

**DIN EN 16602-70-26**

ICS 49.060; 49.140

**Entwurf**

Einsprüche bis 2018-02-08  
Vorgesehen als Ersatz für  
DIN EN 16602-70-26:2015-06

**Raumfahrtproduktsicherung –  
Quetschen von hochzuverlässigen elektrischen Verbindungen;  
Englische Fassung prEN 16602-70-26:2017**

Space product assurance –  
Crimping of high-reliability electrical connections;  
English version prEN 16602-70-26:2017

Assurance produit des projets spatiaux –  
Sertissage des connexions électriques à fiabilité élevée;  
Version anglaise prEN 16602-70-26:2017

**Anwendungswarnvermerk**

Dieser Norm-Entwurf mit Erscheinungsdatum 2017-12-08 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfs besonders zu vereinbaren.

Stellungnahmen werden erbeten

- vorzugsweise online im Norm-Entwurfs-Portal von DIN unter [www.din.de/go/entwuerfe](http://www.din.de/go/entwuerfe) bzw. für Norm-Entwürfe der DKE auch im Norm-Entwurfs-Portal der DKE unter [www.entwuerfe.normenbibliothek.de](http://www.entwuerfe.normenbibliothek.de), sofern dort wiedergegeben;
- oder als Datei per E-Mail an [nl@din.de](mailto:nl@din.de) möglichst in Form einer Tabelle. Die Vorlage dieser Tabelle kann im Internet unter [www.din.de/go/stellungnahmen-norm-entwuerfe](http://www.din.de/go/stellungnahmen-norm-entwuerfe) oder für Stellungnahmen zu Norm-Entwürfen der DKE unter [www.dke.de/stellungnahme](http://www.dke.de/stellungnahme) abgerufen werden;
- oder in Papierform an den DIN-Normenausschuss Luft- und Raumfahrt (NL), 10772 Berlin, Burggrafenstr. 6, 10787 Berlin.

Die Empfänger dieses Norm-Entwurfs werden gebeten, mit ihren Kommentaren jegliche relevanten Patentrechte, die sie kennen, mitzuteilen und unterstützende Dokumentationen zur Verfügung zu stellen.

Gesamtumfang 58 Seiten

DIN-Normenausschuss Luft- und Raumfahrt (NL)

## **Nationales Vorwort**

Dieses Dokument (prEN 16602-70-26:2017) wurde vom Technischen Komitee CEN/CLC/TC 5 „Raumfahrt“ erarbeitet, dessen Sekretariat von DIN (Deutschland) gehalten wird.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 131-06-02 AA „Interoperabilität von Informations-, Kommunikations- und Navigationssystemen“ im DIN-Normenausschuss Luft- und Raumfahrt (NL).

Dieses Dokument (prEN 16602-70-26:2017) basiert auf ECSS-Q-ST-70-26C Rev.1.

Dieses Dokument ersetzt DIN EN 16602-70-26:2015-06.

Dieses Dokument enthält unter Berücksichtigung des DIN-Präsidialbeschlusses 1/2004 nur die englische Originalfassung von prEN 16602-70-26:2017.

Dieses Dokument wurde speziell zur Behandlung von Raumfahrtsystemen erarbeitet und hat daher Vorrang vor jeglicher Europäischer Norm, die denselben Anwendungsbereich hat, jedoch über einen größeren Geltungsbereich (z. B. Luft- und Raumfahrt) verfügt.

### **Änderungen**

Gegenüber DIN EN 16602-70-26:2015-06 wurden folgende Änderungen vorgenommen:

- a) Überarbeitung von Anhang A inklusive Korrektur von Tabelle A-1.

## Nationaler Anhang NA (informativ)

### Begriffe und Abkürzungen

Die Benummerung der folgenden Begriffe und Abkürzungen ist identisch mit der Benummerung in der englischen Fassung.

