

IOWA DEPARTMENT OF NATURAL RESOURCES

IN THE MATTER OF:

MIDWEST LABORATORIES, INC.

Lab Certification No. 64

**NOTICE OF INTENT TO
REVOKE LABORATORY
CERTIFICATION**

**TO: Midwest Laboratories, Inc.
Attn. Kennard Pohlman, President
13611 B Street
Omaha, NE 68144-3693**

I. SUMMARY OF INTENDED ACTION

The Iowa Department of Natural Resources (Department) is providing notice of its intent to revoke the laboratory certification for Midwest Laboratories, Inc. (Midwest), Department identification number 64, as specified in Division V below. This revocation action will be effective thirty (30) days after receipt of this notice, unless you file a notice of appeal contesting this action and request an administrative hearing within thirty (30) days of receipt of this notice.

Any questions regarding this notice should be directed to:

Relating to Certification Requirements:

Joe Zerfas, Laboratory Certification Office
Iowa Department of Natural Resources
401 S.W. 7th Suite I
Des Moines, Iowa 50309
Ph: 515/725-0343
Email: joe.zerfas@dnr.iowa.gov

Relating to Legal Issues:

David Wornson, Attorney
Iowa Department of Natural Resources
Henry A. Wallace Building
Des Moines, Iowa 50319-0034
Ph: 515/242-5817,
Email: david.wornson@dnr.iowa.gov

II. JURISDICTION

The Department is taking this action pursuant to the authority granted in Iowa Code section 455B.114 and administrative rules adopted by the Environmental Protection Commission (Commission). See chapter 567 Iowa Administrative Code (IAC) 83.

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

III. STATEMENT OF FACTS

1. Midwest operates a laboratory in Omaha, Nebraska certified by the Department pursuant to Iowa Code section 455B.113 and Commission rules in chapter 567 IAC 83. Iowa law requires all laboratories to be certified for all services provided to clients for the purpose of satisfying environmental regulatory duties. Certification is not required for laboratory services provided for non-regulatory purposes. Certification must be renewed every two years from the date of original certification. Midwest's laboratory certification must be renewed by January 1 of each odd-numbered year. Laboratories may be certified for testing services required for environmental regulatory programs and for specified analytes and applicable analytical methods within each program area.
2. Beginning with the certification renewal period of January 2007, Midwest was certified for specified analytes and analytical methods within the following environmental regulatory programs: Safe Drinking Water Act (SDWA), Clean Water Act (CWA), Underground Storage Tank (UST), Solid Waste (SW) and Contaminated Sites (CS).
3. Beginning around March of 2008, the Department initiated a process of offering compliance assistance and progressive discipline as a result of the lab's continuing difficulties in submitting timely and accurate compliance data and particularly the failure to submit acceptable performance evaluation (PE) samples (sometimes referred to as proficiency test (PT) samples). As a result of these deficiencies and concerns as to the overall quality control at this laboratory, the Department and staff of the University of Iowa Hygienic Lab (UHL) conducted an ad hoc inspection of the Midwest lab pursuant to Commission rules. UHL is the Department appointed appraisal authority as provided in 567 IAC 83.6(4)"a".
4. The UHL and Department staff conducted a lab inspection on July 16, 2008. The Department issued Midwest a notice dated August 15, 2008 which included a facility "Evaluation Report" dated August 15, 2008 summarizing the results of the inspection. The report identified a number of deficiencies that needed corrective action and which had been chronic problems such as (1) incomplete and inaccurate laboratory analytical reports to clients; (2) failure to properly report "non-detection" results; and (3) lack of internal auditing and quality control measures to assure accurate and complete testing performance and data reporting. The report also noted that subsequent to the July 16, 2008 inspection, Midwest submitted an unacceptable PE result for fecal coliform WW method 9221E A-1 and failed to submit a PE result for fecal coliform SDWA method 9221E.
5. The August 15, 2008 notice and evaluation report specified corrective actions and submittal due dates Midwest must meet. The Department notified Midwest that it intended to revoke certification for specified coliform bacteria methods applicable to the SDWA program (SDWA method 9221E) and CWA program (WW method 9221E A-1) due in part to the lab's failure to timely perform annual PE analysis. The report also required Midwest to undertake

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

certain remedial measures by specified dates and provided compliance assistance guidance. See attached "Evaluation Report", Exhibit A.

