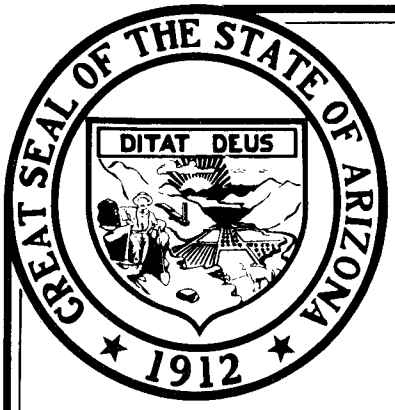

PERFORMANCE AUDIT

STATE AGRICULTURAL LABORATORY

Report to the Arizona Legislature
Prepared by Arthur Young & Company
For the Auditor General
October 1984
84-8

DOUGLAS R. NORTON, CPA
AUDITOR GENERAL

STATE OF ARIZONA
OFFICE OF THE
AUDITOR GENERAL

October 30, 1984

Members of the Arizona Legislature
The Honorable Bruce Babbitt, Governor
Dr. Ivan J. Shields, Director
Arizona Commission of Agriculture and Horticulture

Transmitted herewith is a report prepared for the Auditor General by Arthur Young & Company, A Performance Audit of the State Agricultural Laboratory. An April 27, 1983, resolution of the Joint Legislative Oversight Committee authorized the Auditor General to conduct the performance audit as a part of the Sunset Review set forth in A.R.S. §§41-2351 through 41-2379.

This performance audit report is submitted to the Arizona State Legislature for use in determining whether to continue the State Agricultural Laboratory beyond its scheduled termination date of July 1, 1986. The report makes recommendations to improve the accuracy of laboratory reports, recommends eliminating the certification of privately owned laboratories serving agriculture, and addresses needed changes in both statutes and agency regulations.

The Arthur Young project staff, my own staff and I will be pleased to discuss or clarify items in the report.

Respectfully submitted,

Douglas R. Norton

Douglas R. Norton
Auditor General

Enclosure

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EXECUTIVE SUMMARY

The State Agricultural Laboratory is a division of the Arizona Commission of Agriculture and Horticulture. It provides the agricultural identification and testing services which support regulatory monitoring programs administered by other agencies for the protection of public health, livestock and the agricultural economy. The State Agricultural Laboratory administers the certification of laboratories providing agricultural laboratory services.

The State Agricultural Laboratory was established by the laws of 1980, Chapter 152, House Bill 2281 and operates under the authority of ARS Title 3, Chapter 1, Article 4.

We believe the State Agricultural Laboratory serves the public interest and that its operation should be continued. However, the performance audit identified a number of findings which should be addressed by the Legislature, the Commission of Agriculture and Horticulture (the Commission) and/or the State Agricultural Laboratory (the Agency).

- The lack of documented policies and an effective quality assurance program may be affecting the reliability of test results in the Analytical Section.
- The certification of laboratories providing agricultural testing services may no longer be necessary.
- (*) If the laboratory certification program is continued, administration should be improved and the program costs recovered through higher fees.
- (*) Regulations have not been published and the draft regulations should be revised before publication if the certification program is continued.

(*) • The Agency may not be providing all of the mandated services.

(*) • The statutes are not clear with regard to the reporting of test results by private laboratories.

• Two Arizona agencies are currently authorized by statute to provide certification of laboratories to provide agricultural laboratory services.

Following is a brief summary of each finding:

A. The lack of documented policies and an effective quality assurance program may be affecting the reliability of test results in the Analytical Section. (See Finding I, pages 19-25.)

The lack of written policies and a formal documented quality assurance program raises questions about the reliability of testing services provided by the Analytical Section. A review of 409 official reports disclosed 29 reports with obvious indications of probable discrepancies. A detailed examination of these 29 reports resulted in the identification of 16 separate problems which currently exist, including the reporting of erroneous or misleading test results. These problems exist primarily because management policies are not written and enforced, and a formal documented quality assurance program is not in place. We recommend that both be accomplished.

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*All or portions of these findings are irrelevant if the legislature determines that the laboratory certification program is no longer necessary.

B. The certification of laboratories providing agricultural testing services may no longer be necessary. (See Finding II, pages 26-35.)

Certification offers the opportunity to verify that a laboratory is capable of providing the service desired. The issue is whether or not the provision of this assurance is still necessary, i.e., (1) will harm occur if the laboratory's ability to perform the service is not certified and (2) can the users properly evaluate the qualifications of those offering the service?

There are three types of agricultural laboratory-customer relationships which may require certification:

- A private laboratory serving the private sector
- A private laboratory serving a government agency
- A government laboratory serving another government agency

Under the present circumstances of private agricultural laboratories serving the private sector, other programs provide protection of public health, livestock and the agricultural economy. These include the U.S. Department of Health Grade A Pasteurized Milk Ordinance administered by the Dairy Commissioner and the Feed, Fertilizer and Pesticide laws administered by the State Chemist. Because these laws provide controls other than certification, we believe that private enterprise has sufficient incentive to continue appropriate testing without the laboratory certification program.

In the case of a private laboratory providing services to a government agency, presumably procurement of these services would be established by contract. Requirements to demonstrate proficiency should be included in the provisions of the contract. Thus, a general certification program is not

necessary unless all agencies must apply uniform rules to demonstrations of proficiency. The same would be true for interagency agreements in the case of one government laboratory serving another government agency. The interagency agreement takes the place of the contract unless the relationship is directed by statute.

Therefore, it appears that certification of laboratories to provide agricultural testing services could be discontinued and the respective statutes terminated.

C. If the laboratory certification program is continued, administration should be improved and the program costs recovered through higher fees. (See Finding III, pages 36-42.)

1. Certification Program Effective Administration

Administration of the certified laboratories program is minimal and consists primarily of:

- Processing the initial application, including an on-site inspection and demonstration of proficiency.
- Processing the annual renewal of certificates.
- Handling problems on an exception basis when brought to the attention of the Assistant Director.
- Occasional splitting of samples with a laboratory to compare results.
- Receiving, reviewing and filing of certified aflatoxin test results from the certified laboratories and check sample program results.

While this may satisfy the literal statutory requirements, we do not believe the statutes' intent is satisfied. In our opinion, the present administration of the certification program does not provide reasonable assurance that

the certified laboratories continually provide accurate and timely results. Without more effective administration, the program exists in form but lacks substance.

2. Recovery of Program Costs

All cottonseed products must be tested for aflatoxin by a certified laboratory. Since private laboratories derive economic benefit by becoming certified, the certified laboratories should bear the cost of an effective program. The statutory fee limits of $200 for initial certification and $100 for renewals are insufficient to recover the costs. The fee proposed by the draft regulation is $10. Our estimate of the annual cost of a more effectively administered certification program is $935 per laboratory.

More effective administration of the laboratory certification program and increased fees to recover the costs are recommended if the certification program is continued.

D. Regulations have not been published and the draft regulations should be revised before publication if the certification program is continued. (See Finding IV, pages 43-49.)

Promulgation of regulations for the laboratory certification program is the responsibility of the Commission. Regulations have not been published.

The current draft (January 1982) regulations are inconsistent regarding who has authority to grant or renew a certificate, i.e., the Commission (according to the statutes) or the Assistant Director (according to the regulations).

Additionally, the draft regulations should be revised to clarify provisions for application and certification of samplers and authority for more effective certification program administration.

We recommend that appropriate revisions be made to the draft regulations and that publication be aggressively pursued.

E. The Agency may not be providing all of the mandated services. (See Finding V, pages 50-57.)

1. Milk Testing

The definition of agricultural laboratory services provided in ARS §3-141 appears to include (the testing of) milk for residue and nutrient analysis since it is within the scope of a "raw, processed or manufactured agricultural commodity and product." However, the legislative intent is not clear. Milk testing is being provided by the Department of Health Services. We have been advised by the Agency that they are presently precluded from providing this service due to resource limitations, including space, equipment and personnel.

2. Meat Testing

Meat testing is administered by the Agency but the actual testing is conducted by the U.S. Department of Agriculture (USDA) laboratory in San Francisco. The USDA funds half of the cost. However, turnaround time is longer than would be required locally since the samples are sent to San Francisco. State Agricultural Laboratory management has told us they have the capability and have assisted with meat testing in the past. A study should be conducted to determine the feasibility of performing the meat

testing locally, particularly if the USDA will continue to fund half of the cost.

3. Laboratory Certification

In accordance with ARS §3-145, all laboratories which provide agricultural testing services to agencies or departments of the state require certification by the Agency. The State Seed Laboratory and the Department of Health Services laboratory provide such services, but are not certified by the Agency.

4. Sampler Certification

The Agency has interpreted the statutory authority to certify laboratories to include the certification of samplers. It is not clear, however, whether certification of samplers should be restricted to the private sector only, which is the present practice, or should include state agency employees who collect agricultural samples.

We recommend that the above services be evaluated and brought into compliance with the mandatory provisions of the statutes or otherwise be clarified.

F. The statutes are not clear with regard to the reporting of test results by private laboratories. (See Finding VI page 58.)

ARS §3-145.C states "A certified laboratory shall report test results only to the party who provided the original sample." Certified laboratories which currently provide the Agency with copies of private sector results of aflatoxin tests are clearly in violation of this particular statute. However, in

an opinion from the Arizona Legislative Council, the laboratories may not be in violation of state law by reason of an apparent conflict among several statutes. Rephrasing of ARS §3-145.C is recommended.

G. Two Arizona agencies are currently authorized by statute to provide certification of laboratories to provide agricultural laboratory services. (See Finding VII, page 59.)

It appears that both the Commission and the Department of Health Services (DHS) have statutory authority to grant certification to laboratories for agricultural laboratory services. This leads to confusion for the applicant and gives rise to potential conflict between the two agencies. We recommend the legislature consider a revision to the DHS statutes to remove the authority to certify laboratories for the provision of agricultural laboratory services.

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INTRODUCTION AND BACKGROUND

Arthur Young & Company has completed a performance audit of the State Agricultural Laboratory for the Office of the Auditor General. This performance audit was conducted during the period of May through September 1984. The information, findings and recommendations presented in this report are based on the program and operational status at the time of the audit review.

A. The Need for Testing Services

The issue of pesticides and pesticide contamination is significant. Most have proven harmful to human health. They are increasing in use and more dangerous ones are being developed and used; the problem is expanding. The potential harm to human health and the economy is already proven.

Timely testing is essential both in the identification of diseases and in preventing their spread. The effect on the economy or human health could be disastrous. The spread of a disease in livestock could eradicate the herd. For example, if brucellosis testing was not performed, the disease would not be controlled, resulting in a reduction in the calf crop. Additionally, the disease can be transmitted to humans. While not usually fatal to humans, it can be debilitating, resulting in undulating fever, weight loss and other symptoms. The disease is controlled through the brucellosis monitoring program supported by testing.

The potential threats of aflatoxin in milk, brucellosis in livestock, infestation by the mediterranean fruit fly and the hazards of EDB are all generally recognized problems in Arizona which require the support of analytical laboratory services to control.

B. Background and General Description

The State Agricultural Laboratory (the Agency) is a division of the Arizona Commission of Agriculture and Horticulture (the Commission). It provides the agricultural identification and testing services which support regulatory monitoring programs administered by other agencies for the protection of public health, livestock and the agricultural economy. The State Agricultural Laboratory also administers the certification of laboratories providing agricultural laboratory services.

The State Agricultural Laboratory was established by the laws of 1980, Chapter 152, House Bill 2281 and operates under the authority of ARS Title 3, Chapter 1, Article 4. The directed effective date was January 1981. Laboratories of the Agriculture and Horticulture Commission, State Chemist and Livestock Sanitary Board were combined to create the State Agricultural Laboratory. The objectives were twofold:

1. To consolidate laboratory activities related to agriculture, and
2. To provide certification to laboratories providing agricultural laboratory services. (At that time, a specific problem existed relative to the accurate analysis of aflatoxin in cottonseed.)

The State Agricultural Laboratory is basically a service agency. House Bill 2281 mandated that the Laboratory be created to provide services to specific agencies:

1. Chief Veterinary Meat Inspector
2. The Board of Pesticide Control
3. The Livestock Sanitary Board
4. The Office of the State Chemist
5. The Commission of Agriculture and Horticulture

The Agency may contract with any other agency or private sector laboratory to provide laboratory services for the protection of the agricultural community and the public health. The Agency also has one regulatory function: It recommends certification and enforces regulation of all laboratories which offer guaranteed analysis services for agricultural activities.

The State Agricultural Laboratory provides services largely to those five agencies which are mandated by law. Services are also provided to the Structural Pest Control Board. More limited analytical services are provided to several other state agencies, local governments and Indian tribes.

