REPORT OF

THE

STATE AUDITOR

Department of Public Health
and Environment
Laboratory and Radiation Services Division

Performance Audit
May 2002

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STATE OF COLORADO

Joanne Hill, CPA
State Auditor

OFFICE OF THE STATE AUDITOR
(303) 866-2051
FAX(303)866-2060

Legislative Services Building
200 East 14th Avenue
Denver, Colorado 80203-2211

May 9, 2002

Members of the Legislative Audit Committee:

This report contains the results of a performance audit of the Laboratory and Radiation Services Division within the Colorado Department of Public Health and Environment. The audit was conducted pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government. The report presents our findings, conclusions, and recommendations, and the responses of the Department of Public Health and Environment.

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STATE OF COLORADO
OFFICE OF THE STATE AUDITOR **REPORT SUMMARY**

JOANNE HILL, CPA
State Auditor

Department of Public Health and Environment
Laboratory and Radiation Services Division
Performance Audit
May 2002

Executive Summary

By statute the Colorado Department of Public Health and Environment is authorized to establish chemical, bacteriological, and biological laboratories to conduct investigations and examinations for the protection of the public health. Each year, the Department's Laboratory and Radiation Services Division (The Laboratory or Division) receives approximately 250,000 specimens for testing at its main laboratory in Denver and its two branch labs in Durango and Grand Junction. The Division's testing services include analyses for rabies, sexually transmitted diseases, newborn genetic disorders, urine drug analysis, environmental contaminants, and blood alcohol content. Among the significant findings and recommendations resulting from our audit are:

- **There is no clear relationship between the Laboratory's fees and its associated costs for testing services.** Therefore, general funds subsidize the costs for services that might otherwise be cash-funded. Although the Laboratory is primarily cash-funded through revenue from the 139 fees it assesses, we identified cases where fees do not cover the costs for testing services in spite of statutory mandates. The Department needs to routinely and thoroughly evaluate Laboratory costs and ensure fees are set appropriately and in keeping with statutory intent.

- **Improvements in various accounting activities could reduce costs and increase revenue.** The large volume of samples received and tests conducted at the three Laboratory facilities, in addition to the number of fees assessed, invoices processed, and revenues collected, necessitate sound accounting practices. We identified opportunities to improve customer billing, past due accounts collection, sample testing and accounts receivable reconciliation, and branch lab oversight.

- **The Laboratory does not have a uniform sample management system for use in tracking samples, monitoring the status of testing, or for compiling data on the 250,000 specimens it processes each year.** Consequently, comprehensive sample information is either unavailable or is laborious to obtain. The Laboratory is in the process of implementing a new sample management system. The Department needs to commit to a time line for full implementation and to ensure all necessary data elements are addressed and all lab units adopt standard data entry and recording practices.

For further information on this report, contact the Office of the State Auditor at (303) 869-2800.

- **The costs and benefits of the two branch labs are unclear.** Compared with the main Laboratory in Denver, the Division's branch laboratories, located in Durango and Grand Junction, conduct limited testing in terms of numbers and types of tests. In addition, less than one-half (48 percent) of the branch labs' expenditures are recovered through fee revenues. We also found that many, if not all, of the tests conducted at the branch labs could be conducted elsewhere. The Department should assess the costs and benefits of the branch labs to ensure they are cost-effective and provide a benefit to the public.

We make 13 recommendations for improving these and other Laboratory activities and operations to which the Department of Public Health and Environment fully or partially agrees. A summary of the recommendations and the Department's responses can be found in the Recommendation Locator on the following page. Our complete audit findings and recommendations and the responses of the Department of Public Health and Environment can be found in the body of the audit report.

RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
1	14	Ensure Laboratory fees are set in accordance with statutory mandates by regularly evaluating the costs for Laboratory testing; ensuring various revenue sources are used appropriately; and proposing legislative, regulatory, or other fee and revenue changes, as needed.	Department of Public Health and Environment	Agree	10/31/02
2	18	Improve billing practices by evaluating prepayment options and adopting a monthly billing cycle.	Department of Public Health and Environment	Agree	Implemented
3	22	Improve efforts to collect outstanding receivables by referring past due accounts to Central Collections, shortening its due date period, developing a system for identifying accounts receivable, reconciling internal records, changing "write-off" policies, and implementing a prior audit recommendation to ensure the adequacy of accounts receivable software.	Department of Public Health and Environment	Agree	12/31/02
4	25	Implement standard accounting practices to reconcile samples received, tested, prepaid, or billed.	Department of Public Health and Environment	Agree	06/30/03
5	26	Improve oversight for accounting activities at the two branch labs by implementing adequate internal controls such as terminating the practice of sending cash though the mail and periodically reconciling revenues with tests conducted.	Department of Public Health and Environment	Agree	07/01/02
6	28	Improve Laboratory revenue estimates by implementing and documenting a process for identifying cash revenue collections, including an evaluation of fee revenue trends.	Department of Public Health and Environment	Agree	07/01/02

RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
7	34	Strengthen the quality assurance program by assessing existing policies and practices, implementing methods for monitoring systemwide compliance, and conducting internal audits.	Department of Public Health and Environment	Agree	06/01/02
8	38	Implement a comprehensive, centralized specimen management system that provides accurate, accessible tracking and other information.	Department of Public Health and Environment	Agree	06/30/03
9	42	Assess operations at the branch laboratories to ensure they are cost-effective and provide a benefit to the public. This should include assessments of the need for testing services, availability of other methods for meeting public needs, costs, and methods of providing oversight for service delivery.	Department of Public Health and Environment	Agree	12/31/02
10	44	Improve customer service by developing hard-copy and electronic user manuals including complete information on services and tests available, fees, turnaround times, and testing procedures and forms.	Department of Public Health and Environment	Agree	10/31/02
11	45	Determine whether the use of customer surveys is a cost-effective method of obtaining customer feedback.	Department of Public Health and Environment	Agree	12/31/02
12	47	Determine which equipment and instruments should be regularly inventoried, define inventory requirements in the Quality Assurance Manual, and ensure staff comply with inventory requirements.	Department of Public Health and Environment	Partially Agree	10/31/02
13	48	Focus training efforts and resources by identifying training needs and priorities and maintaining training records and budgets.	Department of Public Health and Environment	Agree	06/30/02

Note: Implementation date for recommendations with multiple parts is date of full implementation.

Background and Description

Division Authority and Structure

The Colorado Department of Public Health and Environment (CDPHE or the Department) is statutorily authorized to establish, maintain, and approve chemical, bacteriological, and biological laboratories, and to conduct such laboratory investigations and examinations as it may deem necessary or proper for the protection of the public health. The Department's Laboratory and Radiation Services Division (the Laboratory or the Division) is the agency responsible for discharging these statutory directives.

The Division's current organizational structure was established in 1997 when the Radiation Control Division and the Emergency Management Program were combined within the Division of Laboratory Services. Generally, the Division's functions are organized into four programmatic areas:

- **Director's Office.** The Director's Office provides support and direction through five sections: administration, business management, technical information program, building operations, and quality assurance.

- **Laboratory Services.** Laboratory testing is conducted in two primary areas–chemistry and microbiology. The Chemistry program conducts tests to protect public health and the environment from chemical contamination such as pesticides, heavy metals, and cancer-causing chemicals in drinking water, soils, and other compounds. The Microbiology program's testing is directed at protecting against communicable diseases, reducing the adverse effects of inborn metabolic defects, and protecting the environment and the food supply against biological and chemical contaminants. Laboratory Services' staff also investigate disease outbreaks.

- **Radiation Services and Certification Program.** This program inspects and monitors approximately 4,000 X-ray facilities and 2,500 clinical, environmental, and dairy laboratories statewide. The program also trains and certifies law enforcement operators of alcohol breath-testing devices used in Colorado as well as certifying, maintaining, and repairing such devices.

- **Radiation Services and Management Program.** Among its responsibilities, this program licenses hospitals, industries, government agencies, and universities

that use radioactive materials. In addition, Radiation and Management staff promote public awareness and testing of radon.

The Division's main laboratory facility is located in the Lowry Development Authority Complex in Denver. The Division also operates two branch labs in Durango and in Grand Junction.

Laboratory Testing Program

The Division's main laboratory facility and the two branch labs receive approximately 250,000 specimens for testing each year. Specimens include soil, food, dairy products, drinking or waste water, and tissue/blood samples from humans or animals. Depending upon the type of test needed, specimens are analyzed by one of the following units within the Chemistry and Microbiology programs.

Chemistry

Environmental Radiation measures background radiation and detects contamination; also monitors for the safe usage of radioactive materials.

Environmental Chemistry comprises inorganic and organic chemistry tests. Inorganic chemistry tests include analyses of water, air filters, and plant effluents for man-made and naturally occurring pollutants. Organic chemistry tests analyze contaminants such as pesticides and herbicides in environmental samples and food stuffs.

Toxicology provides urine drug screens and blood alcohol analysis for law enforcement agencies and abuse programs, as well as providing courtroom testimony for local law enforcement.

Microbiology

Environmental Microbiology tests milk, drinking water, swimming water, and consumer products for bacterial contamination and other undesirable components.

Public Health Microbiology works in conjunction with other agencies to investigate food-borne outbreaks such as salmonellosis and shigellosis. The unit also conducts tests for sexually transmitted diseases.

