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质量管理体系程序文件

QUALITY SYSTEM PROCEDURE

纠正和预防措施控制程序
Corrective and Preventive Action Control Procedure

编制 Initiated by：___

审核 Reviewed by：__

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1 目的(Purpose)

本程序规范了为消除实际或潜在的不合格而采取纠正预防措施的流程, 以确保类似或潜在不合格不再发生, 促进质量管理体系的持续改进。

The procedure clarifies the process to adopt corrective and preventive action to eliminate the existing or potential non-conforming and prevent similar non-conforming in the future and promote the sustained improvement of the quality management system.

2 范围(Scopes)

本程序适用于本公司质量管理体系范围内纠正措施和预防措施的制定、实施与有效性验证。

The procedure is applicable to the establishment, implementation and validation of corrective and preventive action within the quality management system.

3. 定义(Definitions)

3.1 **纠正**: 为消除已发现的不合格所采取的措施;

Correction: Action to eliminate a detected nonconformity.

3.2 **纠正措施**: 为消除已发现的不合格或其他不期望情况的原因所采取的措施;

Corrective action: Action to eliminate the cause(s) of a detected nonconformity or other undesirable situation.

3.3 **预防措施**: 为消除潜在不合格或其他潜在不期望情况的原因所采取的措施;

Preventive action: Action to eliminate the cause of a potential nonconformity or other undesirable potential

4 职责(Responsibilities)

4.1 质量管理体系内各部门负责将质量管理体系持续改进的机会, 包括不合格情况、潜在不合格情况、改进机会反馈至 QA。

The departments within quality management system are responsible for reporting to QA of the improvement opportunities of quality management system, including non-conforming, potential non-conforming and sustained improvement.

4.2 QA 是纠正预防措施的统筹管理部门, 负责对改进的机会进行分析评价, 评审采取纠正预防措施的必要性, 确定调查部门对改进机会进行调查, 并根据调查结果确定改进部门或改进流程,评审改进部门制定的纠正预防措施, 跟踪纠正预防措施的实施情况, 验证纠正预防措施的有效性。并对所有纠正预防措施进行归档整理。

QA is the supervising department for corrective and preventive actions and is responsible to analyze and evaluate the opportunities of improvement, verify the necessity of adopting corrective and preventive actions and confirm the responsible department to investigate. QA is also responsible for the implementation and validation of the effectiveness of corrective and preventive actions. QA shall file the final records of corrective and preventive actions.

4.3 改进部门负责制订和评审纠正预防措施，并确保纠正预防措施按要求有效的执行。

The responsible departments are responsible for establishing and reviewing the corrective and preventive actions and ensuring the implementation.

5 工作流程(Working procedures)

5.1 纠正预防措施来自于质量管理体系范围内，引起产品不合格或潜在不合格或者其他质量问题的各过程。数据来源一般来自于日常管理以及定期的统计分析，可包括但不仅仅限于以下来源:

A CAPA may arise due to a flaw in the process that may have caused product non-conformance, potential non-conformance and/or other quality problems in the scope of the quality system. The Data is based on daily management and periodic data analysis. This data includes but is not limited to the following:

a) 产品的让步接收和产品不合格的处理 Concessional acceptance of products and the disposition of non-conforming;

b) 体系审核与评审（包括管理评审、内部质量体系审核、认证公司或顾客委托进行的第三方审核、顾客的第二方审核） System audit or review(including management review, internal audit, authentication company or the third party the customer consigned, the second audit conducted by the customer);

c) 工程设备管理过程 Engineering and Equipment Management Process;

d) 供应商管理过程 Vendor Management Process;

e) 顾客抱怨或市场反馈 Customer complaint or marketing feedback;

f) 产品退回 Product withdrawal;

g) 生产异常和偏差 Production abnormity and deviation;

h) 工艺分析和改进 Process technical analysis and improvement;

i) 其他的过程分析机会 Other process analysis opportunities

j) 其他需要评估和批准的潜在输入 Unforeseen potential inputs that may warrant evaluation and approval。

5.2 纠正预防措施的启动 The initiation of corrective and preventive actions

5.2.1 纠正预防措施的启动条件 The initiation condition of the corrective and preventive actions

1）内外审核产生的不合格以及管理评审改进输出均需要启动 CAPA;

CAPA should be initiated when a non-conformance is generated from an internal or external-audit.

