

PERUVIAN TECHNICAL STANDARDS OF THE HEALTH SECTOR

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Executive – Directorate of Standardization
INACAL

Siempre con el pueblo



INACAL

NATIONAL INSTITUTE OF QUALITY

We are the executing entry and highest regulatory authority that conducts the **National System for Quality in the country.**

(Attached to the Ministry of Production)

Our purpose is to promote and ensure compliance with the **National Quality Policy** with a view to:



DEVELOPMENT AND COMPETITIVENESS OF ECONOMIC ACTIVITIES.



CONSUMER PROTECTION.



INACAL ON 4 AXES



Directorate of STANDARDIZATION

Approves the Peruvian Technical Standards, they are not regulations and are voluntary.

STANDARDIZES production processes, with the aim of increasing the quality and safety of products and services.

It contributes to competitiveness, intensifies competition and increases exports.



Directorate of ACCREDITATION

It evaluates the technical competence of conformity assessment organisms to guarantee a reliable and nationally and internationally recognized service.

We support the development of competitive products and services at the national and international level, guaranteeing safety and compliance with quality standards.



Directorate of METROLOGY

It guarantees the international traceability of measurements.

It provides calibration services for measuring equipment and instruments to calibration laboratories and industry.

It guards national standards to ensure uniformity of measurement in the country.



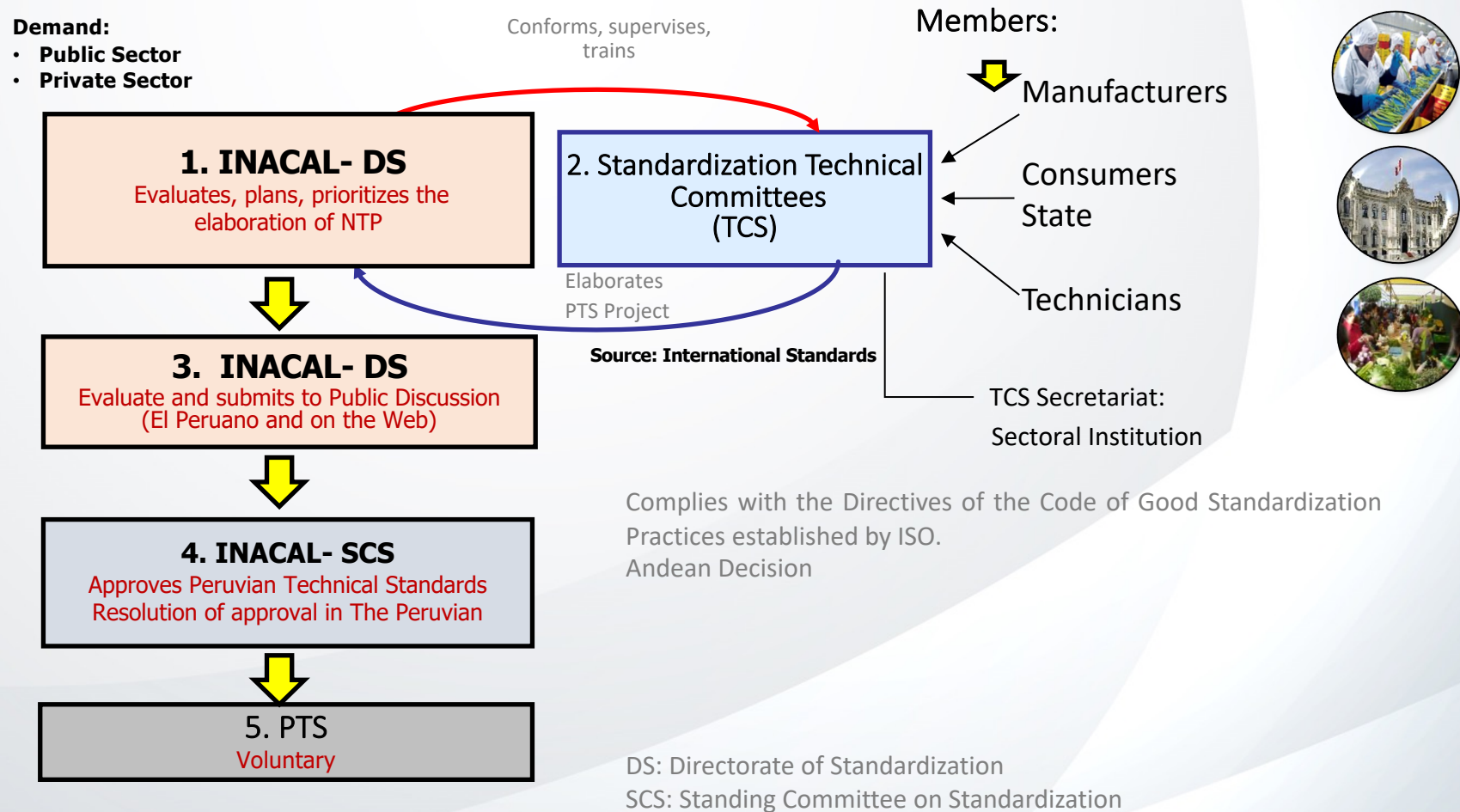
Directorate of STRATEGIC DEVELOPMENT OF QUALITY

It promotes an adequate management and implementation of the National Policy for Quality and the development of the Culture of Quality.

