

SENATE BILL NO. 839

January 14, 1998, Introduced by Senator HOFFMAN 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:

1 PART 205 LABORATORY ACCREDITATION

2 SEC. 20501. AS USED IN THIS PART:

3 (A) "ACCREDITATION" MEANS THE PROCESS BY WHICH THE DEPART-
4 MENT RECOGNIZES A LABORATORY AS MEETING QUALIFICATIONS OR STAN-
5 DARDS UNDER THIS PART OR IN RULES PROMULGATED UNDER THIS PART.

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

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

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

7 (E) "APPLICANT" MEANS A LABORATORY APPLYING TO THE DEPART-
8 MENT TO BECOME AN ACCREDITED LABORATORY.

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

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

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

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

20 (J) "DOUBLE BLIND PROFICIENCY TESTING SAMPLE" MEANS A PROFI-
21 CIENCY TESTING SAMPLE SUBMITTED TO A LABORATORY AS A REGULAR
22 SAMPLE AND NOT IDENTIFIED AS A PROFICIENCY TESTING SAMPLE.

23 (K) "LABORATORY" MEANS A LABORATORY THAT ANALYZES
24 ENVIRONMENTAL SAMPLES FOR MONITORING OR COMPLIANCE WITH STATE
25 ENVIRONMENTAL LAW. LABORATORY FACILITIES HOUSED IN 2 OR MORE

1 BUILDINGS ARE A SINGLE LABORATORY IF THOSE BUILDINGS ARE AT THE
2 SAME LOCATION.

3 (I) "LABORATORY DIRECTOR" MEANS THE INDIVIDUAL EMPLOYED BY A
4 LABORATORY WHO HAS ULTIMATE RESPONSIBILITY FOR LABORATORY OPERA-
5 TIONS, INCLUDING BUT NOT LIMITED TO QUALITY CONTROL, RESULT
6 REPORTING, PERSONNEL CONTROL, AND SIGNATURE AUTHORITY FOR THE
7 VALIDATION STATEMENT SUPPLIED WITH EACH SET OF LABORATORY
8 RESULTS. LABORATORY DIRECTOR INCLUDES A QUALIFIED INDIVIDUAL
9 DESIGNATED BY THE LABORATORY DIRECTOR AS HIS OR HER
10 REPRESENTATIVE.

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

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

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

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

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

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

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

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

11 (U) "QUALITY CONTROL" MEANS THE SYSTEM OF TECHNICAL ACTIVI-
12 TIES, THE PURPOSE OF WHICH IS TO MEASURE AND CONTROL THE QUALITY
13 OF ANALYTICAL SERVICES SO THAT SPECIFIC PERFORMANCE CRITERIA ARE
14 MET.

15 (V) "RAW DATA" MEANS THE QUALITATIVE OR QUANTITATIVE MEA-
16 SUREMENTS RECORDED FROM CHEMICAL, PHYSICAL, BIOLOGICAL, MICROBIO-
17 LOGICAL, RADIOLOGICAL, OR OTHER SCIENTIFIC DETERMINATION, OR
18 RECORDED OBSERVATIONS AND COMMENTS RELEVANT TO THE MEASUREMENTS
19 IN UNEDITED FORM.

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

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

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

3 (Z) "VALIDATION STATEMENT" MEANS A STATEMENT THAT IS PRO-
4 VIDED WITH EACH SET OF RESULTS SIGNED BY THE LABORATORY DIRECTOR
5 INDICATING THAT ALL OF THE REQUIREMENTS OF THIS PART AND RULES
6 PROMULGATED UNDER THIS PART HAVE BEEN MET RELATIVE TO ALL ANALYT-
7 ICAL STEPS AND QUALITY CONTROL ASSOCIATED WITH A SET OF LABORA-
8 TORY RESULTS.

9 SEC. 20502. (1) BY RULES PROMULGATED UNDER THIS PART, THE
10 DEPARTMENT MAY REQUIRE THAT ANALYTICAL DATA REQUIRED UNDER THIS
11 ACT AND SUBMITTED TO THE DEPARTMENT FOR ENVIRONMENTAL REGULATORY
12 MONITORING OR COMPLIANCE PURPOSES BE PRODUCED OR DEVELOPED BY A
13 LABORATORY ACCREDITED BY THE DEPARTMENT UNDER THIS PART FOR THE
14 CATEGORIES, PARAMETERS, ANALYTES, OR METHODS FOR WHICH THE ANA-
15 LYTICAL DATA ARE SUBMITTED.

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

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

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

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

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

9 (C) THE DATA ARE CONSISTENT WITH THE ENVIRONMENTAL PROTEC-
10 TION AGENCY SUPERFUND LABORATORY CONTRACT IN EFFECT AT THE TIME
11 THE DATA ARE PRODUCED.

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

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

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

1 (6) EACH LABORATORY SHALL BE INDIVIDUALLY ACCREDITED.

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

9 (8) MOBILE LABORATORIES OWNED BY THE SAME PERSON BUT NOT
10 DESCRIBED BY SUBSECTION (7) MAY, AT THE OPTION OF THE OWNER, BE
11 CONSIDERED A SINGLE LABORATORY UNIT FOR PURPOSES OF GRANTING
12 ACCREDITATION, BUT ARE SEPARATE LABORATORIES FOR PURPOSES OF SAT-
13 ISFYING THE PT TESTING, ON-SITE ASSESSMENT, AND OTHER REQUIRE-
14 MENTS OF ACCREDITATION.

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

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

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

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

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

18 (3) THE DEPARTMENT SHALL CHARGE ACCREDITATION FEES AS PRO-
19 VIDED IN SECTION 20510 TO IMPLEMENT THIS PART AND OVERSEE EACH
20 CONTRACTOR HIRED OR APPROVED BY THE DEPARTMENT, AS NECESSARY, TO
21 IMPLEMENT THE ACCREDITATION PROGRAM UNDER THIS PART AND RULES
22 PROMULGATED UNDER THIS PART. A CONTRACTOR OR CONTRACTORS HIRED
23 BY THE DEPARTMENT SHALL BE THE LOWEST RESPONSIVE BIDDER OR
24 BIDDERS QUALIFIED TO UNDERTAKE THE CONTRACTUAL RESPONSIBILITIES.
25 A CONTRACTOR SHALL ASSESS FEES FOR ITS SERVICES AS ESTABLISHED IN

1 THE CONTRACT WITH THE DEPARTMENT. THE FEES SHALL BE PAID
2 DIRECTLY BY LABORATORIES THAT ARE OR SEEK TO BE ACCREDITED.

3 (4) BEFORE SUBMITTING AN APPLICATION FOR ACCREDITATION TO
4 THE DEPARTMENT, AN APPLICANT SHALL PARTICIPATE IN PT UNDER SEC-
5 TION 20508. THE PT RESULT REPORT SHALL BE SUBMITTED WITH THE
6 APPLICATION FOR ACCREDITATION.

