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Global Project Quality Infrastructure  
Country Component India  
B5/2, 4th Floor, Safdarjung Enclave  
New Delhi 110029, India

**T** +91 11 4949 5353

**E** [qi-india@giz.de](mailto:qi-india@giz.de)

**I** [www.giz.de/en/worldwide/32230.html](http://www.giz.de/en/worldwide/32230.html) | [www.gpqi.org](http://www.gpqi.org)

**Editors**

Khushwant Singh, Alok Kesari

**Design**

Seema Sethi Design LLP, New Delhi, India

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**On behalf of**

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Berlin, Germany



Federal Ministry  
for Economic Affairs  
and Energy

December 2018, New Delhi, India

# **MAKING SAFE MACHINES A STANDARD IN INDIA**

**Insights and Recommendations from  
Comparing Regulations in India and Germany**

## ABOUT THIS PUBLICATION

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This publication was funded by the German Federal Ministry for Economic Affairs and Energy as part of its Global Project Quality Infrastructure (GPQI). The Global Project Quality Infrastructure facilitates political and technical dialogues with partner countries. Its goal is to reduce technical barriers to trade, enhance product safety, and strengthen consumer protection. The dialogues focus on opportunities and challenges related to legislation, market surveillance, standardisation, conformity assessment and accreditation, and market surveillance. They include relevant line ministries, regulators, public agencies, accreditation and standards bodies, industry associations, companies, technical and scientific institutions. The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH – the German Agency for International Cooperation – has been commissioned by the German Federal Ministry for Economic Affairs and Energy to support the implementation of GPQI in Brazil, China, India and Mexico.

In India, the German Federal Ministry for Economic Affairs and Energy and the Indian Ministry for Consumer Affairs, Food & Public Distribution have established the *Indo-German Working Group on Quality Infrastructure* to strengthen bilateral collaboration. The Working Group brings together representatives from relevant ministries, including the Ministry of Commerce and Industry (MoCI), Ministry of Electronics and Information Technology (MeitY), Ministry of Heavy Industries and Public Enterprises (MoHI), Ministry of Road Transport and Highways (MoRTH), Ministry of Power (MoP) as well as experts from the Bureau of Indian Standard (BIS), industry, associations including the Confederation of Indian Industry (CII) and accreditation bodies including the Quality Council of India (QCI). The mutually agreed work plan reflects key areas of the economic relations between both countries. It covers topics ranging from automotive, electric vehicle and charging infrastructure, machinery safety, Industry 4.0, IT security and data protection to market surveillance. The Indian country component of GPQI supports the implementation of the mutually agreed annual work plan of the Working Group.

This publication is a result of the activities of the Indo-German Working Group on Quality Infrastructure. It was prepared in collaboration with expert members of the Mechanical Engineering Industry Association (VDMA), Samir Kanchan from Macsafe India, and with support of BDB India Private Limited and Dr. Kari Hiepko-Odermann. It is the second volume in a series of publications on quality infrastructure.

The presentation of the material in this publication does not imply the expression of any opinion whatsoever by the German or Indian Government. The publication was produced without formal editing from the German Federal Ministry for Economic Affairs and Energy or any Indian Ministry.

## FOREWORD

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We all benefit from safe machines. Machines that conform to relevant safety requirements protect workers and the environment. Safe machines also contribute to efficient production processes and thus are a key pillar of a robust economy.

A working culture that acknowledges the importance of machinery safety requires comprehensive regulations substantiated through high standards and elaborated conformity assessment procedures.

The Indo-German Working Group on Quality Infrastructure has been a very conducive forum to discuss the significance of machinery safety. German and Indian regulators and industry experts have not only exchanged information to understand each other's approaches. They also shared experiences on how to develop new and existing regulations and standards related to functional and electrical safety while drawing on good practices from Germany.

This publication is the result outcome of the many constructive fruitful exchanges in the Working Group. It provides an overview of the regulatory framework in India with regards to machinery safety, and challenges faced by the industry. It also compares machinery regulations in India with those in the European Union (EU).

This study is of interest for regulators, managers and industry associations alike. I am hopeful that it will contribute to strengthening machinery safety in India, and further deepen the Indo-German industrial collaboration, for the benefit of both sides.

### **Stefan Schnorr**

Director General  
Digital and Innovation Policy  
Federal Ministry for Economic Affairs and Energy  
Germany



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## LIST OF ABBREVIATIONS

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<b>BIS</b>	Bureau of Indian Standards
<b>CE</b>	European Conformity
<b>CEN</b>	European Committee of Standardisation
<b>CENLEC</b>	European Committee for Electrotechnical Standardization
<b>CII</b>	Confederation of Indian Industry
<b>DGFASLI</b>	Directorate General Factory Advice Services & Labour Institutes
<b>EC</b>	European Commission
<b>EN</b>	European Standard
<b>EU</b>	European Union
<b>GIZ</b>	Deutsche Gesellschaft für Internationale Zusammenarbeit
<b>Gol</b>	Government of India
<b>GPQI</b>	Global Project Quality Infrastructure
<b>IEC</b>	International Electrotechnical Commission
<b>ISO</b>	International Organization for Standardization
<b>MD</b>	Machinery Directive
<b>MED</b>	Mechanical Engineering Department
<b>MeitY</b>	Ministry of Electronics and Information Technology
<b>MoC</b>	Ministry of Commerce and Industry
<b>MoHI</b>	Ministry of Heavy Industries and Public Enterprises
<b>MoL&amp;E</b>	Ministry of Labour & Employment
<b>MoP</b>	Ministry of Power
<b>MoRTH</b>	Ministry of Road Transport and Highways
<b>OEM</b>	Original Equipment Manufacturer
<b>OHS</b>	Occupational Health and Safety
<b>QCI</b>	Quality Council of India
<b>TC</b>	Technical Committee
<b>VDMA</b>	Mechanical Engineering Industry Association
<b>WG</b>	Working Group

## EXECUTIVE SUMMARY

Reports show that several thousand occupational accidents take place annually in India. Only 20 percent of India's 465 million workers are covered under its existing health and safety legal framework. One factory inspector is responsible for over 500 factories. These figures demonstrate why improving machinery and worker safety is important in India.

New opportunities for the machinery industry have opened through a focus on manufacturing, especially through the *Make in India* initiative. Launched in 2014, it has the objective of job creation and skill enhancement which will lead to transforming India into a global design and manufacturing hub.

In 2016, the Indian government introduced the *National Capital Goods Policy* which highlights the need of mandatory standards, minimum acceptable safety, and environment and performance standards for machinery. A technical committee for machinery standards was also established by the Bureau of Indian Standards (BIS). Certain safety regulations, new for Indian manufacturing, and an established part of European manufacturing, will increase the demand in India for high-quality machines, manufacturing components and technologies, and at the same time ensure the safety of Indian workers.

Recognising these recent developments, this study, conducted within the framework of the Indo-German Working Group on Quality Infrastructure provides a comprehensive look at the current situation in India and challenges faced by the industry, and also compares machinery directives in India and the European Union (EU). The study identifies and recommends cooperation opportunities between India and Germany.

### The study:

- » documents the current regulatory framework in India for machinery safety.
- » examines policy trends for machinery safety in India.
- » offers a reference for existing standards, standards currently being developed, and their harmonisation with international standards.
- » compares the current Indian regulations and European Machinery Directives.
- » identifies specific technical regulation challenges faced by German industry in India.

### Regulatory framework in India is supported by three governmental pillars:

The first pillar is the Ministry of Labour & Employment (MoL&E). It is responsible for the health, safety, and welfare of workers. Of the several labour related statutes enacted by the Central Government, the *Factories Act of 1948*, amended by the *Factories (Amendment) Act, 1987* and the *National Policy on Safety, Health & Environment at Work Place* have been elaborated on in this study because of their importance. The government agency which provides technical assistance to the ministry in formulating national policies, the Directorate General Factory Advice and Service Institute (DGFASLI), coordinates the administration of the *Factories Act*.

The second pillar of the regulatory framework is the Bureau of Indian Standards (BIS) which formulates Indian Standards for machinery safety through its technical committees. The third pillar is the Ministry of Heavy Industries & Public Enterprises (MHI&PE) which introduced the *National Capital Goods Policy* in 2016 outlining minimum acceptable safety, environmental impact standards, and performance requirements for machinery.

