COUNCIL OF EUROPE
PUBLIC HEALTH COMMITTEE
(Partial Agreement)

RESOLUTION AP-CSP (07) 1
(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP) on 21/02/2007

Certification of suitability to the monographs of the European Pharmacopoeia (revised version)

欧洲议会
公共卫生委员会
（局部协定）

决议AP-CSP (07) 1号

2007年2月21日

欧洲议会公共卫生委员会（局部协定）（CD-P-SP）通过

欧洲药典适用性证书（修订版）

The public Health Committee (Partial Agreement) (CD-P-SP) consisting, for the purposes of the Convention on the Elaboration of a European Pharmacopoeia, of delegations appointed by the Parities to the said Convention, namely the delegations of Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, "the Former Yugoslav Republic of Macedonia", France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom and the European Union.

Considering the implementation of the Procedure for the certification of suitability of monograph of the European Pharmacopoeia adopted on 1 July 1993 by the Public Health Committee (Partial Agreement) (CD-P-SP) in its resolution AP-(CSP (93) 5 and revised on:

- 4 October 1996 Resolution AP-CSP (96) 5
- 8 May 1998 Resolution AP-CSP (98) 2
- 22 December 1999 Resolution AP-CSP (99) 4

Having regard to the decision by the European Pharmacopoeia Commission at its session of November 2006 to update and complete the resolution AP-CSP (99) 4.

Has therefore decided to amend the resolution AP-CSP (99) 4 and to replace it by the text attached.

根据建立欧洲药典协定公约，公共卫生委员会（局部协定）(CD-P-SP)由以下公约成员国指定代表组成，即以下国家代表：奥地利、比利时、波斯尼亚和黑塞哥维那、保加利亚、克罗地亚、塞浦路斯、捷克共和国、丹麦、艾沙尼亚、芬兰、“前南斯拉夫的马其顿共和国”、法国、德国、希腊、匈牙利、冰岛、爱尔兰、意大利、拉脱维亚、利陶宛、卢森堡、马耳他、门的内哥罗、荷兰、挪威、波兰、葡萄牙、罗马尼亚、塞尔维亚、斯洛伐克共和国、斯洛文尼亚、西班牙、瑞典、瑞士、土耳其、英国和欧盟。

鉴于公共卫生委员会（局部协定）(CD-P-SP)于1993年7月1日在其AP-(CSP (93) 5号决议及以下决议修订版中同意执行欧洲药典适用性证书程序，

- 1996年10月04日 决议AP-CSP (96) 5号
- 1998年05月08日 决议AP-CSP (98) 2号
- 1999年12月22日 决议AP-CSP (99) 4号

以及欧洲药典委员会2006年11月会议决定更新和完善AP-CSP (99) 4号决议，

现决定修订AP-CSP (99) 4号决议，并以后附全文取代之

INTRODUCTION
引论

The manufacturer of a substance will be able to provide proof that the quality of the substance is suitably controlled by the relevant monographs of the European Pharmacopoeia by means of a certificate of suitability granted by the Certification Secretariat of the European Directorate for the Quality of Medicines (EDQM) (as described in the EU Directives on the Community code relating to medicinal products for human and veterinary use, the CHMP/CVMP guideline on Summary of Requirements for Active Substances and any relevant national regulation (see 7). To apply for a certificate a manufacturer will submit a detailed dossier (refer to the relevant EDQM documents describing the content of the dossiers – see 7) which may contain confidential data.

原料药制造商应提供证据证明：欧洲药典个论能够良好控制其产品质量，可使用EDQM证书处颁发的欧洲药典适用性证书来证明（见：EU对于共同体人用或兽用药法典的指令，CHMP/CVMP关于活性物质要求总结指南，以及各国法规（第7段））。为申请COS证书，制造商需提交可能包含机密信息详细申请材料（参见EDQM对申报资料要求的有关文件）。

The procedure is intended to be applied for the assessment of quality with regards to the criteria of the monograph(s) as appropriate.

证书程序适用于评价药用物质是否药典个论质量标准。

The certificate of suitability certifies that by applying the relevant monographs of the European Pharmacopoeia, if necessary with an annex appended to the certificate, it is possible to check whether or not the quality of the substance is suitable for use in medicinal products. In other words, it ensures that all possible impurities and contamination from this particular route of manufacture (including source materials) can be fully controlled by the requirements of the monographs.

