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Innovation Opportunity and Challenge of Standardization in Response to COVID-19 Pandemic and the Socio-Economic Impact: A Case Study in Indonesia

Bambang Prasetya ^{1,*}, Daryono Restu Wahono ¹, Yopi ¹ and Candraditya Prasetya ²

¹ Research Center and HRD, The National Standardization Agency of Indonesia (BSN), Building 430-PUSPIPTEK, South Tangerang 15314, Banten, Indonesia; daryono@bsn.go.id (D.R.W.); yopi@bsn.go.id (Y.)

² Balikpapan College of Economics (STIEPAN), Jln. Major Pol. Zainal Arifin No. 166, Balikpapan 76114, East Kalimantan, Indonesia; candraalbayan@gmail.com

* Correspondence: bambang.prasetya@bsn.go.id or bambang.prasetya@gmail.com

Abstract: The COVID-19 health crisis has disrupted various aspects of life: social, economic and work models in organizations, such as government organizations, private organizations, and businesses. To overcome this situation, a number of appropriate activities are needed to directly overcome the various problems in public health, both preventive and curative. In line with that, activities have also been taken to recover from the impact caused by the COVID-19 pandemic. This paper describes the role of standardization in response to the COVID-19 pandemic, including the business process of formulation and development of standards, conformity assessment procedures, and the role of metrology in providing calibration services. Moreover, the role of the implementation of standards to overcome the socio-economic impact and innovation is also discussed. The method used in this report is based on observation and secondary data. The observation was carried out in Jakarta and surrounding cities, which are representatives of the islands of Java and Bali. A short overview of the literature regarding Coronavirus, the principal role of standardization, regulation, innovation, and its social-economic impact were obtained from secondary data from various sources.

Keywords: COVID-19 pandemic; standardization; conformity assessment; metrology; socio-economic impact; innovation; small medium enterprises (SME) role model



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1. Introduction

The outbreak of COVID-19, which started in Wuhan, China, has become a global problem around the world. On March 11, 2020, WHO declared COVID-19 a global pandemic and it has since threatened public health and life-related systems. It had become a global health and humanitarian crisis. The COVID-19 pandemic affected society at the macro, meso, and micro levels [1,2]. It created significant pressure on the health system needs, especially for efforts to prevent transmission and reduce deaths. Based on the current pattern of the spread of COVID-19, the identification of vulnerabilities and regions of relatively severe impact are dense areas, areas with relatively large informal employment structures, and areas with prominent economic structures in tourism, manufacturing, trade, and transportation sectors. There has been a great pressure on the health care system, especially on prevention, basic and referral health services, health insurance (health security), and health human resources, especially for detection and surveillance, laboratory testing, provision of protective equipment, and medical equipment. The handling of the pandemic and the prevention and curative efforts of COVID-19 have hampered the achievement of key health development targets, such as maternal and child health, community nutrition, and disease control [3]. Muhyiddin et al. [4] reported a review of Indonesia's pandemic and recovery acceleration policies. The most important aspect is that vaccination programs that are already running and have been scheduled must be implemented consequently. The

combination of the vaccination program and the LSSR (large-scale social restriction) policy will achieve herd immunity in a relatively short time.

From an economic perspective, COVID-19 has put great pressure on almost all aspects of life. Similarly to the world economy, the Indonesian economy has also been negatively affected by COVID-19. The negative impact was felt by almost all economic actors. People's income and consumption fell sharply as a result of restrictions on people's movement. Investment is estimated to be affected as a result of the disruption to companies' balance sheets due to the decline in revenues and the cessation of several production activities. International trade was affected by the low level of trading activity at the global level, which also led to a decline in commodity prices. The health of the financial sector is also expected to decline. These various disturbances have an impact on macro and development goals. The instability of the world economy has resulted in a decline in the exchange rate and pressure on the domestic economy. The decline in demand due to the decline in people's purchasing power also affected domestic production [5–7].

The COVID-19 pandemic is affecting the economy from the supply side and demand side. On the supply side, companies reduce the supply of raw materials and labor, resulting in unhealthy and constrained supply chains. From the demand side, there has been a lack of demand and decreased consumer confidence in the products. SMEs have a significant impact on COVID-19. SMEs are very vulnerable to being affected by business disruptions, because of their frequency of use being directly related to tourism and transportation, as well as culinary industries that require fast suppliers, all of which have been significantly affected by COVID-19 [8,9]. For public and private organizations, a crisis such as a pandemic is a strategic challenge, and the associated disruption of demand and capacity, increased uncertainty, and financial instability forces a reassessment and restructuring of business operations [10,11]. Managerial attention is required to assess how the disruption affects customers and employees [12,13].

To face a huge impact both from the health and economic perspective, the government needs to make policy responses quickly and correctly. Learning from the steps taken by various countries, the policy response to mitigate the impact of COVID-19 can be divided into four stages. The first is to strengthen the health sector, the second is to protect the public and the business world, the third is to reduce pressure on the financial sector, and the fourth is the recovery program, i.e., economic resilience and recovery of people's lives after the COVID-19 pandemic. Related to this program and its activities, standardization as part of national management plays a specific role, not only in handling the pandemic in relation to health problems and supporting facilities but also for innovating activities for responding to the need for a new business model and supply change, which is very important for strengthening national competitiveness [14]. This paper will report the challenge and role of standardization in response to the COVID-19 pandemic through changes to the business process of formulation and development standards, conformity assessment procedures, and the role of metrology in providing calibration services, as well as the role of the implementation of standards and innovations to overcome the socio-economic impacts. The method used in this report is based on observation in Jakarta and surrounding cities and secondary data from various sources.

