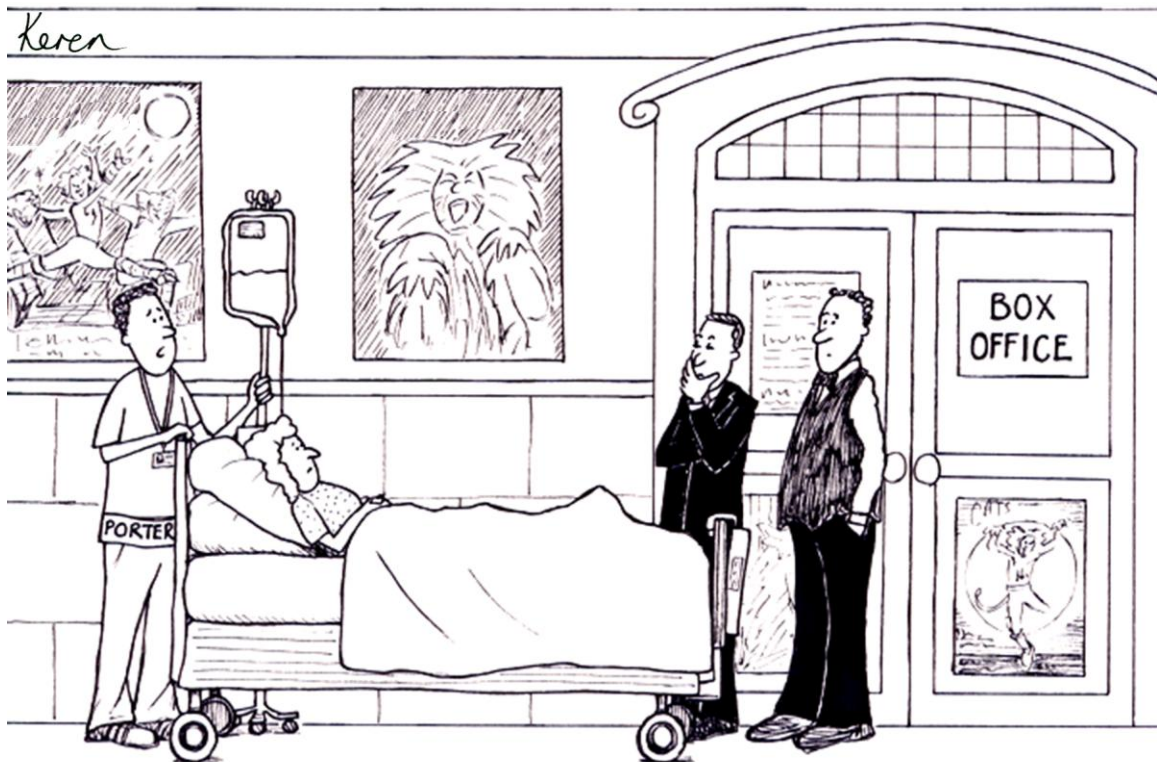


KEEP YOUR EYES ON THE PRIZE

AN ASSESSMENT FRAMEWORK FOR THE REGULATORY ARRANGEMENT ON THE USE OF MEDICAL TECHNOLOGY IN HOSPITALS



"But they told me to take her down to theatre..."

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**AN ASSESSMENT FRAMEWORK FOR THE REGULATORY ARRANGEMENT
ON THE USE OF MEDICAL TECHNOLOGY IN HOSPITALS**

Master thesis

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EXECUTIVE SUMMARY

Medical technology is evolving at a remarkable rate, prompted by its major role in health care services. The Health Care Inspectorate monitors this technological advance and should take action whenever the quality of care and/or patient safety is at risk. Regulation is therefore inevitable. However, as far as the use of medical technology in care institutions is concerned, there are still some gaps. This research explores how a regulatory arrangement specifically aimed at the use of medical technology in hospitals could complement the Inspectorate's current regulatory arrangement and how it should take form.

The 2006 Twenteborg accident, claiming the life of a patient, served as the motive for this research, as it is a typical example of the complexity entailed in regulating the use of medical technology in hospitals. The main research question was therefore: ***'What amendments can be made in the Health Care Inspectorate's regulatory arrangement to enhance patient safety when using medical technology in hospitals?'***

In order to find the answer, the research included an analysis of the current regulatory arrangement of the Inspectorate, an analysis of several theories on regulation, a field analysis, and an analysis on the specific complexities entailed in regulating the use of medical technology. The research also included a design & evaluation phase, to make an assessment framework for a regulatory arrangement specifically aimed at the use of medical technology in hospitals and assess the Inspectorate's current regulatory arrangement.

The Inspectorate's current regulatory arrangement includes a cycle of enforcement and three inspection instruments, namely phased, thematic and incident-based supervision. Medical technology is regulated by means of the Medical Devices Act and the Care Institutions Quality Act. The first act regulates the production and trade of medical devices and is thus essentially meant for manufacturers, whereas the latter regulates the use of medical technology, thus essentially regulating care institutions. In this way a clear distinction is made between supervision on the production and trade of medical devices and supervision on the use of these medical devices. However, actual practice has shown that it is hardly feasible to keep these two apart.

The cycle of enforcement and the inspection instruments are based on three regulation theories namely system-based, risk-based and responsive regulation. Fundamental to the system-based regulatory approach is that the regulatee should have a self-regulatory capacity and thus aims for regulation on the system-level. The risk-based approach aims for selective regulation and requires the regulator to *'pick important problems and fix them'*. The responsive regulation approach focuses on interventionist response and tries to establish a synergy between punishment and persuasion. Each theory has a number of opportunities and risks that need to be considered when applying them.

Many of the risks or complexities that were identified in the theory were confirmed by the field analysis. The field analysis also provided some additional insights into other (practical) complexities. An analysis of the complexities has revealed that they are mostly created by the multi-actor environment, by organizational and technical issues, or by the formal obligations the Inspectorate has to comply with.

An adequate regulatory arrangement and thus the standards of the assessment framework should be designed in such a way that the opportunities and the risks identified in the analyses of the theories and the field analysis should be reckoned with, in that one should try to gain advantages from the opportunities and try to reduce or prevent the risks. Furthermore, as the Inspectorate's current regulatory arrangement consists of a combination of different regulatory theories, the assessment framework should also provide standards which enable a practicable combination of theories. Keeping the above in mind, I have designed an assessment framework. It is intended to serve as an assessment tool for the Inspectorate and can be interpreted as a normative checklist or guideline to verify if and the extent to which the standards are imbedded in the regulatory arrangement.

Upon assessing the Inspectorate's current regulatory arrangement by means of the assessment framework, a number of shortcomings were identified including communication issues, accountability issues and issues regarding the content and focus of the actual inspections. The recommendations to the Inspectorate therefore also include suggestions as to how to improve on these aspects.

The general conclusion of this research is that the Inspectorate's current regulatory arrangement still has a number of gaps, especially with regard to the use of medical technology in hospitals. These gaps can be narrowed by a more meticulous design of the regulatory arrangement. The general complexity of regulating the use of medical technology is mainly due to the multiplicity of aspects, each of which should be given careful consideration. The title of this report was inspired in the light of this complexity. *Keep Your Eyes on the Prize* is a warning that one should not lose sight of the main objective, which is the quality of care, with the focus on patient safety.

The main recommendation is therefore to use the designed assessment framework as a guideline to gain perspective on regulating the use of medical technology in hospitals. It should be noted, however, that the designed assessment framework still needs some finishing touches, as it was not feasible to include them in the limited time frame of this research. The finishing touches include the aspects of a measurable assessment, which should enable the user to obtain a valuable rating of the situation, and the terms of reference, which should specify the usage. As medical technology is now also increasingly used in nursing homes, it may be worthwhile finding out if the assessment framework can also be applied in a wider setting than just hospitals.

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INTRODUCTION

Medical technology is evolving at a remarkable rate prompted by, among other things, its major role in health care services. Even though the new developments in general enhance the quality of care, it is inevitable that along with these new and emerging technologies also new risks arise. It is the task of the Health Care Inspectorate (Inspectie voor de Gezondheidszorg - IGZ) -hereinafter referred to as the Inspectorate- to monitor these developments and take action whenever the quality of care and/or patient safety is at risk.

Nowadays, society is becoming more articulate and demanding towards the Inspectorate in terms of accountability. This has led to questions being raised about the effectiveness of the Inspectorate's performance. As the Inspectorate is aware that it is a convenient target of criticism, it is constantly aiming to improve performance. One of its organizational goals is therefore to take a close look at the effectiveness of its inspections. The Inspectorate believes that an assessment of its performance will be doubly beneficial, since that will not only promote its learning capabilities, but also prove to society its reason for existence.

This research combines all the above mentioned aspects by exploring how a regulatory arrangement specifically aimed at the use of medical technology in hospitals should take form. The introductory part contains the definition of this research, which should clarify the research objective, scope and approach. The introductory part also includes a partial description of the Twenteborg case, which has been the motive for this research and will provide the reader with some information in the field of research.

1. RESEARCH DEFINITION

This research was set up on the basis of Verschuren's Manual (1988) to formulate a problem definition for scientific research. This chapter is entirely about the research definition, which contains a problem definition, the delineation of the scope of the subject, and the research approach.

PROBLEM DEFINITION

The problem definition describes the research objective and the research questions, as well as a few other valuable aspects that were identified during the problem exploration. These include the motive to set up the research and the relevance of the research.

Motive

The motive to start this research was the report by the Dutch Safety Board (de Onderzoeksraad Voor Veiligheid - OVV) [OVV, 2008] -hereinafter referred to as the Safety Board- about the fire accident that occurred on September 28th 2006 in Twenteborg hospital in Almelo, which was caused by failure of a medical device. According to the Inspectorate [IGZ, 2008: 75], "the fire claimed the life of a patient who was undergoing surgery in the operation theatre at the time. Her death caused a

widespread concern, with many questions being raised by the medical profession, hospital management, manufacturers of ceiling-mounted supply units and the general public, both in the Netherlands and abroad". As there had never been an accident like this before, this caused quite a stir. As a result, several investigations by different parties were instigated including that of the Dutch Safety Board.

The Safety Board's investigation was carried out almost at the same time as that of the Inspectorate, but only after several investigations by other parties. The Safety Board took notice of all the investigations and the findings, but its own investigation revealed that there were some inconsistencies in the roles and responsibilities of the hospital, the Inspectorate and the manufacturer regarding safety in the use of medical technology.

According to the Safety Board, the hospital failed to provide good (patient-safe) care. However, due to the lack of clarity in the manufacturer's responsibilities (towards the hospital) regarding maintenance and safety, the hospital has not been able to take appropriate measures. Therefore the Safety Board recommends that the responsibilities of the manufacturer towards the hospitals regarding maintenance and safety should be clearly specified. Furthermore, the Safety Board points out that regulation on the use and maintenance of medical devices is lacking and recommends that the Inspectorate should establish a clear, unambiguous regulatory arrangement on potentially harmful medical devices and that the Inspectorate should no longer just presume that care providers fulfill their responsibility to provide good care, but actually verify whether this is indeed the case.

Research objective

This research aims to contribute to the improvement of patient safety by means of an evaluation of the regulatory arrangement on the use of medical technology in hospitals. The concept of inspection can roughly be defined as the entire process of collecting information, assessment of this information and intervention if necessary. In this research paper, a regulatory arrangement refers to an elaboration of all the formal and material aspects, which together form the manner in which inspection should take place.

In order to evaluate the Inspectorate's current regulatory arrangement regarding the use of medical technology in hospitals, it is important to:

- (1) get a basic understanding of inspection on the use of medical technology in hospitals and all the complexities that this process entails;
- (2) design an assessment framework to support:
 - a. a qualitative evaluation of the Inspectorate's current regulatory arrangement and
 - b. the formulation of recommendations for possible improvements.

Relevance

Societal relevance - Public health care is a broad societal issue in which patient safety in the use of medical technology plays only a small part. In recent years, however, this part has been getting a lot of attention worldwide due to the current trend to improve patient safety and the accelerated

development of health care technology of late. This research aims to provide a basic understanding of how the establishment of a proper regulatory arrangement can contribute to the improvement patient safety in the use of medical technology in hospitals.

Theoretical relevance - Various forms of review, one of which is inspection, are increasingly used to assess performance. In the health care sector this is also commonly used. However, there still is little scientific evidence on the effectiveness of review. This research aims to design an assessment framework to evaluate the quality of the Inspectorate's regulatory arrangement on the use of medical technology in hospitals and may thus be a contribution to the small amount of existing scientific evidence on the effectiveness of review.

Research questions

The main research question aims for recommendations. However, in order to provide better insight into the research, six sub questions have been derived from the main question. They are divided into two parts, viz. analysis and design & evaluation.

Main research question

What amendments can be made in the Health Care Inspectorate's regulatory arrangement to enhance patient safety in the use of medical technology in hospitals?

Sub research questions

A. Analysis

1. How does the Inspectorate currently carry out inspection on patient safety in the use of medical technology in hospitals?
2. Who are the other actors involved in patient safety in the use of medical technology in hospitals and what are their interests?
3. What existing theories, models or concepts of regulatory arrangements could be used for comparison with the Inspectorate's current regulatory arrangement?
4. Which are the typical complexities of regulating the use of medical technology in hospitals and how do they impact assessments of the regulatory arrangement?

B. Design & Evaluation

1. How can an assessment framework for the evaluation of the Inspectorate's regulatory arrangement be designed, taking these complexities into account?
2. How can the strengths and weaknesses of the Inspectorate's current regulatory arrangement -that were identified in the evaluation- be translated into recommendations for improvement of patient safety in the use of medical technology in hospitals?

SCOPE

Terminology: Regulation

Regulation is considered to include all the regulatory activities that are executed within a specific domain by an (external) regulatory agency. Regulation is long-term oriented and tries to organize activities in such a way that better conditions for achieving the desired (societal) objectives are created. [Mertens, 2002]. These activities range from activities for a compliant setting to activities for a more deterrent setting. Regulatory arrangements can be described systematically by means of analyzing certain points of interest. The Commission Holtslag introduced the term 'regulatory arrangement', which is considered to comprise all the formal and material aspects of regulation [Mertens, 2001-2009: 100]. The commission [Commission Holtslag, 1998: 23, 25-26] designed a checklist in which these points of interest are elaborated. This will be used as a guideline in the analysis phase to describe the Inspectorate's current regulatory arrangement. These points of interests are -in a nutshell-:

1. Relationship pattern and administrative arrangement
2. Relationship with other regulatory bodies
3. Motive(s) for regulation
4. Function/purpose of regulation
5. Object(s) of regulation
6. Method and procedure for executing regulation
7. Relevant legislation and/or policy frameworks
8. Regulation policy
9. Information relations

Research object

In this research paper inspection is considered to be regulation that is executed by a governmental agency. The research field is limited to three aspects namely the regulatory agency, the arrangement itself and the domain. The Health Care Inspectorate, more specifically, the Medical Technology program, is regarded as the regulatory agency. Within the arrangement, the focus is on patient safety in the use of medical technology in hospitals. The domain is limited to hospitals with the emphasis on their responsibilities regarding patient safety in the use of medical technology.

In this research, the long-term objective is to improve patient safety in the use of medical technology. In order to achieve this, this research tries to formulate an opinion about the Inspectorate's current regulatory arrangement on the use of medical technology in hospitals. The Inspectorate, particularly the Medical Technology Program, can therefore be considered the main object of research, since the regulatory arrangement on the use of medical technology in hospitals falls under its portfolio. The recommendations are intended for the Inspectorate, in particular the Medical Technology Program.

RESEARCH APPROACH

Analysis

The analysis phase is mainly descriptive research, which serves to provide a basic understanding of the field of research. This includes an analysis of relevant theories on regulation, a more in-depth analysis in the Inspectorate's current regulatory arrangement regarding medical technology and an analysis of the stakeholders' involvement. Theories on regulation will be analyzed by means of desk research namely literature search. Desk research on documentation, laws and regulation concerning the Inspectorate will be done to analyze the Inspectorate's current regulatory arrangement on medical technology in hospitals. For field analysis, interviews with experts in the field, namely inspectors and hospital staff will be held.

Design & Evaluation

This phase includes the setup of the assessment framework and the evaluation of the Inspectorate's current regulatory arrangement. The assessment framework will include a number of standards that will be derived from the findings of the analysis phase. By means of this assessment framework, the Inspectorate's current regulatory arrangement will be evaluated. The research ends with conclusions attempting to answer the research questions formulated at the beginning of the thesis and giving a number of recommendations to the Inspectorate regarding patient safety in the use of medical technology.

READING GUIDE

The introductory part concludes with an elaborate description of the Twenteborg case in chapter 2 with the object to explain why this case was taken as the motive for this research. Part A: Analysis starts with chapter 3, which is entirely dedicated to the Health Care Inspectorate and explains their current regulatory arrangement. Chapter 4 includes the theoretical framework, which explains the three regulation theories on which the Inspectorate's current regulatory arrangement is based. This chapter pinpoints the complexities of regulation that are found in the theory. The field analysis that includes both an actor analysis and an analysis of the interview data can be found in chapter 5. This chapter mainly provides more insight into the practical side of the complexities of regulation. Part A is concluded with chapter 6, which describes specific examples of complexities identified in the chapters 4 and 5, proving that a regulatory arrangement on the use of medical technology is quite different from any other kind of regulatory arrangement. Part B: Design and Evaluation consists of chapter 7 and 8. Chapter 7 deals with the development of the assessment framework. Chapter 8 is an evaluation of the Inspectorate's current regulatory arrangement by means of the designed assessment framework. Chapter 9 contains the final conclusions and chapter 10 contains the recommendations to improve the current regulatory arrangement in order to enhance patient safety in the use of medical technology in hospitals.

2. THE TWENTEBORG CASE: UNRESOLVED DISPUTE

The two reports about the investigations concerning the accident in Twenteborg Hospital by the Safety Board [OVV, 2008] and the Inspectorate [IGZ, 2008] respectively, show that there is a dispute on the roles and responsibilities of the actors involved. This chapter aims to elaborate on the dispute regarding safety and maintenance of a medical device. The discussion will especially focus on the motives for the actions of the main parties involved namely the hospital, the manufacturer and the Health Care Inspectorate. The chapter concludes with a short recapitulation of some contradictory issues that are key to this research.

THE ACCIDENT

On September 28th 2006 there was a serious fire in an operating theatre in Twenteborg Hospital in Almelo claiming the life of a patient. Leakage of pure oxygen at high pressure caused the fire which spread rapidly. The plastic components of the ceiling-mounted anesthesia workstation and other equipment nearby caught fire, resulting in thick smoke development. It turned out that the oxygen hose in the ceiling-mounted anesthesia workstation was damaged, so that oxygen could escape. The exact cause of the defective oxygen hose could not be ascertained, but it was established that the oxygen hose needed to be replaced years ago. As there had never been an accident like this before, this case caused quite some concern in the Dutch society and abroad [IGZ, 2008; 75].

RELEVANT LAWS & REGULATION

The laws most relevant to these investigations concerning the patient safety and maintenance of medical devices are [IGZ, 2008: 43-45; OVV, 2008: 25-31]:

- Care Institutions Quality Act (Kwaliteitswet Zorginstellingen - KWZ)
- Working Conditions Act (Arbeidsomstandighedenwet)
- Medical Devices Decree (Besluit Medische Hulpmiddelen - BMH)
- Commodities Act (Warenwet)
- Individual Health Care Professions Act (Wet op de Beroepen in de Individuele Gezondheidszorg - BIG)
- Medical Treatment Contracts Act (Wet op de Geneeskundige Behandelingsovereenkomst - WGBO)

The Care Institutions Quality Act requires hospitals to provide good care, which entails that both the provision of the health care and the environments in which this takes place are of good quality. The Working Conditions Act elaborates on this environment requiring safety not specifically focused on patients, but safety in general for everyone in the hospital including the hospital staff, the patients and the visitors.

The Medical Devices Decree, which is identical to the European Medical Device Directive \MDD 93/42/EEC, also focuses on safety, but is mostly concerned with the requirements medical devices have to comply with before they are placed on the market. The Commodities Act, a forerunner of

the Medical Devices Decree, applies to medical devices that were supplied before the year 1998 [IGZ, 2008: 43].

The Individual Health Care Professions Act and the Medical Treatment Contracts Acts require a demonstrable risk analysis and safety approach concerning treatment of a patient.

In addition to these legal products, there are also a number of non-legally binding standards and guidelines. These are mostly concerned with the quality of care processes and also the requirements medical devices have to comply with before they are placed on the market. As these non-legally binding standards and guidelines are of less relevance to this research, they will not be discussed in great detail.

DESCRIPTION OF THE SITUATION

The field of medical care is becoming more and more complex and the rapid advancement of medical technology plays a significant role in this. The complexity in the medical field not only requires more dedication of the health care system, but also more of the health care professionals and their mutual interaction in the attempt to design a safe and high quality health care system [IGZ, 2008: 45].

According to the findings of the Inspectorate [IGZ, 2008: 45] the probability of the occurrence of the Twenteborg accident was small, but it happened nonetheless because of a combination of several shortcomings in the system. Highly overdue maintenance of a potentially harmful medical device caused by negligence was just one of the many shortcomings. Table 1 provides an overview of the criticisms by the Inspectorate and the Safety Board about the Twenteborg Hospital's and the manufacturer's shortcomings regarding the safety and maintenance of the anesthesia workstation. The report of the Safety Board also criticizes the Inspectorate. A great deal of the criticisms by the Inspectorate and the Safety Board overlap, but the Inspectorate's report clearly tends to blame the hospital, while the Safety Board stresses the faults of the manufacturer and the Inspectorate.

