BRITISH STANDARD

BS CECC
00016:1991

Harmonized system of quality assessment for electronic components

Basic specification: Basic requirements for the use of statistical process control (SPC) in the CECC System

Committees responsible for this British Standard

This British Standard was entrusted by the Electronic Components Standards Policy Committee (ECL/-), upon which the following bodies were represented:

BEAMA Ltd.

British Standards Society

British Telecommunications plc

EEA (The Association of the Electronics, Telecommunications and Business Equipment Industries)

Electronic Components Industry Federation

Ministry of Defence

National Supervising Inspectorate

Society of British Aerospace Companies Limited

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Contents

National foreword

This British Standard has been prepared under the direction of the Electronic Components Standards Policy Committee. It is identical with CECC 00016:1990 "*Harmonized system of quality assessment for electronic components: Basic specification: Basic requirements for the use of statistical process control (SPC) in the CECC System*", published by the European Committee for Electrotechnical Standardization (CENELEC) Electronic Components Committee (CECC).

This standard defines the requirements for the application of statistical process control (SPC) in the CECC System in order to improve the quality of processes, products and services by continually reducing process variation.

Cross-references

International standard	Corresponding British Standard
CECC 00114:RP 14 Part II	BS CECC 00114: *Quality assessment procedures* Part 2:1991 *Qualification approval of electronic components* (Identical)
CECC 00114:RP 14 Part III	BS CECC 00114: *Quality assessment procedures* Part 3:1991 *Capability approval of an electronic component manufacturing activity* (Identical)
EN 29001	BS 5750: *Quality systems* Part 1:1987 *Specification for design/development, production, installation and servicing* (Identical)

The British Standard which implements the CECC Rules of Procedure is BS 9000 "*General requirements for a system for electronic components of assessed quality*" — Part 2:1991 "*Specification for the national implementation of the CECC System*".

The Electronic Components Standards Policy Committee has reviewed the provisions of CECC 00011 to which reference is made in the text and has decided that they are acceptable for use in conjunction with this standard.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the CECC title page, pages ii to iv, pages 1 to 6, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Förderverein für Elektrotechnische Normung (FEN) e. V.
Cenelec Electronic Components Committee

CECC

Système Harmonisé d'Assurance de la Qualité
des Composants Electroniques

SPECIFICATION DE BASE

EXIGENCES DE BASE POUR L'APPLICATION DE LA MAITRISE STATISTIQUE DE ROCESSUS (SPC) DANS LE SYSTEME CECC

Harmonized System of Quality Assessment for
Electronic Components

BASIC SPECIFICATION

BASIC REQUIREMENTS FOR THE USE OF STATISTICAL PROCESS CONTROL (SPC) IN THE CECC SYSTEM

Harmonisiertes Gütebestätigungssystem für
Bauelemente der Elektronik

GRUNDSPEZIFIKATION

GRUNDLEGENDE ANFORDERUNGEN FÜR DIE ANWENDUNG STATISTISCHER PROZESSREGELUNG (SPC) IM CECC-SYSTEM

1 Edition
Issue
Ausgabe

CECC 00 016

1990

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Foreword

The CENELEC Electronic Components Committee (CECC) is composed of those member countries of the European Committee for Electrotechnical Standardization (CENELEC) who wish to take part in a harmonized System for electronic components of assessed quality.

The object of the System is to facilitate international trade by the harmonization of the specifications and quality assessment procedures for electronic components, and by the grant of an internationally recognized Mark, or Certificate, of Conformity. The components produced under the System are thereby acceptable in all member countries without further testing.

At the date of printing of this specification, the member countries of the CECC are Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom, and copies of it can be obtained from the addresses shown on the blue fly sheet.

Preface

This Basic Specification was prepared by the CECC Task Force on Statistical Process Control.

The text of this specification was circulated to the CECC for voting in the document indicated below and was ratified by the President of the CECC for printing as a CECC Specification.

Document	Date of Voting	Report on the Voting
CECC(Secretariat)2480	February 1990	CECC(Secretariat)2628

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1 Introduction

CECC approved components are released under either Qualification Approval (see CECC 00114:RP 14 Part II), or Capability Approval (see CECC 00114:RP 14 Part III).