2）客户投诉、生产异常以及不合格品需根据各自程序文件的规定启动 CAPA;

CAPA should be initiated according to the request of the relevant procedures when there is a customer complaint, production abnormity, and/or NCMR.

3）其它来源的不合格（潜在不合格）的信息，由 QA 协同相关部门根据附件 2 《风险评估表》对不合格（潜在不合格）信息进行分析，以评审采取纠正预防措施的必要性。风险评估需记录在《纠正预防措施报告单》Section A。

For a non-conformance (potential nonconformity) generated from other sources, QA should cooperate with

relevant department to determine the necessity of the initiation of corrective and preventive actions according to the Appendix 2 “Risk Assessment”. The risk assessment result should be recorded in the section A of “Report of Corrective and Preventive Action”.

5.2.2 启动的 CAPA 由提出部门填写《纠正预防措施单》中 Section A: 不合格（潜在不合格）的描述时,应针对不合格（潜在不合格）的事实进行陈述; 并明确不合格（潜在不合格）的来源；同时 QA 负责将其登记于纠正预防措施数据库中，对产生的纠正预防措施的状态进行跟踪汇总。

The initiating department shall fill in Section A “Report of Corrective and Preventive Action” about the description of non-conforming or potential non-conforming; point out the source of the non-conforming (potential non-conforming); and the CAPA should be registered by QA in the corrective and preventive actions data-base and follow up on them.

5.2.3 CAPA 需由 QA 提供统一编号,《纠正预防措施单》编号方法为：BC-××***。××表示纠正预防措施发生年份，***表示各年度各类纠正预防措施的顺序号。

The CAPA number should be assigned by QA. The numbering of “Report of Corrective and Preventive Action” is BC-××***. ×× indicates the year when corrective and preventive actions occur. *** indicates the sequential numbers of the occurred corrective and preventive actions in each year.

5.2.4 质量部应及时把纠正预防措施信息加入到 CAPA 数据库中。CAPA 数据库位于 QS 工作数据库中，内容包括：不合格（潜在不合格）来源及情况描述、提出人、日期、纠正/纠正（预防）措施的制订、改进部门、预计完成时间、纠正预防措施的实施和纠正预防措施有效性确认。

Quality department shall keep records on the Access of the CAPA Control. The database is located in the QS folder, including: source and description of the issue, initiator, date, proposed Correction/ Corrective(Preventive) Actions, improvement department, due date, CAPA implementation and Verification of the CAPA Effectiveness.

5.3 原因的调查分析 The investigation

5.3.1 提出部门将《纠正预防措施单》交 QA，QA 根据不合格（潜在不合格）描述指定调查部门（或调查人）对不合格情况进行调查分析，确定产生不合格（潜在不合格）发生的原因。

The initiating department shall submit “Report of Corrective and Preventive Action” to QA. QA shall designate investigation departments or investigator to carry out the investigation on the non-conforming according to the description of non-conforming or potential non-conforming to clarify the reasons for non-conforming or potential non-conforming.

5.3.2 调查部门（或调查人）应及时组织调查，并要求至少在 5 个工作日内得出调查结果（对技术性问题的调查时间要求在 10 天之内完成）,并将调查分析填写在 Section B 上。调查分析应包括所有发生背景，发

生的原因，改进部门（一项不合格可能包括几个责任部门)。

Investigation department or investigator shall carry out investigation in time and results shall be reached in no more than five workdays. （technical problem should be Investigated within 10days）, The analysis of investigation shall be filled in Section B. Investigation analysis shall include the background, causes, and responsible departments (a single non-conforming is possibly affect several responsible departments).

5.4 纠正/纠正预防措施的制定 The establishment of correction/corrective and preventive action

5.4.1 QA 将对调查部门反馈的《纠正预防措施单》中的原因分析及调查情况进行确认，认可后传达到改进部门，如果 QA 对原因分析和调查结果有异议，应协同调查部门（人）进行再调查。

QA shall confirm the investigation described by investigator and distribute the 'Report of Corrective and Preventive Action' to the responsible departments. If QA disagree with the causation, QA should cooperate with investigation departments (personnel) to investigate it again.

