

SEMI S10-0423^E

SAFETY GUIDELINE FOR RISK ASSESSMENT AND RISK EVALUATION PROCESS

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NOTICE: Conformance to the ‘should’ provisions of this Safety Guideline is necessary to declare conformance to this Document. Conformance to ‘may’, ‘suggested’, ‘preferred’, ‘recommended’, ‘NOTE’, or ‘Related Information’ provisions is not necessary to declare conformance.

NOTICE: The section symbol (§) is used to reference a numbered section, paragraph, or header and all subordinate paragraphs, headers, and embedded material (i.e., EXCEPTIONs, lists) therein. The paragraph symbol (§§) is used to reference a particular numbered paragraph and embedded material therein. When duplicated (i.e., §§§ and §§§§) the symbols are used to reference more than one section or paragraph, respectively.

NOTICE: Paragraphs entitled ‘NOTE:’ are not an official part of this Standard or Safety Guideline and are not intended to modify or supersede the official Standard or Safety Guideline. These have been supplied by the global technical committee to enhance the usage of the Standard or Safety Guideline.

^E This Safety Guideline was editorially modified in December 2023 to add Note 9 and to correct a processing error. Changes were made to §§ 6.1.3, 6.10.2.2.4, 6.10.2.2.4.1, and 6.10.2.2.4.2.

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1 Purpose

1.1 The primary purpose of this Safety Guideline is to define a consistent means of risk estimation which can be invoked by other SEMI Safety Guidelines.

NOTE 1: That material is in § 6, § 7, Appendix 1, and Appendix 2.

1.2 A secondary purpose of this Safety Guideline is to describe, generally, several other aspects of risk assessment (e.g., assembling information and personnel, hazard identification) and of risk control (e.g., risk evaluation and risk reduction).

1.3 This Safety Guideline provides a procedure for carrying out risk assessments on equipment in the semiconductor and similar industries and is intended for use by suppliers and purchasers as a reference for EHS considerations.

1.4 This Safety Guideline is also intended to assist in the development of strategies to prioritize and control risks.

2 Scope

2.1 This Safety Guideline is intended to apply to the assessment of risks throughout the lifecycle of equipment.

2.2 This Safety Guideline may also be applied to processes or facilities.

NOTE 2: Risk assessments are usually performed based on documentation and on inspection or testing of representative (e.g., with similar hazards and risk controls) equipment, but the result is usually considered to apply to the entire population of such equipment.

2.3 This Safety Guideline provides recommendations for assembling information and personnel for risk estimation.

2.4 This Safety Guideline describes the hazard identification process.

2.5 This Safety Guideline defines a process and specific criteria for risk estimation.

2.6 This Safety Guideline describes the risk evaluation and risk reduction processes.

NOTICE: SEMI Standards and Safety Guidelines do not purport to address all safety issues associated with their use. It is the responsibility of the users of the Documents to establish appropriate safety and health practices, and determine the applicability of regulatory or other limitations prior to use.

3 Limitations

3.1 This Safety Guideline is not intended to be used to verify compliance with regulatory requirements.

3.2 This Safety Guideline does not provide specific guidance on any aspect (e.g., risk reduction, mitigation, avoidance, or transfer techniques) of risk management other than risk estimation.

3.3 This Safety Guideline is not intended to explain specific hazard analysis techniques, such as Fault Tree Analysis (FTA), Event Tree Analysis (ETA), Hazard and Operability Studies (HAZOP), and Failure Mode Effect Analysis (FMEA). However, it recognizes that these techniques exist and that they are adequately covered elsewhere.

NOTE 3: Related Information 2 provides summary information and references for applicable techniques.

3.4 This Safety Guideline does not establish what level of risk is acceptable.

NOTE 4: Some SEMI Standards Program documents state what level of risk is acceptable.