6. On August 26, 2008, the Department issued a notice revoking Midwest's certification for "Micro WW method 9221E A-1" ("micro" means microbiology) based on its failure to document a passing PE sample within a 12 month period and "Micro SDWA method 9221E" for failure to timely analyze a satisfactory PE sample within a 12 month period. The Midwest certification for all regulatory programs was also downgraded to provisional in accordance with Commission rule 567 IAC 83.7 based on findings the lab had (1) failed to satisfy the Department that it was consistently maintaining the required standard of quality; and (2) failure to accurately report compliance data in a timely manner to the Department or clients, thereby impairing timely compliance with regulatory programs. The August 26, 2008 notice specified a series of remedial actions and submittal due dates Midwest must complete in order to resolve deficiencies noted in the August 15, 2008 "Evaluation Report". See attached Exhibit B.

7. Midwest submitted letters to the Department dated October 1 and October 3, 2008. The October 1, 2008 letter included a passing PE for fecal coliform method WW 9221E A-1 for which the lab had submitted an untimely and failing PE result subsequent to the July 16, 2008 inspection. Midwest did not submit a passing PE for fecal coliform SDWA method 9221E which it had failed to submit subsequent to the July 16, 2008 inspection. Midwest submitted PE results for a fecal coliform method for which they were not certified, WW fecal coliform SM 9223B (Quantitray). (They were certified for several SDWA 9223B methods). Midwest requested re-instatement of certification for the revoked WW method 9221E A-1 and additional certification for WW method 9223B (Quantitray) but did not request recertification of SDWA 9221E although it is not clear if it did or did not seek recertification of this method.

8. The October 3, 2008 letter includes a number of PE sample results for methods for which the lab is not certified and requests immediate "reinstatement" for SDWA method 9222B which had not been revoked. Although the letter attachments included a passing PE result for SDWA 9221E analyzed on September 30, 2008, the letter confuses the issue by either requesting or not requesting re-certification of this method.

9. By letter dated October 9, 2008, the Department responded to Midwest's October 1 and 3, 2008 letters. The Department stated that Midwest had not submitted sufficient documentation to warrant reinstatement of the revoked methods, SDWA fecal coliform method 9221E and WW fecal coliform method 9221E A-1. The Department declined to add certification for WW method 9223B.

10. Midwest submitted a letter dated October 16, 2008 which included passing PEs for the revoked fecal coliform SDWA method 9221E and WW 9221E A-1 and also a number of methods for which they were not certified. The letter requested reinstatement of certification for (1) WW 9221E A-1; (2) SDWA method 9222B and 9221F which they mistakenly assume had been revoked and (3) new certification for WW methods 9223 and EPA 1603. It is not clear if they sought recertification of revoked method SDWA 9221E. The letter also enclosed a thick

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

document which appears to be selected parts of the lab's standard operating procedures without any explanation as to the changes which were responsive to the Department's August 15, 2008 Evaluation Report and corrective action requirements.

11. On October 16, 2008, the Department issued a revised certificate dated October 16, 2008 revoking Midwest's certification for all SDWA Micro and Nitrate methods and CWA Micro methods. The notice also advised Midwest that the Department was downgrading its certification to provisional for all other parameters in all environmental regulatory programs. See Attached Exh. C. The basis for the downgrade included the following:

- a. Failure to satisfy the Department that Midwest is consistently maintaining the required standard of quality control.
- b. Failure to accurately report compliance data in a timely manner to the Department and clients, thereby impairing compliance with environmental program regulations.
- c. Failure to timely complete and submit documentation of the remedial measures specified in the August 15, 2008 Evaluation Report.
- d. Although PE samples were submitted for SDWA and WW Micro methods within the corrective deadlines required in the August 15, 2008 Evaluation Report and August 26, 2008 certification notice, Midwest had failed to timely submit and accurately analyze PE samples. For example, during the July 16, 2008 on-site inspection, Midwest staff indicated Micro PE samples were available at the lab. Midwest lab staff was advised to make sure to analyze the samples using the correct analytical method. However, Midwest submitted PE analytical results using a method for which the lab was not certified, WW 9221D. Prior to receipt of the PE sample results required following the July on-site inspection, the last PE result for SDWA 9221F was performed on September 8, 2006, well beyond the required annual sampling.

12. The Department staff and UHL staff conducted a second onsite appraisal on January 30, 2009 as part of the January 2009 renewal process. In addition to the onsite wrap-up meeting following the inspection, the Department advised Midwest by email dated February 11, 2009 of the results of the onsite audit and deficiencies. This information was also communicated orally by telephone and with a written preliminary draft to assist Midwest in responding.

