more broadly, the role of the public in the governance of nuclear risks [Kerveillant 2017]. CLI are federated within the National Association of Local Information Commissions (ANCCLI).

under the current regulatory framework, the operator’s agreement; only ASN inspectors have a legally enforceable right of access.

The activities of consultation bodies and, more generally, public participation in safety oversight mechanisms, contribute to enhancing the transparency of the regulatory system, supporting its ability to be accountable to the public, strengthening its democratic legitimacy, and helping prevent certain tendencies such as excessive complicity between the regulatory authority and regulated entities (“regulatory capture”). Through their ongoing mediation work, these bodies also help mitigate the risks of populist reactions to risks that receive intense but short-lived media attention [Breyer 1993; Lodge and Hood 2002].

- ▷ **Elected officials**, as well as the mechanisms of representative democracy in general, contribute to the proper functioning of risk oversight, especially by overseeing the activities of the regulator<sup>9</sup>. Notably, the role of the Parliamentary Office for the Evaluation of Scientific and Technical Choices (Opecst) in France can be mentioned. This body annually interviews the president of the nuclear safety authority ASN as well as the director-general of the Institute for Radiological Protection and Nuclear Safety (IRSN), the TSO.
- ▷ **Customers of a company** and consumers can be considered third parties who play a role in certain forms of regulation, especially through labeling mechanisms<sup>10</sup>. Labeling mechanisms make it possible to influence practices where national authorities and legislators have limited influence, especially production activities situated in other countries.

Another indication of the regulatory role played by the commercial partners of firms comes from a study conducted in the USA, which found that US companies declare that their investments in tracking and reducing the use of toxic substances in their products are more determined by the private requirements laid out by their clients, as specified in their commercial contracts, than by national regulations [Vandenbergh 2013].

- ▷ **Shareholders and investors** in a company are third parties who generally have an interest in the company preventing major accidents (which can be financially costly), maintaining a favorable “ESG” rating for socially responsible investment, and avoiding reputational effects caused by environmental violations. They also have the capacity to influence company decisions through shareholder votes or their presence – for major shareholders – on the board of directors (for an illustration, see the description of actions by a group of investors concerned with mine dam safety proposed on page 42).

#### Indirect regulation of climate obligations

Example

In 2022, the U.S. Securities and Exchange Commission (SEC), the regulatory authority for financial markets in the USA, proposed new regulations concerning climate impact disclosure obligations for publicly traded companies, focusing on the environmental aspect of non-financial reporting. The rules require listed companies to describe their climate-related risks and how they are managed. They must report their greenhouse gas emissions, and these disclosures must be verified by an independent entity. The companies are required to state which members or subcommittees of the board/executive committee are responsible for climate issues, and what skills the board members possess in this context. The companies must disclose the processes and frequency through which the board is informed about and discusses climate issues.

The approach taken by the SEC (information obligation or “attention regulation”) can be seen as an alternative to prescriptive regulations regarding climate effects. The principle is that investors have an interest in reducing climate impacts and their pressure will encourage firms to implement relevant policies to control this risk, more effectively than a global regulation would allow.

<sup>9</sup> *Quis custodiet ipsos custodes?* or “Who will guard the guards?” – an ancient theme of reflection found in Plato’s dialogues.

<sup>10</sup> As examples of labels related to environmental issues, the organic label, the Forest Stewardship Council (FSC) label concerning sustainable forestry, the Marine Stewardship Council (MSC) label for sustainable fishing, and the Better Cotton Initiative label for fair cotton trade can be mentioned.



**Control of tax and social declarations of subcontractors**

An experiment in the construction sector in Sweden [Van de Walle and Raaphorst 2019] consisted of requesting **principal contractors to verify the accuracy of tax and social declarations of their subcontractors**. This experiment aligns with a suggestion by the OECD that tax inspectors could benefit from developing collaborations with external partners<sup>11</sup>. The chapter describes the dialogue established between tax inspectors who seek to enlist the supervisors of a construction site in a time-consuming verification process that is not mandatory for the principal contractor, but which could help prevent reputation risks associated with a subcontractor engaged in tax evasion. It aligns with a social norm of combating fraud.

**4.2 Liability of third parties in case of insufficient care**

If third parties play a role in the social control of risks, do they incur liability if their actions are later deemed to be deficient?

The liability (legal responsibility) of third parties involved in the social control of risks is interesting to analyze [Verbruggen 2022]. Several cases described below illustrate the nature of responsibilities that plaintiffs can seek, at least when the role of the third party is formally defined, and highlight the way in which these issues are taken on board by both regulatory third parties and safety authorities.

- ▷ In the case of the **PIP breast implant scandal** (*cf.* box on page 24), after a decade of legal proceedings and conflicting judgments, the Paris Court of Appeal in 2021 **confirmed the liability** of the third-party certification body due to negligent shortcomings. The court ruled that the German notified body, TÜV, along with its subcontractor, its French subsidiary, should have detected irregularities by analyzing the manufacturer’s supplier accounting. It ordered them to compensate victims for breaching their “duties of control, prudence, and vigilance in the exercise of their mission”. This judgment followed a **2017 ruling** by the European Court of Justice that deemed notified bodies “subject to a general duty of care attached to their intervention in the procedure for the CE declaration of conformity” and “required to exercise vigilance, so that when there are indications suggesting that a medical device may not comply with requirements [...] must take all necessary measures to fulfill the prescribed obligations”. The European court also stated that the “conditions under which a negligent failure [of a notified body] to fulfill the obligations that are incumbent upon it [...] may be of a nature to incur liability towards those recipients, are a matter for national law” (civil liability legislation in European Union member states has not been harmonized).