3.5 Use SEMI S14 for fire risk assessment criteria for equipment.

4 Referenced Standards and Documents

4.1 SEMI Standards and Safety Guidelines

SEMI F1 — Specification for Leak Integrity of High-Purity Gas Piping Systems and Components

SEMI S2 — Environmental, Health, and Safety Guideline for Semiconductor Manufacturing Equipment

SEMI S8 — Safety Guideline for Ergonomics Engineering of Semiconductor Manufacturing Equipment

SEMI S14 — Safety Guideline for Fire Risk Assessment and Mitigation for Semiconductor Manufacturing Equipment

4.2 Other Documents

Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on Fluorinated Greenhouse Gases and Repealing Regulation (EU) No 842/2006¹

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)²

NOTICE: Unless otherwise indicated, all documents cited shall be the latest published versions.

5 Terminology

5.1 Definitions

5.1.1 *administrative control* — specification of a behavior or a work practice.

5.1.2 *baseline* — for the purposes of this Safety Guideline, ‘baseline’ refers to operating conditions, including process chemistry, for which the equipment was designed and manufactured. [SEMI S2]

5.1.3 *elimination* — physical removal of the source of a hazard.

5.1.4 *engineering control* — a physical feature that isolates personnel from a hazard.

5.1.5 *exposure to a hazard* — situation in which a hazard is present which can, but does not necessarily, result in harm.

5.1.6 *frequency of harm* — how often harm is caused by a hazard.

5.1.7 *harm* — physical injury or damage to health of people, or damage to equipment, buildings, or the environment.

5.1.8 *hazard* — a condition that has the potential to cause harm.

5.1.9 *hazard analysis* — the process of determining the scenario(s) involving the identified hazards.

5.1.10 *hazard identification* — the process of determining which, if any, characteristics of an object are hazards.

5.1.11 *hierarchy of controls* — the list, in order of decreasing effectiveness and decreasing preference, of risk controls:

1. Elimination
2. Substitution
3. Engineering Controls
4. Administrative Controls
5. Personal Protective Equipment (PPE)

5.1.12 *lifecycle* — the entire life of a piece of equipment, from conceptual design through disposal.

5.1.13 *likelihood* — the expected frequency with which harm will occur, expressed as the percentage of unit-years in which the harm has occurred or is expected to occur.

NOTE 5: The Likelihood Groups are defined in Appendix 1.

5.1.14 *maintenance* —planned or unplanned activities intended to keep equipment in good working order. Refer also to the definition for *service*.

5.1.15 *material* — a single species or a mixture.

5.1.16 *modification* — change of the equipment that can introduce new hazards and risks.

5.1.17 *mixture* — two or more species that are combined physically, but not chemically. That is, the species within the mixture are the species that would exist if the mixture were separated.

5.1.18 *operation* — the use of equipment to perform its intended function.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0517>

² Available at https://unece.org/search_content_unece?keyword=ghs&f%5B0%5D=content_types%3Apublication

5.1.19 *personal protective equipment (PPE)* — equipment and clothing worn to reduce potential for personal injury from hazards (e.g., chemical gloves, respirators, safety glasses).

5.1.20 *primary containment* — the first level of containment (i.e., the container, piping, or other component) that is intended to come into immediate contact on its inner surface with the material being contained during normal operation, maintenance, and service. Primary containment does not include exhaust handling components (e.g., ducting and exhausted enclosures). [SEMI S6]

5.1.21 *residual risk* — risk remaining after risk controls, if any, have been implemented.

5.1.22 *risk* — a function of expected severity and likelihood of harm(s) from a hazard.

NOTE 6: The risk categories are defined in Appendix 1.

5.1.23 *risk assessment* — a procedure through which knowledge and experience of design, use, incidents and accidents, and harm are brought together to measure the risks for specified scenarios of the equipment being assessed. Risk assessment includes determining the use and limits of the machinery, hazard identification, and risk estimation.

5.1.24 *risk control* — a means of reducing the risk associated with a hazard.

5.1.25 *risk estimation* — determination of the risk associated with a particular situation, including determination of the severity and the likelihood.

5.1.26 *risk evaluation* — the process of deciding if risk reduction is required.

