

Research

How Agencies Inspect

A Comparative Study of Inspection Policies in Eight Swedish Government Agencies

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SKI PERSPECTIVE

Background

The regulatory approach used by SKI has an impact on the licensee and, therefore, indirectly on the safety of the nuclear facilities. The regulatory policy and its implementation also influences the way SKI is working and the competency needed by the regulator as well as by the industry. One of SKI's tasks is to be able adjust the regulatory approach to current and future needs.

Little research is available on the use of regulatory strategies, methods and activities used by regulatory agencies in their work (to assure safety), as well as their impacts. To address this gap in knowledge, SKI has contracted two separate research projects. This project, where the focus is on comparing inspection policies in Swedish government agencies, and another one where regulatory strategies across selected countries, are studied and compared.

SKI's purpose and goals

The goal of this research project is to gain knowledge about selected Swedish agencies and their inspection policies. All the selected agencies are working with issues regarding health, environmental protection or safety. A number of persons at each agency have been interviewed about the regulatory work at their organizations. A questionnaire was developed as a first part of the project, and it was used during the interviews.

In addition to provide insights as a basis for improvement within SKI, the purpose has been to promote exchange of experience between agencies with similar tasks. By this study SKI also wanted to contribute to the development of competency in this field of research.

Results

A lot of information has been gathered and analyzed during the project. The focus of the research is on comparing agencies and their practices. The report includes an analysis regarding similarities and differences in a number of areas across the agencies. The report also provides information and evidence on the problems related to comparison between agencies, partly due to the difference in the use of definitions. The recommendations resulting from this study focus on improving cooperation among Swedish agencies and on improving inspection methodologies, areas where further analysis is suggested.

The conclusions and recommendations in the report belong to the persons participating in this work, and are not necessarily the same as the once drawn by SKI.

Further plans

SKI is planning a seminar with representatives from the participating organizations to discuss the content of the report. SKI is also considering other ways to inform about these results.

Effects on SKI

This study has led to increased knowledge regarding the way the participating organizations fulfil their tasks. The results, together with the results of the study on regulatory strategies,

will be discussed in seminars. The information will contribute to a deeper understanding of the regulatory tasks and form a basis for decision on possible changes. At the same time the results demonstrate the fact that more research is needed to better understand and evaluate the impact of regulatory work.

Project information

Project coordinator at SKI; Irène Blom

Project number; 02157

SKI-PERSPEKTIV

Bakgrund

Den tillsynsstrategi som SKI tillämpar påverkar tillståndshavarnas verksamhet och därmed också indirekt, säkerheten. Tillsynsstrategin påverkar också arbetssättet vid SKI och den kompetens som krävs vid myndigheten, såväl som i industrin. I SKI:s uppgift ingår att kunna anpassa tillsynsstrategi och tillsynsriktning till aktuella behov och framtida förändringar.

Få studier har gjorts av myndigheters övergripande strategier, metoder och aktiviteter för att bedriva tillsynsverksamhet. Effekten av tillsyn har heller inte varit föremål för omfattande studier. För att öka kunskapen om tillsyn och få underlag till förbättringar, har SKI beställt två forskningsprojekt, med olika inriktning. Detta projekt, som fokuserar på att jämföra tillsynsarbetet vid ett antal myndigheter i Sverige. Det andra projektet, fokuserar på tillämpningen och erfarenheterna av olika strategier, vid tillsynen av kärnteknisk verksamhet, i ett antal länder.

SKI:s syfte

Syftet med detta projekt har varit att bidra till ökad kunskap om hur tillsynen bedrivs vid ett antal myndigheter i Sverige. De myndigheter som valts ut arbetar alla med tillsynen av hälsa, miljö eller säkerhet. Ett antal myndighetsrepresentanter har intervjuats med stöd av ett frågeformulär, som utvecklats inom projektet.

Förutom att bidra till att öka kunskapen om tillsynen och ge underlag till förbättringar, syftar arbetet och resultaten till att främja erfarenhetsutbytet mellan olika myndigheter med likartade uppgifter. SKI ville också med denna studie bidra till att utveckla kompetens och intressera forskare för området.

Resultat

En stor mängd information har samlats in, analyserats. Studiens fokus har varit att jämföra myndigheter och deras sätt att bedriva verksamheten. Rapporten innehåller därför en redovisning av likheter och skillnader mellan myndigheterna, inom ett antal områden. Man pekar också på svårigheter med att jämföra myndigheterna, bland annat på grund av de olika tolkningar av begreppen ”tillsyn” och ”inspektion”. Rapporten innehåller också förslag till fortsatt analys av några områden där myndigheterna skiljer sig väsentligt och förslag till områden för samarbete.

De slutsatser och rekommendationer, som redovisas i rapporten, gäller för dem som genomfört studien och sammanfaller inte nödvändigtvis med SKI:s bedömningar.

Fortsatt verksamhet

SKI planerar att genomföra ett seminarium med de deltagande organisationerna för att diskutera rapportens innehåll. Också andra former för att sprida informationen övervägs.

Effekt på SKI:s verksamhet

Den genomförda studien har redan givit ökad kunskap om hur ett antal svenska myndigheter arbetar med tillsynsuppgiften. Resultaten kommer, tillsammans med resultaten i studien om olika tillsynsstrategier, att diskuteras vid olika seminarier. Sammantaget förväntas resultaten bidra till ett bredare perspektiv på hur tillsynen kan bedrivas och därmed också utföra

underlag för beslut om eventuella förändringar. Samtidigt visar resultaten att ytterligare forskningsinsatser krävs för att bättre förstå och bedöma effekten av tillsynen.

Projektinformation

Projekthandläggare på SKI; Iréne Blom

Projektnummer; 02175

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This report concerns a study which has been conducted for the Swedish Nuclear Power Inspectorate (SKI). The conclusions and viewpoints presented in the report are those of the author/authors and do not necessarily coincide with those of the SKI.

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Abstract. Eight Swedish authorities with inspection tasks in the areas of health, safety, and environmental protection have been compared, namely the authorities responsible for nuclear safety, radiation protection, railway, marine and aviation safety, environmental protection, chemicals control, and health and safety on workplaces. Significant differences in inspection policies and practices between the authorities were found, such as: diverging definitions of supervision and inspection that complicate comparisons, different priority-setting principles for inspections, variations in inspection frequencies (between 13 and 0.03 inspections per company and year), different practices with respect to notifying companies before inspection visits, and in particular, large differences in the extent to which non-compliance with regulations is reported to legal authorities. It was concluded that these agencies have much to gain from increasing their cooperation in methods development, evaluation studies, and education of inspectors.

Keywords: risk management, Sweden, supervision, inspection, regulation, self-control, evaluation.

List of abbreviations

CLEEN	Chemical Legislation European Enforcement Network
ECAC	European Civil Aviation Conference
EU	European Union
FOR	Flight Operation Report
IAEA	International Atomic Energy Agency
ICAO	International Civil Aviation Organisation
ISO	International Organization for Standardization
JAA	Joint Aviation Authority
JAS	Järnvägsinspektionens administrativa system [administrative system of the Railway Inspectorate]
NEA	Nuclear Energy Agency (of the OECD)
OECD	Organisation for Economic Co-operation and Development
SAMTILL	Samverkansgruppen för tillsynsfrågor [cooperation group for supervision issues]
SARA	Informationssystem för arbetsställen [informationssystem for workplaces]
SEK	Swedish krona [the Swedish currency]
TSI	Technical Specifications for Interoperability
UN	United Nations

1. Introduction

Whereas national differences in regulation and enforcement have been the subject of several studies (Vogel 1986. Jasanoff 1992. Münch 1995.), much less research has focused on how policies and practices differ between different policy areas. In a previous study (Johannesson et al 1999), risk management practices in three policy areas in Sweden were compared, namely occupational safety and health, environmental protection, and chemicals control. Large differences were found between these three agencies, in particular with respect to inspection practices and to the role of inspection activities in the overall strategy for regulation and enforcement. The purpose of the present study is to investigate the nature of such differences more closely, using a wider selection consisting of eight Swedish government agencies. We hope that improved knowledge of these differences can be useful for practitioners when trying to learn from each other's experiences in developing their methodology for inspection.

The eight agencies were selected for their major roles in the Swedish regulation of risks to human health and safety and to the environment. The Swedish Nuclear Power Inspectorate is responsible for safety in Swedish nuclear installations, for nuclear waste disposal and for the country's obligations according to non-proliferation treaties. This agency has three divisions: the Office of Reactor Safety, the Office of Nuclear Non-Proliferation, and the Office of Nuclear Waste Safety. This study will only be concerned with the inspection work of the Office of Reactor Safety and the Office of Nuclear Waste Safety. In some parts of this report, these two branches are treated separately.

The Swedish Radiation Protection Authority is responsible for protection against adverse effects of both ionizing and non-ionizing radiation. The Swedish Railway Inspectorate is responsible for safety in rail bound traffic, and the Maritime Safety Inspectorate for safety on Swedish ships and in Swedish waters and harbours. The Swedish Aviation Safety Authority has a corresponding responsibility for civilian aviation in the country.

The Swedish Environmental Protection Agency is the major governmental organisation in the area of environmental protection, and coordinates activities by

regional and local organizations in this field. Contrary to the other agencies included in this study, it does not itself inspect, but has the role of guiding and coordinating local and regional inspectors belonging to other agencies. The Swedish National Chemicals Inspectorate is responsible for protection against risks to human health and the environment from chemical substances and biotechnological organisms. The Swedish Work Environment Authority is responsible for inspections concerning the work environment, including health and safety issues on workplaces.

