

Department of Energy

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EVALUATION OF RESPONSE, VERIFICATION OF CORRECTIVE ACTION, AND CLOSURE OF DEFICIENCY REPORT (DR) YMQAD-96-D053 RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT OQA-SA-96-014 OF SOKKIA CORPORATION (SCPB: N/A)

The Yucca Mountain Quality Assurance Division staff has evaluated the response and verified the corrective action of DR YMQAD-96-D053. The response and verification have been determined to be satisfactory. As a result, this DR is considered closed.

If you have any questions, please contact either Robert B. Constable at (702) 794-5580 or Richard L. Maudlin at (702) 794-1302.

[Cobert 1) Countries

Richard E. Spence, Director Yucca Mountain Quality Assurance Division

YMQAD:RBC-1898

Enclosure: DR YMQAD-96-D053

cc w/encl:

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

[®] □Performance Report
Deficiency Report
NO. YMOAD-96-D053

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Rev 07/03/95

		PAGE _1_ OF _3 QA: L
PERFORMANC	CE/DEFICIENCY REPORT	
1 Controlling Document:		2 Related Report No
QARD, DOE/RW-0333P, Revision 5	OQA-SA-96-014	
3 Responsible Organization:	4 Discussed With:	
Kiewit/PB / SOKKIA Corp.	D. Haas / Al Kesselring	•
5 Requirement/Measurement Criteria:		
QARD, Section 4.0, Subsection 4.2.1 states in part	t: " Procurement Document Prepara	ation:
Procurement documents issued by each Affected of the item or service being procured		ring provisions, as applicable to
C. Quality Assurance Program Requi	irements including:	
	plier to have a documented Quality e Quality Assurance Requirements initiation of work."	
6 Description of Condition:		
Contrary to the above:		
 K/PB has not incorporated in their procure documented QA program that implements SOKKIA Corporation does not have a docu QARD. Examples of QARD Elements not a Procurement Document Control, Implement Services, Control of Measuring and Test Examples. 	the applicable requirements of the output of	QARD. sees the applicable portions of the are not limited to: Organization, I, Control of Purchased Items and
		(Cont'd on Page 3)
7 Initiator Carlo	9 QA Review	(Contra on Fage 5)
Richard L. Maudlin Date 22/	16 QAR Spanelle	Date 4/22/16
10 Response Due Date:	11 QA Issuance Approval	1 of Det
20 Working Days From Issuance	QAR (PR)/AOQAM (DR)	1. pl 1kt Date 5/2/9/
12 Remedial Actions		
SEE PAGE 6		
Date 5/6/		Date
15 Remedial Action Response Acceptance QAR Date	16 PR Venfication /Closure QAR \(\begin{align*} \(\begin{align*} A \\ align	Date

Exhibit AP-16.1Q.1

DR NO. YMOAD-96	-D053	<u>-</u>
PAGE _2_ OF	3	
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17	Recommended	Actions:

- Take immediate action to incorporate QA requirements in present and future POs with SOKKIA 1.
- SOKKIA to develop a QA Manual to address applicable requirements of QARD. Kiewit/PB to review and accept 2. SOKKIA QA Manual.
- SOKKIA to develop implementing procedures to implement QA Manual as appropriate.
- Kiewit/PB to investigate any possible impact of work by SOKKIA in the absence of an acceptable QA program, determine root cause as to why QA requirements were not included in POs, and identify action to preclude
- Resolve specific items referenced in this DR.

18 Investigative Actions:

SEE PAGES 4 AND 5

19 Root Cause Determination:

SEE PAGE 6

20 Action to Preclude Recurrence.

SEE PAGE 6

71 Response By	. ,	22 Corrective Action Completion Due Date
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23 Response Accepted	5/,	24 Response Accepted 1
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QAR	Date	AOQAM
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QAR Sofand.	Date 3/31/96	ADDAM Chest Sumable Date 6-5-96

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PERFORMANCE/DEFICIENCY REPORT

Block 5, Requirement/Measurement Criteria, cont'd

QARD, Section 2.0, Subsection 2.2.1 states in part: "Quality Assurance Program Documents:

B.....Organizations shall establish implementing documents applicable to their scope of work that translate Quality Assurance Requirements and Description (QARD) requirements into work processes."

