Generic Clearance for CDC/NIOSH/NPPTL

Formative Respirator and Protective Clothing Laboratory Testing

OMB Control Number: 0920-1381 Expiration Date: 01-31-2026

Supporting Statement A

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- **Goal of the study:** The goal of this generic information collection request is to enable CDC/NIOSH to support the development and evaluation of personal protective equipment (PPE) performance requirements and test methods as specified within 1) federal regulations by NIOSH, Food and Drug Administration (FDA), and the Mine Safety and Health Administration (MSHA) and (2) voluntary consensus standards published by organizations such as the American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM) International, and International Organization for Standardization (ISO). Reflective of these standardized methods, data collection efforts at CDC/NIOSH are routinely conducted using human subjects in a laboratory setting that are generally consistent across NPPTL studies with only the boundary conditions changing (e.g., environmental conditions such as heat or humidity, human subject activity such as simulated surgery or climbing a ladder, and distance between two subjects communicating by spoken word). These consistent data collection efforts seek to 1) inform the validation or revision of current performance standards and test methods and 2) support the development of new standards or test methods.
- **Intended use of the resulting data:** The resulting data will benefit the federal government in that the performance standards and test methods supported will directly aid in ensuring the adequate protection via PPE of workers across a variety of industry sectors. Furthermore, the continued research in these methods will ensure the performance standards and test methods are up to date with an ever-evolving workplace safety climate as well as technological advancements in PPE. Through this data collection, ultimately the federal government will be able to efficiently react to the PPE protection needs of workers across the country thereby fulfilling CDC/NIOSH's mission.
- **Methods to be used to collect:** The methods used to collect the information from human participants will include health screenings, demographic information collection instruments, psychometrically supported surveys of user experience and perception of PPE, direct physiological measurements of response to PPE, biological measures of physiological responses, anthropometric measures of body size and shape, measures of PPE fit, and measures of the body's movement through space (biomechanics).
- **The subpopulation to be studied:** Study participants will include persons from the general population who are considered to be generally healthy, thus are safe to participate in all study procedures.
- **How data will be analyzed:** The data will be analyzed using various methods to be further defined for individual projects submitted under the Generic Clearance.

  In addition to submission of the instruments utilized, all collections submitted under this generic pathway will also include a full supporting statement Part A that describes the tool/method/intervention under development, identifies the targeted respondent populations, includes a justification for any incentives offered, assesses applicability of the Privacy Act and includes a complete Privacy Impact Assessment if necessary, and an accompanying Supporting Statement Part B if any statistical methods are employed for sampling or analyses in the study.

  For each package that may fall under the auspices of this generic information collection, NIOSH does not claim that the organizations and respondents will be statistically representative of the entire working population and is not claiming generalizability of results.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The National Personal Protective Technology Laboratory (NPPTL) is a division of the National Institute for Occupational Safety and Health (NIOSH) which operates within the Centers for Disease Control and Prevention (CDC). NIOSH is the federal institute specifically dedicated to generating new knowledge in the field of occupational safety and health and responsible for transferring that knowledge into practice for the betterment of workers.

NPPTL was established in 2001, at the request of Congress, with the mission of preventing disease, injury, and death for the millions of working men and women relying on personal protective technology (PPT). PPT plays an important role in keeping many workers within various industries safe while performing their professional duties. To achieve the Laboratory's mission, NPPTL conducts scientific research, develops guidance and authoritative recommendations, disseminates information, and responds to requests for workplace health hazard evaluations. The development of NPPTL filled a need for improved personal protective equipment (PPE) and focused research into PPT.

Respiratory protection, a specific type of PPE commonly tested by NPPTL, is the cornerstone of NPPTL's efforts. One of the primary responsibilities of the Laboratory is to test and approve respirators used in U.S. occupational settings. This function ensures a standard level of quality and filtration efficiency for all respirators used within a U.S. workplace setting. The NPPTL Respirator Approval Program exists to increase the level of worker protection from airborne particulates, chemicals, and vapors.

In addition to respirators, NPPTL conducts research on other types of PPE, including chemical-resistant clothing, hearing protection, gloves, eye and face protective devices, hard hats, sensors to detect hazardous substances, and communication devices used for safety deployment of emergency workers. NPPTL PPE research examines exposure to inhalation hazards, dermal hazards, and any other hazardous environmental threats within an occupational setting.

