BS EN ISO 14123-1:2015

BSI Standards Publication

Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery

Part 1: Principles and specifications for machinery manufacturers

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National foreword

This British Standard is the UK implementation of EN ISO 14123-1:2015. It supersedes BS EN 626-1:1994+A1:2008 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee MCE/3, Safeguarding of machinery.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 1: Principles and specifications for machinery manufacturers (ISO 14123-1:2015)

Sécurité des machines - Réduction des risques pour la santé résultant de substances dangereuses émises par des machines - Partie 1: Principes et spécifications à l'intention des constructeurs de machines (ISO 14123-1:2015)

Sicherheit von Maschinen - Minderung von Gesundheitsrisiken, die auf Gefahrstoffemissionen von Maschinen zurückzuführen sind - Teil 1: Grundsätze und Festlegungen für Maschinenhersteller (ISO 14123-1:2015)

This European Standard was approved by CEN on 10 October 2015.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 14123-1:2015) has been prepared by Technical Committee ISO/TC 199 "Safety of machinery" in collaboration with Technical Committee CEN/TC 114 “Safety of machinery” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2016, and conflicting national standards shall be withdrawn at the latest by May 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 626-1:1994+A1:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 14123-1:2015 has been approved by CEN as EN ISO 14123-1:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of EU Directive 2006/42/EC aimed to be covered

This European Standard has been prepared under a Commission's standardisation request M/079 to provide one voluntary means of conforming to essential requirements of EU Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006).

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European standard and Annex I of Directive 2006/42/EC

Essential Requirements of Directive 2006/42/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.5.13	Clauses 4 to 8	

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WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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The committee responsible for this document is ISO/TC 199, *Safety of machinery*.

This second edition cancels and replaces the first edition (ISO 14123-1:1998), of which, by taking ISO 12100 into account, it constitutes a minor revision.

ISO 14123 consists of the following parts, under the general title *Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery*:

— *Part 1: Principles and specifications for machinery manufacturers*

— *Part 2: Methodology leading to verification procedures*

Introduction

The structure of safety standards in the field of machinery is as follows:

a) **type-A standards** (basic safety standards) giving basic concepts, principles for design, and general aspects that can be applied to machinery;

b) **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 (for example, safety distances, surface temperature, noise);

   — type-B2 standards on safeguards (for example, two-hand controls, interlocking devices, pressure-sensitive devices, guards);

c) **type-C standards** (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

This document is a type-B1 standard as stated in ISO 12100. Its primary purpose is to give guidance to the writers of type-C standards when machines are identified as emitting hazardous substances as a significant risk. This part of ISO 14123 can also be used as guidance in controlling the risk where there is no type-C standard for a particular machine.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

— machine manufacturers (small, medium and large enterprises);

— health and safety bodies (regulators, accident prevention organizations, market surveillance etc.);

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

— machine users/employers (small, medium and large enterprises);

— machine users/employees (e.g. trade unions, organizations for people with special needs);

— service providers, e.g. for maintenance (small, medium and large enterprises);

— consumers (in case of machinery intended for use by consumers).

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

The requirements of this document can be supplemented or modified by a type-C standard.

For machines that are covered by the scope of a type-C standard and that have been designed and built according to the requirements of that standard, the requirements of that type-C standard take precedence.

INTERNATIONAL STANDARD **ISO 14123-1:2015(E)**

Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery —

Part 1: Principles and specifications for machinery manufacturers

1 Scope

This part of ISO 14123 establishes principles for the control of risks to health resulting from hazardous substances emitted by machinery.

This part of ISO 14123 is not applicable to substances that are a hazard to health solely because of their explosive, flammable or radioactive properties or their behaviour at extremes of temperature or pressure.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100 and the following apply.

3.1
intended use
use of a machine in accordance with the information for use provided in the instructions

[SOURCE: ISO 12100:2010, 3.23]

3.2
hazardous substance
any chemical or biological agent that is hazardous to health

EXAMPLE Substances or preparations classified as very toxic, toxic, harmful, corrosive, irritant, sensitizing, carcinogenic, mutagenic, teratogenic, pathogenic or asphyxiant. For EU countries, see also Regulation (EC) No 1272/2008[3].