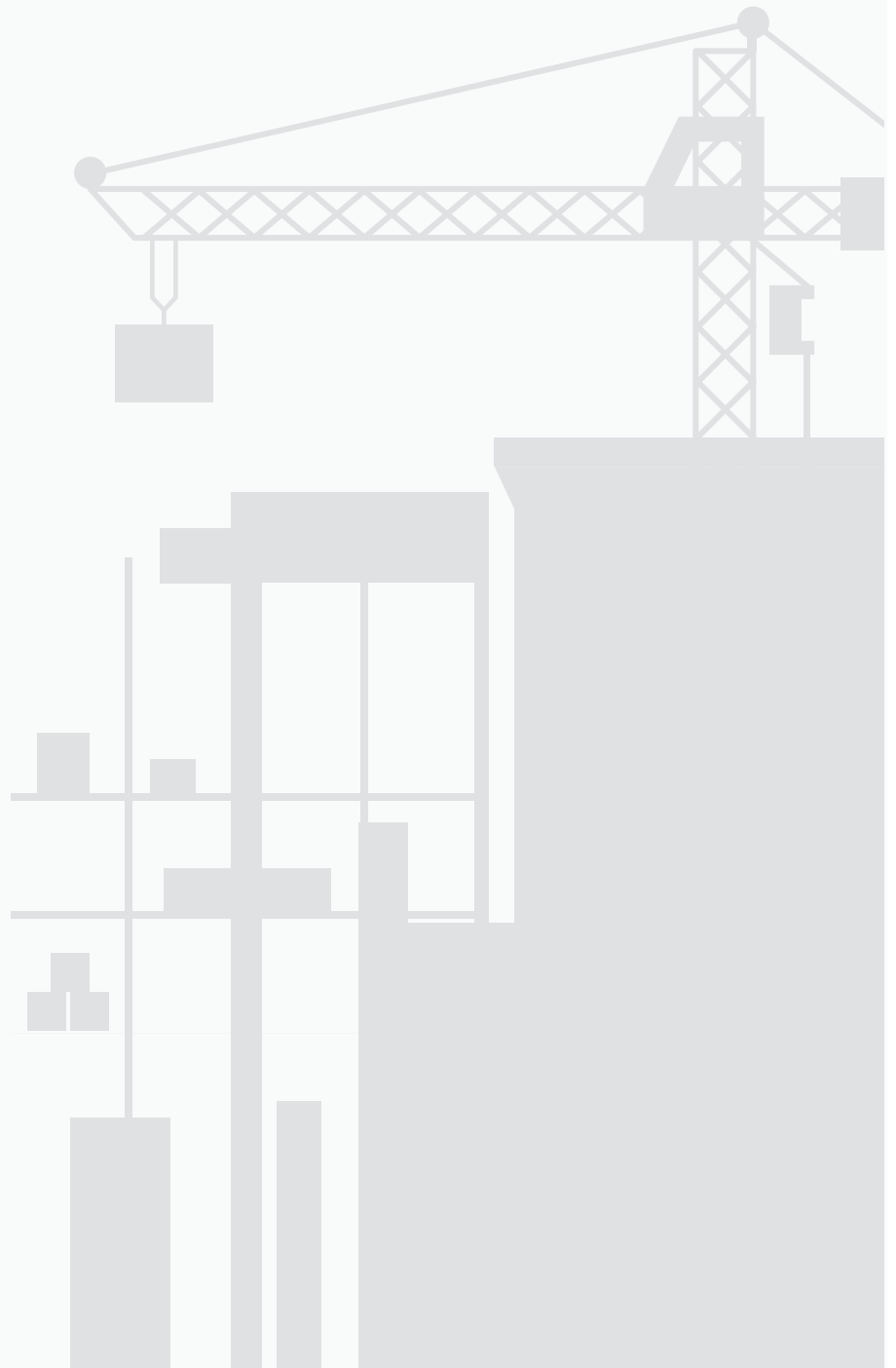
A comparison of the European/German system and the Indian system shows that the EU framework is based on two well-established but separate legal frameworks. The Machinery Directive is for the provisioning of safe machines on the market and addressed to the manufacturer. The second one is for workplace safety addressed to the employer and shall provide

a safe environment for machinery and labour. While in India, safety obligations are directed towards occupational health and safety (OHS) requirements prescribed in the *Indian Factories Act*. Other differences in conformity assessment procedures and enforcement of the regulations are highlighted as a part of this study.

The main concerns of the European machine manufacturers are the lack of a comprehensive machinery safety regulation in India and discrepancies in the enforcement of the existing regulations between the federal states. These concerns ultimately have a bearing on the price of machines – and factor into their competitiveness.

The limited scope of the Indian *Factories Act, 1948* clearly establishes the need for more comprehensive regulations. These new regulations need to meet safety standards ensuring both workplace and machinery safety, while at the same time considering the leverage of emerging manufacturing processes in India, like Industry 4.0.

This study recommends a comprehensive approach including measures such as strengthening the regulatory framework, classification of ISO and IEC standards adopted without modification, awareness among the users and decision makers, and conformity assessment for both new and used machines.



## INTRODUCTION

The International Labour Organization (ILO) reports that more than 2.3 million workers around the world die in occupational accidents or from work-related diseases each year. Available information from India indicates that several thousand annual occupational fatalities happen. And, if incidents from the unorganised manufacturing sector were also factored in, the actual numbers in India would likely be much higher. Machinery related accidents affect the lives of workers and their families and can also harm the environment. On average there is only one factory inspector for every 500 Indian factories, and less than a quarter of India's 465 million workers are covered under the country's existing health and safety legal framework.<sup>1</sup>

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Beyond the ethical responsibility, the short- and long-term financial benefits of ensuring safe work environments are finally being recognized.

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Beyond the ethical responsibility, the short- and long-term financial benefits of ensuring safe work equipment like machinery and safe workplaces are finally being recognized. Accidents damage the reputation of firms and lead to production losses. The ILO estimates that accidents and work-related diseases cost the global economy around three trillion US dollars annually.<sup>2</sup> These aspects illustrate why both machinery and worker safety are crucial topics for every firm, every worker, and every policy framework. The application of the ILO-recommendations is the first step to improve workplace safety. The proposed technical requirements of the ILO-recommendations are very close to the requirements of the EU Legislation regarding workplace safety.

Safer work environments are receiving increased attention not only in India, but in other emerging economies where industry best practices are being actively adopted. During the past few decades, a growing number of countries have recognized the value of these measures and developed and introduced safety requirements in accordance to their national laws. Successful implementation of safety culture involves a specific understanding of the needs, standards, technical regulations, and the conformity challenges a country faces. Separate national developments have created various standards for identical products and vastly different procedures for gaining access to markets.

Currently, two main models are being used. In one, countries place responsibility on manufacturers and importers. This model is generally combined with effective market surveillance; where authorities prevent unsafe products from entering the market. In other countries, a restrictive concept has been introduced, based on obligatory certification. Both versions have advantages and limitations. The differences between these models shows that a harmonization of individual national standards and conformity assessment procedures with international standards and international procedures has become important in facilitating trade.

Manufacturers and trade agencies working between Europe and India encounter several specific challenges. These challenges can be attributed to the high bureaucratic effort and time investment required for market entry with differing state and national regulations creating time consuming hurdles. The repercussions of these delays then greatly influence the initial and life-cycle cost of products. Recognizing this, the Indian government introduced the *National Capital Goods Policy* in 2016 which highlights the need for mandatory standards, minimum acceptable safety, and environment and performance standards for machinery. A technical committee for machinery standards was also established by the Bureau of Indian Standards (BIS).

*“With the support of the Global Project Quality Infrastructure, the Indo-German Working Group on Quality Infrastructure has helped to level the playing field for machinery safety in India. For the first time, comparable standards were introduced. This is actually a game changer.*

Heinrich Bruellau  
Former COO  
Schmersal India Pvt. Ltd.

1 <https://www.weforum.org/agenda/2017/03/workplace-death-health-safety-ilo-fluor/>;  
<https://timesofindia.indiatimes.com/business/india-business/48000-die-due-to-occupational-accidents-yearly-study/articleshow/61725283.cms>;  
<https://indianexpress.com/article/india/india-others/2010-12-over-4000-died-on-shop-floor-but-thats-fraction-of-total/>;  
[http://www.dgfasli.nic.in/dashboard/dashboard\\_annexure2.pdf](http://www.dgfasli.nic.in/dashboard/dashboard_annexure2.pdf);  
<https://www.deccanchronicle.com/lifestyle/health-and-wellbeing/201117/almost-48000-people-die-in-occupational-accidents-every-year-study.html>

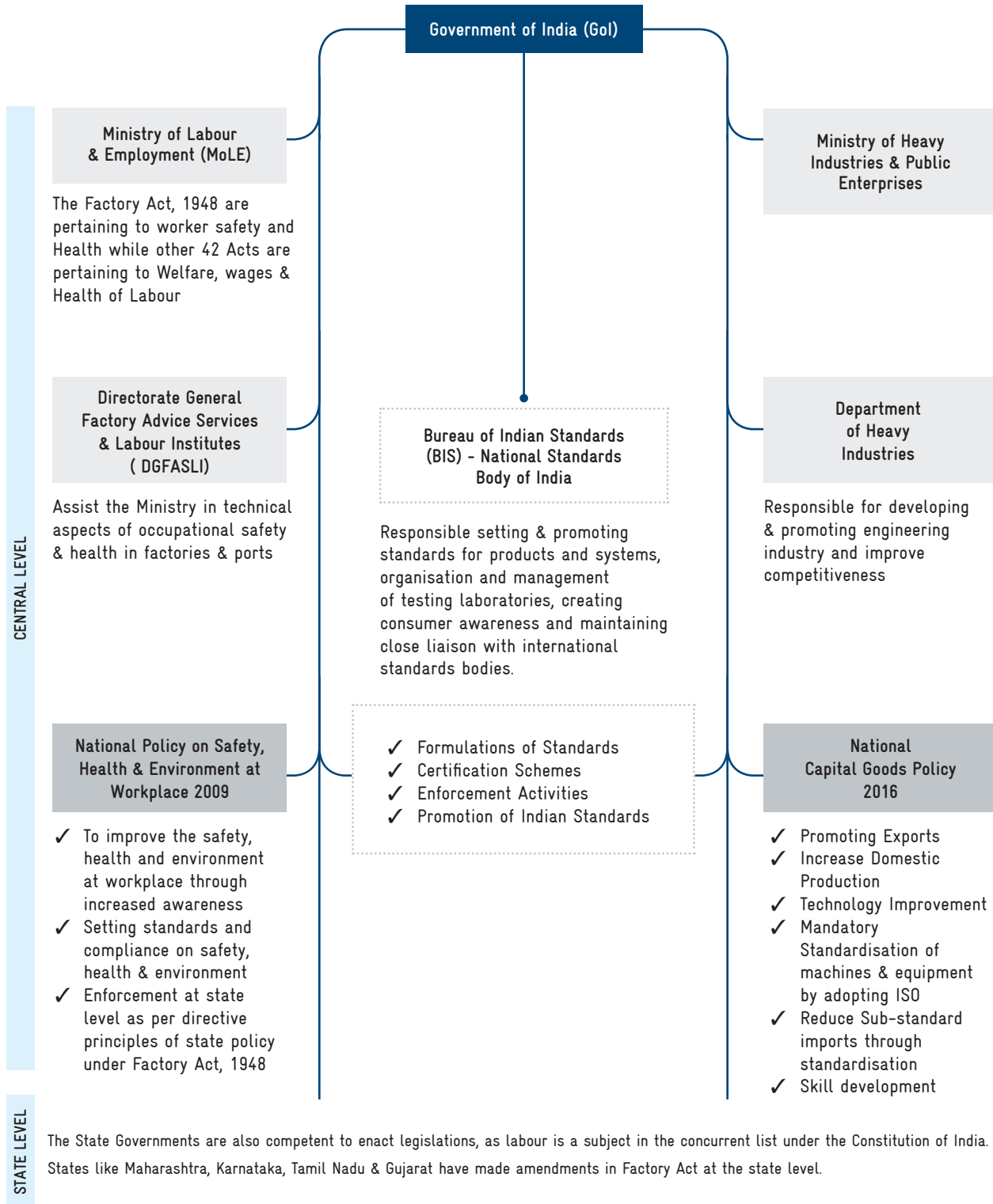
2 <https://www.weforum.org/agenda/2017/03/workplace-death-health-safety-ilo-fluor/>

The Indo-German Working Group on Quality Infrastructure recognised the further development and importance of machine standards in India and conducted the following study with the support of the Indian country component of the Global Project Quality Infrastructure (GPQI).

