STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED PERMANENT RULES RELATING TO DRUG AND ALCOHOL TESTING LABORATORIES; LICENSING

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Commissioner of Health, (hereinafter "commissioner"), pursuant to Minnesota Statutes, sections 14.05 to 14.12 and 14.22 to 14.28, presents facts establishing the need for and the reasonableness of the above captioned proposed permanent rules.

In order to adopt the proposed rules, the Commissioner must demonstrate that she has complied with all the procedural and substantive requirements of rulemaking. Those requirements are that: 1) there is statutory authority to adopt the rule, 2) all necessary procedural steps have been taken, 3) the rules are needed, 4) the rules are reasonable, and 5) any additional requirements imposed by law have been satisfied. This statement demonstrates that the Commissioner has met these requirements.

I. STATUTORY AUTHORITY

The statutory authority of the Commissioner of Health to adopt the rules pertaining to licensure of laboratories performing drug and alcohol tests from Minnesota employees is outlined below. Specific statutory authority for each rule is discussed in detail as part of the rule-by-rule justification.

- Minnesota Statutes, section 181.953, requires the commissioner to adopt rules for the licensure of laboratories performing drug and alcohol tests on employee urine and blood samples.

- The commissioner may adopt reasonable rules pursuant to Minnesota Statutes, section 144.12, for the preservation of the public health.

II. COMPLIANCE WITH RULEMAKING PROCEDURAL REQUIREMENTS

Minnesota Statutes, sections 14.05 - 14.12 and 14.22 - 14.28, specify certain procedures which must be followed when an agency adopts or amends rules. Procedures applicable to all rules (Minnesota Statutes, sections 14.05 - 14.15) have been complied with by the commissioner. The commissioner has determined that the adoption of proposed parts 4740.1000 to 4740.1080 is non-controversial and has elected to follow procedures set forth in Minnesota Statutes, sections 14.22 - 14.28, which provide for an expedited process for the adoption of non-controversial administrative rules without holding a public hearing.

Minnesota Statutes, section 14.10, requires an agency that seeks information or opinions from persons outside the agency for adoption of rules to publish notice of such action in the State Register. This will serve to notify interested persons in the community of the opportunity to submit comments or data on the subject of the rules. A

notice of solicitation of outside information or opinions appeared in the State Register, on August 17, 1987, at Volume 12, Number 7, page 294.

The adoption of these rules will not require expenditure of public money by local public bodies of greater than $100,000.00 in either of the two years following promulgation, nor do these rules have any impact on agricultural land. (Minnesota Statutes, section 14.11, 1986.)

Pursuant to Minnesota Statutes, section 14.23, the commissioner has prepared this statement of need and reasonableness which is available to the public.

The commissioner will publish a notice of intent to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statutes, section 14.14, subdivision 1(a). The notice will include the following statements:

a) that the public have 30 days in which to submit comments on the proposed rules;
b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
c) giving information pertaining to the manner in which persons shall request a hearing; and

d) that the rule may be modified if modifications are supported by data and the views submitted.

e) other information required by Minnesota Statutes, section 14.22.

If 25 or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rules, the agency shall proceed under the provisions of Minnesota Statutes, sections 14.131 - 14.20, and notice of hearing shall be published in the State Register.

If no hearing is required, the commissioner will submit the proposed rules and notice as published, the rules as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval of the rules.

These rules shall become effective five working days after publication of a notice of adoption in the State Register.

Non-Mandatory Actions by the Commissioner

The commissioner of health, pursuant to the authority granted under Minnesota Statutes, section 15.059, established in September, 1987, a "Technical Advisory Group". This group of toxicologists and laboratory professionals reviewed drafts of proposed rules. Review included assessment of standards, Threshold Detection Levels (Confirmatory Test Levels) and license fees. In December, 1987, the Commissioner established a second "Advisory Group"

which consisted of Representatives of Employers, Unions, government Human Rights Advocate Groups and principal authors of the bill.

The "Technical Advisory Group" and the "Advisory Group" provided direct advice on Laboratory Standards, Chain-of-Custody and Confirmatory Test Levels.

The technical advisory group, consisting of seven prominent toxicologists and scientists, reviewed the proposed rules. Members of the group included:

- Fred Apple, Ph.D., Hennepin County Medical Center;
- Kingsley LaBrosse, Ph.D., Medtox, New Brighton;
- Thomas P. Moyer, Ph.D., Mayo Clinic;
- David Ehresman, MT(ASCP), St. Paul-Ramsey Medical Center;
- John H. Eckfeldt, M.D., University of Minnesota Hospitals;
- Larry Bowers, Ph.D., University of Minnesota Hospitals; and
- S. G. Jejurikar, Ph.D., Forensic Toxicology, Bureau of Criminal Apprehension, State of Minnesota.

