

Draft Omnibus Technical Regulations (OTRs) for Safety of Machinery

Preamble

The machinery sector is an important part of the engineering industry and is one of the major sources of all industrial activity. Several thousand occupational accidents take place annually in India. The loss of lives, injuries and the social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.

The National Capital Goods Policy notified by the Department of Heavy Industry, Government of India, expresses the need of mandatory standards, minimum acceptable safety, and environment and performance standards for machinery.

Several countries and economic blocks such as the EU have notified technical regulations for the safe design, manufacture and installation of machinery through compliances with essential requirements and international standards. As a result of the National Capital Goods Policy, the Bureau of Indian Standards has adopted the core ISO and IEC Standards for machinery safety, which are now available to the industry for adoption and also for initiating a regulatory framework in India.

Taking into account, the scale, both in terms of volumes and diversity, the regulatory framework for machinery safety needs to be easy to implement, without causing unnecessary burden of compliance costs. It also needs to draw upon the bench-strength of conformity assessment bodies in India, many of which have wide experience of carrying out conformity assessment of machinery during course of importing countries' compliance requirements.\

In view the above considerations, a proposed framework for technical regulation (QCO) for machinery safety in India drawing enabling power from the BIS ACT, 2016 is placed below for stakeholder consultation and eventual adoption.

The QCO shall be supplemented with a guideline document based on good practices and standards that would provide step by step guidance, and be able to answer basic questions of the industry as to which standards are applicable for them, which aspects should they consider for hazard reducing processes like risk assessment, and how to apply and implement safety solutions.

1, Short title and commencement. —(1) This Order may be called the Safety of Machinery (Quality Control) Order, 2019.

This Order, unless specified otherwise, shall come into force with effect from 1st day of October , 2019

2. Application — This Order shall be applicable in respect of:

- a) Machinery
- b) Partly completed machinery and sub-assemblies
- c) Lifting accessories including construction site hoists intended for lifting persons or persons and goods.
- d) Chains, ropes and webbings
- e) Mechanical transmission devices

Exclusion – this Order excludes from its scope, the following types of machinery and equipment

- a) All automotive vehicles, water transport vessels and air transport vehicles and machinery and equipment which is part of such transport vehicles
 - a. However machinery mounted on these vehicles, such as pumps, engines, hoists, used for other applications shall be covered by this Order
- b) Firearms
- c) Defence Artillery and communications equipment or machinery specifically designed for use for defence applications
- d) All aviation machinery and equipment falling under purview of DGCA
- e) All machinery and equipment falling under purview of AERB
- f) All machinery and equipment used in mines falling under purview of Director General of Mines Safety
- g) Spare parts, components that are not classified as partly completed machinery or sub-assemblies
- h) Electrical high voltage and low voltage equipment, switchgear, transformers, meters, appliances covered under specific (Quality Control) Orders notified by Central Government under Bureau of Indian Standards Act, 2016
- i) Equipment classifies as medical devices notified under Medical Devices Rules, 2016

3. Definitions - — In this Order, unless the context otherwise requires, -

machinery means any assembly, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

- i. For the purpose of this Order, the term machine shall be read as synonymous with machinery
- ii. A machine or assembly shall not be excluded by mere absence of a connecting device to a power source, or a mounting device

- iii. A machine where the drive system is human effort, shall normally be excluded unless the number of moving parts in the machine is more than two

partly completed machinery means an assembly which is almost machinery but which cannot in itself perform a specific application. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery covered within the scope of this Order

- I. A drive system or a prime mover is partly completed machinery.

authorised representative means any person who is a citizen of India who has received a written authorization from the manufacturer to perform on his behalf all or part of the obligations and procedures connected with this Order

- II. An authorized representative shall normally be resident in India

placing on the market means making available machinery or partly completed machinery in India, with a view to distribution or use with or without a commercial transaction

- I. Supply of a partly completed machinery to an assembler for integration into a completed machinery shall be included within the meaning of the term 'placing on the market'

Notified Body means a conformity assessment body, having its registered office in India, notified by the Department of Heavy Industry as a body competent to carry out the, assessment, and verification of machinery and installation site for establishing conformity with standards;

All other terms used in this Order or in relation to safety of machinery shall have the same meaning as specified in IS/ISO 12100:2010 *Safety of machinery — General principles for design — Risk assessment and risk reduction*

Market Surveillance means activities carried out and measures taken to confirm compliance to this Order towards conformance of machinery that have been placed in the market, with the notified Standards and to collect and analyse information gained from such activities