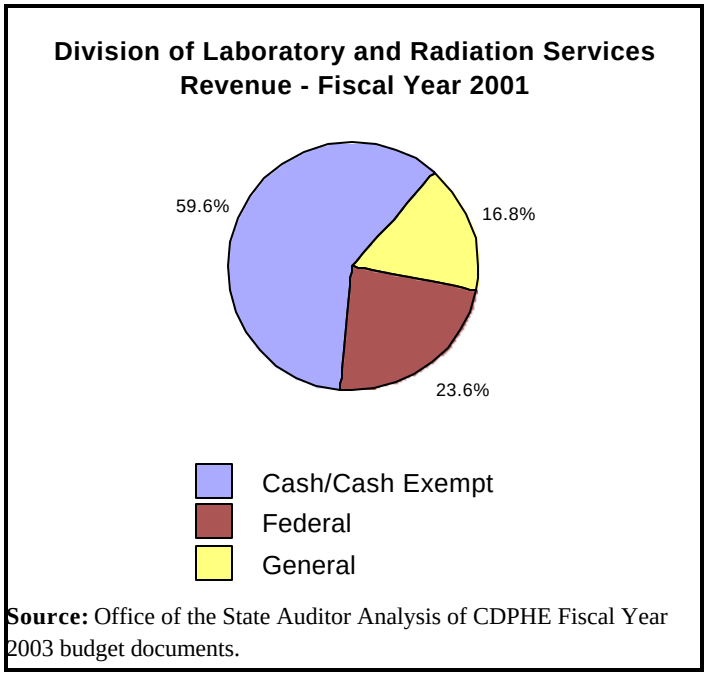
Serology/Virology analyzes blood specimens for premarital tests and for diseases of public health significance such as vaccine-preventable diseases; hepatitis A, B, and C; rubella; sexually transmitted diseases; and animal-borne diseases. The unit also conducts screening

and confirmation testing for HIV, and tests for outdoor-associated infections such as rabies, plague, and hantavirus.

Newborn Screening tests blood specimens for more than 60,000 newborns each year for six different genetic disorders.

Division Funding and Staffing

For Fiscal Year 2001 the Division received $8.6 million in revenue and employed 87.3 FTE. Almost 60 percent, or about $5.1 million, of the Division's funding was cash funds derived from fee revenue. General funds accounted for 17 percent ($1.4 million) and federal funds represented 24 percent ($2 million) of total revenue.



Source: Office of the State Auditor Analysis of CDPHE Fiscal Year 2003 budget documents.

Fees

The Division of Laboratory and Radiation Services has 139 different fees for the specimens it analyzes and the tests it conducts. Almost one-half of the fees (49 percent, or 68 of 139) are for Inorganic Chemistry tests. The single largest revenue generator, however, is the Newborn Screening Program. In Fiscal Year 2000 newborn screening tests generated 50 percent of the Division's cash revenue.

Statutes authorize the Executive Director of the CDPHE to assess fees for laboratory tests. In most cases, the Department can determine the amount of the fee. However, a few fees

such as those associated with the Newborn Screening program and X-ray inspections are set in statute. By statute, the fee for the newborn screening test is to be set at an amount sufficient to cover the costs for the initial test and for any follow-up tests and treatments. Increases in the newborn screening fee cannot exceed $5 at any single time, except that they may be adjusted annually to reflect changes in the Consumer Price Index (CPI). Fees for X-ray inspections are set at $30 and $50 for certification stickers and inspections, respectively. The remaining fee amounts are established through Department-level rules and regulations.

Prior to November 2001, there had been no changes in the amounts at which fees were set since Fiscal Year 1996. Effective November 1, 2001, the Department approved the Division's request to adjust fees based on the Denver/Boulder CPI for the past five years. Fees were increased by an average of about 20 percent per test. Without the increases, the Division estimated that laboratory testing would operate at an average loss of $5.94 per analysis, or about $7.5 million in total.

Purpose and Scope

The purpose of this audit was to review the efficiency and effectiveness of various Laboratory and Radiation Services Division operations. Our review focused primarily on the Division's planning and management activities as they relate to laboratory operations, fiscal administration, and customer service. Audit procedures included reviewing documentation, analyzing data, and interviewing staff at the Laboratory and Radiation Sciences Division, the Department of Public Health and Environment, and other agencies and organizations. Audit work was performed from May 2001 through December 2001.

We would like to acknowledge the staff at the Laboratory and Radiation Services Division and the Department of Public Health and Environment for their efforts and cooperation during the audit.

Fiscal Management

Chapter 1

Background and Overview

Cash funds are the Division's single largest funding source. As the following exhibit shows, in Fiscal Year 2001 almost 60 percent, or $5.1 million, of the Division's total revenue derived from cash sources, primarily fee revenue. In addition, between Fiscal Years 1999 and 2001, the Division's spending relative to cash funds grew at a faster rate than its federal and general fund spending.

Division of Laboratory and Radiation Services
Expenditures by Funding Source
Fiscal Years 1999-2001

Fund	1999	2000	2001	Percent of 2001 Total	Percent Change 1999-2001
General	$ 1,311,785	$ 1,361,841	$ 1,442,302	16.8	9.9
Cash/Cash Exempt	4,411,241	4,533,457	5,098,102	59.6	15.6
Federal	2,101,560	2,032,151	2,020,066	23.6	-3.9
TOTAL	**$ 7,824,586**	**$ 7,927,449**	**$ 8,560,470**	100	9.4

Source: Office of the State Auditor Analysis of CDPHE and Joint Budget Committee documents.

The Division has 139 different fees for the various testing, licensing, and certification activities it conducts. Fees range from $1.85 for a streptococcus culture test to $65,000 for a radioactive materials license. Only 5 of the Division's 139 fees are specifically created in statute—Newborn Screening, streptococcus, and three fees associated with radiation licensing, certification, and control. The 134 other fees administered by the Division are established by the Department and/or the State Board of Health.

General Funds Subsidize the Costs for Testing

The Division does not routinely determine its costs for conducting testing activities. Consequently, fee revenue is not sufficient to cover costs. As a result, general funds subsidize the costs for testing services that might otherwise be cash-funded. For fees that are statutorily mandated, the General Assembly is clear in directing that fees be set at amounts sufficient to cover costs:

Newborn Screening. Section 25-4-1004 (2), C.R.S., states that the Executive Director of the Department of Public Health and Environment shall assess a fee which is ***sufficient to cover the costs of (such) testing and to accomplish the other purposes of the statute.*** In addition, Section 25-4-1004.5 (2)(b), directs that fee increases be ***sufficient to include the costs of providing follow-up and referral services*** (emphasis added). However, the increase is not to exceed $5, except that it may be adjusted annually to reflect any change in the Consumer Price Index.

Streptococcus. Section 25-4-1202 (1), C.R.S., directs the Executive Director of the Department of Public Health and Environment to "establish the fees to be collected for any streptococcus culture test performed by the Department." Also, the fees for the test ***"shall reflect direct and indirect costs"*** (emphasis added).

Contrary to statutory mandate, we found that for streptococcus testing, fee revenue falls significantly short of the Division's corresponding expenditures. In Fiscal Year 2001, streptococcus tests at the Grand Junction laboratory represented about 49 percent of that lab's total workload. Yet, revenues from the $1.50 streptococcus test (effective November 1, 2001, the fee was increased to $1.85) represented only about 12 percent of Grand Junction's total revenue. For the streptococcus test fee to have actually covered the estimated cost for conducting the streptococcus test, it would have to have been set at about $13, an increase of almost 770 percent, over the Fiscal Year 2001 fee amount. In the absence of sufficient fee revenue, general funds subsidize the costs for streptococcus testing in Grand Junction.

We found other examples where the costs for particular testing services exceed associated fee revenue. Although statutes do not expressly mandate that the costs for all Laboratory testing be entirely cash-funded, we question whether the use of general or other funds to subsidize deficiencies in cash funds is appropriate or in keeping with legislative intent in all cases. For example:

- **Parolee Urine Testing.** Statutes specify that as a condition of parole, every parolee ***at his own expense*** (emphasis added) is to submit to random chemical testing to determine the presence of drugs or alcohol. The Department is to set the fee to be charged for urine testing. In Fiscal Year 2001 the Toxicology Lab unit (which conducts the urine testing) did receive general fund support, in addition to cash funds, for its operations. It is unclear, however, whether general funds may have been used to finance any part of parolee urine testing. In addition, during the five months the Toxicology lab was shut down in the Year 2000, the Division contracted with a private laboratory for testing services. According to Division staff, the private lab's charges for testing services were higher than the Division's fees for performing similar tests. The Division did not pass along the additional charges to its customers. Rather, the Division made up the difference through other funding sources.

- **Premarital Blood Tests.** Colorado does not require premarital blood tests for rubella and syphilis. However, the Laboratory does conduct them on a limited basis. Colorado residents planning to marry in another state that requires the test may have their blood test performed by the Division and the results (per a reciprocal agreement among all states) will be accepted by the other state. In Fiscal Year 2000 the Laboratory conducted 78 rubella and 83 syphilis tests. The total costs associated with the tests were about $3,000. This compared with associated fee revenue of approximately $1,700. According to Laboratory staff, general funds were used to cover the deficit in cash revenue for premarital testing.

It should be noted that at the time of our audit, the Division did not compile or maintain complete revenue and expenditure data by test, by groups of tests, or by individual laboratory unit (serology, toxicology, chemistry, etc.). Therefore, it is difficult to determine with any accuracy or completeness the various revenue sources used to finance the Division's different tests or lab units.

Cost Data Are Essential for Setting Fees

The Division's lack of adequate cost information is not a new issue. In two prior audits (1989 and 1991) we found that the Division needed to develop a cost allocation system. Without a system for routinely evaluating and allocating costs, accurate, up-to-date information is not available, and the Division does not know whether:

- Fees are set appropriately to recover costs.

- Individual labs are operating cost-effectively.

- Particular tests are cost-effective or cost-prohibitive to perform.

- Services are provided efficiently or could be provided in a more efficient way.

Effective November 1, 2001, the Department approved an across-the-board increase for the Division's 139 fees. This was the Division's first fee increase in more than six years. As part of this fee increase process, the Division solicited input from Laboratory customers. Fees were increased based on the Denver/Boulder/Greeley Consumer Price Index (CPI) to reflect general cost-of-living increases between 1991 and 2002. As a result, all of the Division's fees increased by 20 percent.