The Commissioner will send copies of proposed rules, as they appear in the State Register, to over 170 individuals, groups, laboratories, and government agencies registered as interested parties.

III. SMALL BUSINESS CONSIDERATIONS

The impact of rules on small businesses was examined as required by Minnesota Statutes, chapter 14.115. The affect was considered by the following methods:

- at least one of the members of the technical advisory group owns and operates a small business,

- The Minnesota Association of Commerce and Industry reviewed preliminary drafts of the rules,

- over thirty laboratories which have applied for transitional laboratory approval to perform drug and alcohol testing will receive copies of the rules, as they appear in the State Register, for comment,

- and the administrative requirements for application and renewal of a license were established to simplify or consolidate application and reporting requirements.

Impact of Standards

The standards proposed by rule have the potential of raising costs for all laboratories performing drug and alcohol tests in the workplace. A key area of contention involved the National Institute for Drug Abuse (NIDA) requirement that initial screening tests and confirmatory tests be conducted by the same laboratory.

The cost of equipment necessary for confirmatory tests is in the hundreds of thousands of dollars. To assure that a smaller laboratory may compete with larger laboratories, the rules allow a laboratory to perform only initial screening tests. The laboratory must forward samples positive on the initial screening test to a laboratory licensed by the commissioner to perform confirmatory tests. In addition, a copy of the chain-of-custody procedures used between laboratories must be submitted to the commissioner for review.

Other standards outlined by rule are either required by Minnesota Statutes, section 181.953 or are considered to be good laboratory practice among members of the laboratory community. These practices include participation in a proficiency testing program, conduct and documentation of internal quality assurance, adherence to sound chain-of-custody procedures, and the use of proper confirmatory test methods.

NIDA Standards and National Committee for Clinical Laboratory Standards (NCCLS) were consulted during advisory group discussions. NIDA is a division of the United States Department of Health and Human Services. NIDA is in the process of developing standards for employee drug testing for federal agencies. Unions, employers, and other governmental units are looking to NIDA as a model program for drug testing in the workplace. The NCCLS is an organization dedicated to the standardization of laboratory practices. Members include persons in public health, medicine, the laboratory diagnostics industry, and the academic setting.

Impact of License Fees

The legislature requires that the commissioner recover the costs of administering the laboratory licensure program through fees. The costs of conducting the program, combined with the relatively small number of laboratories offering specialized toxicology testing, will have an impact on small laboratories. However, testing job applicant and employee samples for drugs and alcohol is but one specific segment of the toxicology testing market. Laboratories may choose to enter, or not enter, the target market. Laboratories performing significant numbers of tests for employers will not be forced out of the market place. It is logical to assume that the added cost of licensure will be passed on to the user of such services.

The approval from the Department of Finance for licensure fees is attached as Appendix A.

Rules are written in two parts. The first, part 4740.0100 to 4740.0170, addresses general administrative issues. Parts 4740.1000 to 4740.1080, address the technical standards specific to alcohol and drug testing.

IV. RULE-BY-RULE JUSTIFICATION

4740.1000 **Purpose and Scope**

Minnesota Statutes, section 181.953 requires that the Commissioner of Health assure that laboratories meet defined standards when testing Minnesota employees for drugs or alcohol. Licensure of these laboratories is the method to be used for assessment of compliance.

4740.1010 **Definitions**

Terms used in the rule are defined to promote a better understanding of the rule.

4740.1020 **License Required**

The paragraph states that a laboratory must possess a valid license to test employee/job applicant samples for drugs and alcohol testing from Minnesota employees. This is consistent with Minnesota Statutes, section 181.953, subdivision 1(a) which states that an employer who requests

or requires an employee or job applicant to undergo drug or alcohol testing shall use the services of a testing laboratory licensed by the commissioner.

National Institute for Drug Abuse (NIDA) requires that a laboratory performing drug and alcohol testing perform both the initial screening test and the confirmatory test. This practice would be in contradiction with Minnesota Statutes, section 14.115, which deals with the affect of rules on small business. It is reasonable to require laboratories which do only the initial screening test to send samples with presumptive presence of a drug or alcohol to a laboratory licensed by the commissioner, using strict written chain-of-custody procedures.

