



**Department of Energy**  
 Office of Civilian Radioactive Waste Management  
 Yucca Mountain Site Characterization Office  
 P.O. Box 98608  
 Las Vegas, NV 89193-8608

JAN 25 1995

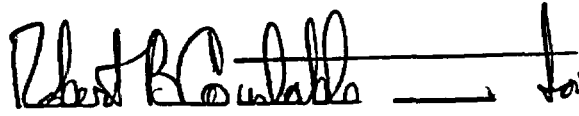
L. Dale Foust  
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 for Yucca Mountain  
 Site Characterization Project  
 TRW Environmental Safety Systems, Inc.  
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 Las Vegas, NV 89109

EVALUATION OF AMENDED RESPONSE AND EXTENSION REQUEST TO  
 CORRECTIVE ACTION REQUEST (CAR) YM-94-076 RESULTING FROM YUCCA  
 MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-94-01 OF  
 THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT AND OPERATING  
 CONTRACTOR (SCPB: N/A)

The YMQAD staff has evaluated the amended response and extension request to CAR YM-94-076. The extension request has been determined to be satisfactory; however, the amended response has been determined to be unsatisfactory for the following reason.

The third amended response accepted by YMQAD on November 29, 1994, committed to developing a process to determine if software falls under Quality Assurance Requirements Document Supplement I requirements for Scientific & Engineering (S&E) software. These issues were to be resolved in revisions to the Quality Assurance Procedure 19 series procedures. The fourth amended response commits to developing a classification process for S&E software in a revision to Nevada Line Procedure (NLP) 2-0 which does not address classification of S&E software at a program level. NLP-2-0 addresses only Waste Isolation Evaluations, Test Interference Evaluations, and Determination of Importance Evaluations and not all S&E software.

If you have any questions, please contact either Robert B. Constable at 794-7945 or John F. Pelletier at 794-7538.

  
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Richard E. Spence, Director  
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-1802

Enclosure:  
 CAR YM-94-076

010054

YMP-5

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 PDR WASTE  
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NH03 1/1  
 WM-1/1  
 102.7

L. Dale Foust

-2-

JAN 25 1995

cc w/encl:

T. A. Wood, HQ (RW-14) FORS

~~J. G. Spraul~~, NRC, Washington, DC

S. W. Zimmerman, NWPO, Carson City, NV

R. L. Robertson, M&O/TRW, Vienna, VA

Richard Jiu, M&O/Duke, Las Vegas, NV

R. P. Ruth, M&O/TRW, Las Vegas, NV

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV

D. G. Sult, YMOAD/QATSS, Las Vegas, NV

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**CORRECTIVE ACTION REQUEST**

1 Controlling Document OCRWM QARD DOE/RW-0333P, Revision 01	2 Related Report No. YMP-94-01
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3 Responsible Organization M&O	4 Discussed With Jim Houseworth
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5 Requirement:

1) QARD DOE/RW-0333P, Supplement I.2.5 states:

That acquired software shall be documented sufficiently to demonstrate the ability of the software to meet the needs of the affected organization.  
(Continued on next page)

6 Adverse Condition:

Contrary to the above, QARD requirements, Waste Isolation Evaluation of Construction Water for Package 2C, DI#BARE00000-01717-2200-00008 and Waste Isolation Evaluation: Tracers, Fluids, and Materials for Use in the Package 2C Exploratory Studies Facility Construction, DI#BARE00000-01717-2200-00007, indicate that the software package Macsymba (Macsymba Inc. PC Version 417.125) were used in the evaluation of both WIEs. Specifically the WIE for Tracers, Fluids, and Materials uses the Macsymba program to provide the analytical solution of an integrated three dimensional dispersive transport equation. Section 4.2 of the WIE identifies the saturated advection-dispersion model for nonreactive chemical transport as a critical model for nonreactive chemical transport as a critical model. There is no documentation that this software meets the needs of the affected organization.

Contrary to the above, regarding NLP-19-1, Revision 0, there is no objective evidence that requirements for verification of Macsymba software in Step 5.1.2, were performed before use in the WIEs.

