Appropriate handwriting paper record manner

Refer WHO Guidance, PIC/S Guideline

1. Standard Operating Procedure（SOP)

(1) Both of handwriting and digital data shall be satisfied requirements of data integrity.

Through the data life cycle period, handwriting data shall maintain attributable, legible, contemporaneous, original, accurate, complete, indelible/durable and available, (ALCOA+). SOP(Standard Operating Procedure) to realize above requirements shall be created.

(2) SOP to overview appropriate documentation and document management shall be prepared in quality management system. These procedures shall include as below.

a. Creation, reviewing and approval of documents and procedure.
b. Creation, distribution and management of blank formats (masters, logs, etc.) to use to record data.
c. Records retrieval and disaster recovery processes.
d. Operator/recorder identification method, data entry format, record of corrections and periodic reviews for accuracy, reliability and completeness shall be defined and completed handwriting paper record.

(3) Stipulate below items in SOP, be complied, be recorded and be reviewed.

(4) The operation and management of handwriting paper documents are complicated, so it is important to educate the person in charge on SOP.

2. Basics of recording

(1) Requirements for ink

a. For paper records, the ink should be indelible.
b. No use of pencil or erasures, erasable objects, or erasable ballpoint pens.

(2) Record change

a. Use of single-line cross-outs (to read the original description) and record changes with name, date and reason. To be recorded these to record set (i.e. the paper equivalent to the audit trail)
b. No use of opaque correction fluid or otherwise obscuring the record

(3) Recording paper requirements

a. Create a dedicated blank form for the records. It must be properly designed so that the blank form/document on which the activity is recorded meets all requirements and has sufficient space to fill in.

Manage and publish sequentially numbered pages.

Have a unique identity (including version number).

Controlled issuance of sequentially numbered copies of blank forms (i.e. that allow all issued forms to be accounted for)

Must be checked, approved, signed and dated. And there is an entry for it.

Controlled issuance of bound, notebooks with sequentially numbered pages (i.e. that allow detection of missing or skipped pages)

Provide enough space in the blank form to write all necessary data.

b. Issuance of blank form/document

Issuance management must be managed thoroughly and avoided unnecessary printing.

Assign the desiccated person to issue, and the personnel of testing can not be allowed to issue or copy.

Make it clear to record the detail of who and when copied.

Apply clear method to distinguish authorized copy(e.g. using stamps, color coding on paper not in the work area, or other appropriate system)

Version control is required and manage no use old version or to utilize it illegally.

(4) Record manner requirements

a. Original data must be recorded on official controlled document (Lab-note, batch record, report format) at the same time and place to be generated or observed any activity.

b. The hand writing record shall be created by the person who conducts it.

c. Any unused blank spaces in the document should be voided (e.g., strike-through lines), dated, and signed.

d. Handwritten entries should be in clear, legible.

c. It is unacceptable to record data first in unofficial documentation (e.g. on a scrap of paper) and later transfer the data to official documentation (e.g. the laboratory notebook).

d. Some paper output from the system, such as thermal paper, will fade over time. These records should be signed and dated indelible true copies and kept.

3. Signature and date/time are important to provide attribution to data in paper records.

(1) Signatures can be of the following types

a. Basis is complete handwritten signature.

b. Filling in initials (defined in the procedure for use)

c. The use of personal seals is discouraged generally, but if used, they should be kept and controlled to be used by the person only. (The date must be handwritten to be recognized as the principal).

(2) Write the date by hand. If the activity is time-related, also write the time.

a. The activity is recorded on paper, accompanied by the date of the activity (and time as well, if time sensitive).

It is unacceptable to go back or accelerate the time of record.

The date/time to be recorded shall be actual data input date/time.

b. Use as much as possible the paper outputs, etc., of measuring instruments that record time.

It should be a time source that cannot be changed by unauthorized personnel.

In this case only a paper record will be kept, so it is important that the signature and date/time be handwritten.

c. Clocks at the test site and clocks of the equipment should be time aligned by using the time provided by the National Institute of Information and Communications Technology (NICT) in Japan Standard Time.

4. Record archives

(1) Safe and managed paper archive

a. Records must be retained throughout the retention period. Retained Data and document should ensure to be protected from intentional or inadvertent change or loss.

b. The area where data are stored must be locked and access control (e.g., the ability to capture who enters and exits).

c. Keep a record of documents taken out from the storing area, as stipulated in the SOP.

(2) Access to the archived data

a. Data management is performed by the personnel of quality assurance management that is independent from business unit and he is given access privilege.

b. The access to archived data is defined in SOP.

c. The personnel who has interest can't access to the archived data.