13. As the result of a questionable Midwest analytical report submitted to the Department Water Supply section in January 2009 by a public water supply owner, Sparboe Farms, Inc, the Department lab certification officer determined that there were numerous and serious reporting errors. Further investigation revealed that Midwest was either inaccurately reporting or failing to assure verification of critical information such as date and time of initial sampling, failing to accurately report maximum detection limits (MDLs), and failing to properly document calculation of MDLs. The Department engaged in a series of communications with Midwest to determine the cause and cure for these reporting errors which raised serious issues as to the quality control procedures within the lab.

14. The Department issued a letter dated May 7, 2009 enclosing a renewal laboratory certification and a revised letter dated May 14, 2009 notifying Midwest that it was revoking

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

certification for all SDWA Micro, Nitrates and VOCs and CWA Micro methods. The notice included the technical audit from the January 30, 2009 on-site inspection, a narrative based on the audit explaining in part the deficiencies warranting this action as well as "Attachment 1" which specified remedial actions Midwest must undertake. In particular, the notice and attached narrative referenced the serious reporting deficiencies arising out of review of analytical reports provided to Midwest's client, Sparboe Farms. These reporting errors and the Department's investigation of them established that (1) inaccurate methods were being reported; (2) methods for which Midwest was not certified were being reported; (3) MDLs and level of quantitation results (LOQs) were not being properly recorded and calculated in the laboratory; and (4) required tracking and sample location data was not being managed and properly reported.

15. The Department letter dated May 7, 2009 specified remedial actions Midwest must take to retain certification and remove the revocations. The notice clearly cautioned that Midwest must take the initiative in a self-directed manner to seriously review, audit and take corrective action to satisfy the Department that its quality assurance processes meet regulatory standards. See Exhibit D including Attachment 1. Those measures included:

1. Notify all Iowa clientele of the analytes and methods subject to revocation within 3 business days and confirm this notification to the Department by May 13, 2009. The confirmation must include a copy of the notice and a list of Iowa clientele notified.
2. Comply with annual PE sampling requirements including submission to the Department prior to applicable reporting periods.
3. Provide a written response by May 15, 2009 to all deficiencies and recommendations contained within the narrative of the attached certificate with a description of the action taken/to be taken and proposed due dates where applicable.
4. Develop an internal audit program that identifies and resolves administrative and procedural deficiencies as required by Commission rules and the Department's inspections. The scope of the program shall include those factors outlined in Attachment 1 which was originally provided to Midwest as a draft on February 11, 2009 and final form on May 7, 2009.

16. Midwest responded to the May 7, 2009 letter by letter dated May 14 and a follow up letter dated May 15, 2009. The May 15, 2009 letter noted that Midwest had simply downloaded various chapters of the Iowa Administrative Code to make them available to staff without any direction as to what portions of the rules applied to the deficiencies and corrective actions identified by the Department and UHL as part of the last two onsite inspections. Midwest stated that it would develop an internal audit plan and submit it to the Department by May 30, 2009 and develop and submit a revised SOP by July 15, 2009. The Department has received neither the internal audit plan or revised SOP.

17. Midwest has failed to adequately respond to the corrective actions outlined in the May 7, 2009 letter and Attachment 1 in that it (1) failed to include a list of Iowa clientele who had been issued the notice of revoked analytes and methods; (2) failed to submit a written response to the recommendations in the on-site audit and certification narrative included in the May 7, 2009

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

certification notice; and (3) failed to submit a proposed internal auditing program that addresses the factors outlined by the Department.

18. The failure to seriously respond to the concerns expressed in the Department's May 7, 2009 letter and attached onsite narrative is a continuation of the failure to seriously develop and implement similar corrective actions required in the Department's August 26, 2008 letter and Evaluation Report. The SOP documents submitted by Midwest in its October 16, 2008 letter did not provide any explanation of changes made and did not include revisions previously suggested by the Department's appraisal officer. Midwest did not implement the internal audit to verify the accuracy of SDWA data reporting or submit the 3-month study results.

19. The Department in consultation with and agreement from the UHL laboratory appraisal team has determined that sufficient cause exists to seek revocation of Midwest's laboratory certification for all environmental programs.

IV. CONCLUSIONS OF LAW

1. Iowa Code section 455B.113 requires the director of the Iowa Department of Natural Resources (Department) to certify laboratories which perform laboratory analyses of samples required to be submitted to the Department. The Environmental Protection Commission (Commission) is authorized to adopt implementing administrative rules. Iowa Code section 455B.114 authorizes the director of the Department to take disciplinary action including suspension or revocation of a laboratory certification for cause including criteria enumerated in rule.