The State Agricultural Laboratory certifies all laboratories which offer guaranteed analyses of agricultural products. For all practical purposes, this means laboratories offering aflatoxin testing. Aflatoxin is a carcinogen which occurs in cottonseed products. Because aflatoxin has been a problem in Arizona, all cottonseed products must have a certificate issued by a certified laboratory at the time they are sold. The Agency certifies the ability of these laboratories to conduct accurate analyses for aflatoxin.

In addition to certifying private laboratories, the State Agricultural Laboratory also certifies samplers. These samplers are persons who take samples for laboratory analysis. To become a certified sampler, one must apply to the State Agricultural Laboratory, which will then send a sampler's test and the rules and regulations on aflatoxin. This is essentially an open book test, but it is believed that it at least provides some assurance that samplers have seen and are aware of the regulations governing aflatoxin, and that an appropriate sample for testing purposes will be taken.

C. Organization and Administration

The State Agricultural Laboratory is a division of the Commission of Agriculture and Horticulture. The Assistant Director of the Laboratory is the State Chemist. He serves half-time in this capacity, as does the Executive Secretary. The State Chemist also has responsibility for regulating the quality of feed, fertilizers and pesticides. In this role he is a major user of the agricultural laboratory.

The State Agricultural Laboratory has two major divisions, the Analytical Section and the Biological Section.

The Analytical Section does all chemical analyses. These analyses include formulation testing (label claim) of fertilizers, pesticides and animal feeds, and testing for pesticide and mycotoxin residues including aflatoxin. In this capacity the State Agricultural Laboratory ensures that products for agriculture and for consumers are in fact what they are claimed to be. The section has a total of eight employees:

One Section Manager (Chemist)
Two Service Supervisors (Chemists)
Two Analytical Chemists
Two Laboratory Technicians
One Secretary

The Biological Section conducts testing on plants, entomology and animal samples. Basically this section identifies insects, analyzes plant tissues and analyzes samples drawn from animals, such as blood samples for brucellosis or antibiotic content. The section has a total of six employees:

One Section Manager (Systematic Entomologist)
One Service Manager (Systematic Entomologist)
Two Laboratory Technicians
One Typist
One Plant Pathologist (Approved in FY 84-85 budget)

In addition, the Biological Section has two federally funded positions in the Animal Disease Laboratory. The Section Manager also has responsibility for coordinating seed and meat testing.

The laboratory administration (the State Chemist/Assistant Director) and Analytical Section are located at the University of Arizona experimental farm at Main and Longmore in Mesa. Laboratory facilities at this location occupy the west wing of the main building. The Biological Section is located at the Agriculture and Horticulture Building in Phoenix at 1688 West Adams.

D. Operating Budget

The State Agricultural Laboratory operating budget is appropriated from the general fund. A five-year summary of the budget is provided in the following table:

Table 1

State Agricultural Laboratory Operating Budget

	80-81 Actual (1)	81-82 Actual	82-83 Actual	83-84 Estimate	84-85 Budget (2)
FTEs	12	15	13	13	14(3)
Personnel Services	$90,800	$292,400	$259,200	$261,500	$300,900
Employee Related Expenses	17,600	63,000	51,100	54,400	71,900
Professional and Outside	26,400	43,000	78,100(4)	41,200	27,900
Travel: In-State	1,100	3,800	3,800	3,800	9,000
Travel: Out-of-State	1,400	3,100	3,100	3,100	3,100
OOE	22,700	71,800	64,700	64,700	64,300
Equipment	17,700	82,600	61,900	41,600	41,600
Totals	$177,700	$559,700	$521,900	$470,300	$518,700

(1) Laboratory began operation in present form in January 1981. Amounts reflect what was transferred in as of January 8, 1981.

(2) Breakdown of approved budget provided by A. Spires, April 19, 1984.

(3) Addition of full-time Plant Pathologist. These services were previously provided under contract with the University of Arizona.

(4) Included funding for the State Chemist (one-half) and secretary (one-half). This funding was subsequently included in the State Chemist's budget. (The State Chemist is also Assistant Director of the Agricultural Laboratory.)

E. Service Measurements

A five-year summary of the work load volumes for State Agricultural Laboratory services is provided in the following table:

Table 2

State Agricultural Laboratory Analysis Volumes

		80-81 Actual	81-82 Actual	82-83 Actual	83-84 Actual	84-85 Estimate (1)
1.	Insect Identifications	12,620	11,869	9,728	24,168	15,000
2.	Animal Blood Tests(2)	151,400	154,153	132,471	126,826	130,000
3.	Seed Tests(3)	500	664	644	494	500
4.	State Meat Tests(4)	125	108	208	144	150
5.	Fertilizer Formulation Analyses	1,072	810	881	1,102	1,400
6.	Feed Formulation Analyses	1,374	630	603	1,110	600
7.	Pesticide Formulation Analyses	433	197	448	435	450
8.	Residue Analyses	155	589	1,392	1,155	1,200
	Totals	167,679	169,020	146,375	155,434	149,300

(1) Taken from the 1984-85 Operating Budget.

(2) The State Agricultural Laboratory only provides one (1) FTE for this function. Two other FTEs in the Animal Disease Laboratory are USDA employees.

(3) The actual testing is performed by Agricultural Seed Laboratories, Phoenix (a private laboratory).

(4) The actual testing is performed by the USDA, San Francisco, California.

SUNSET FACTORS

In accordance with ARS §41-2354, the Legislature should consider the following 12 factors in determining whether the State Agricultural Laboratory within the Arizona Commission of Agriculture and Horticulture should be continued or terminated.

1. Objective and purpose in establishing the State Agricultural Laboratory.

   The State Agricultural Laboratory was established by the laws of 1980, Chapter 152, House Bill 2281. The objectives of the legislature in establishing the State Agricultural Laboratory were twofold:

   a. To consolidate the resources providing raw agricultural products testing services, and

   b. To provide certification to laboratories providing analysis of agricultural products. (At that time, a specific problem existed relative to the accurate analysis of aflatoxin in cottonseed.)

   The legislature clearly stated this intent in the laws of 1980:

   "The purposes of this act are:

   1. To establish a state agricultural laboratory as a division of the Arizona commission of agriculture and horticulture to assume the functions of providing laboratory services to:

      (a) The chief veterinary meat inspector.
      (b) The board of pesticide control.
      (c) The livestock sanitary board.
      (d) The office of the state chemist.
      (e) The commission of agriculture and horticulture.

2. To provide laboratory service to agriculture for the protection of the agricultural community and the public health.

3. To provide certification to laboratories providing services and to prescribe criteria for certification."

"§3-144. State agricultural laboratory; maintenance and purpose

A. The state agricultural laboratory is established and maintained to carry out this article and for laboratory examinations, diagnosis, analysis, testing, quantifying and identification necessary to perform the functions and duties assumed or succeeded to pursuant to §3-142."

The objectives should be reexamined relative to the certification of laboratories since the certification program may no longer be necessary. (See Finding II, pages 26-35.)

2. <u>The effectiveness with which the State Agricultural Laboratory has met its objective and purpose and the efficiency with which the State Agricultural Laboratory has operated</u>.

The State Agricultural Laboratory has generally been effective in meeting its objectives and purpose. Identification and testing services are being provided. A laboratory certification program is being administered. However, improvements are needed.

The Laboratory does not have written policy guidelines regarding testing and the recording and reporting of test results. The Laboratory does not have a documented quality assurance program. As a result, inaccurate results have been reported by the Analytical Section and the probability of this occurring is greater than necessary. (See Finding I, pages 19-25.)

If the laboratory certification program is continued, effective administration of the program needs to be improved and administrative costs recovered through higher fees. (See Finding III, pages 36-42.)

Regulations have not been published by the Commission. (See Sunset Factor 4.) The draft regulations need to be improved, particularly to clarify the authority of the Agency Assistant Director to effectively administer/enforce the certification program. (See Finding IV, pages 43-49.)

The Agency may not be providing all of the mandated services. However, the statutes are not clear with regard to the testing of raw milk. Although certification is the responsibility of the Commission, not all laboratories which require mandatory certification pursuant to ARS §3-147 have been certified, specifically the State Seed Laboratory and the Department of Health Services laboratory. (See Finding V, pages 50-57.)

The Agency does not have a formal system for measuring its efficiency or effectiveness beyond counting the number of tests performed. Lack of work space and expanding needs for testing services may further impact future efficiency and effectiveness.

Nevertheless, the Agency has demonstrated the ability to anticipate and respond to trends such as the recent ban placed on use of the pesticide EDB. The agencies served by the State Agricultural Laboratory generally concurred that the Laboratory has been responsive to their needs.

3. The extent to which the State Agricultural Laboratory has operated within the public interest.

The State Agricultural Laboratory serves the public interest by providing testing services in support of regulatory enforcement programs which exist to protect public health and the agricultural economy. These monitoring and enforcement programs would be virtually useless without analytical support.

Some of the benefits realized by the general public through the identification and analytical services provided are:

a. Confidence by the general public of both Arizona and other states that the products they buy are clean and safe according to the standards checked.

b. The consumer generally doesn't have to worry about getting what he/she is paying for as presented on the label. The monitoring program supported by testing, provides a deterrent to the unscrupulous marketer.

c. The agriculture/agribusiness community has increased confidence because of expertise available to respond to problems.

d. Having testing services available helps to stabilize prices because of ability to react, solve problems and reach agreements while minimizing economic losses.

Because of rapid pest identification by the Biological laboratory and follow-up by Commission field personnel, the state has had no major outbreak of exotic pests. Arizona has experienced a continued reduction of the incidence of brucellosis among its livestock due to the detection services of the agricultural laboratory. Since the organization of the State Agriculture Laboratory there has been no major public reactions to the fear of pesticide. Rapid identifications of residues and subsequent information to the public have prevented any outcry. There has been no major problem with

aflatoxin since testing was begun and test methods were standardized through certification. A number of judgments have been made in favor of the agencies supported, partially based on the analytical work done for them.

Implementation of the laboratory certification program is an excellent example of serving the public interest in response to a problem. Development and implementation of test procedures for aflatoxin in cottonseed and the laboratory certification program had the effect of improving the quality of milk and improving the quality and market price for cottonseed as a commercial feed, both intra- and interstate. The costs of test services have stabilized through private sector competition to provide these services. However, it is not certain that continuation of the laboratory certification program is in the best public interest. We believe that private enterprise has sufficient incentive to continue this service without the regulatory aspects of the laboratory certification program. (See Finding II, pages 26-35.)

4. <u>The extent to which rules and regulations promulgated by the State Agricultural Laboratory are consistent with the legislative mandate</u>.

In accordance with ARS §3-147, rules and regulations: "The <u>commission</u> shall prescribe reasonable rules and regulations for..." (emphasis added). The State Agricultural Laboratory is clearly not responsible for promulgating the rules and regulations. Additionally, rules and regulations have not been published.

Nevertheless, the draft (January 1982) rules and regulations were reviewed. They appear to be consistent with legislative mandate except for who is authorized to grant certification.

The draft regulations identify the Assistant Director as having this authority. The statutes appear to clearly reserve this authority for the Commission. (See Finding IV, pages 43-49.)

5. The extent to which the State Agricultural Laboratory has encouraged input from the public before promulgating its rules and regulations and the extent to which it has informed the public as to its actions and their expected impact on the public.

The Commission is responsible for prescribing rules and regulations.

Pursuant to ARS §3-147.B, an advisory committee was formed to assist in the formulations of rules and regulations. Appropriate public notice was given and a public hearing was held on October 8, 1981. A review of the minutes of this public hearing did not disclose any major problems with the proposed regulations. Adoption of the regulations was ordered by the Commission at its meeting on February 11, 1982. Nevertheless, regulations have not been published.

The Commission is considering holding a second public hearing since some changes have been made and because considerable time has passed since the first public hearing without the rules being published.

If the decision is to continue the certification program, we recommend that the regulatory changes recommended in Finding IV (pages 43-49) be considered and incorporated as appropriate before the next public hearing.

6. The extent to which the State Agricultural Laboratory has been able to investigate and resolve complaints that are within its jurisdiction.

The State Agricultural Laboratory has adequately investigated and resolved complaints that are within its jurisdiction. Actually, most complaints which might arise fall within the jurisdiction of the Commission or the agency submitting the sample to the laboratory for identification or analysis.

The few complaints received that are within the agency's jurisdiction have been related to the accuracy of test results determined by the Agency or a private certified laboratory. All were resolved quickly--and in the case of the Agency, the findings were upheld.

7. The extent to which the Attorney General or any other applicable agency of state government has the authority to prosecute actions under enabling legislation.

The Commission, Agency and Attorney General appear to have adequate authority under the statutes, but their ability to enforce may be limited because rules and regulations have not been published.

8. The extent to which the State Agricultural Laboratory has addressed deficiencies in the enabling statutes which prevent it from fulfilling its statutory mandate.

At this time, no deficiencies are known to be present in the enabling statutes which prevent the Commission or the Agency from fulfilling its statutory mandate.

