Bachelor's thesis

Chemical and Materials Engineering

2021

Elli Aaltonen

ACTION RESEARCH FOR HYTEST TO IMPROVE HEALTH, SAFETY AND ENVIRONMENT MATTERS

TURKU AMK *

TURKU UNIVERSITY OF APPLIED SCIENCES

Elli Aaltonen

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Responsible business is increasingly affected by expectations, requirements, and policies. Expectations come from, among others, global megatrends, requirements are controlled by legislation, and policies are created by large, international organizations such as the United Nations. To facilitate the management of responsible operations in companies, international standards have been created. Such standards are for example the Environmental Management Standard ISO 14001 and the Occupational Health and Safety Management Standard ISO 45001. With the help of standards, a company can clarify its health, safety, and environmental (HSE) practices, which are an essential part of responsible business conduct.

This thesis was commissioned by HyTest, a Finnish-origin company founded in 1994. HyTest develops, produces, and supplies antibodies and other raw materials for the *In Vitro* diagnostic industry to more than 50 different countries. HyTest reports its responsibility issues to its owner, Summa Equity, and would like to improve the level of its HSE performance. HyTest chose ISO 14001 and 45001 as its improvement tools because the company already has a certified Quality Management System based on the ISO 9001 standard. The objective of the thesis was to find out the current state of HyTest compared with the requirements of standards 14001 and 45001, and to develop and make proposals for improving the level of health, safety, and environmental performance.

The thesis was carried out as an action research, which is characterized by the researcher's participation in the development of the action and its progress in cycles. The thesis represents one research cycle, where the first stage was the planning of the work, the second the data collection and the third the analysis of the collected material. After analyzing the data, a measure to improve HyTest's HSE matters was planned and implemented, and the effectiveness of the measure was assessed. The material was collected by reviewing the company's existing documentation on HSE issues. The Quality Management System, work instructions and indicators were also studied. In addition to getting acquainted with the documentation, the members of the Occupational Safety and Health Committee, among others, were asked for more information.

As part of the research, an HSE manual was created for HyTest. In addition, the thesis presents suggestions for further improvement of HyTest's HSE issues. It was decided to introduce the HSE manual as a clarifying document that could be developed and improved if HyTest wanted to certify an HSE management system. The implementation of the manual will improve the level of HSE operations compared to the current state.

KEYWORDS:

ISO 14001, ISO 45001, Corporate social responsibility, HSE management

Elli Aaltonen

TOIMINTATUTKIMUS HYTESTILLE TERVEYS-, TURVALLISUUS- JA YMPÄRISTÖASIOIDEN PARANTAMISEKSI

Vastuulliseen yritystoimintaan vaikuttavat entistä enemmän siihen kohdistuvat odotukset, vaatimukset ja linjaukset. Odotuksia luovat muun muassa globaalit megatrendit, vaatimuksia kontrolloidaan lainsäädännöllä ja linjauksia tekevät suuret, Yhdistyneiden Kansakuntien (YK) kaltaiset järjestöt. Yritysten vastuullisen toiminnan johtamisen helpottamiseksi on luotu kansainvälisiä standardeja, kuten Ympäristöjohtamisen standardi ISO 14001 ja Työturvallisuus- ja työterveysjohtamisen standardi ISO 45001. Standardien avulla voidaan selkeyttää ja yhtenäistää yrityksen terveys-, turvallisuus- ja ympäristökäytäntöjä, jotka ovat oleellinen osa vastuullista liiketoimintaa.

Opinnäytetyön toimeksiantaja HyTest oy on Suomessa 1994 perustettu, kansainvälinen yritys, joka kehittää, tuottaa ja toimittaa vasta-aineita ja muita *In Vitro* -diagnostiikkateollisuuden raaka-aineita yli 50 eri maahan. HyTest raportoi vastuullisuusasioistaan omistajalleen Summa Equitylle, ja haluaisi parantaa työterveys-, työturvallisuus- ja ympäristötoimintansa tasoa. Apuvälineiksi HyTest valitsi standardit ISO 14001 ja 45001, sillä käytössä on jo sertifioitu ISO 9001 -standardiin pohjautuva laadunhallintajärjestelmä. Aiheeksi opinnäytetyölle valikoitui HyTestin nykytilan selvittäminen verrattuna standardien 14001 ja 45001 vaatimuksiin sekä toiminnan kehittäminen ja ehdotusten tekeminen toiminnan tason parantamiseksi.

Opinnäytetyö toteutettiin toimintatutkimuksena, jolle on luonteenomaista tutkijan osallistuminen toiminnan kehittämiseen ja sen eteneminen sykleissä. Opinnäytetyö edustaa yhtä tutkimussykliä, jossa ensimmäinen vaihe oli työn suunnittelu, toinen tietojen keräys ja kolmas kerätyn aineiston analysointi. Aineiston analysoinnin jälkeen suunniteltiin ja toteutettiin toimenpide HSE-asioiden parantamiseksi ja toimenpiteen vaikuttavuutta arvioitiin. Aineisto kerättiin tutustumalla yrityksen olemassa olevaan dokumentointiin ympäristöä, työturvallisuutta ja työterveyttä koskevista asioista. Myös laadunhallintajärjestelmään, työohjeisiin ja indikaattoreihin tutustuttiin. Dokumentointiin tutustumisen lisäksi tehtiin kyselyjä muun muassa työsuojelutoimikunnan jäsenille.

Tutkimuksen toimenpiteenä tehtiin HyTestille HSE-käsikirja. Käsikirjan lisäksi opinnäytetyössä esitetään ehdotuksia HyTestin HSE-asioiden parantamiseksi. HSE-käsikirja päätettiin ottaa käyttöön toimintoja selkeyttävänä dokumenttina, jota voitaisiin kehittää ja parantaa, mikäli pyrittäisiin luomaan sertifioitu HSE-järjestelmä. Käsikirjan ansiosta saatiin parannettua HyTestin HSE-toiminnan tasoa lähtötasoon verrattuna.

