Vulnerability analysis method for manufacturing
Case study of emergency production of masks

Kurdve, M.[ab], Mattsson, S.[a], Thuresson, U. [a], Stenlund, P. [a], Ström, M. [a], & Wäppling-Raaholt, B. [a]
[a]*RISE Research Institutes of Sweden, SE-412 58 Gothenburg,Sweden*
[b]*Department of Technology Management & Economics, Chalmers University of Technology, Sweden.*
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ABSTRACT

Purpose

To support the vision of Industry 5.0 manufacturing companies must ensure human-centricity, sustainability and resilience. In this article human-centricity, sustainability and resilience is supported through a vulnerability analysis performed on the emergency production of face masks. The aim was to analyse vulnerabilities/risks and find an approach applicable for critical and emergency production in the case of face mask production.

Design/methodology/approach

The production process, not in continuous use, was observed and analysed by operation personnel and assessment experts covering different aspects. In the vulnerability analysis energy, material, personnel, and maintenance supply of a production process for face masks was analysed.

Findings

Findings show that instructions and manuals as well as procedures for how to employ and train personnel need to be part of the emergency/contingency planning, it is not enough to store the equipment. New opportunities using digital and visual technologies can be utilised.

Research limitations/implications

The emergency production of face masks is an example of moving from Manufacturing readiness level (MRL) 6 to 10, which includes supporting the human need for instructions, looking at waste and material production as well as handling resilience through emergency preparedness

Practical and Social implications

This research is crucial for society since during Covid, Swedish healthcare needed temporary domestic production of personnel protective equipment. The analysis can be supplemented with social and environmental sustainability assessment.

Original/value

This paper contributes with enhanced practical and academic understanding of human factor importance in emergency production.

Keywords: Emergency production, Vulnerability analysis, Human factors, Training, Continuity

1 Introduction

The aim of this article is to experiment on how a qualitative vulnerability analysis can be used when assessing resilience and support in the ramp-up of emergency production of face masks. This means having organisational abilities to go from MRL of 6 to 10 i.e. going from a proof-of-concept manufacturing to demonstrate full production with lean production practices in place. In the project "Resilient material and product supply in case of crisis and conflict" a face mask machinery (see Figure 1) was acquired and set-up for contingency reasons at RISE, Research Institutes of Sweden, to be able to run emergency production of face masks and investigate societal resilience development.

Figure 1. The face mask production equipment.

From a societal perspective resilience development and vulnerability analysis is urgent since three quarters of businesses in Sweden have, according to a survey from 2023, not worked with their contingency plan for disruptive events (Combitech, 2023). On one hand, Swedish companies are seen as innovative (Bisson, 2023) and many Swedish manufacturing companies adhere to lean production which sets standardized operations and reduction of disturbances high on the agenda (Oudhuis and Tengblad, 2022). On the other hand, the pandemic highlighted the urgency of being prepared for crisis situations.

1.1 Background

Industry 5.0 is a vision that is said to go beyond profit and focuses on three core elements: human-centricity, sustainability, and resilience (European Commission, 2021). Companies should take advantage of new technology but implement it so that all responsible stakeholders are included i.e. operators using the technology should be included, production sustainability and its resilience are crucial. Production in industry has over the past decades become more vulnerable to disruptions due to globalisation, outsourcing and cost efficiency trends (Ekström et al., 2023). To counteract disruptive shortage, emergency production or contingency production may be one option. *Emergency production* can be said to be a production line that is run in case of emergency and is usually not in continuous use or has to be increased beyond regular supply production capacity (Yang et al., 2024).

In emergency production having a sustainability approach include social, environmental and economic aspects. Acute crisis situations or emergency events are not normal occurrences (Alexander, 2014; Al-Dahash et al., 2016), characterized by ambiguity and demand of urgent responses (Zamoum and Gorpe, 2018). They may lead to increased need of certain materials such as face masks during COVID. It is a solution utilizing production processes that are discontinuous and starts or ramp up in case of emergency.

Here social aspects can be considered through human-centricity. Other aspects of society such as work environment for users and producers of the face masks as well as e.g. saving the people from disease can also be included here. In case of emergency and non-continuous production human-centricity is crucial due to that to adapt to crisis utilizing personnel production resources is an enabler (Kurdve and Arvidsson, 2022). Such an approach should include having appropriate skill and training (Hernandez-de-Menendez et al. 2020; Okorie et al., 2020) and that technology supports the human to that she/he can perform tasks in an efficient way (Romero et al., 2021; Bechinie et al., 2024). Due to that skills only can be learned through continued practice (Soltero and Boutier, 2012) technology and/or instructions that support the work tasks should be adapted (Mattsson & Fast-Berglund, 2016). In addition, appropriate training should be provided so that they fit the individual (Taylor, 2005).

Environmental sustainability can connect to resilience by being resource efficient and choosing renewable or environmentally friendly materials and energy sources. To maintain continuity of a production process it is necessary to secure supply of raw materials, energy, operative labour, and maintenance (including both maintenance competence and spare parts).

Economic sustainability of emergency production mainly mean that additional cost needed is kept lower than alternative solutions. An emergency production is an option when the cost of using the regular supplier is greater than emergency production cost (Huang et al., 2018). In a crisis situation it may not be a cost issue but rather if the regular source can supply at all (Yang et al., 2024).