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

12 (6) THE APPLICANT SHALL SUBMIT AN APPLICATION FOR ACCREDIT-
13 ATION TO THE DEPARTMENT ON FORMS PRESCRIBED BY THE DEPARTMENT.
14 THE APPLICANT SHALL SUBMIT THE ACCREDITATION FEE WITH THE
15 APPLICATION. THE APPLICATION FOR ACCREDITATION SHALL SATISFY ALL
16 OF THE FOLLOWING REQUIREMENTS:

17 (A) THE APPLICATION SHALL INCLUDE THE LEGAL NAME OF THE LAB-
18 ORATORY, LABORATORY MAILING ADDRESS, TELEPHONE NUMBER, FULL
19 ADDRESS AND LOCATION OF THE LABORATORY, THE NAME, TELEPHONE
20 NUMBER, AND ADDRESS OF THE LABORATORY OWNER, NAME AND THE TELE-
21 PHONE NUMBER OF THE QUALITY ASSURANCE OFFICER, NAME AND TELEPHONE
22 NUMBER OF THE LABORATORY DIRECTOR, AND THE HOURS OF OPERATION.

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

1 (C) THE APPLICATION SHALL INCLUDE A CERTIFICATION OF
2 COMPLIANCE STATEMENT SIGNED AND DATED BY THE INDIVIDUAL SPECIFIED
3 IN SUBDIVISION (D) AND WHICH STATES:
4 "_____ ("THE APPLICANT") UNDERSTANDS AND ACKNOWLEDGES
5 THAT THE LABORATORY IS REQUIRED TO BE CONTINUALLY IN COMPLIANCE
6 WITH PART 205 (LABORATORY ACCREDITATION) OF THE NATURAL RESOURCES
7 AND ENVIRONMENTAL PROTECTION ACT, 1994 PA 451, MCL 324.20501 TO
8 324.20519, AND RULES PROMULGATED UNDER PART 205, AND IS SUBJECT
9 TO THE PENALTY PROVISIONS IN PART 205. AUTHORIZED REPRESENTA-
10 TIVES OF THE DEPARTMENT MAY MAKE ANNOUNCED OR UNANNOUNCED INSPEC-
11 TIONS OF AN APPLICANT OR ACCREDITED LABORATORY, AND REVIEW ANY
12 DATA REQUIRED TO BE SUBMITTED TO THE DEPARTMENT UNDER PART 205
13 AND RULES PROMULGATED UNDER PART 205 OR ANY INFORMATION ASSOCI-
14 ATED WITH SUCH DATA, TO DETERMINE THE EXTENT OF COMPLIANCE WITH
15 THE CONDITIONS OF ACCREDITATION AND THESE REGULATIONS.
16 ADDITIONALLY, THE APPLICANT AUTHORIZES THE OFFICIALLY DESIGNATED
17 STATE INSPECTOR TO MAKE COPIES OF ANY ANALYSES OR OTHER RECORDS
18 RELEVANT TO THE ACCREDITATION AND COMPLIANCE PROCESS, AND TO
19 REMOVE COPIES FROM THE FACILITY FOR PURPOSES OF EVALUATION OR
20 REGULATORY ENFORCEMENT. THE REFUSAL TO ALLOW ENTRY BY THE REPRESENTATIVES OF THE DEPARTMENT AT REASONABLE TIMES OR DURING NORMAL
21 BUSINESS HOURS OR TO ALLOW COPIES OF RECORDS RELEVANT TO LABORATORY ACCREDITATION TO BE MADE IS A VIOLATION OF A CONDITION OF
22 ACCREDITATION AND SHALL RESULT IN DENIAL OR LOSS OF
23 ACCREDITATION. THE APPLICANT HEREBY CERTIFIES THAT ALL ANALYSES
24
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1 PERFORMED ARE DONE IN ACCORDANCE WITH PART 205 AND RULES
2 PROMULGATED UNDER PART 205. THE UNDERSIGNED CERTIFIES THAT HE OR
3 SHE IS AUTHORIZED TO SIGN THIS APPLICATION ON BEHALF OF THE
4 APPLICANT/OWNER AND THAT BASED ON HIS OR HER KNOWLEDGE AND
5 BELIEF, THE INFORMATION PROVIDED IN THIS ACCREDITATION APPLICA-
6 TION IS ACCURATE.".

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

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

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

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

15 (7) WITHIN 30 DAYS AFTER RECEIVING AN APPLICATION, THE
16 DEPARTMENT SHALL REVIEW THE APPLICATION, DETERMINE WHETHER THE
17 APPLICATION IS ADMINISTRATIVELY COMPLETE, AND NOTIFY THE APPLI-
18 CANT OF ANY ADDITIONAL ITEMS THAT ARE NECESSARY TO MAKE THE
19 APPLICATION ADMINISTRATIVELY COMPLETE.

20 (8) WITHIN 30 DAYS AFTER DETERMINING THAT AN APPLICATION IS
21 ADMINISTRATIVELY COMPLETE, THE DEPARTMENT SHALL REVIEW THE APPLI-
22 CATION, THE ON-SITE ASSESSMENT REPORT, AND THE RESULTS OF THE
23 APPLICANT'S PT SAMPLES. BASED ON REVIEW OF THIS INFORMATION, THE
24 DEPARTMENT MAY APPROVE FULL ACCREDITATION FOR ALL REQUESTED
25 PARAMETERS, MAY APPROVE ACCREDITATION FOR A SUBSET OF THE

1 REQUESTED PARAMETERS AND DENY ACCREDITATION FOR OTHERS, OR MAY
2 DENY ACCREDITATION FOR ALL REQUESTED PARAMETERS. DENIAL OF
3 ACCREDITATION IS SUBJECT TO SECTION 20513.

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

7 (10) THE DIRECTOR OF THE DEPARTMENT OF ENVIRONMENTAL QUALITY
8 OR HIS OR HER DESIGNEE SHALL ISSUE A CERTIFICATE OF ACCREDITATION
9 TO LABORATORIES THAT COMPLY WITH THE ACCREDITATION REQUIREMENTS
10 UNDER THIS PART. THE CERTIFICATE SHALL INCLUDE THE NAME OF THE
11 LABORATORY AND THE ACCREDITATION EXPIRATION DATE AND SHALL
12 INCLUDE OR SHALL HAVE APPENDED A LIST OF THE CATEGORIES, PARAME-
13 TERS, ANALYTES, OR METHODS FOR WHICH THE LABORATORY IS
14 ACCREDITED. THE CERTIFICATE IS THE PROPERTY OF THE DEPARTMENT
15 AND SHALL BE RETURNED TO THE DEPARTMENT UPON EXPIRATION OR LOSS
16 OF ACCREDITATION.

