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Distribution

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) TREND EVALUATION FOR THE SECOND SEMESTER 2002

The enclosed report provides the results of the Office of Quality Assurance evaluation of deficiencies trended during the period beginning July 1, 2002, and ending December 31, 2002. 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-0718

Enclosure:
OCRWM QA Trend Report for
Quality Program Deficiencies
Second Semester 2002

cc w/encl:
File, NQS, Las Vegas, NV
Records Processing Center = "16"



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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE TREND REPORT
FOR
QUALITY PROGRAM DEFICIENCIES

Second Semester 2002

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Date 4/3/03

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EXECUTIVE SUMMARY

The purpose of this trend report is to summarize trend-related actions initiated as part of the “real time” analysis conducted during the period July 1, 2002 through December 31, 2002 (Second semester 2002). The report also includes a composite analysis of all deficiencies reported during the period and identifies emerging quality assurance (QA) program issues.

There were no significant condition adverse quality trends identified during this report period, however the composite analysis identified two areas where Suspect Trend Investigation Reports (STIR) have been initiated to evaluate further the potential for identification of an adverse trend. Both of these areas were reported as an emerging issue in the last trend report.

- **Untimely submittal of QA Records**

The last trend report considered that the most significant change in reported deficient conditions is reflected in QA records. Specifically, the major contributor to this program element concerned the submittal of QA records to the Records Processing Center within prescribed time limits. Although the number of deficiencies identified has decreased slightly in the records area, the number of deficiencies in sub-element “timely submittal of records” has continued to increase. In order to obtain an appropriate perspective on this concern, STIR BSC-03-002, has been issued to provide a specific investigation into the subject. Results will be reported on the STIR and in the next trend report.

- **Inadequate content in implementing documents**

The last trend report identified that deficiencies associated with the failure to meet technical requirements had increased. BSC’s subsequent evaluation did not identify that the identified deficiencies represented any need for further action. However, the sub-element of “inadequate content in implementing documents” continues to show a marked increase in the number of conditions trended in this category. STIR BSC-03-001 has been issued to further evaluate this area.

With respect to the management of the corrective action program, the time to close deficiencies showed a decrease during this trend period from 124 days to 107 days.

1.0 Introduction/Scope

This report provides a summary of trend-related actions taken during the second half of calendar year 2002. The report summarizes trend-related corrective actions taken during the evaluation period and identifies emerging quality program issues.

The scope of this evaluation period is July 1 through December 31, 2002, i.e. second semester 2002. The trend data includes deficiencies identified from several program areas as follows:

Corrective Action Report (CAR)	2
Deficiency Report (DR)	83
Quality Observation (QO)	57
Deficiency Identification and Referral (DIR)	9
Nonconformance Report (NCR)	9
Technical Error Report (TER)	3

The data reported for TERs represents those initiated during the trend period. However, this report provides an initial TER evaluation summary based on 58 additional TERs for the previous semester that had not been input to the system in time for the last report.

The 163 trend inputs summarized above include 28 supplier-related conditions and 135 deficiencies internal to the Office of Civilian Radioactive Waste Management (OCRWM). Although the majority of the analysis described below concentrates on deficiencies internal to the OCRWM program, supplier related deficiencies are also discussed.

This report also assesses the Integrated Safety Management (ISM) program area of Suspect Counterfeit Items (S/CI).

2.0 Summary

This section summarizes the trend analysis results for the evaluation period and discusses any emerging issues resulting from analysis that would be of particular interest to management.

The terms used in this report are defined in AP-16.3Q. Two specific terms as used in this report are summarized as follows:

Adverse Quality Trend – Repetitive occurrences of the same problem, or closely related problems, that indicate a deteriorating quality condition or are sufficiently frequent and important to collectively warrant corrective action.

Emerging Issue – A potential adverse quality trend that, after investigation, did not meet the definition for adverse quality trend but requires management attention to prevent further development of a condition requiring formal corrective action.

A. EVENT CODE TREND EVALUATION

Event trend codes are assigned to each deficiency document upon issuance. Each event code is immediately compared upon entry to the trend database to other entries for the same trend code. This evaluation and the evaluation summarized below assists in identification of adverse quality trends or emerging issues.

The evaluation of the 135 internal deficiencies trended during this period considered the relationship of the event trend codes assigned to these deficiencies with the previous four semesters (second semester 2000 through first semester 2002). The distribution of deficiencies for the current period and the previous four periods is shown in Table 1 below. The information from this table is used to derive the comparison of deficiencies for the current trend-reporting period with the previous trend reporting periods.

