



Department of Energy

Washington, DC 20585

QA: QA


SEP 05 2003

Distribution

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) TREND EVALUATION FOR THE FIRST SEMESTER 2003

The enclosed report provides the result of the Office of Quality Assurance evaluation of deficiencies during the period beginning January 1, 2003, and ending June 30, 2003. This report provides results of trend evaluations to Affected Organizations.

If you have any questions regarding this subject, please contact either Kerry M. Grooms at (702) 794-1367 or me at (702) 794-1460.


R. Dennis Brown, Director
Office of Quality Assurance

OQA:KMG-1810

Enclosure:
OCRWM QA Trend Report for
Quality Program Deficiencies
First Semester 2003

cc w/encl:
Records Processing Center = "16"

NM5507
wm11



SEP 05 2003

Margaret Chu, DOE/HQ (RW-1), FORS
T. J. Garrish, DOE/HQ (RW-2E), FORS
C. A. Kouts, DOE/HQ (RW-20E), FORS
M. E. Bennington, DOE/OQA (RW-3), Las Vegas, NV
K. M. Grooms, DOE/OQA (RW-3), Las Vegas, NV
R. B. Murthy, DOE/OQA (RW-3), Las Vegas, NV
N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV
R. W. Craig, USGS, Las Vegas, NV
William Garfield, BSC, Washington, DC
Collin Moller, BSC, Washington, DC
J. T. Mitchell, Jr., BSC, Las Vegas, NV
D. W. Pearman, BSC, Las Vegas, NV
R. W. Andrews, BSC, Las Vegas, NV
P. K. Casey, BSC, Las Vegas, NV
Leon Fossum, BSC, Las Vegas, NV, M/S 763
R. S. Hajner, BSC, Las Vegas, NV
L. L. Lucas, BSC, Las Vegas, NV
M. J. Mason, BSC, Las Vegas, NV
R. M. Sandifer, BSC, Las Vegas, NV
C. D. Sorensen, BSC, Las Vegas, NV
D. R. Tommela, BSC, Las Vegas, NV
M. D. Voegelé, BSC, Las Vegas, NV
D. D. von der Linden, BSC, Las Vegas, NV
J. S. Whitcraft, BSC, Las Vegas, NV
N. H. Williams, BSC, Las Vegas, NV
R. P. Hasson, NQS, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
M. A. Kavchak, NQS, Las Vegas, NV
E. P. Opelski, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
W. J. Arthur, III, DOE/ORD (RW-2W), Las Vegas, NV
J. R. Dyer, DOE/ORD (RW-2W), Las Vegas, NV
S. P. Mellington, DOE/ORD (RW-50W), Las Vegas, NV
V. W. Trebules, DOE/ORD (RW-20W), Las Vegas, NV
M. E. Van Der Puy, DOE/ORD (RW-30W), Las Vegas, NV
J. D. Ziegler, DOE/ORD (RW-40W), Las Vegas, NV

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE TREND REPORT

FOR

QUALITY PROGRAM DEFICIENCIES

First Semester 2003

PREPARED BY: William J. Glasse
Trend Coordinator

Date 8-21-03

APPROVED BY: R. Dennis Brown
R. Dennis Brown, Director
Office of Quality Assurance

Date 9/3/03

EXECUTIVE SUMMARY

This report includes a composite analysis of all deficiencies reported during the trend period January 1 through June 30, 2003 (first semester 2003).

There were no adverse quality trends identified during this report period. The composite analysis identified one area where an emerging issue warrants management consideration.

Software

Deficiencies trended in this category have continued to increase. The progression of conditions has increased from 7 a year ago, to 10 last trend period, to 14 for the current trend period. Although the specific conditions for this period continue to be distributed among several of the individual sub-elements, it is of concern that the completed actions taken with respect to Corrective Action Report (CAR) BSC-01-C-002 may not have resulted in effective actions to preclude recurrence. The concern may further be noted as a result of the recent software audit conducted in June 2003, which documented eight additional software issues that were not issued until July (not part of the 14 for this period). The causes for these eight additional issues have yet to be determined and may not support an emerging issue.