TÜV has consistently rejected liability, placing blame on PIP, asserting that the manufacturer “did everything to deceive patients, as well as health authorities and the inspecting body, TÜV”. The director of PIP died in 2019, ending legal actions against the company (which had swiftly gone bankrupt following the discovery of the defect).

Since these events and the associated judgments, a quarter of notified bodies have withdrawn from the market for certifying the conformity of medical devices [Glinski and Rott 2019].

- ▷ The **Brumadinho dam disaster** (in the state of Minas Gerais, Brazil) in 2019 resulted in the collapse of a dam at a mining waste reservoir operated by the company Vale SA, leading to the death of 270 individuals. The stability of the dam had been assessed by the company TÜV Süd, in compliance with regulatory obligations for such infrastructure in Brazil. TÜV Süd’s report, submitted four months prior to the dam’s failure, affirmed its stability (although it indicated a safety factor of 1.09, whereas good dam practices aim for a factor above 1.3).

<sup>11</sup> The report suggests that collaborations with private companies, accountants and tax advisors, specialized software providers, and civil society would reduce the operational costs of the authority, improve the effectiveness and fairness of controls, as well as the public’s trust in the oversight process. This suggestion is part of a trend to encourage the **coproduction** of public services through partnerships between public and private entities, using various engagement and enlistment mechanisms listed in the report. Report *Together for better outcomes: Engaging and involving SME taxpayers and stakeholders*. Forum on Tax Administration Compliance Sub-Group, OECD Publishing, 2013. DOI: 10.1787/9789264200838-en.

Brazilian prosecutors pursued legal action against Vale, as well as TÜV Süd, accusing the latter of falsifying documents attesting to the dam's strength. In 2021, Brazilian plaintiffs filed a complaint against TÜV Süd in a German court.

Email exchanges between employees of Vale and TÜV Süd, included in the Brazilian prosecutors' complaint, indicate that TÜV Süd employees were well aware of the significant risks posed by the reservoir but were concerned that Vale might cease using their services if they couldn't devise a risk calculation method that would validate the structure's stability. It is worth noting that the previous risk assessment consultant for this dam, Tractebel, had refused to certify the dam's stability in 2018 and had promptly been replaced by TÜV Süd [Saes and Muradian 2021].

Key issue

These observations highlight the risks of compromising the integrity of oversight activities undertaken by third-party certification bodies that fear that certification decisions which are unfavorable to their clients could lead to loss of business.

In response to this incident, the mining extraction industry has developed a sector-specific standard aimed at improving waste management, the *Global Industry Standard on Tailings Management*. This standard has been adopted by the majority of major multinational companies in this sector. An investor coalition<sup>12</sup> has launched various initiatives to encourage companies from this industry sector to adhere to this standard (creating a global portal for information on such dams, establishing an audit body for mining operators, and adopting voting guidelines during shareholders' general meetings<sup>13</sup>).

- ▷ The legal investigation following the **Erika oil spill** in France in 1999 (*cf.* description on page 24) implicated the maritime classification society Rina<sup>14</sup>. The French judicial inquiry concluded that Rina should not have certified the ship as seaworthy due to the observed corrosion level on board. Following a complex 13-year legal process, Rina was found guilty of pollution offenses (along with the owners and operators of the ship and the company that chartered the ship, Total SA) and was fined, contributing to compensating the victims of the disaster.
- ▷ In the financial sector, the legal investigation into financial misconduct and the **Enron Corporation bankruptcy** in the USA in 2001 implicated its auditor, Arthur Andersen, one of the "big five" consulting firms. In an attempt to hide their auditing negligence regarding Enron's accounts, Arthur Andersen employees deleted emails and destroyed numerous documents, fearing that they might be seized by the financial market regulator, the SEC. The company was found guilty of obstructing justice, although this verdict was later overturned by the US Supreme Court on technical grounds, and Arthur Andersen was dissolved.

<sup>12</sup> The *Investor Mining and Tailings Safety Initiative*, founded in 2019, is co-led by the Church of England Pensions Board and the Swedish Pension Funds Ethical Council, managing assets totaling over 20 trillion USD.

<sup>13</sup> For instance, the Church of England Pensions Board, managing 5 billion GBP in investments, announced in January 2022 that it would vote against executive committee appointments for companies that do not adopt the voluntary GISTM standard

<sup>14</sup> Note that it was the society's *classification* activity, carried out under a commercial contract with the shipowner, that was examined, not its *statutory certification* activity, performed for the Maltese state under a public service delegation and potentially protected by sovereign immunity (which generally prevents a state from being tried abroad). Similarly, port inspection activities carried out by national port authorities benefit from jurisdictional immunity.

### 4.3 Questions raised by the use of third parties

The involvement of third parties in the social control of risk-bearing activities raises numerous questions:

- ▷ What is their **effectiveness** in social control of safety issues, especially when they lack a mandate to act on behalf of society? As illustrated by various cases discussed in this chapter, this effectiveness can at times exceed that of state regulations, particularly in situations where states have limited influence over industrial activities (such as maritime transport), and at times fall short (especially when third parties fear for their commercial activity if they provide an opinion that contradicts their client's interests<sup>15</sup>).
- ▷ What is their **social legitimacy** or “right to govern” [Black 2008]? To what extent do members of the public — if they are aware of this role — trust various third parties to contribute to safety oversight?

The perceived legitimacy of the role of third-party organizations in oversight activities is criticized by some commentators, who point to the risk that the control regime may become an “anonymous faceless bureaucracy” (in Kafka's terms), accountable to no one [Gustafsson 2020].

