ACCAB

Accreditation Commission For Conformity Assessment Bodies

# ACCAB Platinum Plus™ Accreditation

## For

## Certification Bodies, Inspection Bodies, Testing & Calibration Laboratories and Medical Laboratories


## A New Paradigm in the Global Conformity Assessment

ACCAB
Accreditation Commission For Conformity Assessment Bodies

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# INTRODUCTION TO ACCAB:

Accreditation Commission for Conformity Assessment Bodies (ACCAB) is an independent, International Accreditation Body (AB). It works to serve the global communities of businesses and consumers. ACCAB accredits appropriately qualified independent third party Conformity Assessment Bodies (CABs) such as Certification Bodies, Inspection Bodies, Testing & Calibration Laboratories and Medical Laboratories to ensure their competence to carry out specific tasks as per the International Standards & the Benchmarks. ACCAB Accreditation is voluntary in nature.

ACCAB is a trading name for Accreditation Commission For Conformity Assessment Bodies Private Limited. A company limited by shares established in terms of Companies Act, 1956, Republic of India.

ACCAB operates in accordance with the requirements, criteria, rules and regulations laid down in the following documents:

- The requirements of the international standard ISO/IEC 17011 – General requirements for bodies providing assessments and accreditation of conformity assessment bodies
- The requirements and other benchmarks as stipulated in the Publicly Available Documents (PAD) published by various international bodies and ACCAB
- Legally established objectives as per Memorandum & Articles of Association with the Ministry of Corporate Affairs

The Board of Director has overall authority and responsibilities for policies and procedures for the operations of ACCAB. The Board delegates to the Chief Executive Officer (CEO) of ACCAB the responsibility to implement the ACCAB policies and procedures. Accreditation Approval Committees make decisions concerning the granting and continuation of accreditation.

An independent Impartiality Committee representing the broad range of stakeholders reviews and adjudicates on possible conflicts of interest. The authority vested is ACCAB is that assigned to them by the Conformity Assessment Bodies and other Organization it accredits and recognizes by virtue of these applicant and accredited bodies pledging support for the mission and objectives of ACCAB and ensuring that their actions are according to that policy. It is an independent, impartial and non-governmental body and makes no claim to be connected with any government.

ACCAB is an Affiliate Member of International Laboratory Accreditation Cooperation (ILAC) www.ilac.org - is an international cooperation of laboratory and inspection accreditation bodies formed more than 30 years ago to help remove technical barriers to trade.

ACCAB has specific permissions from International Organization for Standardization (ISO), International Laboratory Accreditation Cooperation (ILAC), International Accreditation Forum (IAF) to use their publications / documents / guidelines for the benefit of its Applicant and Accredited Conformity Assessment Bodies.

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## Vision

Our vision is to serve global communities of businesses and consumers. We shall accomplish our vision through the successful implementation of an Accreditation System for Conformity Assessment Bodies and Further Education & Training Institutions that are responsible, responsive, recognized to demonstrate that their business critical processes are competent, professional and ethical resulting in value addition to our stakeholders.

## Mission

To promote advancement of SQAM (Standardization, Quality, and Accreditation & Metrology), which protect the interest of the Global Communities of Businesses & Consumers.


## Quality Policy

- We are committed to provide distinguished and excellent accreditation services globally to the conformity assessment and further education sector
- We shall continually improve the effectiveness of the quality system within the confines of the international standard ISO 17011:2017
- We shall safeguard the integrity, objectivity and impartiality of our accreditation services
- We shall operate within the spirit of all relevant legislations
- Our goal is to serve Global Communities of Businesses and Consumers at all the time

## We Are What We do

- We are an independent, impartial and non-governmental accreditation body
- We consider accreditation as technical trade support activity
- We are responsive to the needs and expectations of our Stakeholders
- We are transparent in our dealings
- We have clarity on the technical approach to the accreditation
- We are open to and accept multiple points of view
- We endeavor to provide differentiated solutions in a cost effective manner

## International Organization for Standardization (ISO)

ISO is a global network that recognizes as to which international standard will be required by business, society, government – develops them and adopts them by the use of transparent procedure in order to be implemented worldwide. It is a federation of national standard bodies amongst various countries, one per country.

