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XXXXXXXXXXXXX 有限公司

质量管理体系管理性文件

QUALITY SYSTEM PROCEDURE

设备控制程序

Equipment Control Procedure

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## 1. 目的 Purpose

加强设备管理，使其在合适的状态下工作，确保不影响产品质量。

The purpose this procedure is to strengthen the equipment management, making the equipment operate in an appropriate state and ensuring that the equipment will not have bad effect on the products.

## 2. 适用范围 Scope

本公司各种产品生产所涉及的全部设备及实验设备。

The procedure is applicable to all the company's manufacturing equipment and R & D facilities.

## 3. 职责 Responsibilities

### 3.1 设备管理组职责

The responsibilities of the equipment management teams should include the following aspects:

#### 3.1.1 负责制订全年的设备管理计划和目标，并组织实施管理

Establish annual equipment management plans and objectives as well as organize and implement the management.

#### 3.1.2 负责设备的状态进行分析，掌握设备技术状态

Analyze and master the equipment technical state.

#### 3.1.3 负责设备档案的汇集和设备台帐的建立.

Take charge of collecting equipment files and establishing equipment list.

#### 3.1.4 负责组织设备引进方案的调研、论证，统筹设备的选型、安装调试、维修保养、改进更新等

Take charge of organizing the investigation and demonstration of the equipment introducing plan and coordinating the equipment type-selection, installation, maintenance, improvement, etc.

#### 3.1.5 负责设备的改进，验收.

Improve and accept the equipment.

#### 3.1.6 负责设备验证的 IQ、OQ 工作

Take charge of IQ and OQ.

#### 3.1.7 负责参与新设备的采购

Engage in the purchasing of new equipment.

### 3.2 生产技术部职责

The responsibilities of Manufacturing Techniques contain the following items.

#### 3.2.1 负责新产品、新工艺相关的设备引进工作的规划方案的工艺评审工作和参数确认工作

Process review and parameter confirmation of the introduction plan on the equipment related to new products and processes.

#### 3.2.2 负责设备的 PQ 验证

Equipment's PQ.

### 3.3 采购部职责

The responsibilities of Purchasing Department should cover the following aspects.

#### 3.3.1 负责新设备的采购管理工作

Take charge of the purchasing management of new equipment.

3.3.2 采购负责联系新购设备供应商进行调试并协助设备管理组进行保修服务

Communicating with the supplier of the new-purchased equipment, optimize the equipment debugging and coordinate with the Equipment Management Teams to carry out the equipment warranty service.

3.4 QA 部职责

The responsibilities of QA include the following item.

3.4.1 负责设备验证的管理工作

Manage the equipment validation.

3.5 设备使用部门职责

The responsibilities of the departments that use the equipment are as follows.

3.5.1 负责本部门设备日常维护保养实施及配合进行定期保养工作

Implement the daily maintenance of the equipment and cooperate with other departments to carry out the periodical maintenance

3.5.2 负责组织培训工作

Organize relevant trainings

**4 设备的控制 The Equipment Control**

4.1 设备管理计划和目标的制定和实施

Establishing and implementing the equipment management plans and objectives

每年初，设备管理组按前一年度的运营情况以及本年度规划，制订出“设备年度保养计划”，分解成每月的定期维护保养内容。由设备管理组及设备使用部门制定本年度“设备年度添置计划”、“备品备件年度添置计划”等计划和目标，每月分解后实施。

At the beginning of each year, the equipment management team in each Production Department draws up the *Annual Equipment Maintenance Plan* which can be resolved into monthly maintenance items according to the company's divisions, the last year's business state and the current year's plan. Annual plans and objectives as “Annual Equipment Addition Plan”, “Annual Equipment Backup Plan”, etc. shall be established and implemented after monthly arrangement by the equipment and device using department.

4.2 设备前期管理 The equipment prophase management

4.2.1 设备购置申请 The equipment purchasing request

设备申购由使用部门提出，并填写采购申请单。

The subscription of the equipment is proposed by the equipment management team of the user department. And fill in the purchase application form.

