



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QUALITY ASSURANCE
SURVEILLANCE REPORT**

64/147

PROJECT NO.: 30.860 & 20.01402.171 **REPORT NO.:** 2002-19 **PAGE** 1 **OF** 33

SURVEILLANCE SCOPE: To audit the SwRI Quality Assurance Department and determine if the department is acceptable to accomplish CNWRA work.

REFERENCE DOCUMENTS: QAP-004, Surveillance Control, and SwRI Auditing Procedures .

STARTING DATE: June 18, 2002 **ENDING DATE:** July 20, 2002
QA REPRESENTATIVE: Bruce Mabrito and Tom Trbovich (working directly for Dr. A. Holt in the SwRI QA Department)

PERSONS CONTACTED DURING ACTIVITY: A. Holt, R. Weber, D. Dunavant, R. Brient, E. Lange, R. Santos, G. Guzman, C. Butcher, B. Gahagan, M. Minor, V. Ganley, W. Smithson, P. Easley, S. Dannelly.

SATISFACTORY FINDINGS: This surveillance, which is the audit of SwRI Cost Center 30, was conducted by B. Mabrito and T. Trbovich, because they were sufficiently removed from the day to day operation of the Institute Quality Systems (CC30) to provide an independent assessment of the implementation of their quality system.

A copy of the Institute Quality Systems Audit Report, No. 02-AR-22 is attached to this Surveillance Report.

Four nonconformance reports were issued from this audit and there were six audit recommendations regarding the Institute Quality Systems Department.

Although the Institute is moving toward an ISO 9000:2000 quality system, division by division, the Institute QA Department continues to serve each division as required by the various contracts. That is, some divisions require ISO 9000:2000, some require ISO 9000:1994, some require other quality systems development and implementation, and Div. 20/CNWRA requires support in the 10 CFR 50 Appendix B/NQA-1 area. They continue to supply Div. 20/CNWRA with the needed support and are determined by the writer of this surveillance report to be acceptable for use by the CNWRA.

UNSATISFACTORY FINDINGS: Unsatisfactory findings identified in the audit will have no impact on the utilization of Institute QA personnel on CNWRA activities.
NONCONFORMANCE REPORT NO.: None, for this surveillance (the audit report had four NCRs) .

ATTACHMENT: Institute Quality Systems Audit Report 2002-AR-22; Institute Quality Systems CC30 Org Chart; Institute Quality Systems Management Review, May 22, 2002.

RECOMMENDATIONS/ACTIONS: Determination of acceptance to use SwRI QA Department for CNWRA needs.

APPROVED: 
CENTER DIRECTOR OF QUALITY ASSURANCE

DATE: 7/22/2002

DISTRIBUTION: ORIGINAL - CENTER QA DIRECTOR / QA Records
ORIGINATOR B. Mabrito
PRINCIPAL SCIENTISTS - Not Applicable
ALL ELEMENT MANAGERS - With No Attachments
B. Sagar, H. Garcia - With No Attachments
M. Ehnstrom, T. Mayces, R. Folck - No Attachments

2492
1/17/02
67/1147

Institute Quality Systems
Memo

July 9, 2002

To: Amos E. Holt, Vice President
Institute Quality Systems

From: Tom C. Trbovich 

Subject: Institute Quality Systems Audit Report 2002-AR-22

Attached is the report of the internal audit of the Institute Quality Systems (IQS) Department conducted June 18-20, 2002. Four unsatisfactory items were documented in Nonconforming Condition (NCR) reports.

The quality program was determined to be effectively implemented. However, six recommendations were made to improve procedure identification and guidance and avoid duplication with the division quality programs.

If there are any questions, please feel free to give me a call at Ext. 3145.

gg

Attachment

3/32
1/17/03
68/147

INSTITUTE QUALITY SYSTEMS AUDIT REPORT
Institute Quality Systems (IQS)
DEPARTMENT 30
AUDIT NO. 2002-AR-22

AUDIT PURPOSE

The purpose of the audit was to verify compliance and the level of effectiveness of the Institute Quality Systems (IQS) Operating Procedures (OP) and Work Instructions (WI). The OPs and WIs implement the *Quality System Manual (QSM) 2000*, which is based on the ISO 9001:2000 requirements.

AUDIT SCOPE

The audit was conducted using a checklist containing 83 inquiries taken from 19 OPs and 11 WIs covering all operations under the QSM except for calibration. The OP-11.0-30-1, "Calibration System," was not covered during this audit since an ISO 17025 accreditation audit had been conducted earlier this year. The audit also included a follow-up of the seven deficiencies found during the last internal audit, 2001-AR-18, which was performed in June 2001.

AUDIT SUMMARY

The audit was conducted from June 18 through 20, 2002, by Thomas Trbovich, audit team leader (ATL) and Bruce Mabrito, auditor. A pre-audit meeting was held June 18, 2002. A post-audit conference to present the results of the audit to IQS department management was held June 20, 2002.

Of the 83 checklist items, 75 were determined to be satisfactorily implemented and documented; and four were determined to be not applicable at the time of the audit. These included:

- No suppliers falling below a rating of 80% requiring the issuance of a SCAR;
- A memo being issued by the QA Manager for CARs issued outside of audits;
- Revisions of CARs, when more suitable action is performed than what was originally identified; and
- Contacts with higher levels of management due to non-responses or inaction.

Four audit items were considered as unsatisfactory and were documented in four Nonconforming Condition Reports (NCR) since they were judged to be isolated occurrences not affecting product quality. IQS department management was advised by the ATL of their responsibility to ensure that corrective actions are taken without undue delay to eliminate discrepancies and their cause.

AUDIT RESULTS

The IQS department OPs and WIs implement a mature quality program that was established at a time when the SwRI® divisions had no internal quality programs. At the present time, many

4/33 1/17/03

69/147

Institute Quality Systems Audit Report
AUDIT NO. 02-AR-22
PAGE 2

of the divisions have their own ISO-based quality programs and the IQS department quality engineering and inspection personnel tend to follow their own division program rather than the IQS system. Though both programs satisfy requirements, it appears in some cases, that parallel programs are being implemented, with the IQS OPs and WIs used primarily in the absence of division program guidance with the decision on which program to use being left to the discretion of the IQS staff. For example, the quality plans initiated by IQS personnel have differing levels of detail dependent on the division quality program. However, in every case, the developed plan met the minimum requirements of IQS OP, "Contract Review and Initial Quality Planning." This OP contains details that can be considered excessive for divisions having their own quality programs and can cause duplicate efforts.

Some inspection personnel perform functions that are covered in multiple procedures or instructions. The decision on which procedure is to be used is based on the individual's knowledge of how or what should be accomplished. This is especially true in the machine shop where the inspector must use machine shop work orders, division procedures or instructions or IQS procedures or instructions to perform inspections. IQS inspection personnel in divisions may use division or IQS procedures dependent on what is identified in division fabrication sheets. Though no deviations were noted and the requirements of the IQS OPs were satisfied, there could be conflicts and duplication of effort among the procedures.

The IQS OP "Audit Performance" is written with a more general approach specifying minimum requirements. A review of three audit reports (2002-AR-04, 2002-AR-07 and 2002-AR-23) was made and they have different audit report formats that make a review difficult to determine if procedural requirements have been met.

The four checklist items considered unsatisfactory included:

- 1) Audit schedules based on the quarterly quality trend information are not being revised as required by OP "Audit Performance", paragraph 3.1.1. See 2002-NCR-38 attached.
- 2) Directions for receiving inspections of customer-supplied products are not being contained in project quality plans as required by OP "Verification of Customer-Supplied Product", paragraph 3.1.2. See 2002-NCR-39 attached.
- 3) No direction is being provided on the purchase order for the receiving inspection of a printed circuit board as noted by WI "Receipt Inspection of Printed Circuit Boards." Only a general receiving and inspection procedure was identified, although inspection personnel performed the inspection per the WI. See 2002-NCR-40 attached.
- 4) Information on customer satisfaction is not being obtained as identified in the OP "Quality Systems Management Review", Paragraph 3.1.4. See 2002-NCR-41 attached.

Overall, it was determined during the audit that the IQS procedures and WIs meet the requirements specified in ISO 9001:2000, and the quality program has been effectively implemented.

AUDIT RECOMMENDATIONS

The following are offered as means of improving the IQS quality program. Response to the recommendations is not required.