适用性证书的含义：只要执行欧洲药典个论规范及必要的附加要求，即可控制该物质是否适用于药用制剂。换句话说，完全执行欧洲典标准就能够完全控制保证该工艺路线（包括初始原料）产生的所有杂质和污染质。

SCOPE 范围

The following procedure is intended to be used for substances for which a monograph (general monograph and/or specific monograph) has been adopted by the European Pharmacopoeia Commission:

- organic or inorganic substances (active or excipients), manufactured or extracted.
- substances produced by fermentation as indirect gene products, which are metabolites of microorganisms, irrespective of whether or not the microorganisms have been modified by traditional procedures or r-DNA technology (see the monograph Products of Fermentation)
- products with risk of transmitting agents of animal spongiform encephalopathies (TSE) (see the monograph Products with risk of transmitting agents of animal spongiform encephalopathies).

The procedure will not be applicable for direct gene products (proteins), products obtained from human tissues, vaccines and blood products and preparations.

The final decision on eligibility of an application for a certificate of suitability for a material of animal origin is taken by the relevant board of the procedure if necessary.

以下程序适用于欧盟药典委员会收载于药典（总论和个论）的物质:

- 制造或萃取的有机或无机物质（活性物质的或辅料剂）;
- 发酵制造的微生物代谢产生的间接基因物质，无论该微生物菌种是用传统方法还是r-DNA技术进行修饰与否（参阅“发酵产品”个论）;
- 有动物疯牛病（TSE）因子传播风险的产品（参阅《有动物疯牛病因子传播风险的产品》规范）。

程序不适用于直接基因产品（蛋白质），由人体组织产品，疫苗及血液产品和制剂。
动物源物质是否适用，必要时将将由相关程序委员会作出最后决定。

HOLDER OF THE CERTIFICATE 证书持有者

The certificate of suitability will be delivered in preference to the manufacturer of substances intended for pharmaceutical use. In special cases where the holder will not be the manufacturer but an authorised agent, a formal agreement is required (included in the application form; see 7).

适用性证书优先颁发给药用物质制造商。若出现持有人不是制造商而是指定代理人的特殊情况，必须有正式协议（包括在申请表中，见第7段）。

PROCEDURE 程序

The procedure for the certification of suitability will consist of the following steps
适用性证书申请程序将由下列步骤构成

1 SUBMISSION OF THE DOSSIER 申请材料的提交

The manufacturer requests a certificate by submitting 2 copies of a dossier in English (preferably) or French according to the CTD format and including the relevant part of the Quality Overall Summary (QOS), and an application form duly filled in (see 7), together with samples of commercial batches and fees.

制造商提交CTD格式的申报文件和质量总结（QOS），一式两份（最好）用英文或者法文，填好申请表（见第7节），以及商业批样品的申报费。

The documentation to be provided by the manufacturer is described in the specific documents published by EDQM for the evaluation of the chemical purity, for TSE risk assessment, for herbal drugs and preparations (see 7). For products bearing a risk of transmitting animal spongiform encephalopathy agents, and for which a specific monograph exists in the European Pharmacopoeia, the applicant may apply for a certificate concerning the general monograph Products with risk of transmitting agents of animal spongiform encephalopathies as well as for the specific monograph, or may wish only to apply for a certificate concerning the general monograph. Where no specific monograph exists for the concerned substance only the documentation related to the TSE-risk evaluation should be supplied.

制造商申报的资料内容规定在EDQM出版的各具体文件：化学纯度、TSE风险评估、草药制剂（见第7节）。对于有疯牛病因子传播风险、且已被欧洲药典收载 的品种，申请 人可以同时按 "有疯牛病因子传播风险的产品"总论和其个论申请证书，也可以只按总论申请证书。所申请物质若没有个论，只需根据TSE-风险评估要求报送文件。

In the application the manufacturer shall declare that the manufacture of the substance in question takes place in accordance with on the requirement of the EU Good Manufacturing Practice (GMP) for the manufacture of starting materials (see 7) and in accordance with the dossier presented. For products with risk of transmitting agents of animal spongiform encephalopathies where GMP guidelines have not been elaborated, a suitable quality assurance system (such as ISO 9000 and HACCP)[1] assuring in particular traceability and batch consistency should be applied. Furthermore, the manufacturer should declare its willingness to be inspected if so requested by a relevant authority. Also, in the case of an application submitted by an authorised agent, the above declaration should form part of the dossier and, furthermore, the authorised agent should also declare its willingness to be inspected (in the application form; see 7)

[1] HACCP = hazard analysis and critical control point.