Perceived legitimacy can be weakened by a potential lack of transparency in the operation of third-party organizations or their links with the regulatory authority. The mechanisms in question can be quite subtle: for instance, the professional association INPO, representing operators of nuclear power plants in the USA (*cf.* discussion on page 11), maintains a cooperative relationship with the NRC, the regulatory authority for the sector. The internal procedures of the NRC instruct its agents to ensure that “INPO programs remain independent from the NRC inspection program to the maximum extent possible”. A General Accounting Office investigation dating back to 1991<sup>16</sup> found that the NRC refrained from publishing certain newsletters on safety issues when it knew that INPO had already alerted operators to the same problem, in order to avoid redundant communications. Since INPO's newsletters were not made public, the GAO argued that the newsletters should always be published by the NRC, regardless of whether INPO had addressed them or not.

- ▷ What is their degree of **independence** from pressures that private actors may exert? One form of lack of independence manifests as the “capture” of third parties, where they represent the regulated entities more than the expectations of the society on whose behalf they conduct their missions. Another issue is the slide toward regulatory capture, in which third parties that are seen as being more attentive to their clients' (industrial) expectations are more successful commercially, as discussed for maritime classification societies (*cf.* § 2.1.3).

Since private third-parties are selected and paid by the companies they oversee, there is an incentive for them to downplay the severity of the issues they detect in order to retain clients. A study conducted in the USA [Short and Toffel 2016] shows that third-party inspectors/auditors are on average less rigorous when they are directly paid by the companies they monitor, when competition between third-party auditors is more intense, when they have a longstanding business relationship with the monitored company, and when the third party has the possibility of selling other non-audit/certification services to the monitored company.

This mechanism of sliding toward regulatory capture was also highlighted by the investigation into the Grenfell Tower fire (London, 2017, 79 deaths). The external insulation

<sup>15</sup> For instance, the U.S. Senate's investigation report on the 2001 Enron financial scandal reveals, “What Committee staff discovered was deeply disturbing — not so much because they uncovered malfeasance or intentional wrongdoing on anyone's part (although that seems to have been present in some cases as well), but because what emerged was a story of systemic and arguably catastrophic failure, a failure of all the watchdogs to properly discharge their appointed roles. Despite the magnitude of Enron's implosion and the apparent pervasiveness of its fraudulent conduct, virtually no one in the multilayered system of controls devised to protect the public detected Enron's problems, or, if they did, they did nothing to correct them or alert investors.” This failure occurred even as Enron adhered to the majority of “procedural” obligations regarding the independence of its board members, the existence of an audit committee, and the use of external auditors.

<sup>16</sup> GAO/RCED-91-122 Report *NRC's Relationship with the INPO*, available online.

system of the building combined polyurethane foam insulation panels and waterproof polystyrene panels. The fire safety certification of the insulation panels for use in high-rise buildings was provided by the private laboratory Building Research Establishment (BRE). The laboratory test that resulted in this certification was fraudulent; the panel supplier had included fire-resistant panels in the assembly made by a subcontractor, in addition to the panels subject to testing. The director of fire certification activities stated to the inquiry committee:

“ We have many clients who spend a lot of money with BRE. We do not want to upset any of them.

- ▷ What are the mechanisms that allow for **evolution of the framework** in which third parties operate, for example to address new threats, incorporate technical innovations, or enable continuous improvement of oversight processes? If third parties work within a highly rigid framework, the control system may gradually become inadequate to meet evolving needs.

For instance, in the case of notified bodies in Europe, standards are periodically revised through a process that involves representatives from the regulated industry, accreditation bodies, and certification bodies.

## Conclusions

This document resulting from the strategic analysis conducted by FonCSI on the regulator-regulatee relationship has highlighted a **gradual evolution** that has occurred from a relationship between dutyholder and regulatory authority, often conducted between experts and with little exposure to external scrutiny, towards a more open relationship involving a **diversity of actors**. The emergence of new organizations and new roles is accompanied by the development of new instruments for social control of hazardous activities: greater leeway is granted to operators or system designers to select the prevention and protection mechanisms that achieve the specified safety objective, and part of the oversight assessing the relevance and conformity of the implemented means are ensured by third-party organizations. Thus, the relationship between the regulatory authority and the regulated dutyholders is embedded in a network of third-party organizations (certification bodies, auditors, insurers, NGOS, etc.) which participate in various capacities in the social control of safety-related issues.

These trends, which are more or less developed depending on the industrial sector, have shifted the regulator-regulatee relationship from a primarily command-and-control dynamic to a more balanced relationship between this pair, and more recently has seen movement towards an approach based on polycentric governance and co-regulation rather than a closed interaction between a decision-maker and a decision-taker:

- ▷ integrating a network of organizations into regulatory activities, including various third-party organizations such as certification bodies, insurers, professional associations and federations, extra-financial rating agencies;
- ▷ accepting that the safety authority delegates certain decisions to the regulated industry, especially when it is difficult for a regulatory body to maintain in-depth technical expertise in complex domains, thus leading to greater reliance on internal control mechanisms established by the firms that design and operate high-hazard facilities;
- ▷ based on a broader range of regulatory instruments than prescriptive regulations, including objective-based rather than means-based regulations, various incentive mechanisms, and obligations to inform the public;
- ▷ involving regulatory activities that go beyond prescription and conformity inspection, such as cooperation, coordination, negotiation, and information; the regulatory authority moves (to a greater or lesser extent depending on the industry sector) to the role of a conductor that orchestrates different activities rather than playing a solo inspector role;
- ▷ requiring greater agility from regulatory actors and increasing the importance of organizational and inter-organizational adaptability and learning.

