EPA/600/R-94/035
March 1994

GENETOX MANAGER SYSTEM - BACTERIAL MUTAGENESIS ASSAYS: USER'S GUIDE

Prepared by:

Larry D. Claxton, Ph.D. and John Creason, Ph.D.

Health Effects Research Laboratory
U.S. Environmental Protection Agency
Research Triangle Park
North Carolina 27711

and

Joe Nader, Way Poteat, and John Orr

Computer Sciences Corporation
4401 Alexander Drive
Research Triangle Park
North Carolina 27711

Prepared Under
Contract # 68-W0-0043
Delivery Order # 507
Task Officer: Larry D. Claxton

June 1993
Version 2.21

Printed on Recycled Paper

PREFACE

This user's guide is the reference manual describing use of the EPA Genetox Manager System. GeneTox Manager is a data capture, data management, and statistical analysis program used for microbial mutagenicity data. Its main purpose is to provide a homogeneous environment for the collection, organization, and analysis of data generated in the laboratory while also supporting a quality assurance program. The complete system consists of both a personal computer (PC) system and a minicomputer (VAX) system, although the PC system can be used as a stand-alone system. The system controls the data collection and management through a user-friendly, menu-driven system that requests specific information and provides uniform methods for data and information entry. GeneTox Manager is capable of performing specialized statistical analysis of the data and creating tabular and graphical summaries. Two versions of the PC system exist: a stand-alone PC only version, and a VAX version. The VAX version of the system is designed to function with VAX FOCUS databases so that the VAX can be used for long-term storage, archiving of files, and the analysis of large groups of data.

GeneTox Manager was developed by the U.S. Environmental Protection Agency. This software is public domain software; therefore, you are free to use and to distribute this software free of charge. You may not market this software, however, without prior consultation with and acknowledgement of the U.S. EPA and its developers.

We only make a few REQUESTS OF THE USERS. First, we request that you provide to the creators of this software proper acknowledgement. [See the title page to the software and to the User's Guide. Also in the near future, we hope to have references that you may cite.] Secondly, realizing that the software is provided free of charge, please understand that we cannot service this software. [Because the source code is available, many consultants and companies that use Clipper® could provide additional help and programming options for you.] Follow the installation and distribution instructions very carefully. If you have problems, first read the section of the User's and Programmer's Guides that deal with problems before contacting us. Most problems that we have seen are due to either not following installation instructions completely (especially in regard to autoexec.bat and config.sys files) or to memory allocation problems. Most all of the memory allocation problems are due to other "resident programs" - please see the guides. If you receive and especially if you distribute the software, be sure to do that in the proper manner. Be sure that you understand the statistics and proper interpretation of the statistical programs. Also understand that statistics do not replace sound scientific judgment and that statistics on a single test does not replace replication of an experiment. Lastly, be sure to read the "readme.1st" file.

We sincerely hope that this software will be useful to you and will aid you in your scientific endeavors.

Acknowledgements

We would like to acknowledge those individuals who used prototype versions of this software and gave us useful, productive comments. Without their suggestions, this product could have not been done. In this regard, we give our thanks to Sarah Warren, Erica Perry, Virginia Houk, Sam Schalkowsky, Mary Beth Lawhorn, and Maria Taylor.

We also want to thank those who gave us permission to use the statistical analysis programs that they developed. These include Dr. L. Bernstein, Dr. D. Krewski, and Dr. A. Stead. If you use information from these statistical programs, we hope that you will give proper acknowledgment to the authors of the statistical manuscripts.

We also want to thank Mr. Ken Laws for providing administrative support that made this project possible, and Drs. Lawrence W. Reiter and Michael D. Waters for creating the scientific support that made our endeavors a joy.

Notice

The software and the user documentation are provided "as is". CSC and EPA make no warranty, express or implied with respect to the software and/or user documentation and specifically disclaims the implied warranties of merchantability and fitness for a particular purpose. EPA and CSC do not warrant that the software will be uninterrupted and/or error free. You are solely responsible for the selection of the software to achieve your intended results and for the results actually obtained.

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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Document Organization

Chapter 1 provides an overall introduction to the GeneTox Manager system, conventions, and operation.

Chapter 2 provides a discussion of each menu in the GeneTox Manager system including the following:

- A brief description of the menu
- A representation of the screen
- User Input
- Processing
- Outputs
- Quality Control

Appendix A provides installation information as well as hardware configuration requirements for execution of the application.

Appendix B (GeneTox Manager Troubleshooting) covers various problems that may occur using GeneTox Manager and how they might be solved.

Appendix C covers system upgrade to version 2.2 from earlier versions using the GeneTox Manager Upgrade utility.

Appendix D covers interfacing GeneTox Manager with an Artek Colony Counter.

Keyboard Notations

The following special terminal keys are referenced:

<keyname> refers to special keys indicated by inclusion within left and right angle brackets (< >). Examples: <F1>, <RET>.

<RET> refers to the carriage return, or RETURN, key. <RET> concludes all operator responses.

<ESC> refers to the escape key, which will quit the current transaction and return to the previous menu.

Representation of Screen Displays

In this manual, the screen displays produced by GeneTox Manager are shown in the form seen by the user.

CHAPTER 1

INTRODUCTION

Overview

The GeneTox Manager system is a U.S. EPA system for the collection, organization, retrieval, and analysis of microbial mutagenicity data. Although the system was designed primarily for the *Salmonella typhimurium* plate-incorporation assay, it will accept data and information for any mutagenicity assay where similar information is obtained.

Microbial assays, especially Salmonella bioassays, are the most common type of mutation tests. These tests determine whether or not a substance interacts with the DNA of the organism in such a way as to create permanent, heritable changes within the DNA. These tests are important because they can be used to screen for both mutagens and genotoxic carcinogens. The Salmonella assay has been reported to have been used by over 2000 laboratories. In comparison to other genotoxicity assays, these microbial assays are relatively rapid and inexpensive. These tests, therefore, generate very large databases.

In order to collect, manage, and analyze microbial mutagenicity data in an orderly and rapid manner, the U.S. EPA (through the services of Computer Sciences Corporation) developed the GeneTox Manager system. Using this system, investigators can use a PC to collect information and data, to provide short-term storage of the information, and to provide selected types of statistical analysis. The complete GeneTox Manager system also includes a VAX FOCUS system that can be used for the archiving of databases and for the analysis of large groupings of data. The total system is designed to achieve compatibility between the PC and VAX system environments. The GeneTox Manager system is designed to be user friendly through the use of a structured menu system, screen entry helps, and other help screens. Reports are both tabular and graphical in nature, and they can be seen on the computer screen, sent to a printer, or written to a PC file. Technical aspects of the GeneTox Manager software (e.g., data field descriptions) are addressed in the Programmer's Guide.

It is the hope of EPA that GeneTox Manager will not only be of benefit to the Agency but will also be of constructive use to others outside of the EPA.

User Interface

The GeneTox Manager system provides a series of high-level menus that guide the user through execution of the application. Menu items are identified by highlighted fields, one for each accessible function. For each function, a submenu is provided with options to perform subsequent subfunctions.

Input screens allow the user to enter GeneTox Manager data. The screens have been implemented with the following design standards:

<F1> ("HELP") may be entered at any screen. "HELP" displays basic information about the screen input and returns to the current screen.

<F2> ("suggestion") may be entered if a selection can be made from a list provided in the suggestion box. If a selectable list is not available, a general help message will appear telling the user that no suggestion list is available.

<Shift-F2> ("expand suggestion text window") may be used to allocate a broader area of the screen for review/selection of data entry field selection values.

<F5> ("enable instrument interface)" may be used to request transmission of data from the colony counter when in the appropriate data entry field.

<Shift-F5> ("review protocol text") may be used to scroll protocol text entered by research scientists.

<F6> ("switch current value") may be used on certain screens to switch the current value for a sample or experiment strain.

<F8> ("edit expanded text field") may be used to edit text in an expanded window for certain descriptor fields.

<F9> ("save expanded text field") may be used to save expanded text window information.

<F10> ("save modified information") may be used from the modify environment to save data/text changes to application databases.

<RET> affirms a field entry and moves the cursor to the next entry field. At the last entry on the screen, the <RET> key accepts the entries on the entire screen and begins validation procedures.

<TAB> will move the cursor to the previous field during data entry.

<UP-ARROW> and **<DOWN-ARROW>**
keys will navigate the user through fields on the screen.

<ESC> key cancels a transaction and returns the user to the previous screen. The current process is aborted.

<PGUP> may be entered to go to the previous screen. If editing the first screen, a message will appear informing the user of this.

<PGDN> may be entered to go to the next screen. If editing the last screen, a message will appear informing the user of this.

Initiation

To start the GeneTox Manager program, type **GTM** at the DOS prompt. If the GeneTox Manager System is not in the DOS path, then move to the subdirectory containing the GeneTox Manager application and execute GTM using the following three commands:

dos prompt> d:<RET>
where <d> is the drive containing the application
dos prompt> CD \subdir<RET>
where <subdir> is the directory for the application
dos prompt> GTM<RET>

Termination

There is only one acceptable method to end a GeneTox Manager session, which is to select the QUIT option on the MAIN MENU. Using the <ESC> key on all GeneTox Manager menus will return the user to the previous menu. **The <ESC> key will also allow a system abort, but this will not reset many of the necessary internal system variables.** If a session is aborted, restart the system, select the QUIT option and quit the system to properly initialize these internal variables. The only viable exit from the entire system is from the MAIN MENU.

Error Messages

Although there are a variety of error messages that can be encountered, they fall into 3 categories (PC-Clipper generated, VAX-Focus generated, and GeneTox software generated).

The GeneTox error messages deal primarily with user input errors (e.g., asking to upload from the PC to the VAX an experiment that does not exist on the PC). To understand these error messages, refer to the portions of the User's Manual that applies to the action being performed. The software also creates a record of certain types of errors in transaction files. In the PC, these transition files fall into one of two categories: *.TRN files and *.*T files. The *.TRN files (e.g., PCDOWN.TRN) record error messages when transferring files from one format to another. The *.*T files are used to record errors encountered during a retrieval/transaction process. The actual format for these files is eeeeeeee.fft where the eeeeeeee.ff corresponds to the experiment name and the "T" is a literal value added to the experiment name to indicate that this file is a "transaction" file. See the Programmer's Guide for further explanations.

The PC-Clipper error messages are messages generated by the Clipper® run-time software. These messages usually allow the user to "continue", "retry", and/or "quit". Most often these messages occur if (1) a program file is missing or (2) not enough memory is available for the program to run. See Appendices B and E and/or a Clipper® manual if these errors occur.

For those having a system that takes advantage of the VAX interface, errors that occur during the transport of data are logged in *.TRN files. See the VAX User's Guide and VAX Programmer's Guide.

CHAPTER 2

USING THE GENETOX MANAGER SYSTEM

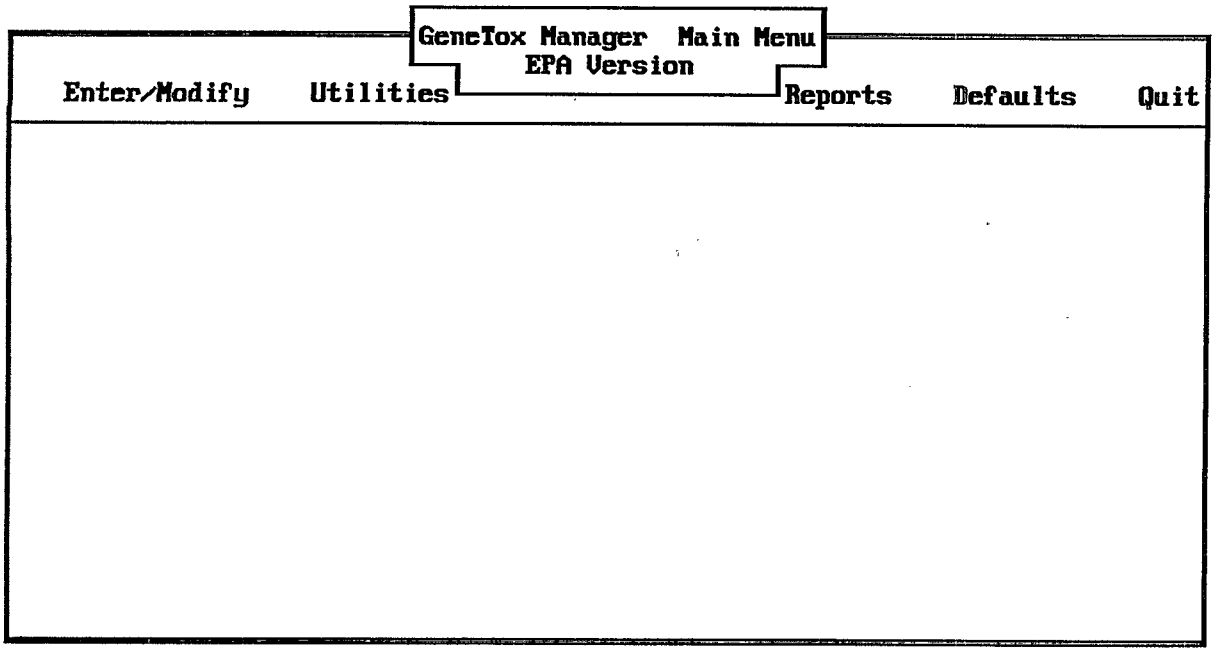
Upon startup, the system will verify that all necessary files are present and display any error messages that occurred during the initialization. After the system has successfully verified that all necessary files are present, the following welcome message will be displayed:

```
Welcome To
GENETOX MANAGER v2.2
Developed by

Dr. Larry Claxton, and
Dr. John Creason
Health Effects Research Laboratory
U.S. Environmental Protection Agency
Research Triangle Park, NC
&
J. Way Poteat, Joseph A. Nader,
Daniel G. Musser, John D. Orr,
Dwyian Davis, and David L. Owens
Applied Technology Division
Computer Sciences Corporation

Press Any Key To Continue
```

After pressing a key, the MAIN MENU for the GeneTox Manager system will be displayed.

GENETOX MANAGER MAIN MENU

The desired option can be selected by either entering the first letter of the option name or by using the arrow keys to highlight the particular function. Each function has an associated submenu and/or input screen(s).



Add New Experiment, Modify Existing Experiment, Modify Existing Samples

User Input

Five options may be selected from the MAIN MENU. To select an option, use the left and right arrow keys to select (highlight) one of the options. After selecting an option, press <RET> to continue with that selection. An alternate selection method is to enter the first letter of the desired option - this method will invoke the requested option without a <RET> or any other keystrokes. Either of these methods can be used on all selection menus in the application.

The five options that can be selected from the main menu are:

Enter/Modify - allows the user to Enter new experiment information, Modify existing experiment information, Change existing sample information, and Maintain Experiment Instructions.

Utilities - allows the user to List the experiments in the PC database, Upload and Download Experiments (VAX Version), Import/Export Experiments, and Archive/De-archive Experiments.