4740.1025 **Exception**

The legislature's intent is that a medical clinic, hospital, or other medical facility employs personnel competent to perform the breath test as an initial screening test for alcohol. Therefore, a medical clinic, hospital or other medical facility need not be licensed to perform a breath test as an initial screening test for alcohol. The exception conforms with Minnesota Statutes, section 181.951, as amended April 14, 1988, Chapter 536, Minnesota Sessions Law Services (West).

4740.1040 **Reciprocity**

The commissioner must grant reciprocity to laboratories licensed by another federal or state agency, under Minnesota Statutes, section 181.953, subdivision 1(c).

4740.1050 **Term of License**

A one year term of license allows more effective program planning and budgeting. The burden of renewal of a license rests with the applicant to control administrative costs.

4740.1060 **Annual License Fee Required**

The Department of Finance approved proposed fees for the Licensure of Laboratories Performing Drug and Alcohol Testing in Workplace, see attached memo dated December 3, 1987, to Dave Hovet. The commissioner of health is required to recover laboratory licensure costs and equipment costs through license fees. The fee schedule reflects the need to recover the costs of an actual on-site inspection through the fixed $1,200.00 base fee, yet recognize that other costs should be covered by the per sample fee.

4740.1065 **Annual Inspection**

Annual inspections will be used to assess compliance with standards. Advisory group members agreed with our contention that annual inspections are necessary for a laboratory licensed for drug and alcohol testing in the

workplace. Non-compliance with rule needs to be detected early to help minimize the risk of errors in testing or reporting of results.

4740.1070 **Performance Standards Required for Issuance of a License**

Subpart 1. Standards Required This simply states that to qualify for issuance of a license, the officers or owner must comply with Subparts 2 to 13.

Subpart 2. Test Samples The type of samples acceptable for drug and alcohol testing are indicated in accordance with Minnesota Statutes, section 181.953, subdivision 1(b)(2). Urine is the usual sample of choice for employee drug and alcohol testing. Blood and breath samples may be used.

Subpart 3. Collection of Urine Samples; Procedures Minnesota Statutes, section 181.953, subdivision 1(b)(3) requires the commissioner to define procedures for sample collection which assure privacy to the employee and job applicant, while minimizing the risk of sample tampering during the sample collection process. Sample collection usually takes place in clinic or other medical facility which is designed, equipped, and staffed for that purpose.

However, the commissioner of health recognizes that samples may be collected in a facility other than a clinic or hospital. The commissioner of health recognizes that not all aspects of items 1 through 10, Specimen Collection, Federal Register, Volume 52, Number 157, Friday, August 14, 1987, page 30639 can be adhered to in a non-clinic setting. However, the commissioner expects that strict sample identification will be maintained through the collection process, consistent with individual privacy issues. National Institute for Drug Abuse (NIDA) guidelines are attached as Appendix B. NIDA, a division of the United States Health and Human Services Department, exists to study issues involving drug abuse.

Subpart 4. Collection of Blood Samples; Procedures

Minnesota Statutes, section 181.953, subdivision 1(b)(3) requires the commissioner to define procedures for sample collection which assure privacy to the employee and job applicant, while minimizing the risk of sample tampering during the sample collection process. Collection of blood is an invasive procedure which could affect the health of an individual. Therefore, the laboratory will have a written procedure for the collection of blood samples. The commissioner recommends the NCCLS Standard (Appendix C) as an acceptable guide for writing the sample collection procedure. The NCCLS is a nationally recognized organization dedicated to the improvement of clinical laboratory testing. NCCLS guidelines are written by experts in the clinical laboratory testing

profession and are reviewed by peers. Comments are sought from all clinical laboratory professionals before guidelines and standards are approved.

Subpart 5. Techniques for Drug Testing The commissioner must determine the tests acceptable for initial testing and confirmatory testing. Any drug test may be used for the initial test if it meets FDA requirements for in Vitro diagnostic products under 21 CFR, Chapter 1, Part 809. The confirmatory test must be done by the gas chromatographic/mass spectrometer (GC/MS). GC/MS is currently recognized as the most specific method for the detection of drugs and drug metabolites. Confirmation of presumptively positive samples by GC/MS will minimize the risk of a false-positive result for an employee or job applicant. Right to a retest of positive confirmed samples essentially eliminates the possibility of a false-positive result. Acceptable testing methods will be reviewed as technology changes and upon formal request for variance.