ASIASANAT:

ISO 14001, ISO 45001, yritysvastuu, HSE-johtaminen

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LIST OF ABBREVIATIONS

AACC	American Association for Clinical Chemistry
BSCI	Business Social Compliance Initiative
EMAS	Eco-Management and Audit Scheme
EU	European Union
HSE	Health, Safety and Environment
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Standards Organization
IVD	In Vitro Diagnostics
KPI	Key Performance Indicator
LCA	Life Cycle Assessment
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational Health and Safety
OHSAS	Occupational Health and Safety Assessment Series
PDCA	Plan-Do-Check-Act
SOP	Standard Operational Procedure
WWF	World Wide Fund for Nature

1 INTRODUCTION

In today's world, it is essential for companies to act responsibly from the social, economic, and environmental point of view. Taking responsibility into account and communicating about it can bring a company competitive advantage. Companies' ethics, values and policies have an impact on the products or services they provide. Sustainability and social responsibility are the values that are expected of companies today. A good way to operate responsibly is by implementing one or several of various management systems. There are many standards and certificates that operate as tools for responsible management. Of these the most popular and widespread are the ISO series of standards. With the help of standards, a company can create a management system that is continuously improved and developed.

The ISO 14001:2015 Environmental Management Standard and the ISO 45001:2018 Occupational Health and Safety Management Standard are well-known tools for the management of Health, Safety and Environment (HSE) matters for companies. HSE management is the key to responsible and sustainable business conduct. This thesis was commissioned by HyTest, an *In Vitro* Diagnostics (IVD) industry reagent supplier company. Sustainable and responsible operations are important for HyTest and finding out the level of operations compared with the requirements of standards 14001 and 45001 was a natural way to start the improvement of HSE matters, as HyTest has a quality system based on the ISO 9001 standard. The company is introduced in more detail in Chapter 2.

The thesis was implemented as an action research because the objective was to create change. The current state of HyTest compared with the requirements of ISO 14001 and 45001 was determined using GAP analysis. The found nonconformities were analysed and an HSE manual was designed to reduce the number of nonconformities.

The thesis begins with the introduction of HyTest and research questions. The theoretical part in Chapter 3 defines the concept of corporate social responsibility, explains HSE management and introduces the main objectives and key concepts of the ISO 14001 and 45001 standards. The research, data collection and data analysis methods are documented in Chapter 4, and the results are presented, and the research is evaluated in Chapter 5. In Chapter 6, conclusions are drawn.

2 COMPANY PRESENTATION AND OBJECTIVES OF THESIS

The thesis worker had previous experience of working on HSE issues, and when the topic for the thesis was suggested by HyTest, it was a situation of mutual benefit. Although the topic was broad and challenging, it was found to be very interesting. The topic was approved, and the scope was defined. This Chapter first introduces the company, and then the objectives set for this thesis.

2.1 HyTest Ltd.

HyTest produces and delivers high quality monoclonal and polyclonal antibodies, antigens, plasma and serum for the IVD industry and is one of the most important raw material suppliers in the world. Reagents are also sold to various distributors, who serve research customers. HyTest is the leading supplier of cardiac biomarkers, and the most important strategic product areas are Cardiac Markers, Metabolic Syndrome, Infectious Diseases, Inflammation and Veterinary Antibodies and Antigens. Other product areas are Tumor Markers, Hormones, Neuroscience, Fertility and Pregnancy, Kidney diseases, Blood Coagulation and Anemia, Gangliosides, Immunology and Serology, Microbial and Plant Toxins and Biodefence. Over 1000 different reagents are produced and delivered every year. (1)

HyTest was established in Turku in 1994 and currently has operations also in Russia, China and the USA. Research and development is located in Moscow, and in China and the USA the company has sales and marketing functions in order to better serve local businesses. HyTest is owned by the Nordic private investment firm Summa Equity, which acquired the share majority in 2018. HyTest has about 100 employees globally, of which around 30 people work in the Turku headquarters.

HyTest delivers reagents to over 50 countries in six different continents. The majority of sales (48 %) comes from the market in China and the USA is the second biggest income source (26 %). Only 3 % of the sales comes from Finland (Figure 1). The revenue of HyTest has been growing for several years and the turnover for the year 2019 was almost 25 million euros. (1)
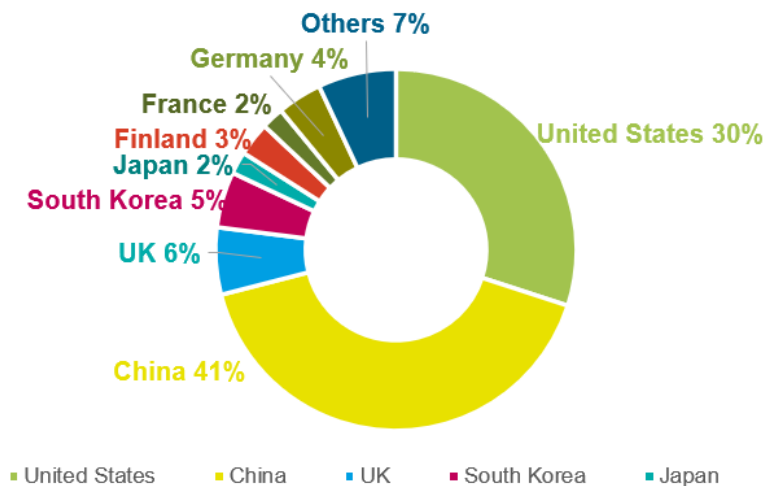
Figure 1. HyTest sales distribution in 2019 (1)

