Change Adapt Improve

Quality and Accreditation Institute

THE VOICE

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www.qai.org.in

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Foreword

Dr. B.K. Rana
CEO, QAI

The Mission of QAI is "To conceive and deliver education, training, accreditation and related programmes in partnership with stakeholders using an approach of co-design and co-creation." Over the past three years, QAI has extended its presence in India as well as in some other countries. The year 2020-2021 has been unprecedented due to COVID-19 Pandemic which has led to several challenges for all sector including healthcare. We at QAI wish to support our participating organisations, government, regulators and stakeholders in appropriate capacity in their endeavours to achieve Quality. We are also committed to support Government of India's commitment towards Universal Health Coverage and Sustainable Developmental Goal-3.

We aim to set international benchmarks for us as an Accreditation Body and I am delighted to report that QAI's Centre for Accreditation of Health and Social Care (QAI CAHSC) has achieved accreditation from the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) making us at par with any other accreditation body globally. This recognition will provide options to Hospitals, Dental Centres, Eye Centres and Imaging Centres to choose QAI accreditation for CGHS empanelment. This will also support our Prime Minister's call of Aatmanirbhar Bharat and Heal in India campaign.

Bringing out this Newsletter is an attempt to spread the awareness and educate stakeholders in current affairs related to Quality, Accreditation, Certification, Conformity Assessment and other key areas of relevance.

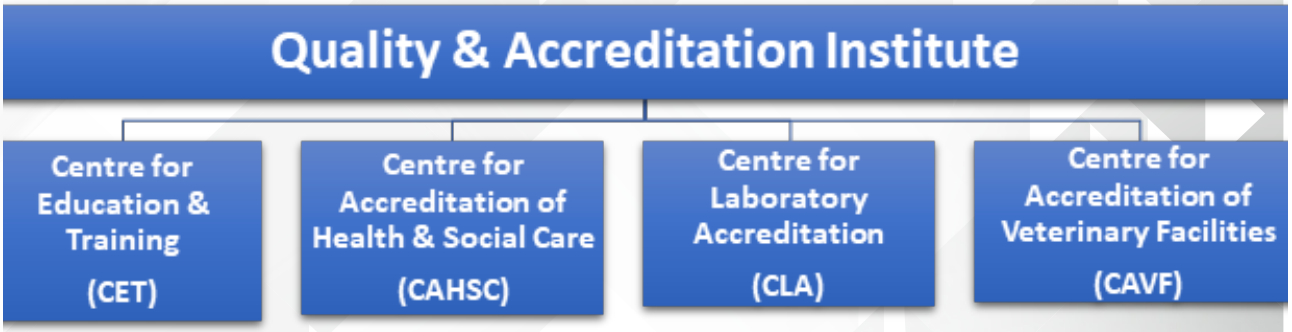
I want to thank all Stakeholders including accredited/ applicant organisations and Staff for helping in spreading QAI mission.

I look forward receiving your continued support to achieve our Mission.

ABOUT QAI

QAI was set up to create an ecosystem of education, training, quality improvement and accreditation/ certification. This organisation provides a platform to stakeholders including professionals and organisations, associated with quality in any way, to share their wisdom and knowledge in order to make its Vision realised. This further provides tremendous opportunities to all concerned to learn and contribute in improving organisations engaged with QAI. Different activities are initiated under different verticals in a manner that they remain independent of each other.

QAI Structure



QAI Programmes

QAI is offering programme under three different verticals:

CET: Centre for Education and Training

- Trainings- specific topic and accreditation standards related
- Education Activities- Internal Auditors, Infection Prevention & Control, Medication Safety, Risk Assessment etc.
- Capacity Building (Setting up Accreditation Bodies, Developing Accreditation Standards)

CLA: Centre for Laboratory Accreditation

- ⇒ Medical Laboratory (ISO 15189) Accreditation Programme
- ⇒ Testing Laboratory (ISO/IEC 17025) Accreditation Programme including food, forensic and veterinary testing labs
- ⇒ Calibration Laboratory (ISO/IEC 17025) Accreditation Programme
- ⇒ Biobanking (ISO 20387) Accreditation Programme
- ⇒ QAI Recognition for Medical Laboratories (Based on the requirements prescribed in Gazette Notification G.S.R.468 (E) dated 18 May 2018 and related amendment dated 14 February 2020 by MOHFW related to Clinical Establishments (Central Government) Rules, 2012

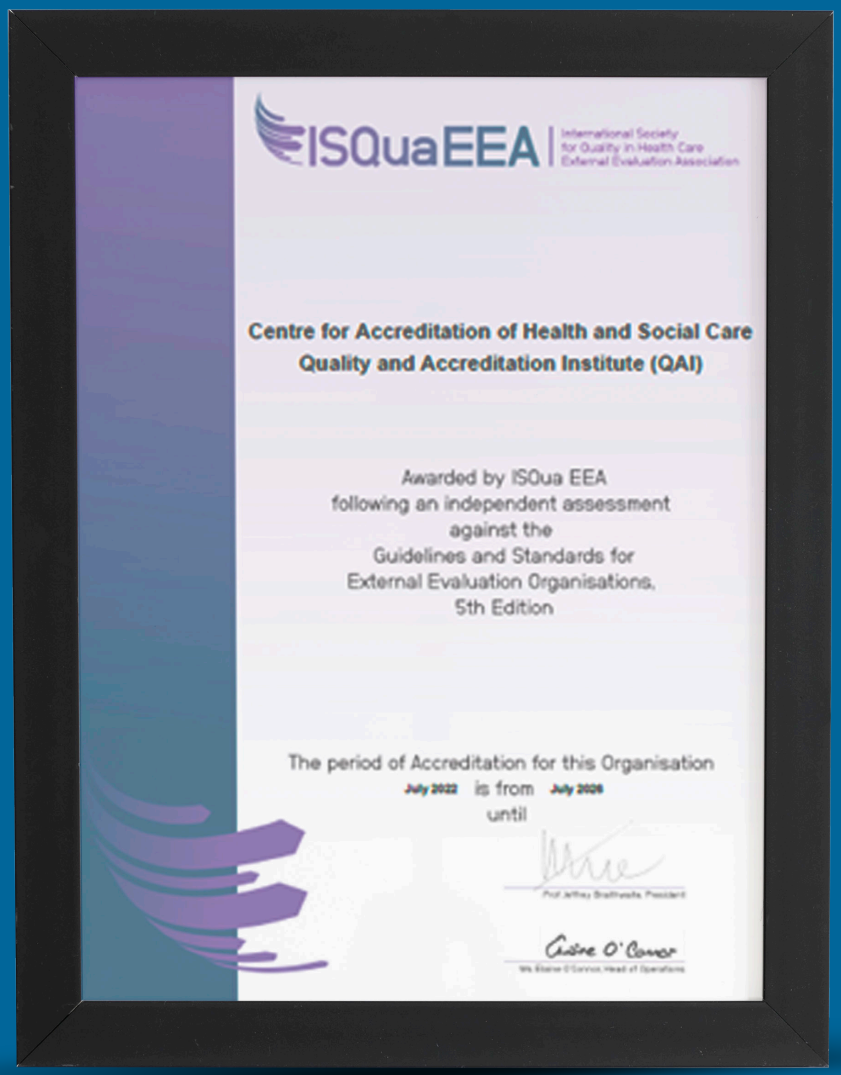
CAHSC: Centre for Accreditation of Health and Social Care