Subpart 6. Techniques for Alcohol Testing Tests for alcohol are specified to, as much as possible, conform with existing rules. Minnesota Rules, 7502.0700.

Subpart 7. Confirmatory Tests Required Samples tested for drugs, drug metabolites and alcohol must be tested by a licensed laboratory. Therefore, a laboratory which is licensed to perform only initial screening tests must confirm the presumptive presence of a drug, drug

metabolite or alcohol through a laboratory licensed to perform confirmatory tests.

Subpart 8. Chain-of-Custody Procedures for Handling Samples The commissioner recognizes that specifics of chain-of-custody procedures will vary from lab to lab. However, possession must be traceable back to the employee from whom the sample was collected. Several sources of information were reviewed concerning chain-of-custody procedures. The Handbook for Sampling and Sample Preservation of Water and Wastewater, Environmental Monitoring and Laboratory, Office of Research and Development, US Environmental Protection Agency, Cincinnati, Ohio, EPA-600/4-82-029, Sept., 1982, pages 348 and 349 outlines criteria for chain-of-custody procedures. The criteria are incorporated into Items A through C, Subpart 8. USEPA samples are collected during enforcement investigations, the evidentiary nature of which requires strong chain-of-custody procedures.

Subpart 9. Storage of Positive Samples Confirmed positive samples will be properly stored to assure that an employee may request a retest. The freezer used to store confirmed positive samples will be locked or located in a secured area to prevent tampering, unauthorized removal or the possible unauthorized disclosure of names of persons with positive results. Minnesota Statutes, section 181.953, subdivision 1(b)(7) and subdivision 3.

Subpart 10. Requirements for Directors The laboratory scientific director shall be fully capable of managing the technical aspects of the laboratory. Language is derived directly from Minnesota Statutes, section 181.953, subdivision 2(1)).

Subpart 11. Proficiency Testing Required Proficiency testing is used as a tool for evaluating laboratory performance by such certification and licensing bodies as MEDICARE/HCFA, The College of American Pathologists and The Joint Commission for Accreditation of Hospitals. Proficiency testing standards are stated in the transitional laboratory requirements, Minnesota Statutes, section 181.953, subdivision 2(2) and proficiency testing is necessary and reasonable as a requirement for licensure. Proficiency testing results will be used as an indicator of laboratory performance between laboratory inspections.

Subpart 12. Procedures for Proficiency Testing The frequency and numbers of samples to be tested are outlined. The College of American Pathologists and American Association of Clinical Chemists provide programs which are widely recognized as acceptable programs. "Blind" proficiency testing, which simulates a real sample, arrives at the laboratory as a routine sample test. Results are considered a better indication of true laboratory performance. A false-positive confirmatory test result for an employee may have serious impact on the employee or job applicant. Therefore, a

false-positive test result for a proficiency testing confirmatory test sample is not satisfactory. The commissioner understands that statistically random errors occur in laboratory testing. Therefore, the laboratory will explain corrective actions implemented to help assure that false-positive results will be resolved prior to issuance of a laboratory report.

Subpart 13. Laboratory Procedure Manual The laboratory procedure manual is a key component of reliable laboratory test results. Clinical-type laboratories should use a format similar to those outlined in **Clinical Laboratory Procedure Manuals,** National Committee for Clinical Laboratory Standards (NCCLS), 1984. Written laboratory procedures are reasonable business and scientific practices. NCCLS guidelines are attached as Appendix D.

4740.1080 **Threshold Detection Levels**

Threshold detection levels or, perhaps more appropriately, confirmatory test levels for the more common drugs of abuse are defined. A group of seven prominent toxicologists reviewed the values (Appendix E). Decisions concerning threshold detection levels for cocaine, benzoylecgonine, opiates, phencyclidine, amphetamines, fentanyl, lysergic acid diethylamide, 3-4-methylenedioxy amphetamine, and alcohol centered on the analytical capabilities of the population of laboratories performing the confirmatory test.

Physiologic effects of possible passive inhalation of marijuana smoke were discussed at length. Although delta-9 tetrahydrocannabinol-9-carboxylic acid may be detected at levels less than 15 ng/ml, members of the advisory group felt that 15 ng/ml is the limit of Δ-9-THC levels in passive inhalation. The Employers Association recommended a 15 ng/ml level for Δ-9-THC.

Threshold detection levels for the remaining hundreds of substances defined under section 152.01, subdivision 1, schedules I through V were set at 1000 ng/ml. Threshold detection levels for the substances not listed are not generally known or documented (Minnesota Statutes, section 181.953, subdivision 1(b)(5)).