- 1) A review of the IQS OPs and WIs should be conducted to determine which procedures should be used by IQS personnel and which should defer to other division OPs or WIs to avoid a duplication of effort. Requirements expected to be complied with should be explicitly identified.
- 2) The IQS organization chart (2/15/02) changed a section from "Quality Systems Technology" to "Quality Systems Audit, Surveillance, and Records." Many of the IQS procedures refer to the Manager, Quality Systems Technology. Some procedures refer to the Manager, Product Quality Assurance as opposed to the Manager, Institute Quality Assurance. The procedures should be corrected to identify the current titles.
- 3) IQS audit reports should contain a statement that responsible managers have been advised of their responsibility to ensure that corrective actions are taken without undue delay to eliminate cited discrepancies and their cause.
- 4) The IQS OP "Contract Review and Initial Quality Planning" requires signatures on quality plans based on dollar values. It is not clear if these are IQS department costs or total contract costs. In addition, quality plans do not normally contain dollar values. Approval by the Quality Engineer who prepared the plan and the Manager, Institute Quality Assurance, appear to be all that is necessary.
- 5) The recent change from OP and WI numbers to titles is creating some difficulties. Division documents still refer to procedure/instruction numbers, while the new titled procedures contain no reference to the previous numbers. A cross-reference listing may aid in eliminating the confusion. In addition, the procedure titles will not fit into spaces provided on purchase requisitions.
- 6) Efforts should continue to have receiving inspection reject codes recorded on the receipt traveler, or recorded electronically as opposed to having the inspectors call the Institute Receiving Department. This way more prompt feedback on vendor performance can be provided to the Purchasing Department.

6/30 11/17/03
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Institute Quality Systems Audit Report
AUDIT NO. 02-AR-22
PAGE 4

PERSONNEL CONTACTED DURING THE AUDIT

A. Holt	1	2	3
R. Weber	1	2	3
D. Dunavant	1	2	3
R. Brient		2	
E. Lange		2	
R. Santos		2	
G. Guzman		2	
C. Butcher		2	
B. Gahagan		2	
M. Minor		2	
V. Ganley		2	
W. Smithson		2	
P. Easley		2	
S. Dannelly		2	

- 1 Attended Pre-audit Meeting
- 2 Contacted During Audit
- 3 Attended Post-audit Meeting



 Thomas Trbovich, Lead Auditor

7/9/02

 Date



 Bruce Mabrito, Auditor

7/9/2002

 Date

APPROVAL:

 Amos Holt, Vice President
 Institute Quality Systems

 Date

433 1/17/02
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NCR

(Edit)
(History)



Report #2002-NCR-0038
Project #30-0300H
Program: QSM
(DOD/NASA & ISO)
By: Tom Trbovich
Date: 2002/07/08

IDENTIFICATION

Summary Description:

Failure to adjust audit schedules based on quarterly trend evaluations.

Description of Discrepancy:

Defect Code: Failure to Follow Procedure

Audit 2002-AR-22 determined indicated no objective evidence existed that audit schedules had been changed based on the results of trend evaluations as required by OP, Audit Performance, Para. 3.2.2. Discussions with the Manager of Quality Systems, Audits, Surveillances and Records indicated that audit schedules had not been changed based on quarterly failure and trend evaluations.

Issued to: Don Dunavant

Response Due: 2002/07/31

RESPONSE

Disposition: _____

Customer Approval of Disposition Required? No

Basis for Disposition:

Disposition Instructions:

Response By: _____

Date: _____

Target Date for Action: _____

APPROVAL

Additional Corrective Action Needed: No

CAR # _____

10 CFR Part 21 Reportable: No

Project Manager: _____ **Date:** _____

QA: _____ **Date:** _____

8/33 1/17/03
73/1/47



NCR

(Edit)
(History)



Report #2002-NCR-0039
Project #30-0300H
Program: QSM
(DOD/NASA & ISO)
By: Tom Trbovich
Date: 2002/07/08

IDENTIFICATION

Summary Description:

Verification of customer-supplied product in quality plans.

Description of Discrepancy:

Defect Code: Failure to Follow Procedure

Project 15-04527, 2 JPL System Flight Computer were received and inspected in accordance with OP "Verification of Customer-Supplied Product" with no instruction being provided in the specific quality plan, PAIP 04527, or the general division 15 plan documents Q-9001-15-1 and Q-9001-15-2 as required by Paragraphs 3.1.1, 3.1.2 and 3.1.3.

Issued to: Rodney M. Weber

Response Due: 2002/07/31

RESPONSE

Disposition: _____

Customer Approval of Disposition Required? No

Basis for Disposition:

Disposition Instructions:

Response By: _____

Date: _____

Target Date for Action: _____

APPROVAL

Additional Corrective Action Needed: No

CAR # _____

10 CFR Part 21 Reportable: No

Project Manager: _____ **Date:** _____

QA: _____ **Date:** _____

CLOSE-OUT

4/33 1/17/03
74/141



NCR

(Edit)
(History)



Report #2002-NCR-0040
Project #30-30 OH
Program: QSM
(DOD/NASA & ISO)
By: Tom Trbovich
Date: 2002/07/08

IDENTIFICATION

Summary Description:

Incorrect instruction provided for receiving printed circuit boards.

Description of Discrepancy:

Defect Code: Failure to Follow Procedure

Purchase requisition no. 60186 (P.O. 223383) indicates inspection to be performed to the OP "Receiving Inspection and Tests" in lieu of the "Receiving Inspection of Printed Circuit Boards" work instruction.

Issued to: Rodney M. Weber

Response Due: 2002/07/31

RESPONSE

Disposition: _____

Customer Approval of Disposition Required? No

Basis for Disposition:

Disposition Instructions:

Response By: _____

Date: _____

Target Date for Action: _____

APPROVAL

Additional Corrective Action Needed: No

CAR # _____

10 CFR Part 21 Reportable: No

Project Manager: _____ **Date:** _____

QA: _____ **Date:** _____

CLOSE-OUT

Method of Verification:

10/22 11/17/02

75/147



NCR

(Edit)
(History)



Report #2002-NCR-0041
Project #30-30 OH
Program: QSM
(DOD/NASA & ISO)
By: Tom Trbovich
Date: 2002/07/08

IDENTIFICATION

Summary Description:

Internal customer satisfaction and effectiveness of the Quality System.

Description of Discrepancy:

Defect Code: Failure to Follow Procedure

OP "Institute Quality Systems Management Review" requires the director IQS to obtain information concerning internal customer satisfaction and effectiveness of the quality system from the SwRI Advisory Committee on Quality Improvement. No objective evidence was presented during 2002-AR-22 to indicate compliance to the requirements of Paragraph 3.1.4 for the 3/28/2002 management review.

Issued to: Amos E. Holt

Response Due: 2002/07/31

RESPONSE

Disposition: _____

Customer Approval of Disposition Required? No

Basis for Disposition:

Disposition Instructions:

Response By: _____

Date: _____

Target Date for Action: _____

APPROVAL

Additional Corrective Action Needed: No

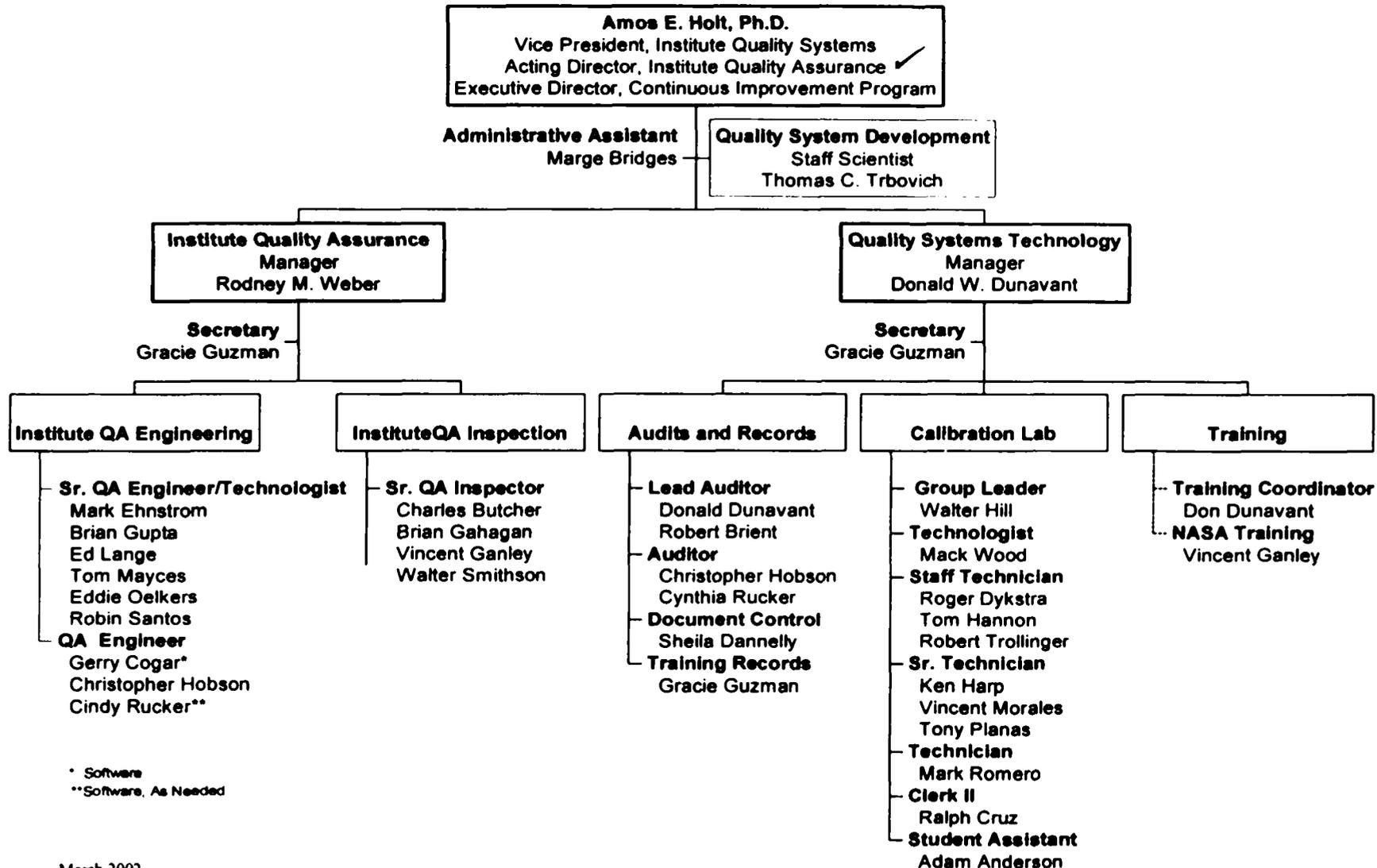
CAR # _____

10 CFR Part 21 Reportable: No

Project Manager: _____ **Date:** _____

QA: _____ **Date:** _____

Institute Quality Systems Institute Quality Assurance, Cost Center 30



March 2002

6/1/02
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10/33 11/17/02
77/147

**Southwest Research Institute™
Institute Quality Systems
Interoffice Memorandum**

May 22, 2002

To: J. Dan Bates
Walter D. Downing

Copy to: John F. Sprencel
Beth A. Rafferty

From: Amos E. Holt *A E Holt*

Subject: Institute Quality Systems Management Review, 2002

In attendance for the review: A. E. Holt, Ph.D., D. W. Dunavant, R. M. Weber
Date Review Conducted: March 28, 2002

In accordance with the Institute Quality Systems (IQS) Operating Procedure (OP), "Management Review," a management review of the IQS Department activities was conducted using both quality system manuals as the governing documents. The quality systems manuals (QSMs) are based on ISO 9001:1994 and ISO 9001:2000. The ISO 9001:2000 standard is the current replacement for ISO 9001:1994, which will no longer be in effect after calendar year 2003.

The review was requested and conducted by Dr. Amos E. Holt, Vice President of the IQS Department and Acting Director of Institute QA, acting in the capacity of Institute Management Representative. Assisting Dr. Holt in the review were Messrs. Donald Dunavant, Manager of Quality Systems Technology, and Rodney Weber, Manager of Institute Quality Assurance (QA). The agenda (see Attachment 1) for the conduct of the meeting was based on the requirements as stated in the above-referenced OP, as well as the perceived needs for the current operating environment. Messrs. Dunavant and Weber collected and supplied the information necessary for the review process.

SUMMARY

The results of the management review indicated that the IQS Department is acceptably performing its mission. The ever-changing expectations and increasing technical requirements being placed on the Institute by clients require continual improvement in management processes as well as in our technical skills. The areas needing continual improvement associated with the Institute Quality Management System are addressed in the discussion text as each agenda item is presented.

+3/03 11/7/03
78/147

The IQS Department has made several very significant improvements in the department's operations during the last operating year. First, the Institute QSMs based on the ISO 9000:1994 and ISO 9001:2000 standards are being operated in concert. This is needed until the current 1994 version is no longer supported or required by existing clients. The QSM addressing ISO 9001:2000 is being modified to include the base requirements of ISO 17025 to support the needs of the Institute's operating divisions. Second, IQS has assisted in the development of ISO 9001:2000-based systems in several of the service divisions. This is an ongoing effort that will require an extended period of time in order to bring the service operations into compliance with the ISO philosophy. When completed, this will facilitate operational efficiencies throughout the Institute. Third, IQS has assisted in the implementation of the Environmental Management System (EMS) of the Institute. The EMS will be operational and certified by January 2003. The management of the EMS is assigned to the Vice President of Services, but the IQS Department has a significant role to play in assisting the Vice President of Services in the establishment, maintenance, and operation of the system. Fourth, IQS has initiated an aggressive surveillance program to support the well-established audit process used at the Institute.

Discussion of Agenda Items

1. Review the quality policy and objectives of IQS for the performance of its activities and the operational system needs of the Institute.

The basic policies and objectives set forth for IQS in the performance of its assigned responsibilities are still valid. There are several suggested modifications to the existing documents being considered that will highlight the necessary elements of the respective ISO systems being implemented. This information is located in the Institute Operating Policies and Procedures Manual (OPP). Specific information related to the conduct of business for the Institute and for the IQS Department is given in OPP 1.1.1, "Preface," 1.1.2, "SwRI Organization, Purpose, and Goals," 1.2.9, "Compliance Quality Assurance Committee," and 10.1.1, "Quality Management System."

2. Evaluate the overall effectiveness and efficiency of the IQS operation.

Measurements are being made in all areas of the IQS operation to determine the effectiveness and efficiency of the activities performed by the IQS Department for the Institute and in areas governed by the division ISO programs. The statistics relating to the audits, approved suppliers list, documentation, and comments and information obtained from auditors who perform audits of our numerous quality systems demonstrate that the system is operating effectively. The metrics used to measure efficiency will be reviewed on a continual basis. The utilization statistics for IQS are continually improving. The adjustments made in resource allocations have proven to be instrumental in helping with elements of efficiency.

Action: The managers are to forecast all resource requirements (people, equipment, and facilities) for the next 24 months.

14/32
11/7/03
79/147

3. Review audit findings for the IQS Department and the performance of audits for the Institute.

In the review of audits conducted by IQS, both internally and externally, it was determined that the audit process is being conducted as designed and is providing value to the Institute. All elements of the audit process are satisfactory. The FY 2002 audit schedule is provided in Attachment 2. Assessment results for all internal audits performed by the IQS Department on organization units using ISO systems are shown in Attachment 3.

Institute operating division QA personnel from Divisions 08 and 16 performed one external audit of IQS. A total of seven findings were noted compared to 31 findings during the audit in the preceding year. All items of concern have been tracked and corrected.

4. Review the corrective action reports (CARs) for IQS and for the Institute.

Mr. Weber supplied information for this part of the review for those CARs that have direct impact on the IQS. A number of CARs are generated in the respective division ISO systems that need to be integrated into one single data base for evaluating the entirety of the Institute operation. Discussion with the ACQI will be needed to investigate the most appropriate way to collect and report on the data. Attachment 4 shows a summary of the IQS CARs and NCRs.

5. Review the customer feedback system and results for the IQS Department and for the Institute.

The majority of all Institute divisions, all divisions and departments with ISO systems, and some support organizations now have formal customer feedback forms. The forms are submitted to the clients upon completion of contracts or at the end of a set period of time. The issue of customer satisfaction and how to obtain accurate and timely information continues to be a question of concern.

Currently, the question of customer satisfaction and the most appropriate way to acquire this information is under consideration by IQS at the request of upper management. A process improvement team is being established with representation from the operating and support divisions.

Action: Dr. Holt and Mr. Dunavant to work with the improvement team and develop a recommendation for an Institute system.

6. Review the adequacy of the QSM and documentation.

The only issue with the manuals and documentation in general is the lengthy time required to process document changes or to develop new ones. This continues to be an issue and will continue to be evaluated. Attachment 5 shows a recent baseline on the subject. The nuclear

15/33
1/17/03
80/147

quality system, previously the Nuclear Quality Assurance Program Manual, was brought under the QSM as a program quality plan.

The addition of the ISO 17025 requirements to the existing QSM will be accomplished prior to the end of the current fiscal year.

7. Evaluate the trends of performance within the IQS Department and the Institute.

Each year, the IQS Department monitors its mission statement, goals, and metrics to ensure continual progress in meeting the goals. These metrics are tracked to evaluate their value in obtaining the required results and then, if inadequate, changed to meet the needs for timely decision making. Attachment 6 shows financial trends.

8. Define those areas within the IQS Department and the Institute that will require changes – either now or in the future.

The purpose of this element in the review is to ensure that IQS is monitoring the collective changes throughout the Institute and is ready with the required resources to meet the needs of divisional and service operations.

The department is continually changing with respect to support of Institute operations and the staff needed to support the operations. More resources are needed in the computer and electronic instrumentation side of the operation, both at headquarters and at remote sites. Our audit/surveillance activities have increased and will likely continue to grow for the next few years.

The implementation of an EMS has and will continue to increase the resource needs of the department.

Action: Management is to develop a five-year plan of what the needs are likely to be in the time frame of the plan. This will include staffing and operational resource requirements. (This action item remains from last year.) We still need to baseline several of our operations in order to have a proper plan.

9. Review and evaluate the organizational structure of the IQS Department in order to supply the needed staff and related training.

