

SEMI S10-1103

SAFETY GUIDELINE FOR RISK ASSESSMENT AND RISK EVALUATION PROCESS

This safety guideline was technically approved by the Environmental, Health, & Safety Committee and is the direct responsibility of the European Environmental, Health, & Safety Committee. Current edition approved by the European Regional Standards Committee on July 1, 2003. Initially available at www.semi.org October 2003; to be published November 2003. Originally published December 1996.

NOTICE: This document was completely rewritten in 2003.

NOTICE: Paragraphs entitled “NOTE:” are not an official part of this document and are not intended to modify or supersede the official guideline.

1 Purpose

1.1 The purpose of this 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 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.

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

NOTICE: This safety guideline does not purport to address all of the safety issues associated with its use. It is the responsibility of the users of this safety guideline to establish appropriate safety and health practices and determine the applicability of regulatory or other limitations prior to use.

3 Limitations

3.1 This guideline is not intended to be used to verify compliance with local regulatory requirements.

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

3.3 This 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 2: 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

4.1 SEMI Standards

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

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

5 Terminology

5.1 Definitions

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

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 3: 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.

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 4: 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.

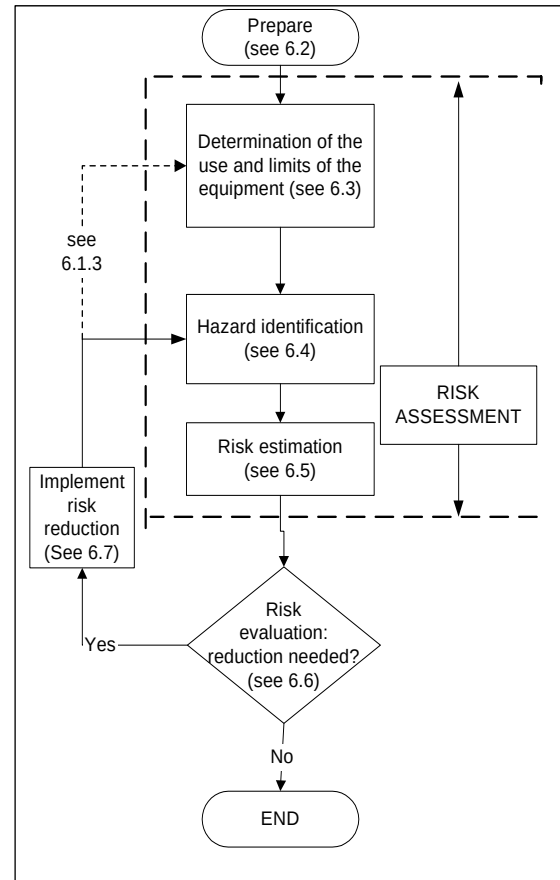


Figure 1
Risk Assessment Flowchart

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 5: 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
- Chemicals or family of chemicals to be used in the equipment.

6.3.1 All lifecycle stages should be considered during the hazard identification e.g.:

- 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 6: 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 Section 6.5.2). Other risk estimates are obtained by comparing the equipment qualitatively to similar equipment (see Section 6.5.3).

6.5.2 The risk estimation using outcome and frequency 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 outcome. The preferred 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 preferred likelihood groups are given in Table A1-2. The likelihood, also called the Probability of Occurrence of Harm can be 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 preferred 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 Benchmark Method — Benchmarks an anticipated or observed hazardous situation against a similar situation. Based on the circumstances in which the hazard occurs, a risk category (Very High to Very Low) is assigned to the risk.

NOTE 7: Benchmarking method should only be used if sufficient adequate and reliable information is available on a similar model or situation.

6.6 Risk Evaluation

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

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 8: 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 9: 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 10: The risk assessment documentation can be used as input for safety reviews, e.g., SEMI S2, S8 or S14 report.

8 Related Documents

8.1 SEMI Standards

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

8.2 US Military Standards¹

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

MIL STD 882D — Standard Practice for System Safety

8.3 International Electrotechnical Commission Standards²

1 Available through the Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120-5099, USA. Telephone: 215.697.3321

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

IEC 61025 — Fault Tree Analysis (FTA)

IEC 61508-5: (1999-04) — Functional Safety of Electrical/Electronic/Programmable Electronic Safety Related Systems - Part 5: Examples of Methods for the Determination of Safety Integrity Levels

IEC 61508-5:(1998-12) — Related Systems - Part 5: Examples of Methods for the Determination of Safety Integrity Levels

8.4 ANSI Standards³

ANSI/RIA R15.06: 1999 — Industrial Robots and Robot Systems — Safety Requirements

ANSI B11 TR3-2000 — Risk Assessment and Risk Reduction – A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools

8.5 ISO Standards⁴

ISO 14121: 1999 — Safety of machinery - Principles for risk assessment

ISO/TR 13849-1:1999/EN 954-1: — Safety of machinery - Safety-related parts of control systems. Part 1: General principles for design