## International Standards

According to ISO/IEC Guide 2:2004 Standardization and related activities – General vocabulary, standard is a document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

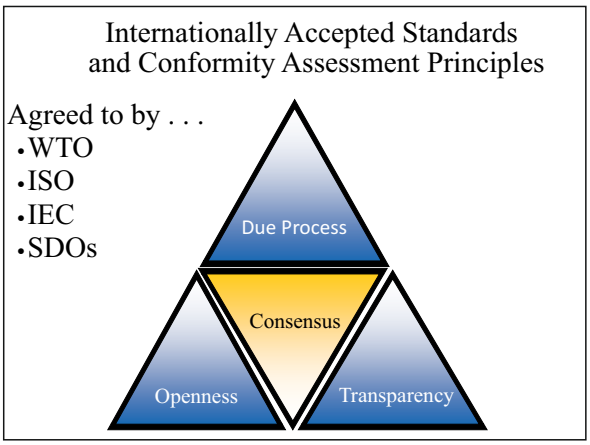
- Standards help to make life simpler and to increase the reliability and the effectiveness of many goods and services we use
- Standards are created by bringing together the experience and expertise of all interested parties such as the producers, sellers, buyers, users and regulators of a particular material, product, process or service
- Standards are designed for voluntary use and do not impose any regulations. However, laws and regulations may refer to certain standards and make compliance with them compulsory
- Voluntary Standards become mandatory only when they are incorporated into contracts or they are referenced or adopted by government agencies as part of a regulation to protect public health, safety, and the environment
- The difference between a standard and a technical regulation lies in compliance. While conformity with standards is voluntary, technical regulations are by nature mandatory

## Conformity Assessment

The process of demonstrating the essential features about a product or services which meet the requirement of standards, regulations and other specification is called conformity assessment. A variety of PROCESSES involved in verifying that goods/services meet acceptable voluntary or mandatory standards such as Testing , Surveillance, Inspection, Assessment, Auditing, Certification and Registration.

Objectives of Conformity Assessment are to:

- Ensure the conformance of products/services with relevant standards (ISO, IEC/BIS etc)
- Encourage international trade (attempts to check trade malpractices)
- Prevent sale of substandard/unsafe product
- Prevent importation of substandard products
- Save lives and property
- Prevent pollution of air and water
- Conserve hard-earned foreign exchange

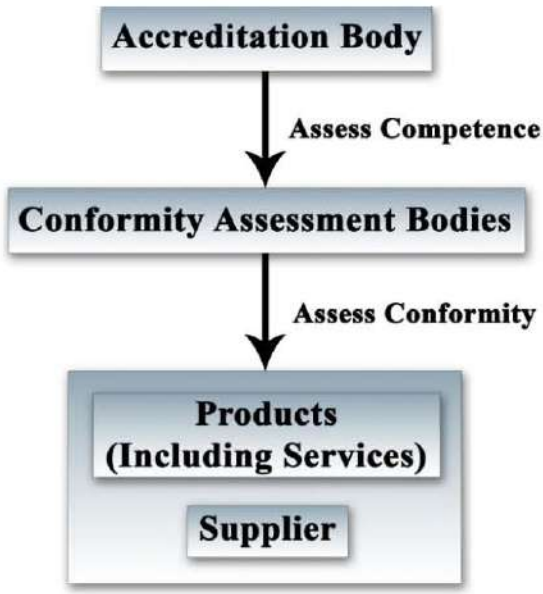


## International Organization for Standardization (ISO)

International Organization for Standardization (ISO) states that "ISO itself has no authority to control conformity assessment activities, whether these are business activities by its members or by other organizations". Further, International Organization for Standardization (ISO) states that "private sector organizations may perform conformity assessment services as a commercial activity or regulatory bodies under a mandate may perform these services when ISO standards have been incorporated into public legislation, the aim of which is to create confidence among suppliers and their clients."

## Accreditation

It is a formal recognition by an independent body, generally known as an accreditation body, certifies Conformity Assessment Body to be capable and competent. Accreditation is not obligatory but it adds another level of confidence, as 'Accredited' means the Conformity Assessment Body has been independently checked to make sure it operates according to international standards.




Accreditation bodies assess the competence of CABs. They can facilitate trade by promoting global acceptance of conformity assessment results issued by accredited CABs. This is strengthened if they are pre-evaluated and are members of mutual recognition arrangements among the accreditation bodies.

CABs assess conformity of products, services and suppliers to specifications and/or requirements.

Purchasers acquire products (including services) that conform to specifications or buy from suppliers that conform to specific requirements. Regulators may set requirements for products and suppliers.

**ISO/IEC 17011:2017(E)**

# ACCAB PLATINUM PLUS™ ACCREDITATION SERVICES:

## ACCAB Accreditation Scheme for the Management Systems Certification Bodies:

ISO/IEC 17021-1:2015- Conformity Assessment - Requirements for Bodies Providing Audit and Certification of Management Systems for Quality Management Systems ISO 9001, Environmental Management Systems ISO 14001, Occupational Health & Safety Management Systems OHSAS 18001, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes ISO 13485, HACCP Based Food Safety Management Systems ISO 22000, Information Security Management Systems ISO 27001 Information Technology Services Management System ISO 20000 Security Management System for Supply Chain ISO 28000, Energy Management System ISO 50001, Ship Recycling Management System ISO 30000, GHG- Verifiers etc.

