Organisational learning and prerequisites for data-driven risk-based regulation
A framework for data-driven risk-based regulation

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Master Thesis Report
2019

TU Delft
Organisational learning and prerequisites for data-driven risk-based regulation
A framework for data-driven risk-based regulation

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in partial fulfilment of the requirements for the degree of

Master of Science
in Engineering and Policy Analysis

at the Delft University of Technology,
to be defended publicly on Monday July 15, 2019 at 14:00.

Student number: 4381912
Project duration: February 11, 2019 – July 15, 2019
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An electronic version of this thesis is available at http://repository.tudelft.nl/.
Executive Summary

Over the course of the last decade the role of data in society, businesses and governments has changed tremendously. New technologies continue to influence the way data is collected, managed and used in organisations public and private alike. For public organisations and governments, the promise of data lies in data-enhanced decision-making. Data-enhanced decision-making gives governments and governmental agencies the possibility to improve by increasing their efficiency and effectiveness.

The Dutch Authority for Nuclear Safety and Radiation Protection (ANVS: Autoriteit Nucleaire Veiligheid en Stralingsbescherming) is the regulatory agency responsible for the regulation of nuclear safety and security, and the regulation of all uses of ionising radiation in the Netherlands. In order to perform their primary task, regulation, the ANVS executes the proactive inspection process by utilising risk-based regulation. The ANVS is a future oriented organisation and subsequently employs a strategy of continuous improvement. The ANVS have noticed the increasing use of data science in the public domain, and subsequently want to improve their regulatory framework via data-driven tools. These data-driven tools could supplement the existing regulatory framework by creating a data-driven risk-based regulation (DDRBR) framework.

While data-driven risk-based regulation has the promise of improving performance by regulatory agencies, often it cannot be directly implemented in a regulatory agency. Challenges impede swift implementation of data-driven risk-based regulation.

Institutional challenges arise in regulatory agencies when demands on resources and expertise are made which may lead to conflict between data scientists with data-enhanced decision-making philosophies, and inspectors with accumulated regulatory mandates through knowledge and expertise.

Additionally, operationalising data for analysis purposes is often daunting for regulatory agencies. As a consequence, regulatory often refrain themselves from taking the leap to centralise data in the inspection process.

The final challenge that arises in regulatory agencies is dependency on tacit knowledge. Throughout the years inspectors accumulate knowledge and expertise which is not made explicit. Subsequently, regulatory agencies become reliant on this extensive amount of tacit knowledge and are vulnerable to organisational brain drains.

Since, these challenges inherently influence the implementation of data-driven risk-based regulation (DDRBR) in regulatory agencies, overcoming these challenges are necessary to create a conducive organisational environment for the development of DDRBR. Given the knowledge gap regarding the prerequisites for achieving DDRBR in
regulatory agencies, this thesis will address this gap by answering the following question: "What are the prerequisites for adopting data-driven risk-based regulation by regulatory agencies?". To answer the research question, this thesis takes a design science research (DSR) approach, which is heralded as a problem-solving paradigm.

In order to identify the prerequisites of data-driven risk-based regulation (DDRBR) a DDRBR regulatory framework was developed for the ANVS using the design science research methodology (See Figure I). The framework addresses and mitigates the effects of three challenges observed at the ANVS: institutional, operationalisation and knowledge challenges. The adverse effects of these challenges are mitigated by providing a well-structured and well-documented approach to the proactive inspection process of the ANVS. The framework incorporates proper data management by centralising the data collection and analysis in the inspection process. It enables the quantification of risks through structured session in which tacit knowledge is shared and made explicit. Finally, it maintains a balance between inspector expertise and data insights.

Implementation and execution of the DDRBR framework subsequently enables regulatory agencies to evaluate their regulatory framework. Evaluation occurs via newly created knowledge and insights, and reflects on the norms regulatory agencies have regarding risks. Additionally, the newly created knowledge and insights might demand changes to policy and licensing requirements. This form of organisational learning enables continuous improvements after each iteration of the DDRBR framework.

Figure I. The DDRBR Framework
The DDRBR framework is tailored to the situation at the ANVS and subsequently mitigates the challenges perceived within the ANVS. In addition to the challenges perceived in the ANVS, however the main research question posed a more general question regarding prerequisites for the adoption of data-driven risk-based regulation. This thesis has identified a typology of prerequisites for DDRBR, prerequisites can be of technical, data, knowledge, societal or organisational nature. The challenges regarding these prerequisites can be observed to various degrees in regulatory agencies.

Technical prerequisites need to be considered to ensure sufficient capacity of the IT infrastructure at regulatory agencies. Often the current IT infrastructure is insufficient to handle the capacity necessary to perform rapid data analysis.

Data prerequisites require good data management by the regulatory agency. Prior to starting the transition to data-driven risk-based regulation agencies should standardise the process of data collection, cleaning, preparation, processing and analysis as well as assess the quality.

Knowledge prerequisites require regulatory agencies to identify and specify risks and their measurable parameters or proxies, in order to facilitate the data-driven inspection process. The risk definitions are often not made explicit and reside in the minds of inspectors at the regulatory agency. In order to perform data analysis these risk definitions need to be rendered explicit.

Societal prerequisites require regulatory agencies to be aware of threats as a result of sizeable amounts of data. The system could become vulnerable to cyber attacks and issues of privacy and ownership of the data, as a result of accumulating data at the regulatory agency.

The final prerequisite is of organisational nature and needs to be considered in order to ensure trust and acceptance by employees and inspectors in the regulatory agency. For DDRBR new practices are necessary and the introduction of these practices will require changes to particular processes and organisational traditions.

To summarise, adopting data-driven risk-based regulation is no easy feat for regulatory agencies. These agencies are often confronted with challenges acting as inhibitors for the adoption of data-driven risk-based regulation. This thesis provides a set of prerequisites in order to succeed in the adoption and implementation. Prerequisites for data-driven risk-based regulation are: technical, data, knowledge, societal and organisational. Meeting these prerequisites enables regulatory agencies to successfully adopt data-driven risk-based regulation.
Preface

This thesis is the fruit of my labour of the previous five months, for me it has been quite a process: researching and writing this thesis. I still remember the onset of this thesis in February: the first meeting with my supervisor Dr. Haiko van der Voort, the first day the Dutch Authority for Nuclear Safety and Radiation protection (ANVS) and the first of many lunches I had with my ANVS supervisor Dr. Majid Farahmand.

I would like to express my gratitude towards everyone involved in the creation of this thesis. Especially, the employees of the ANVS who have made me feel welcome and often gave some of their time to explain the intricacies of their job. In particular my ANVS supervisor Majid Farahmand who supported me every step of the way and made sure I had the access to the resources I needed from the ANVS almost immediately. Additionally, our lunch walks through The Hague helped me tremendously in understanding the challenges the ANVS and similar regulatory agencies face and helped me every step along the way.

I would also like to extend my gratitude towards my thesis committee of TU Delft, consisting of Dr. Scott Cunningham and Dr. Haiko van der Voort. I recall a certain moment in early May where Haiko’s insights proved invaluable for finalising this thesis. After this meeting I met Haiko almost weekly and should like to thank him for his patience and valuable insights.

Finally, I thank my parents for their continuous support, encouragement and creating a calm environment for me to study. I would like to thank my grandmother for proofreading my thesis and pointing out the mistakes in grammar, and my brother for designing the cover of this thesis.

I hope you enjoy reading this thesis,

Mark in ’t Veld
Willemstad, July 2019
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<th>Full Form</th>
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<tr>
<td>ANVS</td>
<td>Autoriteit Nucleaire Veiligheid en Stralingsbescherming (Authority for Nuclear Safety and Radiation Protection)</td>
</tr>
<tr>
<td>DDRBR</td>
<td>Data-driven risk-based regulation</td>
</tr>
<tr>
<td>DSR</td>
<td>Design science research</td>
</tr>
<tr>
<td>SBC</td>
<td>Department of Radiation Control and Crisis Management</td>
</tr>
<tr>
<td>NVB</td>
<td>Department of Nuclear Safety and Security</td>
</tr>
<tr>
<td>MCDA</td>
<td>Multi-criteria decision analysis</td>
</tr>
<tr>
<td>NVWA</td>
<td>Nederlandse Voedsel- en Warenautoriteit (Dutch Food and Consumer Product Safety Authority)</td>
</tr>
<tr>
<td>SodM</td>
<td>Staatstoezicht op de Mijnen (Dutch State Supervision of the Mines)</td>
</tr>
<tr>
<td>Zbo</td>
<td>Zelfstandig bestuursorgaan (Independent administrative authority)</td>
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1
Introduction

In this chapter an introduction is given to the data-driven world which regulatory agencies have to navigate. Opportunities as well as challenges for regulatory agencies are mentioned. The chapter continues by introducing the ANVS, a Dutch regulatory agency, where the research for this thesis was conducted. The ANVS’ aim of embracing data-driven risk-based regulation is admirable; hurdles and potential challenges have to be overcome to achieve the goal set by the ANVS. This chapter concludes by presenting the knowledge gap, and an overview of the thesis on a chapter by chapter basis.

1.1 A data driven world

Over the course of the last decade the role of data in society, businesses and governments has changed tremendously. Devices and appliances are increasingly gathering data with the aim to enhance and gain a deeper understanding of corporate or governmental activities and processes (Zhou et al., 2016). Data collection, and subsequently analysis, is now utilised in almost every sector, whether private or public (Henke et al., 2016). The last decade has seen a rapid growth in the ability of corporations and organisations to exploit vast amounts of data, primarily in order to support decision-making processes. As a result, business analytics and business intelligence fields have been flourishing ever since (Daniell et al., 2016).

An abundance of data, increased computational power and advances in data science have led to a widespread adoption of evidence-based business conduct via data-driven approaches. In the private sector state-of-the-art methods are utilised, such as machine learning and cutting-edge statistical modelling techniques (Henke et al., 2016). These approaches can result in an improvement of organisational performance (Elbashir et al., 2008).

While increased organisational performance has been observed as a result of data-driven business conduct in the private sector, improvements in the public sector are trailing behind in comparison (Höchtl et al., 2016; Daniell et al., 2006). A notable variance from a historical perspective as, quantitative decision-support methods, e.g. Operations Research, were pioneered in the public sector. As the private sector increasingly seems to reap the benefits from exploiting data and data-science, the public sector is trailing in comparison.
Höchtl et al. (2016) argue that inability of governmental departments and agencies successfully adopting data-driven approaches is a result of the bureaucratic environment within the organisation. A suspicion confirmed by Daniell et al. (2016).

The inherent inertia of bureaucratic organisational structures combined with failures of data-driven approach adoption, have created a reluctance within governmental departments and agencies to utilise and explore the use of data (Stragier et al., 2010). Even though opportunities lie in a systematic approach to data collection and analysis, with the promise of better decision-making, reluctance seems to triumph in the public domain (Judd et al., 2017; Philip Chen & Zhang, 2014). Thus, resulting in government struggling to keep up with the rapid developments in the private sector.

1.2 Regulatory agencies

Dutch regulatory agencies are responsible for enforcing and governing the implementation of rules, norms and laws in the Netherlands (ANVS, 2017b). To enforce these laws regulatory agencies can perform inspections of corporations and institutions subjected to these laws, in order to check for noncompliance of the rules and legislation (Black & Baldwin, 2012). In the Netherlands regulatory agencies mainly perform physical inspections. Trained inspectors visit the firms or organisations and check for compliance.

As firms and organisations under regulation move ahead in the current ‘age of digitalisation’ their way of conducting business has changed (Yin et al., 2015). This is often followed by increased performance (Elbashir et al., 2008; Staman et al., 2013). The ability of data science to ameliorate decision-making (Daniell et al., 2016; Van der Voort et al., 2019), is where promise for regulatory agencies can be found. Applying data-driven strategies could provide regulatory agencies with the opportunity to increase their effectiveness of regulating.

This new age of data has been noticed by the governance body of Dutch inspection agencies, the Inspectieraad (Dutch Inspection Council). This council is tasked with ameliorating collaboration and enhancing best practices among regulatory agencies (Inspectieraad, 2018). As of 2018 the Inspectieraad is implementing their regulation innovation strategy (Programma Innovatie Toezicht), which mentions the opportunities that lie in new technologies and implementation of data-driven approaches.

Evidence-based or data-driven regulation by utilising data-analysis is more often than not heralded for its opportunities. However, implementing data-driven regulation poses some challenges as well. As e.g. operationalising the data might seem daunting and difficult for regulators (Black & Baldwin, 2010). Especially, if the current regulation strategy, approach and organisation might not be conducive to change, even though changes in inspection process might be necessary in order for regulatory agencies to capitalise on the advantages of this new data-rich environment.
1.3 Dutch Authority for Nuclear Safety and Radiation Protection

The Dutch Authority for Nuclear Safety and Radiation Protection (Authoriteit Nucleaire Veiligheid en Stralingsbescherming, ANVS) governs and safeguards the nuclear safety and radiation protection in the Netherlands. Forged in 2015 from various agencies, the ANVS is a relatively new organisation and has, per 2017, become an independent administrative authority. The agency has almost full regulatory power over all nuclear and radiation related activities in the Netherlands. It governs and regulates the sector by laying down rules, granting permits, licensing experts and if necessary, take enforcement action (ANVS, 2015). The ANVS ensures that the highest standards of nuclear safety and radiation protection are being met in the Netherlands.

1.3.1 Current situation at the ANVS

Nowadays, there are thousands of firms and organisations that have some appliance emitting radiation (ANVS, 2017b). The ANVS is responsible for ensuring that firms and companies that work with ionising radiation comply with the latest (inter-) national legislation on safety and security (ANVS, 2017b).

As the primary form of regulation by the ANVS is physical inspection, it is an unrealistic goal for the ANVS to enforce and regulate any risk that pose in the radiation sector. However, there needs to be a well-substantiated reasoning in order to assess which risk the ANVS pays special attention to. In order to mitigate risks the ANVS employs their risk-based regulation framework. There is extensive literature on the notion of risk-based regulation, which will be elaborated upon in chapter 2.

In addition, the ANVS states that their current strategy of regulation is more reactive, and subsequently want to tip the scales more towards proactive regulation. Moreover, the current risk-based regulation framework employed by the ANVS lacks substantiation in data, as the ANVS has yet to explore the benefits of data science to their business conduct.

1.3.2 Data-driven risk-based regulation

A possible avenue to explore already identified by the ANVS is enhancing risk-based regulation via data-driven inspection and oversight. While data-driven risk-based regulation (DDRBR) is a promising strategy, true data-driven risk-based regulation has not been applied yet. While data-driven risk-based strategies are already employed in various sectors e.g. road safety management (Wegman et al., 2015) and urban water management (Eggimann et al., 2017), these are not aimed at regulation and therefore not data-driven risk-based regulation. Which is also the case in various regulatory agencies in the Netherlands (Kooi et al., 2018).

Employing risk-based regulation, grounded in data, would enable the ANVS to highlight those locations where the risk of noncompliance with legislation and regulations is the highest. In addition, a data-driven risk-based regulation framework, could e.g. ensure that firms, organisations and institutions with bad compliance receive additional inspections as opposed to firms, organisations and institutions with a good compliance history.
1.3.3 Prerequisites for data-driven risk-based regulation

Implementing data enhanced risk-based regulation strategies at the ANVS can offer an evidence-based approach to regulatory oversight with the incorporation of data (Black & Baldwin, 2010). While the current regulatory framework employed by the ANVS is not necessarily failing per se, progress can be made. While the possibilities for regulatory improvement of inspections by data-driven approaches are rapidly increasing. Organisations such as the ANVS have yet to adopt a structured approach to data collection in their inspection process. It is far more interesting to research what the requirements regarding the organisation are, in order to enable data-driven risk-based regulation in the future.

1.3.4 Impediments for research conducted at the ANVS

As the current environment at the ANVS provides a unique research opportunity as the organisation has to start from scratch, aiming to embrace data-driven risk-based regulation (DDRBR) in the future. Nevertheless, the ANVS have not fully committed to DDRBR as current, more pressing issues, take priority. The ANVS have been engaged in multiple digitalisation processes among which the development of a digital management system with the aim of digitalising and centralising processes within the organisation. In addition, the ANVS have been training a set of new inspectors following the departure of expert-level inspectors combined with a surge in reactive regulatory work. These inspectors are intensely engaged with their core activities.

These factors are part of the organisational setting in which the research will be conducted, and subsequently might impact the outcome or hinder certain research opportunities.

1.4 Knowledge gap

To summarise, data-driven risk-based regulation is currently all the fuss in the landscape, and in research surrounding regulatory agencies. Agencies are pressurised by higher ranks of government to incorporate data analysis into their regulatory framework. While this research acknowledges that this is not an easy feat for regulatory agencies, there is no available roadmap for regulatory agencies to achieve this. Regulatory agencies in The Netherlands desire the utilisation of data-driven risk-based regulation in the near future, in order to improve the regulatory oversight. While the opportunities are almost limitless, real challenges might arise for regulatory agencies during the transition from the current situation to the desired data-driven situation.

It can be assumed that certain organisational changes are necessary in order to create a conducive environment for the development of data-driven risk-based regulation. Regulatory agencies might have to address and overcome certain challenges in order to fully embrace and capitalise on the promises and opportunities the data-driven world holds. The research objective during this thesis research is to determine the prerequisites for adopting data-driven risk-based regulation by
regulatory agencies. Which corresponds to the following research question: “**What are the prerequisites for adopting data-driven risk-based regulation by regulatory agencies?**”. This research will address and research those prerequisites that lead to a conducive organisational environment for the future development of data-driven risk-based regulation.

### 1.5 Overview of thesis structure

This thesis continues in chapter 2 by presenting an overview of the relevant scientific literature, in conclusion the knowledge gap is addressed and subsequently the main research question is identified. Chapter 3 the research methodology of this thesis and the research questions are outlined. Chapter 4 continues by providing the social context and environment of the ANVS. Subsequently, the environment as described in chapter 4 and the knowledge base in chapter 2 provide the stage for the design of data-driven risk-based regulation framework for the ANVS in Chapter 5. Chapter 6 addresses the notion of validation in DSR and validates the framework for data-driven risk-based regulation. Finally, Chapter 7 presents the discussion, reflection and the conclusions in addition to answering the main research question.
Chapter one primarily focused on the demarcation of the problem this thesis aims to address, while this chapter intents to clarify and specify the research area and the research objectives.

In order to take advantage of the promises of the new data-driven world the ANVS has set the horizon goal of achieving data-driven risk-based regulation in the future. A systematic approach to data collection and data management will be necessary to achieve this. The ANVS has yet to fully implement such an approach and is basically starting from scratch. This provides the unique opportunity to research enabling factors or prerequisites in order to achieve risk-based regulation. However, at this moment, there is no research or overview mentioning criteria essential for the development of data-driven risk-based regulation.

This chapter expands on the introduction of the Dutch Authority for Nuclear Safety and Radiation Protection (ANVS), mentioning the intricacies regarding the organisational structure and the domain in which the ANVS operates. The current state of the inspection process at the ANVS is described. The chapter then continues in 2.2 with the regulatory framework, defining risk-based regulation as well as data-driven risk-based regulation, citing challenges and opportunities. Chapter 2.3 focusses on knowledge, primarily tacit knowledge and the creation of organisational knowledge. Subsequently, chapter 2.4 explains the notion of organisational learning and chapter 2.5 addresses the scientific knowledge gap and states the main research question.

2.1 Dutch Authority for Nuclear Safety and Radiation Protection

The Dutch Authority for Nuclear Safety and Radiation Protection (Autoriteit Nucleaire Veiligheid en Stralingsbescherming, ANVS) is responsible for governing and safeguarding the fields of nuclear safety and radiation protection. The ANVS as an organisation is relatively new and was forged in 2015 from various departments across multiple ministries in The Netherlands. As of 2017, the ANVS is a self-governing administrative authority (zelfstandig bestuursorgaan, zbo), granting them independent decision-making capabilities with their own board, while the state secretary of Infrastructure and Water Management still bears political responsibility (ANVS, 2017a). The ANVS combines the fields of nuclear safety and radiation protection as well as security and safeguards (ANVS, 2017a). The ANVS’s main focus is development of legislation, policy, regulations, supervision, licencing and enforcement. It governs and regulates the sectors by laying down rules, granting
permits, licensing experts, performing inspections and, if necessary, take enforcement action (ANVS, 2015).

2.1.1 Organisational structure of the ANVS

The organisation of the ANVS has a clear split between regulating nuclear and radiation activities. There are specific departments dealing with either Nuclear Safety and Security (NVB) or Radiation Control and Crisis Management (SBC) (See Figure 1). Within these larger departments there are divisions tasked with specific activities and proceedings in the department. The Department of Nuclear Safety and Security (NVB) oversees six nuclear (related) facilities. Among the facilities are: nuclear storage, nuclear power, nuclear research and uranium enrichment. In contrast, the Department of Radiation Control and Crisis Management (SBC) oversees multiple sectors in which radioactive sources are utilised such as: healthcare, education, museums, industrial processes etc. Within each sector the number of users varies from less than a hundred to over a thousand regulatees. From a data-analysis viewpoint the department of SBC is therefore much more interesting to apply the notion of data-driven risk-based regulation, due to sheer notion of statistical significance as a result of the number of regulatees.

The ANVS being a zbo means they have three regulatory tools at their disposal: licensing, inspecting and policy-making. These are not independent regulatory tools but can inform and influence each other.

2.1.2 Inspection process at the ANVS

While the department concerned with nuclear safety and security (NVB) is able to inspect all facilities an almost weekly basis, the radiation control department (SBC) cannot afford this due to the sheer size of regulatees. SBC performs two manners of inspection: reactive and proactive; Reactive inspections are the result of a direct event, (anonymous) tip or incident, while proactive inspections are performed to check compliance with rules and regulations, without a reason preceding the inspection.

Even though the ANVS as an organisation is relatively new, a majority of the inspectors are not. Prior to the formation of the ANVS, the inspectors had been working at the Dutch National Institute for Public Health and the Environment (RIVM) or the former ministry of Housing, Spatial Development and Environment (VROM).

As a result, the inspectors employed by the ANVS are knowledgeable and have a great deal of expertise. However, most of this knowledge is inspector specific and a direct result of the expertise gained, i.e. tacit knowledge, during the years as an
inspector. With the expertise of the inspector being primarily tacit, it is therefore notoriously difficult to share or communicate this knowledge and expertise (Nonaka, 1995; Smith, 2001; Inkpen & Tsang, 2005). The notion of tacit knowledge will be elaborated upon in chapter 2.3.

Over the course of recent years, the inspectors at the ANVS have been overwhelmed by incidents, primarily regarding the illegal disposal of radioactive scrap waste (RTL Nieuws, 2018). However, the ANVS aims to change the ratio between reactive and proactive inspections. Aiming to increase the number of proactive inspections performed by the ANVS in the radiation control domain. As a result, the inspection process regarding proactive inspections is currently underdeveloped taking into consideration its ability to enable and implement data enhanced regulation. However, for this thesis it provides an almost unique opportunity and possibility to research necessary enablers or prerequisites for an organisation to achieve data-driven risk-based regulation in the future.

2.2 Regulatory framework

Rather than performing inspections at random, the ANVS operates its inspections in a risk-oriented manner. The regulation and intervention strategy (Toezicht en Interventiestrategie) offers insight into the manner of how risk-based strategies are employed by the ANVS (ANVS, 2017b). With a legal obligation and societal responsibility to implement a well-structured approach to continually improve the nuclear safety and radiation protection in the Netherlands, risk-based regulation frameworks aim to realise improvements in the regulatory oversight performed by the ANVS (ANVS, 2015).

2.2.1 Risk-based regulation

Risk-based regulation strategies involve targeting of enforcement resources on the basis of risk assessments that a regulated corporation or organisation poses to the regulator’s objectives (Black & Baldwin, 2010; Rothstein et al., 2006). While risk-based regulatory strategies have achieved broad acceptance in governments, Baldwin and Black argue that regulatory agencies need to think in a more structured manner about how risk-based regulation can conquer the many hurdles that lie on its path (Baldwin & Black, 2016). These hurdles include but are not limited to issues of digitalisation. Rothstein et al. (2006) even go as far as stating that these strategies and approaches face a range of epistemic, institutional and normative challenges.

Epistemic challenges arise when regulation often asks too much from science and the science is insufficiently advanced to answer the question asked. This can create a considerable scope for regulatory uncertainty and conflict (Rothstein et al., 2006). Institutional challenges arise when considerable demands on resources and expertise are made which may lead to conflicts between data scientists with decision-making philosophies, and inspectors with accumulated regulatory mandates.
The final challenge described by Rothstein et al. is of normative nature. Potential for misalignment of societal and institutional risks arise when stakeholders measure and weigh the costs and benefits of regulatory decision differently. However, later work by Black and Baldwin (2010) state that the difficulties regulators have to overcome are vastly outweighed by the costs of regulatory failure. Nevertheless, the issues raised by Rothstein et al. (2006) shouldn’t be dismissed.

The institutional challenges are of particular relevance for the ANVS, as the agency is practically starting from scratch regarding their data science initiatives. Accumulated regulatory mandates of inspectors might interfere with the ability evaluate the inspection process and subsequently change the inspection process.

2.2.2 Data-driven risk-based regulation

Near the end of 2015 the Dutch government started to realise the enormous impact of digitalisation on society (Kooi et al., 2018). While some regulatory agencies in the Netherlands, such as ACM (Authority for Consumers & Markets), AFM (Authority for Financial Markets) and CTIVD (Committee on the Intelligence and Security Services) have already made the transition to regulatory oversight based on data (Kooi et al., 2018). The Dutch Authority for Nuclear Safety and Radiation protection (ANVS) has yet to adopt digitalisation, in order to improve their regulatory oversight.

Even though there is excitement about data-driven risk-based regulation in scientific literature, governments and regulatory agencies, there is hardly scientific literature available on the development of data-driven risk-based regulation. Literature can be found regarding the utilisation of data-driven tools within governments (Eggimann et al., 2017; Marino et al., 2018; Stragier et al., 2010; Wegman et al., 2015; Zhou et al., 2016). Furthermore, there are severe challenges that need to be addressed and overcome by regulatory agencies in order to succeed in the creation of data-driven tools and subsequently data-driven risk-based regulation (Eggimann et al., 2017; Wegman et al., 2015; Zhou et al., 2016).

