

3D PRINTING & ADDITIVE MANUFACTURING EQUIPMENT COMPLIANCE GUIDELINE

This informative document contains guidelines for assisting manufacturers to identify the appropriate safety standards and associated regulations for equipment associated with additive manufacturing, including 3D printers.



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Equipment Associated with Additive Manufacturing, including 3D Printing

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INTRODUCTION

This informative document contains guidance for identifying the appropriate safety standards and regulations for equipment associated with additive manufacturing, including 3D printers.

The driver for this guide is to associate additive manufacturing technologies and equipment with relevant, existing safety standards for the various current uses, including use as commercial, industrial, consumer, food processing and medical equipment. It also begins the education process on regulatory considerations that manufacturers of 3D printers may need to have an awareness of.

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 are introducing the equipment to be used by consumers in the home, and even by students of varying ages in schools.

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

1 - SCOPE

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

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.

The Guide also introduces known regulatory considerations that manufacturers of 3D printers need to be aware of and that can be important installation and use considerations as 3D printers are used in a wider variety of installation environments, and the associated technologies that the 3D printers utilize expands.

This Guide does not provide guidance on the standards that apply to the parts, components or end products that may be produced using additive manufacturing processes.

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

IEC 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 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

machine used for 3D printing.

3.3 3D PRINTING

fabrication of objects through the deposition of a material using a print head, nozzle, or another printer technology.

4 - GUIDELINE

4.1. GENERAL

Identification of the applicable standard(s) and regulation(s) for 3D printers associated with additive manufacturing typically depends on several factors, including,

- a) intended operating environment, for example home, office, factory, health care facility, bakery, school, 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 and energy sources integral to the equipment, for example laser, resistive heating, UV, etc.;
- d) specific raw materials involved in the printing, and any associated hazards that may be associated with use of these materials during use, or because of production of by-products, including material waste, dust, etc.; and
- e) local or regional regulatory requirements that specify particular requirements and/or standards for specific applications.

Annex A provides some questions that may assist determining the appropriate product standards and regulations that likely will be associated with equipment for additive manufacturing, including 3D printers.

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 B 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.

See Annex C for information associated with the European Union (EU) Machinery Directive and how consideration of the Machinery Directive may need to be factored into a manufacturer's overall business risk management.

4.2.2 CONSTRUCTIONS NOT SPECIFICALLY COVERED

When the equipment involves technologies, materials or methods of construction not specifically covered by the chosen 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.

4.2.3 REGULATIONS

Generally, regulations impacting equipment associated with additive manufacturing will depend on such things as installation environment (for example, workplace or school), raw materials that are utilized, handled and stored (such as powdered metal), and any by-products, such as dust, that may be associated with the manufacturing processes. Other considerations may be valid too depending on the particular equipment and technologies involved.

See Annex D for a discussion of potential regulations for 3D printers intended for use in schools.

See Annex E for a discussion of potential regulations associated with airborne emissions and explosive atmosphere

Annex A

Questions Assisting Identification of Applicable Standards & Regulations for 3D printers

- 1. What installation and/or operating environments does the manufacturer intend the 3D printer to be used in?
 - a. Commercial (for example, office or business)?
 - b. Industrial/Factory?
 - c. Home?
 - d. Bakery?
 - e. Health Care Facility?
 - f. School (for example, primary, middle, junior or high school)?
 - g. Hazardous Location (for example, in or near the presence of flammable gases)?
 - h. Other?
- 2. Who is intended to interface with the 3D printer?
 - a. Ordinary person (user)?
 - b. Instructed person (ordinary person given limited training)?
 - c. Skilled person (service personnel)?
 - d. Child (student), including intended or excluded age groups?
- 3. Does the manufacturer want a product standard that covers a specific country or countries, or is the 3D printer a global product requiring acceptance in multiple countries/regions?
- 4. Are there any local or regional regulations that explicitly cover the 3D printer by reference or interpretation?
- 5. Does the manufacturer's customer purchasing the 3D printer, including any retailers, specify minimum requirements, standards and/or regulations that need to be met as a condition of sale?
- 6. Does the 3D printer have any features that may cause it to be viewed primarily as a machine, such as equipment with considerable accessible mechanical (moving parts) or thermal energy sources (hot surfaces) as the primary potential hazards (versus other more fully or partially enclosed units with enclosures or guards provided as operator safeguards)?
- 7. Does the 3D printer use any raw materials that may have certain characteristics (e.g., highly combustible, or powdered form) that may result in installation or workplace regulations becoming an increasingly important consideration due to by-products from the printer, such as combustible dust or other air-borne emissions?

