Scientific Archivists Group
Promoting excellence in records management

Guidance on the Scanning and Destruction of Original Paper eTMF Records

1. Introduction

The advent of electronic Trial Master File (eTMF) technologies and emergence of associated regulations has generated a shift in the traditional practice of maintaining paper TMFs.

The opportunities presented by eTMF to improve operational efficiencies, enable global access to records, and enhance the integrity of records mean that electronic TMF record generation, management and retention is now more widely practiced and accepted by regulators.

As a consequence, SAG no longer sees practical advantage or regulatory justification for maintaining paper TMFs. However, electronic record keeping presents its own unique challenges that require planning and change management programmes and many organisations are yet to adopt eTMF.

Even amongst those organisations that have adopted eTMF some

- have not exploited all eTMF features (e.g. electronic signatures);
- maintain a hybrid TMF (i.e. a mixture of digital and paper records); and
- continue to maintain paper records, particularly for records identified as requiring (wet-ink) signatures to approve or authenticate information, actions and decisions.

This guidance is aimed primarily at organisations that wish to scan original paper records into an (e)TMF, whether to facilitate information sharing or with a view to replacing original paper records with "true copy"[1] scanned images.

Organisations that follow the recommendations made in this guidance should have greater confidence in their ability

- to produce "true copies"; and
- to legitimately destroy original paper records.

Flowcharts are included in this guidance to help

- determine whether paper records should be scanned (Fig 1 & Fig 2); and
- with validation of scanned images and the process used to create them (Fig 3).

[1] *"A paper or electronic copy of the original record that has been verified (e.g., by a dated signature) or has been generated through a validated process to produce an exact copy having all of the same attributes and information as the original."* *ICH E6 Guidance.*

2. Scanning Documents

In its "Good Clinical Practice Guide", the MHRA acknowledges that the use of eTMFs may require the scanning of some original paper records.

Although the MHRA cautions that any such transfers "should be validated in order to ensure that the transfer …is without loss …and that certifiable copies are made"[3] it also maintains that it is not necessary to review every scanned image before it is approved for inclusion in the eTMF but rather ensure "that the transfer system is effectively validated"[3] and evidential records maintained. Validation and certification should be made by an individual with appropriate authority to undertake these checks.

It is recommended to have "a formal process in place for regular checks …usually on a sampling basis, including escalation procedures where issues arise"[2]. SAG recommends that each organisation adopts a risk-based approach to the validation of the scanning process and stipulates an acceptable volume, period and frequency for QC in its TMF quality plan.

Where the scanning process is to be contracted to a third party, appropriate chains of custody must be set in place and mechanisms/quality controls established to ensure that the scanning processes and criteria are fulfilled.

This guidance assumes that the organisation has

- established support for a scan [and destroy] approach;
- undertaken a risk assessment and change management programme including the provision of any associated training; and
- implemented requisite policies and procedures to define and support that approach.

Those policies and procedures should detail among others:

- the method(s) for preparing records for scanning;
- the checks to be undertaken to ensure accuracy, completeness and reliability of scanned records;
- the method and frequency of regular sampling checks on scanned records; and
- escalation procedures to deal with any issues that arise particularly in relation to:
  - accessibility;
  - accuracy;
  - completeness;
  - image quality (readability); and
  - metadata accuracy.

Though not mandated, consideration should be given to the employment of OCR (optical character recognition) technology in the scanning process to facilitate the

[2] *MHRA Good Clinical Practice Guide (Ch 10.5.4. and Ch 10.5.5)*

search and retrieval of records. This is likely to be a separate process supplementary to the scanning process itself and necessitate the use of (an) additional programme(s) or software application(s).

3. Retention of the Original Paper Record

EudraLex Volume 10 requires organisations "take measures to prevent accidental or premature destruction of [essential] documents"[3] and the MHRA caution that "early complete destruction of [original paper] records is not currently recommended or should only be undertaken on a risk-adapted approach"[4]. As a consequence, best practice on whether to scan and destroy remains open to interpretation.

However, the digitisation of paper records for storage in an eTMF may enable earlier destruction of the original paper record provided the scanned image

- remains readily available, complete and legible, and
- contains traceability (an audit trail) of any changes.

The DIA "Framework for the Destruction of Paper"[5] provides a comprehensive assessment regarding the scanning and possible destruction of original paper records.

The MHRA Grey Guide recommends that organisations "undertake a risk assessment in order to decide which documents do not need to be retained on paper, particularly focusing on whether or not the paper version could be obtained upon request"[3].

