

ISO-2 Project WIPP Independent Oversight – DE-AC30-06EW03005

ASSESSMENT OF WIPP QUALITY ASSURANCE DEFICIENCY TRENDS

September 2010



PECOS MANAGEMENT SERVICES, INC.

**ISO-2 Project
Carlsbad, NM**

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ACRONYMS

CAQ	Conditions adverse to quality
CBFO	Carlsbad Field Office
CDA/CDS	Corrected during the audit/surveillance
EPA	U.S. Environmental Protection Agency
HWFP	Hazardous Waste Facility Permit
M&O	Management and Operations
NMED	New Mexico Environment Department
QA	Quality assurance
QAPD	Quality Assurance Program Document
TRU	Transuranic
WIPP	Waste Isolation Pilot Plant

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I. PURPOSE AND SCOPE

The Waste Isolation Pilot Plant (WIPP) is a repository for permanent disposal of U.S. defense-related transuranic (TRU) waste. The scope of this report is to address the adequacy and effectiveness of the facility's quality assurance (QA) deficiency trending and reporting program.

The purpose of this task is to assess the thoroughness, completeness, and adequacy of the trending program in order to ensure issues and deficiencies are adequately analyzed to prevent re-occurrence of problems and to ensure the safety and health of personnel.

II. BACKGROUND

Owned and operated by DOE, the WIPP is authorized by the Waste Isolation Pilot Plant Land Withdrawal Act (as amended), while the U.S. Environmental Protection Agency (EPA) monitors the facility and certifies its compliance under 40 CFR 191. Because some materials disposed at the WIPP are mixed wastes, the facility also operates under a Hazardous Waste Facility Permit (HWFP), which is monitored by the New Mexico Environment Department (NMED). Since WIPP is categorized as a nuclear facility, Title 10 Code of Federal Regulations 830 and associated Price Anderson Act Amendments apply. If a potential issue occurs frequently at various locations, those sites may not be fully implementing Regulation 830 for QA. Criterion 3 of 10 CFR 830.122¹ states the following:

Criterion 3: Management/Quality Improvement

- 1) Establish and implement processes to detect and prevent quality problems.
- 2) Identify, control, and correct items, services, and processes that do not meet established requirements.
- 3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.
- 4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

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DOE developed the Quality Assurance Program Document (QAPD)² to govern the manner in which the above quality regulations are applied to the WIPP program. The QAPD states the following regarding quality trending:

1.3.3.9: Quality Trending

The need for quality improvement is accomplished through quality analysis and trending. To provide reliable trending information, the following activities shall be performed:

- 1) Quality performance data shall be identified, collected, and routinely analyzed to identify opportunities to improve items, services, activities, and processes. This analysis shall consider information from external sources and not be limited to one type of work or to one organization.
- 2) The analyses shall be performed semi-annually to provide for prompt identification of trends adverse to quality. Reports of Conditions Adverse To Quality (CAQ), including those identified during quality assurance audits as Corrected During the Audit/Surveillance (CDAs/CDSs), shall be evaluated to identify adverse quality trends and root causes, with results reported to the organization responsible for corrective actions.
- 3) Program participants will report trending information to responsible management and to the applicable organization.

Additionally, the Corrective Action Program Guide (DOE G 414.1-5)³ provides the following guidance and information for trending of deficiencies:

5.1.2: Trending Identified Problem Findings

Identified problem findings and their associated causes should also be analyzed to determine the existence of trends to identify the same or similar occurrences, generic problems, vulnerabilities, and cross-functional weaknesses at the lowest level before significant problems result. Trending typically identifies problem categories, responsible organizations, and specific activities or conditions. Benefits of trending include the opportunity to:

- 1) Document historical data consistently in measurable, visible terms
- 2) Identify changes in performance as they occur
- 3) Develop leading indicators that identify degrading trends

A consistent trend coding system would assist in analyzing problem findings. Resulting trending data should be constantly analyzed, updated, and summarized, with results reported to management. In analyzing and trending identified problem findings and developing corrective actions, the assessing organization and/or site/organization manager should determine the applicable guiding principles and core safety management functions associated with integrated

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safety management, which are outlined in DOE P 450.4, "Safety Management System Policy"⁴ for each finding. This activity will help managers identify broader causal factors that can reduce the potential for similar problem findings. Input for determining the guiding principles and core functions may be provided by the assessing individual/organization and/or those individuals who evaluate each finding and then design applicable corrective actions.