This study provides a comparative overview of India and Europe's machinery directives. It showcases the acts, legislations and structures that created the current regulatory situation in India. It also identifies the challenges faced by the industry, based not only on the comparative analysis of regulations but on feedback and input from German and European industry experts. Based on these findings, specific recommendations are offered for cooperation activities between India and Germany, which could also minimise technical barriers to trade.

# REGULATORY FRAMEWORK IN INDIA

The regulatory framework in India is supported by three governmental pillars, the Ministry of Labour & Employment, the Bureau of Indian Standards, and the Ministry of Heavy Industries & Public Enterprises. This section offers an overview of the legal and organizational structure for labour welfare and machine regulation in India. The three key ministries and their internal structure are shown along with a catalogue of the relevant legislation.



Source: National Policy on safety, health & environment at workplace 2009, National Capital Good Policy 2016, National Standard Body of India & BDB Analysis

Figure 1 - Regulatory Framework in India

## MINISTRY OF LABOUR & EMPLOYMENT

The Ministry of Labour & Employment (MoL&E) is responsible for the health, safety and welfare of workers. The main responsibility of this ministry is to protect and safeguard the interests of workers, providing a healthy work environment for increased production and better productivity. These objectives are facilitated through the enactment and implementation of various labour laws. These laws regulate the terms and conditions of service, and the employment of workers; like the *Factories Act of 1948 and the National Policy on Safety, Health & Environment at Work Place*. There are presently 44 labour related statutes enacted by the federal, or Central Government, dealing with minimum wages, accidental and social security benefits, occupational safety and health, conditions of employment, disciplinary action, the formation of trade unions, industrial relations and other issues.<sup>3</sup>

There are five relevant national, or Central Labour Acts, that have been enacted by the MoL&E, they are:

- » The Factories Act, 1948
- » The Mines Act, 1952
- » The Dock Workers (Safety, Health and Welfare) Act, 1986
- » The Building and Other Constructions Workers' (Regulation of Employment and Conditions of Service) Act, 1996
- » The Unorganized Workers' Social Security Act, 2008

In addition to the Central Government, the state governments also have the prerogative to enact labour legislation under the Constitution of India. Both the federal and state governments are supported by the Directorate General, Factory Advice and Labour Institutes (DGFASLI). The DGFASLI was initially created in 1945 to support the administration of the Factories Act and to coordinate state-level factory inspection services. DGFASLI now serves as the technical arm, assisting the ministry in formulating national policies.<sup>4</sup> It also advises factories on various issues concerning safety, health, efficiency and the wellbeing of people in work places. It is a subordinate office of the Ministry of Labour & Employment.

### National Policy on Safety, Health and Environment at Workplace, 2009

In February 2009, the Ministry of Labour and Employment announced the *National Policy on Safety, Health and Environment at Workplace*.<sup>5</sup> This establishes a preventive safety and health culture in all the sectors of economic activity in India. Its goal is the elimination of work-related injuries, diseases, fatalities, disasters, and to enhance the well-being of employees. Occupational health and safety is reinforced in India, like in many other countries, by implementing laws which regulate a company's measures to guarantee OHS. This policy and others like it outline the basic minimum requirements.

### The Factories Act, 1948–Amendment 1987

The *Factories Act* regulates the health, safety, welfare, and other working conditions of workers in factories. It pre-dates the 1950 constitution of Indian and illustrates how both national and state governments have historically prioritized a worker safety. The act is enforced by India's state governments through their factory inspectors.<sup>6</sup> Its main objectives are to regulate the working conditions in factories, to regulate health, safety welfare, and annual leave and enact special provision for young people, women, and children who work in the factories. The act covers five areas: 1. working hours, 2. health, 3. safety, 4. welfare, and 5. penalties.

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The Factories Act regulates the health, safety, welfare, and other working conditions of workers in factories.

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<sup>3</sup> <https://labour.gov.in/about-ministry>

<sup>4</sup> <http://www.dgfasli.nic.in/about.htm>

<sup>5</sup> <https://labour.gov.in/policies/safety-health-and-environment-work-place>

<sup>6</sup> <http://dgfasli.nic.in/statutes5.htm>

The *Factories Act* also grants state governments the authority to appoint inspectors, chief inspectors and others. Every district magistrate is also a district inspector. However, no inspections are conducted under the act, they are only carried out based on referrals or complaints.

Chapter IV of the *Factories Act* concerns personnel safety and does not address machinery safety other than adding a regulation for so-called “Dangerous Machines” – power thrashers and agricultural equipment.

Below is a summarization of key points in the Factories Act, 1948 - Amendment 1987, for more details, see the cited sections:

Section 21	The machinery in every factory shall be properly fenced.
Section 22	Only a trained adult male worker, wearing tight fitting clothing which shall be supplied by the occupier, shall be allowed to work near the machinery in motion.
Section 23	No young person shall be employed on dangerous machinery, unless he is fully instructed as to the danger arising in connection with the machine and the precautions to be observed and he has received sufficient training in work at the machine
Section 24	Suitable arrangements shall be made to provide striking gear and devices for cutting off power in case of emergencies.
Section 25	Sufficient precautions shall be taken regarding self-acting machines to avoid accidents.
Section 26	To prevent danger, all machinery driven by power shall be encased and effectively guarded.
Section 28	Hoists and Lifts in a factory shall be periodically inspected by the Competent Person.
Section 29	Lifting Machines, Chains, Ropes and Lifting Tackles in a factory shall be periodically inspected by the Competent Person
Section 30	Where process of grinding is carried on, a notice indicating the maximum safe working peripheral speed of every grind-stone or abrasive wheel etc., shall be fixed to the revolving machinery.
Section 31	Where any plant or machinery or any part thereof is operated at a pressure above atmospheric pressure, effective measures shall be taken to ensure that the safe working pressure of such plant or machinery or part is not exceeded
Section 32	Floors, stairs and means of access shall be soundly constructed and properly maintained.
Section 33	Pits, sumps opening in floor etc., shall be either securely covered or fenced.
Section 34	No workman shall be employed in any factory to lift, carry or move any load so heavy as to be likely to cause him injury.
Section 35	Necessary protective equipment shall be provided to protect the eyes of the workman, where the working involves risk of injury to the eyes.
Section 36	Suitable precautionary arrangements shall be taken against dangerous fumes, gases etc.



Section 37	Every practicable measure shall be taken to prevent any explosion where the manufacturing process produces dust, gas, fume or vapour....
Section 38	Every practicable measure shall be taken to prevent the outbreak of fire and its spread, both internally and externally.
Section 39	The Inspector of Factories can ask the Occupier or the Manager of the Factory to furnish drawings, specification etc., of any building, machinery or a plant, in case he feels that condition of such building, machinery or the plant may likely to cause danger to human life.
Section 40	The Inspector of Factories can suggest suitable measures of steps to take by the Occupier or Manager for implementation, when he feels the condition of any building, machinery or a plant may likely to cause danger to human life.
Section 40-B	Wherein 1000 or more workmen are employed in a factory, the Occupier shall appoint a Safety Officer to look after the safety aspects of the factory.

### The Dangerous Machines (Regulation) Act, 1983

*The Dangerous Machines (Regulations) Act, 1983* was created to control the trade, commercial activities, manufacture, supply, allocation, and utilization of commodities of any establishment that manufactures hazardous equipment. This act reflects changes in the domestic agricultural industry of India in the early 1980s and focuses solely on power threshers and other machines intended to be used in the agricultural or rural sectors. Machines are defined as dangerous if they are “used in the agricultural or rural” sector and the Central Government has classified these machines as being able to cause an “operator death, dismemberment of any limb or other bodily injury”.<sup>7</sup>

### Provisions Related To Machinery Safety

The two acts introduced above, the *Factories Act, 1948-Amendment 1987* and the *Dangerous Machines (Regulations) Act, 1983* share the legal guidelines for enforcement of machinery safety in India.

#### 1. Risks related to machinery and tools

Employers must ensure complete mitigation of risks posed by machinery at the work place.

See: *The Factories Act, 1948 [No. 63 of 1948] (Sections 21 to 30)*

#### 2. Duty of designers and/or manufacturers of machineries in relation to the occupational safety and health of machine operators

Designers, manufacturers and importers of articles, and substances used in factories are under an obligation to ensure that the article does not pose health risks to labour. They must adequately test the product before making it available to workers, and to take steps to ensure that the necessary information about the article is made available to the workers prior to its use. Consequently, manufacturers of an article are also under an obligation to ensure the safety of the workers at different work premises, who are using the manufactured articles.

See: *The Factories Act 1948 [No. 63 of 1948], (7B)*

The law stipulates that it is the duty of manufacturers, designers, and dealers of dangerous machinery to ensure the machinery’s compliance with industry standards, and must provide clear legible indicators on machines, including points beyond which physical human contact must be avoided.

<sup>7</sup> See: *The Dangerous Machines (Regulation) Act, 1983 (Section 3b).*

The manufacturers of dangerous machinery must ensure that the machinery complies with established safety requirements. Furthermore, the manufacturers are obliged to label the machinery with the appropriate danger signals, manufacturing details, and power requirements.