#### 3.1 Begriffe aus anderen Normen

- a) Für die Anwendung dieses Dokuments gelten die Begriffe nach ECSS-S-ST-00-01, insbesondere die folgenden Begriffe:
  - 1) Annahme;
  - 2) Analyse;
  - 3) Los;
  - 4) Bauteil;
  - 5) Konformität;
  - 6) Verunreinigung.
- b) Für die Anwendung dieser Norm gelten die Begriffe nach ECSS-Q-ST-60-05, insbesondere die folgenden Begriffe:
  - 1) Prozessidentifizierungs-Dokument (PID) (en: process identification document)
- c) Für die Anwendung dieser Norm gelten die Begriffe nach ECSS-Q-ST-70-08, insbesondere die folgenden Begriffe:
  - 1) elektrische Verbindung

#### 3.2 Für diese Norm spezifische Begriffe

##### 3.2.1

##### **einstellbares Verpresswerkzeug**

Crimpwerkzeug mit einstellbarem Teil (Einstellvariable), das die Anschluss- oder Aderendhülse am Leiter einkerbt oder zusammenpresst

##### 3.2.2

##### **Crimpanordnung**

Kombination von Crimpwerkzeug, Crimpstück und Anzahl und Art der durch die Technischen Lieferbedingungen festgelegten Drähte

ANMERKUNG 1 Beispiele für Crimpstücke umfassen Kabelschuh, Spleiß und Aderendhülse.

ANMERKUNG 2 Drahtarten umfassen Werkstoff, Größe, Oberflächenausführung und Los, wenn es sich nicht um von der ESCC qualifizierten Draht handelt.

ANMERKUNG 3 Crimpwerkzeug, basierend auf der Kombination von Werkzeugreferenz, Einstellung und Positionierer (wenn erforderlich).

### 3.2.3

#### **Crimpwerkzeug**

mechanisches Werkzeug für die Herstellung einer dauerhaften Verbindung zwischen einer Einrichtung mit Drahtanschluss und einem Leiter durch Druckverformung oder Verformung der Anschlusshülse um den Leiter mit dem Ziel eines guten elektrischen und mechanischen Kontakts

### 3.2.4

#### **Aderendhülse**

kurzes Metallrohr zur Herstellung von Quetschverbindungen am Außenleiter von geschirmten oder Koaxialkabeln

### 3.2.5

#### **inhärente Drahtstärke**

Zugfestigkeit eines in einer Crimpverbindung angewendeten Drahts, bestimmt durch eine spezielle Zugprüfung

### 3.2.6

#### **Kabelschuh**

Metallrohr mit einem mit einer Bohrung versehenen Flansch für die Befestigung an einem Anschlusspunkt

### 3.2.7

#### **Spleiß**

Metallrohr zum Zusammenfügen von zwei oder mehr Leitern

### 3.2.8

#### **Anschluss**

Anschlussklemme

Metallvorrichtung zur Herstellung elektrischer Verbindungen

## 3.3 Abkürzungen

Für die Anwendung dieser Norm gelten die Abkürzungen in ECSS-S-ST-00-01 und die folgenden Abkürzungen:

| <b>Abkürzung</b> | <b>Bedeutung</b> |  |
|------------------|------------------|--|
|------------------|------------------|--|

|            |                                                   |                                        |
|------------|---------------------------------------------------|----------------------------------------|
| <b>AWG</b> | amerikanische Drahtnorm, amerikanische Drahtlehre | (en: American wire gauge)              |
| <b>DRD</b> | Dokumenten-Anforderungsdefinition                 | (en: document requirements definition) |
| <b>IPA</b> | Isopropylalkohol                                  | (en: iso-propyl alcohol)               |
| <b>KIP</b> | Schlüsselprüfpunkt                                | (en: key inspection point)             |
| <b>MIP</b> | Hauptprüfpunkt                                    | (en: mandatory inspection point)       |
| <b>NCR</b> | Nichtkonformitätsbericht                          | (en: nonconformance report)            |
| <b>PID</b> | Prozessidentifizierungs-Dokument                  | (en: process identification document)  |
| <b>QA</b>  | Qualitätssicherung                                | (en: quality assurance)                |
| <b>RFA</b> | Genehmigungsantrag                                | (en: request for approval)             |
| <b>RFW</b> | Antrag auf Aufhebung                              | (en: request for waiver)               |
| <b>RH</b>  | relative Luftfeuchte                              | (en: relative humidity)                |

September 2017

ICS 49.060; 49.140

Will supersede EN 16602-70-26:2014

English version

## Space product assurance - Crimping of high-reliability electrical connections

Assurance produit des projets spatiaux - Sertissage de connexions électriques hautes fiabilités

Raumfahrtproduktsicherung - Falten von hochzuverlässigen elektrischen Verbindungen

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/CLC/TC 5.