If a crisis is seen as a propagating process rather than an acute crisis situation or event, then the counteracting resilience management process can be seen as including, preparedness, response (to the acute crisis) and recover/restore stages (Williams et al. 2017). Here understanding and reducing vulnerabilities is a key component in preparedness and resilience management.

1.2 MRL and production ramp-up

As a way of describing emergency production ramp-up the manufacturing readiness level is used. *MRL* is used to “demonstrate the increase in manufacturing maturity required to transition to the next higher level” (Wheeler and Ulsh, 2010; see table with characteristics of each step in Appendix) and is designed to handle manufacturing risks while increasing the ability to develop technology. MRL was developed to measure the maturity of manufacturing technologies (developed bu the US Department of Defense). Similarly, the Technology Readiness Level was developed by NASA to describe companies' readiness level to new technologies (Mankins, 2009). MRL ranges from “Feasibility Assessment” to “Full Rate Production Demonstrated”. Full rate production demonstrated means that “...all materials, manufacturing processes and procedures, inspection and test equipment are in production and controlled to six-sigma or some other appropriate quality level. Rate production unit costs meet goals, and funding is sufficient for production at required rates. Lean practices are well established and continuous process improvements are ongoing” (Wheeler and Ulsh, 2010, p. 11). Due to that manufacturing product development process (PDP) is complex (Karniel and Reich, 2011) the higher levels include a more detailed description than the lower (Wheeler and Ulsh, 2010). In this study MRL needs to go from level 6 to level 10 which means going from a prototype development into full scale production in a limited time.

The ramp-up process is dependent on product and process expertise, supplier and designers' competence and equipment expertise, involvement of operator team, internal technical competency, quality of training and testing of equipment, relationship and communication with the equipment and spare part supplier (Islam et al., 2022). Since requirements may have been unclear, or unknown when the production system was designed, problems may occur during production ramp up. Production ramp-up concerns initial pilot series of production, ensuring product quality and production performance (Wiktorsson et al 2018).

1.3 Emergency production of face masks and research gap

During the Covid pandemic, the Swedish healthcare, together with healthcare around the world, experienced a shortage of personnel protective equipment (PPE) (Ranney et al., 2020). As proposed solution temporary domestic production – emergency production was suggested. The preparedness for starting up emergency production were often perceived as low in Sweden during Covid. There thus exists a practical as well as research need for studies on set-up of emergency production and how to assure resilience and preparedness, of such production.

Due to that MRL normally should be taken step by step, this article is suggesting a fast track for developing emergency production. The requirements for such a production need to be specified and based on previous research. Due to that little research exists on emergency production ramp-up, the study is using an exploratory approach to find relations between theory of lean production as well as what research exist within emergency production, contingency analysis, vulnerability analysis and on securing skill and training within industry.

1.4 Purpose

The research aim is as mentioned *to experiment on how a qualitative vulnerability analysis can be used when assessing resilience and support continuity in ramp-up of emergency production.*

The practical purpose of this study was twofold. First to find, test and demonstrate a simple and fast way to perform vulnerability analysis and find improvements, with regards to material, personnel, and maintenance continuity, of an emergency production process of face mask production at RISE. Secondly to reflect on different approaches to give generalizable advice to especially SMEs who may have similar challenges.

2 Theory

2.1 Emergency and contingency production

The supply of many products has over the past decades become more vulnerable to disruptions due to globalisation, outsourcing and cost efficiency trends (Ekström et al., 2023). Contingency planning for disrupted global supply chains can include several options to improve security of supply (Paul and Chowdhury, 2021). Improved forecasting may increase the available response time of a disruption. Multiple sourcing is often an alternative that reduce risk of and severity of disruptions. Emergency stock is common to use especially for short time disruptions. Emergency production or contingency production is here mainly a measure for longer time occurring disruptions. War times and global pandemic has been examples of such longer time disruptions where further measures, such as emergency production has been a commonly used approach (Chen et al., 2021)

Emergency production can be said to be a production line that is run in case of emergency and is usually not in continuous use. There are several terms that could be used for, emergency production, e.g. crisis production, contingency production, backup production, reserve production, alternative production, temporary production etc. Traditionally in Sweden it has been a part of government contingency plans at specially assigned production facilities (named "K-företag", Swedish for War-critical-firms) for wartime to set-up protected production of critical supplies (Ingemarsdotter et al., 2018). Usually this was carried out by firms who also maintain regular production. Today when a substantial supply of, especially cheap, consumables are produced abroad it may be more important to have an ability to set up national emergency production as a contingency plan for long term disruptions. In such measures there is also a need to plan for raw material supply, possibly using multiple sourcing, emergency stock and substitution etcetera for the raw materials supply (Chen et al., 2021).

2.2 Continuity and vulnerability analysis

Continuity can be said to be the ability to continue to provide products/services within accepted timeframes and with predefined levels of capacity/performance in the event of a disruption (ISO 22300:2018). This definition is not exactly in line with how emergency production is used. Since emergency production is set up as a recovery strategy in the event of a disruption, in this paper we have preliminary defined the continuity for emergency production as the ability to start or ramp up provision of products/services within accepted timeframes reaching predefined levels of capacity/performance after a disruptive event. A continuity plan is a guide on how to manage an interruption and to resume, recover and restore the delivery of products and services disruption (ISO 22300:2018). Here we have applied that as the plan to initialize and assure emergency delivery of products and services disruption.