Note 1 to entry: For the definitions of "chemical agent" and "biological agent", see EN 1540.

4 Risk assessment

4.1 An identification of hazards and assessment of the foreseeable risks resulting from substances hazardous to health shall be made by the machinery manufacturer. This process shall cover, as far as possible, any potential hazard that can arise from exposure of persons to the machine at any phase of its life cycle.

NOTE Details of the methodology of risk assessment are given in ISO 12100.

4.2 The level of risk depends on the properties of the hazardous substances, the likelihood that personal exposure will occur and the degree of exposure. The health effects of hazardous substances can be

— short-term or long-term, and

— reversible or irreversible.

4.3 Hazardous substances can occur in any physical state (gaseous, liquid, solid) and can affect the body by

— inhalation,

— ingestion,

— contact with the skin, eyes and mucous membranes, or

— penetration through the skin.

4.4 The hazardous substances can be generated from

— any part of a machine,

— substances present in the machine, or

— material arising directly or indirectly from articles and/or substances processed by the machine or used on the machine.

4.5 The phases of the machine life cycle can include the following (see also ISO 12100:2010, 5.4):

— transport, assembly and installation;

— commissioning;

— use;

— all modes of operation, including start-up and shut-down/stopping;

— failure

— setting or process/tool changeover;

— cleaning and housekeeping;

— adjustment;

— maintenance and repair;

— dismantling, disabling and, as far as safety is concerned, scrapping.

5 Types of emissions

5.1 Airborne emissions

5.1.1 Airborne emissions can represent significant sources of exposure to hazardous substances. Inhalation is usually the most significant of all the routes of entry (see 4.3). In addition, airborne emissions can enter the body by other routes, particularly when substances are deposited on a body surface or when they are ingested.

5.1.2 Airborne emissions can arise from various sources, including the following:

— machining, e.g. sawing, grinding, sanding, milling;

— evaporation and thermal convection, e.g. open tanks, crucibles, solvent baths;

— hot-metal processes, e.g. welding, brazing, soldering, profile-cutting, casting;

— material handling, e.g. hopper-charging, pneumatic conveying, sack-filling;

— spraying, e.g. painting, high-pressure cleaning;

— leaks, e.g. at pump seals, flanges;

— byproducts and effluents, e.g. gases from drosses, rubber vulcanization fumes;

— maintenance, e.g. emptying filter bags;

— dismantling processes, e.g. breaking of lead batteries, stripping of asbestos insulation;

— combustion of fuel, e.g. internal combustion engine exhausts;

— apparatus for mixing food;

— metalworking, e.g. nitrosamines from water-soluble metalworking lubricants.

5.1.3 Some examples of airborne hazardous substances are as follows:

— respiratory irritants, e.g. sulfur dioxide, chlorine, cadmium fumes;

— sensitizers, e.g. isocyanates, enzymes, colophon fumes;

— carcinogens, e.g. asbestos, chromium(VI), benzene, vinyl chloride monomer;

— fibrogenic dusts, e.g. free crystalline silica, asbestos, cobalt;

— asphyxiants, e.g. nitrogen, argon, methane;

— biological agents, e.g. *Legionella pneumophila*, dusts from mouldy hay;

— substances that affect specific parts of the body, e.g. mercury (nerve system, kidneys); lead (nerve system, blood); carbon tetrachloride (nerve system, liver); carbon monoxide (blood).

5.1.4 Airborne emissions can be subject to techniques of evaluation based on the measurement of concentrations of substances in the breathing zone of the persons involved. The results of such measurements are usually compared with suitable criteria.

5.1.5 There are many methods of sampling air and analysing the sample for airborne contaminants. Sampling methods and analytical techniques should be selected according to the nature of the airborne contaminant.

5.2 Non-airborne emissions

5.2.1 Non-airborne emissions can be significant sources of exposure to hazardous substances by ingestion, contact with skin, eyes or mucous membranes or penetration through the skin (see 4.3).