This is an on-going effort and will continue on a periodic basis as the requirements of the different technical operations and quality, regulatory requirements, and customer expectations change. Currently, the need for additional staff for the audit section and temporary help in the inspection section has been identified. The reasons for the increased staff are due to increasing requirements in the audit sector and the retirement of three key staff in the Calibration Laboratory, management, and quality assurance areas. In contrast, the need for QA engineers (QAE) is expected to decline over the next few years as the divisions and service operations become more

16/37 1/17/52
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established in the ISO quality system. If the service divisions require operational status to the ISO-based technology within the next two years, then additional QAE assistance needs to be considered. Fulltime staff for this contingency is not warranted at this time.

10. Review IQS Department interaction with the Contracts and Purchasing departments.

Executive management is in full support of the implementation of the ISO-based quality system approach for all service units. Careful planning will be required to meet the needs and to ensure that the operations of these units are not interrupted as they adapt. The Purchasing Department and then the Contracts Department are our first priorities. It has been recognized that the touch points between these two operations must be brought on line with ISO systems approach in order for the ISO based systems in these others groups to work efficiently. Human Resources, Program Development Office, Staff Development Office, Information Technology Center, and Financial Data Systems are also considering adopting the ISO system approach. To make the transition as smooth as possible, training of essential staff in each of the service organizations has begun and will be required for the next 12 months. The status of ISO system implementation for the Institute is shown in Attachment 7.

11. Review IQS interface with other Institute systems and operational structures.

The Institute has a number of systems that would benefit from a smooth interface - Accounting, Contracts, Purchasing, Quality Assurance, Human Resources, Facilities and others. The opportunity to interface all of these systems is resident in the current Costpoint system. How this can be done has yet to be determined, but the need to explore the actual opportunity from the myth is a must. One additional management system that has begun operation is the environmental management system. The touch points and interfaces with this new management system are still evolving and will most certainly expand to other units in the Institute.

12. Review the use of statistics in IQS operations.

Establishment of a new work order system in the IQS Department will facilitate the collection of more reliable data to be used to determine the need for resources and to provide the opportunity for the use of statistical analysis. We must use this tool to remove the subjectivity from the data used in determining the directions to be taken by IQS. Statistical approaches are being applied to the Project Deliverables System in order to improve on-time delivery for projects.

ACTION ITEM STATUS FROM THE MANAGEMENT REVIEWS OF 2000/2001:

- Publish the goals of the organization. This was COMPLETED and the goals are listed on the IQS web page.
- Complete the ongoing procedure transition to the QSM. COMPLETED for ISO 9000:1994 and ISO 9001:2000.

17/32 1/17/02
82/1147

- Establish a tracking and action plan for reducing the number of CARs and a way to address all corrective actions in a timely manner. This is considered to be 50% COMPLETE. The only element remaining is the timely portion of the requirement. The item is NOT COMPLETE. We may have a system issue, not a measurement issue.
- Define, proceduralize, and implement a training program for all QA staff. COMPLETED, with organization change and the appointment of a training coordinator.
- Establish where metrics are needed and develop appropriate means to measure IQS functionality and benefit. COMPLETED
- Establish a system for receiving and tracking customer complaints. COMPLETED. However, as mentioned in the current review, the process needs to be re-evaluated.
- Provide utilization projections for FY 2002. COMPLETED
- Use the regular scheduled meetings of the QAEs and the inspection staff to focus IQS issues. COMPLETED
- Draft a revised customer feedback form for use in the Calibration Laboratory. COMPLETED
- Draft a tracking form that will accompany all documents throughout the review process to better understand the time required in each step and where changes can be made to gain efficiency. COMPLETED and Implemented
- Develop a five-year plan for the IQS. NOT COMPLETE.

ACTION ITEM STATUS FROM THE MANAGEMENT REVIEW OF 2002:

- Operational plan for the next fiscal year and the five-year plan. (Carried over)
- Work with the Service divisions in the implementation of ISO-based procedures.
- Managers to forecast resource requirements for next 24 months.
- Set up and implement an Institute customer feedback process improvement team.

18/33
11/7/02
83/147

Agenda

Annual Management Review of Institute Quality Systems (IQS)
Operations and Performance
Thursday, March 28, 2002

1. Review the quality policy and objectives of IQS for the performance of its activities and the operational system needs of the Institute.
2. Evaluate the overall effectiveness and efficiency of the IQS operation.
3. Review audit findings for IQS and the performance of audits for the Institute.
4. Review the corrective action reports for IQS and for the Institute.
5. Review the customer feedback system and results for IQS and for the Institute.
6. Review the adequacy of the quality system and its performance, documentation, and manuals.
7. Evaluate the trends of performance within the internal IQS system and for the Institute.
8. Define those areas within the internal IQS system and for the Institute that require or will require change.
9. Review and evaluate the organizational structure of the IQS operation in order to supply the needed staff and related training.
10. Review IQS interactions with the Contracts and Purchasing departments.
11. Review the IQS interface with other Institute systems and operational structures.
12. Review the use of statistics in IQS operations.

FY 2002 INTERNAL AUDIT SCHEDULE

**Revision 3
April 1, 2002**

DIVISION/CC AUDITED		AUDIT SCOPE	(LEAD) AUDITOR	SCHEDULED	COMPLETED/ AUDIT #	PREVIOUS AUDIT/ AUDIT #
01	Chemistry	NQAPM, ISO 9002	(DWD) RDB	February 2002	February 2002 02-AR-0004	October 2000 00-AR-0040
		FTQA Plan, FLL QA Plan, ISO 17025	(DWD)	March 2002	March 2002 02-AR-0008	September 1999 99-AR-0024
		Chemical Demilitarization Johnston Island	(DWD)	November 2002	November 2001 01-AR-0033	November 2000 00-AR-0045
		Chemical Demilitarization Umatilla, OR	(DWD)	October 2001	October 2001 01-AR-0037	NA
		Chemical Demilitarization Pine Bluff, AR	(DWD)	June 2002		NA
03	Engine & Vehicle Research	ISO 9001	(DWD) CDH	March 2002	March 2002 02-AR-0007	February 2001 01-AR-0003
				August 2002		September 2001 01-AR-0017
		Environmental Management System	(RDB) (RDB)	May 2002 July 2002		N/A N/A
07	Training Systems and Simulators	QSM		September 2002		September 2001 01-AR-0029
		O'Fallon, IL Scoping Visit	(RDB)	November 2001	November 2001	NA
		Ogden, UT Scoping Visit	(DWD)	TBD		NA
08	Automotive Products and Emissions	ISO9000-2000, ISO 17025	(RDB) DWD CDH	January 2002	January 2002 02-AR-0003	December 2000 00-AR-0046
				Environmental Management System	(RDB) (RDB)	May 2002 July 2002
		QSM		November 2001	December 2001 01-AR-0041	November 2000 00-AR-0042
09	Aerospace Electronics & Information Technology	SQA-Warner Robins	(DWD)	February 2002	February 2002	
		SQA-Huntsville		TBD	2002-SR-0055	
		SQA-Okla. City		TBD		
10	Automation and Data Systems	QSM		November 2001	N/A	No Auditable Activities in 2001
		Bioengineering - GMP	(RDB)	February 2002	February 2002	January 2001

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FY 2002 INTERNAL AUDIT SCHEDULE
Revision 3
April 1, 2002

DIVISION/CC AUDITED		AUDIT SCOPE	(LEAD) AUDITOR	SCHEDULED	COMPLETED/ AUDIT #	PREVIOUS AUDIT/ AUDIT #
					02-AR-0005	01-AR-0002
		EMCR - Guide 25	(RDB)	June 2002		April 2001
						01-AR-0009
		SED - CMM SQA	(RDB)	March 2002	March 2002	March 2001
					02-AR-0010	01-AR-0007
14	Applied Physics	QSM, NQAPM	(RDB)	January 2002	January 2002	January 2001
					02-AR-0002	01-AR-0001
15	Instrumentation & Space Research	QSM, NQAPM	(DWD) RDB CDH	January 2002	January 2002	August 2000
					02-AR-0001	00-AR-0033
16	Signal Exploitation and Geolocation	ISO 9001		July 2002		July 2001
						01-AR-0016
18	Mechanical & Materials Engineering	QSM	(DWD)	April 2002		April 2001
						01-AR-0011
		API Q1 (FCTF)	(DWD)	May 2002		May 2001
						01-AR-0013
20	CNWRA	CQAM		August 2002		August 2001
						CNWRA-01-2
30	Institute Quality Systems	ASL Annual Surveys	SCD	January 2002		January 2001
		Semi-annual Rating	RDB	January 2002	January 2002	January 2001
				July 2002		July 2001
		Calibration Lab Z540	CMR (RDB)	October 2001	October 2001	March 2000
					01-AR-0036	00-AR-0013
		Calibration Lab - Management Review	DWD	May 2002		May 2001
		Department Management Review	AEH	April 2002		April 2001
		Quality Assurance - QSM		June 2002		June 2001
						01-AR-0018

