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Title: Minimum Requirements for Controlling Environmental Contamination of Components

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Other documents affected:

Page:

All pages per Issue 2 Draft B attached.

Paragraph:

All pages per Issue 2 Draft B attached.

Original wording:

Proposed wording:

Updated for ESCC references in lieu of ESA/SCC and replacement of references to FED-STD-209 by corresponding references to ISO 14644. Addition of text to require appropriate identification in the PID of those operations performed under controlled conditions.

Justification:

Changes are mostly editorial for the conversion to ESCC.

The additional text concerning the PID is to reinforce implementation of the requirements in a practical manner.

FED-STD-209 was cancelled in November 2001 and superseded by ISO 14644. Clean room classes are labelled differently. Crossreferencing leads to the use of Class 4 through 8 to correspond to Class 10 through 100000.

Attachments:
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Pages 1 to 11

MINIMUM REQUIREMENTS FOR CONTROLLING ENVIRONMENTAL CONTAMINATION OF COMPONENTS

ESCC Basic Specification No. 24900

Issue 2 - DRAFT B	
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DCR No.	CHANGE DESCRIPTION
	Technical and editorial changes per DCR

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1. SCOPE

1.1 PURPOSE

This specification defines the minimum requirements for a system applicable to the manufacturing, testing and storage of electronic, electrical and electromechanical (EEE) components to minimise the effects of contamination from the environment. This system shall consider, as a minimum, the following environmental factors: light, electromagnetic fields, electrostatic voltages, temperature, humidity, vibration and shock, chemical liquids, chemical vapours and particles.

1.2 WARNING

This specification considers only contamination issues affecting the reliability of EEE components. This specification does not address, nor shall its application be such as to conflict with, national or international health and safety regulations.

2. RELATED DOCUMENTS

2.1 APPLICABLE DOCUMENTS

The following ESCC specifications, at current issue, form part of, and shall be read in conjunction with, this specification.

ESCC 20600	Preservation, Packaging and Despatch of ESCC Electronic Components
ESCC 21300	Terms, Definitions, Abbreviations, Symbols and Units
ESCC 22700	Requirements and Guidelines for the Process Identification Document (PID)
ESCC 22800	ESCC Non-conformance Control System
ESCC 23800	Electrostatic Discharge Sensitivity Test Method

2.2 REFERENCE DOCUMENTS

ISO 14644	Cleanrooms and associated controlled environments
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3. TERMS AND DEFINITIONS

The terms, definitions, abbreviations, symbols and units defined in ESCC Basic Specification No. 21300 shall apply. In addition the following definitions are used:

Contaminant	Any undesirable substance, radiation or environmental condition present in the manufacturing, testing or storage environment that can act in an adverse manner on a component so as to cause subsequent problems or failure during manufacturing, testing or use.
Cleanroom or clean workstation	An enclosed area, designed, equipped, maintained and controlled in such a way that the degree of contamination of a product can be controlled.

Cleanliness class	A categorisation for cleanroom or clean workstation of the maximum number of particles allowed in a given volume of enclosed air.
Visually clean	Visually clean to the normal unaided eye (except corrected vision) when examined under oblique white light (540-1600 lux) and from a distance of 30 to 60 cm.

4. **GENERAL ENVIRONMENTAL CONTAMINATION CONTROL REQUIREMENTS**

The Manufacturer shall maintain an environmental contamination control system described by an issued quality procedure. This shall include provisions for the assessment of the required conditions for each step of the manufacturing process used for a particular component. Potential sources of contamination shall be controlled and maintained so as not to exceed allowed levels.

Operations or processes to be performed under specifically controlled environmental conditions, e.g. cleanroom, special lighting, electromagnetic field control, etc, should be clearly indicated in the PID, e.g. by inclusion in the flow charts. Detailed requirements shall be specified in appropriate issued operating procedures.

Non-conformances, relating to out of control environmental contamination affecting manufactured ESCC qualified component lots or the Manufacturer's ability to respond to orders for ESCC components, shall be grounds for initiating the ESCC non-conformance system. This shall be done in accordance with ESCC Basic Specification No. 22800.

5. **REQUIREMENTS FOR AIRBORNE PARTICLE CONTROL**

When the prevention of airborne particle contamination requires the use of purpose built facilities such as cleanrooms, clean workstations and other controlled areas or rooms with restrictions enforced to enhance cleanliness, the following general conditions shall be met:

- Building material and finish shall be selected to avoid emission or attraction of particles.
- Furniture shall be kept to a minimum in the work areas and arranged to allow easy and thorough cleaning.
- Working areas and the contained equipment and tools shall be maintained as visually clean with no loose material (dirt, dust, machining or solder particles, lubricants, etc.) present.
- Eating, drinking and smoking shall be prohibited in the work area and washrooms. Rest areas etc. shall be outside and segregated from the work area.
- Access rules shall apply for personnel, materials and equipment.
- Entry/exit areas shall provide for appropriate segregation between the controlled and uncontrolled areas and prevent the ingress of contaminants (e.g. airlocks)
- Management and discipline methods, operator and supervisor training shall be defined and implemented.