在申请文件中，制造商应声明所申报产品的生产符合“欧洲起始物质生产质量管理规范”(GMP)（见第7节），并与申报文件一致。对有疯牛病因子传播风险的产品，由于目前还没有GMP准则，应该执行相应的质量保证体系，以保证产品可追踪性和批间一致性性（如ISO 9000和HACCP）[1]。此外，制造商应声明愿意接受有关当局的现场检查。如果由指定代理人提交申请，上述声明应构成申请书的一部分，而且，指定代理人同样应声明愿意接受检查（声明也在申请表格中，见第7节）

2. ACKNOWLEDGEMENT OF RECEIPT
收函通知

The Certification Secretariat, after having verified that the dossier submitted is complete, sends an acknowledgement of receipt within eight days which constitutes the official record of the request for a certificate of suitability. Once the dossier is received, and if acceptable, the Secretariat has four months to designate two assessors and have the dossier examined and one month to implement the conclusions and, where appropriate, to deliver the certificate of suitability.

证书处核实所收到的申报文件的完整性后，于八天内寄出收函通知，这意味着适用性证书申请的正式备案。收到申报文件之后，认证处有四个月指定两位评审员对文件进行审阅，并再一个月作出结论并颁发适用性证书，如果通过的话。

3. DESIGNATION OF ASSESSORS
指定评审员

For each dossier, the secretariat designates two assessors, who are chose according to their expertise and the dossier to be examined from a list approved by the Certification Steering Committee (according to the "terms of reference"; see 7) and published periodically on the EDQM web site. The assessors sign a confidentiality agreement and a declaration of interests.

秘书处为每份申报资料指定两个评审员，评审员来自COS证书管理委员会（根据“标准术语”，见第7节）批准的人员清单，并根据个人专长指定。该清单定期发布于EDQM网站。同时，评审员需签署保密协议，和无利益冲突声明。

The assessors examine the dossier submitted and prepare a report in three parts:
评审员对资料进行审核，分三部份出具评审报告:

- Report A or "Confidential report". This report includes an exhaustive critical assessment of the data provided and is kept in the confidential dossier for certification of suitability. Report A can be made available, on request to any marketing authorization body, in the

context of an identified medicinal product license application referring to this substance and the manufacturer would be informed at the same time.

报告A或“保密报告”：包括详细的评审意见，以密件形式存放于证书处。该报告可以在销售许可证（MA）批准部门需要时提供，但必须是针对对使用该原料药的指定制剂销售申请，同时，原料药生产厂会得到通知。

- Report B or "request for revision of the monograph", when updating of the monograph is requested, this report contains the information that the relevant Group of Experts of the European Pharmacopoeia needs to update the monograph which has been shown to be inadequate. It is prepared so as not to divulge the confidential information in the dossier. This part of the report shall be sent to the manufacturer prior to its transmission to the expert group concerned.

报告B或“修订药典个论请求”：申请修订药典个论时，该报告包括欧洲药典委专家组更新药典所需要的信息，必须说明现行药典不适用的内容。报告不得泄露COS申请资料的保密内容，并在提交专家组之前交给生产厂。

- Report C or "Comments for the inspectors". This report contains any useful information for an inspection and/or any specific request for inspection and specified which GMP guidelines/Quality Assurance system are referred to in the dossier when EU GMP requirements do not apply.

报告C或“检查官意见”：包括现场检查的有关信息或要求进行检查的内容，说明欧洲EU GMP不适用时，COS申报资料适用哪一个GMP。

4. ASSESSMENT
评审

The assessment will be done by assessors, assisted by the Certification Secretariat. In case of doubt the relevant Technical Advisory Board (TAB) (status and role defined in Terms of Reference; see 7) is consulted. Such consultation may be requested by the assessors or by the Certification Secretariat.