Even during this fee increase process, the Department did not undertake a comprehensive evaluation of actual costs. Also, there is no documentation to support the basis for the Division's fees prior to the recent increase. Consequently, there is no way to determine whether an across-the-board increase was justified or whether some fees needed to be adjusted more or less than others. We did find, however, the recent fee increase from $1.50 to $1.85 for the streptococcus test will not be sufficient to cover its costs for this test, as mandated in statute. As previously stated, we estimate that the streptococcus fee would have to be about $13 (based on 2001 expenditure data) for the Division to recover its associated costs.

We also compared the Division's fees for tests with the fees charged for similar services at two private labs in the State. As shown in the following exhibit, we found that the Division's fees for nine randomly selected tests are significantly less than the fees charged by two private counterparts. The comparison with private laboratory fees is relevant in that it represents another factor the Division should consider in evaluating costs, setting fees, and assessing overall operations.

Laboratory and Radiation Services Division
Fee Comparison With Private Laboratories (1)

Test	Lab Unit	Division Fee	Private Lab A Fee	Private Lab B Fee	Fee Difference Per Test
Ethylene/Dibromochloro propane (EDB/DBCP)	Organic Chemistry	$102.00	NA (2)	$200.00	$98.00
Total Organic Carbon	Organic Chemistry	$60.00	NA	$75.00	$15.00
Total Suspended Solids	Inorganic Chemistry	$14.10	NA	$30.00	$15.90
Fecal Coliform	Environmental Microbiology	$30.60	NA	$80.00	$49.40
Volatile Organic Compounds (Air)	Organic Chemistry	$288.00	NA	$410.00	$122.00
Oil and Grease (Water)	Inorganic Chemistry	$68.40	NA	$150.00	$81.60
Urine Drug Confirmation	Toxicology	$32.10	$150.00	NA	$117.90
LSD Screen	Toxicology	$18.00	$50.00	NA	$32.00
Blood Alcohol	Toxicology	$18.00	$50.00	NA	$32.00

Source: Office of the State Auditor analysis of CDPHE data and data provided by two private laboratories.
Note: (1) Labs were randomly selected from a list of certified laboratories in the State.
(2) NA = Not applicable; test is not conducted.

Costs, Fees, and Funding Sources Need to Be Evaluated

Currently there is no clear relationship between the Department's Laboratory fees and its costs. Also, unless expressly stated in statute, the funding rationale for most of the Laboratory's operations is unknown. The Department should ensure that fees are set in accordance with statutory intent by:

- **Evaluating Costs**. As discussed above, costs should be regularly reviewed on a per test and/or per lab unit basis.

- **Assessing various fee options.** Fees should be assessed to determine whether they are sufficient to cover costs, both entirely or partially. This should include an assessment of fees and costs on an individual test basis, on a lab unit basis, or by grouping like testing services. In some cases, this might mean that fee amounts would be so high as to limit or prohibit the ability of some users to pay. Consequently, the Department could decide to eliminate certain tests, contract them out, or reduce the financial burden on users by identifying other funding sources. Currently there are 139 different fees for Laboratory services. Possibly, the Department could reduce this number and consolidate the fees for particular types of tests.

- **Identifying appropriate funding sources.** The majority of the Laboratory's fees are not referenced in statute. According to Division staff, the Lab operates under the assumption the Executive Director of the Department of Public Health and Environment has the authority to alter its fee structure based on the appropriations specified in the Long Bill. Although the general funds appropriated to the Laboratory are not necessarily earmarked for specific purposes, the Department has never clearly articulated to the General Assembly where general funds are being used. We identified at least two areas in which general funds appear to be subsidizing what should be cash-funded operations. We believe the Department should undertake a systematic review to determine whether existing funding streams are reasonable and in accordance with law. The Department should report to the General Assembly and propose legislative changes, where needed.

Recommendation No. 1:

The Department of Public Health and Environment should ensure that Laboratory fees are set in accordance with statutory mandates and in keeping with legislative intent by:

a. Regularly evaluating the costs for Laboratory testing.

b. Ensuring various revenue sources are used appropriately.

c. Proposing legislative, regulatory, or other changes to fee structures and revenue sources, as needed.

Department of Public Health and Environment Response:

a. Agree. The Division is developing a fee setting policy and will regularly evaluate all fees (every other year on a rotating basis) to verify test costs are recovered through fee collections. The policy will be implemented in July 2002. The LARS Fiscal Office will complete test costs/fee analyses on 50% of the fees by June 2003 and will complete the remainder by June 2004.

b. Agree. As part of the test cost and fee recovery analysis, the Division will annually compare actual costs to appropriated funding levels to verify that fund splits accurately reflect the correct cost centers. The Division will revise budget submissions as appropriate.

c. Agree. The Division increased fees through an internal review process in November 2001, pursued legislative changes to increase statutorily set X-ray fees (HB02-1232) and will present a fee increase proposal to the Board of Health in May 2002 for Radioactive Materials fees. The Division will continue to propose fee adjustments as appropriate after fully evaluating costs, appropriate funding sources and customer impact.

Improved Billing Practices Would Reduce Costs and Increase Revenue

Division staff do not prepare the billing for tests performed at the Laboratory. Rather, the various laboratory units within the Division forward documentation of the tests performed to the Department of Public Health and Environment's accounting staff, who, in turn, process customer invoices. In Fiscal Year 2001 the Department processed about 12,000 invoices for the Division's laboratory services. As the following table shows, in one month alone—May 2001—the Department processed 1,060 invoices totaling more than $445,000. Staff processed the invoices on a daily, weekly, monthly, or test-by-test basis, depending upon when the laboratory unit conducting the analysis forwarded testing information.

Laboratory and Radiation Services Division
Invoices Processed by CDPHE in May 2001

Laboratory Test	Billing Period	Total Invoices*	Total Amount Invoiced
Streptococcus	Weekly	64	$ 390
Newborn Screening	Monthly	87	252,455
Water Bacteria	Daily	587	14,668
Chlamydia	Monthly	20	2,788
HIV	Monthly	29	4,219
Water Chemistry	Daily	66	6,846
Drug	Monthly**	137	21,773
Premarital	Monthly	4	63
X-Ray Inspection	Daily	13	378
Radiation License	Monthly	34	103,735
Hazardous Waste Uranium	When Occurs	19	37,726
TOTAL		**1,060**	**$ 445,041**

Source: Office of the State Auditor analysis of CDPHE accounts receivable documents.
Notes: * Individual invoices may include charges for multiple tests.
** Billing is sometimes on a daily basis.

The Department's current billing practices could be more efficient. The process of invoicing is labor-intensive, requiring about 130 hours per month of Department staff time. We estimate the Department could save a substantial portion of the approximately $29,360 in staff time spent processing invoices annually if it were to adopt more efficient and effective billing practices. Prepayment and the adoption of a standard billing cycle are two methods used by other public and private laboratories that could reduce the Department's processing costs and increase revenue collections.

Prepayment Should Be Considered

We contacted public and private laboratories in Colorado as well as other state's government laboratories and identified two practices the Department should consider for improving its payment and billing processes. These include:

- **Prepayment.** In June 2001 the Division had almost $100,000 in accounts receivable. Most of the public and private laboratories we contacted have adopted prepayment policies. Among private laboratories, prepayment is commonly required of first-time clients, clients with bad payment records, and infrequent or small-volume users of these laboratories' services. The Colorado Bureau of Investigation's laboratory (CBI) requires prepayment by most customers, although large-volume users typically are invoiced. In New Mexico, prepayment is required for all newborn screening tests performed at that state's laboratory. Staff at the private labs we spoke with told us that they require prepayment either at the time testing is requested or prior to the release of test results.

  For frequent or large-volume users of the Laboratory, invoicing may be the better option. Possibly, the Department could require prepayment of single-test users or for testing services costing less than a designated threshold, such as $50. In May 2001 more than one-half (55 percent or 587) of the 1,060 invoices processed by the Department were for water bacteria testing. The average invoice amount was $25 and individual customers accounted for 22 percent (127) of the total invoices issued. Private-sector businesses represented 42 percent (244) of the invoices and about 37 percent (216) of the invoices were issued to other governmental entities. At the time of our audit, we found that the Department "wrote off" any outstanding accounts receivable of less than $50, and almost no collection efforts were made.

  Prepayment also would significantly reduce the costs associated with invoicing. If such a prepayment policy had been in place in Fiscal Year 2001 for testing services costing less than $50, the total number of invoices would have been reduced by 64 percent, from 11,709 to 4,224. Correspondingly, the costs for processing would have been reduced. The Department should assess various prepayment options to determine under what conditions or for which customers prepayment would be most cost-effective.

- **Monthly Invoicing.** The Department has not adopted a standard billing cycle. Instead, Department staff bill some customers once per month for all tests conducted within that period, while other customers are billed per test multiple times per month; sometimes on a daily basis. The number of times a customer is invoiced depends largely on the frequency with which the various units within the Laboratory forward testing information to the Department. Some lab units forward information on a daily basis, some weekly, and some accumulate all of the testing information for each customer on a monthly basis and then send it to the Department. With a few exceptions, monthly invoicing is the standard

practice among all of the laboratories we contacted. The Department and the Laboratory should work together to reduce the frequency of billings and implement a standard monthly invoicing cycle.

Recommendation No. 2:

The Department of Public Health and Environment should improve its billing practices by evaluating prepayment options and adopting a monthly billing cycle.