9. The extent to which changes are necessary in the laws of the State Agricultural Laboratory to adequately comply with the factors listed in the Sunset laws.

If the legislature agrees that the certification of agricultural laboratories is no longer necessary, a major revision of ARS Title 3, Chapter 1, Article 4 (ARS §§3-141 through 3-149) will be necessary. (See Finding II, pages 26-35.)

If the decision is to continue the certification program, several statutory concerns should be addressed.

It appears that statutory clarification would be appropriate for ARS §3-145.C which states "A certified laboratory shall report test results only to the party who provided the original sample." Certified laboratories which currently provide the Agency with copies of the results of aflatoxin tests are clearly in violation of this statute. However, the laboratories may not be in violation of state law by reason of an apparent conflict among several statutes. (See Finding VI, page 58.)

The Department of Health Services (DHS) also appears to have statutory authority to grant certifications for agricultural testing services. This type of dual authority does not appear to be in the best public interest. We recommend the legislature consider a revision to the DHS statutes to remove the authority to certify laboratories for the provision of agricultural testing services. (See Finding VII, page 59.)

Since the certification program results in a direct economic benefit to the certified laboratories, we believe the certified laboratories should bear the cost of a more effectively administered program. The legislature should consider substantially increasing the fees for initial and renewal certificates as set forth in ARS §3-146. (See Finding III, pages 36-42.)

10. The extent to which the termination of the State Agricultural Laboratory would significantly harm the public health, safety or welfare.

The State Agricultural Laboratory provides agricultural testing services in the broad areas of environmental and formulation diagnostic testing. These testing services are provided specifically to support regulatory programs designed to safeguard the public health and agricultural economy. The potential threats of aflatoxin in milk, brucellosis in livestock, infestation by the mediterranean fruit fly and the hazards of EDB and other pesticide residues are all generally recognized problems in Arizona which require the support of analytical services to control.

The major consequences of not having laboratory testing services would be:

a. Monitoring/enforcement programs would be virtually useless without analytical support.

b. The public would not be protected from known health hazards which would result from such as pesticide residues or diseases which are carried in the food chain.

c. The economy would suffer as a result of higher losses of agricultural commodities stemming from infestations of insects, plant diseases or livestock diseases.

If the State Agricultural Laboratory did not provide these services, the agencies they serve would have to seek services elsewhere. However, some of these services are not otherwise available in Arizona except possibly from the Universities.

11. The extent to which the level of regulation exercised by the State Agricultural Laboratory is appropriate and whether less or more stringent levels of regulation would be appropriate.

Regulation of laboratories insofar as the certification program is concerned could be eliminated. (See Finding II, pages 26-35.)

If the decision of the legislature is to continue the laboratory certification program, then the proposed regulations need to be strengthened to support effective administration of the program. (See Finding IV, pages 43-49.)

12. The extent to which the State Agricultural Laboratory has used private contractors in the performance of its duties and how effective use of private contractors could be accomplished.

The Agency currently uses a private laboratory to do the seed testing. Private laboratories are also used as "referee" laboratories when the results of the Agency or another certified laboratory are challenged. Seven private laboratories currently provide testing for aflatoxin in cottonseed in support of the regulatory program under the Commercial Feed Law. At least two private laboratories have now developed the capability to test for EDB although they are not currently doing this in direct support of agency regulatory enforcement programs.

In areas where there is no profit margin, the private sector has not developed expertise for the diagnosis. However, there is expertise available in the private sector for many of the routine tests performed by the Agency. Therefore, there is the potential for the Agency to contract for services, thereby making resources available for expanded services such as milk or meat testing, providing that space and equipment are available.

The Agency is concerned that the cost of private sector testing for regulatory enforcement purposes might be higher because their results may be subject to litigation. The private laboratories we talked to did not support this theory. We believe this concern could be resolved through the competitive bid process for the services. In the specific case of seed testing, we were advised that development of this capability within the Agency has been considered. It was determined that the cost for doing so far outweighs the cost of contracting with the private sector, primarily because the volume of tests for enforcement purposes was insufficient.

The Agency is also concerned that if a private laboratory's results were challenged and a litigation took place, expenses for appearances at hearings might negate any dollar savings. However, according to Agency management, no court litigation involving test results has occurred and appearances at hearings to attest to the results are estimated at not more than five or six since the Agency was established.

FINDING I

THE LACK OF DOCUMENTED POLICIES AND AN EFFECTIVE QUALITY ASSURANCE PROGRAM MAY BE AFFECTING THE RELIABILITY OF TEST RESULTS IN THE ANALYTICAL SECTION.

FINDINGS

The testing services (analyses and identifications) provided by the State Agricultural Laboratory appear generally to be accurate. In the very few instances where test results have been challenged, split samples have been submitted to reference laboratories such as other private laboratories, the USDA and the California Department of Agriculture. In all instances, Agency management reports that results were confirmed by the reference laboratory. However, the reliability and accuracy of the test results may be questionable because the Agency does not have a formal documented quality assurance program.

Quality assurance is the concept of maintaining the ability of a laboratory to furnish reliable information. The Agency does not have a written policy for quality assurance. The only formal activity associated with a quality assurance program is the participation in six (6) check sample programs. There are currently no written procedures to ensure that proper testing procedures are used or that test results are interpreted and reported accurately. The Agency has been evaluating the quality assurance program used by Montana. As of August 1, 1984, no decision has been made to implement the Montana program or adopt any other formal program.

To further evaluate the propensity for error due to the lack of written policy and procedural guidelines, an examination of the Analytical Section laboratory records was conducted. The records examined consisted of the Master Log, State Chemist Official

Reports and Laboratory Data Books. The examination consisted of evaluating the completeness of the records, determining if an appropriate audit trail existed between them, determining if reported results accurately reflected the test results, and whether or not laboratory management policy was being followed.

A total of 409 State Chemist Official Reports were reviewed. These reports covered the approximate time periods of the first three months of 1983 and of 1984. From these, a total of 29 reports were selected which appeared to have obvious discrepancies. These 29 reports were then compared to the other laboratory records.

Our findings indicate that laboratory procedures and records require substantial improvement. Following is a summary of the findings based on review of the 29 reports. Since there is no written policy, "stated policy" refers to that which was verbally conveyed to us by laboratory management.

A. There were a number of examples where an Official Report had been issued and later reissued reflecting different results. The first reports did not indicate that they were "unofficial" or "preliminary." The reissued reports did not indicate that they superceded, amended or revised the first. Therefore, it would appear that the recipient would be free to act based on whichever report was most favorable, particularly since no "date reported" is indicated (see paragraph L below). It was noted that for those changed reports indentified in our sample, if there was a change in the pass or fail result, in every case the change was from "violation" to "pass."

B. The stated policy is that if only one test is performed and the results are within the permitted analytical variance

(PAV), the result is considered as a pass. However, if more than one test is conducted (policy is then a minimum of 3) the results shall be averaged in order to determine if it passes or is a violation, and the deficiency or excess shall be based on the difference between the average and the guarantee. In the latter case, the PAV does not apply. What we found in most instances of more than one test was pass/fail determination being based on the single result which yielded the least deficiency and would be indicated as a pass if that single result were within the PAV. This resulted in some samples being passed which should have been violations.

C. There were several instances in our sample where tests were run more than three times. In some cases, subsequent tests were run after the results had been reported. There was no obvious explanation as to why extra tests were done. There was also no indication that a supplemental report had been issued. Justification for running additional tests should be documented.

D. Many entries in the lab data books, and virtually all entries in the Aflatoxin Analysis data book, are done in pencil. Several erasures with changed entries were identified with no record of the prior entry and no explanation. The standard practice for laboratory data books is for all entries to be in ink. Errors should be marked out with a single line through so they are still legible. A note explaining the reason for the correcting entry should be entered.

E. Entries in a laboratory data book should not be out of chronological order as was noted in the Aflatoxin Analysis data book. At the very least, such an entry should be approved by appropriate management and so noted in the data book along with the explanation.

F. The stated policy is that if the result of the first test is a "violation," the test will automatically be rerun in duplicate (two more times). Yet, in at least three of the examples identified in paragraph A above, the single result reflected on the first report indicated that the test should have been rerun before being reported.

G. The stated policy is that all test results are checked/reviewed by someone other than the person performing the test. There were many instances where only one set of initials was reflected in the lab data books and on the test reports. There were also instances where results were apparently miscopied from the lab data book onto the report or the reported result did not match any test result. This would suggest that reviewing/checking is not habitually performed.

H. In some instances a test result is entered on the report and then scratched out. The result indicates that it was an apparent anomoly and should not be considered in the pass/fail determination. In these instances, we suggest that the result not be recorded on the report and be so noted in the lab data book.

I. Many entries in the lab data did not reflect a date the test was performed or the initials of the person performing the test. In several books, these columns have been dropped entirely. The stated policy is that a different person perform the retests. This was not readily evident from the lab data books because of the missing initials.

J. Many columns in the lab data books are incomplete and notes are either unclear or nonexistent. Every column should be completed for each test entered. Clear, concise notes should be entered, explaining any unusual condition, which may clarify or otherwise aid interpretation of the test results.

K. The pages of the lab data books should be sequentially page numbered, preferably with preprinted page numbers. It would also be helpful if the page number of the previous test run on a sample was indicated in the notes or in an additional column for that purpose.

L. Virtually none of the State Chemist Official Report forms reflect a "date reported" in the space provided in the margin. Some also were incorrectly marked "pass" when they should have indicated "violation."

M. Many of the State Chemist Official Report forms do not include a description of the material being tested. This would be helpful to the laboratory in those instances where the brand name is not self explanatory (e.g., liquid fertilizer, dry fertilizer, goat feed).

N. The stated policy is to indicate a lot number for the sample, otherwise insert "none." In 9% of the reports sampled, this entry was left blank. In 1% of the reports sampled, there was no entry for lot size.

O. The stated policy is that all test result entries on the bottom of the State Chemist's Official Report are to be initialed by the person performing the test. In a sample of 241 reports from 1984, 20 reports (8.3%) had initials missing. (However, the need for these initials on the test report is questionable.)

P. It was suggested by laboratory management during our review that laboratory personnel not make the pass/fail determination on samples submitted by and reported to the State Chemist on his Official Report form. The laboratory should only record the test result. The pass/fail determination and amount of

deficiency or excess should be determined by the State Chemist's office. We concur, particularly since this is basically how test results for other agencies are handled. However, we believe that additional information may be useful in judging the test results and should be considered for inclusion with the reported test results to all agencies.

1. For those procedures where permitted analytical variances have been established, indicate the PAV value if only one test is conducted and reported.

2. Indicate the detection level for the particular test procedure, particularly when the reported results are close (to be defined) to the detection limit, 'trace' or 'none detected.'

3. Indicate the test procedure used to determine the results.

In reviewing each of the 29 reports and the above findings with management, they concurred that there were obvious discrepancies or other questions for which, in general, no apparent logical explanation was available from the lab data books or other records.

CONCLUSIONS

The lack of written policies and a formal documented quality assurance program raises questions about the reliability of the testing services. From the above findings, one must conclude that inaccurate test results have been reported and that the probability for them is above a reasonable limit.

The proposed regulations for laboratory certification (R3-1-205) requires that each applying laboratory "...submit proof that it has a precision and accuracy control program for each service it

provides. Such a program must be compatible with generally recognized practices followed by agencies such as ..... the Arizona State Agricultural Laboratory." Without a formal documented quality assurance program, the Agency is operating on a double standard. (See also Arizona Legislative Council Memo, Fact Situation E, pages 7 and 8 in the appendix.)

RECOMMENDATIONS

1. State Agricultural Laboratory management policies regarding testing and documentation procedures should be put in written form, reviewed with all laboratory personnel and enforced.

2. The State Agricultural Laboratory should develop and implement a formal quality assurance program.

FINDING II

THE CERTIFICATION OF LABORATORIES PROVIDING AGRICULTURAL TESTING SERVICES MAY NO LONGER BE NECESSARY.

FINDINGS

A. Introduction and Background

It appears from our audit findings that three factors influenced regulation of agricultural laboratory services, i.e., establishment of the laboratory certification program.

1. There existed a high potential for harm to public health.
2. There were economic factors which encouraged government involvement.
3. Government was influenced to do so by the private sector, both from business and the general public.

Aflatoxin is a known potent carcinogen. The stimulus for the certification program was the identification of levels of aflatoxin in milk which were considered to be above acceptable limits. This occurred in 1978. From the information available, the Governor of Arizona determined there was a potential threat to public health and that the levels of aflatoxin were above the State established limits. He therefore ordered the dumping of thousands of gallons of milk causing a major economic impact on the dairy industry.

Additionally, several states threatened to embargo Arizona cottonseed, thereby affecting a significant part of the market. Cottonseed from Arizona would not be permitted in those states unless it were accompanied by a report certifying that it was below the FDA limits for aflatoxin.