2.2.3 Challenges and prerequisites for data-driven risk-based regulation

The challenges could act as inhibitors for regulatory agencies aiming to adopt data-driven risk-based regulation. Eggimann et al. (2017) and Zhou et al. (2016) define a set of challenges regarding data which should be addressed in the development of data-driven risk-based regulation.

In order to capitalise on the promise of data-driven risk-based regulation, the agency should be able to: turn data into information (data processing), make information available to its users (data availability), address the issues of data quality and uncertainty (data quality) and achieve low operating and maintenance costs for measurements (data costs) (Eggimann et al., 2017). Other data challenges as mentioned by Zhou et al. (2016) are regarding privacy and cybersecurity: is the data stored by the government or regulatory agencies sufficiently protected (cyber...
security), and should regulatees have the right to see which data is collected and used for analysis (data privacy).

In addition to these generic data challenges, Eggimann et al. describe an additional challenge worth special consideration when developing data-driven tools. According to Eggimann et al. changes in engineering and management practice are necessary for data-driven tools to succeed. Increased availability to data requires changes to management and engineering practices which should be able to consider the adaptation of new types of risk models (Eggimann et al., 2017). However, due to restrictions on time, organisational resources and an aversion to risks, managers in the public domain are often not conducive to promoting innovative change (Eggimann et al., 2017).

Although the literature on challenges in data-driven risk-based regulation is scarce, there are likely to be additional challenges regulatory agencies need to address in order successfully embrace data-driven risk-based regulation. This thesis will focus on identifying those challenges and answering the main research question by stating the prerequisites for regulatory agencies aiming to embrace data-driven risk-based regulation.

### 2.2.4 Data-driven risk-based regulation artefact

Agencies are pressurised by higher ranks of government to incorporate data analysis into their regulatory framework (Government of the Netherlands, 2017). While this research acknowledges that this is not an easy feat for regulatory agencies, there is no available roadmap for regulatory agencies to achieve this.

![Figure 2. Framework combining decision-analysis and risk-analysis (Linkov et al., 2014)](image)
However, the research by Linkov et al. (2014) comes close to providing a framework for achieving data-driven risk-based regulation. The framework by Linkov et al. (See Figure 2) combines traditional, often quantitative, risk-based regulation techniques with decision analytics.

According to Linkov et al. decision-analytical techniques are an essential requirement for integrating evidence-based data. The framework thus combines decision-analytics with risk-analysis to facilitate data-enhanced risk-based regulation.

A benefit relevant for regulatory agencies is that the framework developed by Linkov et al. (2014) enables the integration of technical information and expert judgment regarding perceptions of risks. However, the research and framework does not include a structured explanation of how to implement, nor does it explain the activities of the ‘boxes’ in the framework. Even though Linkov et al. do not explain in detail the activities the framework entails, the decision-analysis stage of the framework corresponds to multi-criteria decision analysis as presented in Linkov & Moberg (2012). The risk-analysis stage of the framework is consistent with risk assessment and analysis. An overview of risk assessment methodologies can be found in e.g. (Siu, 1994).

While developed as a decision-making aid, there is a lack of regard of the tacit knowledge that needs to be extracted in order to perform decision-analytics and subsequently quantify risks. Nevertheless, Linkov et al. (2014) do provide an avenue to explore for further research regarding the development of data-driven risk-based regulation.

2.3 Tacit knowledge and knowledge creation

The notion of knowledge and expertise, regarding inspectors, has been invoked multiple times in thesis. This sub-chapter will subsequently focus on the role of knowledge and knowledge creation in organisations.

2.3.1 Tacit and explicit knowledge

Nonaka describes knowledge as a justified true belief, rather than focussing on objective truthfulness (Nonaka, 1995). This distinction is important as it considers knowledge as a personal belief and emphasizes the importance of the justification of said beliefs.

A formal definition of different types of knowledge goes back as far as 1966, where Polanyi classified human knowledge into two distinct categories: tacit and explicit knowledge (Polanyi, 1966). Explicit knowledge refers to a type of knowledge that is transmittable via formal, systematic language. It is academic or technical data or even information described in formal language (Smith, 2001). Explicit knowledge with the individual can be gained through formal education or academic study (Smith, 2001, Nonaka, 1995).
Tacit knowledge has a personal quality and makes it incredibly difficult to transfer. In addition, it tends to be local and cannot be found in manuals, databases or books (Smith, 2001). Tacit knowledge is cognitive or technical knowledge made up of values, beliefs, perceptions, assumptions and mental models (Smith, 2001; Nonaka, 1995). Technical tacit knowledge can be observed as mastery of a skill such as Michelin star chef. Cognitive tacit knowledge incorporates mental models and perceptions that are so ingrained in an individual that they are often taken for granted by the individual (Smith, 2001). Such mental models and thus tacit knowledge are invaluable for inspectors and is best described as their fingerspitzengefühl regarding the evaluation of risks.

2.3.2 Knowledge creation

For organisations, especially those that rely on tacit knowledge of individuals, it is of utmost importance to share and create knowledge with the purpose of organisational continuity. Since tacit knowledge is difficult to share, an organisation is at risk of losing knowledge as employees leave (Smith, 2001). Intelligent organisations, therefore, aim to facilitate the process of knowledge creation. However, this is not a straightforward process.

As knowledge is inherently a part of individuals, only individuals can create knowledge (Nonaka, 1995). Therefore, organisations cannot create knowledge without individuals (Nonaka, 1995). What organisations can do is try and increase knowledge creation by individuals as much as possible and crystallise the newly created knowledge as part of the knowledge network of an organisation.

The process of organisational knowledge creation relies almost exclusively upon individuals within the organisation. A success factor for organisational knowledge creation is therefore the commitment of the individual to the cause, i.e. promoting the formation of new knowledge within the organisation (Nonaka, 1995). According to Nonaka the three factors inducing commitment from individuals are: intention, autonomy and fluctuation.

The principle of intention relates to how individuals form their mental models and inherent mental framework in which they make sense of the environment around them. Without considering intention of the individual, it is impossible to assess the value of knowledge created. (Nonaka, 1995).

Autonomy of the individual within the knowledge creating organisation, increases the probability that individuals are motivated to create new knowledge. An organisation granting additional autonomy is more likely to succeed in capturing and interpreting newly created knowledge (Nonaka, 1995).

Finally, fluctuation is defined by Nonaka as a disturbance or change that enables individuals to generate new patterns of interaction, as a result from continuously interacting with the world beyond the organisation. While intention is inherently important for motivation, interactions with the external world is where new knowledge is formed.
2.3.3 Organisational knowledge creation

With a definition and distinction of knowledge, tacit and explicit, and the enablers for knowledge creation clustered under commitment, Nonaka presents a model for knowledge conversion. Knowledge can be created by converting tacit and explicit knowledge (Nonaka, 1995). The four different modes of knowledge conversion are: socialisation, combination, externalisation and internalisation (See Figure 3).

Socialisation is the mode of conversion which enables tacit knowledge conversion among individuals. It is generated via learning-by doing through observation (Smith, 2001).

Combination, the second mode of knowledge conversion, enables sharing explicit knowledge. This mode combines different pieces of explicit knowledge into a new whole (Smith, 2001) through reconfiguration of existing information.

Externalisation and internalisation, the conversion of tacit knowledge into explicit knowledge and vice versa, is based on the notion tacit and explicit knowledge are complimentary and can evolve through mutual interaction processes.

Externalisation then is achieved through sharing best practices and securing them in formal writing or schemas.

Internalisation involves reframing or interpreting explicit knowledge using expertise knowledge of individuals so that knowledge can be internalised or accepted by others. A practical example would be medical experts discussing a case based on the facts and decision-making at the time, with the aim of trying to understand the decision-making of an individual.

Organisations often operate with mostly tacit knowledge rather than explicit knowledge (Falconer, 2006). The ANVS also relies upon a considerable amount of tacit knowledge especially the inspection process. It can be assumed that ANVS first has to render tacit knowledge of inspectors explicit before data-driven risk-based regulation can be utilised. Additionally, effective handling of tacit knowledge is a prerequisite for organisational learning (Falconer, 2006).

2.4 Organisational learning

Unfortunately, few organisations are able to handle tacit and explicit knowledge in an effective manner (Falconer, 2006). Exceptions are those organisations that are skilled at the creation, acquiring and transfer of knowledge and at changing organisational behaviour patterns to reflect new knowledge and insights (Smith, 2001). However,
what are effective drivers for an organisation to increase its proficiency in handling different types of knowledge?

The field of organisational learning can be traced back to Argyris and Schön (1978). While individual knowledge creation is a requirement for organisational learning, it is more complex and more dynamic than the individual learning (Nonaka, 1995). Argyris and Schön define two distinct types of learning: single-loop and double-loop learning (See Figure 4).

![Figure 4. Single and double-loop learning (Argyris & Schön, 1978)](image)

Single-loop learning is when flaw is detected and remedied without changing the underlying framework (Argyris & Schön, 1996). This makes single-loop learning incredibly effective when something new is learned and progress is subsequently made. Simultaneously single-loop learning can be very ineffective when the underlying framework or norm is not a point of discussion and larger patterns within an organisation are not subject to change. An interesting notion when applied to the inspection process at the ANVS.

A manner to mitigate the inherent ineffectiveness of single-loop learning is double-loop learning (Argyris & Schön, 1996). During double-loop learning processes the underlying framework or norms are the focal point of discussion. When the underlying framework or norm changes, actual processes within an organisation can change. The organisational changes following double-loop learning might prove to be essential for the incorporation of new processes within an organisation. Which is an interesting notion for organisations attempting to change their processes.

The effectiveness of organisational learning is depended upon the recognition and creation of knowledge (Falconer, 2006). The creation and absorption of knowledge, e.g. by application of the knowledge creation spiral by Nonaka (1995), is what prompts organisations the act upon that knowledge (Falconer, 2006).

For the ANVS learning might prove to be essential in order to achieve true risk-based regulation in the future. Especially, when knowledge creation or new insights call for changes in the inspection process. This learning process as an outcome of newly created knowledge and data-driven insights is uncharted territory for the ANVS. Subsequently, the implications of the combination of knowledge creation and organisational learning in order to achieve data-driven risk-based regulation are crucial for regulatory agencies aiming to embrace data-driven risk-based regulation.
2.5 Knowledge base

This literature review has identified three major scientific theories relating to the problem definition as identified and described in chapter one, the desire for regulatory agencies to embrace data-driven risk-based regulation. Even though all three scientific theories, organisational learning (Argyris & Schön, 1978), knowledge creation (Nonaka, 1995) and the fusion of decision-analytics and risk analysis (Linkov et al., 2014), have their respective merits, none can be directly applied to the situation regulatory agencies face.

The research and framework by Linkov et al. (2014) does not include a ready-to-go approach, nor does it describe the relationships among the ‘boxes’ of risk-analysis and decision-analysis. In addition, there is a lack of regard of the tacit knowledge that needs to be extracted in order to perform decision-analytics and quantify risks. Additionally, Linkov et al. (2014) presuppose an availability of the data necessary for model creation and subsequently risk-model estimation, a requirement which is not met by the ANVS. However, Linkov et al. (2014) provide an avenue to explore for further research regarding the development of data-driven risk-based regulation, even though it was not developed for regulatory purposes.

The notion of knowledge creation as defined by Nonaka (1995), contributes how tacit knowledge can be internalised by an organisation as well new knowledge creation from multiple sources of tacit knowledge. If executed effectively elements of Nonaka might prove to be useful for regulatory agencies like the ANVS. However, a scarcity regarding explicit knowledge in the organisation makes organisational knowledge creation complex. Additionally, simply applying the notion of knowledge creation does not produce data-driven risk-based regulation. Therefore, in order to prove useful for fulling organisational desires towards DDRBR, knowledge creation needs to be applied in conjunction with other approaches.

Finally, organisational learning, a consequence of the skilled application of handling of knowledge sources, is not a concept that can be directly applied in each organisation. Nevertheless, for regulatory agencies applying organisational learning in general might prove to be beneficial regarding inspection processes. As a regulatory agency approaches DDRBR, novel insights should prompt an evaluation of methods currently employed within the regulatory framework. Evaluation resulting in organisational learning loops with intent to increasing efficiency or realise improvements. However, to achieve this a conducive environment within the organisation is necessary, as is the documentation of the inspection process, including the decision-making regarding expert judgement.
2.6 Knowledge gap and research question

This literature review shows that there is an absence regarding the development and the prerequisites for successful data-driven applications to risk-based regulation within regulatory agencies. The desire of regulatory agencies to embrace and capitalise on the promises of the data-driven world is strong, as is the case for the ANVS. Because of their ambition to continually realise improvements in regulatory oversight, especially concerning the inspection process, data-driven risk-based regulation might be the best strategy to realise those improvements. While risk-based regulation has a proven track record, hardly any research mentions the ability of data-driven techniques in order to improve risk-based regulation. Nor is there any research mentioning the prerequisites for data-driven risk-based regulation or organisational elements conducive to the development of data enhanced regulation.

As the ANVS is starting from scratch regarding data enhanced regulation the work by Van Bulderen (2018) does not apply to this case. The ANVS have neither embraced a structured approach to data collection nor do they have the knowledge base of data scientists which were present during the research done by Van Bulderen.

The ANVS is thus best described as an organisation attempting to improve regulatory oversight by aiming to achieve data-driven risk-based regulation within the inspection process. What this literature has shown is that knowledge creation is a presupposition for organisational learning. As the inspection process within many regulatory agencies is primarily tacit, exploiting the expertise of the inspectors, it is extremely hard to combine the tacit knowledge with explicit knowledge (Nonaka, 1995). The expertise of the inspectors needs to be converted into explicit knowledge before learning processes can begin.

This thesis research will therefore address the knowledge gap regarding the prerequisites for achieving risk-based regulation within a regulatory agency. The research objective of this thesis will be determining the necessary factors in order to create a conducive organisational environment for the development of data-driven risk-based regulation. The main research question for this thesis will be: “What are the prerequisites for adopting data-driven risk-based regulation by regulatory agencies?”. The literature review suggests developing an expanded learning model, for which the framework by Linkov et al. (2014) provides a good base line. The expanded learning model can include the notions of knowledge creation as defined by Nonaka (1995). In addition, research will be done in order to determine the prerequisites or requirements for a conducive organisational environment which will enable the development of data-driven risk-based regulation. In chapter 3 the methodology of this thesis is expanded upon and sub-research questions are defined in order to help answer the main research question.
3

Research Approach

With a clear demarcated problem presented in chapter one and a well specified research area and knowledge gap specified in chapter two, chapter three of this thesis will address the research approach conducted. The best research approach, as always, depends on the research objectives. Given the research gap explained in chapter two, there is a lack of scientific literature on data-driven risk-based regulation. This chapter will address how this research gap will be filled using design-science research (DSR). This research paradigm is renowned for centralising its problem-solving capacities in real-world situations.

In chapter 3.1 an introduction on design science research is given and core concepts of the methodology are explained and expanded upon. In addition, a generic research approach is outlined. As chapter 3.2 continues, a specific research methodology is developed, utilising the concepts defined in 3.1.

3.1 Design science research methodology

With a firmly established knowledge gap regarding data-driven risk-based regulation, the desire for regulatory agencies in the Netherlands to attain this form of regulation seems impossible. Design science research (DSR), a problem-solving paradigm with the purpose of ameliorating the efficacy of organisations by designing artefacts (Hevner et al., 2004; Wieringa, 2014), provides a paradigm able to deal with such a situation. The ability of the DSR paradigm of incorporating stakeholder goals and social context through the design of an artefact, appears to be the right approach to attain the goals specified by the ANVS.

Design science research as a paradigm has three crucial components: the object of study and its two major activities (Wieringa, 2014). In DSR the object of study is an artefact in context, and its major activities are the design and investigation of this artefact in context.

3.1.1 Design science

The artefacts under study in DSR are primarily designed for interaction with the organisational problem context, in order to improve something within that context. The problem context of this thesis, as elaborated upon in chapters one and two, is the inspection process within regulatory agencies and in particular the inspection process of the ANVS.

An artefact is to be interpreted broadly, Hevner et al. (2004) mention constructs, models, methods and instantiations, while Wieringa (2014) takes an even
broader definition, and only excludes certain artefacts such as: people, values, desires, fears, goals and norms. As these are a given to a design science researcher as a component of the problem context, not the artefact to be designed. An important note for DSR is that the artefact as such does not solve any problem, it is the interaction between the problem context and artefact that contributes to problem-solving (Wieringa, 2014). Therefore, a study of the artefact or the context alone is insufficient, and emphasis is placed on the interaction.

The problem context of an artefact is extended in DSR by the stakeholders of said artefact and the knowledge basis by which the artefact was designed (Hevner et al., 2004; Wieringa, 2014). This extended context is the contextual framework for design science research (See Figure 5).

![Figure 5. Design science research conceptual framework (Wieringa, 2014)](image)

### 3.1.2 Design science framework

The social context (Wieringa, 2014) or environment (Hevner et al., 2004) comprises the stakeholders, who may affect the research or are affected by the research. This includes possible users of the artefact to be designed. In addition, it defines the problem space, which includes the interaction environment with the artefact, which are the phenomena of interest (Hevner et al., 2004).

The knowledge context or knowledge base is composed of existing theoretical foundations and methodologies from science and engineering. The knowledge base includes all prior, relevant research conducted, e.g. specifications of currently known designs or foundational theories (Hevner et al., 2004; Wieringa, 2014). A DSR project
uses the knowledge base and may add to it by producing a new design or answering knowledge questions.

The knowledge base and its inherent methodologies provide guidelines for the design cycle, in which the artefact is built, developed, justified and evaluated according to the needs of the social context or environment. Scientific rigor is then achieved by the appropriately application of existing theoretical foundations and methodologies. During this thesis empirical methods are primarily used to evaluate the quality and efficacy of an artefact. The exact methods and their descriptions will be elaborated upon in 3.2.

Finally, contributions of the research need to be assessed in the appropriate environment in order to validate and determine relevance or utility. As the DSR paradigm is a problem-solving paradigm, utility in the social context or environment is paramount. As a justified theory that is not useful for the environment contributes as little as an artefact that solves a non-existent problem (Hevner et al., 2004).

As has been well-established now, DSR is a problem-solving paradigm. From this fundamental principle of this research paradigm Hevner et al. (2004) derive a set of guidelines which highlights the notion that considerable knowledge and understanding of a problem and its solution are acquired during the development and application of an artefact (See Table 1).

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Description</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline 1: Design as an Artefact</td>
<td>DSR must produce a viable artefact in the form of a construct, a model, a method or an instantiation.</td>
<td>Model, adaptation of Linkov et al. (2014) specified to the situation at the ANVS.</td>
</tr>
<tr>
<td>Guideline 2: Problem relevance</td>
<td>The objective of DSR is to develop technology-based solutions to important and relevant business problems.</td>
<td>ANVS wants to move to a more data-adapt organisational conduct, artefact will help them achieve this.</td>
</tr>
<tr>
<td>Guideline 3: Design evaluation</td>
<td>The utility, quality and efficacy of a design artefact must be rigorously demonstrated via well-executed evaluation methods.</td>
<td>Using technical action research (Wieringa, 2014) at the ANVS, the artefact will be validated and evaluated.</td>
</tr>
<tr>
<td>Guideline 4: Research Contributions</td>
<td>Effective DSR must provide clear and verifiable contributions in the areas of the design artefact, design foundations and/or design methodologies.</td>
<td>Linkov et al (2014) is applied in the risk-management field, does not account for intricacies regarding tacit knowledge, does not account for lack of data availability.</td>
</tr>
<tr>
<td>Guideline 5: Research Rigor</td>
<td>DSR relays upon the application of rigorous method in both the construction and evaluation of the design artefact.</td>
<td>Empirical methods will be used to describe phenomena encountered during the evaluation and design phases.</td>
</tr>
<tr>
<td>Guideline 6: Design as a Search process</td>
<td>The search of an effective artefact requires utilising available means to reach desired ends while satisfying laws in the problem environment.</td>
<td>Notion of satisficing (Herbert Simon), it is more important for an artefact to work than explaining why it works.</td>
</tr>
<tr>
<td>Guideline 7: Communication of Research</td>
<td>DSR must be presented effectively both to technology-oriented as well as management-oriented audiences.</td>
<td>Artefact will be presented to both the board of the ANVS as the inspectors and data scientists, as well as publication of this thesis.</td>
</tr>
</tbody>
</table>

Table 1. Design science research guidelines and thesis compliance (Hevner et al., 2004)
These guidelines provide support for the evaluation of ‘good’ design science research. Compliant with the guidelines by Hevner et al. Table 1 provides an overview of how this thesis will adhere to these principles of good DSR.

While these guidelines help researchers in validating their research, Hevner et al. do not provide a clear research approach. However, the slack is tightened by Wieringa’s work on design science research (Wieringa, 2014). This thesis will primarily focus on the approach as defined by Wieringa but will incorporate elements from DSR as explained by Hevner et al. such as the guidelines for DSR.

### 3.1.3 Design and engineering cycles

A DSR project iterates over the designing and investigates activities necessary for the development of the artefact. The design cycle itself can be decomposed into three separate tasks: problem investigation, treatment design and treatment validation.

The design cycle is part of a larger cycle, in which the result of a design cycle is transferred to the real-world context. This engineering cycle as Wieringa states, is a problem-solving process with the following structure (See Table 2).

<table>
<thead>
<tr>
<th>Design activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem investigation</td>
<td>What phenomena must be improved and why?</td>
</tr>
<tr>
<td>Treatment design</td>
<td>Design an artefact that could treat the problem</td>
</tr>
<tr>
<td>Treatment validation</td>
<td>Would this design treat the problem?</td>
</tr>
<tr>
<td>Treatment implementation</td>
<td>Treat the problem with the designed artefact</td>
</tr>
<tr>
<td>Implementation evaluation</td>
<td>How successful has the treatment been? Which may launch a new iteration of the engineering cycle.</td>
</tr>
</tbody>
</table>

**Table 2.** Engineering cycle as defined by Wieringa (2014)

The design activities of problem investigation and implementation are very similar as the same question is asked, however with varying purpose. Implementation evaluation aims to evaluate a treatment after application in the original problem context, while problem investigation is preparation for the design of such a treatment by learning more about the problem to be treated (Wieringa, 2014).

For engineers it is customary to say that they are designing solutions, however Wieringa avoids the use of such a term, as it can blind researchers to the fact that an artefact solves problems only partially or even not at all. Wieringa proposes treatment as is used in health-care as it inherently suggests an artefact (medicine) interacting with the environment (human body) in order to treat a real-world problem (healing).

Treatment is defined as the interaction between the artefact and its problem context. As mentioned earlier, DSR does not only focus on just the design of the artefact but includes the design of the desired interaction between the artefact and its problem context, with the aim of treating the problem. Treatments, and hence artefacts are designed. These designs are documented in a specification, often the specification describes a decomposition of the artefact into its parts (Wieringa, 2014).

Implementation is defined as the applications of the treatment to the original problem context, i.e. technology transfer to the problem context. However, in real-world problems, DSR is always restricted to the first three tasks of the design cycle:
problem investigation, treatment design and treatment validation. Transfer of the new artefact to the original context is not part of the research project but may be done (Wieringa, 2014).

3.1.4 Validation and evaluation

The notion of treatment validating is performed in order to justify that treatment actually contributes to stakeholder goals if it is implemented. Within the larger engineering cycle validation is performed prior to implementation, as it seeks to investigate the effects of the interaction between an artefact prototype and a model of the problem context while comparing these with requirements on the treatment (Wieringa, 2014). This enables the development of a design theory, i.e. a theory of the properties of the artefacts and its interaction with the problem context, enabling the researcher to predict effects of artefact implementation.

Validation is contrasted with evaluation, which is the investigation of a treatment applied by stakeholders in the field. Within the engineering cycle evaluation is done after implementation, with the additional benefit of hindsight, increasing the ability of improving the design theory.

During validation research, a prototype artefact is exposed to a model of the context in order to assess performance. Frequently utilised methods to conduct validation research are single-case mechanisms of which technical action research (TAR) is a special case. This method tests a new prototype artefact in the real-world by using it to solve a real-world problem. This core validation research is done in the field, while the artefact is still under development, in order to assess performance under real-world conditions.

3.2 Research framework

The generic overview of the design science research as presented in 3.1 is specified in this sub-chapter. The main research question will be decomposed into 3 sub-research questions with the aim of helping to answer the main research question. First a short introduction and justification of the problem investigative is given. This is followed by the definition of the sub research questions, accompanied by a short explanation of the research objectives of each question. A more extensive methodological approach of the individual research questions is presented in 3.2.2 through 3.2.4.

As has been established by the overview in 3.1 the problem investigative approach as defined by Wieringa (2014) will be conducted. Choosing the problem-oriented research approach over the implementation evaluation approach is the consequence of a thin knowledge base regarding data-driven risk-based regulation. As a result, prior potential helpful artefacts are practically non-existent. Additionally, the environment or social context in which the research will be conducted is the Dutch Authority for Nuclear Safety and Radiation protection (ANVS). While the organisation is very professional and competent, they are trailing behind in the adaptation of data-enhanced decision-making and regulation. Therefore, a problem-oriented research is
much more attainable and potentially more valuable for the organisations similar to the ANVS.

3.2.1 Research questions

The problem investigative approach within the broader paradigm of DSR, as defined by Wieringa (2014), prescribes the execution of multiple iterations of the design cycle. The design cycle distinguishes three components: problem investigation, treatment design and treatment validation. The research approach and subsequently the research questions will follow the same structure as the design cycle.

With the research objective of determining prerequisites for regulatory agencies aiming to achieve data-driven risk-based regulation within their inspection process, the main research question is: "What are the prerequisites for adopting data-driven risk-based regulation by regulatory agencies?". To answer this main research question the following sub questions are formulated:

Sub question 1: How can the existing risk-based regulation framework at the ANVS be improved?

