

June 20, 1995

IG-1

INFORMATION: "Audit of the Department of Energy's Commercial Laboratory Quality Assurance Evaluation Program"

The Secretary

BACKGROUND:

The audit was undertaken because of problems identified during prior Office of Inspector General audit work. This audit work identified problems related to quality assurance at both subcontract commercial laboratories and M&O contractor operated laboratories.

DISCUSSION:

The audit disclosed that contractors conducted redundant quality assurance evaluations of commercial laboratories, did not evaluate others, applied standards inconsistently, produced inconsistent results, and did not communicate those results among contractors. We found that 103 of the 206 quality assurance evaluations covered by our review were redundant. One laboratory was subjected to 11 redundant evaluations. Based on a one-year evaluation cycle and contractor reported average evaluation costs of \$11,631, elimination of the 103 redundant evaluations could have resulted in an estimated savings of about \$1.2 million per year.

We also concluded that a third-party laboratory accreditation program, commonly used by other Federal agencies and private sector firms, could provide overall cost, quality and efficiency benefits to the Department. We estimated the Department could have avoided about \$2.4 million per year by adopting such a third-party accreditation program. Overall, we estimated that implementation of this recommendation would result in savings to the Department of about \$12 million over a five-year period.

We recommended that the Assistant Secretary for Environment, Safety and Health develop and implement a coordinated third-party commercial laboratory quality assurance program by:

- (1) requiring that commercial laboratories participate in a third-party accreditation program as a condition for award of laboratory analytical services contracts;
- (2) phasing-in to existing laboratory contracts, as allowed, the third-party accreditation program;
- (3) developing and

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implementing Department specific evaluation standards and methods of application with the selected third-party accreditor; and (4) providing for ongoing monitoring, coordinating and

oversight of laboratory accreditation issues to ensure that all Departmental concerns are addressed in a uniform and timely manner. The Office of Environment, Safety and Health concurred with the recommendation and is planning actions to correct the problems noted in the report.

(Signed)

John C. Layton  
Inspector General

Attachment

cc: Deputy Secretary  
Under Secretary  
Assistant Secretary  
for Environmental Management  
Assistant Secretary for Human Resources  
and Administration

U.S. DEPARTMENT OF ENERGY  
OFFICE OF INSPECTOR GENERAL

AUDIT OF THE DEPARTMENT OF ENERGY'S  
COMMERCIAL LABORATORY  
QUALITY ASSURANCE EVALUATION PROGRAM

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Report Number: DOE/IG-0374  
Date of Issue: June 21, 1995

Capital Regional Audit Office  
Germantown, Maryland 20874

AUDIT OF THE DEPARTMENT OF ENERGY'S  
COMMERCIAL LABORATORY  
QUALITY ASSURANCE EVALUATION PROGRAM

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U.S. DEPARTMENT OF ENERGY  
OFFICE OF INSPECTOR GENERAL  
#1  
OFFICE OF AUDIT SERVICES

AUDIT OF THE DEPARTMENT OF ENERGY'S  
COMMERCIAL LABORATORY  
QUALITY ASSURANCE EVALUATION PROGRAM

Audit Report Number: DOE/IG-0374

SUMMARY

The Department of Energy (Department), through its contractors, contracts with commercial analytical laboratories for the analysis of samples related to environmental management activities and worker health and safety programs. Over 100 commercial laboratories located throughout the United States perform sample analyses for the Department. Because of problems identified during previous audit work, we initiated our audit to determine whether the Department's commercial laboratory quality assurance evaluation program was effective and efficient.

The Department's method of performing quality assurance evaluations of commercial analytical laboratories was not cost effective or efficient. Contractors at many of the Department's sites conducted multiple evaluations of the same commercial laboratory. In contrast, some laboratories were not evaluated to determine their ability to provide analytical services. In addition, methods used to perform evaluations and report results varied among contractors. Finally, quality assurance evaluation results were not communicated to other contractors.

These problems occurred because the Department's quality assurance policy guidance did not require development and implementation of a coordinated commercial laboratory quality assurance program. The Department did not require contractors to coordinate efforts, develop uniform standards and methods, or to communicate the results of their evaluations to other contractors. Contractors were only required to initially evaluate and periodically confirm that laboratories were capable of providing quality analytical data.

