

## Preparation of True Copies

Chapter 9:

DOCUMENTATION  
AHETF-9.H.O.

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### 1.0 PURPOSE AND SCOPE

- 1.1 This Standard Operating Procedure (SOP) describes the process for making true or exact photocopies of original raw data to be used in place of the original data by the Agricultural Handlers Exposure Task Force (AHETF).
- 1.2 All original study data will be retained by the AHETF and all original facility records will be the responsibility of the individual contractors; however, copies of these data may need to be produced to complete study files, facilitate preparation of the report(s), or be used in auditing the final report(s).

### 2.0 PROCEDURE

- 2.1 The necessary data will be photocopied by the contractor. All copied pages of raw data will be immediately reviewed by the persons making the copies for clarity and completeness.
- 2.2 Any pages that are poorly copied (*i.e.*, smeared, unclear, too light or dark, missing text, *etc.*) are not acceptable, and must be re-photocopied.

- 2.3 Individual pages will be certified as a true, exact, or certified copy, either with an appropriate rubber stamp or written by the person(s) verifying the copied pages. The person's initials (or a signature) and the date verified must be noted on the copied page(s).
- 2.4 Whole sections of data (e.g., chromatogram sets, entire data notebooks, etc.) must be verified completely, but only the cover page of the set need contain the true copy designation and the person's initials and date. In addition, the cover page must indicate the total number of pages in the set and clearly state that all pages contained in the set are true copies. All pages in such a set must be paginated or otherwise marked to ensure they remain together.
- 2.5 True copies must be handled as raw data (when replacing the original data), and are subject to all AHETF and GLP handling and retention requirements.
- 2.6 True copies may be discarded by the AHETF or contractors only when the original raw data are properly archived and there is no longer a need for such copies. Verification must be obtained from the Study Director, Task Force Manager, AHETF QAU, or designated archive facility(s) before disposal.
- 2.7 Copies of data made for transfer of information within the AHETF need not be authenticated. Only copies of data intended to replace the original raw data must follow the above listed procedures.