It investigates and identifies the demand and opportunities for the development of quality infrastructure, identifies gaps in quality and the development of intervention strategies.

HOW ARE THE TECHNICAL STANDARDS DEVELOPED?

Standardization



International Organization for Standardization - ISO



SCOPE

Peru has been a full active member of ISO since 2007.

For the 2020 – 2022 period we are members of the ISO Council.

The point of contact is the Directorate of Standardization as the National Standardization Agency.



PROCEEDS

Under the category of full member, INACAL-PERU actively participates by issuing voice and vote in international standardization.

Work on international standardization actively through 79 mirror committees, highlighting the following committees:

- **ISO/TC 215 Health informatics**
- **ISO/TC 283 Occupational health and safety management systems**
- **ISO/TC 229 Nanotechnology**
- **ISO/TC 198 Sterilization of health care products**

Freely dispose of the catalog of ISO Standards that has more than 20,000 international standards.

We represent ISO in Peru.

Work in HEALTH if the TSCs

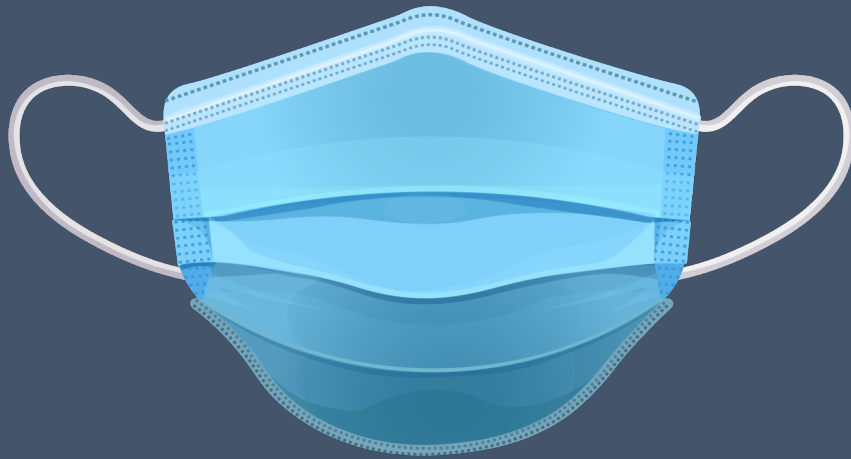
Topics	Standardization	Structure
<p>EQUIPMENT, MATERIALS, MEDICAL DEVICES</p>	<ul style="list-style-type: none"> - TSCs of Health Care Technology, which contains the following Subcommittees of: <ul style="list-style-type: none"> ➤ Health care packaging, ➤ Medical materials, ➤ Absorbent personal hygiene products, ➤ Medical devices and equipment, ➤ Disinfection and sterilization of medical devices. ➤ 98 PTS - Among the most relevant PTSs is the PTS 329.200 Surgical Mask and - PTS 329.201 Respirator. 	<p>Subcommittees:</p> <p>a. Disinfection and sterilization of medical devices Secretariat: Health Guild – Lima's' Chamber of Commerce Some members: General Directorate of Medicines, Supplies and Drugs – Ministry of Health, among others.</p> <p>b. Medical Devices and Equipment Secretariat: Health Guild – Lima's' Chamber of Commerce Deputy Secretary: Faculty of Sciences and Engineering of the PUCP Some members: <i>National Health Institute of the Children San Borja</i> <i>General Directorate of Medicines, Supplies and Drugs – Ministry of Health, among others</i></p> <p>c. Absorbent personal hygiene products Secretariat: Health Guild – Lima's' Chamber of Commerce Some members: <i>General Directorate for Medicines and Drugs – DIGEMID</i> <i>National Center for Quality Control – INS, among others</i></p> <p>d. Medical materials Secretariat: Health Guild – Lima's' Chamber of Commerce Some members: <i>General Directorate of Medicines, Supplies and Drugs – Ministry of Health</i> <i>National Center for Quality Control – National Institute of Health, among others.</i></p>

Work in HEALTH if the TSCs

Topics	Standardization	Structure
ATTENTION TO THE EMERGENCY CAUSED BY COVID-19	<ul style="list-style-type: none">- TSCs of Peruvian Technical Standards, Related Texts and other documents for the attention of the Health Emergency (COVID-19)- Subcommittees:- Protective box for intubation and extubation- Pulmonary ventilators- Face shields- Bags for corpse transportation,- Preventive measures for the return to work- Ultraviolet (UV) lamps for disinfection	Secretariat: Directorate of Standardization Some members: National Center for Quality Control – National Institute of Health, Directorate of Metrology, Universidad Nacional Mayor de San Marcos, among others.