This research question serves two distinct purposes, expanding on the knowledge base already created in chapter two and identifying the problem context regarding the inspection process within the ANVS. With this dual purpose the knowledge base as well as the social context or environment are covered.

The research methods used to answer this question are described in 3.2.2.

Sub question 2: What are the design requirements for a data-driven risk-based regulation framework and what does the framework look like?

This is the design phase of the thesis, where the knowledge base and social context are combined in order to generate requirements for improvement in the social context, subsequently influencing the designed artefact. The sub question will result in an artefact, which inherently includes the requirements. As a result, this provides the opportunity to subsequently validate and justify the design, for which the responsibilities lie within the following research question.

The research methods of sub question 2 are elaborated upon in 3.2.3.

Sub question 3: To what extent does the DDRBR framework solve the problem context and satisfies its design requirements?

The final sub question is concerned with design, or artefact validation. As validation research is executed before implementation the designed artefact of sub question 2 to the original problem context. However, in order to validate and justify in a meaningful manner, elements of the artefact will interact with a model of the problem context at the ANVS, using the technical action research (TAR) approach.

The research methods of sub question 3 are detailed in 3.2.4.
3.2.2 Methodology sub question 1

With the aim of identifying the social context, environment, and hone the problem area and knowledge bases, this research questions will be answered using qualitative methods. Wieringa provides a checklist for what to include in the reporting of a design science research project, as this master thesis is. The task of defining the social context and environment are explorative of nature. However, in exploratory research it is useful to think about who might be interested in project results within the organisation. In order to determine these stakeholders, information will be gathered through multiple methods: interviews, participation observation and internal documents at the ANVS.

In addition to researching the organisation and their beliefs and goals towards data-driven risk-based regulation it is useful to refine and polish the knowledge base and potentially add to the defined research area as presented in chapter 2. This will entail performing desk research, utilising scientific research papers to sharpen the knowledge base.

3.2.3 Methodology sub question 2

With the stakeholder goals identified and knowledge base sharpened, artefact design can commence. This research question concerns itself with the development phase of the DDRBR framework. The predefined knowledge base with well-established theories and methodologies provide a design framework for the DDRBR framework. However, during the development of the artefacts novel insights can lead to additional input from social context or knowledge base. The rigor cycle and relevance cycle will aid in this process.

As a result, a data-driven risk-based regulation framework is designed with respect to social context and knowledge base while maintaining novelty.

3.2.4 Methodology sub question 3

In problem investigative research in DSR the artefact and treatment are not transferred to the original problem context. However, in order to maintain validity of the research conducted in order to design treatment and artefact, validation has to occur prior to implementation.

Technical action research (TAR) is a validation method which uses an artefact prototype or components of an artefact in a real-world context, with the aim of helping a client learn from this. TAR is a special case of a single-case mechanism experiment (Wieringa, 2014). The distinction with a single-case mechanism resides in the addition of investigating responses of interaction with the treatment with the aim of helping the client, i.e. ANVS.

In addition to validation of the artefact and treatment via TAR, the design will be communicated with several organisational levels among which the board of the ANVS and the inspectors of the ANVS.
The design science research (DSR) approach, as introduced in chapter three, emphasises the social context and environment. The fusion of the knowledge base and the environment provide the terrain in which the artefact is designed. With the knowledge base predefined in chapter two, this chapter will explore the environment of the ANV and subsequently answering the first sub research question: “How can data-driven techniques improve the existing risk-based regulation framework at the ANVS?”. 

This sub research question serves the dual purpose of describing the regulatory framework currently employed by the ANVS, as well as how this can be improved. However, the notion of improvement is fuzzy. What is improvement and according to whom? The observations mentioned in this chapter are the result of participating within the organisation, (un)structured interviews and informal conversations with ANVS employees.

Chapter 4.1 starts by briefly recapitulating what the kind of organisation the ANVS is. Chapter 4.2 elaborates upon the regulatory instruments available to the ANVS. Subsequently, chapter 4.2.1 through 4.2.3 elaborate on the three major regulatory instruments at the disposal of the ANVS and the regulatory cycle is introduced. Thereafter, chapter 4.3 focuses on in-dept analysis of the inspection framework at the ANVS. Finally, chapter 4.4 provides the conclusions of the analysis and will answer the sub research question corresponding to this chapter.

4.1 ANVS

The Dutch Authority for Nuclear Safety and Radiation protection (ANVS), is the regulatory agency responsible for safeguarding the Netherlands in the fields of nuclear safety and radiation protection (ANVS, 2017). The ANVS is a relatively new regulatory agency created in 2015 by merging various departments from multiple ministries in the Netherlands. Per August 1st, 2017 the ANVS has become an independent administrative authority (zbo), granting the ANVS independence from the Ministry of Infrastructure and Water Management in compliance with international directives. Even though the ANVS is independent and has its own decision-making capabilities, the state secretary for Infrastructure and Water management still bears political responsibility (ANVS, 2017a). While the ANVS combines the fields of nuclear safety and radiation protection, this thesis focusses on the inspection process within the department that regulates the radiation protection
sector. A justification based on preference of the ANVS, and research opportunities within that sector.

Since, the ANVS is a regulatory agency with independent status, it has a vast range of regulatory instruments at its disposal. The ANVS’s is responsible for the development of legislation, policy, regulations, supervision, licensing and enforcement (ANVS, 2017a). It governs and regulates the radiation protection sector by laying down rules, granting permits, licensing experts, performing inspections and if necessary, take enforcement action (ANVS, 2015).

4.2 Regulatory instruments

The range of regulatory instruments that the ANVS has at its disposal can be combined into three distinct categories: policy-making, licensing and inspecting. While these regulatory tools might seem particularly distinct, these are not independent activities as they can inform and influence one another. Ideally, these three major regulatory instruments are seen as part of a cycle (See Figure 6).

### 4.2.1 Policy-making

Policy-making is one of the three primary activities within the ANVS and the department for radiation control (SBC). The ANVS functions as the de facto legislative power in the field while the state secretary for Infrastructure and Water Management is the de jure politically responsible entity. Within the confines of this relationship the ANVS helps the state secretary prepare for new legislation and drafts implementation of EU-directives. In this role it functions as the administration of the state secretary.

In addition to legislative power, the ANVS is responsible for drafting, developing and implementing policy in the radiation protection sector. This means implementation of EU-directives or other international directives as well as the implementation of policy made by the organisation itself.

### 4.2.2 Licensing and registration

The ANVS is responsible for the licensing of experts, appliances and granting permits for the use of radioactive substances. In order to determine whether an exemption, permit or licence is granted the ANVS applies a risk-based regulation strategy. The ANVS calls this a ‘graded approach’ where increasingly dangerous activities are subjected to stricter criteria. As a result of this, different activities with ionising radiation require a different level of exemption. For certain activities a registration by
the ANVS is sufficient, while other activities need to be compliant with the general binding rules and a permit or licence is required in order to work with ionising radiation. The ANVS will grant or deny permits or licenses based on merits of the application of the regulatee seeking an exemption.

4.2.3 Inspections

The final regulatory instrument of the ANVS is monitoring regulatees via inspections. There are two forms of direct contact between the ANVS and regulatees, proactive and reactive. Proactive contact consists of routinely or randomly conducted inspections, whereas reactive contact is the result of complaints, whistle-blowers or incidents.

Physical ‘footfall’ inspections are the primary tool employed by the ANVS to inspect compliance. However, this type of inspection is expensive in both time and other resources (Baldwin and Black, 2012). In order to mitigate these burdens on regulatory resources the ANVS employs a risk-based regulation framework for inspections (ANVS, 2017b). This inspection and enforcement strategy (toezicht- en interventie strategie) enables the ANVS to mitigate the burden on regulatory resources while maintaining a keen eye on the sector.

Nowadays, regulatory agencies are employing data analysts in order to supplement and support their regulatory framework (Kooi et al., 2018). While the biggest regulatory agency in the Netherlands (NVWA) employs an entire team of data analysts, the ANVS only employs one data analyst. This is mainly due to the fact that the ANVS as a regulatory agency is relatively new. However, another factor which prohibits the effective use of data analysts is the lack of data availability in the organisation. Therefore, the notion of data-driven risk-based regulation for the ANVS should be viewed as a goal on the horizon.

4.2.4 Regulatory cycle

The regulatory cycle as presented in Figure 6 illustrates how policy-making provides conditions for granting or denying the licensing or registration of a regulatee. Licenced and registered organisations or individuals subsequently become regulatees and are can become subjected to inspections. Ideally, the results of inspections are evaluated and if necessary, lead to a policy change. However, while the cycle exists within the ANVS, as certain processes are not very well-documented. As a result, it reduces the capabilities of the organisation to learn and subsequently improve.

The elements of the cycle could be improved and elaborated upon in chapter 4.3

4.3 Inspection framework

While the ANVS has a vast area to regulate, it shares part of the regulatory power regarding ionising radiation with other regulatory agencies in the Netherlands. As prolonged exposure to ionising radiation is harmful for humans the sector is regulated by three regulatory agencies. The ANVS, Inspectorate SZW (Sociale Zaken en Werkgelegenheid) and the Health and Youth Care Inspectorate (IGJ, Inspectie
Gezondheidszorg en Jeugd) regulate different parts of the sector (Government of the Netherlands, n.d.). An overview of these regulatory agencies and their respective domains are presented in table 3.

While these regulatory domains might seem distinct, the ANVS takes over in case of a ‘radiation event’ as the regulatory body. The treatment after such an event is best described as reactive inspection, while proactive inspections are routine or random inspections. This chapter continues by elaborating on these two distinct fields and how the ANVS operates within them.

<table>
<thead>
<tr>
<th>Regulatory agency</th>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANVS</td>
<td>Regulation of organisations, firms and institutions utilising ionising radiation, as well as transport of radioactive substances and expert licensing</td>
</tr>
<tr>
<td>ISZW</td>
<td>Regulation of the utilisation of ionising radiation in the work environment with emphasis on safety of employees</td>
</tr>
<tr>
<td>IGJ</td>
<td>Regulation of safety and security of health care, medicines and medical applications with emphasis on safety of patients</td>
</tr>
</tbody>
</table>

Table 3. Regulatory agencies and domains regarding ionising radiation (Government of the Netherlands, n.d.)

As illustrated by Table 3, the ANVS regulates the organisation, firms and institutions that require an exemption to utilise ionising radiation or radioactive substances. The nature of activities that organisations apply are diverse. Ionising radiation or radioactive substances are used in or by e.g. museums, veterinarians, dentists, hospitals, universities, chip manufactures and welding companies. The nature and frequency of the activity determines the risk that an organisation or sector poses.

The ANVS may inspect all these companies in order to check for compliance in accordance with the rules and regulations under which they operate. As already briefly mentioned in chapter 4.2.3, the ANVS conducts inspections in two manners reactive and proactive inspections. Chapters 4.3.1 and 4.3.2 will elaborate on the process of these two types, how they are executed within the organisation and potential improvements.

### 4.3.1 Reactive inspections

Reactive inspections or investigations are the result of complaints, whistle-blowers or post-incident investigations (Baldwin & Black, 2012). The ANVS uses the same categorisation as defined by Baldwin and Black (2012). In 2018, the ANVS has handled 398 reactive investigations, of which 248 complaints and 150 post-incident investigations (ANVS, 2019). A 14 percent increase compared to the previous year (ANVS, 2019). The rise in reactive inspections is mainly attributed to increased radioactive waste in scrap and increased notifications form Dutch Custom Authority.

The amount of reactive investigations has been increasing the last years. Settling reactive investigations are a burden on regulatory resources, especially the inspectors. As a result, the amount of proactive inspections performed are trailing in comparison. This burden could be reduced via standardisation of how certain events should be handled. One of the ANVS inspectors stated: “standardisation of the inspection process
would aid me in the determining the right course of action”. This lack of standardisation makes a structured approach to data collection challenging.

At the time of writing the ANVS is investing in the standardisation of the reactive inspection process. While change is afoot, inspectors state that the ANVS can still improve by further changing certain processes. However, a better documentation of evaluations and assessments by inspectors is still called for. As of now only the cases in which ANVS inspectors deem intervention necessary are catalogued. This makes a reflection process hard and difficult.

Consequently, implementing more standardised processes would enable to collect data in a structured manner, increasing the ability to evaluate prior interventions and serve as a database to review. Because of the ANVS to move towards data-driven risk-based regulation, changes within the inspection processes seem necessary. A notion widely supported within the ANVS.

**4.3.2 Proactive inspections**

Proactive inspections or audits are inspections performed on a routine or random basis. These proactive inspections can be performed via three separate strategies (Baldwin & Black, 2012) (See Table 4). The ANVS currently employs risk-based and theme-based strategies for their proactive inspections.

<table>
<thead>
<tr>
<th>Type of inspection</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-based</td>
<td>Related to the level of risk an activity presents</td>
<td>It is cumbersome to quantify all risks</td>
</tr>
<tr>
<td></td>
<td>Riskier activities are reviewed more often</td>
<td></td>
</tr>
<tr>
<td>Theme-based</td>
<td>Well balanced between thematic risk and firm-specific risks</td>
<td>Difficult establishing scope of the theme</td>
</tr>
<tr>
<td>Random</td>
<td>Uses minimal resources in selection</td>
<td>Does not consider risk in selection of the to be inspected regulatee</td>
</tr>
<tr>
<td></td>
<td>No unfairness during selection process</td>
<td></td>
</tr>
</tbody>
</table>

*Table 4. Types of proactive inspections (Baldwin and Black, 2012)*

As a result of the heavy burden of reactive inspections the proactive inspection process and execution is underdeveloped. However, the ANVS aims to shift more towards proactive inspections by finalising the standardisation of the reactive inspection process.

The proactive inspections that are performed rely heavily upon the (tacit) knowledge and expertise of the inspectors. Inspectors need to assess risks independently for each situation. For relatively new inspectors this is difficult, as one of the more experienced inspectors said: “In the first three years of my job, a documentation of risks regarding certain sectors would have made a great contribution to my judgement process”.

The expert judgement necessary to make good decisions, cannot be learned through formal education (Nonaka, 1995). The expert judgement is primarily tacit and is developed over the years by doing. As a result, the ANVS is primarily reliant upon the expertise of the inspectors it employs. Even though these inspectors are experts
in their field, the organisation is at risk of losing this knowledge whenever an inspector leaves the ANVS.

As well as in the reactive inspection process, inspectors would prefer to standardise elements of the inspection process. Which will be necessary in order to facilitate the gradual change towards data-driven risk-based regulation within the organisation.

4.3.3 Conclusions regarding inspections

The amount of reactive investigations has been increasing the last years. As settling reactive investigations are a burden on regulatory resources, especially the inspectors. The amount of proactive inspections performed by the ANVS are trailing in comparison.

Additionally, the ANVS is heavily reliant upon the expertise of its inspectors. While the team of inspectors consists of highly knowledgeable individuals it leaves the organisation at risk of losing the expertise. A possible measure to mitigate this is a more structured and documented approach in the inspection process. Even inspectors when asked, agree that a well-documented inspection process will lead more structured approach. Furthermore, a well-structured and well-documented inspection process also enables the transfer of knowledge and the possibility of evaluation and learning after the inspection process is finalised.

Such an approach will enable the ANVS to start analysing data from their own inspections process as well as facilitate a way for inspectors to evaluate difficult or extraordinary cases. While such an approach cannot be described as data-driven risk-based regulation yet, it will lower the threshold for the ANVS in order to adopt data-driven risk-based regulation.

4.4 Conclusions sub question 1

Now the first sub research question: “How can the existing risk-based regulation framework at the ANVS be improved?”, can be answered. The ANVS is best described as regulatory agency starting the processes of data-driven risk-based regulation. The processes of aiding the ANVS in fully embracing data-driven risk-based regulation is therefore not the end point of thesis. However, it can help facilitate the first steps towards the horizon goal of data-driven risk-based regulation.

However, changing processes within the regulatory framework of the ANVS will be necessary in order to realise improvements and moving closer towards the horizon goal of the ANVS. What are the changes necessary and what are current problems hindering the ANVS from progress?

According to inspectors within the organisation improvement to the regulatory framework can be achieved via standardisation of processes, evaluation of particular or extreme cases and being able to consult a database of previous cases handled by the ANVS. In addition to aiding the inspectors, a well-structured approach to the inspection framework enables the possibility of structured data-collection and subsequently analysis by the ANVS data-analyst.
As the ANVS is about to embark on the journey towards the promised lands of data-driven risk-based regulation, critical processes in the inspection process need to be resolved first. In order for the organisation to improve the regulatory framework change will be necessary, a notion agreed upon by both inspectors and data analysts.

Such a process will need to respect the expert judgement of the inspectors as well as try to extract expert knowledge from the inspectors, in order to quantify risks and thus gaining the ability to measure and analyse risks. Not only will this heighten the ability to perform analysis, it can also facilitate an evaluation process among inspectors with the aim of sharing expert (tacit) knowledge. Subsequently, this might strengthen the regulatory cycle mentioned in 4.2.4.

As the ANVS desires to embrace data-driven risk-based regulation with the aim of improving their regulatory framework, changes have to be made to the current environment to enable this. In order to assist the ANVS, and regulatory agencies in a similar situation, an artefact is designed which aims to address and mitigate the challenges regulatory agencies face during the period of exploration towards data-driven risk-based regulation.
The knowledge base was introduced in chapter 2 and the social context and environment of the organisation in chapter 4. This chapter will focus on the design of an artefact able to assist regulatory agencies, starting from scratch regarding their data science capabilities, moving towards the desire to embrace data-driven risk-based regulation. The design-science research (DSR) approach combines the environment and the knowledge base, and uses them as a context for the design process. This chapter presents a novel design artefact, with the aim of helping the ANVS. It will do so by answering the following sub research question: What are the design requirements for a data-driven risk-based regulation framework and what does the framework look like?

The research question concerns itself with the development phase of the artefact design. The structure of this chapter will adhere to the same structure. Chapter 5.1 presents an overview of the requirements for the design artefact, following an analysis of the environment and the knowledge base. Chapter 5.2 continues by describing the design process. Subsequently chapter 5.3 introduces the artefact designed for the ANVS. Chapters 5.4, 5.5 and 5.6 describe the distinct phases in the artefact. Finally, chapter 5.7 answers the sub research questions and presents conclusions.

**5.1 Requirements of design artefact**

The environment of this research is the inspection framework of the ANVS, the context in which the artefact will interact. Wieringa calls this process treatment design (Wieringa, 2014), however the notion of treatment implies improvement from the current situation. This chapter will take a less rigid approach to the notion of treatment.

As the current situation is the result of not yet implementing data-driven risk-based regulation in the environment yet. One could argue that there is nothing to treat, but rather design an approach to reach a new manner of regulatory conduct. Therefore, the design artefact will create a new situation aiming to start the process of data-driven risk-based regulation within the organisation.

Chapter 5.1.1 will analyse the current challenges of data-driven risk-based regulation from the environment within the ANVS. Subsequently, in chapter 5.1.2 the
opportunities of data-driven risk-based regulation for the ANVS are analysed, which subsequently leads to the artefact design requirements, presented in chapter 5.1.3. The artefact requirements form the basis of the artefact design. In DSR the artefact interactions are the object of study, while validation takes the design requirements into account. How the artefact is validated is described in chapter 6.

5.1.1 Challenges for data-driven risk-based regulation at the ANVS

The lack of incorporation of data analysis in the organisation of the ANVS creates a barrier which needs to be penetrated, in order to grow towards the target of data-driven risk-based regulation. It is certainly not due to a lack of willingness among the inspectors, as they unilaterally agreed that data-driven risk-based regulation can aid their work as inspectors. However, the inspectors were also cautious and stated that there should be a balance between data insights and expert judgment. Thus, the new data insights should not devalue or replace their own instincts and expertise.

The main challenge in keeping the ANVS from data analysis is the lack of a structured approach in which data is collected in the organisation. As elaborated upon in 4.3.1 most of the reactive inspections are the result of contaminated radioactive scrap (ANVS, 2019). While all these cases will vary slightly, the vast majority of information necessary to judge these cases are similar. The risks inspectors need to account before judgement are similar, as the risk levels in each case will vary. The similarity of risks is even higher when performing proactive inspections. There are often hundreds of organisations utilising ionising radiation in the same way. In each of these organisations the risks are identical, while only the risk levels vary.

However, this can be challenging, especially for new inspectors. The ANVS currently have some relatively new inspectors. Discussing risks in a cooperative setting of all inspectors would enable the organisation to quantify what the risks are and subsequently how they are measured and judged by inspectors. This could serve a dual purpose of aiding new inspectors in judgement (knowledge creation), enabling data collection and analysis as risk definitions are standardised among inspectors.

The three challenges the ANVS have to overcome in order to start the process of embracing data-driven risk-based regulation are presented in Table 5. These three dimensions (See Table 5) are the result of analysis of structured interviews with employees of the ANVS and the design iterations as described in chapter 5.2. Employees were asked whether they were familiar with the concepts of data-driven risk-based regulation and how it could aid them during their jobs. Among the interviewed are inspectors with varying level of expertise and data analysts. Detailed information on the interview protocol can be found in appendix I.

<table>
<thead>
<tr>
<th>Data-driven risk-based regulation challenges at ANVS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Balance expert judgement and data insights</td>
</tr>
<tr>
<td>2. Data management</td>
</tr>
<tr>
<td>3. Quantify risk</td>
</tr>
</tbody>
</table>

Table 5. DDRBR inhibitors at ANVS
5.1.2 Opportunities for data-driven risk-based regulation at the ANVS

As already mentioned in chapter one, the possibilities of data-driven risk-based regulation are vast. Cutting-edge techniques are not only reserved for the private sector but can be implemented in the public sector as well. However, as the ANVS is in an early stage of data analytics it is more useful to focus on the small changes that can improve the ANVS’ regulatory framework.

The ANVS data analyst made a clear distinction between internal data and external data. He stated that: “When the ANVS has fully succeeded in management of internal data, in a structured manner, we could approach other regulatory agencies or third parties for supplementary data”.

The internal data can be defined as facts and information available from an organisation’s information system. The collection and analysis of internal data within the ANVS is unsophisticated. While there have been initiatives of data analysis in order to convey the opportunities of data science, this has not been incorporated in a structured manner in the organisation. This has created a situation in which the data management of the internal data is lacking. As a result of this situation the ANVS have yet to approach other regulatory agencies or other parties for possible relevant data regarding their regulatees.

Given the possibilities of analysing their own data, the ANVS should structure and include data analysts in the process of inspecting. A data analyst with knowledge regarding how to collect data in a structured and possibly automated manner could prove to be invaluable for the ANVS. A data analyst with a different skill set from the inspectors can lead to fruitful discussion and new knowledge (Van Bulderen, 2018).

If the ANVS can succeed in defining risks and risk-parameters, i.e. the metrics that measure a specific risk, in such a manner that enables analysis of these risks after the data collection, the ANVS is on the path towards data-driven risk-based regulation. After this structured approach to data management in the organisation it is implemented the analysis part can be automated, and results can be presented to interested stakeholders at the interval of their choosing.

The combination and interaction of data insights and expert knowledge of inspectors may also enable evaluation of cases. A desire from the inspectors within the ANVS was the ability to reflect on inspection cycles or programmes with the aim of learning. Not only will it help inspectors to share experiences and mental models, it will create knowledge for the organisation. Subsequently, evaluation of the inspections and risks can be enabled via data collected during inspections.

5.1.3 Requirements for DDRBR Framework

The analysis of the opportunities of DDRBR and the challenges the ANVS have to overcome in 5.1.1 and 5.1.2 provide us with the requirements the artefact should adhere to. The artefact should therefore mitigate the challenges the ANVS have, which are currently preventing the ANVS from progressing towards DDRBR.
The requirements for the artefact design correspond with the challenges identified for the ANVS in 5.1.1 (See Table 6). These challenges correspond with the first three requirements in the requirement list.

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Data &amp; expert judgement balance</td>
<td>For the inspectors it is important that data insights will not replace their work; it should support and aid inspectors in their judgement of risks.</td>
</tr>
<tr>
<td>2. Quantify risks</td>
<td>From a data analysis viewpoint, it is necessary to standardise the risk definitions in order to perform meaningful analyses. Additionally, for inspectors the quantification could aid (junior) inspectors in their judgement process</td>
</tr>
<tr>
<td>3. Data management</td>
<td>To continually perform analyses, the notion of data collection and analysis should be embedded in the inspection process. Without embedding of good data management in the ANVS will not overcome its challenges</td>
</tr>
</tbody>
</table>

Table 6. Requirements for artefact design

5.2 Design process

An artefact in the most general sense is something created by individuals for a practical purpose (Wieringa, 2014), while Hevner et al. (2004) limit their definition of an artefact to constructs, models, methods and instantiations. Even though Wieringa (2014) provides a very broad definition of an artefact, the artefact that will be presented in 5.3 will be a model process for regulatory agencies.

The design process of the artefact was developed in a rather explorative manner. As the starting point of the first design cycle was to develop a model capable of determining risks, using Bayesian statistical inference methods. This model was aimed at achieving true data-driven risk-based regulation within the ANVS. However, given the impediments as already presented in chapter 1.3.4 and the challenges of the organisational setting of the ANVS in chapter 5.1.1 this was impossible to achieve in the duration of this thesis project. This sub chapter will be an overview of the problem framed in chapter 5.2.1. Subsequently artefact exploration and consideration are described in chapter 5.2.2. Finally, the method of design for the artefact is mentioned in chapter 5.2.6.

5.2.1 Design iterations

Design is often described as a cycle which should be performed through multiple iterations of the design cycle (Wieringa, 2014). This thesis follows the problem-investigation methodological approach within the design-science research (DSR) paradigm (Wieringa, 2014). Design cycles in DSR, and specifically in the problem-investigation approach consist of three major activities: problem investigation, artefact design and artefact validation. A design cycle is demarcated by a (radical) change in any of these three activities. For example, the second design cycle had a sharpened problem as opposed to the first design cycle.
However, all design cycle iterations have considered the notion of improving the regulatory framework of the ANVS via data science. Moreover, data-driven risk-based regulation has always been at the core of all design cycles.