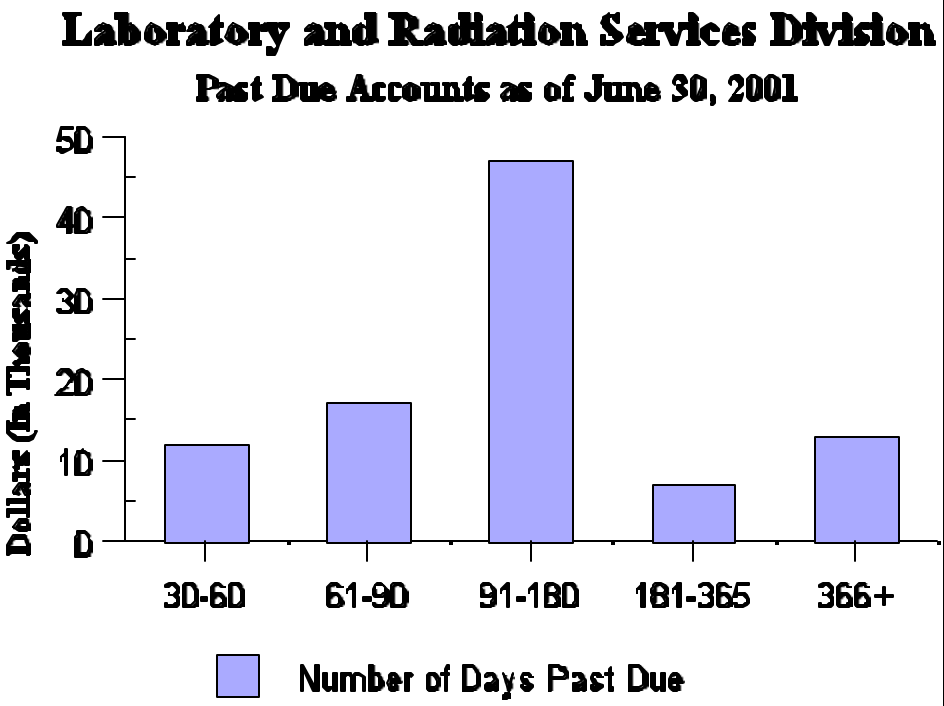
Department of Public Health and Environment Response:

Agree. The Division implemented a pre-payment policy effective March 2002 that requires customers submitting sample requests totaling less than $50 per month pay at the time of submission. Water bacteria and water chemistry tests, which account for 62% of all billings, are now processed monthly (effective March and May 2002, respectively). Due to limited resources in the Department's Accounting office, the Division will convert the remaining daily/weekly billings to a monthly process when an automated system is implemented.

Collections Need to Be Improved

On June 30, 2001, there were 264 Laboratory and Radiation Services Division customer invoices more than 30 days past due that the Department had not referred for collection. These invoices totaled almost $100,000 for the fiscal year to date. Individual invoices ranged from $.50 to more than $6,500. By statute, "State agencies are to refer to the State Controller all debts due the State which the agency has been unable to collect within thirty days after such debts have become past due...." As the following exhibit shows, invoices between 91 and 180 days delinquent represented the single, greatest dollar value of total delinquencies—about $47,000 of the total $99,458 outstanding.

Successful debt collection becomes increasingly difficult as delinquencies age. A 1997 study on federal debt collection found that debt between 181 and 365 days delinquent had an average collection rate of about 11.9 percent. The recovery rate decreases significantly to about 3.7 percent for debt more than two years old. For debt more than two years old (731 days or more) recovery is 1 percent or less.



Source: Office of the State Auditor analysis of CDPHE past due accounts data as of June 30, 2001.

According to staff at Central Collection Services located within the Department of Personnel and Administration, recovery rates also vary by state agency. Central Collections staff report their recovery rate for CDPHE is about 18 percent for accounts between 30 and 90 days old. After 90 days, Central Collections turns the receivables over to private collection agencies. On the basis of Central Collections' recovery rate for CDPHE and on national recovery rate data (for accounts more than 90 days past due), we estimate that only about $12,000 of the Division's outstanding, year-to-date accounts receivable (as of June 30, 2001) is likely to be collected given current Department practices. In analyzing the Division's past due accounts, we found that:

- Other state, federal, and local government entities accounted for about 23 percent, or $22,890, of the total debt owed. Some of these entities included local law enforcement agencies, city and county governments, and United States military hospitals.

- Some individual customers were responsible for a significant portion of the total debt because they represented multiple past due accounts. For example, one hospital in Guam owed the Division more than $16,300 for six outstanding invoices for Newborn Screening Services.

The primary reason receivables remained outstanding at the time of our audit was that the Department of Public Health and Environment was not actively pursuing their collection or turning accounts over to Central Collections in a timely fashion. Although our current audit focused on the Laboratory and Radiation Services Division, we found that deficiencies in the Department's debt collection practices are systemic.

The Department Needs to Strengthen Collection Practices

In addition to turning past due accounts over to Central Collections as prescribed in statute, there are several other steps the Department should take to improve its collection of delinquent accounts.

- **Shorten the "due date" time period.** Currently the Department gives clients 60 days to pay their bills. It is only when an account becomes 30 days past due that the Department refers it to Central Collections. This means that an account is not turned over for collection for 90 days, or about three months. Because the ability to collect debt decreases over time, the Department should reduce the time clients have to pay their bills from 60 to 30 days so that past due accounts are turned over to Central Collections at 60 rather than 90 days. A 30-day payment period is not uncommon among other public and private laboratories we contacted.

- **Increase the frequency of reconciliations.** State Fiscal Rules require state agencies to reconcile internal records to Central Collections' reports showing the amounts of past due accounts on a periodic basis, but not less than quarterly. According to Department staff, this reconciliation currently occurs only on an annual basis. If errors are made either by the Department in not forwarding account information to Central Collections or by Central Collections in recording the amounts collected, the errors can remain undetected for up to one year.

- **Improve customer notification of accounts receivable**. According to Department staff, customers should be notified of past due accounts. However, staff told us that because of limited staffing resources, the majority of customers are not notified. Therefore, few, if any, collection efforts are made by the Department prior to turning accounts over to Central Collections.

- **Change accounts receivable "write-off" policy.** The Department only sends past due accounts valued at $50 or more to Central Collections. Accounts under $50 are "written off." There are at least two problems with this practice as it relates specifically to the Laboratory and Radiation Services Division. First, as stated previously, a significant portion (64 percent) of the Division's customer invoices are for $50 or less. Second, Department staff told us that when customer's individual invoiced amounts accumulate to more than $50, they are referred for collection. We found, however, that this may not be occurring because staff do not always accumulate outstanding invoices for individual customers. We identified at least 14 customers with multiple transactions valued at under $50 each. These customers continued to do business with the Division, although they had existing past due accounts. In addition, we found several examples of customer accounts that had not been accumulated and, therefore, were "written off," although they totaled more than $50 due from individual customers.

- **Implement a prior audit recommendation related to the adequacy of accounts receivable software.** The Department's accounts receivable system does not identify which accounts have been referred to Central Collections and which have not. Consequently, it is a time-consuming process for staff to manually make this identification and move the proper accounts over to collections. In our Fiscal Year 1999 Statewide Financial Audit (released in March 2000), we found that the Department needed to perform a post-implementation review of its new accounts receivable software application. As we reported in 2000, the application was required to replace a system that was not Y2K compliant. The prior audit found that a post-implementation review was needed to verify that application processes were meeting expectations and original processes had appropriately been abandoned or incorporated into the new automated processes.

  The Department agreed to implement our recommendation by March 2000. Our current audit found that the Department did not implement this recommendation. We believe that the Department needs to implement the prior audit recommendation to review its accounts receivable software applications to ensure that the processing options replicated from the pre-Y2K system are the best options available under the new system and that issues of reconciliation, debt referral, and invoicing are adequately addressed.

Recommendation No. 3:

The Department of Public Health and Environment should improve its efforts to collect outstanding receivables by:

a. Referring all past due accounts to Central Collections in accordance with statute.

b. Shortening its due date period from 60 to 30 days and referring outstanding accounts to Central Collections in 60 rather than 90 days.

c. Developing a system for identifying the status of accounts receivable.

d. Reconciling internal records and Central Collections reports, at least quarterly, as specified in State Fiscal Rules.

e. Making changes to its accounts receivable write-off policies to ensure that collection efforts are made appropriately.

f. Implementing a prior audit recommendation to ensure the adequacy of accounts receivable software.

Department of Public Health and Environment Response:

a. Agree. The Department has committed one full time employee to analyze and refer all past due accounts to Central Collections in accordance with statute.

b. Agree. Effective March 1, 2002, the Department has shortened its account due date period from 60 to 30 days and will refer outstanding accounts to Central Collections in 60 rather than 90 days.

c. Agree. The Department has hired a consultant to analyze its current accounts receivable system and to determine if the current system can be enhanced to, among other things, identify the status of accounts receivable. Depending upon the financial resources available, the Department will enhance the current system or consider the development of another system

that can analyze the status of accounts receivable. The consultant's report on the accounts receivable system is due to the Department by May 31, 2002.

d. Agree. In the past, the Department has informally reconciled its internal records with the Central Collection reports on a monthly basis. Starting the quarter ending March 2002, the Department documents the quarterly reconciliation of the internal records and Central Collection's reports, as specified in State Fiscal Rules.

e. Agree. Effective March 1, 2002, the Department has changed its accounts receivable write-off policies to ensure that collection efforts are made appropriately including the referral of accounts under $50.

f. Agree. A consultant is currently reviewing the Department's accounts receivable system. Implementation of the prior audit recommendation to ensure the adequacy of the accounts receivable software is one of the main areas of the consultant's review.

Reconciliation Practices Are Not in Place

In Fiscal Year 2001 the Denver Laboratory and the two branch labs conducted at least 1.3 million analyses on approximately 250,000 specimens and collected more than $5 million in revenues from the 139 fees assessed. However, the Department cannot ensure that all revenue, accounts receivable, and cash receipts are accurately recorded and received because no process is in place to reconcile the number of samples received by the Labs with the number tested/rejected, the number of results reported, and the amount collected or invoiced. Reconciliation is a critical element of adequate internal control. Internal controls are necessary to ensure assets are safeguarded, to promote accurate and reliable accounting data and records, to encourage compliance with policies and procedures, and to support operational efficiency. In an agency like the Laboratory and Radiation Services Division, which relies heavily on fee revenue, reconciliation has added importance for the following reasons:

- **Provides one method for managing the high volume of samples that pass through the various labs on any given day.** As stated previously, in Fiscal Year 2001 the Division processed approximately 250,000 samples. Tests on these samples were conducted by the numerous laboratory units within the

Division and by the two branch laboratories. Reconciliation provides one method for ensuring samples are processed and test results are reported. For example, the Division does not charge customers for non-viable samples that reach the Laboratory beyond the time for which they can be reliably and accurately tested. Only samples tested are billed. Therefore, it is essential to compare samples received with samples tested to ensure that only those samples which are tested are billed.