The Swedish administrative system has three geographical levels: central, regional, and local. Five of these authorities carry out their inspections exclusively on a central level (the Nuclear Power Inspectorate, the Radiation Protection Authority, the Railway Inspectorate, the Aviation Safety Authority, and the Chemicals Inspectorate¹). The Maritime Safety Inspectorate carries out inspections exclusively on a regional level. The Swedish coast is divided into three inspection districts (with offices in Stockholm, Gothenburg, and Malmö, respectively). The Work Environment Authority exercises the major part of its inspections on a regional level, namely in its ten districts. The Environmental Protection Agency represents the most decentralized organisation of inspections. In its area of competence, inspections are primarily carried out by inspectors in the 290 municipalities, and to a smaller extent on a regional level through the 21 county administrations.

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¹ In chemicals legislation, inspection of manufacturing and importing companies is carried out by the Chemicals Inspectorate, while retailers of chemicals are inspected by the local (municipal) authorities. (Local authorities also have the right to inspect manufacturers and importers, but in practice they seldom do so.)

2. Methodology

Making use of the regulation and inspection literature, we compiled a list of 87 questions about each agency's inspection activities. Answers to these questions were obtained through document studies and interviews. At each agency an interview of about three hours was made with the head of the inspection department. These interviews were written out, and submitted to the interviewed person for comments and corrections. In this way we obtained detailed descriptions of inspection activities and policies in the eight agencies. This material is available in a report in Swedish (Lindblom et al 2003).

The issues treated in this material include, for instance:

- centralized vs. decentralized organisation of inspections
- the nature of the regulations used in inspections (degree of specificity, etc.)
- the division of responsibilities between the agency and the inspected companies
- priority-setting among inspection activities
- training and education of inspectors
- quantitative indicators such as the frequency of inspections on an average company²
- announced vs. unannounced inspections
- the extent to which inspectors give advice to inspected companies
- the measures taken in cases of non-compliance
- the role of self-control and systems inspections
- routines for evaluation of inspections and inspection methods

By means of the methodology chosen, we have been able to obtain a clear picture of the official views of each of the inspecting agencies. In order to determine the actual nature of their inspection activities, extensive empirical studies of each of these agencies would have been needed. Given the explorative and hypothesis-generating

nature of the present work, we consider the chosen methodology adequate for its purpose.

² For simplicity we use the term “company” for inspected organisations, although some inspected organisations are not companies.

3. The role of inspections in the work of the agencies

The quantitative indicators reported in *Table 1* reveal large differences between the agencies under study. The Work Environment Authority, with 800 employees, is the largest of these authorities, followed by the Environmental Protection Agency with about 550 employees (but in this number the local and regional supervising agencies are not included). The smallest authority, the Railway Inspectorate, has only 32 employees. Three agencies use 45 % or more of their resources for inspection (the Maritime Safety Inspectorate, the Railway Inspectorate, and the Work Environment Authority). Two agencies use 15-20% of their resources for inspection (the Nuclear Power Inspectorate and the Aviation Safety Authority) and two use about 5 % of their resources for inspection (the Radiation Protection Authority and the Chemicals Inspectorate).

It is interesting to compare these figures with how important the authorities consider inspections to be among the tasks that they have according to their instructions. For this purpose we made use of a categorization of supervising agencies that has been developed by the Swedish National Audit Office (RRV, 1996). They distinguish between the following four categories of supervising agencies. (It should be observed that supervision is a somewhat wider concept than inspection.)

- A) *Pronounced supervising agencies.* According to their instructions, supervision is their major task.
- B) *Agencies with both supervision and other activities.* In their instructions these agencies have explicitly stated tasks of supervision beside other activities.
- C) *Agencies with unclear regulation.* These authorities are generally conceived of as supervising agencies, but the task of supervision is stated in an indistinct way: the word supervision or control does not occur in their instructions.
- D) *Agencies with adjacent assignments.* These agencies have in their instructions responsibilities that conceptually are close to supervision, e.g. a special responsibility to follow up and evaluate.

Four of the eight authorities considered themselves to belong to group A, namely the Nuclear Power Inspectorate, the Maritime Safety Inspectorate, the Aviation Safety Authority, and the Work Environment Authority. The remaining four authorities, namely the Radiation Protection Authority, the Railway Inspectorate, the Chemicals Inspectorate, and the Environmental Protection Agency, considered themselves to belong to group B, i.e. agencies with both supervising tasks and other activities. The Environmental Protection Agency described itself as a combination of alternatives B and D. None of the agencies placed itself in group C. As can be seen in *Table 1*, there is no strong connection between how an authority described itself in terms of these groups and the resources it spent on inspection.

“Supervision” (in Swedish: “tillsyn”) is a central term in discussions of inspection and related activities, but its usage is far from uniform in different sectors of society. In a previous study (Rudén et al 1998) supervision activities were classified in the following categories:

- a) Regulatory work
- b) Inspection
- c) Coordination of supervision
- d) Checking rule abidance
- e) Taking measures against transgressions of the law
- f) Granting of permits
- g) Preventive measures; counselling and information
- h) Work with the companies’ self-inspection, and control programmes

In our interviews we asked the agencies which of these activities they regarded as part of their supervision activities. The result is summarized in *Table 2*. (The Environmental Protection Agency was excluded from this table because it does not perform inspections but provides guidance for local and regional inspecting authorities.) Inspection was considered by all these agencies as part of their supervising activities. Furthermore, almost all of them count checking rule abidance and granting of permits as supervision activities. Exceptions are the Maritime Safety Inspectorate which does not count the former and the Chemicals Inspectorate which does not count the latter. More than half of the agencies consider regulatory work, measures against transgressions of the law, and working with the companies’ self-

inspection as parts of their supervising activities. However, the Radiation Protection Authority, the Railway Inspectorate, and the Chemicals Inspectorate did not include regulatory work. The Office of Nuclear Waste Safety, the Railway Inspectorate, and the Maritime Safety Inspectorate left out measures against transgressions of the law. The Maritime Safety Inspectorate excluded work with the companies' self-inspection.

A majority of the agencies included preventive measures such as counselling and information as part of their supervising activities, (though several make reservations against counselling). However, a minority consisting of the Office of Reactor Safety, the Radiation Protection Authority, the Railway Inspectorate, and the Chemicals Inspectorate did not include these activities as part of supervision.

Only three of the authorities included coordination of supervising activities: the Radiation Protection Authority, the Aviation Safety Authority, and the Environmental Protection Agency.

The Aviation Safety Authority and the Environmental Protection Agency included all of the categories (a) – (h) as supervising activities. Next comes the Work Environment Authority which included all but (c) (i.e. coordination of supervising activities). The Chemicals Inspectorate was most restrictive in its use of the term “supervision”, and included only three or four of the listed types of activities: inspection, checking rule abidance and measures against transgressions of the law, and (with some hesitation) work with the companies' self-inspection.

It is notable that the concepts of supervision and inspection, although of central importance in both the internal work and the external communications of these agencies, are used in different ways by the different agencies. The differences in usage of these words make both quantitative and qualitative comparisons between the agencies more difficult to perform and to interpret.

4. The legal frameworks

The types of demands made in the regulations used in inspections are summarized in *Table 3*. All the authorities under study reported that they have an extensive or at least a rather extensive set of rules to follow. No one replied that there are only few rules and regulations in their area of competence. Three authorities, the Maritime Safety Inspectorate, the Environmental Protection Agency, and the Work Environment Authority said that the set of rules and regulations is very extensive. The Aviation Safety Authority reported that the authority has a couple of “shelf metres” of rules to follow. The Work Environment Authority is the sole agency to explicitly say that they are trying to reduce the volume in order to make the rules more accessible and efficient.

4.1 The origin of regulations

Table 4 summarizes the answers to our question who establishes the rules and regulations that the inspected companies have to comply with.

The authorities themselves. Five of the agencies state that they themselves establish the regulations that are used in inspections, namely the Nuclear Power Inspectorate, the Radiation Protection Authority, the Railway Inspectorate, the Work Environment Authority, and the Environmental Protection Agency. The Railway Inspectorate also inspects the compliance with rules issued by other authorities (namely the Swedish Rescue Services Agency’s regulation on hazardous goods and the Work Environment Authority’s shunting instructions).

Several of the agencies explicitly state that they have a significant influence over rules that they do not themselves issue. The Nuclear Power Inspectorate mentions that they can put forward proposals for consideration by the Ministry of the Environment, and are in fact obliged to do so. Presumably, this is also true for the other agencies. The Aviation Safety Authority is influential since it has an unusually large role in international collaborations, their aviation safety director being the chairman of several international working groups. Several other authorities have considerable influence for similar reasons.

Parliament and government. Only four authorities specifically mention that they inspect according to laws and ordinances established by the parliament or the government. However, not too much should be made of this difference. From a formal point of view, all regulations used by the agencies under study derive their legal validity in Sweden from decisions by parliament or government.

