最新 ISO9001：2015 一整套程序文件汇编

中英文版本

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- 设施设备策划与管理程序中英文版本

生产过程控制程序中英文版本
实验室管理控制程序中英文版本
市场预测管理程序中英文版本
试生产控制程序中英文版本
特殊特性识别和标识程序中英文版本
统计技术选择和应用程序中英文版本
文件和资料控制程序中英文版本
物料采购控制程序中英文版本
信息和数据分析程序中英文版本
有害物质管理程序中英文版本
质量方针与目标控制程序中英文版本

File Name 文件名称	Measurement System Analysis Control Procedure 测量系统分析控制程序	File NO. 文件编号	MP/Q 15-L	Edition 版次	A/1	Page NO. 页次	1/6

1、Purpose/目的

It is to analyze and evaluate the variation of measurement system, so that we can make sure whether the measurement system is satisfied with the requirement and insure accuracy of the measurement data.

对测量系统的变差进行分析评估，以确定测量系统是否满足规定的要求，确保测量数据的准确性。.

2、Scope/适用范围

It is applied to all the measurement systems, which are used to verify whether products meet the requirements.

适用于本公司用以证实产品符合规定要求的所有测量系统。

3、Responsibility/职责

3.1 QC department is responsible for the management of measurement system analysis.

3.1 品质部负责测量系统分析的归口管理。

3.2 Gager of QC department is responsible for making a total analysis of being used measurement system every year.

3.2 品质部计量工程师负责组织每年对公司在用测量系统进行一次全面的分析。

3.3 Production department, central research institute and engineering department assist in concrete implementation of measurement system analysis.

3.3 生产部、中央研究院、工程部协助测量系统分析的具体实施。

3.4 Gager of QC department is responsible for organizing. And production department, central research institute and engineering department are separately responsible for concrete implementation of measurement system analysis of new products, modified design and new or maintained measurement tool.

3.4 品质部计量工程师负责组织，生产部、中央研究院、工程部负责新产品/发生设计更改/新购量具或经维修过测量系统分析的具体实施。

4、Definition/定义

4.1 Measurement system: it refers to the assembly of characteristics of the measured value of operation, procedure, measurement tool, equipment, software and operator and the whole process of gaining the measurement results.

4.1 测量系统(Measurement system): 用来对被测特性赋值的操作、程序、量具、设备、软件以及操作人员的集合，用来获得测量结果的整个过程。

4.2 Bias: it refers to the difference between the observed average value and the datum value

4.2 偏倚(Bias): 指测量结果的观测平均值与基准值的差值。

4.3 Stability: it refers to the total variation of the measured average value, which is gained through

measuring the same datum or a single characteristic of parts during a sustained period by measurement system. That is, bias changing with time

4.3 稳定性(Stability): 指测量系统在某持续时间内测量同一基准或零件的单一特性时获得的测量平均值总变差,即偏倚随时间的变化。

4.4 Repeatability: it refers to measured value variation by an operator who measures the same quality characteristic of the same product several times with the same measurement tool

4.4 重复性（Repeatability）：是指由同一位评价人，采用同一量具，多次测量同一产品的同一质量特性时获得的测量值的变差。

4.5 Reproducibility: it refers to measured value variation by different operators who measure the same quality characteristic of the same product with the same measurement tool.

4.5 再现性 (Reproducibility)：是指由不同评价人用同一量具，多次测量同一产品的同一质量特性时获得的测量平均值的变差。

4.6 Resolution: it refers to the ability to inspect and truly indicate the tiny changes in the tested characteristic

4.6 分辨率、分辨力（Resolution）：测量系统检出并如实指示被测特性中极小变化的能力。

4.7 Linearity: it refers to the variation of the bias gained by the measurement working in the expected scope

4.7 线性（Linearity）：量具在预期工作范围内，偏移值的差值。

4.8 Blind test: it refers to the measured result gained on the condition that the operator has no idea that he is evaluating the measurement system, or which product is being tested.

4.8 盲测：指在实际测量环境中，操作者事先不知正在对该测量系统进行评价，也不知道所测为那一只产品的条件下所获得的测量结果。

4.9 Measured measurement system: the measurement result can be described in concrete continuous data; this kind of measurement system is called measured measurement system.

4.9 计量型测量系统：测量系统的测量结果可用具体的连续的数值来表述,这样的测量系统称之为计量型测量系统.