5.1.27 *risk reduction* — the process by which the risk is reduced.

NOTE 7: Risk can be reduced by reducing severity or likelihood.

5.1.28 *scenario* — a causal chain involving the hazard and ending in one or more instances of harm to personnel, damage to equipment or facility, or in release of material from primary containment.

5.1.29 *secondary containment* — the second level of containment, the purpose of which is to contain material should it be released from its primary containment due to failure or to maintenance, or service operations. This pertains to both liquids and gases.

5.1.30 *service* — unplanned activities intended to return equipment that has failed to good working order. Refer also to the definition for *maintenance*.

5.1.31 *severity* — the extent of potential credible harm.

NOTE 8: The Severity Groups are defined in Appendix 1 and Appendix 2.

5.1.32 *species* — a particular kind of atom, ion, or molecule or a mixture that, in accordance with this Safety Guideline, is to be considered as if it were a particular kind of atom, ion, or molecule.

5.1.33 *substitution* — replacement of the source of a hazard with one resulting in lower risk.

6 Procedures

6.1 General Guidelines

6.1.1 Figure 1 shows the essential steps of the risk assessment and control processes.

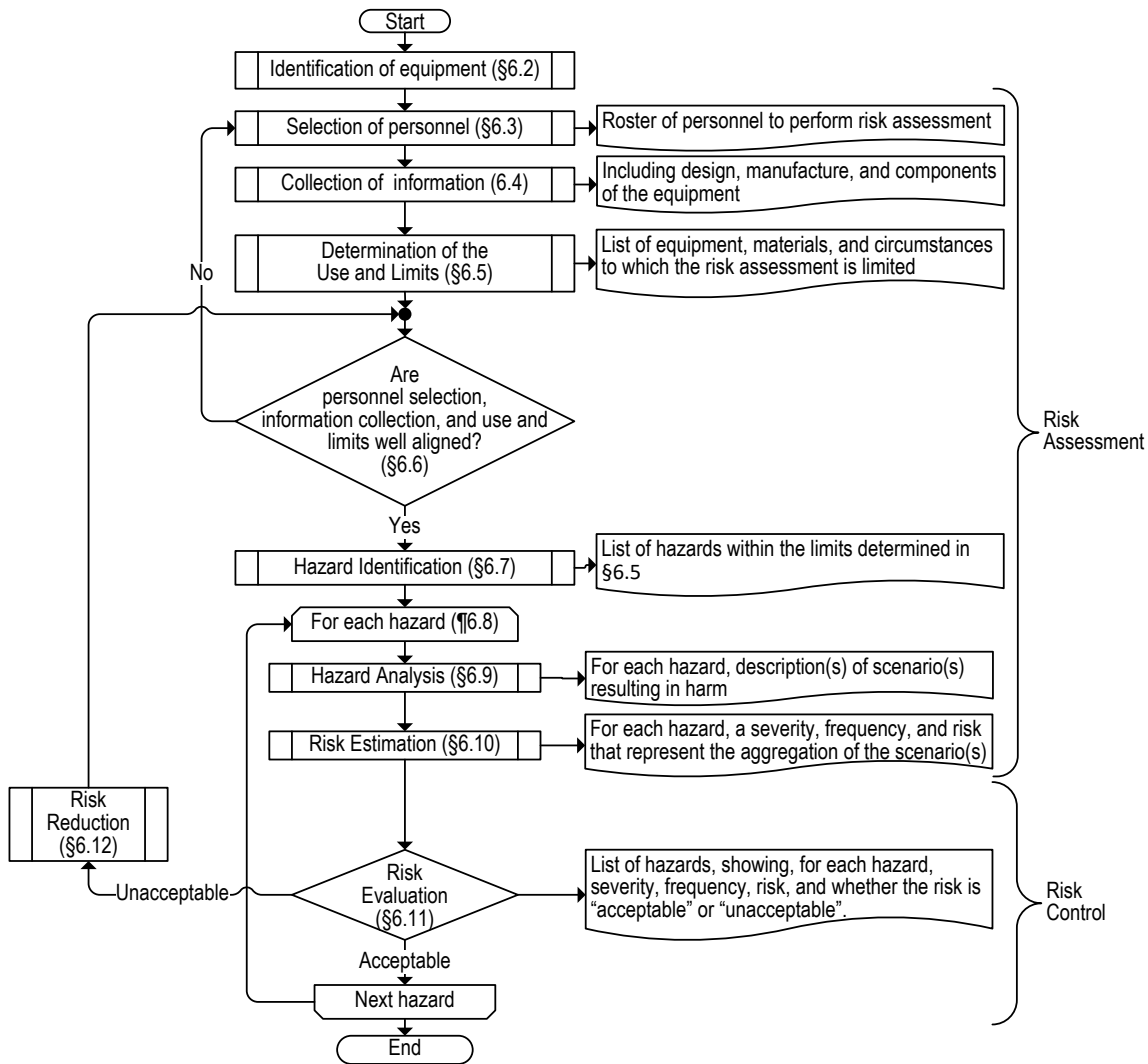


Figure 1
Risk Assessment and Control Flow Chart

6.1.2 Risk assessment should be initiated early in the design phase and updated as the design matures.

6.1.3 After a modification of the equipment or of its use that can change risks or introduce new hazards, reconsider §§ 6.2 through 6.5. Refer to Figure 1.

NOTE 9: An Excel workbook (S10WORKBOOK.XSLX) for recording foreseen or observed incidents and calculating risk is provided (for convenience, as using it is not a SEMI S10 conformance criterion) among the Supplementary Materials on the SEMI Website: <http://dom.semi.org/web/wstandards.nsf/supvnm>.

6.2 Identification of Equipment

6.2.1 Identify the equipment, the risk of which is to be assessed and controlled. That equipment may include items, such as vacuum pumps, that are considered by some to be ‘support equipment’. State what option(s) and configuration(s) of the equipment, including support equipment, are under consideration.