One initial step in making a continuity plan is to analyse critical constraints of the process; vulnerabilities, risks and opportunities and then investigate availability of resources needed and assess and mitigate risks and vulnerabilities (Lindström et al., 2010). Here, somewhat simplified, known potential constraints (assessable probability and effects) were referred to as risks and less known or quantifiable potential constraints were seen as vulnerabilities. There will always be certain events may occur unpredictably, making it impossible to plan for their timing or frequency. However, while the occurrence of these events may be uncertain, their potential impact on processes can still be anticipated and prepared for, as the processes themselves are understood (Paul and Chowdhury, 2021). The Swedish Civil Contingency Agency (MSB) supports with tools and methods for risk and vulnerability analysis of communities such as ROSA and FORSA to be used by communities (MSB, 2024). In these, effects of a number of scenarios/events are assessed then the vulnerability at different functions or processes are identified. The aims in this study coincide with the communities' aim for a higher resilience but starts in assessing the function/process and vulnerability with less focus on scenarios.

In order to maintain continuity of a production process it is necessary to secure supply of raw materials, energy, operative labour, and maintenance (including both maintenance competence and spare parts). There has been some focus in media on energy and IT-related disruptions, however with experiences from Covid, Russian invasion of Ukraine and other long term crises energy and IT supply disturbances occur, they can be severe but usually they are resolved within a shorter time scale. Disruptions like lack of material supply or work force disruptions are on another timescale both on occurrence and resolving.

2.3 Securing skills and lean training within industry

In order to secure production, securing availability of personnel with appropriate skills and competences is crucial. A survey with 71 manufacturers rated organisational flexibility and employee skills and know-how as to enablers for manufacturing continuity and manufacturing repurposing (Okorie et al., 2020). A company or process owner needs to evaluate what skills and competence is needed to run the process and document how to retain those skills and competences. A strive to make jobs possible to do for unskilled personnel may be important when designing the production process for emergency production since it will not be run in full scale other than when the emergency occurs. Design of operator instruction could be guided by the general production strategy values such as operator safety, good quality and efficiency (Kurdve 2018).

There is a growing realization that lean is not a system to implement merely for increased efficiency but rather a learning system for the discovery of problems and development of people through problem-solving (Powell & Coughlan, 2020). Thus, a rethinking of lean as a learning system through problem-based learning and action learning is relevant. Production improvements tools benefit from the lean go-to-gemba concept making them hands-on and operational, support collaboration and engagement, easy to learn and implement by being visual and time efficient, while being focused on a limited area of influence and support systematic standardized work (Shahbazi et al., 2019; Faulkner and Badurdeen, 2014; Mlkva et al., 2016). Commonly, lean process analysis and improvement tools build on value stream mapping (VSM) (Seth et al., 2017). Regular VSM is used to illustrate the main processes, and their operations, together with lead times, buffers and information flows (Rother and Shook, 1999) while simplified VSM for managerial overview may be conducted in a less detailed way (Medbo and Carlsson, 2013; Kurdve and Salonen, 2016). Simplified Value Stream Mapping (VSM), do not significantly differ from other process mapping methods (e.g. IDEF0 or similar) where processes are divided into operations with inputs and outputs. Several additions to VSM exist, extending the analysis to further resource flows, ergonomics etc.

Standardised work (StdW), is a lean production cornerstone and aims at getting operators to perform a task in the best-known way in line with the strategic values (e.g. safe with good quality and efficient). Liker and Meier (2006) explain implementation of StdW by identifying all work steps, time for each step, and draw schematic pictures of the work area and the operators in a standardised operations procedure (SOP) chart. Just a SOP is not enough to bring anyone off the street and do the job, or all details of the operations, but StdW is essential for both efficient improvement work and job training (Liker and Meier, 2006).

Using StdW as a basis, a methodology called training within industry (TWI) (Dinero, 2010), was developed in the US during the Second World War to quickly train housewives to work in the industry while the regular (male) labour force served in the war. TWI contains three main elements: Job instruction, where operators' individual abilities are used to train for the job, Job Methods, where the job is broken down in line with the SOP, highlighting safety, quality and efficiency risks/problems, and Job Relations, dealing with the attitude of supervisors towards the operators. The breakdown of jobs in TWI contributes to deeper understanding and increased knowledge of each step in a work process (Dinero, 2010). The principles behind StdW and TWI are old, but still valid although the application of these principles can be significantly supported and improved by new digital and visualisation technologies. Learning work skills can be seen as a process reducing uncertainty for doing the work task (Kurdve 2018). Skills can only be learned through continued practice (Soltero and Boutier, 2012). However, intuitive work can be supported by visual cues such as signs i.e. visualizations or cues that are connected to the operators' previous knowledge (Rassmussen, 1983). Signs activate a certain behaviour and can refer a rule of a situation in an environment e.g. how to sterilize a tool. The SOP should be simple to follow so that just enough information is presented at the right time, supporting again the active cognitive process, (Mattsson et al., 2016; Sheridan, 2002). In addition, instructions should be structured according to how the work is currently carried out, the layout should be consistent and easy to follow (Osvalder and Ulfvengren, 2009; Inaba et al, 2004) and include clear and concise headings and pictures are preferred over text (Ganier, 2004). The design of the pictures should be realistic, have big contrasts and only include relevant details (Osvalder and Ulfvengren, 2009).

Guidelines for how to design instructions based on the above learnings were recently developed in a Vinnova funded project DIGITALIS. The guideline which focuses on assembly operations, was used in adapted form to the machine operator instructions needed for this study (see 3.3).