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

23 SEC. 20504. (1) ACCREDITATION WITHIN CATEGORIES,
24 PARAMETERS, ANALYTES, OR METHODS SHALL BE RENEWED ANNUALLY. TO
25 BE ELIGIBLE FOR RENEWAL OF ACCREDITATION, THE ACCREDITED

1 LABORATORY SHALL REMAIN IN COMPLIANCE WITH THE REQUIREMENTS OF
2 THIS PART AND RULES PROMULGATED UNDER THIS PART.

3 (2) THE ACCREDITED LABORATORY MAY INITIATE RENEWAL OF
4 ACCREDITATION BY SUBMITTING ALL OF THE FOLLOWING TO THE DEPART-
5 MENT WITHIN 60 DAYS BEFORE THE ANNUAL EXPIRATION DATE ESTABLISHED
6 THROUGH INITIAL ACCREDITATION:

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

12 (B) FEES REQUIRED UNDER SECTION 20510.

13 (C) THE RESULT REPORTS OF ALL PT SAMPLES FOR ACCREDITED
14 ANALYTES OR PARAMETERS ANALYZED WITHIN THE LAST YEAR UNDER SEC-
15 TION 20508.

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

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

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

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

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

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

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

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

22 SEC. 20506. (1) THE DEPARTMENT MAY ENTER INTO AGREEMENTS
23 WITH THE GOVERNMENT OF ANY OTHER STATE OR THIRD PARTY
24 NONGOVERNMENTAL ENTITY FOR THE PURPOSE OF RECOGNIZING
25 OUT-OF-STATE ACCREDITATION OF LABORATORIES IF SUCH AGREEMENTS ARE

1 AUTHORIZED BY RULES PROMULGATED BY THE DEPARTMENT AND IF THE
2 DEPARTMENT DETERMINES THAT ACCREDITATION STANDARDS OF THE OTHER
3 STATE OR THIRD PARTY PROGRAMS ARE EQUIVALENT TO THE ACCREDITATION
4 STANDARDS OF THIS PART AND THE RULES PROMULGATED UNDER THIS
5 PART.

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

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

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

18 (B) THE NEW OWNER AGREES TO MAINTAIN RECORDS, DATA, AND
19 REPORTS FOR ANY ANALYSES GENERATED BEFORE LEGAL TRANSFER OF
20 OWNERSHIP OCCURS IN ACCORDANCE WITH THIS PART OR RULES PROMUL-
21 GATED UNDER THIS PART.

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

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

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

4 (B) DEFINE THE CATEGORIES, PARAMETERS, ANALYTES, AND ACCEPT-
5 ABLE METHODS FOR WHICH A LABORATORY MAY BECOME ACCREDITED.

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

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

13 (A) APPROVE THE USE OF ALTERNATIVE TEST PROCEDURES IF SUCH
14 ALTERNATIVE TEST PROCEDURES ARE APPROVED BY THE UNITED STATES
15 ENVIRONMENTAL PROTECTION AGENCY FOR A SIMILAR USE.

16 (B) APPROVE THE USE OF ALTERNATIVE TEST PROCEDURES IF THE
17 APPLICANT DOCUMENTS THAT THE QUALITY OF DATA PRODUCED BY THE PRO-
18 POSED METHOD IS AS GOOD OR BETTER THAN THE QUALITY OF DATA
19 PRODUCED BY THE EXISTING APPROVED METHOD.

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

22 (D) UNDERTAKE DOUBLE BLIND PT STUDIES OF ACCREDITED LABORA-
23 TORIES THROUGH THE USE OF SAMPLES FROM A PT PROGRAM OR SAMPLES
24 FROM OTHER QUALIFIED SOURCES. THE DEPARTMENT MAY USE THE RESULTS
25 OF SUCH PT SAMPLES TO SELECT LABORATORIES FOR FURTHER INSPECTION,

1 REQUIRE ANALYSIS OF PT SAMPLES IN THE PRESENCE OF DEPARTMENT
2 REPRESENTATIVES, REQUIRE CORRECTIVE ACTION, REVOKE ACCREDITATION
3 SUBJECT TO THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA
4 306, MCL 24.201 TO 24.328, OR COMMENCE CIVIL ACTIONS AS DESCRIBED
5 IN SECTION 20516.

6 (E) ENTER INTO AGREEMENTS, CONTRACTS, OR COOPERATIVE
7 ARRANGEMENTS UNDER TERMS AND CONDITIONS APPROPRIATE WITH OTHER
8 STATE AGENCIES, FEDERAL AGENCIES, INTERSTATE AGENCIES, POLITICAL
9 SUBDIVISIONS, EDUCATIONAL INSTITUTIONS, LOCAL HEALTH DEPARTMENTS,
10 OR OTHER PUBLIC OR PRIVATE ORGANIZATIONS, OR INDIVIDUALS TO
11 ADMINISTER THIS PART.

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

14 (A) THE LABORATORY SHALL PARTICIPATE IN PT FOR ALL CATEGO-
15 RIES, PARAMETERS, ANALYTES, AND METHODS FOR WHICH THE LABORATORY
16 IS ACCREDITED AND FOR WHICH A PT PROGRAM EXISTS.

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

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

24 (D) A LABORATORY SHALL EXAMINE OR TEST, AS APPLICABLE, THE
25 PT SAMPLES RECEIVED FROM THE PT PROGRAM IN THE SAME MANNER AS

1 ROUTINE ENVIRONMENTAL SAMPLES. EACH ANALYST RESPONSIBLE FOR
2 ANALYSIS OF A PT SAMPLE SHALL TEST THE PT SAMPLE THE SAME NUMBER
3 OF TIMES THAT ROUTINE TESTS ON ENVIRONMENTAL SAMPLES ARE
4 PERFORMED. THE LABORATORY DIRECTOR AND EACH ANALYST SHALL ALSO
5 SIGN THE PT RESULT REPORT OR A STATEMENT ATTACHED TO THE PT
6 RESULT REPORT ATTESTING THAT ALL SAMPLES WERE ANALYZED IN THE
7 SAME MANNER AS ROUTINE SAMPLES. ALL ANALYST SIGNATURES SHALL BE
8 LINKED TO THE PT SAMPLE ANALYZED SO THAT THE ANALYST RESPONSIBLE
9 FOR EACH PT SAMPLE IS CLEARLY IDENTIFIED. THESE SIGNED STATE-
10 MENTS SHALL ACCOMPANY THE LABORATORY RESULTS TO THE PT PROGRAM.

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

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

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

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

1 (B) LABORATORIES SHALL NOT SEND A PT SAMPLE OR A PORTION OF
2 A PT SAMPLE TO ANOTHER LABORATORY FOR ANY ANALYSIS FOR WHICH
3 ACCREDITATION IS SOUGHT.