6.2.2 Decide whether or not each piece of support equipment is to be included in the equipment that is the subject of the risk assessment.

6.3 *Selection of Personnel to Perform Risk Assessment*

6.3.1 Select personnel (e.g., designers, equipment manufacturers, field engineers, end-users, third party evaluators, a risk assessment leader, and someone with experience in hazard identification). with the necessary knowledge and experience of the task(s), equipment, or process(es) being assessed.

6.4 *Collection of Information* — Collect information on the design (e.g., drawings, mock-up, and hardware), manufacture, and components of the equipment.

6.5 *Determination of the Use of the Equipment and Limits of the Risk Assessment* — Consider at least the following aspects:

- lifecycle stages
- person(s) who interact with the equipment
- areas in which equipment is used
- support equipment intended to be used with the equipment
- chemicals or family of chemicals to be used in the equipment

6.5.1 The lifecycle stages that are to be considered in the risk assessment should be decided. Which are to be included can be specified by a standard or Safety Guideline that calls for the use of SEMI S10. If they are not, they should be determined by the purpose and intended application of the risk assessment.

NOTE 10: Lifecycle stages include:

- design and development
- equipment manufacturing
- transportation
- installation
- maintenance and service
- use
- modification
- decommissioning
- disposal (include reuse and, recycling)

6.5.2 *Personnel Who Interact with the Equipment*

6.5.2.1 Identify the roles (e.g., ‘operator’, ‘equipment maintenance staff’, ‘equipment supplier’s field engineers’, ‘bystanders’) of the personnel whose interactions with the equipment are to be considered in the risk assessment and the general nature (e.g., ‘wafer production’, ‘routine maintenance’, ‘installation’) of the interactions.

6.5.2.2 The personnel and their interactions should be consistent with the lifecycle stages selected in ¶ 6.5.1.

6.5.3 *Areas*

6.5.3.1 Identify location(s) (e.g., cleanroom, subfab, aircraft, outdoors) in which the equipment will be during the stages and interactions identified above.