5.2.2 Non-airborne emissions can be produced in various circumstances, including the following:

— migration from open sources, e.g. splashing and evaporation/condensation leading to secondary emissions;

— opening machinery, e.g. for maintenance;

— entry into machinery, e.g. for inspection;

— material handling, e.g. charging, sampling, disposal;

— handling machinery parts, e.g. dismantling;

— incorrect operation, e.g. overfilling;

— leaks, e.g. at pump seals, flanges;

— ruptures.

5.2.3 Exposure to non-airborne emissions can cause impairment of health as a result of a variety of hazardous properties associated with different materials. Some examples of these materials include the following:

— corrosives, e.g. sulfuric acid;

— irritants, e.g. wet cement;

— sensitizers, e.g. chromium compounds, epoxy resins;

— carcinogens, e.g. used quenching oil, beryllium oxide, polycyclic aromatic hydrocarbons;

— biological agents, e.g. infected cutting oils, infected blood.

The impairment of health can be local at the point of contact or can be the result of effects elsewhere in the body (systemic or target organ). With some materials, both situations can occur, e.g. phenol.

5.2.4 Non-airborne emissions cannot be evaluated by measurements of concentration of substances in the air. Criteria based on these concentrations cannot be used. Other criteria may be established, e.g. limits regarding microbial concentrations in cutting oils.

5.2.5 In some cases it can be relevant to carry out quantitative assessments of surface contamination. The criteria to be applied should be based on both toxicological and practical considerations. Techniques for measuring such contamination include

— chemical analyses of wipes,

— use of fluorescent tracers,

— colorimetric indications, and

— count of microorganisms.

6 Requirements and/or protective measures for elimination and/or reduction of risk

Risks from exposure to hazardous substances shall be reduced as far as practical, taking into account scientific and technical methods and limits relating to exposure and the external environment. In selecting the most appropriate risk reduction methods, the manufacturer shall take protective measures to reduce the risks from exposure to hazardous substances as close to the emission source as possible. The manufacturer shall apply the following principles, in the order given, taking into account the state of the art (see also the “three-step method” in ISO 12100:2010, 6.1):

a) design of machinery to eliminate or prevent risks resulting from exposure to hazardous substances (“inherently safe design measure”);

b) design of machinery to reduce risks that cannot be eliminated, in the following order of priority ("safeguarding and complementary protective measures"):

   1) reduction of emission;

   2) reduction by ventilation or other engineering means;

   3) reduction of exposure by machinery operation or segregation.

c) information about the residual risks to the user and advice on protective measures to be implemented by the user to reduce exposure.

NOTE A list of possible protective measures is given in Annex A.

7 Information for use and maintenance information

7.1 Information for use

7.1.1 The manufacturer shall state in the instruction manual the intended use of the machine, the hazardous substances that can be generated by the machine (see 4.4) and the operating procedures. The manufacturer shall specify, when necessary, the competence level (achieved by training) required to operate the machine. The manufacturer shall provide in the instruction manual appropriate details of setting and operating conditions of the machine that can result in a reduction of risks.

7.1.2 When the machine is equipped with means of reducing the risk to health, the machinery manufacturer shall supply information on its correct use and factors that can adversely affect its performance.

7.1.3 When there is no such provision of means of reducing the risk to health, methods of reduction and/or testing that are suitable and proven shall be specified by the manufacturer.

7.1.4 If leaks, spills or uncontrolled releases of a hazardous substance can be foreseen, the manufacturer shall provide information to limit the extent of risk to health and to regain adequate control as soon as possible. The information should cover, where appropriate, emergency procedures, safe disposal of the substance and suitable protective equipment to enable the source of release to be safely identified and repairs to be made.

7.1.5 The manufacturer shall provide information on the necessary personal protective equipment and on hygiene arrangements.

7.2 Maintenance information

The machinery manufacturer shall provide sufficient instructions for the maintenance of the machine without risk to health.