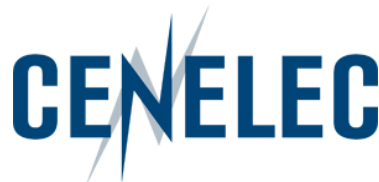
If this draft becomes a European Standard, CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN and CENELEC in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation. Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

**Warning** : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



**CEN-CENELEC Management Centre:**  
**Avenue Marnix 17, B-1000 Brussels**

## Table of contents

|                                                                 |           |
|-----------------------------------------------------------------|-----------|
| <b>European Foreword</b>                                        | <b>5</b>  |
| <b>1 Scope</b>                                                  | <b>6</b>  |
| <b>2 Normative references</b>                                   | <b>8</b>  |
| <b>3 Terms, definitions and abbreviated terms</b>               | <b>10</b> |
| 3.1 Terms defined in other standards                            | 10        |
| 3.2 Terms specific to the present standard                      | 10        |
| 3.3 Abbreviated terms                                           | 11        |
| 3.4 Nomenclature                                                | 12        |
| <b>4 Principles</b>                                             | <b>13</b> |
| <b>5 Requirements</b>                                           | <b>14</b> |
| 5.1 Preparatory conditions                                      | 14        |
| 5.1.1 Facilities                                                | 14        |
| 5.1.2 Tools and equipment                                       | 15        |
| 5.2 Crimping operations for different types of interconnections | 17        |
| 5.2.1 General                                                   | 17        |
| 5.2.2 Material selection                                        | 18        |
| 5.2.3 Process review and documentation                          | 19        |
| 5.2.4 Contact barrel and single wire crimping                   | 19        |
| 5.2.5 Contact barrel and multiple wire crimping                 | 20        |
| 5.2.6 Ferrule shield crimping                                   | 22        |
| 5.2.7 Lug and splice wire crimping                              | 22        |
| 5.3 Requirements for crimp configuration qualification          | 25        |
| 5.3.1 General                                                   | 25        |
| 5.3.2 Qualification process test procedure                      | 26        |
| 5.3.3 Sealing and marking                                       | 28        |
| 5.3.4 Batch to batch variation                                  | 28        |
| 5.4 Test methods                                                | 28        |
| 5.4.1 General                                                   | 28        |
| 5.4.2 <<deleted>>                                               | 28        |

|                                                                                |                                                                                  |           |
|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------|
| 5.4.3                                                                          | Tensile strength .....                                                           | 29        |
| 5.4.4                                                                          | Metallography .....                                                              | 30        |
| 5.5                                                                            | Quality assurance .....                                                          | 31        |
| 5.5.1                                                                          | General .....                                                                    | 31        |
| 5.5.2                                                                          | Personnel training and certification .....                                       | 31        |
| 5.5.3                                                                          | Workmanship .....                                                                | 34        |
| 5.5.4                                                                          | Visual inspection .....                                                          | 36        |
| 5.5.5                                                                          | Shift performance inspection and test for harness manufacturing .....            | 38        |
| 5.5.6                                                                          | Calibration of crimping tools .....                                              | 39        |
| 5.5.7                                                                          | Records .....                                                                    | 40        |
| 5.5.8                                                                          | Nonconformance .....                                                             | 41        |
| 5.5.9                                                                          | Special crimping activities at spacecraft level, modifications and repairs ..... | 41        |
| 5.6                                                                            | Document requirements .....                                                      | 44        |
| <b>Annex A (informative) Crimp configurations and tools .....</b>              |                                                                                  | <b>45</b> |
| <b>Annex B (informative) Examples of typical ultimate axial strength .....</b> |                                                                                  | <b>52</b> |
| <b>Bibliography .....</b>                                                      |                                                                                  | <b>54</b> |