6.5.3.2 Determine the relevant (specified range or, for a particular piece of installed equipment, the actual) environmental conditions (e.g., temperature, relative humidity, ventilation) of each location.

6.5.4 *Excluded Support Equipment* — Identify the support equipment that is used with the equipment being assessed, but is not part of the equipment being assessed. This information is needed to determine the behavior at the equipment boundaries.

6.5.5 *Chemicals* — Determine the process chemicals (e.g., 10% silane in hydrogen, 49% hydrofluoric acid) and auxiliary chemicals (e.g., heat transfer fluid, vacuum pump oil) that are to be included in the risk assessment.

NOTE 11: When a risk assessment is performed for equipment, but the specific use of the equipment is not known, the chemicals included are usually those in the equipment manufacturer's baseline recipe(s).

6.6 Check whether personnel selection, information collection, and use and limits are well aligned. If they are not, add personnel and collect additional information as necessary.

6.7 *Hazard Identification*

6.7.1 Select hazard identification technique(s) to be used in this risk assessment.

NOTE 12: Related Information 1 contains an example of a checklist to assist in identifying hazards.

6.7.2 Identify, within the limits determined in § 6.5 and using the selected technique(s), anticipated hazards that could result in harm at each lifecycle stage.

6.8 For each hazard identified in ¶ 6.7.2 follow the process described in §§ 6.9 through 6.11.

6.9 *Hazard Analysis*

6.9.1 Select hazard analysis technique(s) to be used in this risk assessment.

NOTE 13: Related Information 2 contains examples of hazard analysis techniques.

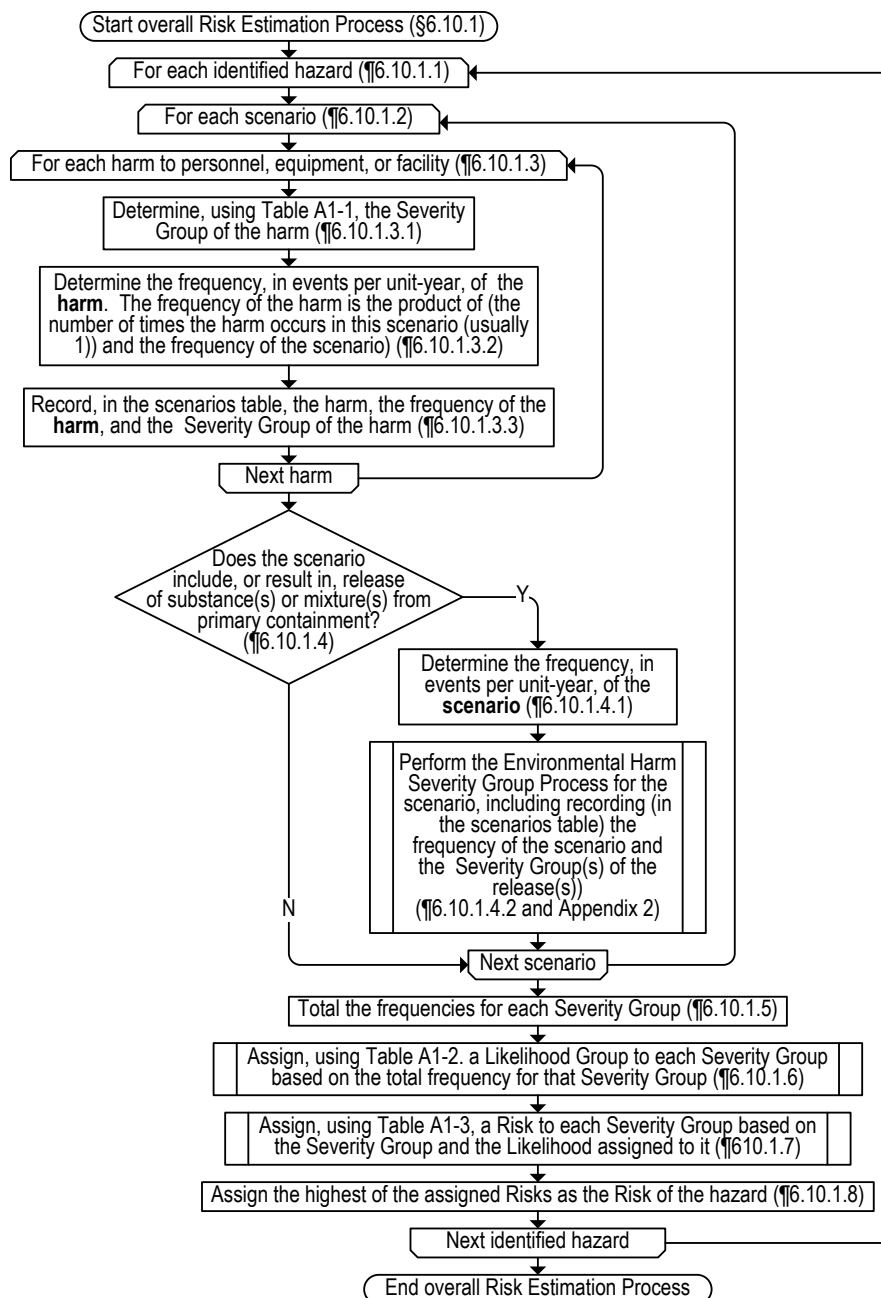
6.9.2 Identify the scenario(s) by which each hazard can result in harm(s) and the harm(s) that can result from each hazard.