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FY 2002 INTERNAL AUDIT SCHEDULE
Revision 3
April 1, 2002

DIVISION/CC AUDITED	AUDIT SCOPE	(LEAD) AUDITOR	SCHEDULED	COMPLETED/AUDIT #	PREVIOUS AUDIT/AUDIT #	
Support Cost Centers	SwRI® Radiation Lab – Radiation Safety Program		August 2002		August 2001 01-AR-0027	
	Purchasing - QSM	(RDB)	March 2002		September 2001 01-AR-0034	
	Human Resources - DFWP	(DWD)	May 2002		April 2001 01-AR-0010	
	Program Development Office - COI		July 2002		July 2001 01-AR-0020	
	Environmental Management System - Services		(RDB)	May 2002		N/A
			(RDB)	July 2002		N/A
All CCs doing Nuclear-related activities	10CFR21 Posting	SCD	June 2002		January 2001 2001-SR-0026	

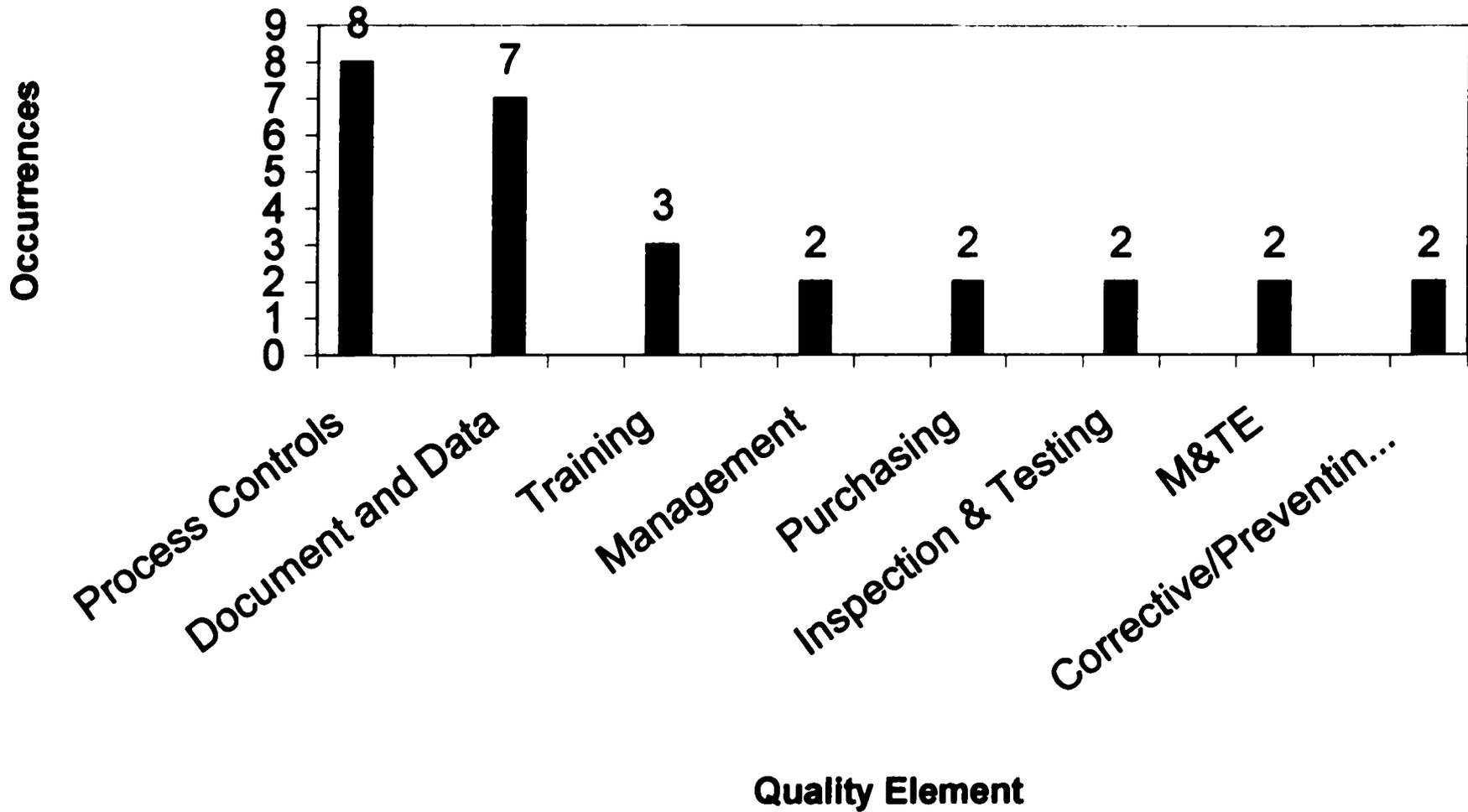
New since last revision

Approved by: Donald W. Dunavant
Donald W. Dunavant, Manager
Quality Systems Technology

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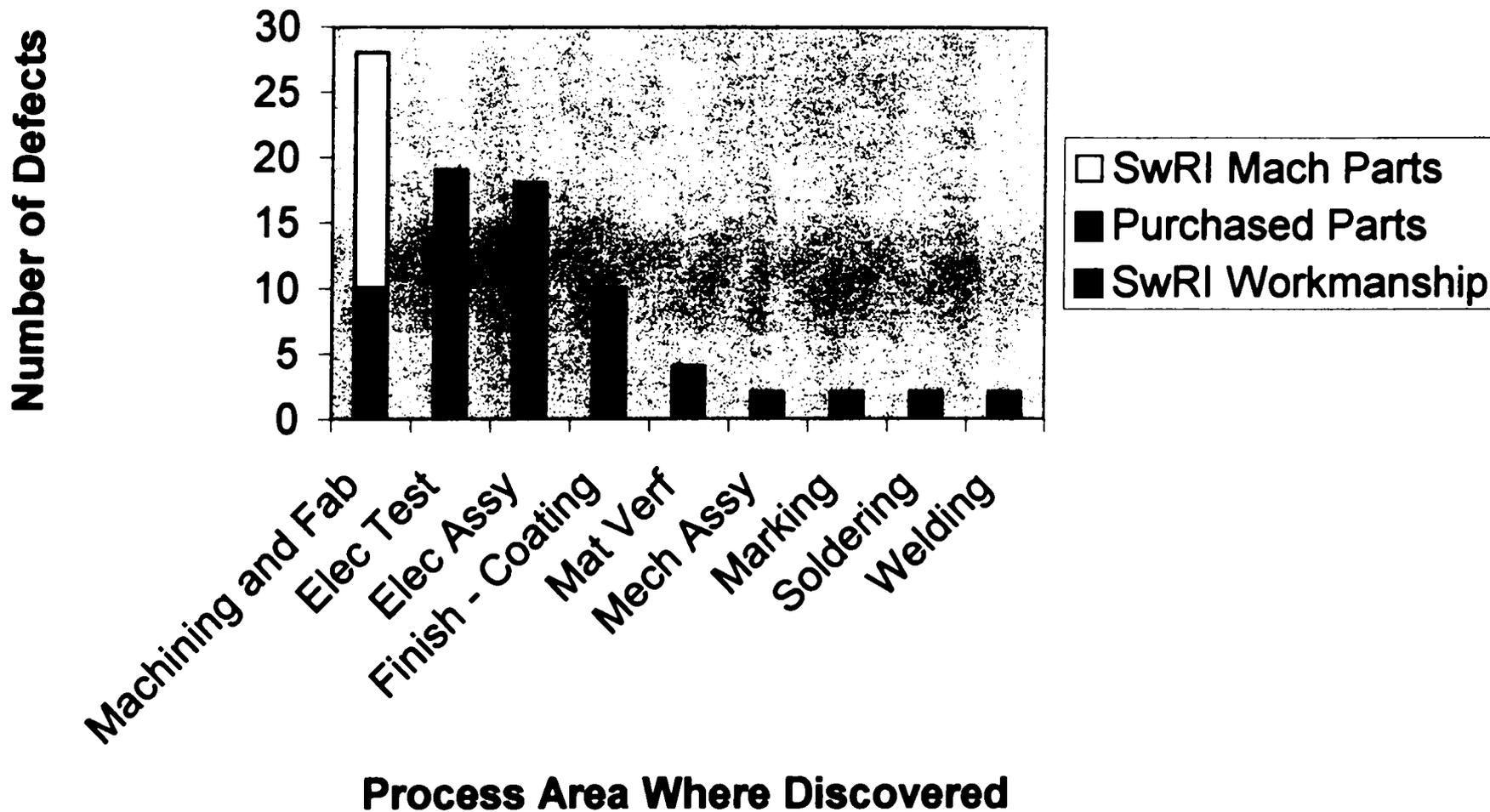
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NCR/CAR SUMMARY 2001