The possibility of having to dump more milk because of contaminated feed posed a threat of further economic losses to dairying. The agricultural business community, through various representative organizations, collaborated with the State to find a solution. The solution sought, and subsequently developed and implemented, was the testing of cottonseed for aflatoxin.

Cottonseed is particularly attractive as a feed for lactating cattle because of its high protein content, availability and relatively lower cost when compared to other high-protein feed products. It was also known to be the source of the aflatoxin. Therefore, the agriculture business community wanted assurance that the cottonseed they bought was below the levels of aflatoxin contamination which might result in adulteration of the milk or injury to livestock. The answer was obviously to have the cottonseed tested before purchase, something for which they did not have the capability. They also did not have the means to determine if a laboratory they might select to do the testing could produce reliable results. They therefore turned to the State for this assurance.

The private laboratories which could provide the test services wanted some assurance that all laboratories would require the same equipment and have to follow the same procedures. This was to preclude a laboratory from using a less expensive, less reliable method to an unfair competitive advantage.

B. Current Status

The State and industries involved have established what appears to be an effective program for controlling aflatoxin levels in cottonseed and thus in milk. The agricultural laboratory certification program established by HB 2281 was

initiated in January 1981. Mandatory certication is required in order to provide agricultural laboratory services to agencies of the State and for providing guaranteed analysis to distributors of commercial feed or whole seed for consumption by livestock.

Approved methods of sampling and testing cottonseed for aflatoxin are delineated in Department of Health Services Regulations R9-17-311 through R9-17-321. Since release of these regulations in June 1981, the limit of aflatoxin in cottonseed for use in the rations of non-dairy animals has been raised from 100 parts per billion to 300 parts per billion. Approved methods of sampling and testing cottonseed for aflatoxin are also delineated in the Commercial Feed Regulations R3-3-41 through R3-3-56, issued in August 1984. (Note: DHS is currently revising its regulations on aflatoxin in cottonseed to eliminate specification of the testing procedures since the Commercial Feed regulations now include them.)

Milk is routinely sampled as an end product under the requirements of the U.S. Department of Health and Human Services Grade A Pasteurized Milk Ordinance. This ordinance is incorporated by ARS §3-605. The Dairy Commissioner has enforcement responsibility and sets the sampling and testing frequency if greater than federally recommended minimums are used. According to the Dairy Commissioner, Arizona currently has the most stringent milk testing program in the United States. The permissible level of aflatoxin in milk is established by the State. Milk which exceeds 0.5 parts per billion aflatoxin is considered adulterated and cannot be used, blended or otherwise, in any product for human consumption. In addition, the United Dairymen of Arizona association imposes fines for milk which does not conform to established quality standards.

Arizona cottonseed once again has an established interstate market. This has occurred due to the high quality, competitive price and the fact that each shipment is accompanied by a laboratory certification of the aflatoxin content.

The only private laboratory agricultural testing service provided to the private sector requiring mandatory certification by the State Agricultural Laboratory at this time is for aflatoxin in cottonseed. Certification is required by ARS §3-145.B because it constitutes the provision of guaranteed laboratory analysis information to distributors of commercial feed and whole seed for consumption by livestock. However, this has been interpreted by the Agency to exclude in-house quality control laboratories operated by a processor/distributor which do not otherwise provide this service to the public.

The program which has been implemented, as far as the private laboratories are concerned, has been voluntary. The decision to develop the capability and become certified to test cottonseed for aflatoxin has been a profit-motivated business decision.

C. Criteria for Regulatory Control by Certification

Certification is a form of regulation which grants recognition to individuals or businesses who have met predetermined qualifications set by a state agency. Only those who meet the qualifications may legally use the designated title. Typically, noncertified businesses may offer similar services to the public as long as they do not describe themselves as being "certified." Certification is especially appropriate when the public needs assistance in identifying competent practitioners,

but where the risks to health and safety are not severe enough to warrant licensure.[1]

In contrast to the typical certification program, the Arizona program prohibits the offering of services without certification if (1) those services are provided to a state agency or (2) if it constitutes the provision of guaranteed analysis to distributors of commercial feed for consumption by livestock.

The specific criteria that were examined to determine if the certification program is still necessary are:

- Whether the unregulated practice of an occupation poses a serious risk to consumers' life, health, and safety, or economic well being.
- Whether potential users of the occupational service can be expected to possess the knowledge needed to properly evaluate the qualifications of those offering the service.
- Has the least restrictive level of regulation been applied so as to miminize any harmful regulatory effects such as a decrease in the availability of practitioners or higher costs of goods and services.

An equally important criterion is whether or not the marketplace provides a solution.[2]

1. It is intended that no profession, occupation, business, industry or other endeavor be subjected to the State's regulatory power unless the exercise of such power is necessary to protect the public health, safety or welfare from significant and discernable harm or damage.

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1. Benjamin Shimberg and Doug Roederer, Occupational Licensing: Questions a Legislator Should Ask, The Council of State Governments, Lexington, Kentucky, March 1978, pp 4-5

2. Jonathan Rose, "Occupational Licensing: A Framework for Analysis," Arizona State Law Journal, Volume 1979, Number One, p. 190

In the case of the private laboratory certification program per se, this cannot be established since other regulatory controls exist. Specifically, these include the Grade A Pasteurized Milk Ordinance and the Commercial Feed Laws. These laws protect public health by requiring end product testing.

2. The second consideration is whether consumers of a particular service are able to make an informed and intelligent selection of the service providers, free from undue exploitation by the provider.

   The agriculture industry and its various associations are not considered to be uninformed. Their selection of a service provider in the case of testing for aflatoxin in cottonseed is assisted by the publication of the proper methods in the Commercial Feed Regulations and the issuance of a report of the results which contains an attest statement. Should there be a question regarding the accuracy of results being obtained by a particular laboratory, the issue can be brought to the attention of the State Chemist, who enforces the Commercial Feed Regulations, for appropriate action. Such actions include making investigations, embargoing material and levying fines. Additionally, other forms of legal redress are available to the industry.

   Testing of cottonseed for aflatoxin as well as any other testing of raw agricultural products by (private) laboratories should be continued. In the specific case of aflatoxin testing, purchasers of commercial feed containing cottonseed should ensure that the distributor provide a report which contains signed attest statements by the sampler and by the laboratory that the sampling and testing procedures specified in the Commercial Feed

Regulations have been complied with. To make the assumption that harm would result would imply that laboratories would act irresponsibly and would falsely attest to their results.

The attest statements which currently appear on the Aflatoxin Certification Program form are as follows:

Sampler Attest Statement:

"I certify this sample was taken in accordance to Regulation R3-3-53 of the Arizona Commercial Feed Law, A.R.S. 24-901 through 24-917."

Laboratory Attest Statement

"I certify this sample was prepared and analyzed in accordance with procedures stated in Regulation R3-3-54 of the Arizona Commercial Feed Law, A.R.S. 24-901 through 24-917."

3. Government should provide only the minimum level of regulation.

Certification appears to be the most appropriate form of regulation for the conditions that existed in 1980 when House Bill 2281 was passed. Since that time, appropriate test procedures for aflatoxin have been developed and implemented and competent practitioners established. The risks have been reduced and sufficient information has been disseminated so that users no longer need assistance in identifying competent practitioners. The Commercial Feed Laws and the Commercial Feed Regulations issued in August 1984 provide suitable guidelines for the control of aflatoxin in commercial feed for livestock.

4. Government intervention to protect consumers is only necessary when the market fails to perform this function.

   Admittedly, this was the case in 1978 with respect to aflatoxin in cottonseed. However, an effective program for controlling aflatoxin in cottonseed has been established in the marketplace. Appropriate sampling and testing procedures are promulgated by the Commercial Feed Regulations. Regulation of milk poses economic penalties sufficient to expect that appropriate testing would continue without certification of samplers and laboratories by the State.

If it is desirable to have private laboratories perform compliance testing services in support of a State regulatory function (e.g., the State Agricultural Laboratory were to contract for the provision of specific services by the private sector), demonstration of the proficiency of the selected laboratory to provide the specified services should be contractually established on a case-by-case basis. In any event, the relationship here is private to government rather than private to private. The underlying purpose is to monitor for compliance, from which enforcement action may result. Therefore, performance by the laboratory should be contractually established between the regulating agency and the private laboratory, not by a general certification program.

Examination for proficiency could still be provided by the State Agricultural Laboratory. For example, the Dairy Commissioner may desire to contract with a private laboratory to do the milk testing. The State Agricultural Laboratory could assist the Dairy Commissioner in assessing the proficiency of the laboratory (i.e., certify the ability of the laboratory to perform the service).

CONCLUSIONS

The agricultural laboratory certification program could be discontinued for the following reasons:

A. It cannot be established that deregulation by eliminating the certification program would result in a serious risk to public health or to the agricultural economy.

B. Users of the laboratory services are not considered uninformed and are guided in their selection of a service provider by the Commercial Feed Regulations.

C. Adequate service providers have been established in the marketplace.

D. The combined effects of the Arizona Dairy Laws and regulations and the Commercial Feed Laws and regulations provide the necessary regulatory control. They also provide incentive to continue appropriate testing.

E. Elimination of the certification program does not preclude laboratories from issuing a report which would contain an attest statement indicating how their results were derived.

RECOMMENDATIONS

Certification of laboratories desiring to perform agricultural testing services should be discontinued. However, in the testing of cottonseed for aflatoxin, private laboratories should continue providing reports of the test results which contain a statement, signed by them, attesting that the testing methods (or for samplers, the sampling procedures) used comply with the Arizona Commercial Feed Regulation. The agricultural industry and other state (non-Arizona) regulatory agencies should be advised that no

cottonseed should be accepted for feed unless accompanied by a laboratory report which includes the attest statement. A laboratory should not accept a sample for which an attested result is requested unless the sample submitted is accompanied by a signed attest statement. These requirements could be incorporated through the commercial feed law and/or regulations.

Should the certification program be continued by the State, the effectiveness of its administration should be improved. Sufficient resources will be necessary to do so, and a fee sufficient to recover the cost should be charged. (See Finding III, pages 36-42.)

FINDING III

IF THE LABORATORY CERTIFICATION PROGRAM IS CONTINUED, ADMINISTRATION SHOULD BE IMPROVED AND THE PROGRAM COSTS RECOVERED THROUGH HIGHER FEES.

FINDINGS

As of August 1, 1984, the Sampling and Laboratory Certification Regulations R3-1-201 through R3-1-210 (January 1982) have not been approved and published. However, the Assistant Director of the State Agricultural Laboratory is operating an interim certification program.

To date, the administration of the interim certification program has been adequate to the extent that there have not been any major problems. In May 1984, a laboratory certified to conduct residue analysis was decertified by the Assistant Director because of a lack of qualified personnel to perform tests. However, information about the lack of qualified personnel was provided by an outside source, not as a direct result of administering the program.

The current administrative procedures used by the State Agricultural Laboratory include the following:

- Processing of initial applications and renewal applications for interim certification
- Reviewing and verifying the applicants: (a) precision and accuracy control program; (b) methodology program; and (c) physical, sanitary and safety program.
- Inspecting the applicants facilities and equipment, and evaluating the qualifications of the laboratory personnel prior to initial certification.
- Receiving, reviewing and filing certified aflatoxin test results.

These procedures are minimal and, at best, are reactive rather than proactive. An administrative program which is more substantive, more objective and which more closely satisfies the statutory intent of such a program is needed. The reason given by Agency management for not doing so is that they have insufficient resources.

A. Improve Program Administration

Improved administrative guidelines were developed with assistance from the State Agricultural Laboratory management. Following is a listing of the major activities included.

1. Applications will be processed for initial certification or certification renewal.

2. A review of the applicant's laboratory personnel qualifications should be included as part of the requirements for certification. The qualifications of personnel performing analytical tests are as important relative to accurate results as the method and equipment used.

3. Random visits to certified laboratories should be made at least quarterly to conduct a review and obtain a portion (split) of a recent sample tested. Random site visits are necessary to assure that unreported changes have not occurred, equipment is maintained, records are in order and that precision and accuracy controls are maintained.

4. Conduct analyses on portions (splits) of samples obtained from certified laboratories. Check samples sent to a laboratory for analysis tend to be biased because the laboratory knows they are being tested and therefore are more careful. Samples obtained by random site visits

provide the opportunity to verify that the results of the certified laboratory are accurate on a continuing basis. They are more representative of the normal operation.

5. Receive, review and file participant check sample program test results. A review of the laboratory's performance trend is an indicator of its precision and accuracy.

6. Receive, review and file all certified test results. This provides the opportunity to identify undesirable trends in test results.