PPE performance requirements and test methods are specified within (1) federal regulations by NIOSH, Food and Drug Administration (FDA), and the Mine Safety and Health Administration (MSHA) and (2) voluntary consensus standards published by organizations such as the American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM) International, and International Organization for Standardization (ISO). Thus, the information collected from human subjects in a laboratory setting are generally consistent across NPPTL studies with only the boundary conditions changing (e.g., environmental conditions such as heat or humidity, human subject activity such as simulated surgery or climbing a ladder, distance between two subjects communicating by spoken word, various PPE use durations, or the use of novel PPE designs). Considering these consistent data collection methods employed with only changes in boundary conditions specified to a specific industry or standard, NPPTL requests a generic information collection package for laboratory-collected information for testing respirators and protective clothing.

Data collection for this project is authorized under the OSH Act of 1977 (29 USC 669 Section 20(a)(1)) (Attachment A).

2. Purpose and Use of Information Collection

NIOSH has a continuing need to a more comprehensive understanding of the impacts of wearing respirators and protective clothing on workers to inform relevant performance standards and associated test methods towards the goal of adequately protecting workers across a variety of industries via PPE as well as reducing the burden of wearing the PPE on the workers themselves. Further supporting this need for respiratory protection research advancement as an important subset of PPE, a 2007 assessment conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM), the committee recommended that NIOSH continue to engage in research that enhances the understanding of respirator use in the U.S. to inform accurate decision making in this area. Towards this goal, barriers to use which often include the physiological and perceptual burden on the workers using respirators must be systematically examined to ultimately inform the associated performance standard adjustments and ensure proper protection while reducing user burden. These types of research activities are directly what is being proposed in this package.

In addition, an ever-changing United States workforce, workplace safety environment with new and evolving hazards, and continual development of new respirator and protective clothing technologies necessitate the constant revision of PPE implementation and performance standards to ensure both sustained protection and usability. For example, in 2017 the healthcare and social assistance industry sector employed more U.S. workers than the manufacturing sector. (Thompson 2018) This is in stark contrast to 2000, where there were 7 million more workers in the manufacturing sector and 2.4 million more in the retail sector than in healthcare.(Thompson 2018) These major shifts in the U.S. economy and associated increases in PPE demand and use represent the potential for a drastic change in how respirators and other PPE are used and managed in the workplace. Second a changing workplace safety environment must be considered. For example, novel infectious disease outbreaks such as the Ebola outbreak in 2014 and the COVID-19 pandemic in 2020 require sometimes drastic changes to the design and protection of PPE or the way workers wear PPE during work. Lastly, PPE-related technological advancements such as the introduction of novel sensors, improved design and construction, manufacturing advancements, and the introduction of nanotechnologies to name a few require continual re-consideration of the associated performance standards.(Zimmerling and Chen 2021) These new technologies, designs, construction approaches, and use cases must be tested in an efficient manner to understand the direct impact on workers and necessary revisions to performance standards or test methods to accommodate the changing market.

This package will allow for the federal government to maintain a relevant and considerate scientific understanding of federal regulations and voluntary consensus standards that govern the performance; test method; or use, design, or construction of respirators and protective clothing allowing for robust PPE protection to the United States workforce while ensuring low burden and high usability in a consistently changing PPE environment. To achieve this goal, this package requests recurring information collection from human subjects which will directly examine the interaction between human subjects and PPE under varying boundary conditions. The types of data collection may include measurements of physiological, perceptual, and biomechanical responses to wearing PPE as well as examining PPE fit across various body shapes and sizes to ensure adequate protection and low user burden across a variety of use scenarios. The objective of this request specifically is to enable NIOSH to engage in these types of information collection activities in a time- and resource-efficient fashion, catalyzing improved

worker health and safety experiencing novel workplace safety and protection scenarios. None of the studies proposed under the auspices of this generic IC intend to produce results that can be generalized beyond the scope of each study.

The information collected for a project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. In some cases, personally identifiable information (PII) will need to be collected primarily for the purpose of facilitating payment. If it is, PII will be kept in a separate location and accessible only to the project-specific research staff. This information will be destroyed when the participant's contribution to the project has ended. Under no circumstances will an individual be identified using a combination of variables such as sex, race, birth date, and/or other descriptors.

3. Use of Improved Information Technology and Burden Reduction

All data collected will require human subjects to complete in-person testing sessions where they will wear various PPE while being monitored for physiological, biological, or biomechanical changes to their body or answer questions about their wearing experience. Additionally, anthropometric measurements of their body and of how the PPE fits their body may be included in the in-person testing sessions. To reduce burden to the human subjects and to comply with the Government Paperwork Elimination Act, Public Law 105-277, title XVII, signed into law on October 21, 1998, data collection will occur in the most time efficient and technologically advanced fashion possible. Technologically advanced equipment, regular maintenance, adequate planning, sufficient staff resources, and appropriate physical environments will support every project to reduce measurement errors, human subject down time, and equipment-related delays during all data collection sessions. Measurements will only be taken when they directly relate to the advancement of the PPE performance or protection for the relevant worker population as per each study's individualized aims. Lastly, all human subjects will be informed and voluntarily consent to the specific study procedures and associated time commitment prior to the initiation of any study procedures.

