Indian Standards on Medical Devices & Hospital Planning

MEDICAL DEVICES FOR CLINICAL EXAMINATION

- **IS 3390 : 1988- Specification for sphygmomanometers mercurial**

Standard lays down the requirements for mercurial sphygmomanometers used for measuring arterial blood pressure in human beings.

IS/IEC 80601 (Part 2 / Sec 30) : 2018 Medical electrical equipment Part 2 - 30 particular requirements for basic safety and essential performance of automated non - Invasive **sphygmomanometers**

- **IS 3391 : 1965- Specification for stethoscopes**

Standard lays down the requirements for binaural stethoscopes used for the detection and study of sounds arising within the human or animal body. It does not cover special stethoscopes such as multiple lead diaphragm ones or those with extra chest pieces used for demonstration purposes.

MEDICAL DEVICES FOR CLINICAL EXAMINATION *contd*

- **ISO 15197 : 2013 In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (First revision)**

Specifies requirements for *in vitro* glucose monitoring systems intended for self-measurement by lay persons for management of diabetes mellitus

- **IS 17407 : 2020 – Digital Otoscope – Handheld type**

Standard provides general functional requirements of an otoscope that is digital, handheld type, portable, battery operated and has a display screen with suitable software to capture store and transfer images to examine the external auditory canal and the tympanic membrane of human ear.

ANAESTHETIC & RESUSCITATION DEVICES

Ventilators

IS/ISO 80601-2-12 : 2011 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

Specifies basic safety and essential performance of a ventilator in combination with its accessories.

IS/ISO 10651-3 : 1997 Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators

Specifies requirements for portable lung ventilators designed for use in emergency situations and transport.

IS/ISO 10651-4 : 2002 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators

Specifies requirements for operator-powered resuscitators intended for use with all age groups and which are portable and intended to provide lung ventilation to individuals whose breathing is inadequate

ANAESTHETIC & RESUSCITATION DEVICES *contd*

Ventilators

IS/ISO 10651-5 : 2006 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators

Specifies the basic safety and essential performance requirements for gas-powered emergency resuscitators intended for use with humans by first responders.

IS/ISO 10651-6 : 2004 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices

Specifies the basic safety and essential performance requirements for home-care ventilator support devices, intended mainly for use in home care.

Suction Apparatus

IS/ISO 10079 Part 2 : 2014 Medical Suction Equipment Part 2 Manually Powered Suction Equipment

Specifies safety and performance requirements for manually powered suction equipment intended for oro-pharyngeal suction. It applies to equipment operated by foot or by hand or both

CARDIOVASCULAR MEDICAL DEVICES

- **IS/ISO 25539-2:2012 Cardiovascular implants — Endovascular devices — Part 2: Vascular stents**

Provides requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

- **IS 11566 : 1986 Specification for valve retractors**

Specifies material, dimensions and other requirements for valve retractor: Jsed in cardiovascular surgery

- **ISO 7199 : 2016 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)**

specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans.

OPHTHALMIC IMPLANTS

Intraocular Lenses (Iol)

IS/ISO 11979 : Part 2:1999 Ophthalmic implants - Intraocular lenses: Part 2 optical properties and test methods

Applicable but not limited to non-toric, monofocal IOLs intended for implantation into the anterior segment of the human eye

IS/ISO 11979 : Part 3:2006 Ophthalmic implants - Intraocular lenses: Part 3 mechanical properties and test methods

Applicable to all types of IOLs intended for implantation in the anterior segment of the human eye.

IS/ISO 11979 : Part 5:2006 Ophthalmic implants - Intraocular lenses: Part 5 biocompatibility

Applicable to any IOL whose primary indication is the correction of aphakia.

IS/ISO 11979 : PART 6:2014: Ophthalmic implants - Intraocular lenses: Part 6 shelf - Life and transport stability testing

Specifies tests by which the shelf-life of sterile IOLs in their final packaging can be determined.

OPHTHALMIC IMPLANTS

Intraocular Lenses (Iol)

IS/ISO 11979 : PART 7:2006 Ophthalmic implants - Intraocular lenses: Part 7 clinical investigations

Specifies particular requirements for clinical investigations for posterior and anterior chamber monofocal IOLs for the correction of aphakia & far distance.

IS/ISO 11979 : PART 8:2006 Ophthalmic implants - Intraocular lenses: Part 8 fundamental requirements

Specifies fundamental requirements for all types of IOLs excluding corneal implants and transplants.

