ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP-3.1

STANDARD OPERATING PROCEDURE FOR EQUIPMENT SELECTION, IDENTIFICATION AND VALIDATION

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1. ACRONYMS AND DEFINITION

RCDC	Royal Center for Disease Control
QMS	Quality Management System
WHO	World Health Organization

2. PURPOSE

To ensure the equipment is properly selected, installed, validated and maintained disposed off according to established procedures or manufacturer's instructions. To ensure the selection of equipment that complies with all regulatory and statutory requirements (*including CE Marking*, etc.).

3. APPLICATION

ThisSOP is applicable strictly to laboratory equipment selection of RCDC.

4. RESPONSIBILITIES

It is the responsibility of each lab personnel at RCDC to follows strictlyequipment selection criteria during equipment procurement.

5. ASSOCIATED DOCUMENTS

- Inventory or stock register
- QC form
- Equipment identification form

6. PRECAUTIONS

Prior to equipment selection check the current stock, necessity and urgency of equipment, check the price of equipment before selection.

7. PROCEDURE

7.1 Equipment selection

7.1.1 Selection of equipments for the laboratory is important part of equipment management. Factors that affect selection of equipmentinclude:

- Specification
- Maintenance (Availability of spares and servicing)
- Environmental issues
- Operation & maintenance manuals
- Cost

Therefore, RCDC in line with Medical Supply and Procurement Division (MSPD)tender listwill evaluate the equipment selection based on following criteria:

- value for money
- end user's past experience with justification
- specification
- availability
- in-country distribution
- registration of the supplier
- post-delivery support

7.1.2 He/she from respective section is responsible focal person (TWGP member and section incharge) for equipment selection.

7.1.3 Review specifications of all the equipments and prepare final agreed lists of the indents before onward submission to DoMSHI.

7.1.4 Verify all the indented items, in order to ensure there is no duplication and right quantity is indented in your respective section.

7.1.5 Lead the discussion in your respective section on annual indent list, check the current items and list down the needy ones (see Figure 1).

7.2 Quality Assurance (QA) Inspection of the equipment

7.2.1 At least two member of TWG will visit to MSD, Phuntsholing if required to inspect the quality assurance of the indented items.

7.2.2 Make sure you carry your final signed annual indent list document with you during visit.

7.2.3 Check three most important things i.e. whether it is the right item, right specification and right quantity of the item.

7.2.4 Once QA inspection is over, make sure you receive the right item to RCDC.

7.2.5 If QA inspection is done in RCDC follow the same principle of three most important things and same person will be responsible to send back the QC forms to MSD on time.

7.2.6 After QI, send the QI report to the TWG leader

7.3 Equipment Identification

All compounding and storage containers, processing lines and major equipment used during production of a batch of drug product shall be properly identified at all times to indicate their content.

7.3.1 Identify major equipment by distinctive identification number or code such as serial #, model #, equipment #, etc.

7.3.2 Segregate into batches to show the specific equipment used in the manufacture of each batch of drug product.

7.4 Equipment Validation (function checks)

If the equipment and associated techniques are new, validation processes will be important. In order to verify that equipment is working according to the manufacturer's specifications, it is necessary to monitor instrument parameters by performing periodic function checks. This should be done before using the instrument initially, then with the frequency recommended by the manufacturer.These function checks should also be done following any instrument repairs. Some examples of function checks are daily monitoring of temperatures and checking the accuracy of wavelength calibration.

7.4.1 Perform validation test by running samples in parallel, using both old and new equipment and methods for a period of time to determine that the expected results can be obtained.

7.4.2 These validation procedures should be completely recorded.

7.4.3 A reception checklist to verify that the appropriate model is received as ordered, and that the equipment is functioning correctly and achieving performance requirements.

7.4.4 A laboratory that has a quality management system in place must also perform acceptance testing on donated equipment.

7.4.5 If the equipment doesn't comply with the specifications of the laboratory, the laboratory should not accept the equipment as it will not be able to assure quality results with that equipment.

7.4.6 Appoint staff member responsible for the piece of equipment and authorizing staff members to use the piece of equipment (task of the laboratory manager).