Additionally, human subjects may be asked to answer questionnaires related to their demographic background, their health, and occupation in an effort to ensure participant safety during testing as well as characterize the human subject information relative to the collected research variables. Again, to reduce the human subject burden as per the Government Paperwork Elimination Act, these types of questionnaires will be distributed electronically whenever possible. This approach ensures data quality but decreases respondent burden with built-in skip logic. Most often electronic platforms such as CDC's Research Electronic Data Capture (REDCap), an approved IT platform, will be used.

Though electronic technologies will be used by many of the individual projects in this data collection, the nature of some proposed activities requires direct interaction between respondents and project staff, especially in the case of in-depth focus groups and psychological observation and monitoring.

4. Efforts to Identify Duplication and Use of Similar Information

NPPTL is the national leader in conducting respiratory protection and personal protective clothing (PPC) research to examine exposures to many common occupational hazards. The Laboratory collaborates with other federal agencies, academic institutions, standards development organizations, and contracting mechanisms to advance this mission. NIOSH is also

the lead agency on objectives within the National Strategy for a Resilient Public Health Supply Chain that aim to coordinate PPE activities across agencies to: 1) launch a new public health supplies innovation center and 2) launch a new product standardization task force. Lastly, NPPTL have representatives on all major standards committees allowing us to liaison with any other federal partners participating in private sector initiatives related to the project proposed in this generic submission.

5. Impact on Small Businesses or Other Small Entities

The data collection effect reflected in this request is being done on an individual level where individuals volunteer for participation in studies in their own free time. As such, the data collection itself will in no way negatively impact small businesses or other small entities with additional paperwork or task burdens. With that said, the outcomes of the research (advancement of respirator and PPC standards) will support the availability of up-to-date PPE information and designs that reflect evolving worker needs. This will in turn decrease the burden on small employers and workers to decide how, when, why, and form whom PPE should be used to maintain adequate protection. If in the unlikely case that an individual study involves information or assessments directly related to small businesses or other small entities, the methods used to minimize burden will be explained in each study submitted under this generic.

6. Consequences of Collecting the Information Less Frequently

The information collection described in this package will be completed on a reoccurring basis across the lifespan of this generic. The timeline for data collection is largely driven by regulatory agendas, timeframes established by standards development organizations, or by urgent needs such as an infectious disease outbreak or pandemic. This data collection request and associated timeline allows for collection of information in a timely and efficient way without significant lag from need identification to solution generation or intervention. If this research were not conducted at all or in this manner, the contemporary needs and challenges of workers who wear PPE may not be able to be considered efficiently enough to have large scale impact on the evolving PPE standards or manufacturing system. Thus, the workers may not be supported or protected adequately. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

The Federal Register notice was published for this collection on July 18, 2025, Vol. 90, No. 136, pg. 33959 - 33961. (See Attachment B) One comment was received but it was non-substantive and CDC/NIOSH wasn’t able to provide a response since the commenter didn’t provide contact information.

No other public contacts and opportunities for public comments were received.

Representatives from CDC NIOSH were engaged to develop this request. The names and representatives are available upon request.

9. Explanation of Any Payment or Gift to Respondents

Human subjects who participate in the research activities outlined in this generic will be compensated for their time. Incentives will not exceed $40 per hour for participation in data collection unless compelling evidence is provided that recruitment is very difficult for a particular study or subgroup. These incentives will be provided directly to the subject.

Tokens of appreciation may be offered in cash or kind for these activities for several reasons:

- Eligibility criteria for human subject research studies are usually very specific. Some of these criteria are determined by the subject matter of the study (e.g., questions or interventions may be relevant only to people with certain health conditions). The more specific the subject matter, the more difficult it is to recruit eligible subjects. In this case compensation may be needed to incentivize participation and aid in recruitment.
- Respondents are usually asked to travel to an interview or laboratory site, which involves transportation and uses their valuable time. While the study data collections will all be done on a voluntary basis and at a time that is convenient for the subject, compensation for their time spend in the study sessions will be offered to offset their time spent in the study.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Depending on the specifics of the individual investigation (i.e., data collection project), the Privacy Act may or may not apply to an information collection. The appropriate CDC NIOSH contacts are consulted for an official Privacy Act determination for each induvial investigation. Although personally identifiable information (PII) may be collected, in some instances NIOSH will not receive any identifiable information from any of the individual projects. In such cases, when the individual data collection activities do require respondents to provide identifying or potentially identifying information to local project staff and/or answer sensitive questions, the information will be removed from any data sent to NIOSH, and NIOSH will, at no time, have access to any local data that contains identifiers. Local project staff will verify that any individually identifiable information that has been collected during the course of their activities has been removed from information transmitted to or shared with NIOSH.

