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ISO Certification for Laboratories and Faecal Sludge Management

Authors: Arvind Singh Senger

Research support: Megha Tyagi, Ashitha Gopinath, Kalyana Chakravarth Sama, Saumya and Vinod Vijayan

Editor: Akshat Jain

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41, Tughlakabad Institutional Area
New Delhi 110062
Phones: 91-11-40616000
Fax: 91-11-29955879
E-mail: sales@cseinida.org
Website: www.cseindia.org

ISO Certification for Laboratories and Faecal Sludge Management

ISO standards are a set of internationally recognized standards that were created to help companies establish homogeneity in management, provision of services and product development in their industries.

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from more than 160 countries, with one standards body representing each member country. ISO is a non-governmental organization established in 1947 and based in Geneva. Its mission is to promote standardization to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activities. ISO's work results in international agreements which are published as International Standards and other types of ISO deliverables.

The rules that govern the work procedures of ISO and the International Electrotechnical Commission (IEC) are formally laid down in a set of ISO/IEC Directives. Along with several related guidance documents, these directives are designed to ensure transparency and fairness in international standards development. They also allow for all interested stakeholders to have a voice through their national standards body representatives in ISO.

The American National Standards Institute (**ANSI**) empowers its members and constituents to strengthen the market position of the US in the global economy while helping to assure the safety and health of consumers and the protection of the environment. ANSI is the sole US representative and full dues-paying member of ISO. As a founding member, it plays an active role in ISO's governance and technical work. Through ANSI, the US has immediate access to the development processes of ISO standards. ANSI currently participates in 79 per cent of all active ISO technical committees and holds the international secretariat position in 15 per cent of those committees. Secretariats provide policy guidance, project and administrative management, and strategic leadership to enable the work of ISO technical committees to progress.

The International Laboratory Accreditation Cooperation (**ILAC**) started as a conference in 1977 to develop international cooperation for facilitating trade by promoting the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of mutual recognition agreements among accreditation bodies that would fulfill this aim. The ultimate aim of ILAC is increased use and acceptance of results from accredited laboratories by industries as well as governments, including results from laboratories in other countries. In this way, the free-trade goal of a 'product tested once and accepted everywhere' can be realized.

Good laboratory practice (GLP), in the experimental (non-clinical) research arena, is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of products or results. GLP was first introduced in New Zealand and Denmark in 1972. It was instituted in the US following cases of fraud committed by toxicology labs in data submitted to the FDA by pharmaceutical companies. Industrial BioTest Labs (IBT) was the most notable case, where thousands of safety tests for chemical manufacturers were falsely claimed to have been performed. These issues were made public in the hearings at the US Congress, which led to the United States Food and Drug Administration (FDA)'s publication of Proposed Regulations on GLP in 1976. The Environmental Protection Agency (EPA) had also encountered similar problems in data submitted to it, and issued its own draft GLP regulations in 1979 and 1980. GLP is a quality system concerned with the organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. It was followed a few years later by the Organization for Economic Co-operation and Development (OECD) Principles of GLP in 1982/ 1992/ 1998; the OECD has since helped promulgate GLP to many countries.

Available certifications and standards for laboratories

1. ISO 9001:2015; Standard for Quality Management

Scope: This is a globally recognized standard for quality management. It helps organizations of all sizes and sectors to improve their performance, meet customer expectations and demonstrate their commitment to quality. Its requirements define how to establish, implement, maintain, and continually improve a quality management system (QMS). Implementing ISO 9001 means the organization has put in place effective processes and trained staff to deliver flawless products or services time after time.

What are the benefits of ISO 9001?

- Customer confidence: The standard ensures that organizations have robust quality control processes for services in place, leading to increased customer trust and satisfaction.
- Effective complaint resolution: ISO 9001 offers guidelines for resolving customer complaints efficiently, contributing to timely and satisfactory problem-solving.
- Process improvement: The standard helps identify and eliminate inefficiencies, reduce waste, streamline operations, and promote informed decision-making, resulting in cost savings and better outcomes.

- Ongoing optimization: Regular audits and reviews encouraged by ISO 9001 enable organizations to continually refine their quality management systems, stay competitive and achieve long-term success.
- Providing products and services that consistently meet the needs of customers
- Enhancing customer satisfaction through a process of continual improvement

Accreditation agencies: Swisscert India and Bureau Veritas India

2. ISO 15189:2022; Medical laboratories, requirements for quality and competence

Scope: This applies to medical laboratories in developing their management systems and assessing their competence. It is also applicable for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.

