	Code	Revision Number	Date of entry into force	Page	Of pages
	PR-15-OP	1	1 July 2005	1	8
Quality Management System – Policy and Programme Support Section					
MEASUREMENT EQUIPMENT AND SOFTWARE					

1. PURPOSE

To ensure that all equipment/software used to produce measurement results that are reported to the customer complies with the pertinent specifications, is calibrated and is properly maintained.

2. SCOPE

This procedure applies to all measuring equipment/software in the Section used to produce results reported to the customer, regardless of where it is used.

3. RESPONSIBILITIES

Unit Head

— To ensure, within the possibilities, financial resources for the procurement of equipment/software.

Service Group Leader

— To select the needed equipment/software (in consultation with the laboratory technician)

— To choose an adequate method and time frame for calibration for each piece of equipment

— To define acceptance criteria for calibration or function checks of equipment

— To evaluate and check equipment calibration data against these criteria.

Laboratory Technician

— To operate equipment/software according to authorized manuals

— To perform necessary and manageable equipment calibration and maintenance

— To report any (suspected) malfunction, damage, adjustment or repair of equipment/software to the Service Group Leader

— To keep all equipment related records (check of compliance with specification, calibration results, maintenance and repair reports)

— to support the Service Group Leader on purchase and disposal of equipment

	Function	Name	Signature and Date
Authorized	Section Head	K. Mrabit	2005/07/22
Approved	Unit Head	Pascal Deboodt	2005.07.27
Approved	Service Group Leader	R. Cruz-Suarez	2005.07.25
Approved	Service Group Leader	John Hunt	JH 2005-07-01
Registered	Quality Manager	J. Zeger	21 June 2005

Health Physics Technician (for equipment stationed in Seibersdorf) and
Data Clerk (for equipment stationed in VIC)

- to perform inventory of OP section equipment,
- to keep track on loaned equipment,
- to update database records on equipment

Quality Manager

- to maintain a compiled list of measurement equipment / software used within the testing laboratory to create results reported to the customer.

4. ADDITIONAL INFORMATION

ISO17025	General requirements for the competence of testing and calibration laboratories
EAL-G19	Calibration and maintenance of measuring and test equipment in testing laboratories
EAL-G12	Traceability of measuring and test equipment to national standards
WI-33-IC-06	Incoming equipment test, data entry in the equipment database
WI-33-IC-07	Equipment database maintenance and data verification
WI-33-IC-08	Disposal of PPS section equipment
WI-33-IC-09	Inventory of PPS Section Equipment
WI-33-IC-13	Loan and return of IAEA equipment located at PPS Section

5. DESCRIPTION

5.1 PROCUREMENT

Measuring equipment/software producing values to be reported to the customer shall be procured according to the specifications set for the accuracy, sensitivity and robustness of the measurement method.