If toxicological justification is needed, advice will be sought from a toxicologist assessor for this specific question.

If necessary, the assessor or the relevant technical advisory board requests a laboratory evaluation by the laboratory of the EDQM on the sample supplied.

评审员在证书处协助下对文件进行评估。有疑问可向技术顾问委员会（TAB）（构成和作用见标准术语，第7节）咨询。可由评审员或认证处要求进行咨询。

如果需要论证毒理学合理性，将由毒理学评审员提出评审意见。

必要时，评审员或技术顾问委员会可要求欧洲药品质量管理局实验室评估申报样品。

The assessors and, if necessary, the relevant technical advisory board, finally present one of the four conclusions below:
评审员，以及必要时，相关技术顾问委员会最后提交以下四种结论之一:

4.1 *The monograph is able to control the quality of the substance and/or the substance meets the criteria of the monograph Products with risk of transmitting agents of animal spongiform encephalopathies.*

Consequently, the certificate of suitability is granted.

As regards the chemical impurities, if necessary, the transparency of the monograph by mentioning the impurity (ies) tested is improved while taking any measures required to protect the confidentiality of the information (industrial property) with the agreement of the manufacturer.

During a subsequent revision of the monograph, the names of known and controlled impurities that do not concern matters of industrial property are published with the agreement of the manufacturer. In the interim period this (these) impurity (ies) is (are) mentioned in the certificate itself.

If, in exceptional cases, the names of one or more impurities, which are not already mentioned in the existing monograph, for confidentiality reason cannot by published in the European Pharmacopoeia such names need to be given in the certificate.

4.1 药典个论能够控制申报产品质量，以及/或者符合《携带疯牛病因子传播风险的产品》个论标准。

结果: 授予适用性证书。

化学杂质控制: 必要时，在药典中提出有关杂质检验项目，同时采取措施保护原厂的资料信息（工业产权）保密性，但事先征得原厂同意。

在不影响工业产权前提下，并征得原厂同意，在药典修订版（增补版）中收载已知名杂质项目。在此之前，仅在CEP证书中做出规定。

个别情况下，药典未收载的一个或多个杂质基于保密原因不能收载于欧洲药典时，则必须在CEP证书中做出规定。

4.2 *The monograph is not able fully to control the quality of the substance, but the information provided (new, validated, analytical method and/or additional tests) nevertheless*

guarantees that the quality of the substance is adequately controlled (note: this situation is not applicable for cases of TSE risk assessment).

Consequently:
The certificate of suitability is granted. In the certificate is given the full text of the additional test and the full list of named impurities including their limits controlled by that test.

With the agreement of the manufacturer the Secretariat asks the relevant Group of Experts of the European Pharmacopoeia to initiate the appropriate revision process to include an adapted test so as to be fully suitable to control the quality of the substance from this manufacturer as well.

If necessary, the transparency of the monograph by mentioning the impurity (ies) tested is improved while taking any measures required to protect the confidentiality of the information (industrial property) in an agreement with the manufacturer.

During a subsequent revision of the monograph, the names of known and controlled impurities that do not concern matters of industrial property are published in agreement with the manufacturer. In the interim period this (these) impurity (ies) is (are) mentioned in the certificate itself.

If, in exceptional cases, the names of one or more impurities, which are not already mentioned in the existing monograph, for confidentiality reason cannot by published in the European Pharmacopoeia such names need to be given in the certificate.

4.2 *药典个论不能完全控制申报产品质量，但申报资料（新的，经过验证的分析方法，和/附加检验项目）能证明该产品质量能够得到良好控制（注意：这种情况不适用于“携带疯牛病因子传播风险的产品”。）*

结果:
授予适用性证书。证书会罗列出附加检验项目和所有已知杂质清单及限量标准。

在原厂同意的前提下，秘书处将请有关欧洲药典专家组启动修订药典的程序，包括批准的检测项目，从而也能完全控制该生产厂制造的原料药质量。

必要时，改进药典中杂质检验项目，同时采取措施保护原厂的资料信息（工业产权）保密性，但事先征得原厂同意。

在不影响工业产权前提下，与原厂达成协议，在药典修订版（增补版）中收载已知名杂质项目。在此之前，仅在CEP证书中做出规定。

个别情况下，药典未收载的一个或多个杂质基于保密原因不能收载于欧洲药典时，则必须在CEP证书中做出规定。

4.3 *The information supplied is incomplete and does not allow a conclusion.*

The Secretariat requests the missing information on the manufacturing process, material sourcing, starting materials, additional test methods, validation studies, etc. The additional information received will be assessed within twelve weeks and may allow one of the previous conclusions.