NOTE: Implementing Line Procedure NLP-19-1, Revision 0 states that Macsymba is not considered scientific and (or) engineering software. There is no  
(Continued on next page)

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	8 Response Due Date: 20 Working Days From Issuance
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11 Required Actions:  Remedial  Extent of Deficiency  Preclude Recurrence  Root Cause Determination

12 Recommended Actions:

7 Initiator John F. Pelletier <i>John F. Pelletier</i> 8/4/94	14 Issuance Approved by: QADD <i>[Signature]</i> 8.5.94 Date
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15 Response Accepted QAR <i>[Signature]</i> Date 11/23/94	16 Response Accepted QADD <i>[Signature]</i> Date 11.23.94
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17 Amended Response Accepted QAR <i>John F. Pelletier</i> Date 9/2/94	18 Amended Response Accepted QADD <i>[Signature]</i> Date 9.12.94
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19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____
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**CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)**

5 Requirements (continued)

- 2) QARD DOE/RW-0333P, Supplement I.2.6 states:

That software activities shall be documented sufficiently to demonstrate the ability of the software to meet the needs of the affected organization.

- 3) Implementing Line Procedure NLP-19-1, Revision 0, Section 5.1.2 states:

That formulas and algorithms used during the analytical process with statistical analysis and interactive numeric and symbolic algebra software, should be verified by both of the following methods:

- a. Extracted directly from an appropriate and recognized source (e.g., textbook, handbook) and entered correctly.
- b. Verifying the results of their results of their use by means of a similar software package or an alternate calculation.

6 Adverse Condition (continued)

objective evidence that this software is not scientific and (or) engineering software and thus exempted from the QARD requirements. This software is used in WIEs.

Further, 5.1.2 specifically states that formulas and algorithms used during the analytical process with statistical analysis and interactive numeric and symbolic algebra software, should be verified by both of the following methods:

There is no objective evidence that these requirements were performed before use in the WIEs.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

I. Corrective Action Response for CAR YM-94-076

A. Remedial: Macsyma is a general purpose program for symbolic and numerical mathematical manipulations that has been widely accepted and used in the scientific and engineering community for more than a decade. As opposed to typical scientific and engineering software, there is no standard set of model equations that are solved. Each use of Macsyma involves the creation of unique mathematical expressions that require verification for the specific application. In this respect, Macsyma is similar to commercial spreadsheet software like Lotus. Therefore, the standard use of Macsyma is inconsistent with global verification and validation (V&V) concepts for scientific and engineering software and its exemption from these requirements is justified.

Objective evidence of calculation verification was not provided in the preparation of the identified Waste Isolation Evaluations (WIEs). Verification checks were performed as good engineering practice, but are not formally documented under our current procedures. Such evidence will be provided by incorporating the verification steps described below as an attachment to the affected WIEs:

1. Identify those calculations performed using Macsyma.
2. Comparison of symbolic mathematical expressions similar to those used in the WIEs that were derived by Macsyma with expressions given in mathematical handbooks.
3. Present hand calculations for numerical evaluations performed with Macsyma that are representative of the types of calculations performed in the affected WIEs.

B. Extent of Deficiency: The identified deficiency is present only in the following WIEs:

Waste Isolation Evaluation, Construction for Package 2C Excavation of the ESF North Ramp  
DI: BABE00000-01717-2200-00008 Rev. 00

Waste Isolation Evaluation: Tracers, Fluids, and Materials for Use in the Package 2C Exploratory Studies Facility Construction  
DI: BABE00000-01717-2200-00007 Rev. 00

In addition, we recognize that a formal system within the M&O does not exist for identifying whether software is or is not exempt from QARD Supplement I requirements for scientific or engineering software. These decisions are currently made at the group manager level and, in the absence of specific criteria, may result in a nonuniform application of QA requirements for software.

C. Preclude Recurrence: NLP-3-17 will be revised to incorporate verification criteria for use of commercial off-the-shelf (COTS) software not subject to global V&V requirements as described in NLP-19-1 Rev. 00. Two members of the Performance Assessment and Modeling Department received training on NLP-19-1 Rev. 00 on 8/10/94.

A formal M&O-wide system for identifying if software falls under the QARD definition of scientific or engineering software will be developed.

8/11/94

L.V. RTE. JLY. 08/94-114

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

2. Response Actions

Revise affected WIEs to incorporate objective evidence of Macsma calculation verification. Revise NLP-3-17 to incorporate verification criteria for use of COTS software not subject to global V&V requirements as described in NLP-19-1 Rev. 00. Develop formal M&O system for classification of software with respect to the applicability of QARD Supplement I.