Key Milestones:

QAI becomes the first accreditation body in India to achieve ISQua Accreditation in less than five years of operations
QAI is the ONLY accreditation body in India having ISQua Accreditation as an Organisation and Two Sets of Standards.

QAI Accreditation is eligible for Central Government Health Scheme (CGHS) empanelment of Private Hospitals, Eye Centres, Dental Centres & Imaging Centres.

ISQuaEEA International Society for Quality in Health Care External Evaluation Association
Accredited Organisation 2022-2026



Launched 12 Accreditation Programmes within a span of 5 years

International Recognitions and Affiliations

Institutional Member of the International Society for Quality in Health Care (ISQua)

www.isqua.org

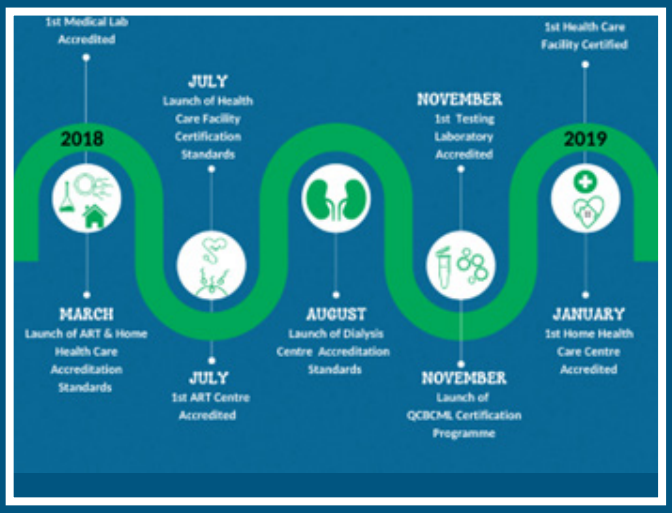
Board Member of the International Society for Telemedicine and eHealth (ISfTeH)

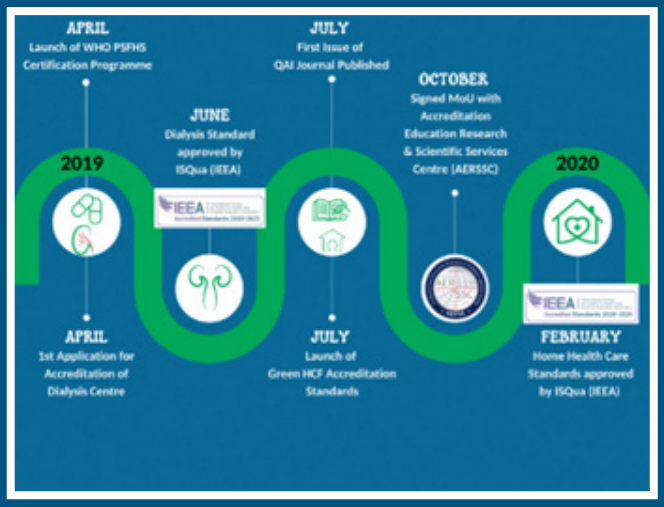
www.isfteh.org

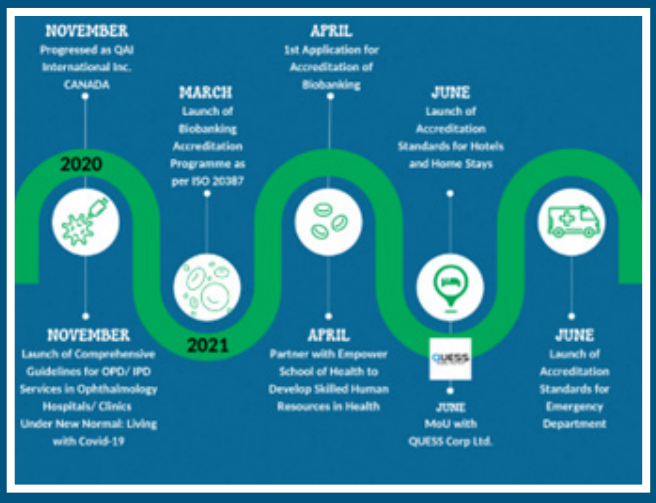
Associate Member of Asia Pacific Accreditation Cooperation (APAC)