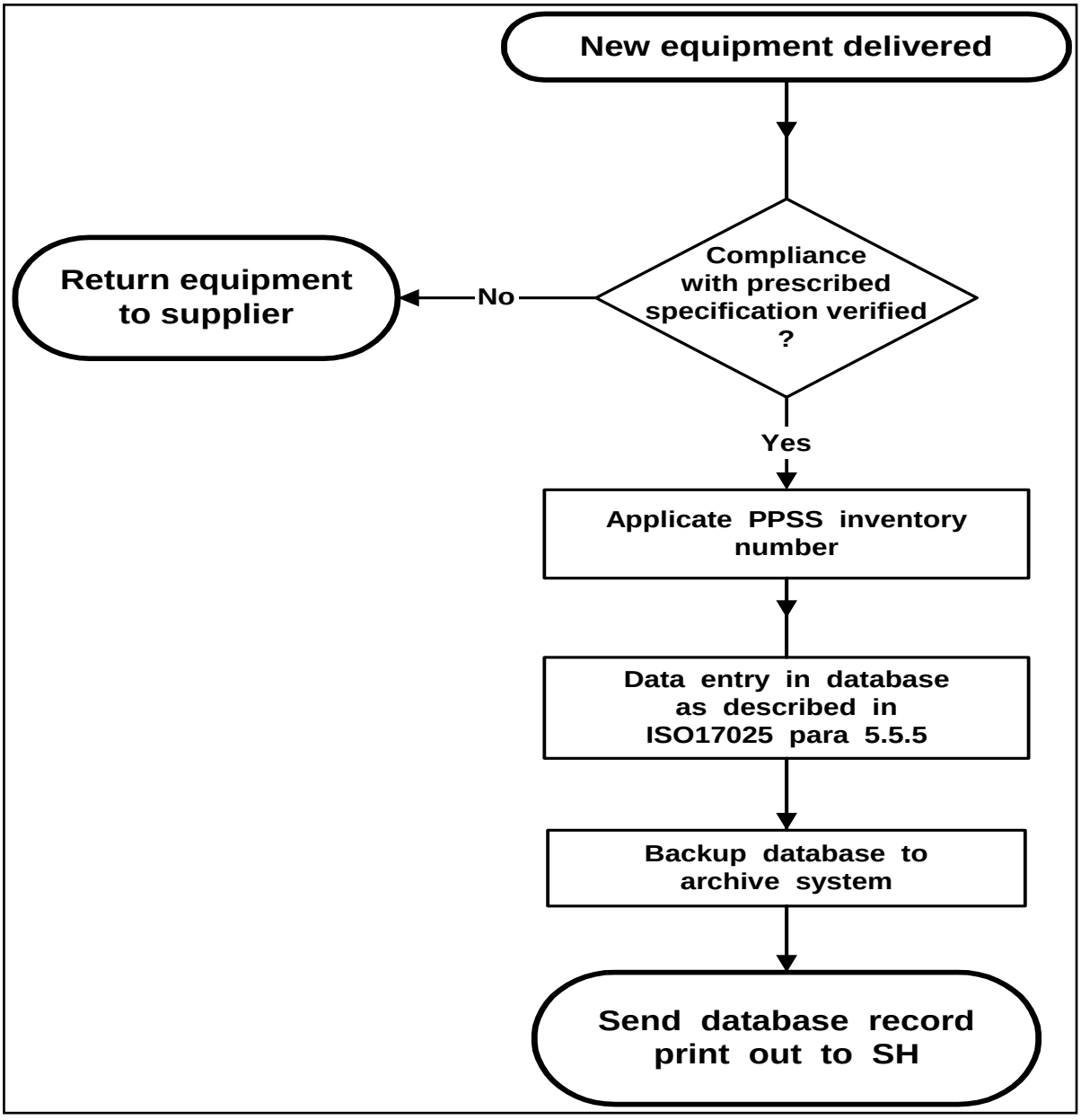
These specifications shall be elaborated by the Service Group Leader. It is advisable to invite the cooperation of the laboratory technician who will operate the equipment and, if the need arises, of the Quality Manager. The actual procurement process shall follow the guidelines laid down in procedure PR-04-OP (“Purchasing”).

Acceptance of measuring equipment/software into service shall be based on verification of compliance with the prescribed specifications. Upon acceptance of a new measurement device, the Quality Manager must be informed, and information on the new equipment shall be added to the database of all equipment/software according to flowchart 1.

Necessary data shall be supplied by the Service Group Leader:

— identification of equipment/software, with any unique identifier (e.g. serial number)
— name of calibration procedure
— name of maintenance plan.

Flowchart 1: Entering new equipment into service



5.2 CALIBRATION

Measuring equipment, producing values to be reported to the customer, must be calibrated before use.

The Service Group Leader, in collaboration with the laboratory technician must provide an adequate procedure for calibration, a time schedule and acceptance values. This can be done by authorizing the equipment manufacturer's instructions, set out in a manual.

Every calibration shall be performed according to this procedure and shall be adequately recorded. The calibration results must be checked against the acceptance values stated by the Service Group Leader. If this check is negative, adequate measures must be taken (apply PR-08-OP "Corrective and preventive actions", keeping the impact of the problem and the possible costs in mind).

Results of the calibration process are quality records, which have to be kept by the laboratory technician in charge.

5.3 MAINTENANCE, ADJUSTMENTS, REPAIR

All measuring equipment/software, regardless of the point of use, must be kept in working order. If the Service Group Leader sees a necessity, a maintenance/update plan must be put in place. This plan shall state all necessary work, the time schedule, applicable working procedures and the person responsible for the maintenance/update work. Work done, according to this plan, shall be recorded by the laboratory technician responsible for the measuring equipment.