The certificate of suitability is not granted as long as the information is still incomplete.

4.3 *申报资料不完整，无法作出结论。*

认证处会要求补充生产工艺、原料来源，起始原料，附加检验方法，验证等资料，并在收到补充资料十二周内进行评估，然后做出上述结论。

只要申报资料不完整，就不授予COS证书，

4.4 *The monograph is not suitable to control the quality of the substance or an agreement on testing methods for (a) given impurity (ies) or an agreement on the TSE risk assessment has not been reached or the information provided(even after several requests) do not demonstrate compliance with the current requirements.*

Consequently:
A justification for the decision not to grant a certificate of suitability will be given. Before rejection the manufacturer will be given the opportunity to present his position during an appropriate hearing with the relevant technical advisory board.

The licensing authority of the member states of the Convention is immediately informed in confidence of this decision in every case where the decision is taken for non-administrative reasons.

4.4 *药典个论无法控制申报产品质量，或无法就某一杂质检验方法或TSE风险评价达成共识，或申报的资料（即使多次要求之后）无法证明其符合现行规定要求。*

结果:
认证处提出拒绝授予COS证书的论据。在拒绝之前，制造商将有机会在听证会上向有关技术顾问委员会陈述其观点和立场。

以非行政理由作出的所有裁决将以保密方式通知公约成员国的销售许可证审批部门。

5. NOTIFICATION OF THE DECISION
决定的通知

The Certification Secretariat takes the necessary measures to implement the decisions of the assessors, and the relevant technical advisory board when necessary within 4 weeks.

评审员和有关技术顾问团做出上述决定之后，证书处在4周之内执行。

6. FOLLOW UP TO CERTIFICATION OF SUITABILITY
适用性证书的维护

6.1 Failure to comply with the following will render the certificate void:
不能满足下列条件时，COS证书将失效:

6.1.1 Any change (administrative or technical) that may or may not affect the quality, safety or efficacy of the substance, must be reported to the Certification Secretariat of the EDQM so that the dossier can be reassessed and updated.

影响或不影响产品质量、安全性或药效的所有变更（管理变更或技术变更），都必须向EDQM证书秘书处申报，便于再次评审和更新申报资料。

These changes are classified as notification, minor and major according to the impact on the quality, safety or efficacy of the substance. Special considerations apply to products with risk of transmitting agents of animal spongiform encephalopathies. The procedure to follow and the documentation to be submitted are described in specific documents published by EDQM (Guideline on requirements for revision/renewal of certificates of suitability and Procedures for revision/renewal of certificates; see 7).

根据对产品质量、安全和药效影响的程度，变更分为通知、微小变更和重要变更。对于有动物海绵状脑病转播风险的产品还应有特别考虑。变更程序和申报资料要求在EDQM出版具体文件中做了规定（COS证书修订/更新规定指南和COS证书修订/更新程序；见第7节）。

6.1.2 The dossier associated with the certificate will be updated every five years with at least a statement that no changes that may affect the quality, safety or efficacy of the substance have been made. After this renewal the certificates should normally be of unlimited validity provided the conditions for its validity, in particular those mentioned under 6.1.1, are respected.

申报文件和证书每五年应更新一次，至少应提供声明，说明没有可能影响产品质量，安全性或药效的变更。COS证书更新后，其有效性一般是无限期。但必须符合其有效性条件，特别是必须符合6.1.1项下规定的条件。

6.1.3 In case where the monograph(s) to which the certificate refers is revised by the European Pharmacopoeia Commission, the manufacturer has to show compliance with the new requirements. The Certification Secretariat will ensure that the quality of the substance still meets the criteria of the revised monograph(s). The Secretariat will then either send a revised certificate to the holder or ask him to update its dossier in compliance with the revised monograph(s).