PTS – SURGICAL MASK

PTS 329.200: 2020 MEDICAL MATERIALS Surgical masks. Requirements and test methods



- It specifies the manufacturing, design, performance requirements, and test methods of surgical masks intended to **limit the transmission of infectious agents from medical personnel to patients during surgical procedures and other medical settings with similar requirements.**

Surgical masks type I are used for patients to reduce the risk of spreading infections, particularly in epidemic or pandemic situations.

MANAGEMENT IN THE FACE OF THE HEALTH EMERGENCY



**Quality
that
provides
security**

Virtualization and adaptation of the standardization process. 73 Active Committees.
Access to users through various online platforms.

Creation of the **TSC for the attention of the Health Emergency (Covid-19)**.

36 Peruvian Technical Standards and Related Texts published in the framework of the Health Emergency for the sectors:

- **Health:** Surgical masks, respirators, mechanical ventilators, face shields, personal protective clothing, among others.
- **Management:** Risk management, resilience, remote audits, support to MIPYMES.
- **Tourism:** to implement sanitary protocols.

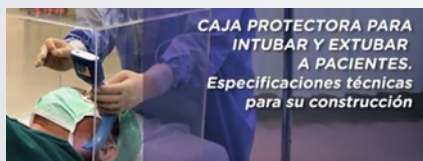
3 Published Guides: Cleaning and disinfection guide/Guide for MIPYMES in times of crisis/Guide for preventive measures for the return to work.

14 virtual events, 2 400 people in all regions of the country, sensitizing stakeholders and the general public on the best practices to implement preventive health measures and for the frontal fight against the pandemic.

MANAGEMENT IN THE FACE OF THE HEALTH EMERGENCY

➤ Produce relevant Technical Standards

HEALTH



SECTORIAL

Peruvian Technical Standards Finder



<https://www.inacal.gob.pe/cid/categoria/normas-tecnicas-peruanas>

Platform “Normas Libres”

A screenshot of the "Normas Libres" platform interface. It features the INACAL logo and the slogan "Perú, calidad que deja huella." The main heading is "INACAL pone a disposición de la ciudadanía y partes interesadas". Below this, there are two red buttons: "NORMA TÉCNICA PERUANA 231.141 TEJIDOS. Definiciones de los términos genéricos y tejidos básicos (descargar)" and "NORMA TÉCNICA PERUANA 231.400 TEXTILES. Etiquetado para prendas de vestir y ropa para el hogar (descargar)". A text block below explains that these standards are referenced in R.M. N° 135-2020-MINSA. The interface includes a search bar, a "Buscar" button, and a "Registrate" link for users without an account.

A screenshot of the "Normas Libres" platform interface showing a list of standards. It features the INACAL logo and the slogan "Perú, calidad que deja huella." The main heading is "INACAL pone a disposición de la ciudadanía y partes interesadas". Below this, there are two red buttons: "NORMA TÉCNICA PERUANA 231.141 TEJIDOS. Definiciones de los términos genéricos y tejidos básicos (descargar)" and "NORMA TÉCNICA PERUANA 231.400 TEXTILES. Etiquetado para prendas de vestir y ropa para el hogar (descargar)". A text block below explains that these standards are referenced in R.M. N° 135-2020-MINSA. The interface includes a search bar, a "Buscar" button, and a "Registrate" link for users without an account.

A screenshot of the "Normas Libres" platform interface showing a login form. It features the INACAL logo and the slogan "Perú, calidad que deja huella." The main heading is "Normas Libres: Módulo de lectura en línea de Normas Técnicas Peruanas". Below this, there is a sub-heading "Acceso al sistema". The form includes two input fields: "Ingrese email" and "Ingrese clave". A red "ACCEDER" button is located below the fields. A "Registrate" link is provided for users without an account.

Platform “Sala de Lecturas Virtual”

Virtual reading room of Peruvian Technical Standards



Reading of the total content of Peruvian Technical Standards for a period of 72 hours after free registration.



The adoptions of the Standards and related texts of the ISO and IEC are not found in this platform because they have intellectual property rights in conjunction with the international standardization organizations previously mentioned.



<https://salalecturavirtual.inacal.gob.pe:8098/>

Links of interest

PUBLICATIONS:

- Reading room link:

<https://salalecturavirtual.inacal.gob.pe:8098/>

- Free standards link:

<https://normaslibres.inacal.gob.pe:8095/>

- Virtual store:

https://tiendavirtual.inacal.gob.pe/0/home_tienda.aspx



NATIONAL INSTITUTE OF QUALITY

THANK YOU

SORAYA LASTRA

Executive of the Directorate of
Standardization