Table 1: Overview of findings of the Inspectorate's and the Safety Board's investigations [IGZ, 2008; OVV, 2008]

	Findings of the Inspectorate	Findings of the Safety Board
Twenteborg Hospital	Poor maintenance of the anesthesia workstations	Incorrectly categorizing the anesthesia workstation
	Deployment of maintenance staff with an inadequate level of expertise and modifications made to the anesthesia workstations in an irresponsible manner	Taking over maintenance of a potentially harmful medical device without having the necessary knowledge about the status of the device and the maintenance specifications
	Inadequate internal supervision of the activities conducted by maintenance staff	Not being aware of the increasing safety risks that may result from overextended use of worn-out parts of potentially harmful medical devices
Manufacturer	Dräger failed to ensure the safety of the equipment during actual usage	Dräger did not maintain the anesthesia workstations in accordance with its own instructions and guidelines
	Between 1997 and 2003, Dräger did not maintain the anesthesia workstations in accordance with its own instructions and guidelines	The hospital was not provided with the maintenance instructions and product specifications. Neither at the time of the installation, nor at the time the contract was terminated
Health Care Inspectorate	When the maintenance contract was cancelled by the hospital in 2003, Dräger failed to inform Twenteborg Hospital of outstanding maintenance issues which were of essential importance to the safety of the equipment	
		Not adequately fulfilling the responsibility of supervision on hospitals concerning patient safety and medical devices
		Not adequately fulfilling the responsibility of supervision on manufacturers of medical devices
		Omission to pass on reports submitted by an English NCA regarding similar problems

Using the two reports, I have tried to give a description of the situation per actor, starting with the manufacturer, then the hospital and finally the Health Care Inspectorate. In each description, I highlight the censures regarding safety and maintenance of the medical device and try to explain the reasoning behind the actors' actions.

The hospital

The Care Institutions Quality Act requires hospitals to guarantee patient safety, whilst the Working Conditions Act requires general safety for everyone in the hospital. Furthermore, there are a number of non-legally binding standards requiring good quality of care processes in order to ensure patient safety. As the Twenteborg accident seriously violated a patient's safety, in fact, caused the death of a patient, the hospital's actions relevant to this accident were analyzed and assessed. The hospital was strongly criticized for several violations [IGZ, 2008: 49-50; OVV, 2008: 51], but even though one cannot justify the mistakes, one can try to understand the hospital's course of action at the time. The charges were:

- (1) poor maintenance of the anesthesia workstations
- (2) not being aware of the increasing safety risks that may result from overextended use of worn-out parts of potentially harmful medical devices,
- (3) incorrectly categorizing the anesthesia workstation,
- (4) taking over maintenance of a potentially harmful medical device without having the necessary knowledge about the status of the device and the maintenance specifications, and
- (5) acting irresponsibly by making a modification to the workstation.

During the contract period, the hospital apparently fully trusted the manufacturer's capabilities and did not interfere with their maintenance activities on the workstation. The hospital was therefore unaware of the risk classification of the workstation and the increasing risks attached to overextended use of worn-out parts. Mainly due to financial reasons, but also because of ignorance of the safety risks, the hospital chose not to replace the parts when this was recommended by the manufacturer [IGZ, 2008: 51, 21]. In 2002, after the hospital was advised to replace all entire workstations, they planned to do so on the short run, but did not. This, combined with their underestimation of the necessity of proper maintenance and also for economical reasons -presumably saving on expensive maintenance for soon-to-be-replaced devices-, led the hospital to terminate the maintenance contract with the manufacturer in 2003. The hospital categorized the ceiling-mounted anesthesia workstation as a non-medical device and therefore as a device that did not fall under the responsibility of the Medical Instrumentation Department, but under the responsibility of the Technical Service Department [OVV, 2008:49]. The reasoning behind this was twofold:

- (1) the workstation was not in direct contact with the patient; and
- (2) the workstation was considered part of the gas- and power system, which also falls under the Technical Service Department.

However, according to the European Directive (93/42), the workstation *is* a medical device. Due to this incorrect categorization by the hospital, a potentially harmful medical device was left in the hands of a department that did not have the proper knowledge to maintain it, as it turned out. Believing it was perfectly well capable of handling maintenance of the medical device themselves, the

hospitals decided to take over tasks that require specialized knowledge without consulting the manufacturer first. It later also turned out that the Technical Service Department had made a modification to the workstation in 2004 [OVV, 2008: 50]. This was not entirely without risks and may even have been the cause of the leakage in the oxygen hose [IGZ, 2008; 49]. In 2005, the hospital requested a new quotation to replace the workstations, but a final decision was postponed [OVV, 2008; 48].

The manufacturer

With regard to the maintenance service responsibilities of the manufacturer towards the hospital, both reports indicate that the manufacturer made some mistakes [IGZ, 2008: 53-55; OVV, 2008: 51]. In the first place, by failing to ensure the safety of the equipment during actual usage. Secondly, by not informing the hospital about the increasing safety risks if worn-out component parts were not replaced. Thirdly, by continuing their service contract, all the while knowing that there was an increased safety risk due to the use of worn-out parts. And fourthly, by not providing the hospital with the necessary safety and maintenance information after the service contract was terminated.

Even though these points prove serious negligent behavior on the part of the manufacturer, one can understand the reasoning behind the decisions of the manufacturer. The ceiling-mounted anesthesia workstation in question was installed by the manufacturer in 1985. According to the Inspectorate [IGZ, 2008: 43], the Commodities Act was operative at that time and still applies to this medical device. This Act requires the manufacturer to provide users with safety information obtained from vigilance and post marketing surveillance, something which the manufacturer failed to do. Among other things the manufacturer was responsible for the maintenance of this device since they had a contract for 'inspection care' from 1988 until 2003 [OVV, 2008: 47]. 'Inspection care' is regarded as a minor form of maintenance and entails periodic maintenance once a year, not including the costs of replacement of parts. According to the manufacturer's maintenance manual, all cables and flexible hoses must be replaced every twelve years. So in this particular case the cables and hoses had to be replaced in 1997 [IGZ, 2008: 49] and the manufacturer failed to do this. However, the manufacturer claims that the hospitals refused replacement of the hoses for financial reasons. Even though the hospital did not heed the manufacturer's advice, the maintenance contract was continued. It is clear now, and perhaps even understandable, that the manufacturer put its own interests first and opted for a continuation of the maintenance contract instead of risking losing an important client. In 2002, which was also the last year that periodic maintenance was carried out by the manufacturer, the manufacturer notified the hospital that the device would be 'out of service', in other words, availability of parts could no longer be guaranteed and the hospital was advised to replace all ceiling-mounted anesthesia workstations. However, the hospital disregarded the advice and the maintenance contract was -abruptly and without any explanation- terminated by the hospital in 2003. Apart from the fact that it is not common practice of the manufacturer to provide the clients with the user's manual and product specification, the abrupt termination of the contract did not give the manufacturer the opportunity to pass on the necessary safety and maintenance information to the hospital. Given the circumstances, that is to say the sudden unilateral termination of the service contract, one can understand why the manufacturer was not eager to provide the hospitals with further safety and maintenance information. In 2005, the manufacturer once again made an offer for

replacement of the workstations, in response to a request from the hospital, but in the end the hospital still decided to postpone the replacement.

The Health Care Inspectorate

The Inspectorate is responsible for supervision of compliance with the Care Institutions Quality Act and the Medical Devices Decree. The Medical Devices Decree requires manufacturers to report (near) incidents involving medical devices to the Inspectorate. In addition, there is a non-legally binding European standard system¹ requiring that incidents are reported to a National Competent Authority – NCA, who is responsible for spreading warnings about these incidents, depending on their severity, to NCA's of other member states. In the Netherlands the Inspectorate is the NCA. With regard to the Inspectorate's responsibilities, the Safety Board [OVV. 2008; 61] has identified three main tasks of the Inspectorate that are relevant to the accident, namely:

- (1) supervision on hospitals concerning patient safety and medical devices
- (2) supervision on manufacturers of medical devices; and
- (3) pay heed to reports submitted by manufacturers and other NCA's

According to the Safety Board [OVV. 2008; 65], there is a lack of clarity regarding these tasks, insofar that:

- (1) there is no external supervisory body to supervise the quality and safety of medical devices in the postproduction phase; and
- (2) in respect of NCA responsibility, there are no fixed criteria to determine in what cases warnings should be spread.

The Inspectorate performs inspection by means of three kinds of instruments namely:

- (1) phased supervision
- (2) thematic supervision; and
- (3) incident-based supervision.

Phased and thematic supervision are often based on the priorities that the Inspectorate has set in her long-term policy plans. Incident-based supervision is characterized as reactive supervision, as this kind of supervision only takes place in the event of incidents of a structural or on-going nature or in the event of serious calamities of which the Twenteborg accident is an example. All forms of supervision are risk-based, which enables the Inspectorate to set priorities and reduce the heavy inspection workload.

Prior to the accident, the Inspectorate was not overly concerned about Twenteborg Hospital. The last relevant inspections, prior to the accident were the thematic inspection in 2002, entitled: *Kwaliteitsborging van medische apparatuur in ziekenhuizen: verbeteringen noodzakelijk (Quality assurance of medical devices in hospitals: needing improvement)* and its follow-up in 2005: *Kwaliteitsborging van medische apparatuur in ziekenhuizen: nog steeds onderschat (Quality assurance of medical devices in hospitals; still underestimated)*. The findings of these investigations concerned all hospitals in the Netherlands and were focused on the

¹ Guidelines on a medical devices vigilance system (MEDDEV 2.12-1 – rev. 4,5)

introduction, management and use of medical devices in hospitals. The Inspectorate planned to continue with this activity in 2007 checking if and how quality assurance of medical devices is really embedded in the hospitals. The results of these investigations were published in *The State of Health Care Report of 2008*.

After the accident, the Inspectorate started an investigation (by means of incident-based supervision) and found some serious flaws in the hospital's quality and safety systems. It was also discovered that the Administrative Board showed some shortcomings. Based on these findings, the Inspectorate temporarily intensified supervision on Twenteborg Hospital. Every step to be taken during the restart of operations had to be reported to the Inspectorate first. After major improvements, the Inspectorate decided that the intensified supervision was no longer necessary.

In response to the Safety Board's report, the Inspector General (2008) explained that within the hospital, the Supervisory Board is responsible for the (internal) supervision on the Administrative Board. The Inspectorate operates in system-level -according to the Care Institutions Quality Act- and is therefore only responsible for supervision on internal supervision, also known as meta-regulation². The Inspectorate's supervision is mainly based on trust and intervention takes place only when there are indications that the internal supervision is not functioning correctly. This begs the question whether it is practicable and/or desirable to conduct structural supervision on operational level in all hospitals if there are no grounds for doing so. Since the Inspectorate has to cope with a shortage of manpower and inspection visits are generally experienced as extra work pressure by the hospitals, one should seriously consider how or in what cases structural inspection on the operational level should be carried out³.

Supervision on manufacturers of medical devices is done either directly by the Inspectorate or indirectly through a Notified Body - NB. The Medical Devices Decree safeguards the quality and safety of medical devices until they are placed on the market. Apart from Post Marketing Surveillance – PMS, which is a legal obligation for manufacturers to review experience gained in the postproduction phase for continuous product improvement, there are no other legally binding obligations that contribute to safeguarding the quality and safety of medical device in the post-production phase. Once a device has been delivered to the hospital, the hospital is considered the owner and therefore it is the hospital that is responsible for its use, maintenance and safety. When a hospital outsources maintenance of its medical devices to an external organization, there is no supervisory body to monitor this. Neither is there a supervisory body to monitor internal maintenance. The Inspectorate considers this a duty of the hospital, since it is the hospital that has the final responsibility for the use, maintenance and safety of its medical devices.

In the Netherlands, the Inspectorate is the NCA and therefore one of its -non-legally binding- duties is to report incidents to and by other NCA's. In its report on the Twenteborg case, the Safety Board points out that the Inspectorate failed to inform the hospitals in the Netherlands about the non-official reports in 2003 and 2004 by the English NCA on similar incidents [OVV, 2008: 63, 64]. As it turned out, the Inspectorate has processed these reports according to standard procedure, that is to

² The term meta-regulation refers to what is known in Dutch as 'meta-toezicht', 'tweede lijns toezicht' or 'toezicht op toezicht'.

³ In reference to many of Inspectorate's documentation [BKZ, 2005; Bureau Inspectieraad, 2009] it is clarified that structural supervision on operational level is impracticable. These also state the drive towards reducing the regulation burden.

say two inspectors independent of each other assessed these reports, and it was decided that it was not necessary to warn hospitals. However, there are no fixed criteria, on which such decisions, that is to say whether or not the hospitals should be warned. Still, the Inspectorate persists that this was the right decision, as the reports in question did not regard the same problems [IGZ, 2008: 8].

RECAPITULATION

An analysis of the motives behind the actions of the parties involved proves that it is difficult to point out the ‘culprit’ in the Twenteborg accident. In light of the upcoming trend of developing a blame-free culture in the medical field, it also seems unreasonable to find out who is to blame. One should rather learn a lesson from this horrible accident. Each party had responsibilities, in the first place towards the patient, but also towards each other and towards society, but for some reason they failed to fulfill them. The aim of this research is to look into the issues emanating from the investigation of the Twenteborg accident and lie outside the legal framework, as these issues caused quite some confusion amongst the actors.

One contradictory issue that was brought up in this case and that lies outside the legal framework, but is key to this research, is the responsibility to supervise the postproduction phase, particularly the maintenance of medical devices. The trend nowadays in the medical world is to describe positions in terms of responsibilities, competencies and duties, in order to establish more clarity and transparency in the line of work. However, the disadvantage of this system is that it narrows down the area of responsibilities, so that a lot of responsibilities are “up in the air” and nobody can be held responsible. Meurs⁴ identifies this as an administrative paradox. Something similar occurred in the Twenteborg case. The report of the Safety Board explicitly states that the maintenance by the manufacturer was inadequate, but none of the parties assumed the responsibility for monitoring this. The hospital claimed they had confidence in the manufacturer’s maintenance and simply assumed that everything was okay. The Inspectorate denied any responsibility for the monitoring of maintenance on medical devices and criticized the hospital for simply assuming that everything was in order and not even bothering to check. So the manufacturer was the only one who was aware of the inadequate maintenance status of the medical device, while at the same time he would benefit from continuation of the maintenance contract. In conclusion, nobody supervised maintenance and nobody shouldered the responsibility. This leads us to the following remarkable issue, which is described in the next paragraph.

At the moment there is no direct (external) supervision on the quality and safety of a medical device in the postproduction phase. Neither is there supervision on maintenance carried out internally and on outsourced maintenance. In the Twenteborg case, the Inspectorate was of the opinion that it was a task of the hospital and stressed that maintenance on medical equipment is an internal affair. This raises the question: *Should the hospital be blamed for relying on the contracted maintenance company?* Another thing that should be kept in mind is that a hospital often chooses to outsource maintenance because it does not have qualified personnel to do the job. It is therefore quite logical to assume that if one is not qualified to perform maintenance, one cannot check whether outsourced maintenance was done

⁴ Prof. Dr. Pauline Meurs described what she calls an ‘administrative paradox’ during her lecture on June 10th, 2010 entitled ‘Meer transparantie is niet genoeg’. This was part of a cycle of five readings ‘Toezicht en Vertrouwen’, organized by the Health Care Inspectorate.

correctly. So even though it is in the interest of the hospital that maintenance of the medical equipment is monitored, it is difficult to hold it responsible, since it simple does not have the staff to do this. In the Twenteborg case things became even more complicated when the hospital terminated the maintenance contract and decided to assume the responsibility for maintenance. It is not surprising that the cry for better-organized regulation grows louder. This leaves us with the crux of the matter: How can the regulation of medical devices in hospitals take form, taking into account that the Inspectorate should be able to get an overview of the situation and is it do-able? This leaves us with the crux of the matter: What is the most feasible way/system to regulate the use of medical technology in hospitals, which allows/enables the Inspectorate to overview the situation?

The Twenteborg case was taken as the motive for this research, because it clearly reflects the complexities surrounding the regulation of the use of medical technology in hospitals. One thing that clearly came to the fore in this particular case was the triangle of the main actors with a shared, interconnected responsibility (see figure 1), but an unequal division of liability when things go wrong.

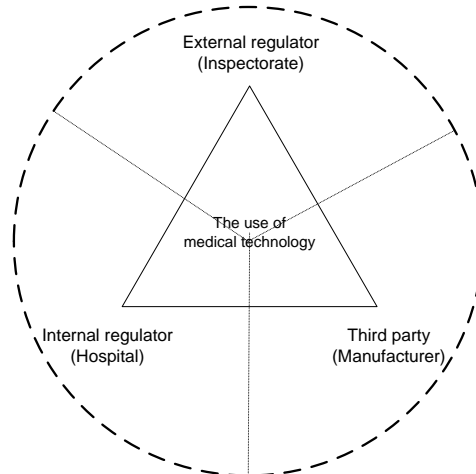


Figure 1: Explanatory model regarding the shared, interconnected responsibility in the use of medical technology in hospitals

The difficulty/problem of three different actors having the joint responsibility to provide good quality care with the focus on patient safety may lie in the following:

- Each of the three actors is partly responsible; however, there are no clear boundaries as to where the responsibility of one actor ends and where the responsibility of the other begins.
- Each actor has its own individual interests at stake, which may go against the other actors' interests or hamper the other actors in their efforts to fulfill their share of the collective responsibility.
- All three actors master a different field of knowledge; in order to be able to fulfill their share of the collective responsibility, they need assistance from the other actors. For example, in order for the hospital to provide and maintain good quality of care, it sometimes has to rely on the technical expertise of manufacturers when it comes to maintenance of medical devices or training in the use of medical devices.

The above gave rise to the following questions:

- How can a regulatory arrangement deal with this complexity?
- How is regulation on the use of medical technology currently arranged?
- Which actors are involved?
- What does the theory say about regulatory arrangements and other complexities that are involved?

Taking these questions as the starting point of this research, the tone was set for the analysis phase of this research. The analysis phase comprises three main subjects, namely the current role of the Inspectorate, theories on regulation, and a field analysis in which the involvement of the main actors is analyzed.

PART A: ANALYSIS

3. THE HEALTH CARE INSPECTORATE'S REGULATORY ARRANGEMENT

This entire chapter is dedicated to the Health Care Inspectorate. First it will briefly describe the Inspectorate's duties and mission. Then, all relevant aspects concerning the inspection arrangement on medical technology in hospitals will be discussed, starting with a general description of the government-wide inspection and then gradually zooming into the inspection arrangement on the use of medical technology in hospitals. The chapter will conclude with a recapitulation of the Inspectorate's current inspection arrangement on medical technology in hospitals.

DUTIES AND MISSION OF THE HEALTH CARE INSPECTORATE

The Health Care Inspectorate is a unit of the Public Health Supervisory Service and falls under the Ministry of Welfare, Public Health and Sports. Based on the Public Health Act (Gezondheidswet) the Inspectorate investigates the state of public health, monitors compliance with the laws and regulations, detects violations and gives advice and information, asked as well as unasked for. The Inspectorate is responsible for the supervision on compliance with twenty-five laws, which differ in type and extent within the health care sector [IGZ, 2008c]. The General Administrative Act (Algemene Wet Bestuursrecht - AWB) generally regulates the authorities of the Inspectorate [Mul, 2010].

The mission of the Inspectorate is to promote public health by effectively maintaining the quality of care, prevention and medical products. In order to do so, the Inspectorate makes use of advisory, persuasive and compulsory measures to impose on care providers, if necessary. The Inspectorate also advises the Council of Ministers, particularly the minister of Welfare, Public Health and Sports. [IGZ, 2008c].

In the Inspectorate's long-term policy plan 2008-2011, the three topics: Quality of Care with the Focus on Patient Safety, and Innovation in Enforcement Methods and Research on Inspectorate's Performance in Terms of Effectiveness and Efficiency, get special attention. These topics are more or less related to this research about the regulatory arrangement on patient safety in the use of medical technology in hospitals. The subject of this research is therefore not only current, but also relevant, particularly for the Inspectorate.

TERMINOLOGY: SUPERVISION⁵ AND ENFORCEMENT

The terms supervision (toezicht) and enforcement (handhaving) are often mixed up. These terms can be differentiated by the severity of applicable measures. The Delineating Vision on Inspection 2005 (Kaderstellende Visie op Toezicht 2005 - KvoT 2005) defines supervision and enforcement as follows [BZK, 2005: 18].

⁵ The Inspectorate uses the term supervision for the Dutch word 'toezicht'.

The definition of supervision is: to collect information about whether an action or matter complies with the requirements, assess this information and act on it, if necessary.

When an inspector is authorized to take repressive measures, in other words, when he has the power to take compulsory measures and/or restrict someone's freedom, this is called "enforcement". Administrative law (bestuursrechtelijke handhaving) aimed at establishing compliance with the law and restoring order corresponds with the term "supervision". Criminal prosecution (strafrechtelijke handhaving), however, aims to defend and suppress, and then the term "enforcement" is used. This is essentially the difference between the two terms.

GOVERNMENT-WIDE INSPECTION

Renewal Inspection (Vernieuwing Toezicht - VT) is a government-wide program that generally aims to reduce the inspection burden by twenty-five percent and to promote/enhance the performance of all government Inspectorates in terms of effectiveness and efficiency. The program was presented in 2008 and will last until 2011. A more specific aim of this program is to bring about a relationship with its inspectees -i.e. the objects that are being inspected- based on trust/confidence. If the Inspectorate has ascertained that the inspectee has a good quality system and shows acquiescent behavior, the inspectee may gain the Inspectorate's "trust" and receive fewer inspection visits. This program falls under the Health Care Inspectorate's portfolio.

In light of this program, a modern inspection arrangement was developed as a renewed version of the classic vertical external inspection. This revised inspection arrangement is based on the renewed principles of KVoT 2005 and the objective is to reduce the inspection burden by twenty-five percent.