## Figures

|                                                                                  |    |
|----------------------------------------------------------------------------------|----|
| Figure 1-1: Example of interconnections described in this Standard .....         | 7  |
| Figure 5-1: Example of crimping tools .....                                      | 16 |
| Figure 5-2: Example of a typical connector barrel and single wire crimping ..... | 20 |
| Figure 5-3: Example of a typical connector barrel and multi-wire crimping .....  | 21 |
| Figure 5-4: Example of a typical ferrule shield crimping .....                   | 22 |
| Figure 5-5: Examples of typical lug and splice wire crimping (1 of 2) .....      | 24 |
| Figure 5-6: Examples of typical lug and splice wire crimping (2 of 2) .....      | 25 |
| Figure 5-7: Qualification process test procedure flow chart .....                | 27 |
| Figure 5-8: Quality control during crimping operation .....                      | 33 |
| Figure 5-9: Visible workmanship standards .....                                  | 35 |
| Figure 5-10: Workmanship examples and crimp micro-sections .....                 | 36 |
| Figure 5-11: Shift performance test flowchart .....                              | 43 |

## Tables

|                                                                                                 |    |
|-------------------------------------------------------------------------------------------------|----|
| Table A-1 : Guideline for selector setting - Four-indent crimp (dispersive) - Single wire ..... | 47 |
| Table A-2 : Guideline for selector setting - Four-indent crimp (dispersive) - Two wires .....   | 48 |

|                                                                                                                                       |    |
|---------------------------------------------------------------------------------------------------------------------------------------|----|
| Table A-3 : Guideline for selector setting – Four-indent crimp (dispersive) – Two different wires.....                                | 49 |
| Table A-4 : Guideline for selector setting – Four-indent crimp (dispersive) – Single wire .....                                       | 49 |
| Table A-5 : Guideline for selector setting – Four-indent crimp (dispersive) – Two identical wires .....                               | 49 |
| Table A-6 : Guideline for die selection – Regular hexagon (compactive ) – Ferrule coaxial shield crimp.....                           | 50 |
| Table B-1 : Typical ultimate axial strength for compactive and dispersive crimped joints manufactured using qualified ESCC wires..... | 52 |

## European Foreword

---

This document (prEN 16602-70-26:2017) has been prepared by Technical Committee CEN/CLC/TC 5 “Space”, the secretariat of which is held by DIN (Germany).

This document (prEN 16602-70-26:2017) originates from ECSS-Q-ST-70-26C Rev.1.

This document is currently submitted to the CEN ENQUIRY.

This document will supersede EN16602-70-26:2014.

This document has been developed to cover specifically space systems and will therefore have precedence over any EN covering the same scope but with a wider domain of applicability (e.g.: aerospace).

# 1

## Scope

---

This Standard specifies:

- Requirements for the following crimping wire connections intended for high reliability electrical connections for use on spacecraft and associated equipment operating under high vacuum, thermal cycling and launch vibration:
  - removable contacts, single wire
  - removable contacts, multiple wires
  - coaxial contacts, ferrules
  - lugs and splices.

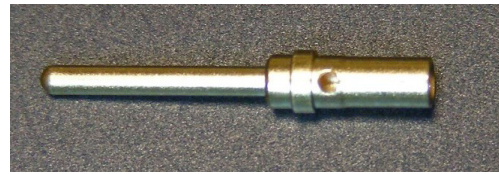
NOTE These are the most commonly used crimping wire connections and are represented in Figure 1-1.
- The general conditions to be met for the approval of connections other than the above mentioned ones.

NOTE Additional forms of crimps, not covered in this standard, are listed (not exhaustively) in the informative Annex A.
- Product assurance provisions for both the specific and the generic connections mentioned above.
- Training and certification requirements for operators and inspectors (clause 5.5.2), additional to those specified in ECSS-Q-ST-20.

This standard may be tailored for the specific characteristics and constraints of a space project, in conformance with ECSS-S-ST-00.