See: *Dangerous Machines (Regulation) Act, 1983* [No. 35 of 1983], (13-17)

*Dangerous Machines (Regulation) Act, 1983* [No. 35 of 1983] (Chapter IV, Sections 3-17), and *The Factories Act 1948* [No. 63 of 1948], (Sections 7B)

### 3. Duty of designers, manufacturers, importers or suppliers of machineries to provide machinery information.

Designers, manufacturers, and importers of articles and substances used in factories are under a duty to ensure that the article does not pose health risks to the workers, to adequately test the product before making it available to workers, and to take steps to ensure that the necessary information about the article is made available to the workers prior to use. These laws make manufacturers, designers, and dealers of dangerous machinery responsible for ensuring compliance of the machinery are following industry standards.

See: *Dangerous Machines (Regulation) Act, 1983* [No. 35 of 1983] (Chapter IV, Section 13), and *The Factories Act, 1948* [No. 63 of 1948] (Section 7B)

### 4. Duty to purchase machineries from authorised/certificated suppliers or only if approved/certificated

Employers are obliged to purchase and use machinery that complies with the prescribed industry standards.



See: *Dangerous Machines (Regulation) Act, 1983* [No. 35 of 1983]

### 5. Maintenance of machinery and equipment

The law stipulates that employers and users of machinery and equipment in India, are obligated to conduct periodic maintenance in an organised way, and to ensure that the machinery is compliant with the prescribed industry standards.

See: *The Factories Act, 1948* [No. 63 of 1948]

## LIMITATIONS

	Act	Limitations
	Factories Act	Although there are several provisions under the acts for safety, they lack universal enforcement.
	Dangerous Machines (Regulation) Act	The state governments are empowered to make rules under the enabling provisions as well as general provision, which vary from state to state, leading to little uniformity in enforcement. States like Maharashtra, Karnataka, Tamil Nadu, and Gujarat have made amendments to the Factories Act, however these amendments are not successfully implemented at the ground level. The Dangerous Machines (Regulation) Act are to limited machines like power thrashers and agricultural equipment while other machines are not considered.

## BUREAU OF INDIAN STANDARDS

The second pillar of the regulatory framework is the Bureau of Indian Standards (BIS) – the National Standards Body, working under the aegis of the Ministry of Consumer Affairs, Food & Public Distribution. It formulates Indian Standards for machinery safety through its technical committees.

The BIS, was established under the Bureau of Indian Standards Act, 1986 (revised in 2016) for the “harmonious development of standardisation, conformity assessment, and quality assurance of goods, articles, processes, systems, and services”.<sup>8</sup> The BIS has a long institutional history reaching back to 1946 when its predecessor, the Indian Standards Institution, was formed. It focuses on both the interest of consumers and industry, and is involved in various activities including standards formulation, conformity assessment, laboratory services, training, and information services.

The BIS follows the six principles for standards development that are expressed in the agreement on Technical Barriers to Trade, commonly referred to as the TBT Agreement, an international treaty administered by the World Trade Organization. Including openness, transparency, impartiality and consensus, effectiveness and relevance, coherence and, development dimension. For the formulation of Indian Standards, BIS functions through the Technical Committee structure comprising of Sectional Committees, Subcommittees and Panels set up for dealing with specific subjects under respective Division Councils. To ensure that standards are developed in accord with national interests, the committee structure of BIS seeks to bring together individuals and groups with substantial interest in a subject. After considering all significant viewpoints through a process of consultation the decisions in BIS technical committees are reached through consensus. As a policy, the standards formulation activity of BIS has been harmonized with the relevant guidelines of the International Organization for Standardization (ISO).

### Procedure for Establishment of Indian Standards

Excerpts from Bureau of Indian Standards Rules, 1987 [Chapter III Section 7, a-h]:

- a) Any Ministry of the Central Government, State Governments, Union Territory Administrations, consumer organizations, industrial units, industry-associations, professional bodies, and members of the Bureau and members of its technical committees may submit proposals to the Bureau for establishing a standard or for revising, amending, or cancelling an established standard by making such request in writing.
- b) The work of formulation of standards on any specific subject shall be undertaken when the Division Council concerned is satisfied because of its own deliberations or on investigation and consultation with concerned interests that the necessity for standardization has been established.
- c) When the subject has been so investigated and the need established, the Division Council concerned shall assign the task of formulating the standard to an appropriate Technical Committee or shall appoint a new Technical Committee for the purpose.
- d) When request for establishing a standard for any specific subject has not been accepted after its due consideration, the proposer is informed of the decision.
- e) A draft standard prepared and duly approved by a Committee is issued in draft form and widely circulated for a period of not less than one month amongst the various interests concerned for critical review and suggestions for improvement. The wide circulation may be waived if so decided by the Sectional Committee where the matter is urgent or non-controversial.
- f) The appropriate Technical Committee thereafter finalizes the draft standard giving due consideration to the comments that may be received. The draft standard after it has been approved by the Sectional Committee and submitted to the Chairman of the Division Council concerned for adoption on its behalf.

<sup>8</sup> <https://www.bis.gov.in>

- g) All established standards are reviewed periodically, at least once in five years, to determine the need for revision or withdrawal. Standards which in the opinion of the Sectional Committee need no revision or amendment are reaffirmed by the Sectional Committee.

Special attention is given to multidisciplinary areas such as energy conservation, environmental protection, rural development, and safety. The Sectional Committee of BIS examines the adoption of ISO/IEC standards wherever available and required. The BIS is engaged in formulation of Indian Standards for the following sectors through a Division Council for each sector:

- » Chemicals
- » Civil Engineering
- » Electronics and Information Technology
- » Electro Technical
- » Food & Agriculture
- » Mechanical Engineering
- » Management and Systems
- » Medical Equipment and Hospital Planning
- » Metallurgical Engineering
- » Petroleum Coal & Related Products
- » Production & General Engineering
- » Transport Engineering
- » Textiles
- » Water Resources

### Standards Development Process

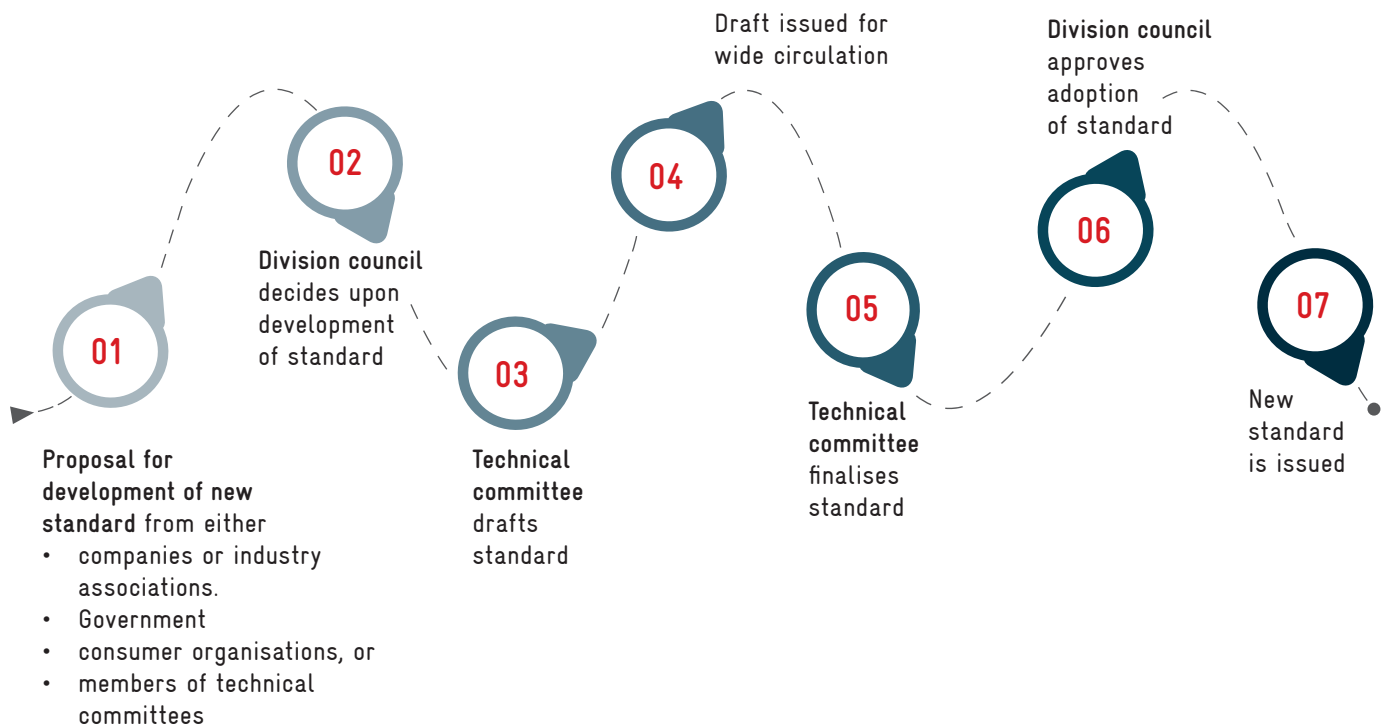


Figure 2 – Standards Development Process

## Standards related to machinery safety

The BIS has various technical committees, most relevant for this study are the Mechanical Engineering Department MED 40 Safety of Machinery, Electrotechnical Department ETD 44 Safety of Machinery- Electrotechnical Aspects, and Chemical Department CHD 8 Occupational Safety and Health.

A more recent committee under Mechanical Engineering Department, MED 40: Safety of Machinery has been established and mirrors the International Organization for Standardization's ISO/TC 199 Safety of Machinery. The BIS committee has finalized 32 Indian Standards (under print) which are an adoption of the corresponding ISO standard.

### Published Standards

IS No. & Year	Title
IS 16806 (Part 6):2018 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
IS 16806 (Part 7):2018 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
IS 16912:2018 ISO 21469:2006	Safety of machinery - Lubricants with incidental product contact - Hygiene requirements

Table 1 – List of Published Indian Standards (Non-electrotechnical)

### Draft Standards under Wide Circulation:

ISO Standards	Standards formulation Under New Committee MED 40 in India (doc no) <sup>1</sup>	Description
ISO 13854:2017	MED 40 (13240)	Safety of Machinery Minimum gaps to avoid crushing of parts of the human body

### Finalized Draft Indian Standards under Print

ISO Standards	Standards formulation Under New Committee MED 40 in India (doc no) <sup>2</sup>	Description
ISO 12100:2010	MED 40 (11995)	Safety of machinery - General principles for design - Risk assessment and risk reduction
ISO 13849-1:2015	MED 40 (11996)	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design
ISO 13849-2:2012	MED 40 (11997)	Safety of machinery - Safety-related parts of control systems - Part 2: Validation
ISO 13850:2015	MED 40 (11998)	Safety of machinery - Emergency stop function - Principles for design
ISO 13851:2002	MED 40 (11999)	Safety of machinery - Two-hand control devices - Functional aspects and design principles

<sup>2</sup> These are temporary document numbers and once printed they will be aligned to corresponding ISO standards.