NOTE 14: Human error, including reasonably foreseeable misuse, can contribute to the risk of other hazards.

6.10 *Risk Estimation* — This is the determination of the severity and frequency of harm expected from a hazard. The 'risk' assigned to the hazard depends on the severity and frequency of the associated harm(s).

6.10.1 *Process to be used when SEMI S10 is Invoked by Other SEMI Safety Guidelines*

NOTE 15: The overall risk estimation process described in § 6.10.1 is shown in Figure 2. The number in parentheses at the end of a block in that Figure identifies the paragraph to which the block corresponds.



#1 The parenthetical numbers identify the corresponding portions of the text.

Figure 2
Risk Estimation Process

6.10.1.1 The procedures in §§ 6.10.1.2 through 6.10.1.8 should be performed for each hazard identified in § 6.7.

6.10.1.2 The procedures in §§ 6.10.1.3 through 6.10.1.4 should be performed for each scenario identified in § 6.9 that includes:

- harm to people,
- harm to equipment or a facility, or
- a release from primary containment of material that is ozone depleting, global warming, or aquatically toxic.

NOTE 16: The determination of whether a substance is ozone depleting, globally warming, or aquatically toxic is discussed in Appendix 2.

6.10.1.3 The procedures in ¶¶ 6.10.1.3.1 through 6.10.1.3.3 should be performed for each harm to people, equipment, or a facility that can occur in the scenario.

6.10.1.3.1 Determine, using Table A1-1, the Severity Group of the harm.

6.10.1.3.2 Determine the frequency of the harm. The frequency of the harm is the product of (the number of times (usually 1) the harm occurs in this Scenario) and (the frequency of the scenario).

6.10.1.3.3 Record, in a scenarios table, the harm, the frequency of the harm, and the Severity Group of the harm.

NOTE 17: Figure 3 provides a recommended format for a scenarios table.