The lack of a coordinated commercial laboratory quality assurance evaluation program resulted in excessive cost, duplication of effort, and potentially placed the Department at risk that its decisions on worker health and safety issues and environmental matters may be based on unreliable data. Contractor provided cost estimates indicated that the Department spent about \$2.4 million for commercial laboratory evaluations conducted for Fiscal Year 1993, and that approximately \$1.2 million of that amount was attributable to duplicative evaluations. The failure to evaluate some laboratories, inconsistent evaluation and reporting methods, and failure to communicate results of evaluations to other contractors increased the risk that the Department may rely on analyses from laboratories with quality assurance problems.

Adoption of our recommendation to implement a third-party laboratory accreditation program, would eliminate the need to spend the \$2.4 million annually for quality assurance evaluations of commercial laboratories. Under this approach, subcontract laboratories bear all costs of accreditation and are required to participate as a condition to bid on analytical service contracts. Third-party accreditation would provide assurance that laboratories are evaluated to clear and consistent common standards and that reporting and communication of evaluation results is uniform within the Department.

The Assistant Secretary for Environment, Safety and Health agreed with the problems addressed in the report and agreed to take action with respect to our recommendations. Management agreed to adopt either the recommended third-party accreditation approach or an alternative approach that would eliminate redundancies and correct the conditions cited in our report. In addition to interim measures to facilitate the sharing of evaluation results, management stated that it would establish a Process Improvement Team to consider alternatives for implementing our recommendations and would provide its recommendations within 180 days of the final audit report. Management also stated that the team would be a cooperative effort to include representatives from the Offices of the Assistant Secretary for Environmental Management and the Deputy Assistant Secretary for Procurement and Assistance Management.

(Signed)

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Office of Inspector General

## PART I

### APPROACH AND OVERVIEW

#### INTRODUCTION

The Department of Energy (Department), through its contractors, contracts with commercial analytical laboratories for the analysis of samples related to environmental management activities and worker health and safety programs. These contractors consist of management and operating contractors, environmental restoration management contractors, and lower tier subcontractors (contractors). Over 100 commercial laboratories located throughout the United States perform sample analyses for the Department.

The purpose of our audit was to determine whether the Department's commercial laboratory quality assurance evaluation program was effective and efficient. Specifically, our audit objective was to determine whether the Department's method of qualifying commercial laboratories resulted in redundant quality assurance evaluations.

## SCOPE AND METHODOLOGY

The audit was performed from May through October 1994. Field work was performed at the Department's Oakland, Idaho, and Albuquerque Operations Offices during that period. We also collected information through survey techniques from the Chicago, Nevada, and Richland Operations Offices. In addition, we used information gathered during a previous audit from the Department's Oak Ridge and Savannah River Operations Offices and the Rocky Flats Field Office.

Our review focused primarily on quality assurance evaluations of commercial laboratories conducted by contractors during Fiscal Year 1993. We also included evaluations that were scheduled in Fiscal Year 1993 but not completed until Fiscal Year 1994. We collected and reviewed contractor quality assurance evaluation programs, protocols and reports covering 206 separate evaluations. Contractor prepared evaluation cost estimates were also used for determining the overall cost of evaluations.

We based the estimate of cost savings on a one-year evaluation cycle and an average evaluation cost based on contractor prepared estimates. That cycle was chosen because the majority of the contractors covered by our review used a one-year or shorter evaluation cycle. Contractor provided estimates for a typical evaluation were used because contractors did not separately track evaluation costs. To normalize contractor provided estimates that ranged from under \$1,000 to over \$53,000 per evaluation, we totaled the estimates and divided that total by the 30 contractors covered by our review. This method produced an average evaluation cost of \$11,631.

We considered all quality assurance evaluations in excess of one per commercial laboratory per fiscal year to be redundant. We used this approach because most contractors believed that one evaluation per year was adequate and because many commercial laboratories stated that evaluations were virtually identical.

We also collected and evaluated information from subcontract commercial laboratories and other external sources. We reviewed and considered the results of a survey conducted by the International Association of Environmental Testing Laboratories. Information on alternative methods of evaluating laboratories was gathered from a Federal agency and a non-profit third-party laboratory accreditation association.