The Corrective Action Program Guide also presents discussions regarding trending information and analysis of that data, which should focus on causal factors of the findings in order to better address trends and improve the corrective action necessary to effectively address the deficiency. It must be noted that determining the causal factor is not necessarily the same as conducting a "root cause" analysis; it is rather, a process designed to address and define risk and may lead to a detailed root cause analysis. The causal factor is an event or condition that either caused the deficiency or contributed to the unwanted result. If it were not for this event or condition, the unwanted result would not have occurred or would have been less severe.

In order to meet requirements, DOE developed CBFO (Carlsbad Field Office) MP 3.2, "Deficiency Trending and Reporting," a procedure that defines roles and responsibilities as well as the process required to develop semiannual trend reports.⁵

Trends are based on defined trend codes or activity categories and deficiency categories. Activity categories are mainly functional or organizational-type designations, while deficiency categories stem partially from the ISMS categories, training, and records. (*Attachment 1* provides the complete listing of both types.) Before staff can develop a trend code, they must first identify the activity category and then define the deficiency category. The format for the trend code is XX-YY, where XX is the alpha designation for the activity and YY the numerical designation for the deficiency.

Until recently, the last semi-annual trend report available from DOE was issued for the first six months of CY2007. The latest DOE trend reports cover the second half of CY2007 to the present and are presented in a new, single-page format (*Attachment 2*).

III. SUMMARY OF FINDINGS

DOE's revised report provides a statistic for an issue closure time period, which includes average days to closure and minimum and maximum days for issues closed during the six-month reporting period. The report also now includes a bar graph for both activity codes and deficiency codes—each includes an evaluation section, which attempts to provide the number of issues and associated number of sites where issues occurred. However, the new report format does not include a place to record results of every audit and surveillance conducted during DOE and M&O contractor activities at the WIPP; rather, its design is limited to recording audits and surveillances of waste characterization activities. PECOS reviewed all new

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trend reports made available to us. We placed the results into a graphical display in an effort to present a straightforward visual by which we could determine the occurrence of any trends. Figure 1 depicts the six deficiency categories, and Table 1 represents the activity categories.

Three deficiency codes account for 83 percent of the 98 issues DOE identified from 2007 to the present:

- 1) Code-01 Definition of Work Process and Proceduralization (10 percent)
- 2) Code-05 Performance of Work (38 percent)
- 3) Code-06 Documentation of Work (45 percent)

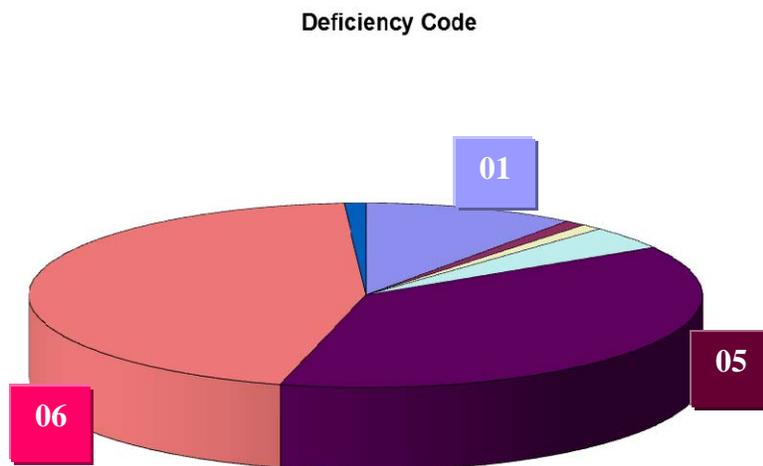


Figure 1. Deficiency Category Distribution (PECOS)

Table 1 summarizes the frequency of occurrence of findings for the 28 activity codes. Seven codes were not identified as being associated with an issue. Of the remaining 21 codes, three were predominant:

1. Acceptable Knowledge (13 percent)
2. Real Time Radiography (10 percent)
3. Transportation (9 percent)

and the remaining 18 codes each represent seven percent or less of occurrence.