3 RESEARCH DESIGN/METHODOLOGY

3.1 RESEARCH APPROACH

This action-based research (Coughlan and Coghlan, 2002) was set as an exploratory case study within the researchers own organisation. The aim, as in all action research, has been to solve a practical problem as well as to contribute to science (ibid). The studied process was approached with background knowledge from lean production and lean product development among participants. Action learning allows participants to propose various actions based on their individual values, experiences, and goals (Coghlan & Coughlan 2011), and learn as a team from those actions. Lean can be seen as an umbrella concept for theories and concepts that supports action learning and explorative learning, the practical methods used were therefore based on lean elements such as visualization, standardized work operations and flow analysis.

After a background literature search on definitions of continuity and vulnerability analysis, and emergency/contingency production, appropriate lean tools that support vulnerability analysis and improvements were chosen. Then support tools for securing the operator's skill and competence were applied to secure operation in the event of a crisis. The tools were applied on the emergency production process and results of the different steps were discussed and concluded.

The base of this study was empirical. Literature was searched to support the empirics, using Scopus and Google scholar, but also grey literature such as standards, advise by the Swedish authority MSB and related sources. The searches were not in a format of comprehensive literature review in the field, rather, simpler keyword searches were used to find explanations of terms and aims needed to choose appropriate methods and perform the empirical study. In addition, operating instructions and documentation from the equipment supplier were used (see list of materials below).

3.2 MATERIALS USED IN EMPIRICAL TRIALS

The operations case study involved a face mask machine, documentations and raw materials supplied with the equipment:

a) Face Mask Machine: TESTEX APL 80
b) Three different rolls of Non-woven Materials for face mask production
c) Plastic coated metal wire intended as a nasal clip
d) Elastic threads for ear-bands
e) Testex Operating Instructions ed 2 in English (Manual)
f) Testex film testex-changement-de-barrette-nasale (Changing the nasal-clip metal wire)
g) Testex film testex-changement-de-bobine (Changing the roll of non-woven material)
h) Testex film testex-changement-elastique (Changing the elastic thread)
i) Specifications for (currently used) non-woven material

Operative personnel involved were: two employees who participated in commissioning and training from the supplier in connection with equipment delivery (Instructor/Mentor) and two employees with no prior experience of operating the production equipment for face masks

(Trainee/Adept). In addition, three assessment experts supported the different process assessments.

3.3 METHODS USED IN EMPIRICAL TRIALS

The production process was observed and analysed by the appointed process operation personnel together with production assessment experts. Different assessment approaches covered different aspects. The lean production approach was deemed as supportive in the primary and secondary tasks to perform vulnerability analysis and find continuity improvements of the production process.

The process mapping parts (1&2 below) were building on simplified value stream mapping (VSM). The process mapping needs to be quick and time efficient. The reasons for using the VSM based methods were that all involved personnel were used to the VSM syntax and visualizations. In addition, VSM has a ready format for improvement suggestions and future state.

The analysis was done in the following three steps:

i. Resource input mapping: this initial process map aims to quickly map all input and output resources of a process and has a common base with environmental value stream mapping (EVSM) (Kurdve et al., 2011) a VSM that also visualizes material and waste flows and energy and water consumption and was used to analyse all inputs and outputs of the process and discover potential vulnerabilities. The mapping took approximately one hour to do but with additional investigations of raw material supply and documentation.

ii. Engineering Process Development Value Stream Map (PD-VSM): To identify critical components of the manufacturing process a similar more detailed VSM inspired approach in accordance with PD-VSM as described by Ström et al (2013) was used. The mapping took approximately six hours in total to complete and was done in two three-hours sessions. The start-up process and the flow of material through the machine was mapped. Active parts in the machine were identified for each step. The machine was partly disassembled to allow for identification of possible critical parts hidden by covers. Initial documentation of the machine was poor and could not support the mapping as expected. It is assumed that this very well can be the case in many situations thus making the mapping activity more demanding since the documentation did not provide any guidance on how critical different parts were.

iii. Assessment and securing operational competence: The operator instructions were assessed. Since standardized operator instructions or procedures were missing for the process, the operator activities were mapped, checked against the instruction manuals and documented in accordance with SOP (standard operator procedures). Trials using these SOPs gave input to new more visual SOPs and training materials. The visualizations needed to support intuitive cognitive processes therefore they were simplified (supporting operational work tasks suggested by Mattsson et al., 2020). These activities took several hours but not several days.

3.4 RESEARCH LIMITATIONS

The study focused on a process that will run in case of emergency. It was not in continuous use. The practical methods utilized may be straight forward for people used to a lean production context, while for others not used to lean production it may be perceived as more difficult. The three activities were performed with several weeks between each step. This may have both helped and hampered the learning process. Learning is helped since substantial time for reflection was given between the exercises. The learning may have been hampered due to details that are forgotten between the activities.

4 FINDINGS

The purpose has been met by performing a primary task, to find and test a simple and fast way to perform vulnerability analysis and continuity improvements of an emergency production process in the case of face mask production in Sweden. A secondary task was to apply the learnings on the face mask emergency production process and improve the process.

4.1 RESOURCE INPUT MAPPING

The Resource input process mapping was performed using environmental value stream mapping (EVSM) with some exclusions. In the EVSM all the operations of a process were drawn together with all buffers of productive material. Then all resource and information inputs and outputs were drawn into the map. The exact process time and setup times were omitted compared to a regular EVSM. For each input the requirements were specified. This process which can be operated by a single operator is fairly simple and contains two operational steps and postprocessing:

- Operation 1. Folding, joining, and cutting of the mask
- Operation 2. Connecting ear strings to the mask.
- Post-processing includes packaging and random sample testing of the products.