Renewed principles of KVoT 2005

The renewed version of inspection is based on six principles, namely selectiveness, decisiveness, cooperativeness, independence, transparency and professionalism. Each of these principles is based on an underlying objective of inspection and worked out in starting points for compliance and execution inspections [BZK, 2005: 45-55]. The selective principle refers to inspection efficiency in two aspects. Firstly, the extent to which the government bears the responsibility for regulation; and secondly, the inspection arrangement based on risk assessment and cost-benefit analyses. The decisive principle refers more to the effectiveness of inspection in terms of intervention activities. These can be either supervision or enforcement activities, depending on the severity of the violation. The cooperative principle focuses on burden reduction. By means of cooperation between inspectorates, both the inspectorate and the inspectee organization can get burden reduction. Cooperation between inspectorates can be established in various ways, ranging from information exchange to joint inspection visits. Independence guarantees an honest and acceptable judgment. Given that inspectorates constantly have to operate in a field of tension, caused by pressure from the different parties involved, such as society and politics, it is important that the inspectorate's judgment is not influenced by any of these parties. The transparency principle refers mainly to the accountability to the public. Society is becoming more demanding towards inspectorates in terms of

public accountability. Transparency focuses on utility, necessity, guarantee for independence, choices, findings and results of inspection. Professionalism aims at developing skilled and professional inspection adapted to the environment. In the development of skills, the education and attitude of the individual inspector, the policy and vision of the inspectorates, and the type of occupational group are factored in.

Three types of inspection are distinguished, namely:

- (1) external regulation (nalevingstoezicht),
- (2) government regulation (uitvoeringstoezicht), and
- (3) intergovernmental regulation (interbestuurlijk toezicht) [BZK, 2005: 25-31].

'Intergovernmental regulation is described as the total of processes that take place within the scope of legal matters between the central government, provinces, local authorities, Joint Regulations Act (Wet Gemeenschappelijke Regelingen - WGR) regions and the water boards about the assessment of task management of the lower by the higher governments [BZK, 2005: 31].' This type of inspection lies outside the scope of this research and will therefore not be discussed.

External regulation

External regulation aims at promoting acquiescent behavior and makes sure that activities, products and services meet the established requirements. Parliament, the minister and society are also informed about the effects of policies by means of external regulation, which enables them to determine whether and how policies need to be adjusted or renewed.

The government is responsible for the development and protection of the conditions in which society and market can perform best. The government establishes both the playing field and the rules of the game, and civilians and companies are made to comply with the law by means of external governance. External regulation can involve both regulatory and enforcement activities.

External regulation that is aimed at the protection and enhancement of market operations is called market regulation and is practiced by market inspectors. Market regulation lies outside the scope of this research. However, the introduction of (medical) products on the market will be briefly discussed at a later stage.

Government regulation

This type of regulation is aimed at the execution of public tasks by independent organizations. These independent organizations differ in form, size and tasks and are responsible for the expenditure of a rather large proportion of public funds. To a certain extent the minister is held responsible for the execution of the public tasks and therefore he should at least inspect the legitimate spending of financial resources that are available to these organizations. This often involves inspection of their performance and management. The objects of inspection, the so-called inspectees, can be one specific organization or a small or large group of organizations that do the same type of work.

The extent of the minister's responsibilities and authorities concerning these public tasks are described in the law. The responsibilities can be distinguished in:

1. the responsibility for legitimate and appropriate (receipt and) spending of financial resources; the minister has the authority to control finances by means of checking and steering, and
2. the responsibility for the quality of job execution and the appointment and dismissal of the administrative board. The extent to which the minister is held responsible can vary in the level of detail in the quality of task execution.

LAWS AND REGULATIONS REGARDING MEDICAL TECHNOLOGY IN HOSPITALS

As already mentioned, the Health Care Inspectorate is responsible for the compliance with twenty-five laws concerning health care. A few of these twenty-five laws lie within the scope of this research namely the Care Institutions Quality Act and the Medical Devices Act with its corresponding Medical Devices Decree. There is a striking difference between these laws: whereas the Care Institutions Quality Act has an open formulation, the Medical Devices Decree is formulated very specifically and is not ambiguous. This difference will be discussed in the following paragraphs.

Besides these laws, there are a number of other laws that do not fall under the Inspectorate's province, but are in some way related to patient safety in the use of medical technology in hospitals. This can be illustrated by the legal assessment framework that was used for the Twenteborg case. The Working Conditions Act and the Medical Treatment Contracts Act have also been included in the assessment framework, as they were also relevant to the violations concerning quality of care and patient safety.

The Care Institutions Quality Act deals with the realization of the quality of care by care providers, including hospitals. This law makes use of ambiguous terms such as quality of care or efficient, good care and leaves the interpretation of these terms to the care providers, considering their expertise and experience. Care providers are responsible for the definition of these terms; this is done by developing so-called 'field standards' that are used as the assessment framework during inspection (normtoezicht). In general, field standards are not mandatory regulations; however, they have the status of weighty advice.

The Medical Devices Act and the Medical Devices Decree are mainly about the procedure that manufacturers have to go through before introducing their product on the market. The Medical Devices Decree is a very specific decree that clearly specifies the terms and procedures used, e.g. the CE certification procedure for medical devices of each risk class is described unambiguously. When legislation is formulated in detail, the inspection is also quite clear. This kind of inspection is called rule-based supervision (regeltoezicht).

OTHER RELEVANT REGULATORY BODIES

The General Inspectorate of the Netherlands (Inspectieraad) is a unit of all governmental inspectorates together. The General Inspectorate of the Netherlands tries to establish cooperation among all the governmental inspectorates. This General Inspectorate is also the initiator of the government-wide program 'Renewal Inspection', which is a good illustration of what the General

Inspectorate of the Netherlands tries to establish, namely collective efforts to achieve collective objectives.

The national coordination of inspections in hospitals is a unit of five governmental inspectorates, who are all responsible for ensuring compliance with the relevant legislation concerning hospitals. These five inspectorates are the Health Care Inspectorate, the Labour Inspectorate (Arbeidsinspectie/AI), Housing, Spatial Planning and the Environment Inspectorate - VROM Inspectorate (Inspectie Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer), the Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit - VWA) and the Transport and Water Management Inspectorate (Inspectie Verkeer en Waterstaat - IVW). As part of the government's pursuit of self-improvement in terms of effectiveness and efficiency and the Renewal Inspection program, these inspectorates started to work together five years ago and since then this relationship has only grown closer. The collective efforts of this coordination are found in a number of joint projects.

The Notified Body -NB- is also considered a regulatory body. KEMA has been appointed as the Notified Body within the Netherlands. The NB falls under the direct supervision of a competent authority -the Inspectorate- within the Netherlands. The NB is responsible for verifying that a medical device complies with all statutory decrees of the Medical Devices Decree and it has the authority to grant a CE certification when a product meets all the requirements. Inspection on the execution of PMS also falls under the responsibility of the NB. The relation that the Inspectorate has with the NB differs from the relation the Inspectorate has with the bodies mentioned before, in that the Inspectorate is considered a higher regulatory body, which has the responsibility of supervising the NB.

There are also a number of relevant external certification and accreditation institutes such as the Dutch Institute for Accreditation in Health Care (Nederlands Instituut voor Accreditatie van Zorginstellingen - NIAZ). Even though the Inspectorate takes such accreditations into account when assessing an inspectee, the Inspectorate has no direct relationship with these organizations.

INSPECTION INSTRUMENTS OF THE INSPECTORATE

The IGZ has several forms of supervision that serve as instruments for effective and transparent inspection. These are laid down in official governmental guidelines [IGZ, 2008c; IGZ, 2008d; Mul, 2007]. The most relevant instruments for inspection on patient safety in the use of medical technology in hospitals are the so-called phased supervision, thematic supervision and incident-based supervision (see figure 1). These forms of supervision are all risk-based and executed in phases namely:

- (1) collection of data,
- (2) intervention, and
- (3) imposing (compulsory) measures.

Each phase serves as a filter for the next in order to determine priorities. The outcome of one form of supervision can lead to another form of supervision, linking these different instruments to each other. The main differences between these instruments lie within their function and the way the data are collected.

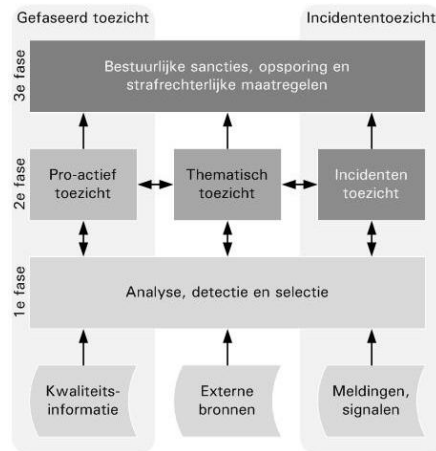


Figure 2: Inspection instruments: phased, thematic, incident-based supervision

Phased supervision

To obtain a generic view on the guarantees for the quality of good care by care providers, the Inspectorate makes use of phased supervision (see figure 2). An external organization, called the Visible Care Agency (Bureau Zichtbare Zorg) is responsible for the development of health care related quality indicators. The task of the Inspectorate starts with the analysis of (structured) data in the form of these indicators about risks in health care, which is the first phase. In the second phase, the Inspectorate instigates several investigations and determines applicable measures based on the outcome of the investigations. The measures are then imposed on the inspectee in the third phase. This kind of supervision is called proactive supervision, sometimes also characterized as interactive supervision [Helderman & Honingh, 2009].



Figure 3: Phased supervision

Thematic supervision

To obtain nation-wide insight into the effects of government policy or specific difficulties in health care, the Inspectorate uses the instrument of thematic supervision. The analysis in the first phase in

this case is based on unstructured data mainly from external resources. The fact that thematic supervision aims to provide nation-wide insight into a specific matter and is based on analysis of unstructured data from external resources implies that there is no structural thematic supervision on one specific matter, e.g. medical technology. However, there should be sufficient indications from signals, reports, political agendas etc., to decide whether thematic supervision on a specific matter is necessary. As this type of supervision generally aims to investigate unknown risks, it is also classified as proactive supervision.

Incident-based supervision

Incident-based supervision takes place in the event of a serious incident, calamity, or an incident of a structural or on-going nature, where investigation of the causes and consequences for the quality of care is considered necessary. Incident-based supervision collects and analyses data on incident reports and/or signals given by manufacturers, civilians, health care institutions and competent authorities of member states. The reports and signals are generally received by the Inspectorate's front office and dealt with by the back office. Each report or signal requires specific handling, depending on its nature and the type of informant. For the sake of effectiveness and efficiency, not every report is investigated thoroughly. In the first instance, the health care providers concerned execute these investigations. Investigation by the Inspectorate is only instigated [IGZ, website, 2010]:

- *'in the case of an extremely serious situation with exceptionally high risks;*
- *if the Inspectorate believes that its own investigation will improve quality within a particular health care sector at one go;*
- *if the health care provider concerned is considered incapable of conducting a satisfactory internal investigation;*
- *if the analysis offered by the health care provider does not meet the required standards;*
- *in cases of significant public interest.'*

THE CYCLE OF ENFORCEMENT

By means of what is called 'the cycle of enforcement' (handhavingscyclus) (displayed in figure A, appendix B), the Inspectorate determines measures that will promote or even enforce the desired behavior of the inspectees. The cycle starts at a point selected by the Inspectorate and prioritizes a number of subjects to investigate in the field of care, public health care and medical products. This is done on the basis of importance, risk, the extent to which the Inspectorate is able to inspect and intervene and whether or not the Inspectorate can do the job. Then, active, interactive and/or reactive data collection takes place, which is used for a general risk-analysis on good care. By means of the different interventions -phased, thematic and incident-based- the Inspectorate monitors these risks. Finally, the Inspectorate makes an evaluation based on the outcome of the interventions and determines what measures need to be taken. By means of the proportionality model and based on the seriousness of the situation and the probability of recurrence, the Inspectorate determines the type of measure(s) to be taken. The enforcement pyramid (scheme A, appendix B) displays the different measures; it starts with persuasive measures at the bottom and gradually changes to compulsory measures at the top. [IGZ, 2008c]

On the basis of the proportionality model (table A, appendix B), the cycle of enforcement is passed through several times during the inspection process. If during the process, the inspectees fail to meet the Inspectorate's requirements again and again, the measures grow more severe.

Additionally, the type of measure depends on the impact of the situation (table B, appendix B) and the probability of recurrence (table C, appendix B). The impact of the situation is determined by the type of damage in relation to the magnitude. The probability of recurrence is determined on the basis of both the health care provider's attitude and the organization providing the health care services or the products, with the focus on quality and safety. Finally, these two aspects are weighed against each other, in order to determine what measure should be taken.

INSPECTION ON MEDICAL TECHNOLOGY

The Inspectorate is organized in ten different programs and each program lies within specific domains, namely:

- (1) curative health care,
- (2) nursing and chronic care,
- (3) public health care, and
- (4) drugs and medical technology.

The Program Medical Technology falls under the drugs and medical technology domain. Within this program, *'the Inspectorate ensures that the manufacturers and suppliers of medical devices observe all relevant legislation, and takes action in the event of a breach of the regulations. The Inspectorate evaluates all incoming reports about malfunctions or quality issues relating to medical devices. It also oversees the activities of KEMA, the 'notified body' for the Netherlands [IGZ, 2010: Medical Devices].'* Moreover, inspectors with medical technological expertise are spread over the different programs and therefore different in function. In this way, the Inspectorate tries to include inspection on medical technology in every program. Medical technology staff members can have either an executive or an advisory role when they participate in regional and national inspection activities.

Supervision on production and trade of medical technology

Inspection on production and trade of medical technology and the quality of medical devices falls under the Medical Technology Program and can be characterized as 'external governance'.

Manufacturers of Risk Class-I medical devices, custom-made medical devices and certain in-vitro diagnostic - IVD medical devices fall under the direct supervision of the Inspectorate. Inspection of these manufacturers takes place by means of phased supervision. However, phased supervision leaves much to be desired these days, due to the Inspectorate's inability to perform inspection of the entire quality circle of medical devices, including PMS. Shortage of manpower and lack of time also play an important role [de Bruijn, 2009: 10-11].

In the light of vigilance, the manufacturer is obliged to report all incidents and near-incidents during the entire product life cycle, regardless of the outcomes in terms of danger/harm. This includes PMS, whereby manufacturers have to start a systemic procedure to review experience gained from devices

in the post-production phase and to implement means to apply necessary corrective actions, in order to achieve continuous product improvement. The execution of PMS, however, still leaves much to be desired, in spite of the fact that this is a legal obligation. The short life cycle of medical devices complicates the proper execution of PMS, because it is difficult to keep up with the constant supply of new product versions that enter the market at a rapid pace [de Bruijn, 2009: 7].

Manufacturers of higher risk class products fall under the responsibility of an NB. Nowadays the certification procedure by an NB is becoming more and more difficult, due to the increasing complexity of medical technology. The procedures by different NB's also differ in quality level, which leaves the manufacturers with the option to choose a less critical NB [de Bruijn, 2009: 7]. The NB's within the Netherlands are annually inspected by the Inspectorate.

Supervision on the use of medical technology

At the moment there is no structural inspection specifically aimed at the use of medical technology. However, the intention is to establish this by means of phased supervision [de Bruijn, 2009: 11]. Unfortunately, the Inspectorate has not reached this stage yet, as the quality indicators for this field have still not been developed.

Thematic supervision on medical technology takes place on a regular basis. An example of thematic supervision that falls within the scope of this research is the one that took place in 2002 on the quality assurance of medical devices in hospitals and its follow-up in 2005. The Inspectorate noticed some serious shortcomings in Dutch hospitals in 2002 and recommended a number of improvement measures [IGZ, 2002]. In 2005, the Inspectorate took the matter in hand again and carried out a follow-up investigation, which revealed that hospitals still underestimate the importance of a quality assurance system for medical devices. The Inspectorate then took corrective measures by demanding a plan of action from all the hospitals who had not adequately implemented the improvement measures [IGZ, 2005]. A follow-up inspection took place in 2007 [OVV, 2008: 63]. The results of this follow-up inspection were included in the 2008 State of Health Care Report.

At present, inspection of the use of medical technology is principally carried out on the basis of information, on reports and signals received (incident-based supervision). As explained earlier, this kind of supervision was initially characterized as reactive supervision. At the moment the Inspectorate is only able to act on incoming reports and signals. This is due to a number of reasons such as inadequate reporting applications and lack of manpower and time. Inadequate reporting also cause big delays in the response time [de Bruijn, 2009: 10-11].

Supervision on hospitals falls under so-called 'government governance' and the Inspectorate has no control over the finances. Hospitals have the public task to provide good quality of care and to some extent the minister is held responsible for the execution of this task. As already mentioned, the extent to which the minister is held responsible can differ in the level of detail in the quality of the task execution.

RECAPITULATION

In the previous section, I have tried to describe the Inspectorate's current inspection arrangement, starting with a general description of government-wide inspection and then gradually zooming into the inspection arrangement on medical technology. In this description I have addressed each of Holtslag's characteristics for a regulatory arrangement. However, the description is mainly based on data obtained from the Inspectorate's policy documentation and therefore does not necessarily cover the implementation of the arrangement in practice. In any case, some interesting conclusions can be drawn from this information.

Governmental inspection instructions are based on the six principles of KVoT 2005 and leave no room for ambiguous interpretations of inspection. The inspection is further distinguished into three types of inspection, of which government governance is the most relevant to this research. The Health Care Inspectorate has adjusted its own regulatory arrangement to the government-wide concept with the emphasis on the six principles and specified it according to the field of application. The regulatory arrangement was shaped by the cycle of enforcement, in which different inspection instruments are used. A careful analysis shows that the KVoT 2005 principles of selectivity, decisiveness and transparency are fundamental to this. The Inspectorate fulfills the principle of cooperativeness by participating in both the General Inspectorate of the Netherlands and the National Coordination of Inspections in Hospitals. Even though the other principles of independence and professionalism are equally important, these are difficult to find in the arrangement.

A study of the relevant legislation regarding medical technology that falls within the Inspectorate's portfolio, namely the Medical Devices Decree and the Care Institutions Quality Act, and its regulation systems reveals that there is a substantial difference. The Medical Devices Decree is aimed at the production and trade of medical devices and the NB's are closely involved. This Decree can be considered the basis of regulating manufacturing practices. Although the focus of this research is not on the production and trade of medical devices, this Medical Devices Decree is relevant. As seen in the Twenteborg case, involvement of the manufacturer in the use of medical technology is inevitable and more often than not, even highly necessary. With the advancement of medical technology, manufacturers are gradually becoming the (sole) experts, in the sense that they are the only ones who know what is inside the box of medical technology and how to handle the contents of this box. Consequently, usage and maintenance of medical technology should be given the attention they deserve.

The Care Institutions Quality Act holds hospitals responsible for the provision of good quality of care. Considering that the hospitals are directly involved in the care process and that they are the ones who are directly affected when something goes wrong in the care process, it seems both logical and justified to give the executive responsibilities to the hospitals. However, in the context of the use of medical technology, factual circumstances indicate that while medical technology is inextricably connected to the care processes of hospitals, users -and therefore hospitals- increasingly alienate from medical technology, in the sense that their technical expertise cannot keep up with the continuous new developments in medical technology. In view of this, the question is now: *Is it reasonable to leave the full responsibility for the provision of good quality of care in the hands of the hospitals only, even*

when it has turned out that their awareness regarding the risks that the use of medical technology entail is insufficient, which is mainly due to their limited technical expertise?

The figure below illustrates how medical devices are currently regulated by the Inspectorate. Ex-ante regulation regulates manufacturers and sets requirements for medical devices before they enter the market, up to the point that they are actually put into service, while ex-post regulation regulates care institutions e.g. hospitals, and focuses on the actual use of medical devices. And while there is a clear difference between ex-ante and ex-post regulation, it is difficult to hold on to this difference in practice. A clear example is that Post Marketing Surveillance is a requirement of the Medical Devices Decree and therefore considered as ex-ante regulation. However, this requirement can only be fulfilled after the device is put into service; users' experiences are the input for PMS.

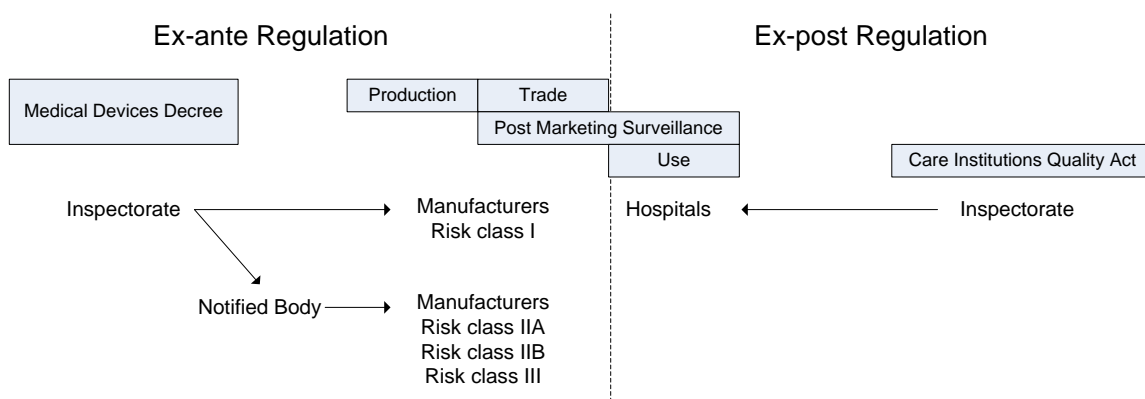


Figure 4: Overview of ex-ante and ex-post regulation on medical technology

Finally, we shall discuss the regulatory arrangement on the use of medical technology. It is obvious that patient safety is high on the agenda of the Inspectorate. The long-range policy plan 2008-2011, explicitly states that the quality of care, patient safety in particular, has high priority. Also the State of Public Health Care reports of the past few years (2004, 2008 and 2009) are all dedicated to patient safety, and the 2004 and 2008 issues were particularly focused on medical technology. However, there is no structural data collection about the use of medical technology in hospitals. Currently, supervision on the use of medical technology in hospitals now mainly takes place by means of thematic supervision and incident-based supervision, which are largely based on unstructured information. The Safety Board clearly recommends in its report [OVV, 2008] that a regulatory arrangement regarding the use of medical technology in hospitals needs to be established, but it is still unclear as to how this should take form. The Inspectorate wants to do this by means of phased supervision with quality indicators, since the kind of information obtained and the frequency are more structural in character. The Inspectorate also wants to improve incident-based supervision by means of a more systematic approach of the process of handling reports [IGZ, 2009a]. At the moment incident-based supervision is only equipped to serve as reactive supervision, while it could take on a more proactive approach if the reports and signals were also to be used to detect trends and make systematic analyses at a higher level. Whether this is sufficient or even appropriate for the regulatory arrangement on the use of medical technology is still the question.