Although the recent increase in identified conditions may be due to the implementation of the CAR actions and recent audit activities, the continued identification of software related deficiencies may be indicative of ineffective corrective actions and is therefore considered to be an emerging issue for management consideration.

The trend report for July to December 2002 (second semester 2002) identified the need to conduct Suspect Trend Investigation Reports for "Untimely submittal of QA Records" and "Inadequate content in implementing documents." Neither investigation indicated that an adverse quality trend exists but supported the overall management concerns with procedure compliance.

In relation to the management of the corrective action program, the time to close deficiencies showed an increase during this trend period from 107 days to 117 days.

1.0 INTRODUCTION AND SCOPE

This report includes a composite analysis of all deficiencies reported during first half of calendar year 2003.

The scope of this evaluation period is January 1 through June 30, 2003, i.e. first semester 2003. The trend data includes deficiencies identified from several program areas as follows:

Corrective Action Report	2
Deficiency Report (DR)	80
Quality Observation (QO)	60
Deficiency Identification and Referral (DIR)	0
Nonconformance Report (NCR)	12
Technical Error Report (TER)	8

The 162 trend inputs identified above represent those issues identified as internal to the Office of Civilian Radioactive Waste Management (OCRWM) scope of work. Supplier-related deficiencies are not evaluated as part of this trend report. Deficient conditions that result from an inadequate procurement process are included in this evaluation.

This report also assesses the Integrated Safety Management (ISM) program area of Suspect Counterfeit Items (S/CI). This was identified in an NCR and is discussed in the next section of this report.

The format and data evaluated for this trend report includes an initial evaluation of an enhanced causal analysis based on Causal Analysis Tree codes developed for the U.S. Department of Energy (DOE) Occurrence Reporting and Processing System (ORPS).

2.0 SUMMARY

This section summarizes the trend analysis results from improved causal analysis, event code evaluation, suspect/counterfeit items, emerging issues, and summary of trend-related deficiencies.

2.1 Causal Analysis

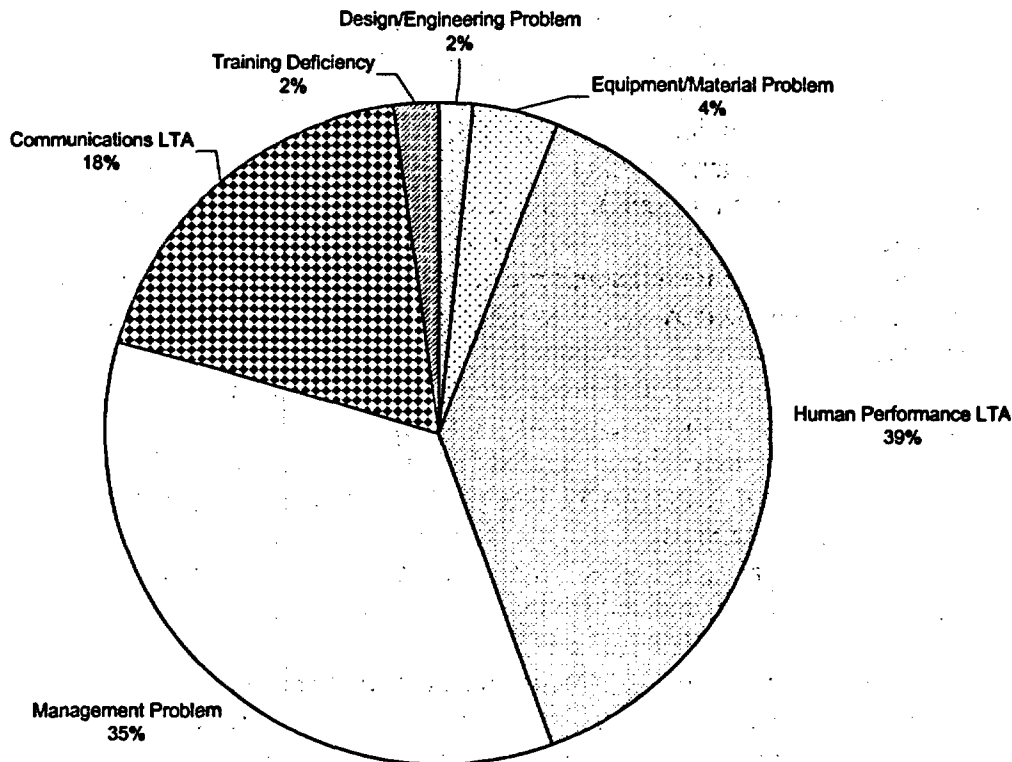
This causal analysis uses a set of Causal Analysis Tree codes associated with ORPS that represents successive branching of causes, i.e. Apparent Cause, Contributing Cause, and Root Cause. The enhanced approach also associates conditions with appropriate management levels described on project organization charts rather than on major affected organization. The causal evaluation for this report represents the continued trending improvements that will evolve with the single point of entry problem resolution system, new Corrective Action Program (CAP) software is scheduled for implementation by September 30, 2003.