4.10 Counted measurement system: compared measurement result of the measurement system with some specified restriction value, if the measurement result meets the restriction value, the part will be accepted, and otherwise, it will be rejected. For example, the diameter of round-stick can be described in this way that whether it can pass the plug guage, or not. This kind of measurement system is called counted measurement system.

4.10 计数型测量系统：测量系统的测量结果与某些指定限值相比较，如果满足限值则接受该零件，否则拒收。如用通过或不能通过塞规的方式来描述一只圆棒直径尺寸,这样的测量系统称之为计数型测量系统。

5.1 The condition of measurement system analysis

5、Procedure Contents/程序内容

5.1 Measurement system analysis condition/测量系统分析条件

5.1.1 Measurement must be standardization

5.1.1 测量作业必须标准化;

5.1.2 The valuator must be chosen from the people who operate the equipment daily

5.1.2 评价人必须是从日常操作该仪器的人中挑选;

5.1.3 The measurement equipment must be approved qualified

5.1.3 测量仪器必须是检定合格状态;

5.1.4 The measurement value of the quality characteristic must be repeatability

5.1.4 质量特性测量值可重复。

5.1.5 Resolution of equipment should read directly the one-tenth of characteristic expected process variation or tolerance. For example, if the characteristic variation of a product is 0.001, equipment should read the change of 0.0001

5.1.5 仪器的分辨力应允许至少直接读取特性的预期过程变差或公差的十分之一。例如，如果产品的特性变差为 0.001，仪器应能读取 0.0001 的变化。

5.2 The time of measurement system analysis: the measuring equipment must be made a measurement system analysis in the following three situations

5.2 测量系统分析时机：在下述三种情况下对测量设备必须进行测量系统分析。

5.2.1 The company regulates that measuring equipment must be made a total measurement system analysis in a fixed time every year; the analysis range is the different types of measurement tools which are qualified and being used.

5.2.1 公司规定每年定期对测量设备进行一次全面的测量系统分析，分析范围是合格在用的不同型号规格的量具。

5.2.2 New or maintained measurement tools having been approved qualified, before they put into use, those equipment must be made a measurement system analysis

5.2.2 新购量具或经维修过的量具重新检定合格投入使用前。

5.2.3 When there are developments of new product or design modification, if the tolerance of new product or design modified product is one-tenth of or less than that of the product which has been made measurement system analysis, measurement system analysis should be planned and made in a proper time. If the tolerance of new product or the product of modified design is more than or equivalent to the tolerance of the product which has been made measurement system analysis, unless the customer has special requirements, otherwise, it only needs to do measurement system analysis evaluation.

5.2.3 新产品开发时或发生设计更改时，如果新产品或设计更改的产品的公差是以作过测量系统分析的产品的公差的 1/10 或更小，则作测量系统分析计划，适时进行测量系统分析；如果新产品或设计更改的产品的公差比以作过测量系统分析的产品的公差更宽或相当，除非客户有特殊要求，否则只做测量系统分析评估。

5.3 Content of measurement system analysis

5.3 测量系统分析内容

5.3.1 The main content is to analyze the repeatability and reproducibility of the measurement system, that is GR & R analysis, and according to the actual need to analyze the stability, linearity and bias. The concrete analysis method refers to*SOP Of Measurement System Analysis*

5.3.1 主要是测量系统的重复性、再现性即GR&R 分析，根据实际需要可对测量系统的稳定性、线性、偏移进行分析。具体分析方法见《测量系统分析作业指导书》

5.3.2 Measured measurement system analysis

5.3.2 计量型测量系统分析

5.3.2.1 Stability analysis

5.3.2.1 稳定性分析

5.3.2.2 Repeatability and reproducibility (R &R) analysis

5.3.2.2 重复性和再现性分析(R &R)

5.3.2.3 Bias analysis

5.3.2.3 偏倚分析

5.3.2.4 Linearity analysis

5.3.2.4 线性分析

5.3.3 Counted measurement system analysis

5.3.3 计数型测量系统分析

5.4 Results of measurement system analysis

5.4 测量系统分析结果

5.4.1 The judgment criterion of result of measurement system analysis refers to *SOP Of Measurement System Analysis*

5.4.1 测量系统分析结果的判断准则见《测量系统分析作业指导书》

5.4.2 If the measurement system analysis can be accepted, the tested measuring equipment can be put into use, the result is filled into the*Measurement System Analysis List*