European and international bodies. The inspection work of three authorities is dominated by international rules and regulations: the Railway Inspectorate, the Aviation Safety Authority, and the Chemicals Inspectorate. In the case of the Railway Inspectorate this refers specifically to the Technical Specifications for Interoperability (TSI) adopted by the European Union, that applies to construction and upgrading of the Interoperable High-Speed Rail Network. The Aviation Safety Authority refers to regulations from several international organisations, in particular the ICAO (International Civil Aviation Organisation), a UN body establishing worldwide general recommendations and standards, and the JAA (Joint Aviation Authority), a European body developing more specific rules from the ICAO recommendations. ECAC is also mentioned. This is a European forum for discussions on civil aviation, that was founded in 1955 as an intergovernmental organisation.

Table 5 summarizes the international influences on regulations mentioned to us in the interviews. The type of influence varies. At one extreme we find binding European directives, and at the other influential international conferences that issue recommendations. In some cases, European regulations only regulate specific issues, to be included in more comprehensive national regulations. In other cases, European regulations may completely replace national law. Some authorities predict greater influence from EU bodies in the future. According to the Maritime Safety Inspectorate international regulations have a much stronger influence on shipping in international than in national waters.

International rules can be either minimum rules that permit stricter regulations on a national level, or harmonized rules that do not allow for differences between countries. Two authorities are mostly or only affected by harmonized EU regulations. The Chemicals Inspectorate has only international harmonized rules to work with. The same applies to the Railway Inspectorate, but in this case the harmonized rules may have national exceptions that are negotiated at a European level and included in the regulation. The Radiation Protection Authority is only affected by international minimum rules. However, the option to issue stricter national rules has not been used.

Therefore, the national regulation on radiation protection coincides with the international recommendations. The Work Environment Authority has both minimum rules (about workplaces) and harmonized rules (about products such as machines and equipment). Both the Environmental Protection Agency and the Maritime Safety Inspectorate emphasize that most international regulations in their respective areas have the form of minimum rules. For the Aviation Safety Authority the picture is more complex. The standards developed by the UN body ICAO are non-binding minimum recommendations, whereas the European regulations and JAA regulations are harmonized rules. An increase in harmonized rules is expected with the increased importance of the ECAC.

Three of the agencies, namely the Environmental Protection Agency, the Chemicals Inspectorate, and the Work Environment Authority, report that European regulations are often more vague and therefore more difficult to apply than national rules. The Environmental Protection Agency claims that EU directives are often “negotiated in a complicated process” and that the rules are not always apparently justified or understandable. They also emphasize the lack of public preparatory papers (bills and reports preceding the issued law) that can help in interpreting the regulations. This makes it difficult to relate the EU rules to the Swedish Environmental Code; their interrelation is often not made clear until there is case law to refer to. According to this agency, the regulations that they have issued themselves are much easier to apply than European regulations.

The Aviation Safety Authority points out that regulations tend to become more detailed as a consequence of the European harmonisation process. The reason for that is that attempts are being made to ensure similar application in all countries. Possibly this will change eventually when the harmonisation process has advanced. According to the Aviation Safety Authority, operative rules for aviation activities tend to be more detailed than rules for the construction of aircraft. The latter is an area where technological innovation may be inhibited by rules that are too detailed.

Standard-setting bodies. Standards (technical and others) have a large impact on the work of three of the interviewed agencies. The Nuclear Power Inspectorate makes ample use of technical and quality management standards. The Radiation Protection Authority uses standards for non-ionising radiation but not for ionising radiation. The Work Environment Authority makes use of an abundance of standards that supplement the directives and regulations with respect to machines and other

products that are subject to safety requirements. Standards are also used by other agencies but to a more limited extent; this applies for instance to areas such as child protecting packages (Chemicals Inspectorate), flight records (Aviation Safety Authority), and vehicle permits (Railway Inspectorate).

Insurance companies. Three of the authorities report that insurance rules have an impact on their inspection activities. The Railway Inspectorate reports that the applicant for an operator's licence must have sufficient insurance. The Maritime Safety inspectorate mentions an obligation to be sufficiently insured when transporting oil. The Environmental Protection Agency reports that all industries that are obliged to have an operator's licence or report their operations must also pay an annual fee to an insurance consortium. If this is not paid it is the task of the inspecting authority to collect the fee. The other five authorities stated that insurance rules have no impact on their inspections.

Regulated industry. All authorities state that the regulated companies have an influence at least through their right to be consulted before regulations are changed. Some also mention that industry exerts influence through lobbying, not least in international organisations.

In summary, the most important trend with respect to the issuance of regulations is an increased use of European regulations. The agencies are in different stages of European harmonisation, but there seem to be parallel issues in the implementation of European regulations, such as an increased volume of regulations and a lack of precision and clarity in some of these regulations.

4.2 Revisions of regulations

Table 6 summarizes the information that we obtained about revisions of regulations. Only two of the authorities have procedures for revisions at regular intervals, namely the Work Environment Authority and the Nuclear Power Inspectorate. The other authorities revise regulations on a more *ad hoc* basis. Two agencies are critical of the rules and regulations. The Maritime Safety Inspectorate and the Work Environment Authority are in the process of improving the rules and regulations in order to make them more suitable to their purposes.

The reasons for revisions vary. In *Table 6*, they have been roughly divided into five main categories: a changed problem picture, technological development or

new research that makes the regulations out of date, accidents or incidents that indicate an insufficiency in current regulations, changes in the (national or international) legal framework, and vagueness in the regulation that leads to misunderstandings.

We find it notable that the routines for revisions of regulations differ so much. Regular overviews of regulations, as undertaken by some of these agencies, might be a useful routine also for other agencies.

4.3 The division of responsibility

The division of responsibility between the authorities and the regulated companies is specified in different legislations for each of the authorities. Despite this, the division of responsibility is structured in essentially the same way for all these authorities. The companies have full responsibility for carrying out their operations in accordance with the rules and regulations. The inspecting agency never takes over that responsibility, but is responsible for supervision and for promoting law-abidance.

”The inspection object is responsible for keeping the operations safe every second of the day and every day of the year, whereas it is the responsibility of the Railway Inspectorate to create rules and order, to have a reasonable supervision and to keep up pressure in the system.”
(The Railway Inspectorate).

Distinctions are often made between direct and indirect or primary and secondary responsibility. Hence, the Maritime Safety Inspectorate points out that ship-owners and captains have the direct responsibility to ensure that their fleets and ships are sea-worthy and that their activities comply with existing regulations. The Maritime Safety Inspectorate itself has an indirect responsibility to inspect that the sea-worthiness of vessels is secured. Similarly, the Environmental Protection Agency points out that the Environmental Protection Code clearly states that the primary responsibility lies with the company, not with the authority. The supervising authorities have a secondary responsibility, that is, to make sure that the companies comply with the legislation.

There is total unanimity among the authorities that this division of responsibility should be maintained. It would simply be unreasonable for the authority

to take the primary responsibility since there are tens of thousands of companies (The Environmental Protection Agency). It is also held forth that the prevailing order lies in the interest of the industry (The Nuclear Power Inspectorate). All eight authorities are under the impression that generally speaking, the allocation of responsibility is sufficiently well defined. Uncertainties that occur do not have so much to do with the allocation of responsibility as with insufficient precision in some regulations.

5. Objectives, priority-setting, and planning

In addition to rules and regulations, inspection activities depend to a large degree on policy decisions such as objectives and priority-setting principles.

5.1 Objectives

All agencies confirm that there are settled objectives (goals) for supervision and inspection activities in their respective fields. The objectives show varying degrees of specificity. Some objectives indicate the general direction of the inspection activity, whereas others are more detailed and concern particular issues. Among the least specific policies are those that refer to sustainable development (Environmental Protection Agency), vision zero³ (Railway Inspectorate), and maintaining an up to date picture of the safety situation (Nuclear Power Inspectorate). Such overall objectives are often laid down in documents adopted by the government, such as instructions and budget documents. The overall objectives are operationalized through specific objectives and plans of supervision that are intended to guide everyday work. The only agency with no such plan is the Radiation Protection Authority. The plans of supervision are often adopted for one year at a time, and contain specific objectives to be attained within that year. Strategic plans and objectives are also adopted for specific districts and departments (Nuclear Power Inspectorate, Environmental Protection Agency and Work Environment Authority).

The objectives and plans of supervision that the agencies adopt guide their activities in a number of ways. Above all, the plan of supervision functions as a starting-point for planning and carrying out inspection activities (e.g. Environmental Protection Agency, Aviation Safety Authority, Work Environment Authority, Chemicals Inspectorate). Furthermore, it guides the allocation of resources and specifies the tasks of the employees (Nuclear Power Inspectorate). The plan of supervision is also used for guidance when the agencies follow up and evaluate the inspection activities (Railway Inspectorate). At the Aviation Safety Authority the

³ Vision Zero was adopted for Swedish railbound traffic in 2001. It means that no one should be killed or seriously injured in railbound traffic and that railbound traffic should be adapted to achieve this goal.

plans are handed over to the Principal Inspectors, who carry out their inspections according to the plans. The Maritime Safety Inspectorate uses the plans of supervision according to the *balanced score card* method.⁴

Four of the agencies under study have objectives for their inspection frequencies, namely the Radiation Protection Authority⁵, the Railway Inspectorate (quantitative annual inspection plans), the Maritime Safety Inspectorate, and the Aviation Safety Authority.⁶ These agencies also report that they have reached their objectives with respect to inspection frequencies. Two other agencies previously had such policies but have now abandoned them. When the Chemicals Inspectorate was started in 1985, an objective was adopted to inspect each object every third year, but this objective has never been fulfilled due to lack of resources. The Work Environment Authority had quantitative objectives 15 years ago, but is now of the opinion that an objective for inspection frequency is counterproductive, at least when the expected inspection frequency is in the 0,1 order of magnitude. The Work Environment Authority considers it more efficient to prioritize the "worst work environments first".