4740.1090 **Variance and Waivers**

Variance and Waiver gives a laboratory the opportunity to apply for an exception or alternative to a specific portion of the rule.

9-2-88

Date

Sr Mary Madonna Ashton

Sister Mary Madonna Ashton
Commissioner of Health
Minnesota Department of Health

JAI 1-5-88
Rev. 8/16/88:rs

Statement of Need and Reasonableness

Minnesota Law, 1987, Chapter 388, Section 4, Subdivision 1 requires the Commissioner of Health to establish fees to approximately equal the costs of conducting a licensure program for laboratories performing drug and alcohol tests of employees in the state. Paragraph 7(d) reads as follows:

The commissioner shall charge laboratories an annual license fee. The fee may vary depending on the number of Minnesota employee samples tested annually at a laboratory. Fee receipts must be deposited in the state treasury and credited to a special account and are appropriated to the commissioner to administer this subdivision, and to purchase or lease laboratory equipment as accumulated fee receipts make equipment purchases or leases possible. Notwithstanding section 144.122, the commissioner shall set the license fee at an amount so that the total fees collected will recover the costs of administering this subdivision and allow an additional amount to be credited to the special account each year sufficient to allow the commissioner to obtain appropriate laboratory equipment for use in administering this subdivision by July 1, 1994.

Under the proposed rule, the laboratory will submit an initial payment of $1,200.00 for the annual license fee with the application for license. The initial payment is not refundable. Following the review of the application, a final payment on the annual license fee shall be due. This final payment shall be based on the formula,

$$\left[\frac{\text{Minnesota Alcohol Samples}}{2} + \text{Minnesota Drug Samples}\right] \times \$3.00/\text{sample}.$$

A sample obtained for both alcohol and drug testing shall be considered one (1) alcohol sample and one (1) drug sample for fee purposes. If the laboratory satisfies application criteria and pays the entire license fee, the laboratory will receive a provisional license. Full licensure may be granted after an on-site inspection to include, but not be limited to, assessment of external and internal quality control, examination of written laboratory procedures, review of records of sample receipt and storage, and an audit of records to ascertain the validity of statistics submitted to the Minnesota Department of Health. Demonstrated compliance with licensure standards will be required to qualify for a license.

Drug and alcohol tests used by laboratories are sophisticated and varied. Initial tests use a variety of chromatographic or immuno-chemical technologies. The confirmatory test method, Gas Chromatography/Mass Spectrometry (GC/MS) demands a high level of training and skill. Therefore, a toxicologist consultant will be hired to perform on-site inspection. A professional-level employee (0.5 FTE) will manage the program and will work with the toxicologist on initial laboratory inspections. A clerk-typist (0.5 FTE) will provide office support.

The fees collected will be used to support the licensure program. We estimate that approximately ten laboratories performing approximately 22,000 drug and alcohol tests of Minnesota employees per year will apply for a license.

Estimated Expenses

Estimated expenses in FY88 are expected to be higher than FY89 due to the costs associated with the rule-making process. Table I shows estimated costs for FY88 and 89, which are $77,400 and $53,000 respectively. The $47,000 appropriation will be returned to the general fund on June 30, 1989.

Estimated Revenue

The license fee consists of a fixed $1,200.00 component to assure that direct inspection costs are recovered. The variable $3.00 per sample tested fee is to cover other program expenses. Fees collected from alcohol samples are 50% of the drug sample fee to reflect relative costs of the test to the employer. A laboratory will establish the license fee by the formula:

$1,200.00 + [(Alcohol samples)(0.5) + Drug Samples] x $3.00 (see Table II).

Estimated revenue for FY88 is:

10 labs x $1,200 fixed license fee	12,000.00
+ [(8,800)(0.5) + 12,800] x $3.00	51,600.00
	63,600.00

	INCOME (FEES)	EXPENSES	EXTRAORDINARY EXPENSES	CASH FLOW	SPECIAL ACCT BAL
7-1-88	$0	$0	$0	$0	$47,000
FY88	$63,600	$77,400	$0	-$13,800	$33,200
FY89	$66,780	$53,000	$47,000	-$33,220	-$20

The license fee is necessary to carry out the tasks required by the law. The fees are reasonable and they meet the statutory criteria for covering estimated license program costs.