5.4.2 根据原因的调查分析，改进部门需要进行纠正、制定纠正(预防)措施；并记录在 Section C 中。

Based on the investigation, the responsible departments should make the correction and the corrective actions (preventive actions) plan; and record them in the section C.

5.4.3 当某一不合格项的改进需几个部门共同进行时，QA 需将《纠正预防措施单》交于相关部门分别制定纠正预防措施。

If not one department is responsible for one CAPA. QA should copy the 'Report of Corrective and Preventive Action' and distribute to related departments to separately establish corrective and preventive actions.

5.4.4 改进部门应针对调查分析结果制定纠正预防措施，改进部门可从人、机、料、法、环、测等影响产品质量的角度制定纠正和预防措施，纠正预防措施的制定应关注其可执行性和执行效果。

The corrective and preventive actions shall be created based on the quality influence factors such as personnel, equipment, material, method and environment. The establishment of actions should take attention of the feasibility and implementation.

5.4.5 改进部门根据不合格情况和实际问题认为不需要制定或是无法制定纠正预防措施时，应在 Section C 中写明理由,QA 根据情况决定是否采取纠正预防措施。若不需则在此栏中注明"不需制定"。

The responsible department shall give explanation in section C when he regards it is unnecessary or impossible to establish corrective and preventive actions according to non-conforming circumstance and actually issues. QA shall decide whether to establish corrective and preventive actions or not and give clear indication of "unnecessary".

5.4.6 若纠正预防措施涉及到更改，则需先填写《更改评估表》(QR091-RE-01）进行评估。

If the corrective and preventive action is related to a Change, the "Change Assessment Form" (QR091-RE-01)

should be completed first.

5.5 纠正预防措施期限的规定 The requirements on the timeline of corrective and preventive actions

5.5.1 对于非技术性的纠正预防措施，责任部门应在七个工作日内制订，同时确定预计完成期限，一般要求在一个月内完成；对于技术性纠正预防措施，责任部门应尽量在一个月之内制定，同时确定预计完成期限，可由改进部门根据复杂性自行规定，必要时提供日程安排。

Non-technical corrective and preventive actions are generally required to be established within 7 workdays by improvement departments. The due date should be issued by improvement departments and is generally required within one month. The technical corrective and preventive actions should be established with one month and should give deadline for implementation. The improved departments may include the schedule based on the complexity regarding technical corrective and preventive actions if necessary.

5.5.2 纠正和预防措施的制定应充分考虑存在的问题对产品质量、生产成本、产品的性能、顾客满意等的影响，以确保纠正预防措施能使质量风险与成本得到平衡。

The establishment of corrective actions shall take full consideration of the existing problems' effect on product quality, production cost, performance, and customer satisfaction to make sure that the corrective actions balance the quality risks and costs.

5.6 纠正预防措施的审批 The approval of corrective and preventive action

纠正预防措施制定后，应首先由部门主管进行审批，确定纠正预防措施的充分性及适宜性；对技术性纠正预防措施，涉及到具体产品的则首先应由该产品的项目主管进行审批，确定该措施的合理性。责任部门将审批后的《纠正预防措施单》交给 QA，QA 对该纠正预防措施的充分性及适宜性再次进行审批。

The department supervisor shall examine and approve the corrective and preventive actions to verify the sufficiency and appropriateness. The project supervisor shall examine and approve the technical corrective and preventive actions relating to particular products to verify the rationality. The responsible departments shall submit the approved 'Report of Corrective and Preventive Action' to QA. QA shall examine the sufficiency and appropriateness for a second time.

5.7 纠正预防措施的实施与有效性验证

The implementation and effectiveness verification of corrective and preventive action

5.7.1 责任部门按要求实施纠正预防措施，并保留相关的原始记录。纠正预防措施完成后，责任部门应将完成信息通知 QA；

The responsible departments shall implement corrective and preventive actions upon requirements and keep the related original records. The responsible departments shall send the information to QA upon the completion of the actions.