5.2 Priority-setting among regulated companies

An inspection agency has at least two types of priority-setting decisions. First, it has to decide which companies to inspect, or how often to inspect different companies. Secondly, it has to decide what aspects of the companies' activities its inspections should focus on. In a previous study, four major principles for priority-setting of inspection activities were distinguished between. (Hansson 1991. Cf. Lindblom and Hansson 2003.) They are all applicable both to the choice of companies and to the choice of aspects or problem areas.

⁴ The balanced scorecard method is a management system that was developed in the early 1990's. It provides a prescription of what businesses should measure in order to 'balance' the financial perspective. Among the things measured are customer relations, relations with the personnel, and education. See: <http://www.balancedscorecard.org>.

⁵ In the areas of personal protection at nuclear technology sites (approximately 10 inspections/year) and medicine (approximately one inspection every 5 years).

⁶ As will be seen in section 7.1 there is no clear correlation between the level of an authority's inspection frequency and whether or not it has a specified goal for its inspection frequency.

- (1) *worst things first*: the highest priority is assigned to the problems considered most serious
- (2) *maximal total improvement*: priority is assigned so that total improvement is maximized
- (3) *best use of agency resources*: priority is assigned so that the total improvement per agency resource input is maximized
- (4) *best use of social resources*: priority is assigned so that the total improvement per total social resource input is maximized

The major difference between (1) and (2) is that the latter takes into account the chances of improvement. Proponents of (2) may hold against (1) that “it is crucial to tackle not only issues that are important, but problems that are amenable to solution” (Wirth and Silbergeld 1995, p. 1878). Proponents of (1) may counter that it would seem unfair, to say the least, to refrain from inspecting a company with the motivation that it is so unwilling to comply that it takes an unusual amount of agency resources to achieve compliance in that company.

The difference between (2) and (3) is unsequential in the agency’s own perspective. In the agency’s own deliberations, in which the resources available to the agency have to be taken as a given, fixed amount, priority-setting principles (2) and (3) will yield the same policy recommendations.

In contrast, the difference between (3) and (4) is substantial. (4) requires that the agency continuously optimizes its activities according to estimates of total costs. Unfortunately, total social costs are very difficult to estimate, due to lack of information and to the unpredictability of technological and social change. Often agencies depend for these estimates on information from companies that have more to lose than gain from providing authorities with truthful and unbiased information on the costs in question.

The Work Environment Authority seems to adhere to priority-setting principle (1). This authority sets priorities according to the principle “worst work environment first”. Criteria for the assessment of the work environment include the number of individuals affected and the consequences of an accident. The Chemicals Inspectorate gives priority to businesses with large volumes, many products, dangerous substances,

and substances with an extensive distribution. This can be seen as a combination of principles (1) and (2).

The Radiation Protection Authority gives priority to objects that may yield high doses of radiation, or that may involve many people with small but not negligible doses, or that the authority needs to know more about. When asked about the four above-mentioned priority-setting principles the Authority says that it mainly adheres to priority-setting principle (1) in the areas of industry and research, principle (3) in the area of nuclear energy and principle (4) in the area of medicine.

The Environmental Protection Agency seems to be closer than some of the other agencies to priority-setting principle (2). The significance (risk) of an environmental problem is balanced against the expected effect of a particular effort as well as the company's own ability to redress the problem. Situations in which the environmental problem is significant and the company's ability to redress the problem inadequate, are prioritized. Similarly, the Railway Inspectorate gives priority to companies and activities that have the most profound effect on traffic safety ("largest improvement effect").

The Nuclear Power Inspectorate inspects all objects regularly, and their priority-setting refers more to the focus of inspections than to the objects inspected. It gives priorities largely to problem areas with high risk significance or potential risk (corresponding to priority-setting principle (1)), but also to new technologies. Random checks unrelated to risk estimates are also made.

The Aviation Safety Authority has as its principle that all objects of inspection shall be inspected, hence they have not developed priority-setting principles for choice between inspection objects.

Quantitative risk analyses are not much used by these agencies for priority-setting purposes. Only one agency confirms that it makes use of quantitative risk analyses (in the standard sense of this term) on a regular basis. The Nuclear Power Inspectorate (the Office of Reactor Safety) uses quantitative risk analyses to a limited extent, but the trend is now towards qualitative risk analyses. In their view, quantitative risk analyses are often inadequate since they are saddled with uncertainty. Despite the fact that technical systems are readily analysable, there is great uncertainty as to how people affect the running of technical systems. The Work Environment Authority makes use of risk analyses, but these are rarely quantitative. The Radiation Protection Authority, the Railway Inspectorate, the Maritime Safety

Inspectorate, the Aviation Safety Authority, and the Environmental Protection Agency report that they do not use complete quantitative risk analyses. Instead, some of these agencies report that they use “primitive” forms of quantitative risk analyses. As already mentioned, the Chemicals Inspectorate gives priority to businesses with large volumes, many products, dangerous substances, and substances with an extensive distribution. This can be described as a form of quantitative risk analysis, although not in the traditional sense of the term.

In summary, there are large differences between the agencies in the ways that they set priorities. These choices are so important for the effects of their inspecting activities that cooperative endeavours to clarify the issues and to better relate priority-setting principles to operative goals should be a useful activity.

5.3 External influence on priority-setting

Priority-setting is clearly influenced by various actors outside the agencies: Parliament, other public agencies, the media, the public, the EU, and others. Most agencies report that questions put forward by the public and the media require a lot of attention. According to the Chemicals Inspectorate, questions and hints from the public guide the agency’s priority-setting to a significant degree. This agency sets its priorities on the grounds of discussions with different actors, making use of hints and proposals from companies, municipal inspectors, the Work Environment Authority, the Swedish Consumer Agency and the public. Similarly, the Work Environment Authority makes use of external proposals when developing its three-year action plan which contains its priorities for inspection. This agency also invites the parties of the labour market to discussions and listens to their opinions on a regular basis. Similarly, the operative agencies under the Environmental Protection Agency have to deal with many applications, complaints, and questions from the public. The Nuclear Power Inspectorate reports that questions put forward in Parliament influence the agency’s priority-setting, since the agency is under obligation to provide Parliament with relevant information.

The agencies cooperate with each other and with other public agencies in a number of ways. Coordination of supervision and inspection activities can take the form of joint inspections, providing each other with expertise, holding joint seminars etc. The Nuclear Power Inspectorate and the Radiation Protection Authority carry out

joint inspections in areas with potentially overlapping responsibilities. The Nuclear Power Inspectorate also cooperates in its inspection activities with other public agencies such as the Work Environment Authority, the Flammable and Explosives Department, the Swedish Emergency Management Agency, the Swedish Agency for Civil Emergency Planning, and the Swedish Rescue Services Agency. In the environmental field there are on-going collaborations between the 11 central public agencies with responsibility for environmental issues. At the central level there is an organized cooperation in the form of an independent council – the Enforcement and Regulations Council. At the regional and local level, supervision and inspection activities are coordinated between the county administrative boards and the municipalities. Supervision is also coordinated between the operative agencies, the Swedish Rescue Services Agency, and the Work Environment Authority. Supervision of dangerous goods is coordinated within the framework of SAMTILL, where all agencies that supervise transportation of dangerous goods at sea, in the air or on land cooperate. This network is managed by the Swedish Rescue Services Agency. As regards the supervision of dangerous goods, the Maritime Safety Inspectorate cooperates with the coastguard, customs and the police.

Some of these agencies also coordinate their inspection priorities with corresponding agencies in other countries. The Chemicals Inspectorate collaborates with other EU agencies in the CLEEN network. This is an informal network of European inspectors that organizes meetings and courses, and performs projects aiming at coordination and development of inspection activities. The Nuclear Power Inspectorate is engaged in a variety of international collaborations. The working group document of the IAEA has a great influence on the Inspectorate's regulatory work. Further sources of influence are the Nuclear Energy Agency (NEA) of the OECD, international conferences and informal research collaborations. The European Union also has an influence through its definition of nuclear waste and through its demand for environmental impact analyses. The Railway Inspectorate cooperates with the Danish Railway Inspectorate concerning supervision of the Öresund bridge and any accidents that may occur there. Furthermore, the Railway Inspectorate participates in European and Nordic collaborations, through which expertise is exchanged when accidents are investigated. Much of the Maritime Safety Inspectorate's international cooperation focuses on environmental issues, such as

prevention of oil leakages. There is also a Baltic cooperation for port reception facilities for ship generated wastes.

6. Personnel and their education

The educational background required for inspecting personnel varies between the agencies. Most of them have specific demands, for example the Nuclear Power Inspectorate, the Radiation Protection Authority, the Maritime Safety Inspectorate, the Aviation Safety Authority and the Chemicals Inspectorate. These agencies stress the importance of having a university education in relevant technology or natural sciences. At the Chemicals Inspectorate some have, besides university education in natural science, taken courses in environmental law, but this is not thought of as necessary. Half of the personnel at the Office of Nuclear Waste Safety have a doctor's degree. The Nuclear Power Inspectorate has a special problem connected to the decision to close down nuclear power in Sweden: There is no need to educate new personnel for running nuclear reactors, but if no such education takes place then there will be a lack of personnel for safety work. To solve this problem, the Inspectorate has contributed financially to university courses in nuclear technology.