The audit was made in accordance with generally accepted Government auditing standards for performance audits and included tests of internal controls and compliance with laws and regulations to the extent necessary to satisfy the audit objective. Accordingly, we assessed the internal controls with respect to the requirement that subcontract commercial analytical laboratories be initially qualified and periodically evaluated to ensure they can provide acceptable results of

analyses. Because our review was limited, it would not necessarily have disclosed all internal control weaknesses that may have existed at the time of our audit.

We did not rely on computer-processed data to accomplish our audit objective. Our estimate of available savings was not based on the results of statistical sampling.

An exit conference was held with representatives of the Office of Environmental Management and the Office of Environment, Safety and Health on December 14 and 16, 1994, respectively. The Deputy Assistant Secretary for Procurement and Assistance Management waived the exit conference. Coordination of Management's final response to our report occurred on June 5, 1995.

#### BACKGROUND

In 1991, the Department established a comprehensive quality assurance program to provide confidence that quality was achieved throughout the broad spectrum of work performed by the Department and its contractors. The Department established quality assurance requirements to ensure that risks and environmental impacts were minimized and that safety, reliability, and performance were maximized through the effective management systems commensurate with the risks posed by the facility and its work.

To achieve these goals as they relate to procurement of laboratory analytical services, the Department's Quality Assurance Program requires all laboratories that provide analytical services be evaluated to ensure they are qualified to perform the required work. Contractors meet these goals by performing quality assurance evaluations of commercial analytical laboratories that analyze samples for the Department. These evaluations are required to ensure that the results of subcontractor sample analyses, critical to decisions regarding environmental and worker health and safety matters, are reliable.

We initiated this audit because of problems identified during prior Office of Inspector General audit work. We reported that the results of quality assurance evaluations were not communicated among contractors during our Audit of the Effectiveness and Efficiency of the Rocky Flats Analytical Services Program, (Report Number CR-B-95-01, dated November 3, 1994). Also, problems related to multiple quality assurance evaluations of subcontract commercial laboratories were identified during a review of subcontract administration.

#### OBSERVATIONS AND CONCLUSIONS

The Department's method of performing quality assurance evaluations of commercial analytical laboratories was not cost effective or efficient. Contractors at many of the Department's sites conducted multiple evaluations of the same commercial laboratory. In contrast, some laboratories were not evaluated

to determine their ability to provide analytical services. In addition, methods used to perform evaluations and report results varied among contractors. Finally, quality assurance evaluation results were not communicated to other contractors.

These problems occurred because the Department's quality assurance policy guidance did not require development and implementation of a coordinated commercial laboratory quality assurance program. The Department did not require contractors to coordinate efforts, develop uniform standards and methods, or to communicate the results of their evaluations to other contractors. Contractors were only required to initially evaluate and periodically confirm that laboratories were capable of providing quality analytical data.

The lack of a coordinated commercial laboratory quality assurance evaluation program resulted in excessive cost, duplication of effort, and potentially placed the Department at risk that its decisions on worker health and safety issues and environmental matters may be based on unreliable data. Contractor provided cost estimates indicated that the Department spent about \$2.4 million for commercial laboratory evaluations for Fiscal Year 1993, and that approximately \$1.2 million of that amount was attributable to duplicative and unnecessary evaluations. The failure to evaluate some laboratories, inconsistent evaluation and reporting methods, and failure to communicate results of evaluations to other contractors increased the risk that the Department may rely on analyses from laboratories that suffer from quality or other problems.

The adoption of our recommendation to implement a third-party laboratory accreditation program would eliminate the need to spend \$2.4 million per year for commercial laboratory quality assurance evaluations. Portions of the Environmental Protection Agency, the Department of Housing and Urban Development, a U.S. Navy activity, and some major corporations have successfully adopted this approach to laboratory accreditation. Under this approach, subcontract laboratories bear all costs of accreditation and are required to participate as a condition to bid on analytical service contracts. In addition, third-party accreditation would provide assurance that laboratories are evaluated to clear and consistent common standards, and that reporting and communication of evaluation results is uniform within the Department.

The lack of a cost-effective and efficient commercial laboratory quality assurance evaluation program constitutes a management control weakness that should be considered when preparing the yearend assurance memorandum on management controls.

