MEMORANDUM

SUBJECT: Review of Region 5 Laboratory Operations
Audit Report Number 2000-P-3

FROM: John T. Walsh /s/
Divisional Inspector General
Headquarters Audit Division

TO: Francis X. Lyons
Regional Administrator

INTRODUCTION AND ACTION REQUIRED

In May 1999, you requested that the Office of Inspector General (OIG) conduct an audit of the Region 5 Central Regional Laboratory (CRL). This report presents the results of our audit. Briefly, we found that many actions identified by the Region's December 1998, Management Systems Review (MSR) have not been completed due to insufficient monitoring, assigning implementation to a single individual, and an organizational structure which called for the Review Team to report its findings to its supervisor, the CRL Director.

On September 23, 1999, we met with you and members of your management team to discuss our findings and suggested recommendations. On October 12, 1999, we received the Region's integrated action plan describing the corrective actions ongoing or planned and the milestones for completion. We reviewed these actions and found that they address our recommendations. As such, we are closing this report upon issuance and no further response is necessary.

The findings, recommendations, and corrective actions described in this report represent the opinion of the Office of Inspector General. Final determination on matters discussed in this report will be made by EPA managers in accordance with established audit resolution procedures. Accordingly, the findings in this report are not binding upon EPA in any enforcement proceedings brought by EPA or the Department of Justice.

BACKGROUND

The Region 5 Central Regional Laboratory, a branch of the Resource Management Division (RMD), provides essential analytical and field support services to Region 5, states, Indian tribes, criminal investigations, and other EPA regions. Analytical support consists of the analysis of environmental samples obtained from the regulated community. The results of CRL's analysis are relied upon for environmental and enforcement decision making. The CRL staff are also called upon to provide advice and expert testimony in Regional and National program decisions, as well as civil and criminal litigation. Their expertise is often used to perform critical environmental analysis for sensitive enforcement cases.

During Fiscal Year 1998, Region 5 program officials identified questionable data being produced by the CRL. Upon further inspection by program and CRL personnel it was determined and reported in the Region's Fiscal Year 1998, Federal Managers' Financial Integrity Act (FMFIA) assurance letter that "data quality and chain of custody were compromised when CRL chemists circumvented the lab's standard operating procedures." As a result, data were provided to the regional program offices for decision making and enforcement actions that were of "unknown quality and indefensible." The potential outcome of these actions lies in making erroneous cleanup and enforcement decisions with this data and spending additional resources to re-sample and re-analyze environmental samples to obtain reliable data. Moreover, because these chemists had been with EPA for many years, the number of projects that may be affected is potentially very large.

Also in September 1998, the Inspector General's Office of Investigations (OIG, OI) was informed of the alleged improprieties regarding the laboratory data. Upon review of the data, OI initiated a criminal investigation of certain CRL personnel. On June 8, 1999, OI recommended that the laboratory cease accepting samples until an independent management and technical audit could be performed at the laboratory. At the time we completed our fieldwork, the extent of the alleged criminal improprieties had not been determined.

In September 1998, the Region 5 Quality Assurance Core Group initiated a Management Systems Review (MSR) of the laboratory's operations. This review was undertaken, in part, to address the concerns raised regarding the data produced by the lab. The MSR identified 23 areas of concern which were grouped into 6 major finding areas: 1) management of the lab, 2) a need for improved communication, 3) a need to strengthen the lab's policies and procedures, 4) a lack of understanding of quality assurance and quality control, 5) problems with chain of custody as well as sampling and data handling problems, and 6) a need for improved training for lab

personnel. To address these findings, laboratory management developed an action plan which included 41 actions to correct the problems identified.

PURPOSE, SCOPE AND METHODOLOGY

The purpose of this audit was to determine the status, and to the extent possible, the effectiveness, of the corrective actions taken to address the findings identified in the MSR and to identify additional actions the laboratory might take to help restore the integrity of the lab. Along with this review, the Agency formed an independent Technical Audit Team consisting of personnel from several other EPA labs to conduct a detailed technical audit of CRL operations. The results of that review are referenced throughout this report.

To accomplish our objectives we met with members of the QA Core who conducted the MSR. We reviewed OIG OI investigative reports. We toured the laboratory and conducted interviews with CRL and Region 5 management and staff to discuss the findings and corrective actions taken in response to the MSR. We reviewed existing CRL policy and procedures, including the procedures for handling incoming samples and disposing of samples. We gathered information on the volume of analysis CRL performs as well as the time to process samples. We reviewed CRL data review, filing, and archiving procedures as well as the lab's FMFIA reporting. Our audit fieldwork was conducted from June 1999, through July 1999, in accordance with Generally Accepted Government Auditing Standards (Government Auditing Standards 1994 Revision).

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FINDINGS AND RECOMMENDATIONS

Many Corrective Actions Remain to be Completed

In September 1998, the Region 5 Quality Assurance Core initiated a Management Systems Review of the CRL to determine whether the lab's quality management system was operating as designed. In December 1998, the Core issued a report to the CRL Director which described 23 areas of concern grouped into 6 major finding areas:

1. Management

- Lack of an approved Quality Management Plan.
- Little or no oversight of day to day operations in the laboratory by management.
- Lack of acknowledgment of authority of group and team leaders.
- Lack of clear delineation of the roles and responsibilities for specific QA processes among the staff and the team leaders.
- Sample scheduling conflicts that cause competition for lab space and instrument time between contract and CRL staff.
- Management gives low priority to QC and customer needs in favor of accepting and analyzing samples.