Scenarios Table for <Insert name or description of hazard>		Severity Group			
		1	2	3	4
Scenario 1					
<i>Harm to People</i>	<Use one row below for each different harm.>				
	<Describe the harm in this box.				
	Enter the frequency of the harm in the appropriate column to the right.>				
<i>Harm to Equipment/Facility</i>	<Use one row below for each different harm.>				
	<Describe the harm in this box.				
	Enter the frequency of the harm in the appropriate column to the right.>				
<i>Harm to the Environment</i>					
	Ozone Depletion				
	Global Warming				
	Aquatic Toxicity				
Scenarios 2 through n	<Replicate the “Scenario 1” block for each additional scenario>				
	Total frequency for each Severity Group				
	Likelihood Group for each Severity Group				
	Risk for each Severity Group				
	Greatest Risk				

Figure 3
Recommended Format for a Scenarios Table

6.10.1.4 If the scenario includes a release from primary containment of material that is ozone depleting, global warming, or aquatically toxic, perform the procedures in ¶ 6.10.1.4.1 and ¶ 6.10.1.4.2.

NOTE 18: The determination of whether a substance is ozone depleting, globally warming, or aquatically toxic is discussed in Appendix 2.

6.10.1.4.1 Determine the frequency of the scenario, in events per unit-year.

6.10.1.4.2 Perform the Environmental Risk Estimation process, as described in Appendix 2.

6.10.1.5 Total the frequencies for each Severity Group.

6.10.1.6 Assign, using Table A1-2, a Likelihood Group to each Severity Group based on the total frequency for that Severity Group.

6.10.1.7 Assign, using Table A1-3, a Risk to each Severity Group based on the Severity Group and the Likelihood assigned to it.

6.10.1.8 Assign the highest of the assigned Risks as the Risk of the hazard.

6.10.2 *Alternative Risk Estimation Methods*

6.10.2.1 There are numerous other ways of estimating the risk associated with a hazard. Some risk estimates are based on identifying the observed and reasonably foreseeable outcomes from a hazard and assigning an expected frequency to each (refer to § 6.10.2.2). Other risk estimates are obtained by comparing the equipment qualitatively to similar equipment.

NOTE 19: If a qualitative comparison is performed, it is preferred that it be done with sufficient and reliable information about similar equipment and situations and that the report states the basis of the finding of similarity between the different equipment and situations.

6.10.2.2 The risk estimation using the severities and frequencies of harms consists of several parts:

6.10.2.2.1 Assignment of a Severity Group to each harm.

6.10.2.2.2 Summing, by Severity Group, the frequencies of the harm(s) related to a hazard.

6.10.2.2.3 Assignment of a Likelihood Group to each Severity Group, based on the total frequency for that Severity Group. The likelihood, or how often harm results from something (e.g., personnel, the environment or equipment) being exposed to a hazard is a function of:

- frequency and duration of exposure to the hazard,
- probability of the occurrence of harm during exposure, and
- probability of avoiding harm during exposure, based on the presence, the extent, or the lack of risk controls.

NOTE 20: Related Information 3 provides further discussion of the factors that determine frequency of harm.

6.10.2.2.4 Identification of the overall risk associated with the hazard, using a suitable table.

6.10.2.2.4.1 The risk for each severity/likelihood combination should be determined.

6.10.2.2.4.2 The greatest risk from all of the combinations should be considered the overall risk for the hazard.

6.11 *Risk Evaluation*

6.11.1 Each hazard is evaluated to decide if risk reduction is needed. This is done, simply, by comparing the risk determined in risk estimation to the relevant criteria for what is considered ‘acceptable risk’ and ‘unacceptable risk’.

NOTE 21: As stated in ¶ 3.4, this Safety Guideline does not establish what level of risk is acceptable.

NOTE 22: Risk acceptance criteria can be established by a document (such as a SEMI Standards Program document) or process that invokes the use of the method in SEMI S10.

6.11.2 If risk acceptance criteria are not established by a document or process that invokes the use of SEMI S10, they may be determined by the party performing the risk assessment. If this is done, considering the following factors is recommended:

- customer expectations
- societal expectations
- feasibility (e.g., costs, technical possibility)
- legal requirements
- industry accident history
- international industry standards
- good engineering and manufacturing practices

6.12 *Risk Reduction*

6.12.1 This Safety Guideline does not establish the procedures or practices by which risk is reduced.

NOTE 23: It is recommended that, where practicable, one follow the hierarchy of controls Hierarchy of controls is defined in ¶ 5.1.11. Further information is available at, for example, <https://www.cdc.gov/niosh/topics/hierarchy/default.html>.