In its operations, HyTest follows ISO 9001:2015 quality standard and has a certified quality system. The quality system ensures that HyTest's products meet the requirements of customers and other interested parties. HyTest invests especially in research and development and is in active collaboration with IFCC and AACC. To ensure its position in the market, HyTest is continually researching and investigating the customers' needs and expectations. At the moment, *in vitro* production is invested to anticipate the possible changes in legislation by the EU regarding *in vivo* production. (1)

2.2 Objectives of the thesis

The subject for this thesis was given by HyTest, based on their needs and the earlier experience of the thesis worker in the field of Health, Safety and Environment. Summa Equity, the current owner of HyTest, invests and develops companies that they believe to provide solutions for reducing climate change, supplying sustainable energy sources and improving education, health and well-being of people (2). In order to better answer these expectations, HyTest saw this opportunity to find out their current state in regard to health, safety and environment issues and possibility to improve.

The objective of the thesis was to get to know the relevant standards ISO 14001 and ISO 45001, find out the current HSE state of HyTest compared to the requirements of the mentioned standards and make proposals for improvement. In addition to this, the outcome could be a suggestion for an HSE system, a manual or both. The system would

not be certified but would be a good basis if the company decided of certifying in the future.

A clear overall view of HyTest's HSE state was attempted to make by studying the existing documentation and asking questions from the people in charge of matters concerning health, safety, and environment. Studying and analysing the data collected it would be possible to determine in which part HyTest would have nonconformities to the requirements of standards ISO 14001 and ISO 45001. Having an HSE manual would bring HyTest closer to meet the demands of the standards and make the document control easier. It will also help in communicating to Summa Equity and all other interested parties that HyTest is taking the necessary actions to meet the growing expectations to continuously improve the level of sustainability as well as the health and well-being of its personnel.

Based on the above-mentioned objectives the following research questions were formed: What is the current state of HyTest concerning health, safety, and environment matters? How does the current state meet the requirements of the standards ISO 14001 and ISO 45001 and what are the nonconformities? How can the current state be improved? How could HyTest better fulfil the demands of the standards? Based on these questions the research method chosen was action research, which is explained more in detail in Chapter 4. Once the method had been chosen, it was clear that an intervention of some kind was to be made, to fulfil the criteria of an action research. As a personal objective, the thesis worker wanted to give the company a concrete outcome that would help HyTest manage HSE matters.

3 CORPORATE SOCIAL RESPONSIBILITY AND HSE MANAGEMENT

3.1 Corporate social responsibility

The basic mission of a company is to generate income for the investing parties. While pursuing profit, companies must comply with the requirements of societies and legislation. This leads to discussion about business ethics and the morality of organizations. (3) Morality and ethics are the basics for corporate social responsibility, which has many definitions. As a summary, corporate social responsibility is about the relationships between an organization and the surrounding society from the social, economic, and environmental point of view, and can be described with the so called three pillars model (Figure 2). The pillars are not always easy to distinguish from each other, as they are interdependent and contain overlaps. Corporate social responsibility can also be considered as an ethical concept, as it is often evaluated from a moral point of view. (3-6)
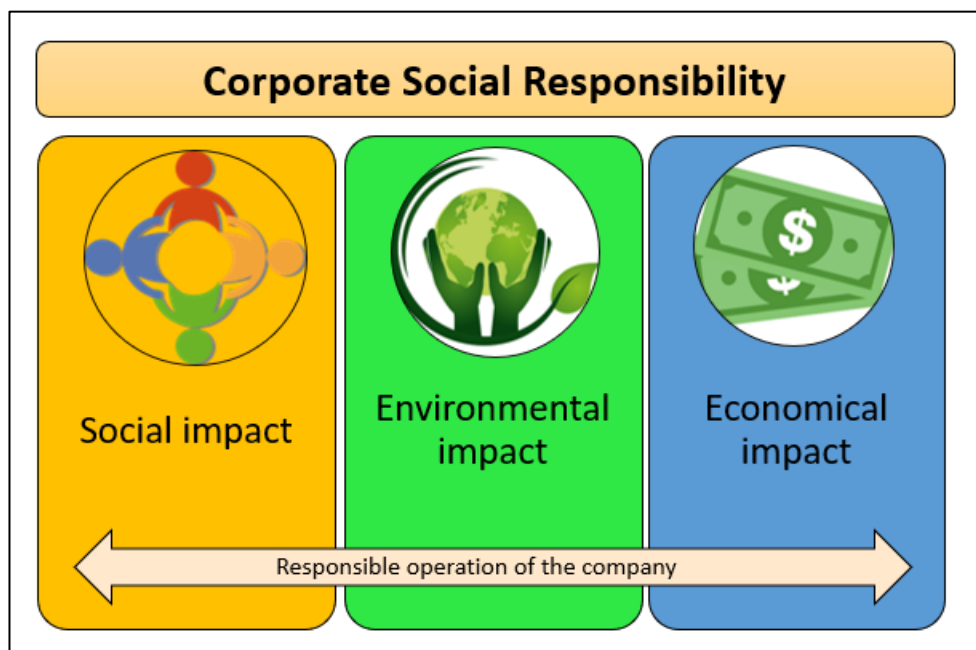

Figure 2. Corporate Social Responsibility – the three pillars model. Adapted from Koipijärvi & Kuvaja. 2017. Yritysvastuu - Johtamisen uusi normaali.

The term corporate social responsibility can have different meanings due to the differences between language, geographical area, and culture, but the core idea is that

organizations react to the needs and expectations of society (3, 4). These expectations are guided with the help of different guidelines and directives, such as the OECD guidelines for multinational enterprises, United Nations' Sustainable Development goals and Global Compact Initiative and the EU directive 2014/95/EU, which obliges large, listed companies or public interest entities to report on social responsibility (6-10). HyTest has a Corporate Governance and Anti-Bribery Anti-Corruption Policy, although it is not considered as a large, listed company or a public interest entity.