## PART II

### FINDING AND RECOMMENDATION

#### Evaluation of Commercial Analytical Laboratories

## FINDING

Sound management practices dictate that the Department should strive to streamline its programs to ensure they operate effectively and efficiently. The Department's program for performing quality assurance evaluations of commercial analytical laboratories was neither cost effective nor efficient. Specifically, contractors conducted redundant quality assurance evaluations of commercial laboratories, did not evaluate others, applied standards inconsistently, produced inconsistent results, and did not communicate those results among contractors. These problems occurred because the Department's quality assurance policy guidance did not require the development and implementation of a coordinated commercial laboratory quality assurance program. As a result, about \$1.2 million was for duplicative evaluations and the estimated \$2.4 million the Department expended for Fiscal Year 1993 commercial laboratory quality assurance evaluations could be saved by adopting a third-party laboratory accreditation program. In addition, the Department is potentially at risk that its decisions on worker health and safety issues and environmental matters may be based on unreliable data.

## RECOMMENDATIONS

We recommend that the Assistant Secretary for Environment, Safety and Health, in coordination with the Assistant Secretary for Environmental Management and the Deputy Assistant Secretary for Procurement and Assistance Management:

Develop and implement a coordinated third-party commercial laboratory quality assurance program. At a minimum, the program should:

1. Require that commercial laboratories participate in a third party accreditation program as a condition for award of laboratory analytical services contracts;
2. Phase-in to existing laboratory contracts, as allowed, the third-party accreditation program;
3. Develop and implement Department specific evaluation standards and methods of application with the selected third-party accreditor; and
4. Provide for ongoing monitoring, coordination and oversight of laboratory accreditation issues to ensure that all Departmental concerns are addressed in a uniform and timely manner.

## MANAGEMENT REACTION

The Assistant Secretary for Environment, Safety and Health agreed with the problems addressed in the report and agreed to take action with respect to our recommendations. Management

agreed to adopt either the recommended third-party accreditation approach or an alternative approach that would eliminate redundancies and correct the conditions cited in our report. In addition to interim measures to facilitate the sharing of evaluation results, management stated that it would establish a Process Improvement Team to consider alternatives for implementing our recommendations and would provide its recommendations within 180 days of the final audit report. Management also stated that the team would be a cooperative effort to include representatives from the Offices of the Assistant Secretary for Environmental Management and the Deputy Assistant Secretary for Procurement and Assistance Management.

#### DETAILS OF FINDING

##### IMPROVING THE EFFICIENCY OF GOVERNMENT

The Vice President's National Performance Review (NPR) emphasized that Government agencies should strive to be more efficient by eliminating program redundancies. The objective of this and other NPR initiatives is to make Governmental programs work better and cost less. In addition, sound management practices dictate that, where practical, the Department should streamline its programs to eliminate duplication and to ensure equitable and consistent treatment of commercial laboratories. In this respect, Departmental resources should not be expended for and commercial laboratories should not be subjected to redundant evaluations.

##### Quality Assurance Evaluation Requirement

The Department's Quality Assurance Order, 5700.6C dated August 21, 1991, requires that contractors confirm that subcontract commercial analytical laboratories that perform analyses for the Department are capable of providing acceptable levels of service. Contractors are required to conduct both initial and periodic quality assurance evaluations of those laboratories. Contractors are responsible for conducting such evaluations as part of their overall quality assurance program. Even though the Department did not specify a required frequency of evaluation, most contractors included in our review had adopted a one-year cycle.

##### COMMERCIAL LABORATORY QUALITY ASSURANCE PROGRAM

The Department's program for performing quality assurance evaluations of commercial analytical laboratories was neither cost effective nor efficient. Specifically, we found that:

\ Departmental contractors performed redundant initial and periodic quality assurance evaluations of commercial analytical laboratories, while others received no evaluations;

\ Quality assurance evaluation methods varied from one contractor to another; and



In contrast to these redundant evaluations, several contractors did not conduct evaluations of small dollar value awards and lower tier subcontract laboratories. These laboratories were allowed to analyze samples even though their ability to provide quality analytical data had not been assessed. Officials for a contractor told us that they did not evaluate laboratories with small dollar value awards because they believed that the cost of the evaluation would exceed the total value of the contract. Another contractor stated that it allowed commercial laboratories to subcontract some or all analytical work to others without evaluating the lower tier subcontractor's ability to perform.