如果欧洲药典个论做了修订，生产厂必须证明其产品符合新的药典要求。证书秘书处将确认其产品仍然符合修订后的药典标准。然后会将修订后的COS证书寄给持有人，或要求他们根据修订后的药典更新其申报资料。

6.1.4 In case of new legal requirements or technical or scientific developments as regards health concerns, the Certification Secretariat ensures that the substance meets the new criteria. If not the certificate is suspended.

在健康领域，有新法规要求、新技术或科学发展的情况下，证书秘书处要确认该产品仍符合新的准则。若否，将暂停证书

6.2 In case of failure to the above mentioned conditions or in case of major/critical deficiencies noticed during inspections, and based on the recommendation of the relevant board, the EDQM can suspended the certificate. The holder will be immediately notified by an official letter listing the reason of the decision and the conditions for restoring the certificate. The letter will be given the opportunity to present his position during an appropriate hearing with the relevant board. The licensing authority of the member states of the European Pharmacopoeia convention is immediately informed in confidence of the decision of the suspension.

不满足上述条件、或现场检查发现重大/至关重要缺陷时，根据有关委员会的建议，EDQM可能暂停COS证书。证书持有人会立即得到官方正式通知，其中说明了原因和恢复COS证书的条件。持有人可以凭此通知在适当的听证会上，向有关委员会陈述其立场。欧洲药典协定成员国的销售许可证（MA）签发部门会立即以保密方式得到暂停COS证书的决定。

7. REFERENCE DOCUMENTS 参考文件

7.1 EU/EMEA documents:
EU/EMEA文件

- EC Directive on the Community code relating to medicinal products for human use (2004/27/EC) amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

  共同体人用药法典的指令(2004/27/EC)（修订2001/83/EC共同体人用药法典指令）

- EC Directive on the Community code relating to medicinal products for veterinary use (2004/27/EC) amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

  共同体兽用药法典的指令(2004/27/EC)（修订2001/82/EC共同体兽用药法典指令）

- CHMP/CVMP guideline on Summary of Requirements for Active Substances in the Quality part of the Dossier (CHMP/QWP/297/97; EMEA/CVMP/1069/02)

  CHMP/CVMP指南：活性物质申报资料质量部份的要求概要：(CHMP/QWP/297/97; EMEA/CVMP/1069/02)

- The Rules governing medicinal products for Human and Veterinary use in the European Union:

  Volume 4 Good Manufacturing Practice (Medicinal products for Human and Veterinary use)
  Volume 2B Presentation and content of the dossier – (Medicinal products for Human use)
  Volume 6B Presentation and content of the dossier – (Veterinary medicinal products)

- 欧盟人用药和兽用药法规:

  Volume 4: 药品生产质量管理规范（人用药和兽用药）
  Volume 2B: 申请资料申报和内容要求 –（人用药）
  Volume 6B: 申请资料申报和内容要求 –（兽用药）

7.2 EDQM documents
EDQM文件

- Terms of Reference – PA/PH/CEP (01) 1
  标准术语 – PA/PH/CEP (01) 1

- Content of the dossier for chemical and microbiological quality - PA/PH/CEP (04) 1
  化学和微生物质量评审申报资料内容 – PA/PH/CEP (04) 1

- Content of the dossier for a substance for TSE risk assessment - PA/PH/CEP (06) 2
  TSE风险产品评审申报资料内容 – PA/PH/CEP (06) 2

- Content of the dossier for herbal drugs and herbal drug preparations quality evaluation - PA/PH/CEP (02) 6
  草药和草药制剂质量评审申报资料内容 – PA/PH/CEP (02) 6

- Guideline on requirement for revision/renewal of certificates - PA/PH/CEP (04) 2
  COS证书修订/更新规定指南 – PA/PH/CEP (04) 2

- Applicant form: request for new certificate of suitability – ECEP/03; request for revision or renewal of certificate of suitability – ECEP/05
  申请表: 新COS证书申请 – ECEP/03; COS证书修订/更新 – ECEP/05

- Procedure for management of revision/renewals of certificates - PA/PH/Exp. CEP/T904 18
  COS证书修订/更新管理程序 – PA/PH/Exp. CEP/T904 18