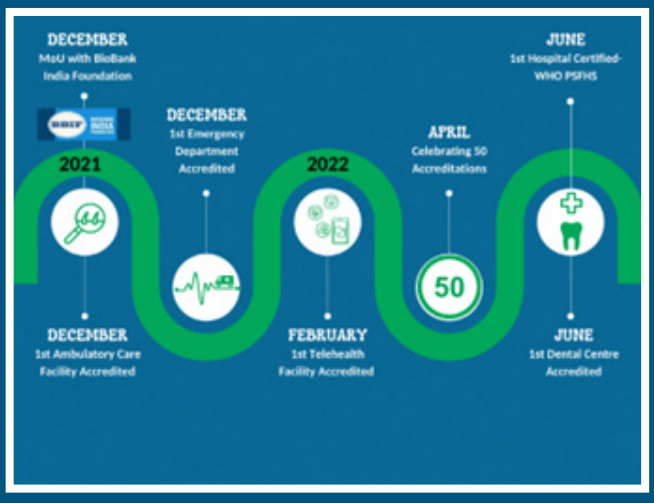
www.apac-accreditation.org

Journey so far since Inception
5 Years









Achievements

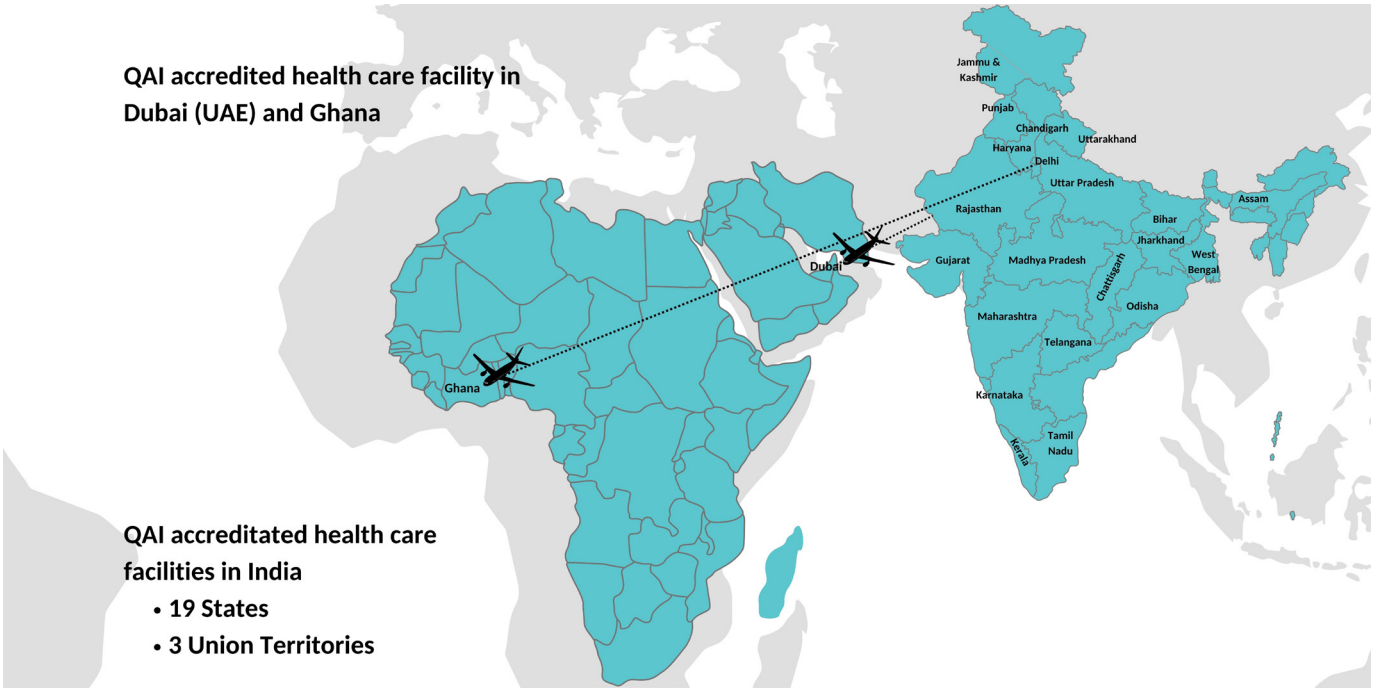
Number of Accreditations/ Certifications
=
60 +

Number of Assessors
=
150 +

Number of Training Programmes Organised
=
50+

Number of trained Internal Auditors
=
300 +

Number of Global Partnerships
=
10



First Medical Laboratory accredited by QAI in Ghana

Eastern Regional Hospital Laboratory, Ghana is the first laboratory in Ghana accredited by QAI in accordance with ISO 15189:2012 in the field of medical testing.

Eastern Regional Hospital Laboratory becomes the first Ghana Health Service facility to obtain ISO 15189 accreditation in Ghana.


Quality And Accreditation Institute
Centre for Laboratory Accreditation
Certificate of Accreditation
EASTERN REGIONAL HOSPITAL LABORATORY
Eastern Regional Hospital
P.O. Box 201, Koforidua, Ghana
has been assessed and accredited in accordance with the Standard
ISO 15189:2012
"Medical Laboratories - Requirements for Quality and Competence"
In the field of
Medical Testing
This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued compliance to the above standard & any other requirements specified by QAI.
QAI/CLA/ML/2022/0013
Valid from: 17 August 2022
Valid until: 16 August 2024
Dr. Bhupendra Kumar Rana
Chief Executive Officer
Prof. Vikram Kumar
Chair, CLA

NATIONAL QUALITY NEWS

Clients Corner

Need for Accreditation of Emergency Departments

Dr Nivetha B, Dr Manzoor Sheik, Dr Saravana Kumar

Dr. Saravana Kumar

National Secretary, Society for Emergency Medicine, India & Chair, Quality SIG, IFEM

Dr. Manzoor Sheik

Head of ED, Dr. Mehtas Hospital global campus, Chennai

Dr. Nivetha B

Head of ED,
Dr. Mehtas Hospital, Chetpet, Chennai

Order in Chaos is a theory which across the globe is both popular and notorious. Till very recently it was the SOP in several Emergency Departments (EDs) worldwide with a rationale that ED is an extremely dynamic place where the entire process flow differs in a matter of minutes based on the acuity of patient presentation and fluctuating volumes. It like going from 0-100 in few seconds. Before we proceed let's understand a little about the ED and its function.

The ED Setting:

The ED of any institution is an entry point for significant number of patients to any healthcare organization. The ED proceedings are expeditious, it caters to various trauma and medical emergencies in both adults and in children round the clock and is adequately staffed with emergency physicians, emergency paramedics and nursing staffs to handle such emergencies at all times and days.

Unlike wards or ICU, the beds in the emergency department are utilized on a continuous basis for different patients on a given day for initial stabilization and are eventually transferred to appropriate inpatient care areas of the Health Care Organization for continuity of care under different specialities (or) discharged from ER after initial treatment with a follow-up advice. The ED also oversees operations of the Ambulance, prehospital Emergency Medical Services (EMS) and coordinates their services and operations.

Salient Quality & Patient Safety concerns in the ED:

- Overcrowding
- Sudden surge in Volumes
- Medication Errors
- Handover & Transition of Care
- ED Violence
- Documentation Error
- Communication Error
- Lack of clinical protocols
- Mechanism for Error Reporting
- Lack of emphasis of Quality

It is now beyond a shadow a doubt clear that the norm is to expected the unexpected in the ED, the challenge lies in not just expecting the unexpected and being prepared for it but also ensuring safe and quality care is provided to the patient while in the ED. This can be possible by having clear set protocols and strong systems and process in place.

The ED formerly known as 'Casualty' was with no clear ownership and a governing specialty but involved multiple stakeholders across various specialities and super specialities. Now that has started to change, Emergency Medicine has emerged as the core specialty relevant to the ED is one of the youngest specialities in the world of medicine and still a teenager in our nation.