5.7.2 责任部门若未能按预计完成期限完成纠正预防措施,则必须填写《纠正预防措施状态报告》向 QA 说明原因，并再次确定完成期限；

The responsible departments shall complete a **CAPA Status Report** with an explanation to QA and provide a new completion date if corrective and preventive actions are not fulfilled on the anticipated date.

5.7.3 QA 或由 QA 指定人员对纠正预防措施的实施进行跟踪,并将结果记录在《纠正预防措施有效性核查报告》中。当所有措施实施完成后，QA 及改进部门应当在至少三个月以后（以获得足够多的数据）对措施的有效性进行验证，同时确认纠正预防措施是否对产品产生不利影响。

QA or assigned specifically person should track the implementation of the corrective and preventive actions and record the results in the CAPA Effectiveness Report. At least three months later after all the actions have been completed; QA and CAPA owner should verify the effectiveness of the actions and ensure that such action does not adversely affect the finished device;

可以对以下质量信息进行统计分析，以得出措施是否有效的结论。如：产品投诉信息、审核信息、生产操作与技术工艺过程、不合格品状况、仪器设备的校验与维护信息、新产品研发过程等，并将验证方法与结果记录在《纠正预防措施有效性核查报告》中。

The conclusion of whether the action is effective or not could be relied on statistics with the following quality data, i.e.; such as, customer complaint data, audit information, manufacturing operation, technical process information, non-conforming material status, calibration and maintenance of apparatuses and equipment, new products research and/or research and development information, etc. Then verifying methods and results should be recorded in the CAPA Effectiveness Report.

5.7.4 各改进部门和 QA 应持续关注各纠正预防措施项的实施情况，必要时（如纠正预防措施实施效果不佳）重新制定纠正预防措施。

Every improvement departments and QA should take continuance attention to each action. If necessary(the effect of implementation is not good),the corrective and preventive action will be working-out again.

5.8 纠正预防措施状态报告 Status Report of Corrective and Preventive Action

5.8.1 若相关部门不能按上面规定的工作时间按时完成原因调查分析、纠正预防措施的制定、实施的工作，必须根据要求填写《纠正预防措施状态报告》向 QA 说明原因。

The responsible departments shall fill in Status Report of Corrective and Preventive Action and provide an explanation to QA if the investigation as to why the establishment and implementation of corrective and preventive action were not fulfilled on the anticipated date.

5.9 纠正预防措施统计分析报告 The statistical analysis report on corrective and preventive action

5.9.1 QA 每月对过去 12 个月启动的纠正预防措施进行分类汇总统计分析，内容包括：

a. 纠正预防措施的状态统计

b. 无效纠正预防措施的统计

c. 纠正预防措施的来源分布

d. 按人员改进 (人)、设备改进 (机)、原辅料改进 (料)、生产工艺产品性能改进、操作程序改进 (法)、环境改进（环）等进行的分类分析和统计。

统计分析的结果如有趋势性，需根据附件 2《风险评估表》评估是否需启动 CAPA。

QA shall sort and analyze the corrective and preventive actions initiated within the last 12 months on a monthly basis. The following items shall be analyzed:

a. The statistics of status for corrective and preventive actions

b. The statistics of non-effective corrective and preventive actions

c. The sources of corrective and preventive actions

d. To carry out analysis and statistics on improvement of personnel training (man), equipment (machine), raw and adjuvant material (material), workmanship and product performance, operation procedures (method), and environment.

If the analysis results show there is any bad trend, QA should evaluate if it's necessary to initiate a CAPA according to the Appendix 2 <<risk assessment>>.

5.9.2 纠正预防措施分析报告应提交管理评审。

The analysis report on effectiveness of corrective and preventive actions shall be submitted for management review.