Remedial Action

Responsible: James E. Houseworth

Anticipated Completion: 8/17/94

Preclude Recurrence

Responsible: Albin Brandstetter and Nathaniel Hodgson

Anticipated Completion: 12/31/94

3. Response Approved:

Jean L. Younker  
Regulatory and Technical Evaluation Manager

Date: 8/11/94

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

I. Corrective Action Response for CAR YM-94-076

A. Remedial:

Objective evidence of calculation verification was not provided in the preparation of the identified Waste Isolation Evaluations (WIEs). Verification checks were performed as good engineering practice, but are not formally documented under our current procedures. Such evidence will be provided by incorporating the verification steps described below as an attachment to the affected WIEs:

1. Identify those calculations performed using Macsyma.
2. Comparison of symbolic mathematical expressions similar to those used in the WIEs that were derived by Macsyma with expressions given in mathematical handbooks.
3. Present hand calculations for numerical evaluations performed with Macsyma that are representative of the types of calculations performed in the affected WIEs.

The above actions are intended to satisfy the confidence that the two WIE's are adequate to support Design Package 2C release, and does not represent a solution to the longer term issue addressed in the next paragraph.

B. Extent of Deficiency: We have reviewed all WIEs and the only ones where Macsyma or similar software was used are listed here:

Waste Isolation Evaluation, Construction for Package 2C Excavation of the ESF North Ramp  
DI: BABE00000-01717-2200-00008 Rev. 00

Waste Isolation Evaluation: Tracers, Fluids, and Materials for Use in the Package 2C Exploratory Studies Facility Construction  
DI: BABE00000-01717-2200-00007 Rev. 00

C. Preclude Recurrence: NLP-3-17 will be revised to incorporate the requirement for the identification of the verification method(s) used on the results of the use of software programs during the performance of Waste Isolation Evaluations. Two members of the Performance Assessment and Modeling Department received training on NLP-19-1 Rev. 00 on 8/10/94.

Develop a process to identify the applicability of Scientific & Engineering Software controls on formulas and algorithms that are used as input to non-S & E software, and the resulting effects. We shall address this issue in revisions of the QAP-19 series procedures and NLP-19-1.

2. Response Actions

1. Revise affected WIEs to incorporate objective evidence of Macsyma calculation verification.
2. Revise QAP-19 series procedures and NLP-19-1 to address controls on formulas and algorithms used as input to non S & E software.
3. Revise NLP-3-17 to incorporate requirements to identify verification method(s) for results of computer analyses used in WIEs.

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**CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)**

Remedial Action

Revision of Package 2C WIEs  
Responsible: James Houseworth and David Sassani  
Anticipated Completion: 8/19/94

Preclude Recurrence

Revision of QAP-19 series procedures  
Responsible: Warren Standley  
Anticipated Completion: 12/31/94

Revision of NLP-19-1  
Responsible: Nathaniel Hodgson  
Anticipated Completion: 12/31/94

Revision of NLP-3-17 Rev. 01  
Responsible: Albin Brandstetter  
Anticipated Completion: 12/31/94

3. Response Approved:

Jean L. Youder  
Regulatory and Technical Evaluation Manager

Date: 8-17-94



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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

I. Corrective Action Response for CAR YM-94-076

A. Remedial:

Objective evidence of calculation verification was not provided in the preparation of the identified Waste Isolation Evaluations (WIEs). Verification checks were performed as good engineering practice, but are not formally documented under our current procedures. Such evidence will be provided by incorporating the verification steps described below as an attachment to the affected WIEs:

1. Identify those calculations performed using Macsysma.
2. Comparison of symbolic mathematical expressions similar to those used in the WIEs that were derived by Macsysma with expressions given in mathematical handbooks.
3. Present hand calculations for numerical evaluations performed with Macsysma that are representative of the types of calculations performed in the affected WIEs.

The above actions are intended to satisfy the confidence that the two WIE's are adequate to support Design Package 2C release, and do not represent a solution to the longer term issue addressed in the section on Preclude Recurrence.

B. Extent of Deficiency: We have reviewed all WIEs and the only ones where Macsysma or similar software was used are listed here:

Waste Isolation Evaluation, Construction for Package 2C Excavation of the ESF North Ramp  
DI: BABE00000-01717-2200-00008 Rev. 00

Waste Isolation Evaluation: Tracers, Fluids, and Materials for Use in the Package 2C Exploratory Studies Facility Construction  
DI: BABE00000-01717-2200-00007 Rev. 00

C. Preclude Recurrence: NLP-3-17 will be revised to incorporate the requirement for the identification of the verification method(s) used on the results of the use of software programs during the performance of Waste Isolation Evaluations. Two members of the Performance Assessment and Modeling Department received training on NLP-19-1 Rev. 00 on 8/10/94.

