	Code	Revision Number	Date of entry into force	Page	Of pages
	PR-09-OP	1	1 July 2005	1	4
Quality Management System – Policy and Programme Support Section					
CONTROL OF RECORDS					

1. PURPOSE

To establish a set of rules dealing with documented results.

2. SCOPE

These rules apply to all records as defined in QM documents within OP.

3. RESPONSIBILITIES

Unit Head/Service Group Leader

— To decide how to dispose of technical records when the period of storage has expired.

Author of a procedure

— To identify necessary records
— To propose a record keeper
(nominated through the authorization of the procedure by the Section Head)
— To define how records are stored (optional).
— To collect, file and store the records
— To maintain the legibility of records
— To facilitate access to the records for authorized persons.

Quality Manager

— To decide how to dispose of managerial records when the period of storage has expired.

	Function	Name	Signature and Date
Authorized	Section Head	K. Mrabit	2005/07/28
Approved	Unit Head	Pascal Deboodt	2005.07.27
Approved	Service Group Leader	R. Cruz-Suarez	2005.07.25
Approved	Service Group Leader	John Hunt	2005-06-21
Registered	Quality Manager	J. Zeger	16 June 2005

4. DESCRIPTION

4.1 Identification

Records are the documentation of the results of work done according to a procedure or working instruction of the Quality Management System. Therefore, records have to be defined in the procedure by the author.

Records may be produced by anybody responsible for the work described in a procedure or working instruction. They may be in any medium, also electronic, but they must always be legible.

Handwritten records (e.g. lab logbooks, checklists, forms, graphs, notes, …), must not be easily erasable (e.g. done in pencil).

If records are kept in electronic form, they have to be backed up as described by the pertinent procedure by a removable data storage medium, which shall be stored in a location separate from the room that contains the original data.

4.2 Content

The content of a technical record shall be defined by the accompanying procedure or working instruction and should, as a minimum requirement, include:

title

index number

ID of instrument used to produce the recorded data (if applicable)

data

calibration data and any factor influencing the accuracy of the data (if applicable)

additional information to enable a repetition of the data evaluation process

signature

date.

4.3 Collection

The person responsible for collecting records deriving from a procedure must be stipulated within the procedure. For quality records emerging from managerial procedures, this person is the Quality Manager, who shall receive all records even if they have been created by different “persons in charge of work”, defined in different procedures.

4.4 Indexing

The index is a unique number describing the record. Indexing is done by the person, who has produced the record. It shall be as described by the originating procedure or in the form :

REC / nature / service / consecutive number / year

e.g.	REC / Audit / MAN / 01 / 2000	describing the first audit report in the year 2000
	REC / Reader / TLD / 122 / 2000	describing the 122nd run of reading TLDs in the year 2000

The consecutive numbering shall start at 1 each year for every type of record.

4.5 Filing

Each person nominated as a record keeper through a procedure shall compile a list of existing records, a file. This file itself is another record and shall be treated according to this procedure.

4.6 Storage

All records shall be stored for at least five years if there are no other periods defined in procedures, contracts, the Agency's Statute or legal documents. Records dealing with personal data (external monitoring and internal monitoring results, personal dose records, etc.) according to the BSS have to be kept for longer periods:

> BSS (Records) 1.49.
> *Exposure records for each worker shall be preserved during the worker's working life and afterwards at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving occupational exposure.*

Records must be stored in a way that protects the integrity of the recorded data. The storage location should, preferably, be defined in the respective procedure, or otherwise be made known to all persons who might have to find the record.

Access to records is restricted to technical personnel for all records originating within their laboratory; Service Group Leader; the Unit Head and Section Head; the Quality Manager and their supervisors. All persons having access to records are required not to disclose the contents to any person, firm, corporation or other entity without written authorization of the customer and the Section Head.

4.7 Maintenance

Records have to be kept legible over the entire storage period. The legibility has to be checked at regular intervals depending on the type of storage medium of the record.

For printed records the person then responsible for record keeping and storage through a visual check may do this every three years on a few records. If there are doubts about the continued legibility of the records through the next storage period, they must be recopied, retyped, put on microfilm or scanned into an electronically stored file.

For electronically kept records, the check shall include not only legibility control of the storage medium, but also a test run of the evaluation software used at this time to work on the data. If there are doubts about the continued legibility of the records through the next storage period, they must be copied onto a new storage medium (preferably not an erasable one) or printed.

4.8 Disposal

When the end of the storage period for technical records is reached, the Service Group Leader, who at this point will be responsible for the work that has generated the records, shall decide on the method of disposal. The Quality Manager (after consultation with the Section Head) will make the same decision concerning managerial records.

4.9 Change

In the case of errors in an original record (e.g. wrong numbers copied by hand, inaccurate data entered into a computer, invalid calibration used, ….), this record must be changed. The change shall be made so that the original (wrong) value stays legible. In the case of handwriting, the wrong value must be crossed out and the correct one noted properly. The correction must be dated and signed by the author. Electronically kept records must be copied to another file with the same file name but extended with a version number. The original file shall be renamed by adding version number zero, thus indicating that a change has been made to the stored data. The newly generated file (with the highest version number) may then be edited with the correction and this should contain the valid data.

These changes may only be made by the record keeping technician, the respective supervising Service Group Leader or the Quality Manager. The Service Group Leader shall be informed about a change in a technical record.

5. RECORDS

List of existing records (files) kept by the staff nominated for record keeping in a procedure.