And although Inspectors may request the production original paper records for inspection and for a period of 10 years after completion of the clinical trial for "full verification that [scanned images of] data were complete, legible and verifiable as accurate copies of the original"[6], there is nothing in applicable regulations, directives or legislation that specifically requires retention of original records following production of a certified copy.

The draft ICH GCP Addendum E6 (R2) -Guideline for Good Clinical Practice[7] usefully states that "when a copy is used to replace an original document, the copy should fulfil the requirements for certified copies". The use of "replace" is significant, a clear indication that there is no need to retain the original record provided

- the scanned image and
- the scanning process used to create it

are validated to ensure that scanned image is a "true copy" of the original record.

4. Conclusion

All decisions regarding the retention of records must be made in consideration of

[3] *EudraLex Volume 10 Ch V*
[4] *MHRA Good Clinical Practice Guide (Ch 10.5.4. and Ch 10.5.5)*
[5] *DIA Framework for the Destruction of Paper Records*
[6] *MHRA GCP Forum*
[7] *ICH GCP Addendum E6 (R2) -Guideline for Good Clinical Practice*

- the need to maintain throughout the required period of retention the authenticity, reliability and usability of the record and any accompanying signatures (whether hard-copy or electronic); and
- the existence and/or anticipation of "legal hold" (although each organisation will have SOPs to govern the "legal hold" process and so this is not reflected in this guidance).

Importantly it should also be noted that a scanned image cannot be deemed "legally inadmissible" solely by virtue of the fact that it is not an original record. All records are "legally admissible"; it is the "evidential weight" that determines the value of the record. And whilst the "evidential weight" of a "true copy" may be challenged, the validated processes used to generate it should provide sufficient documentary evidence to satisfactorily counter any challenges.

Provided scanned images of original paper records satisfy all applicable requirements to meet the definition for a "true copy" (i.e. the scanning process is well-designed, appropriately validated and incorporates sufficient quality management controls to ensure completeness, accuracy and trustworthiness), SAG

- sees no regulatory requirement to retain the original paper record; and
- recommends that the original paper record of a "true copy" may be destroyed as part of routine business practices.

Acknowledgements

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Fig 1: Scanning of original paper records during conduct of the trial