QARD Section 17.0, Subsection 17.2.11 states in part: "Temporary Storage Facility:

....Organizations shall provide for temporary storage of QA records during processing, review, or use until turnover to the OCRWM for disposition, according to the following requirements:

A. QA records shall be temporarily stored in a container or facility with a fire rating of 1-hour, or dual storage shall be provided."

Block 6, Description of Condition, cont'd

Oue to fact that no QA program document exists, activities affecting quality have not been appropriately documented. Examples include:

No documented evidence of qualification and training of personnel performing calibrations.

No documented evidence of evaluation and qualification of suppliers used to calibrate SOKKIA standards.

SOKKIA calibration documentation did not provide for documenting equipment that was found to be out of calibration or nonconforming.

There was no revision control on the electronic calibration test procedures.

No documented evidence exists of review and/or approval of NET2 manuals or electronic test procedures.

(4) Calibration records are not being stored in either a 1-hour fire rated cabinets or in dual storage an no time limits for maintenance of records has been specified.

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Block 18, Investigative Actions (including historical perspective) - Continued

The SOKKIA Corporation was placed on the QSL by RSN in 1993. This action was based on a facility survey of SOKKIA by RSN in August of 1993 during which only Criteria 12 was verified. RSN did not require that SOKKIA have a documented Quality Assurance Program as a condition of qualification and no initial audit by DOE was required at that time. A purchase order was issued by RSN to SOKKIA in February 1994 for calibration services and the first annual review was performed by RSN in August 1994. The acceptance of this annual review was apparently based on SOKKIA's satisfactory performance.

In March 1995, the responsibility for maintaining SOKKIA as a qualified vendor was transferred from RSN to REECo. There is no evidence of any action performed by REECo, during their reign of responsibility, regarding maintenance of SOKKIA as a qualified vendor.

In October 1995, the SOKKIA baton was passed from REECo to Kiewit/PB at which time Kiewit/PB made the erroneous assumption that all was well regarding the basis for qualification of SOKKIA. Assumptions were made that since SOKKIA was already on the QSL, they must have an adequately documented QA Program and they must be performing quality related work. Both of these assumptions were incorrect. In February 1996, Kiewit/PB QA began researching data for the annual evaluation of SOKKIA and since there was no evidence of a SOKKIA QA Program Manual, Kiewit/PB QA contacted SOKKIA and requested a copy of their program. This research also found that no "Q" purchase orders had been issued to SOKKIA since Kiewit/PB assumed responsibility for their maintenance on the QSL. We did find, however, that a "non-Q" purchase order (which should, as understood at that time, have been "Q") was issued to SOKKIA in December 1995 for calibration of Model Net 2 survey instrument. As a result of the non-Q status of the purchase order, a quality assurance review was not performed. This review would have imposed QA Program requirements on SOKKIA. Kiewit/PB DR # K/PB-96-D037, dated 4/9/96, has been issued to Kiewit/PB Procurement concerning the processing of a "Q" activity purchase order as non-Q. The K/PB DR D037 was issued prior to this DOE DR and adequately addresses item 1 in Block 6 which covers the same subject.

The SOKKIA manual was received by Kiewit/PB just prior to the DOE audit of SOKKIA. Upon review of the manual, it was discovered that the manual was a "Certification Manual" and did not adequately address the required QA Program elements. This issue was discussed with the DOE and it was decided to proceed with the audit of SOKKIA to determine the degree of QA program implementation even though the program was not documented. The criteria to be used during the audit was agreed between Kiewit/PB and DOE.

