SENATE BILL NO. 272

February 4, 1999, Introduced by Senators HOFFMAN, BENNETT, DUNASKISS, STILLE, SIKKEMA, BYRUM, GAST, DE BEAUSSAERT, A. SMITH and EMMONS and referred to the Committee on Natural Resources and Environmental Affairs.

A bill to amend 1994 PA 451, entitled

"Natural resources and environmental protection act,"

(MCL 324.101 to 324.90106) by adding part 205.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

PART 205 LABORATORY ACCREDITATION

SEC. 20501. AS USED IN THIS PART:

(A) "ACCREDITATION" MEANS THE PROCESS BY WHICH THE DEPARTMENT RECOGNIZES A LABORATORY AS MEETING QUALIFICATIONS OR STANDARDS UNDER THIS PART OR IN RULES PROMULGATED UNDER THIS PART.

(B) "ACCREDITED LABORATORY" OR "ACCREDITED" MEANS OR REFERS TO A LABORATORY THAT IS IN COMPLIANCE WITH THE ACCREDITATION REQUIREMENTS OF THIS PART.

(C) "ANALYTE" MEANS THE SUBSTANCE OR PHYSICAL PROPERTY CONTAINED IN A SAMPLE FOR WHICH ANALYSIS IS PERFORMED.

(D) "ANALYTICAL DATA" MEANS THE QUALITATIVE OR QUANTITATIVE MEASURES REPORTED TO A STATE OR FEDERAL AGENCY AS THE RESULT OF CHEMICAL, PHYSICAL, BIOLOGICAL, MICROBIOLOGICAL, RADIOLOGICAL, OR OTHER SCIENTIFIC DETERMINATION.

(E) "APPLICANT" MEANS A LABORATORY APPLYING TO THE DEPARTMENT TO BECOME AN ACCREDITED LABORATORY.

(F) "CERTIFICATION OF COMPLIANCE STATEMENT" MEANS A STATEMENT REQUIRED WITH THE APPLICATION FOR ACCREDITATION, SIGNED AND DATED BY THE APPLICANT, ACKNOWLEDGING THAT THE LABORATORY IS REQUIRED TO BE CONTINUALLY IN COMPLIANCE WITH THIS PART.

(G) "COMMERCIAL LABORATORY" MEANS A LABORATORY THAT ANALYZES ENVIRONMENTAL SAMPLES FOR A FEE.

(H) "CONSUMER PRICE INDEX" MEANS THE ANNUAL AVERAGE PERCENTAGE INCREASE IN THE DETROIT CONSUMER PRICE INDEX FOR ALL ITEMS AS REPORTED BY THE UNITED STATES DEPARTMENT OF LABOR.

(I) "DEPARTMENT" MEANS THE DEPARTMENT OF ENVIRONMENTAL QUALITY.

(J) "DOUBLE BLIND PROFICIENCY TESTING SAMPLE" MEANS A PROFICIENCY TESTING SAMPLE SUBMITTED TO A LABORATORY AS A REGULAR SAMPLE AND NOT IDENTIFIED AS A PROFICIENCY TESTING SAMPLE.

(K) "LABORATORY" MEANS A LABORATORY THAT ANALYZES ENVIRONMENTAL SAMPLES FOR MONITORING OR COMPLIANCE WITH STATE ENVIRONMENTAL LAW. LABORATORY FACILITIES HOUSED IN 2 OR MORE BUILDINGS ARE A SINGLE LABORATORY IF THOSE BUILDINGS ARE AT THE SAME LOCATION.

(*l*) "LABORATORY DIRECTOR" MEANS THE INDIVIDUAL EMPLOYED BY A LABORATORY WHO HAS ULTIMATE RESPONSIBILITY FOR LABORATORY

OPERATIONS, INCLUDING BUT NOT LIMITED TO QUALITY CONTROL, RESULT REPORTING, PERSONNEL CONTROL, AND SIGNATURE AUTHORITY FOR THE VALIDATION STATEMENT SUPPLIED WITH EACH SET OF LABORATORY RESULTS. LABORATORY DIRECTOR INCLUDES A QUALIFIED INDIVIDUAL DESIGNATED BY THE LABORATORY DIRECTOR AS HIS OR HER REPRESENTATIVE.

(M) "ON-SITE ASSESSMENT CONTRACTOR" MEANS A PERSON UNDER CONTRACT TO THE DEPARTMENT FOR THE PURPOSE OF PERFORMING ON-SITE ASSESSMENT OF LABORATORIES TO EVALUATE COMPLIANCE WITH THIS PART.

(N) "PARAMETER" MEANS A SINGLE DETERMINATION OR GROUP OF RELATED DETERMINATIONS USING A SPECIFIC WRITTEN METHOD.

(O) "PERSON" MEANS AN INDIVIDUAL, PARTNERSHIP, CORPORATION, ASSOCIATION, OR OTHER LEGAL ENTITY.

(P) "PT" MEANS PROFICIENCY TESTING, WHICH IS TESTING TO DETERMINE WHETHER THE LABORATORY CAN PRODUCE ANALYTICAL RESULTS WITHIN SPECIFIED PERFORMANCE LIMITS.

(Q) "PT PROGRAM" MEANS A GOVERNMENT ENTITY OR A PRIVATE ENTITY UNDER CONTRACT TO OR OTHERWISE APPROVED BY THE DEPARTMENT THAT PROVIDES RIGOROUSLY CONTROLLED AND STANDARDIZED PT SAMPLES.

(R) "PT SAMPLE" MEANS A SAMPLE, THE COMPOSITION OF WHICH IS UNKNOWN TO THE LABORATORY PERFORMING THE ANALYSIS AND IS PROVIDED FOR PT.

(S) "QUALITY ASSURANCE" MEANS AN INTEGRATED SYSTEM OF ACTIV-ITIES INVOLVING PLANNING, QUALITY CONTROL, QUALITY ASSESSMENT, REPORTING, AND QUALITY IMPROVEMENT TO ENSURE THAT ANALYTICAL SERVICES MEET DEFINED STANDARDS OF QUALITY.

(T) "QUALITY ASSURANCE PLAN" MEANS A WRITTEN DESCRIPTION OF THE LABORATORY'S QUALITY ASSURANCE AND ALL ASSOCIATED ACTIVITIES.

(U) "QUALITY CONTROL" MEANS THE SYSTEM OF TECHNICAL ACTIVITIES, THE PURPOSE OF WHICH IS TO MEASURE AND CONTROL THE QUALITY OF ANALYTICAL SERVICES SO THAT SPECIFIC PERFORMANCE CRITERIA ARE MET.

(V) "RAW DATA" MEANS THE QUALITATIVE OR QUANTITATIVE MEASUREMENTS RECORDED FROM CHEMICAL, PHYSICAL, BIOLOGICAL, MICROBIOLOGICAL, RADIOLOGICAL, OR OTHER SCIENTIFIC DETERMINATION, OR RECORDED OBSERVATIONS AND COMMENTS RELEVANT TO THE MEASUREMENTS IN UNEDITED FORM.

(W) "RECIPROCITY" MEANS ACCEPTANCE OF A CERTIFICATION OR ACCREDITATION BETWEEN THE DEPARTMENT AND ANOTHER STATE.

(X) "SAMPLE" MEANS A FIELD OR LABORATORY COLLECTED SAMPLE AND ANY PORTION OF THIS SAMPLE IN THE ANALYTICAL PROCESS INCLUDING A SUBSAMPLE, ALIQUOT, EXTRACT, OR DIGESTATE.

(Y) "STATE AGENCY" MEANS THE STATE GOVERNMENT OF ANY STATE OF THE UNITED STATES OF AMERICA.

(Z) "VALIDATION STATEMENT" MEANS A STATEMENT THAT IS PROVIDED WITH EACH SET OF RESULTS SIGNED BY THE LABORATORY DIRECTOR INDICATING THAT ALL OF THE REQUIREMENTS OF THIS PART AND RULES PROMULGATED UNDER THIS PART HAVE BEEN MET RELATIVE TO ALL ANALYTICAL STEPS AND QUALITY CONTROL ASSOCIATED WITH A SET OF LABORATORY RESULTS.

SEC. 20502. (1) BY RULES PROMULGATED UNDER THIS PART, THE DEPARTMENT MAY REQUIRE THAT ANALYTICAL DATA REQUIRED UNDER THIS

ACT AND SUBMITTED TO THE DEPARTMENT FOR ENVIRONMENTAL REGULATORY MONITORING OR COMPLIANCE PURPOSES BE PRODUCED OR DEVELOPED BY A LABORATORY ACCREDITED BY THE DEPARTMENT UNDER THIS PART FOR THE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH THE ANALYTICAL DATA ARE SUBMITTED.

(2) ANY RULES REFERRED TO IN SUBSECTION (1) SHALL ALSO REQUIRE ACCREDITATION OF A LABORATORY OPERATED BY THE DEPARTMENT FOR ENVIRONMENTAL REGULATORY MONITORING OR COMPLIANCE PURPOSES.

(3) THIS PART DOES NOT PROHIBIT OTHER STATE CERTIFICATION, ACCREDITATION, LICENSING, OR REGISTRATION PROGRAMS ESTABLISHED BEFORE THE EFFECTIVE DATE OF THIS PART. THE STATE DRINKING WATER LABORATORY CERTIFICATION PROGRAM UNDER THE SAFE DRINKING WATER ACT, 1976 PA 399, MCL 325.1001 TO 325.1023, IS UNAFFECTED BY THIS PART UNLESS OTHERWISE PROVIDED BY RULE.

(4) THE DEPARTMENT MAY EXEMPT FROM SUBSECTION (1) DATA FROM LABORATORIES THAT HAVE CURRENT CONTRACTS WITH THE ENVIRONMENTAL PROTECTION AGENCY SUPERFUND CONTRACT LABORATORY PROGRAM IF THE DATA MEET ALL OF THE FOLLOWING REQUIREMENTS:

(A) THE DATA ARE SUBMITTED BY THOSE LABORATORIES TO THE STATE OR FEDERAL GOVERNMENT.

(B) THE DATA PERTAIN TO CLEANUP ACTIVITIES UNDER A SUPERFUND SITE.

(C) THE DATA ARE CONSISTENT WITH THE ENVIRONMENTAL PROTECTION AGENCY SUPERFUND LABORATORY CONTRACT IN EFFECT AT THE TIME THE DATA ARE PRODUCED.