ISO Standards	Standards formulation Under New Committee MED 40 in India (doc no) <sup>2</sup>	Description
ISO 13854:2017	MED 40 (12000)	Safety of machinery -- Minimum gaps to avoid crushing of parts of the human body
ISO 13855:2010	MED 40 (12001)	Safety of machinery -- Positioning of safeguards with respect to the approach speeds of parts of the human body
ISO 13856-1:2013	MED 40 (12002)	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	MED 40 (12003)	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	MED 40 (12004)	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	MED 40 (12005)	Safety of machinery -- Safety distances to prevent hazard zones being reached by upper and lower limbs
ISO 14119:2013	MED 40 (12007)	Safety of machinery -- Interlocking devices associated with guards -- Principles for design and selection
ISO 14120:2015	MED 40 (12008)	Safety of machinery -- Guards -- General requirements for the design and construction of fixed and movable guards
ISO 14122-1:2016	MED 40 (12009)	Safety of machinery -- Permanent means of access to machinery -- Part 1: Choice of fixed means and general requirements of access
ISO 14122-2:2016	MED 40 (12010)	Safety of machinery -- Permanent means of access to machinery -- Part 2: Working platforms and walkways
ISO 14122-3:2016	MED 40 (12011)	Safety of machinery -- Permanent means of access to machinery -- Part 3: Stairs, stepladders and guard-rails
ISO 14122-4:2016	MED 40 (12012)	Safety of machinery -- Permanent means of access to machinery -- Part 4: Fixed ladders
ISO 14123-1:2015	MED 40 (12013)	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	MED 40 (12014)	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	MED 40 (12015)	Safety of machinery -- Hygiene requirements for the design of machinery

ISO Standards	Standards formulation Under New Committee MED 40 in India (doc no) <sup>2</sup>	Description
ISO 19353:2015	MED 40 (12016)	Safety of machinery – Fire prevention and fire protection
ISO 29042-1:2008	MED 40 (12018)	Safety of machinery – Evaluation of the emission of airborne hazardous substances -- Part 1: Selection of test methods
ISO 29042-2:2009	MED 40 (12019)	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	MED 40 (12020)	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	MED 40 (12021)	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	MED 40 (12022)	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 29042-8:2011	MED 40 (12025)	Safety of machinery – Evaluation of the emission of airborne hazardous substances – Part 8: Room method for the measurement of the pollutant concentration parameter
ISO 29042-9:2011	MED 40 (12026)	Safety of machinery – Evaluation of the emission of airborne hazardous substances – Part 9: Decontamination index
ISO 14118:2017	MED 40 (12407)	Safety of machinery – Prevention of unexpected start-up

Table 2 - List of Draft Indian Standards (Non-electrotechnical)

Along similar lines, the Electrotechnical Department of BIS has a technical committee, ETD 44 Safety of Machinery- Electrotechnical Aspects which is a mirror committee of IEC/TC 44. The BIS technical committee has published 8 Indian Standards, and 7 standards are under various stages of processing. These standards are the adoption of the corresponding IEC standard.

#### Standards Published:

Standard No. & Year	Description
IS 16501:2017 IEC 62061:2005	Safety of Machinery – Functional Safety of Safety – related Electrical Electronic and Programmable Electronic Control Systems
IS 16502 (Part 2):2017 IEC 61496 – 2:2013	Safety of Machinery – Electro – Sensitive Protective Equipment Part 2 Particular Requirements for Equipment Using Active Opto-Electronic Protective Devices AOPDs

IS 16503 (Part 1):2017 IEC 61310-1:2007	Safety of machinery –Indication Marking and Actuation – Part 1 Requirements for Visual Acoustic and Tactile Signals
IS 16503 (Part 2):2017 IEC 61310-2:2007	Safety of machinery –Indication Marking and Actuation – Part 2 Requirements for Marking
IS 16503 (Part 3):2017 IEC 61310-3:2007	Safety of machinery – Indication Marking and Actuation – Part 2 Requirements for the Location and Operation of Actuators
IS 16504 (Part 1):2017 IEC 60204-1:2008	Safety of machinery – Electrical Equipment of Machines Part 1 General requirements
IS 16504 (Part 32):2017 IEC 60204- 32:2008	Safety of Machinery Electrical Equipment of Machines Part 32 Requirements for Hoisting Machines
IS 16594 (Part 1): 2017 IEC 614961:2012	Safety of Machinery – Electro – Sensitive Protective Part 1 General Requirements and Tests
IS 16936:2018 IEC TR 62513:2008	Safety of Machinery – Guidelines for use of communication systems in safety related applications
IS 1356 ( Part 1):1972	Electrical equipment of machine tools Part 1 Electrical Equipment of machines for General Use

Table 3 – List of Indian Standards (Electrotechnical)

#### A. Finalised and under Print

Standards formulation Under New Committee ETD 44 in India (doc no)	Description
ETD 44 (10918)	IECTS 61496-4-3 2015 Safety of Machinery – Electro-sensitive protective equipment – Requirements for equipment using vision based protective devices VBPD Additional requirements when using stereo vision techniques VBPDST

#### B. Draft Standards under Wide Circulation Stage

Standards formulation Under New Committee ETD 44 in India (doc no)	Description
ETD 44 (12365)	Safety of machinery Electrical equipment of machines Part 1 General requirements first revision
ETD 44 (12384)	Safety of machinery Electrical equipment of machines Part 11 Requirements for HV equipment for voltages above 1000 V or 1500 V DC and not exceeding 36 kV
ETD 44 (12385)	Safety of machinery Electrical equipment of machines Part 31 Particular safety and EMC requirements for sewing machines units and systems
ETD 44 (12386)	Safety of machinery Electrical equipment of machines Part 33 Requirements for semiconductor fabrication equipment
ETD 44 (12387)	Safety of machinery Electrical equipment of machines Part 34 Requirements for machine tools

Table 4 – List of Draft Indian Standard (Electrotechnical)

The technical committee CHD 8 of Chemical Department, BIS is responsible for formulating standards on occupational health and safety such as ISO 18001 and others.



## MINISTRY OF HEAVY INDUSTRIES & PUBLIC ENTERPRISES

The third pillar of the Indian regulatory framework is the Ministry of Heavy Industries & Public Enterprises (MHI & PE) which introduced the *National Capital Goods Policy* in 2016. This policy defines the minimum acceptable safety, environment, and performance requirements for machinery in India.

The Department of Heavy Industry of the MHI&PE is responsible for promoting the engineering industry, like machine tools, heavy electrical, industrial machinery, and the auto industry in India<sup>10</sup>. The Ministry also looks after the machine building industry and caters to the requirements of equipment for basic industries such as steel, non-ferrous metals, power, fertilizers, refineries, petrochemicals, shipping, paper, cement, sugar and others.

In India, imports contribute around 45% of capital goods demand and domestic capacity utilisation across its sub-sectors is only around 60-70 percent.<sup>11</sup>

India is a importer across capital goods sub-sectors

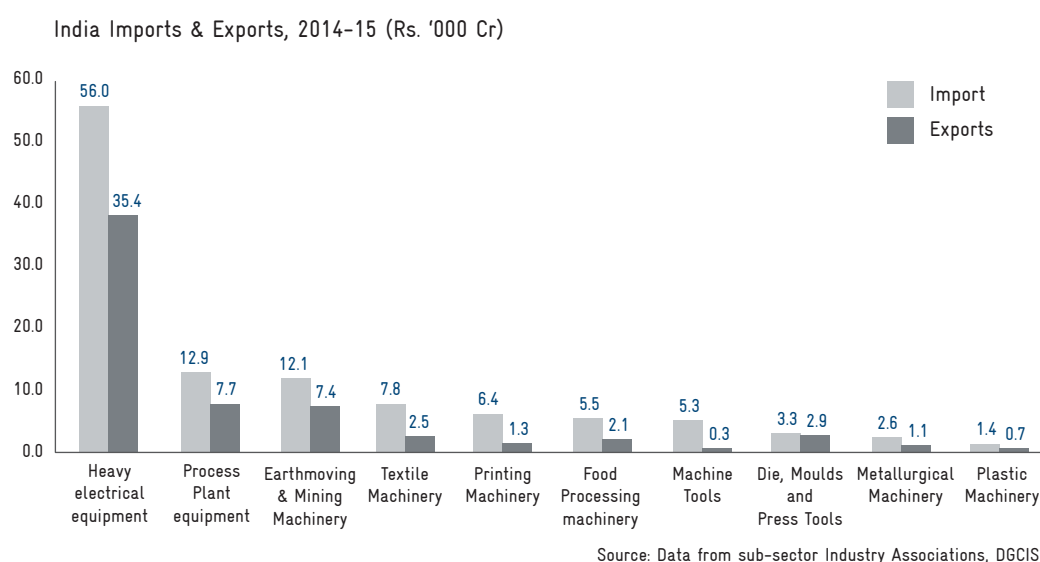


Figure 3 – India Imports and Exports

### 6. National Capital Goods Policy, 2016

The *National Capital Goods Policy 2016* foresees increasing exports from the current 27 percent of production to 40 percent.<sup>12</sup> The policy also aims to facilitate improvement in technology depth across sub-sectors, increase skill availability, ensure mandatory standards and promote growth and capacity building of micro, small and medium enterprises (MSMEs). Key features include:

<sup>10</sup> <https://dhi.nic.in/UserView/index?mid=1369>

<sup>11</sup> Capital goods, as shown on Figure 3 includes heavy electrical equipment, process plant equipment, earthmoving and mining machinery, printing machinery, food processing machinery, dies, moulds and press tools, textile machinery, machine tools, plastic machinery, and metallurgical machinery.