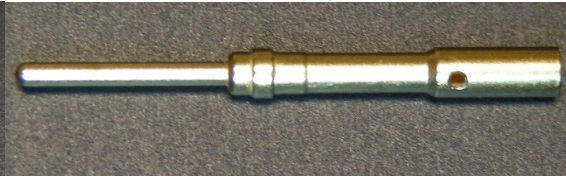
Normal socket



Normal male



Enlarged socket



Enlarged male



MDM socket



MDM male



Coax socket



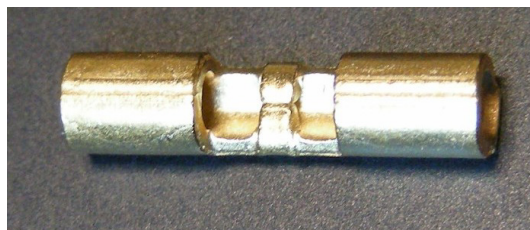
Coax male



Power socket



Power male



Butt splice



Parallel splice



Lug

Figure 1-1: Example of interconnections described in this Standard

## Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this ECSS Standard. For dated references, subsequent amendments to, or revisions of any of these publications do not apply. However, parties to agreements based on this ECSS Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references the latest edition of the publication referred to applies.

| EN reference   | Reference in text                | Title                                                                                                                                                                             |
|----------------|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN 16601-00-01 | ECSS-S-ST-00-01                  | ECSS system - Glossary of terms                                                                                                                                                   |
| EN 16602-10-09 | ECSS-Q-ST-10-09                  | Space product assurance - Nonconformance control system                                                                                                                           |
| EN 16602-20    | ECSS-Q-ST-20                     | Space product assurance - Quality assurance                                                                                                                                       |
| EN 16602-60    | ECSS-Q-ST-60                     | Space product assurance - Electrical, electronic and electromechanical (EEE) components                                                                                           |
| EN 16602-60-05 | ECSS-Q-ST-60-05                  | Space product assurance – General requirements for hybrids                                                                                                                        |
| EN 16602-70    | ECSS-Q-ST-70                     | Space product assurance - Materials, mechanical parts and processes                                                                                                               |
| EN 16602-70-08 | ECSS-Q-ST-70-08                  | Space product assurance - Manual soldering of high-reliability electrical connections                                                                                             |
| EN 16602-70-38 | ECSS-Q-ST-70-38                  | Space product assurance - High-reliability soldering for surface-mount and mixed technology                                                                                       |
| EN 16602-70-71 | ECSS-Q-ST-70-71                  | Space product assurance - Data for selection of space materials and processes                                                                                                     |
|                | SAE-AS-22520,<br>24 October 2011 | Crimping tools, , wire termination, General specification for                                                                                                                     |
|                | SAE-AS-7928B<br>10 March 2011    | Terminals, lugs, splices, conductor, crimp style, copper, general specification for                                                                                               |
|                | ISO 7500-1:2004                  | Metallic materials - Verification of static uniaxial testing machines - Part 1: tension/compression testing machines - Verification and calibration of the force-measuring system |

| EN reference | Reference in text              | Title                                                                                    |
|--------------|--------------------------------|------------------------------------------------------------------------------------------|
|              | ESCC 3901, Issue 2<br>May 2013 | ESCC generic specification No. 3901 Wires and cables,<br>electrical, 600V, low frequency |

## Terms, definitions and abbreviated terms

---

### 3.1 Terms defined in other standards

- a. For the purpose of this Standard, the terms and definitions from ECSS-S-ST-00-01 apply, in particular for the following terms:
  1. acceptance
  2. analysis
  3. batch
  4. component
  5. conformance
  6. contaminant
- b. For the purpose of this Standard, the terms and definitions from ECSS-Q-ST-60-05 apply, in particular for the following terms:
  1. process identification document (PID)
- c. For the purpose of this Standard, the terms and definitions from ECSS-Q-ST-70-08 apply, in particular for the following terms:
  1. electrical connection

### 3.2 Terms specific to the present standard

#### 3.2.1 adjustable indenter tool

crimping ratcheting tool which has an adjustable part (setting variable) that indents or compresses the conductor barrel or ferrule

#### 3.2.2 crimping configuration

combination of crimping tool, crimp item and number and type of wires defined by the procurement specification

NOTE 1 Example of crimp item include lug, splice and contact, ferrule.

NOTE 2 Type of wires include material, size, finish and batch if not ESCC qualified wire.

NOTE 3 Crimping tool based on the combination of tool reference, setting and locator (when necessary).

