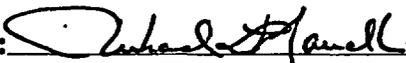


**U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

**AUDIT REPORT
OF
UNITED STATES GEOLOGICAL SURVEY
DENVER, COLORADO**

**AUDIT NUMBER YM-ARC-96-10
MARCH 25 THROUGH 29, 1996**

Prepared by:  Date: 04-25-96
Richard L. Maudlin
Audit Team Leader
Yucca Mountain Quality
Assurance Division

Approved by:  Date: 5/2/96
Donald G. Horton
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) audit YM-ARC-96-10, the audit team determined that the U.S. Geological Survey (USGS) is satisfactorily implementing an effective QA program, with the exception of those areas where deficiencies existed, in accordance with the U.S. Department of Energy Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5 and USGS's implementing procedures for QA Program Elements 1.0, 2.0, 5.0, 6.0, 12.0, 15.0, 17.0, and Supplements I, II and III. Implementation of QA Elements 4.0, 7.0, and 16.0 were determined to be unsatisfactory.

The audit team identified eight deficiencies during the audit that resulted in the issuance of two Corrective Action Requests (CAR), four Deficiency Reports (DR), and two Performance Reports (PR) by the Yucca Mountain Quality Assurance Division (YMQAD). CAR YMQAD-96-C004 identifies numerous problems in procurement, such as: QA requirements not attached to purchase orders, use of suppliers with unresolved deficiencies, and use of suppliers with no documented QA programs; CAR YMQAD-96-C005 identifies problems with the documentation, tracking, and response/follow-up to corrective action documents. DR YMQAD-96-D048 identifies failure to document calibration deficiencies. DR YMQAD-96-D049 documents that USGS Quality Management Procedure (QMP)-12.01, Revision 6, "Instrument Calibration," allows alternative methods to be used to document nonconformances which deviate from Yucca Mountain Administrative Procedure (YAP)-15.1Q, Revision 2, "Nonconformances." DR YMQAD-96-D050 identifies that lists of cited references included in Study Plans and technical reports were not submitted to the Yucca Mountain Site Characterization Office (YMSCO) Research and Study Center. DR YMQAD-96-D051 identifies lost or misplaced Supplier Evaluation and Supplier Verification Reports. PR YMQAD-96-P024 documents that USGS QMP-17.01, Revision 8, "YMP-USGS Records Management for Record Sources," allows for an alternative method of documenting record corrections, which is contrary to the requirements of the QARD. PR YMQAD-96-P025 identifies the lack of documentation in the form of a Requirements Specification and Design Description for software DIFFGIBBS/1.0.

Three deficiencies identified by the audit team were corrected prior to the postaudit meeting as described in Section 5.5.4 of this report. Additionally, there were two recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy of, compliance of, and the effectiveness of USGS's QA program as described in the QARD and USGS's implementing procedures.

In addition, a review of open OCRWM deficiency documents identified during a previous audit of USGS was conducted to determine status of corrective actions.

The QA program elements/requirements evaluated during the audit, in accordance with the approved audit plan, are as follows:

QA PROGRAM ELEMENTS/REQUIREMENTS

- 1.0 Organization
- 2.0 Quality Assurance Program
- 4.0 Procurement Document Control
- 5.0 Implementing Documents
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 12.0 Control of Measuring and Test Equipment
- 15.0 Nonconformances
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- Supplement I, Software
- Supplement II, Sample Control
- Supplement III, Scientific Investigation

The following QA program elements/requirements were not reviewed during the audit because USGS currently has no activities to which these elements apply:

- 3.0 Design Control
- 8.0 Identification and Control of Items
- 9.0 Control of Special Processes
- 10.0 Inspection
- 11.0 Test Control
- 13.0 Handling, Storage, and Shipping
- 14.0 Inspection, Test, and Operating Status
- 18.0 Audits
- Supplement IV, Field Surveying