7.4.7 Instruction of these staff members on their tasks and responsibilities (task of the Equipment Officer).

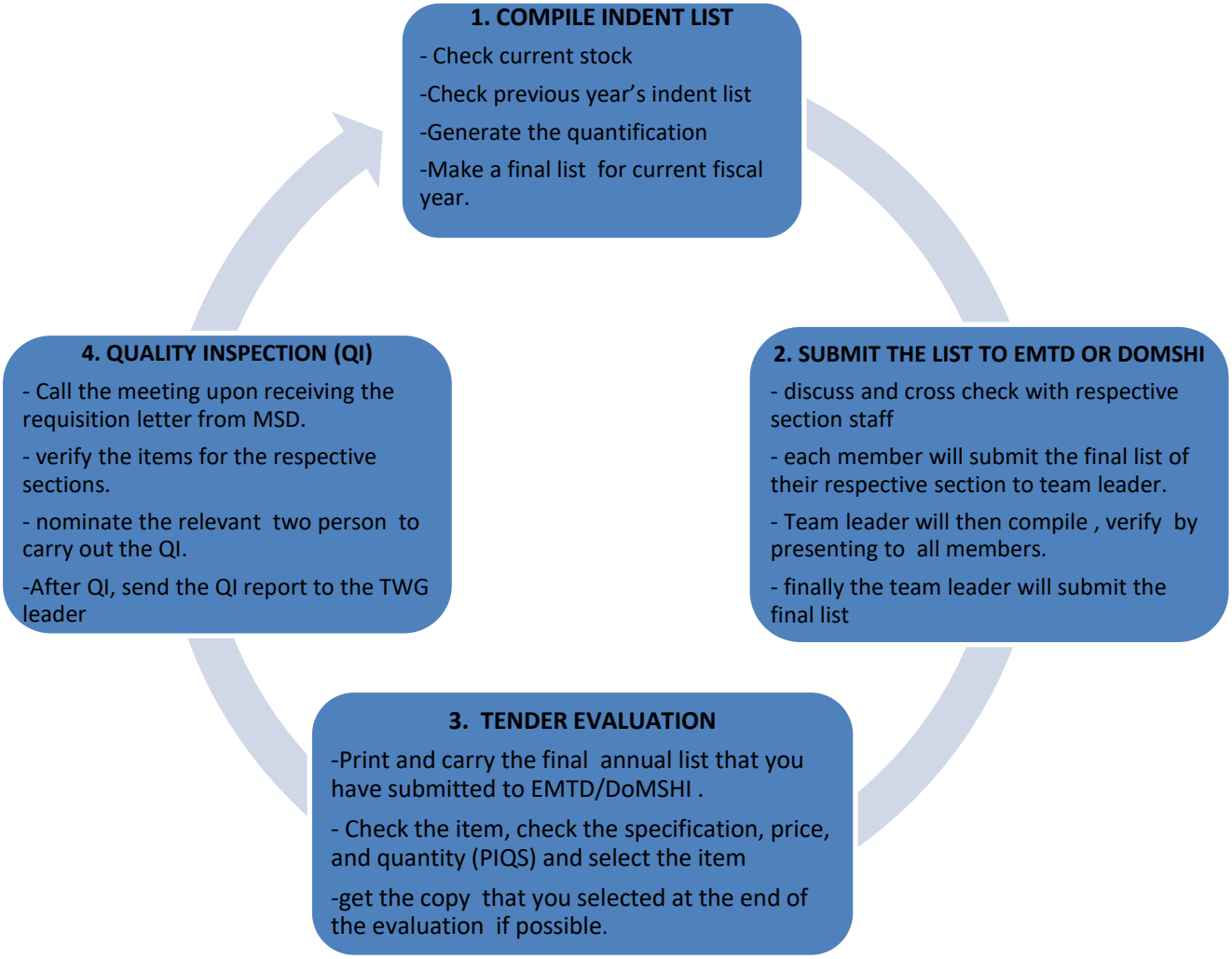

Figure 1: Flow chart of procurement cycle for Technical Working group

13. REFERENCE

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