Annex B

Standards & Technical Committees (TC) Associated with 3D Printers

Application	IEC Standard	IEC TC	EU Directives*	US (UL) Standards	Comments
Home / Office / Business / Commercial	IEC 60950-1, Safety of ITE IEC 62368-1, Safety of AV & ICT Equipment	IEC TC108	Low Voltage (LV), 2009/95/EC, 2014/35/EU Electromagnetic Compatibility (EMC), 2004/108/ EC, 2014/30/EU Restriction of the use of certain hazardous substances (RoHS), 2011/65/EU	UL 60950-1, Safety of ITE UL 62368-1, Safety of AV & ICT Equipment	For US only applications, there may be other options available, such as UL 775, Graphic Arts Equipment For US only applications, see US OSHA Occupational Safety and HEalth Standards, 29 CFR 1910
Industrial (examples: manufacturing / factory floor)	ISO 12100, Safety of Machinery IEC 60204-1, Safety of Machinery	ISO TC199 IEC TC44	Machinery (MD), 2006/42/EC Electromagnetic Compatibility (EMC), 2004/108/ EC, 2014/30/EU	UL Su 2011, Factory Automation Equipment	For US only applications, there may be other options available, such as UL 775, Graphic Arts Equipment
Food Preparation - Household	IEC 60335-2-14, Safety of Commercail Electric Kitchen Machines	IEC TC61	Low Voltage (LV), 2009/95/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, Kitchen Machines IEC 60335-2-75, Safety of Commercial Dispensing Appliances and Vending Machines	IEC TC61	Low Voltage (LV), 2009/95/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	

* See Annex C for information on the EU Machinery Directive (2006/42/EC).

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Annex C Machinery Directive

Introduction

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."

However, some authorities/regulators are taking a view that 3D printers are general 'machines' and not 'ordinary office machinery', and as a result they are not covered by the existing product safety standards associated with the EU Low Voltage Directive (LVD). Therefore, some of these products are being required by EU authorities to meet the provisions of the Machinery Directive.

As a result, for 3D printers used in offices, homes and similar locations, there remains some question whether this equipment is covered under the scope of EN 60950-1 or EN 62368-1, standards that are used to assess safety of traditional 2D printers under the LVD. 3D printers, while having some similar characterizations and features of their 2D printer predecessors, also have some hardware-based features that some authorities/regulators tend to consider more similar to machines. While certainly there is not a universally held opinion on this subject, manufacturers of 3D printers need to be aware that selection of a product safety standard, and compliance with such a standard, may be of limited value if an authority/regulator does not accept the standard as meeting local or regional regulations.

To attempt to help the situation, 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. However, the next version of IEC 62368-1 may not be published until 2017/2018.

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.

Due to the uncertainty in the European regulatory environment, manufacturers of 3D printers should consider the need to make a business risk management-based decision whether they are comfortable relying on a product safety standard covered by the LVD, or whether they want more assurance that the product likely will be viewed by EU regulators as a machine.

Since some 3D printer manufacturers may not be familiar with the basics of the Machinery Directive, this Annex concludes with an overview of the Directive and its provisions.

Machinery Directive - Overview

Directive 2006/42/EC (formerly 98/37/EC) applies to machinery, lifting accessories, and associated safety components. The intent of the Directive is to introduce identical requirements for machinery safety for all countries within the European Economic Area (EEA).