Reports - allows the user to Execute a Raw Data report, or one or more of the Statistical Model reports: Bernstein, Histidine, Stead, and Quasi-Stead.

Defaults - allows the user to change the default settings for: Communication Setup, Colors, Protocol File Name, Reindex Databases, Set Location of Application DataBases and Archive Files, and Special Options.

Quit - allows the user to exit the GeneTox Manager system and return to DOS or to continue using the system. **The <ESC> key will also allow a system abort, but this will not reset many of the necessary internal system variables. DO NOT use the <ESC> key to quit unless absolutely necessary (see pg. 3, Termination).**

Processing

The MAIN MENU is the main selection area. It allows the user to select the various options for manipulating data.

Output

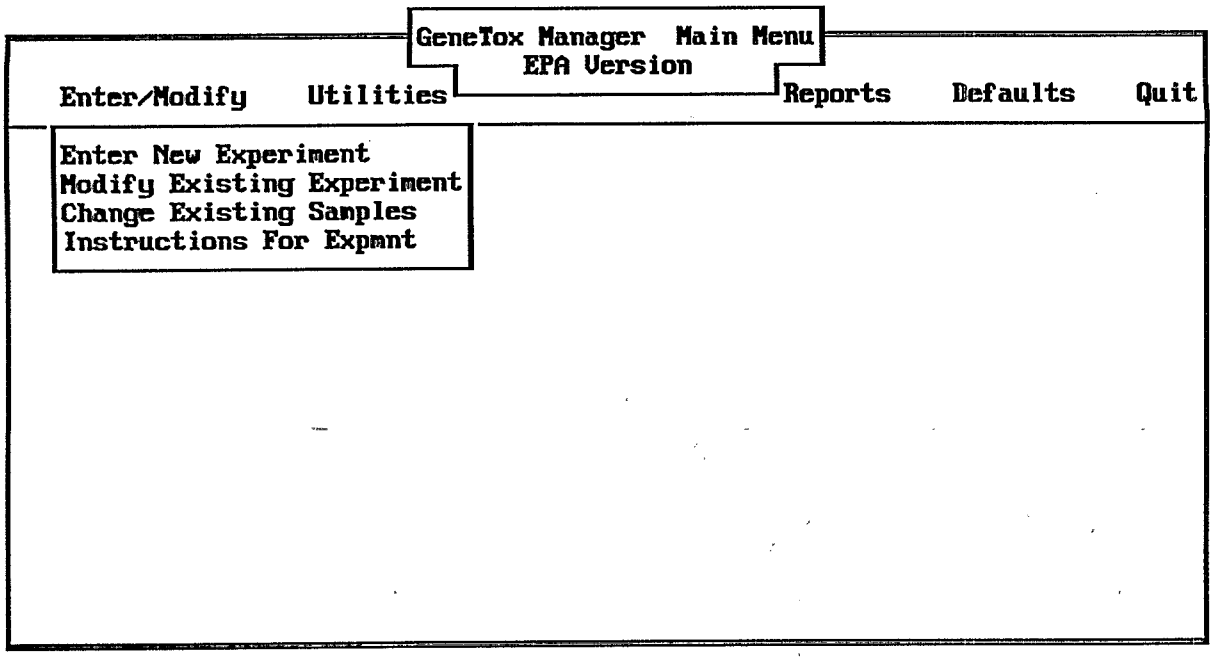
None.

Quality Control

Only keystrokes pertaining to specific menu selections are permitted from this screen.

ENTER/MODIFY MENU

After selecting the ENTER/MODIFY option from the MAIN MENU, the following screen will appear. This screen will allow the user to enter new experiments, modify existing experiments, modify existing sample data, and update the online experiment instructions.



Enter New Experiment Data Into The DataBase

<u>User Input</u>

The following fields are input for the ENTER/MODIFY menu:

Enter New Experiment - allows the user to enter new experiment information.

Modify Existing Experiment - allows the user to modify current experiment information.

Change Existing Sample - allows the user to enter new sample information into the database.

Modify Existing Samples - allows the user to modify existing sample data in the database.

Instructions for Experiment - allows the user to Select, View, Print, or Modify experiment-specific instructions that are accessible from any point in the GeneTox Manager system.

Processing

The ENTER/MODIFY function provides the general data entry needs for the entire GeneTox Manager system. For both PC only and VAX Versions, all initial data entry as well as data modifications must be performed on the PC, not on the VAX. Updated information must then be uploaded to the VAX as a separate step. This approach is taken to ensure that databases on the PC are current with the master databases stored on the VAX.

Outputs

None.

Quality Control

Only keystrokes pertaining to specific menu selections are permitted from this screen.

ENTER NEW EXPERIMENT MENU

To invoke the Data Entry phase of GeneTox Manager, select ENTER NEW EXPERIMENT from the ENTER/MODIFY option. Upon selection, the following screens will appear in the order in which they are listed below. A more detailed explanation of each screen follows.

User Input

Experiment Description - allows the user to enter general, descriptive information about the experiment.

Assay Type Selection - allows the user to enter the Assay Type for the experiment.

Final Strain Entry - allows the user to enter the Final Strain information into the system.

Neg/Pos Control Entry - allows the user to enter the Positive and Negative Control information for the experiment.

Activation System Information - allows the user to enter metabolic Activation System Information for the experiment.

Sample Specific Data - allows the user to enter Sample Specific Data information. This is the first screen where unique experiment data can be entered; therefore, it is the first place the user is allowed to save data and exit the system.

Strain and Activation Selection - allows the user to enter the dose units to be used with the sample.

Quality Assurance Checks - allows the user to enter the Quality Assurance Checks for the experiment.

Dose Data Entry - allows the user to enter the Dose Data specific to the experiment.

Experimental Remarks - allows the user to enter the Experimental Remarks that pertain to the experiment.

Continue Screen - allows the user to continue entering dose response data or to return back to the Enter/Modify menu.

Processing

The ENTER NEW EXPERIMENT function provides the user with the capability to enter new experiment information into the system according to the sequence of screens described on the following pages.

Outputs

None.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow the user to correct it.

EXPERIMENT DESCRIPTION

After selecting the ENTER NEW EXPERIMENT option from the ENTER/MODIFY menu, the user will be presented with the following screen. This screen allows the user to enter descriptive information about the experiment into the database.

```
                    GeneTox Manager
                Experiment Description

Entry Date......: 06/05/92                Data Entered By.:
Experiment Date.:   /  /                  Lab Technician..:
Research Lab....:                         P Investigator..:
Lab Book Number.:                         Experiment......:

                    Suggestion Box:
          DATE OF DATA ENTRY
The date the experiment is being entered into
the computer (usually today's date)

F1- Help    F2- Suggestion    ↑F3- View Instr    ESC- Abort
```

User Input

The following fields are input for the EXPERIMENT DESCRIPTION screen:

Entry Date - date sample data is entered into the PC.

Experiment Date - date the experiment was conducted.

Research Lab - unique four character code representing the Lab responsible for conducting the experiment.

Lab Book Number - lab notebook number associated with the experiment, up to 25 alphanumeric characters.

Data Entered By - initials of technician entering the sample data into the PC, up to four characters.

Lab Technician - initials of technician who performed the experiment, up to four characters.

Principal Investigator - initials of principal investigator responsible for the experiment, up to four characters.

Experiment - unique experiment name, up to 10 characters.

EPA has limited this somewhat to fulfill EPA laboratory needs. The EPA format is AAAAYYNNNN where AAAA is an alphanumeric code for a project, YY is numeric indicator of the year in which the project started, and NNNN is a sequential numeral indicating a specific experiment or test. The system, however, will allow a user to enter only the AAAA portion or the AAAA portion plus any numeral. NOTE: This identifier must not conflict with any previous entry because it is one of the key identifiers by which data is retrieved. We suggest that you order you experiment numbering in some very logical manner and that you keep a log of that numbering system.

Processing

The EXPERIMENT DESCRIPTION function allows the user to enter descriptive information about the experiment into the database. The option of SAVE/EXIT is not available at this point, as all of the information is considered header information and can be duplicated for many experiments.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

ASSAY TYPE SELECTION

The user will be presented with the following screen. At this point the user will select an assay type that applies to the experiment being conducted. If an assay type does not fit the experiment, exit the data entry phase by pressing <ESC> and select the DEFAULTS menu. This menu will allow the user to change, add, or delete assay types.

```
                    GeneTox Manager
                 Assay Type Selection

Sel Cd Test Type Description                Min   Hour Temp°C Temp°F

 A)  1 Standard Plate Incorporation Assay    0    0.0   37.0   98.0
 B) 17 Kado Microassay                      90    1.5   37.0   98.0
 C)  5 Preincubation assay - standard       90    1.5   37.0   98.0
 D)  3 Plate test - Billips-Rothenberg Ch.   0    0.0   25.0   77.0
 E) 19 Plate test - Tedlar Bag               0    0.0   37.0   98.0
 F) 22 Spiral Assay                          0    0.0   37.0   98.6
 G) 18 TLC/Ames Plate Test                   0    0.0   37.0   98.0

                    Suggestion Box:

          SELECTION OF THE TYPE OF ASSAY
     Use the up and down arrow keys to select the
     type of assay performed then press the
     enter key <Enter>.

F1- Help        F2- Suggestion  Enter- Continue
```

To select an assay type, press the letter that designates the type desired or use the arrow keys to highlight the selection and press <RET>.

User Input

The following field is input for the ASSAY TYPE SELECTION screen:

Assay Modified - changes to the standard assay type that was used. The default value will be "NONE". If a change was made, the user has 35 characters to enter a description of the change. Additional information can later be entered into the REMARKS screen.

Processing

The ASSAY TYPE SELECTION performs no validation on the assay types that were entered from the DEFAULTS menu. The user cannot change any information contained in this menu; changes can only be made from the DEFAULTS menu.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

FINAL STRAIN ENTRY

The user will be presented with the following screen. At this point the user will enter the strains, strain date, activation level and culture density used within the experiment.

```
                    GeneTox Manager
                  Final Strain Entry

1) Strain:        Str Date:        Level:    Cul Density:
2) Strain:        Str Date:        Level:    Cul Density:
3) Strain:        Str Date:        Level:    Cul Density:
4) Strain:        Str Date:        Level:    Cul Density:
5) Strain:        Str Date:        Level:    Cul Density:
6) Strain:        Str Date:        Level:    Cul Density:
7) Strain:        Str Date:        Level:    Cul Density:
8) Strain:        Str Date:        Level:    Cul Density:
9) Strain:        Str Date:        Level:    Cul Density:

                 Suggestion Box:
        The Selectable List of Salmonella typhimurium
        strains is as follows:
        (Use <shift,F2> to see expanded list)
        TA98
        TA100

      F1- Help      F2- Suggestion      ESC- Abort
```

User Input

The following fields are input for the FINAL STRAIN screen:

Strain - strain associated with the sample being used in the experiment. The user will be limited to 20 strain/activation combinations per experiment.

Strain Date - date the master plate or culture was prepared.

Level - metabolic activation level to be used with this strain. This should be either 0 (no activation), 1 (first activation level), or 2 (second activation level).

Culture Density - cells per milliliter of overnight culture or other appropriate designation, up to 11 characters.

Processing

The FINAL STRAIN ENTRY function validates that the items being entered are valid as defined in the data dictionary and through lookup tables.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

NEG/POS CONTROL ENTRY

After completing the previous screen successfully, the user will be presented with the NEG/POS CONTROL ENTRY screen. This screen will allow the user to enter the positive and negative control information for the experiment. Control data for all strains being used should be entered at this time.

```
                    GeneTox Manager
          Negative/Positive Control Entry

 Strain: TA98    Str Date: 06/05/92 Level: 0  Cul Density: 1 x 10 e9

   Cd Control Name          Amount  Unt Plt#1  Plt#2  Plt#3  Plt#4  PLT#5
1)  0                        0.000        -1s    -1s    -1s    -1s    -1s
2)
3)
4)

                         Suggestion Box:

          Select CONTROL CODE AND CONTROL NAME
           (Use shift-F2 to see expanded list)
           Negative (Solvent) Controls:
          50 - Negative (No Solvent)
          51 - Distilled water
          52 - Normal Saline

     F1- Help    F2- Suggestion    F6- Change Strains    ESC- Abort
```

User Input

The following fields are input for the NEG/POS CONTROL ENTRY screen:

Control Code - two-digit code that indicates negative or positive control. Positive control numbers range from 1 - 49. Negative control numbers range from 50 - 99.

Control Name - name of control that corresponds to code, up to 20 characters.

Amount - amount delivered per plate.

Units - units for amount per plate.

Plate Counts 1-5 - actual plate counts. If an automatic colony counter is directly attached to your PC on the serial line, you may take advantage of the automated instrument interface for collecting plate counts. A laboratory is responsible for obtaining and establishing its own hardware and connections for interfacing the colony counter with the PC. The instrument interface is enabled by pressing <F5>, whereupon a highlighted window will be displayed in the upper, left-hand corner of the screen indicating that the instrument is enabled. The <F5> is a toggle function key, such that pressing it will alternately enable and disable the instrument interface. If <F5> is entered in a field other than Plate Count, the instrument is enabled so that as soon as the user moves to a Plate Count field, control passes to the instrument. Alternatively, pressing <F5> in a plate count field to enable the instrument interface will immediately pass control to the instrument.

Data is passed from the instrument to the PC through the following process:

Either 1, 3, or 5 readings will be taken from the instrument per plate depending on the iterative reading setting in the application. (The default iterative count is 3. The median value is accepted as the plate count of record.) The iterative count can be set to a different value via the Special Options menu of the Defaults function.

When control is passed to the instrument, the number of counts to be taken per plate will be displayed in the suggestion window in the lower, middle portion of the screen. Data is accepted to the PC by pressing the <PRINT> button on the Omni-Interface box. Then, an additional instrument reading of the sample can be taken by pressing the <COUNT> key on the Artek Counter. Each iterative reading will be displayed in the suggestion window, and the median value will be displayed in the current plate count data entry field.

To enter a -1 in the current plate count field, press <ENTER>. To cancel the current plate count reading from the instrument, press <ESC>. To disable the instrument interface and return to manual mode, press <F5>.

Code - code that appears after the plate count has been entered indicating the condition of the plate (eg, s, satisfactory; c, contaminated; etc.). May be changed if needed, but not necessary. To change this field, move to the Plate Count following the Code to edit. Then press the <TAB> key to move back to the Code field.

Processing

The NEG/POS CONTROL ENTRY function allows all positive and negative controls to be entered from one location and used throughout the system. There is a limit of 20 strain/activation combinations that may have positive and negative controls.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

The code field is validated from a lookup table. The other fields are validated as numeric only.