Develop a classification process to determine if software falls under the QARD Supplement I requirements for Scientific & Engineering (S&E) software. This process will also address the applicability of S&E software controls on formulas and algorithms that are used as input to non-S&E software, and the resulting effects. We shall address these issues in revisions of the QAP-19 series procedures and NLP-19-1.

2. Response Actions

1. Revise affected WIEs to incorporate objective evidence of Macsysma calculation verification.
2. Revise QAP-19 series procedures and NLP-19-1 to address classification of software to determine applicability of QARD Supplement I requirements and applicability of S&E software controls on formulas and algorithms used as input to non-S&E software.
3. Revise NLP-3-17 to incorporate requirements to identify verification method(s) for results of computer analyses used in WIEs.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Remedial Action

Revision of Package 2C WIEs  
Responsible: James Houseworth and David Sassani  
Anticipated Completion: 8/19/94

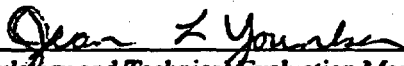
Preclude Recurrence

Revision of QAP-19 series procedures  
Responsible: Warren Standley  
Anticipated Completion: 12/31/94

Revision of NLP-19-1  
Responsible: Nathaniel Hodgson  
Anticipated Completion: 12/31/94

Revision of NLP-3-17 Rev. 01  
Responsible: Albin Brandstetter  
Anticipated Completion: 12/31/94

3. Response Approved:

  
Regulatory and Technical Evaluation Manager

Date: 9-1-94

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

1. Partial Verification of CAR YM-94-076

Reviewed the revised two affected Waste Isolation Evaluations packages associated with Design Package 2C. WIE Construction water for Package 2C Excavation of the ESF North Ramp DI:BABE00000-01717-2200-00008, Rev. 03, and WIE Tracers, Fluids, and Materials, and Excavation Methods for Use in the Package 2C Exploratory Studies Facility Construction DI:BABE00000-01717-2200-00007, Rev. 03. The WIEs were revised and objective evidence such as hand calculations were provided and incorporated to ensure that the calculations used in the WIEs were verified.

Verified that symbolic mathematical expressions similar to those used in the WIEs that were derived by "Macysma" with expressions given in mathematical handbooks provide similar results.

Verified the output of the algebraic functions calculated by the computer program "Macysma" with the output of the algebraic functions calculated by a similar computer program "Mathematica".



John F. Pelletier, QAR

9/2/94

Date

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1. Corrective Action Response for CAR YM-94-076

A. Remedial:

Objective evidence of calculation verification was not provided in the preparation of the identified Waste Isolation Evaluations (WIEs). Verification checks were performed as good engineering practice, but are not formally documented under our current procedures. Such evidence will be provided by incorporating the verification steps described below as an attachment to the affected WIEs:

1. Identify those calculations performed using Macsysma.
2. Comparison of symbolic mathematical expressions similar to those used in the WIEs that were derived by Macsysma with expressions given in mathematical handbooks.
3. Present hand calculations for numerical evaluations performed with Macsysma that are representative of the types of calculations performed in the affected WIEs.

The above actions are intended to satisfy the confidence that the two WIE's are adequate to support Design Package 2C release, and do not represent a solution to the longer term issue addressed in the section on Preclude Recurrence.

B. Extent of Deficiency: We have reviewed all WIEs and the only ones where Macsysma or similar software was used are listed here:

Waste Isolation Evaluation, Construction for Package 2C Excavation of the ESF North Ramp  
DI: BABE00000-01717-2200-00008 Rev. 00

Waste Isolation Evaluation: Tracers, Fluids, and Materials for Use in the Package 2C Exploratory Studies Facility Construction  
DI: BABE00000-01717-2200-00007 Rev. 00

- C. Preclude Recurrence: A revised line procedure (NLP-2-0) for Determination of Importance Evaluations (DIE) is planned. Under the revised line procedure, Waste Isolation and Test Interference Evaluations (TIE) will be documented as sections of the DIE rather than separate documents. The revision of NLP-2-0 consolidating DIE, WIE, and TIE procedures will incorporate the requirement for the identification of the verification method(s) used on the results of the use of software programs during the performance of DIEs. Two members of the Performance Assessment and Modeling Department received training on NLP-19-1 Rev. 00 on 8/10/94.