- **Helps ensure samples are recorded and accounted for correctly.** Numerous systems are used by the different laboratory units within the Division to record sample information. Various delivery methods are used including courier drop-offs, customer "walk-ins," mail deliveries, and drop-box submissions. Not all of the samples delivered to the Laboratory are processed through the central receiving desk where some sample data are recorded. Rather, laboratory staff pick up samples from the mail room, drop box, or directly from walk-in customers. Without a standard method for accepting samples and recording sample information, it is essential that the Department institute reconciliation measures to ensure that correct fee amounts are assessed and fee revenues are collected and appropriately deposited.

- **Allows for timely detection and correction of accounting errors.** In reviewing the Department's invoicing records for May 2001, we found that at least 33 customers out of approximately 1060 were either billed when they had already paid for services or were billed an incorrect amount. According to Department staff, the majority of billing errors are identified by customers. Relying on customers to identify billing and other accounting errors is not good business practice. More significantly, by not reconciling tests conducted with accounts receivable and revenues collected, the Division cannot ensure it is receiving the funds it is due or that it is not overcharging customers. For example, customers notified the Toxicology Lab that it was undercharging them. Toxicology staff found that this was indeed the case. By manually reviewing test results and billing records, Laboratory staff found that in just a one-month period, they had undercharged customers about $2,000 for tests which had been conducted. At the time of our audit, Toxicology Laboratory management were still reviewing records for additional errors.

- **Reduces the risk for fraud and irregularities.** As stated previously, the Department accepts numerous forms of payment for the Laboratory's services. Reconciling the number of samples tested to the payments received, invoiced,

or contracted for is the only way to ensure fees have been charged, and payments and deposits have been made.

To improve controls over cash and accounts receivable, one of the first things the Division should do is develop a system for routinely reconciling all samples received, tested, prepaid, or billed. This reconciliation should then be forwarded to the Department for reconciliation with cash collected and the amounts deposited. Periodically, the Department should reconcile accounts with the original test result reports and other documentation maintained by the Division.

Recommendation No. 4:

The Department should develop a system to reconcile samples received to samples tested. Then samples tested should be reconciled to amounts received. Finally, amounts received should be reconciled to amounts deposited on a monthly basis.

Department of Public Health and Environment Response:

Agree. The Division is incorporating a revenue tracking and reconciliation module in the development of an automated invoicing system set for implementation in June 2003. The Division will compare reports generated by the new system to laboratory analysis data from the LITS Plus system to identify discrepancies between samples processed, cash collected, amounts invoiced and fund revenues. The Division is developing a manual reconciliation process for FY2003 but cannot guarantee data accuracy until LITS Plus and the new invoicing system are in production and generating comparison reports.

Accounting Practices at the Branch Labs Are Lax

In Fiscal Year 2001 the two branch laboratories, located in Durango and Grand Junction, expended more than $296,000 and collected about $143,000 in revenues for the 25,000 specimens staff analyzed. We found that the two branch labs operate relatively autonomously, with little oversight. This lack of oversight is clearly evident in relation to accounting practices. For example, we found:

- **Cash is sent through the mail.** The Grand Junction laboratory does not use a locked bag to send its weekly cash receipts to the Department. In Fiscal Year 2001 the lab sent approximately $12,400 in cash and checks via certified mail to CDPHE. More than $5,000 of this total was in currency. Certified mail provides assurance that mailings are delivered to a particular location. However, anyone at the location may sign for the delivery. This is problematic because the Division and Department have not instituted procedures for reconciling cash receipts sent from Grand Junction with those received in Denver. Consequently, there is no way to ensure that cash and checks sent from Grand Junction are ever deposited in the proper account.

- **Cash receipts are not reconciled with tests conducted.** The Department does not reconcile the amount of fee revenues received with the number of samples that were tested at the branch labs. In Durango, the San Juan Valley Health Department collects the cash for testing done by the lab and sends a check, once a month, to the Department. As described above, Grand Junction sends cash and checks for the tests conducted on a weekly basis. Both of the labs also use different systems to record specimen information. In neither case are the numbers of tests conducted reconciled with revenue collected at the branch labs and received by the Department. At a minimum, reconciliation should occur monthly.

The Department needs to improve accounting oversight at the branch labs by ensuring that cash receipts are safeguarded and accurately reconciled. This should be done by first requiring the Grand Junction lab to cease sending cash through the mail. Instead, both branch labs need to deposit cash receipts in the State's bank account at the nearest Grand Junction and Durango locations. The Division also needs to implement uniform test documentation and reconciliation practices at both laboratories.

Recommendation No. 5:

The Department should improve oversight for accounting activities at the two branch labs by implementing adequate internal controls. This should include:

a. Terminating the practice of sending and receiving cash through the mail.

b. Adopting standard methods of recording and reporting the numbers of tests conducted and the amounts of revenues collected.

c. Reconciling, at least monthly, revenues received with tests conducted.

Department of Public Health and Environment Response:

a. Agree. As of April 2002, the Grand Junction branch laboratory staff deposits cash and checks into the State account at the State bank in Grand Junction.

b. Agree. The Division will develop a workload tracking spreadsheet to be used by branch lab staff. By July 2002, the branch lab staff will complete data fields identifying the sample number and type of test performed as well as revenue collection information. The Division will incorporate the Branch Labs into the LITS Plus system in the final system implementation.

c. Agree. The branch laboratories now forward their weekly sample documents (as of March 2002), cash received and billing information to the Division Fiscal Officer. The Division's fiscal office is compiling data to compare with revenues received before forwarding the information to Accounting for accounts receivable processing. The Division will reconcile the data monthly to the workload tracking spreadsheets.

The Laboratory's Revenue Forecasts Need Improvement

As the following table shows, the Division's fee revenue estimates are typically greater than actual fee revenue. Specifically, in Fiscal Years 1998-2000, the Division estimated considerably more in cash revenues than it actually collected. Revenue estimates were 27 percent greater than actual cash revenue in Fiscal Year 1998, and 15 and 13 percent greater in Fiscal Years 1991 and 2000, respectively. In Fiscal Year 2001, estimates showed a marked improvement.

Cash Fund (Fee Revenue) Estimates and Actuals Fiscal Years 1998 - 2001				
Fiscal Year	**Estimate**	**Actual**	**Dollar Difference Estimate-Actual**	**Percent Difference Estimate-Actual**
1998	$ 4,861,592	$ 3,547,602	$1,313,990	27%
1999	4,254,287	3,618,700	635,587	15%
2000	4,409,822	3,853,293	556,529	13%
2001	5,263,379	5,501,392	-238,013	-5%
Source:	Office of the State Auditor analysis of Joint Budget Committee and CDPHE budget documents.			

It is important that revenue projections be as accurate as possible so that budget decisions reflect agency needs. Because the Division's cash funds are derived almost entirely from fees, reasonable projections are necessary to address programmatic or other changes in a timely and appropriate manner. If, for example, revenue is not sufficient to cover costs in certain areas, then the Division needs to make appropriate budget adjustments, including requests for additional revenue from other sources, such as the General Fund, or to make adjustments in fees.

Division staff recognize the need for improvements in this area. In fact, as noted above, revenue projections for Fiscal Year 2001 were significantly closer to actual revenue than in previous years. However, it appears that no systematic method has been used to project revenue. Division staff were unable to provide any documentation of the method(s) used and indicated that revenue projections were essentially "guesstimates." The Division should analyze its underlying data—samples received, tests conducted, fees charged, and revenues collected—and develop a standard forecasting methodology. This methodology could be applied on a laboratory unit basis, on groups of tests, and for the Laboratory in its entirety. We encourage the Division to develop a revenue forecasting method that is most appropriate for its budgetary and funding requirements.

Recommendation No. 6:

The Department of Public Health and Environment needs to improve Laboratory revenue estimates by implementing and documenting a process for accurately identifying cash revenue collections, including an evaluation of fee revenue trends.

Department of Public Health and Environment Response:

Agree. The Division will review fund trial balance reports and workload reports to verify revenue collections and sample activity for all of the funds in the Division beginning in July 2002. The Fiscal Office will also develop and maintain a long-term revenue tracking system for trend comparison. The automated invoicing system will generate sample load and revenue reports that will be compared for accuracy.

Laboratory Operations

Chapter 2

Background and Overview

Quality assurance is essential for the Department to maintain the high level of service necessary to protect the public health. In addition, as the entity charged with overseeing the testing standards of other diagnostic laboratories in the State, it is incumbent upon the Department to take the lead in demonstrating a high level of quality service. Although the Division has developed quality assurance policies and procedures, we found deficiencies related to comprehensiveness and implementation. Most notably, existing policies are not sufficiently monitored to ensure their implementation throughout the Laboratory. Therefore, as we discuss in this chapter, we believe the Department needs to make improvements in a number of programmatic areas to "ensure analytical and support services provided by the Laboratory (Laboratory and Radiation Services Division) are the highest quality."

Lab Closures Result From a Lack of Quality Assurance

The Division's Toxicology Laboratory provides analysis of urine and blood specimens in accordance with drinking and drugged driver laws. Laboratory certification is important in terms of law enforcement and for use of test results in criminal proceedings. According to Laboratory staff, about 90 percent of samples submitted to the Toxicology Laboratory are from law enforcement sources.

