European Medicines Agency
Inspections

London, 20 September 2007
SOP-EMEA/INS/GCP/197218/2005

Procedure no.: INS/GCP/3/VI

ANNEX VI

TO PROCEDURE FOR CONDUCTING GCP INSPECTIONS REQUESTED BY THE EMEA:

FILE STRUCTURE AND ARCHIVING OF DOCUMENTS RELATING TO CHMP REQUESTED INSPECTIONS – IN MEMBER STATE AND AT EMEA

GCP Inspectors Working Group

Applies to: EMEA, EU/EEA Inspectorates	
Summary of scope: This procedure describes the content, management and maintenance of inspection files during and after a GCP inspection requested by the EMEA.	
Keywords: GCP Inspection, inspection file, archiving	**Public**
Supersedes: N/A	

Finalisation	**Date**
Adoption by GCP Inspectors Working Group	5 September 2007

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: GCP@emea.eu.int http://www.emea.europa.eu/

1 INTRODUCTION

This procedure applies to all CHMP requested Good Clinical Practice (GCP) inspections.

According to the procedure for co-ordinating GCP Inspections requested by the EMEA (INS/GCP/1), the Reporting Inspector is responsible for the management of the Live Central Archive related to the GCP inspection.

The live central archive (synonym: Central Inspection File) is an organized body of records produced or received by the Reporting Inspector during the performance of the GCP-inspection and is preserved by the Reporting Inspectorate. It contains all correspondence concerning the inspection, documents submitted by the applicant and the documents retrieved and copied during the inspection.

In analogy to the Central Inspection File, the Lead Inspectors participating in the inspection have to open Local Inspection Files. The following remarks apply to the Local Inspection Files as well. Local SOP's according to the management of documents are not affected by this procedure, except where it is more stringent in relation to inspections coordinated by EMEA.

2 MANAGEMENT OF THE INSPECTION FILES

2.1 Responsibilities

The Reporting Inspector (RI) should establish the Central Inspection File for the inspection immediately after appointment as RI. The Lead Inspectors (LIs) should establish the Local Inspection Files immediatetly after appointment. The general layout of these files should be in accordance with the format as described in the appendices to this procedure. All entries in the files should be made or completed at the time each action is taken and should be added in chronological order within the sections of the appendix.

All participating inspectors ensure that all validated copies of relevant data/documents are routed to the Reporting Inspector so that the information can be incorporated into the Central Inspection File and archived properly during the conduct of the inspection.

- Locally collected information (copies of site documents, etc.) is filed into the Local Inspection File(s) according to the procedures of the concerned inspectorates. A copy of all local information that is of a general importance or reflects on the whole of the inspection is sent to the Reporting Inspector to be incorporated into the Central Inspection File, in particular documents which prove conditions, practices or processes that might adversely affect the rights, safety and/or wellbeing of the trial subjects and/or the quality and integrity of data.

2.2 Storage

The Integrated Inspection Report with the attached Inspection Reports has to be forwarded to the EMEA and all concerned Inspectorates (see section 2.2.1 of the procedure for reporting GCP inspections requested the EMEA, INS/GCP/4). The EMEA has the legal ownership of inspection reports once the EMEA has received and accepted the reports. Confidentiality and ownership of the reports is covered by the "Statements of Principle" agreed by the EMEA and the National Competent Authorities and published on the EMEA website (ref. 2).

The Central Inspection File has to be maintained at the Reporting Inspectorate, the Local Inspection Files are preserved by the concerned inspectorates. It is the responsibility of the involved inspectorates to store the Inspection Files under conditions that prevent accidental or premature destruction of the documents according to national requirements.

The inspection files should be stored safely in a suitable archive for the whole retention period. It is strongly recommended that only authorised personnel have access to the archives.

Documents may be stored electronically, onto human readable media or other new media as changes in technology demand. If documents are to be archived using electronical or optical media, the methods for transferring the data to these media should be validated. A suitable backup-strategy must be implemented to prevent loss or destruction of data. There must be a possibility to generate hardcopies throughout the period of retention.

2.3 Confidentiality and security

Each involved authority is responsible for ensuring the correct application of applicable data protection requirements.