4. Classification of Machinery:

Machinery shall be classified in the following risk categories:

- a) Class 1 -Low risk: Machinery with minor hazards to the user / operator
- b) Class 2 – Moderate risk: Machinery with major hazards that may cause serious injury or temporary disability to user / operator
- c) Class 3: -high risk: Machinery with critical hazards that may cause maiming, permanent disability of limbs or fatality

5. Prohibition of manufacture, storage, sale, distribution etc

No person shall from the date of enforcement of this order, himself or through any person on his behalf manufacture, or store for sale, sell or distribute machinery or partly completed machinery, which do not conform to the specified standards and do not bear the Machinery Safety Mark specified by the Bureau of Indian Standards

6. Obligations of the manufacturer—A machinery manufacturer or his authorized representative shall ensure that the machinery produced and placed in the market by him meets the minimum essential principles of safety of machinery as specified in

Type A Standards

a) ISO 12100:2010 *Safety of machinery — General principles for design — Risk assessment and risk reduction* for all machines

b) IS 16504 (Part 1) : 2017 (IEC 60204-1 : 2008) *Safety of Machinery — Electrical Equipment of Machines Part 1: General Requirements* for electrical machines and other machines with electrical equipment and systems

Type B Standards

Standards as specified in Schedule 1

Type C Standards

When specifically notified by Central Government in respect of any type of machinery

An overseas manufacturer shall designate an authorized representative who shall undertake legal liability for and on behalf of the manufacturer to comply with this Order

Depending on Risk classification of the Machinery as specified in Section 4, the machinery manufacturer or his authorized representative shall follow the conformity assessment procedure and certification route as specified in Section 7

Notwithstanding any independent conformity assessment, it shall be the responsibility of the manufacturer to ensure that the machinery produced and supplied by them conforms to the requirements of the Standards referred in schedule 1.

It shall be the responsibility of the person installing the machinery at the work-site that the installation arrangements including the machinery and its part conform to the requirements of the Standards referred in schedule 1.

7. Conformity Assessment Procedure

(1) Class 1 Machinery

Before placing any machinery or partly completed machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

- a) Ensure that it satisfies the relevant safety requirements set out in the Standards specified in Schedule I,

- b) Prepare a technical file referred to in Schedule 2
- c) Prepare a Certificate of self-declaration of conformity in accordance with Schedule 3, and ensure that it accompanies the machinery
- d) Affix the Machinery Safety Mark, specified by the Department of Heavy Industry, on the Machine provided the machine demonstrates compliance with the applicable standards based on self-assessment
- e) Register the Machinery or partly completed machinery on the On-line registry portal established by the Department of Heavy Industry
- f) Upload the technical file and Certificate of self-declaration on the On-line registry portal

Any changes to a Class 1 machinery that has been registered shall be recorded on the On-line registry portal followed by uploading a revised technical file and Certificate of self-declaration

(2) Class 2 Machinery

The manufacturer or his authorised representative of a class 2 machinery or partly completed machinery shall:

- a) Ensure that it satisfies the relevant safety requirements set out in the Standards specified in Schedule I,
- b) Prepare a technical file referred to in Schedule 2
- c) Make an application for a type examination to a notified body having accreditation for the relevant technical area in which the machinery falls
- d) Submit the technical file for the evaluation of the notified body
- e) Offer the machinery or its prototype sample for physical verification, or testing or both, to the notified body. Where assembly, installation and commissioning of the machinery is carried out at the user's premises, the testing or verification shall be carried out in appropriate stages as determined by the Notified body
- f) Upon receipt of Type Examination Certificate, register the Machinery or partly completed machinery on the On-line registry portal established by the Department of Heavy Industry
- g) Upload the technical file and Type Examination Certificate on the On-line registry portal
- h) Affix the Machinery Safety Mark, specified by the Department of Heavy Industry on the registered machinery type subsequently produced and supplied for placing in the market

Any changes to a Class 2 machinery that has been registered shall be informed to the notified body with relevant changes in the technical file. The changes shall be recorded on the On-line registry portal followed by uploading the revised technical file and revised Certificate if issued

Upon receipt of an application for certification of class 2 machinery, a notified body shall:

- a) examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with

the relevant provisions of the standards referred to in Schedule 1, and those elements whose design is not based on the relevant provisions of those standards