5.4.2 若测量系统可以接受，则此测量设备投入使用，结果填入《测量系统分析清单》

5.4.3 If the measurement system analysis can not be accepted, the measurement system analysis should be improved, and then make measurement system analysis, till the measurement system can be accepted

5.4.3 若测量系统不可接受，则对测量系统进行改善，然后再进行测量系统分析，直到测量系统可接受。

5.5 Records

5.5 记录

5.5.1 The record of production must be arranged, stored and filed in line with *Record Control Procedure*

5.5.1 产生的记录按《记录控制程序》进行整理、保存、归档。

6、Supporting Documents/支持性文件

6.1 *Measuring Equipment Control Procedure*

6.1 《测量设备控制程序》

6.2 *Record Control Procedure*

6.2 《记录控制程序》

6.3 *SOP of Measurement System Analysis*

6.3 《测量系统分析作业指导书》

7、Related Quality Records/相关质量记录

7.1 *Measurement System Analysis List*

7.1 《量具稳定性 X-R 控制图》

7.2 *Measuring Tools Repeatability and Reproducibility Data Record Chart*

7.2 《量具的重复性和再现性数据记录表》

7.3 *Measuring Tools Repeatability and Reproducibility X-R Control Chart*

7.3 《量具重复性和再现性 X-R 控制图》

7.4 *Measuring Tools Repeatability and Reproducibility Report*

7.4 《量具的重复性和再现性报告》

7.5 *Counted Measuring Tools R&R Report*

7.5 《计数型量具 R&R 报告》

7.6 *Measurement System Analysis Plan/Evaluation*

7.6 《测量系统分析计划/评估》

7.1 *X-R Control Chart of Measuring Tools Stability*

7.7 《测量系统分析清单》

8、Flow Chart/流程图

Procedure/工作流程	Contents/工作内容	output information/输出信息	Responsible department/责任部门
The condition of measurement system analysis/测量系统分析条件	1. Measurement must be standardized 1 测量作业必须标准化 2. The valuator must be chosen from the people who operate the equipment daily. 2. 评价人必须从日常操作仪器的人中挑选 3. The measurement equipment must be approved qualified. 3. 测量仪器必须是检定合格状态 4. The measurement value of the quality characteristic must be repeatability; 4. 质量特性可重复 5. Resolution of equipment should be at least the one-tenth of characteristic expected process variation or tolerance 5.仪器的分辨力应至少是预期过程变差或公差的 1/10;	SOP of measurement 测量作业指导书; Operator 操作人员; Qualified measuring equipment 合格的测量仪器。	Production department, 生产部 QC department 品质部 Central research institute 中研究 Engineering department 工程部
The measurement system analysis time 测量系统分析时机	1. make a total measurement system analysis to measuring equipment in a fixed time every year 1. 每年定期对测量设备进行一次全面的测量系统分析; 2. after new or maintained measurement tools having been approved qualified 2. 新购量具或经维修的量具经检定合格后 3. new product or design modified product 3. 新产品或发生设计更改的产品	Equipment that needs measurement system analysis 要进行测量系统分析的仪器 measurement system analysis plan/evaluation 测量系统分析计划/评估	Production department/生产部 QC department/品质部 Engineering department/工程部 Central research institute /中研院
The content of measurement system analysis 测量系统分析内容 Improve measurement system 改善测量系统 Measurement system analysis 测量系统分析	1. analyze the repeatability and reproducibility of the measurement system, that is GR & R analysis, 1. 主要是测量系统的重复性和再现性分析（GR&); 2. According to the actual need to analyze the stability, linearity and bias. 2. 根据实际需要可对测量系统的稳定性、偏倚和线性进行分析。	Repeatability and reproducibility(R &R) analysis /GR&分析 Stability analysis /稳定性分析 Bias analysis /偏倚分析 Linearity analysis/线性分析	QC department 品质部
Measurement system can be accepted 测量系统可以接受 Filled into “measurement system analysis list” 填入 “测量系统分析清单” Measurement system analysis report/测量系统分析报告	1. To test and collect data on the spot 1. 到现场进行测试、收集数据; 2. To analyze the tested data 2. 对测试得到的数据进行分析。	Measured data 测量数据	QC department/品质部 Engineering department/工程部 Central research institute /中研院 Production department/生产部

1、Purpose/目的

Building up a procedure of transportation, storage, package, protection and delivery of raw materials、semi-finished product and finished product, so as to insure the quality of raw materials、 semi-finished product and finished product.