7. Collect samples from lots tested by certified laboratories to evaluate the performance of samplers and laboratories.

8. Evaluate the effect of all changes in certified laboratories which may impact their qualification for certification.

9. Maintain and update certified laboratory and sampler files.

At the time of certification renewal, the Assistant Director should review the applicants' file. From information placed in the file, the Assistant Director can objectively make recommendations to the Commission for certification renewal or revocation.

Additionally, the following actions should be taken for clarification or compliance with statutes:

1. The Notice of Certification should stipulate the agricultural service or services as outlined in the regulations and specify appropriate restrictions.

A Notice of Certification issued to a laboratory identifies the specific services certified, but does not correlate these services to the laboratory services outlined in the draft Sampling and Laboratory Certification Regulation R3-1-203. For example, a laboratory conducting analyses for aflatoxin levels in cottonseed products is issued a Notice of Certification stating, "This document grants certification...to (name of laboratory) for 'Laboratory Analysis of Cottonseed Products.'" The Notice of Certification does not identify which of the agricultural services outlined in the draft regulations are certified. The Notice of Certification should read, "This document grants certification...to (name of laboratory) in accordance with regulation R3-1-203.A.10, limited to the laboratory analysis of aflatoxin levels in cottonseed products." This administrative change would help clarify ambiguities that exist between the wording of the certificate and the regulations.

2. The Assistant Director should be granted authority to issue interim certification until such time as the Commission grants final certification.

   Under the current certification program, the Assistant Director issues a Notice of Certification which is subject to approval by the Commission. However, these certificates have not been approved by the Commission.

   ARS §3-145.F states, "The commission shall issue a certificate to an applicant if the assistant director is satisfied that the applicant has complied with rules and regulations prescribing standards for certified laboratories." Therefore, the Commission should grant final approval of the

certification after the Assistant Director has indicated interim approval. This action should be taken at the next scheduled Commission meeting after interim approval is granted. The Commission should authorize the Director to sign the Notice of Certificate indicating final approval of the Commission. The minutes of the meeting will be the official record of the Commission's approval.

The certificate should be modified to indicate interim approval by the Assistant Director and a signature block added for Commission approval by the Director.

B. Recovery of Program Costs

Certification programs are normally considered a form of industry self regulation. To the extent that the State has assumed this responsibility, because such a program does not presently exist for agricultural laboratories, the State has not been appropriately reimbursed for its services. So far, no fee has been charged for certification (because regulations have not been published) and the proposed fee is only $10. The present statutory limit on such fees is $200 for an initial certification and $100 for certification renewal (ARS §3-146). These amounts are insufficient to cover the actual costs of an effectively administered agricultural laboratory certification program.

The cost of instituting an administrative program such as outlined above is estimated to be at least $935 annually per certified laboratory. The basis of this estimate is provided as Exhibit A on the following page. We have been advised by State Agricultural Laboratory management that private certification programs range in cost from $1,200 to $3,000 annually.

EXHIBIT A

ESTIMATED ANNUAL COST PER LABORATORY FOR CERTIFICATION

Description of Activity	Estimated Annual Cost
Laboratory Visits	
4 visits per year @ 4 hours per visit times $10 per hour[1]	$160
Split Sample Analysis[2]	
4 laboratory samples plus 2 field samples; 6 samples @ $100 per sample[3]	600
Review Check Sample Program Test Results	
7 tests per year @ .25 hours per test times $10 per hour	18
Review and File Certified Test Results	
.5 hours per week times 52 weeks; 260 hours times $10 per hour for 7 labs[4]	37
Evaluate Certified Laboratory Changes	
1.5 lab changes @ 4 hours per evaluation times $10 per hour for 7 labs[4]	9
Maintain Certified Laboratory Files	
1.5 hours per week times 52 weeks times $10 per hour for 7 labs[4]	111
TOTAL ESTIMATED ANNUAL RECURRING COST PER LABORATORY	$935

(1) Agency management estimate of average hourly cost including fringe.
(2) Based on samples of cottonseed tested for aflatoxin.
(3) Current agency fee for three aflatoxin tests per sample.
(4) Agency management estimate based on experience with 7 certified laboratories.

CONCLUSIONS

Current administration of the certification program is minimal and is not proactive. Administrative procedures can and should be improved to provide greater assurances of conformance to the regulations. The cost of instituting a program such as outlined above is estimated to be at least $935 annually per certified laboratory. According to management, the State Agricultural Laboratory has been hampered by lack of financial and human resources to establish an effective administrative program.

RECOMMENDATIONS

If the decision of the legislature is to continue the certification program, the following actions are recommended:

A. Effective administrative procedures should be developed and implemented immediately for the certification program.

B. The certificate should be revised and the Commission should start approving certification as directed by the statutes.

C. The statutory fee limits should be revised and fees sufficient to recover effective program costs should be imposed.

FINDING IV

REGULATIONS HAVE NOT BEEN PUBLISHED AND THE DRAFT REGULATIONS SHOULD BE REVISED BEFORE PUBLICATION IF THE CERTIFICATION PROGRAM IS CONTINUED.

FINDINGS

The State Agricultural Laboratory was created by the laws of 1980, Chapter 152, HB 2281, to be effective January 1981. Public hearings were originally conducted on the draft regulations in October 1981. Adoption of the regulations was ordered by the Commission at its public meeting on February 11, 1982. Nevertheless, regulations have not been published. Due to the time lapse and subsequent changes to the regulations since the initial public hearings, the Commission is presently considering holding another public hearing.

There are currently seven private laboratories that are certified. Even though the regulations have not been officially promulgated, regulatory actions have been taken when applicable. The most recent (May 1984) was the decertification of a private laboratory conducting pesticide residue analysis. The reason for the action was lack of qualified personnel to perform the analyses. However, the laboratory retained its certificate for aflatoxin testing and guaranteed label analysis of commercial feeds.

Review of the proposed Sampling and Laboratory Certification regulations R3-1-201 through R3-1-210 (January 1982) identified several improvements which would aid the State Agricultural Laboratory in effectively controlling and administering the certification program.

A. The regulations should identify certification application procedures for sampling.

Proposed regulation R3-1-202.A, which deals with whom may apply for certification states:

"A. Any person who desires to operate a certified agricultural laboratory shall apply to the Commission of Agriculture and Horticulture for a certificate on a form for that purpose provided by the Assistant Director. The application form shall be prepared and signed by both the owner of the laboratory and the person supervising the laboratory."

Proposed regulation R3-1-203.B, which deals with services for which a certificate may be obtained, states, "A certificate may be obtained for such services as sampling..." Although the regulations indicate a certificate may be obtained for sampling, they do not specify application procedures. (For further information, see page 3)

B. <u>The regulations should identify procedures for granting certification to samplers</u>.

The proposed regulations require that prior to granting certification:

- Each (laboratory) applicant shall submit proof that it has a precision and accuracy program for each certified service it provides (R3-1-205).
- A laboratory must identify testing methods and procedures to be used (R3-1-206).
- A laboratory must participate in check sample programs for each of the services for which certification is requested. The ability of the laboratory to perform with accuracy and precision will be evaluated using the results obtained for each check sample (R3-1-207).

The regulations are specific in identifying the procedures for granting certification to a laboratory; however, they do not specify procedures for granting certification to a sampler.

C. The State Agricultural Laboratory should know the participants' check sample program tests results.

Check sample programs are conducted in such a manner that the participants are identified on a published summary of the results by a code number. This is done to protect the confidentiality of the participants. Proposed regulation R3-1-207.B states:

> "B. Individual laboratory evaluation will be on the basis of results obtained for each sample in relationship to results, grouped by methods, received from all laboratories participating in that check sample program."

Individual laboratory check sample program code numbers are not known to the Agency unless voluntarily disclosed by the laboratory. The proposed regulations do not require disclosure.

D. The regulations should provide specific authority for the State Agricultural Laboratory to administer the certification program.

In order for any regulatory program to be successful, effective administration is required. Such administration may require regulatory authority, i.e., the Agency may require specific regulatory authority in order to enforce the following administrative procedures.

- Reviewing a certified laboratory's or sampler's records
- Obtaining copies of certified results
- Obtaining portions (splits) of samples tested by the certified laboratory for comparative analysis by the State Agricultural Laboratory
- Requiring certified laboratories to retain records for specified periods of time (i.e., retention schedules)
- Evaluating the qualifications of certified laboratory personnel to perform tests

- Inspecting certified laboratory equipment and equipment service/maintenance records
- Initiating proceedings to revoke/suspend certification.

The proposed regulations do not clearly provide the Agency this specific authority.

E. The regulations should require a certified laboratory to notify the Assistant Director of any changes within the laboratory.

The impact of any change in a certified laboratory's personnel, management, ownership, facilities, test equipment or test procedures may be significant in terms of its ability to maintain its qualification for certification. In May 1984, a laboratory certified to conduct residue analysis was decertified by the Assistant Director because of a lack of qualified personnel to perform the tests. Information about the change in laboratory personnel came from another source. Without this information, the Assistant Director may not have discovered the change. As a result, the laboratory would have been in the position to provide potentially unreliable or inaccurate residue analyses. There is no requirement in the proposed regulations for a certified laboratory to notify the Assistant Director of such changes.

F. The regulations should be consistent and should not conflict with the statutes regarding who has authority to grant certification.

The proposed regulations R3-1-202.C states:

> "C. The Assistant Director shall grant or renew or refuse to grant or to renew a certificate within thirty (30) working days of his receipt of the application."

Whereas R3-1-209 states:

> "The Assistant Director has the responsibility to review and to screen all certification application forms for the adequacy of precision and accuracy control programs for the Commission. If the Assistant Director finds that the applicant satisfies precision and accuracy requirements, he shall grant certification subject to approval by the Commission at its next meeting..."

However A.R.S. 3-145, paragraph F states:

> "F. The commission shall issue a certificate to an applicant if the assistant director is satisfied that the applicant has complied with rules and regulations prescribing standards for certified laboratories."

and A.R.S. 3-148 states:

> "The commission may refuse to grant or renew a certificate or suspend or revoke a certificate..."

Regulation R3-1-202.C which indicates the Assistant Director has the authority to "grant" (rather than "grant subject to approval" or "recommend") certification conflicts with the intent of the statutes and is not consistent with R3-1-209.

G. <u>The regulations should require certified laboratories to identify official samples received that do not meet regulatory guidelines</u>.

A certified laboratory may receive a sample from a certified sampler that may not fall within the guidelines of the Commercial Feed Regulations. These regulations pertaining to the sampling of whole cottonseed require that:

- A gross sample taken from a lot must be a minimum of thirty (30) pounds (R3-3-53.C.1).
- A gross sample shall consist of not less than ten (10) probes or stream sample passes (R3-3-53.C.1).
- The sample container shall consist of clean cloth, burlap, paper or plastic mesh bags (R3-3-53.C.2).

The sampling and Laboratory Certification Regulations do not specify what a certified laboratory should do when receiving certified samples that do not conform to the Commercial Feed Regulations guidelines. They should provide certified laboratories the authority to refuse certified samples that do not meet the guidelines. An alternative might be to require the laboratory to "qualify" their test results by noting the sample deficiency on the test report.

H. Certification of samplers should be restricted to those who sample cottonseed or cottonseed products.

Certification of all samplers of agricultural products may have far reaching effects, beyond that intended by the statutes or regulation. (For discussion on this point, see Finding V, page 54.)

CONCLUSIONS

The January 1982 draft regulations could be improved in several areas which would enhance enforcement and clarify requirements.

RECOMMENDATIONS

A. It is recommended the Commission of Agriculture and Horticulture take the following actions to clarify regulatory procedures and the authority of the State Agricultural Laboratory:

1. Identify certification application procedures for samplers.

2. Identify procedures for granting certification to samplers.

3. Authorize the Agency to receive individual certified laboratory's check sample program test results.

4. Provide the Agency with appropriate authority to administer the certification program.

5. Require certified laboratories to notify the Assistant Director of any changes within the laboratory.

6. Clarify who has the authority to grant, renew, refuse to grant or to renew a certificate.

7. Provide guidelines to certified laboratories for handling samples that do not meet Commercial Feed Regulations.

8. Limit the requirement for certification of samplers to only those who sample cottonseed or cottonseed products.

B. The Commission should aggressively pursue publication of the Sampling and Laboratory Certification Regulations.

FINDING V

THE AGENCY MAY NOT BE PROVIDING ALL OF THE MANDATED SERVICES.

FINDINGS

A. General Organization and Operation

The State Agricultural Laboratory is divided into two sections - chemical analytical and biological. The Chemical Analytical Section contains a formulations and a residue laboratory. The Biological Section contains entomology, animal disease and plant pathology laboratories. Each section has responsibility for specific mandated tasks. For example, the Biological Section is responsible for the identification of insects, parasites, bacteria and pathogenic organisms. The Chemical Analytical Section is responsible for residue, nutrient and formulation analyses.

The State Chemist also serves as the Assistant Director of the Agency.