Develop a classification process to determine if software falls under the QARD Supplement I requirements for Scientific & Engineering (S&E) software. The applicability of S&E software controls on formulas and algorithms that are used as input to non-S&E software will also be addressed. We shall respond to these issues in revisions of the QAP-19 series procedures.

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2. Response Actions

1. Revise affected WIEs to incorporate objective evidence of Macsyma calculation verification.
2. Revise QAP-19 series procedures to address classification of software to determine applicability of QARD Supplement I requirements and applicability of S&E software controls on formulas and algorithms used as input to non-S&E software.
3. Revise NLP-2-0 to incorporate requirements to identify verification method(s) for results of computer analyses used to evaluate waste isolation or test interference impacts.

Remedial Action

Revision of Package 2C WIEs  
Responsible: James Houseworth and David Sassani  
Completed: 8/19/94

Preclude Recurrence

Revision of QAP-19 series procedures  
Responsible: Chuck Stafford  
Anticipated Completion: 12/31/94

Revision of NLP-2-0  
Responsible: Albin Brandstetter  
Anticipated Completion: 12/31/94

3. Response Approved:

Stuart L. Roy for JLY/emb  
Regulatory and Technical Evaluation Manager

Date: 11/17/94

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I. Corrective Action Response for CAR YM-94-076

A. Remedial:

Objective evidence of calculation verification was not provided in the preparation of the identified Waste Isolation Evaluations (WIEs). Verification checks were performed as good engineering practice, but are not formally documented under our current procedures. Such evidence will be provided by incorporating the verification steps described below as an attachment to the affected WIEs:

1. Identify those calculations performed using Macsysma.
2. Comparison of symbolic mathematical expressions similar to those used in the WIEs that were derived by Macsysma with expressions given in mathematical handbooks.
3. Present hand calculations for numerical evaluations performed with Macsysma that are representative of the types of calculations performed in the affected WIEs.

The above actions are intended to satisfy the confidence that the two WIE's are adequate to support Design Package 2C release, and do not represent a solution to the longer term issue addressed in the section on Preclude Recurrence.

B. Extent of Deficiency: We have reviewed all WIEs and the only ones where Macsysma or similar software was used are listed here:

Waste Isolation Evaluation, Construction for Package 2C Excavation of the ESF North Ramp  
DI: BABE00000-01717-2200-00008 Rev. 00

Waste Isolation Evaluation: Tracers, Fluids, and Materials for Use in the Package 2C Exploratory Studies Facility Construction  
DI: BABE00000-01717-2200-00007 Rev. 00

C. Preclude Recurrence: A revised line procedure (NLP-2-0) for Determination of Importance Evaluations (DIE) is planned. Under the revised line procedure, Waste Isolation and Test Interference Evaluations (TIE) will be documented as sections of the DIE rather than separate documents. The revision of NLP-2-0 consolidating DIE, WIE, and TIE procedures will incorporate the requirement for the identification of the verification method(s) used on the results of the use of software programs during the performance of DIEs. Two members of the Performance Assessment and Modeling Department received training on NLP-19-1 Rev. 00 on 8/10/94.

Develop a classification process to determine if software falls under the QARD Supplement I requirements for Scientific & Engineering (S&E) software. The applicability of S&E software controls on formulas that are used as input to non-S&E software will also be addressed. We shall respond to these issues in the revision of NLP-2-0.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

2. Response Actions

1. Revise affected WIEs to incorporate objective evidence of Macsymba calculation verification.
2. Revise NLP-2-0 to incorporate requirements to identify verification method(s) for results of computer analyses used to evaluate waste isolation or test interference impacts. Also address classification of software to determine applicability of QARD Supplement I requirements and applicability of S&E software controls on formulas used as input to non-S&E software.

Remedial Action

Revision of Package 2C WIEs

Responsible: James Houseworth and David Sassani

Completed: 8/19/94

Preclude Recurrence

Revision of NLP-2-0

Responsible: Peter Hastings

Anticipated Completion: 2/28/95

3. Response Approved:

Maitha W. Proddator for Jose L. Yoncker  
Regulatory and Technical Evaluation Manager

Date: 12/22/94