<sup>12</sup> <https://dhi.nic.in/writereaddata/Content/Capital%20Goods%20Policy%20Final.pdf>

- » The introduction of minimum safety requirements - to develop a policy document ensuring that requirements are at par with global benchmarks.
- » Definitions of minimum acceptable safety, environment and performance requirements for machinery.
- » The policy also calls for mandatory standardisation, which includes defining the minimum for acceptable standards and the adoption of IOS norms.
- » Significant enhancement to the capacity, capability and infrastructure of the standards, testing and certification schemes.<sup>13</sup>

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<sup>13</sup>The framework for this policy is in development stage and is yet to incorporate legislations.

# LEGAL FIELDS IN THE EUROPEAN UNION AND TRANSPOSITION IN GERMANY

At the European level, both regulations and directives shape policy. The European Commission (EC) requires EU Member States to achieve certain objectives by EU Directives, that have to be transposed into national law and EU Regulations that become directly valid.<sup>14</sup>

The directives are transposed by the Member States into national laws. The connection between standardization and legislation in the EU is assured by the “New Legislative Framework”. This principle, introduced in 1985, promotes the coherence and consistency of mandatory health and safety legislation supported by voluntary harmonised standards. The German legislative framework is characterised by the transposition of all European Directives without modification of the regulated issues. The directives are implemented literally on the national level.

Technical standards substantiate the more general requirements for product safety, reflects the state of the art and product conformity of European Directives into more practical specifications for a safe product design. These standards are developed by the European standardisation organisations CEN, CENELEC, and ETSI. Combined with the publication of the reference of harmonized European standards in the Official Journal under a European Directive, these standards are an important pillar for proving the safety of products even though the application of the standards is voluntary. The comprehensive application of harmonized standards is an elementary trigger for the so-called presumption of conformity.

## EU Machinery Legislation

The regulatory framework for the European Union and Germany on machinery safety is divided into two complementary areas of responsibility. The first component addresses the manufacturer’s liability for a safe machine and the second component addresses the employer’s liability for a safe workplace. The European machinery legislation has a balanced approach with common directives for manufacturers and social directives for the users. One of the main legislations governing the harmonisation of essential health and safety requirements for machinery at the European Union level is the *Machinery Directive 2006/42/EC*, which:

- » promotes the free movement of machinery within the Single Market, and
- » guarantees a high level of protection for EU workers and citizens.<sup>15</sup>

The *Machinery Directive* only applies to products that are to be placed on the European Union market for the first time.<sup>16</sup>

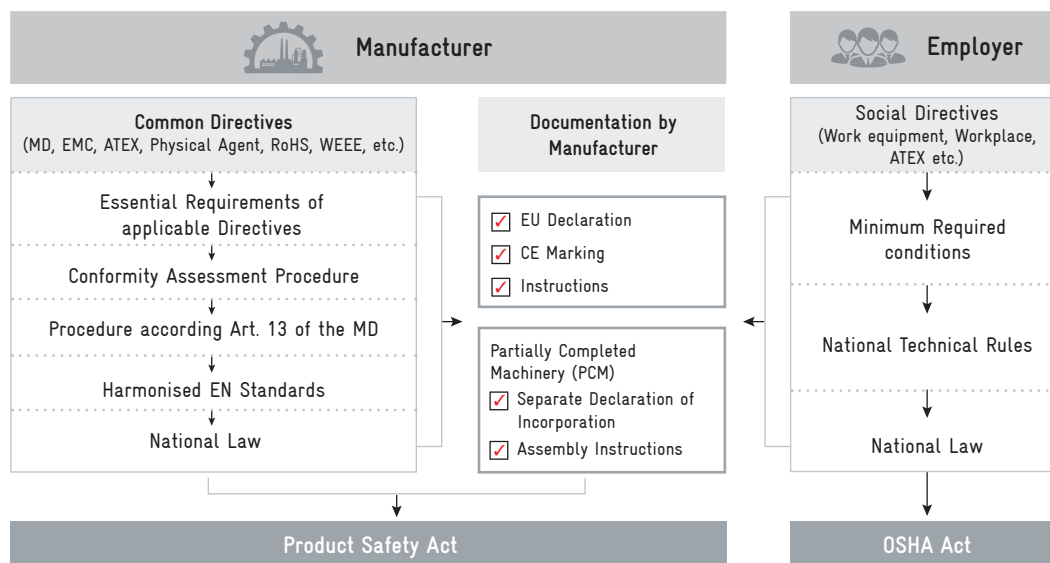


Figure 4 - EU Machinery Legislation

<sup>14</sup> <http://www.marketing.rockwellautomation.com/safety-solutions/sv/MachineSafety/LegislationAndStandards/LegislationAndStandards>

<sup>15</sup> [https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery\\_en](https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en)

<sup>16</sup> [https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery\\_en](https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en)

The CE Marking is a mark of compliance with the European Commission's directives. The mark on a product indicates that it complies with the required level of protection in all relevant EC directives.

## System of Standards for Machinery Safety

European countries and economic operators, like manufacturers, often take the initiative in proposing the standards and establishing them as ISO/IEC international standards. The International Electrotechnical Commission (IEC) prepares international standards for all electrical and related technologies, and the International Organization for Standardization (ISO) prepares international standards for all technologies other than electrical and related technologies (machinery and management).

Europe's EN Standards are prepared by the European Committee for Standardization and the European Committee for Electrotechnical standards CEN/CENELEC.<sup>17</sup> IEC/ISO international standards are implemented without duplicating the efforts of various agreements. Member countries of the WTO/TBT Agreements ensure the adoption of international standards as own national standards.<sup>18</sup>

## Structure of Standards Related to Machinery Safety

Machinery safety standards in Europe are clearly defined in three sections:

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

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:

- » Type-B1 standards on particular safety aspects (e.g., safety distances, surface temperature, noise)
- » Type-B2 standards on safeguarding devices (e.g., two-hand controls, interlocking devices, pressure-sensitive devices, guards)

Type-C standards (machinery safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

Type-A standards provide a general overview of hazard identification and Type-B standards provide typical requirements addressing conventional application of safety aspects or devices, while Type-C standards probe deeper into the respective details as they apply to a specific industry or machine group.

## Structure of Standards Related to Machinery Safety<sup>19</sup>

Type	Category	ISO	IEC
Type C	Safety requirements for specific machinery	ISO 16092 ISO 10218	-
Type B	Generic Safety Standards (applied to different type of machinery)	ISO 4413, ISO 4414, ISO 13849 ISO 13854, ISO 13857, ISO 13855 ISO 14118, ISO 14120, ISO 14119 ISO 13856, ISO 13851	IEC 60204 IEC 61496 IEC 61508
Type A	Basic Safety Standards that can be applied to all machinery	ISO 12100	-

Table 5 – Standards related to machinery safety

## CE Marking

The CE Marking is a mark of compliance with the European harmonised legislation. The marking of a product indicates that it complies with the requirements of all relevant EU legislation. CE labelled machines can be imported and transferred within the EU without restrictions. National



<sup>17</sup> For more information, see: <https://www.cenelec.eu/>

<sup>18</sup> [http://www.omron-ap.co.in/service\\_support/technical\\_guide/safety\\_component/safety\\_requirements.asp](http://www.omron-ap.co.in/service_support/technical_guide/safety_component/safety_requirements.asp)

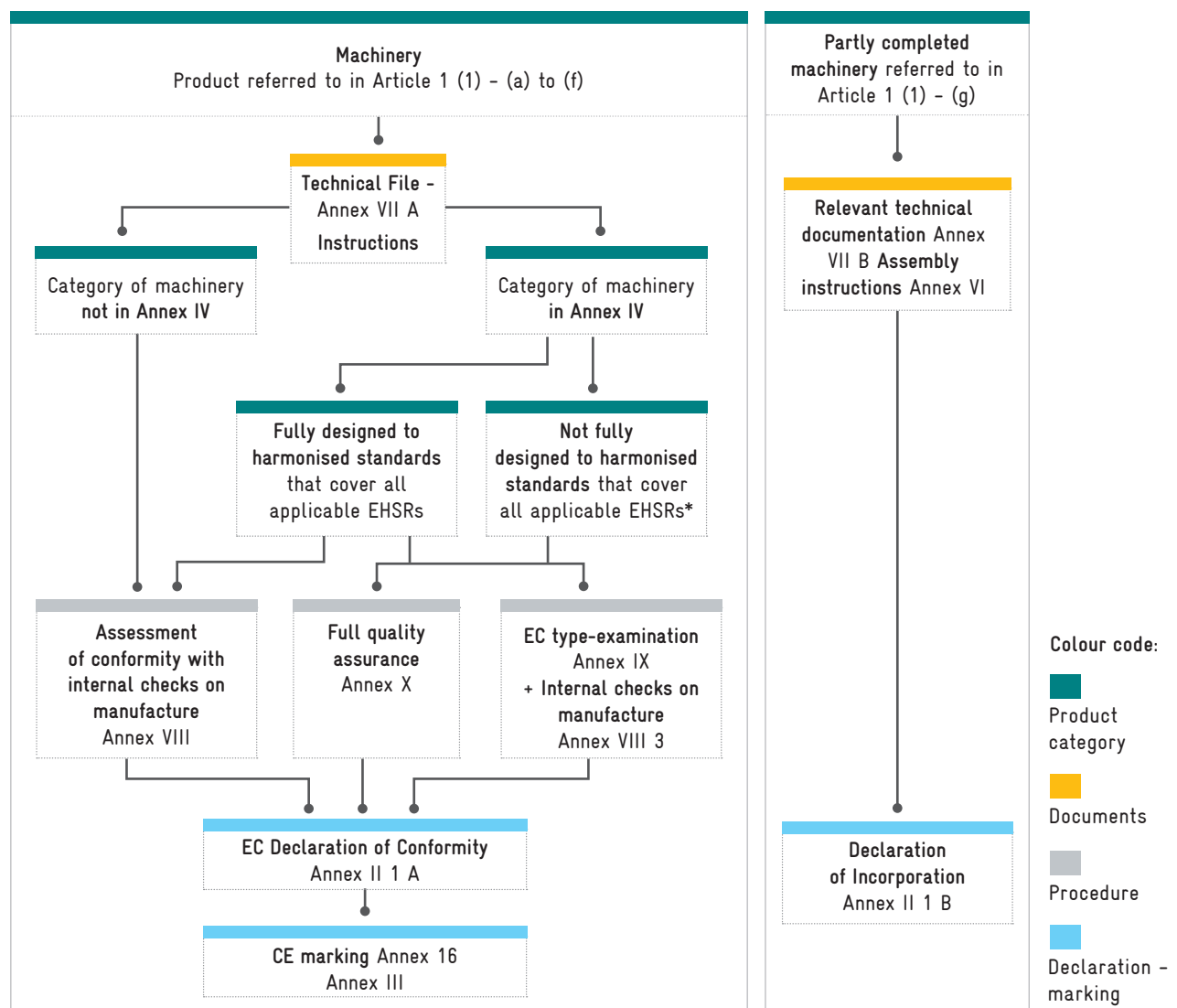
<sup>19</sup> This list is not exhaustive, and the complete list can be found at [https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery\\_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery_en)

authorities in Europe carry out market surveillance to prevent the market from unsafe products. The manufacturer has to prove the compliance with all applicable provisions of the CE marking with a comprehensive technical file, the documentation of the conformity assessment procedure.