ACTIVATION SYSTEM INFORMATION

The user will be presented with the following screen. At this point, the user will enter a code for the S9 type and lot number, amount of activation mixture used per plate, QA information, and the S9 type and lot description.

```
                    GeneTox Manager
              Activation System Information

S9 Type And Lot Number.......:    000

                              Level 1  Units     Level 2  Units

Activation Mixture Per Plate.:          {    }              {    }
S9 Sterility Check (Before)..: 1
S9 Sterility Check (After)...: 1
S9 Lot Description...........:

                        Suggestion Box:

          FIRST CHARACTER INDICATES ANIMAL TYPE:
          M = MOUSE
          H = HAMSTER
          R = RAT
          G = GUINEA PIG
          B = RABBIT

F1- Help  F2- Suggestion  F8- Expand Des  F9- Save Des  ESC- Abort
```

User Input

The following fields are input for the ACTIVATION SYSTEM INFORMATION screen:

S9 Type - type of metabolic activation system (S9 type) that is being used for the experiment. Each character is validated from a lookup table. For example MLA091 indicates that the ninety-first lot of mouse liver Aroclor-induced S9 activation batch was used.

S9 Lot Number - unique three-digit code representing the specific lot of S9 that is being used for the experiment.

Activation Mixture Per Plate - activation mixture per plate for levels 1 and 2. The user may enter an activation amount per plate for each level.

Units - respective units for the activation mixture per plate. This item will default to microliters and does not require an entry unless the user desires to change it.

S9 Sterility Before - one-digit code representing the sterility of the S9 before the experiment. The codes are presented to the user in the suggestion box.

S9 Sterility After - one-digit code representing the sterility of the S9 after the experiment. The codes are presented to the user in the suggestion box.

S9 Description - description for the S9 type and lot number. To exit from the description field press <PgUp> or <PgDn>. Pressing <F8> will allow an expanded description to be entered and pressing <F9> will save the description.

Processing

The ACTIVATION SYSTEM INFORMATION function defines the information associated with the S9 type and lot for the experiment.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

Only the S9 type will be validated; the other information will be left to the user's discretion. If the S9 type is not entered, a warning message will be displayed telling the user that the information entered will not be retained if the S9 type is left blank.

SAMPLE SPECIFIC DATA

After successfully completing the NEG/POS CONTROL ENTRY screen, the user will be presented with the following screen. This screen allows the user to enter sample information specific to its analysis under an experiment into the database.

```
                    GeneTox Manager
                Sample Specific Data

Sample Id............:
Sample Description...:
Source/Batch/Lot.....:
CAS Number...........:

                Suggestion Box:

        SAMPLE IDENTIFICATION NUMBER

The format of the Sample Identification Number
is:  AAAAYYNNNN
  where  AAAA is a four letter identifier
                 of the source for the sample,
         YY identifies the year the sample
           was received, and
         NNNN is a sequentially assigned

F1- Help  F2- Suggest  F8- Expand Des  F9- Save Des   ESC- Abort
```

User Input

The following fields are input for the SAMPLE SPECIFIC DATA screen:

Sample ID - unique field that identifies the sample, up to 10 characters. The first four characters can be alphanumeric but the remaining six must be numeric. NOTE: If you have entered a sample previously and are returning to this screen from the Continue screen by choosing "Change Sample ID", this sample ID will be automatically incremented by GeneTox Manager (i.e., if sample IARC930001 was the last sample entered, the new sample ID will be IARC930002). If you do not wish to number your samples consecutively, you may change the sample ID.

Sample Description - description for the sample that is being used in the experiment, up to 51 characters. Pressing <F8> will allow an expanded description to be entered and pressing <F9> will save the description.

Source/Batch/Lot - identification for the source, batch, and lot number of the sample, up to 51 characters.

CAS Number - CAS number associated with the substance being tested, up to 15 characters.

Processing

The SAMPLE SPECIFIC DATA function allows the user to enter sample information specific to an experiment into the database. Each field uniquely identifies the experiment and lists some of the aspects of the sample.

Note: When entering a sample id which has been previously defined to the system, the remaining fields on this screen will be filled with current values for the sample. Any changes to these values WILL NOT be stored in the database. To change general sample information, see the Change Existing Sample function described later in this document.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

The system will check for the existence of a duplicate sample ID. If one exists, the system will display the information associated with that sample. Solvent units will be checked against a lookup table. If an error is detected, the user will be notified and allowed to correct the entry.

STRAIN AND ACTIVATION SELECTION

After successfully completing the SAMPLE SPECIFIC DATA screen, the user will be presented with the following screen. The current strain is listed.

```
GeneTox Manager
Strain & Activation Selection

Current Strain...: TA98
Strain Date......: 06/05/92
Activation Level.: 0
Culture Density..: 1 x 10 e9
Dose Units.......: (ug )

Suggestion Box:

Enter in the following format or select:
ug - micrograms
mg - milligrams
ul - microliters
ml - milliliters
m3 - cubic meters (gases, air samples)
uM - micromoles

F1- Help  F2- Suggestion  F6- Change Strains  ESC- Abort
```

User Input

The only input at this screen is the DOSE UNITS to be used for the sample when this strain is being used. Press <F6> to change the strain.

Processing

The STRAIN AND ACTIVATION SELECTION function allows the user to select what sample dose units to associate with the individual strains.

Outputs

A dose unit is associated with each strain.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

QUALITY ASSURANCE CHECKS

After successfully completing the STRAIN AND ACTIVATION SELECTION screen, the user will be presented with the following screen. A header will appear from this point on to allow the user to identify the sample that is being worked on.

```
                    GeneTox Manager
                Quality Assurance Checks

 Samp Id: SAMP920001   Strn: TA98    Strn Date: 12/12/12   Act Levl: 0

Solvent Description..:
Solvent Amount/Plate.:    0        PhenoCopy Check Code.....:  1
Solvent Units........:             Sample Sterility Before..:  1
Hours Of Incubation..:   0.00      Sample Sterility After...:  1

                    Suggestion Box:
              SOLVENT DESCRIPTION

          Enter the name of the solvent for the sample.

        F1- Help      F2- Suggestion      ESC- Abort
```

User Input

The following fields are input for the QUALITY ASSURANCE CHECKS screen:

Phenocopy Check - one-digit code representing the phenocopy check code. The user is presented with appropriate codes within the suggestion box.

Sample Sterility Before - one-digit code representing the sterility of the sample before the experiment. The user is presented with the appropriate codes within the suggestion box.

Sample Sterility After - one-digit code representing the sterility of the sample after the experiment. The user is presented with the appropriate codes within the suggestion box.

Solvent Description - description of solvent used for the test substance.

Solvent Amount/Plate - amount of solvent used per plate.

Solvent Units - units to be associated with solvent.

Hours of Incubation - hours that the plates were incubated.

Processing

The QUALITY ASSURANCE CHECKS function allows the user to enter codes that represent the state of the bacteria and the sterility of the sample being used.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

All fields are validated from a lookup table. If an invalid entry occurs, the system will display an error message and allow correction.

DOSE DATA ENTRY

After successfully completing the QUALITY ASSURANCE CHECKS screen the user will be prompted with the following screen. This screen will allow the user to enter the actual test data into the computer.

```
                    GeneTox Manager
                    Dose Data Entry

  Samp_Id: SAMP      Strain: TA98   Strn Date: 12/12/12  Ac: 0

  Dose (J  )  Plt#1 Cd   Plt#2 Cd   Plt#3 Cd   Plt#4 Cd   Plt#5 Cd

   Zero Dose Not Entered.....
1)    0.000
2)
3)
4)

                    Suggestion Box:
              DOSE AMOUNT
          Enter the numeric indication of the dose amount.
          Be sure to note the units at the top of the
          column.

F1- Help  F2- Suggestion  F5- Colony Counter  ESC- Abort  PgDn- Continue
```

User Input

The following fields are input for the DOSE DATA ENTRY screen:

Dose - amount of the dose for each level used during the experiment, up to 20 doses.

Plate#1 - 5 - actual colony count (by the technician or the colony counter). If an automatic colony counter is directly attached to your PC on the serial line, you may take advantage of the automated instrument interface for collecting plate counts. The instrument interface is enabled by pressing <F5>, whereupon a highlighted window will be displayed in the upper, left-hand corner of the screen indicating that the instrument is enabled. The <F5> is a toggle function key, such that pressing it will alternately enable and disable the instrument interface. If <F5> is entered in a field other than Plate Count, the instrument is enabled so that as soon as the user moves to a Plate Count field, control passes to the instrument. Alternatively, pressing <F5>

in a plate count field to enable the instrument interface will immediately pass control to the instrument.

Data is passed from the instrument to the PC through the following process:

Either 1, 3, or 5 readings will be taken from the instrument per plate depending on the iterative reading setting in the application. (The default iterative count is 3. The median value is accepted as the plate count of record.) The iterative count can be set to a different value via the Special Options menu of the Defaults function.

When control is passed to the instrument, the number of counts to be taken per plate will be displayed in the suggestion window in the lower, middle portion of the screen. Data is accepted to the PC by pressing the <PRINT> button on the Omni-Interface box. Then, an additional instrument reading of the sample can be taken by pressing the <COUNT> key on the Artek Counter. Each iterative reading will be displayed in the suggestion window, and the median value will be displayed in the current plate count data entry field.

To enter a -1 in the current plate count field, press <ENTER>. To cancel the current plate count reading from the instrument, press <ESC>. To disable the instrument interface and return to manual mode, press <F5>.
NOTE: A -1 indicates to the software system that a plate count was not recorded. It is the system's way of determining the number of plates per dose.

Cd (Code) - one character code representing the type of plate reading that was taken. This field does not have to be entered. The system will default to "s" as values are read in. To change this field, move to the Plate Count following the Code to edit. Then press the <TAB> key to move back to the Code field.

Processing

The DOSE DATA ENTRY function allows the user to enter experiment specific data that represents the results of the experiment.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

The system will validate each code from a lookup table. If an invalid entry occurs, the system will display an error message and allow correction. Dose and plate counts are verified only as numeric values.

EXPERIMENTAL REMARKS

After successfully completing the DOSE DATA ENTRY screen the user will be prompted with the following screen. The remarks screen will allow the user to enter text about the experiment.

```
GeneTox Manager
Experimental Remarks
Samp Id: SAMP920001   Strn: TA98    Strn Date: 12/12/12   Act Leul: 0
Experimental Remarks

Suggestion Box:
REMARKS (Press sF2 for information)
F1- Help  F2- Suggestion  F7- Dose Screen  F9- Save Des  ESC- Abort
```

User Input

The following field is input for the EXPERIMENTAL REMARKS screen:

Remarks - text to explain the results or some other point about the experiment. When finished entering the remark press <F9>. This will terminate the data entry phase and bring up the next screen.

After entering the remarks text and pressing <F9>, the user will be asked if they wish to append an instruction set to the remarks text. If the user answers yes, they will be presented with another prompt which asks if they wish to append the currently selected instruction set. Answering yes appends the instruction set currently selected for this experiment. Answering no allows the user to select a particular instruction set that has been previously entered and saved. After appending, the user is returned to editing the remarks text and may make changes to the appended instruction text. Pressing <F9> a second time causes the remarks text plus the appended instruction set to be saved.

Processing

The EXPERIMENTAL REMARKS function allows the user to enter experiment-specific remarks about the way the experiment concluded or any text that the technician believes is pertinent to the experiment. Up to 700 characters may be entered for the remarks.

Outputs

No data is saved at this point. The data is held in temporary variables until the user elects to save it at the CONTINUATION screen.

Quality Control

No validation is made on the remarks. The user may enter any valid character represented by the PC.

NOTE: Any special characters used may not be represented correctly on the VAX since the VAX does not support DOS's extended character set.

CONTINUATION

After successfully completing the EXPERIMENTAL REMARKS screen the user will be prompted with the following screen. This screen will allow the user to continue entering dose response data, change sample ID and description, save data and exit, return to the remarks field to continue editing or exit without saving.

```
GeneTox Manager
Experimental Remarks

Samp Id: TEST920001   Strn: TA98    Strn Date: 06/05/92   Act Level: 0

Continue Entering Dose Response Data
Change Sample Id & Description
Save Data And Exit
Resume Editing The Remarks Field
Exit Without Saving Data

Suggestion Box:

REMARKS (Press sF2 for information)

F1- Help   F2- Suggestion   F9- Save Des   ESC- Abort
```

User Input

The following fields are input for the CONTINUATION screen:

Continue Entering - allows the user to continue entering dose response data for any remaining strains for the present sample. All previously entered data is saved. User is returned to the Strain and Activation Selection screen and the next strain is selected.

Change Sample ID - allows the user to change samples and enter dose response data for the new sample while remaining in the same session (i.e., none of the General or Control information is changed). All previously entered data is saved. User is returned to the Sample Specific Data screen and the sample ID is incremented (i.e., if sample IARC930001 was the last sample entered, the new sample ID will be IARC930002).

Save Data and Exit - allows the user to save all data entered and exit to the main menu.

Resume Editing - allows the user to return to the remarks field to continue editing.

Exit without Saving - aborts the data entry sequence for the current sample. Any data entered prior to reaching this screen is saved from this screen by choosing "Continue Entering", "Change Sample", or "Save And Exit". General experiment data is saved when continuing from this screen after entering the dose response data for the first sample. Dose response data for each sample is saved when continuing from this screen or choosing "Save Data and Exit". Therefore, choosing "Exit without Saving" will only abort saving data for the current sample, unless this sample is the first sample entered for the experiment.

Processing

The CONTINUATION function allows the user to continue entering dose response data or to exit back to the MAIN MENU.

Outputs

All data is saved at this point unless the user chooses EXIT WITHOUT SAVING DATA or presses <ESC> to abort. If the user chooses to EXIT WITHOUT SAVING or presses <ESC>, no data will be saved and the MAIN MENU will appear. If data is saved at this point, an output file is also generated which contains all of the information for the experiment in condensed form. This file serves as a back-up file of experiment data in addition to the data loaded directly to the PC databases.

The naming convention for this output file is as follows:

eeeeeeee.ffB where

eeeeeeee are the first 8 characters of the experiment name,
ff are the 9th and 10th characters of the experiment name, and
B is a literal value appended to the experiment name to
indicate that this file contains backup experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with a "B" still appended to the end (e.g., an experiment name of CSCT910001 will yield a back-up filename of CSCT9100.01B, while an experiment name of TEST will yield a back-up filename of TESTB).

Quality Control

If CONTINUATION OF DOSE DATA ENTRY is chosen, there is a check for any strains for which no data has been entered. If no more of these strains remain, the PC will not allow this option to be selected. Conversely, if SAVE DATA AND EXIT is chosen and there still remain unentered dose responses for strains, the PC will prompt the user for verification to exit without completing the data entry for this session.

If the user chooses to CHANGE SAMPLE ID, as in the SAVE AND EXIT option, the PC will check for remaining unentered dose data for strains and prompt accordingly. This option will "rewind" to the SAMPLE SPECIFIC DATA screen and allow additional samples to be added.

> **NOTE:** No data in the Experiment Description, Assay Type Selection, Final Strain Entry, Neg/Pos Control Entry, or Activation System Information screens will be displayed or changed when the CHANGE SAMPLE ID OPTION is selected.