(5) THE DEPARTMENT MAY ACCEPT SAMPLE RESULTS PRODUCED BY A NONACCREDITED LABORATORY IF BOTH OF THE FOLLOWING REQUIREMENTS ARE MET:

(A) A WRITTEN REQUEST FOR A VARIANCE IS SUBMITTED TO THE DEPARTMENT BY THE PERSON WHO IS REQUIRED TO SUBMIT THE DATA FOR REGULATORY PURPOSES EXPLAINING WHY A VARIANCE IS NECESSARY AND WHY SUCH SAMPLE RESULTS WERE NOT OR COULD NOT BE PRODUCED BY AN ACCREDITED LABORATORY.

(B) THE SAMPLE RESULTS ARE SUBMITTED WITH THE METHOD AND ALL METHOD VALIDATION DATA, CALIBRATION DATA, RAW DATA, AND QUALITY CONTROL DATA, OR AT THE OPTION OF THE DEPARTMENT, WITH A DATA VALIDATION REPORT FROM AN ON-SITE ASSESSMENT CONTRACTOR UNDER CONTRACT TO THE DEPARTMENT.

(6) EACH LABORATORY SHALL BE INDIVIDUALLY ACCREDITED.

(7) MOBILE LABORATORIES OWNED AND OPERATED BY A STATIONARY LABORATORY AND UNDER THE CONTROL OF THE LABORATORY DIRECTOR OF THE STATIONARY LABORATORY MAY, AT THE OPTION OF THE STATIONARY LABORATORY, BE CONSIDERED PART OF THE STATIONARY LABORATORY FOR PURPOSES OF GRANTING ACCREDITATION BUT ARE SEPARATE LABORATORIES FOR PURPOSES OF SATISFYING THE PT TESTING, ON-SITE ASSESSMENT, AND OTHER REQUIREMENTS OF ACCREDITATION.

(8) MOBILE LABORATORIES OWNED BY THE SAME PERSON BUT NOT DESCRIBED BY SUBSECTION (7) MAY, AT THE OPTION OF THE OWNER, BE CONSIDERED A SINGLE LABORATORY UNIT FOR PURPOSES OF GRANTING ACCREDITATION, BUT ARE SEPARATE LABORATORIES FOR PURPOSES OF SATISFYING THE PT TESTING, ON-SITE ASSESSMENT, AND OTHER REQUIREMENTS OF ACCREDITATION.

(9) AN ACCREDITED LABORATORY SHALL NOT SUBCONTRACT SAMPLE ANALYSES PERFORMED FOR THE PURPOSE OF DEMONSTRATING COMPLIANCE WITH ANY ENVIRONMENTAL LAW, REGULATION, OR RULE IMPLEMENTED BY THE DEPARTMENT, UNLESS THE SUBCONTRACTOR LABORATORY IS ACCREDITED FOR THE NECESSARY CATEGORIES, PARAMETERS, ANALYTES, OR METHODS.

(10) AN ACCREDITED LABORATORY IS NOT ELIGIBLE TO CONTRACT WITH THE DEPARTMENT FOR ON-SITE ASSESSMENT OF LABORATORIES OR TO PROVIDE PT SAMPLES UNDER CONTRACT TO OR OTHERWISE APPROVED BY THE DEPARTMENT.

(11) DEPARTMENT ON-SITE ASSESSMENT CONTRACTORS AND PROVIDERS OF PT SAMPLES UNDER CONTRACT TO OR OTHERWISE APPROVED BY THE DEPARTMENT ARE NOT ELIGIBLE FOR ACCREDITATION.

SEC. 20503. (1) UPON REQUEST FROM A LABORATORY SEEKING ACCREDITATION, THE DEPARTMENT SHALL MAKE AN APPLICATION PACKAGE AVAILABLE TO THE LABORATORY CONSISTING OF MATERIALS AND INFORMATION WHICH MAY INCLUDE THE APPLICATION FORM, A COPY OF THIS PART AND APPLICABLE RULES, AN ACCREDITATION MANUAL, THE ACCREDITATION CATEGORIES, A LISTING OF ACCEPTABLE METHODS, LISTING OF ANALYTES FOR WHICH ACCREDITATION IS AVAILABLE, THE IDENTIFICATION OF EACH PT PROGRAM, AND THE NAME OF ON-SITE ASSESSMENT CONTRACTORS UNDER CONTRACT TO THE DEPARTMENT.

(2) A LABORATORY SHALL NOT SUBMIT TO THE DEPARTMENT AND THE DEPARTMENT SHALL NOT ACCEPT AN APPLICATION FOR ACCREDITATION IF ACCREDITATION HAS BEEN DENIED OR THE ACCREDITATION HAS BEEN REVOKED FOR THAT LABORATORY AND THE 6-MONTH PERIOD UNDER SECTION 20514(4) HAS NOT EXPIRED.

(3) THE DEPARTMENT SHALL CHARGE ACCREDITATION FEES AS PROVIDED IN SECTION 20510 TO IMPLEMENT THIS PART AND OVERSEE EACH CONTRACTOR HIRED OR APPROVED BY THE DEPARTMENT, AS NECESSARY, TO IMPLEMENT THE ACCREDITATION PROGRAM UNDER THIS PART AND RULES PROMULGATED UNDER THIS PART. A CONTRACTOR OR CONTRACTORS HIRED BY THE DEPARTMENT SHALL BE THE LOWEST RESPONSIVE BIDDER OR BIDDERS QUALIFIED TO UNDERTAKE THE CONTRACTUAL RESPONSIBILITIES. A CONTRACTOR SHALL ASSESS FEES FOR ITS SERVICES AS ESTABLISHED IN THE CONTRACT WITH THE DEPARTMENT. THE FEES SHALL BE PAID DIRECTLY BY LABORATORIES THAT ARE OR SEEK TO BE ACCREDITED.

(4) BEFORE SUBMITTING AN APPLICATION FOR ACCREDITATION TO THE DEPARTMENT, AN APPLICANT SHALL PARTICIPATE IN PT UNDER SECTION 20508. THE PT RESULT REPORT SHALL BE SUBMITTED WITH THE APPLICATION FOR ACCREDITATION.

(5) BEFORE SUBMITTING AN APPLICATION FOR ACCREDITATION TO THE DEPARTMENT, THE APPLICANT SHALL UNDERGO AN ON-SITE ASSESSMENT FROM AN ON-SITE ASSESSMENT CONTRACTOR UNDER SECTION 20509. THE APPLICANT SHALL SUBMIT THE ON-SITE ASSESSMENT REPORT WITH THE APPLICATION FOR ACCREDITATION.

(6) THE APPLICANT SHALL SUBMIT AN APPLICATION FOR ACCREDITATION TO THE DEPARTMENT ON FORMS PRESCRIBED BY THE DEPARTMENT. THE APPLICANT SHALL SUBMIT THE ACCREDITATION FEE WITH THE APPLICATION. THE APPLICATION FOR ACCREDITATION SHALL SATISFY ALL OF THE FOLLOWING REQUIREMENTS:

(A) THE APPLICATION SHALL INCLUDE THE LEGAL NAME OF THE LABORATORY, LABORATORY MAILING ADDRESS, TELEPHONE NUMBER, FULL ADDRESS AND LOCATION OF THE LABORATORY, THE NAME, TELEPHONE

NUMBER, AND ADDRESS OF THE LABORATORY OWNER, NAME AND THE TELEPHONE NUMBER OF THE QUALITY ASSURANCE OFFICER, NAME AND TELEPHONE NUMBER OF THE LABORATORY DIRECTOR, AND THE HOURS OF OPERATION.

(B) THE APPLICATION SHALL INCLUDE THE SPECIFIC CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH ACCREDITATION IS SOUGHT.

(C) THE APPLICATION SHALL INCLUDE A CERTIFICATION OF COMPLIANCE STATEMENT SIGNED AND DATED BY THE INDIVIDUAL SPECIFIED IN SUBDIVISION (D) AND WHICH STATES:

"_____ ("THE APPLICANT") UNDERSTANDS AND ACKNOWLEDGES THAT THE LABORATORY IS REQUIRED TO BE CONTINUALLY IN COMPLIANCE WITH PART 205 (LABORATORY ACCREDITATION) OF THE NATURAL RESOURCES AND ENVIRONMENTAL PROTECTION ACT, 1994 PA 451, MCL 324.20501 TO 324.20519, AND RULES PROMULGATED UNDER PART 205, AND IS SUBJECT TO THE PENALTY PROVISIONS IN PART 205. AUTHORIZED REPRESENTATIVES OF THE DEPARTMENT MAY MAKE ANNOUNCED OR UNANNOUNCED INSPECTIONS OF AN APPLICANT OR ACCREDITED LABORATORY, AND REVIEW ANY DATA REQUIRED TO BE SUBMITTED TO THE DEPARTMENT UNDER PART 205 AND RULES PROMULGATED UNDER PART 205 OR ANY INFORMATION ASSOCIATED WITH SUCH DATA, TO DETERMINE THE EXTENT OF COMPLIANCE WITH THE CONDITIONS OF ACCREDITATION AND THESE REGULATIONS. ADDITIONALLY, THE APPLICANT AUTHORIZES THE OFFICIALLY DESIGNATED STATE INSPECTOR TO MAKE COPIES OF ANY ANALYSES OR OTHER RECORDS RELEVANT TO THE ACCREDITATION AND COMPLIANCE PROCESS, AND TO REMOVE COPIES FROM THE FACILITY FOR PURPOSES OF EVALUATION OR REGULATORY ENFORCEMENT. THE REFUSAL TO ALLOW ENTRY BY THE

REPRESENTATIVES OF THE DEPARTMENT AT REASONABLE TIMES OR DURING NORMAL BUSINESS HOURS OR TO ALLOW COPIES OF RECORDS RELEVANT TO LABORATORY ACCREDITATION TO BE MADE IS A VIOLATION OF A CONDITION OF ACCREDITATION AND SHALL RESULT IN DENIAL OR LOSS OF ACCREDITATION. THE APPLICANT HEREBY CERTIFIES THAT ALL ANALYSES PERFORMED ARE DONE IN ACCORDANCE WITH PART 205 AND RULES PROMULGATED UNDER PART 205. THE UNDERSIGNED CERTIFIES THAT HE OR SHE IS AUTHORIZED TO SIGN THIS APPLICATION ON BEHALF OF THE APPLICANT/OWNER AND THAT BASED ON HIS OR HER KNOWLEDGE AND BELIEF, THE INFORMATION PROVIDED IN THIS ACCREDITATION APPLICATION IS ACCURATE.".