The Railway Inspectorate and the Work Environment Authority hire inspectors with a wide range of educational backgrounds. The Work Environment Authority hires inspectors with various types of college level ("post-gymnasium") education, which includes engineers, behavioral scientists, qualified teachers, trained social workers, chemists, etc. The Railway Inspectorate does not consider university education an absolute requirement, instead they stress previous knowledge of the industry. Both these agencies put much emphasis on the inspectors' personal qualities, such as analytical and communicative abilities.

Courses in inspection methodology are not available in most Swedish universities. (As an exception, Umeå University has a 5 week course in the methodology of health and environment work, as part of its 4 year programme in health and environment protection.) Therefore, most agencies combine education for their inspectors with a period of apprenticeship. The Work Environment Authority has a one-year internal training period for new inspectors. During that period the new inspector does not perform inspections independently. Normally it takes almost one and a half year before the new inspector performs inspections on her or his own. The Chemicals Inspectorate has a similar model of apprenticeship; all newly employed

inspectors perform inspections together with an experienced inspector during their first year.

The Aviation Safety Authority has at present an education period of one week. This is the minimum requirement. The course has been criticized and an attempt is made to improve it. The Aviation Safety Authority emphasizes that apart from education, experience is very important in this kind of work.

The Railway Inspectorate develops an individual course of study for each new employee according to what they lack in comparison to a governing document that specifies what inspectors should know. The Office of Reactor Safety applies both education and models of apprenticeship. They say that there is a dilemma for a relatively small authority to set up educations for the newly employed. Young people tend not to stay for long at the agency, but require a large amount of training because of their lack of working experience. For that reason, the Office of Reactor Safety mostly employs people who already have experience from the industry or other authorities. The Nuclear Power Inspectorate has developed a specified list of the competences required for inspectors and supervisors. The competences of the individual inspector are then supplemented with courses intended to meet these requirements, including courses in inspection and supervision methodology, relevant regulations, and the supervision strategy adopted by the agency.

The Environmental Protection Agency reports that municipal inspectors often have their education from universities and technical colleges. They seldom have formal education in inspection method; this is instead taught through some form of apprenticeship.

In summary, there seems to be a need for more developed education in inspection method, but most of these authorities are too small to arrange this for their own personnel. Cooperation between the authorities may be a way to solve this problem.

7. Inspections and inspection styles

7.1 Inspection frequencies

Quantitative information about the inspections performed by these authorities is summarized in *Table 7*. There are large differences in inspection frequency between the agencies. The Office of Reactor Safety makes 100 inspections per year of its 8 objects, which results in an inspection frequency of approximately 13. This is by far the highest inspection frequency among these agencies. The same agency's Office of Nuclear Waste Safety comes second with an inspection frequency of 1.8. The Maritime Safety Inspectorate performs 4784 inspections of 3000 objects, resulting in an inspection frequency of approximately 1.6. The Aviation Safety Authority reports an inspection frequency of approximately 1 for about 400 objects. The Railway Inspectorate performs 300 inspections per year at 900 objects, which corresponds to an inspection frequency of approximately 0.3. The Work Environment Authority performs 28 000 inspections per year, which is by far the largest number of inspections among these agencies. This agency also has the largest number of objects (270 000) hence its inspection frequency is approximately 0.1. The Chemicals Inspectorate performs 250 inspections of its 2300 objects, which also gives an inspection frequency of approximately 0.1. The Radiation Protection Authority makes 80 inspections per year of its 2500 objects, which results in the lowest inspection frequency among these agencies, approximately 0.03. There is a tendency for inspection frequencies to be higher in the authorities that deal with risks of accidents where causal connections are clear, and lower in authorities that deal with long-term effects of chemicals or radiation with more complex cause-effect relationships.

It is worth noting that two agencies have a much higher number of inspections per inspector and year than the others, namely the Maritime Safety Inspectorate and the Work Environment Authority with 96 respectively 70 inspections per inspector and year. The Chemicals Inspectorate comes third with 33 inspections per inspector and year.

7.2 Inspections on site or document inspections?

There is quite some diversity in how much emphasis the agencies put on on-site inspections. Some of these agencies devote most of their resources to inspecting documentation and correspondence, while others focus almost entirely on inspections on site. All agencies perform both forms of inspections. The Radiation Protection Authority and the Office of Nuclear Waste Safety mainly conduct document inspections. The Aviation Safety Authority carries out document inspections fairly often. Both the Office of Nuclear Waste Safety and the Chemicals Inspectorate report that they have a 50/50 mix of inspections on site and document inspections. The Chemicals Inspectorate states, as a reason for this mixed strategy, that they have neither the time nor the resources to visit every company. The Railway Inspectorate, the Work Environment Authority, and the Maritime Safety Inspectorate mostly perform on site inspections.

7.3 Inspection without notification?

All but one of these agencies typically notify the company to be inspected before their visit. The only exception is the Maritime Safety which mostly conducts inspections without prior notification. Several reasons were given for notifying in advance. One common reason is that it is important to have access to relevant staff when conducting the inspection. This is particularly important for systems inspections. Another reason is that the notification in itself can lead to improvements in the company. Clearly, the purpose of inspections is to achieve improvements, not to catch offenders.

However, even those agencies that normally notify tend to perform some inspections without prior warning. The Aviation Safety Authority and the Office of Nuclear Waste Safety point to unnotified inspections as advantageous from the viewpoint of credibility. The Environmental Protection Agency points out that surprise inspections can be used to make sure that the agency has a correct picture of the company. In a similar vein, the Work Environment Authority points out that if the issue is how work is actually performed on the workplace, then unannounced inspections are useful.

The Work Environment Authority sometimes uses notifications *without* inspections as a method to promote law abidance. A supervision campaign can start

by letters being sent out to all employers in a particular branch of industry, notifying them that inspections focused on that branch will be performed. Only a minority of these companies will in fact be inspected, but it is believed that the notification will lead to improvements also in some of the uninspected companies.

7.4 Supervision campaigns

A supervision campaign is a temporary focus of inspections either on a particular problem area or on a particular category of objects, such as companies in a particular region or a particular branch of industry. All agencies carry out supervision campaigns.⁷ The frequency of these campaigns varies between the agencies. The Radiation Protection Authority and the Aviation Safety Authority carry out supervision campaigns only sporadically, whereas the Railway Inspectorate and the Work Environment Authority carry out a few such campaigns every year. Most agencies direct their campaigns towards areas with known or suspected shortcomings. Some campaigns have their origin in political pressure or in a common EU strategy.

The Nuclear Power Inspectorate carries out supervision campaigns in areas where flaws have been detected. These campaigns are parts of the plan of action, which is adopted on a yearly basis. The Maritime Safety Inspectorate and the Aviation Safety Authority also carry out inspections in areas where flaws have been detected. The Railway Inspectorate carries out supervision campaigns on the basis of the priorities that the agency sets. Campaigns are decided on the grounds of expected efficiency, and concern specific themes. The Work Environment Authority carries out campaigns on a yearly basis. These campaigns concern issues such as stress, violence and threats at the workplace, machines used in the farming industry, ladders and scaffoldings etc. They are chosen in the light of EU decisions. The last time the agency carried out a campaign around 1 600 businesses were inspected in two days. All inspectors are employed on these occasions.

7.5 Strict or lenient inspections

⁷ The Chemicals Inspectorate carries out regional inspection activities that would be called supervision campaigns in the terminology of most other authorities, but they themselves prefer not to call them supervision campaigns.

Although the choice between a strict ("legalistic") and a lenient ("negotiating") inspection style is controversial and much discussed, it is difficult to operationalize this difference. Our methodology is of course not suited for determining possible differences in this respect between the agencies' inspections in actual practice. We tried, however, to determine differences between the agencies' declared opinions on these issues by asking questions related to the strictness–leniency dimension.

When asked if the authority's style is firm or lenient most of the authorities reply that they are lenient, but firm when needed. The Aviation Safety Authority is representative when they say they are not enemies to the companies – they have to be able to have discussions with the companies.

All the inspecting agencies answered essentially in the negative when asked whether they use the scope for interpretation left open in the regulations to negotiate with the inspected companies. However, both the Chemicals Inspectorate and the Work Environment Authority sometimes negotiate the time frame for improvements. The Environmental Protection Agency, itself not an inspecting agency, is an exception since it acknowledges that local inspectors may at times be involved in negotiations about the demands that they make on the inspected company. This confirms earlier research that indicates a comparatively lenient and negotiating attitude among municipal inspectors. (Johannesson et al 1999. Johannesson and Johansson 2000.)

All agencies, except the Chemicals Inspectorate, see risks concerning the independence of inspectors. Most agencies have or intend to introduce a rotation system, in order to prevent inspectors from developing loyalties with the companies that they inspect. (It should be noted that such a system is only needed if inspection frequencies in at least some of the inspected companies are relatively high.) The Work Environment Authority and the Railway Inspectorate conduct many inspections with two inspectors in order to avoid that the independence of inspectors is compromised. At the Railway Inspectorate "calibration meetings" are arranged annually, to make sure that the assessments of inspectors will not differ. The Nuclear Power Inspectorate recruits many inspectors from the nuclear industry and has a policy not to let an inspector inspect a company that she or he has recently worked for. They also have strict policies concerning the social behaviour of inspectors, not accepting invitations to lunches or dinners with industry representatives.