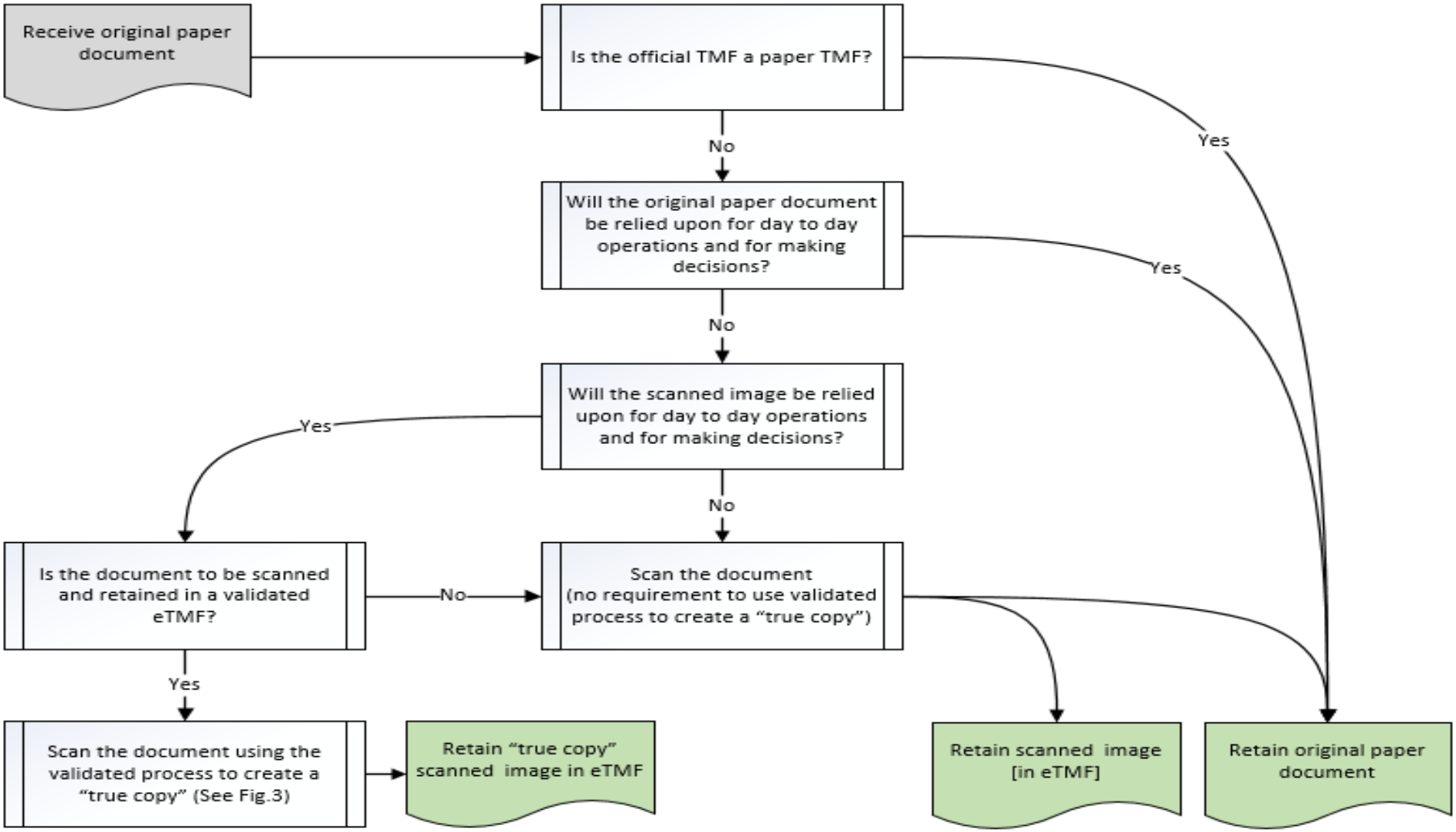


Fig 2: Scanning of original paper records after conclusion