If NIOSH or its representative is receiving and/or storing personal identifiable information as a part of a specific project, then the Privacy Act may apply and the specific actions required to ensure the security of that information will be discussed in the documentation for each project submission.

Certificates of confidentiality may be sought for individual data collection activities that involve sensitive and potentially identifiable information at the local project level. Also, depending on the specifics of the project, the assurance of confidentiality afforded in accordance with Section 308(d) of the Public Health Service Act (42USC242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347) may apply.

As methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each project as they are developed. Projects will acquire IRB approval when appropriate and submit documentation. Participation in all research activities is strictly voluntary. Respondents will be provided with an informed consent form prior to the start of information collection and will be allowed to ask questions about the project before

deciding whether to participate or not. These forms will be included in each individual collection request. The consent form describes the purpose of the study, specifies specific procedures that will be conducted, and describes protections for the respondent's privacy and confidentiality.

On occasion, collecting information about sensitive topics requires that we do not collect personal identifiers at any point. Collection of these identifiers may place the respondent at risk of potential harm resulting from breach of confidentiality. In these cases, a waiver of documentation of informed consent is requested (i.e., no respondent signatures on a consent form), but the same consent and confidentiality protection information is still imparted to the respondent.

Persons participating in all projects conducted or sponsored by NIOSH will be informed that their data will be maintained in a secure manner, and that the data will only be used for purposes stated in the consent form. Although the identities of respondents may be known to local project personnel who conduct interviews and interact with respondents, data collected regarding such sensitive topics will not be stored or accessed in a Privacy Act system of records, and the respondents' identifying information will not be submitted to CDC. Only authorized project staff will be allowed to have access to study information (whether identifiable or not) and all information will be kept in a locked cabinet and/or locked office with limited access.

Information might be collected electronically or on paper (depending on the individual information collection request). Electronic means include handheld devices, computer-assisted self-interview (CASI), audio computer-assisted self-interview (ACASI), computer-assisted telephone interview (CATI), web-based surveys, or other point of service collection devices. Paper copies are the common mode for Focus group interviews.

Electronic data collection and data management systems used for these activities will comply with the current encryption security standards from National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). Each individual request under this generic clearance will provide adequate descriptions of information systems that will be used in their study.

If NIOSH, or its representative, receives and/or stores personal identifiable information, then the Privacy Act may or may not apply. Each individual collection will be evaluated separately. Generally, all individually identifiable information collected by local partners would be unlinked or stripped from the data base that is submitted to CDC. Web-based methods for survey or intervention delivery may also be evaluated under this generic approval and may involve the hosting of a website in order to conduct the evaluation. There will be no websites or internet content directed at children under the age of 13. Individual collection requests submitted under this generic approval will describe any web-based material involved.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB requirements are investigation specific. Some investigations require IRB approval while others fall within the IRB exemption criteria (45 CFR Part 46.104) or are considered a non-research, public health surveillance activity (45 CFR Part 46.102(l)(2). For individual investigations, the appropriate CDC NIOSH contacts are consulted for an official research determination.

Each individual project ICR will address human subject participation and IRB approval. Because methods and materials may differ between individual projects, appropriate human subjects

review procedures will be conducted for each project as they are developed. Projects that need IRB approval will be submitted with a copy of the approval document. If the study has been determined to be exempt from IRB, a copy of the exemption determination will be attached. If the appropriate CDC official has determined that the data/ information collection is not research involving human subjects, the information collection submitted under this generic clearance will state that IRB approval is not required.

Sensitive Questions

At times, the information collected related to human subject medical history may involve sexual attitudes and practices, use of illegal substances or other matters that are commonly considered private. Race and ethnicity data, as well as diagnoses of medical conditions that may affect employability or insurability may also be viewed as sensitive or even threatening by a portion of respondents. The reasons for collection of sensitive information and their application for the improvement of CDC's prevention efforts for the specific study sample will be addressed in the specific requests. The procedures used to obtain consent and the content of the consent form will also be explained and justified.