Table 1 – Frequency of CAQs by Activity (PECOS)

TREND CODES		
Activity Category	Code Number	No. of Times Identified with CAQ
Acceptable Knowledge	AK	13
Audits and Assessments	AA	1
Control of Measuring and Test Equipment	MT	2
Corrective Action Program	CA	5
Characterization Data	CD	1
Data Validation	DV	3
Design Control and Engineering	DE	0
Document Control	DC	5
Gas Generation Testing	GG	2
Headspace Gas Sampling and Analysis	HG	6
Management	MA	1
Non-Destructive Assay	ND	6
Organization and Resources	OR	0
Performance Demonstration Program	PD	0
Procurement	PS	0
QA Program and Implementation	QA	5
Real-Time Radiography	RT	10
Receiving/Receipt Inspection	RI	0
Records Management	RM	4
Safety/Operations	SA	0
Sampling Techniques	ST	1
Software	SW	4
Training and Qualifications	TQ	7
Transportation	TR	9
TRUPACT-II Leak Testing	TL	2
Visual Examination	VE	7
Waste Handling Operations	WH	0
Work Processes	WP	4

PECOS also developed *Table 2*, which provides information regarding the number of conditions adverse to quality issued and the number of CARs closed during each reporting period. The DOE trend reports did not identify any trends during reporting periods.

Table 2. Summary of Results of QA Audits (PECOS).

PERIOD	CARS/CDAS/CDSS ISSUED	CARS CLOSED
1st Half 2010	19	5
2nd Half 2009	6	4
1st Half 2009	8	5
2nd Half 2008	24	15
1st Half 2008	20	8
2nd Half 2007	21	6
	98	43

IV. CONCLUSIONS

When PECOS assembled all of the deficiency data presented in the last six semi-annual reports as depicted in Attachment 3 and reviewed them over the three years of available data—as opposed to a single six-month period—it became evident that looking at a single six month time period with respect to trends could be missing both positive and negative trends, as well as failing to recognize obvious areas needing improvement. This indicates that the new format and process for trending are not adequate. For example, one deficiency category of the work process, “Identification of Work Steps” (*Code-02*), does not present a trend, while the “Definition of Work Process and Proceduralization,”(*Code-01*) which would encompass the identification of work steps addressed in *Code-02* , accounts for 10 percent of the issues. Because there is not enough evidence to determine whether a negative trend has developed under *Code-01*, it should be flagged for additional monitoring. Regarding *Code-05* “Performance of Work” and *Code-06* “Documentation of Work,” a comparison of the graphs in Attachment 3 indicates that there is an overall long-running issue with compliance with the requirements under these codes has developed: almost three-quarters of the issues identified by DOE are associated with one of these two codes. In reviewing individual reports, this becomes evident in light of the fact that while both codes are continually displayed on the DOE graph, evaluations in the individual reports say no trends have been detected, which may be true. Nevertheless, the purpose of the semi-annual reports should be to identify those codes and categories that have continuing compliance issues so they can be further scrutinized. Also, *Code-07*, Records Processing, shows a jump in the first half of CY 2010 after two years of no

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findings, which could be a precursor of an upward trend, and should have been flagged for additional monitoring.

Regarding trend codes, though acceptable knowledge (Code AK) represents 13 percent of the issues, distribution among the codes is random enough to preclude development of a negative trend; nevertheless for purposes of early detection, the top three activity categories: Acceptable Knowledge, Real Time Radiography, and Transportation should receive close review to ensure a negative trend does not develop.

Additionally, under the new, single-page report format, there is not enough information to ensure issues have been appropriately assigned. The original format included data associated with the issues and included an analysis for use in comparing and identifying trends over the previous six-month reporting period.

Further, the trend reports do not reflect the accurate information with respect to CARs. For example, in the example Trend Report shown in Attachment 2, it is reported that 12 CARs were issued in that period; however, the weekly assessment reports provided by DOE for that period indicate that 24 CARs were issued in that six-month period. Further, the graph showing the days for CAR closure in that period shows only 3 CARs have been closed and infers that those 3 were part of the 12 issued in that period. Thus, the graph showing the days required to close CARs is factually inaccurate since there are still 9 CARs open and the days required to close them is still increasing. In fact, the most recent QA Assessment Report indicates that 6 of the CARs issued during that period are still open as of the September 27, 2010 – from 140 to 160 days since issued and still counting.