The major insights gained during the three design cycles are presented in 5.2.2 through 5.2.5, for an even more detailed and elaborate exposition of the empirical design process readers are referred to Appendix III (See Appendix III).

5.2.2 Prior to start thesis project

Prior to starting the master thesis project in early February, a master thesis preparation course was taken and the foundation for this master thesis project was created in that course.

During this period, I received a graduation proposal from the ANVS (Internal document). In this proposal the ANVS stated that the student’s work should contribute to data-driven regulation at the ANVS. Specifically stating: “Initially, the research will focus on the collection of available unstructured data within the ANVS, subsequently preparing the data and execution of data analysis with the purpose of data-driven regulation at the ANVS”.

In this period, I met briefly on two occasions with Dr. Majid Farahmand of the ANVS (December 19th and January 22nd). These meetings were mostly concerned with familiarising with one another as well as conveying the abilities of an EPA MSc student to the ANVS. Additionally, the research topic was discussed and the ANVS was interested in the development of a data-driven tool or model which would enable them to assess risks and subsequently prioritise those risks. The ANVS ensured that necessary data was available to conduct such an analysis albeit that the data would be unstructured and was in need of pre-processing.

As a result of the ANVS graduation proposal and the confirmations of the ANVS a master thesis research proposal was drafted which aimed to research how data-driven tools could aid in applying data-driven risk-based regulation at the ANVS. Sub questions focused on: assessing the contribution of data-driven tools to risk-based regulation, identification of risk-parameters and the development a Bayesian Network model. This proposal relied heavily on the assertion of the ANVS that the necessary data was available within the organisation.

5.2.3 First design cycle: An explorative beginning (February – March)

After the initial master thesis preparation phase the research truly commenced in early February. The first week of thesis research I was engrossed with familiarising with the ANVS processes as well as briefly introducing myself and the research topic to a multitude of ANVS employees.

The first deadline in the thesis project was less than a month from the start. Thus, there was a sense of urgency in determining whether the initial master thesis research proposal was feasible. In order to assess the feasibility of the proposal a considerable amount of informal exploratory conversions commenced with various ANVS employees with different occupations.
These exploratory and unstructured informal conversations proved invaluable at the start of the thesis project. It became clear that there was a clear separation of tasks within the ANVS, represented by two different departments: NVB and SBC. NVB is responsible for nuclear safety and security while SBC regulates the application and utilisation of ionising radiation in the Netherlands. SBC regulates thousands of regulatees; therefore, SBC employs a risk-based strategy to determine the inspection frequency, based on the inherent risk of the application the regulatee has a licence or exemption.

The distinction between regulatory domains divided between SBSC and NVB became clear in the first few weeks. As a result, the research scope was sharpened to focus on the radiation protection sector (SBC) rather than the entire organisation (ANVS).

I conducted targeted conversations to gather more information with ANVS employees. The ANVS is a relatively small regulatory agency, employees are approachable and often do not mind elaborating on their line on work. As consequence I was able to secure an interview with the most senior inspector at the ANVS within a short period of time.

The inspector distinguished two manners of performing inspections: reactive and proactive. Reactive inspections are the result of a incidents, whistle-blowers or complaints (Baldwin & Black, 2012). The ANVS uses the same definition for reactive inspections. Proactive inspections or audits are inspections performed on a routine or random basis. The ANVS employs a theme-based strategy. Every iteration of proactive inspection round inspectors and policy analysts discuss what is the primary subject or regulation in the next period. However, the inspector stated that the proactive inspection process is underdeveloped which is primarily the result of an immense amount of reactive investigations and inspections the inspectors need to conduct.

While it is possible to employ risk-based regulation in reactive inspections, it is nearly possibly to predict where the next incident will occur. Proactive inspections often encompass hundreds of regulatees per domain under regulation. While the ANVS does not have the resources to visit all of these regulatees by physical 'footfall' inspections, the ANVS wants to employ a risk-based framework grounded in data. This would enable the ANVS to highlight which regulatees present more risk and identify where the risk of noncompliance is highest. The ANVS could subsequently deploy its assets in order to check for compliance.

Additionally, the inspector was excited by the opportunities that data-driven initiatives would contribute to the inspection process. The proactive inspection process in particular is the ideal candidate for data-driven initiatives to supplement the ANVS’ regulatory framework. However, simultaneously the inspector also stated that their expertise cannot be replaced by data and thus require a certain level of autonomy. Therefore, it is important that inspectors participate in the development of data-driven initiatives at the ANVS in order to ensure the acceptation of the new technological tools.
Within those first days I was asked to join the risk-oriented project group within the ANVS. The goal of the project is to develop an ANVS wide, integrated strategy for risk-based regulation. The members of this project team consist of ANVS employees with multi-disciplinary background from all three departments (NVB, SBC and SCO). The participants have backgrounds in policy, licensing, inspections (NVB, SBC) and a data analyst (SCO). This ‘taskforce’ was assembled by decree of the supervisory board of the ANVS, which wanted to see an ANVS wide strategy using risk-based regulation.

The first meeting of the risk-orient taskforce commenced in late February. The first meeting as an exchange of information about what the participating employees perceived to be risk-based regulation. The focus regarding risk-based regulation was primarily on inspections, which is a convenient point to start. However, as the discussion was not leading anywhere, I intervened and asked the participants to think about risk-based regulation in a more general manner.

The ANVS is a special type of regulatory agency as is an independent administrative authority (zbo, zelfstandig bestuursorgaan). This grants the ANVS the ability to influence policy and legislation, a notable distinction from other regulatory agencies.

The intervention led to a more productive discussion about risk-based regulation as a strategy for policy and licensing as well as inspections.

While the ANVS is one organisation, it doesn’t operate as one organisation. The departments of SBC and NVB operate almost entirely separate. In my opinion this is the result of the way the ANVS was formed in 2015, as various departments across ministries were combined to form the ANVS. As a result, the departments have their own domains nuclear safety and security (NVB) and radiation protection (SBC).

Sessions and project groups like these enable the ANVS to learn the ‘best practices’ from each other. Even though, the domains are different that does not mean that the departments cannot learn anything from one another. This meeting led to the identification of the literature by Nonaka (1995) on knowledge creation and knowledge sharing.

Throughout the period of the first design cycle nearly every day there would be conversations reflecting on observations and events within the ANVS. During these informal conversations two major issues surfaced. As Dr. Farahmand stated that the research proposal was too optimistic and did not accurately represent the situation at the ANVS. While some data was collected, this was not performed in a structured manner.

Even though data is collected during inspections, it is not performed in a structured or standardised manner. Often only data of noncompliance was stored in the form of text in reports. Additionally, the data that is collected is not stored in a standardised manner which inhibits quick data analysis.

It became clear that assumptions prior to this period at the ANVS were off-target. Initially it was assumed that the construction of a risk-based model using internal data was truly possible. It became apparent that the organisation was facing some
dilemmas regarding the implementation of data management in their primary business process. The ANVS is first and foremost a regulatory agency, as a consequence the focus lies on regulating. While the ANVS have mentioned data opportunities in their strategy of continuous improvement (ANVS, 2015), an approach to data analysis has yet to reveal itself. However, there are multiple projects within the organisation aimed at digitalisation, in addition to performing the tasks of the day-to-day. This is used as an argument for commitment to data-driven initiatives in the short term. Consequently, data-driven initiatives are side-tracked or postponed a phenomenon which has occurred at multiple regulatory agencies (NVWA, SodM; See Ch.6 Validation).

Regulatory agencies often find themselves in a catch-22, how to improve the regulatory framework without constraining the agency from conducting business? (Beaudrie & Kandlikar, 2017) Unsuccessful attempts might lead to regulatory failure. This dilemma prevents regulatory agencies from continuing on the path towards data-driven risk-based regulation.

5.2.4 Second design cycle: Framework scoping & prerequisites (March – May)

The second design cycle took into account the considerations and findings for the previous design cycle. As a result of limited data availability, the scope of this thesis project was realigned to a more explorative research approach identifying the challenges on the path towards data-driven risk-based regulation.

Data-driven risk-based regulation is the renowned concept in landscape and research surrounding regulatory agencies. However, there is a clear gap in the scientific literature on how to achieve data-driven risk-based regulation. While the benefits of data science, big data and evidence-based decision-making can be substantial, there is no available roadmap for regulatory agencies to achieve data-driven risk-based regulation. The scope of the research was subsequently realigned to reflect this knowledge gap.

There is ample scientific literature stating the benefits of data-enhanced decision-making (Staman et al., 2013; Höchtl et al., 2016; Kooi et al., 2018). Regulatory agencies often have to fend for themselves in the development of such a data-driven risk-based regulation framework. The absence of scientific literature on the topic does not help, nor does bureaucratic inertia and the lack of an innovative environment in governments (Höchtl et al., 2016). Governmental agencies and departments such as regulatory agencies often have inhibitors or challenges in their organisational environment preventing these agencies from adopting data-driven risk-based regulation.

The research objective in this thesis was subsequently sharpened to identify these challenges in the environment via a single-case mechanism at the ANVS in order to determine the organisational prerequisites for data-driven risk-based regulation.

The second meeting of the risk-oriented task force occurred on March 25th. The aim of the meeting was presenting how risk-based approaches were implemented in the different domains. Once more the distinction between the departments became clear.
This meeting in particular functioned as a forum where the different departments could present their implementation of risk-oriented or risk-based regulation. SBC follows the graded approach to risk as presented in Black and Baldwin (2012), where the nature of the application determines the degree of licence a regulatee needs.

A current SBC project, aimed to standardise the questions asked during an incident is reported, was already developed by NVB. NVB already has such a protocol, which was unknown until this was revealed during this meeting. Even though the questions will be significantly different elements of such a protocol could inspire or function as a baseline.

In particular this event and a later event in this design cycle led to the conclusion that notion of knowledge creation would be very important for the ANVS in order to develop risk-based regulation. This led to a desk research process into knowledge creation.

Additionally, the meeting provided insights into the proactive inspection process. This was supplemented by desk research of internal ANVS documents to gain a complete overview of the proactive inspection process.

During the meeting ANVS employees asserted that there is a chasm between inspecting, licensing and policy-making. According to the employees it could be beneficial to promote information sharing among these echelons. Increased information sharing could act as catalyst for the ANVS.

Reinforcing this policy cycle and facilitating cooperation and sharing among these echelons addresses the challenge of data management. Consolidating the record keeping systems of licences and registrations would create an “end-to-end” database which could help inspectors and the inspection process as well as improve the ability to share data with other regulatory agencies.

The realignment of the research objectives and a change of scope meant that partly the desk research needed to be supplemented. The research objective is determining the prerequisites for adoption of data-driven risk-based regulation by regulatory agencies. The result of the desk research is mostly presented in chapter two, three and four and has implications for the design of the DDRBR framework as presented in chapter five.

In order to determine the prerequisites, the obstacles and challenges that regulatory agencies face in the adoption of data-driven risk-based regulation need to be identified. The desk research was conducted, and the results are presented in chapter two and chapter four. The challenges identified were found in literature as well as observed within the ANVS. Moreover, in the third design cycle, during external validation sessions (See Chapter 6), similar obstacles were identified at other regulatory agencies in the Netherlands.

During this design cycle formal interview were conducted with multiple inspectors and the ANVS data analyst. These formal interviews followed the protocol as presented in Appendix I. The aim of these interviews was to assess the familiarity of inspectors with
data-driven risk-based regulation and discover inspectors’ opinions on the data-driven risk-based regulation.

The interviews determined that the concept of data-driven risk-based regulation was unclear and even vague for inspectors. However, when explained what data-driven tools and data-driven risk-based regulation could contribute all inspectors agreed that it would aid their jobs. Nevertheless, all inspectors asserted that changes within the ANVS are a necessity in order to realise the benefits of data-enhanced regulation. As the manner in which inspections results are not standardised or the risk parameters explicitly defined.

These interviews determined that the inspectors at the ANVS are open to data-driven initiatives within the ANVS. However, the inspectors also expressed concern that data-driven tools should not replace the expert judgement of the inspectors but should function as an aid for the inspectors. The challenge of addressing inspector autonomy is something found in literature (Rothstein et al., 2006) as well and should be dealt with in order to realise data-driven risk-based regulation.

This thesis utilises design science research (DSR) approach as a methodological framework for the development of a process model. This process model should aid regulatory agencies in addressing the challenges regulatory agencies face when implementing data-driven risk-based regulation.

The design requirements function as mitigating factors for the challenges of data-driven risk-based regulation. The DDRBR framework artefact was developed to improve the current situation. Three main challenges were identified institutional, operationalisation and knowledge challenges. All three challenges have a base in scientific literature (Rothstein et al., 2006; Black & Baldwin, 2012; Nonaka, 1995; Smith, 2001) as well as being observed within the ANVS and other regulatory agencies.

These three challenges for data-driven risk-based regulation are addressed by defining the design requirements in such a manner that these challenges should be mitigated. The design requirements for the data-driven risk-based regulation framework are presented in Table 6 (p. 33).

Rather than starting with the design of a new artefact, DSR advocates a search process of already existing artefacts which could satisfy the design requirements and hence improve the context.

The scientific literature on data-driven risk-based regulation is scarce, there is no framework, roadmap or set of requirements which could aid organisations in the implementation of data-driven risk-based regulation. However, there are certain applications of data-driven risk-based tools (Wegman et al., 2015; Zhou et al., 2016; Eggimann et al., 2017). While these tools are not developed for regulatory purposes challenges that are addressed in the development of these data-driven risk-based tools might be transferable to the creation of data-driven risk-based regulation.

Scarcity in the scientific literature enabled a broader search for an artefact which incorporated knowledge creation and the use of data for risk-based application. This led to the identification of research by Linkov et al. from 2006, which combined
management strategies with quantitative modelling techniques and a research process of hypothesis testing as well as evaluation feedback loops. In the broad sense the strategy by Linkov et al. (2006) begins with establishing goals, modelling a system and selecting and implementing a strategy and subsequently evaluating the effectiveness of the strategy compared with the goals.

The work by Linkov et al. in 2006 provided something resembling of a framework for a much broader audience for risk-related fields. The work by Linkov et al. (2014) combined traditional quantitative risk assessments with qualitative decision-analytics to form a framework for risk-based standards. According to Linkov et al (2014) decision-analytics are a vital addendum for integrating evidence-based data in a broader strategy. Additionally, the framework enables both the integration of technical information (data) and expert values and opinions and the opportunity for evaluation and subsequently learning.

The framework by Linkov et al. (2014) was chosen as a base line to develop the DDRBR framework. Their combination of decision analytics and modelling techniques was compelling to use for the development of a data-driven risk-based regulation framework. However, as more thoroughly explained in chapter two and chapter five the framework does not account for the problems regulatory agencies face regarding their dependency on expert knowledge from inspectors. This meant that the framework of Linkov et al. (2014) could not be directly applied for risk-based regulation purposes.

The third meeting of the risk-oriented task force took place just be for Easter on April 18th. The meeting was unstructured as there was no predefined purpose established as had been done for previous meetings. The meeting functioned as defining what was readily available within the ANVS and what was lacking in order to define the ANVS wide integrated strategy. By this time the first draft of an adapted version of the framework by Linkov et al. (2014) was constructed. During this meeting I presented my initial findings and initial proposal for a data-driven risk-based regulation framework.

The taskforce was excited about a standardised approach for proactive inspections and interested in the potential contributions data analysts could provide. Especially, as currently the ANVS lacks the necessary data to conduct data analysis to provide new insights. The framework could function as process learning tool for the ANVS to become a more data mature organisation. However, the version presented did not account for the balance between expert judgement from inspectors and the data philosophies of data analysts, nor did it address the issues of rendering tacit knowledge explicit. The idea of combining the efforts of data analysts and inspectors was well received and the SBC section invited me to join a meeting of all inspectors were optimisation of reactive work would be discussed in order to potentially provide meaningful insights.

A week prior to the reactive investigation optimisation meeting I hadn’t heard from the ANVS taskforce ‘colleague’. Eager to participate and acquire potentially valuable
information in a meeting where all SBC inspectors would be present, I contacted the responsible colleague whether I would be able to observe and potentially participate. The colleague got back to me and told me after deliberation with the inspectors that the output of the meeting would be valuable but that I was not welcome at the meeting. I was surprised by this response as the same colleague had invited me and ask to join to potentially offer some insights. After pressing for participation and talking to the departmental head I was welcome at the meeting.

During the meeting an interesting discussion among inspectors arose around the topic expert judgement, expert knowledge and implicitly tacit knowledge as a concept. Expert knowledge or tacit knowledge in general is gained through learning-by-doing and many years of observing, interacting and learning from the environment. While more senior inspectors did not necessarily feel that rendering tacit knowledge regarding risks or risk parameters was beneficial, junior inspectors stated that they were looking for additional support as their expert knowledge was not as well developed as their more senior colleagues.

I was allowed to shed some light on the subject of tacit knowledge and expert knowledge and generalised the discussion to the topic of rendering tacit knowledge explicit. A senior inspector stated that while at the moment there would be no added benefit for a list of quantified risks, it would have helped tremendously during the first three years as an inspector.

The meeting concluded with inspectors stating that the quantifying risks would help the inspectors. Additionally, it increases the need for a well-documented process as well as facilitates the ability to reflect on decision-making. As a result, the inspectors are able to learn via evaluating the well-documented decision-making process which includes quantified risks.

While this meeting was aimed at optimising the reactive inspection process key insights gained during this meeting are applicable to the proactive inspection process as well. Once more it has been established that the autonomy and the expert knowledge of inspectors should be valued and actively incorporated in the framework. Additionally, by actively involving inspectors a sense of ownership is created and therefore acceptance of a data-driven risk-based regulation framework.

From the meeting with SBC inspectors followed that quantification of risks renders tacit knowledge explicit. Well-documented risks and decision-making processes allow for ex-post evaluation and offer an ability to learn. Which could be ameliorated by new data insights as a result of ANVS wide risk definitions. This could also reduce the difference in judgement from inspectors as risk definitions are standardised.

Finally, the model from Linkov et al. (2014) provides an interesting combination of decision-analytics with quantitative modelling methods. While it does not satisfy the design requirement it does provide a rough base line for the eventual DDRBR framework.
5.2.5 Final design cycle: Framework development and validation (May – July)

the development and finalising the data-driven risk-based regulation (DDRBR) framework. It has been established that the framework by Linkov et al. (2014) by itself is insufficient for a DDRBR framework, however it does provide a clear base line with elements that are compelling to include in the DDRBR framework. Such as the ability to quantify risks and facilitate cooperation between data analysts and inspectors. Consequently, the final design cycle focussed on creating an artefact, inspired by the framework of Linkov et al. (2014), compliant with the requirements and challenges of the ANVS environment.

The final design cycle took place from early May to the end of this thesis in July. During this period, I would be embedded in the ANVS environment for two or three days a week. This design cycle was primarily concerned with the framework design tailored to the situation at the ANVS. The period was also spent on writing the thesis and performing validation at the ANVS and external validation at two other regulatory agencies.

For an artefact it is necessary to satisfy the design requirements in order to facilitate a data-driven risk-based regulation process. It has been established that the framework by Linkov et al. (2014) is not directly applicable to the situation at the ANVS nor does it satisfy all design requirements. However, it provided a base-line for the design DDRBR framework as decision-analytical approach is able to facilitate multiple stakeholders (employees) with different backgrounds and perspectives.

The observations in previous design cycles confirm that it is important to include data analysts as well as inspectors in during the entire inspection process. In order to create acceptance of data analysis by the inspectors, as well as the opportunity to provide insights and learn. Therefore, the DDRBR framework describes the preparation phase as a process similar to decision-analytical approach by Linkov et al. (2014).

The DDRBR framework applies all of the literature presented in chapter two in order to mitigate the challenges regulatory agencies face in the adoption of data-driven risk-based regulation. The framework incorporates the decision-analytical approach as presented by Linkov et al. (2014) in the preparation phase. In addition, the DDRBR framework incorporates the modes of knowledge conversion by Nonaka (1995). The four modes of conversions are integral to the stages in the model. All four modes of conversion are used in different stages of the DDRBR framework in order to create organisational knowledge.

It has been determined in previous design cycles that the current manner in which data is collected at the ANVS is inadequate for meaningful data analysis. Data-driven risk-based regulation inherently relies on the data in order to make well-substantiated decisions which regulatees to inspect. The ANVS have data, but as established in the first design cycle not of high enough quality in order to create models for DDRBR.
Often data is not readily available however, if available necessary expertise is required to operationalise the data. The ANVS only employs one data analyst, the capacity to perform data analysis might impede the ability to perform the necessary tasks of data cleaning, preparing and analysing in a short period. The data management process should be streamlined as much as possible via the standardisation of data collection. The analysis phase of the DDRBR framework standardises the process and facilitates quick data analysis and the possibility to provide quick feedback of the results to inspectors.

Included in the preparation phase is the quantification of risk parameters. Quantifying risks partly mitigates the challenge of inadequate data in the organisation by rendering tacit knowledge regarding risks explicit. This enables a standardisation of risk definitions with the ANVS and provides a set of parameters which need to be measured and collected in order to perform data analysis.

The two phases of the model: preparation and analysis, provide structure and facilitate well-documented process of data-driven proactive inspections. The data-driven inspections performed as a result of the analysis phase enable the data analysts to validate and reflect on the risk model estimations.

The notion of organisational learning and loop-learning surfaced during this period. The ability of an organisation to be able to improve via learning is determined by well-defined norms, and well-documented results, which commence an evaluation and learning process. This evaluation process is invaluable in order to improve existing ‘process infrastructure’ in organisations. Learning processes are facilitated by the model on multiple levels and are elaborated upon in chapter 5.7.

5.2.6 Artefact exploration and consideration

Chapter 5.2.1 through chapter 5.2.5 elaborated on the design cycles iterated over the course of this thesis project. Additionally, it referenced the framework by Linkov et al. (2014). Their framework has proven to be an integral part of the DDRBR framework design, presented in chapter 5.4.

The framework combines the uses of decision-analytics in the form of multi-criteria decision methods (MCDA) and risk analysis and assessment. This combination, at first glance, fitted the situation of the ANVS almost perfectly, even though it was presented as a generic approach for risk-based decision making, not for data-driven risk-based regulation (Linkov et al., 2014).

Furthermore, the framework is not detailed in how it should be executed in an organisational setting. While Linkov et al., (2014) present their framework (Figure 2) and describe three sets of activities for both decision-analytics and risk-analysis, it is insufficient for implementation.

The risk-analysis part of the framework has a lack of regard for data availability. It supposes the availability of data, which was not the case for this thesis research.
Additionally, the decision-analytical activities show a lack of regard for tacit knowledge, supposing that alternatives or risks can be quantified, especially as this type of knowledge is particularly hard to share (Nonaka, 1995; Smith, 2001). Finally, it does not account for the expert judgement of the inspectors working in the organisational setting. As expert knowledge is often invaluable for organisational knowledge, it would be wise not to disregard this knowledge base.

Nevertheless, to the best of my knowledge, it was the only model, tool or method to even approximate the steps necessary for regulatory agencies to embrace data-driven risk-based regulation. Linkov et al. (2014) make a compelling case for combining traditional risk-assessment techniques with decision-analytics. This combination can ensure the integration of evidence-based data while valuing judgements from experts, stakeholders or even the effected public. This combination of balancing expert judgement with data is what is truly important for regulatory agencies. Therefore, the framework by Linkov et al. (2014) provides a clear base line and starting point for further analysis and development of the design artefact.

The DDRBR framework not only uses Linkov et al. (2014) as a baseline but incorporates the four modes of knowledge creation as defined by Nonaka (1995). Throughout this thesis the importance of knowledge creation has been conveyed and functions as a principal component for designing the DDRBR framework. All four modes of knowledge conversion are incorporated into different stages of the DDRBR framework.

The first stage: Goal Identification & Scope Definition utilises socialisation. Externalisation is performed via the subsequent stages: Risk Identification and Risk Parameter Identification & Scaling. Combination is the result of Data Analysis and Model Building. Finally, internalisation facilitates learning done via the final stage Risk Insights and the evaluation and learning process.

5.2.7 Design methodology

As previously mentioned in this thesis DSR, especially the problem investigative approach as defined by Wieringa (2014), is a problem-solving paradigm. DSR fulfils this promise via the design and study of an artefact in a problem context (Hevner et al., 2004; Wieringa, 2014). However, the artefact design was not performed by the thesis researcher in isolation. A scale of inclusion of other participants during design phases ranges from ethnographic methods, i.e. design in isolation, to co-development, i.e. design in groups (Muller et al., 1993). The methodology for the design approach in this thesis can be placed right in the middle, which is the field of participatory design. Participatory design is a design method which utilises the direct involvement of people in the development of artefacts (Kensing & Blomberg, 1998; Spinuzzi, 2005; Halskov & Hansen, 2012). The methodology originated in Scandinavia, where it was utilised as a design method showing promising results regarding stakeholder involvement (Muller et al.,1993).

The approach chosen in this thesis to design the artefact resembles participatory-design the most. While maintaining control as researcher over the
actual designs, changes to the artefact were often made according to desires or difficulties addressed by inspectors or other ANVS employees. This provided a conducive environment for discussion about the artefact. The rapid cycles of validation and design were of invaluable help to the design of the artefact.

5.3 A data-driven risk-based regulation framework

Design science research eventually leads to the development of an artefact (Hevner et al., 2004; Wieringa, 2014). With the requirements of the design defined in sub chapter 5.1, and an extensive description of the design process in sub chapter 5.2, this sub chapter presents the design artefact (See Figure 7).

The scientific literature distinguishes two types of classifications for design artefacts: product and process artefacts and technical and socio-technical artefacts (Venable et al., 2012). A product artefact are technologies (tools and diagrams) that people utilise for the completion of a task. Process artefacts are procedures or methods that guide people to accomplish a task (Venable et al., 2012). Socio-technical artefacts are artefacts which require human interaction to provide utility, while technical artefacts do not require human interaction once implemented (Venable et al., 2012).