ACCAB Platinum Plus™ Accreditation requires that Certification Bodies for the Management Systems conform to the most recent versions of the following International Standards as applicable:

a. ISO/IEC 17021-1:2015 Conformity Assessment - Requirements for Bodies Providing Audit and Certification of Management Systems
b. ISO/TS 22003:2013 - Food Safety Management Systems – Requirements for bodies providing audit and certification of food safety management systems
c. ISO/IEC 27006:2015 -Information Technology -- Security Techniques -- Requirements for bodies providing audit and certification of information security management systems
d. ISO 28003:2007- Security Management Systems for The Supply Chain – Requirements for bodies providing audit and certification of supply chain security management systems
e. ISO 30003:2009-Ships & Marine Technology – Ship Recycling Management System - Requirements for bodies providing audit & certification for ship recycling management
f. ISO 14065:2013 Green House Gases - Requirements for green house gas validation & verification bodies for using accreditation or other forms of recognition
g. ISO 19011:2011- Guidelines for Auditing Management Systems
h. Relevant ACCAB Accreditation Requirements

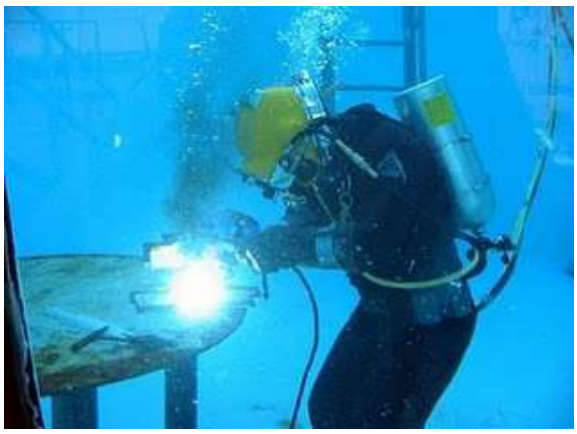
## ACCAB Accreditation Scheme for Product Certification Bodies:

ISO/IEC 17065:2012 Conformity Assessment- requirements for bodies certifying products, process & services (or EN 45011 as it is known in its European version) is for those certification bodies that require demonstrating their competence to certain regulatory authorities. ISO/IEC 17065:2012 accreditation is to be performed against a reference standard or standards. The reference standard may be the production and processing standards of a national regulation (often a national standard) but may also be your own or another organization's private standard.

ACCAB Platinum Plus ™ Accreditation requires that the Product Certification Bodies must conform to the most recent version of the following standards:

a. ISO/IEC 17065:2012 Conformity Assessment - Requirements for bodies certifying products, processes & services
b. Demonstrated Technical Competence specific to the field in which product certification is done
c. Relevant ACCAB Accreditation Requirements

## ACCAB Accreditation Scheme for Bodies Operating Certification of Persons:



ISO/IEC 17024:2012 Conformity assessment – General requirements for bodies operating certification of persons. This standard provides a benchmark for certification bodies offering certification of individuals applicable to any occupation.

ACCAB Platinum Plus™ Accreditation requires that the Certification Bodies must conform to the most recent version of the following standards:

a. ISO/IEC 17024:2003 Conformity assessment – General requirements for bodies operating certification of persons
b. Relevant ACCAB Accreditation Requirements

## ACCAB Accreditation Scheme for Inspection Bodies

ISO/IEC 17020:2012 "General Criteria for the Operation of Various Types of Bodies Performing Inspection" is an internationally recognized standard for the competence of the inspection bodies. Many people confuse ISO 17020 with ISO 9001, which is a generic quality management system. ISO 17020 requires evaluation of the technical competence of an inspection body.

ACCAB Accreditation requires that Inspection Bodies must conform to the most recent version of the following standards:

a. ISO 17020:2012- General Criteria for the Operation of Various Types of Bodies Performing Inspection
b. Demonstrated Technical Competence specific to the field in which inspection is done
c. The ACCAB Accreditation Scheme Manual

## ACCAB Accreditation Scheme for Testing & Calibration Laboratories

ISO/IEC 17025:2017 standard is mainly used by testing and calibration laboratories, initially known as ISO/IEC Guide 25, though there are many commonalities with requirements and it applies directly to those organizations that produce testing and calibration results/certificates.

