OMCL Network of the Council of Europe QUALITY ASSURANCE DOCUMENT

PA/PH/OMCL (07) 105 DEF

ARCHIVING

Full document title and reference	Archiving PA/PH/OMCL (07) 105 DEF
Document type	Guideline
Legislative basis	-
Date of first adoption	April 2001
Date of original entry into force	April 2001
Date of entry into force of revised document	December 2007
Previous titles/other references	This document replaces document PA/PH/OMCL (2000) 54 2R
Custodian Organisation	The present document was elaborated by the OMCL Network/EDQM of the Council of Europe
Concerned Network	GEON

Archiving within the OMCL Network

Guideline for OMCLs

1. INTRODUCTION

A questionnaire on archiving throughout the European Network of Official Medicines Control Laboratories (OMCL) was distributed in 1999 and the outcome was presented and discussed at the Annual QA meeting in Strasbourg, 23-24 June 1999. Since it became obvious that archiving routines needed to be harmonised between the control laboratories within the Network, it was decided that a guideline on archiving within the OMCL Network should be elaborated.

Since the meeting in 1999, the international standard ISO 17025 has been adopted. ISO 17025 is more comprehensive than EN 45001 regarding archiving and therefore the need for a detailed guideline has been reduced. However, retention times of records have to be established and in order to harmonise minimum retention times within the OMCL Network this guideline has been elaborated.

2. OBJECTIVE

The purpose of this guideline is to state recommended retention times of records and samples within the OMCL Network.

The recommended retention times in this guideline are proposed as **minimum times**. The requirements in ISO 17025, national legal requirements and any agreements with the client should be adhered to.

3. SCOPE

The guideline covers studies performed within the OMCL.

4. ARCHIVING OF RECORDS

Records (e.g. method descriptions, standard operating procedures, raw data, results and reports) should be archived for at least five years after the date of the report.

Records from Batch Release activities should be archived in accordance with the EC Administrative Procedure for Official Control Authority Batch Release.

5. ARCHIVING OF SAMPLES

If any samples in unopened primary packaging remain after the analysis, they should be archived until the report and all administrative actions have been finalised.