2. Communication

- Staff lack knowledge of project background and objectives on which they work.
- Little communication between teams and groups.

3. Policies and Procedures

- SOP for many analytical methods and logistical processes at CRL are either out of date or non-existent.
- Procedures to determine method detection limits (MDLs) not consistently applied throughout CRL.
- Data review and data validation are not clearly defined in CRL procedures and staff do not understand what each type pf procedure is meant to accomplish.
- Responsibilities and procedures are not in place to ensure that all staff have designated, trained alternates when staff are not available for any reason.

4. Analysts lack and understanding of the values of QA/QC in laboratory operations.

- Many staff are not evaluating the quality of the data based on appropriate quality control criteria.
- Many staff do not have a complete understanding and appreciation of their role and responsibility for QA activities in the laboratory operations.

5. Sample Handling, Chain of Custody, and Data Archival

- Verification of sample preservation upon sample receipt by CRL staff is incomplete.
- Sample tags are not properly stored and consolidated with sample data and custody records.
- Data archival procedures are not documented nor consistent throughout CRL.
- Electronic sample data records do not exist for some analysis.
- No clearly documented responsibility for archiving electronic records.
- No secure, central storage f known electronic records.
- No verification that electronic data is retrievable.

6. Training

- Analysts are not receiving basic training that are required to perform their job efficiently and to ensure the quality of data they are responsible to generate.
- Ineffective cross training of analysts.

To address these findings, CRL management developed an action plan which included 41 corrective actions (See appendix 2). Our review of the corrective actions showed that while some have been completed, many had either not been addressed or did not adequately address the findings from the MSR. Of the 41 corrective actions planned, about 30 remain to be completed. As a result, many of the problem areas identified by the MSR continue to exist and the quality of the results that the lab is producing remains questionable. We identified three reasons these actions were not completed.

First, while CRL developed the corrective action plan to address the findings, there was little follow through by the CRL Director and RMD senior management to ensure that the corrective actions were implemented and effective in correcting the deficiencies noted. For example, one of the recommendations from the corrective action plan was to annually update existing Standard Operating Procedures (SOP) and develop new SOPs where necessary. While CRL updated some SOPs, they did not develop a mechanism to track whether SOPs had been updated. Because CRL has over 100 SOPs, a simple tracking system will help maintain up to date SOPs. Additionally, the MSR corrective actions were not being monitored and tracked by the CRL Director nor RMD management, and we saw no evidence that the CRL Director was keeping RMD senior management apprised of progress.

Second, responsibility for implementing the corrective action plan was given to the CRL Quality Assurance Coordinator. Our review showed that the QA Coordinator is responsible for overseeing all QA/QC activities in the lab as well as acting as the sample coordinator and coordinating lab projects with program offices. The QA coordinator is also heavily involved in assisting the Office of Regional Counsel and the OIG OI in determining the extent of work effected by the chemists in question. According to the Technical Systems Audit Report, QA/QC activities and sample coordination require two full-time employees at some other EPA labs. Given the amount of work the QA coordinator is currently responsible for, we believe that responsibility for implementing the corrective actions should have been more evenly distributed among CRL management and staff.

Finally, we found that the Quality Assurance Core Group, who conducted the initial review of the laboratory, report directly to the CRL Director. Thus, when the CRL Director finalized the corrective action plan, it was sent to the QA Core (i.e. his own staff). The QA Core has no authority over the CRL Director and therefore has little control as to whether or not the corrective action plan gets implemented. In 1996, the Office of Research and Development's Quality Assurance Division conducted a review of Region 5's quality assurance practices and questioned the organizational independence of the QA Core as it relates to laboratory operations. Specifically, the report stated that having the regional quality assurance manager supervised by a line manager (CRL Director) who is responsible for important environmental data generation activities creates a potential conflict of interest. The Region responded that the QA Core would report administratively to CRL, but for on programmatic issues would report to RMD. Because the lab is a branch of RMD, we believe that organizational independence could be better achieved if the QA Core would report any activities regarding the laboratory to the Assistant Regional Administrator for RMD rather than the CRL Director.

Conclusions

The findings identified by the MSR as well as the limited progress achieved in strengthening CRL operations indicate that there is a need for improved management, accountability and oversight of the CRL operations. The corrective actions resulting from the

MSR are achievable and will help the lab re-establish its integrity and credibility, but will require increased attention by CRL and RMD management.

Recommendations

We recommend that:

1.1 The CRL Director revise the corrective action plan to ensure that the corrective actions are responsive in addressing the findings from the MSR. The plan should also be revised to reflect the current estimated time frames of completion. The new plan should be approved by the Assistant Regional Administrator for RMD.