6 相关文件(Relevant Documents)

6.1《不合格品控制程序》Non-Conforming Control Procedure（QP200）

6.2《内部质量审核程序》Internal Audit Procedure（QP180）

6.3《更改控制程序》Change Control Procedure（QP090）

6.4《数据分析、应用程序》Data Analysis and Application Procedure（QP210）

6.5《生产过程控制程序》Manufacturing Process Control Procedure（QP120）

6.6《顾客沟通程序》Customer Communication Procedure（QP170）

6.7《投诉处理流程》Customer Complaint Procedure（QR311）

6.8《更改评估程序》Change Assessment Procedure(QR086)

7 相关记录(Relevant Records)

7.1 纠正预防措施报告单 Report of Corrective and Preventive Action QP220-RE-01

7.2 纠正预防措施状态报告 CAPA Status Report QP220-RE-02

7.3 纠正预防措施有效性核查报告 CAPA Effectiveness Report QP220-RE-03

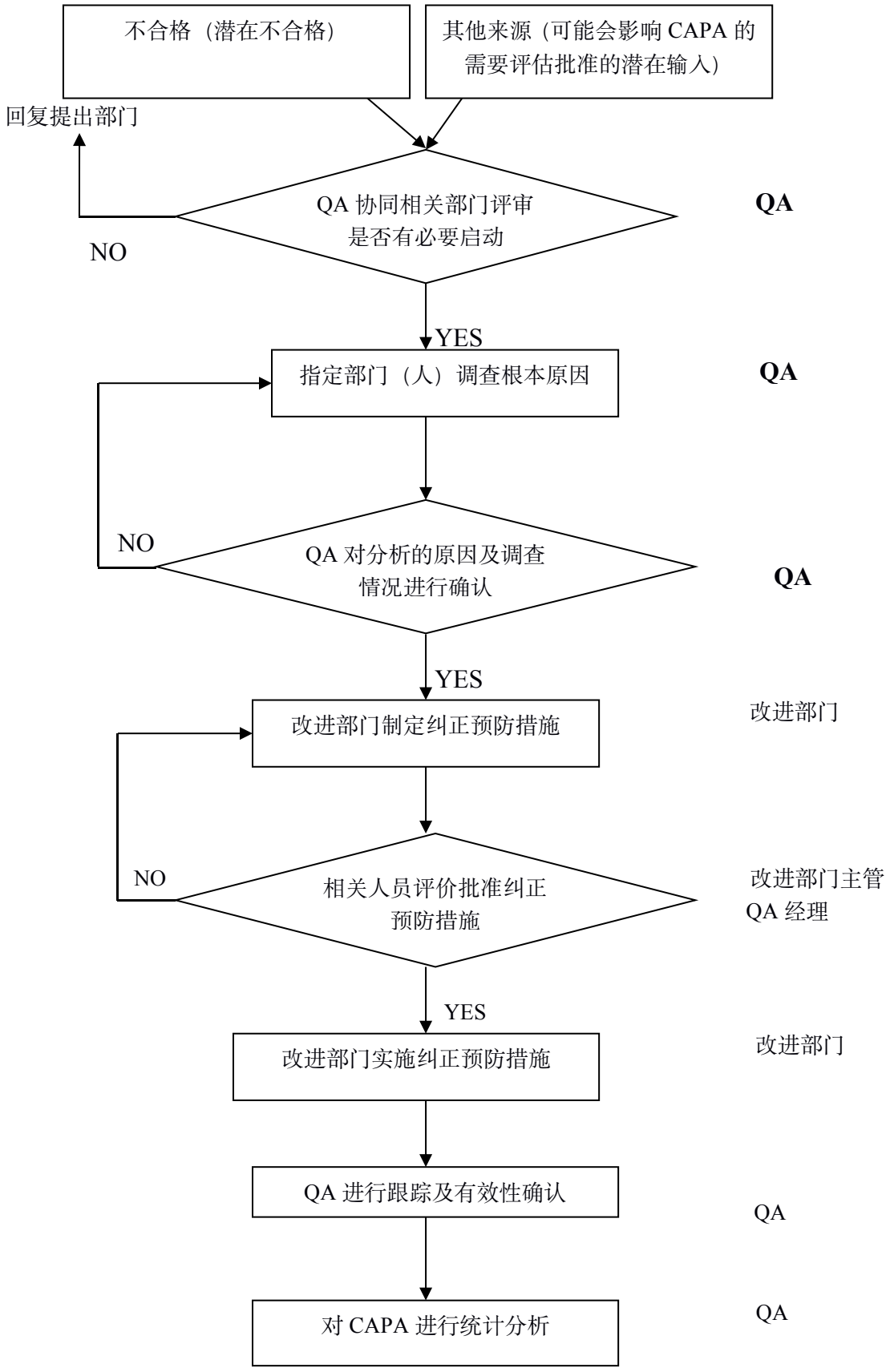
8 附件(Appendixes)