Adjustments to the settings of measuring instruments should only be made during maintenance or repair and must always be followed by calibration of the equipment. The adjusted and verified (by the calibration) settings shall be recorded in an equipment logfile kept by the laboratory technician responsible for the measuring equipment.

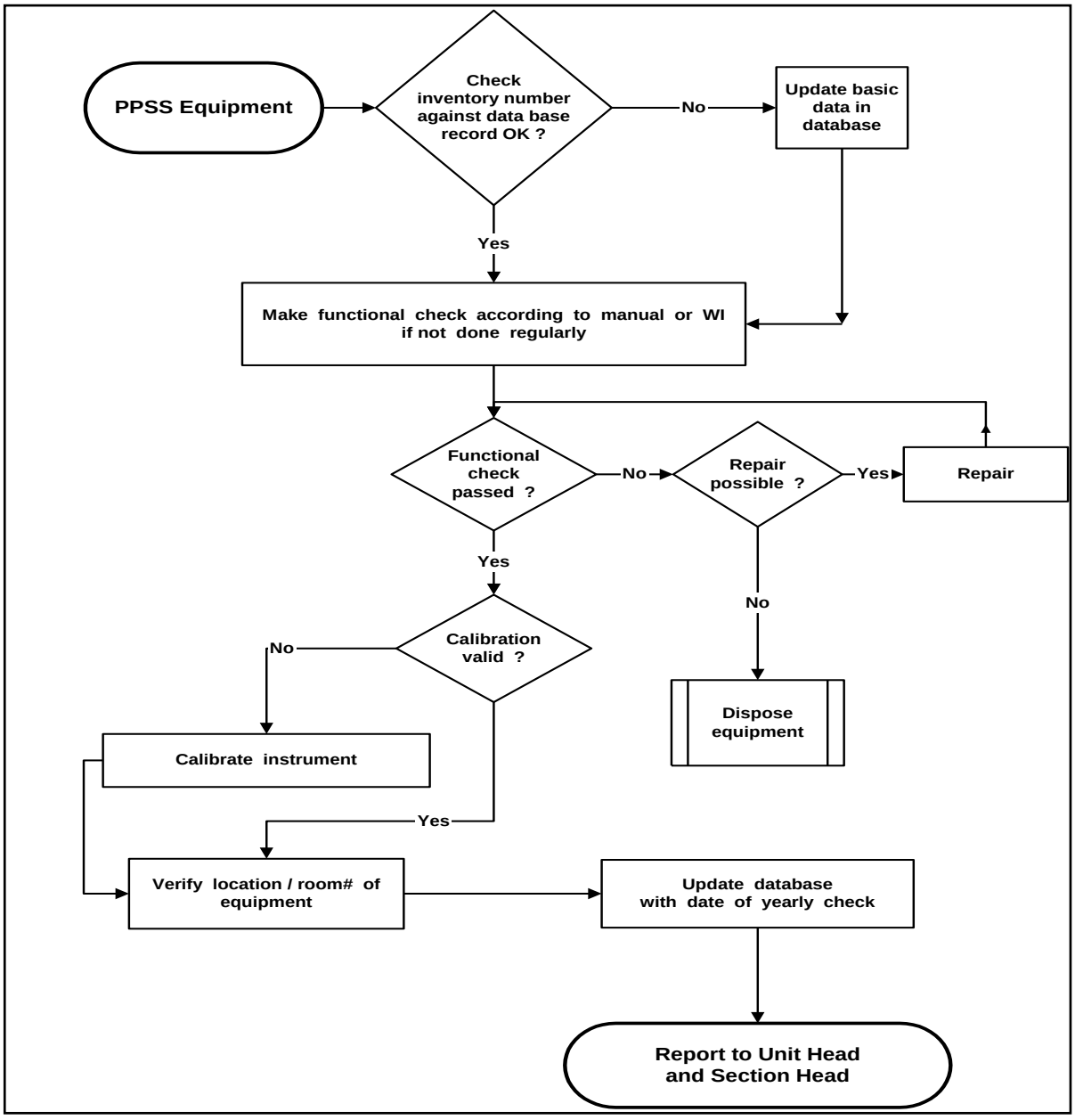
Repairs to measuring equipment may be necessary to restore it to working condition and may be performed in house or outside. In both cases, the repaired instrument must be treated as newly purchased and submitted to a compliance test according to the stated measuring conditions. Equipment may only be put into service again if this test is passed. The result of this test shall be recorded in the equipment logfile kept by the laboratory technician responsible for the measuring equipment.