#### Variations in Evaluation Methods

Quality assurance evaluation methods varied from one contractor to another. While most evaluations covered the same general subject area, the depth and specificity of coverage varied significantly. For example, several evaluation programs required only that the evaluator complete a yes/no type checklist. In contrast, one evaluation program consisted of over 142 pages of detailed technical questions. That checklist required the evaluator to provide detailed support for each exception found. Many variations between these two extremes were observed.

Commercial laboratories also reported that variations in evaluation methods and evaluator qualifications made it difficult to adequately prepare for evaluations. Respondents to a survey conducted by the International Association of Environmental Testing Laboratories stated that some evaluators did not have sufficient training and experience to enable them to understand the area of chemistry they sought to evaluate. These laboratories stated that reviewers concentrated mainly on the area of chemistry with which they were most familiar, overemphasized some areas, and virtually ignored others. Laboratories also cited differences in interpretations of standards that required them to make frequent and unnecessary changes to their methods of operation.

We also noted a number of inconsistencies in the amount of contractor resources dedicated to performing quality assurance evaluations. Preparation time, length of site visit, number of personnel assigned, and average evaluation costs varied significantly from one contractor to another. Evaluation preparation time usually involved preliminary reviews of laboratory quality assurance documents and required from 2 to 112 hours. Site visits were conducted by from 2 to 10 persons and required from 1 to 5 days to complete. Contractors reported that typical costs ranged from just under \$1,000 to over \$53,000 per evaluation.

#### Results of Laboratory Evaluations

Contractors did not share the results of quality assurance evaluations with one another. Contractor officials stated that even though they recognized that duplicative evaluations were

occurring, they did not consult with one another regarding scheduling and did not share the results of evaluations with other contractors. Both Department and contractor officials stated that some laboratories failed to qualify or were suspended from work for one site but continued to test samples for other sites. These officials told us that even when they learned of these failures or suspensions, they did not notify other known laboratory customers.

The quality of reporting results of evaluations also varied significantly among contractors. A number of the contractors covered in our review prepared well documented reports that identified findings, cited supporting requirements, and specified required corrective actions. Some, however, produced poor quality reports of evaluation in which findings could not be readily identified. One contractor did not prepare a report at all and retained only the completed checklists as proof of its evaluation. Another contractor prepared only a bid review sheet for preaward evaluations and did not detail evaluation results.

Both Departmental and contractor officials at Headquarters and in the field acknowledged that because evaluation results were not shared, some sites used laboratories that had failed to qualify for work at other sites. While most of the officials indicated they would be interested in knowing what laboratories had failed evaluations and the basis for the failures, they stated that current contracting methods did not permit the exchange of such information.

#### QUALITY ASSURANCE REVIEW APPROACH

These problems occurred because the Department's quality assurance policy guidance did not require development and implementation of a coordinated commercial laboratory quality assurance program. The Department did not require contractors to coordinate efforts, develop uniform evaluation and reporting methods, or to communicate the results of their evaluations to other contractors. The Department's Quality Assurance Program required only that contractors initially evaluate and periodically confirm that laboratories were capable of providing quality analytical data.

#### EFFECT OF CONTINUING CURRENT METHOD

The lack of a coordinated commercial laboratory quality assurance evaluation program resulted in excessive cost, duplication of effort, and potentially placed the Department at risk that its decisions on worker health and safety issues and environmental matters could be based on unreliable data. Redundant evaluations conducted by contractors resulted in significant unnecessary expenditures. The failure to evaluate some laboratories, inconsistent evaluation and reporting methods, and the failure to communicate results of evaluations to other contractors increased the risk that the Department may rely on analyses from laboratories that suffer from quality or other problems.

The Department's method of evaluating commercial laboratories resulted in unnecessary expenditures. Based on a one-year evaluation cycle and contractor reported average evaluation costs of \$11,631, elimination of the 103 redundant evaluations would result in estimated savings of about \$1.2 million per year. Savings of about \$2.4 million for the 206 evaluations covered by our review could be avoided by adopting the recommended third-party accreditation program. Over a 5-year period, our recommended approach would result in an estimated savings, without adjustment for inflation, of about \$12 million. These estimates do not consider indirect charges for items such as the development and maintenance of evaluation programs and checklists.