MODIFY EXISTING EXPERIMENT

After selecting the MODIFY EXISTING EXPERIMENT option from the ENTER/MODIFY menu, the user will be prompted with other screens to specify exactly which data is to be modified. These screens will allow the user to modify existing experiment data in the database. After choosing what data is to be modified, the user will be presented with the screens associated with the data. Each screen is defined in the ENTER NEW EXPERIMENT section of this manual. Please refer to that section for instructions.

After selecting either Modify Existing Experiment or Change Existing Samples, the user is presented with the following screen:

```
GeneTox Manager  Main Menu
        EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit
Enter New Experiment
Modify
Change
Instru
Date:      03/08/93
Initials:
Reason:

F8 - Expanded Reason  F9 - Save Expanded Reason

Modify Experiment Data Contained In the Database
```

The user is required to enter their initials and a reason for the modification before they are allowed to continue. This feature was implemented in accordance with the Good Laboratory Practices standard, and provides a method of tracking user modifications to experiment and sample data. Modification information is appended to the S9 Description for Experiment data modifications; for sample modifications, the information is appended to the Sample Description.

```
GeneTox Manager  Main Menu
        EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit
Enter New Experiment
Mo
Ch   General Exper.  Data
In   Control Exper.  Data
     Existing Sample Data
     Dose Response   Data
     New Sample      Data
     Delete Sample   Data

Modify Experiment Data Contained In the Database
```

User Input

The following options are available from the MODIFY EXPERIMENT screen:

General Experiment Data - allows modification of the following: Experiment Description, Assay Type Selection, Final Strain Entry and Activation System. After selecting one of these options, the user is required to enter the experiment name and research laboratory associated with that experiment.

Control Experiment Data - allows modification of the control data. The user is required to enter the experiment name.

Sample Specific Data - Under the modify experiment function, sample information can be modified that applies to analysis of a sample under a given experiment. Sample specific data, however, cannot be changed in this environment and is displayed for information only. To change sample specific data, see the Change Existing Sample function described later in this document.

In the modify experiment environment, the following sample information can be modified: Sample Specific Data, Current Strain Selection, Quality Assurance Checks and Experimental Remarks. After selecting one of these options the user is required to enter the experiment name and the sample ID of the sample to be modified.

Dose Response Data - allows modification of the Dose Response Data. The user is required to enter the experiment name and sample ID of the sample to be modified.

New Sample Data - allows the registration of additional samples to an existing experiment.

Delete Sample Data - allows deletion of a sample from its association with an experiment strain. User is required to enter the experiment name and sample ID, and to choose the strain from which to delete. If the sample is not used for any other experiment strains, it is permanently deleted from the database.

Processing

The MODIFY EXISTING EXPERIMENT function provides the user with the capability to change data contained in the database. The MODIFY routine allows modifications to categories of previously entered data: General Data, Control Data, Sample Specific Data, Dose Response Data, and New Sample Data. This simplifies the process for making minor modifications. Each section is modified individually, with modifications saved/aborted separately.

NOTE: The screens have been defined in the ENTER NEW EXPERIMENT section of this manual. Please refer to the appropriate section to obtain help on these screens.

Outputs

None.

Quality Control

Search Criteria (Experiment Name, Sample ID) are validated. If an invalid entry occurs, the system will display an error message and allow correction. All other fields are validated in similar fashion to their counterparts in the ENTER NEW EXPERIMENT function.

CHANGE EXISTING SAMPLES

After selecting the CHANGE EXISTING SAMPLES option, the user will be prompted for a sample id for an existing sample. After validation, the system will present the user with a screen of sample specific data (equivalent screen to the one under ENTER NEW EXPERIMENT for sample specific data). Refer to the SAMPLE SPECIFIC DATA description under the ENTER NEW EXPERIMENT section for details on the sample fields that may be modified. Modification tracking is also done on Sample Data (see Modify Existing Experiment).

INSTRUCTIONS FOR EXPERIMENT MENU

The following options will be available to the user upon selecting the INSTRUCTIONS menu:

Add - allows the addition of new instruction sets to the instruction database.

View - prompts for the path and allows inspection of the available instruction sets.

Modify - prompts for the path and allows the modification of any available instruction sets.

Delete - prompts for the path and allows the removal of available instruction sets.

Select - prompts for the path and allows for the selection of an instruction set to be used during the GeneTox Manager session or until a new set is chosen.

Transfer - prompts for the source path and permits the transfer of an instruction set to another disk or path.

Print - prompts for the path and generates a printout of the selected instruction set.

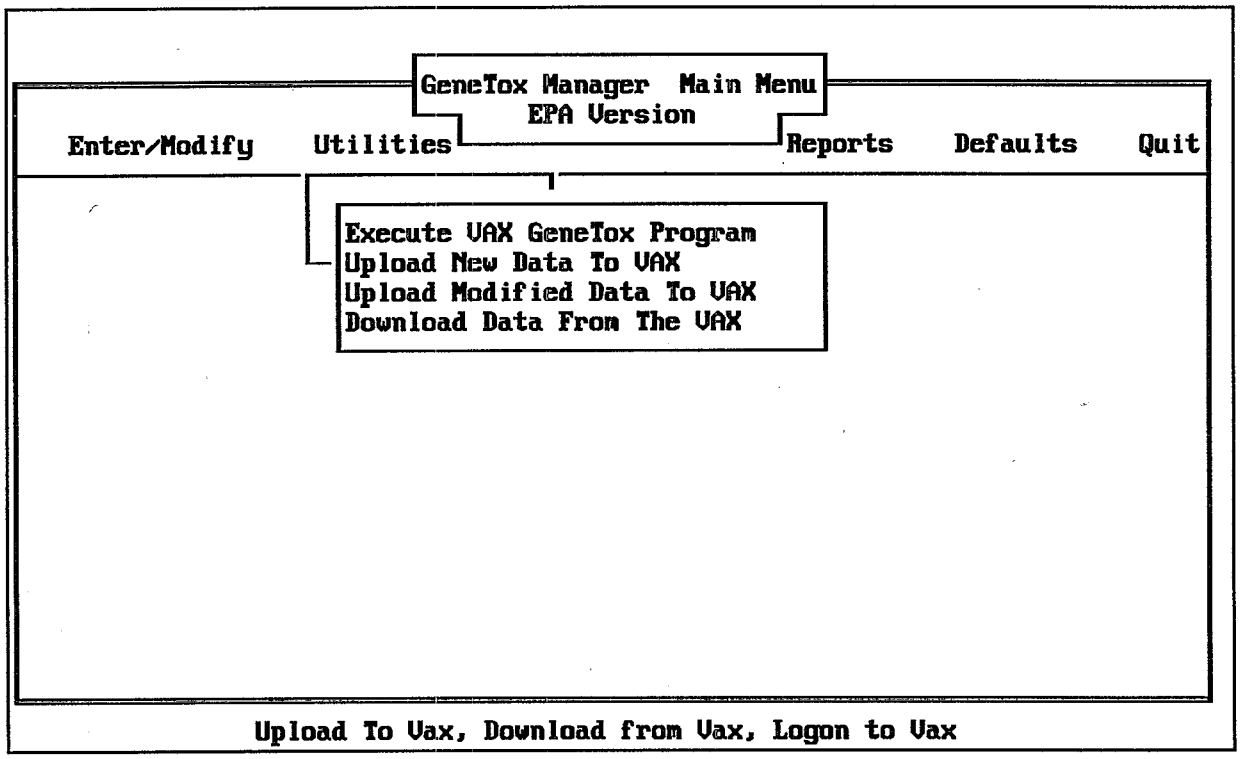
UTILITIES MENU

After selecting the UTILITIES option from the MAIN MENU, the user will be presented with two options: PC FUNCTIONS and VAX FUNCTIONS.

VAX FUNCTIONS MENU (Accessible to VAX Version Only)

The communications programs are driven by predesigned script files that are specific to the VAX setup at the U.S. EPA Laboratory in Research Triangle Park, North Carolina. Using a VAX version of GeneTox Manager at another site may require some modifications to these files. This applies to all functions under the VAX FUNCTIONS menu.

The following menu lists VAX functions:



Execute VAX GeneTox Program - Allows user to connect to the VAX as if logged in at a VAX Terminal. Provided to allow user to access VAX GeneTox Manager programs without exiting PC system. Users may also access the VAX without using the PC GeneTox Manager Program.

Upload New Data To VAX - Extracts all data for the specified experiment to a file on the PC, transfers the file to a VAX and loads the data to master Focus databases.

Upload Modified Data To VAX - Performs an equivalent function to the one above for new experiment data, but in this case applies to modified data for an existing experiment.

Download Data From The VAX - Extracts data for an experiment from the VAX Focus databases, downloads the file to the PC and loads the information into PC databases. Downloaded experiments are in "Read Only" status and cannot be modified.

EXECUTE VAX GENETOX PROGRAM

This Function is provided to allow the user to run the VAX FOCUS version of the GeneTox Manager without leaving the PC Application. The user is logged on to their VAX account through PathWorks using the DEC SetHost communications program and the VAX GeneTox upload program is executed.

User Input

User must provide the SetHost script program with the user name and password of the VAX account they are logging in under. User exits by typing "lo <RET>" (logout) at the VAX $ prompt and then using Control-F10 to exit SetHost and return to the PC GeneTox program.

Processing

User is logged in by SetHost (assuming user name and password are correct) and the VAX GeneTox program is executed.

Output

Behaves as if the user were logged on to the VAX through a DEC Terminal.

UPLOAD NEW DATA TO VAX

This function allows the user to extract all data for an experiment to a file and subsequently upload the data to VAX master databases. The user is logged on to their VAX account through PathWorks using the DEC SetHost communications program and a VAX GeneTox upload program is executed.

The SetHost program is driven by a predesigned script file that is specific to the VAX setup at this laboratory. Using a VAX version of GeneTox Manager at another site may require some modifications to this file.

User Input

Experiment name for which to upload data. User name and Password for the VAX account they wish to login under.

Processing

This function will search application databases for the requested experiment name. If the experiment name does not exist, the user will be notified in an error message and allowed to try again. This function will only extract data for an experiment which has NOT already been uploaded to the VAX previously. To upload revised experiment information, use the UPLOAD MODIFIED DATA TO VAX function.

If incomplete or invalid data is found for the experiment requested, the user is notified via a message to the screen and the processing of this data file to the VAX is terminated. If, on the other hand, a clean extract file is generated, the system will then attempt to establish communications to the VAX using SetHost.

If appropriate communication to the VAX can be established, the extracted file is transferred to the user's VAX account and a Focus upload procedure is invoked to load the extract file to Focus master databases. A verification message is displayed to the user at the end of this process to indicate successful completion of the upload or an abnormal abort situation.

A log file which provides further information on the VAX database upload results is also generated to the user's VAX account.

Outputs

- A file containing all experiment data for the experiment name requested on the PC.
- Updated VAX master databases containing new information based on the experiment requested.
- Resetting of a flag in the PC databases which indicates that the experiment has now been uploaded to the VAX. A log file which provides detailed information on the VAX database upload. The file is named as follows:

mmddhhuu.LOG- where
mm is a 2 character code for the current month
dd is a 2 character code for the current date
hh is a 2 character code for the current hour
uu is a 2 character code for the current minute

For purposes of this file name, CURRENT is defined as the point in time that the log file was opened (i.e., when loading of data to the VAX began).

Quality Control

The experiment name field is validated. If the experiment does not exist in the application databases, an error message to that effect is displayed to the user. In addition, the extraction file is validated for completeness before attempting to transfer it to the VAX. And, finally, the upload of VAX databases is validated with results documented in a log file and in a display message to the user at the completion of the process.

GeneTox expects the PathWorks network software to be loaded in order to make the connection to the VAX. Uploading will not be possible if the PC is booted without the network. If user name or password are entered incorrectly, the login will not be completed. To exit sethost, press <Cntrl-F10> to exit and return to GeneTox Manager.

UPLOAD MODIFIED DATA TO VAX

This function is very similar to the function described immediately above, UPLOAD NEW DATA TO VAX. The difference in this function is that the user may extract "data modifications" for a specified experiment to a file and subsequently upload the data to VAX master databases. Note that modified data may represent only a portion of the total information available for a given experiment.

DOWNLOAD DATA FROM THE VAX

This function allows user to download data previously uploaded by another user with NEW or MODIFIED UPLOAD. The user is logged on to their VAX account through PathWorks using the DEC SetHost communications program and the VAX GeneTox download program is executed. Downloaded data is stored in the databases in "Read Only" status. Downloaded Experiments may NOT be modified, re-uploaded, or archived.

The SetHost program is driven by a predesigned script file that is specific to the VAX setup at this laboratory. Using a VAX version of GeneTox Manager at another site may require some modifications to this file.

User Input

User must provide GeneTox Manager with the user name and password of the VAX account they wish to login under. User must also provide the experiment name of the experiment to download. Users may only download data that does not currently exist on their PC. The system will inform the user of any conflicts with existing experiment names of experiments currently stored on their PC and may require the user to rename their current experiment or the download experiment depending on the circumstances.

Processing

User is logged on to the VAX through the specified account and a download program is run. The specified experiment data is extracted from the VAX databases and a file containing the experiment data is created. This File is called "PCDOWN.VAX". PCDOWN.VAX is transferred to the PC. Downloaded data is then loaded into the PC databases.

Output

GeneTox informs user of current status throughout the process (i.e. when running VAX extract program, transferring file, processing downloading file, and saving data to the databases). If any errors occur the user is informed. A transaction file PCDOWN.TRN is created on the PC in the same directory as the GeneTox Manager Databases which will contain specific information on any errors encountered. This file can be viewed by the user with the DOS TYPE command or with a text editor of the user's choice.

Quality Control

Downloaded data is validated before saving it to PC databases. User is notified of success or failure of download attempt. Specific errors are written to transaction log file PCDOWN.TRN on the PC. Errors encountered when extracting data from VAX FOCUS databases are written to the PCDOWN.VAX download file. This file can be viewed by the user with the DOS TYPE command or with a text editor of the user's choice.

PC FUNCTIONS MENU

After selecting the PC FUNCTIONS option from the UTILITIES menu, the following screen will appear:

```
GeneTox Manager  Main Menu
EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit

List Experiments In Database
Reindex GeneTox Manager Databases
Retrieve Backup Experiment Data
Import/Export Experiment Data
Delete Read Only or Download Exp
Archive/Dearchive Experiment Data
Import Spiral Systems Data

List Experiments, Extract Files, Use Vax Files, Reindex Databases
```

Functions available from this menu include the following:

List Experiments In Database - Provides a list of all experiments defined to the PC system.

Reindex GeneTox Manager Databases - Reindexes PC based databases to ensure data integrity.

Retrieve Backup Experiment Data - Allows user to reload backup copies of previously entered experiment data should the original data become corrupted.

Import/Export Experiment Data - Allows user to share experiments between different PC copies of GeneTox Manager. Imported experiments are in a "Read Only" status and cannot be modified.