Region 5 Response

The corrective action plan has been revised to more directly respond to the findings of the MSR and has been expanded to integrate additional findings from the OIG review. Time frames for the corrective actions have been reviewed and, if necessary, revised to reflect the Region's current realistic expectations for achievement. The ARA has approved the revised Integrated Corrective Action Plan, and has assigned an Associate Director of the RMD to work with the CRL Director in assuring that the actions are, indeed, responsive to the issues and effective in their implementation.

1.2 The CRL Director assign responsibility for addressing individual corrective actions to the appropriate CRL staff. The Director should ensure that staff are allocated sufficient time for addressing the corrective actions and are held accountable for their completion.

Region 5 Response

The revised Integrated Corrective Action Plan assigns both primary and support/oversight responsibility for each of the actions outlined. Completion of the Integrated Corrective Action Plan has been identified as the top priority for all managers and staff of the CRL, and no additional samples will be accepted at CRL until all of the corrective actions addressing critical weaknesses have been completed. Thereafter, the time necessary to complete or carry out continuing corrective actions will be factored into the plans and schedules for initiating new work in the CRL. The ARA, the Associate Director of RMD, the CRL Director, and the CRL Deputy Director will all ensure and share in accountability for completion of the corrective actions.

1.3 The CRL Director develop a tracking system to monitor progress in addressing the corrective actions.

Region 5 Response

The Integrated Corrective Action Plan will serve as the primary tool for tracking and monitoring progress in addressing the corrective actions.

1.4 The CRL Director provide the Assistant Regional Administrator, RMD, on a quarterly basis, a status report on the corrective actions taken with explanations for any missed milestones. The report should include a section describing the effectiveness of the corrective actions taken in addressing the findings from the MSR.

Region 5 Response

The CRL Director will meet on a monthly basis with the ARA and Associate Director to report on the status of corrective actions, including explanations for any failures to adhere to established time frames and on the effectiveness of the actions undertaken. The ARA will provide quarterly status reports to the Regional Administrator and the Region's Senior Leadership Team.

1.5 The Quality Assurance Core conduct an independent follow-up review of the MSR to determine the effectiveness of the corrective actions taken. This review should be undertaken at the beginning of calendar year 2001.

Region 5 Response

The QA Core had originally proposed such a follow-up to the MSR, and the ARA will task the Regional QA Manager with completing the follow-up review by the end of fiscal year 2000. In addition, the QA Core has been instructed to work with the CRL QA Coordinator to report any quality assurance concerns about CRL activities directly to the ARA.

ADDITIONAL AREAS OF CONCERN AND OBSERVATIONS

Technical Audits Can Help Improve CRL Operations

Regional program managers base environmental and enforcement decisions on CRL-generated data that is considered to be scientifically sound and defensible. To help ensure the scientific soundness and defensibility of lab data, technical lab audits are conducted to examine a lab's data analysis operations and associated data quality procedures. Conducting such audits provide an assessment of the current status of lab operations and the quality assurance/quality control systems used by a lab. Regular or periodic use of technical audits serve to identify deficiencies in lab processes and quality assurance/quality control procedures and help identify actions necessary to correct deficiencies found. While the CRL recognizes the benefits of technical audits by including them as a requirement in their Quality Management Plan, no technical audits had been completed prior to the technical audit conducted in conjunction with this audit.

At the Regional Administrator's request, an external technical audit was conducted at the CRL during August 1999. Questions of the scientific soundness and defensibility of CRL data analyses had arisen as a result of the alleged improper data manipulation by two CRL analysts being investigated by the OIG's OI. An audit team was assembled in response to this request consisting of personnel from Regions 1,2,3,4,6,7 and the National Enforcement Investigations Center (NEIC). Examples of areas reviewed by the team included, but were not limited to, chain of custody procedures, instrumentation/equipment maintenance, quality assurance protocols, data review process, and lab operating conditions. Audit findings identified both critical and non-critical areas in need of corrective action at the CRL and verified the need and importance for such technical audits. Performing periodic technical reviews will help ensure consistent data quality and reinforce the Region's confidence in the scientific soundness and defensibility of CRL-generated data.

Recommendation

2.1 We recommend that the ARA for the RMD arrange for periodic, independent, and unannounced technical reviews of laboratory data. Such reviews should be performed no less than once every three years.

Region 5 Response

The need for and method for conducting and resourcing such reviews is currently a topic of discussion among the community of regional laboratories and among the Regional Science and Technology Directors and the Agency's Office of Regional Operations. Region 5 will participate in the process that develops from those discussions.

CRL Can Improve Overall Planning

Beyond routine analysis of samples, CRL also performs additional longer-term projects for the program offices such as method development for Selenium analysis and studies such as the ongoing Endocrine Disruptor project. They also are responsible for conducting a number of other functions such as validating methods, exploring new analysis methods, updating Standard Operating Procedures, maintaining historical QC charts, and developing analysis control charts as well as other functions. From discussions with CRL personnel and reviewing the MSR, we found that there was no long-term planning for such projects; rather they are fit in around routine sampling activities. According to the MSR, however, routine sampling takes precedence over such projects. Further, the MSR found that when the lab agrees to do such projects, they are often open-ended agreements without milestones and due dates. These projects may require CRL management to devote staff, provide specialized training, acquire additional equipment, as well as requiring close coordination with program offices. While these projects and activities are consistent and necessary to carry out the lab's mission, we found they are not being given equal priority when compared to sample analysis. According to the MSR, these activities "help increase user and staff confidence and build the capability and capacity of the CRL for the Region. Quality control activities must not be side-lined to accommodate sample analysis productivity. If this were to continue, data of unknown and questionable quality will result." Strengthening and maintaining the credibility of the lab will require a concerted effort by lab and Regional management to balance the demand for long- and short-term projects with routine sample analysis.