(D) THE APPLICATION AND THE CERTIFICATION OF COMPLIANCE STATEMENT SHALL BE SIGNED AND DATED BY 1 OF THE FOLLOWING INDIVIDUALS:

(*i*) IF THE APPLICANT IS A CORPORATION, A PRINCIPAL EXECUTIVE OFFICER OF AT LEAST THE LEVEL OF VICE PRESIDENT.

(*ii*) IF THE APPLICANT IS A PARTNERSHIP, A GENERAL PARTNER.

(*iii*) IF THE APPLICANT IS A SOLE PROPRIETORSHIP, THE PROPRIETOR.

(7) WITHIN 30 DAYS AFTER RECEIVING AN APPLICATION, THE DEPARTMENT SHALL REVIEW THE APPLICATION, DETERMINE WHETHER THE APPLICATION IS ADMINISTRATIVELY COMPLETE, AND NOTIFY THE APPLICANT OF ANY ADDITIONAL ITEMS THAT ARE NECESSARY TO MAKE THE APPLICATION ADMINISTRATIVELY COMPLETE.

(8) WITHIN 30 DAYS AFTER DETERMINING THAT AN APPLICATION IS ADMINISTRATIVELY COMPLETE, THE DEPARTMENT SHALL REVIEW THE APPLICATION, THE ON-SITE ASSESSMENT REPORT, AND THE RESULTS OF

THE APPLICANT'S PT SAMPLES. BASED ON REVIEW OF THIS INFORMATION, THE DEPARTMENT MAY APPROVE FULL ACCREDITATION FOR ALL REQUESTED PARAMETERS, MAY APPROVE ACCREDITATION FOR A SUBSET OF THE REQUESTED PARAMETERS AND DENY ACCREDITATION FOR OTHERS, OR MAY DENY ACCREDITATION FOR ALL REQUESTED PARAMETERS. DENIAL OF ACCREDITATION IS SUBJECT TO SECTION 20513.

(9) ACCREDITATION SHALL REMAIN IN EFFECT FOR 1 YEAR, UNLESS REVOKED BY THE DEPARTMENT OR UNLESS DISCONTINUED BY ACTION OF THE ACCREDITED LABORATORY.

(10) THE DIRECTOR OF THE DEPARTMENT OF ENVIRONMENTAL QUALITY OR HIS OR HER DESIGNEE SHALL ISSUE A CERTIFICATE OF ACCREDITATION TO LABORATORIES THAT COMPLY WITH THE ACCREDITATION REQUIREMENTS UNDER THIS PART. THE CERTIFICATE SHALL INCLUDE THE NAME OF THE LABORATORY AND THE ACCREDITATION EXPIRATION DATE AND SHALL INCLUDE OR SHALL HAVE APPENDED A LIST OF THE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH THE LABORATORY IS ACCREDITED. THE CERTIFICATE IS THE PROPERTY OF THE DEPARTMENT AND SHALL BE RETURNED TO THE DEPARTMENT UPON EXPIRATION OR LOSS OF ACCREDITATION.

(11) THE MOST CURRENT CERTIFICATE AND THE MOST CURRENT LIST OF CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH THE LABORATORY IS ACCREDITED SHALL BE POSTED CONSPICUOUSLY IN THE LABORATORY AND A COPY SHALL BE MADE AVAILABLE BY THE ACCREDITED LABORATORY, UPON REQUEST, TO ANY PARTY UTILIZING OR REQUESTING THE SERVICES OF THE LABORATORY.

SEC. 20504. (1) ACCREDITATION WITHIN CATEGORIES, PARAMETERS, ANALYTES, OR METHODS SHALL BE RENEWED ANNUALLY. TO

BE ELIGIBLE FOR RENEWAL OF ACCREDITATION, THE ACCREDITED LABORATORY SHALL REMAIN IN COMPLIANCE WITH THE REQUIREMENTS OF THIS PART AND RULES PROMULGATED UNDER THIS PART.

(2) THE ACCREDITED LABORATORY MAY INITIATE RENEWAL OF ACCREDITATION BY SUBMITTING ALL OF THE FOLLOWING TO THE DEPARTMENT WITHIN 60 DAYS BEFORE THE ANNUAL EXPIRATION DATE ESTABLISHED THROUGH INITIAL ACCREDITATION:

(A) THE RENEWAL APPLICATION AND ALL RELEVANT INFORMATION UPDATED AND SIGNED BY THE INDIVIDUAL IDENTIFIED IN SECTION 20503(6)(D). APPLICATIONS FOR RENEWAL OF ACCREDITATION SHALL ALSO INCLUDE THE ACCREDITATION EXPIRATION DATE AND ANY DEPARTMENT-ASSIGNED LABORATORY ACCREDITATION NUMBER.

(B) FEES REQUIRED UNDER SECTION 20510.

(C) THE RESULT REPORTS OF ALL PT SAMPLES FOR ACCREDITED ANALYTES OR PARAMETERS ANALYZED WITHIN THE LAST YEAR UNDER SECTION 20508.

(D) A COPY OF THE MOST RECENT ON-SITE ASSESSMENT REPORT UNDER SECTION 20509(3).

SEC. 20505. (1) AN ACCREDITED LABORATORY MAY AUGMENT THE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH IT SEEKS ACCREDITATION DURING ANNUAL RENEWAL OF ACCREDITATION UNDER SECTION 20504.

(2) AT TIMES OTHER THAN DURING AN ANNUAL RENEWAL OF ACCREDITATION, AN ACCREDITED LABORATORY MAY AUGMENT THE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH IT IS ACCREDITED BY MAKING A SEPARATE APPLICATION TO THE DEPARTMENT.

(3) AN APPLICATION TO AUGMENT ACCREDITATION SHALL INCLUDE ALL RELEVANT APPLICATION INFORMATION REQUIRED IN SECTION 20503. THE LABORATORY SHALL SUBMIT THE APPLICATION FEES REQUIRED UNDER SECTION 20510.

(4) IF A LABORATORY APPLIES TO AUGMENT ACCREDITATION FOR 2 OR FEWER ANALYTICAL METHODS DURING ANY 1 ACCREDITATION YEAR, THE ON-SITE ASSESSMENT MAY BE DEFERRED UNTIL THE NEXT ON-SITE ASSESSMENT REQUIRED AS A PART OF THE ACCREDITATION RENEWAL PROCESS. THE EVALUATION AND APPROVAL OF SUCH METHODS SHALL BE BASED ON REVIEW OF THE WRITTEN STANDARD OPERATING PROCEDURE AND THE INITIAL DEMONSTRATION OF METHOD PERFORMANCE AS SPECIFIED BY RULE.

(5) AN APPLICATION TO AUGMENT ACCREDITATION SHALL INCLUDE A PT RESULT REPORT DEMONSTRATING SUCCESSFUL PARTICIPATION IN PT NOT MORE THAN 6 MONTHS BEFORE APPLYING FOR ACCREDITATION.

(6) THE RENEWAL DATE FOR CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH ACCREDITATION IS AUGMENTED SHALL BE THE ANNUAL ACCREDITATION RENEWAL DATE.

(7) AN ACCREDITED LABORATORY MAY SURRENDER ACCREDITATION FOR ANY ACCREDITED CATEGORIES, PARAMETERS, ANALYTES, OR METHODS AT ANY TIME BY FILING WITH THE DEPARTMENT A WRITTEN REQUEST SIGNED BY THE LABORATORY DIRECTOR.

SEC. 20506. (1) THE DEPARTMENT MAY ENTER INTO AGREEMENTS WITH THE GOVERNMENT OF ANY OTHER STATE OR THIRD PARTY NONGOVERNMENTAL ENTITY FOR THE PURPOSE OF RECOGNIZING OUT-OF-STATE ACCREDITATION OF LABORATORIES IF SUCH AGREEMENTS ARE AUTHORIZED BY RULES PROMULGATED BY THE DEPARTMENT AND IF THE DEPARTMENT DETERMINES THAT ACCREDITATION STANDARDS OF THE OTHER STATE OR

THIRD PARTY PROGRAMS ARE EQUIVALENT TO THE ACCREDITATION STANDARDS OF THIS PART AND THE RULES PROMULGATED UNDER THIS PART.

(2) THE FEES REQUIRED FOR INITIAL ACCREDITATION OR RENEWAL OR AUGMENTATION OF ACCREDITATION THROUGH A RECIPROCITY AGREEMENT UNDER THIS SECTION ARE THE FEES PROVIDED FOR BY SECTION 20510.

(3) ACCREDITATION CAN BE TRANSFERRED WHEN THE LEGAL STATUS OR OWNERSHIP OF AN ACCREDITED LABORATORY CHANGES WITHOUT AFFECTING ITS STAFF, EQUIPMENT, OR ORGANIZATION IN A MANNER THAT WOULD PREVENT THE LABORATORY FROM MAINTAINING COMPLIANCE WITH THIS PART. ACCREDITATION SHALL BE TRANSFERRED IF ALL OF THE FOLLOWING OCCUR:

(A) THE CHANGE IN OWNERSHIP OF AN ACCREDITED LABORATORY IS REPORTED TO THE DEPARTMENT BY THE LABORATORY DIRECTOR IN WRITING WITHIN 10 BUSINESS DAYS AFTER THE CHANGE TAKES PLACE.

(B) THE NEW OWNER AGREES TO MAINTAIN IN ACCORDANCE WITH THIS PART OR RULES PROMULGATED UNDER THIS PART RECORDS, DATA, AND REPORTS FOR ANY ANALYSES GENERATED BEFORE LEGAL TRANSFER OF OWNERSHIP.

(C) THE NEW OWNER PAYS A TRANSFER FEE TO THE DEPARTMENT.

SEC. 20507. (1) THE DEPARTMENT SHALL DO ALL OF THE FOLLOWING:

(A) DEVELOP AN ACCREDITATION MANUAL DETAILING THE REGULATIONS, REQUIREMENTS, GUIDANCE, AND ACCREDITATION PROCEDURES FOR ACCREDITATION UNDER THIS PART.

(B) DEFINE THE CATEGORIES, PARAMETERS, ANALYTES, AND ACCEPTABLE METHODS FOR WHICH A LABORATORY MAY BECOME ACCREDITED.