B. Description of Mandated Services

1. The Agency is required by ARS §3-142 to provide agricultural laboratory services as defined in ARS §3-141 which encompass residue and nutrient analysis of:

   - Raw, processed or manufactured agricultural products
   - Soil
   - Plant or animal tissue
   - Commercial whole feed including whole seeds and any feed, mixed or unmixed, that is used in the feeding of livestock
   - Fertilizer
   - Water for irrigation purposes or consumption by livestock (residue analysis only)

In addition, the Agency is required to provide:

- Quantitative analysis of ingredients in pesticide formulations
- Germination and purity analysis of planting seed
- Identification of insects, parasites, bacteria and pathogenic organisms in raw, processed or manufactured agricultural products and commodities and in plant or animal tissue
- Services necessary to carry out §24-104, subsection D (meat inspection)
- Any other services compatible with or incidental to those laboratory services provided pursuant to §§3-142 and 3-143

By definition of purpose, the Agency is also required to provide:

- Laboratory service to agriculture for the protection of the agricultural community and the public health
- Certification to laboratories providing services and to prescribe criteria for certification

2. The Agency is required by ARS §3-142 to provide laboratory services specifically for five state agencies:

- The Chief Veterinary Meat Inspector
- The Board of Pesticide Control
- The Livestock Sanitary Board
- The Office of the State Chemist
- The Commission of Agriculture and Horticulture

C. Evaluation of Mandated Laboratory Services

Each of the statutorily specified users was surveyed to determine the extent to which they utilize the services of the State Agricultural Laboratory. Approximately 90% of work performed by the Chemical Analytical Section is for the Office of the State Chemist. All other work, including work for other state agencies represents 10% of the total

volume. The Biological Section primarily serves ACAH, the Chief Veterinary Meat Inspector and Livestock Sanitary Board. Both sections service agriculture for the protection of the agricultural community and public health.

The Agency currently uses external sources for two testing services. Agricultural Seed Laboratories, a private laboratory, provides germination and purity analysis of planting seed. The USDA in San Francisco provides content analysis of meats sold to state institutions (e.g., prisons, hospitals). These services are provided for the state seed inspector and the chief veterinary meat inspector, respectively. The Agency is responsible for paying all invoices submitted by the two external sources; however, the Agency is not involved in the submission of samples or the analysis of the test results. This fiscal responsibility is performed in the Biological Section.

1. Milk Testing

   According to a representative of the Agricultural Committee, it is the legislature's intention to have the Agency provide all laboratory services for raw agricultural commodities, including milk. The definition of agricultural laboratory services provided in ARS §3-141 appears to include (the testing of) milk for residue and nutrient analysis since it is within the scope of a "raw, processed or manufactured agricultural commodity and product." However, it is not clear from the statutes that milk testing is included as a mandated service. The Dairy Commissioner is not one of the five specifically-listed agencies. Milk testing is presently being provided by the Department of Health Services.

2. Meat Testing

Meat testing is administered by the Agency but the actual testing is conducted by the U.S. Department of Agriculture laboratory in San Francisco. We understand that the State Agricultural Laboratory has the capability and, in fact, has performed some of the meat testing in the past. The meat being tested is specifically designated for use in State institutions such as the prisons and hospitals. It would appear that on the basis of turnaround time, it would be more efficient to have the testing performed locally, either by the State Agricultural Laboratory or by contract with a private laboratory. However, the USDA currently funds half of the cost of the meat testing program. Therefore, a study should be conducted to determine the feasibility of performing the meat testing locally, evaluating both cost and efficiency.

3. Plant Pathology

Plant pathology services were previously provided part-time under contract with the University of Arizona. According to the Commission Director, this arrangement did not fully satisfy the requirements of the Agency. Starting in FY 84-85, a full-time position for a plant pathologist was requested and approved. However, the position has not been filled.

D. Evaluation of Certification Services

The statutes place responsibility for promulgating regulations and for issuing certificates on the Commission. Regulations have not been published.

In the absence of published regulations, certificates have nevertheless been issued by the Assistant Director to private laboratories.

1. Certification of Laboratories

ARS §3-143.D.2 says that the Assistant Director shall "Enforce rules and regulations established pursuant to §3-147 for the mandatory certification of laboratories...including those laboratories that are a part of a state agency or department or a political subdivision of the state." (Emphasis added.) The Department of Health Services laboratory which conducts the milk testing for the Dairy Commissioner has not been certified by the Agency. (For further discussion, see Arizona Legislative Council Memo, Fact Situation A, pages 1 to 4 in the Appendix.)

Since the Agricultural Seed Laboratory provides laboratory services to the Agency, certification is mandatory per ARS §3-145.A. This laboratory has not been certified by the Agency. However, this laboratory had previously been designated as the state seed laboratory under the authority of ARS §3-233 and ACAH regulation R3-1-110/111.

2. Certification of Samplers

The appropriateness of test results from a sample may well depend on how the sample was obtained. Therefore, regulation of the sampler appears to be an appropriate extension of the current statutory authority to certify laboratories. Certification of samplers is included in the draft Agency regulations. It is not clear, however, whether certification of samplers should be restricted to the private sector only, which is the present practice, or should include state agency employees who collect agricultural samples.

It would be more consistent if agency employees who conduct sampling were required to be certified since, by statute, agency laboratories that provide agricultural laboratory services are required to be certified. Obviously, this would include all state employees who collect agricultural samples. Affected personnel would include all Commission inspectors, inspectors of the State Chemist and of other agricultural boards and commissions. Department of Health Services personnel that collect agricultural samples would also be affected as would dairy industry truck drivers who collect samples for the Dairy Commissioner.

E. Other Services Not Mandated

The State Agricultural Laboratory provides testing services for other state agencies such as the Department of Game and Fish and the Structural Pest Control Board. However, there are not any formal interagency agreements and in many instances, the services provided are not paid for by the requesting agency. Prior to FY 84-85, testing services were provided under contract to the Department of Health Services (DHS). However, DHS contracted with a private laboratory for these services for FY 84-85.

CONCLUSIONS

The Agency appears to be providing most of the mandated services required by the statutes and by the users to the users' satisfaction. However, certain deficiencies may exist.

A. Plant pathology services are not currently being provided because the position has not been filled. We understand that interviews have been conducted and an offer extended.

B. Formal interagency agreements do not exist with agencies other than those mandated. Therefore, the Agency is not being properly reimbursed for services provided.

C. Milk testing is not being provided by the Agency. However, it is not clear whether or not this is a mandated service.

D. Meat testing should be evaluated to determine the feasibility of performing the testing locally.

E. Not all laboratories which require certification have been certified, specifically the state seed laboratory and the DHS laboratory.

F. The requirement to certify samplers of agricultural products is not clear.

RECOMMENDATIONS

The following actions are recommended:

A. The Commission and the Agency should continue efforts to procure the services of a qualified plant pathologist.

B. The Commission and the Agency should develop interagency agreements with those agencies not mandated by statute that require agricultural laboratory services. An estimate of the cost of these services should be provided to the requesting agency by the State Agricultural Laboratory for inclusion in their budgets. Such estimates should be based on forecasts, provided by the agencies being served, of their anticipated volume by type of service.

C. The legislature should clarify its intent with respect to milk testing. If it is the legislature's intent to have the Agency provide milk testing then:

1. The Dairy Commissioner should be added to the agencies specified in ARS §3-142.

2. The legislature should direct that a study be made of the Department of Health Services to ascertain to what extent equipment and personnel resources are dedicated to milk testing.

3. The Commission and the Agency should prepare and submit the appropriate budgetary request pursuant to establishing the capability to perform milk testing.

D. The Commission should conduct a study of the present meat testing program to determine if it would be feasible and beneficial to have the meat testing done locally.

E. If the certification program is continued, the Commission should direct the Assistant Director to proceed with the evaluation of laboratories which require certification and have not been certified.

F. If the certification program is continued, the Commission should clarify regulatory requirements for certification of samplers. Consideration should be given to certifying only those who sample cottonseed or cottonseed products whose distribution is intended for livestock.

FINDING VI

THE STATUTES ARE NOT CLEAR WITH REGARD TO THE REPORTING OF TEST RESULTS BY PRIVATE LABORATORIES.

FINDING

The State Agricultural Laboratory receives a copy of the certified results of all tests performed for aflatoxin in cottonseed by certified laboratories. The Aflatoxin Certification Program form contains a direction at the bottom which says, "Copy to: Arizona State Agricultural Laboratory, P.O. Box 1586, Mesa, Arizona 85201." There is no requirement in the draft regulations for copies of any certified results to be provided. Further, ARS §3-145.C states:

> "A certified laboratory shall report test results only to the party who provided the original sample."

Certified laboratories which currently provide the Agency with copies of the results of aflatoxin tests are clearly in violation of this particular statute. However, in an opinion from the Arizona Legislative Council, the laboratories would not be in violation of state law by reason of an apparent conflict among several statutes. (See Arizona Legislative Council Memo, Fact Situation C, pages 5 and 6 in the Appendix.)

CONCLUSION

Statutes regarding the reporting of test results to a state agency by a certified laboratory are in apparent conflict and should be clarified.

RECOMMENDATION

If the laboratory certification program is continued, we recommend the legislature consider a revision to ARS §3-145.C which would clarify the Agency's authority to receive copies of certified laboratories' certified services analytical results.

FINDING VII

TWO ARIZONA AGENCIES ARE CURRENTLY AUTHORIZED BY STATUTE TO PROVIDE CERTIFICATION OF LABORATORIES TO PROVIDE AGRICULTURAL LABORATORY SERVICES.

According to Arizona Legislative Council opinion, the Department of Health Services (DHS) also has statutory authority to grant certifications for agricultural testing services, specifically the testing of ammoniated cottonseed or cottonseed products, including authority to issue regulations to enforce. (See Arizona Legislative Council Memo, Fact Situation D, pages 6 and 7 in the Appendix.) This situation clearly provides an option for the applicant desiring to test ammoniated cottonseed to apply for certification to either the Department of Health Services or the State Agricultural Laboratory. If application were denied or if certification were revoked by one, certification could conceivably be granted by the other. This type of dual authority does not appear to be in the best public interest.

According to DHS management, no laboratories are certified by them for the provision of agricultural laboratory services, nor has any laboratory applied.

We recommend the legislature consider a revision to the DHS statutes to remove the authority to certify laboratories for the provision of agricultural testing services.

OTHER PERTINENT INFORMATION

A. THE ANALYTICAL SECTION WORK LOAD IS CONTROLLED BY THE STATE CHEMIST.

The work load of the Analytical Section is controlled by the State Chemist who is also the Agency Assistant Director. If a backlog accrues, as State Chemist he directs his field inspectors to reduce the number of samples they collect; if more work is needed, the inspectors are instructed to collect more samples. Because the capacity of the laboratory influences the number of samples taken, the sampling program may not be as effective as it should be.

It is unknown whether or not the sampling conducted by the Office of the State Chemist is sufficient to provide reasonable assurance to the public that feed, fertilizer and pesticide products available on the market are safe, meet label claim and otherwise conform to regulations.

It would appear, nevertheless, that having the same person as State Chemist and Assistant Director of the State Agricultural Laboratory creates the potential for conflict of interest. The State Agricultural Laboratory is directed by statute to provide laboratory services to the Office of the State Chemist. Therefore, the laboratory work load generated by the State Chemist should be accommodated and should be viewed no differently than service requirements generated by the other user agencies.

B. THE STATE AGRICULTURAL LABORATORY FACILITIES ARE CROWDED.

Both the Analytical and Biological Sections of the State Agricultural Laboratory are extremely crowded. For example, in the Biological Section, current reports are stored on top of a refrigerator and historical reports in precious cabinet space. The Biological Section Manager's office also houses the reference library, a systematic entomologist and a microscope work station. In the Analytical Section, solvents which should be isolated due to their hazardous nature are stored in the laboratory. Sample weighing is done in the same small storage room where the samples are stored. The Analytical Section Manager's office is in a store room. We were told by the Commission Director that the Plant Pathologist, when hired, will share his office.

Additionally, all of the counter tops in the wet chemistry section (formulation laboratory) need to be refinished or replaced. An obvious conclusion based on a tour of the facilities is that there is a loss of efficiency which is directly attributable to the work environment including space limitations. These conditions also have an obvious negative impact on the ability of the Agency to provide additional services.

C. STATE AGRICULTURAL LABORATORY PROFESSIONALS COULD BE USED AS TRAINERS.

The Biological Section Manager identified several problems which inhibit the effectiveness of both the laboratory and the ACAH field inspection personnel. Examples include:

- Submittal of specimens which are mislabeled, broken or damaged, resulting in the return of the specimens without analysis.

- Improper maintenance of field data books.
- Submittal of specimens which should have been identified by the field personnel.