The regulatory instruments used by a state authority and the oversight activities undertaken by various types of third-party organizations (including the operating companies themselves) coexist in many industry sectors, and can **mutually reinforce** each other. Several cases described in this document illustrate the potential **complementarity** between **public and private mechanisms**:

- ▷ the complementarity between a private mechanism for ship classification and port inspections carried out by states (see page 18);
- ▷ the reciprocal reinforcement between the private “vetting” mechanism for tankers (led by the international association OCIMF) and inspections carried out by port authorities (see description on page 24);
- ▷ in the aviation sector, the links sometimes established between IOSA and ISAGO inspections run by IATA and the monitoring activity undertaken by national authorities (see page 37);
- ▷ in the nuclear energy sector, the professional association INPO and the US regulatory authority, NRC, collaborate and exchange information under a “memorandum of agreement”. Additionally, forms of informal cooperation reported in the book [Rees 1994] indicate that if an operator’s incorporation of INPO recommendations is deemed insufficient, INPO may suggest that NRC transpose the recommendations into regulatory obligations.

[Verbruggen 2013] mentions the benefit for a third party involved in oversight but lacking coercive powers, to have a “gorilla hidden in their closet”, whose mere mention will often persuade a reluctant firm.

These regulatory developments have impacts on the effectiveness of oversight, as well as on the perceived legitimacy of the actions of regulatory authorities. They require agility, adaptability, and learning capabilities from all the concerned actors, along with a reflexive consideration of emerging challenges and ways to combine different control instruments.

Several other significant trends affecting safety oversight activities, mentioned by the strategic analysis group but not elaborated in this document due to space constraints, also underscore the importance of agility in oversight:

- ▷ The phenomenon of **regulatory inflation** that affects many industry sectors, as each incident or accident leads to the creation of new requirements that add to the existing corpus.
- ▷ The **globalization of reference frameworks**, linked to the development of international standardization and the globalization of trade between states (this phenomenon is particularly evident in the aviation sector, which has converged around a small number of authorities and designer-manufacturers who hold normative powers).
- ▷ Challenges related to the certification and safety oversight of **learning software components** (“black boxes” with artificial intelligence), and the shifting of responsibility for safety issues firstly from system operators to system designers, then towards the designers of safety-critical components.
- ▷ From an institutional point of view, the development of independent safety authorities as an alternative to inspectorates attached to ministries. The underlying assumption is that their independence from the state apparatus can lead to higher levels of public confidence in the regulatory activity.

The dynamics of these various mechanisms and their successive reconfigurations are worth studying, as they reflect the different adjustments and trade-offs made to remain acceptable, both for the regulator and the regulated entities, as well as in relation to third parties and the public.

Co-regulation mechanisms were first developed in sectors with significant technological and social innovation, such as advertising and the internet. Industrial safety is a field where societal expectations for protection are stronger, and innovation in social control and regulation is less prominent. For this reason, we observe slower evolution towards these forms of control that give more importance to third-party organizations in this field than in others. The scope

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within which third parties can act is also more limited, with the most critical subjects are still handled through the “classical” regulator-regulatee relationship. This reflects a certain level of conservatism that is easily justified when it comes to major accident hazards.

Interested readers will find further insights from the work of researchers who work on the regulator-regulatee relationship, extending certain points discussed in this report, in the open-access book published in the *SpringerBriefs in Safety Management* series managed by FonCSI, titled *The regulator-regulatee relationship in high-hazard industry sectors: New actors and new viewpoints in a conservative landscape* [Le Coze and Journé 2023].





# Internal control and its articulation with external oversight in the French nuclear power sector

**Authors:** Noëlle Laneyrie (EDF), Cécile Laugier (EDF) and Olivier Chanton (IRSN)

The priority given to safety in the nuclear industry has led to the development of a robust framework for safety oversight. In addition to the external oversight by one or more regulatory bodies, the nuclear industry has also put in place internal control mechanisms within the organizations that operate nuclear facilities. These internal nuclear safety oversight mechanisms are designed to implement the principle of independence from operational teams and from line management in a manner which is appropriate for each hierarchical level within the organization. The result is an interlocking arrangement of oversight mechanisms at different scales within the system, allowing for fairly comprehensive coverage of the variety of organizations, situations, and activities that deserve special attention in terms of safety. Internal control mechanisms have existed in various forms among French nuclear operators since their inception, but recent regulatory changes following the creation of the ASN (Autorité de sûreté nucléaire, the French nuclear safety regulator) in 2006 have introduced new formalism to them.

In the first part of this annexe, we will describe the main internal and external oversight mechanisms that have existed since the 1980s and 1990s. Subsequently, we will discuss recent developments influenced by the regulations introduced by the ASN. We will touch on some of their effects in terms of regulatory practices and organizations. Lastly, we will discuss the main benefits and costs, as well as the insights gained from the articulation between internal and external controls.

This description is primarily focused on the evolution of internal oversight mechanisms at EDF, the French electric utility which operates the largest nuclear power plant fleet in the world.

## A.1 The independent nuclear safety assessment line: a mechanism based on experience from major accidents in the 1980s

### A.1.1 The role of the independent nuclear safety assessment line on a nuclear power plant

In the 1980s, an independent safety role separate from the production teams, the Radiation Protection and Safety Engineer (*Ingénieur Sûreté Radioprotection* or ISR), was established at EDF following the lessons learned from the Three Mile Island accident<sup>1</sup>. Present during shifts, their responsibilities included:

- ▷ Ensuring that nuclear safety requirements (the prevention of radiological accidents) and radiation protection are considered in daily operational activities;

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<sup>1</sup> The Three Mile Island accident (TMI) in 1979 in the USA was the first internationally significant nuclear accident. There were no casualties, and environmental releases were minimal. However, significant damage occurred within the facility, and the fuel ("core") melted.