![Figure 7. Framework for data-driven risk-based regulation](image)

According to this classification the design artefact is a socio-technical process artefact. The artefact provides a tool or procedure for data-driven risk-based regulation for regulatory agencies, which is a process requiring human interactions in order to demonstrate its utility regarding the design requirements of chapter 4.
The framework consists of 2 distinct phases, the preparation phase and the analysis phase. As can be seen in Figure 7 the phases are separated by the inspection process. The inspection process of actually visiting and auditing is not considered in the scope of this research. The inspectors at the ANVS are experienced and proficient, and need no require interference. The actual inspections where data is collected are assumed to be exogenous to the model. However, as the data collection takes place during the inspections, the abstraction is made that in the data collection stage the type of questions asked by an inspector can be influenced. This will be the result of the risk parameter identification and score stage in phase one, prior to the execution of the inspection process.

Chapters 5.4 through 5.6 will give a detailed description of what the activities exactly entail, and by which employees it should be performed, and why should it work. Chapter 5.4 describes the preparation phase, chapter 5.5 gives some insights into the inspection process. Finally, chapter 5.6 describes the stages of the analysis phase of the model.

5.4 Preparation phase

The DDRBR Framework, consists of two phases. The first phase is aimed at preparing the organisation for the actual inspections. During preparation phase the aim is to quantify risks and their respective risk parameters. This serves the purpose of externalisation, which is rendering tacit knowledge explicit, and providing the ANVS with a structured approach to incorporate data science in their inspection process. The preparation phase is essential in ensuring that the correct data is collected during the inspection process in order to ease the subsequent analysis phase.

The preparation phase consists of three stages, which will be explained and elaborated upon in chapter 5.4.1 through 5.4.3.

5.4.1 Goal identification and scope definition

The stage of goal identification and scope definition is the first set of activities that need to be performed in the framework. In this stage the goals of a round of inspection should be specified. The ANVS prefers to focus on certain aspects such as safeguards or security in an industry, i.e. thematic inspections. It is important to specify the goal for the inspections, as well as the scope. E.g. the ANVS wants to check for compliance of regulatees with high intensity radioactive substances (HASS: High Active Sealed Sources). The goal is then to determine compliance levels by regulatees while the scope is regulatees utilising high intensity radioactive substances.

As this phase is inspired by the model of Linkov et al. (2014), the first stages follow a top-down decision analytical approach. However, it is not specified who should execute this stage. As the tasks entail defining the scope and goal of the inspections, this stage can be executed similar to how inspections are prepared now in the ANVS. A small team of employees with various backgrounds: policy, licensing, data analysis and inspectors. This will strengthen the regulatory cycle as introduced in chapter 4, it
could also facilitate transfer of knowledge via socialisation (Nonaka, 1995) in this environment. Since, knowledge transfer and creation are not paramount in this particular stage, they could provide an added benefit.

Finally, this stage uses mostly existing ‘infrastructure’ and processes within the ANVS, the stage is not particularly novel but should be viewed as the starting point for the model. Linkov et al. (2014) introduced this phase utilising multi-criteria decision analysis (MCDA). However, this method relies on the identification of alternatives, which is not the case during the inspection process (Linkov & Moberg, 2012). Nevertheless, elements of this approach such as criteria and metric generation are still applicable to process. This particular stage draws on theoretical knowledge of the framework by Linkov et al. (2014) as well as the notion of knowledge creation by Nonaka (1995).

5.4.2 Risk identification

The second stage, following the goal and scope definition, concerns itself by defining risks to monitor during inspections, and how to emphasise risks compared other risks. Given the scope and goal defined in the previous stage, this stage identifies those risks corresponding to the scope and goal. Expanding on the example in 5.4.1, for the ANVS risks regarding regulatees using HASS sources, are e.g. financial risk, safety, security etc. In this stage it is important to define these areas of risks, specifically aimed at the goal and scope of the inspections as defined in the previous stage.

This stage takes its inspiration from Linkov et al. (2014) as well, however their framework focuses on criteria generation and weighting by which alternatives are scored (MCDA method). As already mentioned in chapter 5.4.1 alternatives are not considered, since the risks regarding the scope and goal already identified. Thus, this stage identifies and specifies the risk areas corresponding to the goal and scope. These risks could be defined by the same group as in the previous stage, because this is a diverse group of employees with varying backgrounds and knowledge. This process is best described as externalisation defined by Nonaka (1995). During this stage tacit knowledge, regarding risks, is made explicit during this process.

This stage aims to identify areas of risks for the regulation process of inspections. It does so via externalisation (Nonaka, 1995), as inspectors and other employees define and identify the risks given the scope and goal of the previous stage.

5.4.3 Risk parameter identification & scaling

The final activity in the preparation phase is called risk parameter identification and scaling. This stage uses the generated areas of risk defined in the previous stage, and defines those parameters that accurately predict or represent the risks which have to be measured. In the example of regulatees using HASS sources risk parameters corresponding to the risk areas are e.g. financial solvency and quality of the packaging. This stage will generate the necessary parameters in order to quantify risks and subsequently provide a scale for measuring the risk parameters.
This stage is based on the metric identification and scoring from Linkov et al. (2014). It takes the previous stage of risk identification as its starting point and further specifies the parameters that actually serve as proxies, or measure the risks identified in the previous stage.

Risk parameter identification and defining scales should be executed by preferably all inspectors, in combination with a data analyst. While the inspectors know from expertise what parameters to look at in order to determine risk, the data analyst can aid in the definition of the parameter scales in order to maximise data analysis capabilities. E.g. for an inspector it is sufficient to know whether the educational level is high enough. However, from a data analysis point of view you would want to know what the exact education level is, in order to perform meaningful analyses.

If performed in the right way they also provide the opportunity to reflect and evaluate upon certain risk parameters via findings from data analysis. Additionally, it makes risk parameters explicit. It serves partly in combination with the previous stage as externalisation, making tacit knowledge regarding risk explicit.

To summarise, this stage concludes the preparation phase by identifying risk parameters and their measuring scales according to the areas of risks defined in the previous stage. It creates new knowledge via externalisation (Nonaka, 1995). It aims to quantify risks in order to maximise evaluation purposes within the organisations and make tacit knowledge from inspectors explicit.

5.5 Inspection process

As the preparation phase is finalised the organisation will be ready to actually collect data regarding risk-parameters during the inspections. While this part is included in the model, it is best described as an ANVS black box component. The actual processes of inspectors performing inspections will not necessarily change. The model does and will not prescribe how inspectors should perform their inspections however, they should adhere to the ‘rules of the game’ provided in the preparation phase.

The quantified and operationalised risks of second and third stage of the preparation phase, enable the regulatory agency to identify a sample of regulatees, adhering to the scope defined, to inspect in order to collect data. Either inspectors will physically measure the risk parameters during the current process, or a digital inspection process will be used to measure risk parameters.

In the case of footfall inspections, inspectors should not be limited to ‘measuring’ the risks identified by them and others, but they should keep an open eye to potentially other risks. Even though knowledge regarding risks can be made explicit, the expert knowledge of inspectors is paramount and is therefore remarkably valuable during these footfall inspections, one might even say irreplaceable.

It is important to note that the actual data collection does take place during this stage. Inspectors perform inspections at organisations where risk parameters are
observed and measured. Inspector involvement during preparation phase was essential for acceptance of the new process. Actively involving inspectors will mitigate difficulties regarding acceptance of the new process, as they are a major contributor during the preparation phase. As a result, a sense of ownership is created among inspectors as they are major contributors during the preparation phase.

5.6 Analysis phase

After the inspections have been performed during the inspection process, the second phase of the model can commence. In the analysis phase, the aim is analysing these results and creating new insights, or at least provide descriptive statistics, which are both valuable contributions to the ANVS.

The analysis phase consists of three stages, which are explained and elaborated upon in 5.6.1 through 5.6.3.

5.6.1 Data collection and preparation

The first stage of the analysis phase consists of activities regarding data collection and data preparation. This stage follows the actual inspection process and aims at preparing the data for analysis, as well as the collection of data from the inspection process. Therefore, this stage should be partly executed simultaneously with the inspection process, since that process functions as the sample for data collection. Continuing the metaphor: after (digital) inspection by the ANVS of organisations with HASS sources, risks previously defined in the risk parameter identification stage are measured in these organisations. The data regarding these risk parameters are observed and therefore collected by inspectors. Subsequently, the data need to be digitalised and prepared for analysis.

During proactive inspections, inspectors investigate the compliance of the regulatees. Risks are often regarded as implicit during inspections and the risk parameters are only measured when noncompliance is determined.

During the data collection part of this stage it is important to maintain the balance between the autonomy and expertise of the inspectors and the data that needs to be collected in a structured manner. Inspectors need to observe and measure a minimum set of information necessary to perform data analysis. This minimum set of data needs to be observed from regulatees. The exact manner in which this will be executed will be open to discussion among the inspectors and data analysts. Nevertheless, apart from this minimum set of data the inspectors are free to conduct the inspection in the way they deem necessary. As inspectors might observe potential risks outside the scope, they shouldn’t turn a blind eye because it is outside of the scope previously defined.

This stage is a cooperation between data analysts and ANVS inspectors. While the data analysts can offer knowledge on how to actually collect the data and prepare it for analysis, inspectors have live interaction with the regulatee. They potentially offer insights whether the collection method is best suitable given the risk parameters.
This stage functions as a transfer of the process to the data analysts who are responsible for handling and processing the data in the analysis phase. Data collected is in need of cleaning and processing before analysis and the construction of risk models can commence in the subsequent stage.

Summarising this stage is performed partly simultaneously with the inspection process, since this is the area in which the data is collected. After collection, data is prepared for analysis by data analysts. This stage does not necessarily create any new knowledge but rather helps in the solidification of the process of proper data management in the organisation.

5.6.2 Data Analysis and model building

After data collection and preparation in the first stage of the analysis phase, this stage is concerned with data analysis and risk model building. While the necessary data preparation was performed in the previous stage, data analysis can subsequently commence. This stage aims to analyse the data collected during inspection process, and subsequently provide the means to conduct an analysis regarding the risks e.g. via the construction of a risk model. This stage is related to the second stage of the first phase, the risk identification stage. The analysis aims to provide insights in e.g. how the defined risk parameters correlate, in order to predict the security or safeguarding risks in the sector.

This stage is almost exclusively performed by data analysts with formal knowledge of statistical inference and other analysis methods. This is the first formal analysis process concerning the internal data, analyses such as descriptive statistics, correlations and regression models are within capabilities of the ANVS. If the process is iterated multiple times, the data regarding regulatees grows and trends regarding certain risk parameters can be identified. This could enable the organisation to take a proactive approach to policy development or licensing requirements, thus reinforcing the regulatory cycle.

However, it might be interesting to include a few inspectors in the data analysis process. While they will not be able to help data analysts, it can be useful to include inspectors in order to show what is actually done with the data they collected. Data visualisation can act as an important catalyst in order to facilitate discussion and increase inspector involvement. This is an easy to implement process and makes inspectors more involved in the entire process.

To summarise: the data analysis and model building stage aims at analysing the collected data during the inspection process and assessing risks via e.g. models. It will subsequently analyse the risk parameters in order to analyse their contributions to the risk areas. This provides a link between the analysis phase and preparation phase of the model. Additionally, it creates new organisational knowledge via the combination of the inspector’s definition of risks and data insights regarding risks (Nonaka, 1995).
5.6.3 Risk estimations or insights

The final stage of the second phase, and thus the DDRBR framework, is the risk estimation and data insights stage. This final stage uses the analyses performed in the previous stage and brings the process to an end by answering the goals of this inspection round. It is performed by data analysts in combination with the team responsible for the goal identification and scope definition. It presents the results of the inspections and subsequent data analysis to the original ‘problem owners’ within the organisation. Additionally, the risk models and data analyses need to be verified by conduction actual data-driven inspections.

The analyses performed by the data analysts provide insights in the risks that were observed and measured in the inspection process. It is, as opposed to all other stages, more of an evaluation stage. The analyses from the previous stage are interpreted (e.g. certain risk parameters tend to be highly correlated with noncompliance), as a result new knowledge is created by combination (Nonaka, 1995). Additionally, the result of the model iteration and a performed round of inspections might lead to new insights for policy or licensing, thus reinforcing the regulatory cycle.

5.7 Organisational evaluation and learning process

The final phase of the DDRBR framework is the organisational evaluation and learning process. Introduced in chapter two, knowledge creation is a prerequisite for the process of organisational learning (Nonaka, 1995; Smith, 2001; Falconer, 2006). The preparation phase of the DDRBR model facilitates the process of knowledge creation in multiple stages of the framework. A standardised, well-documented execution of the DDRBR framework enables organisations to reflect, evaluate and learn.

The first learning cycle is an individual learning cycle rather than an organisational learning cycle. Sharing tacit knowledge among inspectors through defining and quantifying risks for the proactive inspection process, facilitates discussion and leads to mutual understanding. The added benefit for the organisation is that knowledge is created by making these cognitive mental models regarding risks explicit.

Rendering tacit knowledge, regarding risk parameters, explicit enables regulatory agencies to measure the values of the risk parameters. Measuring these risk parameters during inspection is data collection and subsequently enables analysis. Analysis of the inspection process might reveal new insights regarding dependency or clustering of performance on certain risk parameters. Additionally, it enables the organisation to display proactive inspection results on an aggregated level. This enables regulatory agencies to provide feedback to the entire sector under regulation.

Data-driven inspections are performed as a result of execution of the analysis phase, where risks are estimated and high risk regulatees identified. Execution of data-driven inspections provides additional data which should be utilised to verify and validate
these risk estimations. This validation and verification processes reflect on the risk estimations in the analysis phase and provides the opportunity to assess the quality of the risk estimations performed.

Structuring the proactive inspection process and centralising the use of data in this process enables a regulatory agency to reflect and evaluate the entire proactive inspection process. The manner in which the actual ‘footfall’ inspections are performed might change. Additionally, the regulatory agency can even evaluate the DDRBR framework and make changes according to their specific needs.

The final learning opportunity that arises from satisfying the prerequisites of data-driven risk-based regulation is the evaluation of the regulatory cycle. The insights gathered during this proactive inspection process may lead to changes in policy, as the proactive inspection process revealed that legislation is too strict or too laissez-faire. This evaluation processes have implications for policy, which subsequently affects licensing requirements and thus changes risk parameters.

5.8 Conclusions DDRBR requirements

After careful analysis of the environment and the development of the DDRBR framework the sub research, question two: “What are the design requirements for a data-driven risk-based regulation framework and what does the framework look like?” can be answered.

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challenge 1: Data and expert judgement balance</td>
<td>As inspectors often require a certain level of autonomy, as a result of their expert knowledge, the balance between data scientists, data insights and expert judgement should be managed. DDRBR will not replace inspectors nor will it command certain actions from inspectors. It exists to improve the available knowledge on risks, support inspectors during expert judgement and potentially discover new insights. Therefore, careful consideration of the balance between expert knowledge and data insights is necessary in order to achieve DDRBR.</td>
</tr>
<tr>
<td>Challenge 2: Risk quantification</td>
<td>Risk quantification is an essential element of DDRBR, as it enables the regulatory agency to measure specific predefined risks. It is important as it renders tacit knowledge of inspectors regarding risks explicit and subsequently enables operationalisation of the risk definitions. Therefore, risk quantification is a vital process in order to achieve DDRBR.</td>
</tr>
<tr>
<td>Challenge 3: Data management</td>
<td>Proper data management should be part of the primary process in regulatory agencies. Without integration in the primary process, data is not collected and analysed in a well-structured and continuous manner. Which leaves regulatory agencies at risk of neglecting data science initiatives and are therefore unable to achieve DDRBR.</td>
</tr>
</tbody>
</table>

Table 7. Challenges regulatory agencies need to address in the early stage of DDRBR
As regulatory agencies progress in the process towards data-driven risk-based regulation, the agency will be met with inhibitors or challenges which will impede further development. For regulatory agencies at the beginning of the process of embracing data-driven risk-based regulation, three major challenges have been identified: data and expert judgement balance, quantification of risks and data management. Regulatory agencies need to address these challenges properly in order to continue the path towards data-driven risk-based regulation (See Table 7).

<table>
<thead>
<tr>
<th>Phase</th>
<th>Stage</th>
<th>Contribution in mitigating challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>Stage 1: Goal identification and scope definition</td>
<td>Involvement of multi-disciplinary team to create affiliation of the process (Challenge 1).</td>
</tr>
<tr>
<td></td>
<td>Stage 2: Risk identification</td>
<td>Involvement of multi-disciplinary team to create affiliation of the process (Challenge 1). Identified risk areas by inspectors lead to better understanding and render tacit knowledge explicit (Challenge 2).</td>
</tr>
<tr>
<td></td>
<td>Stage 3: Risk parameter identification and scaling</td>
<td>Involvement of inspectors contributes to affiliation of the process (Challenge 1). Identified risk areas by inspectors lead to better understanding and render tacit knowledge explicit (Challenge 2). Risk quantification and proper measuring scales ensure convenience and simplifies analyses (Challenge 3). Additionally, it centralises the notion of data importance in the primary process of the ANVS (Challenge 3).</td>
</tr>
<tr>
<td>Analysis</td>
<td>1. Data collection and preparation</td>
<td>Includes involvement of inspectors to create affiliation (Challenge 1). Measuring risk parameters over compliance increases the ability to analyse results (Challenge 3).</td>
</tr>
<tr>
<td></td>
<td>2. Data analysis and model building</td>
<td>Generates previously unknown insights regarding risks and demonstrates the need for proper data management in the primary process of the organisation (Challenge 3)</td>
</tr>
<tr>
<td></td>
<td>3. Risk estimations or insights</td>
<td>Demonstrates the capabilities of well-structured and documented analysis thus reinforcing the need for data to be central in the primary process (Challenge 3)</td>
</tr>
</tbody>
</table>

*Table 8. Adherence to design requirements of DDRBR framework on stage level.*
The challenges as presented in Table 7, also function as design requirements for the framework. The artefact is a socio-technical process artefact which addresses these challenges and tries to mitigate them (See Figure 8). The artefact description describes in detail how each stage and phase contribute in the mitigation of these three factors (See Table 8).

In the DDRBR the two phases aim to resolve the challenges of the organisations, allowing regulatory agencies to advance in the process of implementing data-driven risk-based regulation. The manner in which these stages individually contribute to the mitigation of the challenges, i.e. adhere to design requirements, are presented in Table 8.

![Figure 8. Overview of the framework for data-driven risk-based regulation](image)

The DDRBR framework adheres to the design requirements and mitigates the challenges these design requirements represent. The DDRBR framework provides a well-structured approach for regulatory agencies aiming to utilise data-driven risk-based regulation as a regulatory strategy.

When the requirements for design are met and the DDRBR framework is applied correctly it can facilitate evaluation and subsequently learning processes. As a result of carefully defining goal and scope and subsequently measuring and analysing risks, evaluation becomes possible as a result of the well-structured and documented approach to measuring risks. As the analyses of data collected during inspections offers new insights it can lead to changes regarding licensing or even policy changes, thus reinforcing the regulatory cycle in regulatory agencies.
Additionally, for the regulatory agencies the explicit knowledge that is created during the application of the DDRBR framework reduces the exposure to brain drains when inspectors and their expert knowledge leave the organisation.

The framework incorporates the four modes of knowledge creation as defined by Nonaka (1995). The first stage: *Goal Identification & Scope Definition* utilises socialisation. Externalisation is performed via the subsequent stages: *Risk Identification* and *Risk Parameter Identification & Scaling*. Combination is the result of *Data Analysis and Model Building*. Finally, internalisation facilitates learning done via the final stage *Risk Insights* and the evaluation and learning process.
Chapter five defined a framework for data-driven risk-based regulation and gave elaborate descriptions regarding the use and intention of the model. Chapter six will focus on the validation of the process artefact. In the problem investigate approach, which this thesis research conducts, an artefact is validated prior to implementation. As a result, artefact validation prior to implementation is more complicated than post implementation. Additionally, there are a myriad of ways to evaluate and validate in DSR, and thus a lack of consensus of how to perform artefact evaluation. Therefore, this chapter will answer the following research question: *To what extent does the DDRBR framework solve the problem context and satisfies its design requirements?*

Chapter 6.1 explains the necessity of validation research in the design science research field. Chapter 6.1.1 describes the research purpose of validation in DSR and defines utility and quality as the criteria of validation. Chapter 6.1.2 briefly explains the methodology and design of the validation research, while chapter 6.1.3 and 6.1.4 present the questions asked to determine the quality and utility of the DDRBR framework. Chapter 6.2 explains the procedure followed during validation and introduces the two other participating regulatory agencies during validation research.

Analysis of the validation results is discussed in chapter 6.3. Chapter 6.4 presents the feedback of expert validation on the DDRBR framework as well as the prerequisites of data-driven risk-based regulation. Finally, chapter 6.5 concludes the chapter by answering the research question.

### 6.1 Validation in design science research

In the design science research field, there is a widespread affirmation that conducting an evaluation is an essential activity of rigorous DSR (Venable *et al.*, 2012). DSR evaluation or validation is performed by determining the validity of the design artefact (Hevner *et al.*, 2004; Venable *et al.*, 2012; Wieringa, 2014). Without validation the results and conclusions of DSR are unjustified claims that the design artefact, if implemented in practice, will achieve its purpose (Venable *et al.*, 2012). Evaluation in DSR is therefore described as ‘crucial’ (Hevner *et al.*, 2004) and ‘essential’ (Venable *et al.*, 2012).

Even though evaluation is described as essential and crucial, Wieringa (2014) makes a distinction between evaluation and validation. Evaluation is contrasted with validation, which is the investigation of a design artefact after implementation. In the design cycle, and thus in the problem-investigative approach, validation occurs before implementation in the problem context (Wieringa, 2014). Therefore, evaluation and
validation serve different research goals in DSR, which subsequently require different research approaches.

Venable et al. (2012) do not make as clear a distinction such as Wieringa (2014) does but rather describe different evaluation periods: ex-ante (prior to artefact implementation) and ex-post (after artefact implementation). Ex-ante evaluation researches the evaluation of a yet to be implemented artefact. Ex-post evaluation, by contrast, researches the evaluation of an already implemented artefact.

Even though Venable et al. (2012) do not make the same distinction as Wieringa (2014), it can be assumed that ex-ante evaluation and validation are similar. Therefore, in the design and execution of validation research in this thesis, ex-ante evaluation (Venable et al., 2012) and validation research (Wieringa, 2014) are treated as the same. Additionally, they shall henceforth be addressed as validation, in this thesis.

6.1.1 Validation research purpose

The third guideline of Hevner et al. (2004) prescribes that “the utility, quality and efficacy of a design artefact must be rigorously demonstrated via well-executed evaluation methods”. Unfortunately, further guidance on the execution of validation is omitted by Hevner et al. (2004). However, both Wieringa (2014) and Venable et al. (2012) address this omission.

Validation in DSR is executed in order to justify that the design artefact contributes to the improvement of the original problem situation (Wieringa, 2014). Additionally, execution of rigorous validation is what solidifies DSR as a proper science (Venable et al., 2012). Without validation DSR provides, at best, unsubstantiated hypotheses about the capabilities of the design artefact to ameliorate the problem situation. In addition, to utility Hevner et al. (2004) identified quality and efficacy of the design artefact (See Table 9).

<table>
<thead>
<tr>
<th>Validation criterion</th>
<th>Description</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility</td>
<td>Evaluate an instantiation of a designed artefact to establish its utility and efficacy for achieving its stated purpose (Venable et al., 2012).</td>
<td>Determine the effectiveness of an artefact’s capabilities in solving or improving the problem context</td>
</tr>
<tr>
<td>Quality</td>
<td>Evaluate the formalised knowledge about a designed artefact’s utility for achieving its purpose (Venable et al., 2012).</td>
<td>Determine if the artefact satisfies the requirements and if the artefact addresses the purpose stated by the requirements</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Evaluate the degree to which the artefact produces its desired effect considered narrowly, without addressing situational concerns (Venable et al., 2012).</td>
<td>Determine if the artefact is responsible for the problem context to improve.</td>
</tr>
</tbody>
</table>

Table 9. Validation in design science research criteria

There is a general consensus on the importance of the three major validation criteria: utility, quality and efficacy (Hevner et al., 2004; Venable et al., 2012; Wieringa, 2014). However, the efficacy criterion aims to determine whether the artefact was
responsible for the improvements in the problem context. Since technology transfer or artefact implementation are not a part of this research, the artefact will not be validated with the efficacy criterion. Nevertheless, the utility and quality criteria will be used for validation.

6.1.2 Validation methods and design

Having established the purpose of validation research and defined the two validation criteria, it is necessary to describe the method of the validation research execution. The classification of DDRBR framework as a socio-technical process artefact has implications for the validation (Venable et al., 2012).

Additionally, the problem investigate approach (Wieringa, 2014) chosen in this thesis also influences the validation. Chapter three briefly broached the subject, the problem-investigative approach inherently requires (ex-ante) validation in a (model) context of the problem environment. Venable et al. (2012) describe such as situation as a naturalistic environment. In a naturalistic environment, validation explores artefact performance in its real environment (problem context), which is equivalent to validation research as described in the problem-investigate approach. Naturalistic ex-ante validation (Venable et al., 2012) or validation research (Wieringa, 2014) has the added benefit for the environment: a low risk to the participating organisation (Venable et al., 2014).

Given the choice for development of an artefact by analysing a single-case, the method for validation: technical action research (TAR) is chosen as it provides the added benefit of aiding the organisation in which it was developed. External validation was used to supplement the results of validation at the ANVS in order to increase the generalisability of the outcomes.

6.1.3 Utility of DDRBR Framework

The utility of a design artefact in DSR is determined by effect questions. It aims to determine whether the artefact, if implemented, would produce the desired effects in the organisational context (Venable et al., 2012; Wieringa, 2014). In order to determine utility for potential users and stakeholders it is necessary to validate whether artefact implementation is capable of producing the desired interactions and effects. Questions in order to determine utility are structured along the following protocol: To what extent does the DDRBR framework produce [effect] in the organisational context?