Table 1
Distribution of Deficiencies

ELEMENT	DESCRIPTION	2000-2	2001-1	2001-2	2002-1	2002-2
1	Organization	5	1		4	
2	Program	14	5	17	25	24
3	Design	9	2	2	2	6
4	Procurement Document Control	2	2	3	2	5
5	Implementing Documents	15	7	19	25	27
6	Document Control	6	6	7	12	6
7	Control of Purchased Items/Services	3	4	3	4	8
9	Control of Special Processes			1		
10	Inspection		1	1		
12	Control of M&TE	7	10	11	14	10
13	Handling, Storage, and Shipping	1	1	1	2	2
15	Nonconformances	2	1		2	2
16	Corrective Action	6	5	3	3	4
17	QA Records	24	7	7	20	18
18	Audits	6	1			3
19	Software	4	3	7	7	9
20	Sample Control		5	5	1	1
21	Scientific Investigation	8	15	17	20	20
22	Field Surveying		2			1
23	Electronic Management of Data	5	1	3	1	2
27	Violation of Technical Requirement	1		2	4	
28	Technical Error Reports				58	3

Based on the distribution of deficiencies during the second semester 2002, a chart of the deficiencies ranked by the number of deficiencies in each program element is shown in Chart 1 below. The chart also compares the number of deficiencies categorized in each area with the distribution reported in the last two trend reports. This chart was derived from the data provided in Table 1 and shows which of the QARD program elements are more affected by quality assurance program deficiencies. Each of the program elements shown were subjected to a detailed evaluation as noted below.