The operating environment of companies has broadened significantly over the last few decades, due to the globalization of business conducts. The expectations for corporate social responsibility come from global megatrends like global warming and discussion about environmental issues, economic inequality caused by the gap between the poor and the rich and changes in people's ethical values. (3, 6) Recent studies suggest that companies can gain significant benefits in terms of company value, company reputation, financial performance, and customer loyalty by acting responsibly (11-14). These benefits act as incentives for companies to create strategic business models that include corporate social responsibility. Today, it is considered important that companies exceed expectations and act as pioneers in terms of responsibility. This demands the absolute commitment of management, consistency, and long-term goals. The company's mission, vision, policy, goals, and actions must reflect the objectives it has set for corporate social responsibility. When integrated properly to the company's business strategy and processes, wanted outcomes regarding sustainability can be achieved. (3, 6)

3.2 Health, Safety and Environment Management

Since the 1980s, expectations for environmentally friendly activities and sustainability have increased, leading to the development and implement of environmental management (6, 15). Safety management became an area of interest as early as the beginning of the 20th century, when the first workmen Compensation Act came into force (16). From just safety management, the term has evolved and expanded into Occupational Health and Safety Management. A safety management system is a useful tool for a company to systematically control the performance of workers and machines, as well as the physical environment. (16) Social responsibilities of companies have developed over time, from the early days of industrialization and globalization to modern times, when the expectation for socially responsible conduct is to do more than just have a safe working

environment. A socially responsible company, at least in the western countries, promotes the well-being of employees, improves occupational safety and staff skills beyond the obligations of the legislation and the collective agreements. In developing countries legislation is still under improvement, and the focus of social responsibility is largely on voluntary activities to for example prevent the use of child labour. (3)

As there is no one-size-fits-all way to implement corporate social responsibility, companies can themselves assess and decide on the appropriate methods and tools (4). Examples of tools to control corporate social responsibility are the international standards such as ISO 9001, ISO 14001 and ISO 45001 and the EU's Eco-Management and Audit Scheme (EMAS). Of the above systems, ISO 14001 and 45001 are presented in the Chapters 3.2.1 and 3.2.2, because they were the tools HyTest chose for improving its HSE matters. For organizations, who want to operate in a socially responsible way, there are also standards of which the best known and most used are SA8000 (provided by Social Accountability International), BSCI (Business Social Compliance Initiative by SIS Certification) and ISO 26000. ISO 26000 is not meant for certification but is intended to provide basic information on the content of social responsibility. (6, 17-19)

With the help of management systems, companies try to influence and control environmental and safety aspects, that can include, among others, reducing greenhouse gas emissions, reducing the carbon footprint, product life cycle assessment, reducing the water footprint, energy use, waste or by-product generation, sustainability and safety of production and products, and the sustainable use of natural resources (20). For companies that already have an existing management system, such as ISO 9001, it is a good option to integrate the environmental and health and safety management into the quality system. There are several proponents of systems integration, such as cost-effectiveness, speed of implementation, and system consistency. But regardless, whether the company decides to integrate or not, a certified quality system serves as the basis for establishing an HSE management system. (21, 22) HyTest has a certified Quality Management System based on standard ISO 9001. This will most likely be helpful in creating and implementing any other, corresponding standard, as there already is existing knowledge and know-how regarding management systems.

3.2.1 ISO 14001

The aim of environmental management is to control environmental aspects, improve the level of environmental protection, use resources more efficiently and assess and prevent serious environmental damage. To facilitate these issues, organizations can use the international standard ISO 14000 -series to help. International standards create common rules for all organizations globally, promote the equal treatment of companies, remove barriers to trade and increase the comparability of data. The most important standard in the ISO 14000 -series of standards is ISO 14001, which provides a comprehensive environmental management tool for companies. Other standards of the ISO 14000 -series cover, among others, topics like reporting and reducing greenhouse gas emissions (ISO 14064 – ISO/TR 14069), Environmental labels and declarations (ISO 14020 – ISO 14026), Environmental performance evaluation (ISO 14031 and ISO 14034), Environmental communication (ISO 14063) and Life Cycle Assessment (ISO 14040). (20, 23)

With the help of ISO 14001 organizations can respond to the changes in environmental conditions and stay in balance with socio-economic needs. The standard provides a systematic approach to environmental management and helps organizations to continually improve their environmental performance. ISO 14001 specifies requirements by which, in addition to the requirements set by environmental legislation, companies can achieve the outcomes set for environmental management. (20, 23)

The Environmental Management Standard ISO 14001 is based on a few cornerstones, which are context of the organization, leadership, planning, support, operation, performance evaluation, and improvement. Leadership means the top management shall be committed to the management system, establish, implement, and maintain an environmental policy and ensure the relevant resources. Planning includes the actions to address risks and opportunities by determining the environmental aspects and compliance obligations and designing the appropriate actions to manage the above-mentioned. By determining and providing sufficient resources, awareness, communication, and documented information needed for establishment, implementation, and maintenance of environmental management system, the organization ensures its success in environmental management. Operational planning and control consistent with a life cycle perspective, as well as emergency preparedness and response, are the key elements in operations in accordance with the ISO 14001 standard. Performance evaluation consists of monitoring, measurement, analysis, and evaluation, which include audits and management

reviews. Continuous improvement comes from evaluating the system, identifying the nonconformities and their root causes, taking corrective actions, and measuring their effectiveness. (23) The basis of ISO 14001 is the Plan, Do, Check, Act (PDCA) -concept, which will be further explained in Chapter 3.4 Continual improvement.