Both the Inspectorate's inspection instruments and the cycle of enforcement have a strong theoretical basis. The design of Inspectorate's instruments are based on system-based regulation [Honigh & Helderma, 2009: 21], while the cycle of enforcement is based on Sparrow's risk-based, thus selective regulation and Ayres & Braithwaite's responsive regulation [Robben, 2010: 7]. The following chapter will deal more in-depth with these regulation theories, in order to get a better understanding of their principles and the extent to which they are embedded in the Inspectorate's current regulatory arrangement.

4. THEORIES ON REGULATION⁶

This chapter will elaborate on a number of theories on regulation that were explored in relevant literature. These theories will be used as the theoretical framework for the Inspectorate's current inspection arrangement on patient safety in the use of medical technology in hospitals. The first section will deal with the question: 'What is regulation?' The following sections will elaborate on system-based regulation, risk-based regulation and responsive regulation respectively. The final section will provide a recapitulation of the theory.

The aim of this chapter is to provide a basic understanding of regulation and what aspects to take into consideration when establishing or evaluating a regulatory arrangement. To shift the focus to an inspection arrangement, I have added some constituent characteristics of inspectorates. This is not only to clarify what is generally expected of inspectorates, but also to give an idea of the aspects that make governmental regulation so complex. To make it easier, I have included some of the regulatory characteristics and some of the inspectorate's characteristics in the explanation of several theories on regulation. To keep the focus on the subject of this research, I specifically elaborate those theories on which the Inspectorate's current inspection arrangement is based. These are cutting-edge theories that are often used, also in different regulatory fields. In this chapter, the criticisms on each of these theories will be discussed.

WHAT IS REGULATION?

Mertens (2001-2009: 33) states that *'regulation is a control mechanism, which can be used to attain the desired unity within a social configuration. The term regulation is in place when task execution is left to 'an other', but that it is uncertain that this will be executed adequately by the 'other'. Regulation then serves to monitor whether there have been any violations of standards.'* Other commonly used terms that fit the above definition are (external) review, supervision, enforcement and governance. These terms have various interpretations and definitions. For instance, Mertens defines regulation in terms of its function, while the Inspectorate uses the term 'supervision' and describes this in terms of different phases of the supervisory process. The Inspectorate changes 'supervision' into 'enforcement' when repressive measures are taken. In this report, regulation, (external) review, supervision and governance are considered synonyms which more or less boils down to the idea of a control mechanism with an (indirect) administrative function, which aims to attain long-term societal objectives by means of monitoring possible violation of (legal) standards and intervening, if necessary. Keeping to the Inspectorate's interpretation of enforcement, this term will rarely be used and only when repressive measures are discussed.

⁶ The term regulation is used for what is called in Dutch 'toezicht'.

*Optimal regulation*⁷

In his search for ‘optimal regulation’, Van der Heijden (2009: Chapter 3.2.1) starts off with an approach in which he pinpoints a few characteristics of regulation in general that influence whether regulation will lead to compliance. These characteristics are adequacy, feasibility, adaptability and certainty. He explains the significance of each of these characteristics by means of collecting critical points that actually indicate the considerations that need to be made when evaluating or establishing ‘optimal regulation’.

In his explanation of the term *adequacy*, he says that the formal goals should actually to be attainable when regulatees -i.e the bodies that are being regulated- show compliant behavior. However, some goals aim at prevention rather than achievement, which often cannot be converted into measurable outcomes. Nevertheless compliant behavior can be stimulated, considering that compliance comes from fear of the consequences of non-compliance and from the belief that regulation is in one’s own personal interest and is legitimate.

Feasibility generally refers to the extent to which regulation considers the regulatee’s ability to comply with the relevant standards and the regulator’s ability to detect non-compliance. When considering the regulatee’s ability to comply, aspects such as physical or economic inability, but also non-familiarity with regulation, need to be taken into account. On the other hand, the regulator’s ability to detect non-compliance, mostly refers to the extent to which specific expertise is required, the regulator’s limited capacity, but also to the extent to which non-compliance is traceable. Adaptability in regulation means the extent to which regulation can be adjusted to specific circumstances, either given or future circumstances. This can be by formulating open standards that can be interpreted according to the circumstances. This also includes modifying sanctions to suit the circumstances.

Certainty refers to establishing a clear understanding of what is meant by regulation and how regulation takes place. This implies that there should be an unambiguous interpretation of what is meant by regulation, that roles and responsibilities have to be clarified, but also that contradictory legislation that may cause confusion must be reduced to a minimum.

Governmental regulation

As the focus within this research is on regulation by the Health Care Inspectorate, it seems only natural to emphasize governmental regulation -also referred to as inspection. Inspectorates are generally charged with regulation; however, regulation does not necessarily mean the same as inspection. According to Mertens (2001-2009: Chapter 7.13), inspectorates fulfill a number of tasks that cannot strictly be labeled as regulatory tasks. Over the years, they have acquired a number of characteristics, which all have an influence on their task execution. These (nine) characteristics identified by Mertens will be elaborated in the following paragraph.

⁷ Van der Heijden admits that this term might be somewhat disputable and points out that he uses this as a convenient short-hand in his analysis of different forms of regulation (2009: 40-41).

Inspectorates are often characterized by their (1) professional expertise. They (2) employ inspectors who have the necessary expertise and can make independent judgments. Inspectorates have a (3) clear profile to the public at large and carry a responsibility towards the inspectee, but also towards the administrative and political environment. Therefore, the Inspectorates' regulation is aimed at promoting compliant behavior, in order to achieve societal objectives, rather than punishing non-compliance. Their (4) inspection methodology is based on risk-analysis and effective ways to achieve compliance. (5) Inspectorates operate on behalf of the government and have the authority to do so. The Inspectorate actually (6) represents the people and tries to enhance confidence in the functioning of social systems. The Inspectorates' (7) working method is determined by principles of equal treatment of all their inspectees, political priorities, risk assessments, desired levels of interventionist response and concepts on detection and threats. Inspectorates (8) investigate factual circumstances, judge them based on legal standards, and intervene when necessary and in a way that is appropriate to the situation. (9) This is reported back -sometimes publicly- to the inspectee or to the entire domain of inspection.

Regulatory strategy

Regulation has made a fair development over the years and can take on various forms. Van der Heijden (2009: 43) describes the regulatory strategy⁸ in terms of two aspects. The first is the aspect of tactical choices that mostly refer to the allocation of resources, setting targets and monitoring outcomes. The second aspect regards the different types of action to be taken, which in the main refers to the type of sanctions or incentives. The next two sections will introduce theories on regulation, of which the first and second are framed as concepts that focus more on the tactical choices, while the third theory emphasizes the actions to be taken. The latter tends to overlap with what Van der Heijden calls a regulatory style⁹, in which he refers to the behavior of the regulator towards the regulatee.

SYSTEM-BASED REGULATION

The trend towards decentralization and the increasing autonomy of institutions has, among other things, presumably also played a role in the shift from governmental regulation to what is called 'horizontal regulation'. Even though the term 'horizontal regulation' is often used, this is misleading, because regulation is always "vertical" [Mertens, 2001-2009: 97; Helderma & Honigh, 2009: 31]. Internal regulation is a more appropriate term for what is meant by 'horizontal regulation'. In other words, governmental regulation in its most obvious form is when the government makes an evaluation and a decision to intervene, based on information obtained from direct 'on-site' observations [Mertens, 2001-2009: 112]. This is more towards command-and-control in which the government sets rules and enforces them. The shift towards internal regulation actually refers to institutions having a more self-regulatory capacity and the government having the task to oversee

⁸ Van der Heijden actually uses the term enforcement instead of regulation or regulatory. As he does not necessarily refer to taking repressive measures, the term regulation or regulatory fits better within terminology agreed upon in this report.

their process of self-control, thus the term internal regulation. This however, requires a great deal of confidence from the part of the government in the institutions' self-regulatory capacity. To be able to monitor this, the government establishes (horizontal) arrangements with these institutions in terms of accountability. This concept is also known as system-based regulation.

Nowadays system-based regulation is more frequently considered the alternative for classic vertical regulation. In their book, Helderma and Honigh¹² (2009) elaborated on system-based regulation and how this can be applied to governmental regulation. Their analysis and interpretation on the concept of system-based regulation is described in the following paragraphs.

Helderma & Honigh (2009) compare system-based regulation to cybernetic systems thinking, in which the self-regulatory capacity of social systems is central. The core of cybernetic systems thinking believes that social systems can only be monitored by means of steering signals from internal control systems. This theory strongly believes in autonomous sub-systems and their internal control. This is the same in system-based regulation. A fundamental condition of system-based regulation is that the regulatee should have a self-regulatory capacity. According to this concept, the capacity to self-regulate can be considered the capacity to control potential risks with negative external effects or the capacity to maintain a minimum level of quality. *'Ideally, the regulatee will monitor whether its own rules and standards are being attained through its own internal assurance system (p.111).'*

In a further elaboration of this concept, Helderma & Honigh distinguish the regulation regime into two dimensions, namely the components of system-based regulation and what they call 'sectoral conditions'. The first refers to what system-based regulation could mean in terms of data collection, implementation of standards and the capacity of the regulator to influence the behavior of the regulatee. The latter refers to conditions that influence the functioning of the system, which include (1) the primary risks that need to be regulated, (2) the social and political perception of those risks and (3) the self-regulatory capacity of the regulatee.

Components of system-based regulation

The components of system-based regulation include (1) data collection, (2) formulating an opinion based on this data and (3) deciding a suitable intervention. Deliberating how the components of system-based regulation can take form, Honigh & Helderma (2009: 35) indicate that the extent to which the components correspond with each other need to be considered. When looking at the Inspectorate's inspection instruments, the Inspectorate collects structured as well as unstructured information, structured information meaning scores for quality indicators. When applying this to the use of medical technology, the complexity lies in objectifying and measuring. In the medical field there is currently a trend to focus on preventable adverse events. The aim is to prevent. This brings us back to what Van der Heijden (2009) calls one of the difficult matters in the aspect of adequacy. Even if one comes up with several decent quality indicators, such as the user's level of training or the

⁹ See footnote 4.

number of user errors, it is still difficult to assess these. Which standards will be used for assessment? What are appropriate measures to influence the behavior of the regulatee? These are careful considerations. In the use of indicators, the regulator also runs the risk of fixation on the performance outcomes and losing sight of the actual objective. To overcome this, the focus has shifted from performance indicators on the product to performance indicators on the process. Whether this is really a successful and efficient solution, is questionable.

Sectoral conditions

The components mentioned above have to fit within the sectoral conditions, namely (1) the primary risks that need to be regulated, (2) the social and political perception of those risks and (3) the self-regulatory capacity of the regulatee. These conditions largely determine the functioning of the system.

With regard to the primary risks that need to be regulated, one must consider two aspects: the relation between the risk and the risk-taker and the extent to which a risk can be traced back to the risk-taker. The first aspect needs to be considered to preclude so-called ‘moral hazard’. When one is in a position to pass the possible negative consequences of a risk onto another or onto society, one is more likely to take that risk or even bigger risks, than when one has to weather the consequences oneself [Winter & de Ridder, 2010: 7]. In the use of medical technology in hospitals it seems almost impossible to preclude moral hazards. Medical technology is applied by practitioners and usually it is the patients who have to weather the consequences. This unfortunate position really leaves the patient with only one option: have confidence in the practitioner’s competence and sense of responsibility. Whether the practitioner actually takes this responsibility or has the required competence is still an open question. The 2008 State of Health Care report [IGZ, 2008b] states that the competence for actions taken leaves a lot to be desired. One should remember that the Inspectorate “represents the public” -in this case the patient- and one of its obligations is to enhance the public’s confidence in the functioning of social systems. The Inspectorate should therefore try to find incentives for the practitioner to actually take responsibility for his/her actions and ensure that (s)he is competent. Furthermore, the extent to which risks can be traced back to the risk-taker is also an important aspect to be considered in the use of medical technology. The following may illustrate this. Radiation in health care is applied to diagnose, but also to treat. Its application should therefore be carefully considered, since, as we all know, it may be very harmful to one’s health in the event of overexposure. However, (over)exposure to radiation can easily be explained away because it is easy to cover it up. Radiation is rather commonly used and therefore it is difficult to trace back whether the overexposure was the result of carelessness or not. This is exactly the kind of problem that one encounters when considering what Van der Heijden (2009) calls “feasibility” of the regulatory arrangement on the use of medical technology in hospitals.

The social and political preferences and perception of risks refer to the social acceptance standard of risks. This is also an important aspect when considering the Inspectorate’s obligations towards the political and public environment. What kind of impact do the consequences of risks have on society

¹² Helderma & Honigh (2009) use the term meta-regulation instead of system-based regulation. The term meta-regulation, however, is more often used for another concept of regulation that does not necessarily involve systems.

and to what level is this tolerated? Medical technology is rapidly advancing and this is not only generally accepted, but also stimulated by society, who is not entirely unaware of the risks that are involved. This acceptance standard could be the result of the existing confidence in social systems, in particular, the health care regulatory system. Still, occasionally the public needs some reaffirmation that this confidence is justified, and then the Inspectorate may find itself stuck between a rock and a hard place. An illustration of the field of tension in which the Inspectorate operates is the following. When a serious incident, similar to the Twenteborg accident, occurs, the Inspectorate has the obligation towards both the political and the public environment to investigate the incident and report on it. The problem is that these environments immediately become vulnerable when such an incident has taken place. They become suspicious, get a sense of insecurity, tend to forget the inevitability of incidents and demand more accountability from the part of the Inspectorate. What makes things worse is the role of the media who tend to sensationalize such incidents. So, while the Inspectorate tries to enhance society's confidence in the social systems and legitimize its existence by making these issues transparent, it is the same transparency that can cause a feeling of insecurity and thus reduce society's confidence in the systems.

One of the complexities of system-based regulation is that it shifts away from inspections of the primary process and gradually increases the focus on paperwork. As the primary process becomes more complex, the inspector also becomes less familiar with it, which ultimately results in 'superficial' inspections instead of verification inspections [May, 2007]. Van der Heijden (2009: 49-50) elaborates the concept of self-regulation and identifies a number of opportunities and risks. Self-regulation is a broad concept and it is hard to find a definition that is unambiguous. Self-regulation is considered to be hovering between command-and-control and no governmental involvement at all. The degree of self-control or the extent to which the government may be involved, in order to call it self-regulation is unclear. The major opportunities of self-regulators identified are the relevant expertise and knowledge of self, the specialist technical expertise, the assumption that a self-regulator knows more about its sector than a public authority ever could, easy accessibility to those under control in terms of time and money and a higher acceptance level of own rules than externally imposed rules. On the other hand, self-regulation also entails a number of risks. It is difficult to justify that public interest is being served when self-regulators do not have the democratic legitimacy to exercise enforcement. Also the skepticism about the accountability of self-regulators, due to the risk of capture¹⁵, is considered a disadvantage. Furthermore, self-regulation also highly depends on the organization's knowledge and willingness to self-regulate. Willingness refers to the intrinsic motivation to self-regulate, but there is also the matter of enforced self-regulation, in which external parties impose self-regulation. Within the Health Care Inspectorate the transition to system-based regulation was due to a limited regulatory capacity, which is a very important reason, but also pressure from the political environment contributed to the actual introduction of system-based regulation [Honigh & Helderma, 2009: 65].

¹⁵ Capture occurs when a regulator is charged with regulating a system and is captured in that system [Mertens, 2001-2009: 63]. This may result in the regulator acting in favor of that system instead of in favor of public interest.

RISK-BASED REGULATION

Sparrow's proposal to a regulatory reform is to '*pick important problems and fix them*'. He believes that the point of departure in regulation should be to administer a risk analysis in the relevant social domain and manage these risks. Van der Heijden (2009: 46) identifies two main differences between risk-based and traditional regulation. Whereas traditional regulation is based on the input of an activity –the prescriptive standards that need to be met–, risk-based regulation is based on the output of an activity, particularly the risk that it can cause. Risk-based regulation also departs from the fact that risks do exist and are sometimes inevitable and it aims to reduce these risks rather than remain in denial and try to take out non-compliance entirely. Furthermore, Van der Heijden states that this form of regulation is considered effective and efficient, due to its principle of setting priorities. It is expected that risk-based regulation will achieve maximum impacts or outcomes with limited resources. As this form of regulation is also more analytically-based, it is often also considered more legitimate.

However, the fundamental principle in risk-based regulation, which requires the regulator to set priorities by means of selecting the important problems and fix them, is somewhat contradictory to the inspectorate's obligation to treat all of its inspectees equally. Considering that risks are determined by multiplying probability and impact together, it is obvious that spreading the risk will differ from object to object and from domain to domain [Mertens, 2001-2009: 10-11]. This implies that inspectees who are considered to be in a higher risk category will see the regulator more frequently.

Van der Heijden (2009: 46) also points out that the analytical approach –i.e. probability multiplied by impact– can give a false sense of security, which may even intensify, if taken too literally. The accident in the Twenteborg hospital can be characterized as an unexpected and rare event with a high impact and may even be categorized as a so-called Black Swan event¹⁷. However, the impact of such an event is often magnified by both the media and by politicians, which could reduce society's sense of security. It is true that this is not entirely unjustified, but it does make people forget that risks do exist and are sometimes even inevitable, which in turn leads to cries for more (stringent) regulation and demands for more accountability from the part of the Inspectorate.

Furthermore, Van der Heijden (2009: 46) mentions the fact that risks are difficult to objectify. It is as difficult to objectify something that has not occurred yet as it is to determine quality indicators in the concept of system-based regulation. However, once the risks have been determined, there is the danger that the regulator may become blind to new risks. Finally, Van der Heijden states that critics sometimes question whether risk-based regulation is indeed a regulatory strategy or just a tool for allocating resources.

¹⁷ The "Black Swan" events refer to events with the attributes rarity, extreme impact and retrospective predictability [Wikipedia].

RESPONSIVE REGULATION

In the past few decades there has also been a strong tendency towards deregulation. There was an urge for a control mechanism that would result in better goal achievement, i.e. better quality of services, higher levels of safety etc. [Mertens, 2001-2009: Chapter 5]. Contrary to the traditional command-and-control, Ayres and Braithwaite (1992; 25) believe that *'the trick to successful regulation is to establish a synergy between punishment and persuasion'*. They developed a theory on what they called "responsive regulation", whereby the relationship between the regulator and regulatee and the regulator's ability to choose between different sanctions are regarded as the strengths of the model.

Responsive regulation is a policy theory that is used in several policy areas. This theory basically boils down to the idea *"that governments should be responsive to the conduct of those who they seek to regulate in deciding whether a more or less interventionist response is needed"* [Braithwaite, 2006: 886]. Key to this theory is adjustment: the regulator's ability to interpret the rules and adjust its interventionist measures according to the given circumstances. The most distinctive feature of this theory is the enforcement pyramid that starts with a persuasive approach and gradually builds up to more demanding interventions. The idea is that the regulator should start at the base of the pyramid and should only go a level up when the regulatee shows reluctance and dialogue fails. If the moderate forms of punishment fail to achieve the desired goal, the regulator should gradually move up the pyramid. Conversely, at the point where reform and repair is forthcoming, the regulator can level down the pyramid. The responsive regulation theory factors in that persuasion as well as punishment may backfire sometimes and therefore aims to find the right balance between the two. However, *'there are no universal solutions'* [Ayres & Braithwaite, 1992: 5], so regulation needs to be geared up to each specific context, hence the responsiveness.

Braithwaite (2006) further expands this theory by distinguishing three different types of interventionist measures within the pyramid, beginning with restorative justice and gradually building up to deterrence and incapacitation at the top. By starting from the bottom of the pyramid, a regulator can build up legitimacy, and therefore compliance, since compliance is more likely to be reached, according to Tyler (1990), when the regulatee considers regulation to be legitimate. Braithwaite (2006: 888) explains this by means of the following example. *'During a restorative justice dialogue over an offence, the inspector will say there will be no penalty this time, but that she hopes the manager understands that if she returns and finds the company has slipped back out of compliance again, under the rules she will have no choice but to shut down the production line. When the manager responds yes, this is understood, a future sanction will likely be viewed as fair.'* Moreover, Braithwaite elaborates how this theory turns out to be cost-effective. For example, at the base of the pyramid, the regulatee is offered the cheapest and more respectful option. When this fails, the regulator can slowly build up to the more costly attempts to reach compliance [Braithwaite, 2006: 887]. This can work in both ways, i.e. for the regulator and the regulatee, as the measures taken can also become more costly for the regulatee as he moves up the pyramid, up to a point that it is cheaper for the regulatee to comply than if he does not. In some cases, however, it may turn out that non-compliance is not a matter of lack of goodwill to comply or of intentional cheating, but that it has to do with not having the competence to comply. At this point, incapacitation should be the next interventionist response.