2. Literature Review on Pandemics and the Role of Standardization

The Coronavirus pandemic by the World Health Organization (WHO) has been named Coronavirus-disease 2019 (COVID-19). This virus according to ICTV (the International Committee on Taxonomy of Viruses) is categorized as "Severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2)". This virus belongs to the order Nidovirales, family Coronaviridae, subfamily Orthocoronavirinae, which consists of four types, namely Alphacoronavirus, Betacoronavirus, Gammacoronavirus and Deltacoronavirus [15]. The severe acute respiratory syndrome has caused morbidity and mortality at an unprecedented scale globally. Scientific and clinical evidence is evolving on the subacute and long-term effects of COVID-19, which can affect multiple organ systems. Early reports suggest residual effects

of SARS-CoV-2 infection, such as fatigue, dyspnea, chest pain, cognitive disturbances, arthralgia, and decline in quality of life. Cellular damage, a robust innate immune response with inflammatory cytokine production, and a pro-coagulant state induced by SARS-CoV-2 infection may contribute to these sequelae. COVID-19 is now recognized as a multi-organ disease with a broad spectrum of manifestations [16–19].

The very fast speed of the spread of the COVID-19 pandemic gives an indication that the characteristics and dynamics of the Coronavirus are different from previous viruses. It depends on many factors, such as physical condition (humidity, temperature, and climate) and the biological ecosystem. Indonesia is a humid tropical country that can be a good habitat for various microorganisms, including viruses and their variants. The combination of geographical conditions, humidity, and air temperature can create opportunities for variations in micro-climate. The existence of periodization and a relatively high intensity of sunlight can cause virus mutations, so that the opportunity for the emergence of various mutants or new variants is very large [20]. In the history of pandemics affected by the virus, the fact shows that a mutation of the virus leads to different health impacts. Table 1 gives an illustration of virus types and the number of deaths in different periods from 1918–present.

Table 1. Virus type and the number of deaths in different periods.

Periods	Name	Type	Death	Reference
1918–1919	Spanish Flu	H1N1 Virus	More than 50 M	[21]
1957–1958	Asian Flu	H2N2 Virus	1.15 M	[22]
1968–1970	Hong Kong Flu	H3N2	1 M	[23–25]
1981–present	HIV/AIDS	Virus HIV	32 M (estimated March 2020)	[26]
2019–present	COVID-19	Coronavirus	4.8 M per 5 Oct 2021	[27]

Although each viral pandemic event has different characteristics, such as the 1918 flu pandemic and the 2003 SARS bird flu pandemic, in general, the control is generally classified into several actions, each of which has a different level of risk. As illustrated in Table 2, the pandemic control hierarchy can be divided into five levels [28]. Some countries perform this in a different manner. At the first level, the action taken is the use of personal protective equipment (PPE). At this level, the use of masks, washing hands, and maintaining distance are important acts and this is the initial stage of prevention. The next level is controlled with administrative control. At this stage in Indonesia, for example, the implementation of restrictions on movement and activities of people such as LSSR (large-scale social restrictions), setting office hours, work from home (WFH), and work from office (WFO). Third, at the engineering controls level, control is carried out by providing infrastructure such as facilities for isolation for infected people and provision of treatment facilities. At the fourth level, substitution is carried out, namely the act of removing dangerous pathogens (hazard) and the fifth level is the elimination action, which aims to eliminate the pathogen. For actions levels four and five, this requires a more comprehensive study and for COVID-19 there are not many publications that report this action.

Table 2. The control hierarchy for pathogen and chemical hazard.

No	Hierarchy Control	Goals	Effectiveness
1	PPE (personal protective equipment)	Protect the worker: people with PPE	Less effective
2	Administrative control	Change the people at work	
3	Engineering control	Isolate people from the hazard	
4	Substitution	Replace the hazard	Most effective
5	Elimination	Physically remove the hazard	

Ref: adapted from AVMA [28].

In evolving prevention action, the utilization of vaccines plays an important role [29]. A considerable number of SARS-CoV-2 preventive vaccine projects were initiated shortly

after the reporting of this virus, including technologies that generate an inactivated virus vaccine, viral protein subunits vaccine, messenger RNA (mRNA) vaccine, DNA plasmid vaccine, and recombinant human adenovirus type 5 (rAd5) or simian adenovirus type 26 (rAd26) expressing SARS-CoV-2 spike protein, a non-viral replicating vector expressing SARS-CoV-2 protein vaccine, and also replicating viral vector expressing SARS-CoV-2 protein vaccine. So far, there have been at least 30 announced vaccine projects globally and vaccines derived from mRNA, expression using recombinant adenoviral vectors, and inactivated viruses have already gained regulatory approvals in certain countries [30,31]. Wang et al. [32] gave a systematic review of therapeutic development and application including the following areas: epidemiology, virology, and pathogenesis, diagnosis, use of artificial intelligence in assisting diagnosis, treatment, and vaccine development. With the necessary efforts to pursue widespread vaccination, policymakers face a difficult balancing act as they seek to nurture the recovery through efficiently allocated fiscal support while safeguarding price stability and fiscal sustainability. Policymakers can also help entrench a lasting recovery by undertaking growth-enhancing reforms and steering their economies onto a green, resilient, and inclusive development path. Prominent among the necessary policies are efforts to lower trade costs so that trade can once again become a robust engine of growth [33]. Farzanegan et al. [34] give a critical review of globalization and the outbreak of COVID-19.