(C) COMPILE AND MAINTAIN A LISTING OF COMMERCIAL ACCREDITED LABORATORIES THAT INCLUDES THE NAME OF EACH LABORATORY, THE NAME OF THE LABORATORY DIRECTOR, THE MAILING ADDRESS AND TELEPHONE NUMBER OF THE LABORATORY, AND THE CATEGORIES FOR WHICH THE LABORATORY IS ACCREDITED. THIS LISTING SHALL BE REVISED AT LEAST ANNUALLY AND SHALL BE AVAILABLE ON REQUEST WITHOUT CHARGE.

(2) THE DEPARTMENT MAY DO 1 OR MORE OF THE FOLLOWING:

(A) APPROVE THE USE OF ALTERNATIVE TEST PROCEDURES THAT ARE APPROVED BY THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY FOR A SIMILAR USE.

(B) APPROVE THE USE OF ALTERNATIVE TEST PROCEDURES IF THE APPLICANT DOCUMENTS THAT THE QUALITY OF DATA PRODUCED BY THE PROPOSED METHOD IS AS GOOD OR BETTER THAN THE QUALITY OF DATA PRODUCED BY THE EXISTING APPROVED METHOD.

(C) APPROVE AN ANALYTICAL METHOD IS THERE IS NO DEPARTMENT APPROVED METHOD OR IF NO METHOD EXISTS.

(D) UNDERTAKE DOUBLE BLIND PT STUDIES OF ACCREDITED LABORATORIES THROUGH THE USE OF SAMPLES FROM A PT PROGRAM OR SAMPLES FROM OTHER QUALIFIED SOURCES. THE DEPARTMENT MAY USE THE RESULTS OF SUCH PT SAMPLES TO SELECT LABORATORIES FOR FURTHER INSPECTION, REQUIRE ANALYSIS OF PT SAMPLES IN THE PRESENCE OF DEPARTMENT REPRESENTATIVES, REQUIRE CORRECTIVE ACTION, REVOKE ACCREDITATION SUBJECT TO THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, MCL 24.201 TO 24.328, OR REQUEST THE ATTORNEY GENERAL TO COMMENCE A CIVIL ACTION AS DESCRIBED IN SECTION 20516.

(E) ENTER INTO AGREEMENTS, CONTRACTS, OR COOPERATIVE ARRANGEMENTS UNDER TERMS AND CONDITIONS APPROPRIATE WITH OTHER

STATE AGENCIES, FEDERAL AGENCIES, INTERSTATE AGENCIES, POLITICAL SUBDIVISIONS, EDUCATIONAL INSTITUTIONS, LOCAL HEALTH DEPARTMENTS, OR OTHER PUBLIC OR PRIVATE ORGANIZATIONS, OR INDIVIDUALS TO ADMINISTER THIS PART.

SEC. 20508. (1) ALL OF THE FOLLOWING PT REQUIREMENTS SHALL BE MET:

(A) THE LABORATORY SHALL PARTICIPATE IN PT FOR ALL CATEGORIES, PARAMETERS, ANALYTES, AND METHODS FOR WHICH THE LABORATORY IS ACCREDITED AND FOR WHICH A PT PROGRAM EXISTS.

(B) THE LABORATORY SHALL PAY ALL COSTS OF PT REQUIRED FOR ACCREDITATION.

(C) THE PT RESULT REPORT SHALL BE PROVIDED WITH THE INITIAL APPLICATION FOR ACCREDITATION AND ANY APPLICATION TO AUGMENT ACCREDITATION. AFTER ACCREDITATION IS GRANTED, EACH LABORATORY SHALL PROVIDE THE PT RESULT REPORT TO THE DEPARTMENT, WITHIN 30 DAYS FOLLOWING RECEIPT OF THE REPORT.

(D) A LABORATORY SHALL EXAMINE OR TEST, AS APPLICABLE, THE PT SAMPLES RECEIVED FROM THE PT PROGRAM IN THE SAME MANNER AS ROUTINE ENVIRONMENTAL SAMPLES. EACH ANALYST RESPONSIBLE FOR ANALYSIS OF A PT SAMPLE SHALL TEST THE PT SAMPLE THE SAME NUMBER OF TIMES THAT ROUTINE TESTS ON ENVIRONMENTAL SAMPLES ARE PERFORMED. THE LABORATORY DIRECTOR AND EACH ANALYST SHALL ALSO SIGN THE PT RESULT REPORT OR A STATEMENT ATTACHED TO THE PT RESULT REPORT ATTESTING THAT ALL SAMPLES WERE ANALYZED IN THE SAME MANNER AS ROUTINE SAMPLES. ALL ANALYST SIGNATURES SHALL BE LINKED TO THE PT SAMPLE ANALYZED SO THAT THE ANALYST RESPONSIBLE FOR EACH PT SAMPLE IS CLEARLY IDENTIFIED. THESE SIGNED

STATEMENTS SHALL ACCOMPANY THE LABORATORY RESULTS TO THE PT PROGRAM.

(E) PT SAMPLE RESULTS FROM THE PARTICIPATING LABORATORY SHALL BE REPORTED TO THE PT PROGRAM WITHIN THE DEADLINE STATED IN THE SAMPLE PACKAGE.

(2) FOR AN ACCREDITATION PARAMETER OR ANALYTE FOR WHICH A PT SAMPLE OR SAMPLES ARE NOT CURRENTLY AVAILABLE, AS DETERMINED BY THE DEPARTMENT, THE LABORATORY SHALL ESTABLISH AND MAINTAIN THE ACCURACY AND RELIABILITY OF TESTING PROCEDURES BY A SYSTEM OF INTERNAL MANAGEMENT AS DESCRIBED IN RULES PROMULGATED UNDER THIS PART.

(3) ANY APPLICANT OR ACCREDITED LABORATORY PARTICIPATING IN PT SHALL COMPLY WITH ALL OF THE FOLLOWING REQUIREMENTS:

(A) A LABORATORY SHALL NOT ENGAGE IN COMMUNICATIONS WITH ANOTHER LABORATORY PERTAINING TO THE PT SAMPLE RESULTS BEFORE THE DEADLINE FOR REPORTING PT SAMPLE RESULTS.

(B) LABORATORIES SHALL NOT SEND A PT SAMPLE OR A PORTION OF A PT SAMPLE TO ANOTHER LABORATORY FOR ANY ANALYSIS FOR WHICH ACCREDITATION IS SOUGHT. ANY LABORATORY THAT THE DEPARTMENT DETERMINES REFERRED A PT SAMPLE TO ANOTHER LABORATORY FOR ANALYSIS SHALL BE DENIED ACCREDITATION OR HAVE ITS ACCREDITATION PERMANENTLY REVOKED FOR ALL CATEGORIES, PARAMETERS, ANALYTES, OR METHODS. ANY LABORATORY THAT RECEIVES A PT SAMPLE FROM ANOTHER LABORATORY FOR TESTING SHALL IMMEDIATELY NOTIFY THE DEPARTMENT OF THE RECEIPT OF THE PT SAMPLE AND SHALL PROVIDE TO THE DEPARTMENT ALL INFORMATION ASSOCIATED WITH THE RECEIPT OF THE PT SAMPLE. THE DEPARTMENT SHALL DENY OR REVOKE FOR 6 MONTHS ACCREDITATION OF

AN APPLICANT OR ACCREDITED LABORATORY THAT DOES NOT REPORT THE RECEIPT OF A PT SAMPLE FROM ANOTHER LABORATORY.

(C) A LABORATORY SHALL INITIATE CHAIN OF CUSTODY PROCEDURES UPON RECEIPT OF A PT SAMPLE. THE LABORATORY SHALL MAINTAIN A COPY OF ALL RECORDS ASSOCIATED WITH THE ANALYSIS OF A PT SAMPLE, INCLUDING ANALYTICAL WORKSHEETS, FOR A MINIMUM OF 5 YEARS. THIS RECORD SHALL INCLUDE A COPY OF COMPLETED PT RESULT REPORT FORMS USED BY THE LABORATORY TO RECORD PT RESULTS, INCLUDING THE STATEMENTS SIGNED BY THE APPROPRIATE ANALYSTS AND THE LABORATORY DIRECTOR STATING THAT PT SAMPLES WERE TESTED IN THE SAME MANNER AS ROUTINE ENVIRONMENTAL SAMPLES AS DESCRIBED IN SUBSECTION (1)(D).

(4) AN APPLICANT SHALL PARTICIPATE IN PT NOT MORE THAN 6 MONTHS BEFORE MAKING APPLICATION TO THE DEPARTMENT. A PT SAMPLE MAY CONSIST OF EITHER 1 OR 2 CONCENTRATIONS AS DETERMINED BY THE DEPARTMENT. IF THE PT SAMPLE CONSISTS OF 1 CONCENTRATION, THE SINGLE RESULT SHALL BE WITHIN THE ACCEPTANCE LIMIT TO BE ELIGIBLE FOR ACCREDITATION. IF THE PT SAMPLE CONSISTS OF 2 CONCENTRATIONS, BOTH RESULTS SHALL BE WITHIN ACCEPTANCE LIMITS TO BE ELIGIBLE FOR ACCREDITATION.

(5) AN ACCREDITED LABORATORY SEEKING TO MAINTAIN OR RENEW ACCREDITATION SHALL PARTICIPATE IN PT TWICE. THE FIRST PT SHALL BE COMPLETED NOT LESS THAN 6 AND NOT MORE THAN 12 MONTHS BEFORE THE ACCREDITATION EXPIRATION DATE AND THE SECOND PT SHALL BE COMPLETED NOT MORE THAN 6 MONTHS BEFORE THE ACCREDITATION EXPIRATION DATE. A PT SAMPLE MAY CONSIST OF EITHER 1 OR 2 CONCENTRATIONS AS DETERMINED BY THE DEPARTMENT.