IS/ISO 11979 : Part 9:2006 Ophthalmic Implants - Intraocular Lenses: Part 9 Multifocal Intraocular Lenses

Applicable to any IOL primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. far and near).

IS/ISO 11979 : Part 10:2006 Ophthalmic implants - Intraocular lenses: Part 10 phakic intraocular lenses

Addresses specific requirements for PIOLs not addressed in the other parts of IS/ISO 11979.

ORTHOPAEDIC MEDICAL DEVICES

- **IS/ISO 21534 : 2007 Non-active surgical implants — Joint replacement implants — Particular requirements**
- specifies particular requirements for total and partial joint replacement implants, artificial ligaments and bone cement, hereafter referred to as implants
- **IS/ISO 21535 : 2007 Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants**
- provides specific requirements for hip joint replacement implants e.g. for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer, and methods of test.
- **IS/ISO 21536 : 2007 Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants**
- provides specific requirements for knee joint replacement implants e.g. for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer, and methods of test.

DENTISTRY

- **IS 6116 (Part 1): 2021 Dentistry stationary dental units and dental patient chair – Part (1) General requirements**

Specifies requirements, test methods and details of marking for dental patient chairs and applies to all such chairs, regardless of their construction and also regardless of whether they are electrically powered or not.

- **IS/ISO 24234 : 2015 ISO 24234 :2015 Dentistry - Dental amalgam**

Specifies the requirements and test methods for dental amalgam alloys that are suitable for the preparation of dental amalgam, together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking (including those for dental mercury).

ELECTRICAL CLINICAL THERMOMETER & SCREENING THERMOGRAPH

IS/ISO 80601-2-56 : 2017 Medical electrical equipment : Part 2 particular requirements for basic safety and essential performance, Section 56 Clinical thermometers for body temperature measurement

Specifies requirements for basic safety and essential performance of all electrical clinical thermometers used for measuring the body temperature of patients.

IS/IEC 80601(Part 2/Sec 59) :2017 Medical Electrical Equipment : Part 2 Particular Requirements for the Basic Safety and Essential Performance, Section 59 Screening thermographs for human febrile temperature screening

Specifies requirements for basic safety and essential performance of screening thermographs intended to be used for the individual non-invasive febrile temperature screening of a human under controlled environmental condition

IMPORTANT UTILITY ITEMS FOR MEDICAL USE

Face Masks

IS 9473:2002 Respiratory protective devices - Filtering half masks to protect against particles

Specifies requirements and method of sampling and tests for filtering half masks as respiratory protective devices against particles except for escape purposes (N 95 type).

IS 16289:2014 Medical Textiles — Surgical Face Masks – Specification

Specifies the performance requirements and test methods of surgical face masks intended to limit the transmission of infective agents from staff to patients and (in certain situations) vice-versa during surgical procedures in operating theatres and other healthcare services .

IMPORTANT UTILITY ITEMS FOR MEDICAL USE contd

Gloves

IS 4148: 1989 Surgical Rubber Gloves- Specification

Prescribes the requirements and methods of sampling and tests for re-usable surgical gloves

IS 13422: 1992 Disposable surgical rubber gloves specification

Specifies requirements for single-use packaged sterile gloves intended for use in surgical procedures.

IS 15354(Part 1):2018/ ISO 11193-1: 2008 Single-use medical examination gloves Part 1 Specification for gloves made from rubber latex or rubber solution

Specifies requirements for packaged sterile, or bulked non-sterile, single-use rubber gloves intended for use in medical examinations and diagnostic or therapeutic procedures.

IS 6994 (Part 5) : 2021/ISO 374-5 : 2016 Protective Gloves against Dangerous Chemicals and Micro-organisms Part 5 Terminology and performance requirements for micro-organisms risks

Specifies the requirements and test methods for protective gloves intended to prevent penetration of bacteria, fungi and virus.