The government took action to recover the pandemic with three groups, namely enabling the environment, improving productivity, and enacting the job creation law. The first activity focused on improving the business climate, increasing competitiveness, and economic resilience through improvements in the food, energy, and infrastructure sectors. To increase productivity, there is a focus on improving business sectors that have the potential to support the performance of the national economy, including the revitalization of manufacturing, tourism development, as well as empowerment and formalization of micro, small and medium enterprises. As an effort to improve the regulation, the implementation and enforcement of job creation law become one of the vehicles for harmonizing various laws and existing regulations. Standardization and conformity assessment play an important role in this harmonization. Furthermore, one of the most important aspects of harmonization of regulations is the clustering of types of businesses providing goods and services based on the level of risk. The greater the risk, the more stringent regulations are carried out, for example, inspection, certification by third parties, and distribution permits, etc., while for low-risk products, only self-declaration and registration are required [3,35].

According to UNIDO [36], the role of standardization is very important in dealing with the COVID-19 pandemic. As shown in Table 3, standardization including part of the quality infrastructure helps reduce the negative impact of the pandemic crisis and ensures the provision of essential services. This includes quality infrastructure, where standardization and conformity assessments function to ensure the need for relevant standards, accurate measurements (metrology), and guaranteed reliable test results through accreditation. The standards ensure that the technology used in patient care is safe and all users are protected.

Sustainable development goals (SDGs) are often used as a reference and as a holistic indicator. The SDGs are a shared global agenda that all countries have committed to implementing. According to UNIDO, the existence of this pandemic has a very significant impact related to SDG 2 (famine alleviation); SDG 3 (healthy lives and well-being for all); SDG 8 (economic growth and employment); SDG 9 (infrastructure development, industry, and innovation); SDG 12 (responsible consumption and production) and SDG 17 (partnerships to achieve all the goals of the SDGs). In detail, the impact of the pandemic and the role of standardization is depicted in Table 3 [36,37].

According to the ITC (International Trade Center) [38] in its report “Standards support for small businesses during COVID-19” describes the role of standards in helping the SMEs, for fostering competitive, resilient, and sustainable businesses. ISO management standards that are appropriate for this goal are (1). ISO 22313:2020 Security and resilience—Business continuity management systems—Guidance on the use of ISO 2230;

(2). ISO/TS 22318:2015 Societal security—Business continuity management systems—Guidelines for supply chain continuity; (3). ISO 22320:2018 Security and resilience—security and resilience—Organizational resilience—Principles and attributes; ISO 31000:2018 Risk management—Guidelines; (6). ISO 56002:2019 Innovation management—Innovation management system—Guidance; (7). ISO 45001:2018 Occupational health and safety management systems—Requirements with guidance for use; (8). ISO 22000: 2018 Food Safety Management System; and (9). ISO 9001:2015 Quality management systems—Requirements [39]. Another ITC report “The SME Competitiveness Outlook 2021” identifies key areas where small businesses with limited resources can invest to seize opportunities of the green transition, and how business-support organizations, governments, lead firms in value chains, and international organizations can empower small firms to be competitive, resilient and sustainable [40].

Table 3. The role of standardization in the fight against COVID-19 pandemic [36].

Policy	Standards	Accreditation	Metrology	Conformity Assessment	Enterprises
Quality Policy Laboratory Policy	Medical equipment/ protective gear (medical), laboratory standards, business continuity, emergency management, quality control techniques, health, safety and hygiene, sanitation and waste management	Attestation of technical competence International/ mutual recognition	Accurate measurement for reliable testing, quality and accuracy of laboratory tests	Health care facilities and testing laboratories, quality control of medical supplies, medical testing for COVID-19, development of new medication/vaccines, market surveillance and inspection	Shift to produce medical equipment/ protective gear, business continuity, enhanced sanity protocols, avoid disruption of essential inputs to global value chains

3. Methods

This case report is carried out based on the research design as shown in Figure 1, which consists of the scope of work, data collection, data validation, data analysis, narrative description and discussion, conclusion, and suggestion. Data collection has obtained the observation, interview, and secondary data from regulation release, official report, webinars, journal, and other publications. Table 4 describes the data collection, subject of observation and data validation. Part of the data was validated by cross-references, consultation with key people, experts, and role models. The government’s strategies and policies in dealing with the pandemic, including economic recovery policies, are discussed. The role of standardization and conformity assessment in dealing with COVID-19 is based on global trends and several recommendations from UNIDO [36]. The implementation of standard management systems, for recovery and the continuing development in the middle term period, is also analyzed. Some cases of practical businesses and implementation of regulation and standardization were also directly observed, through interviews, and consultations with some experts, regulators, business actors, and conformity assessment institutions. Furthermore, efforts to strengthen competitiveness and innovations are discussed based on data from the testimonies of several role models.