(6) IF THE PT SAMPLE ANALYZED SEMIANNUALLY BY AN ACCREDITED LABORATORY CONSISTS OF 1 CONCENTRATION, THEN BOTH SEMIANNUAL PT SAMPLE RESULTS SHALL BE WITHIN ACCEPTANCE LIMITS. IF EITHER OR BOTH PT RESULTS ARE NOT WITHIN ACCEPTANCE LIMITS, THE LABORATORY SHALL BE PROVISIONALLY ACCREDITED AND SHALL REANALYZE A REMEDIAL PT SAMPLE NOT MORE THAN 30 DAYS AFTER RECEIVING THE UNACCEPTABLE PT RESULT. IF THE REMEDIAL PT SAMPLE RESULT IS ACCEPTABLE, ACCREDITATION FOR THAT ANALYTE IS RESTORED. IF THE REMEDIAL PT RESULT IS NOT WITHIN ACCEPTANCE LIMITS, ACCREDITATION FOR THAT ANALYTE IS REVOKED. TO BECOME REACCREDITED, THE LABORATORY SHALL REAPPLY FOR ACCREDITATION FOR THE AFFECTED ANALYTES THROUGH EITHER AN APPLICATION TO RENEW OR AUGMENT ACCREDITATION.

(7) IF THE PT SAMPLE ANALYZED SEMIANNUALLY BY AN ACCREDITED LABORATORY CONSISTS OF 2 CONCENTRATIONS, THEN 3 OF THE 4 SEMIANNUAL PT RESULTS SHALL BE WITHIN ACCEPTANCE LIMITS. IF LESS THAN 3 OF THE 4 PT RESULTS ARE WITHIN ACCEPTANCE LIMITS, THEN ACCREDITATION IS DOWNGRADED TO PROVISIONAL AND THE LABORATORY SHALL REANALYZE A REMEDIAL PT SAMPLE NOT MORE THAN 30 DAYS AFTER RECEIVING THE UNACCEPTABLE PT SAMPLE RESULT. IF THE PT RESULTS FOR BOTH CONCENTRATIONS OF THE REMEDIAL PT SAMPLE ARE WITHIN ACCEPTANCE LIMITS, THEN FULL ACCREDITATION IS RESTORED. IF THE PT RESULTS FOR 1 OR BOTH CONCENTRATIONS OF THE REMEDIAL PT SAMPLE ARE OUTSIDE ACCEPTANCE LIMITS, THEN ACCREDITATION FOR THAT ANALYTE IS REVOKED. TO BECOME REACCREDITED, THE LABORATORY SHALL REAPPLY FOR ACCREDITATION FOR THE AFFECTED ANALYTES THROUGH AN APPLICATION TO RENEW OR AUGMENT ACCREDITATION.

(8) THE CORRECTIVE ACTIONS TAKEN TO RESOLVE UNACCEPTABLE PT RESULTS SHALL BE THOROUGHLY DOCUMENTED, AND THE DOCUMENTATION SHALL BE MAINTAINED BY THE LABORATORY FOR AT LEAST 5 YEARS FROM THE DATE OF PARTICIPATION IN THE PT.

(9) FAILURE TO RETURN PT RESULTS TO THE PT PROGRAM WITHIN THE TIME DEADLINE SPECIFIED BY THE PT PROGRAM IS AN UNACCEPTABLE RESULT. HOWEVER, THE DEPARTMENT MAY EXTEND A DEADLINE IF IT DETERMINES THAT THE CAUSE OF THE FAILURE WAS BEYOND THE CONTROL OF THE LABORATORY.

(10) A LABORATORY SHALL TEST ADDITIONAL PT SAMPLES AT THE REQUEST OF THE DEPARTMENT IF THE DEPARTMENT DETERMINES THAT 1 OR MORE OF THE FOLLOWING APPLY:

(A) THERE HAS BEEN A MAJOR CHANGE IN OWNERSHIP OR SUPERVISION OF THE LABORATORY.

(B) A LABORATORY CLIENT OR EMPLOYEE HAS ALLEGED SIGNIFICANT NONCOMPLIANCE WITH THIS PART BY THE LABORATORY.

(C) THE LABORATORY OBTAINED UNACCEPTABLE RESULTS ON THE MOST RECENT PT.

(D) THE LABORATORY MUST DEMONSTRATE CORRECTIVE ACTION FOLLOWING AN UNACCEPTABLE ON-SITE ASSESSMENT.

SEC. 20509. (1) APPLICANT LABORATORIES AND ACCREDITED LABORATORIES SHALL BE EVALUATED FOR COMPLIANCE WITH THE ACCREDITATION REQUIREMENTS OF THIS PART BY AN ON-SITE ASSESSMENT CONTRACTOR.

(2) TO OBTAIN INITIAL ACCREDITATION OR TO AUGMENT ACCREDITATION, THE APPLICANT LABORATORY SHALL, NOT MORE THAN 1 YEAR BEFORE APPLYING FOR ACCREDITATION, PASS AN ON-SITE ASSESSMENT CONSISTENT WITH THE ON-SITE ASSESSMENT STANDARDS IN THIS PART AND

RULES PROMULGATED UNDER THIS PART. THE APPLICANT SHALL SCHEDULE AN ON-SITE ASSESSMENT WITH THE ON-SITE ASSESSMENT CONTRACTOR. THE ON-SITE ASSESSMENT CONTRACTOR SHALL PERFORM AN ON-SITE ASSESSMENT OF THE LABORATORY, PREPARE AN ON-SITE ASSESSMENT REPORT, AND SUBMIT THE REPORT TO THE APPLICANT. IF THE ON-SITE ASSESSMENT INDICATES SIGNIFICANT DEFICIENCIES, THE APPLICANT MAY CORRECT THE DEFICIENCIES AND REPEAT THE ON-SITE ASSESSMENT OR PORTION OF THE ON-SITE ASSESSMENT, AS APPROPRIATE. THE APPLICANT SHALL SUBMIT THE ON-SITE ASSESSMENT REPORT TO THE DEPARTMENT AS A PART OF THE APPLICATION FOR INITIAL ACCREDITATION OR THE APPLICATION TO AUGMENT ACCREDITATION, AS APPROPRIATE. THE DEPARTMENT SHALL NOT APPROVE AN APPLICATION FOR ACCREDITATION, UNLESS THE DEPARTMENT HAS FOUND THAT THE ON-SITE ASSESSMENT REPORT IS ACCEPTABLE. THE DEPARTMENT SHALL REVIEW THE APPLICATION, INCLUDING THE ON-SITE ASSESSMENT REPORT, SUBJECT TO SECTION 20503(7) AND (8). APPLICATION DENIAL IS SUBJECT TO SECTION 20513.

(3) TO RENEW ACCREDITATION, THE ACCREDITED LABORATORY SHALL PASS AN ON-SITE ASSESSMENT NOT MORE THAN 2 YEARS BEFORE EXPIRATION OF THE CURRENT ACCREDITATION PERIOD. IF AN ON-SITE ASSESSMENT IS REQUIRED, THE LABORATORY SHALL FORWARD A COPY OF THE ON-SITE ASSESSMENT REPORT TO THE DEPARTMENT NOT MORE THAN 10 DAYS AFTER RECEIVING THE ON-SITE ASSESSMENT REPORT FROM THE ON-SITE ASSESSMENT CONTRACTOR.

(4) THE ON-SITE ASSESSMENT CONTRACTOR SHALL PROVIDE COPIES OF THE ON-SITE ASSESSMENT TO BOTH THE LABORATORY AND THE DEPARTMENT NOT MORE THAN 30 BUSINESS DAYS AFTER COMPLETING THE ON-SITE ASSESSMENT. THE DEPARTMENT SHALL REVIEW THE ON-SITE ASSESSMENT

REPORT AND NOTIFY THE LABORATORY OF ANY EXISTING DEFICIENCIES NOT MORE THAN 30 BUSINESS DAYS AFTER RECEIVING THE ON-SITE ASSESSMENT REPORT. NOT MORE THAN 20 BUSINESS DAYS AFTER NOTIFICATION THAT A DEFICIENCY EXISTS, THE LABORATORY SHALL EITHER CORRECT THE DEFICIENCY AND PROVIDE DOCUMENTATION TO THE DEPARTMENT THAT THE DEFICIENCY HAS BEEN CORRECTED OR SUBMIT A CORRECTIVE ACTION PLAN TO THE DEPARTMENT UNDER SUBSECTION (5). IF THE LABORATORY CHOOSES TO CORRECT THE DEFICIENCY AND SUBMIT DOCUMENTATION TO THE DEPARTMENT DEMONSTRATING THAT THE DEFICIENCY HAS BEEN CORRECTED AND IF SUBSEQUENT DEPARTMENT REVIEW OF THIS SUBMITTAL DETERMINES THE DOCUMENTATION OR DEMONSTRATION IS DEFICIENT, THE DEPARTMENT MAY GRANT THE LABORATORY AN ADDITIONAL 20 BUSINESS DAYS TO PERFORM CORRECTIVE ACTION AND SUBMIT DOCUMENTATION OF THE CORRECTIVE ACTION BEFORE THE DEPARTMENT REVOKES ACCREDITATION.

(5) IF THE LABORATORY SUBMITS A CORRECTIVE ACTION PLAN, THE PLAN SHALL HAVE A COMPLETION DATE OF NOT MORE THAN 6 MONTHS FROM DEPARTMENT ACCEPTANCE OF THE PLAN. NOT MORE THAN 30 BUSINESS DAYS AFTER RECEIPT OF THE PLAN, THE DEPARTMENT SHALL REVIEW THE PLAN AND NOTIFY THE LABORATORY THAT THE DEPARTMENT EITHER ACCEPTS OR REJECTS THE PLAN, AS APPLICABLE. IF THE DEPARTMENT REJECTS THE PLAN, THE NOTIFICATION SHALL IDENTIFY CHANGES THAT WOULD MAKE THE CORRECTIVE ACTION PLAN ACCEPTABLE. IF THE DEPARTMENT DETERMINES THAT ALL DEFICIENCIES WERE NOT CORRECTED WITHIN 6 MONTHS OF ACCEPTING THE CORRECTIVE ACTION PLAN OR NOTIFYING THE LABORATORY OF THE CHANGES REQUIRED TO MAKE THE CORRECTIVE ACTION PLAN ACCEPTABLE, THE DEPARTMENT SHALL REVOKE ACCREDITATION.

(6) IN ADDITION TO ON-SITE ASSESSMENTS REQUIRED AS A PART OF AN APPLICATION FOR INITIAL ACCREDITATION OR TO RENEW OR AUGMENT ACCREDITATION, THE DEPARTMENT MAY REQUIRE FOLLOW-UP ASSESSMENTS TO VERIFY THAT THE CAUSE OF AN UNSATISFACTORY ON-SITE ASSESSMENT HAS BEEN CORRECTED OR TO DETERMINE THE CAUSE OF RECURRING UNACCEPTABLE PT RESULTS. THESE ON-SITE ASSESSMENTS SHALL BE PAID FOR BY THE LABORATORY.