This transformation is fairly recent and there are far few established EDs still a long way to go with abundant scope for improvement, hence accreditation is of paramount importance to both help establish standards of care and quality and also the end user to know which ED is capable of supporting them in possibly their worst time and guarantee quality of care.

Quality health care involves evidence based clinical practice; based on current scientific knowledge, following clinical practice guidelines based on evidence, with the least risk for patients and relatives, involving greater efficiency and greater satisfaction for users and health personnel. The accreditation of health care centres and services is, without doubt, the most widely accepted method for guaranteeing quality.

Accreditation is a systematic process for improving quality of care and it enables managers to assess and evaluate the healthcare system. Accreditation of an organization provides an obvious commitment for improving quality of safety, quality of patient care, ensuring safety surveillance and continuous activities for reducing dangers which threaten patients and staff. The perpetual and indispensable service provided by the emergency departments, it is necessary to re-evaluate the manner of service provision in these departments according to the standards and criteria of accreditation, so that an observance of these criteria will lead to improvement of emergency medicine in India. A universal and thorough improvement of quality will reduce risks for patients and staff. Such risks may be abundant in clinical procedures and physical environments.

Benefits for Patients:

- **Patients are the biggest beneficiary among all the stakeholders.**
- **Accreditation results in high quality of care and patient safety.**
- **The patients are serviced by credential medical staffs**
- **Rights of patients are respected and protected. Patient's satisfaction is regularly evaluated.**

Benefits for Hospitals:

- **Accreditation to a hospital stimulates continuous improvement.**
- **The standards guide the provision of an effective infection control program in the Emergency Department**
- **The standardization of monitoring, storing, reporting the adverse effects of emergency medications and also making sure that they are readily available and replenished in a timely manner**

• It enables the organization in demonstrating commitment to quality care and patient safety thereby ensures best clinical outcomes.
• It raises community confidence in the services provided by the hospital as services provided by credentialed medical staffs.
• It also provides opportunity to healthcare unit to benchmark with the best.
• Certification status also provides marketing advantage in a competitive health care.
• Biomedical waste is managed as per policies and procedures and in accordance of legal policies.

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• Biomedical waste is managed as per policies and procedures and in accordance of legal policies.

Benefits for Staff:

• The staff in an Emergency accredited Hospital is satisfied lot as it provides for continuous learning, good working environment and leadership.
• Efficiencies and competencies of staff also gets improved in an accredited Hospital.
• It improves overall professional development, knowledge and competencies in systematic ways with defined ownership and accountability of all the staff including Medical and Para Medical Staffs.

What cannot be measured cannot be improved:

It is extremely important to understand what the important Quality indicators (QIs) and their corresponding performance analysis which can be both measured and improved. This will give a scope for self-assessment also help identify both areas of strength and weaknesses.

a few key Quality Indicators for emergency departments to measure:

Quality Indicator

1. **Door to Triage time (Nurse)**
2. **Door to Doctor time**
3. **Door to needle time (Stroke)**
4. **Door to needle time (ACS)**
5. **Pain Score Assessment**
6. **Investigation return time**
7. **Nurse : Patient Ratio**
8. **Patient Satisfaction**
9. **Time taken for discharge**
10. **ER Mortality**
11. **Process parameters: Registration, Admission, Left without being seen, Length of Stay**
12. **Safety: Patient falls, Medication errors**
13. **Infection Control**

Recommendations

Dr Mehta's hospital, Department of emergency medicine is the first one in the country to achieve QAI emergency department accreditation and also the first in the country to implement Indian Space Research Organization, AHPI and SEMI ED guidelines for continuous quality improvement.

Dr. Birendra Kumar Yadav

Regional Director, Biobank India Foundation (BBIF)
Manager, National Liver Disease Biobank (NLDB), ILBS

Improving Biobank Through Accreditation

Biobank is a place where biological samples and associated data are collected and stored. These biological samples are used in research and development. Since biological samples are raw material for research and diagnosis, it is important the way biological samples are collected and stored. There are different types of biobanks, depending on the types of biological material they collect and store, source of funding and place of establishment. Biobanks offer multiple benefits to the sectors in which they operate, with considerable growth opportunities. Biobank contribute to scientific progress, not only preserving the samples but also by exchanging its material nationally and internationally for research.

Quality is the key success factor for every biobank. Strategic and Process -oriented quality management system ensures consistently high quality of biospecimens and user confidence, satisfaction in long term. The International Organization for Standardization (ISO) is a global organisation that establishes international standards, headquartered in Geneva, Switzerland. ISO has developed ISO 20387: 2018 standard specifically for biobanking to enable them to demonstrate operational competency and provide biological material and data of suitable quality.

Biobanks face an ever-increasing number of competitors, in addition to the demand for quality and consistency in collection, preservation, quality insurance, traceability, and distribution. Accreditation of biobanks in accordance with applicable standards will continue to gain importance and contribute to enhance the reputation of biobanks. Accreditation is an opportunity and necessity to improve the quality of health service offered, as well as research and development. Accreditation acts as a driving force for biobank to gain reliability for its process, banked materials and their associated data that is decisive to supporting confidence in their use. This increases stakeholders' confidence in the biobank's ability to provide output consistently, and those crucial requirements are being met.

Furthermore, accreditation provides not only outside stakeholder but also valuable insight to the biobank itself. Through accreditation biobanks know its shortcomings, way to further improve or streamline its processes, to potentially reduce costs and improve efficiency. Once biobank create a framework of its improved consistency, it affecting all sectors and increased reliability. Researchers have the expectations for high quality of both samples and associated data. After the accreditation biobank will be able to serve well for internal needs of an institution or outside institution and worldwide.