In an effort to determine the extent of the condition, Kiewit/PB has reviewed the QSL and found no similar problems for vendors initially qualified and maintained on the QSL by Kiewit/PB. We did, however, identify another vendor which, although appearing to be adequately qualified based on a review of their QA Manual, may not be needed on the QSL. This vendor, Surveyors Services, was also inherited by Kiewit/PB from REECo and is currently being investigated to determine if their service is quality related and, if not, they will be removed from the QSL. The actions required to correct the deficiency discussed in this DR have been addressed in remedial actions.

Exhibit AP-16.10.3 Rev. 07/03/95

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PR/DR CONTINUATION PAGE

Block 18 - Investigative Actions - Continued

The entire issue regarding the qualification of SOKKIA has prompted Kiewit/PB to perform an in depth investigation concerning the service that SOKKIA is actually providing, how the equipment is actually calibrated and how the equipment is actually used. As a result of this investigation it has been determined by Kiewit/PB that the SOKKIA Corporation is not needed for the performance of calibration of our Total Station Survey Instruments. The rationale used for this determination is as follows:

Total Station Survey Instruments are used for the determination of distance combined with the measurement of direction and the difference in elevation. The determination of distance is by modulated infrared radiation in a continuous wave at several frequencies with a measurement of phase shift. The accuracy of the distance measured by the various instruments used on this project varies from plus or minus (3mm+2ppm) to (1mm+1ppm). This distance portion of the total stations is calibrated on the NIST baseline at Desert Rock near Mercury. This calibration is performed according to TCP-2.31 which is derived from National Oceanic and Atmospheric Administration Technical Memorandum NOS NGS-10, "Use of Calibration Base Lines". These instruments are compared to the baseline and the residuals are checked by the sigma and three sigma test as per the procedure. An additional test that is applied to the calibration data is the use of a least squares analysis with Chi Square Test. The pass-fail threshold for the Chi Square Test is 5%. The instruments are calibrated by comparison only, the distance measurement is not adjusted, it either passes the calibration test or it fails. If the calibration fails, the instrument is taken out of service and sent to the manufacturer or one of his dealers for service and repair. This procedure is the basis of calibration for these instruments. It is important to note that this calibration is performed to a working standard, established by the National Institute of Standards and Technology, under very near the same conditions as the instrument is used, by the same people that normally use the instrument, and at about the same kinds of distances that are typically used. This calibration could be done at an instrumentation lab to a laboratory standard, however, this laboratory standard would normally be in the range of only two to four meters. Although it is good practice for the lab to do this when they have made any repairs or adjustments to the instrument, it is normally followed by a calibration to a working standard.

The angular measurement portion, both horizontal and vertical, of the total stations is electronic. It is adjustable by several means. These adjustments are made at a repair facility of the manufacturer or one of his dealers. In day to day use the angular measurements are compensated to minimize the collimation error. This is done electronically by functions built into the instrument and used by our personnel in the field as they feel necessary. There is no standard to calibrate this angular measurement function. The angular measurement function is verified by a self-checking procedure which is normal survey practice. "Errors due to instrumental imperfections and/or nonadjustment are all systematic errors, and without exception they can be either eliminated or reduced to a negligible amount by proper procedure." Surveying Theory and Practice-Chapter Six-Angle and direction measurement, Page 252.

In summary, Kiewit/PB has concluded that since the actual calibration of the Total Station Survey Instruments is performed on site at Desert Rock, there is no need to maintain the SOKKIA Corporation on the QSL as a calibration service. SOKKIA will continue to be used as a repair/service facility. A Supplier Evaluation Report (SER) has been issued by Kiewit/PB requesting that SOKKIA be removed from the QSL.

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PR/DR CONTINUATION PAGE -

Block 12, Remedial Actions - Continued

A Supplier Evaluation Report (SER) was issued on 5/8/96 to request that SOKKIA be removed from the QSL. The basis for this action is contained in Block 18.

