

	<b>Code</b> <b>PR-17-OP</b>	<b>Revision Number</b> <b>1</b>	<b>Date of entry into force</b> <b>1 July 2005</b>	<b>Page</b> <b>1</b>	<b>Of pages</b> <b>4</b>
Quality Management System – Policy and Programme Support Section					
<b>CONTROL OF DATA</b>					

## 1. PURPOSE

To set up a set of rules, governing the way to assure correct data entry, transfer and safe data archiving.

## 2. SCOPE

This procedure applies to all data, which are used to arrive at the service rendered to the customer.

## 3. RESPONSIBILITIES

### Unit Head

— To provide, in the possible ways, funds to enable the purchase of necessary equipment.

### Service Group Leader

- To define in technical procedures, which data are necessary to arrive at the final values reported to the customer.
- To define ways of control for data entry and/or data transmission from a measuring device to an evaluation computer.

### IT Officer

- To counsel on acceptable ways of data security, backup and safe archiving.
- To set up and test computers according to the Agency's rules of safe computing and the necessities of data safety.

### Staff

- To operate the computers according to standard and special safety provisions.
- To inform the IT officer about any operating problems, that may influence data security.

	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	2005-05-24

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s:\quality management\quality management documentation\general technical procedures\ PR-17-  
OP\_Control\_of\_data\_V1.doc

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#### **4. EQUIPMENT**

Magneto Optical disk drives and disks with capacity of 1.2 and 4.6 Gbyte

#### **5. DESCRIPTION**

##### **5.1 General**

Each computer that is used for data entry or collection, data transfer and data evaluation must not be connected to a network outside of the section. If data needs to be transferred to a computer, which is connected to outside networks, especially to the Internet, this has to be done by using removable storage media (diskettes, tapes, CD-ROMs, DVDs, etc.).

##### **5.2 Manual data entry**

Manual data entry into a computer, especially entering of numbers, which will later on be used to derive values reported to the customer, shall be accompanied by some systematic checking of the correctness of entered data. The method for this checking shall be detailed in the applicable technical procedure.

##### **5.3 Automatic data transfer from measurement instruments**

Data transfer from some measurement instrument to a computer, used to evaluate this data, shall be checked for correct operation. The method shall be described in the relevant technical procedure or working instruction (e.g.: multiple transfers of the same set of data into different files and crosschecking the evaluation results on these different data sets by the same software routine).

##### **5.4 Self programmed software**

Every piece of software, that is programmed within PPSS, to be used to arrive at values reported to the customer, shall be extensively tested (validated) and documented. This rule also applies to small pieces of software – like macros or EXCEL-sheets – which may be created semi-automatically. Validation may be performed by crosschecking with manual calculations, with other software or test runs with well-defined standard values.

It is not necessary to validate commercial off-the-shelf software bought through and/or installed by IT personnel.

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### **5.5 Computer configuration**

Generally, software and hardware configuration of a computer is done by the appropriate IT personnel. This also applies to computer hardware and software updates, especially regarding the main operating system of a computer.

It is the responsibility of laboratory technicians, if necessary in collaboration with IT personnel, to critically monitor and/or check the correct functionality of any specialized data transfer or evaluation software after a major change in the computer software spectrum.

Such monitoring would be especially advisable after changes in the basic operating system of a computer, after changes in network programs and whenever a new program is additionally installed to a computer used for automatic data transfer and data evaluation.

### **5.6 Data backup**

Each technical procedure, which describes a measurement method, where data is automatically generated in a computer by transfer from a measurement device and any description of an evaluation method using computers to generate data to be reported to the customer, shall incorporate a statement about the method used to save the generated data (files) to a backup medium. The backup method should include an automatic, documented comparison of the original with the backed up data.

The backup procedure used

- should be as automatic as possible,
- should be able to operate unattended,
- should be put on a preferably daily schedule and
- should use an easy to handle backup medium.

The backup procedure shall also state a storage location for the used backup media. This location should, preferably be in a different fire compartment than the original data.

The time span for keeping backups will be in the monthly range.

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## **5.7 Data archiving**

The whole storage period for records is set generally to ten years and may, in some cases, be extended over this period, typically to 30 years, by external regulations (see BSS).

Archiving media to store recorded data over such long periods have to be carefully selected. This will be the responsibility of the IT-officer of PPSS in close consultation with general IT-staff of the Agency and the Section Head for supplying adequate funds.

At this time, it seems not possible to find a storage medium and its corresponding recording device that will be securely functioning over the whole period of up to 30 years. Therefore the following archiving method is operated as long as technology permits it or a general solution for the Agency will be specified.

The archival backup procedure is operated manually. In the TLD lab all files are backed up daily regardless of whether they have been modified since the last backup or not. Magneto Optical (MO) disks are used for backup. Each computer operating the Dose Management Software (DMS) is equipped with a 1.2 Gigabytes MO drive. Groups of three disks are being used in a way so that no disk will be used again within the next two days. On these disks, full backups consisting of programs and data are stored.

When any one of the disks is full, a new group is prepared for its use and the old one will be labelled, write protected and stored inside a fire-proof safe outside the laboratory.

Another system is being used for the Whole Body counter, Urine Analysis laboratory, Siemens Electronic Personal Dosimeter Computer and Harshaw 6600 TLD Reader Computer. It is based on Magneto Optical disks with 4.6 Gigabytes capacity. On these disks only relevant files are being copied.

## **6. RECORDS**

Records emerging from this procedure are documentations of cross-checks on data entry, validation of data transfer between measuring device and computer, documentation of self-programmed software including the validation and eventually documentations of backup and/or archiving media contents. They are specified in the relevant working instructions together with the record keepers.