IMPORTANT UTILITY ITEMS FOR MEDICAL USE contd

Eye Protector & Face Sheild

1. IS 5983 : 1980 -Specification for eye - Protectors

Prescribes requirements for eye protectors meant for protection of eyes against hazards such as flying particles and fragments, splashing material and molten metals, harmful dust, gases or vapours, aerosols and radiation. Specifies five types of eye protectors - Goggles, safety spectacles, safety clip-ons, eye, face, and hand shields, and wire mesh screens

2. IS 8521 (Part 1) : 1977Specification for industrial safety face shields: Part 1 with plastics visor

Prescribes industrial face shields with transparent plastic visor for protection of the face from flying particles or from sprays or flashes of hazardous liquid, molten metals or slag. Specifies three types - Type 1 (face shield without crown protector), Type 2 (face shield with crown protector) and Type 3 (face shield with provision of attachment to a safety helment).

IMPORTANT UTILITY ITEMS FOR MEDICAL USE contd

Blood Bags

IS/ISO 3826-1 : 2013 - Plastics Collapsible Containers for Human Blood and blood components Part 1 Conventional Containers

Specifies requirements for plastics collapsible, non-vented, sterile containers for the collection, storage, processing, transport, separation, and administration of blood and blood components.

IS/ISO 3826-3 : 2006 - Plastics Collapsible Containers for Human Blood and blood components Part 3 Blood Bag Systems with Integrated Features

Specifies requirements, including performance requirements, for integrated features on plastic, collapsible, non-vented, sterile containers

IMPORTANT UTILITY ITEMS FOR MEDICAL USE contd

Bandages

- **IS 11163 : 2021 Medical Textiles — First Aid Dressings — Specification**
- Specifies performance requirements for first-aid dressings intended for medical use.
- **IS 14274 : 1995 Bandage, T - Shaped, calico – Specification**
- Specifies the requirements of bandage, T-shaped, calico mainly used in hospitals as abdominal bandage.
- **IS 14306 : 1995 Bandage, triangular, calico specification**
- Specifies the requirements of bandage, triangular, calico used as a sling for supporting fractured/wounded arm.
- **IS 14316 : 1995 Swabs, small, in bag of 50 – Specification**
- Specifies the requirements of small swabs, in bag of 50 used for dressing of wounds
- **IS 14944 : 2020 Surgical Dressings — Methods of Test**
- Specifies the methods of test for various types of surgical dressings.
- **IS 16111 : 2013 Elastic bandage**
- Standard covers the dimensions and other requirement for elastic bandages intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopaedic purposes

IMPORTANT UTILITY ITEMS FOR MEDICAL USE contd

Medical Textiles

- IS 16468 : 2016 Medical textiles - Absorbent cotton (Sterile And Non - Sterile)
- IS 16469 : 2016 Medical textiles - Open weave bandages
- IS 16470 : 2016 Medical textiles - Elastic surgical adhesive tapes
- IS 16660 : 2017 Medical textiles - Nonwoven bandage rolls
- IS 16668 : 2017 Medical textiles - Salicylic acid adhesive plaster
- IS 16669 : 2017 Medical textiles - Elastic adhesive dressing
- IS 16670 : 2017 Medical textiles - Absorbent cotton ribbon gauze
- IS 17334 : 2019 Medical Textiles - Surgical Gowns and Surgical Drapes
- IS 17423 : 2021 Medical Textiles — Bio-Protective Coveralls
- IS 17349 : 2020 Medical Textiles — Shoe Covers
- IS 6237 : 1971 Specification for handloom cotton cloth for plaster of paris bandages and cut bandages

ASSISTIVE & REHABILITATION DEVICES

Wheelchairs

IS 6571:1991 Rehabilitation equipment - Wheelchairs, non - Folding, adult size, institutional model - Specification

Specifies the requirements for institutional model, adult size, non-folding wheelchairs used in hospitals and similar institution.

IS 7454:1991 Rehabilitation equipment - Wheelchairs, folding, adult size - Specification

Specifies the requirements for adult size, folding wheelchairs used by invalids

IS 8086:1991 Rehabilitation equipment - Wheelchairs, folding, junior size - Specification Specifies the requirements for folding wheelchairs used by invalid children.

IS 17063 :2018 Specification for rehabilitation equipment - rough terrain active wheelchairs, folding, rider - I, adult and child size

Specifies the requirements for manual, folding wheelchairs for rough terrain active mode for urban/rural outdoor mobility to be used by adults and children with disabilities

ASSISTIVE & REHABILITATION DEVICES

Braille (for visually impaired)

IS 11279:1985 Specification for braille slate

Specifies requirements for braille slate used for communicating language by the blind persons.

IS 12152:1987 Specification for pocket frame, braille writing

Specifies requirements for pocket frame used for writing braille.