The lack of sharing laboratory evaluation results potentially puts the Department at risk that its decisions on worker health and safety issues and environmental matters may be based on unreliable data. While this risk is not directly quantifiable, we believe that it is significant. The fact that a laboratory may continue to provide analytical services that directly impact worker health and safety issues or environmental decisions, when it fails to qualify or is suspended for cause, demonstrates the significance of such risk.

The inconsistent application of evaluation and reporting methods also increases the risk that the Department's decisions regarding subcontractor qualifications are inappropriate. Inconsistencies in evaluation and reporting methods and the failure to evaluate small dollar value and lower tier subcontractors increases the risk that unqualified laboratories may be permitted to analyze samples. The Department may also not be able to successfully defend decisions to exclude a laboratory from work for one site while allowing it to analyze samples for another.

#### Third-Party Laboratory Accreditation

The adoption of our recommendation, to implement a third-party laboratory accreditation program, should solve the problems observed during our audit. Portions of the Environmental Protection Agency, the Department of Housing and Urban Development, a U.S. Navy activity, and some major corporations have successfully adopted this approach to laboratory accreditation. Under this program, subcontract laboratories bear all costs of evaluations. Requiring accreditation as a condition to bid on analytical service contracts would reduce expenditures for the administration and conduct of these evaluations. Third-party accreditation would also provide assurance that each laboratory is evaluated to a common standard, that such standards are consistently interpreted and applied, and that reporting and communication of results is uniform across the Department.

Also, adoption of a third-party laboratory accreditation program would not weaken the Department's quality assurance

program. A third-party accreditation program would provide assurance that laboratories are initially qualified to perform analyses. These evaluations, however, as important as they are, speak only to the ability of a laboratory to perform on a given date. Once analysis begins, other additional controls such as monitoring a laboratory's ability to properly analyze quality control and performance samples becomes important.

### PART III

#### MANAGEMENT AND AUDITOR COMMENTS

The Assistant Secretary for Environment, Safety and Health agreed with the problems addressed in the report and agreed to take action with respect to our recommendations. Management agreed to adopt either the recommended third-party accreditation approach or an alternative approach that would eliminate redundancies and correct the conditions cited in our report. In addition to taking interim measures to facilitate the sharing of evaluation results, management stated that it intended to form a Process Improvement Team, to consider quality assurance evaluations and methods as they relate to contractor operated laboratories and will provide its recommendations within 180 days of the final audit report issuance date. Management also stated the team would be a cooperative effort to include representatives from the Offices of the Assistant Secretary for Environmental Management and the Deputy Assistant Secretary for Procurement and Assistance Management. Detailed management and auditor comments follow.

Management Comments: Management agreed that based on its experience with the Department's Laboratory Accreditation Program for External Dosimetry and that of other Federal Agencies cited in our report, the third-party approach to supplier qualification and accreditation is practicable in certain instances.

Management stated that it would establish a Process Improvement Team, in coordination with the Assistant Secretary for Environmental Management and the Deputy Assistant Secretary for Procurement and Assistance Management, to consider alternatives for implementing the recommendations and for correcting the conditions cited in our report. Management pledged to either adopt the recommended approach or an alternative approach that will eliminate redundancies and other reported problems. As an interim measure, Management stated that it was in the process of implementing procedures that will facilitate the sharing of evaluations results between contractors and programs. Management also stated that its Process Improvement Team would consider quality assurance evaluations and methods as they relate to contractor operated laboratories.

Management also recognized that while action was required to correct the reported conditions, it sought to develop and implement the least prescriptive requirements to accomplish that goal. It believed that such requirements, supported by

innovative guidance, would allow managers to create the most efficient processes, using appropriate standards, to accomplish their mission. Management stated that it desires a coordinated approach between suppliers and laboratory contractors to ensure high quality services and products. Based on that philosophy, the Process Improvement Team will be chartered to determine an approach that will eliminate redundancies, and have reasonable and cost-effective application to the Department, its contractors, and commercial contract laboratories. For programs or areas for which the third-party accreditation is adopted, either in whole or in part, management agreed to establish protocols and standards for that option.

Auditor Comments: Management's comments are responsive to our recommendations.

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