- ▷ Providing “human redundancy” for front-line operators in case of accidents. To achieve this, a dedicated procedure allows the ISR to redirect the team towards a more appropriate response based on the assessment of key state functions (reactivity control, water supply, etc.).

From the early 1990s [Clément and Kenedi 2007], the “safe operation” (« sûreté conduite ») approach was developed and implemented, leading to the creation of the “Chief Operator” (*Chef d’Exploitation*, CE) role. This role serves as both the operational team’s manager during shifts and the primary safety authority in real-time. The role of ISR during shifts was replaced by the creation of a Safety Engineer (SE) position, operating during the day. The SE is responsible for conducting an independent assessment of reactor safety status. They have permanent access to the control room and various parts of the facility where they can conduct verifications they deem necessary, similar to inspectors from the ASN. A safety engineer is always on standby and is engaged in case of significant anomalies affecting the facility’s safety status or during specific sensitive operational phases (reactor startup, for example). They then perform an independent analysis of the situation and determine the most appropriate strategy, prioritizing safety. Each day, as well as during degraded situations, SE and CE conduct a joint assessment of the situation. In case of disagreement, resolution is made by a representative of the management.

Safety Engineers undergo comprehensive training on facility operations, safety principles, and regulations. This training is identical to that of front-line operators and Chief Operators, including simulator training in both normal operation and incident/accident management. It is assessed through evaluations and a qualification process. They are also subject to a review board composed of national experts and experienced peers from other plants.

The independent nuclear safety assessment line (in French, *Filière Indépendante de Sûreté*, hereafter FIS) is composed of the following roles at each plant:

- ▷ A member of the management team specifically responsible for promoting safety and safety culture (mission leader or Safety Quality director);
- ▷ Safety Engineers and a team of quality auditors, who perform independent verification, provide advisory support to operational teams, and offer safety expertise.

An internal EDF standard sets minimum staffing levels for these roles. Their consistent presence over the long term is ensured through a dedicated Workforce and Skills Management system, overseen at the national level.

## **A.2 Maintaining an independent perspective: an approach practiced at various levels**

The concept of independent internal oversight is structured and implemented at multiple levels within EDF: at the level of each power plant, with the local FIS, as described in the preceding paragraph, as well as at the national level.

Historically, the initiative was first initiated at the national level, with the establishment of the Nuclear Inspectorate within the Thermal Production Department (SPT) of EDF as early as 1974<sup>2</sup>. It was through the reflections on nuclear safety and the lessons learned from major accidents that this organizational structure was extended to different levels, from the control room to the executive committee of the company.

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<sup>2</sup> The Nuclear Inspectorate (*Inspection Nucléaire* or IN) is under the authority of the head of SPT. It is a “working group responsible for providing an independent perspective on safety and radiation protection activities during operations”. The report by Bernard NOC (1982) recommended the creation of Safety Quality Departments at the plants, defined as “A parallel structure providing assistance and control for safety and quality matters.”

### A.2.1 At the Nuclear Production Division Level

The independent nuclear safety assessment line consists of:

- ▷ The Delegated Safety Director, who directly supports the division director on safety matters.
- ▷ The Nuclear Inspectorate (IN), which has progressively expanded its scope since its establishment. IN currently comprises around forty experienced inspectors. Every 4 years, it conducts a comprehensive assessment of the 15 domains related to NPP operations on each plant, focusing particularly on safety, environmental protection, radiological protection, and compliance with EDF's standards and international standards. The independent nuclear safety assessment line (FIS) of the site is assessed during these comprehensive inspections. An intermediate evaluation, targeted at identified weaknesses highlighted by the comprehensive assessment, is carried out at intermediate intervals. IN can also initiate thematic audits following specific events (self-mandate) or conduct reactive inspections at the request of the Delegated Safety Director or the director of the Nuclear Production Division.

### A.2.2 At the EDF Executive Committee level

Since the 1980s, an Inspector General for Nuclear Safety and Radiological Protection (IGSNR) and their team have been advising the president of EDF and providing an overall assessment of nuclear safety across the entire group. This assessment covers the French nuclear fleet as well as EDF subsidiaries' nuclear plants abroad, primarily in the United Kingdom. Radiological protection was added to the IGSN's scope in the 2000s. Since 1988, the Inspector General has produced an annual report which is made available to the public. This report includes an assessment of the FIS, particularly the Nuclear Production Division and the NPPs, but today also the engineering and project areas.

To compile the report, the IGSNR dedicates 80 to 90 days per year to site visits and field interviews at NPPs, engineering departments, central services, and support units (training, maintenance, R&D, etc.). The interviews cover all levels of the organization, and are undertaken without the presence of management. They aim to capture how safety is understood, practiced, and ensured in everyday reality. On-site, the IGSNR frequently accompanies plant managers, safety engineers, inspectors, maintenance technicians, observing them in their daily tasks. In engineering and R&D, discussions are held with design engineers and experts in key safety domains such as fuel, core physics, climatic and natural hazards, support functions, HOF, etc.

### A.2.3 At the level of design engineering entities

In 2015, EDF established a "Design Authority" following the recommendations of the INSAG-19 guide<sup>3</sup>. The Design Authority operates in the realm of design, whereas the previous independent internal organizations operated in the realm of nuclear power plant operations. Its role is to ensure that decisions regarding modifications, operational changes, and spare parts specifications are made with a complete understanding of their impact on safety. It also advises the operator on design improvements based on a "cost-benefit" approach. This holistic approach aims to evaluate all effects of a change, including economic costs, implementation and operational complexity, potential negative consequences (regressions, environmental impact, or personnel safety), weighing them against the expected benefits, particularly from a safety perspective. Although the Design Authority is not strictly an oversight body or an official part of the FIS, its role is pivotal in ensuring safety.