### 3.2.3 crimping tool

mechanical ratcheting tool used for permanently attaching a wire connection device to a conductor by pressure deformation or by reshaping the barrel around the conductor to establish good electrical and mechanical contact

### 3.2.4 ferrule

short metal tube used to make crimp connections to the outer conductor of shielded or coaxial cables

### 3.2.5 intrinsic wire strength

tensile strength of a wire used in a crimped assembly, determined by a specific pull test

### 3.2.6 lug

metallic tube with drilled flange projection for fixing to a connection point

### 3.2.7 splice

metallic tube for joining two or more conductors to each other

### 3.2.8 terminal

metallic device that is used to make an electrical connection

## 3.3 Abbreviated terms

For the purpose of this Standard, the abbreviated terms from ECSS-S-ST-00-01 and the following apply:

| Abbreviation | Meaning                         |
|--------------|---------------------------------|
| AWG          | American wire gauge             |
| DRD          | document requirement definition |
| IPA          | iso-propyl alcohol              |
| KIP          | key inspection point            |
| MIP          | mandatory inspection point      |
| NCR          | nonconformance report           |
| PID          | process identification document |
| QA           | quality assurance               |
| RFA          | request for approval            |
| RFW          | request for waiver              |
| RH           | relative humidity               |

## 3.4 Nomenclature

The following nomenclature applies throughout this document:

- a. The word “shall” is used in this Standard to express requirements. All the requirements are expressed with the word “shall”.
- b. The word “should” is used in this Standard to express recommendations. All the recommendations are expressed with the word “should”.

NOTE It is expected that, during tailoring, recommendations in this document are either converted into requirements or tailored out.

- c. The words “may” and “need not” are used in this Standard to express positive and negative permissions, respectively. All the positive permissions are expressed with the word “may”. All the negative permissions are expressed with the words “need not”.
- d. The word “can” is used in this Standard to express capabilities or possibilities, and therefore, if not accompanied by one of the previous words, it implies descriptive text.

NOTE In ECSS “may” and “can” have completely different meanings: “may” is normative (permission), and “can” is descriptive.

- e. The present and past tenses are used in this Standard to express statements of fact, and therefore they imply descriptive text.

---

## 4 Principles

---

This Standard is structured such that the necessary level of quality is achieved, consistently maintained and high reliability of the end product assured. The following principles are covered:

- Preparatory conditions to determine the availability of facilities, tools and equipment, along with obligatory hazard and health precautions.
- Specific interconnections, as identified in the Scope above, are then covered in detail including
  - Material selection,
  - Process identification and documentation.
- New crimp combinations beyond those identified in the Scope.
- Test methods and acceptance criteria for both specific and generic types of interconnections are specified.
- Quality assurance measures for both the operator and the inspector are prescribed:
  - Training and certification of personnel,
  - Calibration of tools and equipment,
  - Workmanship standards and acceptance criteria,
  - Inspection criteria and sequence,
  - Records from material incoming inspection through delivery of the end product, including KIP, MIP, travellers, follow-up sheets, log books, traceability samples and the handling of deviations by RFA or NCR.

It is important to perform the work taking into account health and safety regulations, and in particular the national standards on this subject.

# 5

## Requirements

---

### 5.1 Preparatory conditions

#### 5.1.1 Facilities

##### 5.1.1.1 Overview

The requirements in this clause can generally be met by using cleanrooms. It is not, however, mandatory to use a cleanroom.

NOTE Depending on supplier and customer business agreement.

##### 5.1.1.2 Facility cleanliness

- a. The supplier shall provide cleaning services for production facilities where high reliability crimping is performed.
- b. Production facilities where high reliability crimping is performed shall be maintained in a clean and tidy condition.
- c. Loose material that can cause contamination of the crimped connection shall be removed.

NOTE For example: Dirt, dust, oils and cut wire strands.

- d. Furniture shall be kept to a minimum in the work areas and be arranged to allow easy and thorough cleaning of the floor.
- e. Working surfaces shall be covered with an easily cleaned hard top, antistatic mat or have a replaceable surface of clean, non-contaminating silicone-free paper.

##### 5.1.1.3 Environmental conditions

- a. The crimping area shall have a controlled environment, which limits entry of contamination.
- b. The area shall be continuously controlled as follows:
  - 1. room temperature:  $(22 \pm 3) ^\circ\text{C}$ ;
  - 2. relative humidity:  $(55 \pm 10) \%$ .