Delete Read Only or Download Experiment - Allows user to delete experiments that are in "Read Only" status from the database. (Imported or Downloaded Experiments Only)

Archive/Dearchive Experiment Data - Allows user to archive/dearchive old experiment data to reduce size of databases.

Import Spiral Systems Data - Allows user to import data collected by a Spiral Biotech's laser scanner/counter using the Spiral Biotech data collection program.

LIST EXPERIMENTS IN DATABASE

This function allows the user to review a list of all experiment names logged to the system.

User Input

The following input field is provided for this function:

Experiment Name - defines the experiment name(s) to be listed. A partial definition of the name will generate a list of all experiments meeting the defined letters. A response of a blank field will generate a list of all experiments logged to the system.

The following selection criteria are supported: (1) all experiments; (2) experiments that have been previously uploaded; (3) experiments that have not been previously uploaded; (4) read only experiments.

Processing

This function will search application databases for all experiment names in the system meeting the character mask provided by the user.

Outputs

A list of the experiments in the PC database is generated to the terminal, printer, or file, based upon the user's choice.

Quality Control

The experiment name field is validated. If the experiment does not exist in the application data bases, an error message to that effect is displayed to the user.

REINDEX GENETOX MANAGER DATABASES

This function allows the user to reindex PC based databases to ensure data integrity. It is most advisable to use this function whenever it is suspected that an index file has been corrupted.

User Input

No user input is required for this function.

Processing

This function will select each application database and regenerate defined indices for each.

Outputs

A set of new indices for application databases is generated. As each database is selected and indexed, a notification message is displayed to the user on the screen.

Quality Control

Each database is indexed according to key fields defined in the application code.

RETRIEVE BACKUP EXPERIMENT DATA

A backup copy of experiment data is saved every time you enter or modify an experiment. This Function is provided to retrieve this backup data should experiment data in the databases become corrupted. Backup data will normally reside in the same directory as the GeneTox Manager databases.

The naming convention for this backup data file is as follows:

eeeeeeee.ffB where
eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
B is a literal value appended to the experiment name to indicate that this file contains backup experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with a "B" still appended to the end (e.g., an experiment name of CSCT910001 will yield a back-up filename of CSCT9100.01B, while an experiment name of TEST will yield a back-up filename of TESTB).

User Input

User enters the experiment name for which to retrieve backup data, and optionally the drive and DOS path where the backup file is located if the backup file is not found in the default directory.

Processing

If the backup file is found, data is restored to the databases. If any data for the experiment currently exists in the databases, the user is warned that data will be over-written as part of the retrieval process.

Output

A transaction log is created with a DOS filename similar to the backup file, but with the letter "T" as the third letter of the extension. This file contains error messages describing any errors encountered in the retrieval process. The user is also informed of the success or failure of the retrieval attempt.

Quality Control

System checks for existence of a backup data file first in the directory containing the GeneTox Manager Databases (where they are located when generated), and then in a user specified directory, and informs the user if the data cannot be located. System also informs user if backup file is in invalid format. Specific errors noted in backup file will be recorded in the transaction log.

IMPORT/EXPORT EXPERIMENT DATA

The following menu is displayed when selecting IMPORT/EXPORT EXPERIMENT DATA.

```
GeneTox Manager  Main Menu
        EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit

List Experiments In Database
Reindex GeneTox Manager Data Bases
Ret
Imp  Import Experiment Data from File
Del  Export Experiment Data to File
Arc

List Experiments, ReIndex, Retrieve Backups, Import/Export, Archive/Dearchive
```

EXPORT EXPERIMENT DATA TO FILE

This function allows user to share experiment data with other GeneTox users. Data is exported in "Read Only" status - receivers cannot modify the data. An output file of experiment data is generated. The naming convention for this file is as follows:

eeeeeeee.ffR where

eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
R is a literal value appended to the experiment name to indicate that this file contains exported experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with a "R" still appended to the end (e.g., an experiment name of CSCT910001 will yield an export filename of CSCT9100.01R, while an experiment name of TEST will yield an export filename of TESTR).

User Input

Experiment Name for which to export data; and Drive/DOS Path location for exported experiment file.

Processing

Creates export file of experiment data. Any errors noted will be recorded in the export file.

Output

Export file containing experiment data.

Quality Control

User informed of any errors in drive or pathname specified, and of any errors encountered in generating the export file. Specific error information is written to the export file.

NOTE - If errors occur in generating export file, export file will NOT have the correct format and may NOT be subsequently imported by another user. Cause of the error must be fixed and a new export file generated.

IMPORT EXPERIMENT DATA FROM FILE

This function allows user to bring data exported by another user into their databases. Imported experiments have "Read Only" status and cannot be modified, re-uploaded, or archived. Import data files have the following format:

eeeeeeee.ffR where

eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
R is a literal value appended to the experiment name to indicate that this file contains exported experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with a "R" still appended to the end (e.g., an experiment name of CSCT910001 will have an import filename of CSCT9100.01R, while an experiment name of TEST will have an import filename of TESTR).

User Input

Experiment Name; Location of import file - drive and DOS path. Users may only import data that does not currently exist on their PC. The system will inform the user of any conflicts with existing experiment names of experiments currently stored on their PC and may require the user to rename their current experiment or the import experiment depending on the circumstances.

Processing

Experiment added to databases in "Read Only" status.

Output

Displays messages when processing import file and saving data. Errors are written to a transaction log file. Transaction file has DOS filename similar to the import file, but with the letter "T" as the third letter of the extension.

Quality Control

User notified if import file cannot be found, or if specified drive and path are incorrect. User notified if import file has incorrect format. Specific format errors are recorded in the transaction log.

DELETE READ ONLY OR DOWNLOAD EXPERIMENT

This function allows user to delete experiments imported from other users or downloaded from the VAX databases. Experiment data is permanently deleted.

User Input

Experiment name of experiment to be deleted.

Processing

Deletes all data associated with the experiment from the databases.

Output

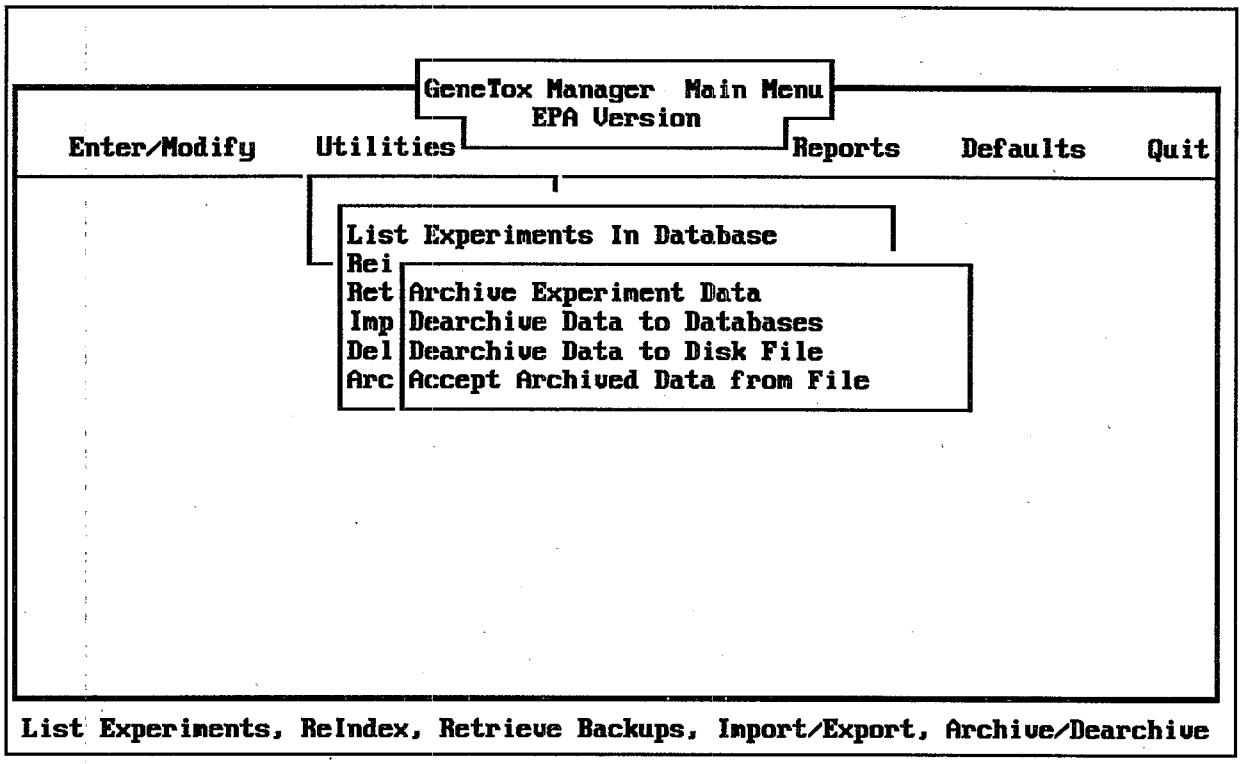
None.

Quality Control

Informs user if experiment does not exist. Will NOT allow deletion of experiments that have not been either imported or downloaded. A function to delete ANY experiment is provided under the password protected options in SET SPECIAL OPTIONS under the DEFAULTS menu.

ARCHIVE/DEARCHIVE EXPERIMENT DATA

The following menu will be displayed after selecting ARCHIVE/DEARCHIVE EXPERIMENT DATA:



The Archive/Dearchive options may be used for two purposes: to remove unused data from the working databases for long term storage; or to transfer ownership of data from one user to another. When transferring ownership, the procedure used will depend on the location of the experiment data.

Transfer Ownership (from Databases): To transfer ownership of data that is currently contained in your working databases (has not been archived), you will use the "Archive Experiment Data" option to archive it to floppy diskette (or a shared file service) from which the receiving user will dearchive the data using "Dearchive To Databases". The receiving user needs to know the location of the archived data and the password under which it was archived.

Transfer Ownership (from Local Archives): To transfer ownership of data that has been archived to an archive file located on your hard drive, you will use the "Dearchive Data To Disk File" option, and place the file on floppy disk (or a shared file service). The receiving user

needs to know only the experiment name and the location of the file in this case, not the password. To bring this data into their databases, the receiver uses "Accept Archived Data From Disk" and provides the experiment name and location (DOS drive and path) when prompted.

Transfer Ownership (from Shared Archives): To transfer ownership of data that has been archived to a shared archive (an archive file to which both users have access, on a shared file service, for example), you will merely need to provide the receiving user with the location and password for the experiment. The receiving user can dearchive the data using "Dearchive To Databases" by specifying the password an location when prompted.

ARCHIVE EXPERIMENT DATA

This function allows the user to remove experiment data from the PC databases. Archived data will be compressed using the PKZIP compression utility and stored in a specified archive file in a user specified location. Experiment data must be in Inactive status (uploaded to VAX databases) before archiving on the VAX version of GeneTox Manager. Archiving experiment data will reduce the size of the GeneTox databases and increase the speed of reports. Archiving data will also save disk space. Experiments are archived using a specified password, and may not be dearchived without that password.

User Input

User enters name of experiment to archive, password for archive file, and location and name of archive file. Default location values are set at system installation or changed with LOCATE ARCHIVES in the DEFAULTS menu. The default archive file has the filename "GTMARCHV.ZIP". The user may override any of these default values.

Processing

Experiment data is generated in the same format as exported experiment data. The naming convention for this output file is as follows:

eeeeeeee.ffX where

eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
X is a literal value appended to the experiment name to indicate that this file contains archived experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with an "X" still appended to the end (e.g., an experiment name of CSCT910001 will yield a filename of CSCT9100.01X, while an experiment name of TEST will yield a filename of TESTX).

This file is then compressed using the PKZIP compression utility and added to the specified archive file. Data is then deleted from the databases and a database containing information concerning archived experiments is updated with experiment name, password, location, and date for this archive file (See LIST ARCHIVED EXPERIMENTS under the SPECIAL OPTIONS of the DEFAULTS menu).

Output

Experiment data is compressed and placed in the user specified archive file. Any specific errors encountered in generating the output data file are written to the file. If an error occurs archiving of the experiment data will be aborted. This file can be viewed by the user with the DOS TYPE command or with a text editor of the user's choice.

NOTE - because the location for the archive file is specified using a DOS drive and path name, the actual archive file can be generated on the PC hard disk, on floppy diskette for transfer to another user, or on a network file service by specifying the proper drive and path names.

Quality Control

User is informed if experiment does not exist, drive and path are incorrect, or not enough space is left on disk for archive file. If an error occurs during archiving, data is NOT deleted from the databases.

DEARCHIVE DATA TO DATABASES

This function allows the user to dearchive previously archived experiment data from a compressed archive file.

User Input

Experiment name and password of file to dearchive. The password must be the same password used to archive experiment (If the password has been forgotten, use LIST ARCHIVED EXPERIMENTS function under SET SPECIAL OPTIONS of the DEFAULTS menu). Optionally, a user specified drive, path, and archive filename if a record of this experiment is not stored in the user's archived experiments list.

Processing

Archived experiments database is searched for an entry indicating that this experiment was archived. If found, the drive, path, and filename information stored in the database is used to retrieve the archived data. If the entry does not exist, or the file is not found, the user is prompted for the location of the archived experiment (drive, path, and archive filename). This allows the user to dearchive experiments that have been archived by another user if they know the experiment name, password, and location.

The PKUNZIP decompression utility is used to decompress the requested experiment and the data is then restored to the databases. The entry for the archived experiment is then deleted from the archived experiments list.

Output

GeneTox Manager informs the user when decompressing and saving data, and when errors occur during processing decompressed data file. A transaction log file is created during the dearchival attempt. Any errors noted in processing the dearchived data are written to this log file.

The naming convention for this transaction log is as follows:

eeeeeeee.ffT where

eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
T is a literal value appended to the experiment name to indicate that this file contains transaction data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with a "T" still appended to the end (e.g., an experiment name of CSCT910001 will yield a log filename of CSCT9100.01T, while an experiment name of TEST will yield a log filename of TESTT).

Quality Control

The user is informed of any errors - incorrect password, drive, path or archive file not found, experiment data not found in archive file, decompression unsuccessful, or problem processing decompressed data. Specific errors are reported in the transaction log.

DEARCHIVE DATA TO DISK FILE

This function is provided to allow users to place dearchived data into a disk file which may be given to other users and added to their databases using ACCEPT ARCHIVED DATA FROM FILE. This function is similar to IMPORT EXPERIMENT DATA, but data is not restricted to "Read Only" status.

PLEASE NOTE:
The receiving user may modify the experiment data. DEARCHIVING TO DISK FILE by one user followed by ACCEPTing ARCHIVED DATA FROM FILE by another user effectively transfers ownership of the experiment data from one user to another.

User Input

Same inputs as for DEARCHIVE DATA TO DATABASES. The user also specifies output drive and path for the dearchived data.