Accreditation agencies: NABL and QAI, India

NABL: National Accreditation Board for Testing and Calibration Laboratories under Ministry of Commerce and Industry (govt. body), Gurugram

QAI CIA: Quality & Accreditation Institute, Centre for International Accreditation (private organization), Noida

» SEARCH RESULT: SIGNATORIES TO THE ILAC MUTUAL RECOGNITION ARRANGEMENT

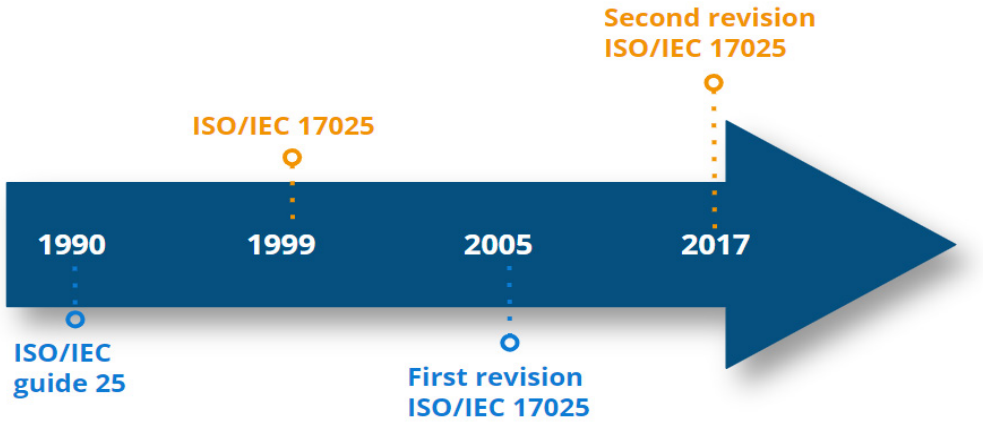
Name	Economy	Scope	Original Signing Date	Website & Accredited Facilities
QAI CIA Quality and Accreditation Institute, Centre for International Accreditation	INDIA	Testing: ISO/IEC 17025 Medical Testing: ISO 15189	10 Dec 2022 10 Dec 2022	Website

3. ISO/IEC 17025:2017; General requirements for the competence of testing and calibration laboratories

Scope: ISO/IEC enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. It also helps facilitate cooperation between

laboratories and other bodies by generating wider acceptance of results between countries. Test reports and certificates can be accepted from one country to another without the need for further testing, which, in turn, improves international trade.

ISO 17025 provides the "*General requirements for the competence of testing and calibration laboratories*". This standard can be applied in all laboratories and it specifies the requirements of their practices to raise confidence in their ability to provide reliable and valid testing, calibration and sampling results.



What are the benefits of 17025?

- Better reputation and enhanced client confidence: The ISO 17025 standard is internationally recognized. It shows that a laboratory is operating successfully and providing valuable results, efficiently and effectively. It shows that the laboratory operates with high levels of confidentiality and impartiality, which attracts a lot of clients and promotes confidence in the brand image.

- Constant improvement of activities and documentation: Constantly improving system processes and protocols, while adopting a risk-based approach drives laboratories to always find the most economical ways to improve their activities.

Accreditation agencies: NABL, QAI and FDAS, India

NABL: National Accreditation Board for Testing and Calibration Laboratories under Ministry of Commerce and Industry (govt. body), Gurugram

QAI CIA: Quality & Accreditation Institute, Centre for International Accreditation (private organization), Noida

FDAS: Federation for Development of Accreditation Services (non-profit organization), Gurugram

» SEARCH RESULT: SIGNATORIES TO THE ILAC MUTUAL RECOGNITION ARRANGEMENT

Name	Economy	Scope	Original Signing Date	Website & Accredited Facilities
QAI CIA Quality and Accreditation Institute, Centre for International Accreditation	INDIA	Testing: ISO/IEC 17025 Medical Testing: ISO 15189	10 Dec 2022 10 Dec 2022	Website

» SEARCH RESULT: SIGNATORIES TO THE ILAC MUTUAL RECOGNITION ARRANGEMENT

Name	Economy	Scope	Original Signing Date	Website & Accredited Facilities
FDAS Federation for Development of Accreditation Services	INDIA	Calibration: ISO/IEC 17025 Testing: ISO/IEC 17025	28 Aug 2023 28 Aug 2023	Website

4. ISO/IEC 17043:2023; Conformity assessment — General requirements for the competence of proficiency testing providers

Scope: This standard specifies general requirements for the competence and impartiality of proficiency testing (PT) providers and consistent operation of all PT schemes.