4.2.2 设备选型 The type-selection of the equipment

4.2.2.1 设备管理组依据符合生产要求，易于清洗、消毒，便于生产操作和维修、保养，并能防止差错和减少污染的原则协助生产部提出确定机型、生产厂家供采购部参考；经过适当设计、建造、放置和安装的新设备，要利于保养、调试、清洁和使用；

Under the principle of being consistent with manufacturing requirements, being easy to clean, sterilize and maintain as well as preventing errors and reducing pollution, the equipment management teams, coordinating with Production Departments, present the confirmed type and manufacturer for Purchasing Department's reference. The new equipment, by appropriate design, construction, placement and installation, should be easy to maintain, debug, clean and use.

4.2.2.2 新产品、新工艺相关设备的引进，由设备管理组会同相关部门进行调研，经过技术经济水平论证后，确定型号订货。设备管理组负责将应征验证合格的新设备增补到定期维护保养计划内容中。

The type and order of the introducing equipment related to new products and processes should be determined after the investigation of Equipment Development Department and other relevant departments as well as the acquisition of technical and economical demonstration.

#### 4.2.3 设备采购 The equipment purchasing

采购部根据审批后的申请单以及选型资料落实采购工作，签订合同时下列技术要素将做为合同条款的一部分。

Purchasing Department implements the purchasing according to the approved request and type-selection information. The following technical factors will be regarded as parts of the purchasing contract.

技术协议必须包括下列要素：

- 设备名称、数量、产地
- 设备应是全新的，并附有产地证明和合格证
- 主要技术性能指标
- 交货日期、安装和调试
- 质量索赔条款
- 明确验收标准和验收方式
- 明确保修期和售后服务要求
- 技术协议必须与商务合同同时生效
- 必要时，明确培训计划和要求，以及技术文件要求

Technical contract shall include below factors:

- Name, quantity and origin of the equipment;
- The equipment should be new and attached with certificate of origin and certification;
- Major technical indicators;
- Delivery date, installation and debugging;
- Quality claim clauses;
- Acceptance standards and manners;
- Warranty and after-sales service requirement;
- The technical contract should be effective with the business contract;
- The training plan and requirement as well as technical documents should be identified, if necessary.

#### 4.2.4 设备验收 The equipment acceptance

4.2.4.1 设备到公司后采购人员通知设备管理组到场验收，设备管理组根据设备装箱单和合同进行开箱检查和清点工作。设备开箱后，由使用部门根据设备的布置情况把设备放置到相应地点。

After the equipment delivered to the company, the purchasing personnel should inform the equipment management team of relevant departments to check and count the equipment according to the equipment packing list and contract.

4.2.4.2 验收后，对于重要关键设备，设备管理组依据开箱情况填写《设备开箱检查记录》(QP040-RE-02)，如实记录设备验收情况，做出符合性判断。对不符合要求的由采购部负责退货或调换。确认符合要求的设备可实施安装、调试。其余一般设备和低值易耗设备只做简单验收，如合格即可直接移交使用部门，并填写《设备开箱检查记录》(QP040-RE-02)。

After the equipment acceptance, the unpacking status of the critical equipment should be recorded in the *Equipment Open-package Inspection Record* (QP040-RE-02) and the conformities of the equipment should be judged. The equipment falls to be consistent with the requirement should be returned or exchanged by Purchasing Department, while the conforming equipment will be installed and debugged. The general equipment and low-value consumables will only carry out a simple acceptance and will be handled to the use department with a completed *Equipment Open-package Inspection Record* (QP040-RE-02) if approved.

#### 4.2.5 设备安装调试 The equipment installation and debugging

##### 4.2.5.1 设备安装由设备管理组组织人员进行，相关的部门协助设备安装开展工作。

The equipment management team, coordinating with relevant departments, should take charge of the equipment installation.

##### 4.2.5.2 设备安装到位后，由设备管理组负责做“调试中设备”标识并组织进行调试；

After the equipment installed, the equipment management team should affix the “Debugging Equipment” and organize debugging.