Block 19, Root Cause Determination - Continued

It has been determined that the root causes of these issues were the poor assumptions made by Kiewit/PB during transition regarding the basis for qualification of vendors which were inherited from other affected organizations and not performing a proper review to verify the adequacy of these basis. In addition to the poor assumptions, another contributing factor was the processing of the calibration purchase orders as non-Q which has been documented on Kiewit/PB DR-96-037.

Block 20, Action to Preclude Recurrence - Continued

Based upon the root cause determinations, Kiewit/PB has taken the position that we will not accept the responsibility for the maintenance of vendors initially qualified and placed on the QSL by another Affected Organization without first performing a review to verify that the vendor was properly qualified.

KIEWIT/PB

YUCCA MOUNTAIN PROJECT TECHNICAL CONTROL PROCEDURE KIEWIT/PB TCP-2.34

REV. 0

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EFFECTIVE DATE: 09/01/95

O/A: L SCPB: N/A

Approved:

CONTROL OF SURVEY EQUIPMENT TCP-2.34

1.0 PURPOSE/SCOPE

1.1 Purpose

This procedure provides requirements for the receipt, initial calibration status, use, recalibration, and general control of survey equipment used for quality verification activities.

1.2 Scope

This procedure is applicable to all survey equipment that requires calibration and will be utilized for quality verification activities. This procedure is not applicable to rulers, tape measures and other commercial equipment that provide adequate accuracy for their intended use. *(12.2.5) Other types of equipment may be covered by Reference 2.1.

2.0 REFERENCES

- 2.1 MCP-12.0, Control of Measuring and Test Equipment
- 2.2 MCP-15.0, Control of Nonconforming Items

3.0 **PROCEDURE**

3.1 General

- (1) Survey equipment used for quality verifications shall be assigned an identifying number when received by the Kiewit/PB survey organization. Where practical, the equipment shall be labeled, tagged or otherwise marked with its identification number.
- (2)

^{*} Superscript numbers denote QARD requirements and are provided for guidance purposes only.

3.1.1 Data Package

- A data package shall be developed for each piece of survey equipment issued an identifying number that will be used to maintain records of: (12.2.1E)(12.2.1F)(12.2.2:1s)
 - A. Assigned identification number(12.2.6A)
 - B. Calibration standard and date of calibration, based on the type of equipment, required accuracy, intended use, and other conditions affecting measurement control. (12.2.1C:15)(12.2.6B) For survey equipment used in one-time-only applications, the calibration shall be done both before and after use. (12.2.1C:25)
 - C. Calibration data, including implementing document(s) and revision level (12.2.6C)(12.2.6H)
 - D. Identification of individual(s) performing calibration(s)(12.2.6D)
 - E. Results of calibration and statement of acceptability^(12,2,6F)
 - F. Operating status (in service, out of service). Survey equipment taken out of service shall be calibration checked, as applicable, to verify its accuracy since its last calibration check.
 - G. Other information pertinent to the applicable equipment
 - 3.1.2 The following information shall be documented in the appropriate Work Package(s): (12.2.2.2.2s)
 - A. Date(s) used
 - B. Identification of the process monitored
 - C. Data collected
 - **D.** Items inspected
 - E. Equipment identification

3.2 Calibration

- 3.2.1 Survey equipment shall be calibrated, adjusted, and maintained at intervals recommended by the manufacturer, but not to exceed one year, or whenever the accuracy of the equipment is suspect. (12.2.1D) Calibrations shall be documented on a Survey Equipment Calibration Record form (Exhibit 5.1). Calibration shall be accomplished against reference calibration standards having traceability to nationally-recognized standards, or as established by the manufacturer. If no nationally-recognized standards or physical constants exist, or the manufacturer has no established method, the basis for calibration shall be documented. Review and acceptance of calibrations shall be indicated on the calibration certification form. (12.2.1A:1s and 2s)(12.2.1C:1s)(12.2.1D.E and F)
- 3.2.2 Calibration standards shall have a greater accuracy than the required accuracy of the equipment being calibrated. If calibration standards with a greater accuracy than required of the equipment being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements. (12.2.1B)(12.2.1B1)
- 3.2.3 The basis for calibration acceptance shall be documented in the applicable equipment's data package with authorization indicated by the Chief of Survey's signature. (12.2.1B.2:1s and 2s)