To perform the evaluation using the Causal Analysis Tree, the DR/CARs and QOs issued since April 2002 were reviewed for assignment of the new causal code. A supplemental database was created to assign the cause categories and the responsible organization for

each of these documents. Subsequent causal evaluations from the new CAP software may consider all conditions, regardless of their "Q" status. Management considers that project related causes for all conditions are reflective of project personnel attitudes that are reflected at all levels of work.

Chart 1 below shows the distribution of the first level cause (Apparent Cause) for the 187 documents evaluated. Some of the documents were coded in multiple areas.

Chart 1 Causal Distribution



The chart above shows that the major contributors to the Apparent Cause of conditions are Human Performance Less Than Adequate (LTA), Management Problem, and Communications LTA. To further assess the expected information from the enhanced causal evaluation, each of the major area were further evaluated as follows:

Human Performance LTA – The Causal Analysis Tree for this Apparent Cause identifies four Contributing Causes. The distribution of conditions within these causes identifies the primary contributing cause as "Skill Based Error" which is further subdivided into seven Root Causes. A primary Root Cause of "Check of work was LTA" has the majority of conditions trended here. "Incorrect performance due to mental lapse" is the second most used trend code. The primary contributing organization is Bechtel SAIC Company, LLC (BSC) Performance Assessment.

Management Problem – Five Contributing Causes are associated with this Apparent Cause. Within these causes “Management Methods LTA” is the significant contributor. Nine Root Causes are identified for this contributing cause with most identified as “Management policy guidance/expectations not well-defined, understood or enforced.” Again, BSC Performance Assessment is the primary contributor.

Communications LTA – Of the four Contributing Causes, the major contributor is “Written Communication Content LTA.” The primary Root Cause from nine potential areas is “Ambiguous instructions/requirements.” Another significant contributor is “Incomplete/situation not covered.” BSC Performance Assessment is identified as the most significant contributor to the causes in these trend categories.

This analysis establishes a baseline for full implementation of the causal analysis approach. The initial evaluation of the data supports earlier conclusions that management has made regarding the primary causes of problems on this project. Management considers, and this analysis supports, that the primary cause of adverse conditions have been related to procedure compliance, both from the personnel and management perspective.

2.2 Event Code Trend Evaluation

Event codes for trend analysis are assigned to each deficiency document upon issuance and immediately compared to the trend database for other entries that used the same trend code. This evaluation assists in identification of adverse quality trends or emerging issues.

The evaluation of the 162 internal deficiencies trended during this period considered the relationship of the event trend codes assigned to those deficiencies to those of the previous four semesters (first semester 2001 through second semester 2002). The distribution of deficiencies for the current period and the previous four periods is shown in Table 1. The information from this table supports the comparison of deficiencies for the current trend-reporting period with the previous trend reporting periods.

