

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 264

[FRL-3213-1]

Statistical Methods for Evaluating Ground-Water Monitoring Data From Hazardous Waste Facilities

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA promulgated regulations for detecting contamination of ground water at hazardous waste land disposal facilities under the Resource Conservation and Recovery Act of 1976 (RCRA). The statistical procedures used to evaluate the presence of contamination have been subject to criticism and require improvement. Therefore, EPA today proposes to revise these statistical procedures and requests comments from the public to assist in the regulatory development process.

DATE: Written comments should be submitted on or before October 23, 1987.

ADDRESSES: The original and two copies of comments on this proposal should be mailed to the Docket Clerk, Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket is open from 9:00 to 4:00 Monday through Friday, except for Federal holidays. The docket number for this rule is F-87-SGWP-FFFFF. The public must make an appointment to review docket materials. Call (202) 475-9327 for appointments. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost \$.20/page.

The official docket for this regulation, including comments received by the Agency, is located in Room MLG 100, U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: For general information contact: RCRA/Superfund Hotline, Office of Solid Waste (WH-563C), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, telephone (800) 424-9346, or (202) 382-3000. For technical information contact James Brown, (202) 382-4658.

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I. Authority

These regulations are issued under the authority of sections 1006, 2002(a), 3004, and 3005 of the Solid Waste Disposal Act (SWDA), as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

II. Background

Subtitle C of the Resource Conservation and Recovery Act of 1976 (RCRA) creates a comprehensive program for the safe management of hazardous waste. Section 3004 of RCRA requires owners and operators of facilities that treat, store, or dispose of hazardous waste to comply with standards established by EPA that are "necessary to protect human health and the environment." Section 3005 provides for implementation of these standards under permits issued to owners and operators by EPA or authorized States. Section 3005 also provides that owners and operators of existing facilities that apply for a permit and comply with applicable notice requirements may operate until a permit determination is made. These facilities are commonly known as "interim status" facilities. Owners and operators of interim status facilities also must comply with standards set under section 3004.

EPA promulgated ground-water monitoring and response standards for permitted facilities in 1982 (47 FR 32274, July 26, 1982), codified in 40 CFR Part 264, Subpart F. These standards establish programs for protecting ground water from releases of hazardous wastes from treatment, storage, and disposal units. Facility owners and operators are required to sample ground water at specified intervals and to use a statistical procedure to determine whether or not hazardous wastes or constituents from the facility are contaminating ground water. As explained in more detail below, the Subpart F regulations EPA promulgated in 1982 have generated criticism. EPA is today proposing to amend these regulations to respond to these concerns.

A. Concerns About Existing Standards

The current Part 264 regulations provide that the Cochran's Approximation to the Behrens Fisher Student's t-test (CABF) or an alternative statistical procedure approved by EPA be used to determine whether there is a statistically significant exceedance of background levels, or other allowable levels, of specified hazardous waste constituents. Although the existing 40 CFR Part 264 regulations have always provided latitude for the use of an alternate statistical procedure, concerns have been raised that the CABF statistical procedure in the current regulations may not be appropriate. It has been pointed out that: (1) The replicate sampling method is not appropriate for the CABF procedure, (2) the CABF procedure does not adequately consider the number of comparisons that must be made, and (3) the CABF does not control for seasonal variation. Specifically, the concerns are that the CABF procedure could result in "false positives" (Type I error), thus requiring an owner or operator unnecessarily to collect additional ground-water samples, to further characterize ground-water quality, and to apply for a permit modification, which is then subject to EPA review. In addition, there is concern that the CABF may result in "false negatives" (Type II error), i.e. instances where actual contamination goes undetected. This may occur when the background data, which are used as the basis of the statistical comparisons, are highly variable due to temporal, spatial, analytical, and sampling effects.

B. Suggested Changes Published in ANPRM

As a result of these concerns, EPA is proposing to change both the statistical procedure and the sampling requirements of the regulations, by requiring that owners or operators more completely characterize the hydrogeology at the facility, and including in the regulations performance standards which the statistical procedures and the sampling methods must meet. Statistical procedures and sampling methods meeting these performance standards would have a low probability of indicating contamination when it is not present and of failing to detect contamination that actually is present. The facility owner or operator would have to demonstrate that a procedure is appropriate for the conditions at that facility and ensure that it meets the performance standard outlined below.