4 (C) ANY LABORATORY THAT THE DEPARTMENT DETERMINES REFERRED A
5 PT SAMPLE TO ANOTHER LABORATORY FOR ANALYSIS SHALL BE DENIED
6 ACCREDITATION OR HAVE ITS ACCREDITATION PERMANENTLY REVOKED FOR
7 ALL CATEGORIES, PARAMETERS, ANALYTES, OR METHODS.

8 (D) ANY LABORATORY THAT RECEIVES A PT SAMPLE FROM ANOTHER
9 LABORATORY FOR TESTING SHALL IMMEDIATELY NOTIFY THE DEPARTMENT OF
10 THE RECEIPT OF THE PT SAMPLE AND SHALL PROVIDE TO THE DEPARTMENT
11 ALL INFORMATION ASSOCIATED WITH THE RECEIPT OF THE PT SAMPLE.
12 THE DEPARTMENT SHALL DENY OR REVOKE FOR 6 MONTHS ACCREDITATION OF
13 AN APPLICANT OR ACCREDITED LABORATORY THAT DOES NOT REPORT THE
14 RECEIPT OF A PT SAMPLE FROM ANOTHER LABORATORY.

15 (E) A LABORATORY SHALL INITIATE CHAIN OF CUSTODY PROCEDURES
16 UPON RECEIPT OF A PT SAMPLE. THE LABORATORY SHALL MAINTAIN A
17 COPY OF ALL RECORDS ASSOCIATED WITH THE ANALYSIS OF A PT SAMPLE,
18 INCLUDING ANALYTICAL WORKSHEETS, FOR A MINIMUM OF 5 YEARS. THIS
19 RECORD SHALL INCLUDE A COPY OF COMPLETED PT RESULT REPORT FORMS
20 USED BY THE LABORATORY TO RECORD PT RESULTS, INCLUDING THE STATE-
21 MENTS SIGNED BY THE APPROPRIATE ANALYSTS AND THE LABORATORY
22 DIRECTOR STATING THAT PT SAMPLES WERE TESTED IN THE SAME MANNER
23 AS ROUTINE ENVIRONMENTAL SAMPLES AS DESCRIBED IN SUBSECTION
24 (1)(D).

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

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

16 (6) IF THE PT SAMPLE CONSISTS OF 1 CONCENTRATION ANALYZED
17 SEMIANNUALLY, THEN BOTH SEMIANNUAL PT SAMPLE RESULTS SHALL BE
18 WITHIN ACCEPTANCE LIMITS. IF EITHER OR BOTH PT RESULTS ARE NOT
19 WITHIN ACCEPTANCE LIMITS, THE LABORATORY SHALL BE PROVISIONALLY
20 ACCREDITED AND SHALL REANALYZE A REMEDIAL PT SAMPLE NOT MORE THAN
21 30 DAYS AFTER RECEIVING THE UNACCEPTABLE PT RESULT. IF THE REME-
22 DIAL PT SAMPLE RESULT IS ACCEPTABLE, ACCREDITATION FOR THAT ANAL-
23 YTE IS RESTORED. IF THE REMEDIAL PT RESULT IS NOT WITHIN
24 ACCEPTANCE LIMITS, ACCREDITATION FOR THAT ANALYTE IS REVOKED. TO
25 BECOME REACCREDITED, THE LABORATORY SHALL REAPPLY FOR

1 ACCREDITATION FOR THE AFFECTED ANALYTES THROUGH EITHER AN
2 APPLICATION TO RENEW OR AUGMENT ACCREDITATION.

3 (7) IF THE PT SAMPLE CONSISTS OF 2 CONCENTRATIONS ANALYZED
4 SEMIANNUALLY, THEN 3 OF THE 4 SEMIANNUAL PT RESULTS SHALL BE
5 WITHIN ACCEPTANCE LIMITS. IF LESS THAN 3 OF THE 4 PT RESULTS ARE
6 WITHIN ACCEPTANCE LIMITS, THEN ACCREDITATION IS DOWNGRADED TO
7 PROVISIONAL AND THE LABORATORY SHALL REANALYZE A REMEDIAL PT
8 SAMPLE NOT MORE THAN 30 DAYS AFTER RECEIVING THE UNACCEPTABLE PT
9 SAMPLE RESULT. IF THE PT RESULTS FOR BOTH CONCENTRATIONS OF THE
10 REMEDIAL PT SAMPLE ARE WITHIN ACCEPTANCE LIMITS, THEN FULL
11 ACCREDITATION IS RESTORED. IF THE PT RESULTS FOR 1 OR BOTH CON-
12 CENTRATIONS OF THE REMEDIAL PT SAMPLE ARE OUTSIDE ACCEPTANCE
13 LIMITS, THEN ACCREDITATION FOR THAT ANALYTE IS REVOKED. TO
14 BECOME REACCREDITED, THE LABORATORY SHALL REAPPLY FOR ACCREDIT-
15 ATION FOR THE AFFECTED ANALYTES THROUGH AN APPLICATION TO RENEW
16 OR AUGMENT ACCREDITATION.

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

21 (9) FAILURE TO RETURN PT RESULTS TO THE PT PROGRAM WITHIN
22 THE TIME DEADLINE SPECIFIED BY THE PT PROGRAM IS AN UNACCEPTABLE
23 RESULT. HOWEVER, THE DEPARTMENT MAY EXTEND A DEADLINE IF IT
24 DETERMINES THAT THE CAUSE FOR NOT PARTICIPATING WAS BEYOND THE
25 CONTROL OF THE LABORATORY.

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

4 (A) A MAJOR CHANGE IN OWNERSHIP OR SUPERVISION OF THE
5 LABORATORY.

6 (B) SIGNIFICANT ALLEGATIONS OF NONCOMPLIANCE WITH THIS PART
7 BY LABORATORY CLIENTS OR EMPLOYEES.

8 (C) UNACCEPTABLE RESULTS ON THE MOST RECENT PT.

9 (D) TO DEMONSTRATE CORRECTIVE ACTION FOLLOWING AN UNAC-
10 CEPTABLE ON-SITE ASSESSMENT.

11 SEC. 20509. (1) APPLICANT LABORATORIES AND ACCREDITED LABO-
12 RATORIES SHALL BE EVALUATED FOR COMPLIANCE WITH THE ACCREDITATION
13 REQUIREMENTS OF THIS PART BY AN ON-SITE ASSESSMENT CONTRACTOR TO
14 THE DEPARTMENT.