The external inputs to the first operation were three (different) rolls of non-woven polypropylene materials for face masks, a plastic-coated steel wire (nose clip) and electricity (220V, 50Hz, 1kW). The second operation external input was nylon and cotton-based ear band and pressurized air (6-7 bar), it also received electricity from operation 1, see Figure 2. The packaging is not part of the equipment and can be set-up in different ways depending on the logistic needs of how to send the product, in this case manual bulk-packaging in boxes with plastic bags is assumed. The machinery needs to be set up within a hygiene area, clean enough to ensure the hygiene demands of the product.

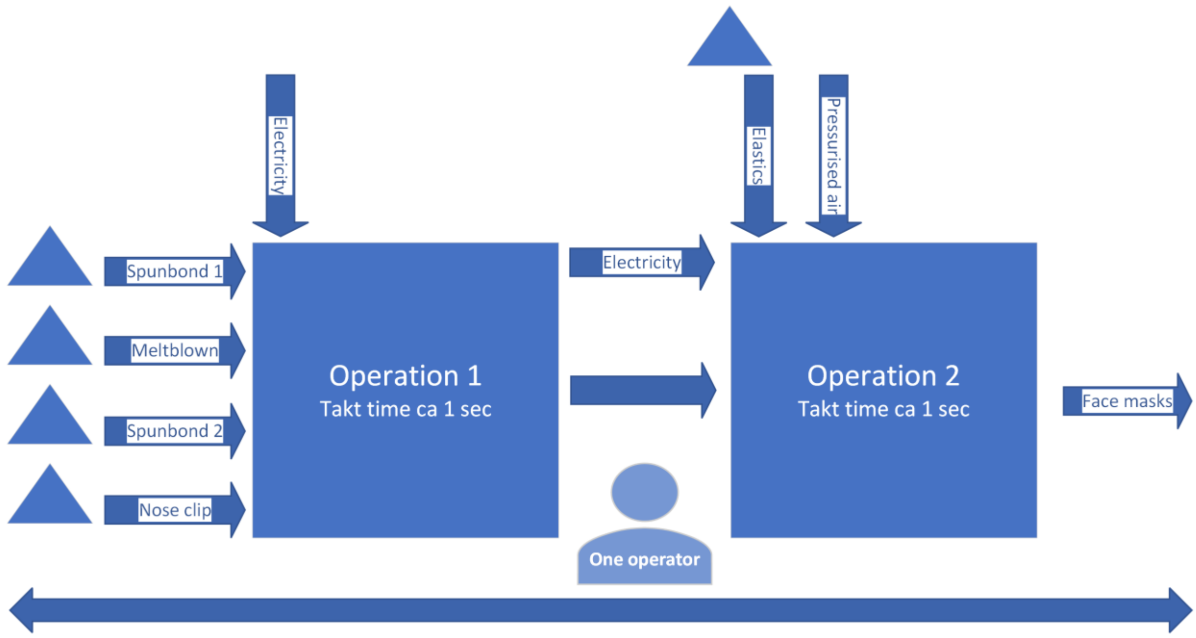

Figure 2. Schematic resource input VSM of process.

Although the production process function and inputs to the process was known, the quantitative probabilities of discontinuities and effects on such discontinuities were unknown. Thus, a qualitative assessment of the vulnerabilities and risk of discontinuity was made assessing the risk of discontinuity as high, low or none. Here risk in normal production is given quantitatively by a function of probability and exposure of occurrence and the effect or damage of an occurrence but for discontinuous production with lack of statistical data, a qualitative assessment is necessary. Regarding the vulnerability of the process, the electricity and pressurized air demands, as well as availability of hygiene area, were regarded as commonly available at thousands of places in Sweden and since the machinery can be moved easily in cars or trucks, a local power failure is not seen as a long-term restriction to continuity of operations, see Table 1. The availability of raw materials however is deemed as more critical. Assessment of the raw material supply showed that the current state supply was from different countries in Europe and thus has a risk of disturbances in case of e.g. pandemic crisis. Redundant (dual) sourcing in the near region (EU or preferably nationally within Sweden could reduce risk, and emergency storage of raw material was another option from this analysis. In order to meet supply, continuity tests with alternative raw materials and tests of how to meet quality demands of products with domestic raw materials were recommended.

Table 1. Initial vulnerability analysis

Input	Risk of dis-continuity	Comment/recommendation
Energy (electricity, air)	Low	Common electricity may be disrupted locally
Infrastructure (building)	Low	Common business facility may be disrupted locally
Raw material (PP non-woven and elastics): Meltblown: MELTBLO (France) Spunbond: THRACE (Greece) Plastic coated metal tread (China) Elastics: NITEX (Bulgaria)	High	Near sourcing or stockpile. For each material check if local and/or dual sourcing is possible, else stockpile. European sources were available for all materials
Maintenance	High	Investigate critical components & instructions
Operators	High	Rework instructions & training

Potential lack of maintenance and spare parts for repair of the machinery were seen as a risk for discontinuity. This led to the need for doing a process development value stream map to investigate critical maintenance parts and maintenance instructions.

The process always needs at least one active operator, and at the time of study only 3-4 personnel could operate the equipment and none of them have had time to practice enough on the operation. Thus, further development of operator instructions and training were deemed as necessary.