Designated cleanrooms and clean workstations shall be specified, certified and maintained with a measurable cleanliness level using calibrated particle counters. When cleanliness is controlled to a lesser extent, cleanliness levels shall be evaluated by observation of the working surfaces as visually clean.

Three categories of facilities shall be considered for the preparation of applicable cleanliness requirements: cleanrooms, controlled areas and other areas.

5.1 **MINIMUM QUALITY ASSURANCE REQUIREMENTS FOR CLEANROOMS OR CLEAN WORKSTATIONS**

For cleanrooms or clean workstations the Manufacturer shall establish and document the:

- Cleanliness class(es) according to ISO 14644 Part 1.
- Method used for cleanliness class certification.
- Monitoring requirements (methods, frequency, parameters measured and recorded: cleanliness, temperature, relative humidity, overpressure, air flow rate, laminar air velocity).
- Garment specifications (refer to Appendix A).
- Dressing and gowning requirements.
- Frequency of changes of garments.
- Action and shutdown limits.
- Alarms and recovery actions.
- Housekeeping requirements (definition of various cleaning methods and frequencies, authorised materials, type and change frequency of filters).
- Tools, materials, furniture and equipment requirements.
- Entry / exit area controls.
- Equipment and materials incoming and outgoing procedure.
- Prohibited materials.
- Personnel access rules and maximum occupancy.
- Prohibited personnel actions.
- Personnel training.
- Cleanliness non-conformance recording.

5.2 MINIMUM QUALITY ASSURANCE REQUIREMENTS FOR CONTROLLED AREAS (CLEANROOMS EXCLUDED)

A controlled area is considered to be an area or room where air is filtered and maintained in overpressure relative to adjacent areas.

For controlled areas the Manufacturer shall establish and document the:

- Filtered air monitoring requirements (methods, frequency, parameters measured and recorded: overpressure, temperature, relative humidity, air flow rate).
- Garment specifications and frequency of changes.
- Housekeeping requirements (definition of various cleaning methods and frequencies, authorised materials, type and change frequency of filters).
- Action and shutdown limits.
- Alarms and recovery actions.
- Tools, materials, furniture and equipment requirements.
- Entry / exit area controls.
- Equipment and materials incoming and outgoing procedure.
- Prohibited materials.
- Personnel access rules and maximum occupancy.
- Prohibited personnel actions.

5.3 MINIMUM QUALITY ASSURANCE REQUIREMENTS FOR OTHER AREAS

Where cleanliness requirements do not justify the use of cleanrooms or controlled areas, a Manufacturer shall as a minimum establish and document the:

- Housekeeping requirements (definition of various cleaning methods and frequencies).actions.
- Prohibited materials.
- Personnel access rules.
- Prohibited personnel

6. REQUIREMENTS FOR TEMPERATURE CONTROL

For ambient electrical testing, the temperature shall be controlled as specified by the pertinent ESCC Detail Specification. For any other temperature controlled work area, the ambient temperature shall be maintained within a specified range with defined action and shutdown limits.

In all cases, methods for permanent or sampling temperature measurements and recording shall be documented and records retained.

7. REQUIREMENTS FOR HUMIDITY CONTROL

For humidity controlled work areas relative humidity shall be maintained within a specified range with defined action and shutdown limits. Unless otherwise required and documented the range shall be 55%±10%. Methods for permanent or sampling humidity measurements and recording shall be documented and records retained. Hygrometers shall be calibrated at least once every six months.

The humidity environment for packaging shall be compatible with the requirements of ESCC Basic Specification No. 20600.

8. REQUIREMENTS FOR VIBRATION AND SHOCK CONTROL

Mechanical vibrations or shocks originating from the internal or external environment can adversely affect the accuracy required during mechanically critical processes. Any such process shall be identified and the associated equipment decoupled from vibration sources. Documented controls shall be established to monitor the continuing effectiveness of the preventive measures.

The effects on identified susceptible processes shall be assessed before commissioning newly installed plant or equipment producing vibration or shock byproducts.

9. REQUIREMENTS FOR LIGHT CONTROL

Light environmental conditions shall be in accordance with the specific requirements of the processes. For the correct execution of tasks requiring visual assessment or inspection, working surfaces shall be provided with a minimum uniform, shadowless light intensity and shall be free from severe reflections. These tasks shall be identified and the light intensity specified.

Wherever special lighting conditions are needed, documented controls shall be established to monitor and maintain the specified requirements.