15 (2) TO OBTAIN INITIAL ACCREDITATION OR TO AUGMENT ACCREDIT-
16 ATION, THE APPLICANT LABORATORY SHALL, NOT MORE THAN 1 YEAR
17 BEFORE APPLYING FOR ACCREDITATION, PASS AN ON-SITE ASSESSMENT
18 CONSISTENT WITH THE ON-SITE ASSESSMENT STANDARDS IN THIS PART AND
19 RULES PROMULGATED UNDER THIS PART. THE APPLICANT SHALL SCHEDULE
20 AN ON-SITE ASSESSMENT WITH THE ON-SITE ASSESSMENT CONTRACTOR.
21 THE ON-SITE ASSESSMENT CONTRACTOR SHALL PERFORM AN ON-SITE
22 ASSESSMENT OF THE LABORATORY, PREPARE AN ON-SITE ASSESSMENT
23 REPORT, AND SUBMIT THE REPORT TO THE APPLICANT. IF THE ON-SITE
24 ASSESSMENT INDICATES SIGNIFICANT DEFICIENCIES, THE APPLICANT MAY
25 CORRECT THE DEFICIENCIES AND REPEAT THE ON-SITE ASSESSMENT OR

1 PORTION OF THE ON-SITE ASSESSMENT, AS APPROPRIATE. THE APPLICANT
2 SHALL SUBMIT THE ON-SITE ASSESSMENT REPORT TO THE DEPARTMENT AS A
3 PART OF THE APPLICATION FOR INITIAL ACCREDITATION OR THE APPLICA-
4 TION TO AUGMENT ACCREDITATION, AS APPROPRIATE. THE DEPARTMENT
5 SHALL NOT APPROVE AN APPLICATION FOR ACCREDITATION, UNLESS THE
6 DEPARTMENT HAS FOUND THAT THE ON-SITE ASSESSMENT REPORT IS
7 ACCEPTABLE. THE DEPARTMENT SHALL REVIEW THE APPLICATION, INCLUD-
8 ING THE ON-SITE ASSESSMENT REPORT, SUBJECT TO SECTION 20503(7)
9 AND (8). APPLICATION DENIAL IS SUBJECT TO SECTION 20513(3).

10 (3) TO RENEW ACCREDITATION, THE ACCREDITED LABORATORY SHALL
11 PASS AN ON-SITE ASSESSMENT NOT MORE THAN 2 YEARS BEFORE EXPIRA-
12 TION OF THE CURRENT ACCREDITATION PERIOD. IF AN ON-SITE ASSESS-
13 MENT IS REQUIRED, THE LABORATORY SHALL FORWARD A COPY OF THE
14 ON-SITE ASSESSMENT REPORT TO THE DEPARTMENT NOT MORE THAN 10 DAYS
15 AFTER RECEIVING THE ON-SITE ASSESSMENT REPORT FROM THE ON-SITE
16 ASSESSMENT CONTRACTOR.

17 (4) THE ON-SITE ASSESSMENT CONTRACTOR SHALL PROVIDE COPIES
18 OF THE ON-SITE ASSESSMENT TO BOTH THE LABORATORY AND THE DEPART-
19 MENT NOT MORE THAN 30 BUSINESS DAYS AFTER COMPLETING THE ON-SITE
20 ASSESSMENT. THE DEPARTMENT SHALL REVIEW THE ON-SITE ASSESSMENT
21 REPORT AND NOTIFY THE LABORATORY OF ANY EXISTING DEFICIENCIES NOT
22 MORE THAN 30 BUSINESS DAYS AFTER RECEIVING THE ON-SITE ASSESSMENT
23 REPORT. NOT MORE THAN 20 BUSINESS DAYS AFTER NOTIFICATION THAT A
24 DEFICIENCY EXISTS, THE LABORATORY SHALL EITHER CORRECT THE
25 DEFICIENCY AND PROVIDE DOCUMENTATION TO THE DEPARTMENT THAT THE

1 DEFICIENCY HAS BEEN CORRECTED OR SUBMIT A CORRECTIVE ACTION PLAN
2 TO THE DEPARTMENT UNDER SUBSECTION (5). IF THE LABORATORY
3 CHOOSES TO CORRECT THE DEFICIENCY AND SUBMIT DOCUMENTATION TO THE
4 DEPARTMENT DEMONSTRATING THAT THE DEFICIENCY HAS BEEN CORRECTED
5 AND IF SUBSEQUENT DEPARTMENT REVIEW OF THIS SUBMITTAL DETERMINES
6 THE DOCUMENTATION OR DEMONSTRATION IS DEFICIENT, THE DEPARTMENT
7 MAY GRANT THE LABORATORY AN ADDITIONAL 20 BUSINESS DAYS TO PER-
8 FORM CORRECTIVE ACTION AND SUBMIT DOCUMENTATION OF THE CORRECTIVE
9 ACTION BEFORE THE DEPARTMENT REVOKES ACCREDITATION.

10 (5) IF THE LABORATORY SUBMITS A CORRECTIVE ACTION PLAN, THE
11 PLAN SHALL HAVE A COMPLETION DATE OF NOT MORE THAN 6 MONTHS FROM
12 DEPARTMENT ACCEPTANCE OF THE PLAN. NOT MORE THAN 30 BUSINESS
13 DAYS AFTER RECEIPT OF THE PLAN, THE DEPARTMENT SHALL REVIEW THE
14 PLAN AND NOTIFY THE LABORATORY THAT THE DEPARTMENT EITHER ACCEPTS
15 OR REJECTS THE PLAN, AS APPLICABLE. IF THE DEPARTMENT REJECTS
16 THE PLAN, THE NOTIFICATION SHALL IDENTIFY CHANGES THAT WOULD MAKE
17 THE CORRECTIVE ACTION PLAN ACCEPTABLE. IF THE DEPARTMENT DETER-
18 MINES THAT ALL DEFICIENCIES WERE NOT CORRECTED WITHIN 6 MONTHS OF
19 ACCEPTING THE CORRECTIVE ACTION PLAN OR NOTIFYING THE LABORATORY
20 OF THE CHANGES REQUIRED TO MAKE THE CORRECTIVE ACTION PLAN
21 ACCEPTABLE, THE DEPARTMENT SHALL REVOKE ACCREDITATION.

22 (6) IN ADDITION TO ON-SITE ASSESSMENTS REQUIRED AS A PART OF
23 AN APPLICATION FOR INITIAL ACCREDITATION OR TO RENEW OR AUGMENT
24 ACCREDITATION, THE DEPARTMENT MAY REQUIRE FOLLOW-UP ASSESSMENTS
25 TO VERIFY THAT THE CAUSE OF AN UNSATISFACTORY ON-SITE ASSESSMENT

1 HAS BEEN CORRECTED OR TO DETERMINE THE CAUSE OF RECURRING
2 UNACCEPTABLE PT RESULTS. THESE ON-SITE ASSESSMENTS SHALL BE PAID
3 FOR BY THE LABORATORY.