##### 4.2.5.3 调试认为运行不正常或不符合要求，应由采购部负责退货、调换或联系制造厂进行维修；

After the debugging, the improperly operating or unqualified equipment should be returned or exchanged to the manufacturer by Purchasing Department. Also, Purchasing Department can communicate the manufacturer to repair the equipment.

##### 4.2.5.4 对自制设备，在设备开发前，需求部门应提出开发需求、技术参数要求、工艺要求和验收标准，以便在设备制成后，设备开发部门应提供完善的技术资料。由设备管理组会同使用部门技术人员、工艺人员进行自制新设备的安装调试，调试中认为运行不正常或不符合要求应退回设备开发部门进行改进。

Before the development of self-designed equipment, each demand department should propose developing requirements, technical parameter requirements, process requirements and acceptance standards according to the product requirement so that the equipment developing department can provide perfect data after the achievement of the equipment. The equipment management team together with the technical personnel and process personnel of the user department should install and debug the new equipment and return improperly operating or unqualified equipment to the equipment developing department to implement the improvement.

##### 4.2.5.5 调试正常后，可移交使用部门。对过程特别复杂的重关设备还必须填写《设备安装调试过程报告单》

(QP040-RE-03)。当移交使用部门后，使用部门通知 QA 部门，由设备使用部门与 QA 部门共同商议是否需要对该设备进行验证。如需验证，验证依照《验证规程》(QR040) 进行，验证合格则投入使用，否则退回采购部处理；如不需验证，则可直接投入使用。

After debugged normally, the use department shall fill the *Equipment Installation & Debugging Report* (QP040-RE-03) for complicated equipment, the use department will send related equipment information to QA, and then the use department and QA together determine whether the validation will be carried out. If yes, the validation shall be carried out according to the *Validation Regulation* (QR040), equipment can't be used unless the validation is qualified, or it shall be returned to Purchase Department to handle. If no, the equipment can be used directly.

#### 4.2.6 设备管理组根据设备的价值和/或对产品性能影响的重要性，将设备分为“重要关键设备”（简称“重关设备”）、“一般设备”和“低值易耗设备”三级，实行分级管理。

1) 重关设备：对产品性能影响重要或价值高昂的设备

2) 一般设备: 价值大于 2000 元或对产品性能影响一般的设备

3) 低值易耗设备: 价值低于 2000 元且对产品性能影响很小的设备

Based on the equipment's value and, or importance to the product performance, the equipment management team classifies the equipment into three categories, namely, "Critical Equipment", "General Equipment" and "Low-value Consumables" and manage them according to their grades.

1) Critical equipment means the equipment that will have important effect on the products or is valuable;

2) General equipment means the equipment that costs more than 2000yuan or will affect the product performance generally;

3) Low-value consumables mean the equipment that cost less than 2000yuan and will hardly influence the product performance.

4.2.7 设备管理组负责制定一般设备和重关设备的设备操作维护规程。

The equipment management team should establish SOPs of the general equipment and the critical equipment.

#### 4.3 设备档案管理 Equipment Archives Management

##### 4.3.1 设备台账 Equipment Account

4.3.1.1 设备管理组负责建立《设备台帐》(QP040-RE-10),《设备台帐》(QP040-RE-10) 根据实际情况随时更新; 对于重关设备和一般设备, 设备管理组在设备管理中应做到帐、卡、物相符。

The equipment management team should be responsible for establishing and updating the *Equipment Account* (QP040-RE-10) based on the actual situation. For the critical equipment and the general equipment, the equipment management team should ensure consistency of accounts, cards and objects.

4.3.1.2 设备办理验收手续移交使用部门后, 设备管理组应负责设定设备编号, 并在设备的明显位置贴上“完好设备”卡。设备编号采用四节编号法: 大类号、分类号、型别号、公司内顺序号, 具体参照附页(设备分类附表)。

After the equipment accepted and delivered to the user department, the equipment management team should take charge of setting the equipment number and affixing the "Good Equipment" card in the obvious location of the equipment. The equipment is in the employ of a "four-part" numbering manner, namely, category number, classification number, type number and serial number of the company, which is detailed described in the attached sheet called *Equipment Classification Schedule*.