TECHNICAL AREAS

None

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Elements/Requirements</u>
Richard L. Maudlin, Audit Team Leader, YMQAD	5.0, 6.0
James Blaylock, Auditor, YMQAD	Supplements II and III
Mary G. McDaniel, Auditor, YMQAD	2.0, 12.0, and 17.0
Kenneth T. McFall, Auditor, YMQAD	1.0, 2.0, 16.0, and Supplement I
John S. Martin, Auditor, YMQAD	2.0, 4.0, 7.0, and 15.0

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at USGS in Denver, Colorado, on March 25, 1996. A daily debriefing and coordination meeting was held with USGS management and staff, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at USGS in Denver, Colorado, on March 29, 1996. Personnel contacted during the audit are listed in Attachment 1. The list also includes those who attended the preaudit and postaudit meetings.

Cooperation afforded to the audit team during the entire course of the audit was exceptional.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, in general, with the exception of those areas where deficiencies existed, the USGS QA Program is adequate and is being effectively implemented for the scope of this audit except for procurement and corrective

action. Individually, QA Program Elements 1.0, 2.0, 5.0, 6.0, 12.0, 15.0, 17.0, and Supplements I, II, and III are satisfactorily implemented. Implementation of QA Program Elements 4.0, 7.0, and 16.0 were found unsatisfactory. A meeting was held with USGS management to discuss in detail the unsatisfactory areas.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The details of the audit evaluation, along with the objective evidence reviewed, are contained within the audit checklist. The checklist is kept and maintained as a QA Record.

5.4 Technical Audit Activities

None

5.5 Summary of Deficiencies

The audit team identified eight deficiencies during the audit for which two CARs, four DRs, and two PRs were issued. Three deficiencies were corrected prior to the postaudit meeting.

Synopses of deficiencies documented as CARs, DRs, PRs, and those corrected during the audit are presented below. The CARs, DRs, and PRs have been issued by separate letter (YMQAD-96-C004, YMQAD: RBC-1073, dated April 10, 1996; YMQAD-96-C005, YMQAD: RBC-1547, dated April 12, 1996; and YMQAD-96-D048, -D049, -D050, -D051, -P024, and -P025, YMQAD: RBC-1558, dated April 12, 1996) to the responsible individuals in accordance with Administrative Procedure (AP)-16.1Q, Revision 0, "Performance/Deficiency Reporting," and AP-16.2Q, Revision 0, "Corrective Action and Stop Work."

5.5.1 Corrective Action Requests (CAR)

YMQAD-96-C004

The QARD, Revision 5, Section 4.0, "Procurement Document Control," requires that procurement documents issued by each Affected Organization include provisions, as applicable, for the item or service being procured and that suppliers have a documented QA Program that implements the applicable portions of the QARD.

USGS QMP-4.01, Revision 7, "Procurement Document Control/Receipt of Procurement," Section 5.0, requires that the QA Office review procurement documents to ensure that the applicable QA Requirements are complete. The procedure also requires that the QA Office review U.S. Department of the Interior Requisition Forms (DI-I) and attach the appropriate QA requirements attachments to the DI-I forms.

USGS QMP-7.04, Revision 2, "Supplier Evaluation," Section 5.0, requires that upon determination of the need to evaluate a supplier, the QA Manager shall document the inadequacies and their resolution in accordance with AP-16.1Q, Revision 0.

QARD, Revision 5, Section 12.0, "Control of Measuring and Test Equipment," requires that calibration documentation include the identification of the implementing document (including revision level) used to perform the calibration and the identification of the standards used to perform the calibration.

AP-7.4Q, Revision 1, "Maintenance of the Office Of Civilian Radioactive Waste Management Qualified Suppliers List," Section 5.0, requires the qualifier, after receipt of the Office of Quality Assurance initial audit report of the supplier and letter from the Quality Assurance Division Director, evaluate the report and based on the evaluation, complete the Supplier Evaluation Report (SER). USGS QMP-7.04, Revision 2, Section 5.0, requires that if inadequacies are identified the USGS QA Manager determine what actions are to be taken.