We believe that use of the knowledge and experience of the professionals in the State Agricultural Laboratory could make a valuable contribution to the overall effectiveness of ACAH programs as well as to agriculture by:

1. Developing and providing training programs for field inspectors and other interested parties in farming and other agricultural activities.

2. Developing and publishing flyers and brochures which would aid ACAH field personnel and the agricultural community.

Arizona Commission of
Agriculture and Horticulture
1688 WEST ADAMS • PHOENIX, ARIZONA 85007 • (602) 255 4373

FIELD SERVICES

State Agricultural Laboratory
Fruit & Vegetable Standardization

District Offices
Inspection Stations

Office of State Chemist
Board of Pesticide Control

OFFICE OF THE DIRECTOR

October 26, 1984

TO: Douglas R. Norton, Auditor General

FROM Ivan J. Shields, Director

SUBJ: State Agricultural Laboratory
Sunset Audit

Attached are the agency's final responses in regard to the Agricultural Laboratory Sunset Audit, due in your office today.

IJS:AKS:po
cc: Spires

Performance Audit

Office of the
Auditor General
October 1984

COMMISSION OF AGRICULTURE AND HORTICULTURE

Response from Commission of Agriculture and Horticulture - October 15, 1984

FINDING I

The lack of documented policies and an effective quality assurance program may be affecting the reliability of test results in the analytical section.

Recommendations

(1) State Agricultural Laboratory management policies regarding testing and documentation procedures should be put in written form, reviewed with all laboratory personnel and enforced.

(2) The State Agricultural Laboratory should develop and implement a formal quality assurance program.

Response

(1) The State Agricultural Laboratory operates under the administrative policies of the Commission of Agriculture and Horticulture. The Agricultural Laboratory has not issued formal policies to cover program needs, but was addressed by written memos to staff to cover testing and documentation procedures. See attached.

(2) Our laboratory has been accepted as an EPA Enforcement Laboratory which requires written quality assurance program for pesticide testing. Test methods used in the laboratory are AOAC, EPA, and FDA methods which have been documented as reliable results. Many of these methods have built-in quality assurance procedures. In other areas of testing, further documentation will be developed to support the reliability of results issued from the laboratory and will be updated to include uniform instructions to insure accurate documentation.

FINDING II

The certification of laboratories providing agricultural testing services may no longer be necessary.

Recommendations

Certification of laboratories desiring to perform agricultural testing services should be discontinued. However, in the testing of cottonseed for aflatoxin, private laboratories should continue providing reports of the test results which contain a statement, signed by them, attesting that the testing methods (or for samplers, the sampling procedures) used comply with the Arizona Commercial Feed Regulation. The agricultural industry and other state (non-Arizona) regulatory agencies should be advised that no cottonseed should be accepted for feed unless accompanied by a laboratory report which includes the attest statement. A laboratory should not accept a sample for which an attested result is requested unless the sample submitted is accompanied by a signed attest statement. These requirements could be incorporated through the commercial feed law and/or regulations.

Should the certification program be continued by the State, the effectiveness of its administration should be improved. Sufficient resources will be necessary to do so, and a fee sufficient to recover the cost should be charged. (See Finding III, pages 36-42.)

Response

It is the agency's opinion that the Certification Program should not be discontinued. The certification of laboratories did perform a service when the problem of aflatoxin was being resolved. Following that accomplishment, a testing procedure was standardized as in the case of cotton seed for aflatoxin. Private laboratories could continue to provide the test results, but would need to be audited on a periodic basis by the Commission. It is the agency's concern that other chemicals could cause problems of safety to the public's health and welfare, therefore, the same procedure should be followed to solve that problem as we have with aflatoxin.

Arizona agriculture then would not suffer economical setbacks because this certification procedure would insure acceptance in the market place. Some modification of the statutes would be necessary through legislation to allow certification of the other chemicals.

Several changes in the Office of Director and in the Assistant Director's position have caused delays in the full implementation of developing an effective certification program. A renewed effort to develop resources and possibly have a cost for services rendered should be implemented if the certification program is to continue.

FINDING III

If the laboratory certification program is continued, administration should be improved and the program costs recovered through higher fees.

Recommendations

If the decision of the legislature is to continue the certification program, the following actions are recommended:

A. Effective administrative procedures should be developed and implemented immediately for the certification program.

B. The certificate should be revised and the Commission should start approving certification as directed by the statutes.

C. The statutory fee limits should be revised and fees sufficient to recover effective program costs should be imposed.

Response

A. The Commission will need to review its full responsibility of State Agricultural Laboratory as dictated by statute and thus become more directly involved in the administration and certification, by clearly stated rules and regulations.

B. Due to the several findings of the Auditor General's Office, a revision of the certification rules and regulations has been prepared and will soon be submitted for approval and public hearing.

C. We concur with your recommendation, if certification is to continue we will endeavor to make the statutory change.

FINDING IV

Regulations have not been published and the draft regulations should be revised before publication if the certification program is continued.

Recommendations

It is recommended the Commission of Agriculture and Horticulture take the following actions to clarify regulatory procedures and the authority of the State Agricultural Laboratory:

1. Identify certification application procedures for samplers.

2. Identify procedures for granting certification to samplers.

3. Authorize the agency to receive individual certified laboratory's check sample program test results.

4. Provide the Agency with appropriate authority to administer the certification program.

5. Require certified laboratories to notify the Assistant Director of any changes within the laboratory.

6. Clarify who has the authority to grant, renew, refuse to grant or to renew a certificate.

7. Provide guidelines to certified laboratories for handling samples that do not meet Commerical Feed Regulations.

8. Limit the requirement for certification of samplers to only those who sample cottonseed or cottonseed products.

9. The Commission should aggressively pursue publication of the Sampling and Laboratory Certification Regulations.

Response

The draft, dated January 1982, was signed by the Director of the Commission of Agriculture and Horticulture and submitted to the Attorney General's Office in September of 1982.

In the Sunset Auditing process, our attention was drawn to a number of changes that were necessary to be in full compliance with the statutes. However, circumstances may arise that certification will be necessary on other commodity areas. A re-draft of those rules and regulations has been made following the recommendations of the draft copy of the Sunset findings and this will be resubmitted to the Attorney General's Office for approval. The Commission agressively intends to pursue the publication of the sampling and laboratory certification regulations and plans to hold a hearing in the near future.

FINDING V

The agency may not be providing all of the mandated services.

Recommendations

The following actions are recommended:

A. The Commission and the Agency should continue efforts to procure the services of a qualified plant pathologist.

B. The Commission and the Agency should develop interagency agreements with those agencies not mandated by statute that require agricultural laboratory services. An estimate of the cost of these services should be provided to the requesting agency by the State Agricultural Laboratory for inclusion in their budgets. Such estimates should be based on forecasts, provided by the agencies being served, of their anticipated volume by type of services.

C. The legislature should clarify its intent with respect to milk testing. If it is the legislature's intent to have the Agency provide milk testing then:

1. The Dairy Commissioner should be added to the agencies specified in ARS S3-142.

2. The legislature should direct that a study be made of the Department of Health Services to ascertain to what extent equipment and personnel resources are dedicated to milk testing.

3. The Commission and the Agency should prepare and submit the appropriate budgetary request pursuant to establishing the capability to perform milk testing.

D. The Commission should conduct a study of the present meat testing program to determine if it would be feasible and beneficial to have meat testing done locally.

E. If the certification program is continued, the Commission should direct the Assistant Director to proceed with the evaluation of laboratories which require certification and have not been certified.

F. If the certification program is continued, the Commission should clarify regulatory requirements for certification of samplers. Consideration should be given to certifying only those who sample cottonseed or cottonseed products whose distribution is intended for livestock.

Response

A. The Commission is proceeding in acquiring the services of a full-time qualified Plant Pathologist. Presently the State Personnel Office is readvertising the position until such time that a qualified applicant is acquired.

B. The Commission is in the process of developing interagency agreements for services rendered and will plan to incorporate into these interagency agreements the estimated costs associated with the Agricultural Laboratory services which will then be included in other budgets.

C. The 37th Legislature did address, in part, the use of interagency agreements between the Commission of Agriculture and Horticulture, the Dairy Commissioner and Egg Inspector in each of the respective budgets. The footnote instructs us to develop interagency agreements. This could be expanded to include milk testing. Budgetary requests have been made for the past 3 years for additional manpower and funds to enable the State Agricultural Laboratory to meet its statutory obligations.

D. The arrangement of asking an outside agency to conduct meat testing has been acceptable to meet present needs; however, the question of the efficiency and turnaround time needs to be looked into and consideration should be given as to costs and benefits to testing meat samples locally. This would be contingent upon the standards necessary to receive Federal endorsement for meat testing.

E. We concur and this needs to be reviewed annually by the Commission.

F. Under the exacting requirements of today's laboratory methodology it is necessary to sample according to certain recommended practices and that a set of regulatory requirements be developed for the private sector and the State employee who will each be taking samples. These requirements could be made a part of the certification program.

FINDING VI

The statutes are not clear with regard to the reporting of test results by private laboratories.

Recommendation

If the laboratory certification program is continued, we recommend the legislature consider a revision to ARS S3-145.C which would clarify the Agency's authority to receive copies of certified laboratories' certified services' analytical results.

Response

We concur although there needs to be a certain amount of confidentiality regarding these analytical results. In practice, certified laboratories have given this information voluntarily.

FINDING VII

Two Arizona agencies are currently authorized by statute to provide certification of laboratories to provide agricultural laboratory services.

Recommendation

We recommend the legislature consider a revision to the DHS statutes to remove the authority to certify laboratories for the provision of agricultural testing services.

Response

We concur.

OTHER PERTINENT INFORMATION

A. THE ANALYTICAL SECTION WORK LOAD IS CONTROLLED BY THE STATE CHEMIST.

Response

In the cases of heavy work load and limited personnel, priorities will need to be set and the judgement of the State Chemist/Assistant Director will come into play. Presently this does not appear to be a problem. Due to the Agency reorganization and the emphasis on cross training, our inspectors have been able to offer field assistance to the State Chemist as well as the State Agricultural Laboratory.

ARIZONA LEGISLATIVE COUNCIL

MEMO

August 17, 1984

TO: Douglas R. Norton, Auditor General

FROM: Arizona Legislative Council

RE: Request for Research and Statutory Interpretation (O-84-6)

This is in response to a request submitted on your behalf by Mark Fleming in a memorandum dated July 16, 1984.

FACT SITUATION A:

Arizona Revised Statutes (A.R.S.) section 3-143, subsection D, paragraph 2 which deals with the powers and duties of the assistant director, state agricultural laboratory (state lab), states that the assistant director shall:

> 2. Enforce rules and regulations established pursuant to section 3-147 for the mandatory certification of laboratories providing agricultural laboratory services to agencies and departments of this state or its political subdivisions, including those laboratories that are a part of a state agency or department, or a political subdivision of the state. (Emphasis added.)

The auditor general preliminary audit work indicates that the assistant director has not certified the department of health services (DHS) laboratory, the only other state or political subdivision laboratory providing such agricultural laboratory services.

QUESTIONS PRESENTED:

A.1. Do laboratories which are operated by a state agency or department, or a political subdivision of the state, and which provide agricultural testing services pursuant to A.R.S. section 3-141 to a state agency or department, or political subdivision of the state, require certification by the assistant director, state agricultural laboratory?

A.2. If the answer to question A.1. is affirmative, must the state agricultural laboratory also be certified, or is certification unnecessary because of the authority for providing agricultural testing services granted by statute (A.R.S. section 3-144)?

ANSWER:

A.1. Yes.

A.2. No.

DISCUSSION:

A.1. By the clear and unambiguous terms of A.R.S. section 3-143, subsection D, paragraph 2 quoted above, state agency laboratories and political subdivision laboratories

which provide agricultural laboratory services to the state or political subdivisions must be certified. This would include the DHS laboratory. It is actually a three-stage mandate: 1) the commission of agriculture and horticulture must prescribe the rules, A.R.S. section 3-147, 2) the assistant director must enforce the rules, and 3) the rules themselves must require certification in this instance (cf. voluntary certification of laboratories that only provide agricultural laboratory services to nongovernmental entities, A.R.S. section 3-143, subsection D, paragraph 1). The obvious legislative purpose and intent are to assure a high standard of service to state and local government, whether the service is provided by private laboratories or laboratories operated by the government itself. Any other interpretation of this provision would contradict the plain language of the statute and betray the intent and expectation of the legislature.

A.2. Laws 1980, chapter 152 established the state agricultural laboratory as a division of the commission of agriculture and horticulture. The purposes of the act were:

> 1. To . . . /provide/ laboratory services to:
>
> (a) The chief veterinary meat inspector.
>
> (b) The board of pesticide control.
>
> (c) The livestock . . . board.
>
> (d) The office of the state chemist.
>
> (e) The commission of agriculture and horticulture.
>
> 2. To provide laboratory service to agriculture for the protection of the agricultural community and the public health.
>
> 3. To provide certification to laboratories providing services and to prescribe criteria for certification.