Processing

Same as DEARCHIVE DATA TO DATABASES, but an output file similar to the one created when exporting data is created and placed on the user specified drive and path. Data is NOT added to dearchiving user's databases, but is deleted from archive file and from archived experiments list. The created output file has the only data for the dearchived experiment. The naming convention for this output file is as follows:

eeeeeeee.ffX where

eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
X is a literal value appended to the experiment name to indicate that this file contains archived experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with an "X" still appended to the end (e.g., an experiment name of CSCT910001 will yield a filename of CSCT9100.01X, while an experiment name of TEST will yield a filename of TESTX).

Output

GeneTox Manager informs the user when decompressing data, and if errors occur. An output disk file containing experiment data is created.

Quality Control

The user is notified of any errors - invalid password; drive, path or filename or archive file incorrect; output drive or path incorrect; experiment data not found in specified archive file; or error during decompression.

ACCEPT ARCHIVED DATA FROM FILE

This function allows the user to accept data into their databases that has been dearchived by another user using DEARCHIVE TO DISK FILE.

PLEASE NOTE:
The accepting user effectively gains ownership of this experiment. The user may subsequently modify the data for this experiment.

User Input

The user enters the experiment name, drive, and path for experiment data file. Data file will have a filename of the format:

eeeeeeee.ffX where
eeeeeeee are the first 8 characters of the experiment name.
ff are the 9th and 10th characters of the experiment name.
X is a literal value appended to the experiment name to indicate that this file contains archived experiment data.

Note: If an experiment name is less than 10 characters, the filename will be shortened accordingly with an "X" still appended to the end (e.g., an experiment name of CSCT910001 will have a filename of CSCT9100.01X, while an experiment name of TEST will have a filename of TESTX).

Processing

Experiment data file processed and data added to databases if format correct.

Output

The user is informed when processing data, saving data, or errors occur. A transaction log is created. The transaction log has a DOS filename similar to the experiment data file but with a "T" as the third letter of the extension.

Quality Control

User informed of errors in drive, path, experiment data not found, or errors processing data file. Specific errors are written to the transaction log.

IMPORT SPIRAL ASSAY DATA

This function allows users who may be collecting data using a Spiral Biotech laser counter to "import" this data into GeneTox Manager for statistical analysis. User must make the necessary files available to GeneTox Manager. Two files are necessary for the data to be imported into GeneTox Manager. Both files will have a filename equal to the name of the sample being analyzed. The extension of the first file will be .ID; the extension of the second will be .PRN. The first file is created automatically by the spiral program when the sample is entered; the second must be explicitly generated by choosing Export Data from the spiral program menu. Both must be available to GeneTox Manager before the import can proceed.

User Input

User enters the drive, path, and filename (minus extension) of the Spiral sample they wish to import into GeneTox manager. User is then prompted for an experiment name and a sample ID for the spiral data (along with other data required by GeneTox but not provided by the spiral program) on the following screen:

```
GeneTox Experiment/Sample Data

Experiment......:
Research Lab....:
Sample ID.......:
P Investigator..:
Lab Book Number.:

                    Suggestion Box:

              EXPERIMENT  NAME

          Format for Experiment Names is
                   AAAAYYNNNN
            where A = any character,
              Y = denotes the year, and
         N = is a unique number identifier

F1:Help   F2: Suggestion  PgDn:Do Conversion   ESC:Abort
```

Processing

The spiral data is saved to the GeneTox Manager databases.

Output

N/A

Quality Control

GeneTox Manager verifies that the necessary files exist in the specified drive and directory location. User is forced to enter data required by GeneTox Manager but not supplied by the spiral data files. The experiment is added as a newly entered experiment, and the user has full control of the imported data.

REPORTS MENU

After selecting the REPORTS option from the MAIN MENU, the user will be presented with the following screen. This function will allow the user to generate a Raw Data, Bernstein, Histidine, Stead, or Quasi-Stead Model report.

```
GeneTox Manager  Main Menu
EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit

First Experiment Name..:
Last Experiment Name...:
First Experiment Date..:    /  /
Last Experiment Date...:    /  /
First Sample ID Number.:
Last Sample ID Number..:
Research Lab...........:

PgDn-To Continue with Report   Esc-Exit Reports

Gen Reports For The GeneTox Manager System
```

User Input

The following fields are input for the REPORTS menu (at least one but any combination or all of these fields can be used as selection criteria for the report):

First Experiment Name - first or only Session ID. As the first Session ID, the database is searched from this ID, including any identical match.

Last Experiment Name - second Session ID, or the Session ID to search up to, including any identical match.

First Experiment Date - first or only Experiment date. As the first Experiment date, the database is searched from this date, including any identical match.

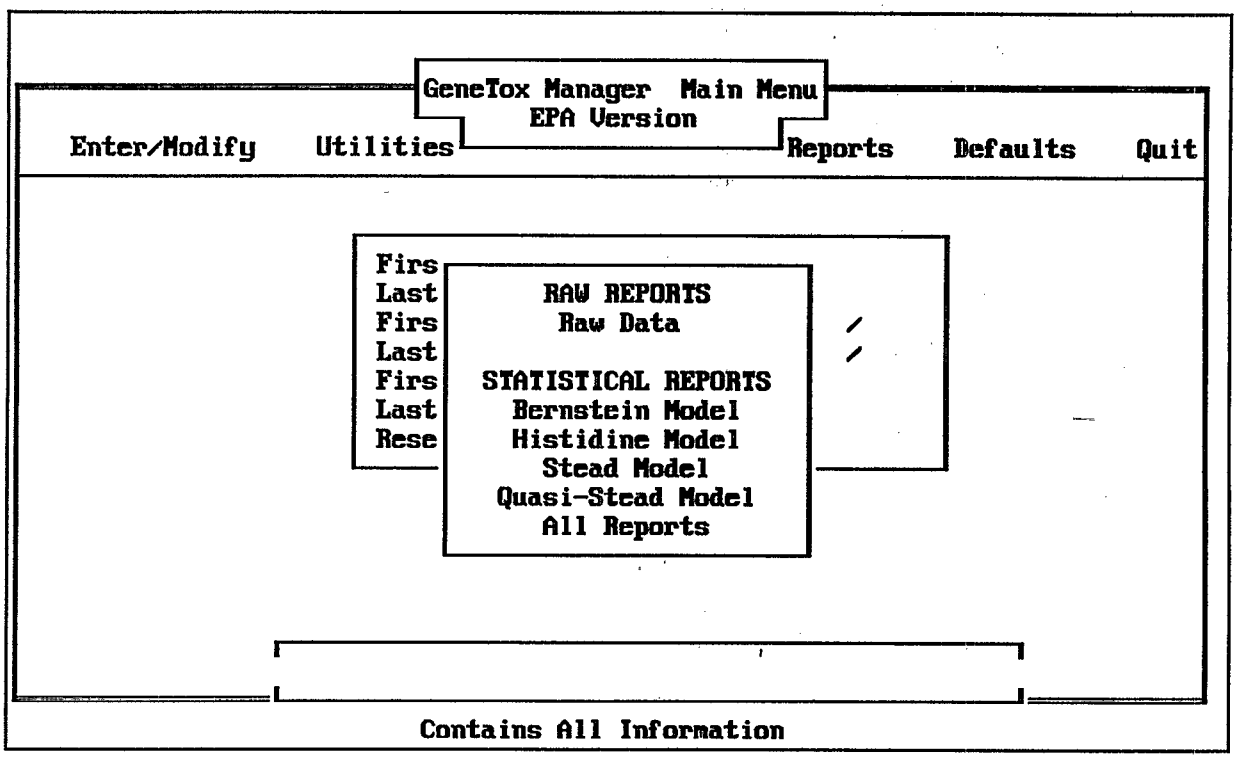
Last Experiment Date - second Experiment date, or the Experiment date to search up to, including any identical match.

First Sample ID Number - first or only Sample ID. As the first Sample ID, the database searches from this ID, including any identical match.

Last Sample ID Number - second Sample ID, or the Sample ID to search up to, including any identical match.

Research Lab - Research Lab to match on.

After the first REPORTS screen has been completed, the following REPORTS screen will appear:



The following fields are input to this screen:

Raw Data - allows the user to execute a report based on the raw data contained in the database. A new database query will be performed when this option is selected.

*** See Note Below ***

Bernstein Model - allows the user to extract data from the PC database to execute the PC-based Bernstein Model report. The report generates a point rejection/linear regression model. The query has already been performed for the databases.

Reference: Bernstein, L., Kaldor, J., McCann, J. and Pike, M.C. (1982) "An empirical approach to the statistical analysis of mutagenesis data from the Salmonella test," Mutation Research, 97, 267-281.

*** See Note Below ***

Histidine Model - allows the user to extract data from the PC database to execute the PC-based Histidine Model report. The report generates a non-linear regression graph based on the dose response data. The query has already been performed for the databases.

Reference: Krewski, D., Leroux, B.G., Bleuer, S.R. and Broekhoven, L.H. (1993) "Modeling the Ames Salmonella/Microsome Assay," Biometrics, 49, 499-510.

*** See Note Below ***

Stead Model - allows the user to extract data from the PC database to execute the PC-based Stead Model report. The report generates a non-linear regression graph based on the natural log of the dose response data. The query has already been performed for the databases.

Reference: Stead, A.G., Hasselblad, V., Creason, J.P. and Claxton, L.D. (1981) "Modeling the Ames test," Mutation Research, 85, 13-27.

*** See Note Below ***

Quasi-Stead Model - allows the user to extract data from the PC database to execute the PC-based Stead Model report. The report generates a non-linear regression graph based on the natural log of the dose response data in a slight variation to the Stead model. The query has already been performed for the databases.

Reference: Creason, J.P. [personal communication].

*** See Note Below ***

All Reports - allows the user to execute every statistical report automatically. Only the statistical reports will be executed by this option. The selected data set is submitted to the models and executed in consecutive order.

*** NOTE ***

- Once a report type has been requested, the system will generate an output file containing formatted information. The user will then be prompted for a desired output device. The user may respond by pressing <RET> for the Screen, or by pressing the letter "S"; the Printer by pressing the letter "P"; or a File by pressing the letter "F" or by highlighting the desired selection and pressing <RET>. If a File is chosen for output, the user will be prompted for the appropriate filename(s).

- If Screen output is chosen, the information will be scrolled across the screen one page at a time. Press <ENTER> to continue display of additional information to the screen.

After directing output to the requested device, the user will be prompted again for the destination of the output (Screen, Printer, or File). Thus, the user may continue to direct the same output to other devices until pressing <ESC> to exit the report function.

Processing

The REPORTS function provides the user with the ability to view the information contained in the database. The user has the option to direct the output to the Printer, the Screen or a File. All queries are made against the PC databases, including the execution of statistical model reports. The Bernstein and Stead models may also be executed on the VAX using data extracted from the VAX FOCUS databases.

Outputs

Each report is output to the Printer, Screen, or a File.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

DEFAULTS MENU

After selecting the DEFAULTS option from the MAIN MENU the user will be presented with the following screen. This screen will allow the user to change the default settings for Communication Setup, Screen Colors, Protocol File Name, Locate Databases, and other Special Options. Each function is intended to allow the user to customize the system to individual needs.

```
GeneTox Manager  Main Menu
        EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit

                           Communication Setup
                           Modify Colors
                           Reset Colors
                           Protocol File Name
                           Locate Databases
                           Locate Archives
                           Set Special Options

Modify The Communications Setup
```

User Input

The following fields are input for the DEFAULTS menu:

Communications Setup - allows the user to select which type of communication option will be used: 1200- or 2400-baud modem, terminal server, or PCSA.

Modify Colors - allows the user to customize any or all of the screen colors.

Reset Colors - resets the screen colors to the original colors.

Protocol File Name - allows the user to choose which protocol file to use while entering an experiment.

Locate Databases - allows the user to reset the location of application databases to a drive and/or subdirectory other than the default.

Locate Archives - allows the user to reset the location of archive files to a drive and/or subdirectory other than the default.

Special Options - password-protected options including: Password Changes, Suggestion box Modifications, Principal Investigator List Modifications, Add or Modify Assay Type Selections, Modify Iteration Count for Plates, and Help Text Modifications.

Processing

The DEFAULTS function provides the user with the ability to customize the system to individual needs.

Outputs

Each function saves the default data to a file named XXXXXXXX.DFT, except for the suggestion and location of databases functions. The suggestion box listing will be saved to a file named SUGGEST.LST and the suggestion box help will be saved to an ASCII file named SUGGEST.HLP.

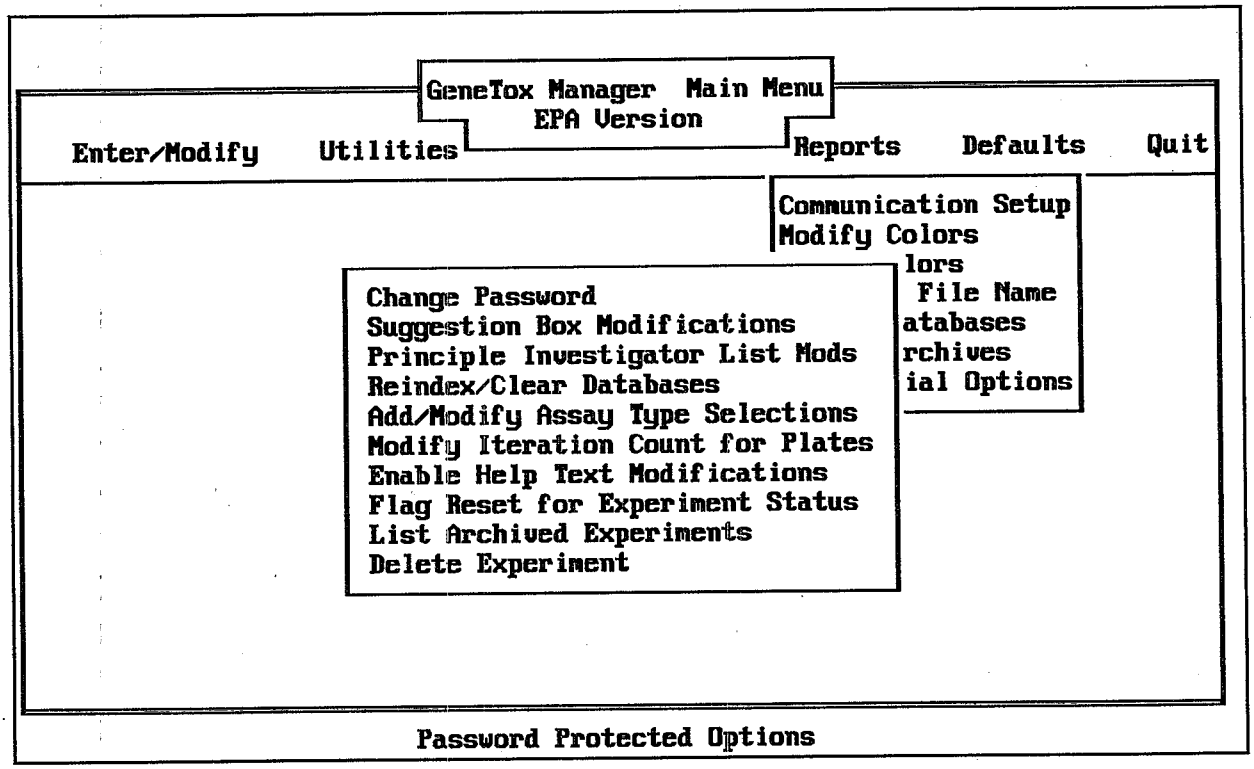
For resetting the database locations, the system maintains a file called DRVPATH.MEM (in the application directory - normally \GENETOX) which defines the database locations. The user has two options to reset the database location. The user can either use the Locate Databases function under the Defaults menu pick or, if a database find error is occurring at start-up, the user can erase the DRVPATH.MEM file and the system will re-prompt for the location of databases. The same applies to the archive location, stored in the file GTMARCHV.MEM.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

SPECIAL OPTIONS

The SPECIAL OPTIONS function of the DEFAULT menu allows the user to modify other defaults. This option is password-protected; when it is selected, the user is required to enter the correct password before changes are allowed. After entering a valid password, the following menu is displayed:



CHANGE PASSWORD

After selecting the CHANGE PASSWORD option from the SPECIAL OPTIONS menu, the user is allowed to change the GeneTox Manager system password.