(3) Retrieval of archived data

Index that can be retrieved is needed.

Data shall be managed to be able to retrieve the required data, and periodical test is necessary to confirm it is achieved.

5. Review and approval of original data

Includes the initial or source capture of data or information and all subsequent data necessary to fully reconstruct the implementation of the activity.

(1) Original data requirements

a. Original data shall be reviewed.

b. The verified true copy must be retained to keep contents and meanings.

c. Original data must be complete, persistent, and easily retrievable and readable throughout the retention period of the record.

It is necessary for original data to be indelible/durable, easily retrievable and readable.

(2) Review and approval by the person in charge

a. The person in charge conducts appropriate review and approval of original paper records

The review must be performed on a test-by-test basis.

The review should be performed by a person in charge or an approver different from the person who conducts the test. (Double check)

b. Specific elements to check when reviewing records

Reviewers are expected to verify all entries, critical calculations, and make appropriate assessments of the reliability of test results in accordance with the principles of data integrity.

c. Person in charge shall evaluate the data changes to original paper record and investigates as required.

Confirm these changes are documented properly.

Confirm that it is justified by empirical evidence.

d. Documentation of data review by the person in charge

It is indicated by signing the reviewed paper record.

If record approval is a separate process, it must be signed as well as reviewed.

(3) Review by quality assurance manager

a. Review as part of self-inspection by sampling or targeting.

Implement review on a planned and regular basis.

Confirm review by the person in charge is complied to SOP.

Verify the final data can be reconstructed from the primary data.

Check for temporal discrepancies, unauthorized modifications, and deletion of data.

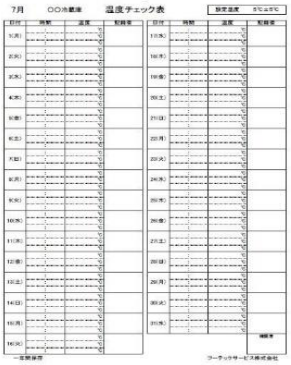
b. Documentation the result of review

6. Example of paper records

(1) Temperature record

a. Temperature recorder


If a paper-based recorder is used, after checking the time consistency, the date, time, and signature should be entered and this paper record should be archived as the original data.



b. Temperature logging table

When a new temperature logging table is created, it can be made appropriate for each measurement condition, such as the conditioning room (thermostatic chamber), test site, and fender body.

(2) Time management of aging test

In the accelerated aging test of JIS K 6257, temperature can be recorded on a recording sheet or data logger.

The controlled items are the time of sample entry/exit of conditioning room.

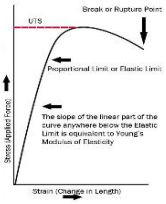
A dedicated format must be created and managed.

Photo capturing the time of entry/exit with a clock is also effective and requires a signature.

(3) Rubber tensile test

a. Automatic measurement





A type of testing machine that automatically tracks between mark lines and records elongation and load.

Since digital data will be recorded as primary data, time management and signatures should be managed with a well-defined procedure.

This level of equipment is necessary to meet JIS K6272.

b. Shopper type

The maximum load is latched and the distance between chucks can be measured.

Measuring the elongation between markers requires skill.

Significant improvement is needed to meet the requirements of JIS K6272.

Measurement error between mark lines within 2%.

The elongation (deflection) must be displayed continuously and the maximum elongation (deflection) must be displayed.

c. Autograph

Usually the load and the distance between chucks are recorded, but measurement between mark lines is required.

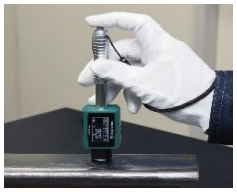
Measurement between markers would require an automatic instrument.

While the old ones were paper records, the newer ones can be recorded in digital data,

For paper records, enter the time and signature so that this paper record chart can be maintained as primary data.

(4) Rubber hardness

Some digital display types can be connected to a PC to record data. In this case, the data is archived as primary data.



With conventional ones, the record will be handwriting on paper, and the only way to keep it in a state of control is to use a special format.

(5) Static ozone test

The ozone test performed according to JIS K 6259-1 requires data on the following items

Ozone Concentration	50±5pphm	Measured by the tester and output digitally or on paper.
Temperature	40±2℃	
Elongation	20±2%	It would seem that formatting and photographic documentation would be useful.
Time	72hours	It would be effective to record the time of entry/exit in a photo and a special format.

pphm： parts per hundred million… ppm①1/100

Testing result recorded with photo is recommended.

(6) Fender compression test

It must be digital recorded.

Paper records are transitional and will eventually be replaced by digital records. We should always aim to go digital.