QARD, Revision 5, Section 5.0, "Implementing Documents," requires implementing documents to include a sequential description of the work to be performed and quantitative/qualitative acceptance criteria for determining activities were satisfactorily accomplished.

Contrary to the above:

- The USGS QMP-4.01, Revision 7, does not meet the QARD requirements in regards to qualifying suppliers, in that the USGS procedure allows qualification of suppliers without an approved QA program.
- The USGS is not, in all instances, providing the appropriate reviews to procurement documents.
- The USGS is not, in all instances, attaching QA requirement attachments to purchase orders.
- The USGS is not, in all instances, documenting supplier deficiencies in accordance with AP-16.1Q, Revision 0, and/or AP 16.2Q, Revision 0.
- The USGS QMPs 4.01, Revision 7; 7.04, Revision 2; and 12.01, Revision 6, do not meet the requirements of the QARD relative to documenting specific information to be included on calibration documentation.
- The USGS is not submitting SERs subsequent to initial and triennial audits.
- The USGS is not resolving deficiencies identified against suppliers of services.
- The USGS QMP 7.04, Revision 2, does not provide sufficient detail for the completion of supplier evaluation checklists.

YMQAD-96-C005

QARD, Revision 5, Section 16.0, "Corrective Action," requires the QA organization to close corrective action documentation in a timely manner when actions are complete.

AP-16.1Q, Revision 0, Section 5.0, requires the Affected Organization PR/DR Coordinator to maintain a log of PRs and DRs. The PR/DR Coordinator is to update the PR/DR log as PRs and DRs are issued or

change in status occurs. The PR/DR Coordinator is to maintain PRs, DRs, continuations, requests for extension and all relevant correspondence for status and records. The responsible individual is to transmit a response by the response due date to the PR/DR Coordinator.

Contrary to the above: (1) USGS-95-D001 was closed over 5 months after completion of corrective action; (2) The PR/DR log has not been maintained current; (3) There is no documentation for USGS corrective action documents USGS-95-D012, -D013, -D014, -D015, and -D017; and (4) There is no documented evidence that the following deficiency documents have ever received a response, (USGS-95-D010, -D016, and USGS-96-D002, and -P006).

5.5.2 Deficiency Reports (DR)

YMQAD-96-D048

USGS QMP-12.01, Revision 6, "Instrument Calibration," requires that upon detection of a deficient condition, a Nonconformance Report (NCR) shall be prepared in accordance with YAP-15.1Q unless an alternative method has been developed within a technical procedure or Scientific Notebook (SN).

Contrary to the above: (1) Documentation for calibrations performed for analytical balances indicated a failure for both preliminary findings and final report and no NCR or other documentation has been issued, and (2) No closing calibration has been documented for Fission-Track System and no NCR or other documentation has been issued.

YMQAD-96-D049

YAP-15.1Q, Revision 2, Section 2.0, "Control of Nonconformances," indicates that this procedure also applies to the evaluation and disposition of the validity of results for items and samples as well as work products when Measuring and Test Equipment (M&TE) is found out of calibration.

Contrary to the above, USGS QMP-12.01, Revision 6, does not require a NCR to be prepared for each instance where M&TE is found out of calibration but allows for an alternative method to be used when specified within a technical procedure or SN.

YMQAD-96-D050

YAP-17.1Q, Revision 0, "Records Management Requirements and Responsibilities," Section 5.0, requires that Affected Organizations/Records Sources submit by correspondence a list of cited references from each study plan or published administrative, technical, or scientific report to the YMSCO Research and Study Center.

Contrary to the above, USGS has not submitted to the YMSCO Research and Study Center any lists of cited references included in Study Plans, etc., since implementation of the requirement on May 17, 1995.