In the Directive, a machine is defined as "an assembly of linked parts or components, at least one of which moves..." This definition encompasses a large range of machines, from simple hand-held power tools through complete automated industrial production lines. There are exclusions, such as for machines which are already covered by other specific directives, including equipment which falls under the scope of the Low Voltage Directive. For example, certain specific types of equipment fit the definition of machinery but are also within the scope of the Low Voltage Directive – as a result they are excluded from the Machinery Directive on the basis that the risks they present are mainly electrical in nature. These include "ordinary office machinery" and "household appliances for domestic use".

The Machinery Directive is mutually exclusive with the Low Voltage Directive, so that either one or the other will apply but not both. Annex I of the Machinery Directive contains requirements for electrical safety, which are based on those of the LVD, so the safety requirements of the two directives are comparable; however, the Declaration of Conformity will cite the Machinery Directive and not the LVD.

Machinery Directive

The vast majority of machinery may be self-certified by the manufacturer who must meet the administrative and essential health and safety requirements of the Directive.

The essential health and safety requirements require manufacturers of machinery to identify the hazards that their equipment contain and assess the risks these hazards present to users. Any risks identified must be reasonably reduced to as low a level as practicable.

More specifically,

Annex I of the Directive gives a comprehensive list of the potential hazards which may arise from the design and operation of machinery, and gives general guidance on what hazards must be avoided. The key provision of Annex I is the need for a risk assessment on the machinery, which helps determines the specific application of the essential health and safety requirements. Detailed requirements are laid out in a series of safety standards. A standard that has been accepted by the European Commission via the process of harmonization is considered a European Norm (designated with 'EN' prefix). Documented conformance with the requirements of the standard gives a 'presumption of conformity' with the requirements of the Directive. Because so many standards are required to cover the full range of machines within the scope of the Directive, the European standards bodies devised a hierarchy to be applied.

- **Type A standards:** These are the most basic standards that set out basic requirements for the safety of machines, including EN ISO 12100:2010, Safety of machinery General principles for design Risk assessment and risk reduction.
- **Type B standards:** These standards address more specific issues, such as design of emergency stops (EN ISO 13850); prevention of unexpected start-up (EN 1037); temperature of touchable surfaces (EN ISO 13732-1), etc.
- **Type C standards:** These standards deal with specific types of machine: for example, EN 1012 deals with safety of compressors and vacuum pumps; EN 792 deals with pneumatic hand tools and EN 201 deals with injection moulding machines for rubber or plastic. There currently is not a specific Type C standard for 3D printers.

The administrative provisions of the Directive require manufacturers to provide documentary evidence that the machinery complies with the Directive, produce a Technical File, sign a Declaration of Conformity, and label the product with certain markings. The vast majority of machinery may be self-certified by the manufacturer, or an authorized representative within the EU. Therefore, as long as the administrative and safety requirements of the Directive are properly satisfied, the manufacturer can perform all of the assessment and documentation procedures themself and does not need formal external test or approval. *continued...*.



More specifically,

The general form and content of the Technical File is specified in the Directive and manufacturers are obligated to make this information available for inspection by the authorities for up to 10 years after the date on which the machine was sold. However, except for machines listed in Annex IV, there is no obligation to produce a copy of the file unless demanded to do so by the enforcement authority. Also, only the enforcement authority has a right to see it; the manufacturer does not have to provide a copy to a customer unless they choose to. Machinery meeting the Directive is required to have the CE mark clearly affixed to indicate compliance. It also is to include the year of manufacture, serial number, and other ratings as required by the relevant standards. An item of equipment may only display the CE mark when the equipment satisfies all relevant directives; for instance machines with electronic functions also need to comply with the requirements of the EMC Directive.

The manufacturer is required to prepare and sign an 'EC Declaration of Conformity', which is a statement that provides the identity of the manufacturer and the machinery for which the manufacturer is claiming compliance. It is signed to confirm that the correct procedures have been followed. If the manufacturer is based outside the European Community, this Declaration must also contain the address of a representative within the EU from whom the authorities can obtain the technical documentation.

Annex IV of the Directive contains a list of numerous types (about 25) of machines that are subjected to special procedures. These must either be made fully in accordance with the provision of the standard, or must be subjected to type examination by a Notified Body. 3D printers are not listed in Annex IV.