4.2 PROCESS DEVELOPMENT VALUE STREAM MAP

A Process Development Value Stream Map (PD-VSM) was created to investigate critical parts and maintenance needs of the process. Part of the map can be seen in Figure 3. Yellow sticky notes were used to state process steps in the machine and blue sticky notes were used to state parts of the machine involved in each step. The parts were classified by marking dots in different colours on the blue sticky notes according to the following: Blue dot for parts that can be replaced. One red dot for parts that are important but not critical and two red dots for critical parts. Finally, a black dot denotes that the part is a wear part (see Figure 3).

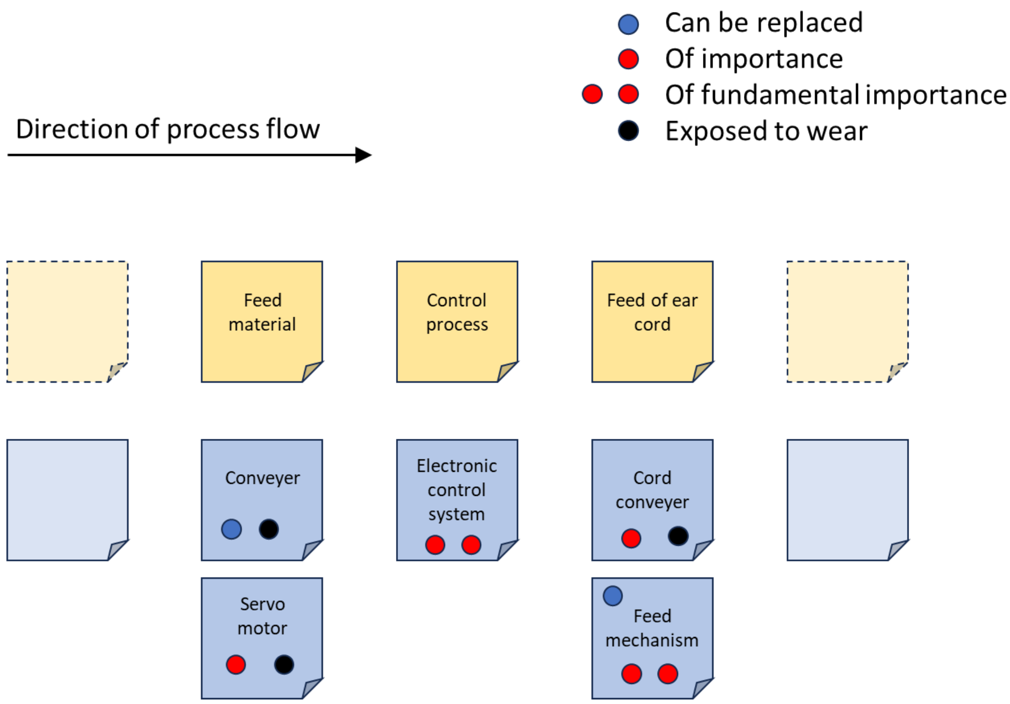

Figure 3. Part of the mapping of the work cycle of the machine for producing personal protection equipment. Yellow stickers denote process steps and blue stickers denote parts active in each step.

As there was no full component register for the equipment, it was investigated whether the PD-VSM method (mapping critical articles and components) could replace a component register. Through this method, a basis for a semi-detailed description of the facility's components and a superficial risk assessment of the included components. To obtain a comprehensive basis for managing critical components, a basic risk assessment could be performed with the supporting of expertise in remedial and preventive maintenance, mechanics, mechatronics, pneumatics, electricity, and power supply.

4.3 OPERATOR INSTRUCTION DEVELOPMENT

The four operators were asked if they "feel confident about how to operate the machinery and produce face masks with good quality". They answered no to this. Thus, since there were not enough trained personnel and the trained personnel needed more training, operator instructions and training materials were developed. The operations manual of the machinery was used together with filming the most experienced operator and a SOP was documented for operation of the machinery. In a group training session where three operators worked on the operation and documented possible errors and critical activities, this was used to incrementally develop the SOP. The SOP was also tested for the case with a new operator to the equipment. This was filmed and analysed in order to further develop SOPs and visual one-point lessons. The SOPs were iteratively developed and tried until the operators felt they could answer yes to the confidence questions that were raised initially.

Training began in a first step by carefully studying the manuals and films provided by the equipment supplier. This was considered to be an important first step in gaining a basic understanding of the manufacturing process before the earlier trained operator demonstrated startup and monitoring. By independently exploring the machine equipment and materials, based on manuals and films, the operator gained a deeper insight of the equipment and the process. Since the material provided by the supplier was mainly in English and partly in French, a translation into Swedish was produced.

The introduction continued with a series of practical exercises that included:

1. Preparation for Startup focusing on safety and connecting necessary utilities.
2. Actual Startup of the facility.
3. Monitoring the facility during operation.
4. Visual Inspection (quality control) of the produced product, in this case, face masks.
5. Shutdown Procedures
6. Unplanned Maintenance, addressing unexpected maintenance of the facility.