(7) THE DEPARTMENT MAY REQUIRE A NEW OR PARTIAL ON-SITE ASSESSMENT IF THE DEPARTMENT DETERMINES THAT A MAJOR CHANGE HAS OCCURRED AT A LABORATORY IN PERSONNEL, EQUIPMENT, OR THE FACILITY THAT MIGHT IMPAIR THE CAPABILITY OF THE LABORATORY TO PERFORM ACCEPTABLE ANALYSIS OF PARAMETERS, METHODS, OR ANALYTES FOR WHICH THE LABORATORY IS ACCREDITED. A MAJOR CHANGE IN PERSONNEL INCLUDES THE LOSS OR REPLACEMENT OF A KEY MEMBER OF THE LABORATORY MANAGEMENT STAFF OR LOSS OF THE ONLY TRAINED AND EXPERIENCED INDIVIDUAL WHO PERFORMS A PARTICULAR TEST FOR WHICH ACCREDITATION HAS BEEN GRANTED.

(8) THE DEPARTMENT IS NOT REQUIRED TO PROVIDE ADVANCE NOTICE OF AN ON-SITE ASSESSMENT WHEN AN ON-SITE ASSESSMENT IS CONDUCTED AT DEPARTMENT EXPENSE.

(9) THE LABORATORY SHALL PERFORM PT SAMPLE ANALYSIS IN THE PRESENCE OF DEPARTMENT REPRESENTATIVES OR DURING AN ON-SITE ASSESSMENT IF REQUESTED TO DO SO BY THE DEPARTMENT.

SEC. 20510. (1) A LABORATORY APPLYING FOR INITIAL ACCREDITATION OR TO RENEW OR AUGMENT ACCREDITATION SHALL SUBMIT ALL FEES REQUIRED UNDER THIS SECTION WITH THE APPLICATION FOR ACCREDITATION. FEES ARE NONREFUNDABLE EXCEPT FOR OVERPAYMENT.

SUBJECT TO SUBSECTIONS (2) TO (8), THE ACCREDITATION FEE SHALL BE THE SUM OF THE FEE FOR EACH ACCREDITATION CATEGORY PLUS EITHER THE INITIAL APPLICATION FEE, THE AUGMENTATION FEE, OR THE RENEWAL APPLICATION FEE AS PROVIDED IN THE FOLLOWING FEE SCHEDULE:

FOR INITIAL ACCREDITATION.....	$ 400.00
TO ANNUALLY RENEW ACCREDITATION.....	$ 200.00
TO AUGMENT ACCREDITATION.....	$ 150.00
FEE PER ACCREDITATION CATEGORY.....	$ 100.00

(2) A FEE TO AUGMENT ACCREDITATION IS NOT REQUIRED IF THE LABORATORY APPLIES TO AUGMENT ACCREDITATION AT THE SAME TIME IT APPLIES TO ANNUALLY RENEW ACCREDITATION.

(3) ACCREDITATION MAY BE TRANSFERRED WHEN OWNERSHIP OF AN ACCREDITED LABORATORY CHANGES, SUBJECT TO SECTION 20506(3). THE ACCREDITATION TRANSFER FEE IS $100.00.

(4) THE ACCREDITATION FEE FOR EACH MOBILE LABORATORY UNIT THAT IS ACCREDITED AS PART OF A STATIONARY LABORATORY UNDER SECTION 20502(7) IS $100.00 PER MOBILE LABORATORY UNIT PLUS THE APPROPRIATE CATEGORY FEE OR FEES.

(5) THE ACCREDITATION FEE FOR MOBILE LABORATORIES ACCREDITED AS A SINGLE LABORATORY UNDER SECTION 20502(8) IS THE FEE DETERMINED UNDER SUBSECTION (1) FOR THE FIRST LABORATORY PLUS, FOR EACH ADDITIONAL MOBILE LABORATORY, THE SUM OF $100.00 AND THE APPROPRIATE CATEGORY FEE OR FEES.

(6) THE DEPARTMENT SHALL ADJUST FEES EACH YEAR BASED ON THE CONSUMER PRICE INDEX. THE DEPARTMENT SHALL DETERMINE ON OR BEFORE DECEMBER 15 OF EACH YEAR, BEGINNING DECEMBER 15, 1997, AN ADJUSTED AMOUNT FOR THE FOLLOWING YEAR. THE ADJUSTED AMOUNT FOR

EACH YEAR SHALL BE DETERMINED BY COMPARING THE CONSUMER PRICE INDEX FOR THE 12-MONTH PERIOD ENDING THE PRECEDING OCTOBER 31 WITH THE CORRESPONDING CONSUMER PRICE INDEX OF 1 YEAR EARLIER. THE PERCENTAGE INCREASE OR DECREASE SHALL THEN BE MULTIPLIED BY THE CURRENT ADJUSTED AMOUNT. THE PRODUCT, ROUNDED UP TO THE NEAREST MULTIPLE OF $1.00, SHALL BE THE NEW ADJUSTED AMOUNT. THE DEPARTMENT SHALL PROVIDE THE ADJUSTED AMOUNT UPON REQUEST.

(7) IN ADDITION TO THE FEES ASSESSED BY THE DEPARTMENT, AN APPLICANT FOR ACCREDITATION SHALL PAY THE FEES REQUIRED BY THE ON-SITE ASSESSMENT CONTRACTOR AS ESTABLISHED IN THE CONTRACT BETWEEN THE DEPARTMENT AND THE CONTRACTOR, AND ANY FEES ASSOCIATED WITH PT.

(8) WITHIN 14 DAYS AFTER THE DEPARTMENTS ENTER INTO A CONTRACT WITH AN ON-SITE ASSESSMENT CONTRACTOR, THE DEPARTMENT SHALL NOTIFY THE CHAIRPERSONS OF THE COMMITTEES OF THE SENATE AND THE HOUSE OF REPRESENTATIVES THAT ARE PRIMARILY RESPONSIBLE FOR ENVIRONMENTAL PROTECTION LEGISLATION OF THE FEES TO BE CHARGED BY THE ON-SITE ASSESSMENT CONTRACTOR.

(9) FEES UNDER THIS PART SHALL BE DEPOSITED IN THE ENVIRONMENTAL RESPONSE FUND SUBACCOUNT OF THE CLEANUP AND REDEVELOPMENT FUND CREATED UNDER SECTION 20108.

SEC. 20511. (1) AN ACCREDITED LABORATORY SHALL ASSURE THAT THE QUALITY OF ANALYTICAL DATA PRODUCED BY THE LABORATORY IS SUITABLE FOR ITS INTENDED PURPOSE AND IS SUPPORTED BY APPROPRIATE DOCUMENTATION. AN ACCREDITED LABORATORY SHALL ASSURE THAT THE QUALITY OF ANALYTICAL DATA IS MAINTAINED WITHIN A FRAMEWORK OF QUALITY SYSTEMS IN WHICH STAFF RESPONSIBILITIES AND OPERATIONAL

PROCEDURES ARE DEFINED, DOCUMENTED, AND SUBJECTED TO AUDIT ON A REGULAR BASIS, WITH TIMELY CORRECTIVE ACTION TAKEN BY THE LABORATORY AS NEEDED.

(2) THE QUALITY SYSTEMS SHALL INCLUDE ALL QUALITY ASSURANCE POLICIES AND QUALITY CONTROL PROCEDURES AND SHALL BE DOCUMENTED IN A LABORATORY QUALITY ASSURANCE PLAN. THE LABORATORY SHALL MEET ANY ADDITIONAL OR MORE STRINGENT REQUIREMENTS SPECIFIED BY ANALYTICAL METHODS OR SPECIFIC REGULATORY PROGRAMS FOR WHICH THE DATA IS BEING USED TO DEMONSTRATE COMPLIANCE.

SEC. 20512. (1) AN ACCREDITED LABORATORY SHALL PROVIDE THE LABORATORY ACCREDITATION NUMBER, EXPIRATION DATE, AND VALIDATION STATEMENT SIGNED BY THE LABORATORY DIRECTOR WITH EACH SET OF RESULTS. THE VALIDATION STATEMENT SHALL READ, "I CERTIFY THAT I AM THE LABORATORY DIRECTOR WITH ULTIMATE RESPONSIBILITY FOR LABORATORY OPERATIONS AND THAT, TO THE BEST OF MY KNOWLEDGE, THESE ANALYSES WERE PERFORMED, AND THE RESULTS ARE REPORTED, IN FULL COMPLIANCE WITH PART 205 OF THE NATURAL RESOURCES AND ENVIRONMENTAL PROTECTION ACT, 1994 PA 451, MCL 324.20501 TO 324.20519, AND RULES PROMULGATED UNDER PART 205.".

(2) THE LABORATORY SHALL MAINTAIN ALL LABORATORY RECORDS ASSOCIATED WITH ACCREDITATION PARAMETERS OR SPECIFIED IN ADMINISTRATIVE RULES, INCLUDING RAW DATA ASSOCIATED WITH EACH ANALYSIS, CHANGES IN METHOD STANDARD OPERATING PROCEDURES, AND THE LABORATORY QUALITY ASSURANCE PLAN, FOR A MINIMUM OF 5 YEARS UNLESS A LONGER PERIOD IS SPECIFIED IN A RULE PROMULGATED UNDER THIS PART.

(3) THE LABORATORY DIRECTOR OF AN ACCREDITED LABORATORY SHALL NOTIFY THE DEPARTMENT OF ANY CHANGES IN KEY ACCREDITATION CRITERIA INCLUDING THE LABORATORY LOCATION, OR THE LOSS OF KEY PERSONNEL, WITHIN 30 DAYS FOLLOWING THE CHANGES.

SEC. 20513. (1) THE DEPARTMENT SHALL DENY AN APPLICATION FOR INITIAL ACCREDITATION OR TO RENEW OR AUGMENT ACCREDITATION IF ANY OF THE FOLLOWING OCCUR:

(A) FAILURE TO PARTICIPATE OR UNSATISFACTORY PERFORMANCE IN PT AS REQUIRED BY THE DEPARTMENT.

(B) FAILURE TO SUBMIT THE CERTIFICATION OF COMPLIANCE STATEMENT WITH THE APPLICATION AS REQUIRED BY SECTION 20503.

(C) SUBMISSION OF PT RESULTS GENERATED BY ANOTHER LABORATORY.