The desired effects the artefact produces are knowledge creation, standardisation and organisational learning. In order to assess all three elements, specific questions (See Table 10) are answered on a seven-point Likert-scale (Totally disagree, strongly disagree, slightly disagree, neutral, slightly agree, strongly agree and totally agree).
<table>
<thead>
<tr>
<th>Element</th>
<th>Validation criterion</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge creation</td>
<td>Utility</td>
<td>Facilitate knowledge creation among inspectors?</td>
</tr>
<tr>
<td>Knowledge creation</td>
<td>Utility</td>
<td>Facilitate the operationalisation of risks?</td>
</tr>
<tr>
<td>Knowledge creation</td>
<td>Utility</td>
<td>Facilitate a combination of data insights and expert knowledge?</td>
</tr>
<tr>
<td>Organisational learning</td>
<td>Utility</td>
<td>Facilitate the ability for an evaluation and learning process?</td>
</tr>
<tr>
<td>Standardisation</td>
<td>Utility</td>
<td>Provide a structured approach to the proactive inspection process?</td>
</tr>
<tr>
<td>Standardisation</td>
<td>Utility</td>
<td>Standardises the approach to the proactive inspection process?</td>
</tr>
<tr>
<td>Standardisation</td>
<td>Utility</td>
<td>Facilitate data analysis as the result of proactive inspection process</td>
</tr>
</tbody>
</table>

Table 10. Validation question to determine utility

6.1.4 Quality of DDRBR Framework

Utility determines whether or not the desired effects could be produced by the artefact, validation of quality determines if the artefact satisfies the design requirements (Venable et al., 2012; Wieringa, 2014). For the stakeholder, for which the artefact was developed. It is important to corroborate whether or not the design artefact satisfies the design requirements. Queries aiming to investigate quality are structured according to the following protocol: To what extent is the [effect] generated by the DDRBR framework satisfy the design requirements?

The design requirements of the DDRBR framework are balance expert opinion and data analysts, data management and risk quantification. These design requirements were presented to the expert during the validation session. In order to assess the extent to which the DDRBR adheres to the design requirements, experts were asked specific questions (See Table 11) to assess the quality of the framework on a seven-point Likert-scale (Totally disagree, strongly disagree, slightly disagree, neutral, slightly agree, strongly agree and totally agree).

<table>
<thead>
<tr>
<th>Design Requirement</th>
<th>Validation criterion</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data management</td>
<td>Quality</td>
<td>Meaningful data analysis is possible with the data collected?</td>
</tr>
<tr>
<td>Data management</td>
<td>Quality</td>
<td>The framework brings structure to the way data is handled?</td>
</tr>
<tr>
<td>Data management</td>
<td>Quality</td>
<td>The framework accurately describes the proactive inspection process?</td>
</tr>
<tr>
<td>Balance expert opinion and data</td>
<td>Quality</td>
<td>Inspectors are sufficiently involved in the execution of the framework</td>
</tr>
<tr>
<td>analysts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balance expert opinion and data</td>
<td>Quality</td>
<td>Data analysts are sufficiently involved in the execution of the framework</td>
</tr>
<tr>
<td>analysts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balance expert opinion and data</td>
<td>Quality</td>
<td>Expert knowledge of inspections is incorporated into the framework?</td>
</tr>
<tr>
<td>analysts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk quantification</td>
<td>Quality</td>
<td>Risk quantification and risk parameter quantification are vital to the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>execution of the framework?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk quantification</td>
<td>Quality</td>
<td>Defining risk parameters scales, increases the ability to perform data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>analysis</td>
</tr>
</tbody>
</table>

Table 11. Validation questions to determine quality

6.2 Validation of DDRBR framework

Given the nature of the environment of the ANVS: nuclear safety and radiation protection, the actual artefact was not implemented, nor was it used in a trial case. In order to determine utility and thus validate the DDRBR framework developed for
regulatory agencies, a group session was conducted with multiple ANVS employees of varying backgrounds. Among the participants were employees with experience and background in policy, data analytics and inspectors. While the primary users of the DDRBR framework will be inspectors and data analysts, the execution of the framework may lead to organisational evaluation and learning processes, which will inadvertently affect policy analysts in the ANVS as well.

6.2.1 Validation participants

Three separate validation sessions were conducted in order to assess the quality and utility of the DDRBR framework. Formal validation sessions were conducted at the ANVS and two other regulatory agencies: The Dutch Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit, NVWA) and The Dutch State Supervision of the Mines (Staatstoezicht op de Mijnen, SodM).

These regulatory agencies (NVWA & SodM) have vastly different domains to regulate and operate in an entirely different manner than the ANVS. Dissimilarities among these regulatory agencies are discernible e.g. in terms of size. The NVWA is the largest regulatory agency in the Netherlands, while SodM is a regulatory agency smaller than the ANVS.

Even though these regulatory agencies have dissimilar domains to regulate and vary in size it is fascinating to see that similar challenges regarding data-driven risk-based regulation occur as at the ANVS. Therefore, these external ‘experts’ do possess the proper understanding to validate the DDRBR framework and can reflect on the efficiency and effectiveness of the framework in their organisation.

6.2.2 Validation procedure

The validations were conducted a similar manner. A group of experts would convene in order to assess the utility and quality of the DDRBR framework. These experts would be presented with the challenges regulatory agencies face during or prior to the implementation of data-driven risk-based regulation. Subsequently, the DDRBR framework would be presented in a detailed manner. This might seem a strict and tight presentation there were often interruptions, which was encouraged prior to starting the presentation.

The interruptions often led to useful discussions about the challenges these experts face within their regulatory agency. The major elements of discussion and crucial feedback on the DDRBR framework are elaborated upon in chapter 6.4

6.3 Validation results

This subchapter presents the results of validation conducted at multiple regulatory agencies (ANVS, NVWA and SodM). Even though these three regulatory agencies are rather dissimilar, experts participating in the validation are able to reflect on the challenges and prerequisites in their organisation as well as assess the utility and quality of the DDRBR framework. This dual purpose of validation research increases
the value experts can contribute, as well as increase the generalisability of the outcomes.

The validation session conducted at the NVWA was attended by six experts: The departmental head for data analysis cluster and five data analysts. The validation session at the SodM was attended by three experts: the director of regulatory oversight, the departmental head of geothermal energy and a data analyst. It is noteworthy that the data analyst at SodM has been working as a data analyst for 15 years within multiple regulatory agencies. Finally, the initial validation session at the ANVS was attended by three experts: a policy analyst, an inspector and a data analyst.

The results of the survey assessing utility and quality are combined and presented in chapter 6.3.1 and 6.3.2 representing a response by twelve experts (N=12).

### 6.3.1 Utility

The utility of the framework determines whether the DDRBR framework is able to produce desired effects in context it is applied (Venable et al., 2012; Wieringa, 2014). For the DDRBR framework, experts assessed to what extent the DDRBR framework can produce desirable results for regulatory agencies. Execution of the DDRBR framework enables regulatory agencies to create new knowledge, standardise the inspection process and facilitate organisational learning. In order to assess these three desirable effects, the questions presented in Table 10, were posed to inspectors, data analysts, managers and policy analysts at the ANVS, NVWA and SodM.

<table>
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<tr>
<th>Knowledge Creation</th>
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<th>Standardisation</th>
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<th>Organisational Learning</th>
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Figure 9. Results of utility validation

The results of utility validation are presented in Figure 9, which shows a histogram of the responses. The results show that across all three elements: knowledge creation, standardisation and organisational learning the expert opinion was positive. In general, responses by experts were neutral (4) or higher (See Figure 9), which shows
that the DDRBR framework is able to produce these three effects. Only in two instances a neutral (4) response was given, regarding facilitating standardisation via the implementation of the DDRBR framework. The best scoring utility effect elements are knowledge creation and organisational learning.

6.3.2 Quality

The quality of the framework is determined by assessing whether the DDRBR framework adheres to its design requirements (Venable et al., 2012; Wieringa, 2014). For the DDRBR framework, experts assessed to what extent the DDRBR adheres to its design requirements: the balance between expert judgement and data analysts, risk quantification and data management. The extent to which the DDRBR framework adheres to these three requirements determines the quality of the framework. In order to assess the quality, experts at the ANVS, NVWA and SodM were posed the question presented in Table 11.

The results of this validation are presented in Figure 10, which shows a histogram of the responses by experts assessing the quality of the DDRBR framework. The results show predominantly positive responses (4 or higher). In one instance (3), a junior data analyst at the NVWA was unfamiliar with the term proactive inspection and was therefore unable to assess to what extent the framework accurately represents the proactive inspection process. The design requirement of risk quantification is especially well incorporated into the DDRBR framework according to experts as is reflected in by the high scores (See Figure 10). The final design requirement, the balance between expert judgement and data analysts, gained high scores at the NVWA and the ANVS while the experts at SodM were more cautious.

<table>
<thead>
<tr>
<th>Risk Quantification</th>
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<td>Data Management</td>
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<td>Balance expert judg-</td>
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<td>&amp; data analyst</td>
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Figure 10. Results of quality validation
During quality validation all but one score was awarded a neutral (4) or higher thus determining that the DDRBR framework satisfies the design requirements to a great extent. In particular the risk quantification and the balance between expert judgement and data analysts received multiple excellent scores (7).

6.4 Expert validation insights

The purpose of conducting validation research was not solely reserved for assessing the utility and quality of the DDRBR framework. Moreover, the validation sessions served as a discussion forum to gain expert insights. The purpose of external validation was multi-tiered as these sessions also function to validate the challenges and prerequisites identified in addition to artefact validation. Experts were given the opportunity to reflect on the DDRBR framework as well as the challenges and prerequisites of data-driven risk-based regulation within their regulatory agency.

Chapters 6.4.1 through 6.4.3 will present the major insights provided by the experts at the ANVS, NVWA and SodM. Finally, chapter 6.4.4 will describe modifications to the DDRBR framework as a result of the validation performed.

6.4.1 ANVS

The validation results of the ANVS were particularly positive. All three participants agreed that implementation of the DDRBR framework would realise improvements of the regulatory framework at the ANVS. The inspector was particularly pleased with the framework and stated: “the framework will enable improvements on multiple levels in the inspection process”.

Additionally, the inspector inquired why measuring compliance is not sufficient and specific risk parameters need to be measured. Even though compliance is crucial information for the regulator, data regarding risk parameters enables the regulatory agency and their data analysts to perform meaningful data analysis. Measuring risk parameters enables the analysts not only to track performance of noncompliant regulatees but compliant regulatees as well. Additionally, it provides better insight in the performance of all regulatees on the risk parameters defined.

The policy analyst commented that the framework does not explicitly utilise external data as input in the analysis phase of the DDRBR framework. The analyst mentioned that some regulatory agencies are already very advanced in this stage and utilise multiple data sources in order to assess risks.

The DDRBR framework does not utilise external data sources in the analysis phase, however requesting external data sources from other regulatory agencies is often on the basis of parity and reciprocity. If the ANVS were to request data from e.g. ISZW, they might request data from the ANVS. Such a request is hard to fulfil when the data available is not sufficient. Additionally, external data needs to be verified and validated which is difficult to do when the internal data is lacking. Nevertheless, when the ANVS have sufficiently improved their data warehousing, partially as a result of the DDRBR framework, the framework could very well accommodate the input of external data.
6.4.2 NVWA

The results of expert validation at the NVWA were remarkably positive. The participants in this session at the NVWA were primarily data-analysts, whom stated that the framework would be an improvement over the current situation at the NVWA. Currently, the data analysis cluster at the NVWA is physically separated from the inspectors. The data analysts reside in a different building, than the main building where the inspectors reside. Even though these buildings are separated by 15 minutes walking distance it does provide a physical barrier for interaction. This separation acted as a barrier and the data analysis cluster felt that they could not engage with inspectors in a quick manner, an entirely different situation than the ANVS where inspectors are approachable.

As a result, the data science cluster felt that they were not involved nor have any influence over the inspections process. After the inspection process had been conducted, data analysts at the NVWA receive the data from inspectors. However, there is no expectation nor are there specific requests, so contributions of the data analysis cluster are diminished. Nevertheless, if data analysis provided key insights these would be taken under advisement by the inspectors for a subsequent inspection process.

The NVWA also had similar challenges as occurred at the ANVS regarding standardisation of the inspection process, data management (warehousing), determining the quality of the data as well as acceptance and consciousness of the organisation what data scientist could contribute. This often takes years and is quite the uphill battle to demonstrate the effectiveness of data analysis in a data immature organisation. Which is something many regulatory agencies need to address when starting with data-driven initiatives to enhance the regulatory framework.

6.4.3 SodM

Expert validation results at the SodM were moderately positive. The SodM is in a similar situation to the ANVS regarding adoption of data-driven risk-based inspections. Currently the inspections conducted by SodM are expert driven, i.e. inspectors decide which locations or organisations are visited during an inspection process. The data gathered during these inspections is in the form of text, not values of predefined risk parameters.

The participants of SodM recognised the three challenges (institutional, operationalisation and knowledge) defined in this thesis. It is interesting to note that in all three regulatory agencies digitalisation processes are ongoing. In all three regulatory agencies this is used as an argument for postponing commitment to data-driven risk-based regulation in the short run. Even though digitalisation processes will influence the agency’s capabilities to embrace data-driven risk-based regulation, data analysts’ contributions to prepare the regulatory agency and the new system are often disregarded. The data analyst at SodM stated that as a result, data analysts will
inadvertently create a separate system for data analysis, which defeats the purpose of creating an end-to-end system for licencing, inspections and data analysis.

A recurring theme at these regulatory agencies also was the notion that the day-to-day needs to be executed. As a result, data-driven regulation projects are often sidetracked, postponed or neglected. The data analyst at the SodM stated that hiring data analysts is futile in this early stage as the organisation requires someone who can break the inertia and accelerate the process of DDRBR adaptation.

The data analyst of SodM produced some compelling feedback on the DDRBR framework. The analyst stated that it does not explicitly mention the inspections performed as the result of data-driven insights. There framework has the preparation phase, the inspection phase (where a sample of regulatees are visited to collect data) and subsequently the analysis phase. In the DDRBR framework it does not explicitly state that regulatees are visited as a result of the data-driven process.

This is particularly compelling feedback on the DDRBR framework as the data analyst stated that it was unclear where the actual data-driven inspection took place. Chapter 6.4.4 will address this in a detailed manner and a new iteration of the DDRBR framework is presented.

6.4.4 Modification of the DDRBR framework

The feedback from the SodM data analyst on the DDRBR framework was rather compelling. Therefore, the DDRBR framework has been adapted to better represent the data-driven inspections in the DDRBR framework.

The prior version of the DDRBR framework did not include graphical representation of the data-driven inspections. This has been added for better representation of when the data-driven inspections occur. The regular inspection process has been placed outside of the dotted model boundary in order to reflect the distinction between the current inspection process, the data-driven inspections and the interaction of the DDRBR framework. The inspection process represents the manner in which currently inspections are performed, i.e. expert-driven. During this expert-driven inspection process inspectors are asked to collect supplementary data for the analysis phase, in order to commence the data-driven inspection process.

Additionally, the input for the organisational evaluation and learning process is the entire data-driven component of the DDRBR framework. The execution of the data-driven inspections enables the data analysts to validate and reflect on the models created during the analysis. This is an addition to the evaluation and learning process the DDRBR framework facilitates.

Figure 11 illustrates the new version of the DDRBR framework incorporating the feedback gained during the validation sessions. Noteworthy changes are the addition of the data-driven inspections following the analysis phase, placing the current inspection process exogenous to the dotted model boundaries, and using the entire
model as input for the organisational evaluation and learning process. The model heightens the ability to evaluate and learn by standardisation, increased documentation and knowledge creation.

![Organisational Evaluation and Learning Process Diagram](image)

**Figure 11.** Post validation version of the DDRBR framework

### 6.5 Validation research conclusions

Utilising the external expert validation in addition to the ANVS validation session the third sub question was answered: *To what extent does the DDRBR framework solve the problem context and satisfies its design requirements?* The validation sessions gathered feedback on the prerequisites and challenges of data-driven risk-based regulation, as well as the utility, quality and design of the DDRBR framework. Validation sessions showed that the DDRBR framework would be beneficial for regulatory agencies. The utility and quality of the DDRBR was considered high by all experts. The experts provided useful feedback for on the DDRBR framework which has led to an improvement of the DDRBR framework as presented in Figure 11 in chapter 6.4.4.
Discussions and Conclusions

The final chapter of this thesis concerns itself with a reflection on the research performed. Chapter 7.2 addresses the limitations of this thesis research as a determinant of choices made in the duration of this thesis regarding methodology, scope, problem definition and research area. Additionally, chapter 7.3 discusses possible lines of research which have emerged from this thesis research. Finally, the conclusions and outcome of this research are presented in chapter 7.4. Each research question, as defined in chapter three, will be addressed as well as the main research question. Chapter 7.5 provides a reflection of the thesis project, contributions to scientific research and practical relevance. Finally, chapter 7.6 establishes a link between the main research question and the Engineering and Policy Analysis master’s programme. However, this chapter will start with a brief recapitulation of the problem and research area to refresh the mind of the reader.

7.1 Data-driven risk-based regulation adoption

Over the course of the last decade the role of data in society, businesses and governments has changed tremendously. New technologies continue to influence the way data is collected, managed and used in organisations. Regulatory agencies aim to reap the benefits of data-enhanced decision-making and business conduct via the implementation of data-driven risk-based regulation. Regulatory agencies often work in a risk-oriented manner and regulate accordingly. Risk-based regulation allows the regulatory agency to prioritise the deployment of their resources to regulatees which satisfy the current objective of the proactive inspection process (Black & Baldwin, 2012).

Data-driven risk-based regulation (DDRBR) is a strategy which enhances this process by supplying the regulatory framework with insights produced by data analysis. However, implementation of such an approach is not an unchallenging feat. Often there are organisational dilemmas, challenges or even inhibitors that need to be overcome in order to implement a data-driven risk-based regulation framework at a regulatory agency.

The DDRBR framework developed during this thesis addresses these organisational challenges, and enables the collection, management and analysis of data during the proactive inspection process. The framework satisfies the prerequisites and provides a structured approach to the proactive inspection process, which centralises data collection and analysis in that process. As a result, regulatory agencies are able to create new knowledge, and subsequently perform an evaluation...
and learning process. This learning process facilitates evidence-based discussions and allows for improvements of the regulatory framework.

7.2 Limitations of research

The first limitation of this thesis research is the result of the scope and research execution. The DDRBR framework, or artefact, was developed in a single-case mechanism at the ANVS. While there is ample justification for choosing to do so it harms the generalisability of the outcomes of this thesis research. Even though validation was not only conducted at the ANVS, it diminishes generalisability of the findings. The DDRBR framework may generalise to a different environment that the ANVS.

A second limitation is the lack of a technology transfer or implementation in a real-world context. The problem investigative approach by Wieringa (2014) does not mandate the implementation of the designed artefact in a real-world context. Actually, implementing the artefact would enable evaluation on a different level from the one performed now. Validation was executed on the premises of a theoretical implementation in a model problem context. This means that the risk of a false positive increases.

The third limitation is pertained to the methodological approach taken during this thesis. Design science research (DSR) is not the most rigorous research approach. Although all implementations of DSR stem from Hevner et al. (2004), researchers often define different methodological approaches to DSR (Geerts, 2011; Wieringa, 2014; Johannesson & Perjons, 2014). Even though the most rigorous approach of DSR is presented, in particular by Wieringa (2014) and Johannesson and Perjons (2014), the design process still heavily relies on the creativity and intuition of the researcher.

The final limitation pertains to the small knowledge base on the topic of data-driven risk-based regulation. The notion of data-driven risk-based regulation is relatively new in the regulatory landscape. The existing knowledge base of data-driven risk-based regulation was meagre. Consequently, this influenced the design of the DDRBR framework artefact. As the constructed artefact inherently represents the researcher’s knowledge of the problem context, the artefact designed is an experiment. During the execution of DSR, researchers learn about the environment, problem context, and possible solutions. Therefore, the process of DSR relies heavily on experience and trial-and-error methods. As a result, the small knowledge base leads to an experimental design artefact.

7.3 Future research opportunities

A number of possible future research opportunities have emerged from this thesis. A brief elaboration of potential future research opportunities is addressed here.
As mentioned among the research limitations and throughout this thesis, the omission of artefact implementation or technology transfer harms the generalisability as well as analysing the consequences of artefact implementation.

The implementation of the DDRBR framework at regulatory agencies aims to mitigate the challenges in the organisations. However, the implementation of the artefact might subsequently lead to new dilemmas or challenges for regulatory agencies. The interactions of the DDRBR framework with these dilemmas could create new effects, which could be beneficial or undesirable. The implications as a result of these effects, desirable or not, should be the object of study in future lines of research on this topic.

Two possible challenges and dilemmas that could arise are: IT infrastructure in the agency could become insufficient to quickly handle and process vast amounts of data, expertise of data analysts in the agency could become insufficient to develop increasingly complex risk assessment models.

Data-driven risk-based regulation is currently all the fuss in the landscape, and in research surrounding regulatory agencies. Agencies are pressurised by higher ranks of government to incorporate data analysis into their regulatory framework. While this research acknowledges that this is not an easy feat for regulatory agencies, there is no available roadmap for regulatory agencies to achieve this. This research provides a first step for regulatory agencies at the onset of starting the journey towards data-driven risk-based regulation. Therefore, a future line of research should focus on reviewing how data-driven risk-based regulation is implemented at different regulatory agencies, with the aim of identifying distinct stages in the adoption of data-driven risk-based regulation.

A final line of future research could expand upon, and further develop the DDRBR framework. Currently the framework enables regulatory agencies to share knowledge and collect internal data. However, external data sources from other regulatory agencies with similar domains or third-party data might be interesting to review as a regulator. The DDRBR framework does not utilise external data sources nor does it describe the interactions that might follow from using external data sources.

Nevertheless, the framework could be extended in the data collection phase to include the collection of external data from other regulatory agencies of third parties. However, data sharing among organisations also creates the challenges assessing the data quality and performing validation and verification of the received data. Thus, the final line of inquiry for future research should focus on expanding the DDRBR model to accommodate external data sources and describe and observe new dilemma’s, effects and learning opportunities as a result.

7.4 Conclusions

Chapter three presented the three sub research questions which aimed to assist in answering the main research question: “What are the prerequisites for adopting data-driven risk-based regulation by regulatory agencies?”. Design science
research (DSR) methodology was chosen for thesis research (Hevner et al., 2004; Wieringa, 2014). This methodology has an explorative nature, and accommodates the design of an artefact with the aim of helping a client. As a result, a framework artefact was designed for the Dutch Authority for Nuclear Safety and Radiation protection (ANVS).

### 7.4.1 Conclusions sub research question 1

**Sub question 1:** How can the existing risk-based regulation framework at the ANVS be improved?

Based on the analysis of the knowledge base (Chapter 2), i.e. all relevant methodology and theoretical foundations, and the analysis of the environment (Chapter 4), i.e. people, organisations and technology, in this thesis the regulatory framework of the ANVS could be improved in the following manner.

The current regulatory framework for proactive inspections at the ANVS is underdeveloped, as a result of reduced expert knowledge and an engrossed reactive inspection process. Additionally, data collection, analysis and management are not at the core of the primary inspection process. As change is a prerequisite for progress, changes to the regulatory framework are necessary in order to improve.

The ANVS’ regulatory framework could be improved by standardising the proactive inspection process. A detailed description of how the process should be executed, which activities it entails, and which employees are responsible for performing and managing the inspection process leads to standardisation.

Secondly, a well-structured and standardised approach to the proactive inspection process enables the possibility of structured data-collection and subsequently analysis. Good data management is important for the ANVS, as it provides a mode of knowledge creation.

Thirdly, knowledge creation by inspectors makes the tacit, expert knowledge explicit. As a result, the expert knowledge is contained within the ANVS. Consequently, this leaves the ANVS less vulnerable to brain drains when expert knowledge departs the organisation.

Finally, an evaluation process that facilitates loop-learning will enable the ANVS to reflect on processes and norms stated in the organisation. The structuring and documentation of the proactive inspection process are important determinants for improving the regulatory framework.

### 7.4.2 Conclusions sub research question 2

**Sub question 2:** What are the design requirements for a data-driven risk-based regulation framework and what does the framework look like?

The ANVS is on the onset of embarking on the journey towards data-driven risk-based regulation, where promised riches lie. However, challenges lie ahead as data-driven
risk-based regulation is not achieved easily. Given the current regulatory framework at the ANVS, there are certain challenges that need to be addressed before data-driven regulation can be realised. As a result, the ambition for the organisation is decreased. The three challenges that regulatory agencies need to address are:

Institutional challenges arise when demands on resources and expertise are made, which may lead to conflict between data scientists with data-enhanced decision-making philosophies, and inspectors with accumulated regulatory mandates through knowledge and expertise.

Secondly, operationalising data for analysis purposes is often daunting for regulatory agencies. As a consequence, regulatory often refrain themselves from taking the leap to centralise data in the inspection process.

The final challenge that arises in regulatory agencies is dependency on tacit knowledge. Throughout the years inspectors accumulate knowledge and expertise which is not made explicit. Subsequently regulatory agencies become reliant on this extensive amount of tacit knowledge and are vulnerable to organisational brain drains.

These challenges need to be addressed, in order for organisations to successfully implement data-driven risk-based regulation (DDRBR) in their inspection process. These challenges can be reformulated into three design requirements which the framework artefact needs to adhere to (See Table 12).

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>1. Data &amp; expert judgement balance</td>
<td>For the inspectors it is important that data insights will not replace their work; it should support and aid inspectors in their judgement of risks.</td>
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<tr>
<td>2. Data management</td>
<td>To continually perform analyses, the notion of data collection and analysis should be embedded in the inspection process. Without embedding of good data management, the ANVS will not overcome its challenges</td>
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<tr>
<td>3. Quantify risks</td>
<td>From a data analysis viewpoint, it is necessary to standardise the risk definitions in order to perform meaningful analyses. Additionally, for inspectors the quantification could aid (junior) inspectors in their judgement process</td>
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Table 12: Design requirements for DDRBR framework

The design requirements function as the foundation on which the proverbial house is built. The DDRBR framework (See Figure 9) utilises the four modes of knowledge creation as defined by Nonaka (1995) in order to quantify the risks. Inspector participation is paramount in order to share the tacit knowledge regarding risks, and make those risks explicit. Inspector knowledge is combined with insights from data analysts to ensure that proper data collection occurs, and data analysis is not impeded. Inspectors are subsequently kept in the loop throughout the entire process, to ensure a high level of involvedness from all participating parties.