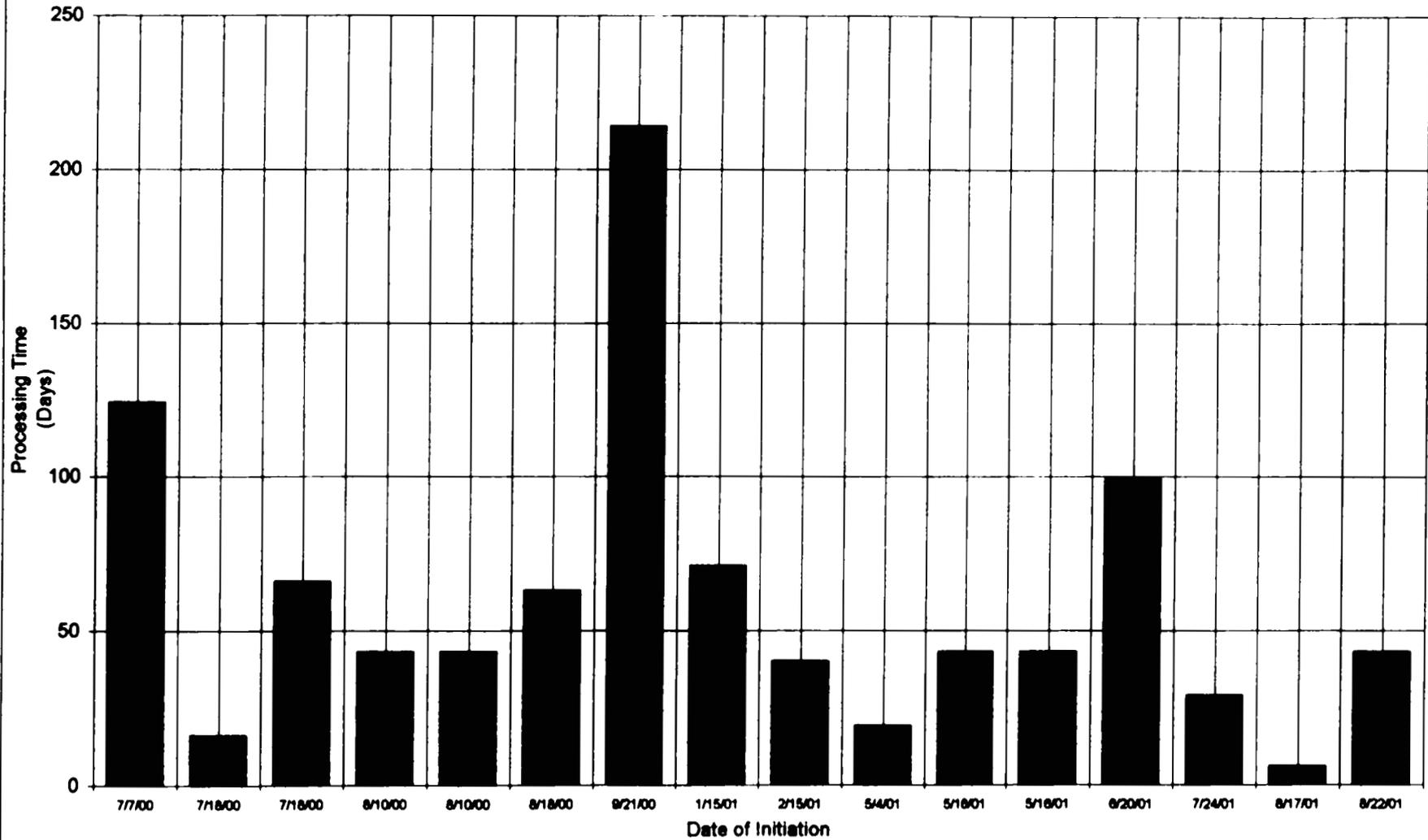
58
Rev 7
23/53

Nonconformance Summary By Defect Type and Process Area



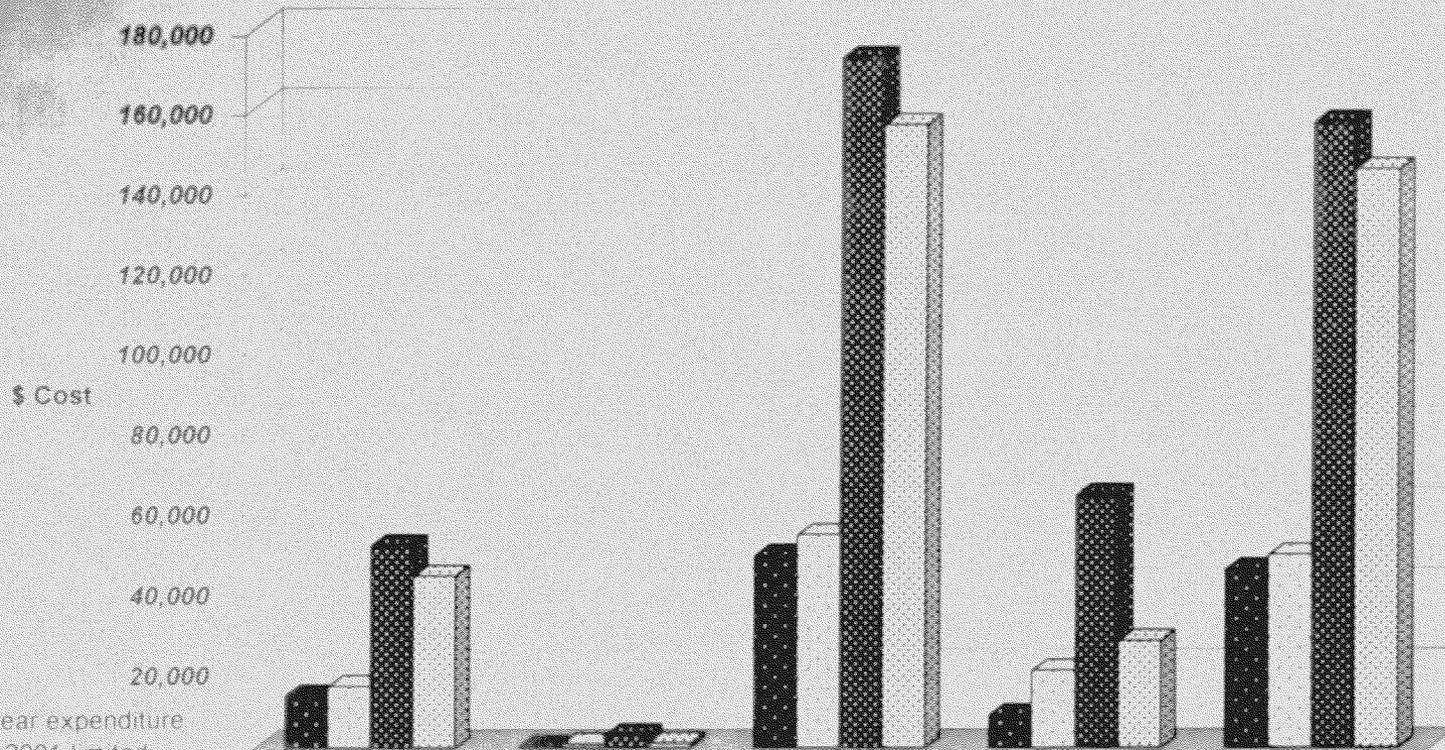
59/1/11
2/1/11
24/1/11

Procedure Processing Times



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8/1/01
11/1/01
25/1/01

Work Order Cost Status, 4th Period*

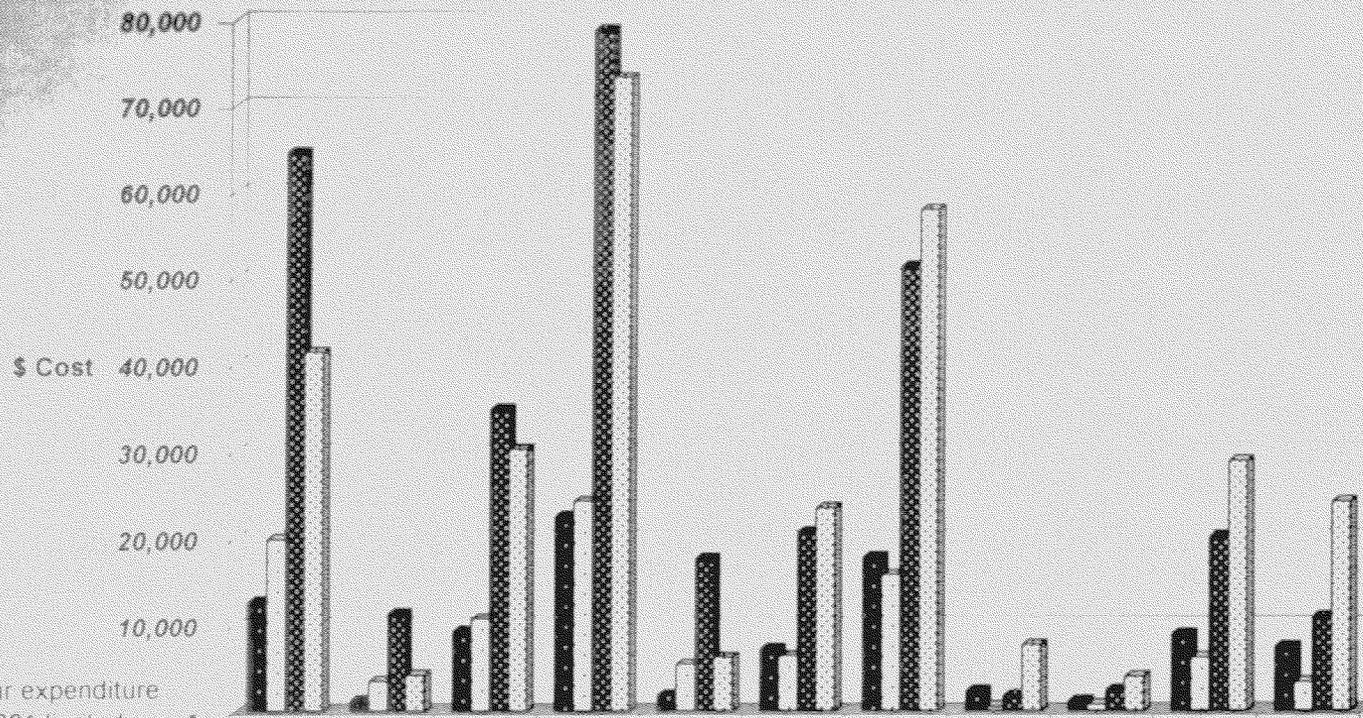


*Assumes linear expenditure based on FY 2001 limited history, 1 to 6 periods

	400, Documentation	410, Web Site	420, Institute Support	500, Planning	510, Management and Meetings
■ Actual Period Costs	13,213	359	47,883	8,244	44,517
□ Expected Period Costs	15,544	1,003	53,089	19,389	48,173
■ Annual Expected Cost	50,518	3,259	172,538	63,015	156,561
□ Projected Annual Cost	42,942	1,168	155,619	26,794	144,680

Work Order Title, Series 400 & 500

Work Order Status, 4th Period*



*Assumes linear expenditure based on FY 2001 limited history, 1 to 6 periods

	600, Resour ce	610, Acquisi tion	620, Compu ter	625, Trainin g CC30	630, Trainin g SwRI	640, Meetin gs	650, Semina rs,	660, Equipm ent	670, Equipm ent/Fac	680, ISO 14000	690, Cal Lab Mainte
■ Actual Period Costs	12,730	1,305	9,291	22,539	1,918	7,228	17,822	2,362	1,225	8,901	7,445