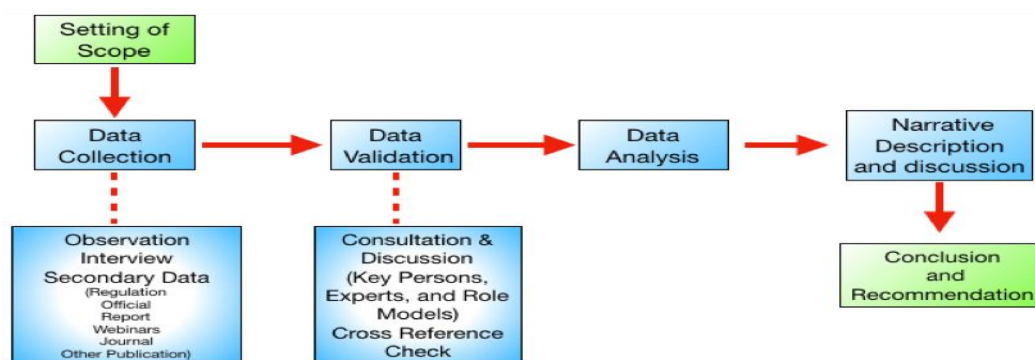


Figure 1. Research design.

Table 4. Data collection, subject-related topics, and data validation.

No	Data Collection	Subject, Related Topics (Number)	Data Validation	Location
1	Observation Webinar Talk show FDG Press release	Standard development (7) Accreditation and conformity assessment (9) Metrology (3) Innovation (15) Regulation (12)	Direct asking of questions	Jakarta Bogor Tangerang
2	Interviews with role model from selected SME	SMEs (21) with following products (medical equipment and device, cloth, food, batik machinery, sport equipment)	Government officer from BSN and the Ministry (industry, trade, agriculture, maritime and fisheries)	Tangerang Bogor Makassar Palembang East Java DIY
3	Secondary data (journal, official report, other publication)	COVID-19 pandemic, standardization, accreditation, metrology, conformity assessment, economic and business, regulatory and policies, innovation	Through comparative analysis of article in journals and other publications	-

4. Results and Discussion

4.1. Role and Challenges of Standardization, Conformity Assessment, and Metrology

4.1.1. Role and Challenges of Standard Formulation and Development

Standardization in dealing with the pandemics plays an important role, especially to ensure safety, quality and traceability. Product standards must especially include medical equipment such as respiratory protection devices, and body protective equipment, such as medical gloves, medical face masks, personal eye protection, and others. Because the existing standard is not fully available for supporting activities during pandemics, it is still necessary to develop new standards obtained by adopting international standards or by modifying international standards processes that are adapted to Indonesian conditions. In developing standards, several things should be considered, including the recognition and acceptance of standards of systems between countries. The acceptance of equality of standards among trading partners (business to business) is considered important to mobilize the demand for medical equipment, which needs a relatively short time.

In general, standards are formulated based on needs assessment and carried out based on the consensus to agree with draft standards among stakeholders and also to refer to scientific evidence. In order to obtain a broad acceptance among stakeholders, the process of the formulation of national standards in accordance with the WTO code of good practice

must meet a number of basic principles; ensure transparency, openness, impartiality and consensus, effectiveness and relevance, and coherence, and to address the concerns of development opportunities [41]. To apply these norms, the development of the national standard of Indonesia (SNI) is carried out through the following formulation stages: (1.) planning of national program for standard development, based on needs analysis and prioritizing, (2.) drafting the SNI draft standard, (3.) depth analysis and assessment through technical meetings, (4.) consensus meetings for the public poll, (5.) public pool and discussion of the results of the opinion poll, (6.) final determination and publication of SNI. The total time required for this process is divided into four types; type I normal track (13 months), type II fast track (9–12 months), type III urgent needs (4 months), and type IV amendment (5 months) [42].

The increasing need for standards as a result of increasing activities in dealing with the COVID-19 pandemic and the existence of a health protocol system during the pandemic has encouraged accelerating services. In terms of standard development, the process of accelerating standard formulation has been carried out, teleconferencing in the formulation of standards (virtual), and developing a program for formulating standards on an urgent track which needs a much shorter time than around 4 months. Mostly the adoption of international standards used this track. There are some international standards that are very important for supporting the activities during the pandemic, as listed in Table 5.

Currently, the availability of the national Indonesian Standard (SNI) related to medical devices and sanitation is as follows: protective clothing 31 standards, hand sanitizer 14 standards, medical gloves 13 standards, ventilator 13 standards, eye protection 6 standards, respiratory protection 4 standards, medical mask 4 standards, and protective gloves 3 standards. In the year 2020 more than 13,000 national standards are available [42].

To support the laboratory management system, medical laboratory management standards are available, namely ISO 15189, ISO 22367, and ISO 14971. These standards are important for evaluating the safety and valid diagnostic test results for the SARS-CoV-2 Coronavirus. To support laboratory testing activities, currently, more than 1700 laboratories have implemented SNI ISO 17025. Standardization of testing laboratories is needed to ensure that product testing for medical equipment is carried out correctly and provides reliable results so that it can respond to the COVID-19 pandemic effectively and on target. For certain laboratories that work with pathogenic biological objects, the application of the ISO 35001:2019 laboratory biorisk management system is very important, especially to ensure the safety of laboratory personnel working with COVID-19 [43]. When handling a pandemic, preventive measures in an industry or organization can be assisted by implementing an occupational health and safety management system, such as ISO 45001. The application of this standard is very important to maintain occupational health and safety, reduce risks in the workplace, and create safer working conditions against transmission of COVID-19 [39].

To support the food processing industry, the implementation of a food safety management system based on SNI ISO 22000 and HACCP (hazard analysis and critical control points) is the key to ensuring food safety. No less important in handling the pandemic is the application of the ISO 14000 environmental management system standard. This standard will be used as a vehicle for better management of the waste generated as a result of the increased use of disposable protective equipment, such as protective clothing, disposable gloves, and medical masks.