7.6 Giving advice

Most of the agencies under study have a policy not to give advice to the inspected companies. They do not have the resources to give advice, and they also point out that it is the companies' responsibility to stay updated. Several agencies also mention that difficult problems concerning responsibility can arise when an authority gives advice. If an inspector suggests a technical solution that turns out to be insufficient or unnecessarily expensive, then the authority's relation to the company will be damaged. Combining the roles of advisor and inspector might also lead to other problems, such as confusion whether a proposal by an inspector is an advice or a requirement.

However, there is in practice some flexibility with respect to giving advice. Certain types of advice are conceived to be less problematic. In particular, advice of a general character, such as how to interpret rules, where to find information etc is often given. The Chemicals Inspectorate estimates that about a fourth of the time spent at an inspected company is used for information for instance about new rules. The inspectors of the Maritime Safety Inspectorate tend to give advice to small ship owners in conjunction with inspections, but the Inspectorate tries to decrease the time spent on giving advice and to rotate inspectors to avoid situations where the inspector might feel personally responsible. The Environmental Protection Agency says that the style of municipal environmental inspections depends on the personality of the inspector and that direct advising occurs, though the authority does not recommend it. Several agencies admit that individual inspectors occasionally might give advice, in spite of the policy not to do so. One reason for this may be psychological; inspectors may prefer to be helpful instead of just making demands.

Several authorities say that they would like to decrease the amount of advice given, and they all claim that there are ways for the inspected companies to get advice from elsewhere, for instance from consulting firms and trade associations. The Work Environment Authority reports that in the 1980's their inspectors gave a lot of advice. The issue of advising or not was thoroughly discussed at the Work Environment Authority in the early 1990's, and as a result a policy decision was made to focus on control – not advising.

In conclusion, most of the authorities under study wish to minimize the time that inspectors spend on giving advice, but at least in some cases it seems difficult to avoid advising in practice.

7.7 Regional differences

Not surprisingly, regional differences in inspection styles were only reported from agencies that have a regional organisation of their inspection activities. The Maritime Safety Inspectorate has observed differences in inspection culture between their regions. Efforts are now being made to rectify the situation. The Work Environment Authority is also aware of some differences in how inspections are conducted around the country. These differences concern inspection style rather than the interpretation of regulations. The Environmental Protection Agency is also aware of differences in how local and regional inspections are carried out. (Such differences have also been pointed out in previous research, cf. Johannesson and Johansson 2000.)

7.8 Dealing with non-compliance

All agencies follow up the discovery of a deficiency by correspondence, and in some cases by re-inspection. Some of the authorities have developed computerized systems to keep track of pending corrections. Hence the Railway Inspectorate has a computerized information system, JAS, for that purpose. This system makes it possible to make certain that no requirements from the authority are left unnoticed. The Work Environment Authority has a similar system, called SARA. The Chemicals Inspectorate has also started to use a database that includes all cases and injunctions as well as the agency's work notes. This means a standardisation of the work procedures, which has resulted in improved efficiency. The Aviation Safety Authority is also considering developing a database that facilitates the follow-up of cases and is helpful in developing statistics and identifying trends.

In the case of non-compliance, all authorities have the option to hand over the matter to the police or the public prosecutor. However, the extent to which this is done in practice differs between the agencies. In some cases, the authorities have other legal opportunities that they consider to be more efficient than handing over the case to the police. The Nuclear Power Inspectorate is a good example of this. They

can order a nuclear reactor to be temporarily shut down. This may cost the operator of the plant several million SEK, whereas a fine will not exceed 20-30 thousand SEK. Similarly, the Marine Safety Inspectorate is authorized to prohibit the use of a ship, and does so in cases of serious infringement of safety regulations.

Five of these agencies seldom or never hand over cases to the police or the public prosecutor, namely the Nuclear Power Inspectorate, the Radiation Protection Authority, the Aviation Safety Authority, the Maritime Safety Inspectorate, and the Railway Inspectorate. The few cases that are prosecuted on initiative from these agencies are typically relatively serious offences such as the causing of accidents, severe violations of the law, or deliberate violations of the authority's orders and regulations. The Aviation Safety Authority points out that reports on incidents are essential for the Authority's preventive work. If such reports gave rise to legal measures, then fewer reports on incidents would be delivered. (This is the case in countries where authorities take legal actions in similar cases.)

The Work Environment Authority prosecutes more often. Common types of cases that they hand over to the police are the employment of under-aged workers and the use of carcinogenic substances without a licence.

Prosecution seems to be quite common for the Chemicals Inspectorate. Common reasons for the Chemicals Inspectorate to prosecute are incorrect labelling of chemical products (for example labels only in a foreign language) and failure to report products to the products register.

The operative agencies under the Environmental Protection Agency are obliged to take legal actions when punishable acts have been committed. According to the agency, they also do that quite often. A common reason for such legal action is failure to submit the annual environmental report.⁸

Several authorities maintain that public prosecutors often do not prosecute even when there are reasons to do so, and that the cases that go to court are often lost. A reason for this, according to some of the authorities, is that prosecutors and courts do not have sufficient understanding and knowledge of the subject-matter in question. The Environmental Protection Agency maintains that there can be cases when it is right for an authority to send a case to the prosecutor, but nevertheless wrong for the

⁸ All companies whose activities require a license are obliged to submit an annual environmental report.

prosecutor to proceed, since the authority and the prosecutor have different instructions and different legal criteria to work with.

The Work Environment Authority is not very successful with prosecutions, and has also experienced different results from different local prosecuting authorities. This authority is presently developing a policy for prosecutions, and it has also started a work group with the National Prosecutor Authority and the National Police Authority. The Work Environment Authority has also approached the Ministry of Industry, Employment, and Communications in this matter, proposing a system of corporate fines. Today it is often difficult to prosecute a company since a responsible person has to be found – the company as such cannot be sent to prison. By using corporate fines a noticeable punishment can be imposed on the company even if the distribution of responsibilities within the company cannot be identified. Such a system is already in use in Norway.

Similarly, the Chemicals Inspectorate discusses its problems with prosecutions with the National Prosecutor Authority. One problem is that the legislation on chemical safety is so complicated that a scientific background is needed to understand it. The situation has however improved somewhat after the introduction of special environmental prosecutors.

In summary, there are remarkable differences between these authorities as regards the extent to which they hand over non-compliance cases to the police and public prosecutor. In our view, these differences are not satisfactory from a legal point of view, and efforts should be undertaken to achieve a more coordinated approach.

8. Self-reporting, self-inspection, and systems inspection

One of the most important issues in the field of inspection is the extent to which control tasks can and should be left to the regulated companies themselves. Hansson (2001) distinguishes between three levels of self-control. The lowest of these levels is documentation. Medical doctors are required to keep case records and truck-drivers to keep track of their work hours. The next level is self-reporting, meaning that the regulated company has to send in the documentation, or a summary of it, to an enforcement agency. Hence, in Sweden and many other jurisdictions polluting industries are required to report regularly on their emissions. The third and highest level is self-inspection. By this is meant that the regulated company is required to organize internal inspections to ensure that regulatory requirements are satisfied. Since the 1970's, audited internal control has gained in importance, in particular in occupational health and safety. (Gustavsen 1980. Wilthagen 1994.) In several countries it has been combined with a systematic use of system monitoring or systems inspection, i.e. inspections aimed at ensuring a sufficient level of internal control. (Wilthagen 1994, p. 368. Dawson et al 1988, p. 268)

In our study we focused on the two highest of these levels of self-control, namely self-reporting and self-inspection.

8.1 Self-reporting

In most cases the regulated companies are required to send reports to the authority. A responsibility to report accidents and incidents is clearly specified and demanded by all the authorities except for the Chemicals Inspectorate whose area of competence does not cover accidents. The reports are used in various ways but most frequently it is emphasized how they are used to identify and interpret tendencies and to structure future work. One reason given for an extensive use of such reports is that the agency has very limited resources to be out in the field. In a terminology used at the Nuclear Power Inspectorate, supervision has both an active and a passive component. The passive component consists of analysing reports that the nuclear power plants send to

the authority, and the active part in the authority being out in the field, seeking information by means of inspection. The reporting part is very important, and the authority is considering extending the report system, but is looking for relevant indicators that can be used to identify the largest safety problems. The reports are also used as a basis for information activities.

Similarly, the Radiation Protection Authority collects reports from the objects regarding accidents, incidents, and general statistics. This statistics includes for example radiation doses due to medical examinations, and importation of radioactive substances.

The Railway Inspectorate has set a cost limit as a guiding-principle as to what shall be reported on in addition to some accidents and near-accidents. All events in railway traffic that have involved serious personal injuries or, when it comes to material damage, exceed one million SEK have to be reported. (The Railway Inspectorate has a commission to provide the Swedish Institute for Transport and Communications Analysis with certain statistics on severely injured or dead.)

In aviation there is a well-developed system for reporting. All serious events should be reported to the authority within 24 hours after the occurrence. The companies have an internal reporting-system, and provide the Aviation Safety Authority with their Flight Operation Reports (FOR). These reports are used to monitor the activities within the companies. It is also possible for instance for an airline pilot to make anonymous reports to the authority. The authority receives 2000 reports annually that are registered in a database and used as a basis for accident prevention.