□ Expected Period Costs	19,867	3,485	10,731	24,247	5,436	6,378	15,785	564	769	6,204	3,362
■ Annual Expected Cost	64,566	11,328	34,876	78,802	17,668	20,728	51,302	1,833	2,498	20,165	10,926
□ Projected Annual Cost	41,373	4,242	30,196	73,252	6,234	23,492	57,923	7,675	3,981	28,928	24,197

Work Order Titles, 600 Series

Work Order Cost Status, 4th Period*



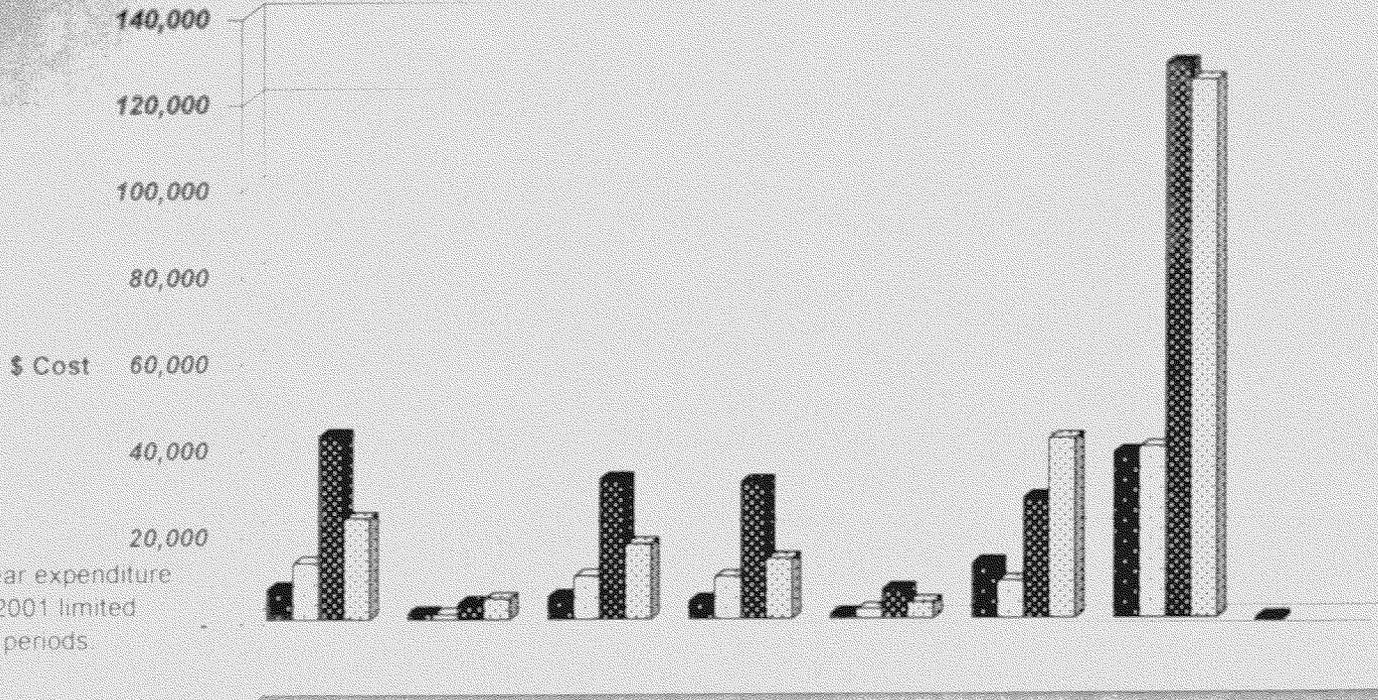
*Assumes linear expenditure based on FY 2001 limited history, 1 to 6 periods

	700, Custom er	710, Contract Review	720, Calibrati on	730, Purchas ing	740, Calibrat e &	750, Complia nce	760, Cal Lab Standar	770, Proficie ncy	780, A2LA mainten	790, Uncertai nty
■ Actual Period Costs	13,853	2,128	757	1,823	5,913	1,034	15,616	147	5,053	11,132
□ Expected Period Costs	6,048	3,568	1,437	2,571	1,181	887	34,088	106	1,157	6,776
■ Annual Expected Cost	19,657	11,595	4,669	8,355	3,839	2,884	110,784	345	3,761	22,023
□ Projected Annual Cost	45,022	6,915	2,461	5,925	19,216	3,360	50,752	479	16,423	36,180

Work Order Titles, Series 700

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Work Order Cost Status, 4th Period*