Sensitive personally identifying information (PII) such as social security numbers may be collected during the individual project data collections as per the individual project's proposed methods. These methods will be outlined clearly in each individual project submission associated with this generic. See section 10 Protection of the Privacy and Confidentiality of Information Provided by Respondents for more details about how this data will be handled.

12. Estimates of Annualized Burden Hours and Costs

We estimate that up to 1,750 individuals could be burdened per year with an estimated annualized burden of 15,591 hours over a three-year period (total three-year burden = 46,773 hours). We anticipate approximately 10 information collections per year which may include examination of human subject physical and psychological responses to wearing PPE or measuring the fit of PPE on the subjects' bodies. Other than the participants' time, there is no cost for participants to respond.

Exhibit A.12.A - Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Members of the general public[1]	Informed Consent	970	1	30/60	485
	Health Screening Questionnaire: standardized form w/ decision logic allowing some questions to be omitted	970	6	1	5,820

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	Demographics Questionnaire: standardized form w/ decision logic allowing some questions to be omitted, W-9 Tax Form, etc.	970	1	30/60	485
	Job-related Data: occupational Tasks, postures used, duration of exposure, etc.	970	1	15/60	243
	Physiological Measurements: chest-worn heart rate monitor strap, COSMED Kb5, SQ2020–1F8 temperature logger, TOSCA 500 pulse oximeter, koken breathing waveform recording mask, etc.	200	6	1.5	1,800
	Biological Measurements: cortisol (stress) levels, pregnancy tests, hydration status, lipids, inflammatory markers, heat shock proteins, etc.	100	6	15/60	150
	Anthropometric Measurements: calipers/digital measuring of facial and body dimensions	750	1	15/60	188
	Respirator Fit Measurements: filter cassettes with air pumps, fit-testing equipment, QLFT/sodium saccharin solution etc.	225	100	15/60	5,625
	Self-Perception Data: level of exertion, perceived comfort level, heat sensation, fatigue, etc.	500	6	15/60	750
	Biomechanics Measurements: force plate, stopwatch, accelerometers, etc.	30	3	30/60	45

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Total					15,591
[1]Members of the general public may include anyone representative of the larger working population within the United States including adults and children between the ages of 8 and 65 years.					

A.12.B Estimated Annualized Costs

Data collections by CDC/NIOSH are generally funded through internal or external research funding and these will be noted in the specific collection requests. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Department of Labor, Bureau of Labor Statistics, May,2019 (http://www.bls.gov/oes/current/oes_nat.htm.) data were used to estimate the hourly wage rate for the general public for the purpose of this generic request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of $25.00 per hour was used as an estimate of average hourly wage across the country.

Exhibit A.12.B - Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Data collection	15,591	$25.00	$389,775

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

NIOSH does not anticipate providing start up or other related costs to private entities.

14. Annualized Costs to the Government

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one NIOSH project officer (GS-12, 13, 14, or 15 levels) who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and dissemination of the results. The NIOSH project officer will provide onsite technical assistance during the data collection. In most cases, a NIOSH data manager or technical assistant (typically equivalent to GS-9, 11 or 12) time will also be required. An estimated average cost per individual activity is listed below, but detailed costs will be submitted with each individual collection request. While many of the proposed data collection efforts will be completed at on-site laboratories thus requiring no travel, a mobile laboratory may be used to measure anthropometry in off-site locations. Thus, investigator travel costs have been included in

the annualized cost estimates to account for associated travel with the mobile laboratory data collections.

Exhibit A.14.A - Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	NIOSH Project Officer (GS-13/14, 0.5 FTE)	$40,641
	NIOSH data manager or technical assistant (GS-9/11, 0.5 FTE)	$13,450
	CDC NIOSH IT Security Compliance	$100,000
	NIOSH Travel (10 trips)	$20,000
	Subtotal, Direct costs	$174,091
Cooperative Agreement or Contract	Data collection equipment, participant compensation, and contractual agreements.	$600,000
	TOTAL COST TO THE GOVERNMENT	$774,091

15. Explanation for Program Changes or Adjustments

This is an extension to a previously approved data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases of individual studies where subjects may be asked to attend several separate data collection sessions. No single data collection activity is expected to take longer than 3 years to complete from inception of information collection to the first report of findings. Proposed timelines will be submitted for each individual data collection activity.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

Centers for Disease Control and Prevention (2020). Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.

Thompson, D. (2018). Health Care Just Became the U.S.'s Largest Employer. The Atlantic.

Zimmerling, A. and X. Chen (2021). "Innovation and possible long-term impact driven by COVID-19: Manufacturing, personal protective equipment and digital technologies." Technology in Society 65: 101541.