- b) carry out or make suitable arrangements to carry out appropriate inspections, measurements and tests to ascertain whether the solutions adopted in respect of the machinery type offered, satisfy the standards referred to in Schedule 1
- c) agree with the applicant as to the place where the necessary inspections, measurements and tests that the type was manufactured in accordance with the examined technical file and the standards will be carried out
- d) If the type examination confirms that the type was manufactured in accordance with the examined technical file and the standards, the notified body shall issue the applicant with a Type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and any conditions relating to the issue of the certificate. A separate certificate shall be issued for each machine type/model
- e) If during the type examination, deficiencies are observed in the technical file or in the prototype sample offered, the notified body shall inform these in writing to the applicant. The notified body may carry out a fresh examination upon submission of the modifications by the applicant
- f) When changes to a registered Class 2 machinery are made, the notified body shall examine these modifications and shall either confirm the validity of the existing Type-examination certificate or issue a new one if the modifications are determined to be significant to impact the safety requirements or the intended working conditions of the type.

(3) Class 3 Machinery

The manufacturer of a class 3 machinery or partly completed machinery shall:

- a) Ensure that it satisfies the relevant safety requirements set out in the Standards specified in Schedule I,
- b) Operate and document a quality system for design, manufacture, in-process controls and inspections, final inspection and testing of the machinery or partly completed machinery. The quality system shall
 - I. conform to ISO 9001:2015
 - II. include technical design specifications of the machinery
 - III. processes and systematic actions that will be used when designing machinery together with the design inspection, design verification and design validation methods
 - IV. the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
 - VI. the quality records, such as inspection reports and test and calibration data

- c) Prepare technical files referred to in Schedule 2 for all the types of machinery or partly completed machinery being manufactured for placing in the market
- d) Make an application for evaluation of the quality system and type examination to a notified body having accreditation for QMS certification and the relevant technical area in which the machinery falls
- e) Submit the quality system documentation and technical files for the evaluation of the notified body
- f) Offer the machinery or its prototype sample for physical verification, or testing or both, to the notified body. Where assembly, installation and commissioning of the machinery is carried out at the user's premises, the testing or verification shall be carried out in appropriate stages as determined by the Notified body
- g) Upon receipt of QMS certificate from the notified body, register the organization as a manufacturer of Class 3 machinery, on the On-line registry portal established by the Department of Heavy Industry
- h) Upon receipt of Type Examination Certificate, register the Machinery or partly completed machinery on the On-line registry portal established by the Department of Heavy Industry
- i) Upload the technical files and Type Examination Certificates on the On-line registry portal
- j) Affix the Machinery Safety Mark, specified by the Department of Heavy Industry on the registered machinery type subsequently produced and supplied for placing in the market

Upon receipt of an application for certification of class 3 machinery, a notified body shall:

- a) Evaluate the adequacy of the submitted Quality Management System for conformance to ISO 9001 requirements and the requirements referred in Section 3 (b) above
- b) Examine the technical files, check that the types were manufactured in accordance with them and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Schedule 1, and those elements whose design is not based on the relevant provisions of those standards
- c) Conduct an onsite audit of the Quality System. The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery.
- d) carry out or make suitable arrangements to carry out appropriate inspections, measurements and tests to ascertain conformance of the machinery types offered, with the technical file and the standards referred to in Schedule 1
- e) agree with the applicant the place where the necessary inspections, measurements and tests will be carried out
- f) Issue a 'Certificate of Conformance' to the manufacturer's quality system, when it is found to be meeting requirements of ISO 9001 and the and the requirements referred in Section 3 (b) above

- g) Issue the applicant with Type-examination certificates, if the type examination confirms that the types were manufactured in accordance with the examined technical files and the standards. The certificates shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved types, the conclusions of the examination and any conditions relating to the issue of the certificates. A separate certificate shall be issued for each machine type/model
- h) Inform in writing to the applicant, any deficiencies that may be observed in the quality management system during the on-site assessment or during type examination, or in the technical file, or in the prototype sample offered. The notified body may carry out a fresh examination upon of submission of the modifications by the applicant
- i) Examine modifications or changes to a registered Class 3 machinery and either confirm the validity of the existing Type-examination certificate or issue a new certificate if the modifications are determined to be significant to impact the safety requirements or the intended working conditions of the type.
- j) Carry out surveillance audit of the registered organization to re-confirm that the quality system is being implemented as documented, and the planned inspections, measurements and tests are being carried out. The notified body may conduct tests on the Type certified machinery on a sample basis to re-confirm that it continues to comply with the safety design features specified in the Technical file. A surveillance audit shall be carried out at least once every year.
- k) Issue an audit report to the organization for every audit of the quality system, together with any deficiencies observed

8. Notified Bodies : (1)The Department of Heavy Industry shall notify the bodies to carry out the assessment of conformity with the specific conformity assessment procedures (Class 2 or 3 or both) and types / categories of machinery for which these bodies have been designated.