PT is widely recognized as an essential tool for demonstrating the competence of conformity assessment bodies. PT can provide evidence of competence and it can be an indicator of an underlying or emerging problem. This standard is intended to promote confidence in the operations of PT providers. It contains requirements for PT providers to enable them to demonstrate that they operate competently and can generate valid evaluations of participant performance. PT involves the use of interlaboratory comparisons for the evaluation of laboratory performance.

Accreditation agency: NABL, India
NABL: National Accreditation Board for Testing and Calibration Laboratories under Ministry of Commerce and Industry (govt. body), Gurugram

5. Implementation of Good Clinical Laboratory Principles (GCLP) or Good Laboratory Principles (GLP)

All laboratories engaged in testing of biological/environmental samples need to establish confidence in the quality and reliability of the results of these tests. These expectations are fulfilled by following GLP/GCLP principles, which define a quality system concerned with the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, reported and archived. It is intended to promote quality test data.

There are many benefits to laboratories that are GCLP/GLP compliant. The primary benefits include:

- Laboratory results (research) that are reliable, reproducible and auditable
- Incidences of false negatives and false positives are reduced
- Results are assured to be of the highest quality
- Results are comparable to those obtained in other compliant laboratories around the world.
- Building the confidence of staff, sponsors and clients
- Resources are efficiently managed, therefore minimizing waste
- Uniformity and standardization of systems

