Medicines Control Authority of Zimbabwe

QUALITY UNIT

TITLE: Standard Operating Procedure for Handling Of Test Items			
SOP Number: TR 5.8	**Revision Number** 8		Page **1** of **5**
Date Issued for training: 30/07/2021	**Effective Date**: 13/08/2021		**Review Date: 08/2023**
Reviewed by:	M Mutasa ..... Name	..... Signature	29/07/2021 ..... Date
Approved by HoU/HoD:	C Kanjere ..... Name	..... Signature	29/07/2021 ..... Date
Authorised for use by: (Quality Manager)	A Chikowore ..... Name	..... Signature	13/08/2021 ..... Date

1.0 PURPOSE

To establish a procedure to be followed when handling test items.

2.0 SCOPE

Applies to all samples received by MCAZ.

3.0 FREQUENCY

All the time when handling test items.

4.0 LOCATION

4.1 The master copy of this procedure is kept in QM's office.
4.2 Controlled copies are issued to Director-General. Heads of Divisions (HoDs), Heads of Units (HoU) and unit staff.

5.0 DEFINITIONS

5.1 Sample management involves receipt, handling, protection, storage, retention and disposal of test items.
5.2 Disposal of samples: any process that involves the permanent removal of samples from the MCAZ sample storage room for reasons that may include destruction or return to customer.
5.3 Dangerous Drug: any drug derived from opium or opium like compounds with potent analgesic effects associated with both significant alteration of mood and behaviour and with potential for dependence and tolerance.

6.0 RESPONSIBILITY

6.1 Samples Officer (SO) is an officer assigned the responsibility of Sample management in the respective Unit/Division.
6.2 Sample Repository Officer (SRO) shall be responsible for sample management.
6.3 Procurement and Administration Unit shall be responsible for facilitating the disposal of expired samples.
6.4 The Director-General shall be responsible for approving samples destruction documentation.

7.0 PROCEDURE

7.1 **Receipt and storage of Samples**

7.1.1 All samples received at MCAZ shall be submitted to the Sample Repository Office.
7.1.2 All samples shall be visual inspected to ensure all requirements are met before acceptance. Samples not meeting requirements shall be rejected.
7.1.3 Deviations for samples received for analysis shall be recorded.
7.1.4 Records of consultations with the customer shall be maintained. A disclaimer shall be indicated on the report indicating that the results may be affected by the deviation.
7.1.5 All accepted samples shall be allocated a unique identification by the SRO which shall be used during the life cycle of the sample at MCAZ.
7.1.6 The Sample Repository Office shall maintain a register of all received samples.
7.1.7 Samples shall be stored at appropriate environmental conditions to avoid deterioration, contamination and damage.
7.1.8 The Sample Repository Office shall forward the samples to the respective Unit/Division.
7.1.9 All dangerous drugs shall be stored under lock and key separated from the rest of the samples.
7.1.10 All Units/Divisions shall ensure that the integrity of samples under their custody is protected.
7.1.11 Entry to all sample rooms shall be restricted to authorised personnel
7.1.12 The samples shall be handled as per SOP (SRO 01) for Receipt, forwarding and Samples Repository Office.

7.2 **Retention of samples**

7.2.1 After analysis remaining samples are stored in the Retention Sample Room/Sample Room 2. The retention period is as per the Samples Retention Policy.
7.2.2 Stock take of all analysed samples is conducted and all expired samples are removed for disposal by incineration according to SOP SRO 03.
7.2.3 MCAZ does not retain medical devices samples.

7.3 Disposal of Samples

7.3.1 A list of all samples to be disposed shall be compiled using form SR04. The list shall be approved by the Director –General.

7.3.2 A copy of the approved form is forwarded to the Procurement and Administration Unit who shall engage external service providers in charge of incineration.

7.3.3 Samples are destroyed under the supervision of the SRO.

7.3.4 Disposal of medical devices samples is handled according to SOP MDMT 021

8.0 APPENDICES/ATTACHMENTS

N/A

9.0 RECORDS

Document Number	Title of Record	Retention Period
N/A	All Units/Divisional files	5 years

10.0 REFERENCES

10.1 MCAZ Laboratory Quality Policy Manual

10.2 SAZS ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories.

10.3 ISO 9001:2015 Quality Management System Standard

10.4 WHO Good Practices for Pharmaceutical Quality Control Laboratories

10.5 SOP MR 4.0 Writing Standard Operating Procedure

10.6 SOP MR 4.13 Control of Records

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
1	January 2008	System Improvement
2	January 2010	System Improvement
3	October 2012	Rolling review Description of changes Section 8.0: Deleted "ATTACHMENT"

Reviewed by:	Approved by HoU/HoD	Authorised for use by QM:
Date:29/07/21	Date:29/07/21	Date:13/08/2021

		Section 9.0: Deleted the "Location Column" from the records table Section 11.0: Deleted the "File Number, Copy Number and Location" columns from the History table. Deleted the title "Location of Document Amendment" from the History table and replaced with "Reason for Change"
4	September 2014	Procedure changed to capture recommendations after SANAS/SADCAS Document Review Audit. Section 7.0 Added sub-sections: 7.3 Retention of samples 7.4 Disposal of sample
5	January 2015	Rolling Review Description of changes Changed the logo to the new MCAZ logo
6	February 2017	Rolling Review
7	January 2019	Rolling review and system improvement Description of change **Section 5.1** "Samples Officer (SO)" **replaced with** "Sample management" **Section 5.2** "Sample Repository Officer (SRO)" **replaced with** "Disposal of samples" **Section 5.3** "Disposal of medicines" **replaced with** "Dangerous Drug" **Section 6.0** To explain roles of Sample Repository Officer and Samples officer and to include responsibility of Procurement and Administration Unit and Director-General. **Section 7.1** "Receipt of Samples for Laboratory Testing **replaced with** "Receipt and storage of Samples " **Section 7.1.1** up to **7.1.12 (New)** **Section 7.2 "**Receipt of Samples for Medical Devices**" deleted** now "Retention of samples**"** **Section 7.3 1** "After analysis remaining samples are temporarily stored in the SRO before being transferred to the EVR sample room for storage (Retention period is as per the Samples Retention Policy)" to **7.2.1** "After analysis remaining samples are stored in the Retention Sample Room/Sample

		Room 2. The retention period is as per the Samples Retention Policy." **Section 7.3.2** "according to SOP SRO 03." **Added** **Section 7.3.3 (New)** **Section 7.4 now 7.3** **Section 7.4.1** All samples to be disposed of are compiled on a disposal form SR 04, which is approved by the Director – General. **to 7.3.1** "A list of all samples to be disposed shall be compiled using form SR04. The list shall be approved by the Director –General." **Section 7.4.2** "A copy of the approved form is forwarded to the maintenance officer who in turn arranges with incineration contractors to dispose the medicines" **to 7.3.2** "A copy of the approved form is forwarded to the Procurement and Administration Unit who shall engage external service providers in charge of incineration." **Section 7.4.3** "Samples are destroyed under the supervision of an inspector and/ the SRO – refer to SOP SRO 03" to **7.3.3** "Samples are destroyed under the supervision of the SRO."