8.1 CAPA 工作流程 CAPA working flow

8.2 风险评估表 Risk Assessment

附件 1

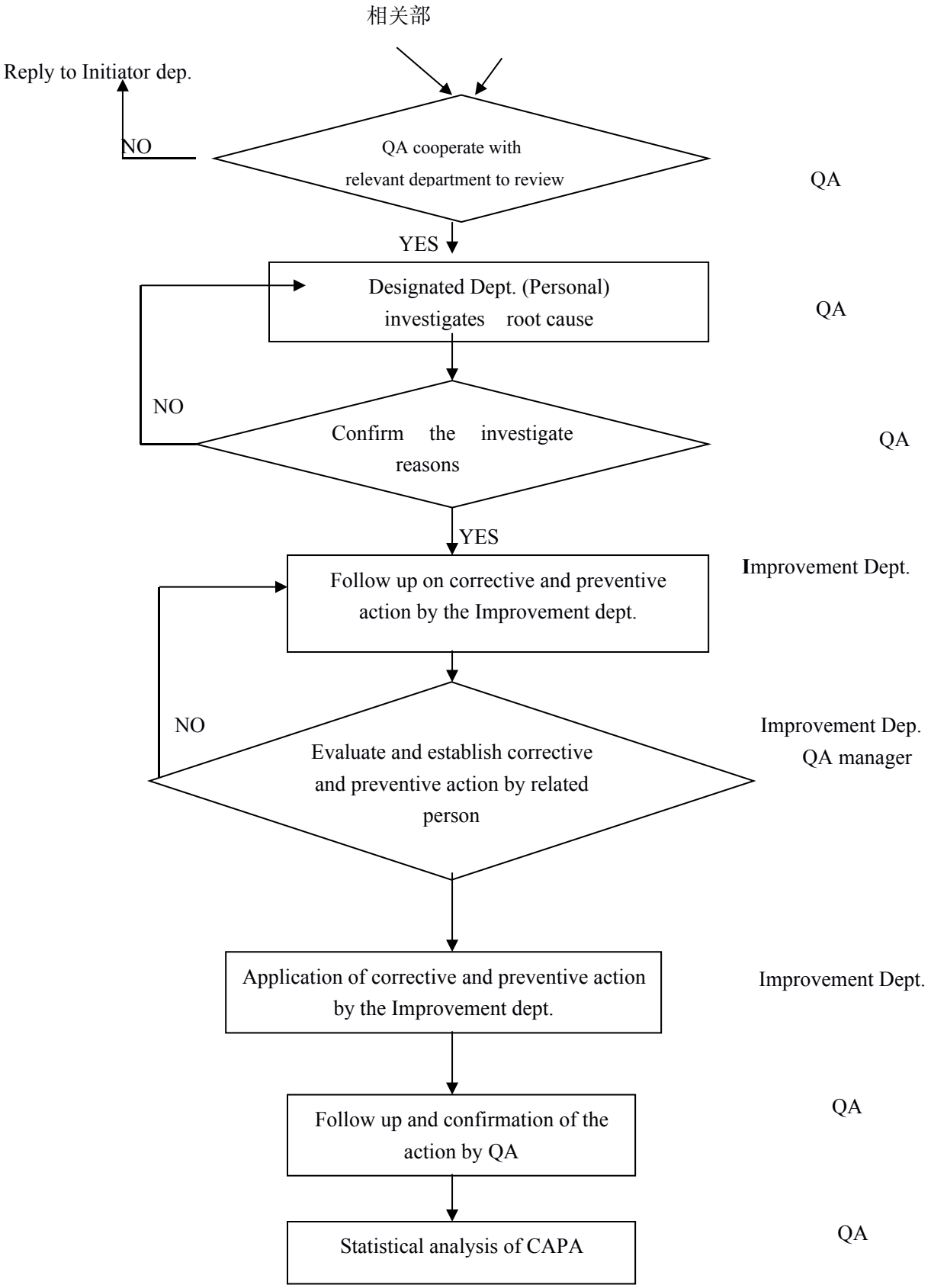
CAPA 工作流程



Appendix 1 **CAPA working flow**

Non-conforming (potential non-conforming)

