National Human Exposure Assessment Survey (NHEXAS)

Arizona Study

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 821560

Standard Operating Procedure **SOP-UA-D-2.0**

Title: Performance of Computer Software: Verification and Validation

Source: The University of Arizona

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Human Exposure Research Branch

Notice: *The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development (ORD), partially funded and collaborated in the research described here. This protocol is part of the Quality Systems Implementation Plan (QSIP) that was reviewed by the EPA and approved for use in this demonstration/scoping study. Mention of trade names or commercial products does not constitute endorsement or recommendation by EPA for use.*

Performance of Computer Software: Verification and Validation

1.0 Purpose and Applicability

This SOP defines the procedure for the initial and periodic verification and validation of computer programs used in NHEXAS, the Border Study and other Health & Environment projects.

2.0 Definitions

2.1 Algorithm = A mathematical or logical procedure to perform a task.

2.2 BORDER STUDY = An alias for "Total Human Exposure Arizona: A Comparison of the Border Communities and the State" conducted in Arizona by the University of Arizona/Battelle/Illinois Institute of Technology consortium.

2.3 HEALTH AND ENVIRONMENT PROJECTS (or H&E) = An umbrella title for all projects funded to M.D. Lebowitz and/or M.K. O'Rourke (or their designees) which examine purported or real relationships among environmental factors and any aspect of human health.

2.4 HRP Site = The Health Related Professions building, located at 1435 North Fremont Avenue; Tucson, AZ 85719. This is an annex of the Arizona Prevention Center and the primary site of NHEXAS, the Border Study, and other Health and Environment projects.

2.5 NHEXAS Arizona: Acronym for **N**ational **H**uman **EX**posure **A**ssessment **S**urvey, a research project conducted in Arizona by the University of Arizona/Battelle/Illinois Institute of Technology consortium.

2.6 Program = A group of related commands or procedures organized logically to perform a specific job.

2.7 Software Package = A program or group of related programs released as a unit by a software publisher or an in-house development team.

2.8 Verification = The process of comparing an item or operation with related documentation to assure completeness and accuracy.

2.9 Validation: The process of checking the results of an item or operation to assure accuracy.

3.0 References

3.1 "The Icon Programming Language -Second Edition-", Ralph E. Griswold & Madge T. Griswold, Prentice-Hall, Inc. 1990

3.2 "Teleform Standard User Guide Version 5", Cardiff Software, 1991-1996.

3.3 "Session C – Computer Validation Vendor Audits, Ninth Annual Society of Quality Assurance Meeting, San Francisco, California, October 4-7, 1993", Darlene M. Looney, Ciba-Geigy Corporation, 1993.

3.4 "Session J, The PC Environment – Validation of Computer Systems", Sam Clark, Quality Assurance: Good Practice, Regulation and Law, Vol. 2, Nos. 1,2, March/June, 1993, pp. 92-95.

3.5 "Session J, Good Automated Laboratory Practices and Other Standards: Validation of Computer Systems in the PC Environment", Kim Nitahara, Quality Assurance: Good Practice, Regulation and Law, Vol. 2, Nos. 1,2, March/June, 1993, pp. 96-100.

4.0 Discussion

To ensure proper validation of data throughout the entire data management process certain protocols must be in place to verify that the software packages perform correctly. The following procedures describe the necessary tasks of each protocol.

A different aspect of validation/verification involves the tracking of data processing batches as they go through the cleaning process. Since the data processing batches are collapsed into cleaning batches, it is necessary to keep track of the processing batches consumed by an individual cleaning batch. This is achieved by the use of Cleaning Batch Sheets, which gives the cleaning batch identifier, the form type, lists the forms in the batch, and lists all the processing batches included. An example of a Cleaning Batch Sheet is given as Figure 2.

5.0 Responsibilities

5.1 The Data Manager will be responsible for scheduling, gathering materials, completing documentation, reporting the completion status of the software to the Project Director, and performing all other tasks involved in the completion of this SOP.

5.2 The Data Coordinator will be responsible for the insertion of test data into every tenth run of each data batch for the continued testing of software packages and programs.

5.3 Additional personnel may be involved in the execution of this SOP in order to complete as quickly and thoroughly as possible.

6.0 Materials and Equipment

6.1 Software package to be examined, including all associated documentation.

6.2 Controlled input to software package (if applicable)

6.3 A HRP local area networked microcomputer or workstation.

6.4 Software Verification/Validation Form.

6.5 Blank paper for hand calculation of program algorithms.

6.6 Writing instrument.

7.0 Procedure

7.1 Initiation of Software Verification/Validation Form

7.1.2 A Software Verification/Validation Form (see Figure 1) is used by the Data Manager

7.1.3 The Software Package Name, Developer of Program Specification, Programmer/Author, and Purpose of Review (items 1-4) sections of the Software Verification/Validation Form are completed.