of the trial

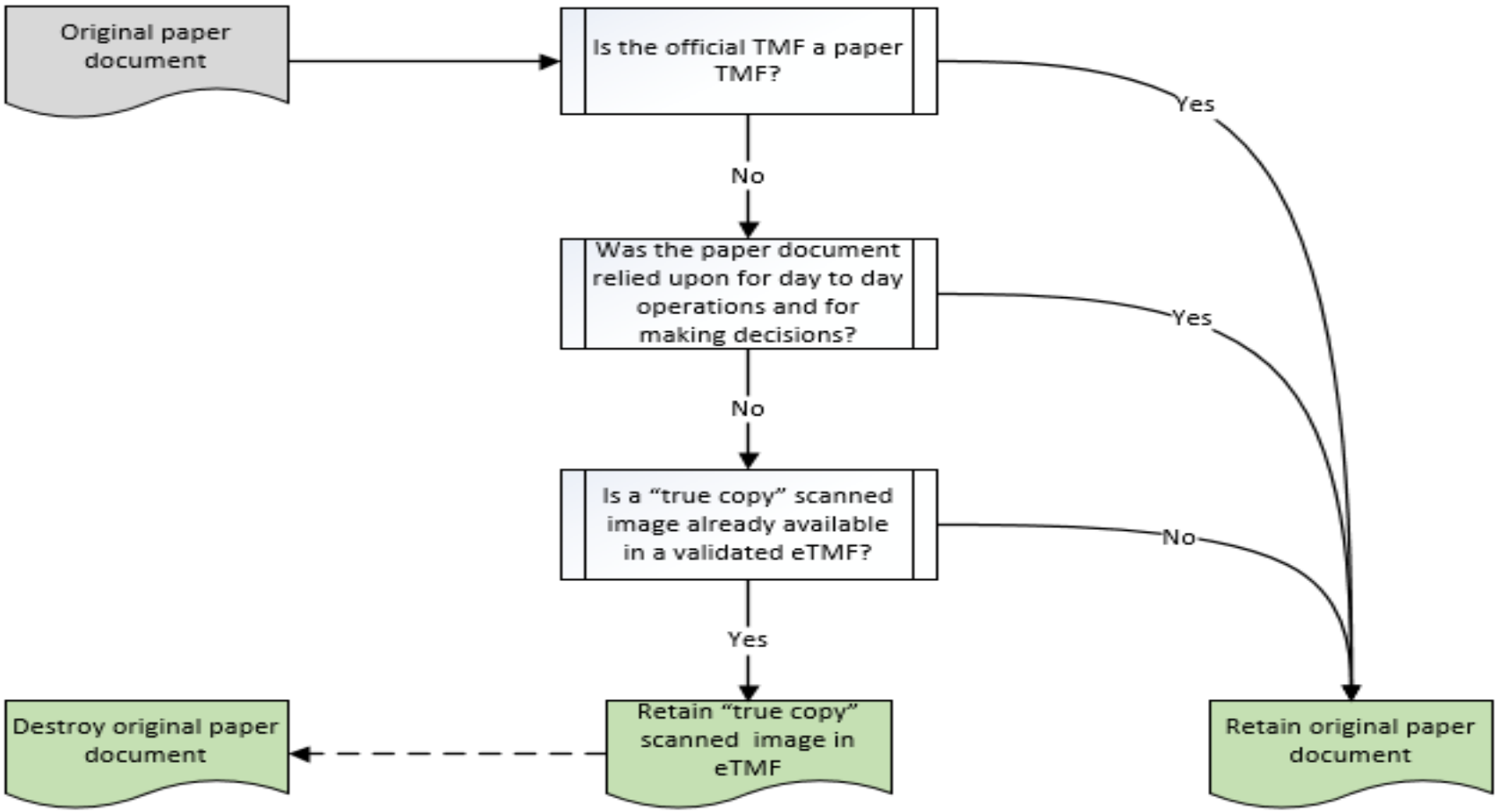
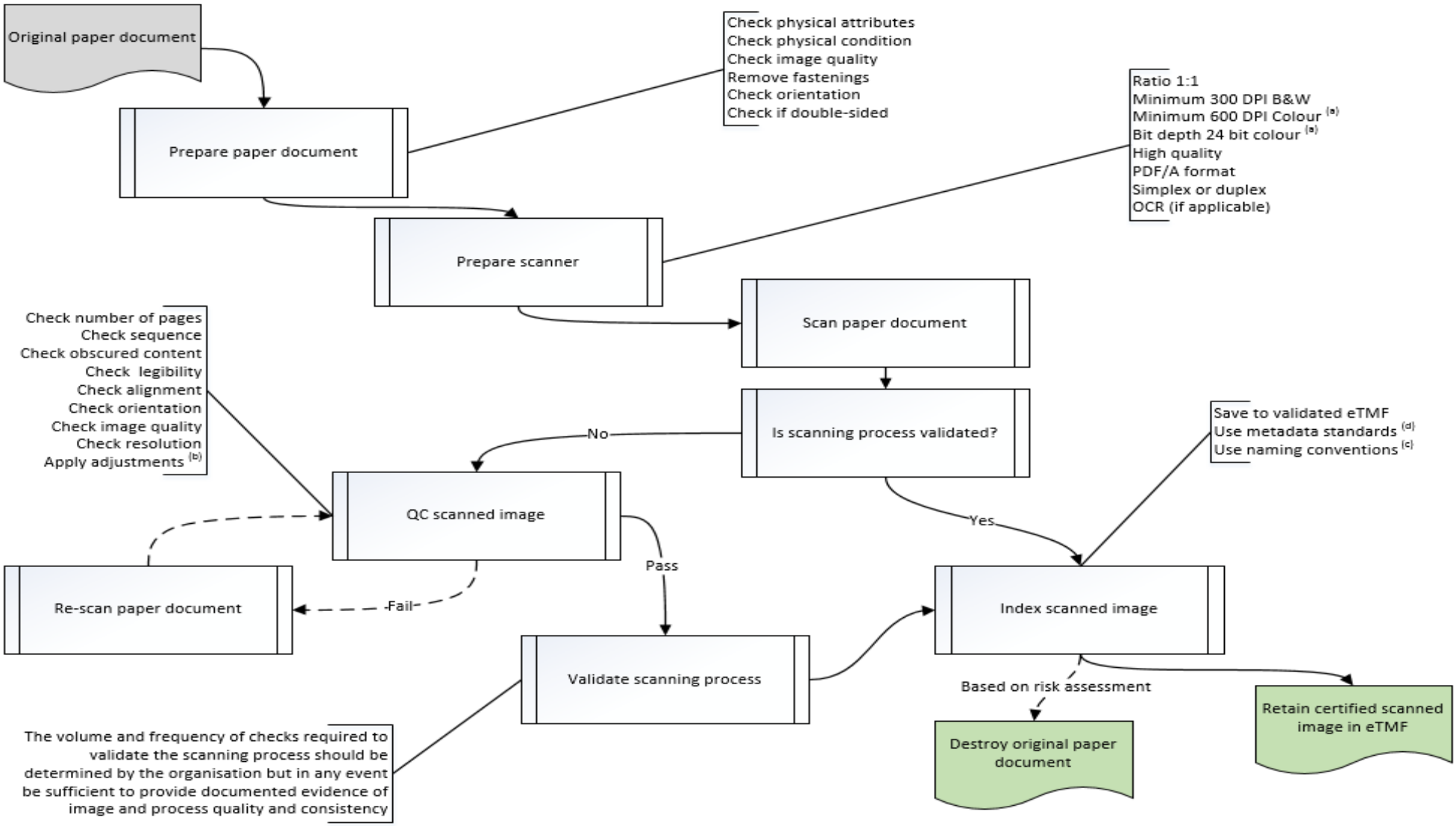