Statistical Process Control (SPC) is a tool which may be used within the CECC System to demonstrate the degree to which the relevant manufacturing processes are under control.

When the technique is properly applied, it can assist in improving the outgoing product quality, particularly where the number of non-conforming items may be expressed as a low number of parts per million (ppm). No conventional sampling plan, nor even 100 % inspection, can accurately separate out these low level non-conforming items.

The only viable approach to quality in this situation is to institute a preventive methodology in the manufacturing process to build quality into the product, adopting a "proactive" method which allows for the improvement of the process on a continuing basis. SPC is used at the operational level to reduce process variation.

SPC is based upon the prevention of failures through the application of statistical tools. It does not eliminate the measurement of products or of product parameters, i.e. inspections, which may be carried out on a sampling basis or 100 %. However, statistical analysis will provide insight into the process and opportunities for improvement. As the process improves, there is a reduced need for extensive testing after the product is completed, with a consequent lowering of the manufacturing cost.

By the use of statistical techniques, process variation with time can be quantified. Corrective actions which are based on this information will lead to continuing improvement in processes and products.

A prerequisite for effective implementation of an SPC system is management commitment. This commitment is demonstrated by involvement and participation in project selection, progress reviews and continuing improvement activities.

2 Scope

This specification defines the requirements for the application of statistical process control (SPC) in the CECC System in order to improve the quality of processes, products and services by continually reducing process variation.

3 Terminology

3.1
common or random cause

a source of natural variation that affects all individual values of the process output being studied

3.2
control loop

a corrective system based on feedback procedure

3.3
control limits

the maximum allowable variation of a process characteristic due to common causes alone. Variation beyond a control limit is evidence that special causes may be affecting the process. Control limits are calculated from process data

3.4
node

a point in the process where form, fit or function is altered

3.5
process

a combination of people, machines, equipment, materials, procedures, methods and environment that produces a given product or service

3.6
special or assignable cause

a source of variation that is intermittent or unpredictable, affecting only some individual values of the process output

3.7
target value

the nominal value of a characteristic

3.8
variation (see Note)

the difference between individual outputs of a process; the source of variation can be grouped into two major classes: common causes and special causes

NOTE "Variability" is sometimes used as an alternative term.

3.9
statistical control

the condition describing the process from which all special causes have been removed and only common causes remain; this is demonstrated by the absence of points beyond the control limits and by the absence of non-random patterns or trends within the control limits

3.10
statistical process control (SPC)

the conversion of data to information using statistical techniques to document, correct, and improve process performance

3.11
failure mode and effect analysis (FMEA)

a disciplined analysis of possible failure modes on the basis of seriousness, probability of occurence and likelihood of detection. FMEA may be applied to both the design and the manufacturing process

3.12
fault tree analysis (FTA)

(*under consideration*)

3.13
process potential

an assessment of process capability made from a relatively small amount of sample data gathered over a short period of time, normally carried out in a period of pilot or pre-production

3.14
process capability

the natural variation of the process due to common causes

3.15
process characteristic

a distinguishing feature of a process or its results on which variables or attributes data can be collected

3.16
process potential index (C_p) and process capability index (C_{pk})

measures of the relationship between the specification limits and the process capability

3.17
control chart

a plot of a process characteristic (for instance displayed as mean, range, standard deviation, percentage of defects) in its natural order (i.e., time of manufacturing)

4 Relationship of SPC with CECC Qualification Approval and Capability Approval requirements

The CECC System is based on the assessment of quality in accordance with comprehensive, consistent and precise specifications. The initial assessment is carried out by means of qualification or capability approval testing, and is followed by testing on a lot-by-lot and periodic basis.

SPC techniques and concepts may be used by the manufacturer as a means of achieving a consistent level of quality in association with the requirements of the CECC System.

For capability approval SPC information may be used in support of the demonstration of capability within the defined technology and for release of product. Such information may be expressed quantitatively, for instance as capability indices.

For qualification approval it is necessary to define and demonstrate a satisfactory correlation between process data and product characteristics before SPC information can be used as part of conformance inspection.