(D) FALSIFICATION OF ANY REPORT OF OR RELATING TO A LABORATORY ANALYSIS.

(E) FAILURE TO PAY THE APPROPRIATE ACCREDITATION FEE WITH THE APPLICATION.

(F) AN UNACCEPTABLE ON-SITE ASSESSMENT, SUBJECT TO SECTION 20509.

(G) MISREPRESENTATION OF ANY MATERIAL FACT PERTINENT TO THE APPLICATION PROCESS.

(2) DENIAL OF ACCREDITATION SHALL OCCUR FOR SPECIFIC CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR THOSE INSTANCES WHERE UNSATISFACTORY LABORATORY PERFORMANCE, PRACTICES, OR ACTIONS ARE SPECIFIC TO SUCH CATEGORIES, PARAMETERS, ANALYTES, OR METHODS.

(3) THE DEPARTMENT SHALL NOTIFY THE APPLICANT OF THE DEPARTMENT'S INTENT TO DENY ACCREDITATION AND IDENTIFY THE BASIS

FOR DENIAL. IF THE BASIS FOR DENIAL IS AN UNACCEPTABLE ON-SITE ASSESSMENT, AFTER RECEIVING NOTICE THAT THE DEPARTMENT INTENDS TO DENY THE ACCREDITATION, THE APPLICANT SHALL HAVE 1 OPPORTUNITY TO CORRECT THE DEFICIENCIES CAUSING THE ON-SITE ASSESSMENT TO BE UNACCEPTABLE. IF THE APPLICANT OPTS TO CORRECT THESE DEFICIENCIES, THE APPLICANT SHALL SO NOTIFY THE DEPARTMENT NOT MORE THAN 10 DAYS AFTER RECEIVING THE DEPARTMENT NOTICE OF INTENT TO DENY ACCREDITATION. AT THE REQUEST OF AN APPLICANT FOR INITIAL ACCREDITATION OR TO AUGMENT ACCREDITATION, THE DEPARTMENT SHALL HOLD THE APPLICATION IN ABEYANCE FOR NOT MORE THAN 6 MONTHS FROM THE DATE THE DEPARTMENT NOTIFIED THE APPLICANT OF THE DEPARTMENT'S INTENT TO DENY ACCREDITATION TO ALLOW THE APPLICANT TO DEMONSTRATE THAT DEFICIENCIES HAVE BEEN CORRECTED. AT THE REQUEST OF AN APPLICANT TO RENEW ACCREDITATION, THE DEPARTMENT SHALL HOLD THE APPLICATION IN ABEYANCE FOR NOT MORE THAN 1 MONTH AFTER THE EXPIRATION OF THE CURRENT ACCREDITATION TO ALLOW THE APPLICANT TO DEMONSTRATE THAT DEFICIENCIES HAVE BEEN CORRECTED. IF THE DEPARTMENT DETERMINES THAT THE CORRECTION OF THE DEFICIENCIES SHOULD BE EVALUATED THROUGH AN ON-SITE ASSESSMENT, THE APPLICANT SHALL MAKE ALL ARRANGEMENTS AND PAY ALL COSTS FOR THE ON-SITE ASSESSMENT.

(4) THE DEPARTMENT SHALL DETERMINE WHETHER TO DENY RENEWAL OF ACCREDITATION AFTER THE LABORATORY HAS AN OPPORTUNITY FOR AN EVIDENTIARY HEARING IN A CONTESTED CASE PROCEEDING UNDER THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, MCL 24.201 TO 24.328.

SEC. 20514. (1) ACCREDITATION REMAINS IN EFFECT UNTIL 1 OF THE FOLLOWING OCCURS:

(A) ACCREDITATION IS REVOKED BY THE DEPARTMENT.

(B) ACCREDITATION IS SURRENDERED BY THE ACCREDITED LABORATORY.

(C) THE ACCREDITATION PERIOD EXPIRES, UNLESS THE LABORATORY FILES A COMPLETE APPLICATION FOR RENEWAL NOT LESS THAN 60 DAYS BEFORE THE EXPIRATION OF THE ACCREDITATION.

(2) THE DEPARTMENT SHALL REVOKE ACCREDITATION FOR CATEGORIES OR ANALYTES IF ANY OF THE FOLLOWING OCCUR:

(A) FAILURE TO PARTICIPATE IN PT FOR ANY CATEGORY, PARAMETER, ANALYTE, OR METHOD FOR WHICH THE LABORATORY IS ACCREDITED AND FOR WHICH A PT PROGRAM EXISTS, AS DETERMINED BY THE DEPARTMENT.

(B) TWO CONSECUTIVE UNACCEPTABLE PT RESULTS.

(C) SUBMISSION OF PT RESULTS GENERATED BY ANOTHER LABORATORY.

(D) FAILURE OF AN ACCREDITED LABORATORY TO REPORT TO THE DEPARTMENT RECEIPT OF PT SAMPLES FROM ANOTHER LABORATORY.

(E) IF ACCREDITATION WAS GAINED THROUGH A RECIPROCITY AGREEMENT WITH ANOTHER STATE AGENCY, WITHDRAWAL, REVOCATION, OR OTHER LOSS OF ACCREDITATION BY THE LABORATORY OR THE ORIGINAL ACCREDITING STATE AGENCY.

(F) MISREPRESENTATION OF ANY MATERIAL FACT PERTINENT TO RECEIVING ACCREDITATION.

(G) MISREPRESENTATION OF THE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH THE LABORATORY IS ACCREDITED.

(H) DENIAL OF ENTRY TO THE DEPARTMENT FOR PURPOSES OF LABORATORY INSPECTION OR ON-SITE ASSESSMENT.

(I) FALSIFICATION OF ANY REPORT OF OR RELATING TO A LABORATORY ANALYSIS.

(J) AN UNACCEPTABLE ON-SITE ASSESSMENT, SUBJECT TO THE REQUIREMENTS OF SECTION 20509.

(K) FAILURE TO PAY THE APPROPRIATE ACCREDITATION FEES.

(3) REVOCATION OF ACCREDITATION SHALL OCCUR ONLY FOR SPECIFIC CATEGORIES, PARAMETERS, ANALYTES, OR METHODS IF UNSATISFACTORY LABORATORY PERFORMANCE, PRACTICES, OR ACTIONS ARE RELATED ONLY TO THOSE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS.

(4) A LABORATORY WHOSE ACCREDITATION HAS BEEN REVOKED IS NOT ELIGIBLE TO REAPPLY FOR ACCREDITATION UNTIL 6 MONTHS AFTER THE DATE ON WHICH ACCREDITATION WAS REVOKED.

(5) THE DEPARTMENT SHALL DETERMINE WHETHER TO REVOKE ACCREDITATION AFTER THE LABORATORY HAS AN OPPORTUNITY FOR AN EVIDENTIARY HEARING IN A CONTESTED CASE PROCEEDING UNDER THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, MCL 24.201 TO 24.328.

SEC. 20515. (1) TO DETERMINE THE ABILITY OF AN ACCREDITED LABORATORY TO PRODUCE VALID ANALYTICAL RESULTS, OR TO EVALUATE THE VALIDITY OF ANY PREVIOUSLY REPORTED ANALYTICAL RESULTS, OR TO EVALUATE COMPLIANCE WITH THE REQUIREMENTS OF THIS PART OR RULES PROMULGATED UNDER THIS PART, THE DEPARTMENT OR THE ON-SITE ASSESSMENT CONTRACTOR MAY REQUIRE THE LABORATORY DIRECTOR TO FURNISH INFORMATION THAT THE LABORATORY IS REQUIRED TO MAINTAIN AS SPECIFIED IN THIS PART OR IN RULES PROMULGATED UNDER THIS PART

AND ANY SUPPORTING INFORMATION. PART 148 IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION. PRIVILEGE AND PROTECTION FROM DISCLOSURE DO NOT APPLY TO INFORMATION REQUIRED TO BE REPORTED TO THE DEPARTMENT UNDER THIS SUBSECTION.

(2) A PERSON REQUIRED TO FURNISH INFORMATION UNDER SUBSECTION (1) SHALL AT THE OPTION OF THE DEPARTMENT DO EITHER OF THE FOLLOWING:

(A) GRANT THE DEPARTMENT ACCESS AT ALL REASONABLE TIMES TO INSPECT AND COPY THE INFORMATION.

(B) COPY AND FURNISH THE INFORMATION TO THE DEPARTMENT, AT NO CHARGE.

(3) ALL INSPECTIONS AND INVESTIGATIONS UNDERTAKEN BY THE DEPARTMENT SHALL BE COMPLETED WITH REASONABLE PROMPTNESS.

(4) IF THE DEPARTMENT IS REFUSED ENTRY OR INFORMATION UNDER SUBSECTION (2), FOR THE PURPOSES OF ENFORCING THE INFORMATION GATHERING AND ENTRY AUTHORITY PROVIDED IN THIS SECTION, THE ATTORNEY GENERAL MAY DO 1 OR MORE OF THE FOLLOWING:

(A) PETITION THE COURT OF APPROPRIATE JURISDICTION FOR A WARRANT AUTHORIZING ACCESS TO THE LABORATORY OR LABORATORY RECORDS PURSUANT TO THIS SECTION.

(B) COMMENCE A CIVIL ACTION TO COMPEL COMPLIANCE WITH A REQUEST FOR INFORMATION OR ENTRY PURSUANT TO THIS SECTION, TO AUTHORIZE INFORMATION GATHERING AND ENTRY PROVIDED FOR IN THIS SECTION, AND TO ENJOIN INTERFERENCE WITH THE EXERCISE OF AUTHORITY PROVIDED IN THIS SECTION.

(C) SEEK CIVIL SANCTIONS ON BEHALF OF THE STATE, AS SPECIFIED IN SECTION 20516, FOR FAILURE TO COMPLY WITH AN INFORMATION OR ACCESS REQUEST.

(5) INFORMATION OBTAINED BY THE DEPARTMENT UNDER SUBSECTION (1) OR (2) SHALL BE AVAILABLE TO THE PUBLIC TO THE EXTENT PROVIDED BY THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231 TO 15.246. THE PROVIDER OF INFORMATION UNDER SUBSECTION (1) OR (2) MAY DESIGNATE THE INFORMATION THAT THE PROVIDER BELIEVES TO BE ENTITLED TO PROTECTION AS INFORMATION OF A PERSONAL NATURE UNDER SECTION 13 OF THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.243. SUCH SPECIFICALLY DESIGNATED INFORMATION MUST BE SUBMITTED SEPARATELY FROM OTHER INFORMATION REQUIRED TO BE PROVIDED UNDER THIS SECTION. A DETERMINATION OF WHETHER TO GRANT AN EXEMPTION FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231 TO 15.246, SHALL THEN BE MADE BY THE DEPARTMENT.

