SEMI S10-0815
SAFETY GUIDELINE FOR RISK ASSESSMENT AND RISK EVALUATION PROCESS

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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.

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1 Purpose

1.1 The purpose of this Safety Guideline is to establish general principles for risk assessment to enable identification of hazards, risk estimation and risk evaluation in a consistent and practical manner. The Document provides a framework for carrying out risk assessments on equipment in the semiconductor and similar industries and is intended for use by supplier and purchaser as a reference for EHS considerations.

1.2 Use of this Safety Guideline is intended to assist in the development of a strategy to prioritize and control risks.

2 Scope

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

NOTE 1: It can 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 hazard control measures) equipment, but the result is usually considered to apply to the entire population of such equipment.

2.2 This Safety Guideline outlines a hazard identification, risk estimation, and risk evaluation process.

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 local regulatory requirements.

3.2 This Safety Guideline does not cover risk reduction, mitigation, avoidance or transfer techniques.

3.3 This Safety Guideline is not intended to explain specific risk assessment 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 Use SEMI S14 for fire risk assessment criteria for equipment.

4 Referenced Standards and Documents

4.1 *SEMI Standards and Safety Guidelines*

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

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

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5 Terminology

5.1 *Definitions*

5.1.1 *controls* — means to prevent or avoid a hazard from causing harm.

5.1.2 *exposure to a hazard* — situation in which a hazard is present which may (but does not necessarily) result in harm.

5.1.3 *frequency of exposure* — how often personnel or equipment are exposed to a hazard.

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

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

5.1.6 *lifecycle* — the entire life of an item of equipment, from conceptual design through to disposal.

5.1.7 *likelihood* — the expected frequency with which harm will occur. Usually expressed as a rate (e.g., events per year, per product, or per substrate processed).

NOTE 4: The likelihood groups are defined in Appendix 1.

5.1.8 *maintenance* — planned or unplanned activities intended to keep equipment in good working order.

5.1.9 *modification* — change of the equipment that may introduce new hazards and risks.

5.1.10 *residual risk* — risk remaining after engineering, administrative, and work practice controls have been implemented.

5.1.11 *risk* — the expected magnitude of losses from a hazard, expressed in terms of severity and likelihood.

NOTE 5: The risk categories are defined in Appendix 1.

5.1.12 *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.

5.1.13 *risk estimation* — derivation of the risk associated with a particular situation from a combination of the severity and the likelihood.

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

5.1.15 *risk reduction* — the process by which the risk is reduced to a lower level.

5.1.16 *service* — unplanned activities intended to return equipment that has failed back in good working order.

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

NOTE 6: The severity groups are defined in Appendix 1.

6 Procedures

6.1 *General Guidelines*

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

6.1.2 A risk assessment should be performed to identify and evaluate potential hazards in the equipment being assessed. Risk assessment should be initiated early in the design phase and updated as the design matures.

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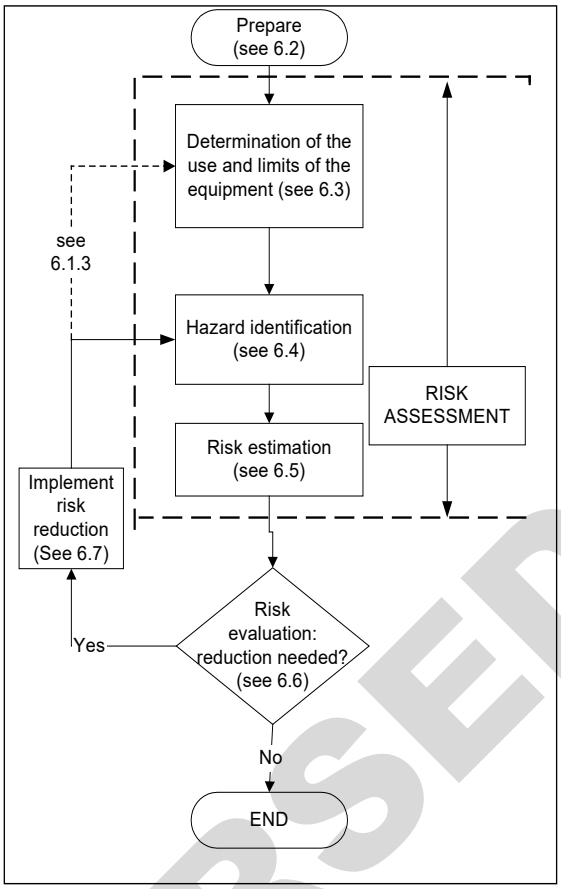

Figure 1
Risk Assessment Flowchart

6.1.3 After a significant modification (i.e., one that can introduce new hazards and/or risks in the design), reconsideration of use and limits of the equipment may be necessary (see Figure 1).

6.2 *Preparations for Hazard Identification and Risk Estimation Process*

6.2.1 The assessment should be carried out by those with the necessary knowledge and experience of the task, equipment, or process being assessed.

NOTE 7: To have an effective process, good preparation is essential.

6.2.2 Select the reviewers (e.g., designers, equipment manufacturers, field engineers, end-users, third party evaluators, a risk assessment leader and someone with experience in hazard identification).

6.2.3 Select the risk assessment technique.

6.2.4 Collect information on the design (e.g., drawings, mock-up, and hardware).

6.2.5 Determine the scope of the assessment.

6.3 *Define Use and Limits of the Equipment* — Consider at least the following aspects:

- Lifecycle stages,
- Person(s) involved,
- Areas in which equipment is used,
- Support equipment intended to be used with the equipment, and

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- Chemicals or family of chemicals to be used in the equipment.