Apart from the EMC and Low Voltage directives mentioned above, other directives that also may affect some equipment falling within the scope of the Machinery Directive include, Directive 2000/14/EC on the noise emission of equipment intended for use outdoors; and Directive 2002/44/EC on human body exposure to vibration.

For machinery intended for use in a flammable atmosphere, the ATEX Directive applies (see Annex E of this Guide), and, additionally, the Restriction on Hazardous Substances (RoHS) and Waste Electrical & Electronic Equipment (WEEE) Directives also may apply to machines that contain electrical equipment, including 3D printers.

For machinery intended for use in a flammable atmosphere, the ATEX Directive applies (see Annex E of this Guide), and, additionally, the Restriction on Hazardous Substances (RoHS) and Waste Electrical & Electronic Equipment (WEEE) Directives also may apply to machines that contain electrical equipment, including 3D printers.



Annex D

3D Printers Intended for Use by Children in Schools

Generally, products intended primarily for use by children often are subjected to more restrictive regulations than products intended primarily for use by adults.

For example, in the U.S., children's products are subject to a set of federal safety rules, called children's product safety rules. The U.S. law defines a "children's product" as a consumer product designed or intended primarily for people 12 years of age or younger.

Therefore, for 3D printers intended for use by people above 12 years of age, the US federal regulations generally are not more restrictive than for adults. It is expected most 3D printers intended to be used in schools will be for use by children above 12 years of age under adult supervision, although this expectation could change further as 3D printers become prevalent in classroom environments.

However, if a manufacturer targets the use of a machine by children 12 years of age and younger, there are additional regulatory considerations. Parts of the U.S. Code of Federal Regulations may be applicable, mainly, Title 16, Chapter II, Subchapter C, Part 1505, Requirements for Electrically Operated Toys or Other Electrically Operated Arcticles Intended for Use By Children.

For such applications, the Consumer Product Safety Commission (CPSC) has given some guidance on what types of products are considered 'children's products' and what types are not. Although 3D printers currently are not specifically mentioned in any of the guidance information, there is some guidance given on science kits and related products when primarily intended for children 12 years of age or younger. That guidance is reproduced here for reference purposes.

What about science kits or other "kits" designed and primarily intended for children 12 years of age or younger-are they considered "children's products"?

Using the four-factor analysis set forth above [(a) intended use by manufacturer, (b) packaging, advertising, and general marketing, (c) whether product is commonly recognized by consumers as a children's product intended for 12 years of age or younger, (d) CPSC Age Determination Guidelines], if it is determined that the "kits" are designed and primarily intended for children 12 years of age or younger, then all elements included in the kit are considered "children's products," and they must comply with the standards. For example, a paper clip, ordinarily a general use item, included in a "magnet kit," would be considered a children's product when it is part of the kit. When manufacturers use component parts or materials not otherwise intended for children and they repurpose those parts or materials as components in their children's products, those manufacturers become responsible for ensuring compliance with children's product safety standards.*

For Europe, although some products intended for use by children are subjected to Directive 2009/48/EC on the safety of toys (Toy Directive), 3D printers intended for schools are not currently mentioned anywhere in the Directive, nor the associated Guidance documents, such as Guidance document No. 16 on electronic equipment aimed at children's use, so it's unlikely this Directive and the associated standards referenced in it would be applied for 3D printers used in schools.

*Courtesy of U.S. CPSC's FAQs: Children's Products - http://www.cpsc.gov/Business--Manufacturing/Business-Education/childrensproducts/FAQs-Childrens-Products/.

Annex E

Regulations Associated with Airborne Emissions

In general, when compliance of equipment is considered in the context of product safety standards and regulations, typically there are several key aspects that need to be considered. These include (a) safety of the product itself and safe use/handling of the product by operators and service personnel, typically as defined by consensus safety standards, and (b) safe operation of the product in the environment it is intended to be used in accordance with any installation regulations associated with safe use and protection of consumers and workers in the workplace.

As discussed earlier in these Guidelines, identification of the appropriate product safety standards for 3D printers is somewhat fluid and is likely to continue to be so until the associated standards bodies study closer whether additional requirements in product standards are needed for 3D printers.