There are two responsible persons controlling the administration of equipment. The HP technician is in Seibersdorf laboratories, and the Data Clerk is in Headquarters. They are responsible for the yearly equipment inventory, loan of equipment, necessary supplies for the equipment and disposal routine.

5.4 YEARLY INVENTORY OF EQUIPMENT

Inventory of RMPS section equipment is made once per year according to flowchart 2. The purpose of this inventory is to verify missing items, changing of equipment location, make functional checks and control date of calibration. Survey on equipment includes check of Agency's number and serial number to prove that they were not modified.

Flowchart 2 Equipment data base maintenance on yearly basis



For measurement equipment the functional check shall be performed according to the instrument manual or a specific WI. The instrument shall be calibrated if needed. HP technician keeps the record on equipment status.

Outcome of the inventory is reported to the Quality Manager, the Unit Head and to the Section Head by the health physics technician. Broken, outloaned and missing items have to be included in this report.

5.5 EQUIPMENT/SOFTWARE MALFUNCTION

Whoever observes equipment/software malfunction or has good cause to suspect incorrect functioning of measuring instruments shall inform the laboratory technician and/or the Service Group Leader responsible for this device.

The laboratory technician shall test the equipment/software and, if malfunction is confirmed, inform the Service Group Leader. The measuring device must be taken out of service and marked as malfunctioning. No further measurements may be made with this instrument until the problem is solved.

If malfunction is confirmed, the Service Group Leader shall start a corrective action procedure (keeping the impact of the problem and the possible costs in mind) for this equipment/software. The Quality Manager shall be informed of this action by the Service Group Leader.

This procedure shall be used to try to find the type of malfunctioning, the probable cause and a way to correct it.

Additionally, the Service Group Leader shall evaluate all measurements made with the currently malfunctioning equipment/software since the start of its malfunction or, if that time is not known, since the last positive calibration to their correctness. The Service Group Leader shall inform any equipment/software users from outside the Section about the malfunction, in case this should have a negative influence on their measurement results.

The results of the initiated corrective action procedure shall be recorded in the equipment logfile kept by the laboratory technician responsible for the measuring equipment.

5.6 DISPOSAL OF EQUIPMENT

The equipment that is going to be written off from OP inventory and disposed should meet the following criteria:

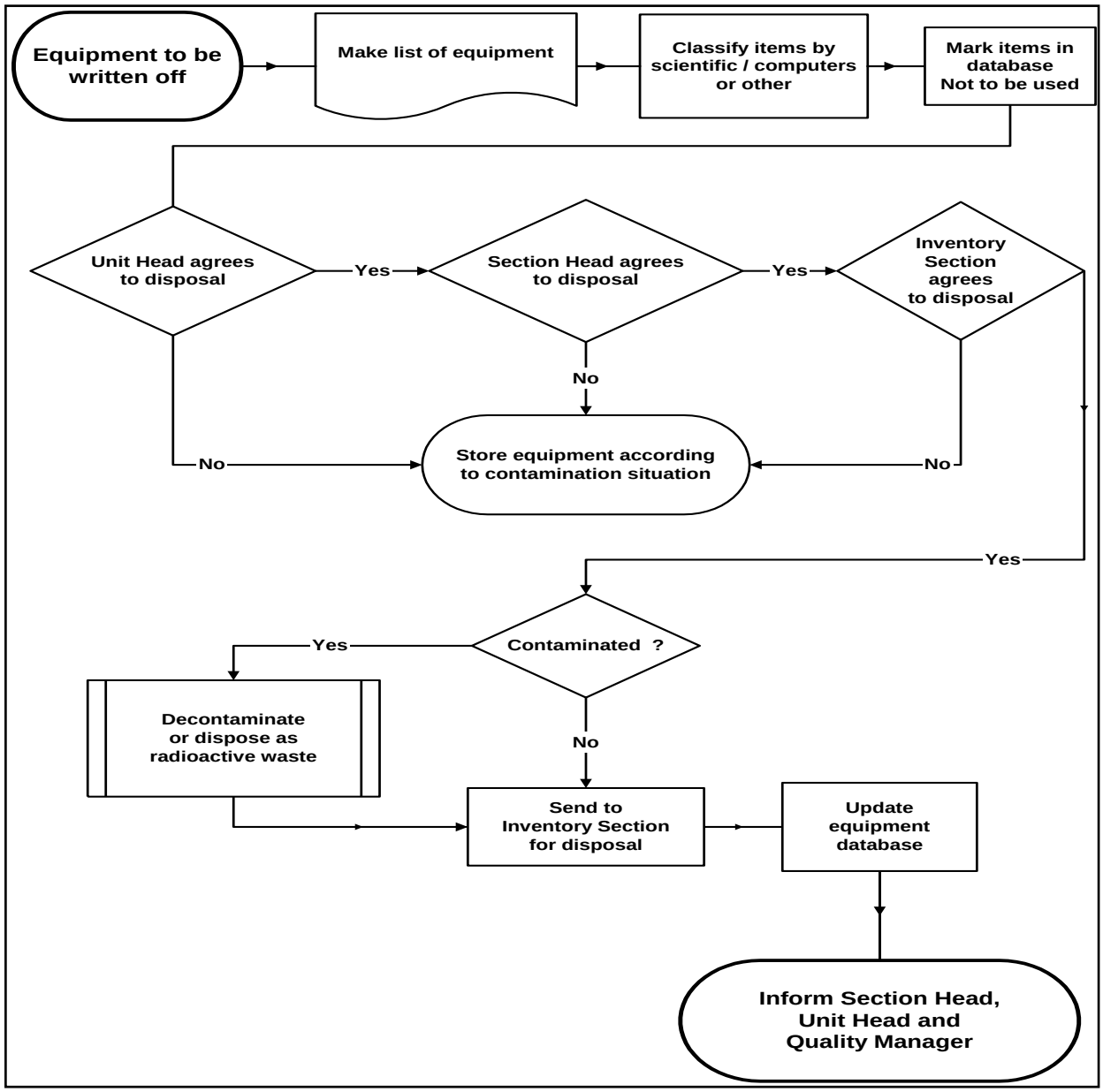
— Physically old, damaged or corroded;
— Contaminated with irremovable contaminations;
— Instrument is impossible to repair;
— Cost of repair is more then cost of new instrument;
— Instrument does not meet requirements for the given type of instruments;
— Instrument could not be calibrated.

The responsible person shall prepare a list of equipment classified by Scientific / Computers / Other and get the approval of the Unit Head for the write off.

After agreement by Unit Head, the Section Head authorization shall be obtained. Then a list of the items is sent to Inventory Section for agreement. If Inventory Section agrees to dispose the equipment, equipment used in Owned Laboratories and by Safeguards must undergo a contamination check (according to flowchart 3). If it passes this it should be sent to Headquarters to the General Services Division for disposal.

The disposed equipment records are printed in separate report and deleted from database. This report is kept by the disposing technician.

Flowchart 3 Disposal of equipment



6. RECORDS

This procedure requires records of:

- specifications for the equipment/software used for procurement and compliance test
- documentation of compliance test performed upon delivery of measurement equipment
- entering of equipment specific data into the general data base
- calibration results
- maintenance plan and any documentation of maintenance done
- performed adjustments or repairs and accompanying calibration report
- corrective action taken
- evaluation of correctness of measurements performed with a possibly malfunctioning instrument.
- performed yearly inventory of equipment
- disposal of equipment

The above records shall be kept in the equipment's specific file or folder within the laboratory by the laboratory technician responsible for the measuring equipment/software.

Records of performed yearly inventory and of disposal shall be kept by the two nominated technicians in Seibersdorf and in Headquarters.

For every measurement equipment there shall be a procedure or working instruction for calibration together with acceptance values. This shall be recorded by the Quality Manager on information by the Service Group Leader.