7.1.4 The Data Manager determines the scope of the verification and/or validation to be performed, then completes the Verification Scope portion of the Software Verification/Validation form.

7.1.5 The remainder of the Software Verification/Validation Form is completed (as applicable) during processing.

7.2 Verification

7.2.1 Documentation related to the software is checked for completeness and preliminary accuracy.

7.2.2 Verification is documented on the Software Verification/Validation form

7.3 Validation

7.3.1 Test data is formulated to thoroughly investigate the accuracy of the algorithms and calculations performed by the program.

7.3.2 Program algorithms and calculations are performed by hand on test data. Results are recorded for comparison with sample program output.

7.3.3 A trial run using the software package with the test data is input. All applicable subprograms, subroutines, and features are examined. Execution time is recorded for benchmark comparison.

7.3.4 Results from the hand calculations are compared with results from the trial run.

7.3.5 If an older, proven version of the program being tested is available, the older program is run with the test data as input. All applicable subprograms, subroutines, and features are examined. Execution time is recorded for benchmark comparison.

7.3.6 Result sets and execution times from the runs of the old program and new program are compared.

7.3.7 If the new program fails any of these tests, a strategy is devised to bring the new program into compliance or use of the program must be prohibited.

7.3.8 Subsequent runs of the test data through the software packages and programs are performed at intervals of every 10 normal data batches.

8.0 Records

Completed Computer Software Verification/Validation Forms shall be attached to appropriate input, source, and output listings. They are archived and retained for inspection for not less than 5 years unless otherwise specified by the Project Director and Sponsor. They are stored in a binder labeled "Software Verification/Validation Form Logbook", located in the Data Technician office in the HRP Site.

Inclusions:

Figure 1: Software Verification/Validation Form (1 page)
Figure 2: Cleaning Batch Sheet (Example) (1 page)

Figure 1: Software Verification/Validation Form

Software Verification/Validation Form

1. **Software Package Name (Unique definition, version, etc., on documentation)**

2. **Developer of Program Specification**

3. **Programmer/Author**

4. **Purpose of Review**

5. **Verification Scope (Data Analyst Only):**

- ☐ **Sample Problem**
- ☐ **Numerical Analysis**
  - ☐ **Complete**
  - ☐ **Spot Check**
- ☐ **Standard Test Case Data Libraries Used**
  - ☐ **Complete**
  - ☐ **Spot Check**
- ☐ **Benchmark Against Existing Program**
- ☐ **Other (Specify):**

6. **Description of Verification/Validation Activities and Findings**

Please continue on other side.

Figure 2: Cleaning Batch Sheet (Example)

02191997.dat
Processed Batch Type : Desc

HHID	IRN	
215914	----	Wed Feb 19 14:37:42 MST 1997
121965	----	Wed Feb 19 14:37:42 MST 1997
682767	----	Wed Feb 19 14:37:42 MST 1997
481436	----	Wed Feb 19 14:37:42 MST 1997
481423	----	Wed Feb 19 14:37:42 MST 1997
481465	----	Wed Feb 19 14:37:42 MST 1997
123121	----	Wed Feb 19 14:37:42 MST 1997
481351	----	Wed Feb 19 14:37:42 MST 1997
481364	----	Wed Feb 19 14:37:42 MST 1997
481263	----	Wed Feb 19 14:37:42 MST 1997
681575	----	Wed Feb 19 14:37:42 MST 1997
184579	----	Wed Feb 19 14:37:42 MST 1997
682161	----	Wed Feb 19 14:37:42 MST 1997
682578	----	Wed Feb 19 14:37:42 MST 1997
451547	----	Wed Feb 19 14:37:42 MST 1997
682392	----	Wed Feb 19 14:37:42 MST 1997
183749	----	Wed Feb 19 14:37:42 MST 1997
681764	----	Wed Feb 19 14:37:42 MST 1997
343943	----	Wed Feb 19 14:37:42 MST 1997
345965	----	Wed Feb 19 14:37:42 MST 1997
345952	----	Wed Feb 19 14:37:42 MST 1997
345268	----	Wed Feb 19 14:37:42 MST 1997
312341	----	Wed Feb 19 14:37:42 MST 1997
681269	----	Wed Feb 19 14:37:42 MST 1997
451954	----	Wed Feb 19 14:37:42 MST 1997
184289	----	Wed Feb 19 14:37:42 MST 1997
681429	----	Wed Feb 19 14:37:42 MST 1997
681243	----	Wed Feb 19 14:37:42 MST 1997
214735	----	Wed Feb 19 14:37:42 MST 1997
451824	----	Wed Feb 19 14:37:42 MST 1997

Batches: 168, 171, 172