Recommendation

2.2 We recommend that the CRL Director and staff, the CRL Board of Directors, and the ARA develop a plan for both short- and long-range activities for the lab.

Region 5 Response

The CRL Director and Deputy Director will work with CRL and the CRL Board to develop an inventory of the projected short- and long-term programmatic and scientific needs and anticipated directions of the various programs that utilize the CRL. As part of this effort, the CRL management and a subgroup of the CRL Board will meet with program Branch Chiefs and Division/Office Directors to gain their direct input to discuss the relative priorities of the various needs. Based upon these discussions and the inventory compiled, the CRL management and Board will develop a framework for a long-term plan that will guide CRL facility and staff development, capital equipment replacement and acquisition, CRL and program interactions, and all CRL analytical and data management operations. Upon approval of the framework by the Region's senior leadership, CRL and program managers and staff will be tasked to develop and implement the various processes and activities necessary to complete and carry out the plan.

Better Communication Needed

Interviews with CRL staff and management revealed an overall frustration with being disconnected from the Region. In our opinion, the need for better communication between CRL staff and Regional program offices contributed to this frustration. Generally, CRL staff are not informed of the specific use of data analyses they are performing for program offices. In addition, CRL analysts are unaware of the actual program decisions and results achieved from the data analyses they generate. Several CRL staff members cited low morale in the lab as a result of not understanding their role and importance to the Region. One CRL staff member described his frustration by saying that we are "being treated like an unwanted stepchild." More frequent communication between CRL staff and regional program offices should help alleviate this frustration by helping the CRL staff better understand the purposes and intended uses of their work and value to the Regional program offices.

CRL staff also expressed concern about the lack of interaction between CRL personnel and all levels of management. We found little evidence of interaction between CRL staff and management, not only within the lab but also at the higher regional organizational levels. Again, more frequent communication and increased interaction between CRL staff and all levels of management should increase morale and help CRL staff better understand their role and importance to the Region.

Recommendation

2.3 In order to address the need for better communication between CRL staff, management, and Regional program offices, the ARA for RMD should hold periodic meetings with all CRL personnel to help CRL staff better understand the value of their role within the Region.

Region 5 Response:

The CRL Director has committed to meet monthly with all CRL personnel and the ARA will attend at least one of those meetings each quarter. In addition, the RA, DRA, and other Regional Senior Managers will be invited to meet with CRL personnel at various times throughout the year.

APPENDIX 1

October 12, 1999

M-9J

MEMORANDUM

SUBJECT: OIG Review of Region 5 Laboratory Operations

FROM: Norman R. Niedergang \s\
Assistant Regional Administrator for Resources Management

TO: Patrick Gilbride
Office of Inspector General (2443)

I wish to thank you again for the work that you and your associates performed in carrying out the Review of Region 5 Laboratory Operations. Your findings and recommendations will be of great assistance to us in taking the steps necessary to ensure that our customers can have full confidence in the integrity and accuracy of the work carried out on their behalf at the Region 5 Central Regional Laboratory.

Attached to this memo is a response to the recommendations that you outlined in your September 23, 1999, briefing for Frank Lyons, our Regional Administrator. As you will see, we have already undertaken a number of actions to implement those recommendations.

In addition, I have attached a copy of our revised Corrective Action Plan which integrates those actions that we are undertaking as a result of our earlier Management Systems Review with those resulting from the findings and recommendations of your review. We will be updating the Corrective Action Plan on a quarterly basis to track the implementation and effectiveness of the actions.

If you have any questions about the attachments or wish to discuss other matters concerning the Review, please feel free to call me at (312) 886-7437, or Barry DeGraff at (312) 886-0147.

Attachments

cc: Francis X. Lyons, Regional Administrator
David A Ullrich, Deputy Regional Administrator

Region 5 Response to Recommendations of the Office of Inspector General from its Review of Region 5 Laboratory Operations Presented in the September 23, 1999 Briefing for Francis X. Lyons, Region 5 Administrator

OIG RECOMMENDATION: The CRL Director revise the corrective action plan to ensure that actions are responsive in addressing the findings of the MSR. The plan should also be revised to reflect current estimated time frames for completion. The new plan should be approved by the ARA for RMD.

> **REGION 5 RESPONSE:** The corrective action plan has been revised to more directly respond to the findings of the MSR and has been expanded to integrate additional findings from the OIG review. Time frames for the corrective actions have been reviewed and, if necessary, revised to reflect our current realistic expectations for achievement. The ARA has approved the revised Integrated Corrective Action Plan, and he has assigned an Associate Director of the RMD to work with the CRL Director in assuring that the actions are, indeed, responsive to the issues and effective in their implementation.