5 General requirements

5.1 The manufacturer shall define an SPC system involving critical or key process nodes.

5.2 The manufacturer shall comply with the following SPC — relevant requirements of EN 29001 "*Quality systems — Model for quality assurance in design/development, production, installation and servicing*":

Clause:	**Requirement:**
4.1	Management responsibility
4.2	Quality system
4.4	Design control
4.5	Document control
4.6	Purchasing
4.8	Product identification and traceability
4.9	Process control
4.10	Inspection and testing
4.12	Inspection and test status
4.13	Control of nonconforming product
4.14	Corrective action
4.16	Quality records
4.17	Internal quality audits
4.18	Training
4.20	Statistical techniques

CECC 00011: Calibration requirements for the CECC System.

These requirements form the infrastructure for the preparation and implementation of SPC.

6 Specific requirements

6.1 Preparing for SPC

6.1.1 ***Quality plans*** (clause **4.4.2** of EN 29001)

The manufacturer shall prepare written quality plans for projects relating to new processes. These plans shall include the activities concerning the definition and testing of the process and its controls.

6.1.2 ***Nodes and characteristics*** (clause **4.9** of EN 29 001)

The manufacturer shall determine appropriate characteristics to be measured for the critical or key nodes. Tools to be used while establishing those characteristics may include Failure Mode and Effect Analysis (FMEA), fault tree analysis (FTA), cause and effect diagrams and process flow charts.

6.1.3 ***Target values and limits*** (clause **4.9** of EN 29 001)

The target values and the limits of the characteristics beyond which the process will produce unacceptable (semi-) finished products shall be established. These limits are called specification limits.

6.1.4 ***Steering means*** (clause **4.9** of EN 29 001)

The manufacturer shall define the steering means necessary to keep the process under control.

6.1.5 ***Work instructions*** (clause **4.9** of EN 29 001)

The manufacturer shall prepare documented work instructions including inspection methods, the definition of deficiencies and the statistical methods to be used by the process operators.

6.1.6 ***Design reviews*** (clauses **4.4** and **4.9** of EN 29 001)

The manufacturer shall organize design reviews at defined intervals during the development of the process. All aspects of the development shall be considered.

6.1.7 ***Process potential studies*** (clause **4.9** of EN 29 001)

The manufacturer shall carry out process potential studies; test runs shall be made to observe the process characteristics. The results shall be statistically analysed, special causes shall be eliminated and unwanted trends shall be corrected.

6.1.8 ***Process capability studies*** (clause **4.9** of EN 29 001)

The manufacturer shall establish the process capability while operating it under actual production conditions until all factors likely to contribute to process variation are reflected in the process output. During the investigation special causes shall be identified and eliminated to leave the process in statistical control. Data resulting from special causes can only be eliminated if there is no possibility of recurrence.

From the process data, control limits shall be calculated and are to be used by operators as a basis for judging whether a process is affected by special causes.

6.1.9 ***Training*** *(clause **4.18** of EN 29 001)*

The manufacturer shall define, implement and maintain an SPC training programme for all personnel (including management) involved with SPC, reflecting the extent of their contribution. Special attention shall be paid to statistical aspects.

6.1.10 ***Management corrective action*** *(clause **4.1.2** of EN 29 001)*

The manufacturer shall define the management involvement in the systematic improvement of the process capability on a continuing basis.

6.2 Process control requirements (clause **4.9** of EN 29001)

6.2.1 ***General***

During production, measurements and observations shall be carried out according to the written instructions. If a characteristic is outside its control limit(s), or if unwanted trends are detected, the process shall be corrected with the aid of defined steering means.

Action shall be taken to prevent shipment of nonconforming products if specification limits are exceeded.

6.2.2 ***Process related purchased materials and services*** (clause **4.6** of EN 29 001)

The manufacturer shall ensure that his suppliers of materials and services have or install a programme for the continuing reduction of variation of process related materials and services defined as critical.

6.2.3 ***Process capability*** (clauses **4.9** and **4.16** of EN 29 001)

The manufacturer shall be able to demonstrate the process capability. This may be done by means of:

— control charts

— process capability indices (C_p, C_{pk})

6.2.4 ***Analyses*** (clauses **4.16** and **4.20** of EN 29 001)

The manufacturer shall gather process data, causes for non-random patterns and results of corrective actions as a basis for continuing improvement. Analyses shall be made at defined intervals and supported by statistical techniques.