Finally, in limiting the trend analysis report to the waste characterization audits and surveillances, the report presents a skewed picture of the QA of WIPP. For example, there are a number of CARs that have been reported on other audits of both the Carlsbad Field Office and M&O contractor activities that have remained open for as long as two-and-a-half years.

V. RECOMMENDATIONS

DOE should revise the deficiency reporting procedure and provide meaningful training to personnel responsible for assigning codes and developing and reviewing trend reports. During the revision of the procedure, DOE should use the corrective action guide and base trending on causal factors as recommended by the guide. In order to standardize causal codes, codes from the occurrence reporting guide should be used, circumventing the need to re-code occurrence report issues.

A six month summary of quality data is essentially a snap-shot of the quality condition. PECOS recommends that these reports include a comparison with the previous reports including explanation of changes in terms of CAQs identified and the ratio of CAQs identified to audits/surveillances conducted in

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increments of three month periods dating back two to four years in order to ensure that any trends over time are identified.

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2. Department of Energy, “Quality Assurance Program Document, Revision 11”, Carlsbad, NM, June 2010
3. Department of Energy, “Corrective Action Program Guide”, Washington, D.C., March 2006
4. Department of Energy, “Safety Management System Policy”, Washington, D.C., October 1996
5. Department of Energy, “Deficiency Trending and Reporting”, Carlsbad, NM, June 2007

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ATTACHMENT 1

DOE Activity and Deficiency Codes

TREND CODES	
Activity Category	Code Number
Acceptable Knowledge	AK
Audits and Assessments	AA
Control of Measuring and Test Equipment	MT
Corrective Action Program	CA
Characterization Data	CD
Data Validation	DV
Design Control and Engineering	DE
Document Control	DC
Gas Generation Testing	GG
Headspace Gas Sampling and Analysis	HG
Management	MA
Non-Destructive Assay	ND
Organization and Resources	OR
Performance Demonstration Program	PD
Procurement	PS
QA Program and Implementation	QA
Real-Time Radiography	RT
Receiving/Receipt Inspection	RI
Records Management	RM
Safety/Operations	SA
Sampling Techniques	ST
Software	SW
Training and Qualifications	TQ
Transportation	TR
TRUPACT-II Leak Testing	TL
Visual Examination	VE
Waste Handling Operations	WH
Work Processes	WP
Deficiency Category	Code Number
Definition of Work Process and Proceduralization	01
Identification of Work Steps	02
Training Materials and/or training Presentations	03
Untrained Personnel	04
Performance of Work	05
Documentation of Work	06
Records Processing	07

ATTACHMENT 2

Example of Current Trend Report

Carlsbad Field Office
Corrective Action Trend Report Activity Trend Analysis

1. Report Period: 01/01/2010 through 06/30/2010	Prepared by: <i>J. Schuetz 8/10</i> J. Schuetz
2. Sites Included: CBFO LANL/C WTS	Approved by: A. Holland
3. Total CARs Issued During Report Period: 12	
4. Total CDAs/CDSs Issued During Report Period: 3	

Descriptive Statistics for those CARs Issued and Closed During the Report Period

5. Number of CARs Closed: 3	8. Maximum Days to Closure: 158
6. Average Days to Closure: 108	9. Minimum Days to Closure: 64
7. Standard Deviation: 47	

10. Average Time to CAR Closure:

11. Evaluation: The 12 CARs are distributed over 3 participants; CBFO received 4 CARs, LANL/C received 2 CARs, and WTS received 6 CARs.

Activity Trend Analysis

12. CARs/CDAs/CDSs By Activity Code for Reporting Period

13. Evaluation: The 8 individual codes are distributed over 3 sites. The RM - Records Management codes are distributed between 2 participants under 3 CARs. The WP - Work Processes codes are assessed to 1 participant under 3 CARs. No trends are indicated.