4.3.2 设备管理组负责对“重关设备”、“待修设备”、“封存设备”等进行标识并检查。

The equipment management team is responsible for identifying and checking the critical equipment, the equipment to be repaired, the stored equipment, etc.

4.3.3 设备管理组对列入固定资产的设备建立档案, 对设备的技术资料等进行统一管理。

The equipment management team should establish records for the equipment that has been enrolled as fixed-assets and manage the technical data of the equipment.

#### 4.4 设备的使用和维护管理 The use and maintenance management of the equipment

##### 4.4.1 设备的日常使用 The daily use of the equipment

##### 4.4.1.1 对设备操作者的要求 The operational requirements of the equipment

1) 新工人在使用设备前或操作者使用新购设备, 必须经设备管理组对其进行一定时间的该设备安全生产有关的上岗培训和设备操作培训, 考核合格后方可上岗独立操作;

The equipment management team should organize pre-post trainings and equipment operation trainings



related to safety for the new employees. The new employees must be trained before using or operating the new purchased equipment and they can only independently operate the equipment after examined qualified.

- 2) 公司内部工种调动的操作者，须进行上岗培训后方可上岗独立操作；

The operator who changes his jobs within the company should receive job training before independently operating the equipment.

- 3) 设备操作者应基本掌握设备的“三好”（管好、用好、保养好）、“四会”（会使用、会保养、会检查、会调整）。

The equipment operator should basically master the following items, literally, “three-goods” making the equipment managed, used and maintained perfectly and “four-abilities” equipped with four abilities, namely, use, maintenance, inspection and adjustment.

#### 4.4.1.2 设备的定人定机 Certain persons for certain equipment

- 1) 属于“重关设备”，由各使用部门提出定人定机的初步名单，经设备管理组审核后实施；

The certain persons for the critical equipment should be proposed by the user department and implemented by the equipment management team's review.

- 2) 属于“一般设备”，由各使用部门根据实际情况实施定人定机。

The certain persons for the general equipment will be carried out by each user department based on actual situation.

- 3) 正常情况下，操作者不得串机使用；

Normally, the operator is not allowed to operate different equipment at the same time.

- 4) 属多人操作的设备，由使用部门指定专人负责保管与维护保养。

The equipment that needs more than one person to operate should be managed and maintained by certain persons appointed by the user department.

#### 4.4.1.3 设备操作人员必须严格按照设备操作维护规程使用设备，一般设备和重关设备责任人应将每天设备运行时间、运行状况记录在《设备日运行记录》(QP040-RE-06) 上

The equipment operator must use the equipment strictly according to the equipment SOPs. The person in charge of the general equipment and the critical equipment should record the equipment daily operational time and state on the *Equipment Daily Operation Record* (QP040-RE-06).

#### 4.4.2 设备的维护与保养 The equipment maintenance

设备管理组建立并保持调试，清洁和保养的设备计划表，以保证达到生产规范。

The equipment management team should establish and keep the equipment debugging, cleanliness and maintenance schedules to ensure regular manufacturing.

设备的维护保养主要由操作者和维修人员负责完成，内容包括日常保养和定期保养：

The operator together with the maintenance personnel should be in charge of the equipment maintenance covering daily maintenance and periodical maintenance.

- 1) 日常保养由操作者负责完成。保养内容：设备操作规程中相关内容；保持设备的整洁；前段需清洗设备清洗完后并填写《设备清洁记录》(QP040-RE-13)。重点是对常用部件的性能、参数、运行条件进行确认，和对设备外表面的清洁卫生处理。



The operator should take charge of daily maintenance which includes the following aspects, namely, relevant matters required in the SOPs, the equipment in clean and tidy condition and completing the *Equipment Cleaning Record* (QP040-RE-13) of the equipment that needs front-end cleaning after the cleaning finished. The key point here is that verifying the performance, parameters and operational condition of the common parts and cleaning the surface of the equipment.