User Input

The following fields are input for the CHANGE PASSWORD option:

New Password - the new password, at least six characters.

Verify Password - enter the new password again to verify.

Processing

The CHANGE PASSWORD option allows the user to change the password needed to get to the SPECIAL OPTIONS menu. This is a security measure against unauthorized changes being made to the system. This password is also used to allow VAX version users to obtain statistical model reports for data that has not been uploaded.

Outputs

The password needed for entry after choosing SPECIAL OPTIONS from the DEFAULTS menu is changed.

Quality Control

The password must be at least six characters long. If the new password entered is not of this length, an error message will result and the user will be prompted to enter it again. Also, the password will be verified. If the same password is not entered in the verification process, an error will result.

SUGGESTION BOX MODIFICATIONS

After selecting the SUGGESTION BOX MODIFICATIONS option from the SPECIAL OPTIONS menu, the user will be allowed to make changes to any of the suggestion boxes that appear on the screen.

User Input

The following fields are input for the SUGGESTION BOX MODIFICATIONS option. After selecting a screen to edit, a message will appear informing the user that information for that screen exists. The user will then be required to enter "Y" to continue editing the suggestion box or to press any other key to return to the menu without editing. If "Y" is entered the next prompt will be "Is this a selectable list?". Enter "Y" if it is or any other key to begin entering the help text.

Experiment Description - allows changing suggestion boxes for: Entry Date, Experiment Date, Research Lab, Lab Book Number, Experiment, Data Entered By, and Lab Technician.

Assay Type Selection - allows changing suggestion boxes for: Assay Selection and Modification to Assay Type.

Final Strain Entry - allows changing suggestion boxes for: Strain, Strain Date, Activation Level, and Culture Density.

Neg/Pos Control Entry - allows changing suggestion boxes for: Control Code, Control Name, Amount for Plate, Control Unit, Plate Count 1-5, and Background Plate 1-5.

Activation System Information - allows changing suggestion boxes for: Characters 1-6 of the S9 type, S9 Level 1, S9 Level 1 Units, S9 Level 2, S9 Level 2 Units, S9 Sterility Before, S9 Sterility After, and S9 Description.

Sample Specific Data - allows changing suggestion boxes for: Sample ID, Sample Description, Source/Batch/Lot, and CAS Number.

Current Strain Selection - allows changing suggestion box for: Dose Units.

Quality Assurance - allows changing suggestion boxes for: Solvent Description, Solvent Amount/Plate, Solvent Units, Hours Of Incubation, Phenocopy Check, Sample Sterility Before, and Sample Sterility After.

Dose Data Entry - allows changing suggestion boxes for: Dose Amount, Plate Count 1-5, and Background for Plates 1-5.

Experimental Remarks - allows changing suggestion box for: Experimental Remarks.

Processing

The SUGGESTION BOX MODIFICATION option allows the user to modify all of the suggestion boxes that appear on the screen. This allows very specific information and help to be shown at the entry screen.

Outputs

The suggestion boxes on the screens will reflect the changes that have been made using this option.

Quality Control

None.

PRINCIPAL INVESTIGATOR LIST MODIFICATION

The PRINCIPAL INVESTIGATOR LIST MODIFICATION option allows the user to add new PI's to the list or modify the ones already in the database.

User Input

The following fields are input for the PRINCIPAL INVESTIGATOR option:

Add PI's to the List - allows the user to enter new PI names to the list.

Modify PI Listing - allows the user to edit the PI names already in the list.

Processing

The PRINCIPAL INVESTIGATOR LIST MODIFICATION option allows entering new PI names to the list or modifying the names currently in the list. The MODIFY option brings up the list of names already entered and allows the user to make changes to these names.

Outputs

The list of PI's is modified and the changes are reflected during the data entry phase.

Quality Control

None.

REINDEX/CLEAR DATABASES

The REINDEX/CLEAR DATABASES option will delete all experiment and sample records from application databases and reindex these databases. Given the impact of this feature on application data, the user is prompted with an ARE YOU SURE YOU WANT TO ERASE ALL RECORDS message, which must be responded to with a Y for the function to continue. The primary use for this feature would be to reset the environment after initial testing of the system with test data or to reset databases that have become corrupted and the contents are non-recoverable.

ASSAY TYPE MODIFICATION

After selecting ASSAY TYPE MODIFICATION from the SPECIAL OPTIONS menu, the user will be allowed to make changes to the Assay Type Selections.

User Input

The following fields are input to the ASSAY TYPE MODIFICATION screen:

Test Type Code	Test Type Description
Time in Minutes	Time in Hours
Temperature in Degrees C	Temperature in Degrees F

Processing

To modify an existing assay, highlight the correct assay to modify by using the arrow keys and then press <SHIFT><F4>. This will bring up the existing data and allow modifications. To add a new assay, press <F4> and the same fields will be brought up, ready for new data to be entered.

Outputs

The new assay types will appear on the ASSAY TYPE SELECTION screen.

Quality Control

All fields except for Test Type Description must be numeric. No other characters are allowed.

MODIFY ITERATION COUNT FOR PLATES

The MODIFY ITERATION COUNT FOR PLATES option allows the user to redefine the number of iterative plate count readings to be taken automatically from the Artek Colony Counter, before calculating a median value and assigning that value in a plate count data entry field. The default value is set to 3; other allowable values are either 1 or 5.

Note that the iteration count set by this option is only applicable when the user intends to automatically collect plate count readings from the Artek Colony Counter (i.e., enabled by having pressed <F5> and moving the cursor to a plate count data entry field).

ENABLE HELP TEXT MODIFICATIONS

The ENABLE HELP TEXT MODIFICATIONS option allows the user to modify the help text that appears on the screen when <F1> is pressed. The help text is brought up on the screen and the user can make modifications.

User Input

The existing help screen is shown on the screen and the user can enter whatever is needed to modify the existing screen.

Processing

The help text screen is modified.

Outputs

After successfully editing and saving the help text, the modified version will be shown on the screen the next time the <F1> key is pressed for help.

Quality Control

None.

FLAG RESET FOR EXPERIMENT STATUS

This function applies only to the VAX Version of GeneTox Manager. Allows user to reset status flags of experiment to "A" (Added, not yet uploaded) or "I" (Inactive, has been uploaded) Status. Flags are automatically reset (to I) after a successful upload, but this function is provided in case of unforseen errors.

User Input

Experiment name to reset and status code (A or I).

Processing

Status flags reset for all data associated with the experiment.

Output

None.

Quality Control

User informed if experiment does not exist or if flags cannot be reset. Status flags cannot be reset on imported or downloaded experiments.

LIST ARCHIVED EXPERIMENTS

This function allows users to view a list of experiments that have been archived from their databases. The list contains experiment names and passwords, and can reveal additional information including archived location (drive, path, and filename) and archive date. Entries are automatically added to the list as experiments are archived and deleted as they are dearchived.

The following screen is a sample display of additional information for an archived experiment:

```
GeneTox Manager  Main Menu
        EPA Version
Enter                                   Reports    Defaults    Quit
  Lis
Exper  Experiment:          TEST920001                Setup
------ Password:            topcat
TEST9  Disk Drive:          C
------ Directory Path:      \GENETOX\DBASE            Name
 <Ret  Archive Filename:    GTMARCHV.ZIP              ases
 <Esc  Date Archived:       06/05/92                  es
 <PgU                                                 ptions
 <PgD
       <Return>  Archive List
       <Escape>  Exit
       <PgUp>    Previous Experiment
       <PgDn>    Next Experiment

Password Protected Options
```

DELETE EXPERIMENT

This function allows users to delete an experiment similar to the PC FUNCTIONS option DELETE READ ONLY OR VAXDOWN but deletes regardless of the status of the experiment.

User Input

Experiment name to delete.

Processing

All data associated with the experiment is deleted from databases.

Output

None.

Quality Control

User informed if experiment does not exist.

QUIT MENU

After selecting the QUIT option from the MAIN MENU, the user will be presented with the following screen. This screen will allow the user to Quit the GeneTox Manager system and return to DOS or to Continue using the GeneTox Manager system.

```
GeneTox Manager  Main Menu
        EPA Version
Enter/Modify   Utilities   Reports   Defaults   Quit
                                     Continue
                                     Quit To Dos

Continue Using The GeneTox Manager System
```

User Input

The following fields are input for the QUIT option:

Continue - do not quit the GeneTox Manager system, continue with the established session.

Quit - quit the GeneTox Manager system and return to DOS.

Processing

The QUIT function provides the user with the ability to exit the system logically by closing all files, databases, and indexes and by releasing all variables in memory. **This is the only viable way to exit the system.**

Outputs

None.

Quality Control

All fields are validated. If an invalid entry occurs, the system will display an error message and allow correction.

APPENDIX A

INSTALLATION INSTRUCTIONS

This appendix provides installation instructions for the GeneTox Manager system and describes hardware configuration requirements for execution of the application. This appendix or similar information is also included on installation diskettes as the README.1ST file.

Please carefully read the instructions below before attempting to install the GeneTox Manager system or executing it for the first time. This information is provided as a supplement to the GeneTox Manager System Users Guide. If you have any questions on the installation process, or on execution of the system, contact your local PC support service (or your local PC guru). As a last resort you may contact Dr. Larry Claxton at MD-68A, HERL, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

1. This system will execute on AT-class, 386-class, 486-class (or compatible) PCs with the following minimum hardware and software configuration:

i) 640 KBytes Random Access Memory (RAM)
*** Note: At least 440K must be available for GeneTox Manager to execute properly (i.e., any memory resident programs plus DOS must not take up any more than 200K). The DOS CHKDSK command will identify how much free RAM you have available on your system.

ii) A hard disk (or Bernoulli type removable disk).with at least 1.55 Mega-bytes of available memory to accommodate system and data files.

iii) MS-DOS version 3.3 or higher.

iv) The following additional hardware and software is recommended to increase GeneTox Manager system performance:

a) Expanded Memory - The availability of expanded memory for use by GeneTox Manager will greatly increase system performance. The memory manager used must conform to LIM EMS 3.2 or higher specifications.

b) Math CoProcessor - A math coprocessor is recommended to decrease the execution time of the statistical models included with GeneTox Manager.

2. Unless you provide a special justification, the **installation diskette will be a 3 1/2" High Density (1.44 Mbyte) diskettes (Quantity 1).**
With special justification and depending on your PC configuration, the following installation diskettes are available to you in one of three forms as listed below:

   i) 5 1/4" High Density (1.2 Mbyte) diskettes (Quantity 1)

   ii) 5 1/4" Low Density (360 Kbyte) diskettes (Quantity 3)

   iii) 3 1/2" Low Density (720 Kbyte) diskettes (Quantity 2)

3. Installation Process: Loading Files From Installation Disks

   Your installation diskettes contain an automated, self-install program which you must execute to load GeneTox Manager to your PC. DO NOT ATTEMPT to install this application manually using DOS copy commands, as certain support files in specific sub-directories will not be appropriately established with this method.

   Rather, insert the installation diskette labelled Disk 1 into your PC and type INSTALL to initiate the installation process. The system will notify you that it is loading installation parameters and then prompt you for your preferred location for application executables and for application databases. Note that default locations are \GENETOX for application executables and \GENETOX\DBASE for application databases. If you enter a sub-directory location that does not currently exist, the program will attempt to create it for you. If it cannot create it, and you have trouble creating the desired sub-directories yourself using DOS, contact your local PC support person.

   Note that at least 1.5 MBytes must be available for loading application executables and 500 KBytes for loading application databases.

   Once sub-directory locations are established, the program will copy the contents of Disk 1 to your hard disk. At the conclusion of this step, the program will prompt you to remove Disk 1, insert Disk 2 into the drive and press <ENTER> to continue. Upon copying the contents of Disk 2, you will follow a similar procedure for Disk 3 if necessary. Finally, you will be instructed to re-insert Disk 1 to handle installation program close-out.

   At the conclusion of the installation, the program will place you in the application sub-directory in preparation for execution of GeneTox Manager.

4. Installation Process: Setting DOS attributes for GeneTox Manager

Two of the DOS related files on PCs which control system operation are the AUTOEXEC.BAT file and the CONFIG.SYS file. For proper execution of GeneTox Manager, minor additions/modifications must be made to both of these files as listed below:

CONFIG.SYS- files and buffers must be set to at least the following values for execution of GeneTox Manager

FILES = 55
BUFFERS = 20

If the above two lines are not already in your current CONFIG.SYS file, add them.

If the two lines are already in your CONFIG.SYS file, make sure that they are set to values at least as high as those listed above.

AUTOEXEC.BAT- a Clipper environmental variable must be established to identify the number of file handles to allocate. Add/Edit the following line in this file:

SET CLIPPER=F:55

** NOTE: For these settings to take effect after editing the above named files, the PC must be re-booted (either via a Cntl-Alt-Del or "shutting off/then back on" the PC).

5. To execute GeneTox Manager, change directories to the sub-directory containing GeneTox Manager executable files, type GTM and press the <ENTER> key.

You must set at least one special option before entering data into the system the first time. That is, you must register the initials of a Principal Investigator. See the "Special Options-Principal Investigator" section of the Users Guide for further information on this.

*** Note: To execute any Special Option, you must enter a valid password. The initial password is GENETOX. Note that the password field is case-sensitive.

6. On-line help is available for the system by pressing the F1 function key. Specific suggestion values are also provided for most data input fields.

APPENDIX B

GENETOX MANAGER TROUBLESHOOTING

This appendix explains what to do if problems occur that cause the system to crash or lock up. These procedures should be followed after a system crash to insure as little data loss as possible and that further system problems are avoided.