The next diagram shows the process flow for conformity assessment. Usually the path on the far left applies with full responsibility for product safety according to the requirements of Annex I of the Machinery Directive by the manufacturer. A compilation of the restricted number of machines named in Annex IV of the European Machinery Directive is filed in the annex.

*Key elements of CE marking:*  
 The product must first show conformity with all relevant directives. The marking must be affixed to the machine and should be clearly visible, legible and indelible. The marking must be affixed in the immediate vicinity of the name of the manufacturer or representative. The CE mark on a machine attests market surveillance authorities and operators the full compliance with the safety requirements of the Machinery Directive's Annex I.  
 Special assessment procedures according Annex IV of the Machinery Directive only exist for a few types of machines. These machines also need an assessment by a notified body and the number of the notified body must be added to the CE mark.

**A comprehensive list of Annex IV products is listed in the following section. Compliance evaluation based on the machinery directive**



\* Harmonised standards are not available, the harmonised standards do not cover all the applicable EHSRs or the harmonised standards are not applied or are only partially applied.

Figure 5 – Compliance evaluation based on Machinery Directive

## Annex IV of the Machinery Directive

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied:

1. Circular saws (single or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
  - a. Sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the work-piece or with a demountable power feed;
  - b. Sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
  - c. Sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the work pieces, with manual loading and/or unloading;
  - d. Sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
2. Hand-fed surface planning machinery for woodworking.
3. Thicknesses for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
  - a. Sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the work piece;
  - b. Sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Machinery for underground working of the following types:
  - a. Locomotives and brake-vans;
  - b. Hydraulic-powered roof supports.
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
14. Removable mechanical transmission devices including their guards.
15. Guards for removable mechanical transmission devices.
16. Vehicle servicing lifts.
17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.
18. Portable cartridge-operated fixing and other impact machinery.
19. Protective devices designed to detect the presence of persons.
20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.
21. Logic units to ensure safety functions.
22. Roll-over protective structures (ROPS).
23. Falling-object protective structures (FOPS).

## COMPARISON OF EUROPEAN UNION AND INDIAN SYSTEMS

A comparison of the EU and Indian systems for machinery safety has been made above. Below, a summary of the four key aspects of the regulatory frameworks, including standards, conformity assessment and enforcement is shown.

Category	European Union/ Germany	India	Conclusion
Regulatory Framework	The framework is based on well-established machinery directive and work equipment directive to ensure machinery and workers safety.	Safety obligations are primarily directed towards occupational health and safety requirements prescribed in the <i>Indian Factories Act</i> , and the <i>New Capital Goods Policy</i> and development of Indian Standards by BIS. The importance of machinery safety is recognized and evolving.	Both EU and Indian systems are at different levels of maturity in terms of regulatory framework. As India is in the process of setting up its system, the EU system could be used as a reference framework.
Standards	<p>a) The German Institute for standardisation, DIN holds the secretariat of ISO/TC 199 Safety of machinery</p> <p>b) Germany is a participating member in the electrical safety aspects group at IEC/TC 44 Safety of Machinery: Electrotechnical Aspects</p>	<p>a) India is also participating member ISO/TC 199. In India MED 40 mirrors this and India has adopted 32 ISO standards as National Standards</p> <p>b) For Electrical safety aspects at IEC/TC 44 India is an observing member. India also has a mirror committee and has adopted 8 IEC standards as National Standards.</p>	Increased machinery safety by adopting current International Standards. India should adopt Internationally harmonised standards. A classification of these standards based on their scope is required.
Conformity Assessment	The EU has a comprehensive compliance framework with compliance marks on products which fulfil EC directives. Safety aspects are ensured –even at the commissioning stage, and during the product lifecycle through market surveillance.	In India, there is no compliance marking system or market surveillance system.	There is an absence of compliance framework and market surveillance in India.
Enforcement	Member States follow the same directives which brings uniformity in implementation and ease of compliance.	The implementation of <i>Indian Factories Act</i> is done by the state governments through their own rules based on the act. This causes enforcement variation and results in increased cost of compliance.	There is a lack of uniformity in implementation of existing rules across the states in India.

Table 6 - EU-India System Comparison

## INDUSTRY CHALLENGES

Machinery safety, in the traditional Indian context, is addressed from an occupational safety standpoint. More recently, there has been a shift in viewing machinery safety as an integral part of product safety.

The Indian Factories Act, 1948, allows each state to formulate its own rules, which results in differing interstate provisions.

The culture of safety and the low perception of safety in the industry, along with reluctance due to the perceived cost of safety installations and equipment, needs to be shifted.

Machinery safety, in the traditional Indian context, is addressed from an occupational safety standpoint. More recently, there has been a shift in viewing machinery safety as an integral part of product safety. The current challenges faced by the industry can be categorized into four areas:

- » central and state level regulations,
- » standardization in machinery safety,
- » compliance, and
- » awareness and capacity building.

A survey conducted as part of this study indicated that European manufacturers are most concerned with the lack of a robust machinery safety regulation in India.<sup>20</sup> The Indian *Factories Act, 1948*, allows each state to formulate its own rules, which results in differing interstate provisions. As industry operates across various states, compliance is difficult and expensive. The scope of the *Dangerous Machinery Act (2007)* was limited to agricultural machinery identified by the Central Government, excluding industrial machines from its jurisdiction. Only in 2016 did the *National Capital Goods Policy* create a formal strategy from the Indian Central Government that emphasised industrial machinery safety – before then only labour safety policies existed.

Because of varying state regulations, and uncertainty about which acts apply for machinery, it is difficult for the industry to identify which criteria are applicable and how to apply standards. This affects their adoption. A comprehensive roadmap, including the classification of standards, and an awareness raising campaign for users, would improve this situation.

Currently, there are no tests or documentary requirements (audits) for new or existing machines in India. Conformity assessment is a key requirement for compliance and it needs to be addressed.

Another challenge is ensuring general safety across industries and outlining specific safety requirements for high-risk sectors, like:

- » packaging machines,
- » press machines,
- » loaders,
- » people handling machines (like lifts),
- » material handling machines (i.e. earth moving machines), and
- » industrial robots.

The European solution for these cases envisages several possibilities:

- » either the application of the MD with clear limits of application, which is always well established according to provision of Article 3 of the MD,
- » a clear assignment to another directive, and
- » a combination of different directives with the aim of applying the directive under which the safety requirements are best regulated, like regulated by the provisions of Art. 3 of the MD.

New manufacturing technologies such as Industry 4.0 and the use of Internet of Things (IoT) could play a role in enhancing machinery safety –perhaps using new ways of tracking processes and machine performance. The present regulations do not adequately reflect the technological advancements made in manufacturing processes.

The culture of safety and the corresponding low perception of safety in the industry, along with reluctance due to the perceived cost of safety installations and equipment, needs to be shifted. The awareness about the value addition brought by safety features and its impact on reducing downtime and enhancing productivity at large is limited. A comprehensive awareness raising campaign paired with capacity building is needed. To achieve this incentives and recognition for those installing and maintaining safe machines is an option. This would involve the industry more and support them for taking the initial steps to develop a safety culture.

All the above factors have a cost bearing on the final selling price of the machine – which then loses price competitiveness to local competition in the market.

<sup>20</sup>For more information on the survey see the participate and respondent profile lists in the annex.



## RECOMMENDATIONS

Based on the expert exchanges conducted while preparing this study and international good practices, the following are recommendations to strengthen machinery safety requirements in India:

**Regulatory Framework: Introduce regulations for machinery safety considering emerging interconnected manufacturing and review the existing regulations for machinery and workers safety to reduce variations at the state level. The examination of the basic requirements for machine safety from Annex I of the European Machinery Directive 2006/42/EC could be a logical step.**

Manufacturing in India is undergoing changes with programmes such as *Make in India*. These changes will also bring in interconnected manufacturing technologies such as Industry 4.0 and require a more structured approach for machinery safety and regulatory framework. The adoption of standards from ISO and IEC will support a smooth coexistence of different industrial stages of development; a key factor for the upcoming industrial development of India. In addition to mandates for safety features in the design of machines, and during their placement in the factory, these regulations could include:

- » essential requirements and/or standards
- » conformity assessment procedures
- » market surveillance procedures
- » penalties for non-compliance, and
- » incentives for compliance

In India, where small machine manufacturers and users co-exist with large manufacturers and users, a step-wise approach is recommendable to implement these regulations. Accident prone machines, like press machines, packaging machines, industrial robots and steel rolling mills, should be included in the initial steps.

Present variations in state regulations pose difficulty for industry operating across states, and requires additional resources for compliance. It is therefore proposed to re-examine these provisions to reduce the variation between the states.