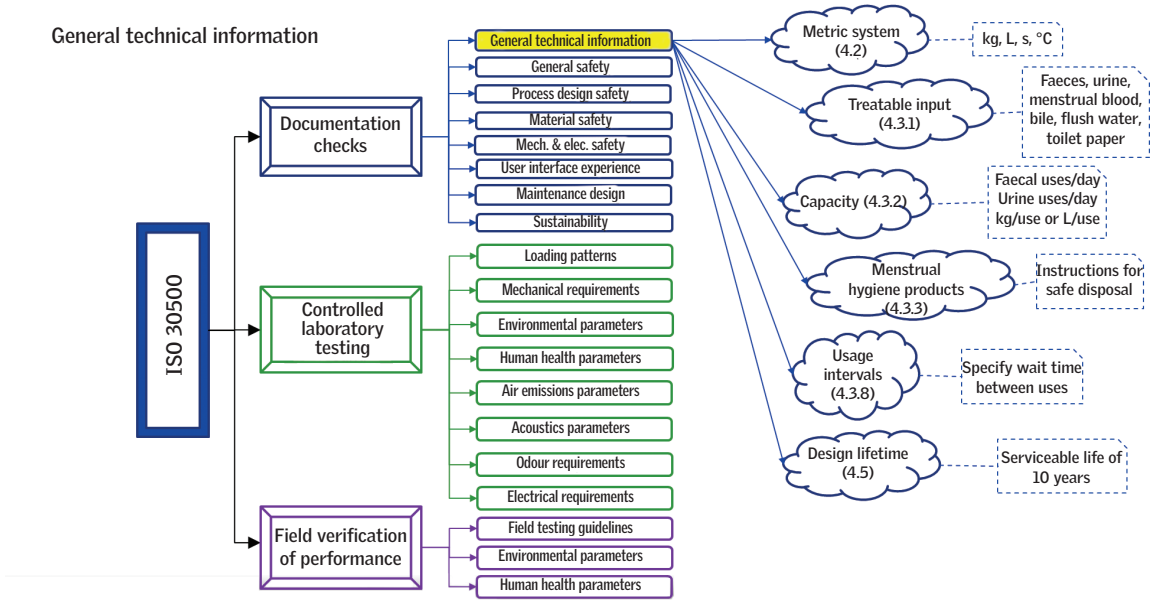
Accreditation agency: None/Not required

Available certifications and standards for faecal sludge management

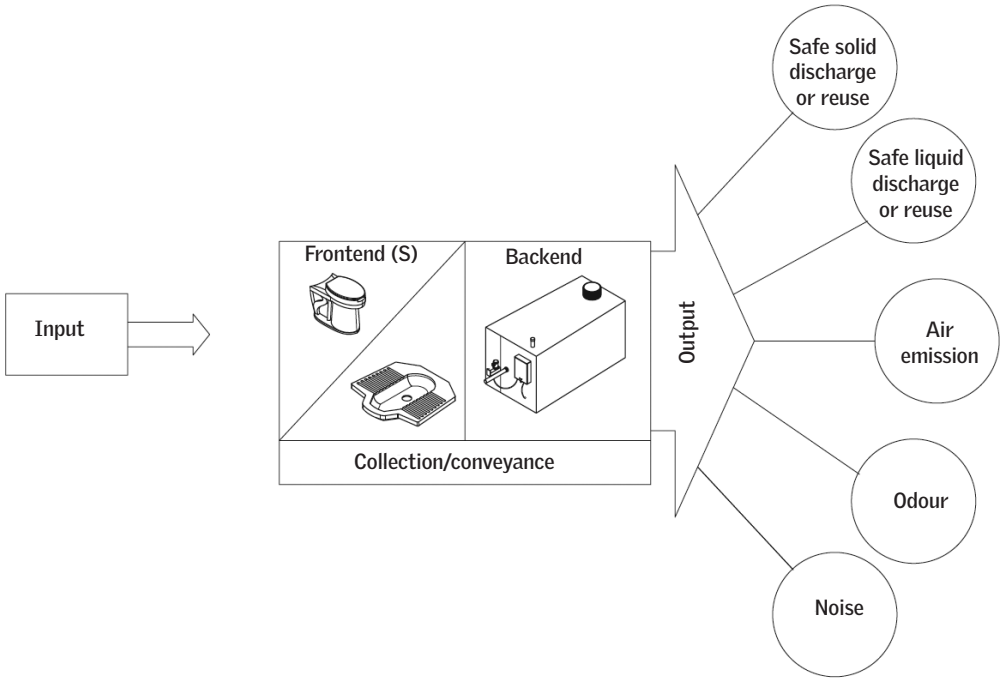
1. ISO 30500:2018; Non-sewered sanitation systems — Prefabricated integrated treatment units — General safety and performance requirements for design and testing

Scope: This specifies general safety and performance requirements for design and testing, as well as sustainability considerations for non-sewered sanitation systems (NSSS). A NSSS, for this document, is a prefabricated integrated treatment unit, comprising frontend (toilet facility) and backend (treatment facility) components that;

- Collects, conveys, and fully treats the specific input within the system, to allow for safe reuse or disposal of the generated solid, liquid, and gaseous output; and
- Is not connected to a networked sewer or networked drainage system.



Source: https://sanitation.ansi.org/Standard/ISO30500



Source: https://sanitation.ansi.org/Standard/ISO30500

Why is ISO 30500 certification important?

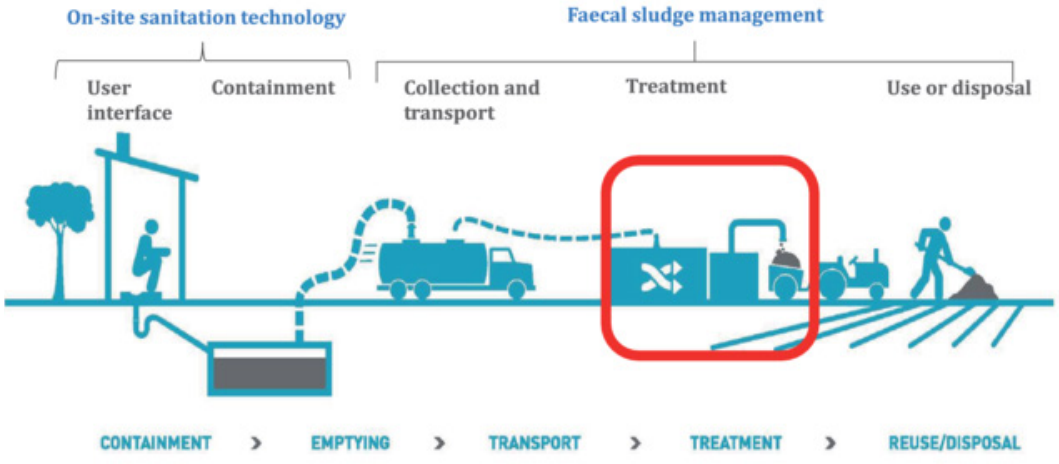
Having a system that is certified ISO 30500 will increase the market penetration of a given product. Certifying systems with ISO 30500 ensures that they are safe for human health and the environment, with robust and reliable performance. Furthermore, it will give these systems global reach. This allows these systems to be developed at scale and sold at mass.