During the pandemic, it was known that many industries were affected as a result of the decline in economic activity. The implementation of risk management standards is needed to strengthen companies' resilience. ISO 31000 has been carried out for a long time in many organizations and companies and has been proven to be able to overcome the crisis. Likewise, during the pandemic and recovery period, the application of this standard is vital as a guide for the design, implementation, and maintenance of risk management. With the combination of the application of other management standards such as ISO 9001, which is quite popular in its application in Indonesia, the resilience of the company or

organization improves. With the implementation of this standard, the company is better prepared to face the negative impact of the crisis. Strengthening company performance in times of crisis can also use standards for security, resilience, and business continuity management (ISO 22301, ISO 22395) and emergency management (ISO 22320, ISO 22316). This standard in several countries has proven to play an important role in dealing with the COVID-19 pandemic. Further implementation of these standards is not only important in the short term, but also in the medium and long term.

Table 5. ISO standard related to medical devices [39].

No	ISO Standard	Thematic Subject of Standard
1	ISO/PAS 45005:2020	Occupational health and safety management—General guidelines for safe working during the COVID-19 pandemic
2	ISO 13688:2013/AMD 1:2021	Protective clothing—General requirements—AMENDMENT 1
3	ISO 80601-2-12:2020	Medical electrical equipment—Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
4	ISO 20395:2019	Biotechnology—Requirements for evaluating the performance of quantification methods for nucleic acid target sequences—qPCR and dPCR
5	ISO 80601-2-74:2017	Medical electrical equipment—Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
6	ISO 80601-2-79:2018	Medical electrical equipment—Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
7	ISO 80601-2-70:2020	Medical electrical equipment—Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
8	ISO 80601-2-84:2020	Medical electrical equipment—Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment
9	ISO 10993-1:2018	Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process
10	ISO/TS 16976-8:2013	Respiratory protective devices—Human factors—Part 8: Ergonomic factors
11	ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 1: Evaluation and testing within a risk management process
12	ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 2: Tests for emissions of particulate matter
13	ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 3: Tests for emissions of volatile organic compounds (VOCs)
14	ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 4: Tests for leachables in condensate
15	ISO 80601-2-80:2018	Medical electrical equipment—Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
16	ISO 19223:2019	Lung ventilators and related equipment—Vocabulary and semantics

4.1.2. Role and Change of Business Process of Accreditation and Conformity Assessment

One of the important pillars in the national quality assurance system is accreditation. Accreditation activities are very important in supporting the application of standards so that the conformity of products, services, processes, and management can run in accordance with the requirements and standards applied. The National Accreditation Committee (KAN) carries out the function of providing formal acknowledgment and approval of the integrity and competence of the Conformity Assessment Body (CAB) to carry out conformity assessment activities. The CABs include test laboratories, certification bodies, inspections, and calibrations.

Currently, most of the accreditation processes are carried out by test and calibration laboratories. It is intended that the results of laboratory testing are valid and reliable and meet the required standards. Laboratory accreditation also ensures that human resources working in laboratories are competent. Likewise, the professional and competent management of the laboratory is able to provide various testing services and several other needs related to handling the pandemic.

During this pandemic, many innovations have been produced from within the country. Because they are generally new products, accreditation of product certification bodies and test laboratories is very necessary to ensure product safety and also to increase public confidence in domestic innovation products.

In relation to the global COVID-19 pandemic, accreditation to CAB by an accreditation agency that is a member of an international accreditation organization is very important, to ensure the compatibility of the use of certificates, whose recognition is needed globally. It is also aimed at facilitating the cross-border mobilization of products and services related to medical devices, testing kits, and items for personal protection. Lack of recognition of testing laboratories, for example, can disrupt the smooth flow of trade.

Internationally recognized certificates from CABs in Indonesia are obtained through KAN recognition by the international accreditation organization ILAC (International Laboratory Accreditation Cooperation), following the MLA (mutual recognition arrangement) scheme, and from the International Accreditation Forum (IAF) through the MRA (multi-lateral recognition arrangement) scheme. The National Accreditation Committee (KAN) continues to make tangible contributions to government programs. Currently, KAN has 13 internationally recognized accreditation schemes.

In response to the COVID-19 pandemic, the accreditation process is faster and has already been performed successfully in more than a year and a half of this pandemic through remote, virtual assessment, applying for digital accreditation, remote assessment, and remote auditing. Following assessments by technical committee meetings are conducted virtually. In general, virtual assessment methodologies can also be improved. To maximize accreditation services, recently, KAN also released a digital service system, the KANIA digital service, by utilizing artificial intelligence (AI), to make it easier for the public to attain the best service. KANIA is embedded in platforms that are popular in the community, such as WhatsApp, Facebook Messenger, Line, and Telegram, which can be accessed 24 h, 7 days a week. This program can make it easier for conformity assessment and fulfills the needs of the customer [43].

Accreditation serves are comprised of CABs from the western part of Indonesia (Sumatra) to the eastern part of Indonesia (Papua). The CABs have involved the testing laboratories, calibration laboratories, inspection agencies, certification bodies for quality management systems, occupational health and safety management systems, laboratory biorisk management systems, information security management systems, education organization management systems, product certification institutes, and proficiency test operators. In 2020, around a total of 2177 CABs have been accredited by KAN, which consists of 312 certification bodies, 114 inspection bodies, 1727 laboratories, and 24 proficiency test providers.