3.2.2 ISO 45001

Having a meaningful work and pleasant working atmosphere help the employees to bring productivity and competitiveness to companies, and by ensuring the physical and mental health in a workplace companies can influence the quality of life and wellbeing of its workers. The employer has a legal obligation to make sure the employees are working in a safe and healthy environment, but the employees also have a responsibility for their own and co-worker's safety. (24) In Finland, the employer must take in to account the occupational health and safety perspective in all areas, from work planning to monitoring results. Operations are based on statutory requirements, aiming for health, safety, and productivity. (25) Compliance is not always easy, as it is on the company's responsibility to monitor changes in legislation. Compliance with laws and regulations can be improved by being not only prescriptive but also proactive. (26) The implementation of an occupational health and safety management system is an example of proactive action.

The standard ISO 45001 is a relatively new standard, and it is based on OHSAS 18001, which was first published in 1999. ISO 45001 was published in 2018, and it will replace the OHSAS 18001. This can probably have an influence of more rapid diffusing of the system. (27) The main difference between OHSAS 18001 and ISO 45001 is the concentration of the latter to the interaction between an organization and its business environment. (28) The purpose of the standard ISO 45001 is to help in managing the occupational health and safety risks and opportunities. The standard enables an organization to fulfil the legal as well as any other obligations and requirements that come from the interested parties. (29)

For achieving a successful OHS management system, an organization needs a strategy approved by management and participated by all levels of organizational functions. Several key factors, such as leadership, communication, performance evaluation, and continual improving promote the implementation and maintenance of an effective OHS management system. The context of organization, the scope of the OHS management

system and the nature of organization's activities are the factors upon which the extent of documented information and the need of resources are dependent on. (29)

The higher-level structure of ISO 45001 is identical to other management standards, like ISO 9001 and ISO 14001, which makes it easier to implement multiple standards into one system. The main differences of ISO 45001 compared to ISO 14001 are the consultation and participation of workers, assessment of risks and opportunities regarding the system and determining the legal and other requirements. (29) The basis of the standards, PDCA concept, is explained in the next chapter.

3.3 Continual improvement

Continual improvement means knowing the objectives of the organization and continually monitoring the steps towards the goals and it can be divided into two major components: monitoring and adjusting. Monitoring is done by asking relevant questions, collecting useful data, and applying the necessary changes. Adjusting means the change from monitoring to accordingly promoting and implementing to achieve the desired results. Success in continuous improvement requires transparency, accuracy, and consistent data processing, as well as good leadership. (30)

A very often used model for continual improving is the Deming cycle, on which the two standards, ISO 45001 and 14001 are based on. The Deming cycle was developed by W. Edwards Deming, who was a scholar and a teacher in American academia. Deming worked as an advisor for top managers and engineers and has been called the "father of the third wave of the industrial revolution" because of his major impact on Japan's industrial success after the 2nd World War. Deming also acted as a consult to corporations, such as Ford, Toyota and Sony, leading to him being the voice of quality in the late 1980's. (31) Deming's Plan, Do, Check, Act -cycle was based on A. Shewhart's Plan, Do, See -model, which was one of the earliest models for process improvement (32).

The Deming cycle is based on four logically consecutive phases to achieve continuous process improvement. The four phases are plan, do, check and act (Figure 3). (32) In ISO 45001 and 14001, the Plan phase is described as the establishment of objectives and processes as well as determining and assessing the risks and opportunities. The next (Do) phase is about implementing the processes as planned. In Check phase,

monitoring and measuring is done against the company's policies and objectives and the results are documented.

Figure 3. Plan, Do, Check, Act from the ISO 45001 and ISO 14001 point of view.

Act phase means taking the necessary actions towards continual improvement. In the model used in ISO standards, leadership (and worker participation) are in the centre of the cycle. (23, 29) The concept of continual improvement served as a model for the chosen research method, as action research is all about continuous cycles of action and reflection. Action research as a research method is presented in Chapter 4.

4 RESEARCH, DATA COLLECTION AND DATA ANALYSIS METHODS

4.1 Action research

Action research can be recognised through the research questions. Traditional qualitative research answers questions such as "what affects the well-being of employees at work?", while action research seeks to answer questions such as "how can the well-being of employees be improved?". (33) The research questions of this thesis were clearly similar to the latter, which is why it was decided to do an action research.

Action research as a term was first used by the American psychologist Kurt Lewin in his article "Action Research and Minority Problems" in 1946 (33). Three key features of action research, cooperativity, democracy, and the changing nature of theory and practice, came to light in Lewin's studies in the 1940s. (34) The term action research was developed to describe the idea of concurrence of research and action (35). Since its early days, action research has been an important part of the development of, for example, teaching, social work, and nursing. (33, 36) In action research, the researcher may play different roles, but in the "purest" form of action research, the researcher is part of a democratic community acting as a solver of the research problem. (36) In this thesis, the researcher solved problems mainly alone, albeit as a member of the community.