(2) As an essential qualifying requirement, a notified body shall be accredited by the National Accreditation Board for Certification Bodies under the Quality Council of India, registered under the Societies Registration Act, 1860 (21 of 1860) set up by the Ministry of Commerce and Industry in the Government of India in accordance with ISO 17065:2012 Conformity assessment -- Requirements for bodies certifying products, processes and services or ISO 17020:2012 Conformity assessment — Requirements for the operation of various types of bodies performing inspection. The accreditation shall include in its scope the relevant technical areas for conformity assessment of machinery safety in accordance with the Standards specified in Schedule 1.

(3) A Notified Body accredited in accordance with section (2) may make an application to the Department of Heavy Industry for registration in Form MD-1 through online portal accompanied with a fee and documents as specified in Schedule 4. The Department of Heavy Industry, on being satisfied, shall register the Notified Body and

issue a registration certificate in Form MD-2. The Registration Certificate shall remain valid in perpetuity, unless, it is suspended or cancelled, provided the Notified body continues to retain valid accreditation and deposits a registration retention fee as specified in the Second Schedule every five years from the date of its issue.

9. Marking and Labelling:

Each machine placed on the market shall be provided with a label, firmly affixed to the product which shall contain the following information:

- a) The Type / make / model of the machine that was registered or Type examined and certified
- b) The name and address of the manufacturer
- c) Brand name under which the machine is marketed (if applicable)
- d) The Serial number of the machine
- e) The Machinery Safety Mark
- f) The Registration / Certification number applicable to the Type / Make /Model
- g) Any other information required under any other law in force

For partly completed machinery, a temporary label shall be attached to each partly completed machinery covering the above information. Where certification of the final machinery uses pre-certified partly completed machinery, the label shall be preserved by the final manufacturer till as long as the warranty of the machine is valid.

10. Penalty for Contravention

Any person who contravenes the provision of this Order shall be punishable under the provisions of the Bureau of Indian Standards Act, 2016.

11. Ensuring the Compliance with these Rules and Market Surveillance

- 2. The appropriate authority may, with a view to securing compliance with this Order -
 - a) require any person engaged in the manufacture, import, distribute, sell, hire, lease, or store of machinery or partly completed machinery to give such information as he deems necessary relating to the manufacture, import, distribute, sell, hire, lease, or store of any machinery or partly completed machinery for the implementation of this Order or require any such person to furnish to him samples of any such machinery or partly completed machinery .
 - b) inspect or cause to be inspected any books or other documents relating to machinery or partly completed machinery kept by or belonging to or in the possession or under the control of any person engaged in the manufacture, import, distribute, sell, hire, lease, or store of any such machinery or partly completed machinery ;
 - c) enter and search any premises and seize machinery or partly completed machinery in finished stock condition (ready for sale) in respect of which it has reason to believe that a contravention of this Order has been committed or the said machinery or partly completed machinery is not of the specified standard.

- d) No manufacturer or dealer shall, refuse to furnish any information or conceal, destroy, mutilate or deface any book, document of machinery or partly completed machinery kept in his possession or under his control.
3. The Department of Heavy Industry, shall set up a Market Surveillance Agency, that shall be responsible for efficient implementation of the Safety of Machinery (Quality Control) Order, 2019.
 4. The purpose of Market surveillance is to ensure that products covered by this Order conform to the relevant specified standards and have followed the due process of conformity assessment as specified in this Order. Market surveillance shall also aim to prohibit placement or withdraw products from the market which, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements.
 5. The Market Surveillance Agency shall be responsible to assess compliance with this Order of the various business operators in machinery supply chain – manufacturer, importer, trader, downstream users.
 6. Market Surveillance would include verifying that any machinery or partly completed machinery placed on market is either Registered and marked under self-declaration, or Type examined and Certified, or Type Examined and Certified under a fully documented Quality system based on its risk classification.
 7. Market Surveillance shall also follow up on compliance of various business operators with the Notices, and Orders issued by the Department.
 8. The market surveillance agency shall draw a surveillance plan to verify compliances through a series of measures, including but not limited to:
 - a) Visits to the manufacturing sites for verifying the availability and technical correctness of Technical file in compliance with the Standards, compliance of the manufactured machinery with the provisions of the technical file, marking and labelling in accordance with this Order, spot tests of the machines where relevant and taking of samples from the manufacturing site for testing in independent and accredited laboratory, where feasible
 - b) Visits to sites of installed machinery to verify conformance of machinery as well as installation arrangement
 - c) Where machines are available for sale in the open market, take samples for testing in independent and accredited laboratory
 - d) Where business operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.
 9. Where the market surveillance authorities find that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the authorities in charge of external border controls (Customs) to prohibit their entry into India.