In practice, responsive regulation does have its limitations. Mascini and van Wijk (2009) stated that there appear to be systematic inconsistencies in the way individual regulators interpret their tasks and

determine a suitable interventionist response. This is due to the freedom that exists to interpret standards according to own insight. On the other hand, restricting this freedom could also hold back regulators from intervening responsively. The Quality Care Institutions Act has an open formulation and is regulated by means of so-called field standards. To some extent the development of field standards meet Van der Heijden's regulatory criteria, namely adaptability and certainty. Open formulation leaves a lot of room for different interpretations. The fact that the field is responsible for designing field standards in collaboration with the Inspectorate, based on this Act, ensures that these are well understood by both parties. The current development of quality indicators for regulation can be constraining, however, in that if interpreted too literally, the regulator's responsiveness may suffer. Also the demands of the political and public environment can constrain the regulator's responsiveness. The call for more accountability puts pressure on the Inspectorate to prove itself. This in turn affects responsiveness because adjustments are made to meet its own priorities, namely to prove its *raison d'être*.

Another limitation is the difference in the way interventions are intended by the regulator and the way they are interpreted by the regulatee. This refers to one of the aspects Van der Heijden (2009) identified as "certainty". Misunderstanding of the regulator's intervention will most likely cause the regulatee to think the intervention is unfair, which can easily result in some form of resistance. Moreover, all punitive measures need to be considered carefully, as they can also entail negative side effects.

RECAPITULATION

The main purpose of this chapter was to explain the fundamental principles of each theory (see table 2), in order to get an idea of the extent to which they are imbedded in the Inspectorate's current inspection arrangement and the complexities they bring about. For the sake of convenience, one could regard system-based regulation as strictly for instruments, risk-based regulation for priority settings, while responsive regulation mainly refers to decision-making concerning suitable interventions. The current regulatory arrangement contains quite an effective combination of strategies, in the sense that the strengths of each theory seem to be well positioned and well used. However, it does not take away the weaknesses, such as the tendency to retreat from the primary process in system-based regulation, becoming blind to new risks in risk-based regulation or the ambiguous interpretation of interventions in responsive regulation. The weaknesses have been clarified by means of specific 'use of medical technology in hospitals' illustrations to show what effect they may have in a specific context. More often than not they are hard -maybe even impossible- to overcome, but this strategic combination of theories still has value. Table 3 provides a schematic overview of the complexities that were identified in the literature.

The next chapter will deal with the practical complexities of regulation that were identified in the field research, which mainly consisted of desk research on the Inspectorate's policy documentation and interviews with experts in the field. The products from the field research are an actor analysis and an analysis of the interview data.

Table 2: Comparison of the theories on regulation

Principles	System-based regulation	Risk-based regulation	Responsive regulation
Regulatory foci	Process or system	Risks that an activity causes	Synergy between punishment and persuasion
Compliance determination	Acceptable functioning self-regulatory system	Establishment of risk management	Cooperative relationship with regulatee
Nature of standards	Process-oriented specifications	Risk-based	Adaptive to circumstances
Basis for achieving regulatory goals	System is designed to meet regulatory goals	Risks that endanger achievement of regulatory goals the most, deserve highest priority	Responsive interventions establish cooperation of regulatee to achieve regulatory goals

Table 3: Opportunities & risks of the theories on regulation

	(OPPORTUNITIES)	(RISKS)
System-based regulation	Knowledge of self	Retreat from inspections on primary process due to increasing focus on paperwork and (inspectors') increasing unfamiliarity with primary process
	Relevant, specialist expertise	Possibility of capture
	Easy accessibility to those under control	Difficulty in objectifying measures
	Higher acceptance level of own rules	Knowledge and willingness to self-regulate determine functioning of the system Difficulty in dealing with moral hazards and risks that are difficult trace Difficulty in meeting with social & political acceptance standards
Risk-based regulation	Effective	Analytical basis can cause a false sense of security
	Efficient	Difficulty in objectifying risks
	Analytical basis builds up legitimacy	Unequal treatment of regulatees
	Accepts and aims to reduce risks	Possibility of becoming blind to new risks
Responsive regulation	Adaptive	Difference in interpretation of interventions
	Builds up legitimacy	Responsiveness can be constrained by standards
	Cost-effective	Responsiveness can be constrained by public and political environment Punitive measures can have negative side effects

5. FIELD ANALYSIS

This chapter is a result of field research that included a study of the Inspectorate's policy documentation, ten interviews with experts in the field, namely from the hospitals and the Inspectorate. During my research, I have also had the privilege to witness a few inspection visits to some hospitals and to one manufacturer. Furthermore, I have also attended several seminars regarding subjects that are closely related to the subject of this research, namely a lecture by Prof. Dr. Pauline Meurs, a Patient Safety Congress on Infection Prevention, organized by the Inspectorate and a seminar held by Drs. Jos Kraus on law and legislation concerning medical devices. In this analysis I have included all these experiences.

The field analysis includes both an actor analysis of the actors that are closely involved in the use of medical technology in hospitals and an analysis of data obtained from interviews with experts in the field. The chapter concludes with a recapitulation that contains a schematic overview of the complexities identified regarding the regulatory arrangement on the use of medical technology in hospitals.

ACTOR ANALYSIS

There are a number of actors involved in patient safety in the use of medical technology in hospitals. Based on their relevance to this research, the number of actors has been limited to these three actors: the government, namely the Health Care Inspectorate, the hospitals and the manufacturers. This research focuses mainly on the Inspectorate, and since both the manufacturers and the hospitals are regulated by the Inspectorate and are also leading actors in the use of medical technology in hospitals, these three actors are considered highly relevant to this research. This chapter will discuss their involvement in detail.

Government

The government is a large organization that is divided into smaller organizations. The Ministry of Welfare, Public Health and Sports, the Health Care Inspectorate, the National Coordination of Inspections in Hospitals and the General Inspectorate of the Netherlands all fall under governmental organizations. Each of these actors play an important role in regulating and monitoring public health care. The Ministry is responsible for the part of institutional regulation that entails legislation, but also for setting targets to urge health care organizations to upkeep a certain standard. The other actors have a responsibility in ensuring compliance with the relevant laws and regulations. This is monitored by means of inspection.

Abstract actor analysis: the Health Care Inspectorate

Interest:	Promote public health by effectively upholding the quality of care; prevention and medical products.
Conflicting issues:	Incongruity in obligations towards the social and political environment and the regulates; there is a gap between what the law prescribes and how things turn out in practice.
Desired situation/objectives:	Innovation in regulatory methods; research on performance in terms of effectiveness and efficiency; focus on patient safety.
Existing or expected difficulties:	Occurrences of serious incidents as a result of medical technological failures and inspection that cannot guarantee 100% coverage; increasingly stringent interventionist response to non-compliance by Inspectorates.
Causes:	Rapid development of medical technology; inability to keep up with advances in medical technology; a demanding society in terms of accountability of Inspectorates towards the people; development of an accountability culture.

Abstract actor analysis: the government (inspection in the health care sector)

Interest:	Protect and promote public health.
Conflicting issues:	Incongruity in obligations towards the social and political environment and regulatees.
Desired situation/objectives:	Attain an unambiguous concept of inspection with special attention for effectiveness and efficiency.
Existing or expected difficulties:	A society that increasingly demands more but is rather contradictory in its demands; on the one hand, it demands deregulation and on the other hand, more frequent and stringent regulation.
Causes:	A more mature and articulate society, development of an accountability culture.

Hospitals

Hospitals and health care professionals, namely doctors, are by law responsible for the provision of responsible and efficient care of good quality. They fall under the direct supervision of the Inspectorate. Hospitals also have the duty to report calamities. In case the calamity concerns a medical device, this should be reported and included in the internal investigation and analysis of the calamity. Hospitals first-handedly deal with professional regulation, which involves control of the individual health care professionals who practice in the health care system. Hospitals can be categorized in academic and general hospitals. The most relevant difference between these two groups of hospitals is that the individual health care professionals are employed by the academic hospital and therefore the academic hospitals can be seen as one organization. The general hospital, however, actually serves as a facility with individual units in which the professionals can practice medicine independently. The different organizational structures can play a role in the way aspects such as patient safety and quality control are imbedded in the organization. The hospitals -more specifically the health care professionals who work in the hospital- are at the user end of medical technology and therefore they are directly involved in the use of medical

technology. Within the hospital, the supervisory board is held responsible for the task-execution at the highest level and superintends this, as this responsibility gradually decreases at the lower levels of the hierarchy.

Abstract actor analysis: hospitals

Interest:	Provide good; patient oriented quality care; positive image.
Conflicting issues:	Incongruity between practicability and what is required by legislation.
Desired situation/objectives:	Prominent position as a health care providers in terms of high-quality and innovative care.
Existing or expected difficulties:	Inadequate maintenance of medical technology; inadequate training in the use of medical technology; lack of clarity about responsibilities and authorities of the parties involved; occurrence of serious incidents as a consequence of medical technological failures; increasingly stringent interventionist response to non-compliance by Inspectorates.
Causes:	Rapid development of medical technology; inability to keep up with advances in medical technology; development of an accountability culture.

Manufacturers of medical devices

Manufacturers are also responsible for the provision of good care. In terms of medical devices that means ensuring product safety and safe application. Before a manufacturer places a product on the market, it needs to have a CE marking. This CE marking shows that a product meets the essential requirements in terms of quality, safety and functionality. When a medical device is introduced on the market, the manufacturer has the legal obligation to perform PMS. As mentioned earlier, manufacturers of risk class-I medical devices, custom-built medical devices and certain IVD medical devices fall under the direct supervision of the IGZ, while manufacturers of higher risk class products fall under the NB’s responsibility.

Abstract actor analysis: manufacturers

Interest:	Continuity of business; positive image; profit.
Conflicting issues:	Safety and practicability issues that conflict with commercial interests.
Desired situation/objectives:	Prominent position as a health care provider in terms of high-quality and innovative medical care products.
Existing or expected difficulties:	Strong demand for advanced medical technology while users increasingly alienate from advanced medical technology in terms of technical knowledge, increasingly (stringent) interventionist response to non-compliance by Inspectorates.
Causes:	Discontinuity in training of users; occurrence of serious incidents as a consequence of medical technological failures; development of an accountability culture.

INTERVIEW DATA

This section includes the data obtained from a number of interviews with experts in this field of work. The aim was to interview respondents from both the Inspectorate and the hospitals in order to get a complete overview of how regulation is experienced. The interviews covered mostly questions about the course of specific on-site inspection visits that the respondent had experienced, if and which measures were taken at that time, the effect of these measures and possible points of improvement towards the Inspectorate regarding these issues. As this research focuses on the use of medical technology in hospitals, the production and trade of medical technology and therefore manufacturers were initially excluded. At a later stage of this research, however, it became clear that these two branches cannot be separated from each other. The analysis in the section about the Inspectorate therefore also includes some information obtained from a manufacturer during an inspection visit. The data are from ten interviews with respondents from the wide range of actors that are involved in the regulation of the use of medical technology in hospitals.

Hospitals

For the interviews in the hospital field, I picked experts from various levels of operation to get an idea of how they experience the Inspectorate and its approach. The respondents¹⁹ ranged from medical instrumentation technicians to managing directors. During the interviews it was difficult to focus on regulation in the use of medical technology, which is quite striking. The respondents were either very technical but hardly ever had anything to do with inspection visits or the respondents worked at a higher level of the organization and therefore hardly knew anything about the medical technology being used in the organization. The respondents with technical know-how were asked how they thought regulation specifically aimed at the use of medical technology should take form, while the respondents at the administrative level were asked their opinion on the Inspectorate's approach in general. Only one respondent had technical know-how and was closely involved with inspection visits.

It was found that the hospitals generally have a positive impression of the Inspectorate and its way of operation. Inspection visits are generally taken seriously by the hospitals and are quite formal. Inspection visits and inspection reports are often considered an effective stimulus to push issues that were primarily considered low priority or issues that were continually postponed because there was no agreement about the way to deal with them. At the same time, however, these inspection visits and reports were sometimes considered inconvenient. The Inspectorate often makes its agenda based on its own risk-analyses, which may differ from the agenda of the hospital, which is based on the hospital's risk-analysis. There is some overlap between the two agendas, but the Inspectorate's requirements demand special attention and have high priority. Therefore, the hospital has to set aside its own priorities, in order to be able to address those of the Inspectorate. This lack of synchronization and difference in priorities is an issue between the Inspectorate and the hospitals and can cause friction.

¹⁹ See the appendix C for the list of respondents

Measures taken by the Inspectorate are generally also considered legitimate and fair. However, there is some difference of opinion as to which extent the Inspectorate's measures are feasible in terms of costs and time. Hospitals often have a hard time realizing the Inspectorate's measures because these are often very costly and time-consuming. Hospitals indicate that it is rather difficult to recruit appropriate (human) resources. The perception of the hospitals is that the Inspectorate does not sufficiently take this problem into account. Particularly the hospitals that have had to weather more severe consequences such as intensified supervision think that the Inspectorate does not take into account whether the imposed measures are actually practicable. Hospitals that do not have this experience consider the Inspectorate's measures reasonably feasible. It is unclear if this is due to the possibility that the Inspectorate tries to exert more pressure on underperforming hospitals.

Another remarkable finding is that the Inspectorate's sanction to 'name and shame' is not appreciated. This ranges from fear to get negative media attention to a suggestion that the Inspectorate should be very careful in applying this sanction. Hospitals generally show understanding for the Inspectorate's way of operation and are quite aware of the Inspectorate's obligations towards society in terms of accountability. In that sense, the Inspectorate's attempt to provide transparency is well appreciated. However, transparency does have a downside. Naming and shaming does not only damage the hospital's image, but it also has other negative side effects. For example, the current focus on incidents and the media's habit to sensationalize them may result in society losing its sense of security and confidence in health care. Consequently, society will demand more (stringent) regulation. This shows that naming and shaming can have a counterproductive effect. Therefore, the Inspectorate is urged to carefully consider the application of sanctions and above all, to make sure that such sanctions are really justified before imposing them.

The fact that the Inspectorate does have the means and authority to take repressive measures is generally accepted and sometimes even expected. This expectation comes from the notion that governmental regulatory bodies should be allowed to carry big sticks, not only to discourage non-compliance, but also to actually deal with organizations that repeatedly violate the rules. Big sticks should be used prudently, however. Hospitals indicate that the Inspectorate has repeatedly burned its fingers and should therefore be careful when deciding on and imposing measures. Not only should the use of the big stick be fully justified, it should also be clear on what criteria the punitive action is based and that there is consistency in the use of the stick. The Inspectorate should really take these recommendations seriously.

Furthermore, managing directors also notice an enormous increase in the workload that this 'accountability culture' brings about. The hospitals are burdened with an increasing amount of work, such as time-consuming administrative work, but the financial resources remain the same. Admittedly, the extra work may promote the quality and safety in health care, but it also has a counterproductive effect, in the sense that the time spent on working through the administrative load, goes at the expense of the time that was actually meant for the provision of health care. There was one respondent with a different opinion. He stated that the administrative burden of assurance systems is a heavy load, indeed, but only in the initial stage. Bedside care providers understandably mostly think in terms of the present, in other words, the patient needs care immediately. However, the time spent to do this administrative work now, will be recovered in the long term. At any rate, an integral approach by the different regulatory bodies concerning hospital inspections seems a solution worth considering. It will not only reduce the regulation burden, but also provide an integral

overview and therefore enable the regulatory bodies to short-circuit possible inconsistencies in regulation. A start has been made in this direction, but it needs to be promoted more.

A respondent with experience in internal regulation of the use of medical technology explained that this regulation involves many hospital departments. It starts with purchasing the medical technology, then it continues its way to the medical instrumentation department, the central sterilization department and even the scheduling of the night shifts. The extensive scale of medical technology requires an organizational structure where lines between the administrative level and the operational level are short-circuited.

The Inspectorate

I also interviewed two inspectors of the Inspectorate. One of them is involved in inspections on medical technology in hospitals and the other is responsible for inspections on the production and trade of medical technology. As mentioned before, I also had the privilege to witness some inspection visits. Two of which were in hospitals and concerned the safety management system and one was at a manufacturer of mechanical instruments that are used in operating rooms, etc. and regarded inspection on production and trade.

In an inspection visit, the inspector talks to the representatives at the highest administrative level. In a hospital this is the administrative board. At the small manufacturer of medical instruments it was the managing director. The discussion mostly concerned policy plans and written procedures about the object of the inspection, in other words, it is a check on whether policy plans and internal regulatory processes are worked out and recorded in documents. The inspection visits can sometimes entail interviews with personnel on the shop floor, but actual checks on the shop floor are limited. The inspection is rather formal. Finally, the visit is concluded with an oral description of the findings based on what was found on paper and on the inspector's instinctive assessment.

The inspectors indicate that they often first try to apply persuasive measures in order to encourage compliance. The interviewed inspectors have the impression that in most cases this method works. However, in the cases where it does not, it means a heavy workload for the Inspectorate and such cases are therefore also the most strenuous. The authority to impose repressive measures is seen as a 'big stick' because the consequences of non-compliance are feared. The inspectors admit that the big stick should be used sparingly. However, this is not the general experience. The interviews with the hospitals reveal that they believe that repressive measures are often colored by political and social influences. The Inspectorate tends to repress in order to prove itself, to justify its existence rather than to achieve compliance.

One of the complexities the Inspectorate has to deal with is the demand for 100% safety, coming from the social and political environment. This is not considered feasible. Incidents and calamities are inevitable if not undesirable, but it is exactly such cases that trigger off the cry for more safety and thus for even more improvement of the system. Another difficulty has to do with the fact that the Inspectorate sometimes has to deal with inspectees who are willing to comply, but who cannot. In such cases, the Inspectorate can only give counsel or make suggestions for possible solutions. Note

that this, too, is not the way it is experienced by the inspectees as seen in the interview data of the hospitals. The Inspectorate generally inspects conformity with the relevant laws and standards. When it is insufficient, the Inspectorate has to lay its finger on the sore spot. Hospitals often tend to experience this as inflexibility on the part of the Inspectorate. The final difficulty observed was that the recommendations from thematic and suchlike reports hold no legal obligation and do not provide the desired stimulus for improvement. A practical measure to be put at the disposal of the Inspectorate would be an intervention or action that has no legal obligation, but still provides enough stimulus for inspectees to comply with. However, such a measure has not yet been thought out.

Manufacturers notice a difference between the intended use of a medical device, in other words why it was designed, produced and traded, and the way in which it is actually used. It seems that users often find a different use for medical devices that were originally intended for some other purpose or off-label use. In most of such cases the users were improvising or doing the most practicable thing. Different usage, however, compromises the legal requirements. Manufacturers should be able to anticipate foreseeable misuse to a certain extent and with PMS it must be possible to overcome unforeseen misuse. However, each of the parties involved face a dilemma. The manufacturer is stuck with the moral consideration whether or not to continue supplying the product, knowing that the device is not used in the way it should, but on the other hand, he has to consider his commercial interests. The user finds himself between a rock and a hard place, knowing that the device is not used the way it should or used for a different purpose, which in the given circumstances is the most practicable solution, although it involves risks. He is quite aware that if something goes wrong, it will be considered a violation of the standards and the hospital will be blamed. The third party facing a dilemma is the Inspectorate, who has to inspect conformity with the law and lay its finger on the sore spot in cases of non-compliance, even though it is well aware of the user's dilemma. This issue of how to deal with off-label use in terms of responsibilities, liabilities and detection, should also be looked into because it is very important.

RECAPITULATION

The field analysis mainly includes information on the experiences of the respondents. The information collected does not only underscore many of the complexities that were already identified at an earlier stage of this research, namely in the analysis of the regulation theories, but it also gives insight into some additional complexities that occur in regulation. The next chapter will discuss all the complexities that were identified in the field analysis, specifically in the context of regulating the use of medical technology in hospitals. The following table provides an overview of all the complexities identified and the additional complexities identified in the field analysis are highlighted.

Table 4: *Supplemented table with opportunities & risks of the theories on regulation*

	(OPPORTUNITIES)	(RISKS)
System-based regulation	Knowledge of own body	Retreating from inspections in primary process due to increasing focus on paperwork and (inspector's) increasing unfamiliarity with primary process
	Relevant, specialist expertise	The possibility of capture
	Easy accessibility to those under control	Difficulty in objectifying measures
	Higher acceptance level of own rules	Knowledge and willingness to self-regulate determine the functioning of the system
		Difficulty in dealing with moral hazards and risks that are difficult trace
		Difficulty in meeting social & political acceptance standards
		Focus on standards may lead to the loss of perspective on initial and main objective
Risk-based regulation		Possibility of information reduction
		Heavy administrative load for regulatees
		Many regulatory bodies with incongruous to even contradictory requirements
		Latitude concerning the use of medical technology complicates regulation
	Effective	Analytical basis can cause a false sense of security
Efficient	Difficulty in objectifying risks	
Analytical basis builds up legitimacy	Unequal treatment of regulates	
Accepts and aims to reduce risks	Possibility of becoming blind to new risks	
	Incongruity in outcomes of different risk-analyses causes confusion about priorities	

Responsive regulation	Adaptive	Difference in interpretation of interventions
	Builds up legitimacy	Responsiveness can be constrained by standards
	Cost-effective	Responsiveness can be constrained by public and political environment Punitive measures can have negative side effects

6. REGULATING THE USE OF MEDICAL TECHNOLOGY IN HOSPITALS

In the discussions of the various theories on regulation and the field analysis, I identified a number of risks that interfere with regulation on the use of medical technology. In the following paragraphs, I will explain the practical complexities of regulation. This includes some of the complexities that were already identified in the discussions of the various theories, which were reinforced by the information obtained in the field analysis, but also the additional complexities that were identified in the field analysis. In the explanations, I use examples that demonstrate how these complexities play out in the specific context of the use of medical technology, in order to show that regulation on the use of medical technology is quite different from other kinds of regulation.