Fig 3: Workflow to create "certified copies" of original paper records



a. SAG recommends that records are scanned in colour only if the colour elements are critical to the interpretation of the content of the record; if not, the record may be copied in black and white.
b. Post scan adjustments to the image to increase legibility are acceptable, provided the limits of what may be undertaken are clearly specified in a formal procedure. It is not acceptable to use the scanning process to remove or add material to the image (for example, to remove the header a fax machine has added) or undertake physical "cut and paste" or "correction fluid" activities on the original paper records.
c. Use lower case characters and avoid using special characters except hyphens and underscores in file names
d. Use metadata standards agreed during establishment of eTMF

References

The references below are listed as referred to to in the processes defined in Fig 3

Prepare Scanner

1. "BS 6498:2002 Guide to preparation of microfilm and other microforms that may be required as evidence"
http://shop.bsigroup.com/en/ProductDetail/?pid=000000000000239896

2. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically."
http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227

3. FDA Industry Guidance – Portable Document Format Specifications[5]
www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf

4. FDA Guidance for Industry – Providing Regulatory Submissions in Electronic Format — General Considerations[5]
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf

5. "ISO-19005-1 Document management: Electronic document file format for long-term preservation Part 1: Use of PDF 1.4 (PDF/A-1)
http://www.iso.org/iso/catalogue_detail?csnumber=38920

6. "PDF/A – A New Standard for Long-Term Archiving" www.pdfa.org/2011/08/pdfa-a-new-standard-for-long-term-archiving

7. PDF/A has been established as a row of standards with several parts. At the time of publication of this guidance, only PDF/A-1 (Part 1) has been approved. PDF/A-1 is subdivided into two levels of compliance:

   a. PDF/A-1a (Level A Conformance) offers full compliance with the currently approved PDF/A Standard ISO 19005-1: Part 1. Use of PDF/A-1a ensures the preservation of a document's logical structure and content text stream in natural reading order. Text extraction is especially important if a document must be displayed on a mobile device (for example a PDA) or other devices in accordance with Section 508 of the US Rehabilitation Act. In such cases the text must be reorganized on the limited screen size (re-flow). This feature is also known as "Tagged PDFs".

   b. PDF/A-1b (Level B Conformance) offers lesser compliance. Use of PDF/A-1b ensures that text (and additional content) can be correctly displayed (e.g. on a computer monitor), but does not guarantee that extracted text will be legible or comprehensible. It therefore does not guarantee compliance with Section 508. However, it does ensure that the rendered visual appearance of the file is reproducible over the long-term.

QC Scanned Image

8. FDA Draft Guidance: Electronic Source Documentation in Clinical Investigations
   http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

9. US National Archives and Records Administration Technical Guidelines for Digitizing Archival Materials for Electronic Access: Creation of Production Master Files – Raster Images http://www.archives.gov/preservation/technical/guidelines.html

10. ISO 12653-1:2000(en)Electronic imaging — Test target for the black-and-white scanning of office documents — Part 1: Characteristics

    https://www.iso.org/obp/ui/#iso:std:iso:12653:-1:ed-1:v1:en

Validate Scanning Process

11. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically."
    http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227

12. FDA Portable Document Specifications
    www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163179.pdf

13. FDA Guidance for Industry Providing Regulatory Submissions in Electronic Format —General Considerations www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf

14. United States. Food and Drug Administration. Guidance for Industry: Computerized Systems Used in Clinical Investigations www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf

Destroy Original Paper Document

15. European Medicines Agency. Q&A: Good Clinical Practice (GCP). Expectations of EU competent authorities on the use of electronic Trial Master Files www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000016.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800296c5&jsenabled=true

16. FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations Guidance for Industry: Part 11; Electronic Records; Electronic Signatures- Scope and Application www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf

17. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227

18. "BS EN15713:2009.Secure Destruction of Confidential Material; Code of Practice

19. The Uniform Rules of Evidence (US 128-0060-00 to 0170-00)