Schedule 1 : List of Standards specifying safety requirements for machinery safety

Type A Standards - (basic safety standards) giving basic concepts, principles for design and general aspects that can be applied to machinery

ISO 12100:2010 Safety of machinery -- General principles for design -- Risk assessment and risk reduction
IS 16504 (Part 1) : 2017 (IEC 60204-1 : 2008) <i>Safety of Machinery — Electrical Equipment of Machines Part 1: General Requirements</i>

Type B Standards - (generic safety standards) dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery

ISO 13849-1:2015 Safety of machinery -- Safety-related parts of control systems -- Part 1: General principles for design
ISO 13849-2:2012 Safety of machinery -- Safety-related parts of control systems -- Part 2: Validation
ISO 13850:2015 Safety of machinery -- Emergency stop function -- Principles for design
ISO 13851:2002 Safety of machinery -- Two-hand control devices -- Functional aspects and design principles
ISO 13854:2017 Safety of machinery -- Minimum gaps to avoid crushing of parts of the human body
ISO 13855:2010 Safety of machinery -- Positioning of safeguards with respect to the approach speeds of parts of the human body
ISO 13856-1:2013 -- Safety of machinery -- Pressure-sensitive protective devices -- Part 1: General principles for design and testing of pressure-sensitive mats and pressure-sensitive floors
ISO 13856-2:2013 Safety of machinery -- Pressure-sensitive protective devices -- Part 2: General principles for design and testing of pressure-sensitive edges and pressure-sensitive bars
ISO 13856-3:2013 Safety of machinery -- Pressure-sensitive protective devices -- Part 3: General principles for design and testing of pressure-sensitive bumpers, plates, wires and similar devices
ISO 13857:2008 Safety of machinery -- Safety distances to prevent hazard zones being reached by upper and lower limbs
ISO 14118:2017 Safety of machinery -- Prevention of unexpected start-up
ISO 14119:2013 Safety of machinery -- Interlocking devices associated with guards -- Principles for design and selection
ISO 14120:2015 Safety of machinery -- Guards -- General requirements for the design and construction of fixed and movable guards

ISO 14122-1:2016 Safety of machinery -- Permanent means of access to machinery -- Part 1: Choice of fixed means and general requirements of access
ISO 14122-2:2016 Safety of machinery -- Permanent means of access to machinery -- Part 2: Working platforms and walkways
ISO 14122-3:2016 Safety of machinery -- Permanent means of access to machinery -- Part 3: Stairs, stepladders and guard-rails
ISO 14122-4:2016 Safety of machinery -- Permanent means of access to machinery -- Part 4: Fixed ladders
ISO 14123-1:2015 Safety of machinery -- Reduction of risks to health resulting from hazardous substances emitted by machinery -- Part 1: Principles and specifications for machinery manufacturers
ISO 14123-2:2015 Safety of machinery -- Reduction of risks to health resulting from hazardous substances emitted by machinery -- Part 2: Methodology leading to verification procedures
ISO 14159:2002 Safety of machinery -- Hygiene requirements for the design of machinery
ISO 19353:2015 Safety of machinery -- Fire prevention and fire protection
ISO 21469:2006 Safety of machinery -- Lubricants with incidental product contact -- Hygiene requirements
ISO 29042-1:2008 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 1: Selection of test methods
ISO 29042-2:2009 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 2: Tracer gas method for the measurement of the emission rate of a given pollutant
ISO 29042-3:2009 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 3: Test bench method for the measurement of the emission rate of a given pollutant
ISO 29042-4:2009 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 4: Tracer method for the measurement of the capture efficiency of an exhaust system
ISO 29042-5:2010 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 5: Test bench method for the measurement of the separation efficiency by mass of air cleaning systems with unducted outlet
ISO 29042-6:2010 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 6: Test bench method for the measurement of the separation efficiency by mass of air cleaning systems with ducted outlet
ISO 29042-7:2010 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 7: Test bench method for the measurement of the pollutant concentration parameter
ISO 29042-8:2011 Safety of machinery -- Evaluation of the emission of airborne hazardous substances -- Part 8: Room method for the measurement of the pollutant concentration parameter

Schedule 2 : Technical file for machinery

The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment.