IS 12184:1987 Specification for stylus for braille writing

Specifies requirements of stylus for braille writing.

IS 14429:1997 Braille shorthand machine - Specification

Specifies requirements of Braille shorthand machine, along with paper roll for use by the visually impaired.

ASSISTIVE & REHABILITATION DEVICES

Contraceptives

IS/ISO 4074 : 2015 ISO 4074 : 2015-Natural rubber latex male condoms - Requirements and test methods

Specifies the requirements for biocompatibility, microbial contamination, design, stability and shelf, life packaging and labelling for male condoms made of natural rubber.

IS/ISO 23409 : 2015 ISO 23409 : 2011-Male condoms - Requirements and test methods for condoms made from synthetic materials

Specifies the requirements for biocompatibility, microbial contamination, design, stability and shelf, life packaging and labelling for male condoms made from 100% synthetic materials or a blend of synthetic materials and natural rubber latex.

IS/ISO 25841 : 2014 ISO 25841 : 2014-Female condoms - Requirements and test methods

Specifies the requirements for quality verification, design, barrier properties, biocompatibility, clinical investigations, bursting volume & pressure, stability and shelf, life packaging and labelling for female condoms for contraceptive purpose and prevention of sexually transmitted infections.

HOSPITAL EQUIPMENT

Medical Beds

Hospital Beds

IS 5029:1979 BEDSTEADS, HOSPITAL, GENERAL PURPOSES

Specifies the requirements of bedsteads suitable for general purposes in hospitals and other similar institutions.

ICU Beds

- **IS 9395 : 1979 Specification for bed, intensive care**

Specifies the requirements for intensive care bed used for the intensive care of the patients in hospitals and dispensaries. It covers materials, shapes and dimensions, construction, performance requirements, workmanship and finish, accessories, instructions for use and maintenance and marking requirements.

HOSPITAL PLANNING & MANAGEMENT

IS 12433 (Part 1) : 1988 Basic requirements for hospital planning Part 1 up to 30 bedded hospital

Covers basic requirements for planning a 30 bedded general hospital in respect to functional programme, functional and space requirements, work-flow analysis, manpower requirements, instruments and equipment. Certain essential requirements for building, services and environment have also been covered.

IS 12433 (Part 2) : 2001 Basic requirements for hospital planning Part 2 up to 100 bedded hospital

Covers basic requirements for planning a 100 bedded general hospital in respect to functional programme, functional and space requirements, work-flow analysis, manpower requirements, instruments and equipment. Certain essential requirements for building, services and environment have also been covered.

HOSPITAL PLANNING & MANAGEMENT

IS 13808 (Part 1) : 1993 Quality management procedures for out - Patient department OPD and emergency services - Guidelines Part 1 upto 30 bedded hospitals

Lays down guidelines for quality management procedures for OPD & emergency services offered in 30 bedded hospitals.

IS 13808 (Part 2) : 1993 Quality management procedures for diagnostic and blood transfusion services- Guidelines

Lays down guidelines for quality management procedures for diagnostic and blood transfusion services offered in 30-bedded general hospitals with reference to: Pathological Services, Imaging Services, ECG Services and Blood Transfusion Services.

IS 13808 (Part 3) : 1995 Quality management for hospital services Upto 30 - Bedded Hospitals - Guidelines Part 3 wards nursing services and operation theatre

Provides basic guidelines for evolving a well planned quality management programme which would result in quality health care to the patients in relation towards nursing services, operation theatre and labour room in a 30 bedded

HOSPITAL PLANNING & MANAGEMENT

IS 13808 (Part 4) : 1996 Quality management for hospital services For 30 - Bedded Hospital - Guidelines Part 4 hospital support services

Lays down guidelines for quality management system for hospital support services offered in a 30-bedded general hospital with reference to Stores, Central sterile and supply department, laundry, kitchen, Housekeeping and maintenance services

IS 13808 (Part 5) : 1996 Quality management for hospital services For 30 - Bedded Hospital - Guidelines Part 5 hospital equipment management

Provides basic guidelines for evolving a well planned programme for equipment management in a 30-bedded hospital which would result in quality health care to the patients.