Deficiency Distribution Comparison

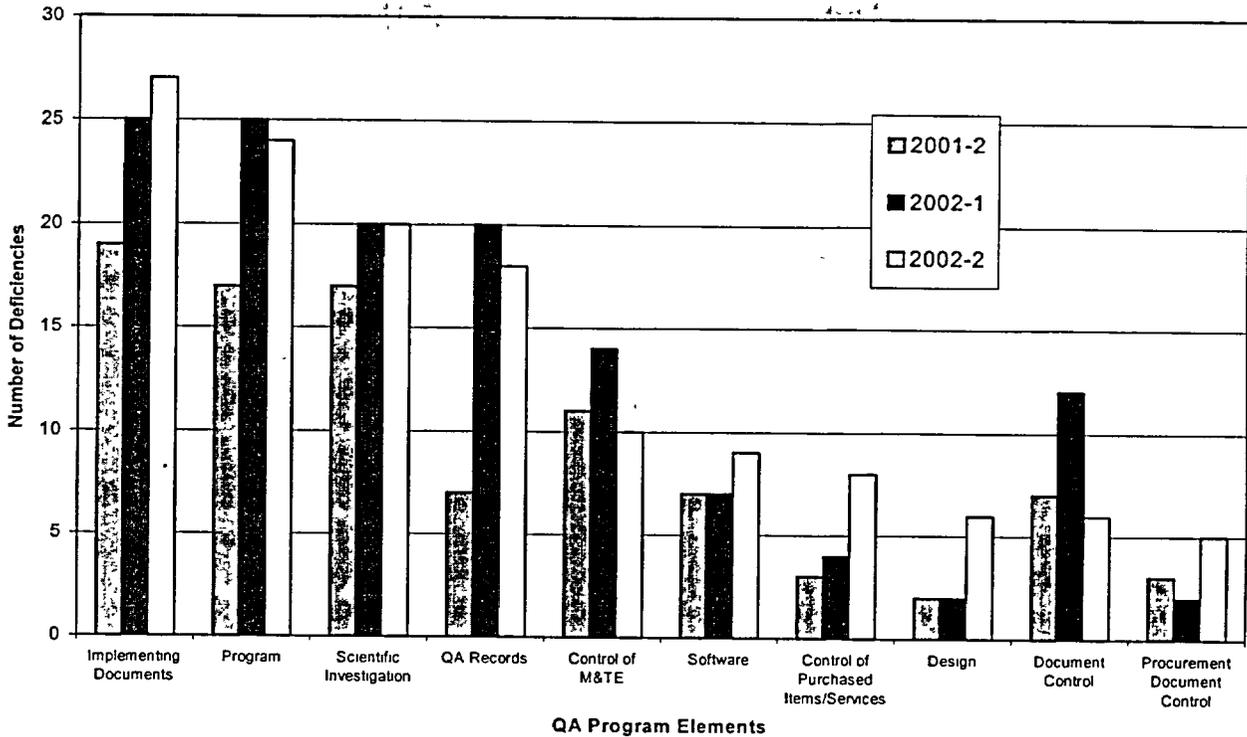
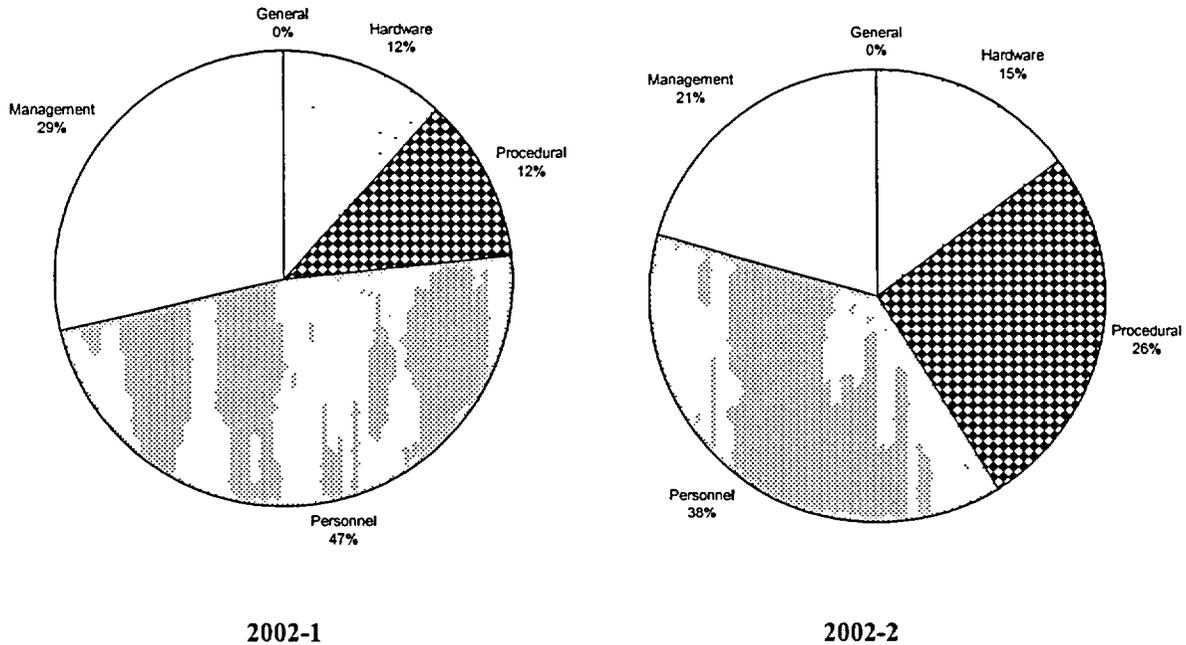


Chart 1

B. CAUSE CODE EVALUATION

Chart 2 below compares the distribution of causes for the last two semesters by major cause groups. The trend data for the previous semester has been updated to reflect the causes reported since the last report. Data for this period is somewhat limited but does support the potential concern regarding inadequate content in implementing procedures as previously discussed. This observation is based on the increase from 12% to 26% in the cause category of Procedural causes and is somewhat reflected in evaluation of the raw data. **Evaluation of data for the current trend period shows that Procedural causes may have an impact on overall performance. These deficiencies are being further investigated associated with the STIR, BSC-03-001 that has been initiated for the event code "inadequate content in implementing procedures.**

Efficient trending of causal factors and organizations responsible for the conditions sited has been recognized as a weak area of the trend analysis program that requires improvement. Management actions have been initiated to improve reporting in this area of the analysis.



**Distribution of Cause Comparison for Last Two Semesters
Chart 2**

C. SUPPLIER RELATED DEFICIENCIES

Supplier-related deficiencies were assessed separately from the above. During the trend period, 28 of the trend inputs were related to supplier audits and surveys. This trend program is neither required nor designed to specifically identify adverse trends within individual suppliers; however, a review of this data has the potential to identify OCRWM related procurement issues that manifest themselves as supplier deficiencies. Data relative to supplier deficiencies continues to show several areas that may be related to procurement practices. **However, BSC has implemented a Supplier QA Improvement Plan that is intended to address the remaining issues that need attention. This area is no longer considered an emerging issue.**

D. SUSPECT/COUNTERFEIT ITEMS

During the last six months (July 2002 through December 2002) no new suspect/counterfeit items have surfaced at the Yucca Mountain Project, **therefore no negative trend is established in this area.**

E. TECHNICAL ERROR REPORTS

Technical Error Reports (TER) were developed to assess impact and manage the correction of errors identified in an approved technical document. The majority of the TER inputs to the trend database were documented in February 2002, however the trend data was not available for trend input until July. The data input for trending to date includes 58 TERs from the initial input and three additional TERs for the current semester. The majority of TERs fall into four major categories: Model Validation, Content, Assumptions, and Typographical errors.