3.3 Handling and Storage

Survey instruments and equipment shall be properly handled and stored as necessary to maintain accuracy. (12.2.4)

3.4 Out-of-Calibration Measuring and Test Equipment

- 3.4.1 Out-of-calibration equipment shall be tagged and segregated by the Chief of Survey to prevent use until it has been recalibrated. If any equipment is consistently found to be out of calibration during the recalibration process, it shall be repaired or replaced. (12.2.3C) Survey equipment shall be considered to be out of calibration and not be used for quality verifications until calibrated if any of the following conditions exist: (12.2.3B:1s)
 - A. The calibration due date or interval has passed without recalibration. (12.2.3A.1)
 - B. The device produces results known or suspected to be in error. (12.2.3A.2)

- 3.4.2 When equipment is found to be out of calibration, the validity of results obtained using that equipment since its last valid calibration, as indicated in that equipment's data package, shall be evaluated by the Chief of Survey. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. The evaluation shall be documented by one of two means: (12.2.3B:251)(12.2.3B:252)(12.2.3B:252a and b)(12.2.6G)(12.2.2.2s)
 - A. Should previously collected data prove to be suspect, a Nonconformance Report (NCR) shall be issued and resolved in accordance with Reference 2.2.
 - B. Should it be determined by the Chief of Survey that previously collected data is adequate and acceptable, the evaluation shall be documented on an Interoffice Memo of Record (IOMR) and inserted into that equipment's data package. The logic used to determine adequacy/acceptability shall be included in the IOMR.
- 3.4.3 Lost or damaged Survey Equipment shall be listed as "Out-of-Service" in the applicable data package.

4.0 RECORDS

The following records generated by this procedure shall be submitted by the Chief of Survey to Records Management for records processing when appropriate measuring and test equipment is taken out of service:

4.1. Lifetime QA Records

Completed Equipment Data Packages for each piece of Survey equipment requiring calibration.

4.2 Non-Permanent QA Records

None

4.3 Project Records

None

5.0 EXHIBITS

All Exhibits are examples. Equivalent forms may be used but must include, at a minimum, all information indicated on the Exhibits.

- 5.1 Survey Equipment Calibration Record Form
- 5.2 History of Changes Form

Exhibit 5.1

KIEWIT/PB YUCCA MOUNTAIN PROJECT SURVEY EOUIPMENT CALIBRATION RECORD

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Exhibit 5.2

KIEWIT/PB YUCCA MOUNTAIN PROJECT HISTORY OF CHANGES

Document Identification No: TCP-2.34

The changes in this revision shall be summarized below in sufficient detail and shall be reviewed each time additional changes to the document are proposed.

Revision or Change

Reason for Change

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Initial Issuance.

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	Sokkia Corporation.	Al Kesselring General Manager
	9111 Barton Street	TELEPHONE
	Overland Park, Kansas 66201	913-492-4900
	ITEM(S)	SERVICE(S)
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EVALUATION OF RESPONSE AND CLOSURE OF DR YMQAD-96-D053

The response to the subject DR has been reviewed and found acceptable in responding to the condition adverse to quality. After a review of K/PB Technical Control Procedure TCP-2.34, Rev. 0, titled "Control of Survey Equipment" and the Supplier Evaluation Report, dated 5/8/96, requesting that Sokkia be removed from the Qualified Suppliers List, it is determined that no further action on the part of K/PB is required. Since K/PB is responsible for the calibrations of surveying equipment, requirements for Sokkia Corporation to be a qualified supplier appears to be over and above what is necessary. Based on your response and review of the above documents, this Deficiency Report is considered closed.

Richard L. Maudlin, OAR