Dr. Neeraj Jain MD (Path)

Founder President, MELAP,
New Delhi & Vice President (Medical)
- Association of Indian Laboratories
(AOIL)

Expectation of Clinician -Quality Assurance

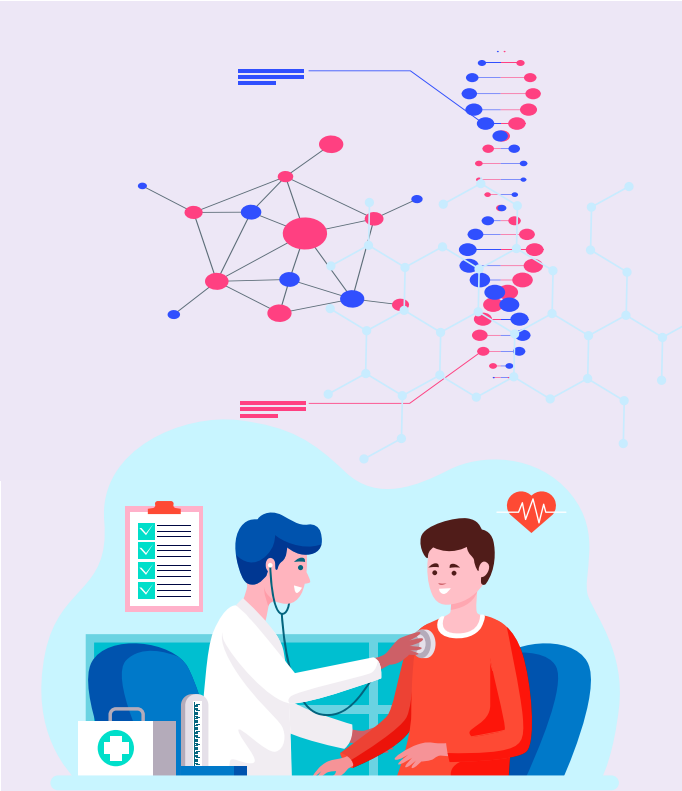
In healthcare today, medical laboratories are key partners in ensuring and maintaining patient safety, and it is seen that laboratory results influence approx. 70% of medical decisions. Quality standards of the laboratory plays a major role in ensuring the correctness of these results, providing better patient care as a whole and promoting excellence. While the absence of the same may lead to unreliable results, causing a delay in treatment, misdiagnosis and an increase in cost due to a need for retesting. COVID-19 Pandemic has affected everyone globally & correct lab diagnosis is very important. Therefore, ICMR has made it mandatory to allow only accredited labs to perform RT-PCR test.

Good quality is never brought about by accident; it is almost always the cumulative result of sincere intentions, dedicated effort, intelligent direction and skilful execution. As a choice, good quality may not necessarily be the easiest or the cheapest; however it is definitely the wisest for both patient health and welfare as well as laboratory credibility.

International standard ISO15189, based upon ISO17025 and ISO9001 standards, provides the basic requirements for establishing competence and serves as the bible for quality in medical laboratories. And while this serves as an excellent guiding principle, no matter how good the quality mechanisms are on paper, truly good quality cannot be achieved if theory is not translated into practice day-in and day-out. competence and serves as the bible for quality in medical laboratories. And while this serves as an excellent guiding principle, no matter how good the quality mechanisms are on paper, truly good quality cannot be achieved if theory is not translated into practice day-in and day-out.

The entire process of managing a sample must be considered including the beginning i.e sample collection to end i.e reporting and saving results.
Laboratory tests are influenced by :

- **Lab environment**
- **Knowledgeable staff**
- **Reagents and Equipment**
- **Quality control**
- **Communications**
- **Process management**
- **Occurrence management**
- **Record keeping**



Following are the Quality essentials which act as building blocks for quality management.

Personnel: Human resources, job qualifications ,job descriptions, orientation, training, Competency assessment, professional development, continuing education.

Equipment: Acquisition, installation, validation, maintenance, calibration , trouble shooting, service and repair, records.

Purchasing and inventory : Vendor qualification, supplies and reagents, critical services, contract review, inventory management.

Process control: Quality control, sample management, method validation, method verification.

Information Management: Confidentiality, Requisitions, logs and records, reports, computerised laboratory information system(LIS)

Documents: Creation, revision and review, control and distribution.

Records: Collection, review, storage , retention.

Occurrence Management: Complaints, mistakes and problems,documentation, root cause analysis, immediate actions, corrective actions and preventive actions.

Laboratory Assessment:

Internal: : Quality indicators, audit reports, audit reviews.

External: Proficiency testing ,inspections, accreditation.

Process improvement : Opportunities for improvement (OFI), stakeholders feedback, problem resolution, risk assessment, preventive actions, corrective actions.

Customer Service: Customer group identification, customer needs, customer feedback.

Facilities and Safety: safe working environment, transport management, Security, Containment, waste management, Laboratory safety, ergonomics. Implementing an efficient Quality Management system does not guarantee a 100% error free laboratory, but it goes a long way in detecting errors that may occur commonly, and prevents them from recurring. It essentially puts us on the path to continuous improvement, and brings us closer to our vision of bettering healthcare facilities every day.

There is a cost associated with Quality, but are we cognizant of the fact that poor quality costs us even more? Quality costs can be offset by quality payoffs like enhanced reputation, loyal clientele, reduced system failures & machine downtime, less need for retesting for complaints etc. However there is no offset for medical implications that may be caused by poor quality, and its impact on not just the laboratories in question but on healthcare as a whole.Thus, implementing and maintaining good quality standards in laboratories is no more a choice, as it is not just the ethical and moral duty of all laboratories to provide accurate, reliable results, but it is essential to all aspects of healthcare and the medical profession.

Important Links

We aim to bring to you the news and updates from the global community. To begin with, we are providing some links to international trade, commerce, standards, conformity assessment and regulatory channels below:

Global Organisations Ruling Trade and Commerce between Nations

- World Trade Organisation - https://www.wto.org/
- World Economic Forum - https://www.weforum.org/
- United Nations Industrial Development Organisation - https://www.unido.org/
- Organization for Economic Cooperation and Development (OECD) (www.oecd.org)
- World Health Organisation (www.who.int)
- Food and Agriculture Organization of the United Nations (FAO) (www.fao.org)
- European Commission - https://ec.europa.eu/info/index_en
- US Food & Drug Administration - https://www.fda.gov/dex_en

International Standards & Conformity Assessment Organisations

- International Organisation for Standardisation (www.iso.org)
- International Accreditation Forum (www.iaf.nu)
- International Laboratory Accreditation Cooperation (www.ilac.org)
- International Society for Quality in Health Care (ISQua) (www.isqua.org)
- ISQua External Evaluation Association (www.ieea.ch)
- International Network of Quality Infrastructure (INetQI) (www.inetqi.net)

Regional Standards & Conformity Assessment Organisations

- Asia Pacific Accreditation Cooperation (www.apac-accreditation.org)
- Asian Society for Quality in Health Care (ASQua) (www.asquaa.org)

IFC and BSI Launch Technical Benchmarking Guide for COVID-19-related PPE

Dr. Nigel H Croft

Introduction

The COVID-19 pandemic had a profound impact on the dynamics of global supply chains for personal protective equipment (PPE). It necessitated an urgent review and, in some cases, a temporary relaxation of the regulatory requirements and technical specifications in certain markets to ensure the ongoing availability of PPE for health care and front-line workers.