If a system error occurs you will be presented with a system error message: A red box with a line of text describing the error and a list of choices below. Choices may include Quit, Retry, and Ignore. The Quit option will be highlighted. Choosing the Quit option will halt system execution at the point of the error and return you to the DOS prompt. It should be selected if choosing Retry does not work. The Ignore option may produce unpredictable results and is not usually available.

If the error occurs during printing, the error message will come from DOS. It will say:
Write fault error writing device LPT1
Abort, Retry, Ignore, Fail?

Your printer may be turned off, off-line, or out of paper. In this case, fix the problem with the printer and press R. Provided the problem has been fixed, the program should proceed normally. Choosing Abort will return to GeneTox without halting execution of the program. Similar problems may occur when accessing a floppy disk drive.

If the error is an "Open error: PATHNAME FILENAME.EXT (DOS Error 2)", GeneTox could not find a particular file it was looking for. It will tell you the name of the file that is missing (FILENAME.EXT) and where the file should be (PATHNAME). Check that directory for the specified file. It may not have been copied from the installation diskettes, or it may have been inadvertently deleted from the hard disk. You may try copying the file manually from the installation diskettes.

If the error is an "Open error: PATHNAME FILENAME.EXT (DOS Error 4)", GeneTox tried to open too many files at once for DOS to handle at its current setting. Check to make sure that the AUTOEXEC.BAT and CONFIG.SYS files were altered as described in Appendix A. Remember to reboot your machine after modifying these files.

Other errors are most likely caused by interaction between GeneTox Manager and other software running simultaneously or by bugs in the system itself. Chances are the error is not recoverable, and the only option will be to choose Quit (or reboot the machine in the case of the system locking up). Choosing the Quit option will cause GeneTox to abort execution and return to the DOS prompt. The following procedure should be followed before restarting GeneTox Manager.

Any time the system has a non-recoverable error, check for the existence of any left-over temporary files. Temp files have filenames of random letters and numbers, usually starting with 0 or 1, and having no extensions (e.g. 01a23e42). GeneTox creates and deletes these files to do work while sorting and indexing databases. If the system crashes, GeneTox may not be able to properly delete these files. Left-over temporary files may interfere with GeneTox and cause further problems. These files should be deleted before restarting GeneTox. These temporary files will reside either in the same directory as the GeneTox executable files (i.e., the directory you start GeneTox from by typing GTM) or in the root directory of that drive. NOTE: Be careful when deleting these temporary files. Other programs may create files in this manner and may use them for other purposes. Check the date/time stamp on these files to see if they were created while GeneTox was running before deleting them.

When restarting GeneTox after a crash, it is always a good idea to first reindex the databases using the ReIndex option under the Utilities/PC Functions menu. If you were entering or modifying data when the system crashed and had not saved that data, it will be lost. Check your Experiment's raw data report to find out what previously entered data has been saved. Unsaved data will have to be re-entered.

If the system "locks up" frequently, attempt to determine if other programs running concurrently with GeneTox Manager are the cause. Remove the statements that load unneeded memory resident programs and device drivers from your AUTOEXEC.BAT and CONFIG.SYS files and reboot your machine. If this solves your problems, you can begin adding the programs one at a time until the problem reappears. You will then know which program or device driver conflicts with GeneTox Manager, and you can arrange to remove it from memory when running the GeneTox Manager application.

One conflict that system managers need to be aware of involves running GeneTox from a network drive or with the DOS SHARE utility installed. The SHARE utility provides file locking and sharing from DOS and is used in some DOS network or multitasking situations. Because GeneTox Manager was not designed as a multiuser application, this will cause conflicts when opening database files. Typical messages that might occur would say "ALIAS DOES NOT EXIST: " and give the name of a database file that could not be successfully opened (i.e., Experiment or General). The only available option will be to Quit to DOS. This problem will only occur when attempting to Modify, Export, or Archive data. Data Entry and Reporting will be unaffected by the problem. The only solution available is to not load the SHARE.EXE program when starting your system or to move GeneTox Manager to a non-network drive (the program and database files should not be run from a network file service).

APPENDIX C

SYSTEM UPGRADE TO VERSION 2.2

Version 2.2 Changes:

The GeneTox Manager version 2.2 has had changes made to the underlying database structures and for that reason a special set of Upgrade diskettes are provided for updating your current databases to the new format. The upgrade will also make any necessary changes to convert from GeneTox version 2.1 to 2.2. Upgrading from version 1.X or 2.0 to 2.2 will require a separate set of Installation diskettes to "reinstall" the new version.

The database changes involved moving several data fields from Sample information to Experiment Specific Sample information. The fields Solvent Description, Solvent Amount, Solvent Units, and Incubation Hours were the fields changed. This change means that this information may now be entered distinctly for each sample analyzed under each experiment strain. Previously, changing this information when re-using a sample in a second experiment would also change the solvent and incubation hours information under the first experiment as well.

The only observable changes to the system involve the data entry and modification screens. In particular the solvent and incubation hours fields have been moved from the Sample Specific screen (the screen where you enter Sample ID and Description information) to the Quality Assurance Checks screen (where you enter the phenocopy and sample sterility information). This is to allow entry of the information for each sample strain combination.

The Upgrade program provided will convert your databases to the new format. The program will simply copy the information from the samples it is currently stored with to the experiment specific sample data. Therefore the solvent and incubation hours information will still be the same for each experiment the sample was used in, but you may now alter the data under each experiment individually without affecting other experiments in which the sample was used.

The Upgrade program will not alter your current data in any respect. However to provide maximum safeguards against data loss, the Upgrade program retains backup copies of the current databases and executables to enable you to recover to the current version of the system should there be any problems encountered during upgrading. You are advised to obtain several "sample" raw data reports and then rerun these reports under version 2.2 to verify your actual data has not been changed. Should you need to restore to the old version use the GTMRest program provided.

The GeneTox Manager User's Guide has been updated to reflect these changes, and a new copy is included with your upgrade diskettes.

Upgrade Procedure:

The number of Upgrade diskettes is dependent on the type of floppy drive available on your system. If you have high-density drives (either 5-1/4 or 3-1/2) you will have only one diskette. If you have a low density 3-1/2 inch drive you will have 2 diskettes. If you have a low density 5-1/4 inch drive you will have 3 diskettes.

To upgrade from version 2.1 to version 2.2, simply insert the disk marked Disk #1 of the Upgrade diskette set and type UPGRADE. This will start the automated Upgrade program provided to update both system executables and databases. The Upgrade program will prompt you for the location of the GeneTox Manager executables and databases (defaulting to C:\GENETOX and C:\GENETOX\DBASE respectively). You must have enough space on the disk drive for the backup of current databases and executables for the upgrade to proceed (about 1.2 Megabytes of free space).

The upgrade will take approximately 15-30 minutes.

Restoration Procedure:

To restore to the old version after an upgrade, simply type GTMRest while in the directory you normally run the GeneTox Manager from by typing GTM. Provide the program with the location for the GeneTox Manager program and Databases as you did in the Upgrade program.

WARNING: GTMRest restores from backups saved from before the upgrade was run. If you have entered or modified any data since the upgrade was run this data will be lost!

Cleanup Procedure:

Two DOS batch files are provided to "clean up" your GeneTox disk after a successful upgrade. They are called CLEANUP1.BAT and CLEANUP2.BAT and are located in the system executables and database directories respectively.

Together they DELETE the backups that allow you to restore to the old version of GeneTox Manager. This will free up the 1.2 Megabytes of disk space the Upgrade program used to backup the old system.

To run these cleanup programs change to the system executables directory (e.g., C:\GENETOX) and type CLEANUP1. After this finishes change to the database directory (e.g., C:\GENETOX\DBASE) and type CLEANUP2.

WARNING: This permanently DELETES the backups saved from before the upgrade was run. You will **NOT** be able to restore to the old version after running either of these files.

Upgrading From Version 1.X or 2.0:

This section covers upgrading from GeneTox Manager versions prior to version 2.1 to 2.0. This is somewhat more complicated. In this case a separate set of Installation diskettes will be provided in addition to the Upgrade diskettes. The procedure is basically to backup to current databases, "install" a new version complete with empty databases, restore the databases from the backups, and then run the Upgrade program to convert to the 2.2 database formats.

Very carefully observe the following instructions.

First we must backup the current databases to retain your data (this is because the installation program "installs" the databases as well, and will overwrite the current ones with empty databases). Two procedures are recommended for this: you may use the DOS backup and restore utility (this is especially helpful if you wish to backup to floppy diskettes); or you may simply create a new directory to hold your backup databases (e.g., MD (make directory) C:\GENETOX\OLDDBS) and copy all the files in database directory to the backup directory (e.g. COPY C:\GENETOX\DBASE*.* C:\GENETOX\OLDDBS).

Once the data are saved, simply run the installation program provided on Disk #1 of the Installation diskette set. After the installation is complete, you can restore your data from the backups (e.g. COPY C:\GENETOX\OLDDBS*.* C:\GENETOX\DBASE). Then execute the new version of GeneTox Manager (by typing GTM) and choose "Reindex GeneTox Manager Databases" from the Utilities-PC Functions menu. Finally you must run the Upgrade program to convert to the new database format.

APPENDIX D

COLONY COUNTER INTERFACE

A serial interface is required between the Artek Colony Counter and IBM AT-class PCs running the GeneTox Manger system.

The interface will require the following hardware:

ARTEK COUNTER - Model 880

Omni-Interface Unit from ARTEK Systems Corporation

Dip Switch settings:		12345678
	Bank 1	00100000
(nearer shell)	Bank 2	11100110

Serial port interface from PC to Omni-Interface box
Parallel interface from Omni-Interface to ARTEK Counter

User Interface will operate as follows:

1) User will press key <F5> to toggle communications (enable/disable) to the colony counter. This key may be depressed to toggle the setting on the Negative/Positive control screen and on the Dose data entry screen.

2) Default reading iterations per plate will be set to 3. A password-protected function under Special Options of the Defaults menu will allow the user to override the reading iterations at either 1 or 5 per plate. The current setting for iterations per plate will be displayed on screens with plate data entry (i.e., the Negative/Positive control screen and the Dose data entry screen).

3) Collecting plate count data from the colony counter will only occur when the cursor is positioned on plate count fields in the Negative/Positive control screen and the Dose data entry screen.

4) For each colony count reading, the user must first press the <COUNT> button on the ARTEK counter, which will register a plate count in the red LED display area on the counter. The user must then press the <PRINT> key on the Omni-Interface box to send the plate count reading down to the PC. NOTE: This plate reading will only be acknowledged by GeneTox Manager if the cursor is currently in a plate count field of either the Negative/Positive control screen or the Dose data entry screen.

Each of the individual readings for a plate count will be displayed in a window on the GeneTox Manager data entry screen when the required number of iterative readings have been sent to GeneTox Manager from the colony counter (i.e., 1, 3 or 5), the system will select the median value and place it in the plate count data entry field. The cursor will in be forwarded to the next plate entry field, or the next dose line (if previously on the 5th plate count)-just as is the case when a user manually enters a plate count.

5) The user can control data collection when in the Instrument Enable mode with the following keys:

<F5> pressing this key when in instrument read mode will toggle the system out of instrument read mode and retain the previous value for the plate count data entry field (i.e., any iterative readings for this plate count will be ignored).

<CR> the system will ignore any iterative readings for this plate count and assign a -1 for the plate count.

< E S C >
the system will ignore any iterative readings for this plate count and proceed to the next data entry field.

APPENDIX E

KNOWN PROBLEMS AND LIMITATIONS

1. GeneTox Manager will not save Strain information to the databases unless at least one Sample has been entered for that Strain. GeneTox Manager will warn the user if Samples have not been analyzed under all Strains when choosing "Save Data and Exit" from the Continue Screen.

2. No replication of Samples is specifically provided for in GeneTox Manager (i.e., you can not run multiple instances of the same Sample in the same Experiment under the same Sample ID). You must enter the information as either two different Sample ID's, or as two entirely different Experiments.

3. You cannot delete Positive or Negative Control information once it has been entered. You can, however, delete a Test Dose by entering 0.0 as the Dose Amount and saving the Dose Response.

4. The Defaults menu option "Communications Setup" was never fully implemented and its setting has no effect on system behavior, even on VAX versions of GeneTox Manager.

5. Version 2.2 of GeneTox Manager is NOT network compatible. No code exists to manage multiple user accesses to network copies of the databases. It can run on networked PCs provided it resides on the hard drive of the workstation it will be used on, and it is accessed by only one user at a time. Attempting to install and run the GeneTox Manager System in a networked environment (i.e., making one copy of the system/databases available to multiple users) will most certainly cause severe problems.

6. There is currently no way (within the system) to get printouts of the screen output displayed by the statistical models. Users can, however, use memory resident screen grabber programs loaded before running GeneTox Manager, to capture these screens for later use in documents. [NOTE! Using the DOS PrintScreen key will not produce a printout of the graphic image.]

To do this using WordPerfect, first load the screen grab utility (GRAB.COM). [NOTE! Loading this utility reduces the amount of memory available for GeneTox Manager. If you have a limited amount of memory available on your system, GeneTox many not execute properly with this utility loaded.] Once the utility is loaded, run GeneTox Manager as normal. When the statistical model has displayed the screen you wish to capture, press <ALT><SHIFT><F9> and them <ENTER> to activate the grab program. A box will appear on the screen. Use the <SHIFT>-arrow keys to size the box, and the <INS> key to toggle between fine/coarse increments. Press <ENTER> to capture the screen area inclosed by the box. The image will be saved to the file GRAB.WPG. Subsequently captured images will be saved to files named

GRAB1.WPG..GRAB999.WPG. These captured images are saved as WordPerfect graphic files and may be printed using WordPerfect 5.0 or above. [NOTE! The captured image will be in color.]

7. The behavior of the GeneTox Manager program can be dependant on the other software (TSRs and device drivers) which are running on the system. One example current users have noticed is that GeneTox Manager will not operate properly while the DOS SHARE utility is resident in memory (see Appendix B: GeneTox Manager Troubleshooting). Some portions of the GeneTox Manager program may operate correctly under certain circumstances, while other portions produce apparently unrelated errors. For example, attempting to use GeneTox Manager with the SHARE TSR produces file opening errors when attempting to open certain database files.

8. GeneTox Manager will probably not be executable or perform correctly when run from certain shell or menuing software due to the reduced memory available to GeneTox Manager. For performance concerns and to prevent errors and data loss that could result when GeneTox Manager runs out of memory under these circumstances, it is recommended that GeneTox be run from the DOS prompt or from a menuing system such as AutoMaxx, which does not stay resident while called programs are executing. Attempting to use GeneTox Manager from Windows (as a DOS application) or from DOSShell is at the user's risk. GeneTox Manager has not been tested under those environments, and performance is certain to be degraded.

NOTE: See also Chapter 8 of the GeneTox Manager Programmer's Guide, "Possible Enhancements" for details on correcting these and other problems with GeneTox Manager.

☆U.S. GOVERNMENT PRINTING OFFICE: 1994 - 550-001/80381