Deficiency Trend Analysis

<p>14. CARs/CDAs/CDSs By Deficiency Code for Reporting Period</p>	<p>15. CARs/CDAs/CDSs Over Time</p>
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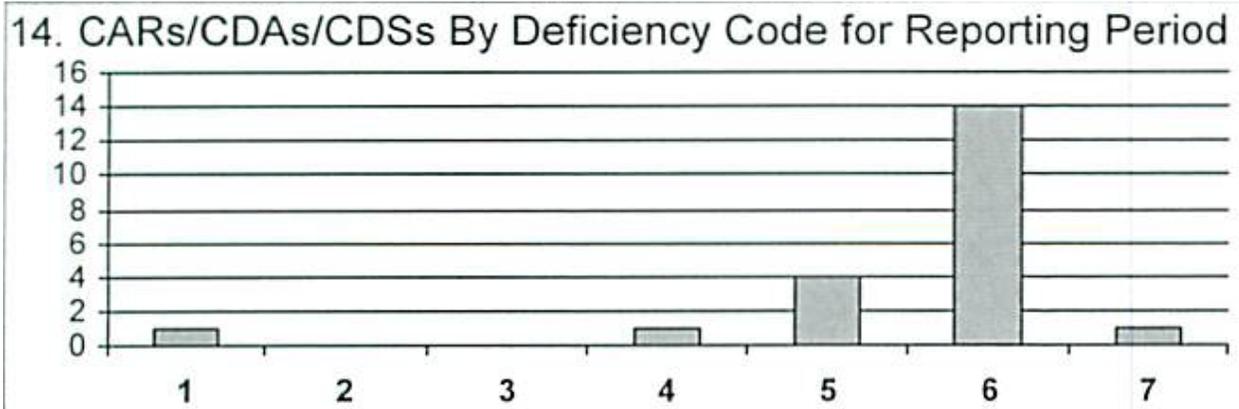
16. Evaluation: The 4 individual codes are distributed over 3 sites. The 05 - Performance of Work codes are distributed between 2 participants under 6 CARs and 1 CDA with 1 site receiving 4 CARs. The 06 - Documentation of Work codes are assessed to 1 participant under 3 CARs and 1 CDA. No trends are indicated.

NOTE: Refer to CBFO Management Procedure MP 3.2, Deficiency Trending and Reporting, for a complete description of trend codes.