More recently, in 2020, in response to a recommendation from the IGSNR, the nuclear engineering division responsible for new projects also established a FIS.

<sup>3</sup> INSAG stands for International Nuclear Safety Advisory Group, which issues instructions setting international standards of excellence for the design and operation of civilian nuclear installations.

#### A.2.4 Whistleblowing and self-assessment

Each actor within the FIS (local level, DPN level, and IGSNR) is positioned as an advisor to the entity director at their respective level and has the right to blow the whistle, which they can exercise by reporting anomalies they witness to their hierarchy. Thus, a serious safety issue detected by an IS at a nuclear reactor, which is not addressed by the site management, can trigger an alert to the President of EDF through the FIS (Head of Safety, DDS, and IGSNR).

Each level of the FIS periodically assesses the level immediately below it.

We have just described the implementation of Independent Safety Sectors at each level of the nuclear operator's organization within EDF. This unique functioning allows the operator to internally ensure the presence of an independent perspective on a daily basis. The FIS operates independently of the operator and does not report to the safety authority ASN, which exercises its own oversight. It's also worth noting the complementarity between the continuous presence of independent safety sectors established by EDF and the inspections carried out by the ASN. In France, inspectors are not "resident", as is sometimes observed internationally. A continuous presence within the operator's teams presents heightened risks of becoming accustomed to the environment and developing excessive proximity to the operator.

Having described the mechanisms of day-to-day internal control through the FIS, we will discuss how internal controls have been established and evolved when the operator needs to make modifications to the installation.

### A.3 Internal control of significant modifications: an integrated approach regulated by ASN, replacing initial internal authorization systems

#### A.3.1 Origin of internal authorization systems

In 2004, EDF submitted a request to the safety authority ASN for an evolution in the regime of administrative authorizations, particularly concerning:

- ▷ Operations involving sensitive draining of the reactor vessel when nuclear fuel is present;
- ▷ Reactor startup (initiation of fission reaction) after a shutdown lasting more than 15 days without significant maintenance;
- ▷ Modifications to the Internal Emergency Plan of a site, reflecting an evolution of the national reference framework.

For the first two cases, ASN had imposed specific authorization provisions following several operational events where preventive measures, whether organizational or technical, were in place but had not functioned satisfactorily. In the second case, ASN had approved the national reference framework. EDF aimed to reinforce its responsibility as a nuclear operator in areas considered to have moderate significance. In support of its request, EDF proposed enhanced control measures either at the local level, relying on a substantiated contradictory opinion from the independent nuclear safety assessment line (FIS), or at the national level. These requests were accepted by ASN, leading to the deployment of the initial internal authorization system starting in 2005.

As the system proved satisfactory to both parties, its extension was swiftly considered desirable:

- ▷ For the operator, it provided greater autonomy and improved responsiveness;
- ▷ For ASN, it allowed the concentration of resources on more critical matters and reinforced one of the founding principles of nuclear regulation, that of "the primary responsibility of the operating company".

The 2007 decree and the 2008 order (see regulatory framework section) facilitated the implementation of the first Internal Authorization Systems (IAS, in French *Systèmes d'Autorisation Interne*).

This additional initial step of internalizing oversight largely addressed the operator's need for responsiveness in the event of an incident requiring deviation from established technical specifications. Nevertheless, the regime of declaration requiring ASN approval remained predominant in terms of volume.

## A.4 Extension to all significant modifications

In 2014 and 2017 (see regulatory framework section), the regulatory framework evolved once again: the concept of internal authorization was abandoned in favor of the notion of mandatory internal control, requiring the operator to establish an Internal Control Body (ICB). This ICB is responsible for reviewing all significant cases (not only those that fell under “internal authorization” in the previous system) and validating the choice of associated regulatory regime: either a declaration or an authorization (in the latter case, ASN remains the sole competent authority for granting the “authorization”). The aim of this change was to allow ASN to optimize resource allocation, to further increase the operator’s responsibility, and to clarify the scope of responsibilities.

Upon the introduction of this new step, ASN set an ambitious goal of 70% of cases falling outside its authorization purview.

The extension was viewed as an opportunity by both parties:

- ▷ For ASN, it allowed the authority and its technical support organization IRSN, to focus on cases of high significance, with the assurance of a robust internal validation mechanism for the rest;
- ▷ For EDF, it led to more autonomy in the majority of cases and fostered increased trust from ASN due to better quality in the cases submitted for its authorization.

While the system is virtuous in developing a sense of responsibility and rigor, its implementation demands substantial resources and introduces additional processing time for cases submitted for authorization:

- ▷ For those responsible for developing cases, this obligation entails justifying and documenting under quality assurance the chosen treatment approach. This involves referring to a “criteria guide” of over 70 pages and formally documenting all proven or potential effects of the proposed modification on various aspects (incident or accident management, resilience to disturbances, environmental impact, waste management, etc.).
- ▷ Ensuring independent verification and formal documentation of the analyses conducted and decisions made within this framework.

The system can, of course, undergo secondary-level verification by ASN at any time, meaning it must be auditable.

EDF’s new internal control system for hardware/technical modifications came into effect in July 2019. It was preceded by a preparation and transition phase. A series of working meetings and discussions between IRSN and EDF were organized prior to the regime change. A working group was established to discuss the criteria set by EDF. An EDF representative joined IRSN’s team responsible for hardware/technical modification expertise to understand IRSN’s organization and working methodology. EDF also developed several documents to guide experts in the new control system. Furthermore, various studies were undertaken, analyzing multiple cases in parallel to compare the results of assessments by EDF’s new organization and those by IRSN on the proposed cases.