In regard to supporting conformity assessment for CABS dealing with a pandemic, KAN has delivered accreditation services for around 70 laboratories and clinics based on

ISO 15189, 100 testing laboratories based on ISO 17025, 40 calibration laboratories based on ISO 17025, five laboratory external quality assurances (PME) based on ISO/IEC 17043, two inspection agencies based on ISO/IEC 17020, and two medical device management system certification bodies based on ISO/IEC 17021. To support safety for medical laboratories, a new scheme is also implemented, which is a laboratory biorisk management system based on ISO/IEC 35001.

The remote audit is also the best choice during the pandemic for most conformity assessment bodies, which releases certificates of the quality management systems, management systems for education organizations, anti-bribery management systems, information security management systems, and product certification. The remote audit is carried out without visiting the location, either in whole or in part, by utilizing information and digital technology. This certification remote audit mechanism is conducted through communication media such as document sharing according to audit needs, through document links and online meeting applications that are mutually agreed with customers.

All activities of conformity assessment were in line with the recommendation of ISO's Committee on Conformity Assessment (CASCO). This recommendation is based on a global survey conducted among the members of ISO/CASCO Strategic Alliance and Regulatory Group (CASCO/STAR) to collect their experience of coping with the COVID-19 pandemic. The key findings from the survey are focused on maintaining business continuity and replacing on-site activities with remote activities. The remote activities are understood as activities within the process of conformity assessment or accreditation, which do not require the physical presence of the assessing personnel at the site of the object of assessment. Remote activities are mainly used as determination activities but can contribute to all functions of conformity assessment, such as virtual meetings (with internal staff or with external clients and stakeholders), web-based document review, remote auditing, assessing and evaluating by ICT, review and decision making by electronic communication (e.g., by circular emails or web-based voting), and e-learning or webinars [44].

4.1.3. Role and Change of Business Process of Metrology and Calibration

In fulfilling the suitability of the characteristics of a product, a series of physical, mechanical, biological, and chemical properties tests are required according to the desired standard. Metrology provides assurance of reliable measurements as the basis for scientific research, technical development, and production. The national metrology (national standard for units of measure) mandated by Law No. 20 of 2014, must be the highest reference for measurement in Indonesia. The task of this standard is to provide, develop, maintain, and disseminate units' standards.

National metrology is needed to support product testing laboratories to ensure that goods, services, and processes meet product quality, environmental, health, and safety requirements, and meet consumer needs and expectations. The level of conformity with the requirements is largely determined by the level of accuracy of the test equipment that must be traced to the international system of units of measure (BIPM) to increase international recognition and acceptance. Thus, users will be able to take advantage of it to expand access to global markets.

For international recognition of national metrological capabilities, all national standards of measurement units must be traced to the international organization BIPM (International Bureau of Weights and Measures) based in Paris. Indonesia's current position has received BIPM recognition for as many as 135 units of measure; for laboratory services currently providing services, there has been as many as 388 calibration service environments. The number of certificates that have been issued is 1157 per year for more than 500 laboratories [42].

In dealing with COVID-19, metrology is very important because chemical and biological measurements require high accuracy and play an important role during the pandemic, especially for reference material standards (CRM). The ability to accurately measure nucleic acids is crucial for COVID-19 molecular testing, which detects the Coron-

avirus' (SARS-CoV-2) genetic material (RNA) using certain techniques. The Consultative Committee on the Quantity of Material CCQM) Working Group on Nucleic Acid Analysis has launched a fast-tracked inter-laboratory study for SARS-CoV-2 RNA genome measurement [44,45].

The traced test results will become a compatible database for various uses of test results so as to increase user confidence. The potential for falsification of data that sometimes occurs will be avoided. The government in handling pandemic cases urgently needs accurate measuring tools, including day to day tools such as thermometers, sphygmomanometers (blood pressure gauges), oxygen flow meters (respirators), fluid flow meters (drugs), and others. All measurement results must be reliable and reliable.

To enhance the metrological service to the stakeholder, the development of a digital best service called SPARTA will be made to efficiently reach the laboratories from Sumatra to Papua. This system is directly related to the task of disseminating SNSU through calibration services. Likewise, for calibration services, remote calibration and analysis support are also carried out on calibration records from service users. The digital service system not only improves the calibration and proficiency testing services but also implements bureaucratic reform that emphasizes efficient and transparent services. The users can more easily access services and can interact with service officers. The information on types of services and prices will be more accessible, and the registration process and process monitoring by customers will also be easier, so as to provide certainty and satisfaction for customers. In these systems information on measurement and calibration services covers six areas of measurement, namely mass and related quantities, length, acoustics and vibration, temperature, electricity and time, and radiometry and photometry. Meanwhile, the proficiency test service covers the quantities found in the field of chemical metrology measurements [42].

4.2. Challenges of Innovation for Medical Device, Diagnostic, and Therapy

The pandemic prompted extraordinary interest in innovation, including calls to inspire, initiate and coordinate innovations beyond those already designed and implemented. Some of these initiatives were global or national in scope. The innovation is mostly very clear in the development of a new product, service, process, and business model. The acceleration of change on business models and services is affected by the available digital and information technology infrastructure.

The business model in several sectors, such as education, trading, logistics, etc. has developed rapidly. Innovation in the product, in general, consumes more time, because the safety aspect and technical performance requires a serial test to be completed with a standard or another requirement. In Indonesia, the innovation during the pandemic focused in general on the field of medical care.