COMPLEXITIES IDENTIFIED (EARLIER) IN THE THEORY

In system-based regulation some complexities were identified in the primary risks that still need to be regulated. As already explained, there is the risk of moral hazards, but the traceability of such risks can also be problematic. As seen in the Twenteborg case, the manufacturer was aware of the risks of overdue maintenance. However, since he would not be the one to account for the consequences, it was 'simply' decided to take the risk. This in turn led to doubts about the Inspectorate's current regulatory arrangement and questions whether the roles and responsibilities of the involved actors are clear. If risks are difficult to trace back, the regulator's work becomes even more complicated. Risks in the use of medical technology are highly dependent on a number of factors. To name a few, the functioning of the device, the training of the user, situational aspects such as the conditions in which the device is used or stored etc. Each factor serves as a condition supporting a safeguarding system. Even though each system should be able to overcome the risks of other systems, each system has its own risks. This may be proof that when something goes wrong, it is often a combination of latent conditions, and opens the way for questions such as: Who is to be blamed? Who will be held responsible? Who is liable?

Reason's so-called Swiss Cheese Model (figure 5) illustrates how defenses, barriers and safeguards can be penetrated by an accident trajectory. Each layer of cheese represents a defense, barrier or safeguarding system that should overcome the latent conditions of the previous. When it works, accidents are prevented, but in less fortunate circumstances all the layers can be penetrated by the accident trajectory. The Twenteborg accident is one of these unfortunate cases, where all the main actors in some way contributed to the cause of the latent conditions in the entire system, which eventually led to the fatal accident (see chapter 2).

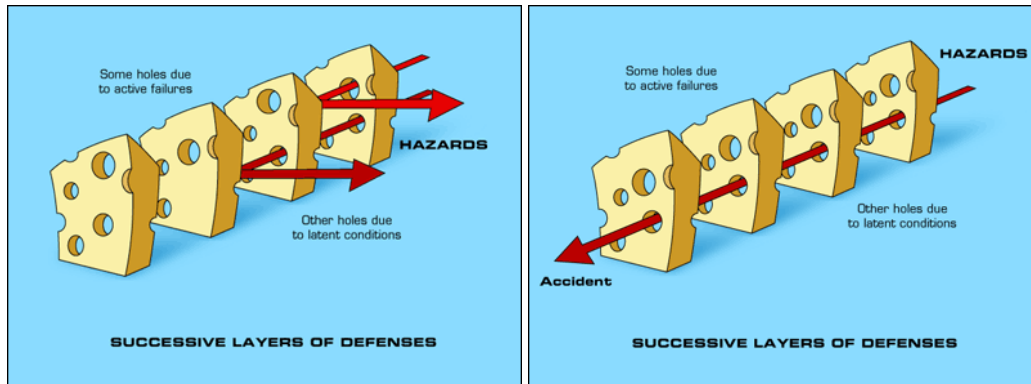


Figure 5: Reason's so-called Swiss Cheese Model [DUMC, 2005]

In the application of risk-based regulation for the use of medical technology, the main complexity is the identification of risks. Considering that advancement of medical technology is primarily to make the care environment safer -and indeed it does so to some extent-, one can imagine why risks with an extreme impact are considered to be extremely rare and difficult to predict beforehand. One may speak of the danger of becoming blind to new risks. The same developments in the health care system regarding medical technology, but also policy and administrative affairs that were primarily initiated to create a safer environment, have resulted in people having more confidence in the system. But this tendency could impede prospective predictability and thus increase the danger of becoming blind to new risks.

Responsive regulation allows the regulator to establish a suitable interventionist response to possible violations of standards. The main problem in this form of regulation is the difference in interpretation of the standards and the interventions. These aspects overlap with some of the difficulties that were identified in system-based regulation, namely the lack of mutual correspondence between components of system-based regulation and the complexity regarding the social and political perception of primary risks that need to be regulated. The first aspect includes the ambiguity in standards in the use of medical technology. The development of field standards is left to the people who work in the field, since they are considered the experts and therefore more capable to develop appropriate standards. And while the field is developing these standards in the form of quality indicators, the Inspectorate simultaneously imposes reports on quality assurance of medical devices in hospitals with recommendations on how this should be established. This creates a somewhat conflicting situation leading to confusion in the field as to what extent they have control over the development of field standards.

The second aspect concerns the interpretation of the interventions by the Inspectorate. The Inspectorate has a number of social and political obligations. Therefore the steering direction of the Inspectorate, particularly incident-based supervision, is often determined by the demands coming from the social and political environment. As to accountability and legitimacy, the Inspectorate tries to provide this by means of transparency. The complexity lies in the possibility that awareness of the obligations of the Inspectorate, cause hospitals to think that repressive measures are taken not so much because the interventions are justified or fair, but more because the Inspectorate has to fulfill its obligations towards the social and political environment, who demand stringent measures,

accountability and legitimacy.

COMPLEXITIES IDENTIFIED IN THE FIELD RESEARCH

The information obtained from the field analysis does not only confirm many of the complexities that impede/complicate regulation on the use of medical technology identified in the discussion of the theories, but it also gives insight into some additional complexities.

The actor analysis highlights the conflicting issues regarding the use of medical technology in hospitals. These conflicting issues show that there is a substantial gap between what the law prescribes and how this takes or can take form in practice. And while feasibility is the determining factor in the way things happen in practice, the factual circumstances show that legislation wins from practicability. The fact that legislation overrules practicability is an indication that one is losing sight of the main objective, i.e. to uphold the quality of care, and instead is focusing more on compliance with the standards. Hospitals have to face the dilemma of making things practicable and weathering the consequences when standards are violated. Manufacturers, on the other hand, are protected in the sense that they do not have any executive responsibilities. In many cases, their responsibilities are limited to giving instructions for use and maintenance of medical devices. Since they do not bear any responsibility in ensuring that their instructions are carried out, they can simply indemnify themselves against liability by providing the client with a manual. In such cases the Inspectorate is restricted in its current role of inspector because it only has to see to it that the law is complied with. The Inspectorate can only point out violations, although it is aware of the dilemma the hospitals have to face.

Honigh & Helderma (2009) point out that the components of system-based regulation are important and that there should be a mutual correspondence between the components. This seems difficult to realize if system-based regulation is applied in the use of medical technology. The problems that occur are explained by means of the following illustration. When things go wrong with a medical device, the parties at the user-end experience this first-hand. However, because of their limited knowledge on the technical aspects of medical technology, they may not be able to identify the error or describe the problem properly. Their report to the manufacturer will just give a shallow description of the event. The manufacturer in his turn has an entirely different field of knowledge, namely one that goes deeper into the technical aspects, and one can imagine that his interpretation of the report may be entirely different from what was intended. The manufacturer is obliged to forward the reports to the Inspectorate. However, the Inspectorate also has an entirely different field of knowledge, so again a different interpretation may be given to the problem. In the end, when the incident reports reach the Inspectorate, which -needless to say is a time-consuming process and substantially delays response time-, it may well be that the collected data deviate considerably from the actual event. This is illustrated in figure 6. Naturally, the number of reports is also important for adequate systematic analyses. In the case of a device that is rarely used, it is difficult to trace possible points of improvement due to lack of information.

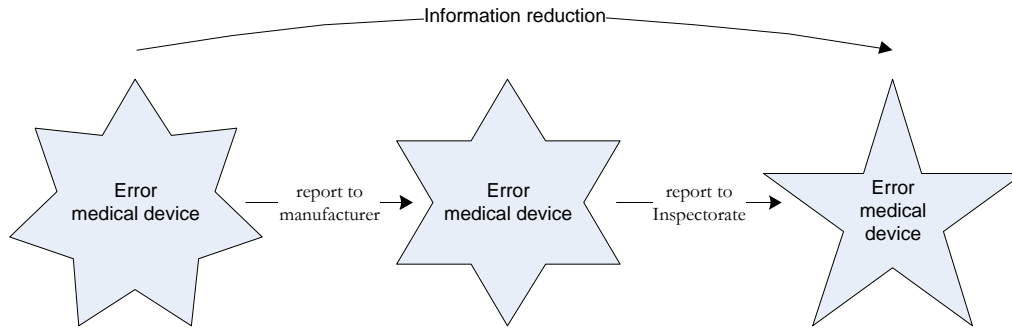


Figure 6: Explanatory model regarding information reduction

Respondents have also indicated that inspection visits and inspection reports are often an incentive to push issues that initially had low priority in the hospital. This shows that capture indeed does occur to some extent in the self-regulatory system of hospitals. Internal regulators are captured within the system, in the sense that they become dependent on internal information and higher authorities within the organization, so that they cannot execute their work properly. For instance, with regard to medical technology, there is a substantial gap between the responsibility that the Medical Instrumentation Department has to shoulder and the authority or authorization to make decisions.

The criticism on the Inspectorate's risk-based approach includes confusion in the hospitals regarding its priority-settings. Incongruous outcomes between the hospitals' risk analyses and those of the Inspectorate raise confusion about what risks deserve more priority.

Another finding is the administrative workload for the hospitals. Hospitals have to cope with so much administrative work that it is sometimes even considered a counter-productive development, in the sense that this is at the expense of care provision. The administrative workload is aggravated by the many regulatory bodies they have to deal with. It is remarkable that while the system-based approach aims to reduce the workload, this objective is not achieved because of more legislation and standards. The interview data also show the difficulty hospitals experience in determining and interpreting the Inspectorate's method of operation. This difficulty is not only caused by incongruous obligations and responsibilities of the actors towards each other and towards others, but the factual circumstances often play a part as well. Sometimes the regulatory bodies can set incongruous or even contradictory requirements.

An additional complexity that was identified in the field analysis is the latitude concerning medical technology in hospitals. In order to regulate the use of medical technology properly in a hospital, participation of the entire hospital staff is required. For example, modern medical technology sets requirements concerning the housing conditions, the user's competencies, etc. and therefore more attention should be given to the purchase of medical technological devices, taking into account the schedules of care providers, specialist knowledge for maintenance and so on. This means that the regulatory arrangement should also enable getting an overview of how the use of medical technology is regulated throughout the entire hospital.

RECAPITULATION

With the above, I have tried to clarify some of the complexities that occur in practice. The following chapter actually builds on all the opportunities and the risks in regulation that were identified in the chapters 4 and 5, but this chapter is essential because it elaborates the complexities that may arise in regulating the use of medical technology in hospitals. This chapter has illustrated how the identified regulatory complexities could play out in the specific context of medical technology in hospitals and it has become clear that a regulatory arrangement specifically aimed at the use of medical technology is quite different from any other kind of other regulatory arrangement. This supports that the design of the final assessment framework is specifically to evaluate a regulatory arrangement on the use of medical technology in hospitals, which will be discussed in the following chapter. The table below provides an overview of the complexities discussed with a brief contextual explanation about the use of medical technology in hospitals.

Table 5: Overview of the complexities discussed (identified in the theory)

Complexities specific to regulation on the use of medical technology in hospitals

The risk of capture in internal regulatory systems of hospitals

Moral hazards are inevitable when using medical technology and therefore the possibility to pass on responsibility for risks taken increases

Focusing too much on standards may cause that one loses sight of the main and initial objective, which is to maintain the quality of care

The possibility of information reduction

Incongruous outcomes of different risk analyses can cause confusion about setting priorities

Difficulty to meet the social and political acceptance standards

System-based regulation entails a heavy administrative workload on the part of the hospitals reducing precious time required for the provision of care.

Many regulatory bodies with incongruous or even contradictory requirements

The incongruous obligations and responsibilities of the actors towards each other and towards others, but also the factual circumstances the actors find themselves in, may result in ambiguous interpretations of the Inspectorate's method of operation

The latitude concerning medical technology throughout the hospital complicates its regulation

PART B: DESIGN & EVALUATION

This chapter focuses on the development of an assessment framework. The assessment framework will be used for the evaluation of the current regulatory arrangement of the Inspectorate. These findings will help to make recommendations for improvement to the Inspectorate.

7. DEVELOPING AN ASSESSMENT FRAMEWORK

The previous chapters highlighted a number of opportunities and risks of the different types of regulation, specifically on the use of medical technology in hospitals. The amended regulatory arrangement should be designed in such a way that it both utilizes the opportunities and prevents or reduces the risks. Furthermore, as the Inspectorate's current regulatory arrangement consists of a combination of different regulatory theories, the assessment framework also provides standards, anticipating a workable combination of the theories. The design approach is represented in figure 7.

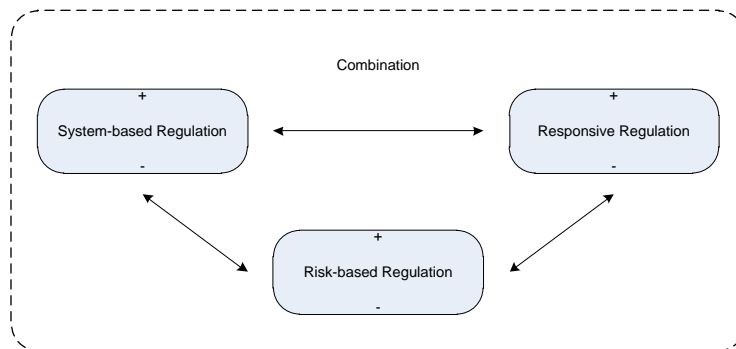


Figure 7: Design approach of the assessment framework

TRANSFORMATION OF RISKS INTO STANDARDS

Standards arise from the specific context in which they will be applied. In this case the context is the regulatory arrangement on the use of medical technology in hospitals. Many different aspects are involved. Table 4 (chapter 5) provides an overview of all the identified complexities and the following paragraphs will address each of these with an explanation that can help in the development of standards.

Difficulties in system-based regulation

Retreating from inspections in the primary process

One danger of system-based regulation is the possibility that the focus on verification inspection may gradually shift to paperwork. This complexity arises from the idea that if procedures are arranged properly, performance will also be good. It creates a tendency to confine the inspection procedures to the paperwork, presuming that the actual inspection was really done. This symptom is reinforced

by the discovery that inspectors gradually alienate from the primary process (of actual inspection) when the focus is just on paperwork instead of on-site verification inspections [Breukers & van Gestel, 2004]. With the advancement of medical technology, the probability of alienation from the primary process is even higher as this field is becoming more and more complex and requires specialized expertise. This is represented in figure 8 below. To overcome this issue, organizational and technical adjustments are required, whereby professionalism of inspectors will play an important role.

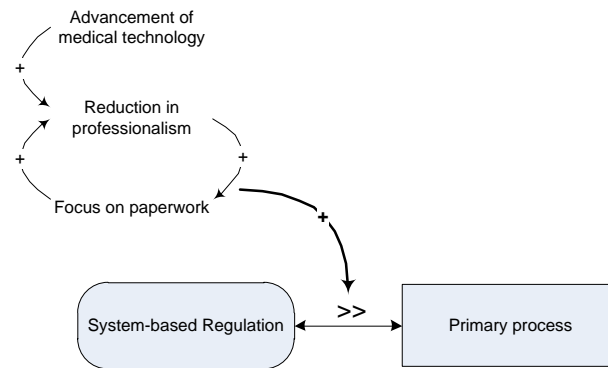


Figure 8: Explanatory model regarding withdrawal from primary process

Possibility of capture, latitude concerning medical technology

System-based regulation also entails the possibility of capture within the internal system that is regulated by the Inspectorate. Hospitals have indicated that inspection visits and reports provide incentives to give initially low priority issues the attention they really deserve. Since self-regulation hovers somewhere between command and control and no governmental involvement at all, system-based regulation may be given a position where there is still a considerable amount of government involvement, but also a high degree of self-regulation. Maintaining a high-degree of self-regulation ensures the utilization of the opportunities of system-based regulation. At the same time, (limited) government involvement can reduce the degree of capture, in the sense that it can compensate in the democratic legitimacy to enforce, which the self-regulatory system lacks. In hospitals issues regarding medical technology are often left to the Medical Instrumentation Department. The Medical Instrumentation Department is a technical, specialist department that is hierarchically and physically located in the lower part of the organization. Their (administrative) authority to (help) make decisions is minimal, although they could give highly specialized advice to the higher echelons of the organization because they have the know-how. To reduce the possibility of capture occurring in the internal system, the (new/amended) regulatory arrangement should also take into account the internal organizational structure and monitor how medical technology is regulated throughout the entire hospital.

Difficulty in objectifying measures

The current development towards indicators is an interesting approach that may be used to overcome the complexity of objectifying measures. Patient safety and quality of care are assessed by means of indicators that (indirectly) give some information about patient safety and quality of care. The implementation of these indicators started off with a quick and dirty set with the slogan 'better

done, than perfect' [van den Berg et al. 2009]. And while there is still some uproar about the validity of these indicators, they have undergone quite a development since they are annually assessed. The difficulty with indicators is the difference between structure, process and performance indicators. There was a withdrawal from performance indicators because of the danger that the focus would be on the performance rather than on the main objective. However, structure and process indicators also entail quite some complexities. All in all, the development of indicators seems a plausible solution for objectifying measures. However, continuous evaluation by a collaboration between the Inspectorate and the field is essential. The indicators can thus be further developed, particularly their validity.

Knowledge and willingness to self-regulate

The knowledge and willingness to self-regulate is largely dependent on the self-regulatory organization. However, the Inspectorate can assist here by taking on a more cooperative role, instead of imposing implementation rules. This standard regards the more behavioral aspects of the Inspectorate. By means of frequent consultations with the organizations concerned, the Inspectorate can design measures that are acceptable to all parties involved. Here, too, continuous assessment is essential. Collaboration between the Inspectorate and the field will also reduce the confusion and ambiguity about the Inspectorate's method of operation.

Moral hazards and risk traceability

The possibility of moral hazards and the difficulty to trace back risks make it extremely hard to regulate the use of medical technology. These difficulties are mainly due to the multi-actor environment. There are many actors involved in the use of medical technology in hospitals: the external and internal regulator, the designer, the buyer, the medical instrumentalist, the user and the beneficiary of medical technology, just to mention a few. Some of these actors have decision-making powers that give them control over matters they sometimes know little about. It is true that the allocation of authorities is not randomly granted, but the authorities do not always correspond with the responsibilities. This creates the possibility that risks arise, the responsibility is passed on and risk traceability is almost impossible. The regulator often only detects this when an unfortunate incident, resulting from such risks, occurs. Such risks can be reduced by holding the main group of actors accountable for the shared, interconnected responsibility, namely the provision of good quality of care, with the focus on patient safety. The triangle of the main actors -the hospital, the manufacturer and the Inspectorate- was already given in chapter 2, figure 1. From the notion of collective responsibility in which one leading ideology is shared by a group [Kroesen, 2006], the concept of some kind of shared accountability can be derived. Bovens (2007) analyses and assesses the concept of (narrow) accountability, which he defines as '*a relationship between an actor and a forum in which the actor is obliged to explain and justify his conduct; the forum can pose questions; pass judgment; and the actor may face consequences*' (p.452). He distinguishes different types of accountability by posing four important questions, namely:

- (1) Accountability to whom?
- (2) Who should be held accountable?
- (3) Accountability for what?
- (4) Why should/does the actor feel compelled to render account?

Within the specific context of the regulation on the use of medical technology in hospitals, these questions can be answered as follows. (1) Accountability is due to the public at large or at least, to the relevant stakeholders, such as interest groups and patient associations. (2) Each of the main actors involved should be held accountable. As these actors are apart and independent from each other, the most suitable strategy to deal with accountability would be to hold each actor proportionally accountable for its actual contribution to the conduct of the (entire) group. A precondition of shared, interconnected responsibility is that the individual responsibilities should link up with each other perfectly. (3) Accountability for the quality of care in which patient safety is the focus. This includes that the actor(s) should account for the process and/or procedural aspects of care provision. (4) As the actors who should render account are three separate actors, independent from each other, the nature of their obligation will also differ. The current regulatory arrangement already requires accountability of the hospital and the manufacturer to the Inspectorate. This system largely corresponds with vertical accountability, in which the forum, in this case the Inspectorate, has the power over the actor, i.e. the hospital and the manufacturer. The Inspectorate in its turn will have to inform the public at large, which corresponds with diagonal accountability, as it concerns an indirect, two-step relationship in which the public at large is the forum. The nature of the obligation is entirely different when the Inspectorate is considered the actor and the public at large the forum. In such a situation, there is no hierarchical relationship, so that the Inspectorate cannot be compelled to render account, but should do this on a voluntary basis with no intervention on the part of the forum. This type of accountability is more like a moral obligation. The purpose of this accountability arrangement is mainly to induce actors to change their behavior in accordance with the desirable societal outcome, which is provision of good quality of care, and to enhance the learning capacity and the effectiveness of the Inspectorate.

Social & political acceptance standards

Meeting the social and political acceptance standards regarding the use of medical technology is tough and is largely related to several of the Inspectorate's formal obligations. While the social and political environment have some awareness of the risks that are involved with the rapid advancement of medical technology, their confidence in the health care system is such that the risks are generally accepted, until something goes wrong. This attitude is reinforced by the media, who have the habit to sensationalize unfortunate events. In order to get social and political acceptance, the Inspectorate has to meet demands regarding transparency and legitimacy, which could lead to some of the complexities that were identified in responsive regulation. The demands of the social and political environment seem to conflict with the Inspectorate's obligation towards its regulatees, since they constrain the Inspectorate's responsiveness and also influence the regulatees' interpretation of the Inspectorate's interventionist response. The demands of the social and political environment may be the result of their high expectations of the health care (regulatory) system or their underestimation of the risks that are involved with the advancement of medical technology. The amended regulatory arrangement should be able to deal with the bickering of the field of tension in which the Inspectorate operates.

Possibility of losing sight of the main objective

The danger of the current focus on standards is that one can easily lose the perspective on the initial and main objective. In the drive to create a safer health care environment many new developments are taking place, which should actually support the creation of a safer environment. Somewhere along the way, however, sight is lost of the initial and main objective due to the growing complexity of the medical field, the increasing number of actors, priorities that seem more urgent, etc. Instead of promoting safety, the categorization of medical devices into various risk classes is increasingly misused as a means to avoid more stringent requirements regarding clinical studies and high costs. The training of medical practitioners is more based on meeting the requirements than on passing on more knowledge and skills. This complexity is related to the other complexity that the focus is now more on paperwork than on actual verification inspections. The inspection on paperwork merely accomplishes strict compliance with laws and standards, whereas verification inspections can provide a better picture of the circumstances and the outcome or performance of procedures. Verification inspections provide far more information than what is put on paper.

