



# 3D PRINTING & ADDITIVE MANUFACTURING EQUIPMENT COMPLIANCE GUIDELINE

*This document contains guidelines for selecting the appropriate safety standards for equipment associated with 3D printing and additive manufacturing.*





# Guidelines for Compliance – Equipment Associated with 3D Printing and Additive Manufacturing

This document contains guidelines for selecting the appropriate safety standards for equipment associated with 3D printing and additive manufacturing.

The driver for this Guide is to associate 3D printing and additive manufacturing equipment with relevant, existing safety standards for the various current uses, including use as commercial, industrial, consumer, food processing and medical equipment.

3D printing (more broadly referred to as additive manufacturing) is the process of using specialized equipment to build a physical object from a three-dimensional digital model, typically by layering many successive thin layers of a material, such as polymers or other materials.

Additive manufacturing technology is most commonly utilized for modeling, prototyping, tooling and short-run production applications. This type of equipment is typically used in a controlled environment and the users of the equipment are typically instructed how to use the equipment in a production line/manufacturing setting.

More recently, the technology has been commonly utilized by do-it-yourselfers, hobbyists and tinkerers. Additionally, some manufacturers offer equipment designed to be used by consumers in the home, and by students in schools.

Often, manufacturers have requested that this type of equipment be investigated to an international (IEC-based) standard since the products are typically being marketed globally.

There are several existing IEC, US, ISO and other publications that adequately cover safety aspects of 3D printing and additive manufacturing equipment. The intent of this Guide is to not introduce new requirements, but to reference appropriate existing standards, with appropriate supplemental considerations, as necessary.

Additional informative material on EMC and hazardous substance requirements is provided in the annex to this guide since it is seen as potentially being helpful to the user of this guide.

*This Guide does not address indoor air-quality emissions resulting from the intended function of the equipment because, (a) such requirements are not currently associated with the minimum safety standards for other forms of equipment used in similar environments, including printers, (b) the air quality associated with the equipment is directly dependent on the raw materials associated with the production (printing) process and the manufacturer may not always have on-going control of the use of such raw materials, and (c) associated voluntary requirements for air-borne emissions are likely to further evolve in the context of additive manufacturing equipment. It is noted in the U.S., there may be other regulations that impact installation of such equipment when installed in the workplace, such as U.S. OSHA Occupational Safety and Health Standards (29 CFR 1910).*

*This Guide also contains a number of questions in an annex that can be useful when answered as part of the process of determining appropriate standards in the context of this Guide.*



## 1 Scope

This Guide provides background and guidance on the use of existing safety standards that are applicable to equipment associated with various applications of 3D printing and additive manufacturing.

This Guide does not introduce new requirements, but references appropriate existing standards, which in most cases should adequately cover the safety of this type of equipment. Appropriate supplemental considerations are provided, as necessary.

## 2 Reference publications

IEC 60204-1, Safety of Machinery – Electrical equipment of machines – Part 1: General requirements

IEC 60335-2-14, Household and similar electrical appliances – Safety – Part 2-14: Particular requirements for kitchen machines

IEC 60335-2-64, Household and similar electrical appliances – Safety – Part 2-64: Particular requirements for commercial electric kitchen machines

IEC 60335-2-75, Household and similar electrical appliances – Safety – Part 2-75: Particular requirements for commercial dispensing appliances and vending machines

IEC/UL 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

IEC/UL 60950-1, Information Technology Equipment – Safety - Part 1: General requirements

IEC 62368-1, Audio/video and communication technology equipment - Part 1: Safety requirements

ISO 12100, Safety of Machinery – General principles for design – Risk assessment and risk reduction

ISO/CD 17296-1, Additive manufacturing –General principles – Part 1: Terminology

ASTM F2792 – 12a, Standard Terminology for Additive Manufacturing Technologies



## 3 Definitions

### 3.1 3D printing or additive manufacturing

A process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies.

### 3.2 3D printer or machine

Machine used for 3D Printing and additive manufacturing.

## 4 Guidelines

### 4.1 General

#### 4.1.1 General

Identification of the applicable standard or standards for the equipment typically depends on several factors, including

- a. Intended operating environment, for example home, office, factory, health care facility, bakery, etc.;
- b. Intended type of user/operator of the equipment, for example ordinary persons (user or operator), skilled persons (service personnel), or instructed persons (persons with limited training);
- c. Specific technologies, hazards and energy sources integral to the equipment, for example laser, resistive heating, UV, etc.; and
- d. Local or regional regulatory requirements specifying particular standards for specific applications.

### 4.2 Standards

#### 4.2.1 Selection of standard

Generally, existing standards that cover similar types of equipment used in similar operating environments may be used for equipment associated with additive manufacturing. These standards are considered suitable since, although the application of the technology associated with additive manufacturing is relatively new, the basic hardware and technology used in the equipment are similar to other forms of hardware and technology covered by existing equipment standards.

See **Annex A** for information on applicable standards.