YMQAD-96-D051

QARD, Revision 5, Section 17.0, "Quality Assurance Records," requires individuals handling QA records to protect them from damage or loss until the records are submitted to the records management system.

Contrary to the above, supplier evaluation and supplier verification reports have been lost or misplaced.

5.5.3 Performance Reports (PR)

YMQAD-96-P024

QARD, Revision 5, Section 17.0, "Quality Assurance Records," requires that corrections to QA records, including documents which will become records, include the initials or signature of the persons making the change and the date the correction was made.

Contrary to the above, USGS QMP-17.01, Revision 8, allows an alternative method for documenting records corrections which does not conform to the requirements of the QARD.

YMQAD-96-P025

USGS QMP-3.03, Revision 5, "Software," Section 5.0, requires that software documentation include a Requirements Specification, Design Description, etc.

Contrary to this requirement, there was no evidence that documentation for DIFFGIBBS/1.0 contained a Requirements Specification or Design Description.

5.5.4 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. Contrary to the requirements of USGS QMP-18.02, Revision 3, "Surveillances," Attachment 1, Surveillance Report 96003-IS did not contain the titles of the personnel contacted. This was resolved during the audit by adding the titles to the Surveillance Report.
2. Contrary to the requirement of USGS QMP-3.03, Revision 5, "Software," Paragraph 5.4.2, there was no documented evidence that the software Configuration Status Accounting Log updates had been submitted to the Local Records Center for all of 1995. This was resolved during the audit by documented evidence that USGS had known of the problem and had generated one report for the year 1995. This condition was documented on a PR (USGS-95-P009) which was initiated prior to the audit and issued on March 26, 1996.
3. Contrary to the requirement of USGS-QMP-2.08, Revision 2, "Non-Federal Contractor Personnel Qualification," Section 5.3, there was no statement of attestation of the experience and education for Petronilo V. (Pete) Rodriguez. USGS knew of this situation and was attempting to obtain the required documentation; the required documentation was obtained during the audit and added to the qualification file.

5.5.5 Follow-up of Previously Identified Deficiency Documents

Follow-up action on two deficiency documents, YMQAD-95-C051 and YMQAD-95-C002, indicated that a minor revision was needed for the former and actions are pending on the latter. It is anticipated that YMQAD-95-C051 will be closed by April 30, 1996, upon receipt of the

revised response containing documentation that serves as verification of corrective action. The latter requires additional actions by USGS such that closure is not imminent.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by USGS management.

1. USGS should establish a formal "check-out" process for USGS or USGS-contractor personnel leaving the Yucca Mountain Site Characterization Project (YMP) or completing assignment to the YMP. The process should address turnover of in-process or completed records; other areas that could be addressed include return/disposition of controlled documents; turnover of YMP equipment; turnover of computer software; and termination of computer system access.
2. In review of USGS Oversight Activity Log it became apparent that in addition to Supplier Evaluation and Verification Reports which were lost and/or misplaced (reference DR YMQAD-96-D051) several oversight activities were performed and drafted over seven months ago that have not been issued to date. While there are no time frames established for the issuance of Supplier Evaluation and Verification Reports and Internal Audits within the USGS program the time it has taken to issue these seems extraordinarily excessive. It is recommended that any issues surrounding these reports be resolved and the reports finalized and issued prior to their loss and/or being misplaced. Examples of a Supplier Verification and an Internal Audit which have not been issued by USGS, for which over seven months have passed since completion, are as follows: Internal Audit No. 95041 and Supplier Verification No. 95048. It is also recommended that USGS evaluate any impact this condition may have had upon their program.