Implementation and execution of the DDRBR framework subsequently enables regulatory agencies to evaluate their regulatory framework. Evaluation occurs via
newly created knowledge and insights and reflects on the norms regulatory agencies have regarding risks. Additionally, the newly created knowledge and insights might demand changes in policy and licensing requirements. This form of organisational learning enables continuous improvements after each iteration of the DDRBR framework.

Sub question 3: To what extent does the DDRBR framework solve the problem context and satisfies its design requirements?

Validation is an important phase of rigorous design science research (DSR). This thesis chose the problem investigative approach to DSR as defined by Wieringa (2014). In this approach an artefact is validated prior to implementation in the original problem context. While there are a myriad of ways to perform artefact validation in design science research, a consensus surrounds the validation criteria of utility, quality and efficacy. However, for DSR projects the notion of artefact implementation influences which criteria can be used for validation as well as the methodology for validation. The problem investigation approach by Wieringa (2014) does not require technology transfer, i.e. implementation in the real-world context. Therefore, the validity criterion of efficacy cannot be determined.

The validation focused on determining the utility and quality of the DDRBR framework. Validation was conducted at the ANVS and two other regulatory agencies: NVWA (Nederlandse Voedsel- en Warenautoriteit, Dutch Food and Consumer Product Safety Authority) and SodM (Staatstoezicht op de Mijnen, Dutch State Supervision of the Mines). Experts assessed the effects of the DDRBR framework: standardisation,
knowledge creation and organisational learning in order to determine utility. These effects were assessed to be beneficial for regulatory agencies to a high degree. Furthermore, experts assessed the quality of the DDBRB framework by determining the extent to which the framework adheres to its design principles. Quality validation determined that the DDRBR framework adheres in a great extent to its design requirements. Therefore, the DDRBR framework positively contributes to improving the regulatory framework and guides regulatory agencies in the adoption of data-driven risk-based regulation.

7.4.4 Conclusions main research question

Main research question: *What are the prerequisites for adopting data-driven risk-based regulation by regulatory agencies?*

The prerequisites of adopting data-driven risk-based regulation at the ANVS are the result of addressing the three challenges observed at the ANVS: institutional, operationalisation and knowledge challenges. The data-driven risk-based regulation (DDRBR) framework addresses and mitigates the challenges by centralising data collection, analysis and management in the inspection process, enabling risk quantification, and maintaining a balance between expert knowledge and data insights.

When these three prerequisites are met, which the DDRBR framework enables regulatory agencies to do so, evaluation and learning processes can be initiated. Regulatory agencies can learn by meeting the prerequisites and implementing the DDRBR framework.

However, the main research question was posed in a more general manner and not solely aimed at the situation at the ANVS. This thesis has identified five types of prerequisites which regulatory agencies should adhere to in order to ensure successful adoption of data-driven risk-based regulation. The types of prerequisites for data-driven risk-based regulation are: technical, data, knowledge, societal and organisational prerequisites.

Technical prerequisites need to be considered by regulatory agencies in order to ensure sufficient capacity of the IT infrastructure. Often the current IT infrastructure is insufficient to handle the capacity for rapid data analysis. Improvements will be necessary in terms of transmission and data storage capacity as well as the capabilities to visualise results in order to provide better data interaction with employees.

Data prerequisites require a good data management by the regulatory agency. Prior to data collection agencies should consider a number of regarding data such as: data warehousing, data cleaning, data preparation, data processing, data analysis and data visualisation. Additionally, what type of software is necessary to conduct these analyse, proprietary software, open-source programming languages or a combination
of both. On top of that, the process needs to be standardised in order to ensure rapid analyses and subsequently feedback to the relevant stakeholders.

Knowledge prerequisites require regulatory agencies to identify and specify risks and risk-parameters in order to facilitate the data-driven inspection process. The definition of risks and risk parameters are often tacit and reside in the minds of expert inspectors at the regulator. In order to perform data analyses and assess risks in a data-driven manner, these risk parameters need to be rendered explicit. Additionally, standardising risk definitions minimises inspectors bias, as well as provide the opportunity to reflect on the importance of risk parameters.

Societal prerequisites require the regulatory agency to be aware of threats of handling sizeable amounts of data. As a result of employing a data-driven risk-based regulation framework, the amount of data the regulatory agency has will accumulate. All smart systems are vulnerable to cyber-attacks and regulatory agencies should be aware and take precautionary measures. Additionally, issues of data ownership and privacy should be addressed.

Finally, organisational prerequisites need to be considered in order to ensure acceptance and trust by employees and inspectors in the regulatory agency. New practices are necessary to facilitate data-driven risk-based regulation. Introducing these practices is often complex and time-consuming and will require changes to particular processes and organisational traditions.

Satisfying the prerequisites for data-driven risk-based regulation will enable regulatory agencies improve their regulatory framework and conduct data-driven inspections. Additionally, it enhances decision-making capabilities and learning processes in regulatory agencies. This enables regulatory agencies to continually improve their regulatory framework with each iteration of the proactive inspection process. This makes regulatory agencies more resilient and places them in a constant state of improvement.

To summarise, adopting data-driven risk-based regulation is no easy feat for regulatory agencies. These agencies are often confronted with challenges acting as inhibitors for the adoption of data-driven risk-based regulation. This thesis provides a set of prerequisites in order to succeed in the adoption and implementation. Prerequisites for data-driven risk-based regulation are: technical, data, knowledge, societal and organisational. Meeting these prerequisites enables regulatory agencies to successfully adopt data-driven risk-based regulation.

7.5 Reflection

In design science research project, there is no natural point of reflection of the research conducted and the contributions to science in general. This chapters aims to
mitigate this and present a reflection on scientific contributions in chapter 7.5.1, uniqueness of the research in chapter 7.5.2 and practical relevance in chapter 7.5.3

7.5.1 Scientific contributions

The challenges of data-driven risk-based regulation when mentioned in scientific literature are often primarily concerned with data challenges. The challenges concern whether the regulatory agency is able to collect, prepare, store, analyse and utilise the data in an appropriate manner. However, prior to when these data challenges become relevant, organisational challenges need to be mitigated in order for the regulatory agency to progress on the path towards data-driven risk-based regulation. Acceptance and trust in the ability of data analysts to meaningfully contribute to the organisations is often more important than mitigating the data challenges, particularly in the early stage of data-driven risk-based regulation adoption. Negative effects arising from a deficiency in acceptance and trust by the organisation and its employees exceed the problems data challenges provide.

The challenges of data-driven risk-based regulation are not the solely applicable to the ANVS or regulatory agencies in general. The typology of prerequisites: technical, data, knowledge, societal and organisational are formulated in a generic manner in order to not solely be applicable to the ANVS. It is probable that organisations, firms and companies aiming to improve their decision-making processes via data-enhanced decision-making will need to address similar issues as the ANVS and regulatory agencies. The typology of prerequisites defined in this thesis could be applied in a more broader environment than regulatory agencies, including private corporations.

Design science research projects primarily focus on the development of an artefact in order to improve the situation of a client or stakeholder. Therefore, the DSR paradigm is an outstanding choice for and Engineering and Policy Analysis (EPA) thesis, as EPA students aim to address grand challenges and provide a policy advice to improve the situation created by the grand challenges. While within the DSR paradigm it is sufficient to prove or demonstrate that it is plausible that the created artefacts lead to an improvement, it is insufficient if the ambition for the thesis research greater than just developing an artefact. Which, in my opinion, is the case for an EPA thesis.

However, during a DSR project is relatively simple to become engrossed with the design of the artefact and lose sight of the initial main research question. DSR practitioners should be aware that the designing an artefact for a research project is a means to an end. It is the implications, effects and outcomes of the design and execution of an artefact that are the relevant insights for a research project.

The DDRBR framework is the first artefact enabling regulatory agencies to adopt data-driven risk-based regulation strategies in a well-structured and standardised manner. It provides data immature regulatory agencies with a process to facilitate the creation of internal data as well as structure the proactive inspection process for data-driven
inspections. The framework is generic enough to allow for inclusions of additional components such as external or third party and is therefore robust.

7.5.2 Uniqueness of research

The benefits and opportunities data-driven risk-based regulation can provide in order to contribute to organisational performance are enthralling. Regulatory agencies are pressured by higher ranks of government to pursue data maturity and thereby increase the efficiency. There is a lot of research conducted on the effects of data-enhanced strategies on organisational performance however hardly any research addresses the hardship of reaching data maturity and for regulatory agencies adopt data-driven risk-based regulation. This thesis addresses the hardship and challenges regulatory agencies face during the adoption of data-driven risk-based regulation and identifies a set of prerequisites for data-driven risk-based regulation adoption.

The ANVS is a regulatory at the onset of embarking on the journey to embrace data-driven risk-based regulation. There was little to none existing infrastructure, which provided a blank canvas for the research conducted during this thesis project. This particular situation allowed for thought-provoking research opportunities. More often than not regulatory agencies have already commenced the process of data-driven risk-based regulation adoption. The situation at the ANVS in early February provided a rare opportunity to research data-driven risk-based regulation in such an early stage.

Data-driven risk-based regulation is heralded for its opportunities to improve the regulatory framework of regulatory agencies. The DDRBR framework, developed as part of this thesis project, provides regulatory agencies with a specified process, which describes the process of executing data-driven inspections. The DDRBR framework is as of yet the sole artefact that enables regulatory agencies to adopt data-driven risk-based regulation and address its challenges.

7.5.3 Practical relevance

The design science research paradigm is aimed at creating an artefact, which if implemented, would improve the current situation in a certain environment. The proactive inspection process at the ANVS functioned as the environment for the DSR project in this thesis. The DDRBR framework provides the ANVS with a standardised and detailed description of the execution of a data-driven inspection process. Employees at the ANVS are excited about the opportunity to implement and execute the DDRBR framework in their organisation. The DDRBR framework will be applied at the ANVS as part of the strategy of continuous improvement in order to perform data-driven inspections.

Even though the DDRBR framework is specifically tailored to the situation at the ANVS, the challenges it addresses are perceived in other regulatory agencies. The DDRBR framework is sufficiently flexible and enables the executors of the framework
to reflect upon the model itself and make necessary adjustments to their specific environment. Therefore, the DDRBR framework is not solely relevant for the ANVS but could be implemented in other regulatory agencies aiming to embrace data-driven risk-based regulation.

The notion of knowledge creation is often defined as an essential element of organisations aiming to innovate and progress. While the importance of knowledge creation is reflected, regulatory agencies could benefit tremendously of actively trying to incorporate the modes of knowledge conversion (Nonaka, 1995). Creating organisational knowledge reduces the vulnerability of regulatory agencies to brain drains if inspectors depart the agency. Even though not all tacit knowledge of these inspectors can be rendered explicit, regulatory agencies should aim to facilitate the process of knowledge creation as it also aids the participants of knowledge creation to gain more expertise.

Regulatory agencies are accountable regarding their conduct of the domain they regulate. The bar of accountability is even higher for regulatory agencies with the status of independent administrative authorities (zbo) such as the ANVS. The DDRBR framework enables regulatory agencies to incorporate a structured approach to data management in the primary processes of the agency. In addition to the benefits data-driven risk-based regulation achieves, a more data mature organisation can provide ancillary benefits.

A data mature regulatory agency is able to maintain a higher standard of accountability by being able to provide clear insights in organisational conduct. The States General of the Netherlands or a Minister of the Crown might inquire information regarding levels of compliance. Implementation of the DDRBR framework enables organisations to be prepared for these types of inquiries by ensuring that the necessary data is available and stored.

Additionally, such an organisation would be able to be better prepared in case of request under the Freedom of Information Act (Wet openbaarheid van bestuur) and could swiftly and surely provide a response to the request. This lowers the administrative burden of such requests and increases the efficiency.

A final ancillary benefit is being able to provide detailed feedback to industry trade associations or professional bodies in industries under regulation by a regulatory agency. Subsequent to inspections in a certain industry, it could be beneficial to provide feedback by presenting aggregated performance indicators of compliance in the sector. Certain trends could be communicated to these organisations possibly influencing the conduct of association members.

7.6 Connection EPA and research area

The Engineering and Policy Analysis (EPA) Master’s programme focusses on analysing and solving complex problems in socio-technical systems. Such complex problems are often referred to as grand challenges. Grand challenges affect organisations and
people on a global scale. The EPA Master’s programme challenges students to use their engineering prowess in order to design solutions for grand challenges.

This thesis addresses the hardship of the integration of data in regulatory agencies, with the aim of realising a form of regulation that capitalises on the promise of data-enhanced decision making. This thesis uses the Design Science Research methodology to design a framework for regulatory agencies that provides a first step on the path towards the proverbial pot of gold on the horizon: data-driven risk-based regulation. For regulatory agencies the data-driven risk-based regulation framework provides an approach to quantify, measure and assess risks which enables organisations to create new knowledge, and learn in order to improve their regulatory framework. Even though this thesis does not use complex modelling paradigms as system dynamics (SD) or discrete event simulation (DEVS), it does lead to the construction of an artefact model. The DDRBR framework, a socio-technical process model, addresses stakeholder and end-user goals and desires by creating a structured process for proactive inspections. This thesis utilised theoretical knowledge and empirical methods, while combining the system perspective and the multi-actor perspective in order to create a process which facilitates the transition towards data-driven risk-based regulation for regulatory agencies.
Reference List


Appendix I: Interview Protocol

Het doel van dit interview is om te bepalen wat de percepties van werknemers binnen de ANVS zijn over het concept van data-gedreven risico-gebaseerd toezicht (data-driven risk-based regulation). Het doel is om aan inspecteurs te vragen hoe DDRBR kan helpen bij de uitvoering van hun taken, wat er in de organisatie veranderd zou moeten worden voor dit bereikt kan worden en de positieve of negatieve perceptie van DDRBR binnen de organisatie.

**Interview protocol**

Het interview dient te beginnen met een kort informeel gesprekje om de persoon die geïnterviewd wordt op gemak te stellen.

Inspecteur X
Naam:
Aantal jaren werkvaring bij de ANVS:

<table>
<thead>
<tr>
<th>Vragen</th>
<th>Antwoorden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ben je bekend met het concept van data-gedreven risico-gebaseerd toezicht?</td>
<td>[Ja, Nee, Beetje]</td>
</tr>
<tr>
<td>Interviewer geeft zijn eigen definitie van DDRBR:</td>
<td>[Open antwoord]</td>
</tr>
<tr>
<td>Data-gedreven risico-gebaseerd toezicht is de implementatie van data-science in combinatie met risico-gebaseerd toezicht. Met als doel om inspecteurs te ondersteunen met als gevolg effectiever als autoriteit op te treden en in de toekomst nieuwe patronen ontdekken met behulp van data.</td>
<td></td>
</tr>
<tr>
<td>Kan jij je vinden in deze definitie en begrijp je hem?</td>
<td></td>
</tr>
<tr>
<td>Hoe denk je dat DDRBR kan helpen bij het uitvoeren van jou taken?</td>
<td>[Open antwoord]</td>
</tr>
<tr>
<td>Question</td>
<td>Answer Type</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Verwacht jij dat er iets veranderd moet worden om DDRB toezicht te kunnen faciliteren?</td>
<td>[Open antwoord]</td>
</tr>
<tr>
<td>Welke processen?</td>
<td>[Open antwoord]</td>
</tr>
<tr>
<td>Waarom niet?</td>
<td>[Optioneel/ Open antwoord]</td>
</tr>
<tr>
<td>Wil je nog wat kwijt?</td>
<td>[Optioneel/ Open antwoord]</td>
</tr>
</tbody>
</table>

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Appendix II: Validation Questions

In this appendix the questions and form are included which has been used for validation purposes at the ANVS, NVWA (Nederlandse Voedsel- en Waren Autoriteit/ Dutch Food and Consumer Product Safety Authority) and SodM (Staatstoezicht op de Mijnen/ Dutch State Supervision of the Mines). Chapter six explained why it is important to perform validation as well as determine the validation criteria: quality and utility.

Validation process
Before experts are able to assess the utility and quality of the DDRBR framework, experts need to be informed what the DDRBR framework does and what its design requirements are. A presentation and subsequently a discussion are performed prior to distribution of the questionnaires to the experts. The presentation emphasises the challenges regulatory agencies face while adopting data-driven regulation as well as the design requirements. Additionally, a detailed explanation of the DDRBR framework is given. The stages are thoroughly explicated in order to provide the experts with as much information as possible before validation commences.

The discussion includes the experts explaining which challenges their regulatory agency faces and what prerequisites for their agency would be in order to adopt DDRBR.

Utility
In order to assess utility of the DDRBR framework effect questions were asked to experts at the ANVS, NVWA and SodM. Effect questions determine whether the DDRBR framework produces the desired effects. Table 10 presents the questions asked to determine utility.

The questionnaire (See Table 10) asks experts to assess whether the DDRBR framework is able to produce the desired effects, i.e. improve the current situation.

Quality
In order to assess the quality of the DDRBR framework, effect questions were asked to experts at the ANVS, NVWA and SodM. Quality determines if the artefact satisfies the design requirements (Venable et al., 2012; Wieringa, 2014). For the stakeholders or organisation, the artefact was developed it is important to corroborate whether or not the design artefact a satisfies the design requirements of the artefact.

The questionnaire (See Table 11) asks experts to assess whether effects generated by the DDRBR satisfy the design requirements.
Keeping the DDRBR framework and its process in mind, to what extent do you agree that the framework is able to produce the following effects? *(Please tick only one box per question)*

<table>
<thead>
<tr>
<th>Effects</th>
<th>Totally disagree</th>
<th>Strongly disagree</th>
<th>Slightly disagree</th>
<th>Neutral</th>
<th>Slightly agree</th>
<th>Strongly agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilitate knowledge creation among inspectors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Facilitates operationalisation of risks</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Facilitates an ability for an evaluation/learning process</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Provide a structured approach to the proactive inspection process</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Standardises the approach to the proactive inspection process</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Facilitates data analysis as the result of proactive inspection process</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Facilitates a combination of data insights and expert knowledge</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

*Table 10. Validation questions to determine utility*
Keeping the DDRBR framework and its design requirements in mind, to what extent do you agree that the framework satisfies the following statements? (*Please tick only one box per question*)

<table>
<thead>
<tr>
<th>Statements</th>
<th>Totally disagree</th>
<th>Strongly disagree</th>
<th>Slightly disagree</th>
<th>Neutral</th>
<th>Slightly agree</th>
<th>Strongly agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert knowledge of inspectors is incorporated into the framework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Meaningful data analysis is possible with the data collected</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>The framework brings structure to the way data is handled</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>The framework accurately describes the proactive inspection process</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Inspectors are sufficiently involved in the execution of the framework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Data analysts are sufficiently involved in the execution of the framework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Risk quantification and risk parameters quantification are vital to the execution of the framework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Defining risk parameter scales increases the ability to perform data analysis</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 11. Validation questions to determine quality
Appendix III: Empirical Process

In this appendix a comprehensive, detailed and elaborate description is given of events and observations that occurred during the thesis process. This appendix aims to give insight into the assumptions made as a result of the events and observations as well as providing a foundation for the application of theoretical knowledge and scientific theories. Certain assumptions have often heavily influenced the direction of this thesis research and subsequently the outcomes.

A detailed and thorough description of the empirical process during this thesis will aim to reduce concerns regarding the reproducibility of the insights and results as presented in this thesis.

The appendix will follow the same structure of design cycles as presented in Chapter five. The structure of the three design cycles allows for a clear overview of the design cycles each with distinct purpose. The empirical process will be presented by giving a cause and description of events or observations that have influenced the thesis outcomes. Thereby giving a clear cause and effect structure to this appendix and the design cycles.

This thesis follows the problem-investigation methodological approach within the design-science research (DSR) paradigm (Wieringa, 2014). Design cycles in DSR, and specifically in the problem-investigation approach consist of three major activities: problem investigation, artefact design and artefact validation. A design cycle is demarcated by a (radical) change in any of these three activities. For example, the second design cycle had a sharpened problem as opposed to the first design cycle.

In this appendix the changes that warranted a new iteration of the design cycle are documented as part of the empirical process.

Prior to start thesis project (December - January)

Chapter five describes three distinct design cycles which were iterated during this master thesis. However, prior to starting the master thesis project in early February, a master thesis preparation course was taken and the foundation for this master thesis project was created in that course.

During this period, I received a graduation proposal from the ANVS (Internal document). In this proposal the ANVS stated that the student’s work should contribute to data-driven regulation at the ANVS. Specifically stating: “Initially, the research will focus on the collection of available unstructured data within the ANVS, subsequently preparing the data and execution of data analysis with the purpose of data-driven regulation at the ANVS”.

In this period, I met briefly on two occasions with Dr. Majid Farahmand of the ANVS (December 19th and January 22th). These meetings were mostly concerned with familiarising with one another as well as conveying the abilities of an EPA MSc student to the ANVS. Additionally, the research topic was discussed and the ANVS was
interested in the development of a data-driven tool or model which would enable them to assess risks and subsequently prioritise those risks. The ANVS ensured that necessary data was available to conduct such an analysis albeit that the data would be unstructured and was in need of pre-processing.

As a result of the ANVS graduation proposal and the confirmations of the ANVS a master thesis research proposal was drafted which aimed to research how data-driven tools could aid in applying data-driven risk-based regulation at the ANVS. Sub questions focused on: assessing the contribution of data-driven tools to risk-based regulation, identification of risk-parameters and the development a Bayesian Network model. This proposal relied heavily on the assertion of the ANVS that the necessary data was available within the organisation.

1st Design Cycle: An explorative beginning (Early February – Mid-March)

After the initial master thesis preparation phase, and a well-deserved winter vacation in Gstaad Switzerland the master thesis project truly commenced at February 11th 2019. The first design cycle started in early February with the first day at the ANVS on February 11th. The first week was process of familiarising with ANVS processes as well as briefly introducing myself and my research topic to a multitude of ANVS employees.

Distinction Nuclear Safety and Radiation Protection

The first deadline in the thesis project was less than a month from the start. Thus, there was a sense of urgency in determining whether the initial master thesis research proposal was feasible. In order to assess the feasibility of the proposal a considerable amount of informal exploratory conversions commenced with various ANVS employees with different occupations.

These exploratory and unstructured informal conversations proved to be invaluable in at the start of the project. It became clear that within the ANVS there is a clear separation of tasks between NVB and SBC. NVB is the department responsible for nuclear safety and security and thus regulates any and all uses of nuclear applications in the Netherlands e.g. uranium enrichment, nuclear power production (EPZ, Borsele), nuclear research (Delft University of Technology) and nuclear waste storage (COVRA, Borsele). While there are only six nuclear facilities in the Netherlands, there are thousands of locations where ionising radiation is utilised. Regulating the use of ionising radiation is the regulatory domain of SBC.

SBC regulates the application and utilisation of ionising radiation in the Netherlands. Applications differ tremendously; however, they are grouped together by the ANVS in 15 distinct sectors based on the risk of the application. Sectors include education, academic medical centres, dentists, laboratories, industrial applications, and governmental services.
The ANVS as presented in its name regulates the fields of nuclear safety and radiation protection and does so via two mostly separate departments. As there are only six nuclear facilities and installations in the Netherlands the ANVS can visit these locations on almost a weekly-basis. NVB therefore does not employ a risk-based strategy to identify the ‘riskiest’ regulatees. SBC cannot afford the luxury of inspection on a weekly basis as there are over a thousand regulatees.

The ANVS and SBC therefore employ a risk-based strategy to determine the inspection frequency as a result of the inherent risk of the application for which the regulatee has a licence or exemption. With the aim of researching the implications of data-driven risk-based regulation it is therefore more interesting for this thesis to focus on the radiation protection sector than the nuclear safety.

**Distinction reactive versus proactive inspections**

The distinction between regulatory domains divided between SBC and NVB became clear in the very first weeks. As a result, the research scope was sharpened to focus on the radiation protection sector (SBC) rather than the entire organisation (ANVS).

I conducted targeted conversations to gather more information with ANVS employees. The ANVS is a relatively small regulatory agency, employees are approachable and often do not mind elaborating on their line on work. As a consequence I was able to secure an interview with the most senior inspector at the ANVS within a short period of time.

The inspector described that there are two manners in performing inspections: reactive and proactive. Reactive inspections are the result of incidents, whistle-blowers or complaints (Baldwin & Black, 2012). The ANVS uses the same definition for reactive inspections. An example of a reactive inspection is when ionising radiation is detected in scrap waste. Often this waste is contaminated and includes a radioactive source (e.g. Cobalt-60).

Proactive inspections or audits are inspections performed on a routine or random basis. The ANVS employs a theme-based strategy. Every iteration of proactive inspection round inspectors and policy analysts discuss what is the primary subject or regulation in the next period. However, the inspector stated that the proactive inspection process is underdeveloped which is primarily the result of an immense amount of reactive investigations and inspections the inspectors need to conduct.

While you could employ risk-based regulation in reactive inspections, you could not possibly predict where the next incident will occur. Proactive inspections often encompass hundreds of regulatees per domain under regulation. While the ANVS does not have the resources to visit all of these regulatees by physical ‘footfall’ inspections, the ANVS wants to employ a risk-based framework grounded in data. This would enable the ANVS to highlight which regulatees present more risk and identify where the risk of noncompliance is highest. The ANVS could subsequently deploy its assets in order to check for compliance.

In addition, the inspector was excited by the idea of incorporating data-driven initiatives into the inspection process. In particular the proactive inspection process
is an ideal candidate for data-driven initiatives to supplement the regulatory framework of the ANVS.

**Risk-oriented strategy ANVS**
Within those first days I was asked to join the risk-oriented project group within the ANVS. The goal of the project is to develop an ANVS wide, integrated strategy for risk-based regulation. The members of this project team consist of ANVS employees with multi-disciplinary background from all three departments (NVB, SBC and SCO). The participants have backgrounds in policy, licensing, inspections (NVB, SBC) and a data analyst (SCO). This 'taskforce' was assembled by decree of the supervisory board of the ANVS, which wanted to see an ANVS wide strategy using risk-based regulation.

