# The Arizona Border Study

***An Extension of the***
***Arizona National Human Exposure Assessment Survey (NHEXAS)Study***
***Sponsored by the Environmental Health Workgroup of the Border XXI Program***

# Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 824719

**Standard Operating Procedure** **SOP-IIT-A-2.0**

**Title:** Standard Operating Procedure for 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
Exposure & Dose Research Branch

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~~Environmental Protection Agency~~ ESG 7.14.97
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~~NHEXAS Arizona Project~~

Title: Performance of Computer Software Verification and Validation

Document No. IIT-A-2.0

APPROVALS

☒ Full SOP ☐ Working SOP #pages 6

On Site Principal Investigator:

Issue Date: April 10, 1995

Project QA Director:

Revision No. 0

Independent Reviewer:

Revision No:
Revision Date:
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Form TP-1

# PERFORMANCE OF COMPUTER SOFTWARE VERIFICATION AND VALIDATION

## 1.0 Purpose and Applicablity

This SOP defines the procedure for the initial and periodic verification and validation of computer programs.

## 2.0 Definitions

| | |
|---|---|
| Algorithm: | A mathematical or logical procedure to perform a task. |
| Benchmark: | A performance standard of a program by which the performance of a similar program can be determined. |
| Program: | A group of related commands or procedures organized logically to perform a specific job. |
| Software Package: | A program or group of related programs released as a unit by a software publisher or an in-house development team. |
| Verification: | The process of comparing an item or operation with related documentation to assure completeness and accuracy. |
| Validation: | The process of checking the results of an item or operation to assure accuracy. |

## 3.0 References

"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.

"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.

"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

None.

**5.0 Responsibilities**

5.1 The Co-Principal Investigator (or his designate) 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 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 IIT subnetwork microcomputer.

6.3 Record of Review of Computer Software Verification.

6.4 Blank paper for hand calculation of program algorithms.

6.5 Writing instrument (pen).

**7.0 Procedure**

7.1 Initiation of Record of Review of Computer Software Verification.

7.1.1 A Record of Review of Computer Software Verification (see figure 1) is used by the Co-Principal Investigator.

7.1.2 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.

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

7.1.4 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. Use of manufacturer's information will assist in this step.

7.2.2 Verification is documented on the Record of Review of Computer Software Verification. Verification includes solutions of unusual examples, book problems and other spot checks.

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 is performed using the software package with the test data as 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. If the difference in execution time between expected and actual time is greater than 15% of the expected, step 7.3.7 will be implemented.

7.3.6 Result sets and execution times from the runs of the old program and the new program are compared. If the difference in the results is statistically significant corrective steps will be taken. If the difference in execution time between an old and new version is larger than 15% of the old, step 7.3.7 will be implemented.

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

**8.0 Records**

Completed Record of Review of Computer Software Verification forms shall be attached to appropriate input, source and output listings. They should be archived and retained for inspection for not less than 5 years unless otherwise specified by the Project Director and the Sponsor.

IIT-A-2.0 Figure 1. Software Verification/Validation Form.

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RECORD OF REVIEW OF
COMPUTER SOFTWARE VERIFICATION

1. SOFTWARE PACKAGE NAME (Unique definition, version, etc. on the documentation)

2. DEVELOPER OF PROGRAM SPECIFICATION

3. PROGRAMMER/AUTHOR

4. PURPOSE OF REVIEW: _____New Program _____Modification (new version)

_____Periodic Review _____Other:_____

5. VERIFICATION SCOPE (Checked Off By Department Manager)

_____ Sample Problem

_____ Mathematical Modeling

_____Complete _____Spot Check

_____ Numerical Analysis

_____Complete _____Spot Check

_____ Standard Test Case Data Libaries Used

_____Complete _____Spot Check

_____ Benchmark Against Existing Programs

_____ Other: _____

6. DESCRIPTION OF VERIFICATION ACTIVITIES AND FINDINGS

IIT-A-2.0 Figure 1. Software Verification/Validation Form.

Page 2 of 3

RECORD OF REVIEW OF
COMPUTER SOFTWARE VERIFICATION

6. DESCRIPTION OF VERIFICATION ACTIVITIES AND FINDINGS (Cont.)

IIT-A-2.0 Figure 1. Software Verification/Validation Form.

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RECORD OF REVIEW OF
COMPUTER SOFTWARE VERIFICATION

SOFTWARE PACKAGE NAME

7. VERIFIED BY:_____ DATE:_____

8. SUMMARY OF REVIEW PROCEDURE AND RESULTS:

Completed Documentation Checklist:

___1. Program Identification
___2. Authors
___3. Purpose
___4. Programming Languages
___5. Restrictions
___6. Computer(s)
___7. Machine Requirements
___ 8. Operating Systems
___ 9. Related Material
___10. References
___11. Method of Solution
___12. Users Manual
___13. Listing
___14. Standard Test Case
___15. Description of the Verification

Reviewed By _____ Date_____

9. COMMENTS REVIEWED AND RESOLVED:

Author _____ Date_____

10. ALL APPLICABLE QA REQUIREMENTS HAVE BEEN MET AND APPROVED BY:

Project Manager_____ Date:_____