2. The Commission has adopted rules establishing the conditions for laboratory certification in chapter 567 IAC 83 applicable to water supply programs, underground storage tank programs, wastewater programs and the solid waste and contaminated sites programs. See 567 IAC 83.1(3). Laboratory certification is valid for a two year period and must be recertified prior to expiration of the certification. All certified laboratories must successfully analyze a performance evaluation testing every 12 months for each analyte and method for which it is certified. See 567 IAC 83.6(2). Laboratories must consent to on-site inspections conducted by the Department or its designee at least every two years, although more frequent on-site visits may be conducted if required by the Department. 567 IAC 83.6(4).

3. Commission rule 567 IAC 83.2 incorporates by reference the *"Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources (2003) (hereafter "Manual")*.

4. Commission rule 567 IAC 83.7 outlines the criteria and procedures to be followed if the Department intends to downgrade a laboratory certification to a "provisional" or take action to suspend or revoke laboratory certification. Pursuant to rule 567 IAC 83.7(3), a laboratory certification may be suspended for the following reasons:

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

a. The department may downgrade certification to “suspended” status based on cause. The reasons for which a laboratory may be downgraded to “suspended” status include, but are not limited to, the following list.

- (1) Failure to analyze a PE sample annually for contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;
- (2) Failure to analyze a PE sample annually within Iowa acceptance limits for contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;
- (3) Failure to correct previously identified deficiencies, which resulted in “provisional” certification status, within the prescribed time frames of 83.7(2)“d”;
- (4) Failure to analyze a PE sample within Iowa acceptance limits when there is not a reliable history of successful PE sample analysis within the past 12 months;
- (5) Failure to satisfy the department that the laboratory is producing accurate data.

5. Pursuant to rule 567 IAC 83.7(5), a laboratory certification may be revoked for the following reasons:

a. The department may revoke certification for cause. The reasons for which a laboratory’s certification may be revoked include, but are not limited to, the following:

- (1) For laboratories of any status, failure to analyze a PE sample within Iowa acceptance limits;
- (2) Failure to satisfy the department that the laboratory has corrected deficiencies identified during the on-site visit within three months for a procedural or administrative deficiency or within six months for an equipment deficiency;
- (3) Submission of a PE sample to another laboratory for analysis and reporting the data as its own;
- (4) Falsification of data or other deceptive practices;
- (5) Failure to use required analytical methodology for analyses submitted to the department;
- (6) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on the on-site visit;
- (7) Persistent failure to report compliance data to the regulated client or the department in a timely manner, thereby preventing compliance with state regulations and endangering public health;
- (8) Subverting compliance with state regulations by actions such as changing the sample type for a noncompliance sample to a compliance sample after its submission to the laboratory, allowing compliance samples to be changed to other noncompliance sample types, or selective reporting of split sample results; or

**IOWA DEPARTMENT OF NATURAL RESOURCES
NOTICE OF INTENT TO REVOKE LABORATORY CERTIFICATION
MIDWEST LABORATORIES, INC.**

(9) For laboratories certified through a reciprocal agreement with another state or third-party accreditation program, loss of certification in either the resident state or third-party accreditation program is cause for immediate revocation of certification in Iowa for the same parameters or program areas for which certification was lost.

b. The department may either downgrade or revoke certification based on cause.

6. The Department in consultation with the UHL appraisal staff has determined that revocation of certification for all environmental programs is justified pursuant to 567 IAC 83.7(5)(a)(1), (2), (5) and (6).


V. TERMS OF REVOCATION

1. Unless this Notice of Revocation is timely appealed as provided in Division VI, below, Midwest's Iowa laboratory certification for all environmental programs shall be deemed revoked 30 days after receipt of this Notice of Intent to Revoke Laboratory Certification.

2. As of the effective date of revocation, Midwest shall comply with 567 IAC 83.7(6)(b) by discontinuing all regulatory laboratory services and providing notice to all Iowa clients and other state certifying agencies of this revocation.

VI. APPEAL RIGHTS

Commission rules at 567 IAC 83.7(4) and 83.7(6) specify your rights to appeal and request an administrative hearing to contest actions specified in this action. The suspension or revocation specified in this action shall be effective within thirty (30) days of receipt of this notice unless a notice of appeal is filed with the director of the Department within thirty (30) days of receipt of this notice. The notice of appeal must identify the specific portion or portions of this notice being appealed and include a short and plain statement of the reasons for appeal. A contested case hearing will then be commenced pursuant to Iowa Code chapter 17A and chapter 561 IAC 7.



RICHARD A. LEOPOLD, DIRECTOR
IOWA DEPARTMENT OF NATURAL RESOURCES

Dated this 3 day of
August, 2009

Midwest Laboratories, Inc, David Wormson, Joe Zerfas, John Kemp, UHIL, I(D), II(d), IV(D), V(D), VI(D).