OIG RECOMMENDATION: The CRL Director assign responsibility for addressing individual corrective actions to appropriate CRL staff. The director will ensure that staff are allotted sufficient time to devote to addressing the corrective actions and are held accountable for their completion.

> **REGION 5 RESPONSE:** The revised Integrated Corrective Action Plan assigns both primary and support/oversight responsibility for each of the actions outlined. Completion of the Integrated Corrective Action Plan has been identified as the top priority for all managers and staff of the CRL, and no additional samples will be accepted at CRL until all of the corrective actions addressing critical weaknesses have been completed. Thereafter, the time necessary to complete or carry out continuing corrective actions will be factored into the plans and schedules for initiating new work in the CRL. The ARA, the Associate Director of RMD, the CRL Director, and the CRL Deputy Director will all ensure and share in accountability for completion of the corrective actions.

OIG RECOMMENDATION: The CRL Director develop a tracking system to monitor progress in addressing the corrective actions.

> **REGION 5 RESPONSE:** The Integrated Corrective Action Plan will serve as the primary tool for tracking and monitoring progress in addressing the corrective actions.

OIG RECOMMENDATION: The CRL Director provide the ARA, on a quarterly basis, a status report on the corrective actions taken with explanations for any missed milestones. The report should include a section describing the effectiveness of corrective actions taken in addressing the findings from the MSR.

REGION 5 RESPONSE: The CRL Director will meet on a monthly basis with the ARA and Associate Director to report on the status of corrective actions, including explanations on any failures to adhere to established time frames and on the effectiveness of the actions undertaken. The ARA will provide quarterly status reports to the Regional Administrator and the Region's Senior Leadership Team.

OIG RECOMMENDATION: The QA Core conduct a follow-up review of the MSR to determine the effectiveness of corrective actions taken by the beginning of calendar year 2001.

REGION 5 RESPONSE: The QA Core had originally proposed such a follow-up to the MSR, and the ARA will task the Regional QA Manager with completing the follow-up review by the end of fiscal year 2000. In addition, the QA Core has been instructed to work with the CRL QA Coordinator to report any quality assurance concerns about CRL activities directly to the ARA.

OIG RECOMMENDATION: The CRL Director and staff, the CRL Board of Directors, and the ARA develop a long term plan for the CRL.

REGION 5 RESPONSE: The CRL Director and Deputy Director will work with CRL and the CRL Board to develop an inventory of the projected short and long-term programmatic and scientific needs and anticipated directions of the various programs that utilize the CRL. As part of this effort, the CRL management and a subgroup of the CRL Board will meet with program Branch Chiefs and Division/Office Directors to gain their direct input to discuss the relative priorities of the various needs that are identified. Based upon these discussions and the inventory compiled, the CRL management and Board will develop a framework for a long-term plan that will guide CRL facility and staff development, capital equipment replacement and acquisition, CRL and program interactions, and all CRL analytical and data management operations. Upon approval of the framework by the Region's senior leadership, CRL and program managers and staff will be tasked to develop and implement the various processes and activities necessary to complete and carry out the plan.

OIG RECOMMENDATION: Until the Resource Management Division is reorganized, the QA Core should report any activities involving CRL directly to the ARA.

> **REGION 5 RESPONSE:** The QA Core has been instructed to report any activities involving CRL directly to the ARA and the Associate Director of RMD.

OIG RECOMMENDATION: The ARA for RMD arrange for periodic, independent, and unannounced technical reviews of laboratory data. Such reviews should be performed no less than once every three years.

> **REGION 5 RESPONSE:** The need for and method for conducting and resourcing such reviews is currently a topic of discussion among the community of regional laboratories and among the Regional Science and Technology Directors and the Agency's Office of Regional Operations. Region 5 will participate in the process that develops from those discussions.

OIG RECOMMENDATION: The ARA for RMD hold periodic meetings with all CRL personnel.

> **REGION 5 RESPONSE:** The CRL Director has committed to meet monthly with all CRL personnel and the ARA will attend at least one of those meetings each quarter. In addition, the RA, DRA, and other Regional Senior Managers will be invited to meet with CRL personnel at various times throughout the year.