In parallel, on the supply side, many non-traditional manufacturers in various parts of the world ramped up their production capabilities, with some even manufacturing PPE for the first time, to help cope with demand. For those aiming to export their products, this means that they have to navigate their way through the many different market requirements around the world to ensure compliance with the relevant standards and technical regulations. These requirements are often similar but not identical, and specify varying test methods and conformity assessment procedures.

It was within this context that IFC (The International Finance Corporation; part of the World Bank Group) partnered with BSI (British Standards Institution) to develop a Technical Benchmarking Guide, with funding provided by the UK's Foreign, Commonwealth & Development Office. The guide is part of broader efforts by IFC and others to support global supply chains for PPE and to provide manufacturers and governments with a tool to expand the manufacturing and supply of PPE that is "fit for purpose", that adequately protects all healthcare workers and is produced without harming the environment.

The Technical Benchmarking Guide for COVID-19-related PPE

The benchmarking guide, launched in July 2022, presents the often complex and sometimes conflicting technical regulations, product standards and conformity assessment criteria in a simple way. It provides manufacturers and purchasers alike with a tool to navigate through the technical regulations, product specifications and conformity assessment requirements associated with 13 selected markets around the world. It is intended to help manufacturers identify the realities of potential new markets and to act as a starting point for them to delve deeper into the specific product requirements and test methods by consulting the relevant standards and technical regulations as necessary. It covers the products and markets shown in Figure 1.

Figure 1 – Products and markets covered by the Technical benchmarking Guide

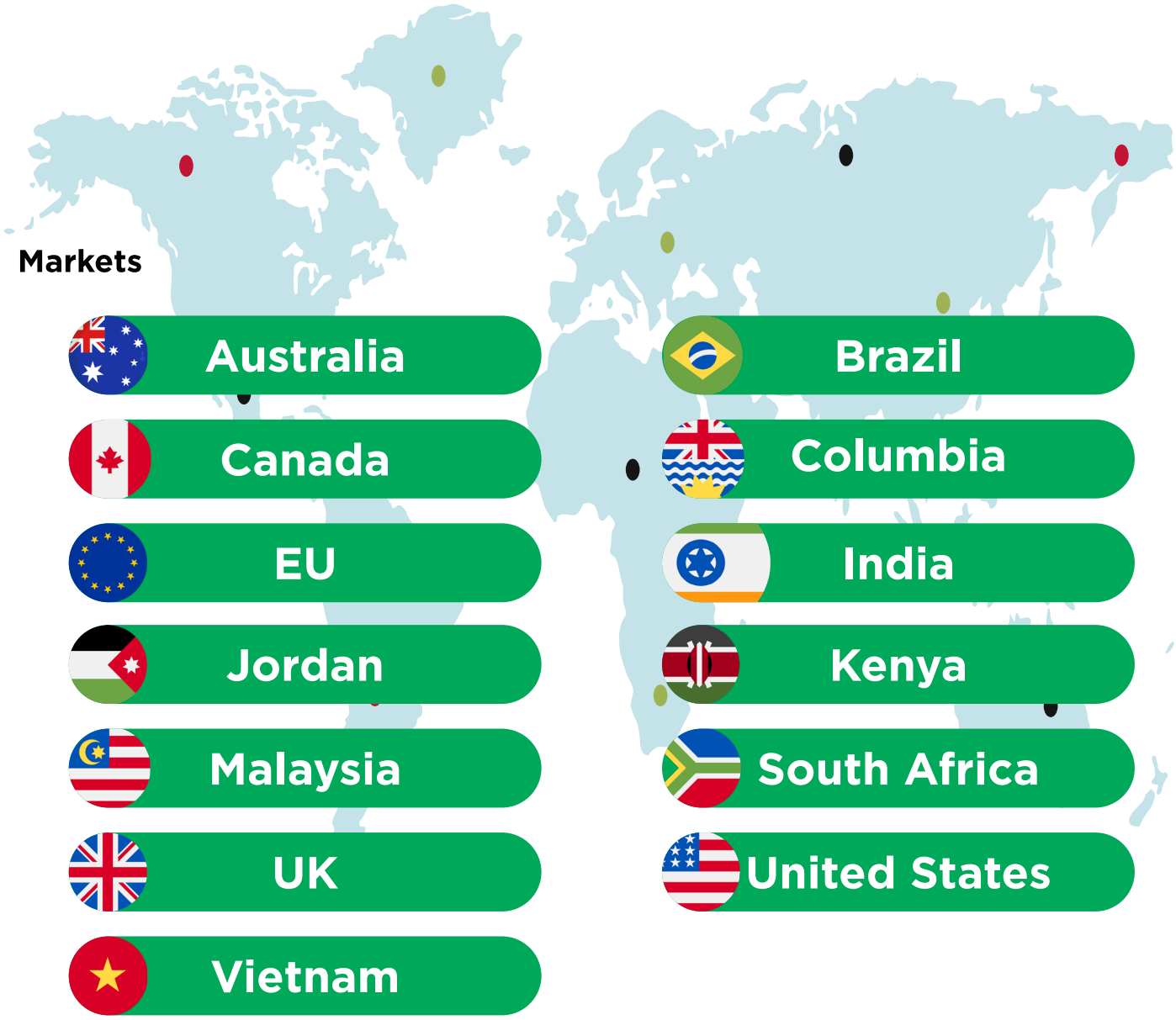
Products

Products

- **Masks**
  - Respirators
  - Medical face masks
  - Community face coverings
- **Eye and face protection**
  - Protective goggles/glasses
  - Face shields
- **Gloves**
  - Medical examination gloves
  - Surgical gloves
- **Clothing**
  - Full-body garments (including protective suits and coveralls) and partial-body garments (including aprons and shoe/head covers)
  - Gowns (including isolation and surgical gowns)

Markets

- Australia
- Brazil
- Canada
- Colombia
- EU
- India
- Jordan
- Kenya
- Malaysia
- South Africa
- UK
- United States
- Vietnam



Healthcare is the protection of mental and physical health by preventing or treating illness. A healthy person is not one with just the absence of disease, but health is a state of physical, mental, and social well-being. In general, healthcare is not practiced with this idea, modern healthcare facilities fix parts as if the person is a collection of mechanical systems. When one thinks about hospitals, what comes to mind is often a cold, sterile environment. Hospitals do not create inviting, healing spaces as people often encounter bad experiences, nervousness and grief in these spaces.