Electricity and compressed air were connected, needed for operation of the equipment. During the initial startup, an issue with the assembly of the elastic cord was immediately identified, leading to troubleshooting a specific machine part. It quickly became evident that a drive belt had been incorrectly placed, likely due to a previous test run where the equipment had not been properly reset before starting up. The exercise was halted, and after discussion, it was decided that an attempt to rectify the drive belt issue and measure it to order a replacement should be performed. This task also highlighted the need for a maintenance log with detailed specifications for all components. The supplier's agent was contacted regarding the drive belt specifications and the possibility of obtaining such a log. The problem was resolved when the drive belt was adjusted and reassembled, allowing for a successful restart of the equipment and the production of approved products. Concurrently, a preliminary version of the operational instructions for startup and monitoring of the equipment was developed.

A third step included self-training and preparation of documentation for Standard Operating Procedures (SOP), and one-point lessons. Following the maintenance work mentioned above, the trainee began self-training in starting and monitoring the process. Each distinct step was documented by describing the operations in an operational/work instruction. The operational instructions' efficacy was evaluated during two sessions with test subjects unfamiliar with the facility, noting necessary improvements and clarifications. The trials occurred weeks apart, and the equipment's sensitivity to displacements was observed when the alignment of the rollers (towards machine part 1) with the non-woven material did not match at the second instance. Consequently, the metal wire serving as the nose clip in face masks was not correctly placed in the mask. It was noted that one-point lessons for certain tasks are desirable since written instructions would become complex for some steps, and that video clips could enhance clarity, thus reducing uncertainty among test subjects. As the facility must be considered as an emergency production, it imposes specific requirements on how instructions are designed. The documentation and group activities with operators helped experimental learning in accordance with Schön, double loop learning, reflection in practice (practicing together while explaining to others what I am doing) and reflection on practice (documentation and explanations what happened after practice). Three one-point lessons and SOPs were developed for starting, running and stopping the process. In addition, changeover instructions for changing the rolls of raw material input and adjustments were documented.

5 DISCUSSION AND REFLECTIONS

The research aim was *to show how a qualitative vulnerability analysis can be used when assessing resilience and support continuity in ramp-up of emergency production.* This was done by finding, testing and demonstrating a simple qualitative vulnerability analysis highlighting improvement potentials, regarding material, personnel, and maintenance resilience, of an emergency production process of face mask production in Sweden. Then, in discussion, reflections of the process, having ramp-up from MRL6-9 in mind (Wheeler and Ulsh, 2010), give generalizable advice to especially SMEs who may have similar challenges.

5.1 A FAST AND SIMPLE VULNERABILITY ANALYSIS

Doing a vulnerability analysis of the resource inputs to the process, could be performed reasonably quickly and it was found not critical to follow a comprehensive framework to identify vulnerability areas. Within one hour it was clear to see that raw material supply, maintenance and assuring skill/competence for operating the process is critical. Here EVSM was used but in the reflection after performing the task it was deemed among participants that other alternatives for input-output analysis would be equally useful.

As a first step critical constraints of the process are identified (Lindström et al., 2010). It was seen that the supply of necessary process matters, e.g. energy, water etc. needs to be included in the contingency planning. Material supply vulnerability analysis requires information from purchasing and supply chain. Improvements such as multiple sourcing and near-sourcing may take too long time in the acute response phase because it is best to apply in the preparation phase of resilience management. Alternatively, to substitute materials to domestic available materials may be technically challenging and require redesign of the product and process why it may not be a feasible option at all when an emergency already has occurred and needs to be done in a preparation phase. In the case of the emergency face mask production process studied, experiments and evaluation of alternate materials are suggested as development and preparation until next pandemic.

Since the emergency production equipment was seldom used, it was difficult to establish what spare parts were critical. The use of PD-VSM was found useful in this sense. In PD-VSM the work process of the equipment was mapped, and each step of the process and involved parts was studied which increased the process understanding, similar to a job breakdown in TWI (Dinero, 2010). Knowledge of this kind is essential for a production ramp-up (Heraud, 2023).

In the used PD-VSM method, probability of failure and likelihood of detection were not assessed as in a process FMEA (failure-mode effect analysis), only whether a part of the equipment is critical to its operation. For regular production equipment data on breakdowns and spare part need is often available in the maintenance system. Such systems usually give occurrence of different failures, useful for estimating probability of different failures for a process FMEA which may be an optional tool to use instead of PD-VSM if the personnel is used to the tool and appropriate data exist. However, for discontinuous emergency production, quantitative data for risk assessment using e.g FMEA is difficult to obtain. Benchmarks with producers and experience from other similar equipment maintenance may be useful.

The PD-VSM method was regarded easier to apply than process-FMEA. It is assumed that factors having an impact on risk are not fully known since future crisis are often unknown and with resulting difficulty to assess risks in such detail as required in a process FMEA need. In the case of a process-FMEA, the environment and the conditions surrounding a production equipment is often designed with clear intentions but in crisis the nature of the crisis is in many cases unintentional. For supply of the critical spare part repair and or emergency production may be needed in certain situations.

As also described in the background the continuity of workers skill was considered as critical. Instructions and manuals as well as procedures of how to employ and train personnel need to be part of the emergency planning, it is not enough to store the equipment. New opportunities using digital and visual technologies can be utilised. In addition, digital learning tools, where the learner can click to find manuals and explanations of standards in a simple way or where operators could be supported by signals such as Andon, or light tool systems that support intuition could be used (Mattsson and Fast-Berglund, 2016). In addition, 'poka yoke' or error-proofing to minimise errors in the process could be utilized (Mattsson et al, 2023). In order to do this, it is necessary to have a workplace that is safe, orderly and where things can easily be found (Liker 2003). With an orderly workplace it was considered easy to make SOPs, visual one-point-lessons and instructions. However, team training and problem solving were required to decide on what to include in SOPs and one-point lessons. Quality assurance and testing of the product needed further development and training of personnel.