Incongruous requirements by regulatory bodies, administrative load

Cooperation between the many regulatory bodies and collaboration with and within the field can reduce the administrative load for regulatees. Agreements on joint inspection visits by more supervisory bodies or clear agreements on information exchange between the regulatory bodies will prevent that the regulatee has to provide the same information over and over again. This will also provide the opportunity to circumvent any confusion on contradictory requirements by different supervisory bodies. Cooperation with and within the field regarding risk-analyses, setting priorities based on mutual cooperation and exchange of best practices can also reduce the workload for regulatees.

Difficulties of risk-based regulation

The previous discussion on risks is closely related to some complexities of risk-based regulation namely the difficulty of objectifying risks and the possibility of becoming blind to or overlooking new risks. The development of medical technology works in two rather contradictory ways. On the one hand, it enhances safety in the medical field and on the other hand, it reduces safety in the sense that the environment cannot keep up with the fast progress, which creates other unknown risks. This rather contradictory development of medical technology may cause the actors involved to overlook the new risks, which will in turn hamper the objectifying of risks. Another complexity identified by the field in risk-based analysis is the incongruity in the outcomes of different risk-analyses. Both the Inspectorate and the hospitals make their own risk-analyses on health care processes. As each of these individual organizations deal with different circumstances, their risk-analyses tend to differ. This causes confusion in the field in which risks deserve the highest priority. To overcome all these complexities, the amended regulatory arrangement should facilitate collaboration and consultation with and within the field regarding risk-analyses. This will provide insight into the multiplicity of risks, and reduce the possibility of overlooking (new) risks. It will also enable collective thinking on how to objectify the identified risks, a more objective perception of those risks, and a joint approach on how to address them. Such an improvement will ensure that the risk-based approach is not only

analytically based, but also well thought-out. Collaboration and consultation will strengthen the opportunities of risk-based regulation even more by increasing its effectiveness and efficiency, while maintaining its principle to accept the inevitability of risks and reduce them. Consultation will enhance legitimacy even more. This approach of risk-based regulation will also give the regulatees the feeling that they are equally treated. Regulatees who are closely monitored for a period when a certain policy prevails because of risks that have high priority then, may be ‘exempted’ in another period when other risks receive high priority.

Difficulties of responsive regulation

When there is an unambiguous understanding of both the standards and the interventions, the opportunities of responsive regulation are fully utilized. However, in practice, things are quite different. A good way to overcome the possibility of ambiguous interpretation of standards, is to leave the development of field standards to the field, and consult the Inspectorate only when necessary. However, strict focus on conformity with standards can constrain responsiveness. Besides, when repressive interventions have negative side effects, these are also less likely to be considered justified and legitimate. Transparency regarding the use of repressive measures may enable regulatees to anticipate the inspection and so compromise its effectiveness.

STRENGTHENING THE COMBINATION OF REGULATORY THEORIES

Each of the regulatory theories has opportunities as well as risks. However, as the framework should serve to assess the Inspectorate’s regulatory arrangement in its entirety, it is important to consider the combination of theories. Table 2 in chapter 4 provides a brief overview of the basic principles of each theory, serving as a tool to compare the theories. This section will compare the theories with each other and develop standards strengthening the combination of the regulatory theories.

System-based versus risk-based regulation

Both system and risk-based regulation have an approach to make regulation more selective. While system-based regulation establishes this by shifting towards self-regulation, risk-based regulation tries to prioritize. With the prevailing vision to make regulation more selective, the combination of these theories seems plausible since they strengthen each other in this aspect. The combination of system and risk-based regulation makes a really selective regulation approach, in the sense that the range of inspection is already considerably reduced when regulating on system-level and will be reduced even more when it is also risk-based. An incongruous issue in the combination of system and risk-based regulation is that the standards in system-based regulation are based on process oriented specifications and therefore on the throughput. In risk-based regulation the standards are based on the risk that an activity may pose and therefore on the output. In this sense, risk-based regulation can be considered complementary to system-based regulation, as it takes one additional step by also

considering the output of an activity.

System-based versus responsive regulation

System-based regulation and responsive regulation overlap in that they both contain the concept of self-regulation. This concept is more fundamental to system-based regulation than to responsive regulation. However, in the responsive regulation theory, there is the concept of enforced self-regulation, in which there is government involvement to oversee the process of self-control. And while enforced self-regulation has a negative connotation, because it is enforced, some government involvement is desirable because it will reduce the possibility of capture in the internal self-regulatory system. Furthermore, enforced self-regulation still requires a great deal of confidence in the self-regulatory capacity of the regulatee, but by involving the government, there is some degree of security. With regard to the regulator's capacity to influence the behavior of the regulatee, responsive regulation complements system-based regulation with the enforcement pyramid. The pyramid is a systematic method to determine an appropriate interventionist response.

Risk-based regulation versus responsive regulation

A common advantage of risk-based regulation and responsive regulation that was identified in the discussion of the theories is that they both enhance legitimacy. Risk-based regulation establishes this by means of its analytical approach, while responsive regulation tries to enhance legitimacy by means of its enforcement pyramid to determine an appropriate interventionist response. However, in practice things are quite different. According to the Inspectorate's definition, regulation has three phases, namely data collection, formulating an opinion and intervening, if necessary. Risk-based regulation ensures legitimacy in the first phase, while responsive regulation establishes this in the intervention phase. In practice, the risk-based approach does not accomplish what it should, as risks are not equally relevant to all regulatees. They are confused and feel that they are burdened with extra work to address risks that are less or even irrelevant. When they do not comply and are disciplined by means of a repressive interventionist response, regulation can lose its legitimacy altogether. The principle of responsiveness in responsive regulation can overcome this. However, this requires a certain level of professionalism, since regulators will have to devise measures tailored to the particular circumstances.

ASSESSMENT FRAMEWORK

When analyzing the complexities, it becomes clear that these complexities either have to do with the issue of a multi-actor environment, issues of a more organizational and technical nature, or issues regarding the formal obligation of the Inspectorate. These are the three main issues that underlie the complexities and possibly also the issues that need to be addressed. With the insights that were obtained in the previous sections of this chapter, it can be concluded that these issues are:

- (1) a multi-actor environment;
- (2) organizational structure and technical adjustments; and
- (3) balance in the Inspectorate's formal obligations.

For the design of the assessment framework, the above grouping was used. The framework consists of three fields that refer to these issues and establish the nature of the standards. The previous sections of this chapter highlighted the important considerations regarding the development of standards for the assessment framework. Wherever possible, the standards take these considerations into account.

The framework is intended as an assessment tool for the Inspectorate. Currently the framework does not include a detailed description of the terms of reference, but it can be interpreted as a normative checklist or guideline to verify if the standards are imbedded in the regulatory arrangement. Neither does the framework include an aspect that allows for a measurable assessment, but it can still give a good indication of the extent to which these standards are imbedded in the regulatory arrangement, by looking at the way they are embedded. The assessment framework is presented below.

Table 6: Assessment framework

	Central idea	Standard
Multi-actor environment	A shared accountability arrangement will hold each of the main actors involved equally accountable for its individual responsibility and contribution to the shared, interconnected responsibility.	A balance in the degree to which each of the main actors involved is held accountable/ answerable in the shared, interconnected responsibility. Special attention should be paid to the potential interface problems that may occur between the (individual responsibilities of) actors.
	Cooperation with the field will enhance an unambiguous interpretation of the regulatory approach as to how compliance with which aspects will be regulated. However, it should be noted that transparency regarding interventions can compromise the effectiveness of the interventions.	Effective and efficient cooperation with the field regarding further development of self-regulatory systems, sharing risk data, setting risk-based policy priorities and the development and continuous evaluation of field standards.
	Cooperation with other supervisory bodies can reduce the heavy inspection workload and provide an integral perspective on the performance of a regulatee under the given circumstances.	Effective and efficient cooperation with other relevant supervisory bodies regarding integral regulation, information exchange and incongruous requirements.
Organizational and technical standards	Government involvement in an enforced self-regulatory arrangement will ensure the utilization of the opportunities of system-based regulation, while at the same time, it will reduce the degree of capture and maintain the democratic legitimacy to enforce.	Enforced self-regulation with limited government involvement; the government's role is balanced; in the beginning cooperative, supportive and advisory, yet they keep the authority to take repressive measures when necessary and legitimate.
	Professionalism will enhance inspections on the primary process and reduce the probability that professionals alienate from the primary process.	Balance in professionalism regarding medical technology and efficiency in regulation, leaving enough room for frequent verification inspections (at random) that also cover the organizational structuring of medical technology.
Formal obligations	A balance in the formal obligations will ensure that there is an equal distribution in the degree to which the (sometimes rather contradictory) obligations are met.	Balance in the formal obligations towards the social and political environment on the one hand and towards the regulatees on the other.

8. EVALUATION

In this chapter the Inspectorate's current regulatory arrangement will be evaluated by means of the assessment framework designed. Each of the three fields distinguished will be addressed separately. As the different standards overlap here and there, they are not all discussed separately.

MULTI-ACTOR ENVIRONMENT

Shared accountability

Currently the Inspectorate considers itself only responsible for supervision on the Supervisory Board of a hospital. However, as the use of medical technology in hospitals requires involvement of a group of main actors, this means a shared, interconnected responsibility of the hospitals, the Inspectorate and the manufacturer. Currently, however, it is mainly the hospitals that are held accountable, while the other actors get off scot-free.

Cooperation with the field

As this is a matter of enforced self-regulation in the field of care, it is of importance that the Inspectorate compensates for the regulatees' lack of knowledge about self-regulation. Rather than stimulating intrinsic motivation to self-regulate, the Inspectorate's current attitude and approach give regulatees the feeling that self-regulation is forced upon them. As a regulatory body, the Inspectorate is the most likely agency to have expertise in regulation and it can therefore assume an excellent cooperative, supportive, but more importantly, advisory role in this process. If the Inspectorate takes on this role, it is not only likely that the field will cooperate, but the intrinsic motivation to self-regulate will also grow.

One difficulty of the risk-based regulation approach by the Inspectorate is that not all regulatees are treated equally. High priority risks can be present in some hospitals but not in others. This is against the Inspectorate's principle of equal treatment, but it has also caused a stir in the field. Hospitals have indicated that the Inspectorate's priority settings often do not agree with theirs. This not only causes hospitals to address a multiplicity of aspects, which is often more than they can handle, but it also causes some 'frustration' at the administrative level about the direction. Which aspects deserve high priority? Should the hospital address aspects that turned out to be high-risk after an internal risk-analysis and run the risk of being disciplined by the Inspectorate for failing to meet their requirements? Or should the aspects that the Inspectorate indicated be addressed, while risking accidents as a consequence of not following through on the internal risk-analysis? Currently, the Inspectorate's cycle of enforcement gathers information from the field and bases its risk-analysis on this information. The outcomes of the risk-analysis are then prioritized without any consultation with the field. However, if the Inspectorate consulted the field first, it could make a considerable difference in the effectiveness and efficiency of the current regulation, since this would not only result in agreement of priorities, but also create a sense of cooperation with the field. The way in

which the Inspectorate currently makes use of the risk-based regulation approach is not optimal, in the sense that the opportunities that this approach offers are not fully utilized.

Currently there is already some cooperation with the field on the development of field standards on the use of medical technology²¹. This, however, mainly concerns field standards on the management of medical devices, rather than on the actual use. The existing quality indicators that are often used include indicators that can provide insight into the entire care process and therefore also include the use of medical technology, if part of the care process. Phased supervision can ensure data collection on a structural basis regarding the use of medical technology, which is currently still lacking, with indicators that provide specific information on the use of medical technology.

The developments on the establishment of a blame-free culture in the field of health care including the introduction and implementation of the safety management system in hospitals seem to be rather positive as far as safety is concerned. The safety management system is an internal system of hospitals that should support their self-regulation. This is a reporting system that allows practitioners to safely report incidents²². The reporting system collects the various incidents, makes it possible to perform systematic analyses and improve, where necessary. Would it be possible to apply this system in the use of medical technology? The first question that comes to mind is how it will work out. The following may serve as a refresher. PMS is an obligation that manufacturers have to institute a systematic procedure to review experience gained from devices in the post-production phase and to implement means to apply any necessary corrective actions, in the pursuit of continuous product improvement. As already stated, PMS was instigated by the Inspectorate, but since it is rather troublesome to carry out, manufacturers do not satisfactorily fulfill this obligation, and it also almost impossible for the Inspector to act upon it. In the first place, it is difficult to keep up with the rapid developments in technology and therefore with the short life-cycle of the equipment. Secondly, it is hard for external parties to get access to internal information. However, this is a matter for the Inspectorate to get a better grip on things, since this is how valuable information can be obtained about the use of medical technology. The PMS obligation holds the manufacturer partly responsible for monitoring the use of medical technology. Manufacturers can be held answerable for not adequately fulfilling this obligation and more active monitoring may help bring about a change in their lax attitude.

This leads to a discussion which also regards the danger of overlooking new risks. The 2008 State of Health Care Report states that training of personnel is inadequate and that this poses a risk. This is undoubtedly an issue, but too often the blame is put on the user's end. Besides the fact that training costs a considerable amount of time and money, it is also difficult to maintain continuity in the training. Because the notion that inadequate training is the risk at stake is deeply imprinted in their minds, hospitals tend to focus on this issue. However, a look on the designer's end may produce some enlightening new insights. PMS information can provide these insights.

²¹ Prestatie-indicatoren Kwaliteitsborging Medische Systemen, NVKF, 29 mei 2007

²² Safe reporting of incidents (veilig incident melden) does not only refer to the objective to promote a safer environment by means of learning from incidents, but also refers to the ability to establish a blame-free culture in which practitioners can talk about their mistakes without the fear of having to weather severe consequences, unless a culpability test proves otherwise.

Cooperation with other relevant supervisory bodies

The Inspectorate's current instrument of incident-based supervision requires some improvements. Information regarding incidents is currently making a detour before it reaches the Inspectorate. This can cause information reduction up to the point that the information is unusable. This is mainly due to the incongruous knowledge field of the chain of actors, through which the information flows. However, this can also be because certain actors, namely manufacturers, have commercial interests at stake should this information reach the Inspectorate. At the moment there is no encouragement to establish direct communication lines between the hospitals and the Inspectorate regarding incident-reporting. By short-circuiting the communication line regarding incident reporting between the hospital and the Inspectorate while maintaining the current communication line between the hospital and the manufacturer, information reduction will be minimized. It will also provide an extra control to monitor manufacturers. In case this entails too much of an administrative load, the setup of the user's platform can be considered. Such a platform can establish data collection from and exchange between users regarding experiences with the use of specific medical technology. A users' platform will benefit all the main actors, as it will most likely result in more user-friendly improvements of medical technology and will shift the administrative load regarding incident reporting with medical technology from the Inspectorate to an external party.

Incident-based supervision is perhaps the most controversial instrument of the Inspectorate. While the aim is to protect and promote the quality and safety of care (currently there is a focus on attaining this by focusing on the prevention of incidents), incident-based supervision is based on the occurrence of incidents. The idea is that valuable lessons can be learned from incidents. This is true indeed and the Twenteborg accident is an excellent example. It is because of experiences with accidents like these, that many people think that incidents are the most productive triggers for improvement. Therefore, why not focus on incidents, since they will surely produce more incentives that may lead to improvements for the future. However, the focus on incidents also can have a counterproductive effect on the societal objectives. It can cause society to forget about the level of safety that has been achieved so far and reduce the sense of security.

In any case, accidents can happen. However, the Inspectorate believes that it is possible to promote quality in the use of medical technology by means of a quality assurance system for the entire cycle of usage of medical devices in hospitals. A few years ago, the Inspectorate tried to establish this with thematic reports on quality assurance, but the impact of these reports was minimal. Upon the Inspectorate's introduction of the current safety management system, questions were raised about the project's durability. But this project seems to have more impact, possibly due to perseverance from the part of the Inspectorate. The safety management system is not specifically aimed at medical technology, but with a few adjustments, it could replace the current quality assurance system, and thus reduce the number of self-regulatory systems. The safety management system can cover all the different phases in the cycle of usage ranging from purchasing to depreciation, just like the quality assurance system. The Inspectorate has entered into an agreement with NIAZ about the current safety management system. This agreement concerns mutual collaboration, in order to prevent extra work for hospitals. In other words, when NIAZ has assessed a hospital on safety management system elements and the results are positive, this hospital will not be assessed again on these elements by the Inspectorate. This kind of agreement could also be applied by adjusting the safety management system in such a way that the focus is more on medical devices. The NIAZ has already

set up several standards for an adequate arrangement concerning the use of medical devices in care processes, which gives an overview of the entire life cycle of medical devices²³. The Inspectorate can make use of these standards and expand these. Apart from such aspects like purchasing and maintenance, the NIAZ standards also pay attention to adequate training of personnel. This was one of the problematic aspects that were identified in the 2008 State of Health Care Report.

ORGANIZATIONAL AND TECHNICAL STANDARDS

Enforced self-regulation with limited government involvement

The current policy of the Inspectorate is more directed towards enforcement than towards cooperation. The Inspectorate should maintain the authority to actually enforce compliance with the law, but a more cooperative, supportive and advisory attitude may prove to be more effective in achieving the ultimate goal, namely improvement of patient safety. Repressive measures should be imposed only for legitimate reasons. However, exceptions make the rule, and since prevention is better than cure, it is understandable that repressive measures are sometimes imposed as necessary precautions. In hindsight the imposition of repressive measures in some cases may have proved to be unnecessary, causing considerable damage to hospitals and the Inspectorate. Good communication in which the Inspectorate does not merely provide information to the general public, but rather explains and justifies its conduct, can prevent such damage. This also brings us back to the behavioral aspects of the Inspectorate. The Inspectorate should be able to admit its mistakes or misjudgments.

Professionalism versus efficiency

Because regulation is such an ambiguous concept, it is difficult to define. However, the General Inspectorate of the Netherlands managed to give a definition for what they consider to be 'supervision' and a definition for system-based regulation. This shows that the General Inspectorate has come a long way at least within Van der Heijden's (2009) characteristic of certainty (see chapter 4); because of these definitions, it is quite clear what is meant by regulation and how this takes place. And as the General Inspectorate is a kind of umbrella organization of all governmental inspectorates, these definitions of supervision and system-based regulation also apply to the Health Care Inspectorate. However, each inspectorate has to adjust its regulatory arrangement to match with its own history, its own identity/character and the legislation it has to uphold.

Within the Health Care Inspectorate, it was determined that the previous classical and labor intensive manner of regulatory execution was no longer feasible. This was the first step towards system-based regulation [Helderman & Honigh, 2009: 65]. The Quality Care Institutions Act also corresponds with the idea of system-based regulation, in the sense that this Act implies that care institutions should self-regulate and the regulator has the responsibility to oversee this process. The Inspectorate's current regulatory arrangement regarding the use of medical technology in hospitals can be

²³ NIAZ Kwaliteitsnorm 2.1, Chapter 4.4 Management van middelen

characterized as enforced self-regulation, whereby the hospitals have to establish a high degree of self-regulation by means of the current safety management system and quality assurance system. However, the extent of government involvement needs to be reconsidered, particularly regarding the level of detail in the responsibility to oversee the quality in task-execution.

Policy documentation and discussions with the administrative board dominate in current on-site inspection visits, while equal distribution of paperwork and verification inspection would probably provide more insight into the situation. The current shift towards system-based regulation has created a tendency to focus on paperwork rather than on verifying how and if the documented procedures really take place in practice. As suggested in chapter 7, this may have something to do with insufficient expertise on medical technology on the part of some inspectors. However, verification inspections are needed to regulate the use of medical technology, since it has appeared that not everything that happens on the shop floor is documented. The Inspectorate seems to be satisfied with well-organized policy documentation. Although this is inherent to both the requirements and the Inspectorate's rationalizations, it may lead to fewer verification inspections. A verification inspection does not only keep the inspector's knowledge/expertise on edge, but it also creates the opportunity for the inspector to gain experience in the circumstances, so that he can devise tailored measures for improvement.

A common factor regarding the internal regulation of medical technology in hospitals that could lead to problems is the organizational structure. It is a well-known fact that the Medical Technology Department is generally placed at the lower level of the organizational hierarchy and has little or no decision-making power. Although it is difficult for the Inspectorate, as an external party, to order organizational restructuring, it can still provide valuable advice in this respect. The Medical technology Department is a crucial in the use of medical technology and should therefore be more involved in the regulation process. So far, the Inspectorate has not given sufficient attention to this aspect.

FORMAL OBLIGATIONS

Balance in formal obligations

The media are a means of communication between the Inspectorate and society. However, the media play a 'dirty' role by magnifying unfortunate events, provoking the Inspectorate to show its teeth. The Inspectorate gets little or no recognition when things go well, but is blamed for the smallest mistake or shortcoming [Mertens, 2001-2009: 113]. The role of the media makes it difficult for the Inspectorate to find the exact ingredients for a justified intervention tailored to the circumstances, without losing society's confidence in the system. In order to prove its legitimacy to the social and political environment, compromises have to be made.

Formal obligations versus effectiveness

How transparent should regulation be, considering the media's influence on society? How can the Inspectorate establish legitimacy, considering that only repressive measures and/or outstanding performance are well accepted by the media? How independent is the Inspectorate really? Many people think that the Inspectorate's operations, particularly its interventions, are influenced by the media and the political and social environment. Establishing a balance in transparency and legitimacy on the one hand and independence on the other is a tough job. Good communication, including clear explanations and justifications of its conduct, especially concerning its policy and accountability, may be the answer. One should keep in mind, however, as explained in the previous chapter, that transparency regarding the use of repressive measures gives regulators the chance to anticipate and so may compromise the effectiveness of the Inspectorate's measures.