6.12.2 The risk assessment may be used to assist in the identification and selection of risk controls.

NOTE 24: SEMI S2 suggests that the following should be considered in the design and construction of equipment:

- regulatory requirements
- SEMI guidelines
- international industry standards
- good engineering and manufacturing practices

6.12.3 If risk reduction measures are implemented, proceed from ¶ 6.6.

7 Documentation

7.1 The risk assessment, evaluation, and reduction should be documented, and the documentation should contain at least the following:

- risk assessment technique(s) used
- reviewers
- date
- identification of the equipment considered
- hazards identified
- risk estimation
- the criteria used to determine if risk reduction is required
- risk evaluation
- risk controls implemented for identified hazards

NOTE 25: The risk assessment documentation can be used as input for safety reviews (e.g., SEMI S2, SEMI S8, or SEMI S14 report).

NOTE 26: Risk assessment techniques include the hazard identification methods, as well as whether the process defined in § 6.10.1 was used.

8 Related Documents

NOTE 27: The documents listed below provide useful background material for carrying out this Safety Guideline but are not cited in this Document.

8.1 *ANSI® Standards*³

ANSI/RIA R15.06 — Industrial Robots and Robot Systems – Safety Requirements

ANSI B11 TR3 — Risk Assessment and Risk Reduction – A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools

8.2 *BSI Standards*⁴

BS 5760-5 — Reliability of Systems, Equipment and Components. Guide to Failure Modes, Effects and Criticality Analysis (FMEA and FMECA)

³ American National Standards Institute, 25 West 43rd Street, New York, NY 10036, USA; Telephone: +1.212.642.4900, Fax: +1.212.398.0023, <http://www.ansi.org>. ANSI trademark is owned by American National Standards Institute.

⁴ British Standards Institution, 389 Chiswick High Road, London, W4 4AL, UK; Telephone: +44.345.080.9000, Fax: +44.20.8996.7001, <http://www.bsigroup.com>.

8.3 IEC® Standards⁵

IEC 60812 — Analysis Techniques for System Reliability – Procedure for Failure Mode and Effects Analysis (FMEA)

IEC 61508-5 — Functional Safety of Electrical/Electronic/Programmable Electronic Safety Related Systems – Part 5: Examples of Methods for the Determination of Safety Integrity Levels

8.4 ISO® Standards⁶

ISO 14121-1 — Safety of Machinery – Risk Assessment – Part 1: Principles

NOTE 28: ISO 14121-1 has been withdrawn by ISO and integrated in ISO 12100.

ISO/TR 14121-2 — Safety of Machinery – Risk Assessment – Part 2: Practical Guidance and Examples of Methods

ISO 12100 — Safety of Machinery – General Principles for Design – Risk Assessment and Risk Reduction

8.5 United States Military Standards⁷

MIL-STD-882D — Standard Practice for System Safety

8.6 Other Documents

AIChE — Several standards covering risk assessment, evaluation and specific topic, focused on chemical products⁸

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

Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on Persistent Organic Pollutants (Recast)⁹

⁵ International Electrotechnical Commission, 3 rue de Varembe, Case Postale 131, CH-1211 Geneva 20, Switzerland; Telephone: +41.22.919.02.11, <http://www.iec.ch>. IEC trademark is owned by International Electrotechnical Commission.

⁶ International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401-1214 Vernier, Geneva, Switzerland; Telephone: +41.22.749.01.11, Fax: +41.22.733.34.30, <http://www.iso.org>. ISO trademark is owned by International Organization for Standardization.

⁷ United States Military Standards, available as freely downloadable PDF files from the ASSIST Quick Search website at <http://quicksearch.dla.mil>.

⁸ American Institute of Chemical Engineers, 3 Park Ave, New York, N.Y., 10016-5991, USA; <http://www.aiche.org>

⁹ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32019R1021>