(Laws 1980, Ch. 152, sec. 1)

Regarding the certification process the statutes provide that the commission prescribe qualitative rules and regulations for laboratory certification. A.R.S. section 3-147. An applicant for certification applies to the state lab on forms prescribed and furnished by the state lab. A.R.S. section 3-145, subsections D and E. The assistant director (of the state lab division of the commission) reports his evaluation of the applicant's compliance to the commission. A.R.S. section 3-145, subsection F. The commission issues or renews, or refuses to issue or renew, the certificate based on the assistant director's evaluation. A.R.S. section 3-145, subsection F; section 3-148. The statutory framework for certification is thus integrated with each level of the organization having an assigned and interdependent role.

To require the state lab to be certified according to the statutory process, the assistant director (being the person responsible for the administration, operation and control of the state lab, A.R.S. section 3-143, subsection A) would file an application with the state lab. A.R.S. section 3-145, subsections D and E. Once his agency has his

application he would conduct a substantive evaluation of his agency's performance and compliance with his employer's rules and regulations. A.R.S. section 3-145, subsection F. If he should find his agency's performance acceptable, the commission, his employer, would have to certify his agency, for according to A.R.S. section 3-145, subsection F:

> F. The commission shall issue a certificate to an applicant if the assistant director is satisfied that the applicant has complied with rules and regulations prescribing standards for certified laboratories. (Emphasis added.)

However, contrary to the foregoing provision, if the commission has its own independent reasonable grounds to believe its division does not comply with the prescribed standards, the commission could refuse to grant or renew its division's certificate. A.R.S. section 3-148. Thereupon the state lab would have to cease operations, the division's existence would be put in doubt, the five enumerated state agencies would be without laboratory services, the provisions of several statutes would be nullified and the legislative purposes in establishing the state lab by statute would be betrayed. All of this scenario must be considered possible, indeed reasonable, if the state lab is required to be certified, because to be subject to certification inherently includes the possibility of failure to be certified.

It is the opinion of this office that the above analysis demonstrates that to require the state lab to be certified results in substantive absurdity. If the legislature had intended that the state lab's existence be subject to administrative action by the commission, it would simply have provided either 1) that the commission could (discretionary) establish a state lab by administrative rule and appoint an assistant director to serve at the commission's pleasure, or 2) explicitly require that the state lab be certified. Instead, the legislature established the state lab by statute, without any authority for an administrative agency to affect its existence and operation, provided an assistant director for the division as an employee of the commission subject to the state personnel rules and gave the assistant director and the state lab both mandatory and discretionary functions. There is no evidence to indicate that the legislature contemplated any jeopardy to the state lab program and functions by subjecting it to certification.

It is a basic assumption of government that a policing agency will apply the same standards of operation to its own conduct as it sets and enforces against the conduct of others. A certificate, being merely an external evidence of substantive performance, is useful when it is issued by a third party in a position to objectively judge performance against established standards. The certification process for agricultural laboratories, however, is administered by the commission, the assistant director and the state lab as an integrated unit with interdependent functions. To require one part of this unit to be judged by another part is a conflict of interest and eliminates objective qualitative analysis. A certificate issued in these circumstances to the state lab would be deceptive and provide no more security or assurance of quality than the statutory organization which makes the state lab a division under the commission to administer the commission's qualitative requirements.

COMMENT:

As shown by the foregoing analysis the conclusion on this question depends on considering several statutes and the interrelationship of multiple agencies and officers.

The statutes in some respects appear inconsistent and lend themselves to varying interpretations. The recommendation of this office is to seek a legislative resolution of the issue.

FACT SITUATION B:

A.R.S. section 3-145, subsections A and B state:

> A. A person who establishes, conducts or maintains a laboratory that provides agricultural laboratory services to agencies or departments of this state or its political subdivisions shall apply for a certificate from the state agricultural laboratory as proof that the laboratory so certified is in compliance with rules and regulations promulgated by the commission for the certification of such laboratories. Any other person providing agricultural laboratory services may apply for such a certificate.
>
> B. A person providing guaranteed laboratory analysis information to distributors of commercial feed and whole seeds for consumption by livestock shall be certified under this section. (Emphasis added.)

A.R.S. section 3-149 further states that "/t/est results certified by the assistant director are prima facie evidence of the facts stated in the results." A number of private sector laboratories provide guaranteed analysis, particularly of cottonseed aflatoxin content, to the agricultural community. The laboratories are certified in accordance with A.R.S. section 3-145, subsection B. However, a private laboratory designated by commission of agriculture and horticulture regulation (R3-1-110) as the state seed laboratory is not certified.

QUESTIONS PRESENTED:

B.1. Is the state liable for malperformance by a private laboratory which has been certified under the mandatory provisions of A.R.S. section 3-145, subsection A or B?

B.2. Is the state liable for malperformance by a private laboratory which has been certified under the voluntary provisions of A.R.S. section 3-145, subsection A?

B.3. Are test results admissible for enforcement purposes from an uncertified laboratory such as the seed laboratory?

ANSWERS:

B.1. No.

B.2. No.

B.3. Yes.

DISCUSSION:

B.1. Under A.R.S. section 12-820.01, as enacted by Laws 1984, chapter 285, section 3, the state is granted absolute immunity from liability for the exercise of an administrative

function involving judgment and discretion in licensing and regulating professions and occupations. Licensing and regulating other activities (such as hunting and driving automobiles) are granted a qualified immunity. An agricultural laboratory business is in the nature of an occupation, and consequently its regulations by the state lab would be accorded an absolute immunity from liability for the private laboratory's malperformance.

B.2. For the reasons explained in B.1. above, the state lab is absolutely immune from liability. The distinction of voluntary certification is irrelevant in this instance.

COMMENT:

The answers to questions B.1 and B.2 represent the analysis of this office of the language and intent of Laws 1984, chapter 285. Our interpretation is that an agricultural laboratory as a business is an "occupation" within the meaning of A.R.S. section 12-820.01. This interpretation obviously has no judicial precedent or support at this time. Since these questions address the issue of state liability which is ultimately to be determined by the courts, the commission, assistant director and state lab should proceed accordingly.

B.3. The distinction between test results from certified as opposed to uncertified laboratories has no bearing on their admissibility in judicial proceedings. If the results are probative and relevant to the action, they are generally admissible. 17 A.R.S. Rules of Evidence, Rule 402. The purpose of A.R.S. section 3-149 is to accord "prima facie" status, not to results of a certified laboratory, but to test results which have been certified by the assistant director. Prima facie evidence stands on its own merits and needs no corroboration. It may, however, be attacked and rebutted as with any other evidence. The words "prima facie" as used in statutes merely mean a fact presumed to be true unless disproved by some evidence to the contrary. Hunsaker v. Smith, 1 Ariz. App. 51 (1965).

FACT SITUATION C:

Department of health services regulation R9-17-320, subsection B states that "/a/ny person ammoniating cottonseed shall file with the department a copy of the written results of the aflatoxin content as determined by an approved or certified laboratory prior to any sale . . . ."

The Aflatoxin Certification Program form for documenting aflatoxin test results includes a preprinted notation at the bottom - "Copy to: Arizona State Agricultural Laboratory, P.O. Box 1586, Mesa, AZ 85201." Presently, the laboratory performing the test sends the copy to the state agricultural laboratory.

A.R.S. section 3-145, subsection C states that "/a/ certified laboratory shall report test results only to the party who provided the original sample."

QUESTION PRESENTED:

C.1. Are private certified laboratories in violation of A.R.S. section 3-145, subsection C if they send a copy of the test results to the state agricultural laboratory when the party submitting the original sample is not an agency or department of this state or its political subdivisions?

ANSWER:

No.

DISCUSSION:

This fact situation addresses an apparent conflict among several statutes. A.R.S. section 3-145, subsection C prohibits disclosure of test results by certified laboratories to anyone, including by implication the state lab. However, A.R.S. section 36-904.01, subsection A provides:

> A. Whole cottonseed and cottonseed products containing aflatoxin may be ammoniated under processes approved by the director to reduce the aflatoxin content to maximum acceptable levels as determined by the director .... After the ammoniation process is completed and prior to any sale ... an analysis shall be performed on a sample drawn according to sampling methods approved by the director. Such sample shall be analyzed by a laboratory approved by the director, or otherwise certified under state law, to determine that the ammoniation has reduced the aflatoxin content to acceptable levels. ... The written results of any such analysis shall be retained for at least three years by the laboratory performing the analysis and by the person ordering the analysis, and a copy shall be filed with the director and provided to any purchaser or transferee, if the ammoniated whole cottonseed or the ammoniated cottonseed product is sold, transferred or distributed after the analysis. (Emphasis added.)

Finally A.R.S. title 24, chapter 7, article 1 imposes inspection responsibilities on the state chemist regarding feeds distributed in the state, including aflatoxin levels. See especially sections 24-906, 24-913 and 24-913.01. Obviously DHS and the state chemist cannot administer their aflatoxin responsibilities unless aflatoxin test results are disclosed to them or, in the case of the state chemist, to the state lab which provides laboratory services to the state chemist.

The rule of statutory construction that applies in the case of conflicting statutes is that special statutory provisions control those that are general. Where statutes first express a general intent and later an inconsistent particular intent, the particular intent will be taken as an exception to the general intent and both will stand. State v. Lumbermen's Indemnity Exchange, 24 Ariz. 306 (1922); State v. Cassius, 110 Ariz. 485, cert. dis. 420 U.S. 514 (1974).

In this case the general rule is that reports of certified laboratories are to be given only to the person providing the original sample. The particular exception is in respect to testing for aflatoxin in feed for sale. In that event, both the director of DHS and the state chemist are involved with specific statutory duties. Since the state lab has the responsibility of providing laboratory services to the state chemist there is no impropriety in designating a copy of the aflatoxin test results to go to the state lab.

FACT SITUATION D:

Department of health services regulation R9-17-315, subsection A, paragraph 1 states:

1. A laboratory which desires to perform testing required by A.R.S. section 36-904.01 and has not been certified by A.R.S. section 3-145 shall first apply to be certified by the Director as a laboratory which meets the standards to perform aflatoxin testing of ammoniated cottonseed stated in this Article. Any laboratory found by the Director to comply with the standards required by this Article will be certified as an approved laboratory. To obtain this certification, the laboratory must apply to the Department for a certificate on a form provided by the Department. The application shall be prepared and signed by both the owner of the laboratory and the laboratory director. (Emphasis added.)

A.R.S. section 3-145, subsections A and B (see Fact Situation B) state that a laboratory that provides agricultural laboratory services "/s/hall apply for a certificate from the state agricultural laboratory . . . ."

QUESTION PRESENTED:

D.1. Does the department of health services have the statutory authority to grant certification for agricultural testing services?

ANSWER:

Yes.

DISCUSSION:

Under A.R.S. section 36-904.01, subsection A (set out in the discussion under Fact Situation C), ammoniated cottonseed is to be submitted for aflatoxin analysis. "Such sample shall be analyzed by a laboratory approved by the director, or otherwise certified under state law, to determine that the ammoniation has reduced the aflatoxin content to acceptable levels." This provision allows two types of laboratories to test ammoniated cottonseed for aflatoxin: 1) a laboratory approved by the director of DHS or 2) a laboratory otherwise certified under state law, presumably certified by the state lab. This provision by its terms allows DHS to approve laboratories for aflatoxin testing purposes and to that extent R9-17-315, subsection A, paragraph 1 complies with the statutory authority. The authority to issue regulations to enforce A.R.S. section 39-901.01, subsection A is found in subsection D of that section and in A.R.S. section 36-911.

FACT SITUATION E:

The preliminary audit work indicates that the state agricultural laboratory does not have a policy statement regarding quality assurance and does not have documented quality assurance procedures.

In practice, the laboratory participates in several programs with federal agencies and national associations in which known samples are analyzed by the agricultural laboratory and another laboratory. The laboratory occasionally splits samples with another laboratory for results verification. All preliminary audit work suggests a high degree of accuracy.

QUESTION PRESENTED:

E.1. Are the agricultural laboratory's existing quality control procedures adequate to ensure the validity of its results for enforcement purposes?

DISCUSSION:

Since this question calls for a subjective application of nonlegal standards this office declines to respond. The function of this office in connection with performance audits by the auditor general is to provide legal research and statutory interpretation. The statutes require the commission of agriculture and horticulture to prescribe administrative rules for certified agricultural labs which affect their precision and accuracy. As discussed under fact situation A.2. above, the state lab is not required to be certified but can be expected to adhere to the same standards which it enforces. If the commission has not adopted an administrative rule regarding quality control, the state lab may informally adopt and follow its own procedures, but determining the sufficiency of that procedure is not a question of law and is properly left to the administrative authority.

cc: William Thompson, Director
Performance Audit Division