NOTE This can include the necessary maintenance to ensure the continuing effective reduction of emissions of hazardous substances. Implementation by the user can be achieved by a structured maintenance programme employing various functional and performance checks at suitable time intervals as far as applicable.

EXAMPLE Such a maintenance programme for the user of a mechanical vibrating screen can include regular checks, as follows, on

— the physical condition of the hardware, including screen covers, inspection hatches, etc. required to maintain the integrity of containment,

— gaskets and seals associated with covers and hatches, to ensure that these are intact and functional,

— flexible connectors on feed and product lines, to ensure that these are still connected and in good condition,

— extraction ventilation, including visual checks, routine mechanical inspection and ventilation performance testing, and

— the accumulation of material.

8 Verification of safety requirements and/or protective measures

A methodology leading to verification procedures for the reduction of risks to health from hazardous substances emitted by machinery is specified in ISO 14123-2.

Annex A
(informative)

Examples of protective measures for reduction of exposure to hazardous substances

NOTE These examples can either be incorporated into the machine design or provided as information for use.

A.1 Elimination and prevention of risks

Examples of protective measures for elimination and prevention of risks are as follows:

— elimination of the operation that causes the emission;

— selection of an alternative production process;

— selection of alternative operations;

— elimination of the use of the hazardous substance;

— substitution of hazardous substances by less hazardous alternatives, e.g. cadmium-free silver solder;

— use of totally enclosed processes and handling systems, e.g. enclosed pumps;

— use of remote controlled and automated processes.

A.2 Risk reduction

A.2.1 Reduction of emission

Examples of protective measures for reduction of emission are as follows:

— use of vapour-return systems, e.g. piping of displaced air to supply tank;

— use of dust-reduced forms, e.g. pellets, granules, flakes or pastilles instead of powders;

— enclosed materials-handling systems;

— dust suppression by wetting;

— maintenance of valves, pumps and flanges;

— prevention of spills and leaks;

— use of liquids that are dust-free when dried out, e.g. use of an anti-stick soap solution on unvulcanized rubber;

— immersion of shafts and seals of reactive liquids to absorb leaks of hazardous substances, e.g. isocyanate pumps;

— fitting covers, flexible or rigid barriers or floating balls to contain emissions from e.g. conveyors, tanks;

— condensation of vapours, e.g. in solvent-degreasing tanks;

— operation of systems under negative pressure;

— process control, e.g. use of thermostats, pressure switches.

A.2.2 Reduction by ventilation

Examples of protective measures for risk reduction by ventilation are as follows (in descending order of effectiveness, for most cases):

— local exhaust ventilation from almost complete to partial enclosure;

— local exhaust ventilation without enclosure;

— air curtains;

— general dilution ventilation, e.g. extraction with clean-air inflow;

— ventilation by building design, e.g. hot processes in high buildings.

A.2.3 Reduction of exposure by machinery operation or segregation

Examples of protective measures for reduction of exposure by machinery operation or segregation are as follows:

— prohibition of non-essential access, e.g. to confined spaces, hazardous operations or high-risk areas;

— separation of hazardous and non-hazardous operations, e.g. by partial enclosures, partitions or separate buildings;

— reduction of the number of employees exposed to hazards, e.g. by multi-skill training or more efficient work practices;

— operation of processes from control rooms with visits to polluted areas only when needed;

— use of bund walls to prevent spread of spills;

— reduction of exposure times.

A.3 Information and other protective measures regarding residual risks

Examples of information to be provided or protective measures to be taken regarding residual risks are as follows:

— regular cleaning or disinfection of contaminated walls, surfaces, etc.;

— provision of means for safe storage and disposal of substances hazardous to health;

— suitable personal protective equipment;

— prohibition of eating, drinking and smoking in contaminated areas;

— provision and maintenance of adequate facilities for washing, changing and storage of clothing, including suitable arrangements for laundering contaminated clothing;

— adequate information, instruction and training for appropriate personnel.

Bibliography

[1] ISO 14123-2, *Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 2: Methodology leading to verification procedures*

[2] EN 1540, *Workplace exposure — Terminology*

[3] REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJEU L/353, 31.12.2008

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