7.0 LIST OF ATTACHMENTS

- Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

ATTACHMENT 1
Personnel Contacted During the Audit

Name	Organization/Title	Preaudit Meeting	Contacted During Audit	Postaudit Meeting
Burnham, P.	USGS/Records Coordinator		X	
Chaney, T.	USGS/QA Manager	X	X	X
Craig, R.	USGS/Technical Project Officer		X	X
Dorsey, M.	CRWMS M&O/Research & Study Center Supervisor		X	
Ducret, L.	USGS/Associate Chief, YMPB	X	X	X
Futa, K.	USGS/Research Chemist		X	
Golos, J.	USGS/Administrative Operations Specialist		X	
Kwak, L.	USGS/Chemist		X	
Luckey, R.	USGS/SZ & EM Team Chief			X
Lykins, A.	USGS/QA Specialist	X	X	X
McKinley, P.	USGS/Data Coordinator		X	
Miller-Corbett, C.	USGS/Software QA Specialist	X	X	X
Mustard, M.	USGS/Hydrologist	X	X	X
Nelson, M.	USGS/Training Coordinator		X	
O'Brien, M.	USGS/QA Implementation Specialist	X	X	
Parks, B.	USGS/Assistant Chief ESIP	X	X	X
Peterman, Z.	USGS/Geologist		X	
Rathray, G.	USGS/Hydrologist		X	
Rodman, W.	USGS/QA Specialist		X	
Rodriguez, P.	USGS/QA Specialist	X	X	X
Scofield, K.	USGS/Hydrologic Technician		X	
Whelan, J.	USGS/Geologist		X	
Whiteside, A.	USGS/QA Implementation Specialist	X	X	
Williams, R.	USGS/Chief ESIP	X	X	X
Woolverton, J.	USGS/QA Implementation Specialist	X	X	
Yang, A.	USGS/Hydrologist		X	

Legend:

- CRWMS M&O..... Civilian Radioactive Waste Management System Management and Operating Contractor
- ESIP Earth Science Investigation Program
- SZ & EM Saturated Zone and Environmental Monitoring
- YMPB Yucca Mountain Project Branch

Attachment II
 Summary of Audit Results

AUDIT YM-ARC-96-10 DETAIL SUMMARY

QA ELEMENT/ ACTIVITIES	DOCUMENTS REVIEWED	DETAILS (Checklist) YM-ARC-96-10	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE- QUACY	COM- PLIANCE	OVER- ALL
1	QARD, Rev. 5	Pg. 2	N	N	N	N	N	SAT	SAT	SAT
	USGS-QMP-1.01, Rev. 5, Mod. 1	Pgs. 3-7	N	N	N	N	N	SAT	SAT	
2	QARD, Rev. 5	Pgs. 8-17	N	N	N	N	N	SAT	SAT	SAT
	QMP-2.02, Rev. 6, Mod. 3	Pgs. 18-19	N	N	N	N	N	SAT	SAT	
	QMP-2.08, Rev. 2, Mod. 3	Pgs. 20-22	N	N	N	1	N	SAT	SAT	
	QMP-2.07, Rev. 2, Mod. 4	Pgs. 23-26	N	N	N	N	N	SAT	SAT	
	YMP-USGS-QMP-18.02, Rev. 3	Pgs. 83-85	N	N	N	1	1	SAT	SAT	
4	YMP-USGS-QMP-4.01, Rev. 7	Pgs. 27-30	YM QAD- 96-C004	N	N	N	N	UNSAT	UNSAT	UN- SAT
	YMP-USGS-QMP-4.02, Rev. 6	Pgs. 31-33	N	N	N	N	N	SAT	SAT	
5	USGS OMP 5.01, Rev. 6	Pgs. 37-38	N	N	N	N	N	SAT	SAT	