Table 1
Distribution of Deficiencies

ELEMENT	DESCRIPTION	2001-1	2001-2	2002-1	2002-2	2003-1
1	Organization	1		4		2
2	Program	5	17	25	26	24
3	Design	2	2	2	6	6
4	Procurement Document Control	2	3	2	5	2
5	Implementing Documents	7	19	25	28	30
6	Document Control	6	7	12	8	10
7	Control of Purchased Items/Services	4	4	4	8	11
9	Control of Special Processes		1			
10	Inspection	1	1			
12	Control of M&TE	10	11	14	10	14
13	Handling, Storage, and Shipping	1	1	2	2	
14	Inspection, Test, and Operating Status					1
15	Nonconformances	1		2	2	4
16	Corrective Action	5	3	3	4	3
17	QA Records	7	7	20	21	26
18	Audits	1			3	1
19	Software	3	7	7	10	14
20	Sample Control	5	5	1	1	3
21	Scientific Investigation	15	17	20	18	33
22	Field Surveying	2			1	
23	Electronic Management of Data	1	3	1	2	2
27	Violation of Technical Requirement		2	4		
28	Technical Error Reports			58	3	8

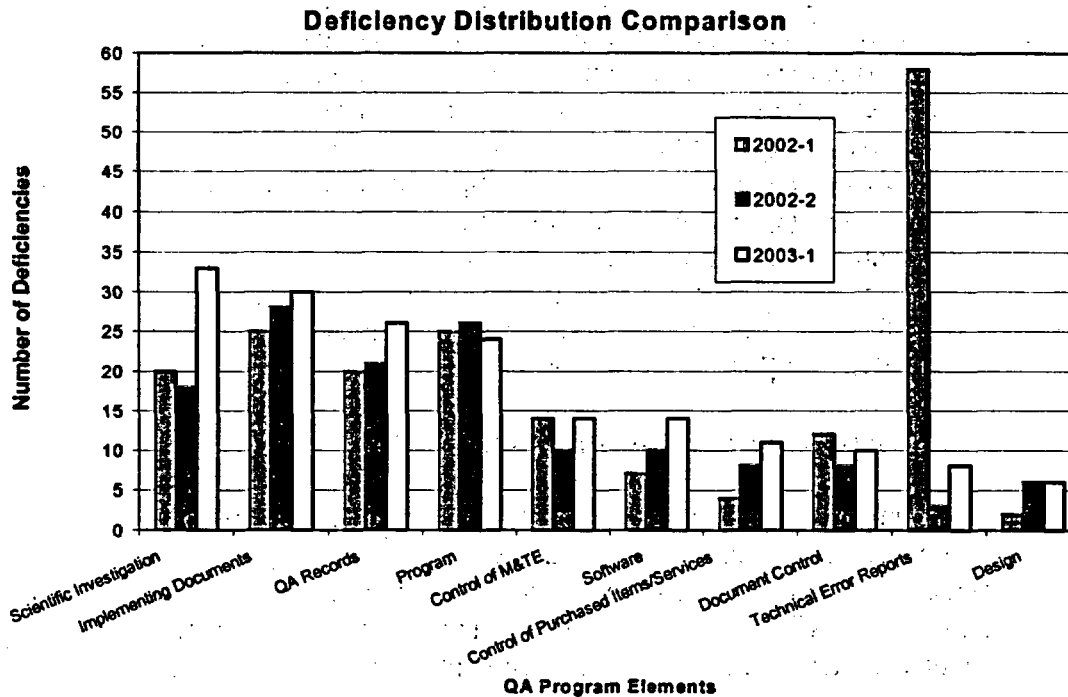


Chart 2

Chart 2 shows the deficiencies ranked by the number of deficiencies in each program element based on the distribution of deficiencies during the first semester 2003. The chart also compares the number of deficiencies categorized in each area with the distribution reported in the last two trend periods. This chart was derived from the data provided in Table 1. Each of the program elements shown was subjected to a detailed evaluation and summarized in section 3.0.

