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U. S. Army Center For Health Promotion and Preventive Medicine
Strategic Initiatives Office (SIO), Quality Assurance Team (QAT)

STANDING OPERATING PROCEDURE
FOR
FINAL REPORT AUDITS


Preparer

03 JAN 2001
Date


Supervisor Approval

1/4/2001
Date

Annual Review

Preparer

03 JAN 02
Date Due Date Comp.

Supervisor

03 JAN 02
Date Due Date Comp.



Preparer

Date Due Date Comp.

Supervisor

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Disclaimer: This Standing Operating Procedure has been prepared for the sole use of the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) and may not be specifically applicable to the activities of other organizations.

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I. PURPOSE. This standing operating procedure (SOP) describes the responsibilities of the QAT with respect to Good Laboratory Practice (GLP) regulations of the Directorate of Toxicology (DToX) study final reports.

II. APPLICABILITY: It is the policy of the USACHPPM that every effort is made to assure that all studies undertaken by TOX and the reports of such studies are of the highest possible quality and adhere to the best standards of professional scientific endeavor. It is the further the policy of USACHPPM that the regulations of the Food and Drug Administration (FDA) (21 CFR Part 58), the Environmental Protection Agency's (EPA) (40 CFR Part 160) and the Environmental Protection Agency's (EPA) (40 CFR Part 792) for Good Laboratory Practices (GLP) in Non-clinical Laboratories be followed in every particular for all DToX studies. To assist in implementation of this policy, a Quality Assurance Team (QAT) has been established as an integral and permanent organizational unit of USACHPPM

III. DEFINITIONS: None.

IV. QUALITY CONTROL: None.

V. PROCEDURE: Final reports produced from non-clinical studies conducted in the DToX will be reviewed as follows:

- A. Final reports will be reviewed according to the appropriate GLP regulations, protocols and applicable SOPs.
- B. The narrative portion of the report is evaluated for correlation between reported and actual methods, and reported and actual results. Stated conclusions are evaluated to confirm that the reasoning involved in arriving at the final conclusions is supported by the actual results. The raw data are reviewed for completeness and GLP compliance.

- C. Any mechanical errors (i.e. typographical errors, misalignments, omissions, incorrect page order, etc.) will be noted.
 - D. Tabular data (individual or summary) are audited by comparison with raw data. A minimum of 20% of the tabular data will typically be audited. Should the error rate exceed 1% the QAT assessor may elect to audit additional data points or reject the report and return it to the study director for 100% verification of all data points.
 - E. Individual animal pathology reports are routinely reviewed for agreement with protocol specifications and adequacy of gross to microscopic correlation, to include tissues, blocks and slide accountability.
 - F. A report submitted for review can be rejected at the discretion of the QAT for the following reasons:
 - 1. Insufficient raw data for review,
 - 2. Poor report quality including incomplete narrative/tabulations, poor photocopy quality and/or excessive mechanical problems,
 - 3. Excessive errors in report narrative or tables.
 - G. A report returned for any of the above reasons must be corrected as necessary and resubmitted for review by the QAT.
 - H. The results of each QAT report audit are documented in a written report prepared by the QAT assessor and submitted to the study director through management. The written response from the study director and all documentation relative to the inspection are retained in the QAT study file.
 - I. Corrected reports (in final form) are resubmitted to the QAT along with study director's response to the QAT audit report. The QAT assessor will review the final report and applicable raw data to assure that appropriate corrections/changes were made. The final report is also examined for completeness, proper collation, pagination and overall copy quality.
 - J. Additional findings or unresolved problems, if any, are reported to the study director for resolution. Resubmission of the final report to the QAT may be required at the discretion of the QAT assessor.
- IV. SAFETY CONSIDERATION. Compliance with all DTOX safety procedures, SOPs and the USACHPPM Chemical Hygiene Plan is mandatory when conducting QAT audits.
- V. REFERENCES:
- A. USFDA Federal Food, Drug and Cosmetic Act (FFDCA); 21 CFR 58 (1979), latest

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edition.

- B. USEPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); 40 CFR 160 (1984), latest edition.
- C. USEPA Toxic Substances Control Act (TSCA); 40 CFR 792 (1983), latest edition.