Similarly, from a regulations perspective, there also remains some uncertainty.

For example, it is difficult to be definitive on the applicable regulations associated with indoor air-quality emissions resulting from the intended function of the 3D printer equipment because, (a) such requirements are not currently associated with the minimum safety standards for other forms of equipment used in similar environments, including 2D 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 airborne emissions are like to further evolve in the context of additive manufacturing equipment.

In the U.S., equipment installed in the workplace is subjected to U.S. Occupational Safety and Health Standards (29 CFR 1910), which have some general provisions for airborne emissions, but the application of these regulations specifically to 3D printers and similar equipment associated with additive manufacturing is evolving.

Annex F

Regulations Associated with Potentially Combustible and Explosive Atmospheres

For 3D printers, such as those associated with laser sintering and powder bed fusion, and potentially involving explosion hazards of reactive, combustible metal powders, such as titanium and aluminum alloys, there may be other considerations that manufacturers have to plan for from a regulatory perspective. For such 3D printers using metal powder and other potentially combustible and explosive materials, keeping aware of the evolving regulations is important.

For example in the U.S., OSHA published in 2009 an advance notice of proposed rulemaking, or ANPR, to consider a comprehensive federal standard to address the variety of workplace hazards found in facilities where combustible solids are handled, used, or stored in a manner that has the potential to generate and release combustible dusts. This activity was thought needed at the time due to a number of recent and past accidents in the workplace involving explosions of combustible dusts.

However, in parallel, and as part of the voluntary standards development process in the U.S., the National Fire Protection Association (NFPA) and associated stakeholders collaborated on refinement of the NFPA standards, NFPA 484, Combustible Metals, and NFPA 654, Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids.

Furthermore, and in an effort to further improve workplace safety and attempt to promote consistency within all the NFPA standards that address combustible dusts and related hazards, NFPA and industry worked on a brand new standard, NFPA 652, Fundamentals of Combustible Dust (scheduled to have a 2015 publication date.)

A key provision of this standard will be that facilities subjected to the NFPA combustible dust standards are to be required to undergo a dust hazards analysis, or DHA, which the standard defines as "a systematic review to identify and evaluate the potential fire, flash fire, or explosion hazards associated with the presence of one or more combustible particulate solids in a process or facility."

Regulations Associated with Potentially Combustible and Explosive Atmospheres

Because so many of the OSHA investigation findings concluded that owners/operators appeared to be unaware of the hazards posed by combustible particulate solids that have the potential to form combustible dusts when processed, stored, or handled, the NFPA committee believed it was essential to establish the DHA as a fundamental step in creating a plan for safeguarding such facilities.

Possibly because of some of the progress Industry has made towards promulgation of adequate voluntary standards, OSHA announced at the end of 2014 that the combustible dust rulemaking was no longer on its list of active regulatory projects, citing other priorities.*

In Europe the potential application of the ATEX Directive (2014/34/EU) remains a consideration for equipment installed and used in a potentially explosive atmosphere. Like the Machinery Directive, the ATEX Directive contains a number of criteria that must be met in order for the Directive to be determined applicable.

The Essential Health and Safety Requirements associated with the ATEX Directive are specific with respect to:

- potential ignition sources of equipment intended for use in potentially explosive atmospheres;
- autonomous protective systems intended to come into operation following an explosion, with the prime objective to halt the explosion immediately and/or limit the effects of explosion flames and pressures;
- safety devices intended to contribute to the safe functioning of such equipment with respect to ignition source and to the safe functioning of autonomous protective systems; and
- components with no autonomous function essential to the safe functioning of such equipment or autonomous protective system(s).

For manufacturers of 3D printers using metal powder and other potentially combustible and explosive materials, it is important to determine how the ATEX Directive may impact the installation of the equipment, including the safe handling, storage and housekeeping of combustible materials.

*Information in this Annex is based in part on information from the March/April 2015 NFPA Journal article, Credible Risk - http://www.nfpa.org/ newsandpublications/nfpa-journal/2015/march-april-2015/features/dust



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