2.3 Suspect/counterfeit Items

During the last six months (January 2003 through June 2003) there was one occurrence of receiving suspect/counterfeit items. Two circuit breakers were received on Purchase Order NN-FPA-00066 that fit this category. Details can be seen in ORPS Report HQ--BSYM-YMSGD-2003-0002 and/or YMP NCR# ORD-03-0049. This incident was not considered a trend, but is indicative of an effective S/CI Program.

2.4 Emerging Issues and Investigations

Emerging issues are identified based on quality program issues that may either be developing, or have the potential to develop into a significant condition adverse to quality (CAQ). This section of the report reviews concerns with the implementation of the quality assurance program that have either been identified as an emerging issue or has been investigated through a Suspect Trend Investigation Report (STIR). The status of emerging issues and investigations are as follows:

- **Untimely submittal of QA Records (STIR results)**

The trend report for the first semester 2002 reported that QA records experienced the most significant increase in reported deficient conditions. Specifically, the major contributor to this program element concerned the untimely submittal of QA records to the Records Processing Center within prescribed time limits. In order to obtain an appropriate perspective on this concern, STIR BSC-03-002, was issued last February to investigate the subject. The STIR investigation concluded that the number of conditions identified represented an insignificant number of records when compared to the total number of records submitted (18 issues vs 180,000 records). As such, no adverse quality trend exists. However, the common cause for identified relates to "failure to follow procedure" that is already a major focus for improvement directed by senior DOE and BSC management.

- **Compliance with technical requirements (STIR results)**

The trend report for the first semester 2002 reported that failure to meet technical requirements also had an increased number of deficiencies. Since it was not clear from the evaluation of current information that an adverse quality trend actually existed, STIR BSC-03-001 was issued to further evaluate a potential problem with inadequate content in implementing documents. The STIR investigation concluded that there are no indications of adverse trends in the adequacy of content in process procedures. As with the results of the records STIR above, the predominant cause for this area is also related to "failure to follow procedures."

- **Software**

Deficiencies trended in this category have continued to increase. The progression of conditions has increased from 7 a year ago, to 10 last trend period, to 14 for the current trend period. Although the specific conditions for this period continue to be distributed among several of the individual sub-elements, it is of concern that the completed actions taken with respect to Corrective Action Report (CAR)

BSC-01-C-002 may not have resulted in effective actions to preclude recurrence. The concern may further be noted as a result of the recent software audit conducted in June 2003, which documented eight additional software issues that were not issued until July (not part of the 14 for this period). The causes for these eight additional issues have yet to be determined and may not support an emerging issue. Although the recent increase in identified conditions may be due to the implementation of the CAR actions and recent audit activities, the continued identification of software related deficiencies may be indicative of ineffective corrective actions and is therefore considered to be an emerging issue for management consideration.

2.5 Summary of Trend-related Deficiencies

The corrective action process allows for "early identification" during event trend code input and initiation of a deficiency document for either repetitive issues or common issues among Affected Organizations. During this trend period, no new adverse quality trends were identified.

- **QA Program Requirements related to Training and Qualification of Personnel (Reported in trend period for Semester 2001-2)**

Significant CAQ BSC-02-C-001 was issued on November 27, 2001, to document an adverse trend in implementation of training program requirements. Corrective actions for this CAR have been tied to the successful completion of several closely related deficiency documents that are considered to be a measure of successful implementation of corrective action. Related DRs are expected to be complete by the end of August 2003.

3.0 EVENT CODE DETAILED ANALYSIS

Based on the distribution of deficiencies shown on Chart 2, the QA Program elements that have five or more deficiencies, have an increasing number of deficiencies, or have sustained a high number of deficiencies for the current trend period were evaluated in depth. The results of these evaluations are as follows:

3.1 Scientific Investigation

Deficiencies trended in this area represent the most significant increase as a trended event. The number of "hits" for this trended element increased from 18 to 33. Eleven of the trended deficiency documents are QOs that represent minor issues. Evaluation of the conditions trended for the Scientific Investigation sub-element are noted below:

- **Data review, adequacy, usage** – Five separate deficient conditions were trended in this area that shows an increase from three to five specific “hits”. The conditions documented include a BSC initiated CAR, BSC(B)-03-C-107, that stemmed from an evaluation of data related deficiency documents issued over the last several years. BSC concluded that management has not effectively corrected data management issues and issued an appropriate CAR. Issuance of this CAR represents the expected “real time” trend considerations as issues are identified. The issuance of the BSC CAR for inadequate data management represents an appropriate “real time” trend action that requires no further trend consideration at this time.
- **Insufficient traceability (Measuring and Test Equipment (M&TE), method, materials, personnel, data source, references)** – The number of “hits” in this element increased from two to five. Examination of the specific deficient documents appears to represent minor related issues that have no quality related impact when corrected. This trend element does not warrant further investigation.
- **Inadequate or incomplete reports** – Five issues were trended in this area. Although an increase from two to five “hits” were noted, two were minor issues corrected on QOs and two are data issues included in the BSC CAR referenced above. No specific conditions associated with this element require additional adverse trend actions.

Deficiency documents trended relative to Scientific Investigation do not represent an event based adverse quality trend other than as documented with the BSC CAR noted above. The population of conditions is distributed among several sub-elements. However, examination of the causal factor for these conditions supports the overall concern for failure to follow or implement procedures as noted earlier in this report.

3.2 Implementing Documents

Deficiencies associated with implementing documents continue to be a significant contributor to the total number in this area. During the last three trend evaluation periods, the number of “hits” increased from 25 to 28 to 30 for this trend period. Specific evaluation of the individual sub-elements that have the majority of the identified conditions are summarized below:

- **Inadequate content in implementing document** – Conditions in this trend code have decreased from 12 to 10. This area had been identified in the last trend report as an area in need of further investigation. A trend investigation was initiated and results documented in STIR BSC-03-001. The results of the STIR were summarized above. Consistent with the STIR results, the specific deficiencies that comprise the 10 “hits” do not represent the need for additional actions. As with the Scientific Investigation results noted above, the conditions continue to reinforce the need to improve the human performance element to comply with procedures.

- **Failure to follow procedures (Quality) – Deficiencies trended in this area as an event are primarily those that do not fit one of the established QARD program sections or are directly related to section 5 for implementing documents. Specific deficiencies trended in this area have increased from 14 to 17 over the three trend evaluation periods. Evaluation of this area in the last trend report suggested that management attention to emphasize the need to always follow procedures could reduce the incidences reported in this category. Examination of the 17 “hits” in this area continues to show a need for management attention towards procedure compliance. In addition, several issues related to the procedure preparation process, specifically procedure preparation compliance, are documented in CAR BSC(O)-03-C-097. The CAR cause evaluation recognizes the need to focus on personnel related actions. The corrective actions for CAR BSC(O)-03-C-097 address not only the specific procedure violation but also the human performance issues. No further corrective actions are currently needed.**

3.3 Quality Assurance Records

The total number trended in this element has increased from 21 to 26 and continues to be one of the major contributors to the event based trending evaluation. Evaluation of the individual sub-elements is as follows:

- **Inadequate preparation, completion, or handling of QA records – Changes in this category (6 to 11) account for the noted increase. Examination of the specific deficiencies that were trended in this category shows that the issues are mostly minor records preparation issues and are widespread throughout the project. Considering the large number of records processed on this project, no further trend related actions are necessary at this time. However, it should be noted that most of the causal factors are related to personnel error.**
- **Records were not collected, assembled, or transmitted to Records Processing Center – This trend category was an area of concern in the last trend report and resulted in the issuance of STIR-BSC-03-002. The STIR investigation, summarized earlier in this report, indicated no adverse trend. The number of “hits” for this category have since decreased from 14 to 10 and continue to be similar types of issues that have not been determined to represent an adverse condition.**

3.4 Program

QA Program related deficiencies continue to be a significant contributor to issues identified during this trend period. This category has several distinct work activities under this major element. Evaluation of the specific trend areas is summarized below.