10. REQUIREMENTS FOR ELECTROSTATIC VOLTAGE CONTROL

A Manufacturer shall establish the electrostatic discharge (ESD) sensitivity of a component in accordance with ESCC Basic Specification No. 23800. For ESD sensitive components a Manufacturer shall establish and maintain a documented ESD control system which ensures that electrostatic potential differences are reduced to levels below the sensitivity of the components. As a minimum, the control programme must address the following points:

- Workstations where ESD sensitive components are assembled, tested or inspected shall be located in areas of controlled relative humidity. The work stations shall be static dissipative, i.e. made of materials with a surface resistivity of 10^5 to 10^{10} Ohms per square and suitably connected to ground. All personnel working in the area shall be suitably connected to ground when handling unprotected components. Work trays and containers, bags, handling fixtures or garments shall be made from static dissipative materials.
- Whenever insulating objects are used, ionised air shall be applied continuously over the work areas in order to neutralise the electrostatic charges. Plastic objects and foils, adhesive tapes and similar products shall be kept out of the work areas. ESD protection shall be improved with conducting floor

or floor mat and conductive seat surfaces. ESD protected areas and ESD sensitive components containers and packages shall bear appropriate warning symbols or notices.

- For electrical testing, all terminals of the test equipment shall be grounded while the component is placed in the test socket.
- For storage, in addition to packaging made from static dissipative material, an external conducting layer shall be used as a shield against external electrical fields for those Class 1 devices established as being particularly sensitive. The external leads of components shall be shorted together with conducting material. All metal shelves, cabinets and lockers used for storage must be appropriately grounded.

The efficiency of the control measures shall be periodically verified and records of measurements retained. Particular attention shall be given to regularly checking the continuing effectiveness of wrist straps and re-usable items such as treated static dissipative plastic containers and foams.

11. REQUIREMENTS FOR ELECTROMAGNETIC FIELD CONTROL

Parasitic electromagnetic fields encountered in the manufacturing environment are hazardous to some sensitive components. Additionally, measurement results can be adversely influenced for a variety of components. Such cases shall be identified and electromagnetic fields reduced to acceptable levels. When appropriate, processes or tests shall be performed in magnetically quiet areas, where machines, electronic equipment, vehicles and personnel traffic are restricted, or in a Faraday cage.

Test methods and processes shall be documented accordingly and acceptable levels for electromagnetic fields maintained by means of regular and documented inspection measurements.

12. REQUIREMENTS FOR GASES, CHEMICALS AND LIQUIDS

Impurities contained in gases, chemicals or liquids used in manufacturing or cleaning processes shall be controlled. Processes critical to chemical impurities and particles contained in processing gases, chemicals or liquids shall be identified. In these cases, the component Manufacturer shall demonstrate that either by the purchase of appropriate products (e.g. electronic grade) or by filtering, the effects of impurities and particles are reduced to acceptable limits.

Required cleanliness of gases, chemicals and liquids shall be maintained by means of regular and documented inspection measurements.

Re-usable products (e.g. solvents, plating and tinning baths) can, over time, accumulate impurities likely to contaminate the components or piece parts processed. Such contamination shall be avoided by the use of documented monitoring and cleaning or replenishment procedures.

Chemicals or materials with aging effects, such that their initial properties can be altered, shall be identified and recorded as limited life items. As such, they shall be identified in operating procedures and bear corresponding and clearly visible labels.

13. REQUIREMENTS FOR CHEMICAL VAPOUR AND CROSS CONTAMINATION CONTROL

Products used in the manufacturing processes of components may generate vapours corrosive to exposed bare materials or may deposit impurities on the devices. Susceptible processes shall be identified and documented control measures, such as the use of evacuation systems, implemented. In cases where contamination of surfaces of piece parts cannot be fully avoided, an appropriate cleaning shall be performed before further processing, or use, in order to restore the initial surface conditions.

Cross-contamination by tools, transport containers, etc. shall be avoided by use of tools and handling fixtures specific to certain operations and/or by cleaning before use in accordance with documented

procedures.

The efficiency of the control measures shall be periodically verified and records of measurements retained.

APPENDIX A GARMENT REQUIREMENTS IN CLEANROOMS

Unless otherwise specified in the Process Identification Document, cleanroom garments shall be adapted to declared cleanliness classes as follows:

ISO Class 4	Hood with complete permanent facial enclosure, coverall, high boots, gloves.
ISO Class 5	Hood with permanent or detachable facial cover, coverall, high boots, gloves.
ISO Class 6	Hood or head cover with complete hair and facial hair cover, coverall, boots, gloves.
ISO Class 7	Hood or head cover with complete hair and facial hair cover, zippered frock, shoe cover.
ISO Class 8	Hood or head cover with complete hair and facial hair cover, zippered frock, shoe cover.

Fabrics

Non-shedding woven fabrics shall be used employing continuous multi filament yarn.

Additional Requirements

Whenever electrostatic sensitive components are manufactured or tested, static dissipative fabrics shall be used.

When minimum requirements for garments do not require facial cover or gloves, and when human contamination is critical to the reliability of the components, facial cover and gloves are also required. Gloves are preferred to finger cots for permanent operations.

For ISO Class 4, the use of special undergarments may also be appropriate.