Evaluation of the TER trend inputs shown in chart 4 below shows that 54% of technical errors have occurred in model validation. The 54% distribution is not unexpected since the corrective actions for CAR BSC-01-C-001 committed to use the TER process to track the results from the Model Validation Status Review. Likewise, 20% of the TERs for content and the 12% typographical errors stemmed from the corrective actions for DR BSC-01-D-142 which also committed to use the TER process to disposition the extent of condition. **Since the majority of trend data relative to TERs were generated during a limited time frame and as the result of investigating known deficiencies, no adverse trends will be identified. The data does however demonstrate the major error categories for consideration.**

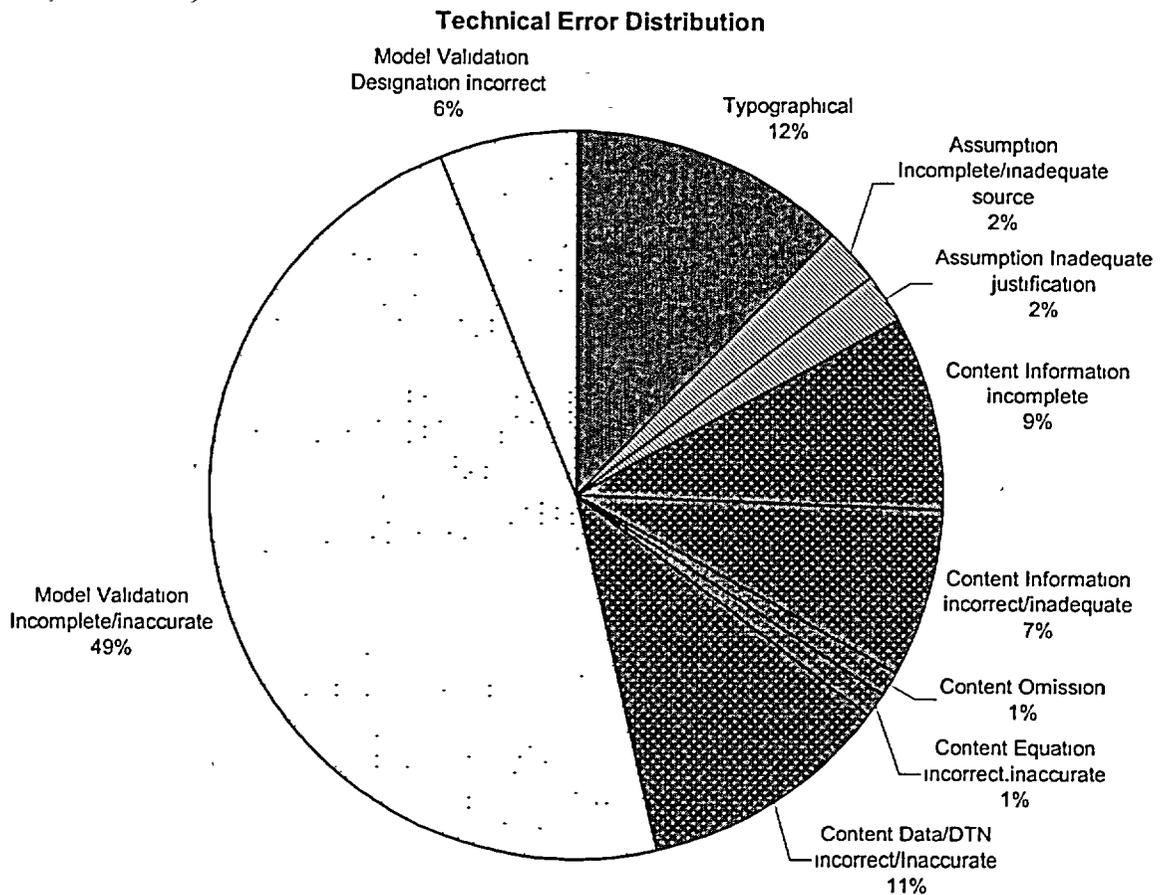


Chart 4

F. EMERGING ISSUES

Emerging issues are identified based on quality program issues that may either be developing, or have the potential to develop into a significant CAQ. This section of the report reviews the status of previously identified concerns with the implementation of the quality assurance program, which were considered to be emerging issues in the last trend report. Issues that were previously listed and are no longer considered in need of special emphasis have been dropped from this discussion. The status of emerging issues are as follows:

- **Untimely submittal of QA Records (Previously Reported)**

The last trend report considered that the most significant change in reported deficient conditions is reflected in QA records. Specifically, the major contributor to this program element concerned the submittal of QA records to the Records Processing Center within prescribed time limits. Although the number of deficiencies identified has decreased slightly in the records area, the number of deficiencies in sub-element “timely submittal of records” has continued to increase. In order to obtain an appropriate perspective on this concern, STIR BSC-03-002, has been issued to provide a specific investigation into the subject. Results will be reported on the STIR and in the next trend report.

- **Compliance with technical requirements (Previously Reported)**

The last trend report identified that the number of deficiencies associated with the failure to meet technical requirement had increased. BSC’s subsequent evaluation did not identify that the increasing number represented any need for further action. However, the sub-element of “inadequate content in implementing documents” continues to show a marked increase in the number of deficiencies trended in this category. Since it is not clear from the evaluation of current information that an adverse quality trend actually exists, STIR BSC-03-001 has been issued to further evaluate this area.

G. SUMMARY OF TREND RELATED DEFICIENCIES

The corrective action process allows for “early identification” during event trend code input and documentation as a deficiency document of quality programmatic issues that are identified as either repetitive or representative of common issues among Affected Organizations. During this trend period, no new adverse quality trends were identified. As noted above, two STIRs have been initiated to perform further investigations. The status of the previously issued trend related CAR is as follows:

- **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 are scheduled for completion by April 2003.

3.0 Detailed Analysis

Based on the distribution of deficiencies shown on Chart 1, the (QA) Program elements that had five or more deficiencies, had an increasing number of deficiencies, or have sustained high number of deficiencies for the current trend period were evaluated in depth for trend considerations. The results of these evaluations are as follows:

Implementing Documents

Deficiencies associated with implementing documents are again a significant contributor to the total number in this area. The number of "hits" for this trend element has again increased from 25 to 27. Specific evaluation of the individual elements and codes as shown on Attachment 1 for element 5 is as follows

- **Inadequate content in implementing document** – The specific conditions trended in this trend code were reported in the last trend period to have increased from 6 to 9 "hits". This period shows a further increase to 13. Subsequent to the last trend report BSC conducted an evaluation of the identified deficiencies and did not consider that the identified deficiencies represented any need for further action. However, with the increase in total deficiency documents trended in this category, including several QOs, it is not clear if the deficiencies represent either an emerging issue or potential adverse quality trend. Although the continued increase in this element would point to an emerging issue, the number of "hits" due to the use of quality observations needs further evaluation. **As a result, STIR BSC-03-001 has been issued to determine the significance of the observed increase in this category of inadequate content in implementing documents.**
- **Failures to follow procedures (Quality)** – The number of deficiencies documented in this category have not changed for this trend period (14). Evaluation of the specific deficiencies shows that over half (8/14) were reported as QOs. Continued increase in this area may necessitate a further investigation, however, the current data does not warrant further action. **Although not considered an emerging issue, management attention to emphasize the need to always follow procedure could reduce the incidences reported in this category.**
- **Failure to follow procedures (Technical)** – Deficiencies in this trend code were one of the contributors to the potential emerging issue documented in the last trend report. **Only one deficiency was reported this period and is no longer considered as part of the emerging issue reported last trend period.**

Program

This number of deficient conditions trended in this category has change little since the last report (25 to 24 “hits”). However, this category has several distinct work activities under this major element. Evaluation of the specific trend areas as shown for element 2 on Attachment 1 is as follows:

- Inadequate personnel selection, indoctrination and training, Lack of or inadequate training, Inadequate personnel qualification – These three related categories continue to have individual deficiencies identified and documented as separate CAQs. The continued reporting of these types of deficiencies relate to the significant CAQ documented on BSC-02-C-001 that was describe in the last trend report. BSC has been advised that closure of this CAR is dependent on the successful closure of several related deficiency documents. **Resolution of this CAR is expected by April 2003.**
- Inadequate reviews (management, readiness, peer or document) – The number of deficiencies trended in this category remains the significant contributor to program related trend issues. However, the numbers of “hits” in this code have decreased from 16 to 13 with the majority of deficiencies for this trend period (9 of 13) documented on a QO. Evaluation of the nature of these conditions shows that all are a relatively minor condition that, when taken collectively, do not represent a potential trend. **The minor nature of these conditions continues to demonstrate that lower threshold conditions are being reported and that these conditions do not represent an adverse quality trend.**

Scientific Investigation

Deficiencies in this trend area are still a significant contributor to the overall conditions adverse to quality. **Although the number of deficient conditions trended in this category have not increased, the specific evaluations of the noted deficiencies for the individual trend codes will warrant continued evaluation as additional conditions may be evaluated. At this time, it is considered that the distribution of trend inputs do not indicate the need for additional management attention.**

Quality Assurance Records

The total number trended for this element has decreased (20 to 18) and this program element continues to be a significant contributor to issues identified during this trend period. Individual trend sub-elements have shown an increase. Evaluation of the specific inputs identifies the emerging and subsequent STIR issue noted below:

- Inadequate preparation, completion, or handling – Although the number of incidences have increased (3 to 4), most are documented as a QO for a minor issue. **No repeating condition adverse to quality exists that requires further evaluation at this time.**

- Records were not collected, assembled or transmitted to Records Processing Center – The last trend report considered that the most significant change in reported deficient conditions is reflected in QA records. Specifically, the major contributor to this program element concerned the submittal of QA records to the Records Processing Center within prescribed time limits. Although the overall trend performance has decreased in the records area, the sub-element trended for timely submittal of records has continued to increase. Since the use of QOs continues to be a significant contributor to this category, it is not clear that this emerging issue represents an adverse quality trend. **In order to obtain an appropriate perspective on this concern, a Suspect Trend Investigation Report (STIR), BSC-03-002, has been issued to provide a specific investigation into the subject.**

Control of Measuring and Test Equipment (M&TE)

Deficiencies trended relative to control of M&TE have continued to vary between 7-14 conditions per trend period. This period experienced a drop from 14 to 10. 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**

Software

The number of deficiencies trended in this category since the last trend report have increased from 7 to 9 “hits”. The 9 conditions appear to be distributed among several of the individual sub-elements and represent little specific change from the last report. **Evaluation of the individual software deficiencies does not indicate any additional adverse quality trend beyond the conditions already documented on CAR BSC-01-C-002. Corrective actions for this CAR are in progress.**

Control of Purchased Items/Services

The deficiencies documented in this trend category have shown a continued increase, doubling from four to eight deficiencies for this trend period. Four of the deficiencies were associated with “Inadequate acceptance of items or services” which, upon closer examination, are not considered to be indicative of an emerging issue. **Since deficiencies are distributed throughout this trend element with little change other than noted, no emerging issue or adverse trend is considered to exist.**

Design

Errors noted in design control represent a minor contribution to the overall deficiency population. However, the increase from two to six identified deficiencies warranted additional evaluation. The specific conditions represent both DRs and QOs in several trend sub-elements. **Design related trend inputs do not represent an area for management attention.**

Document Control

Document control deficiencies have shown a decrease in frequency from 12 to six "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.**

Procurement Document Control

Deficiencies associated with Procurement Document control are also a minor contributor to the overall trend assessment. Within the sub-element of "Inadequate requirements in procurement" documents four new deficiencies were identified. **Review of the specific documents trended does not show any issue that requires additional trend evaluation at this time.**

4.0 Conclusions

The number of internal conditions adverse to quality trended increased about 18% (114 to 135) this trend period. The trend analysis now include TERs, QOs and DIRs. The input of 58 individual trended TERs are not part of the total since they represent conditions from the last trend period that were not input until this period. As the number of evaluations increase within BSC's scope of audit and surveillance performance, the number of specific trend inputs could be expected to increase. Future trend evaluations will continue to focus on the effectiveness of corrective actions to prevent recurrence of document issues.

During the trend period, no additional conditions warranted treatment of as an adverse quality trend. However, collective analysis in two areas that were discussed in the last trend report, i.e. timely submittal of QA records and inadequate content in implementing documents, continued to show increases of documented conditions adverse to quality. The nature of the documents in these areas does not make it clear that either an emerging issue or adverse condition actually exists. Therefore, two STIRs have been issued for further investigation.