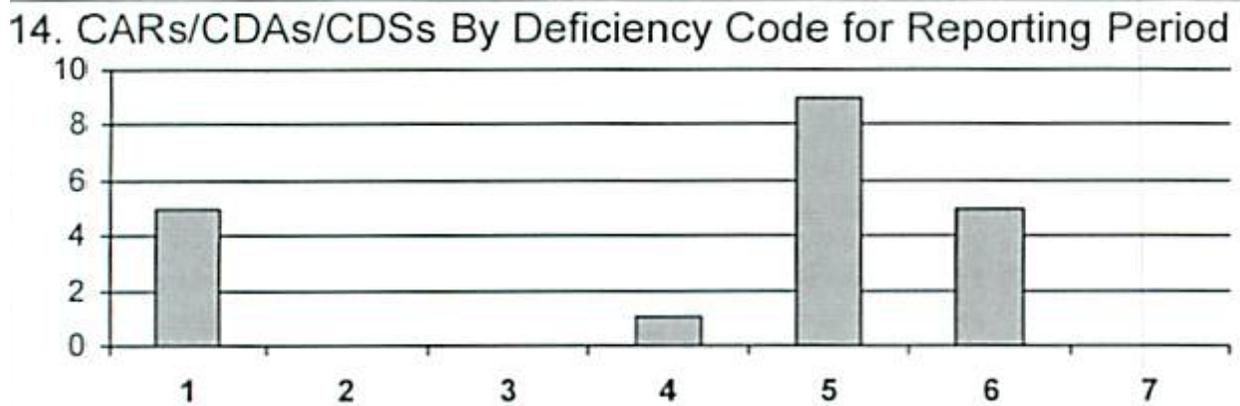
ATTACHMENT 3

Comparison of DOE Trends

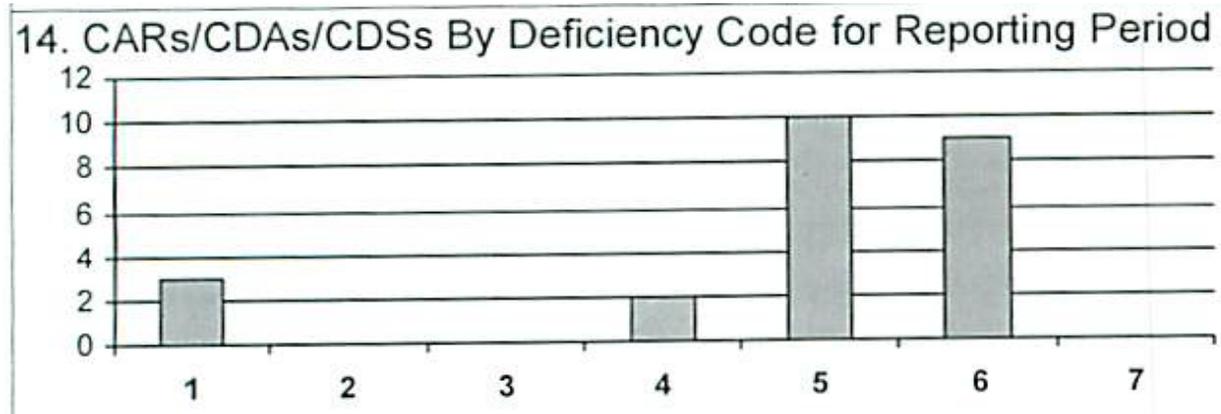
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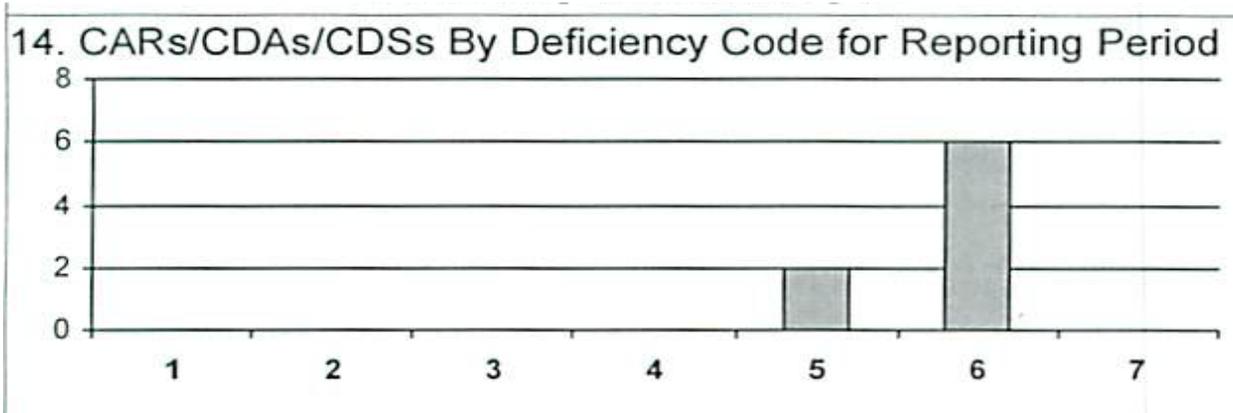
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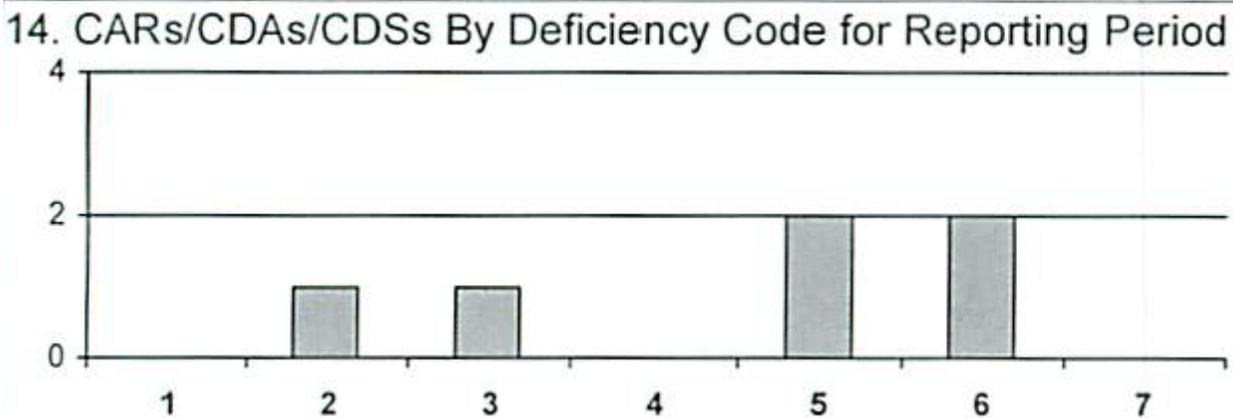
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7/1/09 – 12/31/09



1/1/10 – 6/30/10