Social implications of the study are that the analysis can easily be supplemented with environmental assessment since the initial part is built on environmental VSM. Social sustainability aspects and inclusion can be considered when analysing and securing skills and human resources.

In order to be able to run emergency production of face masks at RISE, further preparedness development areas were identified. Regular training of operators is one area. Another regarded redesign of the product for domestic available raw materials and simplified content, but with fully qualified functional demands in line with Chen et al (2021). Especially if there are possibilities for circular raw material supply. This would require that all materials in the product would be compatible with circulation. Such development will need to include test and verification of function. It could also be considered whether access to and use of the emergency production unit could be applied in normal supply to some extent, to increase flexibility and preparedness.

5.2 MEETING SME CHALLENGES

With regards to general applicability to SMEs the authors regarded the presented process to be an appropriate first step for SMEs to start their resilience management of simple processes, but further development is needed in all three; preparation, response and recovery, phases of resilience management. This may be a first step of meeting the challenges of adhering to Industry 5.0 where human-centricity, sustainability and resilience is at the core (European Commision, 2021). Being able to ramp-up production fast, going from MRL 6 to level 10 is complex and includes several aspects that need to be in place (Karniel and Reich, 2011). One crucial aspect for MRL 10 is lean practices which mean having well established and that continuous process improvements are ongoing" (Wheeler and Ulsh, 2010, p. 11). The process is also dependent not only of its vulnerability to crises but is dependent on e.g. product and process expertise (Islam et al., 2022). Due to these problems may occur during ramp-up where pilot series are needed to ensure product quality and production performance (Wiktorsson et al 2018). Further case studies to different types of producers is recommended. Interviews and surveys with SMEs can give additional knowledge of the current state of practice and challenges for SMEs.

6 CONCLUSION

This paper contributes to enhanced practical and academic understanding of human factor importance in emergency production. The study concludes that a vulnerability analysis with a following continuity risk improvement could be done in a reasonably short time using lean production-based analysis and improvement methods. The analysis was supported by EVSM, PD-VSM and Standardized Work based methods. Supply of energy, material, maintenance, and personnel were major issues to consider. The studied process had main vulnerabilities in raw material supply and competence of operational personnel. The personnel vulnerability could be improved by the introduction of visual instructions based on standardized work. Trainings The learnings of the study point out further development actions regarding domestic material supply and possibly redesign with regards to circular raw material supply. The concluding advice would be to use a tool that the involved personnel are used to.

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Appendix A (fromWheeler and Ulsh, 2010)

MRL level	Name	Characteristics
1	Manufacturing Feasibility Assessed	Top level assessment of feasibility based on technical concept and laboratory data
2	Manufacturing Concepts Defined	Initiate demonstration of feasibility of producing a prototype system or component.
3	Manufacturing Concepts Developed	Manufacturing concepts identified and based on laboratory studies.
4	Laboratory Manufacturing Process Demonstration	Manufacturing processes identified and assessed in lab. Mitigation strategies identified to address manufacturing/producibility shortfalls. Targets set for cost as an independent variable, and initial cost drivers identified.
5	Manufacturing Process Development	Trade studies and laboratory experiments result in development of key manufacturing processes and initial sigma levels. Preliminary manufacturing assembly sequences identified. Process, tooling, inspection, and test equipment in development. Significant engineering and design changes. Quality and reliability levels not yet established. Tooling and machines demonstrated in the laboratory. Physical and functional interfaces have not been completely defined.
6	Critical Manufacturing Process Prototyped	
7	Prototype Manufacturing System	Prototype system built on soft tooling, initial sigma levels established. Ready for low-rate initial production (LRIP). Design changes decrease significantly. Process tooling and inspection and test equipment demonstrated in production environment. Manufacturing processes generally well understood. Machines and tooling proven. Materials initially demonstrated in production. Manufacturing process and procedures initially demonstrated. Design to cost goals validated.
8	Manufacturing Process Maturity Demonstration	Manufacturing processes demonstrate acceptable yield and producibility levels for pilot line. All design requirements satisfied. Manufacturing process well understood and controlled to 3-sigma or appropriate quality level. Minimal investment in machine and tooling - machines and tooling should have completed demonstration in production environment. All materials are in production and readily available. Cost estimates <125% cost goals (e.g., design to cost goals met for LRIP).
9	Manufacturing Processes Proven	Manufacturing line operating at desired initial sigma level. Stable production. Design stable, few or no design changes. All manufacturing processes controlled to 6-sigma or appropriate quality level. Affordability issues built into initial production and evolutionary acquisition milestones. Cost estimates <110% cost goals or meet cost goals (e.g., design to cost goals met). Actual cost model developed for FRP environment, with impact of continuous improvement. Full rate process control concepts under development. Training and budget plans in place for transition to full rate production.
10	Full Rate Production demonstrated and lean production practices in place	The system, component or item is in full rate production. Technologies have matured to at least TRL 9. This level of manufacturing is normally associated with the Production or

		Sustainment phases of the acquisition life cycle. System, components, or items are in full rate production and meet all engineering, performance, quality, and reliability requirements. All materials, manufacturing processes and procedures, inspection and test equipment are in production and controlled to 6-sigma or some other appropriate quality level. Rate production unit costs meet goals, and funding is sufficient for production at required rates. Lean practices are well established and continuous process improvements are ongoing.