Action research has many definitions. What the definitions have in common is that action research is research in action, not research about action. Of the cycles of research and action, the usual outcome is to improve something and have practical consequences. Action research is often, but not always, conducted in collaboration with those affected by the research problem. This makes it a good approach for a research that is about solving problems in working communities. Action research is also commonly used in the field of social sciences. The purpose of an action research is to find a solution to a specific problem, rather than produce generalizable information. (33, 35, 36) In Figure 4 the cycles of action research are presented.
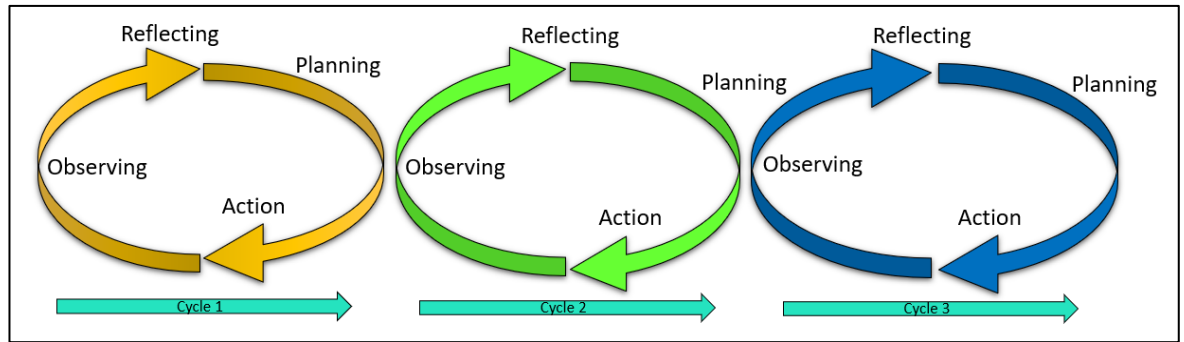
Figure 4. The cycles of Action and Reflecting in action research. Adapted from Brannick & Coghlan. 2012. Doing Action Research in your own Organization.

Participatory research, collaborative inquire, emancipatory research and action learning are sometimes used as synonyms for action research, as they are very similar methods. Action research has different orientations according to philosophical emphases and employee participation. (33) Brannick and Coghlan (2012) have separated four types of doing action research according to intended self-study of the researcher and the system being researched at in their book "Doing Action Research in Your Own Organization". The first type is traditional research, where there is no intended self-study by the researcher or the system. The second type is classical action research, where the system in action is being studied. This type of research is often done by master's level students and focuses on the development of existing projects. Individual reflective study is the third type of research, in which the researcher has self-study intentions in action, but the system does not. This type of action research can be called an action inquiry. In the fourth type, both the researcher and the system have intentions for self-study in action. This type of research demands that the system is committed to a change. (36) This thesis mostly represents research type four because both the thesis worker and the company have self-study intentions.

Action research can sometimes be seen as a research strategy. The assumption of an action research being a research method is not obvious. (34) However, action research is categorised as a type of qualitative research. Like a qualitative research, action research too strives for a profound understanding and interpreting of the problem. Qualitative research is mainly about researching the processes and is interested in the way people see and experience the reality. The researcher has a direct contact with the subject of the research. Qualitative research uses inductive reasoning instead of deductive reasoning as a methodology. Traditional qualitative research is not seeking to impact in

action, as action research does. This feature makes action research a continuum to a qualitative research. Therefore, doing an action research requires knowledge of qualitative research. (33)

An action research starts with defining the problem and forming the research question or questions. The material needed to solve the problem can be gathered using a variety of methods, such as observation and interviews. Asking the right questions helps in choosing the right methods for collecting the material. The analysis of the material should take place in parallel with the collection of the data, in which case it is involved in all stages of the research process. After clarifying the initial situation, the operation of the cycle, or the intervention, is planned, and implemented. And after implementation, the effectiveness of the intervention is assessed. (33) In Figure 5 the cyclical process of this thesis is presented.
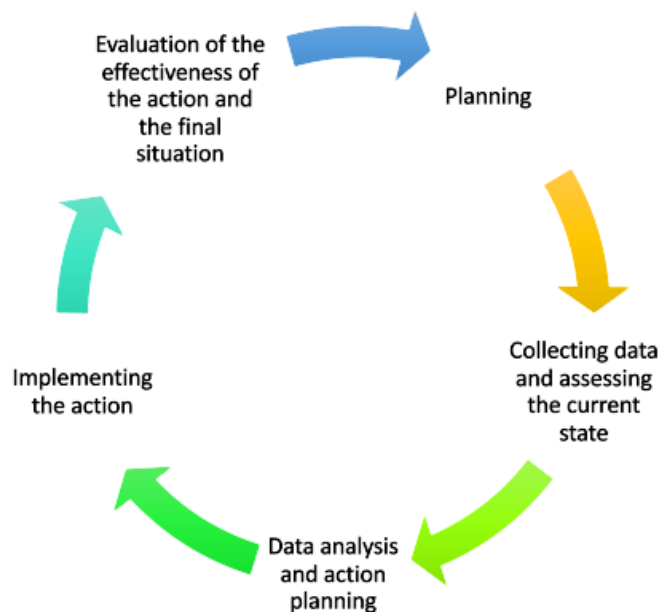
Figure 5. The process cycle of the thesis.

As can be seen from the figure, there is only one cycle of action and reflection in the thesis. However, the development of HyTest's HSE issues is likely to continue after the completion of the thesis, so the cycle will start over again.

4.2 Data collection methods

When planning the thesis, it was already clear that no formal interviews were to be done. The main data acquisition method was to get to know the company's documentation of quality, environmental issues and everything related to health and safety. Under the guidance of the Quality Manager, the company's Quality System was first studied. The Quality System Manual can be found from shared files of the company's computer system, and it is available to all employees. To gain a good level of understanding, the Standard Operating Procedures (SOP's) and Key Performance Indicators (KPI's) were also viewed.

The information concerning occupational health and safety was acquired by searching and reading relevant existing documents and asking the members of the Occupational Health and Safety Committee for additional information. The Occupational Safety Representative was asked about occupational safety issues through the company's internal Teams channel and in person. An email was sent to the Occupational Safety Manager to inquire information about health and safety related documentation.

As HyTest does not have an environmental system, there are very few documents on environmental issues. However, HyTest gives a sustainability report to Summa Equity on a quarterly basis, and this was discussed with the person in charge of the reporting. HyTest's Marketing Communications Manager gave some perspectives on the company's internal and external communications on environmental issues. The above-mentioned discussions took place remotely via Teams.

4.3 Data analysis

To organize the collected data, they were compiled into a table to which the requirements of the standards ISO 14001 and 45001 were added. The requirements were compared with existing data and a GAP analysis was performed. The gap analysis method is widely used, for example, in preparation for version upgrades and certification of standards (37-39). Therefore, it was a natural choice as an analysis method for this thesis. GAP analysis provides knowledge of the current situation, as well as of the measures to be taken to achieve objectives.

The requirements were reviewed on a case-by-case basis and the equivalences and differences were recorded in the table. For nonconformities, what was needed for improvement was recorded and finally, ways and practical actions were considered and documented to carry out the improvement. To get an overall picture, existing activities that affect health, safety or the environment were also recorded in the table. The model of the table can be seen in table 1.

Requirements of ISO 45001 and 14001	Current State of HyTest	What is needed for improving	How to do it in practise? Suggestions for actions	Examples (in use)
4.1 Understanding the organization and its context	No clearly stated HSE mission or policy.	Determining the relevant external and internal issues that HyTest could affect with establishing an HSE system	By stating a few environmental aspects and analysing them (opportunities, threats,) could help to figure out what are the activities, products or services that can interact with the environment. Figure out if there are any aspects that could have an impact on the environment, whether adverse or beneficial.	Packing of products: using recyclable and recycled material, guiding the customers how to recycle with a label on outer package. Environmental risks have been assessed in the disaster recovery plan and stated to be minor.

Table 1. An example of the table used in GAP analysis: Requirements, current state of HyTest, what is needed for improving, suggestions for actions and examples of actions in use.

The GAP analysis table is not documented to the thesis due to confidentiality. The results of the GAP analysis and the current state of HyTest is documented in the next chapter.

5 RESULTS AND PROPOSALS FOR IMPROVEMENT

5.1 Current state compared to the requirements of the standards

After the GAP analysis was done, a clear picture of HyTest's current state of HSE matters could be seen. HyTest operates responsibly, complies with all relevant laws, and is interested in employee well-being as well as recycling and environmental friendliness. HyTest has taken actions to improve many things, but when compared to the requirements of the standards ISO 14001 and 45001, a few main points of noncompliance can be seen. These observations are explained in the following sections.

In ISO 14001 and 45001, the starting point is to identify the context of one's own organization and by understanding your own organization, it is possible to figure out the environmental and the health and safety aspects. HyTest has a Quality Certificate, so it must have an understanding of its context, but this context has not been considered from an HSE point of view. For this reason, HyTest does not have a clearly stated, official policy of regarding health, safety, or environment. This leads to the lack of objectives as well.

Regarding the environmental impacts, there is no existing documentation about considering the environmental risks and opportunities of HyTest. Also, there is no clear policy for documenting health and safety issues. The documents are stored in different places, which makes it difficult to find information for others than the members of the Occupational Health and Safety Committee. Some of the documents are stored electronically, some as paper versions, and the documents are not controlled like the documents of the quality system.

As HyTest does not have a formal HSE policy, there is also little internal or external communication on health, safety, or environmental issues. The lack of communication has led to the lack of awareness. Attempts have been made to create awareness, but there is clearly room for improvement in communication practices.

HyTest currently has no targeted, measurable actions or processes regarding HSE issues. The company issues sustainability reports, but no attempt is made to influence the issues in the report, and the effectiveness of the reporting has not been assessed. While HyTest operates responsibly, a model of continuous improvement is lacking, and only individual issues are addressed from time to time. Continuous improvement could be

achieved by establishing a system to maintain procedures to measure and monitor the level of performance.

5.2 HSE manual

Considering the nonconformities of HyTest's current state regarding the standards ISO 14001 and 45001, it was decided that the best way to start the improvement would be an HSE Manual. The manual would be a tool for standardizing the HSE documentation, creating an HSE policy and objectives, planning the operations by which the objectives are achieved and determining the resources, responsibilities, and authorities concerning HSE matters. It was also decided with HyTest's Quality Manager that the Manual would include guidelines and possibly processes as well.

For the creation of the HSE Manual, corresponding manuals were searched on the Internet and their content was examined. The aim was to make the manual as suitable as possible for HyTest in terms of content and purpose. The suggested policy was partly already existing and stated in other documents. In other respects as well, efforts were made to make the most of existing practices to facilitate the implementation of the manual. The structure of the manual follows the structures of the ISO 14001 and 45001 standards. An attempt was made to keep the entity as light and easy to manage as possible, as official certification was not yet desired. The table of contents of HyTest's HSE Manual is presented in Appendix 1. The content of the manual is considered confidential, and therefore it is not documented in this thesis.

For HyTest, the following objectives were suggested: Energy efficiency, finding new ways of recycling and using recycled material, training, and motivating personnel and promoting the health and wellbeing of employees, favouring responsible products, services, and partners, and reducing emissions from travel. The manual was designed around the above-mentioned objectives. It was decided to remove energy efficiency from the final version, as energy use is not easy to manage due to production needs, for example.

The manual was reviewed with the Occupational Health and Safety Committee and improved based on the comments received. It was decided to take the HSE Manual in use at some point to clarify HyTest's HSE operations. However, the manual will not yet be made into an official, quality-controlled version, but it will be available to employees.

5.3 HyTest's HSE state after the intervention

In the absence of an HSE manual, there were at least 6 major nonconformities when comparing the current state of HyTest with the requirements of the standards ISO 14001 and 45001. Taking the manual into use will reduce the amount to only two major non-conformities. HyTest will have an HSE policy, that is approved by the management, objectives to start the improvement process, a model for documentation, clearly stated operation policies, and a way to communicate HSE issues. A management system and processes for improvement would still be missing, as they were not created in the scope of this thesis. The list of nonconformities will be shorter, which proves that the state of HyTest's HSE matters were improved. Although the manual will probably need to be enhanced before taking it into use, it provides a good basis.