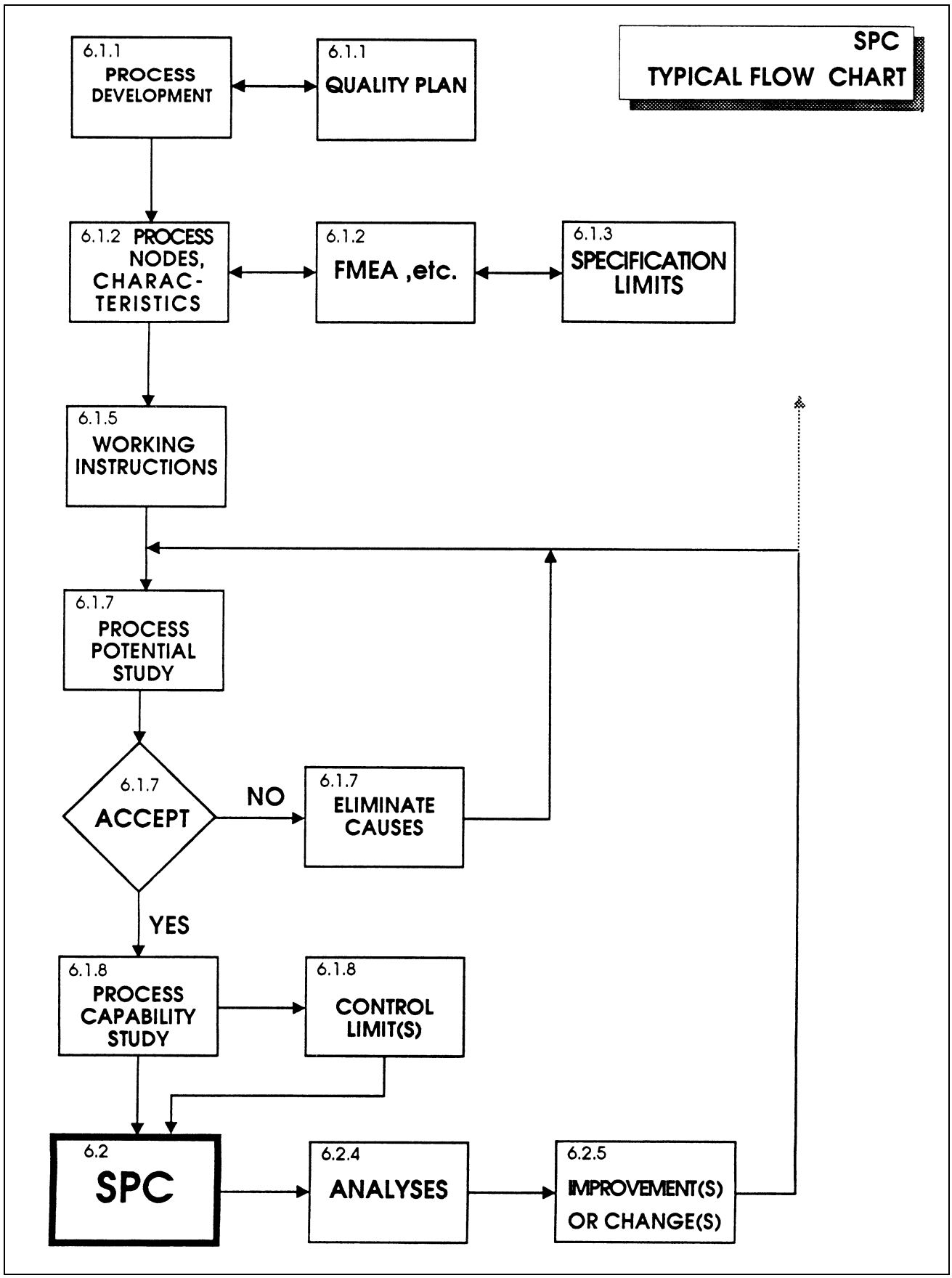
6.2.5 ***Improvement(s) or change(s)***

The manufacturer shall prepare and introduce improvement(s) or change(s) according to the requirements of **6.1**. The extent to which the requirements of **6.1** apply shall be related to the consequences of the improvement(s) or change(s). As a minimum a process potential study and a process capability study shall be carried out. Control limits shall be recalculated accordingly.