In order to support efforts to prevent the spread and transmit, and to overcome the increasing outbreak of Coronavirus-disease 2019 (COVID-19) in Indonesia, the government through the Ministry of Research and Technology/National Research and Innovation Agency plays an active role in integrating, aligning, coordinating, and synergizing research and innovation programs to deal with the COVID-19 pandemic quickly. One of the efforts made is to carry out research, development, assessment, and application activities in a relatively quick time. There are five technological innovation programs and groups from the COVID-19 Research and Innovation Consortium Team for the prevention of COVID-19, namely prevention, screening and diagnostics, medical devices and supporters, drugs and therapy, and multicenter clinical trials (Table 6) [46].

Almost all the results of the innovations are from new products, and therefore for their implementation they must fulfill security requirements. For this, the role of standards in supporting product innovation is very important. In addition, the availability of testing laboratories must be available, including the calibration laboratories, to ensure the traceability of measurement equipment. If the standard is not available, then a new standard is developed, either formulated by oneself or by adopting international standards

from ISO, IEC, and other organizations of standards. The trend of the development of technology will evolve due to the high demand for certain products and mostly it is the end-user involved in the setting of technical specifications. Increased end-user involvement, especially in medical devices and supporting policies, are needed for the acceleration of the development of technology and innovation. However, these potential developments need to be discussed alongside the ethical considerations around social exclusion, collection of and access to data, and privacy, as well as issues related to intellectual property [47].

Table 6. The innovation products to the prevention of spread, handling support, screening and medical diagnostic, and therapy for combating pandemic COVID-19 [46].

No	Preventing of Spreading	Handling Support	Screening and Diagnostics	Medicinal and Therapeutic
1	Rapid diagnostic test microchip	RAISA TIARA Robot	Viral Transport Medium	Convalescence Serum
2	Rapid Diagnostic Test RI-GHA	RAISA BCL Robot	VTM (Viral Transport Medium) Plasmid Eijkman	Herbal Flu Imboost
3	Real Time PCR Test Kit BioCov-19	Decontamination Robot	Control for COVID-19 (pECoc-19)	Quinine Pill
4	Autonomous UVC Mobile Robot	Smart Syringe Pump	Robot RAISA	Anti-COVID-19 Serum
5	OST D	Emergency Ventilators	Mobile Laboratory BSL-2	Mesenchymal Stem Cell
6	Herbal Hand Sanitizer	Powered Air Purifying Respirator	Flocked Swab	Convalescence Serum
7	Insert Mask	Ventilator Vent-I	Sequence Protein S SARS CoV 2	Herbal Flu Boost
8	Air Cleaner	Venindo V01	AI based Medical Imaging System	Quinine Pill
9	Portable Air Purifier	Venindo R03	Smart Biosafety Swab Chamber (BCL-UGM)	Anti-COVID-19 Serum
10	Touchless Mobile Handwasher	GLP-HFNC-01 (High Flow Nasal Cannula)	GAMA Swab Sampling Chamber	
11	N95 Mask Sterilization Box	Cov-Watch	Platform Digital (Cared+)	
12	HR COMED	Aero Dental Suction Unit	Radiograph Sinar X-Digital	
13	APD: Lab-Scale Natural Nano Fibers	Smart Telemedicine Robot “Win-MTA”	Swabidarity	
14	PPE Level 3 and 4	Servant Robot	PCR Isothermal Lamp 2	
15	H2 (Health	Robot Representative Doctor (Doper)	Electronic Nose (E-Nose)	
16	Isothermal	Low-Cost Mobile Ventilators	WGS (Whole Genome Sequencing) SARS-CoV-2	

4.3. Challenges of Standardization Regarding the Socio-Economic Impacts

Based on very valuable experiences during the pandemic, to accelerate economic recovery, and to strengthen national competitiveness and independence, the role of standardization needs to be strengthened. Among the most crucial factors is the availability of standards that are able to answer market needs and government policy needs. Standard development can be directed, among others, to support the supply chain in raw materials or supporting components for manufacturing. About 30 percent of Indonesia's non-oil

and gas imports come from China, which is the largest import. The dependence on industrial raw materials, which were not available during the pandemic, has impacted various important industries. Standardization is needed to provide a reference for local suppliers and also to support the ability to compete with imported raw materials. It is recognized that users, especially the manufacturing industry, still need time to adjust to their existing manufacturing processes, for technical and economic feasibility. Another benefit of the effort to be self-sufficient in raw materials is the creation of new supply chains, business fields, and employment opportunities, which, in the end, can strengthen the national industrial structure. This condition will also invite the research and innovation national agency to drive to all research centers, universities and private sectors to contribute to research, development, and technical-economical assessments in various aspects of production, such as processes, manufacturing, testing, and new product development. To support this effort, it is necessary to analyze data related to industrial needs and data on the development of imports of raw materials.

The impact of COVID-19 hit SMEs significantly, which became very vulnerable due to being affected by business disruptions. SMEs' lack of resilience and flexibility in dealing with this pandemic is due to several things, such as low levels of digitization, difficulties in accessing technology, and lack of understanding of survival strategies in business. The recovery of SMEs has also become an important priority because SMEs have a strategic value for creating family income and employment. There are around 64 million SMEs, mostly located in Java. SMEs in Indonesia employed more than 110 million workers. One of the important aspects in fostering the SMEs is advocacy for the implementation of standards. During advocacy activity, the role model of SMEs in implementing standards will be set up in several locations across all provinces in Indonesia (Figure 2). There are around 707 SMEs, as role models have been advocated, including 452 SMEs in the food sector and 255 non-food SMEs that are spread across 28 provinces. A part of this advocacy has been the facilitation of 98 SMEs in obtaining SNI certification, including certification maintenance [8,42].