建立原材料、半成品和成品的搬运，贮存，包装，防护和交付程序，以达到保证原材料、半成品和成品的质量的目的。

2、Scope/范围

The procedure is applicable to all transportation, storage, package, protection and delivery of raw materials、semi-finished product and finished product of our company.

本程序适用于公司所有原材料，半成品和成品的搬运，贮存，包装，防护和交付。

3、Responsibility/职责

3.1 The warehouse is responsible for the transportation, storage, package, protection and delivery of raw materials, semi-finished product and finished product

3.1 仓库负责货仓内的原材料，半成品和成品的搬运，贮存，包装，防护和交付。

3.2 Production department is responsible for the transportation, storage, package and protection of raw materials, semi product and product

3.2 生产部负责车间的原材料，半成品，成品的搬运，贮存，包装和防护。

3.3 Engineering department is responsible for scientifically setting storage condition and valid period according to the characteristic of raw materials, semi-finished product and finished product.

3.3 工程部负责根据原材料、半成品和成品性能科学地设定贮存条件和有效期。

3.4 QC department is responsible for testing incoming materials、 inspecting the procedure、 examining the quality of product sell out package and testing extended-used inventory raw materials semi-finished product and finished product.

3.4 品质部负责来料检验、过程检验、产品出货包装质量检查，超期库存的材料、半成品和成品的检验。

4、Definition(none)/定义（无）

5、Procedure Contents/程序内容

5.1 Warehouse and each workshop’s transportation

5.1 仓库和各车间的搬运

5.1.1 Using some tools to transport raw materials, semi-finished product and finished product, such as card board, rubber pot, elevator, wheelbarrow, etc.

5.1.1 原材料、半成品和成品使用卡板、胶盆、电梯、手推车等搬运工具搬运。

5.1.2 Handle delicately during the process of loading and unloading. Do not use some savage method

like throwing or rolling.

5.1.2 装卸过程中应轻拿轻放，禁止抛、丢、滚等野蛮方式作业。

5.1.3 Be careful and avoid colliding or dropping to damage goods during the process of transportation

5.1.3 搬运过程中要小心保护，防止碰撞或跌落而损坏货物。

5.1 .4 Protecting the mark carefully during the process of transportation

5.1.4 搬运过程中应保护好标识。

5.1.5 During the process of transportation, if goods are damaged or disordered, QC department is responsible for testing those goods again

5.1.5 搬运过程中如出现损坏，混乱，需由品质部负责重新检验。

5. 2 Warehouse's and each workshop's storage

5.2 仓库和各车间的贮存

5.2.1 Warehouse is divided into several parts of stored region, so as to definite stored region of goods mark(especially distinguish the environmental friendly and environmental polluted materials)

5.2.1 仓库对贮存区域进行划分，以明确货物标识存放的区域（特别要将环保物料与不环保物料加于明显区分）。

5.2.2 Warehouse storage should be classified and marked. At the same time, record the data of purchased goods to insure the goods be first in first out.

5.2.2 仓库贮存应分类及标识，并记录进货的日期，保证货物能先进先出。

5.2.3 Storage of chemical raw materials must be according to *SOP* of *Chemical Dangerous Goods Storage*、*Distribution and Transportation*

5.2.3 化学原材料的贮存按《化学危险品贮存、发放、搬运作业指导书》进行。

5.2.4 Warehouse draws a *Inventory List*, makes an inventory every month, and makes *Materials receiving and distributing List*, *Materials Quantity Account*, so as to keep the number accurate

5.2.4 货仓制定《存货盘点表》， 每个月对仓库的实物进行盘点，做好《物料收发单》、《材料数量帐》，以保持数目的准确性。

5.2.5 Each workshop draws its own *Inventory List* of on-line materials, so as to keep the on-line materials accurate.

5.2.5 各车间制定各车间在线物料的《存货盘点表》，以保持在线物料的准确性。

5.2.6 Raw materials、 semi-finished product and finished product should be pilled up according to the related label or graphical representation of original packing case. The height is usually less than 2.0 meter. The height of pilled goods can be higher or lower according to the weight of goods, but the total height can not over 3.6meter. The goods should be pilled up with card board as much as possible.

5.2.6 原材料、半成品、成品须根据原包装箱的有关标签或图示堆放，堆放高度一般为2.0 米以