- 2) 定期保养以维修人员为主、操作者配合、设备管理员指导。对重关设备和一般设备进行定期保养。对长期使用后产生的性能漂移、参数改变、元器件老化等现象进行现场及时妥善处理或有计划的更换，对运动机件进行有效的润滑和去污垢，对磨损的部件进行及时更换以免隐患变成故障，完成保养后填写《设备保养记录表》(QP040-RE-11)。

Periodical maintenance is directed by the maintenance personnel coordinated with the operator under the guidance of the equipment manager. The critical equipment and the general equipment should be maintained periodically. Such phenomena as performance fluctuation, parameter changing, component aging etc., after long-term use, should be properly dealt with by the site or changed according to plans. Moving parts should be lubricated and decontaminated effectively. While worn components should be changed immediately in case that hidden troubles turn into malfunctions. The *Equipment Maintenance Record* (QP040-RE-11) will be completed after all the maintenance work.

- 3) 《设备保养记录表》(QP040-RE-11) 的 No.由 8 位阿拉伯数字组成。从左往右，前 2 位是设备所在部门的部门代码；第 3 到第 6 位是保养发生时所在的年月；第 7 和第 8 位是流水号，从 01 到 99。

The number of the *Equipment Maintenance Record* (QP040-RE-11) is made up of 8 Arabic numerals, from left to right, the former four is the code of the user department, the fifth and sixth numbers stand for the month when the maintenance is carried out and the last two represent the serial number from 01 to 99.

- 4) 保养依据：设备操作规程中相关内容

The relevant content in SOPs should be regarded as the maintenance basis.

- 5) 保养周期：重关设备每 6 个月进行一次，一般设备每 12 个月进行一次。

The maintenance period is regulated as the following clause that the critical equipment will be maintained every 6 months and the general equipment every 12 months.

- 6) 两次保养之间的间隔须严格按照年度设备维护保养计划执行，如未能按时保养，请在《设备保养记录表》(QP040-RE-11) 上详细记录“未能按时保养”的原因和因此产生的后果。在维护和保养过程中如涉及设备关键部件更改（牵扯到技术参数改变或工艺条件改变的维护保养或技术工艺改进升级性维护），则由 QA 确定是否需要进行验证，验证按《验证规程》(QR040) 进行。

During the interval between the last and the next maintenance, relevant maintaining work must be strictly carried out according to the annual equipment maintenance plan. If not, the reason and result of “not maintaining on schedule” should be recorded in the *Equipment Maintenance Record* (QP040-RE-11). If the maintenance contains the change of the critical components, involving the maintenance of technical parameter changes or process changes, or upgrade maintenance of technical process improvement, then QA will determine whether the validation will be carried out or not (see QR040 *Validation Regulation*).

#### 4.4.3 设备故障管理 Equipment Malfunction Management

在设备运行时，操作者应密切注意设备运转情况，发现故障应立即停机，不能自行处理的，应及时报告班组长，由班组长填写《设备故障报告单》(QP040-RE-08) 报告设备管理组，由设备管理组安排维修人员检修。

维修正常后, 由设备责任人进行试机确认, 设备维修人员应及时将维修情况 (包括停机时间大于 4 小时的, 费用大于 500 元的, 需要进行验证的等有关内容) 详细记录在《设备维修记录》(QP040-RE-09) 上, 交设备维修主管备案; 同时设备责任人应将故障处理情况记录在《设备日运行记录》(QP040-RE-06) 中。如果问题较为复杂严重, (停机维修时间长到影响生产进度, 或要发生大额维修费用去购买部品配件), 则由设备使用部门及时上报生产部直接分管领导处理。

In the equipment run-time, the operator should fix his attention on the working state and when malfunction appears, he should immediately stop the equipment and report it to the group leader instead of dealing with it alone. The group leader is in charge of completing the *Equipment Malfunction Report* (QP040-RE-08) to inform the equipment management team to arrange the maintenance. The person in charge of the equipment should verify the broken-down equipment by testing and the repairing engineers should record the maintenance situation in the *Equipment Repair Record* (QP040-RE-09) containing the following contents that the downtime is more than 4 hours, the cost is more than 500yuan, the matters need validation, etc and submitted to the equipment maintenance supervisor. Meanwhile, the person in charge of the equipment should record the malfunction in the *Equipment Daily Operation Record* (QP040-RE-06). Relatively complicated troubles, for example, the down-time is so long that will influence the production schedule or it will cost a large amount of money to purchase components, should be reported to the production department manager by the equipment user department.