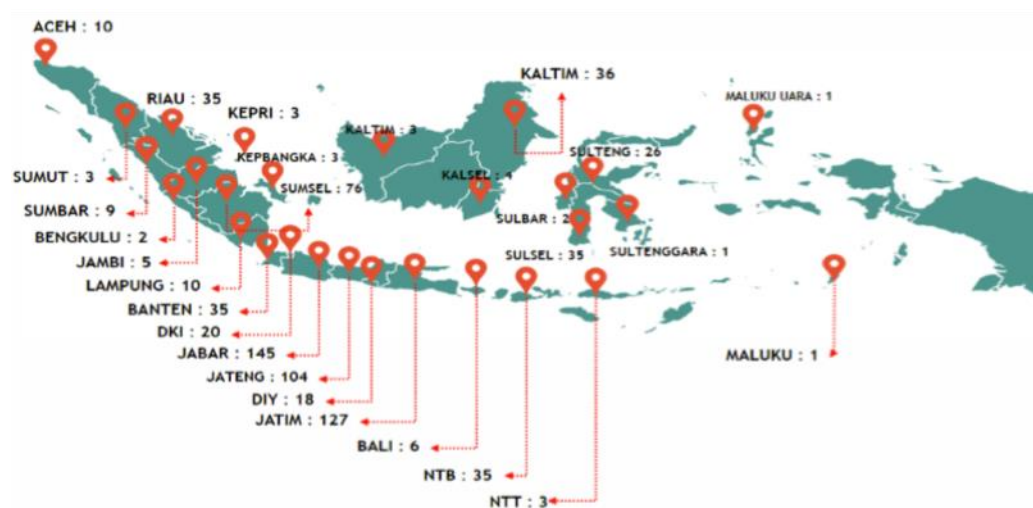


Figure 2. Fostering SME role models in the application of standards in 28 provinces (42).

The systematic approach in coaching and assistance of SMEs starting from awareness, approval, and commitment of business actors, understanding of standard management systems and technical product standards, gap analysis, system development, and implementation to continuous improvement, has had a positive impact on the business performances of SMEs. Business activities have become much improved in the organized production system, there has been an efficient use of resources, decreased rejects and errors, and the building of a better and more disciplined work culture. Several role model testimonials state that the benefits of implementing standards include maintaining sustainable quality, increasing

efficiency, reducing revenue (reducing rejects), facilitating market access, reducing regular inspections cost in the production process, and also encouraging innovation.

SMEs are very diverse and generally use the potential of local resources, which are relatively available in district areas. The assistance of fostering SMEs in these areas includes access to information sources, market information, regulations, places for consultation and assistance, capital incentives, capacity building in online use, use of digital-based technology for marketing, and communication with partners. Zutshi et al. [9] give a systematic review and recommendations concerning enhancing SMEs' resilience in the context of COVID-19. To strengthen the SMEs, researchers can identify and assess the opportunities, interlinkages, and complexities associated with the use of digital technologies for SMEs. Moreover, to support the survivability of SMEs and their value-adding potential, the decision-makers can adopt the recommendations, while researchers and scholars may find it useful to test the viability of applying the proposed framework of recommendations onto SME settings. Digital marketing has been proved as helpful to SMEs in maintaining their sale performance during the COVID-19 pandemic while maintaining customers and sales performances in a sustainable manner, by improving customer satisfaction and building long-term relationships with customers [48,49].

The application of SNI is also able to expand their market access at the national level, in supermarkets, national retailers, e-catalogs, and marketplaces and some of the SMEs that are fostered are able to meet export market requirements (France, United States of America, Australia, Saudi Arabia, Middle East, South Korea, Singapore, and Timor Leste) [50].

In line with the government's program to encourage innovation, the development of standards must also be able to support the development of innovation. Creation of new products and processes have resulted from domestic research. Innovation must be supported in an integrated manner with standards and suitability assessment systems to improve the selling position of innovation products. Innovations that occur in the country are generally driven by community needs, developments in science and technology, and the global market. However, some innovations occur due to changes in community or market behavior. During the pandemic, there were many observations indicating that people's behavior had occurred as a result of this pandemic. Therefore, innovation and standard development support need to pay attention to this, so that the downstream process is getting better.

5. Conclusions and Recommendation

The COVID-19 pandemic has changed various aspects of life, not only regarding health aspects but also economic, social, and environmental aspects. Various government policies have been carried out, both directly related to health, or related to handling the impact of the pandemic. In line with ongoing and planned government policies, standardization including standard development, conformity assessment, and metrology play important roles in supporting health care. These roles start from supporting the handling of the pandemic, both related to medical equipment, personal protective equipment, competent laboratories, and reliable laboratory testing. Significant support of standardization for the government policies and programs can increase the effectiveness in strengthening the supply chain and fostering the SME. For recovery and continuing development post-pandemic, either in the middle- or long-term period will be more effective by implementation of a standard management system. This report is based on observations with selected cities that are representative of the Island of Java. Only two cities outside of Java were included, namely Makassar and Palembang. In future research, due to differences in demographics and conditions of infrastructure in various islands outside of Java, especially the eastern part of Indonesia, it is recommended to make a broader observation location to obtain comprehensive data in Indonesia. The methodology can be conducted in a more systematic manner to achieve better representative data.

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