Attachment II
Summary of Audit Results

QA ELEMENT/ ACTIVITIES	DOCUMENTS REVIEWED	DETAILS (Checklist) YM-ARC-96-10	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE- QUACY	COM- PLIANCE	OVER- ALL
5 (cont'd)	USGS-QMP-5.03, Rev. 8, Mod. 1 & 3	Pgs. 34-36	N	N	N	N	N	N/I	N/I	SAT
	USGS-QMP-5.05, Rev. 4, Mod. 2	Pgs. 39-41	N	N	N	N	N	SAT	SAT	
6	USGS-QMP-6.01, Rev. 6, Mod. 1	Pgs. 42-44	N	N	N	N	N	SAT	SAT	SAT
7	YMP-USGS-QMP-7.04, Rev. 2	Pgs. 45- 45C, 46, & 47	YM- QAD- 96-C004	N	N	N	2	UNSAT	UNSAT	UN- SAT
12	QMP-12.01, Rev. 6, Mod. 2	Pgs. 48-54	N	YM- QAD- 96- D048	N	N	N	SAT	SAT	SAT
15	YAP-15.1Q, Rev. 2	Pgs. 55-56, & 101	N	YM- QAD- 96- D049	N	N	N	SAT	SAT	SAT
16	QARD, Rev. 5	Pgs. 57-58	N	N	N	N	N	SAT	UNSAT	UN- SAT
	AP-16.1Q, Rev. 0	Pgs. 59-64	YM- QAD- 96-C005	N	N	N	N	SAT	UNSAT	

Attachment II
Summary of Audit Results

QA ELEMENT/ ACTIVITIES	DOCUMENTS REVIEWED	DETAILS (Checklist) YM-ARC-96-10	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE- QUACY	COM- PLIANCE	OVER- ALL
16 (cont'd)	AP-16.2Q, Rev. 0	Pgs. 65-70	N	N	N	N	N	SAT	N/I	
	AP-16.3Q, Rev. 0	Pgs. 71-72	N	N	N	N	N	SAT	SAT	
17	QARD, Rev. 5	Pgs. 71-78	N	YM- QAD- 96- D051	N	N	N	SAT	SAT	SAT
	QMP-17.01, Rev. 8	Pgs. 71-78	N	N	YM- QAD- 96- P024	N	1	SAT	SAT	
	QMP-17.03, Rev. 2, Mod. 2	Pgs. 79-81	N	N	N	N	N	SAT	SAT	
	YAP-17.1Q, Rev. 0, ICN 4	Pgs. 81-82	N	YM- QAD- 96- D050	N	N	N	SAT	SAT	
SI	QARD, Rev. 5	Pgs. 86-88	N	N	N	N	N	SAT	SAT	SAT
	USGS-QMP-3.03, Rev. 5, Mod. 3	Pgs. 89-97	N	N	YM- QAD- 96- P025	1	N	SAT	SAT	

Attachment II
Summary of Audit Results

QA ELEMENT/ACTIVITIES	DOCUMENTS REVIEWED	DETAILS (Checklist) YM-ARC-96-10	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE-QUACY	COM-PLIANCE	OVER-ALL
SII	GCP-02, Rev. 2, 10/22/90	Pgs. 99-100	N	N	N	N	N	SAT	SAT	SAT
	GCP-15, Rev. 3, 5/31/94	Pgs. 98-100	N	N	N	N	N	SAT	SAT	
	GCP-16, Rev. 4, 1/18/94	Pgs. 98-100	N	N	N	N	N	SAT	SAT	
	HP-56, Rev. 4, 8/7/95	Pgs. 98-100	N	N	N	N	N	SAT	SAT	
	HP-160, Rev. 2, 3/22/93	Pgs. 98-100	N	N	N	N	N	SAT	SAT	
	GP-32, Rev. 0	Pgs. 98-100	N	N	N	N	N	SAT	SAT	
SIII	YAP-2.2Q, Rev.	Pgs. 102-103	N	N	N	N	N	N/A	SAT	SAT
	YAP-SIII.2Q, Rev.	Pgs. 103-105	N	N	N	N	N	N/A	SAT	
	YAP-SIII.3Q, Rev.	Pgs. 103-105	N	N	N	N	N	N/A	SAT	
TOTAL		105	2	4	2	3	2			

LEGEND:

CDA Corrected During the Audit
 N None
 N/A Not Applicable
 N/I Not Implemented

REC Recommendation
 SAT Satisfactory
 UNSAT Unsatisfactory