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

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

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

20 SEC. 20510. (1) A LABORATORY APPLYING FOR INITIAL ACCREDIT-
21 ATION OR TO RENEW OR AUGMENT ACCREDITATION SHALL SUBMIT ALL FEES
22 REQUIRED UNDER THIS SECTION WITH THE APPLICATION FOR
23 ACCREDITATION. FEES ARE NONREFUNDABLE EXCEPT FOR OVERPAYMENT.
24 SUBJECT TO SUBSECTIONS (2) TO (8), THE ACCREDITATION FEE SHALL BE
25 THE SUM OF THE FEE FOR EACH ACCREDITATION CATEGORY PLUS EITHER

1 THE INITIAL APPLICATION FEE, THE AUGMENTATION FEE, OR THE RENEWAL
2 APPLICATION FEE AS PROVIDED IN THE FOLLOWING FEE SCHEDULE:

3	FOR INITIAL ACCREDITATION.....	\$	400.00
4	TO ANNUALLY RENEW ACCREDITATION.....	\$	200.00
5	TO AUGMENT ACCREDITATION.....	\$	150.00
6	FEE PER ACCREDITATION CATEGORY.....	\$	100.00

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

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

13 (4) THE ACCREDITATION FEE FOR EACH MOBILE LABORATORY UNIT
14 THAT IS ACCREDITED AS PART OF A STATIONARY LABORATORY UNDER SEC-
15 TION 20502(7) IS \$100.00 PER MOBILE LABORATORY UNIT PLUS THE
16 APPROPRIATE CATEGORY FEE OR FEES.

17 (5) THE ACCREDITATION FEE FOR MOBILE LABORATORIES ACCREDITED
18 AS A SINGLE LABORATORY UNDER SECTION 20502(8) IS THE FEE DETER-
19 MINED UNDER SUBSECTION (1) FOR THE FIRST LABORATORY PLUS, FOR
20 EACH ADDITIONAL MOBILE LABORATORY, THE SUM OF \$100.00 AND THE
21 APPROPRIATE CATEGORY FEE OR FEES.

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

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

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

13 (8) WITHIN 14 DAYS AFTER THE DEPARTMENTS ENTER INTO A CON-
14 TRACT WITH AN ON-SITE ASSESSMENT CONTRACTOR, THE DEPARTMENT SHALL
15 NOTIFY THE CHAIRPERSONS OF THE COMMITTEES OF THE SENATE AND THE
16 HOUSE OF REPRESENTATIVES THAT ARE PRIMARILY RESPONSIBLE FOR ENVI-
17 RONMENTAL PROTECTION LEGISLATION OF THE FEES TO BE CHARGED BY THE
18 ON-SITE ASSESSMENT CONTRACTOR.

19 (9) FEES UNDER THIS PART SHALL BE DEPOSITED IN THE ENVIRON-
20 MENTAL RESPONSE FUND SUBACCOUNT OF THE CLEANUP AND REDEVELOPMENT
21 FUND CREATED UNDER SECTION 20108 OF PART 201 (ENVIRONMENTAL
22 REMEDIATION).

23 SEC. 20511. (1) AN ACCREDITED LABORATORY SHALL ASSURE THAT
24 THE QUALITY OF ANALYTICAL DATA PRODUCED BY THE LABORATORY IS
25 SUITABLE FOR ITS INTENDED PURPOSE AND IS SUPPORTED BY APPROPRIATE

1 DOCUMENTATION. AN ACCREDITED LABORATORY SHALL ASSURE THAT THE
2 QUALITY OF ANALYTICAL DATA IS MAINTAINED WITHIN A FRAMEWORK OF
3 QUALITY SYSTEMS IN WHICH STAFF RESPONSIBILITIES AND OPERATIONAL
4 PROCEDURES ARE DEFINED, DOCUMENTED, AND SUBJECTED TO AUDIT ON A
5 REGULAR BASIS, WITH TIMELY CORRECTIVE ACTION TAKEN BY THE LABORA-
6 TORY AS NEEDED.

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

13 SEC. 20512. (1) AN ACCREDITED LABORATORY SHALL PROVIDE THE
14 LABORATORY ACCREDITATION NUMBER, EXPIRATION DATE, AND VALIDATION
15 STATEMENT SIGNED BY THE LABORATORY DIRECTOR WITH EACH SET OF
16 RESULTS. THE VALIDATION STATEMENT SHALL READ, "I CERTIFY THAT I
17 AM THE LABORATORY DIRECTOR WITH ULTIMATE RESPONSIBILITY FOR LABO-
18 RATORY OPERATIONS AND THAT, TO THE BEST OF MY KNOWLEDGE, THESE
19 ANALYSES WERE PERFORMED, AND THE RESULTS ARE REPORTED, IN FULL
20 COMPLIANCE WITH PART 205 (LABORATORY ACCREDITATION) OF THE NATU-
21 RAL RESOURCES AND ENVIRONMENTAL PROTECTION ACT, 1994 PA 451, MCL
22 324.20501 TO 324.20519, AND RULES PROMULGATED UNDER PART 205."

23 (2) THE LABORATORY SHALL MAINTAIN ALL LABORATORY RECORDS
24 ASSOCIATED WITH ACCREDITATION PARAMETERS OR SPECIFIED IN
25 ADMINISTRATIVE RULES, INCLUDING RAW DATA ASSOCIATED WITH EACH

1 ANALYSIS, CHANGES IN METHOD STANDARD OPERATING PROCEDURES, AND
2 THE LABORATORY QUALITY ASSURANCE PLAN, FOR A MINIMUM OF 5 YEARS
3 UNLESS A LONGER PERIOD IS SPECIFIED IN A RULE PROMULGATED UNDER
4 THIS PART.

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

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

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

14 (B) FAILURE TO SUBMIT THE CERTIFICATION OF COMPLIANCE STATE-
15 MENT WITH THE APPLICATION AS REQUIRED BY SECTION 20503.

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

18 (D) FALSIFICATION OF ANY REPORT OF OR RELATING TO A LABORA-
19 TORY ANALYSIS.

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

22 (F) AN UNACCEPTABLE ON-SITE ASSESSMENT, SUBJECT TO SECTION
23 20509.

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

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

6 (3) THE DEPARTMENT SHALL NOTIFY THE APPLICANT OF THE
7 DEPARTMENT'S INTENT TO DENY ACCREDITATION AND IDENTIFY THE BASIS
8 FOR DENIAL. IF THE BASIS FOR DENIAL IS AN UNACCEPTABLE ON-SITE
9 ASSESSMENT, AFTER RECEIVING NOTICE THAT THE DEPARTMENT INTENDS TO
10 DENY THE ACCREDITATION, THE APPLICANT SHALL HAVE 1 OPPORTUNITY TO
11 CORRECT THE DEFICIENCIES CAUSING THE ON-SITE ASSESSMENT TO BE
12 UNACCEPTABLE. IF THE APPLICANT OPTS TO CORRECT THESE DEFICIEN-
13 CIES, THE APPLICANT SHALL SO NOTIFY THE DEPARTMENT NOT MORE THAN
14 10 DAYS AFTER RECEIVING THE DEPARTMENT NOTICE OF INTENT TO DENY
15 ACCREDITATION. AT THE REQUEST OF AN APPLICANT FOR INITIAL
16 ACCREDITATION OR TO AUGMENT ACCREDITATION, THE DEPARTMENT SHALL
17 HOLD THE APPLICATION IN ABEYANCE FOR NOT MORE THAN 6 MONTHS FROM
18 THE DATE THE DEPARTMENT NOTIFIED THE APPLICANT OF THE
19 DEPARTMENT'S INTENT TO DENY ACCREDITATION TO ALLOW THE APPLICANT
20 TO DEMONSTRATE THAT DEFICIENCIES HAVE BEEN CORRECTED. AT THE
21 REQUEST OF AN APPLICANT TO RENEW ACCREDITATION, THE DEPARTMENT
22 SHALL HOLD THE APPLICATION IN ABEYANCE FOR NOT MORE THAN 1 MONTH
23 AFTER THE EXPIRATION OF THE CURRENT ACCREDITATION TO ALLOW THE
24 APPLICANT TO DEMONSTRATE THAT DEFICIENCIES HAVE BEEN CORRECTED.
25 IF THE DEPARTMENT DETERMINES THAT THE CORRECTION OF THE