The effects of the system’s implementation proved significant. The new system contributed to changing how IRSN handles numerous cases but did not result in a significant reduction in its workload. The new regulatory context introduced complexity, including a division of cases based on their regulatory status, leading to challenges in obtaining an overall view.

ASN conducted several inspections and audits in recent years to determine whether the ICB established by EDF had led to a regression in requirements compared to the previous period. According to ASN’s most recent inspections, the process implemented by EDF has gained robustness over the years.

Excerpts from the French regulations applicable to nuclear installations

Example

The French law regarding Transparency and Safety in Nuclear Matters (2006) established a new independent administrative authority, the Nuclear Safety Authority (ASN), and legally framed the authorizations for the creation, modification, and cessation of basic nuclear installations (BNIs). Decree No. 2007-1557 of November 2, 2007, known as the “procedure” decree, specifies, in Articles 25, 26, and 27, the conditions for modifying BNIs during their operation. Article 26 of the decree particularly stipulates that an operator must seek ASN’s authorization when considering a modification to the installation that is compatible with the decree authorizing the BNI’s creation. However, if the envisaged modification could be deemed of minor importance, Article 27 of the decree clarifies that ASN can exempt the operator from the prior declaration procedure specified in Article 26. ASN Decision 2008-DC-106 of July 11, 2008, states that this exemption requires the establishment of an “internal oversight system with sufficient guarantees of quality, autonomy, and transparency and has which been approved by ASN”. This system referred to as the “internal authorization system” (IAS) can also be applied, upon the operator’s request, for carrying out certain specific operations that were previously subject to ASN’s prior agreement. ASN’s decision specifies the objectives of this IAS: “Its objective is to strengthen the primary responsibility of the operator [...], one of the fundamental principles of safety for high-risk activities being that the operating company is responsible”. ASN’s decision is individual, taken on a case-by-case basis, upon the operator’s request, and ASN can terminate the IAS at any time. ASN outlines the operations that can be covered by an IAS and indicates the modalities for issuing internal authorizations.

ASN outlines its expectations regarding the independence of the internal control body: “The operator must justify the independence of the internal control body in relation to individuals directly responsible for operation. Particularly, members of the internal control body must not be under the direct or indirect hierarchical authority of individuals responsible for the proposed operation. The level of independence of the internal oversight body is proportionate to the significance of the operations it will analyze”. Further along, the decision emphasizes “The operator ensures that the internal control body comprises a sufficient number of individuals possessing the necessary skills for each of the technical areas that could be addressed”. The operator must also implement second-level control on operations subject to internal authorizations. The operator must also facilitate ASN’s inspection by providing a forecast program of operations potentially requiring internal authorization. Subsequently, the operator must inform ASN post-operation and provide a set of documents detailing the conducted operations, the body’s opinions, and the control reports carried out for the second-level control. Finally, ASN’s decision outlines the approval modalities for IAS, the modalities of oversight by ASN, and communication by the operator regarding the IAS, especially directed toward Local Information Commissions (CLI).

Since 2008, the three main French nuclear operators, initially CEA (in 2010), followed by Areva and EDF, have requested and been authorized to establish their own IAS. EDF thus developed two IAS to facilitate the management of various modifications in two specific technical domains.

The law of August 17, 2015 (known as the Energy Transition for Green Growth Law, ETGGL), reforms the administrative regime applicable to significant modifications implemented after the authorization for the commissioning of a BNI. Modifications mentioned in Article L. 593-15 of the Environmental Code that do not significantly challenge the safety report or the impact study of the installation are therefore subject to declaration with ASN. The ETGGL law thus strengthens and broadens the declarative regime. This is done according to criteria broadly set out in the law, which ASN Decision of December 18, 2018, and its approval order specify. These provisions put an end to the internal authorization systems described above and to the exemption from declaring certain modifications. ASN’s decision defines and frames the management of significant modifications. This management “comprises their identification, design, validation, the decision to implement them, their implementation, operation modalities, and the experience feedback from their implementation”, covering the execution of 11 actions, also defined in ASN’s decision. The driving force behind these actions is referred to as the “internal oversight body” (IOB). Quite similar to IAS, which is dedicated to “notable modifications of minor importance”, the IOB nevertheless possesses broader and more complex missions and competencies, as it covers all significant modifications.

This extension of the declarative regime is motivated and justified by ASN as it reinforces the operator’s responsibility and the IAS has proved satisfactory to regulatory actors. It entrusts the operator with defining the control provisions it selects for the management of significant modifications to its installations. Nevertheless, ASN reminds that these systems remain under its control.

The decision not only defines the criteria that the IOB must use to decide if a significant modification should be subject to an authorization request, but also specifies the modalities that will make this management system auditable and will enable ASN or other internal control bodies to

carry out their assessment, verification, and/or control tasks.

Since 2018, all French operators, including Andra, have their own internal oversight bodies for significant modifications.

## A.5 Lessons from the interaction of internal and external oversight: risks of complexification and drifts and potential responses

We have identified three types of challenges that have been encountered with the implementation of internal oversight for nuclear safety, and for which appropriate responses have been put in place. It is an important lesson to recall these risks and how to address them.