If the mind has the power to heal, fostering an environment that promotes mental wellness should translate to the physical healing of the body. Architecture has shown that the

Structure and Core Content of the Guide

The guide is split into sections from which the user can choose the relevant areas to access according to their needs:

- Part 1: Introduction and the technical criteria for the various PPE categories in selected markets
- Part 2: Generic descriptions of the main technical features for each PPE product category and associated standards for the selected markets
- Part 3: Market-specific information, including an overview of each market and generic information about the regulatory environment, approaches to standardization, and conformity assessment
- Part 4: Detailed comparisons of the technical requirements for the EU and US markets. International Organization for Standardization (ISO) product standards are also included where available
- Parts 5–15: Detailed fact sheets with comparisons (benchmarking) of the specific requirements for each product/market combination against the reference EU/US market requirements
- Annex A: Additional considerations for manufacturers and purchasers to take into account, including sustainability and diversity/inclusivity (gender) issues, and approaches to conformity assessment and accreditation.

The guide can be downloaded free of charge from the World Bank website:

https://documents.worldbank.org/en/publication/documents-reports/document-detail/099048308082256583/idu0da7152d00e23f04d3f0a23f0cecec0a22344

Simplifying a complex landscape

Overall, the guide seeks to simplify comparisons between the various COVID-19-related PPE categories and markets by using a system of colour coding to highlight similarities and differences. For those who need more detail, it also takes a deeper dive into the technical regulations, product standards, and testing criteria for each PPE/market combination. Making these comparisons is a complex process due to.

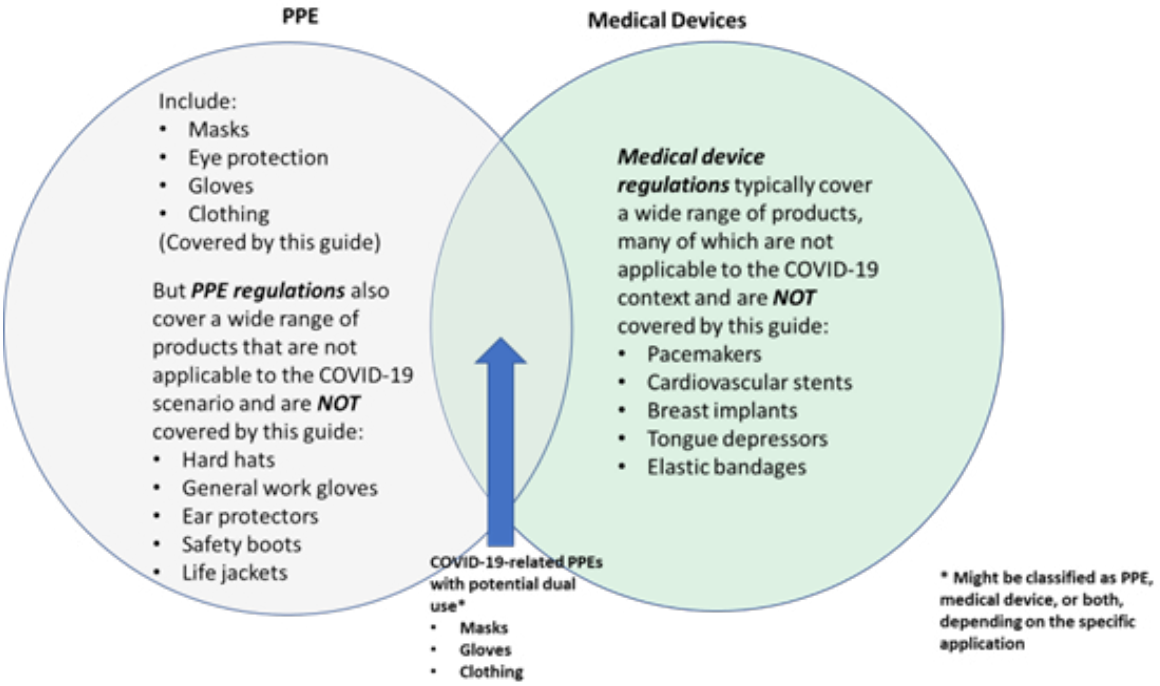
- The different regulatory approaches and relationships between (mandatory) technical regulations and (voluntary) standards used in different markets
- The different technical regulations associated with PPE and medical devices, with some
- PPE categories needing to meet one or both sets of regulations simultaneously
- International standards that are evolving quickly to cater to the needs of a rapidly changing PPE landscape but for which the latest versions are not always adopted at a national level or referred to in legislation. This time-lag in adoption can mean that the relevant standard might not be the latest version

- The different testing methods that are required to demonstrate conformity to the various product standards. This can mean that although a specific category of PPE might be manufactured to meet the requirements of multiple markets, it has to undergo testing using different laboratory methods, approaches, or acceptance criteria. These are often expressed in different units of measurement, for which a direct comparison of results is impossible.

Standards and Technical Regulations

It is generally accepted good regulatory practice for technical regulations to specify "essential requirements" (usually based on generic performance criteria) while the technical details such as material performance characteristics, test methods, and so on are contained in (voluntary) standards. If a product conforms to the pertinent standard (called "harmonized standard" in the EU) then it is assumed that it fulfils the essential requirements in the technical regulations ("presumption of conformity" principle). This approach allows for technical progress to be accommodated through amendments or new editions of standards, while the technical regulation itself remains relatively stable. In some other situations, voluntary standards can become compulsory when directly referenced in the applicable regulations.
Typically, this means that regulations might refer to a wide range of PPE and medical devices, only some of which are relevant for COVID-19-related applications. This can be seen schematically in Figure 2.