Other Sources (potential inputs that may impact CAPA's and /or warrant evaluation and review)


相关部
Reply to Initiator dep.
NO
QA cooperate with relevant department to review
QA
YES
Designated Dept. (Personal) investigates root cause
QA
NO
Confirm the investigate reasons
QA
YES
Improvement Dept.
Follow up on corrective and preventive action by the Improvement dept.
NO
Improvement Dep.
QA manager
Evaluate and establish corrective and preventive action by related person
Application of corrective and preventive action by the Improvement dept.
Improvement Dept.
QA
Follow up and confirmation of the action by QA
QA
Statistical analysis of CAPA

附件 2《风险评估表》

使用下列三个表格来判定风险的等级：

1. 使用表 A 评估严重程度
2. 使用表 B 评估概率程度
3. 根据严重程度及概率程度来判定风险等级。如评判结果落入表 C 的灰区，需要启动 CAPA；如评判结果没有落入表 C 的灰区，则不需要启动 CAPA。

表 A

严重程度	**说明**
严重的	产品性能受到影响，且： ● 直接导致使用者/病人死亡或健康严重损害，或 ● 会产生不正确的信息（比如出错的或损坏的数据），从而造成使用者/病人死亡或健康严重损害。
中度的	产品性能受到影响，且： ● 直接对使用者/病人造成可逆的和/或暂时的伤害，或 ● 会产生不正确的信息（比如出错的或损坏的数据），从而对使用者/病人造成可逆的和/或暂时的伤害。
微小的	只是产品性能受到影响，不会对使用者/病人造成任何伤害。

表 B

发生概率	**说明**
很可能的	在产品寿命期内，在特定的操作下发生过，而且（或者）规律发生，或多次发生；
偶尔的	在产品寿命期内，在特定的操作下发生过，而且（或者）不经常发生，或发生几次；
罕见的	在产品寿命期内，在特定的操作下发生过一次，而且（或者）极少会发生，或未必发生；
不可能的	在产品寿命期内，在特定的操作下预期中不会发生；

表 C

发生概率	**严重程度**		
	严重的	中度的	微小的
很可能的	高	高	中
偶尔的	高	中	低
罕见的	中	低	低
不可能的	低	低	低

Appendix 2 <<Risk Assessment>>

To determine the Risk Assessment Level:

1. Use Table A to assess the severity level.
2. Use Table B to assess the probability level.
3. Then use the severity and probability levels to judge the Risk Level. If the result is in the gray area, CAPA should be imitated; if the result is not in the gray area, CAPA need not be imitated.

Table A

Severity Level	Description
Major	Product functionality is affected, and the failure mode effect could 1) directly result in the death or serious injury of the patient or operator, or 2) indirectly affects the patient such that incorrect information (for example, corrupted or destroyed data) could result in the death or serious injury of the patient.
Moderate	Product functionality is affected, and the failure mode effect could 1) directly result in reversible and/or temporary injury of the patient or operator, or 2) indirectly affects the patient such that incorrect information (for example, corrupted or destroyed data) could result in reversible and/or temporary injury of the patient.
Minimal	Product functionality is affected, but the failure mode effect and its impact on patient results is not expected to result in an impact to patient management.

Table B

Probability of Occurrence	Description
Probable	It has occurred, and/or is likely to occur regularly, or many times during the life of the product under the specified operating conditions.
Occasional	It has occurred, and/or is likely to occur infrequently, or several times during the life of the product under the specified operating conditions.
Rare	It has occurred once, and/or will rarely occur, or is very unlikely to occur during the life of the product under the specified operating conditions.
Improbable	Improbable failure impact is not expected to occur during the life of the product under the specified operating conditions.

Table C

Probability of Occurrence	Severity Level		
	Major	Moderate	Minimal
Probable	High	High	Medium
Occasional	High	Medium	Low
Rare	Medium	Low	Low
Improbable	Low	Low	Low

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Document History Summary

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