KNOW YOUR STANDARDS

Know Your Standard feature has been introduced on Home page of BIS website so as to make it easy for a person (industry or any stakeholder) to access the following information:

- Basic details of the Indian Standard
- Copy of Indian Standard
- Details of BIS licensee against that Indian Standard;
- Product Manual & SIT;
- Details of available testing laboratories;
- Composition of concerned sectional committee
- Cross referred Indian Standard

Accessing Indian Standards

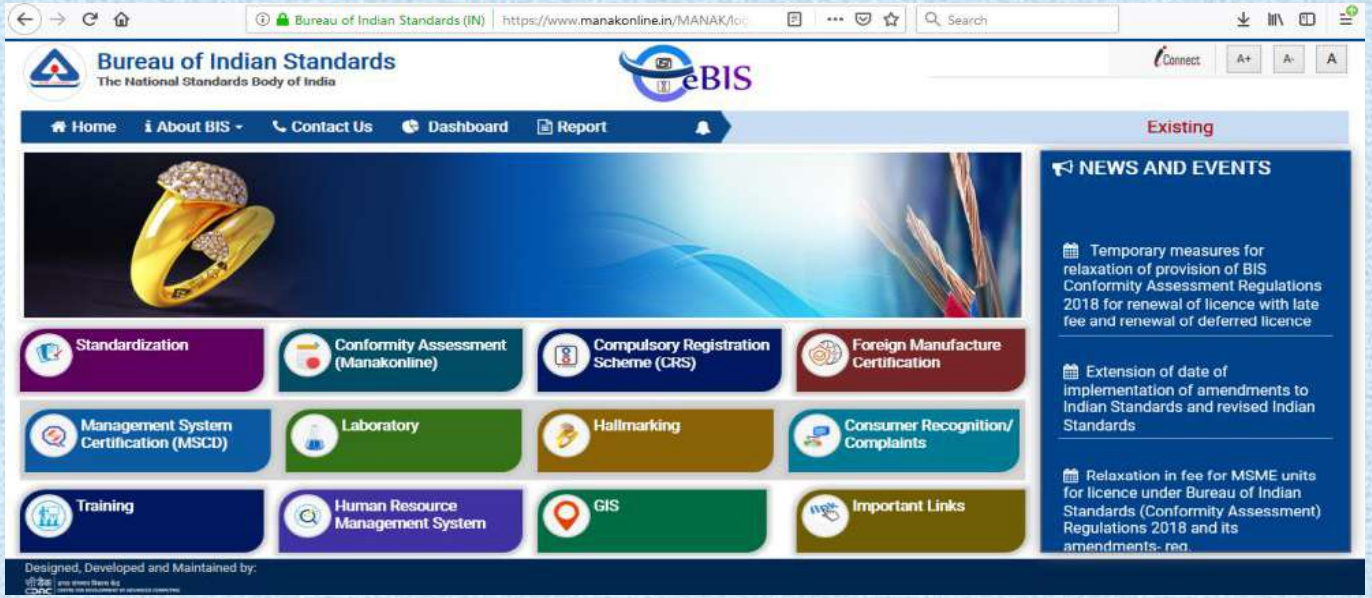
Go to the url below

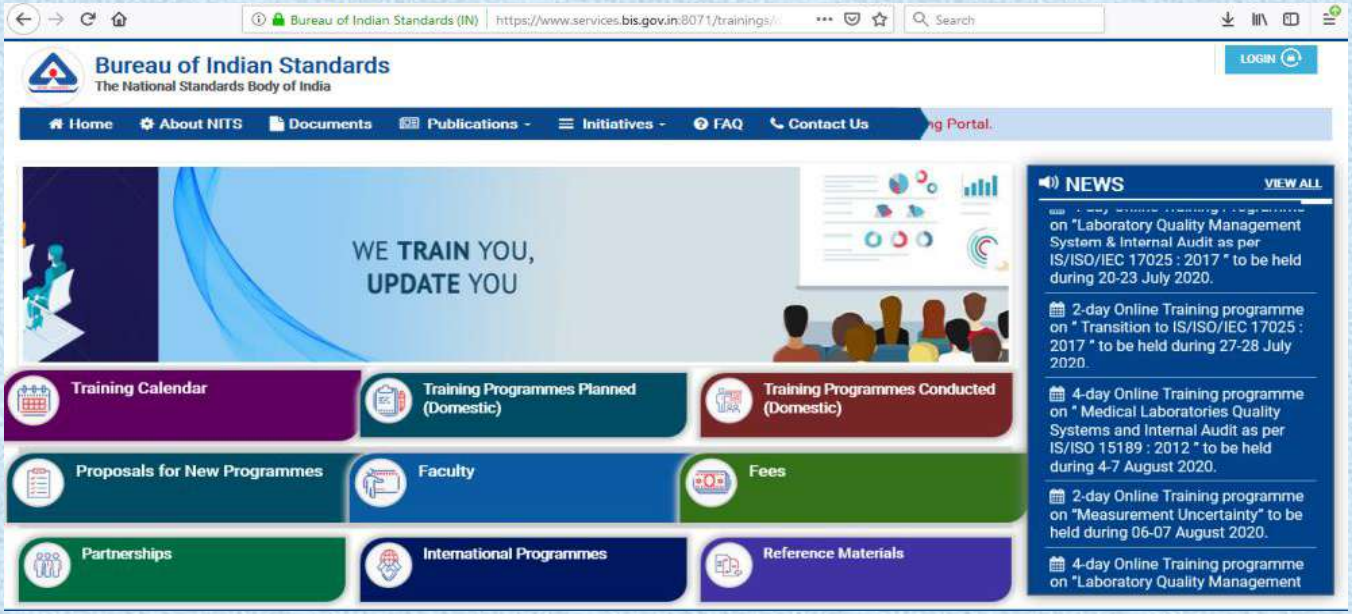
https://www.services.bis.gov.in:8071/php/BIS_2.0/eBIS/