- **Inadequate reviews (management, readiness, peer or document) – The number of deficiencies in this sub-element have decreased over the last three trend periods (16 –13 –8) but remain the significant contributor to this trend**

element. Although a decreasing trend is noted, one of the conditions documented is classified as significant, CAR BSC(O)-03-C-097, which documents inadequate preparation, planning and review of the BSC procedure for managing procedures. No additional actions are required at this time.

- **Inadequate personnel selection, indoctrination, training, or qualification –** Issues trended in this category have increased from two to six over the last three trend periods. Evaluation of the specific conditions for the last period shows that several conditions that were identified were subsequently subdivided between OCRWM and BSC with respect to assuring that position descriptions and subsequent qualifications have been properly completed. The conditions themselves have not been considered significant nor have they represented a continued documentation of repeating conditions. No adverse trend is considered.
- **Lack of or inadequate training –** Training related deficiencies have continued to increase (four reported this trend period. Most of the conditions documented over the last year have been QOs to document minor instances of failure to have all required training completed prior to performing an activity. Evaluation of these deficiency documents do no warrant further consideration as either an adverse trend or emerging issue at this time. The conditions do, however, continue to support the projects concern regarding failures to follow procedures.
- **Lack of or Inadequate Planning –** Four conditions were documented during this trend period. The specific conditions do not represent an adverse trend in need of further attention at this time.

3.5 Control of Measuring and Test Equipment (M&TE)

Deficiencies trended relative to control of M&TE continue to vary between 10-14 conditions per trend period. Examination of the specific trend codes does not show any adverse quality trend or area of potential concern and shows that deficiencies continue to be distributed through the trend categories. Evaluation of the identified deficiencies does not show that an adverse trend exists in this trend category

3.6 Software

Deficiencies trended in this category have continued to increase. The progression of conditions has increased from 7 a year ago, to 10 last trend period, to 14 for the current trend period. Although the specific conditions for this period continue to be distributed among several of the individual sub-elements, it is of concern that the completed actions taken with respect to Corrective Action Report (CAR) BSC-01-C-002 may not have resulted in effective actions to preclude recurrence. The concern may further be noted as a result of the recent software audit conducted in June 2003, which documented eight additional software issues that were not issued until July (not part of the 14 for this period). The causes for these eight additional issues have yet to be determined and may not support an

emerging issue. Although the recent increase in identified conditions may be due to the implementation of the CAR actions and recent audit activities, the continued identification of software related deficiencies may be indicative of ineffective corrective actions and is therefore considered to be an emerging issue for management consideration.

3.7 Control of Purchased Items/Services

The deficiencies documented in this trend category continue to increase, eight to eleven deficiencies for this trend period. Seven of the eleven deficiencies were associated with "Inadequate acceptance of items or services". Most of these conditions have been documented and resolved as a quality observation. Specific evaluation of the conditions are not considered to be indicative of a emerging issue. Since deficiencies are widely distributed with little change, no emerging issue or adverse trend is considered to exist.

3.8 Document Control

Document control deficiencies have shown an increase in frequency from eight to 10 "hits" for this period. The individual documents that were trended in this were reviewed and continue to show no issues at this time that requires additional trend follow-up.

3.9 Technical Error Reports

Eight deficiencies were trended in this category during this trend period. The conditions were distributed over several sub-elements and do not represent an adverse quality trend.

3.10 Design

Errors noted in design control represent a minor contribution to the overall deficiency population. The number of documented conditions remains unchanged at six. Evaluation of the specific design related trend inputs do not represent an area for management attention at this time.

4.0 CONCLUSIONS

The number of conditions adverse to quality trended increased about 20 percent (135 to 162) this trend period. As BSC increases the number of audits and surveillances performed, the number of specific trend inputs could be expected to increase. The new CAP database will also provide methodology to capture issues currently documented and tracked by the Condition Identification and Resolution System. This will enhance the causal evaluation analysis and identify the appropriate management organization responsible for conditions.

During the trend period, no additional conditions warranted treatment of as an adverse quality trend.