1 DEFICIENCIES SHOULD BE EVALUATED THROUGH AN ON-SITE ASSESSMENT,
2 THE APPLICANT SHALL MAKE ALL ARRANGEMENTS AND PAY ALL COSTS FOR
3 THE ON-SITE ASSESSMENT.

4 (4) THE DEPARTMENT SHALL DETERMINE WHETHER TO DENY RENEWAL
5 OF ACCREDITATION AFTER THE LABORATORY HAS AN OPPORTUNITY FOR AN
6 EVIDENTIARY HEARING IN A CONTESTED CASE PROCEEDING UNDER THE
7 ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, MCL 24.201 TO
8 24.328.

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

11 (A) ACCREDITATION IS REVOKED BY THE DEPARTMENT.

12 (B) ACCREDITATION IS SURRENDERED BY THE ACCREDITED
13 LABORATORY.

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

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

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

23 (B) TWO CONSECUTIVE UNACCEPTABLE PT RESULTS.

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

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

3 (E) IF ACCREDITATION WAS GAINED THROUGH A RECIPROCITY AGREE-
4 MENT WITH ANOTHER STATE AGENCY, WITHDRAWAL, REVOCATION, OR OTHER
5 LOSS OF ACCREDITATION BY THE LABORATORY OR THE ORIGINAL ACCREDIT-
6 ING STATE AGENCY.

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

9 (G) MISREPRESENTATION OF THE CATEGORIES, PARAMETERS, ANAL-
10 YTES, OR METHODS FOR WHICH THE LABORATORY IS ACCREDITED.

11 (H) DENIAL OF ENTRY TO THE DEPARTMENT FOR PURPOSES OF LABO-
12 RATORY INSPECTION OR ON-SITE ASSESSMENT.

13 (I) FALSIFICATION OF ANY REPORT OF OR RELATING TO A LABORA-
14 TORY ANALYSIS.

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

17 (K) FAILURE TO PAY THE APPROPRIATE ACCREDITATION FEES.

18 (3) REVOCATION OF ACCREDITATION SHALL OCCUR ONLY FOR SPE-
19 CIFIC CATEGORIES, PARAMETERS, ANALYTES, OR METHODS IF UNSATISFAC-
20 TORY LABORATORY PERFORMANCE, PRACTICES, OR ACTIONS ARE RELATED
21 ONLY TO THOSE CATEGORIES, PARAMETERS, ANALYTES, OR METHODS.

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

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

6 SEC. 20515. (1) TO DETERMINE THE ABILITY OF AN ACCREDITED
7 LABORATORY TO PRODUCE VALID ANALYTICAL RESULTS, OR TO EVALUATE
8 THE VALIDITY OF ANY PREVIOUSLY REPORTED ANALYTICAL RESULTS, OR TO
9 EVALUATE COMPLIANCE WITH THE REQUIREMENTS OF THIS PART OR RULES
10 PROMULGATED UNDER THIS PART, THE DEPARTMENT OR THE ON-SITE
11 ASSESSMENT CONTRACTOR MAY REQUIRE THE LABORATORY DIRECTOR TO FUR-
12 NISH INFORMATION THAT THE LABORATORY IS REQUIRED TO MAINTAIN AS
13 SPECIFIED IN THIS PART OR IN RULES PROMULGATED UNDER THIS PART
14 AND ANY SUPPORTING INFORMATION. PART 148 (ENVIRONMENTAL AUDIT
15 PRIVILEGE AND IMMUNITY) IS SUBJECT TO THE REQUIREMENTS OF THIS
16 SECTION. PRIVILEGE AND PROTECTION FROM DISCLOSURE DO NOT APPLY
17 TO INFORMATION REQUIRED TO BE REPORTED TO THE DEPARTMENT UNDER
18 THIS SUBSECTION.

19 (2) A PERSON REQUIRED TO FURNISH INFORMATION UNDER SUBSEC-
20 TION (1) SHALL AT THE OPTION OF THE DEPARTMENT DO EITHER OF THE
21 FOLLOWING:

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

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

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

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

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

10 (B) COMMENCE A CIVIL ACTION TO COMPEL COMPLIANCE WITH A
11 REQUEST FOR INFORMATION OR ENTRY PURSUANT TO THIS SECTION, TO
12 AUTHORIZE INFORMATION GATHERING AND ENTRY PROVIDED FOR IN THIS
13 SECTION, AND TO ENJOIN INTERFERENCE WITH THE EXERCISE OF AUTHOR-
14 ITY PROVIDED IN THIS SECTION.

15 (C) SEEK CIVIL SANCTIONS ON BEHALF OF THE STATE, AS SPECI-
16 FIED IN SECTION 20516, FOR FAILURE TO COMPLY WITH AN INFORMATION
17 OR ACCESS REQUEST.

18 (5) INFORMATION OBTAINED BY THE DEPARTMENT UNDER SUBSECTION
19 (1) OR (2) SHALL BE AVAILABLE TO THE PUBLIC TO THE EXTENT PRO-
20 VIDED BY THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231
21 TO 15.246. THE PROVIDER OF INFORMATION UNDER SUBSECTION (1) OR
22 (2) MAY DESIGNATE THE INFORMATION THAT THE PROVIDER BELIEVES TO
23 BE ENTITLED TO PROTECTION AS INFORMATION OF A PERSONAL NATURE
24 UNDER SECTION 13 OF THE FREEDOM OF INFORMATION ACT, 1976 PA 442,
25 MCL 15.243. SUCH SPECIFICALLY DESIGNATED INFORMATION MUST BE

1 SUBMITTED SEPARATELY FROM OTHER INFORMATION REQUIRED TO BE
2 PROVIDED UNDER THIS SECTION. A DETERMINATION OF WHETHER TO GRANT
3 AN EXEMPTION FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION
4 ACT, 1976 PA 442, MCL 15.231 TO 15.246, SHALL THEN BE MADE BY THE
5 DEPARTMENT.