6.3.1 The lifecycle stages that are to be considered in the risk assessment should be decided, and may differ depending on the standard requiring the use of SEMI S10. They can include the following:

- Design & development
- Equipment manufacturing
- Transportation
- Install
- Maintenance & Service
- Use
- Modification
- Decommissioning
- Disposal (include reuse, recycling)

6.4 *Hazard Identification* — Identify anticipated hazards that could result, in a reasonably foreseeable scenario, in harm at each lifecycle stage by using an appropriate technique. Hazards can be identified under those headings defined in SEMI S2.

NOTE 8: See Related Information 1 for an example of a checklist to assist in identifying hazards and Related Information 2 for examples of hazard analysis techniques.

6.5 *Risk Estimation*

6.5.1 There are numerous 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 (see § 6.5.2). Other risk estimates are obtained by comparing the equipment qualitatively to similar equipment.

NOTE 9: If a qualitative comparison is performed, it is preferred that it be done with sufficient and reliable information about similar equipment and situations and state the basis of the finding of similarity between the different equipment and situations.

6.5.2 The risk estimation using the severity and frequency of representative harm scenarios consists of several parts:

6.5.2.1 Identification of each observed or reasonably foreseeable outcome of a hazard.

6.5.2.2 Assignment of a severity group to each representative harm scenario. The severity groups are given in Table A1-1.

6.5.2.3 Assignment of a likelihood group to an outcome representing each severity group. The likelihood groups are given in Table A1-2. The likelihood, or how often something (e.g., personnel, the environment or equipment) is exposed to a hazard, such that harm results from the exposure 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 controls.

6.5.2.4 Identification of the overall risk associated with the hazard, using a suitable table. The risk category assignments are given in Table A1-3.

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

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

6.5.3 Regardless of the risk assessment method and rankings used in other work, the results of a SEMI S10 assessment should be reported using the Likelihood, Severity, and Risk terms and definitions in Appendix 1.

6.6 *Risk Evaluation*

6.6.1 Each hazard or set of hazards is evaluated to decide if risk reduction is needed.

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6.6.2 Risk evaluation can be an individual internal process for the equipment manufacturer or the equipment user, or a joint effort by all involved parties.

NOTE 10: This Document does not establish a level of risk for which reduction is required. In the evaluation of risk reduction, various aspects may be taken into account, including:

- Customer expectations,
- Social expectations,
- Feasibility (e.g., Costs, technical possibility),
- Legal requirements,
- Industry accident history,
- International industry standards, and
- Good engineering and manufacturing practices.

6.7 *Risk Reduction*

6.7.1 The risk assessment may be used to assist in the identification and selection of control measures to reduce the risk. Following risk reduction measures, the assessment may need to be reviewed.

NOTE 11: This Document does not specify risk reduction measures that may be necessary following risk assessment. SEMI S2 suggests that the following should be considered in the design and construction of equipment:

- Regulatory requirements,
- SEMI guidelines,
- International industry standards, and
- Good engineering and manufacturing practices.

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 used,
- reviewers,
- date,
- identification of the equipment considered,
- hazards identified,
- risk estimation,
- the criteria used to determine if risk reduction is required,
- risk evaluation, and
- control measures implemented to reduce the risk from identified hazards.

NOTE 12: The risk assessment documentation can be used as input for safety reviews (e.g., SEMI S2, SEMI S8 or SEMI S14 report).

8 Related Documents

NOTE 13: The documents listed below provide useful background material for carrying out this Safety Guideline but are not specially cited in this Document.

8.1 *SEMI Standards and Safety Guidelines*

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

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8.2 *US Military Standards*[1]

MIL STD 1629A — Failure Modes, Effects and Criticality Analysis

MIL STD 882D — Standard Practice for System Safety

8.3 *International Electrotechnical Commission Standards*[2]

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

IEC 61025 — Fault Tree Analysis (FTA)

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 *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

8.5 *ISO Standards*[4]

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

NOTE 14: 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 13849-1 — Safety of Machinery – Safety-Related Parts of Control Systems – Part 1: General Principles for Design

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

8.6 *Other Documents*

SEMATECH #9202963A-ENG — Failure Mode and Effects Analysis (FMEA): A Guide for Continuous Improvement for the Semiconductor Equipment Industry[5]

AIChE — Several standards covering risk assessment, evaluation and specific topic, focused on chemical products[6]

BS 5760-5 — Reliability of systems, equipment and components. Guide to failure modes, effects and criticality analysis (FMEA and FMECA)[7]

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[1] United States Military Standards, Available through the Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120-5099, USA; Telephone: +1.215.697.3321.

[2] International Electrotechnical Commission, 3 rue de Varembé, Case Postale 131, CH-1211 Geneva 20, Switzerland; Telephone: +41.22.919.02.11, Fax: +41.22.919.03.00, http://www.iec.ch

[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

[4] International Organization for Standardization, ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; Telephone: +41.22.749.01.11, http://www.iso.org

[5] SEMATECH, 257 Fuller Road, Suite 2200, Albany, NY 12203, USA; Telephone: +1.518.649.1000, http://www.sematech.org

[6] American Institute of Chemical Engineers, 3 Park Ave, New York, NY 10016-5991, USA; http://www.aiche.org

[7] British Standards institute, 389 Chiswick High Road, London W4 4AL, United Kingdom; http://www.bsi-global.com

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