**Handout 2: Excerpts from a Management of Records Procedure1-16**

The following excerpts are from an ISO15189:2012 accredited laboratory procedure.

1. **Procedure**

**5.1 Create Forms**

*Responsible staff: Document authors*

* + 1. Create a form to capture data generated from performing a procedure. Every form must have a governing procedure, which when filled becomes a record that demonstrates compliance to that procedure.
		2. Assign each form a descriptive title, a unique code and revision status. The code of the form must be derived from the parent procedure with ‘F’ replacing ‘P’ and a numerical suffix to denote the form number.

**5.1.3** Approval of the parent procedure extends to all its associated forms.

**5.2 Create Records**

*Responsible staff: Head of Section, Testing personnel*

**5.2.1** Complete appropriate forms legibly with indelible ink to generate records after performing a procedure. Alternatively, complete the forms electronically.

**5.2.2** Where wrong entries are made, neatly make a single-line strike through with indelible ink, writing the correct information alongside, and initialing and dating each correction. Do not use tippex or erasers. Initials and signatures of all members of staff are recorded on the employee initials and signature form *(QUA-005F1)*

**5.2.3** If wrong entries are made electronically, invalidate the entries and enter correct ones.

* 1. **File Records**

*Responsible staff: Head of Section, Testing Personnel*

* + 1. Label the file to clearly identify the records filed, the date the file was opened as well as the file index.
			1. Index all administrative files as ADM/-----
			2. Index all quality files as QMS/------
			3. Index all safety files as SAF/----
			4. Index all sections files starting with section name/----
		2. File the records according to the date of creation with the latest one on top.

**5.3.3** Store running files in an access controlled area free from potential causes of damage like rain, water, fire, and insects such as termites.

**5.3.4** When the file is full, close the file and indicate closure date on file label.

**5.4 Store Closed Files**

*Responsible staff: Head of Section*

**5.4.1** Store closed files in an access controlled area free from potential causes of damage mentioned in 5.3.3 above.

**5.4.2** Store files in clearly labeled filing cabinets or shelves for easy retrieval.

**5.4.3** Records stored electronically, store on a secure media and an offside location.

**5.5 Destroy Obsolete Documents**

*Responsible staff: Quality manager*

**5.5.1** Destroy records that have exceeded their minimum retention time as indicated on the record retention register (Form QUA-005F2) by shredding or burning.

**5.5.1.1** When burning is the method of choice, collect obsolete documents to be burnt in black domestic plastic bags and keep them in a safe location.

**5.5.1.2** Hand over the bags to waste collection staff on the day of incineration and accompany them to the incinerator to witness the burning.

**5.5.2** Record destroyed documents in the destroyed obsolete records register (Form QUA 002F3).

1. **Appendices**

**8.1** Records retention register *(Form QUA-005F2)*

**8.2** Employee initials and signature form *(Form QUA-005F1)*

**8.3** Destroyed obsolete records register (*Form QUA- 002F3).*

**8.4** Document Training Log *(Form QUA-006F4*).