6 (6) NOTWITHSTANDING SUBSECTION (5), THE FOLLOWING INFORMA-
7 TION OBTAINED BY THE DEPARTMENT AS REQUIRED BY THIS SECTION SHALL
8 BE AVAILABLE TO THE PUBLIC:

9 (A) ALL APPLICATION INFORMATION SUBMITTED TO THE
10 DEPARTMENT.

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

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

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

17 (E) THE LABORATORY QUALITY ASSURANCE MANUAL.

18 (F) ALL PT RESULTS AND PT RESULT REPORTS.

19 (G) THE SIGNED CERTIFICATION OF COMPLIANCE STATEMENT UNDER
20 SECTION 20503 AND THE SIGNED VALIDATION STATEMENT UNDER SECTION
21 20512.

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

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

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

7 (ii) INADEQUATE LABORATORY RECORD KEEPING THAT PREVENTS VAL-
8 IDATION OF REPORTED RESULTS.

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

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

16 SEC. 20517. (1) A PERSON WHO KNOWINGLY DOES ANY OF THE FOL-
17 LOWING IS GUILTY OF A FELONY PUNISHABLE BY IMPRISONMENT FOR NOT
18 MORE THAN 2 YEARS OR A FINE OF NOT LESS THAN \$10,000.00 OR MORE
19 THAN \$25,000.00, OR BOTH, FOR EACH VIOLATION:

20 (A) MAKES A FALSE STATEMENT OR REPRESENTATION IN ANY APPLI-
21 CATION, RECORD, REPORT, OR OTHER DOCUMENT FILED WITH THE DEPART-
22 MENT OR REQUIRED TO BE MAINTAINED UNDER THIS PART OR THE RULES
23 PROMULGATED UNDER THIS PART.

1 (B) DESTROYS, ALTERS, OR CONCEALS ANY RECORD, REPORT, OR
2 DOCUMENT REQUIRED TO BE MAINTAINED UNDER THIS PART OR THE RULES
3 PROMULGATED UNDER THIS PART.

4 (C) AIDS, ABETS, PERMITS, OR FACILITATES THE SUBMISSION OF
5 ANY FALSE STATEMENT OR REPRESENTATION UNDER THIS PART TO THE
6 STATE OR ANY AGENCY OF THE STATE BY ANY OTHER PARTY.

7 (D) REPRESENTS ITSELF AS BEING ACCREDITED UNDER THIS PART IN
8 AN AREA IN WHICH IT IS NOT ACCREDITED.

9 (2) IF A CONVICTION UNDER SUBSECTION (1) IS FOR A VIOLATION
10 COMMITTED AFTER A FIRST CONVICTION, THE PERSON IS GUILTY OF A
11 FELONY PUNISHABLE BY IMPRISONMENT FOR NOT MORE THAN 5 YEARS OR A
12 FINE OF NOT LESS THAN \$50,000.00, OR BOTH.

13 (3) UPON A FINDING BY THE COURT THAT THE ACTION OF A
14 DEFENDANT CONVICTED UNDER SUBSECTION (1) POSES OR POSED A SUB-
15 STANTIAL ENDANGERMENT TO PUBLIC HEALTH, SAFETY, OR WELFARE, THE
16 DEFENDANT IS GUILTY OF A FELONY PUNISHABLE BY IMPRISONMENT FOR
17 NOT MORE THAN 5 YEARS OR A FINE OF NOT LESS THAN \$100,000.00 OR
18 MORE THAN \$1,000,000.00, OR BOTH.

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

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

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

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

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

12 (B) ACCREDITATION PROCEDURES.

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

16 (D) THE LABORATORY REQUIREMENTS FOR ESTABLISHING AND MAIN-
17 TAINING ACCEPTABLE LABORATORY QUALITY SYSTEMS. THESE RULES MAY
18 SPECIFY REQUIREMENTS FOR ALL OF THE FOLLOWING:

19 (i) LABORATORY ORGANIZATION AND MANAGEMENT.

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

22 (iii) PERSONNEL.

23 (iv) PHYSICAL FACILITIES.

24 (v) EQUIPMENT AND REFERENCE MATERIALS.

1 (vi) MEASUREMENT TRACEABILITY OF STANDARDS AND REGENTS.
2 (vii) METHOD CALIBRATION AND PERFORMANCE.
3 (viii) SAMPLE HANDLING, ACCEPTANCE, RECEIPT, AND TRACKING.
4 (ix) RECORD MAKING AND RETENTION.
5 (x) LABORATORY REPORT CONTENT.
6 (E) QUALIFICATIONS FOR ON-SITE ASSESSMENT CONTRACTORS.
7 (F) QUALIFICATIONS FOR PT PROGRAMS.
8 (G) OTHER ASPECTS OF THE ACCREDITATION PROGRAM NECESSARY TO
9 IMPLEMENT THIS PART.
10 (2) THE DEPARTMENT MAY PROMULGATE RULES TO SPECIFY ANY OF
11 THE FOLLOWING:
12 (A) THE PROCEDURES AND CONDITIONS UNDER WHICH THE DEPARTMENT
13 MAY ENTER INTO AGREEMENTS WITH THE GOVERNMENT OF ANY STATE OR
14 THIRD PARTY NONGOVERNMENTAL ENTITY FOR THE PURPOSE OF RECOGNIZING
15 THE ACCREDITATION OF OUT-OF-STATE LABORATORIES.
16 (B) THE TYPE AND AMOUNT OF DOCUMENTATION TO BE SUBMITTED IN
17 SUPPORT OF ALTERNATIVE TEST PROCEDURE APPLICATIONS AND THE REVIEW
18 PROCEDURE, APPLICATION PROCESS, AND APPLICABILITY OF ALTERNATIVE
19 TEST PROCEDURES TO SPECIFIC REGULATORY PROGRAMS.
20 (C) PROCEDURES FOR ESTABLISHING PT PERFORMANCE LIMITS.
21 SEC. 20519. DURING JANUARY OF 1999 AND EVERY ODD-NUMBERED
22 YEAR THEREAFTER, THE DEPARTMENT SHALL REPORT TO THE SENATE AND
23 HOUSE LEGISLATIVE COMMITTEES PRIMARILY RESPONSIBLE FOR
24 ENVIRONMENTAL PROTECTION LEGISLATION WHETHER A NATIONAL
25 LABORATORY PROGRAM HAS BEEN INSTITUTED BY WHICH LABORATORIES ARE

1 RECOGNIZED AS MEETING CERTAIN QUALIFICATIONS OR STANDARDS. IF
2 SUCH A PROGRAM HAS BEEN INSTITUTED, THE DEPARTMENT SHALL INCLUDE
3 IN THE REPORT ITS RECOMMENDATIONS AS TO WHETHER THIS PART SHOULD
4 BE AMENDED OR REPEALED.