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an Accreditation Body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence. It is a mistaken belief that ISO 17025 accreditation is government controlled.

ACCAB 17025 Platinum Plus™ Accreditation requires that the Testing and Calibration Laboratories must conform to the most recent version of the following standards:

1. ISO/IEC 17025:2017 - General requirements for the competence of Testing and Calibration Laboratories
2. Demonstrated Technical Competence specific to the field in which Testing / Calibration is performed
3. Any additional requirements established by ACCAB from time to time

# ACCAB Accreditation Scheme for Medical Laboratories

With the ACCAB 15189 Platinum Plus™ Accreditation your laboratory will standardize processes to an international quality benchmark addressing patient care and safety, engaging staff through teamwork and by maximizing the resources.

This ISO 15189-based accreditation program for medical laboratories will demonstrate your commitment to quality and excellence. Labs that achieve accreditation implement a quality management system based on a documented quality system in order to identify and correct unobvious errors and improve patient safety.

Laboratories use ISO 15189 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an Accreditation Body, since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence. It is a mistaken belief that ISO 15189 accreditation is government-controlled.

ISO 15189:2012 which defines particular requirements for the quality and competence of medical laboratories.

It may be noted that the medical laboratories accredited to ISO 15189:2012(sector specific technical competence and management system standard) are recognized as meeting the management system principles of ISO 9001:2015.

Medical laboratories services are essential to patient care and include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in the laboratory.

ACCAB 15189 Platinum Plus™ Accreditation requires that the Medical Laboratories must conform to the most recent version of the following standards:

1. ISO 15189:2012 Medical Laboratories, particular requirements for quality and competence
2. Demonstrated Technical Competence specific to the field in which Testing is performed
3. Any additional requirements established by ACCAB from time to time

# ACCAB Accreditation Scheme for Good Laboratory Practice (GLP)

The Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

Non-clinical health and environmental safety studies covered by the principles of GLP include work conducted in the laboratories, in greenhouses, and in the field.

GLP principles are applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives and industrial chemicals.

Key Features & Advantages:

- May be useful to the Industries or Laboratories who are dealing in the aforementioned chemicals
- GLP embodies a set of principles that provides a framework within which laboratory studies are planned performed, monitored, reported and archived
- GLP makes sure that the data submitted is a true reflection of the results that are obtained during the study
- GLP makes sure that data is traceable
- GLP promotes the quality and validity of test data used for determining the safety of chemicals and chemical products
- GLP promotes international acceptance of tests

The main duty of GLP monitoring authority is to monitor compliance with GLP Principles by conducting laboratory inspections and study audits. However, in many countries GLP-compliance is voluntary in nature.

ACCAB GLP Platinum Plus™ Accreditation is independently delivered service requires that the Laboratory must conform to the most recent version of following Standards/International Documents:

1. OECD Principles on Good Laboratory Practice
2. Any additional requirements established by ACCAB from time to time

## ACCAB PLATINUM PLUS™ ACCREDITATION SERVICES:

## ACCAB Accreditation Scheme for Good Clinical Practice (GCP)

International Conference on Harmonization (ICH)'s Good Clinical Practices (GCP) is an ethical and scientific quality standard for designing, conducting and recording trials that involve the participation of human subjects. Good Clinical Practice Guidelines include standards on how clinical trials should be conducted, define the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors. Compliance with this standard provides assurance to public that the rights, safety and well being of trial subjects are protected and ensures that the clinical trial data is credible. It also provides assurance of the safety and efficacy of the newly developed compounds.

ACCAB GCP Accreditation is independently delivered service requires that the Clinical Research Organization must conform to the most recent version of International Conference on Harmonization (ICH)'s Good Clinical Practice Guidelines.

## ACCAB Scheme for Bespoke Accreditation

Traditionally industry, trade, business, and professional associations as well as chambers of commerce have played and will continue to play a significant role as a critical link between entrepreneurs and the government. The contributions of these various associations thought to be immense in terms of securing the general acceptance of industry standards, encouraging and enforcing codes of ethics, and increasing the economic welfare of members and individuals. Same is the case with the Conformity Assessment Bodies who wish to offer conformity assessment services where an established Standard / Guide is not available. In order to satisfy these requirements, ACCAB, in consultation with the Technical Advisory Committee will decide on the suitable accreditation criteria keeping the relevant stakeholders interest in mind.

## ACCAB Accreditation Process:

ACCAB

Accreditation Commission For Conformity Assessment Bodies

## Contact Us For Further Details

**Accreditation Commission For Conformity Assessment bodies Private Limited**

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