As a result of performance failures on two consecutive proficiency tests, the Division's Director voluntarily suspended the Toxicology Laboratory's urine drug testing (TOX-UDC) from July through November 2000. Toxicology Laboratory operations were closed during this period. The backlog of urine drug specimens was sent to a private laboratory for testing. Law enforcement agencies were instructed to take blood specimens rather than urine specimens for drug analysis until the matter was resolved. Blood specimens were also tested elsewhere. In the fiscal year prior (1999) to the Toxicology Lab's closure, it conducted 105,220 analyses. In the fiscal year of the Lab's five-month closure—2001—the volume of analyses decreased significantly (77 percent) to 24,278.

Proficiency tests are examinations conducted by outside entities to rate a laboratory's analytical testing and processing of samples and test results. Passage of proficiency tests is required for a laboratory to maintain its certification. The Toxicology Lab's proficiency test failures were for a late submission of test results and for a false positive test result. In both cases, the College of American Pathologists (CAP) gave the Lab a score of "unacceptable." In January 2001, the Toxicology Laboratory failed a third proficiency test. This failure did not result in closure, because the Laboratory had passed the proficiency test that immediately preceded it. Therefore, the January 2001 failure did not constitute a second consecutive failure. However, recurring proficiency test failures is one indicator of problems with service quality.

The closure of the Toxicology Laboratory meant that samples had to be tested elsewhere. For samples that were already at the Lab when it was closed, the Division contracted out for testing services at a higher rate than what it charged customers. The additional cost to the Laboratory was $69,000, which was not recovered through fee revenues. Customers who would have used the Lab, had it been open, had to obtain services through other laboratories, often at significantly higher costs. We estimate the Laboratory lost about 23 percent (50 of 217) of its regular customer base after the closure. Division management stated that sample volume in the Toxicology Lab had been declining prior to the closure for several reasons, including the decrease in employer-mandated drug tests. Although use of the Lab may have been declining for some time, some former customers told us that the Lab's closure directly affected their decisions to use other service providers. Some of these customers have since resumed business with the Lab; others have not.

Quality Assurance Is a Critical Component of Laboratory Operations

National standards related to diagnostic laboratory operations outline various responsibilities that should comprise a quality assurance program. These include evaluating policy effectiveness; identifying and correcting problems; revising policies based on evaluations; ensuring the accurate, reliable, and prompt reporting of results; and documenting all quality activities including problem identification and corrective actions. We did not find sufficient evidence that the Department has adopted policies or implemented practices to ensure that these standards are consistently followed:

- **The Division's Quality Assurance Manual needs improvement.** The Quality Assurance Manual provides direction for its various laboratory program units such as bacteriology, serology, toxicology, and organic chemistry. However, important functions such as central specimen accessioning, report delivery, and customer billing are overlooked. These support functions are not performed

directly by the laboratory program units. However, they directly impact the quality of service provided to the customer. The Manual states that the quality assurance principles defined therein are intended to ensure that analytical and support services are of the highest quality. Without comprehensive policies and practices to address critical support functions, the Division's quality control program falls short of fully satisfying this goal.

- **Corrective action plans with implementation follow-up are needed.** The Division needs to develop a corrective action plan and schedule for each proficiency test failure or low scoring result. After the Toxicology Laboratory failure, the Division identified corrective actions to be taken. However, these did not include dates for implementation or follow-up. We found in subsequent proficiency tests some of the items that were to have been corrected had not been. Timely follow-up is critical to ensure problems are addressed and quality service is maintained.

- **Routine monitoring for data accuracy is inadequate.** The Division's quality assurance policies specify that program managers are to review or delegate the review of all data and reports for accuracy. We found that errors are not caught, because quality control functions for data accuracy are often performed by the same staff who perform the original tests and record test information. In one case, we found a specimen test record containing an incorrect patient name in the logbook. The name on the previous specimen had erroneously been copied. We determined that the lab employee who tested the specimen and recorded the patient information also performed the quality control function. We also identified records that contained incorrect receipt information in two different databases. The lack of segregated duties with regard to recording and reviewing information reduces the likelihood that errors will be caught and corrected.

- **Systematic internal audits are not occurring.** The Quality Assurance Manual specifies that the Division's Quality Assurance Officer is to oversee, review, or conduct three types of audits to verify program compliance with quality control requirements and other aspects of the quality assurance program. We found that one type of audit—the specific area review or investigation—has not been conducted with any regularity. According to the Division's Manual, the Quality Assurance Officer may be requested to investigate a single area or Laboratory operation that can be evaluated in a short time period. The area reviewed may be a complete analytical method, or any part of the Laboratory test process such as sample log-in, report generation, or standard preparation. In the past five years, only two such investigations have been conducted. One was conducted by a customer of the Laboratory to comply with a federal funding requirement. A

significant finding of this review was the lack of documentation of completed work. The most recent investigation, conducted in 1997, was requested by a former Division Director. A work backlog was cited as one of the primary issues in need of resolution. However, we could find no documentation to indicate that this issue was addressed during the audit or that subsequent actions were taken to correct any substantiated problems.

The Division needs to strengthen its Quality Assurance Program. This should be done by evaluating the Quality Assurance Manual to determine where gaps exist, including identifying operations that are currently not addressed, and strengthening overall compliance monitoring. Currently much of the responsibility for ensuring compliance with quality assurance principles is assigned to the individual program managers. Although this is an appropriate assignment of responsibility, the Division should provide greater oversight by developing standard methods of documentation and review for day-to-day activities. In addition, we believe the Division should use the audit policies it has adopted. Periodic specific area reviews could supplement routine quality control monitoring by identifying problems, and recommending and documenting corrective actions.

Recommendation No. 7:

The Department should strengthen its Laboratory quality assurance program by:

a. Assessing the comprehensiveness and effectiveness of its existing policies and practices, and revising or modifying policies, as appropriate.

b. Developing corrective action plans including implementation dates and follow-up evaluations.

c. Implementing methods for monitoring systemwide compliance with quality assurance policies and SOPS among all program units.

d. Identifying and prioritizing operations in need of review; developing an audit schedule; conducting internal audits systematically; and maintaining adequate documentation of all audits, recommendations, and corrective actions.

Department of Public Health and Environment Response:

a. Agree. A section on QA activities relating to sample processing performed by administrative staff was added to the QA manual effective January 2002.

b. Agree. Corrective actions with implementation dates for all failed proficiency testing events will be performed as detailed in the QA manual and became effective upon the change in QA officers in January, 2002.

c. Agree. Program management and supervisory staff will perform or delegate test results QA/QC review independent of the staff performing the test. This will be addressed in staff IPGs for next year and will be effective June 1, 2002.

d. Agree. Upon the change in QA officers effective in November 2001, three independent audits have been performed (2 in drinking water testing, 1 on Total Kjeldhal Nitrogen). This practice will continue as specified in the QA manual.

Improved Specimen Tracking Is Needed

The Division does not have a uniform sample management system for use in tracking specimens, for monitoring the status of testing and test results, or for compiling comprehensive data on the 250,000 specimens it processes each year. Consequently, comprehensive specimen information either is not available or is laborious and time-consuming to obtain. For example, during our audit we requested basic information that was either unavailable or difficult and time-consuming to retrieve:

- Specimen volumes—including the number received, being processed, and completed on a daily, weekly, or monthly basis.
- Turnaround times—the time to process and complete sample analysis.
- Staff workload.
- Customer activity levels.
- Lost samples.

In some cases, statutes and Department regulations prescribe specimen turnaround times. For example, statutes direct the Department of Public Health and Environment or the contracting laboratory to return the results of parolee urine tests to the parole officer within five working days of receipt of the specimen. Department regulations specify turnaround times for both Newborn Screening and Toxicology blood samples. For Toxicology blood samples, Department regulations require that after a hospital or qualified individual draws the blood sample, the Toxicology Lab has 15 calendar days within which to report a result. Currently information on Toxicology Lab turnaround times is not easily retrievable. Without easy access to complete, accurate, and timely specimen information, the Division cannot effectively monitor these and other measures of laboratory services quality and timeliness.

The Various Lab Units Maintain Numerous Systems

We attempted to track samples throughout various laboratory units. However, we found it difficult to compile information with any degree of accuracy or reliability. Each of the seven lab units located in Denver and the two branch laboratories maintain their own systems for recording specimen information. We found that the various lab units maintain at least 23 largely independent sample management systems, consisting of 12 software-based and 11 manual systems. The manual systems maintained by various labs range from log books to groups of card files or requisition forms that require time-consuming manual entry. The specimen information from each of the 23 individual lab systems generally remains within the respective lab units and is not compiled comprehensively or on a regular basis. Also, the various labs do not necessarily collect the same information or record comparable information in uniform ways.

In reviewing the Division's customer survey questionnaire responses for Fiscal Years 1999-2001, we found that the most common complaint from Laboratory users related to the timeliness of services. Specifically, 15 percent (69 of 465) of survey respondents during this three-year period cited lengthy turnaround times as being problematic. Another 5 percent of respondents indicated problems with testing accuracy, lost test results, data entry errors in names and addresses, and billing mistakes. To obtain more specific information about their experiences with the Laboratory, we interviewed a judgmental sample of 13 customers who had responded to the Division's survey. Among those contacted were former and current Laboratory customers, including large-volume users and users who had cited problems with Laboratory services. These 13 customers were responsible for about $750,000 in Laboratory revenue in Fiscal Year 2000. Overall, the majority of the customers offered positive comments about the Laboratory and its staff.

However, the issue of timeliness was again the most common complaint. Nine of thirteen customers indicated that they had experienced lengthy turnaround times from the time samples were submitted to the time test results were received. One customer stated they no longer do business with the Laboratory because of lengthy delays. In Fiscal Year 2000 this customer was responsible for about $20,000 of the Toxicology Laboratory's revenues.

Providing systemwide, continuous tracking to reduce the risk of sample loss or delays in processing, at any stage, is something the Division currently cannot do in an easily accessible or timely fashion. A uniform system for tracking and compiling sample information would provide the Division with a mechanism for identifying and addressing problems such as a lack of timeliness. The Division would be able to pinpoint bottlenecks and delays, whether at the point of sample receipt, sample processing, or test result reporting, and take corrective actions. Thus, customer satisfaction would be improved and the potential loss of customers reduced.