INTEGRATED CORRECTIVE ACTION PLAN FOR THE SEPTEMBER 1998 INTERNAL MSR AND JUNE 1999 OIG MSR

October 12, 1999

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
1B-Little management oversight of day to day laboratory operations	Develop list of oversight activities for lab operations. Develop implementation schedule with responsibilities	November 15, 1999	On-going	CRL Director Deputy Director	Group Leaders	
OIG Management Bullet #1 - Oversight activities not developed or done	See 1B.	November 15, 1999	On-going	CRL Director Deputy Director	Group Leaders	
1C-1-Confusion about supervisory responsibilities by lab staff	1. Change Management of analysts through redefining duties of Group Leaders. 2. Establish Deputy Director Position	January 30, 2000 August 29, 1999	Initial Initial	Deputy Director CRL Director	CRL Director ARA	 Completed
OIG Management Bullet #2- Organic Team Leader rarely present in the lab	A draft organizational plan will replace Team Leaders with 5 Group Leaders for better oversight in the lab	January 1, 2000	Initial	Deputy Director	CRL Director	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
1C-2-Team Leader and Group Leaders' performance agreements need to be updated to reflect duty reassignments	Update Group and Team Leaders' Perf. Agreements to reflect changes from 1C-1	January 30, 2000	Initially and then as needed	Deputy Director	CRL Director	
OIG Management Bullet #3- Organic Team Leader does not always review data packages	The data review process is under review, responsibilities will be redefined and streamlined.	January 1, 2000	Initial	Deputy Director	CRL Director	
OIG Management Bullet #4- No detailed reviews by management were conducted after the alleged incidents were discovered	1. Training for fraud detection and prevention will inform lab staff, management and other data reviewers about these procedures 2. Data review SOPs and processes will be revised to include these procedures	October 20, 1999 January 1, 2000	Initial & Annual Ongoing	CRL Director Group Leaders	Deputy Director QA Coord	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
OIG Management Bullet #5, #6, #7, #8 - Roles and responsibilities of Group Leader and Team Leader authority regarding CRL staff are not defined	See 1C-2. 1 to 1 discussions with CRL staff about workload, SOP development and supervision occurred Group and Team Leader performance standards will be revised. Draft Organization Plan developed	October 1, 1999 January 30, 2000 October 1, 1999	Initial Initial Initial	Deputy Director Deputy Director Deputy Director	CRL Director CRL Director CRL Director	Completed Completed
1E-1 - Problems with samples are not communicated adequately from the field or the lab	Update SOP for Sample Scheduling to allow for better two-way communication of field or lab problems. Programs will be contacted for discussion of this with their management	January 1, 2000	Annual	QA Coord	CRL Director	
1E-2 - There is a need to plan analysis batches to allow for real time QC data evaluation in order to rerun samples with QC problems before sample holding times expire.	Re-evaluate sample analysis batch processes to be able to evaluate QC data in real time.	January 1, 2000	On-going	Analyst	QA Coord Deputy Director	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
1E-3 - Ensure CRL and Contractors are documenting all problems and routine maintenance of instruments in dedicated instrument log books	Establish separate logbooks for CRL and Contractors and review implementation	September 30, 1999	On-going	Group Leaders	QA Coord	Completed
1F-1 - Historical data must be used to establish current QC limits	Establish QC Policy using historical data and implementation schedule will be developed	November 15, 1999	Initial and then as needed	QA Coord	Deputy Director CRL Director	
1F-2 - Sample capacity and method development for new capabilities are not given equal priority	A CRL policy to prioritize workload activities based on program needs will be developed and put in the QMP after discussion with Board of Directors	February 1, 2000	Initial	QA Coord	Deputy Director CRL Director Board of Directors	
2A-1 - Analysts not involved in project planning/Data Quality Objectives (DQO) process for project development	Request for involvement with DQO process will be made to the programs through the Board of Directors. Implementation will follow.	January 1, 2000	On-going	Deputy Director QA Coord	CRL Director Group Leaders Board of Directors	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
OIG Communication Bullets #2 and #3 - No dialog between analysts and program staff to identify project needs and impact of analytical results	See 2A-1	January 1, 2000	On-going	Deputy Director QA Coord	Group Leaders	
2A-2 - No sample rejection policy is documented if QAPP is not approved for a project	Based on current Agency and Regional policies, an approved QAPP will be required and documented in the CRL QMP as a CRL Policy for acceptance or rejection of samples.	November 15, 1999	Initial	QA Coord	CRL Director	
OIG Communication Bullet #1 - QAPP not forwarded with samples as required	See 2A-2. Policy statement and documentation requirements to demonstrate compliance will be discussed with program management before implementation	January 1, 2000	Initial	CRL Director	QA Coord	
3A-1 - Analytical SOPs are out of date	CRL staff will update all SOPs.	January 20, 2000	Initial and then as needed.	Analyst	QA Coord Deputy Director	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
3A-2 - Need to schedule periodic SOP reviews	SOPs will be reviewed annually to determine if revisions are required	October 1, 1999	Initially and as needed	Analysts	QC Coord Group Leaders Deputy Director	Complete
3A-3 - Establish policy for SOP revisions	See 3A-2. This will be incorporated as the SOP revision policy and it will be added to the CRL QMP	November 15, 1999	Initial	QA Coord	Deputy Director	
3B - MDLs are not up to date for all methods or have not been done.	1. A CRL MDL procedure is established. 2. The procedure will be implemented.	October 1, 1999 January 20, 2000	Initial On-going	QA Coord Analyst	Deputy Director Deputy Director QA Coord	Complete
OIG Policies and Procedures Bullets #1 and #2 - Many SOPs not developed or updated. SOP revisions not tracked	See 3A-1, 3A-2, 3A-3 and 3B SOPs will be filed and tracked.	January 20, 2000	Initial and On-going	Analyst	QA Coord Group Leaders Deputy Directors	
3C-1 - Data review SOPs need to be written for all analyses at CRL	Data review SOPs will be developed	January 1, 2000	Initial	Group Leaders	Analysts QA Coord	
4A-1 - Statistical software package needed to evaluate QC data	Acquire a statistical software package to allow CRL staff to evaluate QC data of all types more easily and in real time.	February 1, 2000	Initial	Group Leaders	Deputy Director	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
4A-2 - QC limits are not included in analytical SOPs	QC limits using historical data will be documented in analytical SOPs.	January 20, 2000	Initial and then as needed	Group Leaders Analyst	Deputy Director QA Coord	
4A-3 - No CRL policy on QC limits	CRL Policy on criteria for QC limits will be developed and put in CRL QMP	November 15, 1999	Initial	QA Coord	Deputy Director	
4B-1 - No QA training program for CRL on QA/QC practices	A QA training program will be established and documented in the CRL QMP	November 15, 1999	Annual	QA Coord QA Core	Deputy Director Group Leaders	
4B-2 - QA training not in analyst performance standards	Performance standards will be revised to reflect QA training	January 30, 2000	Annual	Deputy Director	CRL Director	
OIG Understanding Value of QC Bullets #1, #2, #3 - Analysts do not have a complete understanding of their roles and responsibilities for QA activities	See 4B-1 and 4B-2. Training will include Basic Introduction to QA for the CRL, MDL Procedure, Fraud detection and prevention and others to be developed.	October 20, 1999	Initially, through the year, then annually (as refreshers)	Deputy Director QA Coord	QA Core	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
5A - Sample Preservation checks are not being done at time of sample receipt	Sample receipt and Chain of Custody SOP will be updated to include preservation checks	January 1, 2000	Initial and then as needed	Sample Custodian	QA Coord Data Coord	
5B-1 - Bags of old sample tags need to be filed	All older sample tags will be stored in their respective data files	April 1, 2000	On-going	Data Coord	Sample Custodian CRL Director	
5B-2 - Data archival SOP is out of date	Update data archival SOP and data custody procedures	January 1, 2000	Initial and then as needed	Data Coord	QA Coord	
OIG Sample Handling, Chain of Custody, Data Archival Bullets #1, #2, and #3 - Sample tags not stored with data files, data custody outdated, incomplete bench sheets	1. See 5B-1 (sample tags) 2. See 5B-2 (Data custody procedures) 3. Bench sheets will be revised to include sample preparer identification	April 1, 2000 January 1, 2000 November 15, 1999	On-going Initial & as need On-going	Sample Custodian Data Coord Analysts	CRL Director CRL Director Deputy Director	
5C1 - Not following records retention schedule for archiving data	Implement a schedule for archival of records to the Federal Records Center	December 1, 1999	Initial and On-going	Data Coord	CRL Director	