Accreditation agency: TUV SUD

2. ISO 31800:2020: Faecal sludge treatment units — Energy independent, prefabricated, community-scale, resource recovery units — Safety and performance requirements

Scope: This specifies requirements and test methods to ensure performance, safety, operability and maintainability of community-scale resource recovery faecal sludge treatment units (herein addressed as treatment units) that serve approximately, but are not limited to, 1,000–100,000 people. It contains criteria for the functionality, usability, reliability, maintainability and safety of faecal sludge treatment units which:

- Primarily treat faecal sludge;
- Can operate in non-sewered and off-grid environments;
- Are prefabricated, exhibit resource recovery capability (e.g. recovering energy, reusable water, soil amendment products), and are capable of being energy neutral or energy net positive.



Note: The focus of this document is treatment (as despicted in the red box).

Source: https://sanitation.ansi.org/Standard/ISOPC318

The focus of this technical document on non-sewered faecal sludge treatment units is represented by the red box along the sanitation value chain in the above figure, indicating the treatment components of faecal sludge management. The standard aims to facilitate the commercialization and transfer of these treatment units into the market.

What are the benefits of ISO 31800?

- Manufacturers can seek assurance that their prefabricated faecal sludge treatment units are compliant with the requirements in the standard.
- Regulators can use ISO 31800 to develop sound regulations as ISO 31800 was developed using best practices and reflects a consensus of manufacturers, regulators and scientific experts.
- Governments, regulators and operators can be assured that the pre-fabricated treatment units manufactured by the standard can contribute to the protection of public and environmental health.

Accreditation agency: TUV SUD

3. ISO 24521:2016; Activities relating to drinking water and wastewater services — Guidelines for the management of basic on-site domestic wastewater services

Scope: This is an international management standard, written from an operator's perspective. It guides the management of basic on-site domestic wastewater services, using appropriate technologies in their entirety at any level of development. The standard includes guidance for maintenance techniques, training of personnel and risk considerations; user perspectives; guidance on the design and construction of basic on-site domestic wastewater systems; and guidance on planning, operation and maintenance, and health and safety issues. ISO 24521 applies to both publicly and privately operated basic on-site domestic wastewater (black and grey water) services for single and multiple dwellings.

ISO 24521 and ISO 30500 work hand-in-hand to improve health, reduce the environmental impact of wastewater treatment, and offer affordable options for users and communities. Whereas ISO 24521 optimizes existing wastewater services, the publication of ISO 30500 encourages the development of new technologies and solutions as current technologies are failing to address underlying challenges behind the lack of sanitation, including poverty, infrastructure and resources. National standards bodies should consider reviewing and nationally adopting ISO 30500 and ISO 24521 simultaneously.

Accreditation agency: Swisscert, India

4. ISO 24511:2007; Activities relating to drinking water and wastewater services — Guidelines for the management of wastewater utilities and for the assessment of wastewater services

Scope: This applies to publicly and privately owned and operated wastewater utilities but does not favour any particular ownership or operational model. Wastewater is always generated when water is used or consumed. Accordingly, sources of wastewater can be residential, industrial, commercial and institutional. Collected stormwater or (melted) snow can also be considered wastewater, as it often carries contaminants and pathogens picked up from air or ground surfaces on its way to a collection system. In certain circumstances, especially in underdeveloped areas, sanitary waste is collected in an undiluted form. This standard addresses wastewater systems in their entirety and applies to systems at any level of development (e.g. pit latrines, on-site systems, networks, treatment facilities).

Accreditation agency: Swisscert, India

References

1. Guidelines for Good Clinical Laboratory Practices (GCLP), Indian Council of Medical Research, New Delhi.

2. OECD Principles on Good Laboratory Practice

3. ISO 9001; Quality management systems — Requirements

4. ISO/IEC 17025; General requirements for the competence of testing and calibration laboratories.

5. ISO 24521; Activities relating to drinking water and wastewater services — Guidelines for the management of basic on-site domestic wastewater services.

6. ISO 24511; Activities relating to drinking water and wastewater services — Guidelines for the management of wastewater utilities and for the assessment of wastewater services.

7. ISO 30500; Non-sewered sanitation systems — Prefabricated integrated treatment units- General safety and performance requirements for design and testing.

8. ISO 31800; Faecal sludge treatment units — Energy independent, prefabricated, community-scale, resource recovery units — Safety and performance requirements.

9. ISO 15189; Medical laboratories, Requirements for quality and competence

Centre for Science and Environment
41, Tughlakabad Institutional Area, New Delhi 110 062
Phones: 91-11-40616000 Fax: 91-11-29955879
E-mail: subhasish.parida@cseindia.org Website: www.cseindia.org