Until these or similar provisions are in place, a guideline document based on good practices and standards would be beneficial for the industry. This guideline should 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. The guideline can act as a preparatory step towards regulations and could be adopted by the industry on a voluntary basis until regulations are in place. In the long run, a better awareness for machinery safety can be achieved in the country. A governmental organisation for market surveillance should be created for managing and controlling the aspects of product compliance in the market.

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A guideline document based on good practices and standards would be beneficial for the industry.

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**Standards and Conformity Assessment: Develop a roadmap for implementing standards and conformity assessment procedures**

Standards on machinery safety are broadly classified as generic standards and sector specific standards. In the European Union, standards are classified as Type A (basic safety standards), Type B (generic safety standards) and Type C (safety standards for specific machinery) based on their specific scope. This internationally recognized classification (see ISO 12100) makes the selection of standards easy for the user; and is also in line with the EU directives.

A machinery safety standards roadmap for India along with a guideline document would support the implementation of the available standards in the future. A framework based on ISO 12100 (IS 11995) and ISO/TR 22100-1 as applied in the EU could be used as a reference model for classification of standards formulated by the various sectional committees of BIS. Furthermore, the orientation of Indian standards towards international standards to the maximum possible extent will enhance the competitiveness of the Indian industry and its trade prospects. Along with this, the promotion of standards related to occupational health and safety management systems such as recently published ISO 45001: 2018 *Occupational health and safety management systems - Requirements with guidance for use* will also be beneficial for India.<sup>21</sup>

Conformity assessment is one of the key elements in the enforcement of regulations. Introducing a legal conformity assessment procedure in India would offer more confidence in product safety and wider acceptance among users. A legally secured marking of compliant machinery would provide additional support in this area. The conformity assessment for new machines should always be based on the most state-of-the-art standards.

Workplace safety is the combination of both safe machines and additional organisational efforts, like education and the use of personal protective equipment. During a machine's life-span its operating safety needs to be verified on a regular basis. In order to keep workplace safety current, it is in many cases useful to increase the organisational efforts first, as technological retrofitting may exceed reasonable financial frameworks without significant safety increases. Once this relationship shifts, a larger technological retrofitting is necessary.

However, the conformity assessment should not cover only manufactured or imported new machines but also second-hand imported machines, existing machines and partially completed machines. This would also require developing a pool of qualified auditors to ensure compliance on such a large scale.

To facilitate trade and reduce technical barriers to trade, mutual recognition of test results and certification arrangements could also be explored.

### **Awareness and Training: Create awareness among the stakeholders**

Machinery safety is not considered a strategic enabler of sustainable economic growth. It is often only seen as a requirement of legal compliance. The need of the hour is to create awareness among all stakeholders such as managers, machine manufacturers, users, and workers about machinery safety so that a safety culture may be promoted through adopting international good practices.

The need of the hour: Creating awareness about machinery safety, promoting and building a culture of safety through adoption of international good practices.

The first step would be to work together with regulators to sensitise industry management on the long-term detrimental effects of unsafe machines and precautions that can be taken to mitigate these effects. Such sensitisation initiatives would cover awareness of regulations and standards, and would highlight the importance of machinery safety at different stages of designing, installation and operation including documenting the near misses, risk assessment, and auditing. Industry associations can play an important role in developing such a culture.

The second step would be to develop training programs for workers at operational level as part of a life cycle approach, which incorporates safety at every stage of the implementation of a process or product, also taking into consideration future manufacturing technologies such as Industry 4.0. Systematic training programs in industrial institutes would ensure that the working population of tomorrow is aware of their responsibilities to meet required safety precautions, and along with this contribute to a safe work environment.

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The need of the hour: Creating awareness about machinery safety, promoting and building a culture of safety through adoption of international good practices.

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<sup>21</sup><https://www.iso.org/standard/63787.html>

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## Methodology

The objectives of this study were categorised into two parts; the methodology, stakeholders and source of information were planned accordingly.

Objective 1: Regulatory Framework	
Sub-Objectives	<ul style="list-style-type: none"> <li>To analyse the regulatory framework in India relevant to the machinery safety</li> <li>To evaluate the effectiveness of regulation implementation</li> <li>To identify and map aspects of machinery safety not yet covered in India but already addressed in the European Union</li> </ul>
Methodology	A combination of secondary research and primary interviews of stakeholders
Stakeholders focus: primary interview	<ul style="list-style-type: none"> <li>Technical services: Conformity assessment/ compliance / audit and risk assessment agencies</li> <li>Safety automation companies</li> <li>Indian machinery - Original Equipment Manufacturer (OEM)</li> </ul>
Information sources	<ul style="list-style-type: none"> <li>Websites of Bureau of Indian Standards (BIS), Ministry of Labour &amp; Employment (MoL&amp;E), Directorate General Factory Advices &amp; Service Institutes (DGFASLI)</li> <li>Technical presentation of OEM and critical safety components suppliers</li> <li>One to one interaction with industry experts</li> </ul>
Objective 2: Challenges faced by Industry	
Sub-Objectives	To evaluate the experiences and challenges faced by of the stakeholders such as Industry, certification agencies and safety solution providers
Methodology	A combination of secondary research and primary interviews of stakeholders
Information sources	Report of Industry Roundtable organized by GPQI

Table 7 – Overview of Objectives and Methodology

## Respondent profile

Sr. No.	Respondent Category	Number of Respondents
1	Machine Manufacturers	11
2	Government of India	01
3	National Standards Body of India	01
4	Associations	01
5	Automation & Safety Control Provider	05
6	Consultant/ Conformity Assessment Agencies	03
<b>Total</b>		<b>22</b>

Table 8 - Respondents Profile

**List of respondents**

Company Name	Representative
BIS	National Standards Body of India
DGFASLI	GOI - Policy Maker
Pilz	Automation & Safety Controls
Schmersal	Automation & Safety Controls
Mac	Consultant/Certifying agency
Nord	Industrial Machines/components
Lenze	Automation & Safety Controls
Premium Transmission	Industrial Machines/components
Bosch	Industrial Machines/components
Sandvik Mining	Industrial Machines/components
Gudel	Industrial Machines/components
BfW	Association for machine tools
Ace Micromatic	Industrial Machines/components
Thyssen Krupp	Industrial Machines/components
Grind Master	Industrial Machines/components
Festo	Automation & Safety Controls
ATS Conveyor	Industrial Machines/components
Buhler	Industrial Machines/components
Hassia Packaging	Packaging machines
SICK	Consultant/Certifying agency
Rockwell	Automation & Safety Controls
TÜV Rheinland	Consultant/Certifying agency

*Table 9 – Respondents List*

## QUESTIONNAIRE

This questionnaire was used as a guideline for the interactions with experts and stakeholder during the research phase of this study.

### **Machine Manufacturer: Evaluating Machinery Safety Standards & Regulations**

1. How often are you required to export a machinery to European Nations?
2. What essential criterion is required to meet the machine safety standards & regulations prevailing in European nations?
3. What challenges/trade barriers you face pertaining to machine safety design standards, codes, specifications & regulations when exporting in European Nations/Germany?
4. What are the present machine safety standards in India & how different are they in comparison to machine safety standards & regulation in European Nations?
5. Which aspects of machinery safety are not yet covered in India compared to Europe?
6. What are the gaps in standards & Regulation adopted in India in comparison to those implemented in Europe/Germany?
7. What suggestions/changes do you recommend for bridging the gap and reduce trade barriers?

### **User Segment: Evaluating Machine Safety Standards & Regulations in India**

1. How often are you required to import a machinery from European Nations?
2. How critical is machine & human safety during the operation of machine?
3. What precautions do you take to ensure machine & human safety?
4. What challenges/barriers you face pertaining to machine safety design standards, codes, specifications & regulations in India?
5. What are the present machine safety standards applicable for you? Do you find that machine is overdesigned in terms of machine safety standards in India?
6. Which aspects of machinery safety are not yet covered in India compared to Europe?
7. What are the gaps in standards & Regulation adopted in India in comparison to those implemented in Europe/Germany?
8. What suggestions/changes do you recommend in Indian standards and regulations to bridge the gap?.

Machinery and worker safety matter. Unsafe machines pose huge risks, affect workers, their families, the environment, and damage company reputations, while safe machines contribute to efficient production processes and are a key pillar of a robust economy. Machine related accidents take the lives of 2.3 million workers around the world each year. Accidents and work-related diseases cost the global economy three trillion US dollars annually. More and more the ethical obligation of providing safe machines and safe work places is being linked to sustainable economic development in India and other emerging economies.

The Make in India initiative opens opportunities for the machinery industry. By boosting manufacturing and skill development, India aims to become a global manufacturing and design hub. This increases the demand for high-quality machines, manufacturing components, and technologies based on advanced automation and interconnectedness (Industry 4.0). Policy changes are already taking place as Indian factories modernise. The 2016 National Capital Goods Policy brings about mandatory minimum safety as well as environment and performance standards for machinery, while a Technical Committee at the Bureau of Indian Standards develops machinery standards.

This publication, created within the framework of the Indo-German Working Group on Quality Infrastructure, recognises these dynamics and is of interest for regulators, managers and industry associations alike. It is based on the well-acknowledged insight that machinery safety requires comprehensive regulations and elaborated conformity assessment procedures. The study depicts the regulatory framework and challenges identified by the industry. It also compares machinery directives in India and the European Union, and identifies cooperation opportunities between Germany and India. Recommendations include measures to strengthen regulations, processes for classification of standards, conformity assessment for both new and used machines, and promoting awareness raising among users and decision makers.

### **Making Safe Machines a Standard in India**

Insights and Recommendations from

Comparing Regulations in India and Germany | Knowledge Series 2



Deutsche Gesellschaft für  
Internationale Zusammenarbeit (GIZ) GmbH

Sitz der Gesellschaft  
Bonn und Eschborn

Friedrich-Ebert-Allee 36 + 40  
53113 Bonn, Deutschland  
T +49 228 44 60-0  
F +49 228 44 60-17 66

Dag-Hammarskjöld-Weg 1 - 5  
65760 Eschborn, Deutschland  
T +49 61 96 79-0  
F +49 61 96 79-11 15

E [info@giz.de](mailto:info@giz.de)  
I [www.giz.de](http://www.giz.de)