### A.5.1 Restoring primary responsibility for safety to the plant manager

A few years after the introduction of Radiation Protection and Safety Engineers (RPSEs) in the 1980s, their role and position were reviewed. Now called Safety Engineers, they were relieved of Radiation Protection responsibilities and were no longer part of the shift team. This change aimed not only to enhance the independence of the Independent Safety Branch from the operational team on shift but also to reaffirm the primary responsibility of the plant manager for safety. The continuous presence of Safety Engineers had led to a binary division of roles between safety and production, with operational managers naturally focusing on production issues and Safety Engineers being considered solely responsible for safety. This division quickly showed its limitations, and now plant managers are explicitly mandated to assume direct responsibility for nuclear operator safety. To prevent any drift that could lead to the team's deresponsibilization, the Independent Safety Branch is positioned in a role of internal control, reevaluation of decisions, and independent alert.

### A.5.2 The challenge of managing process complexification / rigidification

The establishment of internal oversight bodies represents a significant investment in resources, which can be substantial: for instance, the Independent Safety Branch (ISB) in a nuclear plant comprises about 10 individuals per pair of reactors; the Design Authority set up in 2016 for independent assessment of design integrity involves 15 engineers. The implementation of an organization for evaluating all notable modification cases by an Internal Control Instance (ICI) was estimated in 2018 at 20 Full-Time Equivalents (FTEs).

Additional delays are introduced into processes: the impact of submissions to ICI for ordinary installation modification cases results in an additional 2 to 6 months compared to an average duration of around 1 month for authorization cases and 3 months for declaration cases, which constitute two-thirds of the cases. There is also a fragmentation of cases based on the categories introduced by internal control criteria, complicating the overall view for project managers. Conversely, internal control enables the operator to prioritize internally and to respond very promptly, including over weekends, for urgent cases, which is a vital advantage for electricity production.

Other impacts that are harder to quantify concern the complexity of the organization. For instance, all modification case bearers must assimilate a 70-page document describing criteria solely to determine if their modification is notable or not, and therefore subject to ICI.

Lastly, there is a strengthening of oversight, as internal bodies, whose existence is regulated and are themselves subject to external control, generally tend to over-specify and exercise their control more rigorously than the external authority. This phenomenon has also been observed in the field of pressure equipment regulation, both with internal control bodies referred to as "second-party" organizations, namely Recognized Inspection Services (RIS), and User Inspection Bodies (UIBs)<sup>4</sup>.

<sup>4</sup> RIS and UIB are specialized services for inspecting (or designing) pressure equipment, capable of performing the same tasks as third-party organizations but within the company. These services are audited and recognized by the administration and must meet strict requirements for competence and independence.

### A.5.3 Constant vigilance needed regarding the risks of confusion

The third category of risks associated with internal oversight is the confusion between internal and external control lines. This risk, of course, only applies to voluntary internal controls, established by operators of their own initiative to exercise self-control, with defined scope and methods. This is in contrast to internal controls that correspond to regulatory delegation or exemption. The latter naturally and necessarily undergo external control by the authority that defines their scope and exercise methods in regulatory texts (e.g., the case of Recognized Inspection Services (RIS) and User Inspection Bodies (UIBs) in the field of pressure equipment): this oversight occurs *post facto*, typically in the form of audits, with all activity being traceable and verifiable.

In contrast, the relevance and effectiveness of Independent Safety Branches (ISBs) established by EDF, which have remained consistent for 30 years despite the resource costs they represent, are explained by their independence not only from the operator but also from the authorities. For instance, if an external inspector relies on an internal verification report prepared by the ISB on a specific topic, their investigations and verifications will be influenced and partially redundant with those already conducted. In doing so, the overall effectiveness of the oversight is weakened. On the other hand, the depth and level of creativity of internal oversight are inevitably compromised if issues that they highlight appear to be regularly used by external inspectors. It is beneficial for internal oversight to maintain its autonomy, rigor, and acuity, borne out of its close and thorough control practice. The complementarity of the two types of oversight is tied to respecting their specificity: complete independence assurance for external oversight by the authority and deeper knowledge and proximity for internal oversight through the independent branch. This complementarity can be considered a significant strength for nuclear safety.

### A.6 Internal control: a generally positive impact on safety, transparency, and operator accountability

Despite the limitations mentioned above, the assessment of the many internal controls implemented over time in nuclear safety at EDF is generally positive. The main benefits fall into three categories:

1. In the case of Internal Control Instances (ICIs) for notable modifications, required by the ASN, the objectives were clearly to achieve resource savings for the authority and its technical support, which has indeed been observed. From the operator's perspective, the new internal control has simplified the administrative procedure for numerous cases, now falling under declarations. The additional internal control workload is costly for the operator, as it has been extended to cover all cases, whether subject to declaration or authorization. However, the quality of the cases is better managed, and the operator's accountability is enhanced. Ultimately, the primary benefit for the operator is responsiveness for truly urgent cases, as better internal resource management can be applied for an ICI rather than requesting ASN instruction, especially outside of regular working hours.
2. Better proportionality to the stakes involved, both for the authority and for the operator. The proportionality of means and control intensity according to safety stakes is a shared gain for both the operator and the authority. The 2017 ASN decision on internal controls is a rare example where this proportionality is explicitly translated. In practice, operators adjust the number of people in the ICI based on the modification case category.
3. Internal control does not exclude transparency. The establishment of an independent safety branch also applies to the highest levels of the company and comes with a unique exercise of transparency towards the public. Since 1988, the IGSNR has publicly released its annual report addressed to the President of EDF. The report is often candid and explicit about the weaknesses that need to be addressed.



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[www.FonCSI.org](http://www.FonCSI.org)

6 allée Émile Monso – CS 22760  
31077 Toulouse cedex 4  
France

Twitter: @TheFonCSI  
Email: [contact@FonCSI.org](mailto:contact@FonCSI.org)







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6 allée Émile Monso  
ZAC du Palays - CS 22 760  
31077 Toulouse cedex 4

[www.foncsi.org](http://www.foncsi.org)