ISO/TR 12100-1:1992/EN 292-1: — Safety of machinery - Basic concepts, general principles for design. Part 1: Basic terminology, methodology

ISO/TR 12100-2:1992/EN 292-2: — Safety of machinery - Basic concepts, general principles for design. Part 2: Technical principles and specifications

8.6 Other Documents

SEMATECH⁵ #9202963A-ENG; — Failure Mode and Effects Analysis (FMEA): A Guide for Continuous Improvement for the Semiconductor Equipment Industry

2 Available through the International Electrotechnical Commission, 3, rue de Varembe, Case Postale 131, CH-1211 Geneva 20, Switzerland. Telephone: 41.22.919.02.11; Fax: 41.22.919.03.00 Website: <http://www.iec.ch>

3 Available through the American National Standards Institute, New York Office: 11 West 42nd Street, New York, NY 10036, USA. Telephone: 212.642.4900; Fax: 212.398.0023 Website: <http://www.ansi.org>

4 Available through the International Organization for Standardization, ISO Central Secretariat, 1, rue de Varembe, Case postale 56, CH-1211 Geneva 20, Switzerland. Telephone: 41.22.749.01.11; Fax: 41.22.733.34.30 Website: <http://www.iso.ch>

5 Available through International SEMATECH, 2706 Montopolis Drive, Austin, TX, USA website: <http://www.sematech.org>

AICHE⁶ — Several standards covering risk assessment, evaluation and specific topic, focused on chemical products.

BS⁷ 5760–5:1991 — Reliability of systems, equipment and components. Guide to failure modes, effects and criticality analysis (FMEA and FMECA)

⁶ Available through the American Institute of Chemical Engineers, 3 Park Ave, New York, N.Y., 10016-5991, USA. <http://www.aiche.org>

⁷ Available through the British Standards institute, 389 Chiswick High Road, London W4 4AL, United Kingdom www.bsi-global.com

APPENDIX 1 RISK RANKING TABLES

NOTICE : The material in this appendix is an official part of SEMI S10 and was approved by full letter ballot procedures on April 2, 2003.

NOTE A1-1: The following Tables A1-1 and A1-2 give the groups of severity and likelihood. Other examples can be found in Related Information 3 (Risk Ranking Number) and Related Information 4 (more detailed numerical Severity and Likelihood).

Table A1-1 Severity Groups

<i>Severity Group</i>	<i>People (See Note A1-2.)</i>	<i>Equipment/Facility (See Note A1-3.)</i>	<i>Property</i>
1 – Catastrophic	One or more fatalities.	System or facility loss.	Chemical release with lasting environmental or public health impact.
2 – Severe	Disabling injury/illness.	Major subsystem loss or facility damage.	Chemical release with temporary environmental or public health impact.
3 – Moderate	Medical treatment or restricted work activity (OSHA recordable).	Minor subsystem loss or facility damage.	Chemical release triggering external reporting requirements.
4 – Minor	First aid only.	Non-serious equipment or facility damage.	Chemical release requiring only routine cleanup without reporting.

NOTE A1-2: This number is if 1-2 people are exposed to the risk. The severity group should be reconsidered to a more severe severity group when 3 or more people are involved.

NOTE A1-3: Although it is not a safety risk it adds value to take in account product (e.g. wafers, reticles) damage. No descriptions are given due to the fact of the value and number of products on a equipment can vary. Possible descriptions can be: Rework of a wafer, Rework of a batch, Loss of a batch.

Table A1-2 Likelihood Groups

<i>Likelihood Group</i>	<i>Expected Frequency (% of Units- Year) (See Note 1.)</i>
A – Frequent	More than 1%
B – Likely	More than 0.2% but not more than 1%
C – Possible	More than 0.04%, but not more than 0.2%
D – Rare	More than 0.02%, but not more than 0.04%
E – Unlikely	Not more than 0.02%

Note 1: The frequency (in percent) is calculated by dividing the number of (observed or expected) occurrences by the number of unit-years that the hazard has existed or is anticipated to exist, then multiplying the quotient by 100.

NOTE A1-4: If data are available, they should be used. If data are not available, the frequencies should be estimated.

NOTE A1-5: The following two example calculations are added for clarification of Table A1-2 only:

Example 1:

If something expected to happen 1 time in 5 units operated for 6 years the frequency will become:

$$(1 \text{ time} / (5 \text{ units} \times 6 \text{ year of operation})) \times 100\% = 3.3\% (= A - \text{Frequent})$$

Example 2:

If something expected to happen 2 times on 50 units with 30 are operated for 6 years and 20 are operated for 7 years the frequency will become

$$(2 \text{ times} / (30 \text{ units} \times 6 \text{ year of operation} + 20 \text{ units} \times 7 \text{ year of operation})) \times 100\% = 0.625\% (= C - \text{Possible})$$