The Division Is Implementing a New Sample Management System

The Division is in the process of implementing a sample information management system developed by the Centers for Disease Control (CDC). The conversion to the LITS Plus System will be financed by the CDC, including the cost of the system, training, maintenance, and support. According to CDC documents, LITS is a PC local area network-based system for tracking laboratory specimens that allows specimen information to be entered at a central specimen receiving site (something that currently does not occur in all cases at LARS) and additional specimen information can be entered into the system by any of the individual labs performing tests. Furthermore, laboratory staff can examine all data about a specimen, including information from other lab units that performed tests on the specimen. This, also, is something LARS staff currently cannot do.

The LITS System appears to offer considerable benefits. Laboratory staff in other states that have implemented the system told us they have seen an increase in customer satisfaction as well as improved information availability and accuracy. The Division's current implementation plan calls for converting the majority of the labs by October 2002. We believe this conversion will likely result in similar benefits for LARS' operations.

Although the LITS System does hold promise for improving sample management, there are two areas the Division needs to ensure are addressed:

- **First, at present, the Division does not have plans to implement the system throughout all laboratory units.** Neither the Toxicology Lab nor the Newborn

Screening Program are on the schedule for implementation. According to Division management, they will be included at some point in the future. However, the Division has not committed to a definite time line. We believe it is critical that these labs be included as soon as possible. Otherwise, the problems we noted will not be adequately resolved, and concerns about operations will continue.

- **Second, the Division needs to ensure that all necessary data elements are addressed and that each lab unit adopts standard data entry and recording practices.** The Division should conduct a thorough assessment of all of the data needs in all of the labs to guarantee the new system will provide the information required. In addition, all of the labs need to be in sync with regard to entering and recording data in the same ways. Finally, the LITS system does not include a billing component. We believe the Division should consider options for how billing can more efficiently and effectively be linked to specimens tested. Systems do exist that can be attached or piggybacked onto the LITS System to handle customer billing. The Division should research various options and implement a billing component.

Recommendation No. 8:

The Department should implement a comprehensive, centralized specimen management system for the Laboratory that provides accurate and accessible tracking and other information. This should include:

a. Assessing all data needs and ensuring all laboratory units use standard data entry and reporting elements.

b. Committing to a time line for implementing such a system throughout all laboratory units including Toxicology and Newborn Screening.

c. Evaluating available software options to link the billing function with the specimen management system.

Department of Public Health and Environment Response:

a. Agree. As part of the implementation process for LITS Plus, the new computer system, data needs and reporting elements were assessed to allow for a standardized specimen-accessioning screen. This format will be followed

throughout the lab implementation schedule with completion of all labs expected to be 3rd quarter FY2003.

b. Agree. We commit to add the Toxicology Program and the Newborn Screening Program to the "formal" implementation schedule. The scheduled date for conversion of these labs will be end of 3rd quarter, FY2003.

c. Agree. The LITS Plus system does not have a billing component but the LITS Plus data will be downloaded to the proposed Invoicing and Revenue Tracking system.

The Costs and Benefits of Operating the Branch Labs Are Unclear

In addition to the main Laboratory facility in Denver, the Division operates two branch laboratories located in Grand Junction and in Durango. Compared with the main Laboratory in Denver, the two branch labs' testing is limited both in numbers and types of tests conducted. In Fiscal Year 2001 the two branch labs processed only about 10 percent (25,000 specimens) of the Division's total 250,000 workload. The types of tests conducted by the labs are limited to some public health microbiology analyses, including streptococcus and syphilis (Grand Junction only), and environmental microbiology (water and milk bacteriology and sewage). The two labs do not conduct any organic/inorganic chemistry, newborn screening, or radioactive materials tests as does the Denver Laboratory. In evaluating the operations at the two branch labs, we also found:

- **The labs generate insufficient revenue.** Less than one-half (48 percent) of the expenditures at the two labs is recovered through fee revenues. This compares with about 60 percent of total Division expenditures that are covered by fee revenues. As the following table shows, in Fiscal Year 2001 the two labs generated about $143,122 in revenues compared with expenditures of $296,500.

Branch Labs' Revenue and Expenditures Fiscal Year 2001			
Laboratory	**Expenditures**	**Revenues**	**Percent Difference**
Durango	$103,265	$50,868	49.3%
Grand Junction	193,235	92,254	47.7%
Total	**$296,500**	**$143,122**	**48.3%**
Source: Office of the State Auditor analysis of fiscal information provided by LARS.			

- **Some revenue is forgone in exchange for services.** In Durango, the state lab operates out of the San Juan Valley Health Department. The San Juan Valley Health Department collects all of the revenue the laboratory generates from sewage testing. On the basis of known fee information and specimen numbers provided by the Division, we estimate revenues from sewage testing in Durango to have been about $56,000 in Fiscal Year 2001. In exchange for these revenues, the San Juan Valley Health Department provides space, utilities, and mail service for the branch lab. The services of an administrative assistant are also compensated at a cost of about $16,000 per year. Thus, the state lab in Durango was charged about $3,333 per month in Fiscal Year 2001 for space, utilities, mail, and some support services. The Division does not know whether these charges are reasonable because it has not assessed its costs at the Durango lab, reviewed the rates charged by the San Juan Valley Health Department, or evaluated alternatives to the current arrangement.

- **The Division and Department provide little oversight of the branch labs' activities.** For example, as described in Chapter 1, accounting practices at the branch labs are lax. In addition, neither of the labs has ever been included in an internal review or audit.

Close Proximity to Testing Services Is the Primary Reason Given for Operating the Branch Labs

One reason for operating labs in various locations is the demand or need for services in geographically remote or distant locations from the central lab facility. The need for close proximity to a laboratory exists because some specimens have limited holding times. This means they do not remain viable for extended periods after they have been collected and, therefore, must be tested quickly.

Specimens with the most volatile or limited holding times are environmental microbiological samples. According to Division staff, shipment of these samples to the main laboratory in Denver cannot be guaranteed within the specified holding times. Therefore, tests results may not be valid. However, staff indicated that public health microbiology specimens with holding times greater than five days could be shipped effectively and consistently to the main laboratory for testing. This includes streptococcus specimens.

The Grand Junction lab is the only one of the three Division laboratory facilities that directly tests for streptococcus. In addition, its use as a streptococcus testing facility appears to be limited to health care providers in the Grand Junction area. Testing for streptococcus is available throughout the State through local health departments, hospitals, doctors' offices, and clinics. The test may be conducted directly by a hospital laboratory, for example, or may be sent to another laboratory for processing. Public health microbiology specimens such as streptococcus compose the majority—78 percent—of the specimens processed at the Grand Junction laboratory. These specimens could be sent to the Denver laboratory or to other public or private labs within the seven-day holding time.

The other specimens tested at both Grand Junction and Durango are environmental microbiology specimens. These are the specimens with limited holding times. We found there are other local laboratories, both public and private, which test and analyze these types of samples. Most significantly, there are local health departments throughout Colorado that analyze environmental microbiology samples. We contacted several local health departments, including health departments in northeastern and southeastern Colorado. The labs we contacted are about the same geographical distance from Denver as are the areas currently served by the branch labs. The health departments we contacted in these areas test both water bacteria and sewage samples. In some cases, samples are sent by these laboratories to other labs for testing.

The Department Should Assess the Costs and Benefits of the Branch Labs

Neither of the branch labs, nor the Denver laboratory for that matter, is mandated in statute. Statutes give the Department the authority to establish and maintain laboratories. However, the statutes do not require the Department to do so. That is, the Department may directly operate its own laboratories, or it may indirectly provide laboratory services through other designated laboratories. In addition, although the statutes require the Department to ensure that certain tests, such as those for blood and urine drug and alcohol are available, the statutes do not mandate that the Department directly conduct the tests. For example, Section 24-4-1004, C.R.S., requires that all infants born in the State be

tested for various newborn diseases and that testing be forwarded by the hospital to "the laboratory operated or designated by the Department for such purposes."

We believe the Department should evaluate the costs and benefits of the two branch labs. Cost savings, with little or no impact to service delivery, could be possible through other arrangements, giving the Division the option of closing the labs. Currently personal services costs at the labs represent a significantly higher proportion of total costs than do personal services costs at the central lab. This is due to the higher salary levels of the Durango and Grand Junction laboratory staff who are nearing retirement from state service.

One of the most important considerations in assessing the benefits from the labs is the impact on public health and safety. We found no evidence that the Department or the Division has conducted any needs assessments for the branch labs, for the particular tests they conduct, for relocating them, or for establishing additional labs at other sites in the State. In fact, the two labs have not always been located in Grand Junction and Durango. The Durango laboratory was originally established in the Alamosa area in the late 1960s and the Grand Junction laboratory was located in Glenwood Springs until 1975. It is possible that greater public benefits could be derived from enhancing services at the central lab or through arrangements with other private or public laboratories. At a minimum, the Division needs to undertake greater oversight at the branch labs. Currently they operate with little oversight from the Division or the Department. We found evidence of lax accounting practices and inconsistent record keeping. In addition, there has been no routine review of operations or of operating agreements with local entities to ensure the fiscal interests of the State are adequately protected.

Recommendation No. 9:

The Department of Public Health and Environment, in conjunction with the Division of Laboratory and Radiation Services, should thoroughly assess the operations at branch laboratories to ensure they are cost-effective and provide a benefit to the public. This should include an assessment of the:

a. Need for testing services.

b. Availability and accessibility of other methods of meeting public needs.

c. Costs of current operations, including operating agreements with local entities.

d. Steps needed to ensure adequate oversight.

Department of Public Health and Environment Response:

a-d. Agree. The Department is preparing a Targeted Base Review on the effectiveness of the branch laboratories to include:

- the need for testing services in the relevant areas;
- the availability and accessibility of other methods of meeting public needs;
- the costs of current operations, including operating agreements with local entities; and
- the steps needed to ensure adequate oversight.