NOTE Generally, the identified standards include requirements associated with,

- a. identification and classification of energy sources capable of personal injury or fire (for example, hazardous voltages);
- b. specification of required safeguards (for example, insulation and enclosures);
- c. determination of compliance of such required safeguards (for example, acceptance through prescriptive spacing requirements or performance testing ); and
- d. other common aspects appropriate for such equipment, such as components, markings and instructions, and related considerations.



### 4.2.2 Constructions not specifically covered

When the equipment involves technologies, materials or methods of construction not specifically covered by the standard, the equipment should provide safeguards not less than that generally afforded by the applicable standard and the principles of hazard-based safety engineering.

NOTE IEC 62368-1 is a standard that incorporates hazard-based principles and may serve as an appropriate reference document for constructions not specifically covered in other standards. See Clause 0 of the standard for an overview of the principles of the standard and an introduction to hazard-based safety engineering.



**Annex A (Informative)**

**Table 1**

**Standards & IEC Technical Committees That Cover 3D Printing and Additive Manufacturing Equipment**

Application	IEC Standard	IEC TC	EU Directives*	U.S. (UL) Standard	Comments
Home/Office/ Business/ Commercial	IEC 60950-1, Safety of ITE	IEC TC108	Low Voltage (LV), 2006/95/EC, 2014/35/EU	UL 60950-1, Safety of ITE	For U.S.-only applications, there may be other options available, such as UL 775, Graphics Arts Equipment
	or IEC 62368-1, Safety of AV & ICT Equipment		Electromagnetic Compatibility (EMC), 2004/108/EC, 2014/30/EU	or UL 62368-1, Safety of AV & ICT Equipment	
Industrial (for example, manufacturing)	ISO 12100, Safety of Machinery	ISO TC199	Machinery (MD), 2006/42/EC	UL Su 2011, Factory Automation Equipment	For U.S.-only applications, there may be other options available, such as UL 775, Graphics Arts Equipment
	IEC 60204-1, Safety of Machinery	IEC TC44	Electromagnetic Compatibility (EMC), 2004/108/EC, 2014/30/EU		
Food Preparation - Household	IEC 60335-2-14, Kitchen Machines	IEC TC61	Low Voltage (LV), 2006/95/EC, 2014/35/EU Electromagnetic Compatibility (EMC), 2004/108/EC, 2014/30/EU	UL 982, Motor-Operated Household Food Preparing Machines	Example: 3D Food Printers for household use.
Food Preparation - Commercial	IEC 60335-2-64, Safety of Commercial electric kitchen machines; IEC 60335-2-75, Safety of commercial dispensing appliances and vending machines	IEC TC61	Low Voltage (LV), 2006/95/EC, 2014/35/EU Machinery (MD), 2006/42/EC Electromagnetic Compatibility (EMC), 2004/108/EC, 2014/30/EU	UL 763, Motor-Operated Commercial Food Preparing Machines	Example: 3D Food Printers used in bakeries and other facilities associated with the food industry.
Medical	IEC 60601-1, Medical Electrical Equipment	IEC TC62	Medical Devices (MDD), 93/42/EEC; Electromagnetic Compatibility (EMC), 2004/108/EC, 2014/30/EU	ANSI/AAMI 60601-1, Medical Electrical Equipment	

\*In Europe, the Machinery Directive (2006/42/EC) exempts six categories of electrical machinery from the Directive and directs them to the Low Voltage Directive (2014/35/EU), thus they are not subject to the risk assessment provision and related aspects of the Machinery Directive. Included in these exemptions are “ordinary office machinery,” “information technology equipment,” and “household appliances intended for domestic use.” For 3D printers used in offices, home offices and similar locations, there remains some question whether this equipment is covered under the scope of EN 62368-1, although the basic hardware is similar to office machinery and information technology processing is a key aspect of the equipment’s basic operation allowing a 3D design to be transformed into a 3D object. Therefore, IEC TC108 is taking action to include such 3D printers in IEC 62368-1’s Annex A as an example of equipment covered under the scope of IEC 62368-1. Similarly, for other forms of 3D printers used for domestic food preparation and similar applications where existing standards cover a variety of machines, the standards referenced in the Low Voltage Directive may be viewed as adequate. It is expected some of these issues related to appropriate standards will be more formally clarified in both IEC and EU standards and regulations in the new few years. In the meantime, the decision on what standard or standards to use to comply with EU regulations rests primarily with the manufacturer of the equipment.



## Annex B (Informative)

Questions that assist with the identification of applicable standards for 3D Printing and Additive Manufacturing Equipment.

### A. What operating environment is the equipment intended by the manufacturer to be used in?

- a. Home?
- b. School?
- c. Commercial (for example, office or business)?
- d. Factory?
- e. Bakery?
- f. Health Care Facility?
- g. Other?

### B. Who is intended to interface with the Equipment?

- a. Child (student)?
- b. Ordinary person (user)?
- c. Instructed person (ordinary person given limited training)?
- d. Skilled person (service personnel)?

### C. Are there any local or regional regulations that explicitly cover the equipment by reference or interpretation, such as the EU Machinery Directive?

### D. Does the manufacturer want a standard that covers a specific country or countries, or is the equipment a global product requiring acceptance in multiple countries/regions?