6.2.6 *Maintenance*

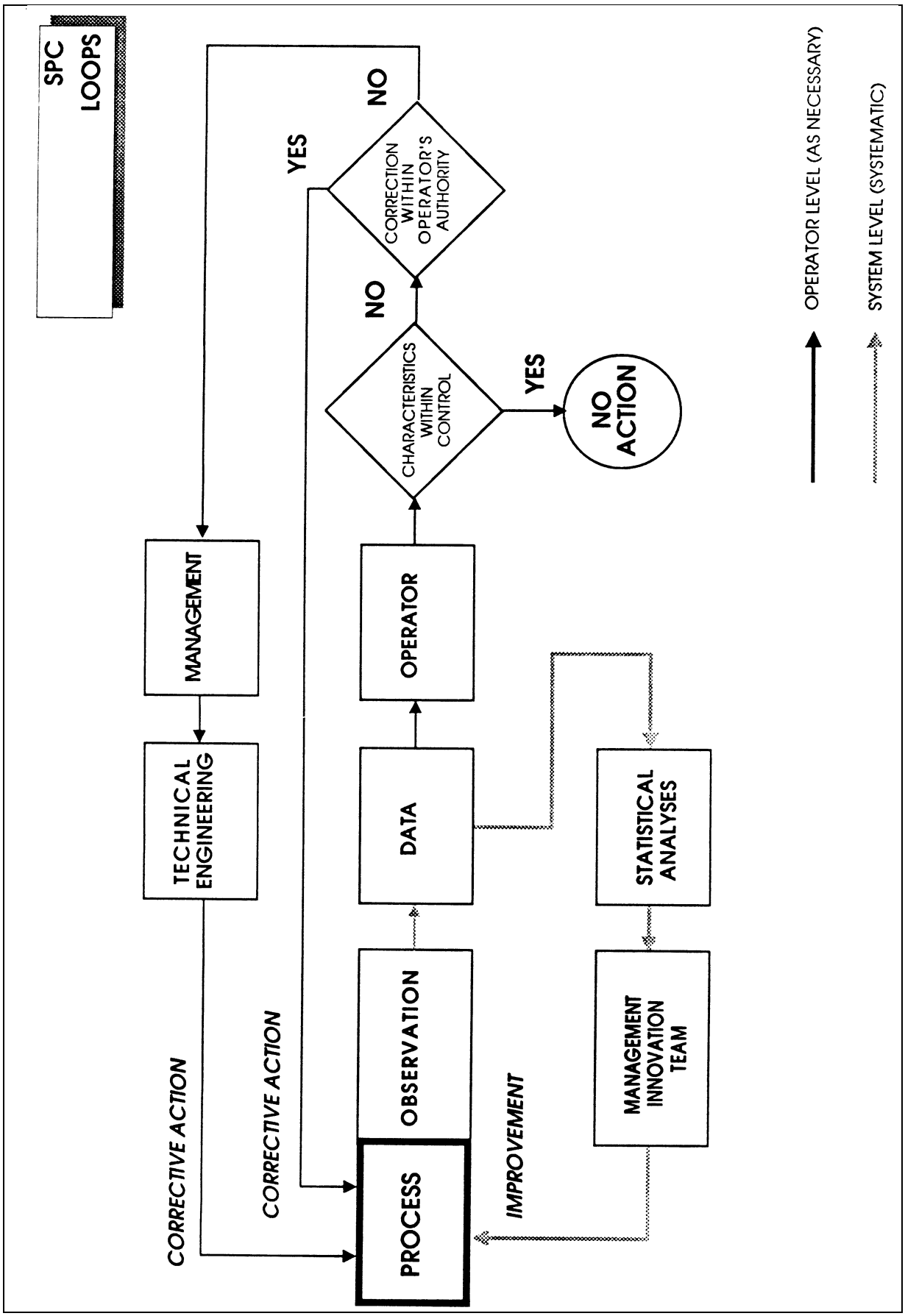
The manufacturer shall establish a programme of preventive maintenance on all production equipment. The programme shall include the process nodes as defined in **5.1** and shall be reconsidered periodically on the basis of historical data.

Annex A SPC Typical flow chart



NOTE The numbers refer to the clauses in the text

Annex B SPC Loops



Publication(s) referred to

See national foreword.

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