RECAPITULATION

The aim of this chapter was to identify some of the Inspectorate's shortcomings regarding regulation in the use of medical technology in hospitals, which can be translated into useful recommendations for improvement. Mostly because of its contradictory obligations towards those it has to regulate and towards the social and political environment, the Inspectorate has to make compromises. The following chapter includes some conclusions regarding the research questions and also some general conclusions, and the subsequent chapter addresses the recommendations that were derived from the shortcomings identified in this chapter as well as some general recommendations.

CONCLUSIONS AND RECOMMENDATIONS

The aim of this research was to assess the Health Care Inspectorate in terms of its regulatory arrangement regarding the use of medical technology in hospitals. This has been done by means of an assessment framework. This part of the report contains the final conclusions of the research and some recommendations to the Inspectorate.

9. CONCLUSIONS

This chapter includes the conclusions with the answers to the sub research questions as well as some general conclusions that can be drawn from the research. Considering that the formulation of the main research question focuses on recommendations towards the Inspectorate, this question will be answered in the final chapter.

CONCLUSIONS REGARDING THE RESEARCH QUESTIONS

A. Analysis

1. How does the Inspectorate currently carry out inspection on patient safety in the use of medical technology in hospitals? (Chapter 3)
2. Who are the other actors involved in patient safety in the use of medical technology in hospitals and what are their interests? (Chapter 5)
3. What existing theories, models or concepts of regulatory arrangements could be used for comparison with the Inspectorate's current regulatory arrangement? (Chapter 4)
4. What are the typical complexities of regulating the use of medical technology in hospitals and how do they impact on assessments of the regulatory arrangement? (Chapters 4 and 5)

The analysis has shown that the Inspectorate's current regulatory arrangement includes a cycle of enforcement that is based on a combination of three regulation theories, namely system-based regulation, risk-based regulation and responsive regulation. Within the regulatory arrangement, there are three instruments for inspection. Phased supervision is rather structural, while thematic and incident-based supervision have a more incidental character. The Inspectorate regulates the production and trade of medical technology as well as its use. The use of medical technology is (currently) mainly monitored by means of thematic and incident-based supervision. However, there is also monitoring by means of quality indicators, which are used for phased supervision on entire care processes. And while there is a distinct difference between the regulation of the production and trade of medical technology and the regulation on the use of medical technology, the field analysis has shown that the main actors -the Health Care Inspectorate, the manufacturers and the hospitals- have a lot of collective responsibilities but different individual interests regarding the use of medical technology. For this reason, it is difficult to maintain the distinction between the two regulation branches. Both the theoretical research and the field research have shown that each of the regulation theories entail many opportunities and risks that are also relevant when applied to the regulation on the use of medical technology in hospitals (see table 4, chapter 5).

B. Design & Evaluation

5. How can an assessment framework for the evaluation of the Inspectorate's regulatory arrangement be designed, taking these complexities into account? (Chapter 7)
6. How can the strengths and weaknesses of the Inspectorate's current regulatory arrangement -that were identified in the evaluation- be translated into recommendations for improvement of patient safety in the use of medical technology in hospitals? (Chapter 8)

Taking into account that the Inspectorate uses a regulatory arrangement of a combination of three theories, each of them with its own opportunities and risks, the simplest norms were used to develop the standards for the assessment framework. These include (1) utilize the opportunities, (2) overcome the risks, and (3) strengthen the combination of the theories. The different regulation theories when applied in the specific context of the use of medical technology in hospitals have shown some theoretical and practical complexities. Since the fundamental principles show some overlap and similar or related complexities, it was possible to distinguish three main fields, establishing the nature of the standards, namely a multi-actor environment, organizational and technical standards and formal obligations.

In the evaluation of the Inspectorate's current regulatory arrangement by means of the assessment framework, it was noticed that the extent to which the standards are fulfilled is insufficient. The Inspectorate is going in the right direction, however. The current regulatory arrangement utilizes many of the opportunities of each individual regulation theory and combines these theories in such a manner that they can potentially strengthen each other's opportunities. However, it still lacks some aspects, so that optimal utilization is hampered. The evaluation has not only provided possible points of improvement, but also largely confirms that special attention should be given to the design of a regulatory arrangement, in order to be able to regulate the use of medical technology in hospitals.

GENERAL CONCLUSIONS

This research has shown that the general complexity of regulating the use of medical technology is mainly due to the multiplicity of aspects that need to be taken into account, such as the involvement of many actors, organizational and technical aspects that enable regulation, but also social and political obligations. Considering these, one can imagine how hard it is to keep supervision and get control of the situation, in order to create or maintain a safe health care environment. The title of this report was inspired in the light of this complexity. *Keep Your Eyes on the Prize* is a warning that one should not lose sight of the main objective, which is the quality of care with the focus on patient safety.

The main conclusion that can be drawn from this research is that for the regulation on the use of medical technology in hospitals, careful attention should be given to the design of the regulatory arrangement. For the sake of clarity, three different fields with similar or related complexities were made, but one should keep in mind that there is a strong interrelation between them. These fields are:

- (1) the multi-actor environment, where the various actors have collective responsibilities, but different and sometimes incompatible interests;
- (2) the rapid advancement of medical technology and the latitude concerning the use of medical devices throughout the hospital, which requires well-considered organizational and technical adjustments; and
- (3) the Inspectorate's formal obligations, which in some cases are conflicting.

The Twenteborg case description, the section with the discussion of the various theories, and the field analysis all show that regulating the use of medical technology in hospitals entails involvement of multiple actors. The advancement of medical technology and its increasingly important role in health care processes have caused an increase in the multiplicity of actors as well as in the degree of their involvement. The extent of the use of medical technology in hospitals requires the involvement of a chain of actors in and outside the hospital who greatly depend on each other. This interdependence is mainly due to the allocation of authorities and the need for expertise. In the current arrangement, the body held accountable/liable for the quality of care, is not the same as the one who executes, and the body who is in charge of execution is not responsible for the medical equipment required etc. This current configuration of responsibilities, authorities and liabilities of the actors involved leaves a lot to be desired, since there are still a lot of gaps.

The advancement of medical technology also requires organizational and technical adjustments in the field of health care. Expansion, especially regarding medical technology, requires a specific regulatory approach since the regulatory capacity remains limited in terms of manpower, but also in terms of specialized expertise. The shift towards system-based regulation ensures more selective regulation, but it also means that self-regulation is put in the hands of the people who are closer to the primary process that needs to be regulated. Therefore, it is more likely that they possess the required expertise regarding the primary process. This requires much more effort/work from the regulatees. It also entails the development of self-regulating systems, field standards and quality indicators, to facilitate governmental meta-regulation and accountability issues. The magnitude of medical technology in hospitals complicates the establishment of an internal self-regulating system for medical technology. The Medical Instrumentation Department is traditionally responsible for medical technology in hospitals. Since this department is placed in the lower part of the hospital's organizational structure and therefore has little or no power, it is difficult for this department to regulate the use of medical technology throughout the entire hospital. All in all, the shift towards system-based regulation requires a lot of additional work/effort from the hospitals. Since the Inspectorate does not manage the hospitals, facilitation rather than imposition would be more effective. The Inspectorate can facilitate by taking on a more advisory and supportive role regarding the self-regulation of hospitals.

The Inspectorate also has obligations towards different actors. The difficulty here is that sometimes the obligations conflict with each other. In some cases meeting one obligation can mean violating another one. The infinite field of tension in which the Inspectorate has to operate, obliges them to find a balance. Risk-based regulation and responsive regulation should be able to assist them in finding this balance. The media, the means of communication between the Inspectorate and society, have such strong influential power that they can bring about a chain reaction. The fear for negative media attention may lead to the Inspectorate sacrificing its independent position, which in turn could upset the balance.

Given the complexity to regulate the use of medical technology in hospitals, this research has tried to provide insight into the many aspects that play a role in the establishment of an effective regulatory arrangement regarding the use of medical technology in hospitals. The assessment framework I proposed provides a solid basis to be used as a guideline, even though it may need some finishing touches in the aspects of the terms of reference and the possibility for a measurable assessment.

10. RECOMMENDATIONS

This chapter contains the recommendations to the Inspectorate regarding the regulatory arrangement specifically aimed at the use of medical technology in hospitals. It also provides the answer to the main research question:

What amendments can be made in the Health Care Inspectorate's regulatory arrangement to enhance patient safety in the use of medical technology in hospitals?

RECOMMENDATIONS TO IMPROVE THE INSPECTORATE'S REGULATORY ARRANGEMENT

In the evaluation of the Inspectorate's current regulatory arrangement by means of the designed assessment framework, a number of shortcomings were identified. The following recommendations may help correct the shortcomings identified.

- The field of tension in which the Inspectorate has to operate makes it difficult to fulfill its obligations towards the bodies it has to regulate and towards the public and political environment because they may be contradictory. Therefore, the Inspectorate should try to navigate and keep a balance between these obligations. A good way to achieve this is by assuming a more cooperative role and enhancing effective communication with all parties involved. Effective communication includes the following aspects:
 - The Inspectorate should give account by means of providing a clear explanation and justification of its conduct, rather than merely making propaganda and providing the general public with information.
 - The Inspectorate's attitude and approach towards its inspectees regarding system-based regulation should be more cooperative, supportive and advisory. This may enhance the willingness of hospitals to self-regulate and improve collaboration with the Inspectorate.
 - The risk-based approach of the Inspectorate is not optimally utilized. An approach with a direct communication line with the field will provide fast and correct feedback about identified risks to and from the field. It will also facilitate agreement about priorities and enable better utilization of the opportunities of the risk-based approach.
- The main actors involved in the use of medical technology in hospitals should assume a shared accountability. These main actors are the hospital, the manufacturer and the Inspectorate. The purpose of such an agreement is mainly to induce actors to modify their behavior in accordance with the desirable societal outcome, which is good quality of care, and to enhance the learning capacity and the effectiveness of the Inspectorate. Special attention should be paid to the potential interface problems that may occur between these individual responsibilities of actors. This shared accountability may be specified as follows:
 - (1) Accountability is due to the public at large or at least to the relevant stakeholders, such as interest groups and patient associations.

- (2) In events involving the use of medical technology, each of the three main actors should be held proportionally accountable for its actual contribution to the conduct of the (entire) group that resulted in the calamity.
- (3) Accountability entails the process and/or procedural aspects of the quality of care in which patient safety is the focus.
- (4) As those who should render account are separate actors who are independent from each other, the nature of their obligation also differs. The current regulatory arrangement ensures that the Inspectorate wields power over the hospital and the manufacturer. These are accountable to the Inspectorate, who in its turn should inform the public. The Inspectorate cannot be compelled to render account, but should do this on a voluntary basis with no intervention on the part of the forum.
- The Inspectorate should improve several aspects regarding the focus and content of its inspections on the use of medical technology in hospitals, as a lot of valuable information could be obtained from the current inspections by just making small improvements on these aspects. These aspects include the following:
 - Since PMS can provide valuable information on the use of medical technology, the Inspectorate has to improve the monitoring of PMS and see to it that manufacturers fulfill their PMS obligations. The Inspectorate's role in this process is of vital importance. Setting up a users' platform can facilitate the manufacturer.
 - The establishment of a users' platform would give users the opportunity to discuss problematic issues regarding the use of medical technology. The users' contribution - experiences, feedback, and recommendations- will provide an invaluable source of information, from which everybody -users, manufacturers and the Inspectorate- can benefit. The users can exchange experiences and make recommendations, the Inspectorate can formulate appropriate measures/precautions and manufacturers can eventually use the information, analyze it and process it in PMS.
 - Acquisition of expert knowledge regarding medical technology is also essential. This means that inspectors will have to receive further training and upgrading, but regular verification inspections will also help to keep inspectors active in the field and updated on new developments. Direct contact with the field should not be underestimated.
 - In the traditional organization charts of hospitals the Medical Instrumentation Department is responsible for medical technology. However, their responsibility is not in tune with their authority. The Inspectorate might have to look into this and see what can be done to change this incongruity.

GENERAL RECOMMENDATIONS

- Developments in health care, and more specifically in medical technology, make it extremely difficult to maintain a good overview of the entire field. More and more aspects are entering the field, which can easily lead to losing sight of the original aim. The Inspectorate, as the main regulator, should not allow this to happen. Maintaining a safe health care environment focused on the quality of care to the patient should remain the primary objective and to achieve this, the Inspectorate should always have an overview and be in control of the situation. This means that the actors involved should be constantly kept aware of this.
- The assessment framework below can be used as a guideline to gain perspective on regulating the use of medical technology in hospitals when designing or evaluating a regulatory arrangement. It is a tool in the form of a normative checklist to verify if and to what extent the standards are imbedded in the regulatory arrangement.
- In order to optimize the assessment framework it needs some finishing touches, more specifically the aspects of measurable assessment, which should enable the user to obtain a valuable rating of the situation, and the terms of reference, which should specify the usage. As medical technology is now also increasingly used in nursing homes, it may be worthwhile finding out if the assessment framework can also be used in a wider setting than just hospitals.

	Central idea	Standard
Multi-actor environment	A shared accountability arrangement will hold each of the main actors involved equally accountable for its individual responsibility and contribution to the shared, interconnected responsibility.	A balance in the degree to which each of the main actors involved is held accountable/ answerable in the shared, interconnected responsibility. Special attention should be paid to the potential interface problems that may occur between the (individual responsibilities of) actors.
	Cooperation with the field will enhance an unambiguous interpretation of the regulatory approach as to how compliance with which aspects will be regulated. However, it should be noted that transparency regarding interventions can compromise the effectiveness of the interventions.	Effective and efficient cooperation with the field regarding further development of self-regulatory systems, sharing risk data, setting risk-based policy priorities and the development and continuous evaluation of field standards.
	Cooperation with other supervisory bodies can reduce the heavy inspection workload and provide an integral perspective on the performance of a regulatee under the given circumstances.	Effective and efficient cooperation with other relevant supervisory bodies regarding integral regulation, information exchange and incongruous requirements.
Organizational and technical standards	Government involvement in an enforced self-regulatory arrangement will ensure the utilization of the opportunities of system-based regulation, while at the same time, it will reduce the degree of capture and maintain the democratic legitimacy to enforce.	Enforced self-regulation with limited government involvement; the government's role is balanced; in the beginning cooperative, supportive and advisory, yet they keep the authority to take repressive measures when necessary and legitimate.
	Professionalism will enhance inspections on the primary process and reduce the probability that professionals alienate from the primary process.	Balance in professionalism regarding medical technology and efficiency in regulation, leaving enough room for frequent verification inspections (at random) that also cover the organizational structuring of medical technology.
Formal obligations	A balance in the formal obligations will ensure that there is an equal distribution in the degree to which the (sometimes rather contradictory) obligations are met.	Balance in the formal obligations towards the social and political environment on the one hand and towards the regulatees on the other.

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APPENDICES

APPENDIX A: TERMINOLOGY

Term	Similar terms	Definition
'Black Swan' event		Event with the attributes rarity, extreme impact and retrospective predictability [Wikipedia].
Capture		When a regulator is charged with regulating a system and gets locked into that system [Mertens, 2001-2009]. This can lead the regulator to act in favor of this system instead of in the public interest.
Enforcement	Coercion	Enforcement: The action of making sure that people obey a particular law or rule. Coercion: The action of making somebody do something that they do not want to do.
Inspectee	Regulatee	Object of inspection, person or body that is being inspected
Meta-regulation		Regulation of a second order (Dutch: toezicht op toezicht).
Post Marketing Surveillance - PMS		An obligation to institute a systemic procedure to review experience gained from devices in the post-production phase and to implement means to apply any necessary corrective actions, in pursuit of continuous product improvement.
Regulation	Inspection, supervision	Regulation is a control mechanism, which can be used to attain the desired unity within a social configuration. The term regulation is in place when task execution is left to 'an other', but that it is uncertain that this will be executed adequately by the 'other'. Regulation then serves to monitor whether there have been any violations of standards [Mertens, 2001-2009].
Regulator		The regulatory agency e.g. the Inspectorate. Person or organization that officially controls an area of business/industry and makes sure that it is operating fairly (Dutch: toezichthouder).
Regulatory arrangement		All the formal and materialistic aspects of regulation [Mertens, 2001-2009: 100]. The commission [Commission Holtslag, 1998: 23, 25-26] designed a checklist which includes points of interest that can be used as a guideline to describe a regulatory arrangement.

APPENDIX B: FIGURES, SCHEMES, TABLES

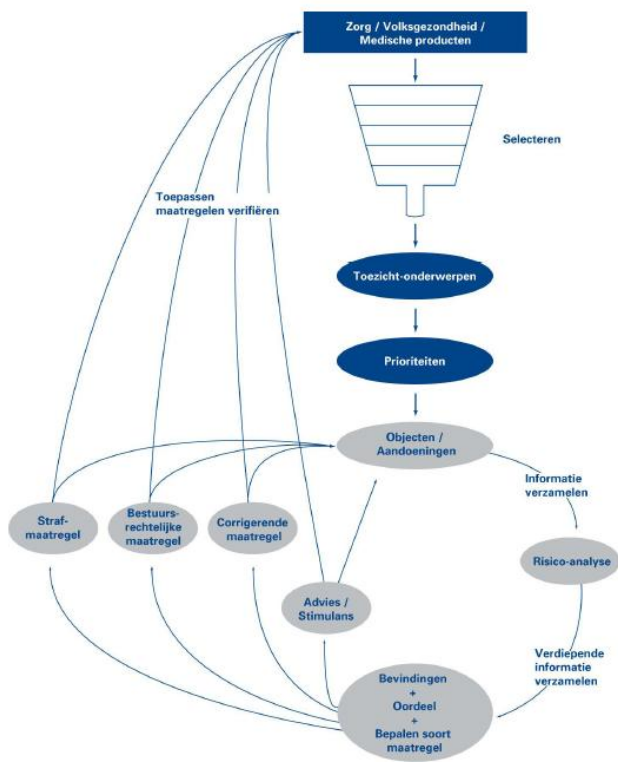


Figure A: Cycle of enforcement [IGZ, 2007]

Scheme A: Enforcement pyramid [IGZ, 2008c]

Strafrechtelijke maatregelen	Aangifte OM Opsporingsonderzoek
Tuchtrechtelijke maatregelen	Tuchtklacht
Bestuursrechtelijke maatregelen	Bevel Aanwijzing Intrekken vergunning Onthouden certificaat In beslag nemen geneesmiddel Bereiding of terhandstelling geneesmiddel beëindigen Apotheek sluiten Last onder dwangsom Bestuurlijke boete
Corrigerende maatregelen	Verscherpt toezicht (inclusief actieve openbaarmaking) Verbeterplan
Advies- en stimuleringsmaatregelen	Campagnes Circulaires Brieven Tijdschriftartikelen Actieve openbaarmaking Rapporten Overtuigen Motiveren

Table A: Proportionally model [IGZ, 2008c]

Advies/ stimuleringsmaatregelen	Corrigerende maatregelen	Bestuursrechtelijke maatregelen	Strafrechtelijke en tuchtrechtelijke maatregelen
Geldt voor 30-100% zorgaanbieders	Geldt voor 10-30% zorgaanbieders	Geldt voor 3-10% zorgaanbieders	Geldt voor 0.1-3% zorgaanbieders

The percentages indicate the magnitude to clarify the model. These percentages differ per sector.

Table B: *Impact of the situation* [IGZ. IGZ-handhavingskader. 2008]

Aantal gevallen Gevolg, risico op of vermijdbaarheid van	Groot	Gemiddeld	Klein
Death	Red	Red	Orange
Disability	Red	Red	Orange
Disease	Red	Orange	Green
Discomfort	Red	Orange	Green
Dissatisfaction	Orange	Green	Green

Dependent on the number of victims (magnitude) and seriousness of the situation, which is distinguished in the five D's of health effects, the impact of the situation can be determined. The different colors indicate the impact; red indicates high, orange indicates moderate and green indicates small impact.

Table C: Probability of recurrence [IGZ. IGZ-handhavingskader. 2008]

Houding \ Structuur	Niet willen	Niet kunnen	Niet kunnen weten
Slecht			
Matig			
Goed			

The probability of recurrence is determined by both the attitude of the health care provider and its organization surrounding the process of providing health care services or products. The different colors indicate the probability; red indicates high, orange indicates moderate and green indicates small impact.

Table D: Measures

Kans op herhaling \ Ernst	Groot(1)	Gemiddeld(2)	Klein(3)
Groot(1)	Strafrechtelijke maatregelen	Bestuursrechtelijke maatregelen	Corrigerende maatregelen
Gemiddeld(2)	Bestuursrechtelijke maatregelen	Corrigerende maatregelen	Advies- en stimuleringsmaatregelen
Klein(3)	Corrigerende maatregelen	Advies- en stimuleringsmaatregelen	Advies- en stimuleringsmaatregelen

By weighing both the impact of the situation and the probability of recurrence against each other, the type of measure can be determined.

APPENDIX C: LIST OF RESPONDENTS

Respondent	Profession	Organization
Dijk van, Arjan	Klinisch Fysicus	Deventer Ziekenhuis
Dijk van, Wim	Voormalige Directeur Patiëntenzorg Voorheen, Inspecteur IGZ	Academisch Ziekenhuis Maastricht
Fiolet, Hans	Huidige Directeur Patiëntenzorg	Academisch Ziekenhuis Maastricht
Graaf de, Yolanda	Manager Patiëntveiligheid	Beatrixziekenhuis, Rivas Zorggroep
Hoekstra, Anco	Inspecteur Medische Technologie	Health Care Inspectorate
Ilmer, Arend	Afdelingshoofd Medische Instrumentatie	Sint Franciscus Gasthuis
Kamps, Hans	Teammanager Medische Instrumentatie	Sint Franciscus Gasthuis
Lansbergen, Michaël	Klinisch Fysicus Afdelingshoofd Zorgtechnologie	Zorggroep Twente
Stomph, Eric	Inspecteur Zorg Thuis, Medische technologie	Health Care Inspectorate
Toet, Jos	Project- en kwaliteitsmedewerker Techniek & Huisvesting	Sint Franciscus Gasthuis