According to the Maritime Safety Inspectorate, the reporting of accidents works reasonably well in the shipping business, but the same cannot be said of the reporting of incidents. This has to do with the special culture and attitudes within shipping. To be a sailor has always been more or less risky and incidents on board are perceived of as normal. The Maritime Safety Inspectorate cooperates with the Swedish Shipowners Association in order to establish a database where accidents and incidents can be reported anonymously. The aim is not to receive detailed reports on who made what onboard, but to document occurrences in order to be able to identify and interpret patterns as a pre-emptive strategy. This is a recent initiative that slowly starts to function. A comparison has been made with a younger inspection authority, namely the Aviation Safety Authority, that had the possibility to structure a system for

reporting accidents from the start, whereas shipping has to work with ingrained patterns and attitudes.

In the environmental field, some inspection objects are required to submit annual environmental reports. Others are required to report accidents and incidents, and yet others to submit information for statistical purposes. The reports are used in different ways by different local and regional authorities. Many reports are not used in everyday work, but are used when special efforts are made. Others are frequently used and have an important role in the inspection work. Some information in the reports is compiled and further reported to the central level.

Manufacturers and importers of chemical products have to report their products once a year to the Chemical Inspectorate's products register. The register contains information on the identity of products, production or importation volumes, ingredients, etc. It consists of information from 2300 companies about 63000 products (containing between 10000 and 12000 different substances). The Inspectorate uses the products register primarily for prioritizing inspection activities.

The Work Environment Authority has a system of reporting. Workplaces are required to report serious accidents and incidents. On the bases of these reports, the Authority decides whether to perform an inspection or to take another type of contact with the workplace. In some cases an accident investigation is performed.

In conclusion, companies have quite extensive obligations to send in reports to the authorities, but the use of these reports varies, and in some cases improved statistical competence might be helpful in making more use of them in priority-setting.

8.2 Self-inspection

Self-inspection means that the regulated company organizes internal inspection (and other forms of supervision) to ensure that regulatory requirements are satisfied. Obviously, a well-functioning system of self-inspection may remove some of the workload from the responsible agency, but it is equally obvious that such a system requires much from the companies in terms of competence, resources, and willingness to satisfy the requirements.

Six of the eight studied agencies require companies to carry out self-inspections. In all these cases there are also written instructions on how these self-inspections

should be carried out. The two exceptions are the Chemicals Inspectorate and the Maritime Safety Inspectorate. The Chemicals Inspectorate currently makes no use of self-inspection, and instead relies wholly on direct and systems inspection. The Maritime Safety Inspectorate has an ambition to increase the amount of self-inspection.

“Today, especially at the smaller shipbrokers, they wait until we come aboard and point out what is wrong, and then they correct it. You get an injunction and don’t have to find the problems yourself.” (Maritime Safety Inspectorate)

This example suggests that industry culture is an important factor for the success of self-inspection. This is confirmed by the Environmental Protection Agency, the Railway Inspectorate, and the Work Environment Authority. They all claim that larger companies have a better basis for effective self-inspection. Other positive factors mentioned are the company’s level of knowledge and its sense of responsibility. A problem noted by the Railway Inspectorate is that companies often handle only the follow-ups well. This is just one part of self-inspection. The whole system consisting of resources, rules, norms, and risk analyses is generally found to be lacking.

In our interviews, several suggestions were made on how the overall efficiency of self-inspection can be increased:

- Procedures for documentation of self-inspection in such a way as to make it easy to control (Nuclear Inspectorate)
- Staff training at the inspected companies (Radiation Protection Authority)
- Concrete industry-specific handbooks (Environmental Protection Agency)
- Information material directed at small companies such as simplified risk mapping and checklists (Work Environment Authority)

The Aviation Safety Authority noted that their system of self-inspection is more or less identical to the ISO 9000 system, and that further development of that system is beyond the authority's range of activities.

8.3 Systems inspections

Systems inspection means that the foci of inspection are various systems, such as production systems, security organisation or knowledge management systems. The idea is to evaluate the company's capacity and will to discover and remedy errors. One of the systems that may be controlled within a framework of systems inspection is a company's system for self-inspection.

The use of systems inspections in the agencies under study is summarized in *Table 8*. A strong trend to increase the already widespread use of systems inspection is notable in this table.

Just as for self-inspection, the agencies report that the efficiency of systems inspection differs between different types of organisations. We found a consensus that organizational size and resources along with the complexity of the organization's activities makes systems inspection both more necessary and more viable. The Nuclear Power Inspectorate, the Railway Inspectorate and the Work Environment Authority all have somewhat simplified procedures of systems inspection for smaller and less complex inspection objects.

In the case of the Chemicals Inspectorate, inspection is aimed at evaluating the capacity of various systems, but the method used is mostly direct inspection. The result is a kind of hybrid between systems inspection and direct inspection, and separating the two seems to be difficult in this case.

A somewhat different perspective on systems inspection can be gained if supervision activities are divided into the five categories proposed by Durbin, Melber and Grimes (2002). As can be seen from *Table 9*, several of the authorities do not at all inspect technical design, whereas all agencies carry out inspections of corrective action systems.

The introduction of self-inspection and systems inspection on a large scale is one of the most important changes in Swedish supervision systems in the last few decades. Unfortunately, this change has taken place without being accompanied by major evaluation efforts. Therefore, we still do not know to what extent these

innovations have had the positive effects on safety and rule compliance that they were intended to achieve. (Lindblom and Hansson 2003)

9. Methodological development and evaluations

Most of the agencies under study evaluate their inspection methods, although the extent of this activity varies. The Office of Reactor Safety conducts an evaluation after each project. The Aviation Safety Authority has developed a new form for evaluation that is based on standardized checklists and forms. These are used for follow-up, complaints, and feedback. The Work Environment Authority has recently run several projects on different aspects of evaluation. Their policy is that before a new method of inspection is adopted as a normal procedure, it must have been evaluated. However, three of the agencies do not at present evaluate their inspection methods, namely the Maritime Safety Inspectorate, the Environmental Protection Agency, and the Chemicals Inspectorate. The Maritime Safety Inspectorate says that this is due to the fact that maritime inspections are a traditional activity.

All agencies under study are at least to some degree involved in development of inspection methodology. The Office of Reactor Safety points out that this work is carried out as a part of an international cooperation. They have developed more distinct definitions of their demands on the companies, with the effect that inspectors have a clearer picture of their tasks. Currently they intend to create a system of safety indicators that industry can use in reporting to the agency. These indicators would measure accidents and incidents, but also the safety culture within organisations. The same agency's Office of Nuclear Waste Safety points to some areas where they have developed new methods, such as risk-informed decision making, safety indicators, and comprehensive risk assessments. The Railway Inspectorate has a coordinating responsibility for several agencies (such as the Rescue Services Agency, the National Board of Housing, Building and Planning, the National Electrical Safety Board, the Work Environment Authority, Banverket⁹, and the Environmental Protection Agency) in developing supervision methods for the implementation of TSI for high-speed trains. Systems inspection is a prioritised area for the Environmental Protection Agency and self-inspection for the Maritime Safety Inspectorate. The Maritime Safety Inspectorate tries to facilitate the task of issuing certificates. A large ship such as a passenger ferry needs several certificates, and the Inspectorate tries to develop a

method whereby as many certificates as possible can be issued during the same inspection so that inspectors only need to go on board the same ship once or twice a year. The Aviation Safety Authority has also started a project on risk-based supervision. The Chemicals Inspectorate has focused on the development of methods for the inspections of articles (products that are not chemical products). This agency has also delegated more responsibility to the inspectors and has started to write citations on site. The Work Environment Authority is focused on developing relatively simple methods concerning psycho-social issues, the organisation of work and negative stress.

All agencies, except the Aviation Safety Authority and the Environmental Protection Agency, state that they need to develop criteria for measuring the success of inspections. According to the Office of Nuclear Waste Safety, the fundamental question is whether the absence of accidents is due to inspections or luck. Both the Radiation Protection Authority and the Nuclear Inspectorate point out that it is hard to evaluate the effects of preventive measures, and are interested in finding methods to do this. The Railway Inspectorate presently makes an attempt to find out if there is a way to measure the effect on traffic safety of their work. The Work Environment Authority is working to develop success criteria for inspections on two fronts. They want to find ways to measure if an inspection has been performed well and to find a method to measure the effects of inspections. This would mean that they would have to develop criteria for good inspections and criteria for good working conditions.

⁹ The authority responsible for rail traffic.

10. Conclusions

We found important similarities and shared principles between the eight authorities. Perhaps most importantly, although the division of responsibilities between the authorities and the regulated companies is specified in different legislations for each of these authorities, the division of responsibilities is structured in essentially the same way. In each case, the companies have full responsibility for carrying out their operations in full accordance with the rules and regulations. The inspecting agency never takes over that responsibility, but is responsible for supervision and for promoting law-abidance. There is total unanimity among the authorities that this division of responsibilities should be maintained. Most of the authorities under study wish to minimize the time that inspectors spend on giving advice. One of the major reasons for this is that advising may lead to misunderstandings with respect to the companies' own responsibility to find the best means to solve their problems.