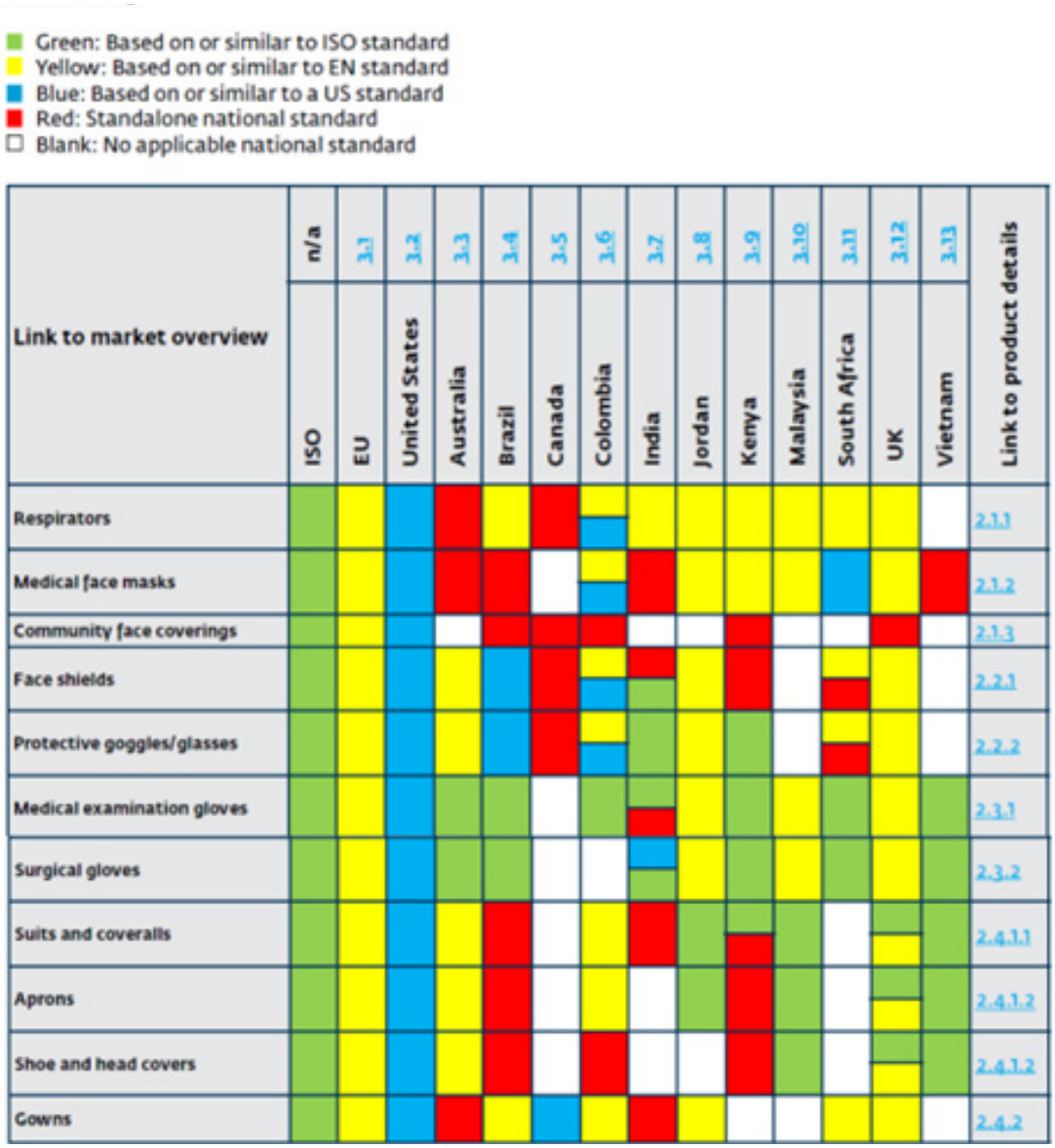
Figure 2: Schematic representation of the interactions between PPE and medical devices



Comparison of standards used in the various markets covered by the guide

At a very high level, Figure 3 shows the basis for different countries' standards for each category of PPE covered by the guide.

Figure 3 – Overview of the basis for national or regional standards in the various markets covered by the guide



We can see from Figure 3, for example, that there is a predominance of EN-based standards for respirators, but for community face coverings there are only national or regional ("stand-alone") standards. For PPE where ISO standards are available (such as surgical and medical examination gloves) these tend to be used as a basis for most national standards in the markets covered by the guide.

By using the two best-known markets - the European Union (EU) and the United States (US) - as reference points, the guide then goes into a deeper analysis of the differences and similarities between product standards used in each of the markets covered by the guide, and also makes detailed comparisons of the test methods that are referenced in those standards

Other important considerations

Circularity and Inclusivity

Although there is still a global paucity of standards and regulations related to sustainability, circularity, inclusivity and gender-related "fit" requirements for PPE, users of the guide are alerted to the need for these aspects to be taken into account, with further details being provided in Annex A of the guide.

In 2021 and 2022, for example, IFC put the spotlight on the need to move away from plastics-based, single-use, disposable PPE toward more sustainable PPE products and business models through IFC's publication "Innovation in Manufacturing Personal Protective Equipment—Toward Sustainability and Circularity."
In November 2021, IFC also convened stakeholders to discuss how PPE procurement and manufacturing can move away from "one size fits all" to cater to specific needs of female and male health care workers with a wider range of products and sizes that fit different body types. Both areas—sustainability and inclusivity/gender—are at the forefront of international attention and represent new opportunities for PPE production and procurement. Standards institutions and governments are expected to develop new technical standards and requirements in both areas.

Guidance for purchasers

In order for purchasers (governments, health care organizations, distributors of medical consumables and/or purchasing agents) to have confidence in the PPE they are buying, they need be aware of a number of factors, including criteria for supplier selection, how to specify requirements, verification of claims of conformity to quality management and/or product requirements and the importance of using accredited conformity assessment providers (for inspection, testing and certification, for example). These topics are explained in more detail by the Guide.

Webinars held to mark the Launch of the Technical Benchmarking Guide

In mid-2022, IFC and BSI held a series of international webinars to launch the guide (see

https://www.ifc.org/wps/wcm/connect/industry_ext_content/ifc_external_corporate_site/manufacturing/events/webinar_how+to+start+ppe+production

Webinar panelists featured representatives from international development organizations, standards bodies, government institutions, and manufacturers.

The main launch event, featuring high-level speakers from the UK, India, Brazil, USA, Greece and Jordan not only focused on the technical aspects of the PPE covered by the guide, but also brought a focus to diversity - specifically the need to design better-fitting PPE for women, and to the environmental challenges stemming from the widespread use of disposable PPE. "We must recognize that society's perception of 'quality' is rapidly expanding to embrace the impact that products, services, and processes have on wider society and the environment," said Lord Jamie Lindsay, President of the UK's Chartered Quality Institute.

The World Health Organization (WHO), which has worked on defining preferred characteristics for PPE and has prioritized the establishment of a global set of PPE standards, also presented at the event. WHO shares IFC's goal to promote better alignment of the various standards for PPE under a set of harmonized global standards that also address sustainability and gender considerations.

Periodic updates to the Guide

Because PPE standards and regulations continue to be revised and developed at the country and global level, IFC and BSI will update the guide periodically until December 2023. Nonetheless, while the guide will provide easy access to important information, the time lag involved in updating means that those working on PPE must always consult the most up-to-date versions of relevant standards and technical regulations.

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