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
5C2 - Electronic sample data records do not exist for some analyses	CRL has determined what electronic data are available and they are located in each Group	August 30, 1999	Initial	Group Leaders	Computer Specialist	Completed
5C3 - No documented responsibility of electronic records	1. Electronic data/record storage policy and SOP is established. 2. Policy will be added to QMP.	July 15, 1999 November 15, 1999	Initial Initial	Dyntel QA Coord	Computer Specialist CRL Director	Completed
5C4 - No central location exists to secure electronic data	CRL has installed a central file server to store electronic data	July 15, 1999	Initial	Computer Specialist	CRL Director	Completed
6A-2 - There is no QA training program for analysts	A QA training program will be established and documented in the CRL QMP See 4B-1.	November 15, 1999	Initial	QA Coord	Deputy Director CRL Director QA Core	MDL training completed Fraud Prevention scheduled Intro to QA scheduled CRL-specific QA in development

MSR Findings	Proposed Corrective Action (CA)	Implementation		Corrective Action Responsibility		Status
		Date	Frequency	Primary	Support / Oversight	
OIG Analyst Training Bullet #1, #2, #3- No QA/QC training program exists, this was identified by QAD in their MSR. Minimal training funds are available to the lab	See 6A-2, above The training in 6A-2 is in-house training with little or no cost.	November 15, 1999	Initial and On-going	QA Coord	Deputy Director CRL Director QA Core	
6B-1 - CRL has an ineffective cross training program for analysts	A cross training policy for analysts will be established for within Groups and added to the CRL QMP.	November 15, 1999	Initial and On-going	Deputy Director QA Coord	CRL Director	
6B-2 - No proficiency test program exists for analysts	An analyst proficiency program will be established and documented in the CRL QMP. It will include an MDL study, initial demonstration of capability (IDOC) study and periodic PE sample analyses. Tracking system established.	January 1, 2000 October 1, 1999	Initial and then as needed On-going	QA Coord QA Coord	Group Leaders CRL Director	 Complete

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Appendix 2

CRL CORRECTIVE ACTION PLAN FOR THE 1998 MANAGEMENT SYSTEMS REVIEW[1]

January 12, 1999

Proposed Corrective Action (CA)	CA Implementation Schedule		
	Start	**End**	**Periodic**
Finalize 1998 Revised CRL QMP	7/12/98	1/31/99	annual
Hold Staff Mtg. to discuss QS roles & responsibilities, Distribute Final MSR report, Distribute 1998 CRL QMP	1/14/99	1/31/99	
Develop list of oversight activities for lab operations w/implementation schedule	1/4/99	3/31/99	on-going
Check laboratory equipment for presence and or use of out dated equipment. [Lab Walk Through]	1/4/99	3/31/99	annual
Change management of technical staff thru organizational structure or rearranging duties of Group, Team Leaders and Lab Director	12/98	1/31/99	
Update Group and Team Leaders' performance agreements to reflect changes above.	12/98	1/31/99	bi-annual
Hold staff meetings to inform them of roles and resp. Under new Quality System, including QA and QC act.	1/14/99	1/31/99	

[1] This corrective action plan has been modified from its original version to include only relevant information on proposed corrective actions and milestones for completion.