In this final section we focus first on the more significant differences that we found between the eight authorities, and then on some topics for possible cooperations between these and other inspecting agencies.

10.1 Potentially problematic differences

Many of the differences in inspection policies and practices between the agencies under study seem to be due to differences in their tasks and in the resources at their disposal. However, this may not be true in all cases. We found seven potentially problematic differences that are worth a closer analysis.

1. The concepts of supervision and inspection are important both in the internal work and the external communications of these agencies. However, these concepts are used in different ways by the different agencies. This makes both quantitative and qualitative comparisons between the agencies difficult to perform and to interpret.

2. There are significant differences in the routines that these agencies have for revising the regulations that they themselves issue. Two of them have procedures for

revisions at regular intervals. The usefulness for other agencies of introducing regular overviews of regulations should be worth considering.

3. There are large differences between the agencies in the ways that they set priorities for inspections. These choices are so important for the effects of their inspection activities that cooperative endeavours to clarify the issues and to better relate priority-setting principles to operative goals should be a useful activity.

4. There are large differences in inspection frequencies between the agencies (between 13 and 0.03 inspections per company and year). These differences are in part a reflection of different risk situations, but may also be a reflection of resource allocations that need not be optimal.

5. There is quite some diversity in how much emphasis the agencies put on on-site inspections. Some of these agencies devote most of their resources to inspecting documentation and correspondence, while others focus almost entirely on inspections on site. Research on the relative efficiency of these methodologies is needed.

6. Most of these agencies have as a standard procedure to notify the company before their inspection visits. The Maritime Safety Inspectorate is an exception; it conducts most of its inspections without prior notification. Here as well, research on the relative efficiency of the methodologies is needed.

7. There are large differences between these authorities in the extent to which they report non-compliance to the police and public prosecutor. This is not only a matter of efficiency but also a matter of uniformity in the rule of law. In our view, efforts should be made to achieve a more coordinated approach.

10.2 Other topics for cooperation

Several of the issues raised in the previous section can be solved through cooperation between these and other inspection agencies. We also found some other problems that can hopefully be solved through cooperation between the agencies.

8. These agencies are in different stages of European harmonisation, but they are all increasingly influenced by European legislation. There seem to be parallel issues in the implementation of European regulations, such as an increased volume of regulations and a lack of precision and clarity in some of these regulations. It is essential that these experiences be compiled and analysed, so that they can influence the Swedish input into the European legislative system.

9. Self-inspections and systems inspections have been introduced in Sweden on a large scale without being accompanied by major evaluation efforts. We do not know to what extent these innovations have had the positive effects on safety and rule compliance that they were intended to achieve. Research on self-inspection and systems inspections should be of common interest for the inspecting agencies.

10. Companies have quite extensive obligations to send in reports to the authorities, but the use of these reports varies. Methodological developments (including statistical methods for dealing with time series) should be useful in several of these agencies.

11. Most of these authorities are too small to arrange a suitable formal education in inspection methodology for their own inspectors. Cooperation may be a way to solve this problem.

12. All agencies under study are at least to some degree involved in the development of inspection methodology and in the evaluation of inspection methods. Most of the agencies are small for such activities, and they all have something to learn from each other's experiences. Cooperation in methods development and evaluation should be useful to all of them.

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Tables

Table 1. Resources for inspection.

	A: Nuclear Power Inspectorate	B: Radiation Protection Authority	B: Railway Inspectorate	A: Maritime Safety Inspectorate	A: Aviation Safety Authority	B: Chemicals Inspectorate	A: Work Environment Authority
Total number of employees (person years)	102	110	32	135	167	120	800
Number of employees who supervise and inspect	62	45	15	50	40	12	400
Number of person years devoted to inspection	> 25	5	15	50	40	7,5	400
Part of total agency resources used for inspection	16 %*	4 %	45 %	50 %	17 %	5,5 %	60 %

A: Pronounced supervising agencies

B: Agencies that perform both supervising and other activities

*This refers to statistics on a wider supervision concept including inspection. No separate statistics on inspection specifically were found.

Since the Environmental Protection Agency performs no inspections of its own it has been excluded from this quantitative comparison.

Table 2 Activities included by the authorities in their definitions of supervision.

	Nuclear Power Inspectorate – Reactor Safety	Nuclear Power Inspectorate – Nuclear Waste	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	Chemicals Inspectorate	Work Environment Authority
Regulatory work	Yes	Yes			Yes	Yes	(Yes)		Yes
Inspection	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Co-ordination of supervising activities			Yes			Yes	Yes		
Checking rule abidance	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Taking measures against transgressions of the law	Yes		Yes			Yes	Yes	Yes	Yes
Licensing	Yes	Yes	Yes	Yes	Yes	Yes	(Yes)		Yes
Preventive measures; counselling and information					Yes	Yes	Yes		Yes
Work with the companies self-inspection; control programme	Yes	Yes		Yes		Yes	(Yes)	Yes	Yes

The parentheses around affirmative answers by the Environmental Protection Agency indicate that these are a part of their supervising and advising responsibilities towards local inspection authorities.

Table 3. The types of requirements in the legislations and rule systems.

	Nuclear Power Inspectorate – Reactor Safety	Nuclear Power Inspectorate – Nuclear Waste	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	Chemicals Inspectorate	Work Environment Authority
Detailed demands on technical solutions or handling	Yes				Yes	Yes	Yes		
Unique demands on individual operators or permit holders	Yes	Yes	Yes	Yes			Yes	Yes	Yes
Demands on results of activities		Yes		Yes		Yes	Yes	Yes	Yes
Demands on measures related to risk assessments	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Demands on processes	Yes	Yes	Yes	Yes		Yes	Yes		Yes
Demands on self inspection	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes

Table 4. The authorities and organisations that have issued the regulations used in inspections.

	Nuclear Power Inspectorate	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	National Chemicals Inspectorate	Work Environment Authority
The authority itself	Yes	Yes	Yes			Yes		Yes
Other authorities			Yes			Yes		
Parliament/Government	Yes			Yes		Yes		Yes
International bodies					Yes			
EU regulations			Yes				Yes	
The inspected Industry			Yes					

Table 5. International organisations with major impact on regulations.

	Nuclear Power Inspectorate	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	National Chemicals Inspectorate	Work Environment Authority
Organisations with impact on regulations	IAEA NEA Symposia EU	EURATOM	EU	MARPOL	ICAO JAA ECAC	IMPEL	EU	EU

Table 6. Revisions of regulations.

	Nuclear Power Inspectorate	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	National Chemicals Inspectorate	Work Environment Authority
Intervals of revisions of regulations								
Fixed intervals ?	Approximately every fifth year	No	No	No.	No	No	No	Every fifth year
Actual frequency of revisions	Every fifth year, but varies between 4-6 years. When needed	On average every 10-15 years			When needed. In future: every 3-5 years.	Constant revisions.	Smaller adjustments every year, larger revisions with several years' interval	
Common reasons for revisions of regulations mentioned by the authorities								
New risks/outdated risks						Yes		Yes
Technical development/new research	Yes				Yes		Yes	Yes
Accidents/Incidents	Yes			Yes	Yes			
Change in legal framework	Yes	Yes	Yes		Yes	Yes		
Vagueness and unclearness	Yes							Yes

Table 7. Numbers and frequencies of inspections.

	Nuclear Power Inspectorate – Reactor Safety	Nuclear Power Inspectorate – Nuclear Waste	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Chemicals Inspectorate	Work Environment Authority
Number of inspections per year	100	10-15	80	300	4784	420	250	28 000
Number of Inspection objects	8	9	2 500	900	3000	420	2 300	270 000
Inspection frequency. (inspections/object per year)	13	1,8	0,03	0,3	1,6	1	0,1	0,1
Number of person years devoted to inspection	23	2	5	15	50	40	7,5	400
Inspections/Inspector person year	4,3	5-8	16	20	96	10	33	70

Since the Environmental Protection Agency performs no inspections of its own it has been excluded from this quantitative comparison.

Table 8. The use of systems inspections.

	Nuclear Power Inspectorate – Reactor Safety	Nuclear Power Inspectorate – Nuclear Waste	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	Chemicals Inspectorate	Work Environment Authority
Use of systems inspection	60% of inspection	90% of inspection	90% of inspection	60% of inspection	25% of inspection	Close to 100% of inspection	Not specified	Used primarily for inspection of articles. Percentage not specified.	20% of inspection
Usage trend	Increasing	Increasing	Increasing	Increasing	Increasing	Constant	Not specified	Increasing for inspection of articles	Constant
Method documentation	Quality system documentation	Quality system documentation	Available	Inspection handbook	Handbook for safety management system auditing	Check lists and standardized forms	None at the time of writing, but under development.	Methods are partially described in the Inspectorate's steering document.	Method handbook

Table 9. Areas of supervision.

	Nuclear Power Inspectorate – Reactor Safety	Nuclear Power Inspectorate – Nuclear Waste	Radiation Protection Authority	Railway Inspectorate	Maritime Safety Inspectorate	Aviation Safety Authority	Environmental Protection Agency	Chemicals Inspectorate	Work Environment Authority
Technical design of the object of inspection		Yes		Yes		Yes			Yes
Quality systems	Yes	Yes	Yes	Yes	Yes	Yes			Yes
Operational risk	Yes	Yes		Yes	Yes	Yes	Yes		Yes
Corrective action systems	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Training and qualifications	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes

