Degree project in Technology

First cycle, 15 credits

MDR’s Impact on Standards Usages and the Relevance for In-house Production of Medical Devices

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Stockholm, Sverige 2022

This project was performed in collaboration with
Swedish Institute for Standards (SIS)

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MDR's Impact on Standards Usages and the Relevance for In-house Production of Medical Devices

MDRs påverkan på användning av standarder och deras relevans för egentillverkning av medicintekniska produkter

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First level, 15 credits
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2022

Abstract

The current regulation for Medical Devices (MDR) entered into force on 26 May 2021, which has entailed major changes to relevant legislation for in-house production of medical devices in healthcare. The relevance for updating existing, or the development of new standards is currently not well documented and determined and the aim of this report is to make recommendations for how the development of standards may be improved and how departments of medical technology (DMT) in practice apply standards at in-house production of medical devices. The sub-areas that are dealt with in in-house production are reprocessing of single use devices, 3D printing and medical technology software. How standards are used to support departments of medical technology in manufacturing in these areas is described and analyzed in this report. Information for the study was collected through semi-structural interviews with several DMTs and relevant authorities. The information was analyzed, discussed, and compared with previous research. The use of standards varied between DMTs, but all interviewees used standards to some extent. The study concluded that there was an interest from DMTs and a potential need to update existing standards and the production of new standards to meet DMT's needs.

Keywords: In-house production, MDR, Reprocessing, 3D-printing, Swedish Institute for Standards, Standards

Sammanfattning

Nuvarande förordning för medicintekniska produkter (MDR) trädde i kraft den 26 maj 2021, vilket har inneburit stora förändringar på relevant lagstiftning för egentillverkning av medicintekniska produkter inom sjukvården. Relevansen för uppdatering av existerande, alternativt utveckling av nya standarder är i nuläget ej väl dokumenterat och klarlagt och målet med denna rapport är att komma med rekommendationer för hur utveckling av standarder kan förbättras samt hur medicintekniska avdelningar (MTA) i praktiken applicerar sig av standarder vid egentillverkning av medicintekniska produkter. De delområden som behandlas inom egentillverkning är reprocessing av engångsartiklar, 3D-printing och medicinteknisk mjukvara. Hur standarder används som stöd av MTA vid tillverkning inom dessa områden beskrivs och analyseras i denna rapport. Information för studien insamlades genom semi-strukturella intervjuer med flera MT-avdelningar och relevanta myndigheter. Informationen analyserades, diskuterades och jämfördes med tidigare forskning. Användandet av standarder varierade mellan MTA, men alla intervjuade använde standarder i någon utsträckning. Det framkom i studien både ett intresse för uppdatering av existerande standarder och framställning av nya standarder för att bemöta MTAs behov.

Nyckelord: Egentillverkning, MDR, Reprocessing, 3D-printing, Svenska Institutet för Standarder, Standarder

Contents

Abbreviations

AIMDD - Active Implantable Medical Devices Directive

CE – Conformité Européene

DMT - Department of medical technology

EEC – European Economic Community

EU – European Union

ISO - International Organization for Standardization

IVDR – In-Vitro medical Devices Regulation

IVO - The Health and Social Care Inspectorate

MDD – Medical Device Directive

MDR – Medical Device Regulation

MPA - Medical Products Agency

MSB - The Swedish Civil Contingencies Agency

NBHW - National Board of Health and Welfare

SIS – Swedish Institute for Standards

SUD – Single Use medical Device

1 Introduction

The EU Regulation on Medical Devices (MDR) is a new regulatory framework that entered into force on 26 May 2021. The aim of the regulation is to ensure the safety and efficacy of medical devices that are in use.

The impact of MDR on current and future standards for in-house production is currently not clear, with the department of medical technology (DMT) being mainly responsible for in-house production of medical devices. In-house production in this context refers to medical devices that healthcare providers, in this case DMT, manufacture or change with the purpose of using said devices within their own operations. The process of in-house production within EU is regulated by the MDR.

Three areas where in-house production is often relevant for DMTs is when 3D-printing devices, when reprocessing used devices and when using medical device software. Previous research within these areas will be presented and discussed in this thesis. Within all three of these areas, general standards for quality management may be applied. When 3D-printing and reprocessing it is often of value to utilize various sterilization standard, whereas when manufacturing medical device software, it is common to use various software related standards [1],[2],[3].

This report investigates and analyzes how standards for medical devices support in-house production and how standards need to be updated to support DMTs in meeting MDR requirements, as well as make recommendations for improvements when developing standards for in-house products and determine if there is a need for new standards.
For in-house production, relevant standards must support DMTs so that they can comply with the MDR. How standards support the in-house production process in practice is currently not clear and the same applies to how DMTs stay up to date with current standards. The MDR came into force at the same time as the Covid-19 pandemic was having a major impact on functionality and work of the healthcare industry. It is currently not clear which changes in the DMTs in-house production process is pandemic related, and which are due to the introduction of MDR.

To carry out the mapping of how DMTs relates to and uses standards, the report need to distinguish which factors are Covid-19 related and which are MDR related. This is needed to ensure that our recommendations for the design of new standards for SIS are relevant, even when Covid-19 might not no longer be. It was intended to come with recommendations regarding what factors are important to consider when developing standards that are resistant to pandemic-like situations.

1.1 Aim

Aims of the project was to come with recommendation for how to improve standards that are commonly used in the in-house production process, which is achieved with the following objectives:

- Determine any need for new standards.
- Map out how standards contribute to the development of in-house medical devices
- Contrast which changes in the in-house production process are due to Covid-19 and which are due to adaptations to the MDR

- Make recommendations for factors that are important to consider when developing standards that are resistant to pandemic-like situations

1.2 Limitation

The scope of this project was restricted to the impact of MDR and not the new IVDR (In Vitro Diagnostic Regulation) regulation. The contents of IVDR are vast and would require its own separate project to be analyzed.

Also, this thesis was limited to the in-house production process for DMTs in Sweden. Subsequent analysis was thus limited and based on nationally relevant regulations.

2 Background

Healthcare organizations are obligated to vigorously screen and analyze all relevant and available medical devices on the market for one or more plausible devices that could resolve the organization's needs. If an appropriate medical device cannot be found, the health care provider may instead resort to in-house development.

The MDR represents the European regulatory requirements for producing, usage, and maintaining in-house developed medical devices in section 5.5 [4]. The Medical Products Agency has introduced additional national regulations in HSLF-FS 2021:32, which complements the European regulations presented in MDR 5.5 for in-house development [5].

In-house development includes medical devices entirely designed and developed by the organization and medical devices that are modified or combined in a way that was not intended. Medical devices developed in-house are not CE-marked and are thus exempt from the process for determining whether the 'General Safety and Performance Requirements' associated with CE-marked medical devices are met [6]. Responsibility, oversight, and usage of these medical devices are thus exclusively limited to the organization, and they must ensure that the medical devices are as safe or safer as comparable CE-marked medical devices [7].

2.1 Reprocessing of Single Use medical Devices (SUDs)

Reprocessing of SUDs refers to the process of turning a used SUD into a reusable medical device with the same capabilities and safety standards as the SUD originally had [8]. Reprocessing of SUDs is allowed by MDR under article 17, but requires the introduction of national regulation, which is mentioned in article 17.2 in MDR[9]. Recent national regulation 2021:631 was introduced to accommodate the need to reprocess SUDs in Sweden, which entered into force on 26 April 2022 [10].

Reprocessing of SUDs has thus been discontinued since the introduction of MDR in 26 May 2021 due to a lack of national regulation. The Medical Products Agency and the Health and Social Care Inspection share responsibility for regulation and oversight of reprocessing of SUDs, where the Medical Products Agency are permitted to issue additional regulation on the subject matter.

2.2 International regulations regarding in-house production

In-house production of in-vivo medical devices in the European Union is primarily regulated by article 5.5 in Medical Device Regulation (EU) 2017/745. This regulation came into force on 25 May 2017 but was not fully implemented until 26 May 2021. The initial implementation date was set to 26 May 2020, but it was delayed one year because of public health challenges due to the COVID-19 outbreak [11].

According to article 5.5, the requirements outlined throughout the MDR do not apply to in-house production of medical devices, with one exception and some conditions. The exception is that relevant safety and performance requirements that are outlined in Annex I of the regulation must be complied with [12]. Annex I sets general requirements for the products performance and safety for both the patient and the user. According to Annex I, the

product must be suitable for its intended purpose and certain requirements are placed on the risk management process during both use and manufacture of the product [13].

The main conditions outlined in article 5.5 that must be met for in-house production can be summarized as follows: There is documentation that clarifies certain aspects of the products and manufacture. There has been an examination of the products in previous clinical uses, and it has been determined that it cannot be replaced with an available, equivalent product. There is information provided that shows that the relevant general requirements are met, as well as information that enables identification of the product and which allows for contact with the manufacturer of the product. There are quality management systems in place during the manufacture and use of the product. The product does not change legal entities, in this case the given health care provider[14].

2.3 National regulation regarding in-house production

In addition to the EU regulation MDR, there are some national regulations that need to be followed in Sweden. These regulations are HSLF-FS 2021:32, which is outlined by the Swedish Medical Products Agency (MPA) and SOSFS 2011:9, which is outlined by the National Board of Health and Welfare (NBHW) [15][16].

The MPA's regulation HSLF-FS 2021:32 provide supplementary requirements for in-house production of medical devices. According to these regulations, The Health and Social Care Inspectorate, IVO must be notified when manufacturing and using in-house medical product, as well as when reporting any adverse events related to said product. IVO's role in the whole process is thus one based on supervision and oversight. In addition to this, there needs to exist an instruction manual in Swedish and documentation of the healthcare provider's organization number, as well as the product identification number must be provided [17]. The regulation also describes requirements for appropriate quality management systems during manufacture and use of in-house product. The MPA's regulation refer to the NBHW for requirements regarding the specifics of the quality management system, which are described in SOSFS 2011: 9.

The NBHW is a government agency, which is responsible for curating knowledge and regulations within the health and welfare sector [18]. SOSFS 2011: 9 provides both regulations and advice regarding quality management systems. There are rules regarding who is responsible for the use of a management system, which in this case is the healthcare provider. Some of these responsibilities include maintenance of the quality of the business, as well as improving the business through planning and evaluations [19]. In the regulation, there is also guidelines and requirements regarding how the management system is built from the ground up. The healthcare provider is advised to use standards and models which can help the basic structure of the management system [20]. The healthcare provider is also required to focus on systematically improving the business through risk analysis, self-monitoring, and internal investigations in cases of irregularities [21]. The regulation also outlines which documentation is also obligatory, and that this duty lies on the healthcare provider.

2.4 Old regulations and their differences from current ones

The new regulations have replaced the older regulations, the MDD (Medical Device Directive 93/42 / EEC) and the AIMDD (Active Implantable Medical Devices Directive

90/385/EEC) were EU directives, as well as LVFS 2003:11 and SOSFS 2008:1 which were national regulations by the MPA and the NBHW respectively.
The previous EU legislation was a directive and not a regulation. Directives set several results that are meant to be achieved by the European member states, but the individual member states must first translate the directives into national law [22]. This means that they were not directly applicable in national law as they first had to be implemented by each member state through national legislation. Regulations such as MDR on the other hand are directly legally binding for every European member state [23].

According to the interview with the MPA, some limited parts of MDR may be regulated nationally, and it is these sections that are covered by the new MPA regulations. Further gathered from said interview, the transition from directives to regulations has had the effect of the new MPA regulations being less explanatory when compared to the older ones, because the MPA previously had to implement the directives and thus also outline exactly how the regulation was meant to be followed. In principle it was often enough to just follow the MPA regulation, with less of a focus on the EU directives.

Furthermore, it was explained by the MPA that previously, they had nothing to do with in-house production because this area was regulated by the NBHW, with IVO being responsible for supervision. This has changed with the MPA now being an authorized body for the regulations, with IVO remaining as a supervising body. Regarding the differences between the newer and older national regulations, it was said in the interview with the MPA that the old NBHW regulations, were quite short and vague when relating to specifically in-house production. The MDR requirements are more specific and thus clear in terms in terms of how it is meant to be interpreted. However, the difference between the two in practice are not great assuming the older regulation was interpreted correctly and the followed fully. The MPA regulation HSLF-FS 2021:52 has replaced SOSFS 2008:1. Much of the content is the same, but some changes have been made. There has been a great focus on clarifying the text and making it more understandable. In the old regulation, the responsibility of various actors was delegated more strictly, whereas it is now up to the caregiver to delegate who is responsible in the management system. This has both pros and cons, as the caregivers right now have more freedom and choice in how they want to delegate responsibility, but the ideal structure is less clear.

Also gathered from the interview, one major change which has occurred due to the new list of regulations, regarding specifically in-house production, is the fact that healthcare providers no longer are allowed to produce products in-house if there exist corresponding products on the market. This means big regulatory changes for reprocessing of single use devices. Reprocessing is defined by the MDR as "... a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization, and related procedures, as well as testing and restoring the technical and functional safety of the used device" [24]. Since the product was purchased initially, there should be more available for purchase, which would mean that there exists a corresponding product on the market. Article 17 in MDR addresses how reprocessing should be done [25]. According to the MDR, it is to be decided nationally for each member state whether reprocessing of SUDs is allowed or not. In Sweden it has been illegal to reprocess single use device since the implementation of MDR. This changed however on 26 April 2022, when the MPA released new regulations, outlining that reprocessing is allowed, that the MPA is authorized to issue further regulations and that IVO is to be the supervising body [26].

Overall, the regulation of reprocessing has become much stricter since the MDR, according to the MPA. Stricter requirements mean higher costs for the healthcare institutions. This means that healthcare providers will need to be more considerate regarding what products are worth reprocessing. Expensive products are more likely to be reprocessed when compared to cheaper ones. The stricter requirements include additional documentation, routines, and quality reviews, all of which involve costs.

2.5 ISO standards regarding in-house production

International Organization for Standardization (ISO) is an international institution that is non-governmental, and its members consists of several national standardization bodies [27]. Sweden's representative in this organization is the Swedish Institute for Standards (SIS). The standards developed by ISO are not legally binding, which means that it is voluntary for companies and organizations to adopt these standards. However, it can be beneficial to follow the ISO standards as they can act as support to comply with MDR and having the ISO backing can lead to increased credibility.

SS-EN ISO 9001- Ledningssystem för kvalitet is a standard for quality management systems, and it is the most used standard by companies and organizations throughout the world. The goal of a quality management system is to meet the requirements from users or customers, which can be done with the help of several business processes [28]. According to SIS, SS-EN ISO 9001 is designed based on fundamental 7 principles: customer focus, commitment from employees, leadership, process approach, improvement, fact-based decision making and relationship management [29]. The two most important ISO standards for in-house production of medical devices are SS-EN ISO 13485-Ledningssystem för kvalitet, medicintekiska produkter and SS-EN ISO 14971:2020/A11:2021-Tillämpning av ett system för riskhantering för medicintekniska produkter.

SS-EN ISO 13485 can be very useful for meeting the relevant general requirements for safety and performance described in MDR. SS-EN ISO 13485 is based on SS-EN ISO 9001 but adapted specifically to comply with the regulations for medical devices. This includes certain requirements that are not covered by SS-EN ISO 9001, while other requirements are omitted [30]. According to SIS7s description of SS-EN ISO 13485, some of the most important components of the standard revolve around design and development, manufacturing, storage, distribution, installation, and decommissioning.

SS-EN ISO 14971 is a standard specifically designed with the goal of applying risk management to medical devices. This standard considers the devices entire lifecycle, from start to finish, while considering various hazards and risks which may arise [31]. Given that the general requirements in MDR places great demands on the risk management process, this standard is key to abiding by the requirements of the regulation.

2.6 Common application of in-house production of medical devices

In-house production of medical devices encompasses many application areas, as the need for hospitals to produce different devices may vary. In this section, three common applications of in-house production is described, 3D printing of medical devices, medical device software and reprocessing of single use devices.

3D printing

3D printing refers to the construction of physical objects from digital schematics [32]. This is done using a 3D printing machine and allows for the possibility of constructing complex devices quickly and with higher precision than one could by hand. This can be useful when producing medical devices, as the margin for error is often very small. This may also be particularly useful when designing products that need to be specified for a given patient, as the measurement can be changed for each device that is printed, in order to suit the patient. The 3D printing is often done outside the premise of the hospital, but many DMTs have these 3D printers on-site, making them an integral part of the in-house production process.

One study by Willemsen et al. 2022 examines two 3D-printed devices, a 3D printed nylon drill guide and titanium spinal column prosthesis [1]. This study provides a solid case of how standards are used in in practice during the in-house production process. For people who have a deformed spinal anatomy, pedicle screws may be drilled into the spine to improve alignment. These have historically been done using free hand, which is relatively safe for certain areas and angles of the spine, but when drilling into the cervical vertebrae, the margin for error is small. Therefore, guides may be put in place on to the spine in order to improve the accuracy of screw alignment. These guides are implants that can be 3D printed specifically to suit the patient. In the Willemsen et al. 2022 study, a CT scan is first done on the patient to get the proper measurements, then the guide is designed based on these measurements. The implant is printed using an in-house 3D lab.

In the study two types of standards are showcased, the general ISO 13485 standard which is used for the company to maintain a high-quality management system and sterilization standards, as the 3D printed devices are sterilized before usage.

General standards:

- ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes

Sterilization standards:

- ISO 11607 –1:2019 - Packaging for terminally sterilized medical devices — Part 1
- ISO 17665:2016 -Sterilization of health care products. Moist heat. Part 1
- EN 285:2016 - Sterilization - Steam sterilizers - Large sterilizers

In the design portion of the construction phase, the standard that is used is ISO 13485. The Medical Technology and Clinical Physics department of the hospitals were ISO 13485-accredited prior to the 3D prior to the new MDR legislation. These departments worked in a multidisciplinary effort with medical staff and engineers in the 3D-lab for the design stage of the construction process. The main elements of the SS-EN ISO 13485 standard that was implemented in this stage was "… risk analysis, traceability of procedures and implants, ISO and equivalent certifications of critical suppliers, and a technical rationale per medical device."

After the guide has been constructed, it must be sterilized. This is done at an in-house facility, using the ISO standards, 11607 (Packaging for terminally sterilized medical devices) and SS-EN ISO 17665 (Sterilization of health care products).

Medical device software

Medical devices can come in many forms. One such is medical device software. This refers to any software used for diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease or disability, as well as any software that investigates, replaces, modifies, or provides information of anatomy [33].

The application of medical device software is spread across several different modalities and application areas. Therefore, the standard usage may also vary greatly depending on the type and aim of the specific medical device software. A 2021 study by Beckers, Kwade and Zanca [3] provides a great presentation of known standard usage for medical device software. The study outlines a great deal of standards that may be used when dealing with medical device software. It's interesting to note that both harmonized and non-harmonized standards are often applied. Relevant standards from the study are presented below.

Standards for the company:

- ISO 13485 - Quality management systems — Requirements for regulatory purposes
- ISO 27001 - Information Security Management
- Product related standards:
- EN ISO 14971 (IEC/TR 80002-1) - Application of risk management to medical devices.
- EN 62366 - Application of usability engineering to medical devices.
- EN ISO 14155 - Good Clinical Practice for clinical investigations with medical devices
- EN 1041 - Specifies requirements for information to be supplied by manufacturers of medical devices
- EN ISO 15223-1 - Symbols to be used with medical device labels, labelling and information to be supplied

Software related standards:

- IEC 82304-1 - Health software — Part 1: General requirements for product safety
- EN 62304 - Medical device software - Software life-cycle processes

The standard-application process may begin as early as the conceptualization stage of the given product[3]. This is because the requirement in Annex I must be met. Quality may be maximized with proper planning and the usage of ISO 13485. Beckers *et al.* concluded that the product specific standards are typically applied in the design and development stage of the product. Furthermore, risk management is of high importance at this stage, with a strong focus on potential risk for the patient, the clinician, and the environment. These factors are addressed by ISO 14971. The risk management can be further divided into of three main stages, where ISO 13485 is continually being complied with, in addition to ISO 14971. Several risks accompanying the product are outlined and evaluated, then these risks are addressed and minimized as much as possible and must consequently show that the steps taken in stage two work as intended.

The study also notes that given the nature of digitized software, data must be analyzed to

meet the requirements in Annex I. Verification and validation are two important parameters for ensuring safety and performance of any device, and these are important factors in the ISO 13485. However, since it is data that must be evaluated, a different standard, IEC 62304 is used. Here there are two primary stages. Firstly, it must be demonstrated that when the software is given input, that it can accurately and precisely produce intended output, and that it can do so consistently. Secondly it must be validated that the user of the software meets the requirements necessary to use it. These two stages can be done in either a simulated or real-life training and they rely on data sets.

After the risk management stage comes the clinical evidence stage[3]. Here, ISO 14155 is used as follows. Using clinical data from the device or from scientific literature, proper safety, and performance, as well as a net-positive risk-reward ratio must be shown. If the data is retrieved is not from the device, the data must be from a device that has met the same requirements as the used device. The data must also be from statistically significant sets, with adequate statistical methodology. Only then can the data be analyzed, thereafter the result is noted in a clinical evaluation report. In this stage ISO 13485 is also used as a supporting system. This standard is thus used throughout the products lifecycle, in conjunction with product specific standards that are applied throughout the process.

Reprocessing

Reprocessing was described and discussed in sections 2.2 and 2.5. With the implementation of new national regulation, this area will be of great importance for how DMTs will work with in-house production.

The standards used when reprocessing medical devices may vary depending on methodology, as different sterilization methods require different guidelines. Below are listed some relevant standards for reprocessing of medical devices [2],[34].

- ISO 13485 Quality management system for medical devices
- EN ISO 17664 - Processing of health care products
- ISO 17665 - Sterilization of health care products - Moist heat
- ISO 11135 - Sterilization of health-care products - Ethylene oxide
- ISO 11137 - Sterilization of health care products — Radiation
- ISO 11139 - Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards
- ISO 15883 – Washer-disinfectors

Reprocessing of single use devices often require sterilization in order to avoid contamination. The guidelines in ISO 14937:2009 are general and may be usable in a variety of sterilization processes, however some of the more common sterilization methods have specified ISO standards, such as the ones listed above. According to 2019 study by McEvoy et. al, ISO 14937 may not be enough on its own for reprocessing of single use devices [34].

ISO 14937:2009 provides aid for DMTs in terms of determining what is important when the outlining the sterilization process as well as the validation stage thereafter. According to ISO 14937, in the sterilization process, the sterilization equipment should be compatible with the sterilizing agent, while emphasizing the safety and consistency of the procedure and the standard also outlines a series of steps that are to be taken to ensure the microbicidal

effectiveness of the sterilizing agent [2]. Some of these include demonstrating the effectiveness of the sterilizing agent, identifying highly resistant micro-organisms, as well as identifying a way to stop the sterilizing agent from being active. In the validation stage, the efficacy and reproducibility of the sterilization process is emphasized.

3 Method

The study was initiated by sending out a general email, which is presented in Appendix 1, to 20 DMTs across Sweden. The scope of the study included every DMT in Sweden which we could successfully locate and reach out to. Appendix 1 was not modified adjusted for the individual recipient.

3.1 Interview

Each interview was conducted semi-structurally, allowing the participant to expand on subjects or questions whenever they wanted to share knowledge, information, or concerns relevant to the subject matter, but which were not directly or thoroughly asked in Appendix 2 or 3, depending on the interview. Participants were primarily employees at DMTs or people who operated as manager for the DMT at the hospital at which they were employed. Participant from MPA were an investigator for the department responsible for medical technology.

Interview method

Interviews with DMTs followed the questions presented in Appendix 2 and follow-up questions were asked whenever possible. Appendix 3 served as the core questions for the interview conducted with MPA.

Four interviews were conducted over digital/video meet up and the remaining interviews were conducted over email. Appendix 2 & 3 was sent out before the digital/video interview was performed, such that participants may prepare before the interview is conducted in order to increase the quality of the interview.

Archiving and recording interviews

Audio from interviews were recorded, whenever permission was granted and was later transcribed. The recording was later deleted whenever the interview material had been analyzed and documented.

4 Results

In this section the results of the semi-structured interviews are presented and further segmented. These segments include improvement areas for standards, the DMTs' usage of standards, changes in in-house production and communication regarding standards.

Approximately 30% of all interview requests that were sent out resulted in either an interview or a few questions being answered over email. Serval DMTs gave a minor description of their current in-house production but were unavailable to participate in our discussion or answer our questions. The latter DMTs often described that they had discontinued their in-house production or lacked knowledge on the subject matter to participate in a constructive interview.

4.1 Complaints and issues with standards

SS-EN ISO 7396-1: 2016 was specifically mentioned during three of the interviews as needing a review and update since interviewers found the standard lacked clear procedures to measure the oxygen level in patient care spaces. This is needed to ensure that the oxygen does not surpass the 22% oxygen level mentioned in The Work Environment Act [36],[35]. DMT that requested/suggested an update of SS-EN ISO 7396 utilized the SIS supplied handbook 370 "Säkerhetsnorm för medicinska gasanläggningar", which has been supplied and developed to aid DMT among other organizations certified with SS-EN ISO 7396, to comply with SS-EN ISO 7396-1: 2016 [36]. The need for an update of SS-EN ISO 7396-1: 2016 was originally noted during the usage of SIS handbook 370, and it was thus assumed that insufficiencies in the recommended procedures from SIS handbook 370 resulted from errors or deficiencies in ISO 7396-1: 2016.

Several DMTs expressed interest in expanding their usage of standards within their organization but felt unable to implement them for various reasons. One DMT rarely implemented/used any standards within their organization since they rarely felt any need for them, but mentioned that if existing standards were either more harmonized and resultingly more practical, their organization would likely find a greater interest in using standards overall.

Request for new standards

DMTs has a common interest in expanding their in-house production, especially in medical devices that are not currently widely developed in their respective organization. In-house production of 3D-printed medical devices and development of software intended to work in conjunction with medical devices within the organization were mentioned in 13 of the interview, though DMT said that no applicable harmonized standard satisfying their needs existed or had been found and expressed their need for these.

ISO 13485 is widely adopted among DMTs, though it was not always applicable/adaptable for all their in-house production as it is too restrictive or too impractical for some of their in-house production needs. A potential solution was suggested to introduce a less extensive version of ISO 13485: 2016 or relevant harmonized standards, as SS-EN ISO 13485: 2016 is impractical to use in their organization. DMTs unanimously expressed that there existed no relevant standards that they know of for reprocessing of SUDS, and several DMTs would

unlikely introduce reprocessing of SUDs without the usage of a well-adapted harmonized standard.

4.2 DMTs usage of standards

DMTs were certified and utilized standards within their organization to varying degrees, though all interview DMTs unanimously agreed that they used or interacted with standards to some extent. Standards were exclusively implemented and used to aid the organization in following current regulations, and the usage of standards without being certified is occasionally used at several DMTs. One DMT rarely applied or used standards within their organization and found the lack of well-adopted and practical standards as the main reason for their exclusion. Another DMT utilized standards within their organization for various tasks and adopted/reviewed their currently adopted standards annually, regardless of whether they were certified, as they found several standards to be critical to their in-house operation.

The frequency at which standards were used at each DMT appeared to be correlated with their knowledge of existing standards and the extent to which they communicated with SIS. This correlation was noted by the former mentioned DMT, as they found the accessibility and knowledge of standards and the updating/development of standards to be a plausible reason for why they were not applying or utilizing standards to any greater extent.

Standards commonly used at DMTs:

The interview DMTs most commonly utilized the following standards.

- SS-EN ISO 14971: 2019 – Medicintekniska produkter, Tillämpning av ett system för riskhantering för medicintekniska produkter
- SS-EN ISO 13485: 2016 – Medicintekniska produkter, Ledningssystem för kvalitet, Krav för regulatoriska ändamål
- SS-EN ISO 7396-1: 2016 – Medicintekniska gassystem, Del 1: Medicintekniska centralgasanläggningar
- IEC 80001-1: 2021 – Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software, Part 1: Application of risk management

Several DMTs stated that they were working with other standards as well, though they were unable to mention or unsure of which ones. A variety of standards for sterilization was adopted as part of the temporary increase in reprocessing SUDs resulting from covid-19.

Several DMTs had 3D-printed devices as part of their in-house production, though no one was aware of or utilized any available standard. One DMT outsourced their 3D-printing production as their 3D-printing was not especially extensive and because it would be too resource-intensive to start up 3D production in-house, though they expressed the possibility to do so in the future and believed a harmonized standards for 3D-printed medical devices would be of great importance to them if this were to happen.

As it relates to medical device software, ISO 80001-1: 2021 plays a prominent role in terms of standard application. This standard is used before, during and after introducing or updating a health information system (meaning any system that is used to store or manage

healthcare information) to mitigate any risk that the reliability of said health information system is affected. Thus, it is used as a risk management tool for IT networks.

None of the DMTs that were interviewed utilized any standards for reprocessing. One DMT described the reason being as them not having any knowledge of any standards related to reprocessing. Another DMT did not use any standards but used the hospitals central sterile services department as aid in reprocessing.

4.3 Changes in in-house production

The implementation of MDR and the pandemic coincided within the same time frame. In this section, the effects of MDR and the COVID-19 pandemic on the in-house production of medical devices will be presented.

MDR based changes

According to one DMT, the work process during in-house production since MDR has improved. This is because the new regulation has entailed updated routines and instructions for in-house production. The same DMT also described the biggest challenge with in-house production since the introduction of MDR has been the maintain and develop competency in relation to the new legislation, as well as understanding what needs to be done differently in practice, as when compared to when MDD and AIMDD was current. More coordination between departments has been necessary to comply with regulation. One DMT decided to stop in-house production entirely due to a lack of resources within the department, with MDR making the process even more strenuous.

COVID-19 based changes

The pandemic did not have an impact on the pre-existing MPA regulations. There were no exemptions made for in-house production during the pandemic regarding the legislation, however the governmental institution, IVO had announced that the circumstances were to be considered regarding their supervision. The MPA did however release temporary regulations, which lowered the requirements for CE marked products. Since in-house produced products do not require CE marking in the first place, this did not have a direct impact on the in-house production process. It also emerged in the interview with the MPA that there are currently government investigations into emergency preparedness. Among others, the NBHW, MSB (The Swedish Civil Contingencies Agency) and the Swedish eHealth Agency have been given government assignments linked to emergency preparedness.

The consensus is that the pandemic increased the pressure on the in-house production process, particularly when it came to reprocessing. Some devices such as ventilation tubes for ventilators needed to be disinfected as there were a lack of replaceable alternatives. In addition to medical devices, DMTs had to produce protective equipment, such as plexiglass covers. Reprocessing is a process that requires heavy amounts of risk management and documentation, meaning an increased workload in the production process. This also meant that compliance with regulation regarding reprocessing was more difficult to achieve.

4.4 Communication regarding standards

In order to understand how DMTs standards contribute to the development of in-house medical devices, it is important to note the communication process as it relates to standards and in-house production. The results regarding this are presented in this section.

Insight into standard updates

The way the DMTs stay up to date with standards vary. One of the primary methods is to check SISs website continuously. Regions in Sweden have an SIS Subscription, online library with SIS, where they have access to standards, which allows them to see the latest version of standards. One DMT has a list of all current standards that are used in their quality management system, which is reviewed and updated once a year. Various individuals in the DMTs also participate in networks for medical technology managers, which keeps them updated around what applies regarding standards. One DMT also previously had a collaborator that worked with standardization bodies, which helped them stay up to date.

Proactive working processes

A recurring sentiment from the DMTs that were interviewed is that a direct line of communication to SIS would be helpful in their work with and application of standards. The information that is provided by SIS is described as good but is primarily accessed through emails and updates on the website. SIS desired to have a direct connection to different DMTs to get better contact with healthcare providers.

Communication with government bodies

The communication between IVO and the DMTs that were interviewed is very minimal. Most of the communication is notifications regarding initialization of in-house production. The communication is described as sporadic rather than continuous, with IVO not being clear in their expectations regarding in-house production. In one interview, the contribution from IVO was perceived as just referring the DMT to the MDR, rather than providing guidance on how to make proper decisions. In another interview, the work from IVO was described as not being proactive enough.

5 Discussion

The low participation rate of the study and the varying extent to which DMTs could answer our questions might insinuate that a more extensive investigation is needed to obtain an accurate summation of the needs of DMTs regarding standards. Future research should thus likely focus on developing a more complete and precise description of DMTs' usage of standards and general operation regarding in-house production. Especially since the results of our study most likely exclusively involved participants with a greater than average interest and knowledge of standards relative to the average knowledge among DMTs.

5.1 Standards usages and complaints

The issue with ISO 7396-1:2016 in relation to The Work Environment Act was one of the few very detailed errors which were reported by the interviewed DMTs. Reported issues with ISO 7396-1: 2016 might already be under investigation as IVO is aware that handbook 370 does not antiquely and properly reflect the requirements in ISO 7396-1: 2016 [39],[37]. The mentioned issue reported with handbook 370 by the interviewed DMT is not specifically mentioned. Whether this issue originates from SIS handbook 370 or ISO 7396-1: 2016 is undetermined. This issue requires an investigation to locate the source of the problem and address it accordingly by either exclusively updating SIS handbook 370 or handbook 370 and ISO 7396-1: 2016.

DMTs almost unanimously agreed that standards should be adopted future within their department, though everyone agreed that adopting new standards was, in many scenarios, not especially practical. Updating existing standards could be a viable solution, as seen previously with ISO 7396-1:2016 and SIS handbook 370; however, most complaints were not that standards did not meet current legislation, but rather that potential standards were to wide and thus too resourceful intensive, or impractical to use relative to the given operation or task. Adapting existing standards which are not explicitly designed for the operation might be unrealistic as it may have negative consequences on others that need the broader aspect of the standard, and it might thus be better to focus on developing new harmonized standards instead.

The goal of a given hospital is often to provide high quality healthcare for patients in a cost-efficient way. Given the nature of hospitals and the DMTs within them, providing beneficial standards that aid said hospitals in their goals may lead to a positive impact on the welfare of the society at large. The importance of this thesis and work like it, is therefore ethical in its essence.

DMTs requesting harmonized standards rather than updating existing ones should indicate that updates to currently adopted or existing standards were not a common complaint about why standards are not frequently adopted within in-house development at DMT. Developing harmonized standards as an extension to existing broader standards would extensively increase in workload for SIS and is potentially unrealistic. However, a proactive collaboration by SIS with DMTs might serve as a possible resolution to this issue.

Interviews with DMTs made it clear that there is a great need for guidance and aid when new legislation is implemented and help whenever DMTs expand their production or development. SIS has an excellent opportunity to inform and collect information during both of these stages and create a systemic, proactive initiative to educate DMTs on how new legislation interferes with standards that they are currently using as well as standards that

might become relevant for them going forward. These meetings should be designed and adapted for each DMT, as it has become apparent through these interviews that DMT needs to be able to send in detailed questions or subject matters, for example, questions regarding 3D-printing of medical devices, and have these questions discussed in detail at a later date with someone that is well prepared and does not resolve to simply quote legislation or standards, which was a common response DMTs got when previously interacting with governmental bodies.

5.2 Changes in in-house production

It seems that new legislation led to an increased workload in the in-house production process. This is compounded by the pandemic being in full throttle in the same time period. It can be concluded that both factors played a role in the increased workload because the pandemic had a relatively larger impact on reprocessing whereas the legislation had an overarching impact on the in-house production process of medical devices. If only one of these factors had an impact on the workload, we would in theory only see an overarching impact on in-house production or just an impact on reprocessing. The increased workload that was observed when reprocessing most likely have and will continue to decrease as the effect of the pandemic lessens, whereas the effect of the legislation is expected to continue. This may not be the case however, as the knowledge of healthcare providers and manufacturers may increase with time as they get used to the new legislation, which may in turn lead to a more efficient work flow and thus we may observe a reduction in workload going forward.

Other than delaying the implementation of the regulations, the pandemic did not affect the regulations regarding in-house production of medical devices directly. However, the temporary MPA regulations that lowered the requirements for CE markings may have had an indirect. Impact on in-house production. This is because lower requirements for CE marking could in theory reduce the need for in-house production, as products would be released to the market with more ease and be more readily available. This would increase the likelihood of finding an equivalent product, which would lessen the demand for in-house production.

Whether it is job of the legislation or the standards to provide a framework that is resistant to the negative impacts of a pandemic can be considered a philosophical or even political question. This is of little importance for the purpose of this project however, because of the on-going government investigations that are underway, as was explained the interview with the MPA. These may lead to new legislation which would render any standard made today obsolete. It is therefore perhaps wise to let these conclude before designing such standards.

5.3 Communication regarding standards

There seems to be three important factors when considering the communication between SIS and the DMTs. These are the quality, availability and applicability of the information that SIS outputs. The information seems to be of high quality, as it suits the demands of the DMTs in their in-house production process. The information is also readily available on SIS's website and in emails that they send. The issue however is that the DMTs have trouble sifting through this wall of information in order to determine what is relevant and thus applicable for them. A potential solution for this is a more proactive work process from SIS's. This would help DMTs with practical application of standards, as well as specifics and details that otherwise might be overlooked or poorly understood. A way this could look is by having a direct line of communication between SIS and a person or department at each hospital. An example would be for them to establish and maintain contact with a person with a certain role in each hospital, such as the head of the DMT. It is important to note however

that this would most likely mean an increased workload for SIS. With the information being more specified as opposed to generalized, it could lead to repetitive information being given to multiple hospitals.

The communication between DMTs and IVO seems to be very poor when it comes to in-house production. The consensus is that more proactive guidance and advice from IVO, regarding interpretation of legislation and how to work in practice would be helpful. The gap here between IVO and the DMTs, could ideally be filled with the use of harmonized standards. The standards can act as a practical blueprint in order to comply with the regulations. With a more direct line of communication to SIS, these issues of interpretation may be alleviated.

5.4 Comparison to previous research

Just in line with previous research outlined in the background we see that there is a heavy emphasis on EN ISO 13485:2016 - Quality management system for medical devices when it comes to the usage of standards [1],[2],[3]. This is unsurprising given that standard provides a base for the structure of the department. We also see a great reliance on EN ISO 14971 - Application of risk management to medical devices, which is also to be expected.

Interestingly no usage of standards for the in-house manufacture of 3D-printed devices were observed, whereas one previous study pointed to the notion that certain DMTs benefit from sterilization-based standards in the process of printing these devices [1]. This trend continues when it comes to reprocessing, as no standards were used for this area either. Interestingly the same standards that one would expect to be used when 3D printing, the sterilization standards were absent when reprocessing.

In a previous study we see a wide array of standards being used for medical device software since the different types of software that exists is vast [3]. Therefore, no specific standard was expected in this area outside the general quality and risk management standards.

5.5 Future work

If one wishes to do work that would expound upon this project, there would be a number of ways it could be done. It may be of interest to conduct a widespread survey amongst the DMTs which may allow for a statistical analysis, and potentially provide a more accurate basis for addressing the aim of this project. A potential downside of this methodology however is that it would be difficult to design the right questions that necessary to answer a given problem description. It would be more difficult to add or subtract questions based on their relevance, and specify the questions for a given DMT, such as one would be able to with structured interviews.

Furthermore, the scope of the project could be expanded to DMTs outside of Sweden, or to look at the effects of the IVDR in addition to the MDR. This project was done in collaboration with SIS, giving further reason to focus on Sweden when analyzing the problem description. The MDR is an EU regulation and thus this type of project may be of interest at standardization organizations in other European countries. The IVDR fell outside the scope of this project, but its effect is of high importance for standardization organizations, DMTs and hospitals in general, and this regulation would therefore be a valuable research area.

6 Conclusion

Construction of a less extensive version of SS-EN ISO 13485 or an equivalent harmonized standard that is directly applicable to the in-house production process within DMTs is requested by many DMTs that struggle to utilize SS-EN ISO 13485 in its current form. There is also a demand for a comprehensive standard for reprocessing of single use devices. If an applicable standard already exists, then an extensive educational aid from SIS is recommended to properly inform DMTs.

A harmonized standard for reprocessing, or an extensive review along with an educational process may be needed to properly meet the practical needs of DMTs. There is also a need to update and specify guidelines for gas systems in handbook 370 to make it more applicable for DMTs in practice.

The primary usage of standards for in-house production within DMTs was to meet regulatory demands. The usage and perceived value of standards varied noticeably in-between DMTs, but every DMT used SS-EN ISO 13485 and SS-EN ISO 14971 in their organization.

The DMTs that did not find great value in standards noted a lack of information as a potential reason. Making the ISO standards more accessible, perhaps by adding a direct channel of contact to various DMTs, is suggested as it could be of great benefit for the DMTs in their in-house production process.

Changes in the in-house production process due to MDR were noted as being somewhat mixed. The new regulations are clearer, and the updated instructions were regarded as beneficial. The regulations were also described as being more demanding, leading to a greater overall workload and thus more taxing when it comes to resources.

On a regulatory level, the only direct impact that the pandemic had on in-house production was that it delayed the entire implementation of the MDR. In terms of the actual in-house production process, the pandemic did have a direct impact by increasing the workload, specifically regarding reprocessing.

We do not recommend developing standards that are resistant to pandemic-like situations currently, because there are government investigations being carried out on emergency preparedness. These could lead to new regulations and if a standard were to be designed right now, there is a risk that it will be overridden by what comes with the government assignments.

7 References

[1] K. Willemsen *et al.*, “Vital Role of In-House 3D Lab to Create Unprecedented Solutions for Challenges in Spinal Surgery, Practical Guidelines and Clinical Case Series,” *Journal of Personalized Medicine*, vol. 12, no. 3, p. 395, Mar. 2022, doi: 10.3390/JPM12030395/S1.

[2] T. Bayrak and S. I. Soylu, “Reprocessing of single use medical devices: A new proposal for a regulation,” *Health Policy and Technology*, vol. 10, no. 3, p. 100553, Sep. 2021, doi: 10.1016/J.HLPT.2021.100553.

[3]R. Beckers, Z. Kwade, and F. Zanca, “The EU medical device regulation: Implications for artificial intelligence-based medical device software in medical physics,” *Physica Medica*, vol. 83, pp. 1–8, Mar. 2021, doi: 10.1016/J.EJMP.2021.02.011.

[4] “Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,” May 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424 (accessed Apr. 15, 2022).

[5] Läkemedelsverket, “Läkemedelsverkets föreskrifter (HSLF-FS 2021:32) om kompletterande bestämmelser till EU:s förordning om medicintekniska produkter,” Jul. 15, 2021. https://www.lakemedelsverket.se/sv/lagar-och-regler/foreskrifter/hslf-fs-2021-32-konsoliderad-foreskrift (accessed Apr. 10, 2022).

[6] BSI, “CE Marking for Medical Devices | BSI.” https://www.bsigroup.com/en-SE/medical-devices/our-services/ce-marking/ (accessed Apr. 11, 2022).

[7] “Egentillverkade medicintekniska produkter | IVO.se.” https://www.ivo.se/yrkesverksamma/medicinteknik/egentillverkade-medicintekniska-produkter/ (accessed May 18, 2022).

[8] “Reprocessing of medical devices.” https://ec.europa.eu/health/medical-devices-topics-interest/reprocessing-medical-devices_en (accessed May 18, 2022).

[9] “Reprocessing av engångsprodukter | Läkemedelsverket.” https://www.lakemedelsverket.se/sv/medicinteknik/tillverka/reprocessing-av-engangsprodukter (accessed May 18, 2022).

[10] ”Förordning (2021:631) med kompletterande bestämmelser till EU:s förordning om medicintekniska produkter Svensk författningssamling 2021:2021:631 t.o.m. SFS 2022:229 - Riksdagen.” https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2021631-med-kompletterande_sfs-2021-631 (accessed May 18, 2022).

[11] “Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (Text with EEA relevance),” Apr. 23, 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32020R0561 (accessed May 23, 2022).

[12] “MDR - Article 5,” Apr. 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=SV#d1e2154-1-1 (accessed Apr. 20, 2022).

[13] “MDR - ANNEX 1,” Apr. 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=SV#d1e32-94-1 (accessed Apr. 20, 2022).

[14] “MDR - Article 5,” Apr. 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=SV#d1e2154-1-1 (accessed Apr. 22, 2022).

[15] Läkemedelsverket, “Läkemedelsverkets föreskrifter (HSLF-FS 2021:32) om kompletterande bestämmelser till EU:s förordning om medicintekniska produkter,” Jul. 15, 2021. https://www.lakemedelsverket.se/sv/lagar-och-regler/foreskrifter/hslf-fs-2021-32-konsoliderad-foreskrift#hmainbody1 (accessed Apr. 10, 2022).

[16] Socialstyrelsen, “SOSFS 2011:9 Socialstyrelsens föreskrifter och allmänna råd om ledningssystem för systematiskt kvalitetsarbete,” Nov. 15, 2019. https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/foreskrifter-och-allmanna-rad/konsoliderade-foreskrifter/20119-om-ledningssystem-for-systematiskt-kvalitetsarbete/ (accessed May 01, 2022).

[17] Läkemedelsverket, “Läkemedelsverkets föreskrifter (HSLF-FS 2021:32) | Kap 4 - Egentillverkade produkter,” Jul. 15, 2021. https://www.lakemedelsverket.se/sv/lagar-och-regler/foreskrifter/hslf-fs-2021-32-konsoliderad-foreskrift#hmainbody4 (accessed Apr. 19, 2022).

[18] Socialstyrelsen, “Om Socialstyrelsen.” https://www.socialstyrelsen.se/om-socialstyrelsen/ (accessed Apr. 15, 2022).

[19] Socialstyrelsen, “SOSFS 2011:9 - Socialstyrelsens föreskrifter och allmänna råd om ledningssystem för systematiskt kvalitetsarbete | Kap 4 - Ledningssystemets grundläggande uppbyggnad,” 2019. https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/foreskrifter-och-allmanna-rad/konsoliderade-foreskrifter/20119-om-ledningssystem-for-systematiskt-kvalitetsarbete/#anchor_f907fec7-ee8e (accessed Apr. 20, 2022).

[20] Socialstyrelsen, “SOSFS 2011:9 - Socialstyrelsens föreskrifter och allmänna råd om ledningssystem för systematiskt kvalitetsarbete,” 2019. https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/foreskrifter-och-allmanna-rad/konsoliderade-foreskrifter/20119-om-ledningssystem-for-systematiskt-kvalitetsarbete/#anchor_b45c632d-019b (accessed Apr. 21, 2022).

[21] “SOSFS 2011:9 Socialstyrelsens föreskrifter och allmänna råd om ledningssystem för systematiskt kvalitetsarbete,” 2019. https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/foreskrifter-och-allmanna-rad/konsoliderade-foreskrifter/20119-om-ledningssystem-for-systematiskt-kvalitetsarbete/#anchor_372d944e-d94b (accessed Apr. 21, 2022).

[22] “Types of legislation.” https://european-union.europa.eu/institutions-law-budget/law/types-legislation_en (accessed Apr. 15, 2022).

[23] “Difference between a Regulation, Directive and Decision - United States Mission to the European Union,” Apr. 13, 2022. https://www.usda-eu.org/eu-basics-questions/difference-between-a-regulation-directive-and-decision/ (accessed May 02, 2022).

[24] “MDR- Article 1,” Apr. 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN#d1e1058-1-1 (accessed Apr. 20, 2022).

[25] “MDR - Article 17,” Apr. 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN#d1e3015-1-1 (accessed Apr. 18, 2022).

[26] Sveriges Riksdag, “Förordning (2021:631) med kompletterande bestämmelser till EU:s förordning om medicintekniska produkter Svensk författningssamling 2021:2021:631 t.o.m. SFS 2022:229,” 2021. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2021631-med-kompletterande_sfs-2021-631 (accessed May 10, 2022).

[27] ISO, “ISO - About us.” https://www.iso.org/about-us.html (accessed Apr. 25, 2022).

[28] SIS, “ISO 9001 - Kvalitetsledningssystem.” https://www.sis.se/iso9001/ (accessed Apr. 29, 2022).

[29] SIS, “ISO 9001 - Kvalitetsledningssystem.” https://www.sis.se/iso9001/dettariso9001/ (accessed May 02, 2022).

[30] SIS, “Standard - Medicintekniska produkter - Ledningssystem för kvalitet - Krav för regulatoriska ändamål (ISO 13485:2016) SS-EN ISO 13485:2016,” Mar. 07, 2016. https://www.sis.se/produkter/foretagsorganisation/foretagsorganisation-och-foretagsledning-ledningssystem/ledningssystem/sseniso1348520162/ (accessed Apr. 20, 2022).

[31] ISO, “ISO 14971:2019 - Medical devices — Application of risk management to medical devices,” Dec. 2019. https://www.iso.org/standard/72704.html (accessed Apr. 29, 2022).

[32] Merriam-Webster, “3D printing Definition & Meaning.” https://www.merriam-webster.com/dictionary/3D%20printing (accessed Apr. 15, 2022).

[33] “MDR - Article 1,” Apr. 05, 2017. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=SV#d1e1058-1-1 (accessed May 01, 2022).

[34] B. McEvoy and N. J. Rowan, “Terminal sterilization of medical devices using vaporized hydrogen peroxide: a review of current methods and emerging opportunities,” *Journal of Applied Microbiology*, vol. 127, no. 5, pp. 1403–1420, Nov. 2019, doi: 10.1111/JAM.14412.

[35] “Huvudsakliga risker med arbete i farlig atmosfär - Arbetsmiljöverket.” https://www.av.se/halsa-och-sakerhet/kemiska-risker-och-luftfororeningar/farlig-atmosfar/huvudsakliga-risker-med-arbete-i-farlig-atmosfar/ (accessed May 18, 2022).

[36] “SIS HB 370 utgåva 2. Säkerhetsnorm för medicinska gasanläggningar,” *2008*. https://docplayer.se/41955379-Sis-hb-370-utgava-2-sakerhetsnorm-for-medicinska-gasanlaggningar.html (accessed Apr. 21, 2022).

[37] A. Lundgren, “Yttrande avseende SIS-remiss 19805 gällande SIS HB 370 Säkerhetsnorm för medicinska gasanläggningar,” Jun. 2020. Accessed: Apr. 20, 2022. [Online]. Available: https://ivo.se/sok/?q=2020-06-11%20Yttrande%20avseende%20SIS-remiss%2019805%20g%C3%A4llande%20SIS%20HB%20370%20S%C3%A4kerhetsnorm%20f%C3%B6r%20medicinska%20gasanl%C3%A4ggningar&time=a&type=w,d&cat=

Appendix 1: Participant interest for interview

Hej,

Vi är två medicintekniska ingenjörsstudenter vid Kungliga Tekniska högskolan och har nyligen påbörjat vårt kandidatexamensarbete. Projektmålet är att se över och analysera standarder och standardiseringsarbetet kopplat till egentillverkning av medicintekniska produkter, med fokus på varderas bidragande till att uppnå MDR. Projektet genomförs tillsammans med vår uppdragsgivare SIS (Svenska Institutet för Standarder) och målet är att komma med rekommendationer för hur ovanstående kan förbättras och eventuella förbättringsområden.

För att utföra projektet vill vi samtala med kunniga inom området och hade uppskattat om vi kunde genomföra en intervju med er. Intervjuerna är tänkt vara 45-75 minuter och genomföras digitalt under vecka 14 - 17. Det är tänkt att intervjuerna skall spelas in och raderas några dagar efter intervjun när informationen från intervjun har sammanställts. Intervjuerna genomförs anonymt och deltagarnas namn och tillhörande organisation kommer ej att nämnas, men kan komma att höra av oss för ett godkännande att använda direkta citat och/eller om delar av er befattning önskas användas. I rapporten kommer det framgå att data/information insamlats från intervjuer.

Intervjuerna anpassas naturligtvis efter era behov och vi uppskattar framförallt om ni informerar oss gällande ert godkännande till ljudinspelning och när ni möjligen är tillgängliga för intervju. Återkommer inom kort med samtyckesformulär om ni godkänner till ljudinspelning.

Vi ser fram emot att höra från er och önskar er en fortsatt trevlig dag.

Med Vänliga Hälsningar
Alexander Söderberg & Birante Soumare

Appendix 2: Interview questions for DMTs

Allmänt om egentillverkning inom er organisation:

Genomför ni egentillverkning?
- Om ja, Vad för slags produkter egentillverkar ni?
- Om nej, har ni gjort det tidigare & varför slutade ni med egentillverkning?

Hur har MDR påverkat arbetsprocessen vid egentillverkning?
Vad har blivit bättre eller sämre?

Vad är de största utmaningar som ni bemöter vid egentillverkning?

Vad har COVID-19 haft för påverkan vid egentillverkning?
Har er produktion förändrats (ex: fokus på skyddsutrustning)

Uppfattar ni att relevant lagstiftning för egentillverkning har förändrats under pandemin?
Temporära eller permanenta förändringar?

Hur ser kommunikationen ut mellan er och IVO?
Kan ni ge ett exempel på hur & när ni kommunicerar med IVO under produktens livscykel?

Hur håller ni er uppdaterade kring de aktuella standarderna?
Har ni några förbättringsförslag för hur ny information kring standarder levereras?

Hur ser kommunikationen ut mellan er och SIS?
Anser ni att behövande information kring aktuella standarder är lättillgängliga?

Utför ni någon typ av 3D printing inom er organisation?
- Är 3D printing en del av er egentillverkning?
- Anser ni att 3D printing inom egentillverkning är möjligt inom er organisation?
- Finns det ett intresse/behov för 3D printing inom er egentillverkning?

Standarder:

Vilka standarder använder ni främst inom egentillverkning på eran organisation?

Vilka standarder anser ni är viktigast vid egentillverkning av medicintekniska produkter?

Tycker ni att standarderna ger tillräckligt stöd för att för att uppfylla de krav som ställs av nuvarande regelverk?
Om ja, har ni något exempel?

Vilka brister/förbättringsområden ser du i standarderna?
- Har ni några förbättringsförslag?

Vad anser ni vara de främsta fördelarna med de standarder som ni använder idag?

I vilket syfte använder ni er av standarder (ex: miljömål, ekonomiska eller för att uppnå nuvarande lagstiftning)?

Reprocessing av medicintekniska SUDs (single use devices):

Reprocessade er verksamhet SUDs innan MDR tillträdde?

- Om ja, vilka typer av produkter?

Har er verksamhet ett behov/intresse att reprocessa SUDs i nuläget?

- Om ja, varför (ex: miljömål, ekonomiska eller tillgänglighets fördelar)?

Vilka standarder används eller anser ni vara aktuella för reprocessing?

Hur skiljde sig erat arbete med reprocessing i förhållande till egentillverkade produkter?

Appendix 3: Interview questions for MPA

Egentillverkning:

Hur stor del av er verksamhet berör egentillverkning (vem arbetar med egentillverkning)?
existerar egen avdelning eller hanteras egentillverkning av en bredare grupp?

Arbetar/samarbetar ni med SIS eller annan myndighet med uppdatering/utveckling av standader?
Om ja, vilket inflytande anser ni att ni har?

Översikt för egentillverkning:
Genomför ni någon form av översikt över hur era föreskrifter förhåller sig på MT-avdelningar?
Om ja, hur genomför ni denna översikt?

Föreskrifter:

HSLF-FS 2021:32 : kompletterande kap 4
bestämmelser till EU:s förordning om medicintekniska produkter

Vet ni hur väl denna föreskrift följs?
Vilka delar av föreskriften är svårast att uppnå (enligt er eller MT-avdelningar)?
Anser ni att dagens standarder (ISO) är tillräckliga (förbättringsförslag?)?
Finns det pågående arbete med att uppdatera föreskriften (rekommendation på standard som bör uppdateras?)?

SOSFS 2011:9 : Socialstyrelsens föreskrifter och allmänna råd om ledningssystem för systematiskt kvalitetsarbete

Vet ni hur väl denna föreskrift följs?

- Vilka delar av föreskriften är svårast att uppnå (enligt er eller MT-avdelningar)?
- Anser ni att dagens standarder (ISO) är tillräckliga (förbättringsförslag?)?
- Finns det pågående arbete med att uppdatera föreskriften (rekommendation på standard som bör uppdateras?)?

HSLF-FS 2021:52 : Gemensamma författningssamlingen
avseende hälso- och sjukvård,
socialtjänst, läkemedel, folkhälsa m.m.

Vet ni hur väl denna föreskrift följs?
Vilka delar av föreskriften är svårast att uppnå (enligt er eller MT-avdelningar)?
Finns det pågående arbete med att uppdatera föreskriften (rekommendation på standard som bör uppdateras?)?

MDR:

Ser ni skillnader på hur föreskrifter kring egentillverkning följs sedan tillträdandet av MDR?
Följs föreskrifterna bättre eller sämre?
Fördelar med tidigare regelverk?

Reprocessing Single Use medical Devices (SUDs):

Vad gäller kring föreskrifterna angående reprocessing?

- Har ni översikt hur reprocessing har förändrats sedan MDR tillträdde?
- Anser ni att reprocessing har varit lagligt i något utsträckning sedan MDR tillträdde?

Kommer nya föreskrifter för reprocessing att träda i kraft den 26/4 (introduktion av reprocessing)?
Om ja, vilka?
Varför introduceras dessa föreskrifter (vilka mål har dessa föreskrifter?)?
Förändringar jämfört med tidigare regelverk (regelverk 2020)?
Om ja, varför introducerades dessa skillnader?

Anser ni att relevanta standarder existerar för reprocessing av SUDs?

- Vilka standarder tror ni främst kommer användas?
- Anser ni att det krävs uppdatering av nuvarande standarder?

Anser ni att det existerande problem med de standarder som användes för tidigare regelsystem?

- Om ja, vilka var problemen?
- Förbättringsförslag, alternativt rekommendation på komplettering till nuvarande standarder?

Covid - 19:

Har Covid-19 haft något inflytande i er uppdatering av 2021:32 & 2021:52?

- Om ja, vilka skillnader?

Har Covid - 19 haft något inflytande över introducerande föreskrifter för reprocessing?
Om ja, vilket inflytande?

Anser ni att covid-19 har gjort det svårare för MT-avdelningar att följa existerande regelsystem?
Om ja, vilka områden?
Förbättringsförslag för standader (områden som bör stärkas i standaderna)

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