This project duration was target at around six months with monthly meetings and therefore proved a unique opportunity to learn more about the ANVS and the varying tasks they perform in the domains of nuclear safety and radiation protection. In addition, it could provide a quick overview how risk-based regulation is applied within the ANVS and how processes such as policy development, licensing and inspections are conducted in a risk-based manner.

**Risk-oriented taskforce ANVS (1st Meeting)**
The first meeting of the risk-oriented taskforce commenced at February 25th. The meeting started by explaining the goals of this project, after the introduction an unstructured discussion commenced about what risk-based regulation actually was. As this was a multi-disciplinary group with different knowledge and different occupations, it was not really a discussion as much as an exchange of information about what the employees perceived to be risk-based regulation (RBR). The focus of RBR was primarily on inspections, which is a convenient point to start and quite clear to define risks and work in on a risk-based manner. As I felt that the discussion was not leading anywhere, I intervened and asked them to think about risk-based regulation in a more general matter.

The ANVS is different from many regulatory agencies as it is independent. With the independence also comes the ability to influence policy, a notable distinction from all other regulatory agencies.

The intervention consisted of reframing the idea of risk-based regulation that it is not only a strategy for inspections, but it is a strategy as well for policy and licensing. This intervention was partly motivated by my desire to know more about the different regulatory tasks the ANVS have and to have a more fruitful discussion about the topic. This subsequently led to a more fruitful discussion about risk-oriented approaches in inspections, licensing and policy analysis.

While the ANVS is one organisation, it doesn’t operate as one organisation. The departments of SBC and NVB operate almost entirely separate. In my opinion this is the result of the way the ANVS was formed in 2015, as various departments across ministries were combined to form the ANVS. As a result, the departments have their own domains nuclear safety and security (NVB) and radiation protection (SBC).
Sessions and project groups like these enable the ANVS to learn the ‘best practices’ from each other. Even though, the domains are different that does not mean that the departments cannot learn anything from one another.

**Informal conversations with ANVS supervisor**
Throughout the period of the first design cycle nearly every day there would be conversations reflecting on observations and events within the ANVS. During these informal conversations two major issues surfaced. As Dr. Farahmand stated that the research proposal was too optimistic and did not accurately represent the situation at the ANVS. While some data was collected, this was not performed in a structured manner. Often only data regarding noncompliance was stored, not from the inspections in which compliance was established. Additionally, the data that is collected is not stored in a standardised manner which inhibits quick data analysis. As a result, the ANVS does not have the necessary data available for the analysis or the creation of a data-driven tool such as a Bayesian Network.

The other insight the data analyst was able to provide was that while the organisation is warming up to the idea of data-enhanced decision-making, the organisation is not actively participating in projects that would enable an ANVS wide awareness of the benefits of data-driven risk-based regulation. He subsequently stated certain employees, often more experienced employees, did not see the added value of utilising data analysis in order to improve the regulatory framework.

**Key observations during this period**
To summarise, the first design cycle was rather explorative of nature as it aimed to validate the assertions made by the ANVS in order to determine the feasibility of the previous research proposal. During this period, it became clear that the data availability was exaggerated. There was limited data available and it was of poor quality. The initial proposal had supposed a more digital mature ANVS, however the current situation at the ANVS is really data-driven risk-based regulation in the early stages.

The ANVS operates in two distinct domains: nuclear safety and radiation protection. This distinction is reflected in the separation of the organisation into two departments NVB, responsible for nuclear safety, and SBC, responsible for regulation of the use of ionising radiation. While SBC has thousands of regulatees, NVB only has six. Therefore, it is much more interesting to focus on SBC for the development data-driven risk-based regulation.

The ANVS is a regulatory agency with independent status (zbo) which gives them the ability to contribute to the legislative and policy process, a notable dissimilarity with other regulatory agencies. In addition to regulating by performing inspections and granting exemptions or licenses, the ANVS can influence the legislation governing the norms set for licensing. Thus, with the ANVS a regulatory cycle can be perceived (Figure 6, p.24), where policy sets the norms for licensing which identifies the regulatees which are to be inspected.

This regulatory cycle is reflected in the SBC department as there are employees which specialise in inspecting, policy-making or licensing. Additionally, SBC makes
the distinction between proactive inspections and reactive investigations. As a result of many reactive investigations the inspection framework for proactive inspections is underdeveloped. Consequently, the ANVS does not perform many proactive inspections however, the ANVS is actively trying to increase the amount of proactive inspections performed.

Inspectors are cautious of embracing data-driven initiatives at the ANVS. The more experienced inspectors state that additional data could aid the inspection process. However, simultaneously inspectors also state that their expertise cannot be replaced by data and thus require a certain level of autonomy. Therefore, it is important that inspectors participate in the development of data-driven initiatives at the ANVS to ensure acceptation of the new technological tools.

2nd Design Cycle: Framework scoping and prerequisites (Mid-March – May)
The second design cycles takes into account the considerations and insights gained from the previous design cycle. As a result of limited data availability, the scope of the thesis research needed to be realigned from development of a data-driven tool for risk-based regulation to a more explorative research identifying the challenges on the path towards data-driven risk-based regulation.

Kick-off Meeting (March 4th)
The feedback from kick-off meeting for thesis reinforced the necessity to change the initial scope of the thesis research. The necessity to sharpen the research objectives was required in order to reflect the actual situation at the ANVS. The access to meaningful data was absent nor was there a straightforward approach to data-driven risk-based regulation.

Data-driven risk-based regulation is the renowned concept in landscape and research surrounding regulatory agencies. However, there is a clear gap in the scientific literature on how to achieve data-driven risk-based regulation. While the benefits of data science, big data and evidence-based decision-making can be substantial, there is no available roadmap for regulatory agencies to achieve data-driven risk-based regulation. The scope of the research was subsequently realigned to reflect this knowledge gap.

Prerequisites of data-driven risk-based regulation
There is ample scientific literature stating the benefits of data-enhanced decision-making (Staman et al., 2013; Höchtl et al., 2016; Kooi et al., 2018). Regulatory agencies often have to fend for themselves in the development of such a data-driven risk-based regulation framework. The absence of scientific literature on the topic does not help, nor does bureaucratic inertia and the lack of an innovative environment in governments (Höchtl et al., 2016). Governmental agencies and departments such as regulatory agencies often have inhibitors or challenges in their organisational environment preventing these agencies from adopting data-driven risk-based regulation.
The research objective in this thesis was subsequently sharpened to identify these challenges in the environment via a single-case mechanism at the ANVS in order to determine the organisational prerequisites for data-driven risk-based regulation.

**Risk-oriented taskforce ANVS (2\textsuperscript{nd} Meeting)**
The second meeting of the risk-oriented task force occurred on March 25\textsuperscript{th}. The aim of the meeting was presenting how risk-based approaches were implemented in the different domains. Once more the distinction between the departments became clear. A current SBC project, aimed to standardise the questions asked during an incident is reported, was already developed by NVB. NVB already has such a protocol, which was unknown until this was revealed during this meeting. Even though the questions will be sufficiently different elements of such a protocol could inspire or function as a baseline.

In particular this event and a later event in this design cycle led to the conclusion that notion of knowledge creation would be very important for the ANVS in order to develop risk-based regulation. This led to a desk research process into knowledge creation.

Additionally, the meeting provided insights into the proactive inspection process. This was supplemented by desk research of internal ANVS documents to gain a complete overview of the proactive inspection process.

This meeting in particular functioned as a forum were the different departments could present their implementation of risk-oriented or risk-based regulation. SBC follows the graded approach to risk as presented in Black and Baldwin (2012), where the nature of the application determines the degree of licence a regulatee needs. Additionally, two employees asserted that there is a split between inspections, licensing and policy-making and that information could be shared in a better way among these echelons within the ANVS.

Reinforcing this policy cycle and facilitating cooperation and sharing among these echelons addresses the challenge of data management. Consolidating the record keeping systems of licences and registrations would create an “end-to-end” database which could help inspectors and the inspection process as well as improve the ability to share data with other regulatory agencies.

What was remarkable was the openness and willingness to share documents, procedures and best practices within this taskforce, as during the first meeting the ANVS employees participating were more reserved and did not exhibit the willingness to share.

**Desk research**
The realignment of the research objectives and a change of scope meant that partly the desk research needed to be supplemented. The research objective is determining the prerequisites for adoption of data-driven risk-based regulation by regulatory agencies. The result of the desk research is mostly presented in chapter two, three and
four and has implications for the design of the DDRBR framework as presented in chapter five.

In order to determine the prerequisites, the obstacles and challenges that regulatory agencies face need to be identified. The desk research that was conducted can be found in chapters two through 4 in this thesis. Some of the challenges identified were found in literature as well as observed within the ANVS. Additionally, in the third design cycle during the external validation meetings, similar obstacles were identified at other regulatory agencies in the Netherlands.

**Formal interviews**

During this design cycle formal interview were conducted with multiple inspectors and the ANVS data analyst. These formal interviews followed the protocol as presented in Appendix I. The aim of these interviews was to assess the familiarity of inspectors with data-driven risk-based regulation and discover inspectors’ opinions on the data-driven risk-based regulation.

The interviews determined that the concept of data-driven risk-based regulation was unclear and even vague for inspectors. However, when explained what data-driven tools and data-driven risk-based regulation could contribute all inspectors agreed that it would aid their jobs. Nevertheless, all inspectors asserted that changes within the ANVS are a necessity in order to realise the benefits of data-enhanced regulation. As the manner in which inspections results are not standardised or the risk parameters explicitly defined.

The inspectors also felt that data should not replace their expert judgement and cannot replace the mental models they have. The autonomy of the inspectors should be protected in this brave new data-driven world.

The data analyst asserted in the same interview that the autonomy of the inspector should be maintained as well as expressing his eagerness to capitalise on the opportunities that lie in data-enhanced regulation. If the proactive inspection process becomes well-documented and standardised, then the data analysis could be expedited tremendously.

These interviews determined that the inspectors at the ANVS are open to data-driven initiatives within the ANVS. However, the inspectors also expressed concern that data-driven tools should not replace the expert judgement of the inspectors but should function as an aid for the inspectors. The challenge of addressing inspector autonomy is something found in literature (Rothstein et al., 2006) as well and should be dealt with in order to realise data-driven risk-based regulation.

**Identification of design requirements**

This thesis utilises design science research (DSR) approach as a methodological framework for the development of a process model. This process model should aid regulatory agencies in addressing the challenges regulatory agencies face when implementing data-driven risk-based regulation.

The design requirements function as mitigating factors for the challenges of data-driven risk-based regulation. The DDRBR framework artefact was developed to
improve the current situation. Three main challenges were identified institutional, operationalisation and knowledge challenges. All three challenges have a base in scientific literature (Rothstein et al., 2006; Black & Baldwin, 2012; Nonaka, 1995; Smith, 2001) as well as being observed within the ANVS and other regulatory agencies.

These three challenges for data-driven risk-based regulation are addressed by defining the design requirements in such a manner that these challenges should be mitigated. The design requirements for the data-driven risk-based regulation framework are presented in Table 6 (p. 33).

**Artefact identification**

Design science research (DSR) focuses on the development of an artefact which aims to improve the situation in the current problem context. In order to determine the capability of the artefact of improving the situation the artefact should satisfy the design requirements. DSR advocates a search process of already existing artefacts which could satisfy the design requirements and hence improve the context, before designing a new artefact.

The scientific literature on data-driven risk-based regulation is scarce, there is no framework, roadmap or set of requirements which could aid organisations in the implementation of data-driven risk-based regulation. However, there are certain applications of data-driven risk-based tools (Wegman et al., 2015; Zhou et al., 2016; Eggimann et al., 2017). While these tools are not developed for regulatory purposes challenges that are addressed in the development of these data-driven risk-based tools might be transferable to the creation of data-driven risk-based regulation.

Scarcity in the scientific literature enabled a broader search for an artefact which incorporated knowledge creation and the use of data for risk-based application. This led to the identification of research by Linkov et al. from 2006, which combined management strategies with quantitative modelling techniques and a research process of hypothesis testing as well as evaluation feedback loops. In the broad sense the strategy by Linkov et al. (2006) begins with establishing goals, modelling a system and selecting and implementing a strategy and subsequently evaluating the effectiveness of the strategy compared with the goals.

The work by Linkov et al. in 2006 provided something resembling of a framework for a much broader audience for risk-related fields. The work by Linkov et al. (2014) combined traditional quantitative risk assessments with qualitative decision-analytics to form a framework for risk-based standards. According to Linkov et al (2014) decision-analytics are a vital addendum for integrating evidence-based data in a broader strategy. Additionally, the framework enables both the integration of technical information (data) and expert values and opinions and the opportunity for evaluation and subsequently learning.

**Framework as baseline**

Even though the main research question was determining the prerequisites of data-driven risk-based regulation the research approach, design science research asks for the development of an artefact which should improve the current situation. The main
research question can partly be answered by scientific literature as well as results from validation and creation of the DDRBR framework.

The framework by Linkov et al. (2014) was chosen as a base line to develop the DDRBR framework. Their combination of decision analytics and modelling techniques was compelling to use for the development of a data-driven risk-based regulation framework. However, as more thoroughly explained in chapter two and chapter five the framework does not account for the problems regulatory agencies face regarding their dependency on expert knowledge from inspectors. This meant that the framework of Linkov et al. (2014) could not be directly applied for risk-based regulation purposes.

**Short iteration cycles**
The framework by Linkov et al. (2014) did provide a baseline but did not satisfy the design requirements. In order to satisfy the design requirements incremental changes were added to the framework. During this period a lot of informal meetings took place in order gain additional information from inspectors, policy analysts and data analysts. They were able to explain what important aspects of the proactive inspection process were and how the model could reflect these aspects. These short validation iterations proved to be immensely valuable for the development of the framework.

**Risk-oriented taskforce ANVS (3rd Meeting)**
The third meeting of the risk-oriented task force took place just be for Easter on April 18th. The meeting was unstructured as there was no predefined purpose established as had been done for previous meetings. The meeting functioned as defining what was readily available within the ANVS and what was lacking in order to define the ANVS wide integrated strategy.

By this time the first draft of an adapted version of the framework by Linkov et al. (2014) was constructed. During this meeting I presented my initial findings and initial proposal for a data-driven risk-based regulation framework. The taskforce gave some useful contributions.

In addition to being excited about a standardised approach for proactive inspections, the taskforce was interested in the contribution data analysts could provide. Especially, as the ANVS lacks necessary data to currently employ data analysts for new insights. The process could additionally function as a learning tool for the ANVS to reach a more data mature organisation. However, the current version of the model presented did not include a balance between data analysts and inspectors nor did it address the issues of rendering tacit knowledge explicit. The idea of combining the efforts of data analysts and inspectors was well received and the SBC section invited me to join a meeting of all inspectors were optimisation of reactive work would be discussed in order to potentially provide meaningful insights.

**Reactive inspection optimisation meeting**
A week prior to the reactive investigation optimisation meeting I hadn’t heard from the ANVS taskforce ‘colleague’. Eager to participate and acquire potentially valuable information in a meeting where all SBC inspectors would be present, I contacted the
responsible colleague whether I would be able to observe and potentially participate. The colleague got back to me and told me after deliberation with the inspectors that the output of the meeting would be valuable but that I was not welcome at the meeting. I was surprised by this response as the same colleague had invited me and ask to join to potentially offer some insights. After pressing for participation and talking to the departmental head I was welcome at the meeting.

During the meeting an interesting discussion among inspectors arose around the topic expert judgement, expert knowledge and implicitly tacit knowledge as a concept. Expert knowledge or tacit knowledge in general is gained through learning-by-doing and many years of observing, interacting and learning from the environment. While more senior inspectors did not necessarily feel that rendering tacit knowledge regarding risks or risk parameters was beneficial, junior inspectors stated that they were looking for additional support as their expert knowledge was not as well developed as their more senior colleagues.

I was allowed to shed some light on the subject of tacit knowledge and expert knowledge and generalised the discussion to the topic of rendering tacit knowledge explicit. A senior inspector stated that while at the moment there would be no added benefit for a list of quantified risks, it would have helped tremendously during the first three years as an inspector.

The meeting concluded with inspectors stating that the quantifying risks would help the inspectors. Additionally, it increases the need for a well-documented process as well as facilitates the ability to reflect on decision-making. As a result, the inspectors are able to learn via evaluating the well-documented decision-making process which includes quantified risks.

While this meeting was aimed at optimising the reactive inspection process key insights gained during this meeting are applicable to the proactive inspection process as well. Once more it has been established that the autonomy and the expert knowledge of inspectors should be valued and actively incorporated in the framework. Additionally, by actively involving inspectors a sense of ownership is created and therefore acceptation of a data-driven risk-based regulation framework.

**Key observations during this period**
The most important insight gained during the second design cycle was the realignment of the research objectives from the development of a data-driven tool to the determining organisational prerequisites for the implementation of data-driven risk-based regulation.

The structured interviews with inspectors and data analysts showed that while data-driven risk-based regulation is ill-defined concept a discussion about improving the inspection framework via data-enhanced decision making was perceived to be beneficial.

Additionally, these interviews as well as the meeting with SBC inspectors showed that it is important for regulatory agencies to involve and consult with inspectors during the data enhancement process. As it creates ownership and thus responsibility and acceptation from different types of employees.
From the meeting with SBC inspectors followed that quantification of risks renders tacit knowledge explicit. Well-documented risks and decision-making processes allow for ex-post evaluation and offer an ability to learn. Which could be ameliorated by new data insights as a result of ANVS wide risk definitions. This could also reduce the difference in judgement from inspectors as risk definitions are standardised.

Finally, the model from Linkov et al. (2014) provides an interesting combination of decision-analytics with quantitative modelling methods. While it does not satisfy the design requirement it does provide a rough base line for the eventual DDRBR framework.

3rd Design Cycle: Framework development and validation (May – July)
The final and third design cycle builds upon the first two design cycles and focuses on the development and finalising the data-driven risk-based regulation (DDRBR) framework. It has been established that the framework by Linkov et al. (2014) by itself is insufficient for a DDRBR framework, however it does provide a clear base line with elements that are compelling to include in the DDRBR framework. Such as the ability to quantify risks and facilitate cooperation between data analysts and inspectors.

This period was the finalising period of the thesis research, in addition to the creation of the final model, most of the time was spent writing the thesis and conducting external validation at other regulatory agencies.

Linkov et al. (2014) as a baseline
For an artefact it is necessary to satisfy the design requirements in order to facilitate a data-driven risk-based regulation process. It has been established that the framework by Linkov et al. (2014) is not directly applicable to the situation at the ANVS nor does it satisfy all design requirements. However, it provided a base-line for the design DDRBR framework as decision-analytical approach is able to facilitate multiple stakeholders (employees) with different backgrounds and perspectives.

The observations in previous design cycles confirm that it is important to include data analysts as well as inspectors in during the entire inspection process. In order to create acceptance of data analysis by the inspectors, as well as the opportunity to provide insights and learn. Therefore, the DDRBR framework describes the preparation phase as a process similar to decision-analytical approach by Linkov et al. (2014).

The DDRBR framework
The DDRBR framework applies all of the literature presented in chapter two in order to mitigate the challenges regulatory agencies face in the adoption of data-driven risk-based regulation. The framework incorporates the decision-analytical approach as presented by Linkov et al. (2014) in the preparation phase.
Often regulatory agencies lack the necessary data to make the immediate transition to data-driven risk-based regulation. Data-driven risk-based regulation inherently relies on the data in order to make well-substantiated decisions which regulatees to inspect. However, data is often not readily available within regulatory agencies and even if data is available, expertise is required in order to operationalise the data. The ANVS have data, but as established in the first design cycle the data is quality is not enough to create models for DDRBR. Additionally, there is only one data analyst within the ANVS which might impede the ability to perform the necessary tasks of cleaning, preparing and analysing in a short period. Therefore, the process of data management should be streamlined as much as possible via standardisation of initially the data collection.

The ANVS have data, but as established in the first design cycle not of high enough quality in order to create models for DDRBR. Quantifying risks mitigates this challenge in part, by explicitly defining risk parameters. Additionally, the process of quantifying risks by inspectors renders tacit knowledge explicit, creates knowledge and standardises the risk definitions with regulatory agencies. Inspectors at the ANVS affirmed that the quantifying risks process would be beneficial.

Validation
In order to determine the validity of the developed DDRBR framework. Validity in DSR is determined by assessing the utility and quality of the framework. Utility is determined when the artefact is able to improve the current situation. Quality is determined by assessing whether the artefact produces the desired effects, i.e. adheres to the design requirements.

Primary validation occurred at the ANVS, in the presence of policy analysts, inspectors and data analysts. All participants were excited about the results, however there were some remarks regarding the evaluation and learning process. At the time of primary validation, the evaluation and learning process was not integrated in the framework but was presented as a result of execution the DDRBR framework. This was the primary insight gained during this validation meeting at the ANVS. Inspectors were delighted and grateful that their contributions were valued, and that emphasis was placed on the involvement of inspectors during the process. The data analysts confirmed this feeling as well and was excited about the new knowledge and insights they would be able to provide to the inspection process.

As a result of this primary validation session at the ANVS, the evaluation and learning process was explicitly included in the DDRBR framework.

External validation
The DSR paradigm focusses on improving the situation, often for a practical example. However, DSR additionally aims to be a proper science and therefore external validation outside of the ANVS need to occur to validate challenges, prerequisites and the DDRBR.

External validation has occurred at two regulatory agencies. The Dutch Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Waren Autoriteit, NVWA) and the The Dutch State Supervision of the Mines (Staatstoezicht op de
Mijnen, SodM). The external validation aimed to reinforce the claims made in this thesis and provide additional explanatory power thus enhancing the generalisability of the results.

Via a contact at the Dutch Inspection Council (Inspectieraad), the governing body of all regulatory agencies, three regulatory agencies were contacted the NVWA, SodM and the Inspectorate for Social Affairs and Employment (ISZW). The NVWA and SodM were interested in participating in validation while ISZW declined.

The purpose of external validation was multi-tiered as these sessions also function to validate the challenges and prerequisites identified in addition to artefact validation.

External Validation NVWA
On June 25th external validation took place at the NVWA in Utrecht. The NVWA is the largest regulatory agency in the Netherlands as they regulate a vast domain. The participants of the validation session were the departmental head for data analysis and multiple data analysts.

It is interesting to note that the data analysis cluster at the NVWA is physically separated from the inspectors. The data analysts reside in a different building, than the main building were the inspectors reside. Even though these buildings are separated by 15 minutes walking distance it does provide a physical barrier for interaction. This separation acted as a barrier and the data analysis cluster felt that they could not engage with inspectors in a quick manner, an entirely different situation than the ANVS.

This validation session was particularly open, productive discussion took place during the presentation. NVWA employees were able to relate to their organisation as well as provide me with the ability to explain the situation at the ANVS. The NVWA has already passed the early stages of data-driven risk-based regulation regarding the data-driven part.

However, the data science cluster felt that they were not involved nor have any influence over the inspections process. After the inspection process had been conducted, data analysts at the NVWA receive the data from inspectors. However, there is no expectation nor are there specific requests, so contributions of the data analysis cluster are diminished. Nevertheless, if data analysis provided key insights these would be taken under advisement by the inspectors for a subsequent inspection process.

This challenge of a physical barrier between inspectors and data analysts hinders the integration of a data-driven process. While can primarily be contributed to the size of the NVWA, it shows the importance of involving both inspectors and data analysts in the process.

The NVWA also had similar challenges as occurred at the ANVS regarding standardisation of the inspection process, data management (warehousing), determining the quality of the data as well as acceptance and consciousness of the organisation what data scientist could contribute. This often takes years and is quite
the uphill battle to demonstrate the effectiveness of data analysis in a data immature organisation. Which is something many regulatory agency face when starting with data-driven initiatives to enhance the regulatory framework.

**External Validation SodM**

On June 27th external validation took place at SodM (Staatstoezicht op de Mijnen, Dutch State Supervision of the Mines). SodM is a regulatory agency smaller than the NVWA and the ANVS. SodM regulates the extraction of minerals and natural gas, and offshore wind energy production in the Netherlands.

The participants of the validation session were the director regulatory oversight, departmental head for geothermal energy and a data analyst. It is noteworthy that the data analysts at SodM has been working as a data analyst for 15 years within multiple regulatory agencies. The validation procedure at SodM was identical to the procedure conducted at the NVWA.

The SodM is in a similar situation to the ANVS regarding adoption of data-driven risk-based inspections. Currently the inspections conducted are expert driven, i.e. inspectors decide which locations or organisations are visited during an inspection process. The data gathered during these inspections is in the form of text, not values of predefined risk parameters.

The participants of SodM recognise the three challenges (institutional, operationalisation and knowledge) defined in this thesis. It is interesting to note that in all three regulatory agencies digitalisation processes are ongoing. In all three regulatory agencies this is used as an argument for postponing commitment to data-driven risk-based regulation in the short run. Even though digitalisation processes will influence the agency’s capabilities to embrace data-driven risk-based regulation, data analysts’ contributions to prepare the regulatory agency and the new system are often disregarded. The data analyst at SodM stated that as a result, data analysts will inadvertently create a separate system for data analysis, which defeats the purpose of creating an end-to-end system for licencing, inspections and data analysis.

A recurring theme at these regulatory agencies also was the notion that the day-to-day needs to be executed. As a result, data-driven regulation projects are often side-tracked, postponed or neglected. The data analyst at the SodM stated that hiring data analysts is futile in this early stage as the organisation requires someone who can break the inertia and accelerate the process of DDRBR adaptation.

The data analyst of SodM produced some compelling feedback on the DDRBR framework. The analyst stated that it does not explicitly mention the inspections performed as the result of data-driven insights. There framework has the preparation phase, the inspection phase (where a sample of regulatees are visited to collect data) and subsequently the analysis phase. In the DDRBR framework it does not explicitly state that regulatees are visited as a result of the data-driven process.