On reasonable request of a Member State inspectorate, the EMEA or the Commission, the documentation could be made available for review. Access will not be provided to parties other than the Commission, the EMEA or the Competent Authorities or the duly appointed experts of these parties, unless otherwise is indicated by legislation[1].

- Whenever an authority grants access to the inspection file(s) or parts thereof, this access should be recorded. If copies of documents are required these may be provided, subject to confidentiality, to the parties mentioned above. The parties in receipt of the documents then bear full responsibility for ensuring their continued confidentiality.

2.4 Retention period and destruction

The retention period of the inspection files is determined by national requirements. The inspection files should be preferably maintained for a period at least of 30 years, or for 10 years after the product has been withdrawn from the market, whichever is the longer. After this time, the inspection files could be removed from the archives for destruction. The signature of the person who is responsible for the destruction of the inspection file and the date of the destruction has to be recorded and should be kept in the archives for unlimited time.

[1] Freedom of Information legislation .

Appendix 1: FORMAT OF THE CENTRAL INSPECTION FILE

1. Table of contents

2. Communication

with EMEA Inspections Sector
with Lead Inspector(s) and participating inspectors
with assessors (Rapporteur and Co-rapporteur)
with inspectees
others

3. Trial related documents

Provided by the applicant/sponsor:
- Protocol and amendments
- Investigators Brochure
- Blank patient informed consent forms
- Copies of IEC-approvals
- Copies of the notification of the clinical trial to the competent authority
- Printout of the Clinical Database
- Other

Provided by Rapporteur/Co-rapporteur:
- Clinical Study Report
- Assessment reports
- List of Questions
- Response to the List of Questions
- Other

4. Inspection related documents

Inspection request
Inspection team composition (central and for each selected site)
Contracts
Time Schedule for the inspection
Inspection Plan
Local Inspection Plans
Other

5. Locally collected information of general importance

Documents retrieved or copied during the inspection

6. Inspection Reports

Inspection Reports
- Prepared in English or the local language when required by local regulations
- English translation (if applicable)

Draft of the Integrated Inspection Report (that was sent to the LIs for comments)
Comments of the Lead Inspectors
Integrated Inspection Report (final version)

Appendix 2: FORMAT OF THE LOCAL INSPECTION FILES

1. Table of contents

2. Communication

with EMEA Inspections Sector
with the Reporting Inspector and participating inspectors
with assessors (Rapporteur and Co-rapporteur)
with inspectees
others

3. Trial related documents[2]

Provided by the applicant/sponsor:
- Protocol and amendments
- Investigators Brochure
- Blank patient informed consent forms
- Copies of IEC-approvals
- Copies of the notification of the clinical trial to the competent authority
- Printout of the Clinical Database
- other

Provided by Rapporteur/Co-rapporteur
- Clinical Study Report
- Assessment reports
- List of Questions
- Response to the List of Questions
- other

4. Inspection related documents

Inspection request
Inspection team composition
Contracts
Time Schedule for the inspection
Inspection Plan
Local Inspection Plan
Records and notes made by the inspectors during the inspection
other

5. Documents retrieved/copied during the inspection

6. List of Findings (if applicable)

Critical findings
Major findings
Minor findings
Comments

[2] Multiple copies of documents from the applicant/sponsor may be sent to each member of the inspection team. One copy has to be retained in the Central Inspection File as required by Appendix 1 of this Procedure. Therefore the concerned inspectorates could decide on the destruction or the return of those documents. The destruction or return of documents has to be recorded in the Inspection File.

7. Inspection Reports

Inspection Report(s) (that was/were sent to the inspectee(s) for comments)
Response of the inspectees
Inspection Report (final version)
Inspection Report (English translation, if applicable)
Integrated Inspection Report (final version)

Appendix 3: REFERENCES AND RELATED DOCUMENTS

1. See "Principal documents taken into account for the preparation of procedures for GCP inspections requested by the EMEA"

2. “Statement of principles governing the partnership between the national competent authorities and the European Agency for the Evaluation of Medicinal Products”
(Doc. Ref: EMEA/MB/013/97.final)