(6) NOTWITHSTANDING SUBSECTION (5), THE FOLLOWING INFORMATION OBTAINED BY THE DEPARTMENT AS REQUIRED BY THIS SECTION SHALL BE AVAILABLE TO THE PUBLIC:

(A) ALL APPLICATION INFORMATION SUBMITTED TO THE DEPARTMENT.

(B) ALL LABORATORY FINAL RESULTS REQUIRED TO BE REPORTED TO THE DEPARTMENT.

(C) THE METHOD OR METHODS USED TO PRODUCE SUCH RESULTS.

(D) ALL RAW DATA, CALIBRATION DATA, AND QUALITY CONTROL DATA ASSOCIATED WITH THE FINAL RESULTS REQUIRED TO BE REPORTED TO THE DEPARTMENT.

(E) THE LABORATORY QUALITY ASSURANCE MANUAL.

(F) ALL PT RESULTS AND PT RESULT REPORTS.

(G) THE SIGNED CERTIFICATION OF COMPLIANCE STATEMENT UNDER SECTION 20503 AND THE SIGNED VALIDATION STATEMENT UNDER SECTION 20512.

SEC. 20516. (1) IN ADDITION TO OTHER RELIEF AUTHORIZED BY LAW, THE ATTORNEY GENERAL MAY, ON BEHALF OF THE STATE, COMMENCE A CIVIL ACTION AGAINST THE LABORATORY FOR 1 OR MORE OF THE FOLLOWING:

(A) RECOVERY OF STATE INVESTIGATIVE, SAMPLING, OR ANALYTICAL COSTS WHERE DATA IS UNUSABLE DUE TO 1 OR MORE OF THE FOLLOWING:

(*i*) ANALYTICAL ERRORS CAUSED BY A LABORATORY'S FAILURE TO FOLLOW LABORATORY QUALITY CONTROL PROCEDURES, ANALYTICAL METHODS, OR THE REQUIREMENTS OF THIS PART OR RULES PROMULGATED UNDER THIS PART.

(*ii*) INADEQUATE LABORATORY RECORD KEEPING THAT PREVENTS VALIDATION OF REPORTED RESULTS.

(B) ENFORCEMENT OF INFORMATION GATHERING AND ENTRY AUTHORITY UNDER SECTION 20515.

(2) EXCEPT AS OTHERWISE PROVIDED IN THIS PART, AN ACTION BROUGHT UNDER THIS PART MAY BE BROUGHT IN THE CIRCUIT COURT FOR INGHAM COUNTY OR IN THE COUNTY IN WHICH THE LABORATORY IS LOCATED OR HAS A PLACE OF BUSINESS OR IN WHICH THE REGISTERED OFFICE OF A DEFENDANT CORPORATION IS LOCATED.

SEC. 20517. (1) A PERSON SHALL NOT KNOWINGLY DO ANY OF THE FOLLOWING:

(A) MAKE A FALSE STATEMENT OR REPRESENTATION IN ANY APPLICATION, RECORD, REPORT, OR OTHER DOCUMENT FILED WITH THE DEPARTMENT OR REQUIRED TO BE MAINTAINED UNDER THIS PART OR THE RULES PROMULGATED UNDER THIS PART.

(B) DESTROY, ALTER, OR CONCEAL ANY RECORD, REPORT, OR DOCUMENT REQUIRED TO BE MAINTAINED UNDER THIS PART OR THE RULES PROMULGATED UNDER THIS PART.

(C) AID, ABET, PERMIT, OR FACILITATE THE SUBMISSION OF ANY FALSE STATEMENT OR REPRESENTATION UNDER THIS PART TO THE STATE OR ANY AGENCY OF THE STATE BY ANY OTHER PARTY.

(D) REPRESENT THAT THE LABORATORY IS ACCREDITED UNDER THIS PART IN AN AREA IN WHICH IT IS NOT ACCREDITED.

(2) A PERSON WHO VIOLATES SUBSECTION (1) IS GUILTY OF A FELONY PUNISHABLE AS FOLLOWS FOR EACH VIOLATION:

(A) EXCEPT AS PROVIDED IN SUBDIVISIONS (B) AND (C), BY IMPRISONMENT FOR NOT MORE THAN 2 YEARS OR A FINE OF NOT LESS THAN $10,000.00 OR MORE THAN $25,000.00, OR BOTH.

(B) EXCEPT AS PROVIDED IN SUBDIVISION (C), IF A CONVICTION UNDER SUBSECTION (1) IS FOR A VIOLATION COMMITTED AFTER A FIRST CONVICTION, BY IMPRISONMENT FOR NOT MORE THAN 5 YEARS OR A FINE OF NOT LESS THAN $50,000.00, OR BOTH.

(C) UPON A FINDING BY THE COURT THAT THE ACTION OF A DEFENDANT CONVICTED UNDER SUBSECTION (1) POSES OR POSED A SUBSTANTIAL ENDANGERMENT TO PUBLIC HEALTH, SAFETY, OR WELFARE, BY IMPRISONMENT FOR NOT MORE THAN 5 YEARS OR A FINE OF NOT LESS THAN $100,000.00 OR MORE THAN $1,000,000.00, OR BOTH.

(3) TO FIND A DEFENDANT CRIMINALLY LIABLE FOR SUBSTANTIAL ENDANGERMENT UNDER SUBSECTION (2)(C), THE COURT SHALL DETERMINE THAT THE DEFENDANT KNOWINGLY OR RECKLESSLY ACTED IN SUCH A MANNER AS TO CAUSE A DANGER OF DEATH OR SERIOUS BODILY INJURY AND THAT EITHER OF THE FOLLOWING APPLIES:

(A) THE DEFENDANT HAD AN ACTUAL AWARENESS, BELIEF, OR UNDERSTANDING THAT HIS OR HER CONDUCT WOULD CAUSE A SUBSTANTIAL DANGER OF DEATH OR SERIOUS BODILY INJURY.

(B) THE DEFENDANT ACTED IN GROSS DISREGARD OF THE STANDARD OF CARE THAT A REASONABLE PERSON WOULD OBSERVE IN SIMILAR CIRCUMSTANCES.

SEC. 20518. (1) PRIOR TO REQUIRING ACCREDITATION, THE DEPARTMENT SHALL PROMULGATE RULES PERTAINING TO THE ACCREDITATION PROGRAM TO SPECIFY ALL OF THE FOLLOWING:

(A) THE LABORATORIES OR REGULATORY PROGRAMS THAT ARE SUBJECT TO ACCREDITATION.

(B) ACCREDITATION PROCEDURES.

(C) THE ACCREDITATION CATEGORIES FOR WHICH ACCREDITATION IS AVAILABLE AND THE ANALYTES, PARAMETERS, AND ANALYTICAL METHODS TO BE INCLUDED IN EACH ACCREDITATION CATEGORY.

(D) THE LABORATORY REQUIREMENTS FOR ESTABLISHING AND MAINTAINING ACCEPTABLE LABORATORY QUALITY SYSTEMS. THESE RULES MAY SPECIFY REQUIREMENTS FOR ALL OF THE FOLLOWING:

(*i*) LABORATORY ORGANIZATION AND MANAGEMENT.

(*ii*) ESTABLISHMENT OF AUDITS, ESSENTIAL QUALITY CONTROLS, AND DATA VERIFICATION.

(*iii*) PERSONNEL.

(*iv*) PHYSICAL FACILITIES.

(*v*) EQUIPMENT AND REFERENCE MATERIALS.

(*vi*) MEASUREMENT TRACEABILITY OF STANDARDS AND REGENTS.

(*vii*) METHOD CALIBRATION AND PERFORMANCE.

(*viii*) SAMPLE HANDLING, ACCEPTANCE, RECEIPT, AND TRACKING.

(*ix*) RECORD MAKING AND RETENTION.

(*x*) LABORATORY REPORT CONTENT.

(E) QUALIFICATIONS FOR ON-SITE ASSESSMENT CONTRACTORS.

(F) QUALIFICATIONS FOR PT PROGRAMS.

(G) OTHER ASPECTS OF THE ACCREDITATION PROGRAM NECESSARY TO IMPLEMENT THIS PART.

(2) THE DEPARTMENT MAY PROMULGATE RULES TO SPECIFY ANY OF THE FOLLOWING:

(A) THE PROCEDURES AND CONDITIONS UNDER WHICH THE DEPARTMENT MAY ENTER INTO AGREEMENTS WITH THE GOVERNMENT OF ANY STATE OR THIRD PARTY NONGOVERNMENTAL ENTITY FOR THE PURPOSE OF RECOGNIZING THE ACCREDITATION OF OUT-OF-STATE LABORATORIES.

(B) THE TYPE AND AMOUNT OF DOCUMENTATION TO BE SUBMITTED IN SUPPORT OF ALTERNATIVE TEST PROCEDURE APPLICATIONS AND THE REVIEW PROCEDURE, APPLICATION PROCESS, AND APPLICABILITY OF ALTERNATIVE TEST PROCEDURES TO SPECIFIC REGULATORY PROGRAMS.

(C) PROCEDURES FOR ESTABLISHING PT PERFORMANCE LIMITS.

SEC. 20519. DURING JANUARY OF 2000 AND EVERY EVEN NUMBERED YEAR THEREAFTER, THE DEPARTMENT SHALL REPORT TO THE SENATE AND HOUSE LEGISLATIVE COMMITTEES PRIMARILY RESPONSIBLE FOR ENVIRONMENTAL PROTECTION LEGISLATION WHETHER A NATIONAL

LABORATORY PROGRAM HAS BEEN INSTITUTED BY WHICH LABORATORIES ARE RECOGNIZED AS MEETING CERTAIN QUALIFICATIONS OR STANDARDS. IF SUCH A PROGRAM HAS BEEN INSTITUTED, THE DEPARTMENT SHALL INCLUDE IN THE REPORT ITS RECOMMENDATIONS AS TO WHETHER THIS PART SHOULD BE AMENDED OR REPEALED.