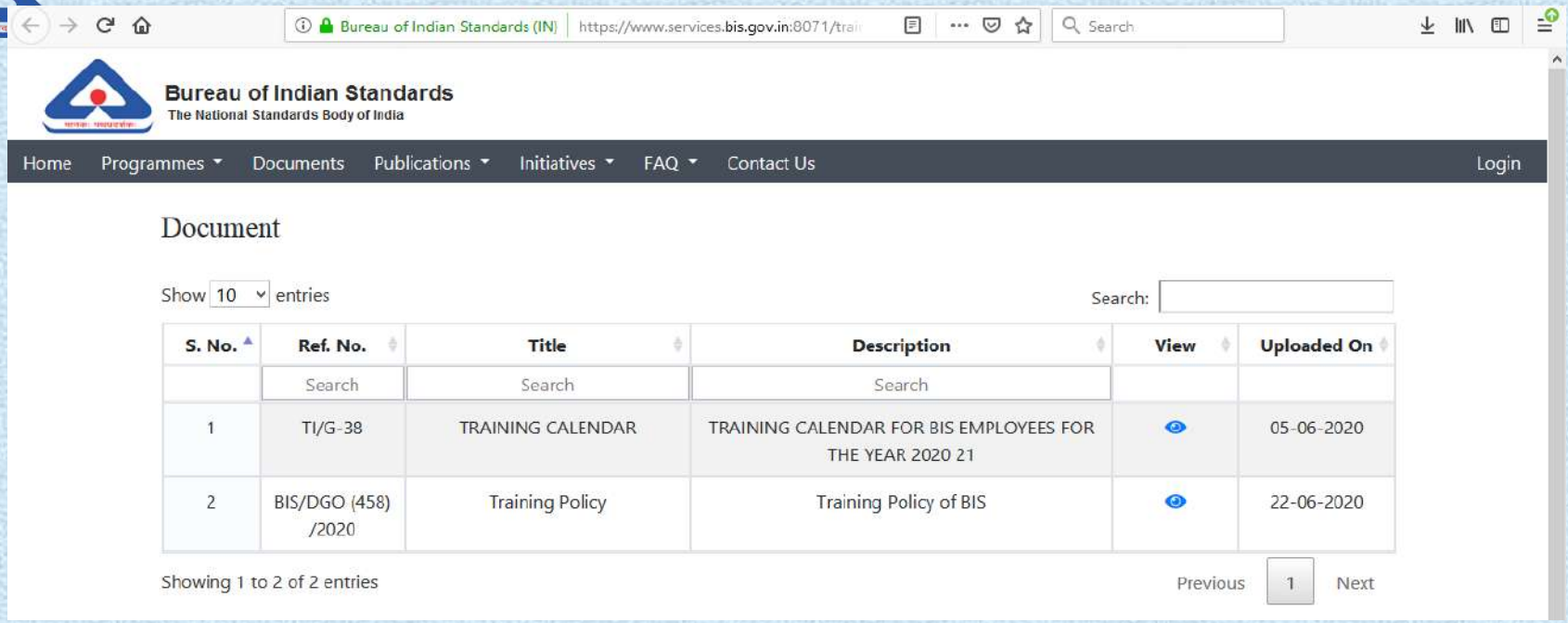
- Click on the "Published Standards" button
- Navigate through the links to find the standard to download
- Click on "Download" button corresponding to the Standard
- The button will redirect to sale portal.
- Register on portal and download the Standard