在停机维修过程中如涉及设备关键部件需要更换, 确认新的关键部件的技术参数是否改变了原有参数及工艺, 则由 QA 确定是否需要进行验证, 验证按《验证规程》(QR040) 进行。

If the down-time maintenance contains the change of the critical components, QA will determine whether the validation is needed or not to see if the new parameters of the new components have changed the original parameters and processes. The validation will be carried out according to the *Validation Regulation* (QR040).

#### 4.4.4 设备检查 Equipment Inspection

为了保证设备经常处于完好的状态下, 必须要对一般设备进行日常开机自检及重关设备定期巡检。

It is necessary to conduct a daily POST (Power-on Self Test) for the general equipment and patrol inspection for the critical inspection.

##### 4.4.4.1 一般设备日常检查 Daily inspection of the general equipment

一般设备日常检查由操作者进行。设备操作者在进入机器正常工作状态之前必须进行开机自检。开机自检的内容主要有: 设备“完好设备”标识牌和运行状态牌是否完整; 开机时是否有异常声音; 各操作按钮是否灵敏可靠; 与各机械部件连接是否紧固。开机自检情况填写在《设备日运行记录》(QP040-RE-06) 上。

Daily inspection of the general equipment is implemented by the operators. The equipment operator should carry out a POST (Power-on Self Test) before the machine gets into normal working status. The content of a POST mainly includes the following items, respectively, to check if the “Good Equipment” card and “Operational” card are complete, to see if there is any noise when powering the machine, to verify the sensitivity and dependability of each operational button and to ensure that the connection of each component is fastened. The POST (Power-on Self Test) circumstance should be completed in the *Equipment Daily Operation Record* (QP040-RE-06).

##### 4.4.4.2 重关设备的定期巡检 The periodical patrol inspection of the critical equipment

- 1) 设备的定期巡检由设备管理组或设备维修人员负责; 定期巡检内容根据《重关设备清单与日常巡检内容》(QP040-RE-15) 进行。

Each equipment management team or equipment maintenance personnel should take charge of the periodical inspection of the critical equipment according to the *Critical Equipment List and Daily Inspection Record* (QP040-RE-15).

- 2) 设备管理组负责依照各个部门全年的设备管理计划和目标编写年度设备维护保养计划，再依照所编写的年度设备维护保养计划对定期巡检的情况进行指导和督促检查；

The equipment management team should be in charge of establishing the annual maintenance plan of the equipment according to the annual equipment management plan and objectives of each department, and then conducting, supervising and inspecting the periodical inspection based on the annual plan.

- 3) 维护保养实施人员在做好定期巡检后，应填写《设备日常巡检记录表》(QP040-RE-07)。

After the periodical inspection, the maintenance personnel should complete the *Equipment Daily Patrol Inspection Record* (QP040-RE-07).

#### 4.4.4.3 检查时如果发现问题按 4.4.3 条处理

If problems are found during the inspection, it will be handled according to 4.4.3.

- 4.4.5 设备调试：将设备调整限度和允许公差说明放在需要定期调试的设备（或附近），或者从事这些调试的工作人员都备有说明。

Instructions of equipment adjusting limitation and allowable tolerance should be placed on or by the equipment that needs regular debugging, or stocked by the debugging personnel.

### 4.5 设备定置管理 Equipment Fixation Management

#### 4.5.1 设备调拨和移装 Equipment allocation and moving

- 4.5.1.1 设备调拨和移装时，设备部负责台帐和标牌更新；变动后设备由 QA 确定是否需要验证，如需验证，按《验证规程》(QR040) 进行，设备应在验证完成后正式启用。

When equipment allocation and moving, the accounts and identifications updated by the equipment department. QA will determine whether the moved equipment needs validating or not, if necessary, it will be implemented according to the *Validation Regulation* (QR040) and the equipment should be used after the validation.