12-24-87
Date

Robert Lindner
Robert Lindner, Ph.D., M.D.
Director, Public Health Laboratories

STATEMENT OF NEED AND REASONABLENESS

Minnesota Statutes, Chapter 181.953, Subdivision 1 (d) requires the Commissioner of Health to establish fees to approximately equal the costs of conducting a licensure program for laboratories performing drug and alcohol tests of employees in the state. The statute reads as follows:

The commissioner shall charge laboratories an annual license fee. The fee may vary depending on the number of Minnesota employee samples tested annually at a laboratory. Fee receipts must be deposited in the state treasury and credited to a special account and are appropriated to the commissioner to administer this subdivision, and to purchase or lease laboratory equipment as accumulated fee receipts make equipment purchases or leases possible. Nothwithstanding section 144.122, the commissioner shall set the license fee at an amount so that the total fees collected will recover the costs of administering this subdivision and allow an additional amount to be credited to the special account each year sufficient to allow the commissioner to obtain appropriate laboratory equipment for use in administering this subdivision by July 1, 1994.

Under the proposed rule, the laboratory will submit the annual license and inspection fee with the application for license. These fees are not refundable. A license will be granted only when a laboratory meets standards set by rule, completes an application form and pays the fees in full.

License fees will be as follows:

Part A Application Fee

Laboratory Annual Gross Income	License Fee $
<$500,000	600
$500,00 to 2.0 Mill	1200
$2.0 Mill to 10.0 Mill	1800
>$10.0 Million	2400

Part B Inspection Fee

$1200 per year per per lab

If the laboratory satisfies application criteria and pays the entire fee, the laboratory will receive a provisional license. Full licensure may be granted after an on-site inspection to include, but not be limited to, assessment of external and internal quality control, examination of written laboratory procedures, review of records of sample receipt and storage, and an audit of records to ascertain the validity of statistics submitted to the Minnesota Department of Health. Demonstrated compliance with licensure standards will be required to qualify for a license.
Drug and alcohol tests used by laboratories are sophisticated and varied. Initial tests use a variety of chromatographic or

immuno-chemical technologies. The confirmatory test method, Gas Chromatography/Mass Spectrometry (GC/MS) demands a high level of training and skill. Knowledge of chain-of-custody procedures is essential. Therefore, a toxicologist consultant will be hired to perform on-site inspection. A professional-level employee (0.5 FTE) will manage the program and will work with the toxicologist on initial laboratory inspections. A clerk-typist (0.5 FTE) will provide office support.

The fees collected will be used to support the licensure program. We estimate that approximately twenty laboratories performing approximately 22,000 drug and alcohol test of Minnesota employees per year will apply for a license. The fees have been set to permit the greatest amount of laboratory participation, consistent with the revenue requirement.

Estimated Expenses

Expenses in FY88 and FY89 are for rule making. Expenses for FY88 were $23,400. Expenses for FY89 are expected to be $30,150. Total expenses over the two year period are estimated at $53,550 (see Table I). No on-site inspections will be conducted during the period.

Estimated expenses in FY90 are $54,000 for licensure and inspection (see Table II).

Estimated Revenue

The license fee is based on two components. Part "A" is based on laboratory annual gross income. The Part "B" inspection fee is fixed at $1200. Fee revenue for FY89 is as follows. It is assumed the revenue for FY90 will be identical.

Part A Application Fee

Laboratory Annual Gross Income	License Fee Per Lab	# Labs	Total Revenue
<$500,000	600	5	3,000
$500,000 to 2.0 Mill	1200	5	6,000
$2.0 Mill to 10.0 Mill	1800	5	9,000
>$10.0 Million	2400	5	12,000
		Total Part A Revenue	30,000

Part B Inspection Fee

$1200 per year per lab x 20 labs = $24,000 Total Inspection Revenue

Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

Total Fee Revenue $30,000 + $24,000 = $54,000

Licensure of Laboratories Performing Drug and Alcohol Testing in the Workplace Income and Revenue FY 88-90

FY	Income	Expenses	Expenses to General Fund	Special Account Balance
88	$47,000	23,400	-0-	23,600
89	$54,000	30,150	47,000	450
90	$54,000	54,000	-0-	450

The license fees are necessary to complete the tasks required by M.S. 181.953. The fees are reasonable, they meet the statutory criteria for covering estimated rule-making and program expenses and they have been reviewed by affected laboratories and other interested parties.

1-18-89
Date

R. Lindner
Robert Lindner, Ph.D., M.D., Director
Public Health Laboratories