The technical file shall comprise the following minimum information:

- a) a general description of the machinery,
- b) the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
- c) full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the relevant safety requirements,
- d) the risk assessment documentation carried out in accordance with Clause 7 of ISO 12100:2010, using the list of hazards mentioned in Annex B of ISO 12100:2010, showing:
 - I. a list of the essential safety requirements which apply to the machinery,
 - II. the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
- e) the standards and other technical specifications used, indicating the relevant safety requirements covered by these standards,
- f) any technical report giving the results of the tests carried out either by the manufacturer or his authorised representative
- g) a copy of the instructions for the use of the machinery in accordance with clause 6.4.5 of ISO 12100:2010, and clause 17 of IS 16504 (Part 1) : 2017 (IEC 60204-1 : 2008) for electrical machines and electrical equipment for other machines.
- h) where appropriate, a description of partly completed machinery and the relevant assembly instructions for such machinery that may be integrated with the machinery
- i) a copy of the self-declaration of conformity

Technical documentation for partly completed machinery

The technical documentation for partly completed machinery must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the relevant safety requirements applied:

It shall comprise a construction file including:

- a) the overall drawing of the partly completed machinery and drawings of the control circuits

- b) full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied relevant safety requirements,
- c) the risk assessment documentation carried out in accordance with Clause 7 of ISO 12100:2010, using the list of hazards mentioned in Annex B of ISO 12100:2010, showing:
 - I. a list of the relevant safety requirements applied and fulfilled,
 - II. the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks.
 - III. the standards and other technical specifications used, indicating the relevant safety requirements covered by these standards,
 - IV. any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
 - V. a copy of the assembly instructions for the partly completed machinery

Where the manufacturer intends to manufacture the same machine model in continuous production, the technical file shall include a monitoring and control plan that will demonstrate how the relevant safety requirements shall be ensured and verified through inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out. The manufacturer shall also maintain quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned in respect of the machinery produced

Schedule 3 Classification of Machinery

(Indicative lists)

Schedule 3 a : List of machines under Class 1

All Hand-held tools such as electric, pneumatic drills, grinders, thread millers and taps, operating at voltages not exceeding 250 volts

Universal Milling and Drilling Machine of rating upto and including 5 KW

All pumps, motors, diesel engines, Gen-sets, compressors of rating upto and including 5 kw

Small lathe machines with bed size upto and including 2 metres

All testing equipment operating at voltages not exceeding 250 volts

Schedule 3 b : List of machines under Class 2

- a) All CNC Turning and Milling Centres
- b) CNC Boring Machines
- c) EDM Machines
- d) Machining Centres
- e) Multi-Axis Turning Centres
- f) NC Cycle-Controlled Lathes
- g) NC Cycle-Controlled Milling Machines
- h) Universal Cylindrical Grinder and grinding centres
- i) CNC Surface and Profile Grinding Machine
- j) Universal Milling and Drilling Machine of rating above 5 KW
- k) Hydraulic Straightening Machine
- l) Mechanical presses upto 1 ton
- m) Shearing and cutting machines that are not hand fed
- n) 3 D Printers
- o) All types of robotic equipment
- p) Laser engraving machine
- q) All Textile machinery
- r) All packaging machinery
- s) All equipment operating at voltages exceeding 250 V
- t) All pumps, motors, diesel engines, Gen-sets, compressors of rating exceeding 5 kw

Schedule 3 b : List of machines under Class 3

- a) All types of sawing machinery for wood and metal working
- b) Surface planning machinery for wood working
- c) All types of machinery that are hand fed and moving parts are accessible to hands
- d) All types of hot and cold hydraulically operated metal forming presses
- e) All types of conveyor belts
- f) All types of in-plant material handling and transportation equipment
- g) All types of rolling mills
- h) All types of compression or injection moulding machines
- i) All types of powered hoists, cranes and lifts
- j) Welding machines, other than manual welding equipment
- k) All equipment having operating at or generating voltages exceeding 1100 v