#### 4.5.2 设备封存和启用 Equipment sealing and enabling

- 4.5.2.1 设备的封存和启用时，设备部负责做好标识，同时进行台帐更新；启封使用的设备由 QA 确定是否需要验证，如需验证，按《验证规程》(QR040) 进行，设备应在验证完成后正式启用。

When equipment sealing and enabling, the identifications prepared and list updated by the equipment department. QA should determine whether the validation is needed or not for the enabled equipment, if necessary, it will be implemented according to the *Validation Regulation* (QR040) and the equipment should be used after the validation.

#### 4.5.3 设备的报废 Equipment scrapping

- 4.5.3.1 为提高生产效率，使设备更能符合生产和发展需要，必须对一些设备进行报废更新。设备的报废申请由使用部门提出，申请提出必须符合设备报废更新原则。

It is necessary to scrap and renew some equipment with the purpose of enhancing productivity and making the equipment more consistent with the developing requirements. Equipment scrapping should be proposed by the user department and applicable to the scrapping and updating principle.

#### 4.5.3.2 报废更新原则 Scrapping and updating principles

1) 主要结构陈旧、精度低劣，生产率不能改装利用者；

The equipment, whose main structure is old, precision is inferior, productivity is low and modification is impossible;

2) 不能迁移的设备，因厂房改建与工艺布置改变必须拆毁者；

The equipment that can't be moved and must be demolished resulting from workshop rebuilding and process change;

3) 腐蚀过甚，无修复价值或继续使用易发生危险者；

The equipment that has been corroded too much, has no repairing values or is easy to cause risks if used continuously;

4) 绝缘老化、性能低劣，无修复价值；

The equipment whose insulation is aged and performance is bad without any repairing values;

5) 因事故或其它灾害使设备遭受严重损坏，无修复价值者。

The equipment that has been badly damaged due to accident or other disasters without any repairing values

4.5.3.3 报废的设备应在显著位置加以标识。

The scrapped equipment should be marked in a prominent position.

4.5.3.4 重要关键设备和一般设备报废按《固定资产管理制度》(AFN003) 进行。

The scrapping of critical equipment and general equipment should be implemented according to the *Fix-assets Management System* (AFN003).

4.5.3.5 低值易耗设备的报废，由使用部门填写《低值易耗设备报废申请单》(QP040-RE-14)，签批后进行

The scrapping of low-value consumables should be recorded in the *Low-value Consumables Scrapping Request* and approved by relevant principals with signatures.

## 5 相关文件 Relevant Documents

5.1 《验证规程》*Validation Regulation* (QR040)

## 6 记录 Records

6.1 《新工艺装备申请单》*Application Form for New Process Equipment* (QP040-RE-01)

6.2 《设备开箱检查记录》*Equipment Open-package Inspection Record* (QP040-RE-02)

6.3 《设备安装调试过程报告单》*Equipment Installation & Debugging Report* (QP040-RE-03)

6.4 《设备定人定机表》*Certain Persons for Certain Equipment List* (QP040-RE-05)

6.5 《设备日运行记录》*Equipment Daily Operation Record* (QP040-RE-06)

6.6 《设备日常巡检记录表》*Equipment Daily Patrol Inspection Record* (QP040-RE-07)

6.7 《设备故障报告单》*Equipment Malfunction Report* (QP040-RE-08)

6.8 《设备维修记录》*Equipment Repair Record* (QP040-RE-09)

6.9 《设备台帐》*Equipment Account* (QP040-RE-10)

6.10 《设备保养记录》*Equipment Maintenance Record* (QP040-RE-11)

6.11 《设备清洁记录》*Equipment Cleaning Record* (QP040-RE-13)

6.12 《低值易耗设备报废申请单》*Low-value Consumables Scrapping Request* (QP040-RE-14)

6.13 《重关设备清单与日常巡检内容》*Critical Equipment List and Daily Inspection Record* (QP040-RE-15)

## 文件更改履历

## Document History Summary

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医课汇  
公众号  
专业医疗器械资讯平台  
WECHAT OF  
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hlongmed.com  
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ECENTEROF  
MEDICAL DEVICE



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