Proposed Corrective Action (CA)	CA Implementation Schedule		
	Start	End	Periodic
Update performance agreements to reflect changes, above.	12/98	1/31/99	bi-annual
Update SOP for sample scheduling to allow for field and or lab problems	1/4/99	1/31/99	annual
Plan analysis batches to allow for real time QC data evaluation in order to rerun samples with QC problems before hold times expire.	1/4/99	9/30/99	
Ensure CRL and contractors are documenting all problems and routine maintenance of instruments in dedicated instrument log books	1/4/99	1/31/99	
Real QC limits and practices must be implemented & documented	1/4/99	9/30/99	annual
Sample scheduling and method development for new capabilities given equal priority	1/4/99	3/31/99	
DQO & sample scheduling process should involve CRL analysts	Now	3/31/99	on-going
Sample request Quality Assurance Project Plan requirement should be placed in QMP as a CRL Policy, with consequences if it is not.	Now		

Proposed Corrective Action (CA)	CA Implementation Schedule		
	Start	**End**	**Periodic**
Team and Group Leaders need to be aware of Data Quality Objectives for projects and project as a whole to under-stand their role and make proper scientific assessments of the sample and data	Now	3/31/99	on-going
CRL staff need to update all Standard Operating Procedures (SOPs).	6/97	9/30/99	annual
CRL Team Leaders and Management need to schedule SOP reviews at least annually for all SOPs	7/1/99	9/30/99	annual
SOP revision policy needs to be added to the CRL QMP	Now		
A CRL Method Detection Limit procedures need to be established, referenced within all analysis SOPs and conducted on all instruments at least annually.	1/4/99	1/31/99	
Data review SOPs need to be written for all analyses at CRL	1/4/99	9/30/99	
Offer data validation as a service to CRL customers, write data validation SOPs similar to CLP Functional. Guides	Future	Future	

Proposed Corrective Action (CA)	CA Implementation Schedule		
	Start	End	Periodic
Cross training program within each lab (room or group) at CRL to ensure redundant coverage should someone be on leave or travel. Management policy instituted to restrict a primary analyst and his or her backup from both being on leave at the same time.	1/4/99	1/31/99	
Acquire a statistical software package to allow CRL and contract staff to evaluate QC data of all types more easily and in real time.	1/4/99	9/30/99	
Update analytical SOPs to include QC criteria	6/97	9/30/99	annual
Add CRL policy on frequency and decision criteria for updating QC limits.	1/4/99	3/31/99	
Establish QA training courses for CRL on QA/QC practices specific to each analysis type.	1/4/99	9/30/99	
QA/QC training added to requirements of the job (performance standards) of Team /Group Leaders, and analysts.	1/4/99	1/31/99	annual
QA/QC training requirements as a policy in QMP.	1/4/99	3/31/99	
Update sample receipt and Chain of Custody (CoC) SOP and include preservation checks, arrangements for bottles and transport arrangements	1/4/99	3/31/99	

Proposed Corrective Action (CA)	CA Implementation Schedule		
	Start	End	Periodic
File all older sample tags in data files	1/4/99	9/30/99	
Update data archival SOP and CoC procedures	1/4/99	3/31/99	
CRL needs to develop schedule or procedure to follow records retention schedules for all data to keep data storage space free and comply with those schedules	"	"	
CRL evaluate the availability of historical electronic records	1/4/99	3/31/99	
CRL establish electronic data/record storage policy and SOP	1/4/99	3/31/99	
CRL establish data security policy and procedures	"	"	
CRL establish procedures and policies to retrieve data generated with out of date hardware and software	"	"	
CRL policy needs to be established for training.	1/4/99	3/31/99	
Establish a QA training program	1/4/99	9/30/99	
Establish a cross training policy with-in groups	1/4/99	3/31/99	
Update analyst qualification with performance evaluation materials and establish frequency, proficiency for such materials.	1/4/99	9/30/99	annual

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Appendix 3

Distribution

Inspector General
Deputy Inspector General for Audit
Deputy Inspector General for Investigations
Divisional Inspector General, Central Investigations Division
Deputy Regional Administrator, Region 5
Assistant Regional Administrator for Resources Management, Region 5
Director, Central Regional Laboratory, Region 5
Director, Office of Regional Operations
Audit Coordinator, Region 5
Agency Follow-up Coordinator, Attn: Director, Resource Management Division
Director, Environmental Science and Assessment Division, Region 2