Improvements in Customer Service Could Result in Cost Savings

Each day, the main laboratory facility in Denver receives about 63 phone calls from customers requesting information. Typically, these information requests relate to submitting samples or to the status of an already submitted sample. Customers have questions about the types of tests available, the ways in which samples must be submitted, the fees charged, and the turnaround times for test results. Because the Division does not provide this information in an easily accessible format (e.g. Web site,) staff spend time responding to inquiries that could be more efficiently addressed in other ways. When customers call the Laboratory, support staff who answer incoming calls may be able to respond to specific inquiries. In about one-half of the cases, support staff refer the calls to Laboratory staff. The time Laboratory staff spend answering telephone inquiries should more appropriately be devoted to processing and analyzing specimens.

The Division's Web Site Could Be Used to Disseminate Information

At least 35 states make information about their laboratory testing fees, sample submission procedures, and test turnaround times and results available on their Internet Web sites. Currently the Division's Web site contains none of this information. Making these data available electronically and through hard-copy formats would enhance customer service and satisfaction by eliminating the need for often time-consuming and burdensome

telephone calls to the Lab. In addition, staff time currently devoted to addressing customer inquiries could be better spent performing laboratory testing services.

The Division should develop a customer handbook or manual containing complete information about services, procedures, fees, and testing times. The handbook should be made available in hard copy format for those who do not have online access. Customers with Internet access could download the handbooks, including the necessary forms for submitting specimens. Changes and updated information could be posted on the Web site for timely dissemination to customers.

Recommendation No. 10:

The Department of Public Health and Environment should improve customer service at the Laboratory by developing a user manual to include complete information on services and tests available, fees, turnaround times, and testing procedures and forms. The manual should be made available to the public in hard copy and electronic formats.

Department of Public Health and Environment Response:

Agree. Work on an electronically available Laboratory Resource Guide, to be posted on the Division's web site, that will include test offerings, prices, methods, turn around time, and specimen requirements and requisitions is in progress. Completion is expected to be in the Fall of 2002.

Customer Surveys Should Be Improved

In Fiscal Years 1999-2001 the Division surveyed the opinions of its customers through a written questionnaire. Generally, the customers who responded to the questionnaire report that they are satisfied with the services provided by the Division. The Division should be commended for this effort to elicit user input. However, we question the value of the survey in its current form for three reasons. First, the survey response rate is very low. Only about 16 percent—or 465—of the estimated 3,000 surveys distributed during the three years were completed and returned to the Division. In addition, the rate of response has declined significantly (47 percent) from a high of 197 completed surveys in Fiscal Year 1999 to a low of 104 in Fiscal Year 2001. Second, the Division does not know the costs

for administering the questionnaire. Third, the Division cannot show that the survey results have been used to address customer concerns or make improvements in service delivery. Consequently, the usefulness of the survey cannot be established.

Division staff told us that they will not be conducting the mail survey in the upcoming year. Rather, they plan to resume using it the following year and every two years thereafter. We believe surveys can be an effective tool and may be particularly appropriate for an agency like the Division that relies significantly on user fees to finance services. Determining user opinions and addressing concerns to improve service delivery can increase customer satisfaction and enhance revenue generation. However, there are steps that should be taken to improve the overall usefulness of future Division surveys. First, the Division should adopt a more systematic approach by validating the number of surveys conducted and by providing staff with clear, written guidelines, including control sheets, for distributing the surveys. Staff also need to determine what, if any, additional actions will be taken to follow up on unreturned questionnaires to improve response rates. Second, costs should be determined, including staff time needed to develop and distribute the surveys as well as to compile and analyze the results. Third, the Division should use these data to assess whether more cost-effective alternatives exist for obtaining customer input such as using online resources or telephone surveys. Finally, the Division should make use of the survey results. We could find no evidence of any actions taken to address concerns or problems identified by survey respondents. Possibly, the Division could post survey results on its Web site along with the steps taken to correct deficiencies.

Recommendation No. 11:

The Department should improve the usefulness of obtaining customer input by assessing costs, identifying alternatives to current methods such as online resources, assigning control numbers or identifiers, validating the numbers of surveys distributed, documenting results, and providing public feedback.

Department of Public Health and Environment Response:

Agree. The Division believes that it is important to have a mechanism to get customer feedback. One idea we are considering is posting our customer interaction survey on the Internet site. However, we are in the process of evaluating the usefulness of the data collected by the current survey tool.

Not All Laboratory Equipment Is Inventoried or Tracked

The Division tracks equipment and supplies in two ways. First, the Division maintains an inventory of fixed assets. Fixed assets are Laboratory equipment and instruments valued at over $5,000. The fixed asset inventory contains 158 items, including breath alcohol testing machines that are placed throughout Colorado with local law enforcement agencies. The total value of the items located on the fixed asset inventory is about $3.1 million. Division staff review the fixed asset inventory list annually, at the close of the fiscal year. The inventory is then reconciled through the Accounting unit at the Department for financial reporting purposes.

The Division also maintains an inventory of supplies and consumable products that are located in the supply storage room in the main laboratory building. There are about 375 consumable items in the storage room ranging in value from $.03 to over $3,600 each. The consumable inventory is tracked on a daily basis through receipts and requisitions. Based on this information, a report is generated and distributed throughout the Laboratory. This information is compiled annually and forwarded to the Department for accounting purposes.

Despite these inventory listings, there are valuable, essential Laboratory instruments and equipment the Division does not inventory or track in any form. These pieces of equipment are not "consumables" and are not valued at over $5,000. They are physically located throughout the main laboratory facility. The total dollar value of these particular equipment items is unclear. However, one unit manager indicated that there may be as much as $25,000 worth of equipment located in his/her laboratory for which there is no inventory.

Division Policies Require Managers to Maintain Equipment Inventories

Of the six major program areas we examined, only one maintains an inventory of equipment valued at under $5,000. In addition, this inventory is incomplete with regard to important information including purchase price, age, and serial number. According to the Division's February 2001 Quality Assurance Manual, each section of the Laboratory must "maintain a current inventory of equipment, identifying the type of equipment, the manufacturer, model number, serial number, location, purchase date, cost, and current status of the equipment." According to the Manual, the policy is intended to ensure that equipment is operational and adequate to perform the necessary functions required of the

Laboratory. The problem we identified with the existing policy is that it does not specify which equipment should be inventoried or the dollar value threshold at which instruments and equipment should be included. The Division is dependent upon its instruments and equipment to provide accurate, reliable testing services to fulfill its mission. This makes it difficult to monitor replacement needs and to ensure equipment is properly maintained and safeguarded against possible theft.

According to State Fiscal Rules, "Each state agency is responsible for ensuring that all equipment acquired by the State is properly accounted for when acquired, inventoried and safeguarded throughout its useful life, and properly accounted for at the time of disposal." We believe the Division's unique mandate and valuable equipment resources necessitate a more thorough accounting than currently exists. Consequently, we believe the Division should determine which items valued at less than $5,000 should be regularly inventoried. Responsibility for compiling and maintaining these inventories should be clearly assigned, and routine reviews and reconciliations should occur.

Recommendation No. 12:

The Department of Public Health and Environment should determine which Laboratory equipment and instruments, valued at less than $5,000 each, should be regularly inventoried. In addition, the Department should clearly define inventory requirements in its Quality Assurance Manual, and ensure program managers and staff are informed of and comply with inventory responsibilities and requirements.

Department of Public Health and Environment Response:

Partially Agree. The Division already complies with all fiscal rules for fixed asset and consumable inventories. However, the Division will develop a policy for annually inventorying laboratory equipment and instruments under $5,000 that is not on the consumable inventory list. Each laboratory will be required to inventory equipment and instruments meeting this definition and complete inventory verification forms by October 2002. The inventory requirements will be included in the Quality Assurance manual.

Deficiencies Exist in Staff Training

Almost three-quarters of the Division's total estimated training expenditures of $180,000 (Fiscal Years 2000 and 2001) were directed at staff who function in administrative and certification capacities such as in the mail room, management, information systems, inspections, and emergency response. By contrast, only about 27 percent of training expenditures were directed toward laboratory staff who conduct diagnostic tests on specimens such as those for DUI, water contamination, HIV, and human disease. It should be noted that some training dollars, such as grant funds, are targeted to specific staff.

Our review of Division training records indicates that Laboratory staff may not be receiving adequate or appropriate training. However, it is difficult to determine the extent of this problem because the Division does not maintain adequate training records, a training plan, or a training budget. The Division cannot ensure that its staff, particularly those who conduct specimen testing, are receiving sufficient, relevant, or timely training. Consequently, Lab operations are negatively affected. As described earlier in this chapter, the Division's Toxicology Lab was closed from July to November 2000 due to failures on two consecutive proficiency tests. According to the federal agencies that certify the laboratories, proficiency testing is one way to determine if lab personnel are properly trained. In the past two years, staff in the Toxicology Lab received only three training sessions, all of which focused on general safety procedures.

If the Division is to continue expending resources for training and staff development, it needs to focus its efforts and resources on those Laboratory staff for whom training is most needed to ensure quality testing services. This could be accomplished by identifying and prioritizing training needs and establishing a process for evaluating specific courses and areas for additional staff development. Employee attendance at training sessions and professional conferences should be tracked through the Division's training database, and training expenditures should be monitored.

Recommendation No. 13:

The Department of Public Health and Environment should focus its Laboratory training efforts and resources on those staff responsible for testing services. This should include the identification of training needs and priorities and the maintenance of training records and budgets.

Department of Public Health and Environment Response:

Agree. More effort will be made to insure testing staff receives at least 8 hours of continuing education directly related to their scientific job responsibilities. This will be accomplished through the performance review and IPG process, providing the availability of program funds. The training record keeping deficiencies has already been corrected. This will be implemented June 2002.

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