Leveraging training & professional support by BIS

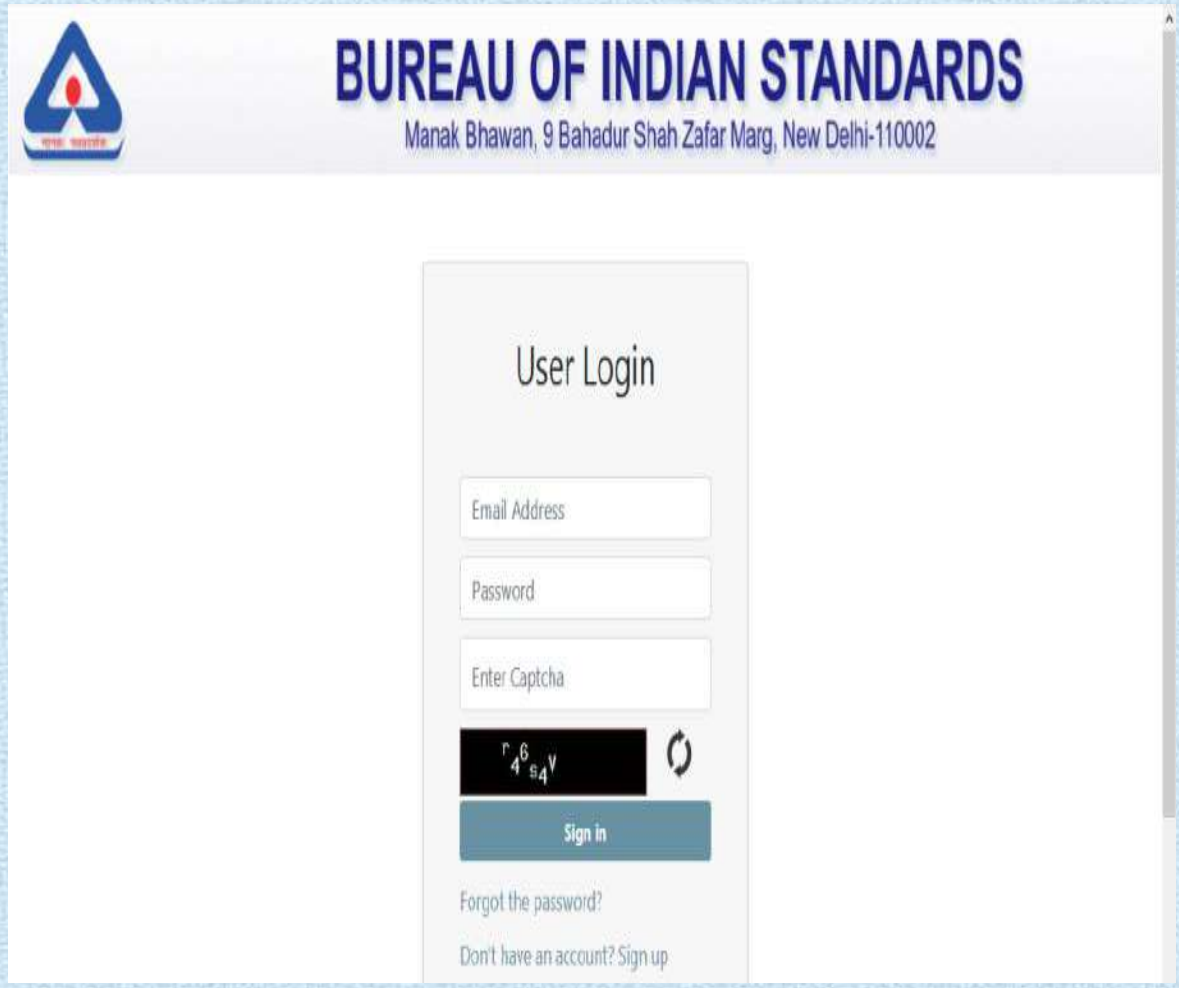
- A training portal has been developed by BIS to cater to the emerging training needs of various stakeholders.
- This training portal enables Industries (including Industry Associations), Central/ State Government organizations, Consumers (including Consumer groups, NGO, RWAs), Research Institutes, Laboratories, Academia, BIS departments/employees, etc. to participate online in the various training programmes conducted by BIS. The participation can be made individually or on behalf of their organization. The interested participants can also propose their own sector specific/skill based training programmes.
- These programmes can be online, offline or blended and they can be conducted at BIS locations or custom locations.
- The participants can access all the relevant course materials, case studies, reference materials, journals, certificates, etc. on the portal.
- This portal has a communication window for easy interaction with BIS.
- The interested stakeholders who want to become/nominate a faculty in BIS can also submit their applications online.
- To access the training portal, please go to e-BIS (www.manakonline.in) home page which will display the various digital services offered by BIS and select training portal. The screenshot of the same are as follows:


Bureau of Indian Standards (IN)
https://www.manakonline.in/MANAK/lo
Search
Bureau of Indian Standards
The National Standards Body of India
eBIS
Connect
A+
A-
A
Home
About BIS
Contact Us
Dashboard
Report
Existing
NEWS AND EVENTS
Temporary measures for relaxation of provision of BIS Conformity Assessment Regulations 2018 for renewal of licence with late fee and renewal of deferred licence
Extension of date of implementation of amendments to Indian Standards and revised Indian Standards
Relaxation in fee for MSME units for licence under Bureau of Indian Standards (Conformity Assessment) Regulations 2018 and its amendments- reg
Standardization
Conformity Assessment (Manakonline)
Compulsory Registration Scheme (CRS)
Foreign Manufacture Certification
Management System Certification (MSCD)
Laboratory
Hallmarking
Consumer Recognition/ Complaints
Training
Human Resource Management System
GIS
Important Links
Designed, Developed and Maintained by:


Bureau of Indian Standards (IN)
https://www.services.bis.gov.in:8071/trainings/
Search
Bureau of Indian Standards
The National Standards Body of India
LOGIN
Home
About NITS
Documents
Publications
Initiatives
FAQ
Contact Us
ng Portal.
WE TRAIN YOU,
UPDATE YOU
NEWS
VIEW ALL
on "Laboratory Quality Management System & Internal Audit as per IS/ISO/IEC 17025 : 2017 " to be held during 20-23 July 2020.
2-day Online Training programme on " Transition to IS/ISO/IEC 17025 : 2017 " to be held during 27-28 July 2020.
4-day Online Training programme on " Medical Laboratories Quality Systems and Internal Audit as per IS/ISO 15189 : 2012 " to be held during 4-7 August 2020.
2-day Online Training programme on "Measurement Uncertainty" to be held during 06-07 August 2020.
4-day Online Training programme on "Laboratory Quality Management
Training Calendar
Training Programmes Planned (Domestic)
Training Programmes Conducted (Domestic)
Proposals for New Programmes
Faculty
Fees
Partnerships
International Programmes
Reference Materials


Bureau of Indian Standards (IN)
https://www.services.bis.gov.in:8071/trai
Search
Bureau of Indian Standards
The National Standards Body of India
Home
Programmes
Documents
Publications
Initiatives
FAQ
Contact Us
Login
Document
Show 10 entries
Search:
S. No.
Ref. No.
Title
Description
View
Uploaded On
Search
Search
Search
1
TI/G-38
TRAINING CALENDAR
TRAINING CALENDAR FOR BIS EMPLOYEES FOR THE YEAR 2020 21
05-06-2020
2
BIS/DGO (458) /2020
Training Policy
Training Policy of BIS
22-06-2020
Showing 1 to 2 of 2 entries
Previous
1
Next


BUREAU OF INDIAN STANDARDS
Manak Bhawan, 9 Bahadur Shah Zafar Marg, New Delhi-110002
भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
Registration
Login
Sign Up for Training Portal
User Type*
New Participant
Alumni
Name*
Mr
Name
Email*
Primary Email
Secondary Email(Optior
DOB*
DOB
Password*
Password
Confirm Password*
Confirm Password


BUREAU OF INDIAN STANDARDS
Manak Bhawan, 9 Bahadur Shah Zafar Marg, New Delhi-110002
User Login
Email Address
Password
Enter Captcha
Sign in
Forgot the password?
Don't have an account? Sign up

THANK YOU