5.4 Proposals for further improvement

As part of its 25th Anniversary Campaign in 2019, HyTest took actions to improve its environmental and social issues in accordance with the UN's sustainable development goals. Although the campaign has been over for a while already, some features has remained and still influence the actions in HyTest's everyday operations. For example, the company recycles more than before, invoicing is completely paperless, and packages sent to customers have recycling instructions for the packaging material. HyTest should continue to favour recyclable and recycled material and take this into account when selecting material suppliers.

HyTest could consider calculating the carbon footprint of its operations in Turku. This process could provide information on what the main sources of carbon emissions are and provide ideas for reducing them. There are a variety of carbon footprint calculators, for example The Finnish Environment Institute has developed several calculators for the use of companies and private persons (40). To help in reducing the carbon footprint, the WWF's Green Office environmental management system and certificate (41) could bring some ideas for reducing the carbon footprint of an office.

Another way to gain knowledge of environmental impact is to do a life cycle assessment (LCA) for the products in general. LCA is a popular way to demonstrate a company's environmental responsibility as well as to meet the regulatory requirements. In the

standard ISO 14001, LCA is also highlighted as the preferable way to assess the environmental impacts and the binding obligations.

Sustainability reporting is something that many companies do, including for example Abcam, which is not exactly a competitor, but a big company in IVD business like HyTest. In its sustainability report, Abcam describes its goals and measures in terms of both social and environmental responsibility (42). Abcam has chosen 7 key points from the UN's Sustainable Development Goals, which were the basis for HyTest's 25th Anniversary campaign as well. Based on this, it may be a good idea for HyTest to publish a sustainability report or build on what was achieved in the 25th anniversary goals. In this way, a more positive image of the company's operations could be achieved.

Regarding the health and well-being of workers, HyTest is already offering comprehensive occupational health care, as well as other benefits including ePassi. But since there is always room for improvement, HyTest employees have suggested a similar "fitness corner" to the Turku office as there is in the China office. This "fitness corner" does not need much equipment, but just a couple of fitness tools to give the employees the possibility to have a break while doing something that is good for both mental and physical health. Also, it could be better communicated especially to new employees what benefits and services for example the health care provider Mehiläinen offers to HyTest employees.

Communication is central for improving HSE matters. Employee awareness of occupational health, safety and environmental issues should be raised, thus better enabling involvement. In addition, there could be some external communication, at least in terms of social responsibility and environmental issues, as acting responsibly has been proven to increase the company's value in the eyes of a customer.

To clarify the work of the Occupational Safety and Health Committee, an annual cycle could be established. The creation of an annual cycle would bring the work of the committee more systematic. The annual cycle could be added to the HSE manual. In addition, the responsibilities of the members of the Occupational Safety and Health Committee could be clearly stated in the HSE manual.

Because some of the employees of HyTest Turku have to travel in their work, there could be a manual or a documented operation policy for these individuals. In the manual or directive, general safety rules could be stated as well as a guideline to help in case of

something unexpected happens. This way the safety of the employees would be better ensured even during business travels.

5.5 Reliability of the research

The reliability of a qualitative research can be assessed by the adequacy of the data, the comprehensiveness of the analysis, and the evaluability and reproducibility of the analysis. The researcher's preunderstanding and interpretations, as well as the choices made, always affect the outcomes of a qualitative research. In action research, the outcomes are valid only for the certain situation and are not transferable or generalizable. Sufficient documentation of the research is usually the starting point for the evaluation of reliability. (33)

The data collection methods used in this thesis were sufficient for the researcher to get an overall picture of the company's operations. The researcher had already been working with HSE matters before this thesis, so there was a preunderstanding of occupational health and safety issues and environmental functions and legislations. Furthermore, a preunderstanding of the company's operations and policies existed as well, as the thesis was made in the researcher's own workplace. Despite of the preunderstanding, it was the target of the thesis worker to be as objective as possible.

The adequacy of the research documentation and the reliability and validity were assessed by the Quality Manager of HyTest, who acted as a representative of the company. In her assessment, it was stated, that the data acquisition methods were comprehensive enough to get a good picture of the current state of HyTest's HSE matters. Also, in her opinion, the documentation provided to the company was clear and adequate. And the result of the research was seen to be valid, as the outcome would probably have been the same, regardless of the researcher. On the other hand, the researcher's experience of the HSE systems was an asset in finding the relevant data. The research met the original objectives and succeeded in clarifying HyTest's HSE matters. Based on the assessment above, this research can be stated as reliable and valid.

The usefulness of this thesis for HyTest is an important factor in the evaluation. The HSE manual was a concrete outcome of the research, and as it will help the company to manage its HSE matters, the objective of the thesis worker has been achieved.

6 CONCLUSION

The research questions were answered and a possible change to operations was achieved. The research questions were: What is the current state of HyTest concerning health, safety, and environment matters? How does the current state meet the requirements of the standards ISO 14001 and ISO 45001 and what are the nonconformities? How can the current state be improved? How could HyTest better fulfil the demands of the standards? The current state was analysed, and the nonconformities were documented. It was decided that the current state could be improved, and the demands of the standards better fulfilled by creating an HSE manual. The thesis worker created the manual, and it was reviewed by the Occupational Safety and Health Committee. The manual was decided to be taken into use after further improvement.

With further improvement. the HSE manual can be of great significance for HyTest to better control its HSE matters. Should a company ever decide to apply for certification to ISO 14001 and / or 45001, the HSE manual is a good basis for creating a management system. And if the manual were to raise awareness and increase understanding of HSE matters, HyTest would be closer to meeting the requirements of the standards. By introducing some of the suggestions for improvement made in this thesis, better performance in HSE matters can be achieved.

The research project was found to be very interesting, as well as useful. Acquainting with the standards and their requirements is likely to be useful in working life, and making the thesis brought the author knowledge and expertise in HSE matters.

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