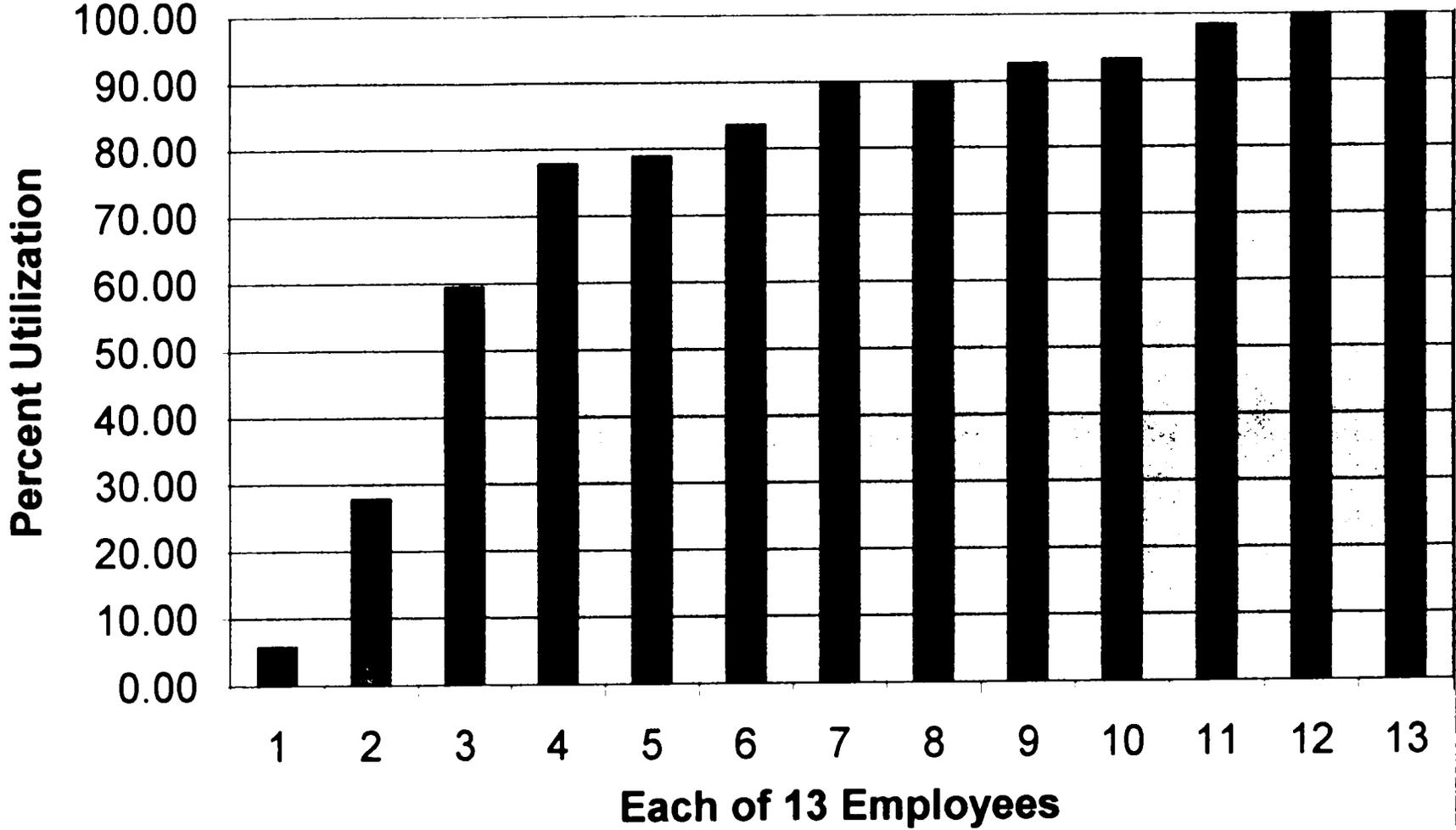
*Assumes linear expenditure based on FY 2001 limited history, 1 to 6 periods.

	800, Measurement	810, QRS Maintenance	820, Statistics	830, Nonconformance	840, QAC Support	850, PDS	860, Audits	899, Multi-Client Calibration
■ Actual Period Costs	7,162	1,462	5,329	4,259	1,115	12,770	38,241	(918)
□ Expected Period Costs	13,069	1,166	9,952	9,726	2,088	8,554	39,436	
■ Annual Expected Cost	42,475	3,789	32,345	31,608	6,786	27,801	128,166	
□ Projected Annual Cost	23,275	4,751	17,318	13,843	3,625	41,502	124,283	

Work Order Title, 800 Series

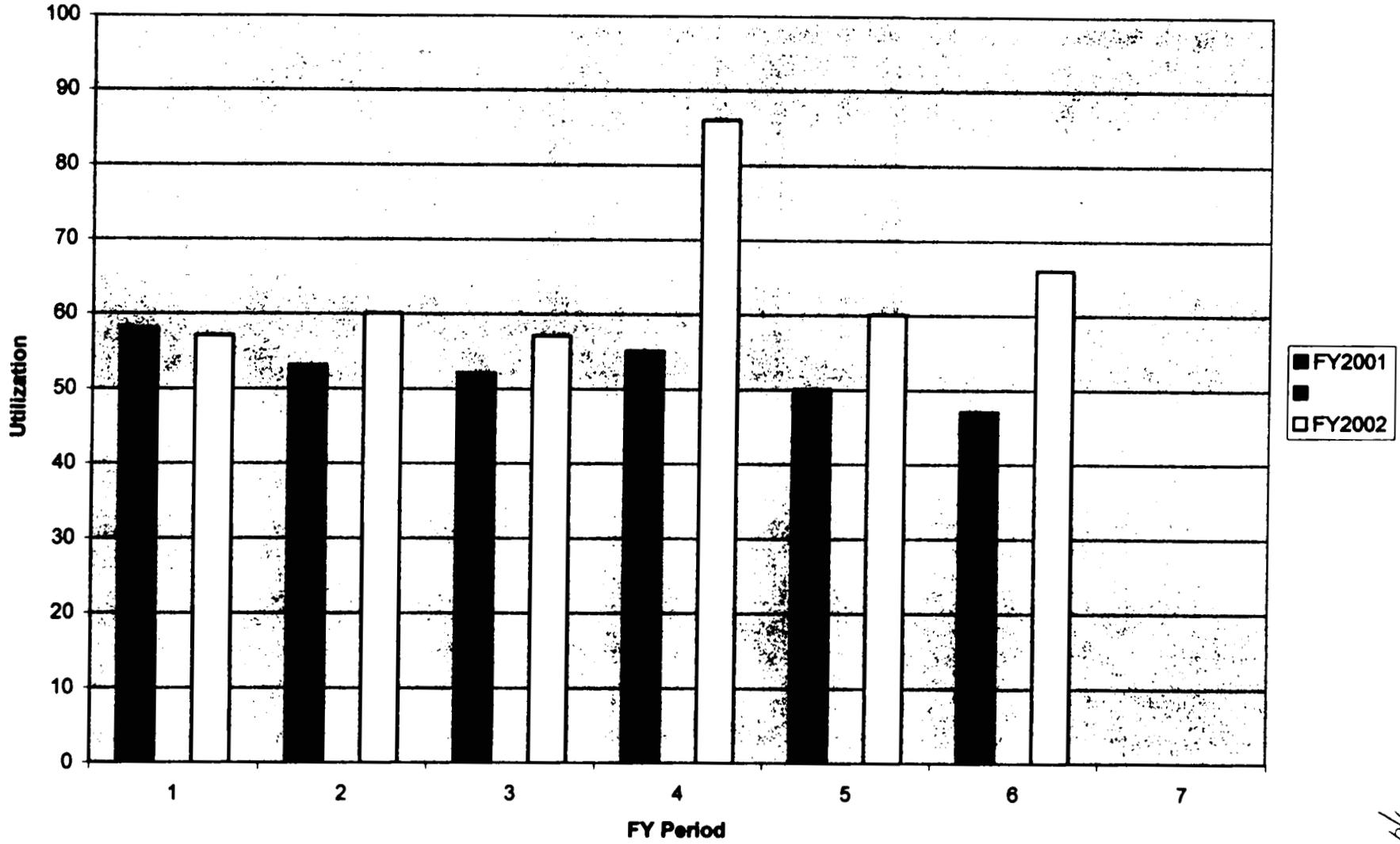
4/4/02

QAE and QAI Utilization 1st Quarter, FY 2002



30/33
1/10

Cal Lab Utilization Comparison



96/1/17

3/13/03

**ISO IMPLEMENTATION AT SWRI
STATUS as of May 6, 2002**

OPERATING DIVISIONS

Div.	Dept.	1	2	3	4	5	Remarks	
		No Activities	Under Consideration	Being Developed	Prep for Audit or Implemented	Certified or Accredited		
01	Fire Tech C&CE	—————→						Guide 25/17025, ICBO. 9002, NSF (All)
03	All	—————→						9001, EAQA
07	All	→						Project Specific Procedures Development When Required. No Recent Activities
08	All	—————→						9002, NQA; Guide 25/17025/EN 45001, A2LA
09	All	—————→						Division Procedures Development
10	BE EMCR Others	—————→						9001/EN 46001, DNV Guide 25/17025/EN 45001, A2LA
14	All	→						Nuclear Program Activities
15	All	—————→						Pre-assessment Complete, DNV, Sept 2001, Addressing Implementation
16	All	—————→						9001, LRQA
18	FCTF DSE ETS Others	—————→						API Q1/Guide 25, API Procedures Released, Project-by-Project Implementation Procedure Implementation in Progress No Significant Client Pressure to Implement ISO
20	All	—————→						The NRC has agreed to allow the Center to investigate implementation of an ISO-based program. A gap analysis has been completed. The program must meet the requirements of NQA-1

97/1/11
5/2/02
1/17/03

**ISO IMPLEMENTATION AT SWRI
STATUS as of May 6, 2002**

SERVICES

<u>Dept.</u>	<u>Sec.</u>	<u>1</u> No Activities	<u>2</u> Under Consideration	<u>3</u> Being Developed	<u>4</u> Prep for Audit	<u>5</u> Certified or Accredited or Implemented	<u>Remarks</u>
30	Cal Lab	—————→					ISO/IEC 17025 -1999, ANSI/NCSL Z540-1-1994, A2LA
30	Proj QA	—————→					
31	Machine Shop	—————→					
42	Buildings & Grounds	—————→					
52	SDO	—————→					
64	PDO	—————→					
68	HR	—————→					
72	Contracts	—————→					
73	Purchasing	—————→					

Handwritten notes:
98/1/10
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