In addition EPA has outlined several sampling methods and types of statistical procedures that the Agency believes will meet the performance standards.

EPA recognizes that the selection of appropriate monitoring parameters is also an essential part of a reliable statistical evaluation. The Agency addressed this issue in a previous Federal Register notice (51 FR 26632; July 24, 1986).

In an advance notice of proposed rulemaking (ANPRM) issued August 20, 1986 (51 FR 29182), EPA solicited information that would help evaluate approaches to determining if a facility is contaminating the ground water. The Agency requested comments on the following performance standards that it was considering:

1. The procedure(s) and sampling requirements must be protective of human health and the environment.

2. The owner or operator must determine the statistical distribution of each parameter or constituent listed in the facility permit. The statistical procedure(s) must be appropriate for the distribution. The owner or operator could demonstrate that the distributions of constituents differ and, thus, more than one procedure is needed at a facility.

3. The procedure(s) should have a low probability of indicating contamination when it is not present and of failing to detect contamination that is actually there. The owner or operator should consider different numbers of sample points for different constituents or procedures.

4. The procedure(s) should be appropriate for the hydrogeologic setting and the physical layout of the ground-water monitoring system.

5. The owner or operator should describe how observations below the detection limit will be handled in the procedure(s).

6. The owner or operator should consider, or control for, seasonal and spatial variability and temporal correlation in developing the procedure(s).

In addition, EPA identified certain statistical procedures that were expected to meet these performance standards and asked for available data on the following:

1. How will the statistical procedures meeting the performance standards perform in actual practice?

2. How sensitive will the procedures be to different distributions?

3. Are data available for EPA to use to determine Type II error levels for the procedures in light of the fact that Type I error (indicating contamination when it

is not present) is closely related to Type II error (missing existing contamination).

4. Are there other statistical procedures or sampling requirements that minimize both Type I and Type II errors? Are there data showing the number of Type II errors expected under any alternate statistical procedure or sampling scheme?

5. Are there modeling or measurement techniques that make it possible to determine the flow path of the ground water from an upgradient well to a particular downgradient well, or to several adjacent downgradient wells?

6. Does transforming data to its logarithm or square root improve conformance to assumptions of a statistical procedure or are there appropriate procedures for untransformed data?

7. If EPA uses a simple comparison of mean concentrations rather than a statistical procedure, would this have acceptable Type I and Type II error levels?

8. What Type I and Type II error levels result for the identified procedures when concentrations of constituents are below the detection limit? What error levels would result for other procedures?

9. Ground-water monitoring data may be autocorrelated (i.e., variation in monitoring parameters may be correlated). Is there information on the degree of autocorrelation at facilities and appropriate corrections such as adjusting the degrees of freedom of statistical tests or procedures that might be more appropriate for autocorrelated data?

10. Are intra-well comparisons appropriate for new facilities?

11. Is there available information that could be used to evaluate the frequency control comparison and to determine an acceptable range for them?

C. Public Comments on ANPRM

No new data or information were supplied by commenters in response to these 11 specific questions. However, commenters expressed several concerns with the six proposed performance standards. One concern was that some of the items in the ANPRM may not really be performance standards for statistical procedures. For example, numbers 1 and 4 are goals appropriate to the entire ground-water monitoring effort, not just to determine the appropriateness of the statistical procedures. Numbers 2 and 5 were thought to be specific requirements that the owner/operator must meet to develop an acceptable procedure, rather than broad performance standards. Finally, the two items that would

usually be construed as specifying performance of a statistical procedure, numbers 3 and 6, were thought to be too general for a procedure to meet. One commenter suggested that the section on performance standards be changed to evaluation criteria for determining the acceptability of a statistical test or procedure.

A consensus of respondents said that performance standards should be specific, yet flexible. Further, they should be site-specific to allow for the unique character of a site to be considered in defining the standard.

Another area of consensus was that performance standards should provide a "systems" approach to ground-water monitoring. That is, the performance standards should address the adequacy of the site characterization, the number and siting of monitoring wells, the sampling frequency and technique, the laboratory analytical methods, and the statistical analysis of the data. All of these components interact to determine the adequacy of a ground-water monitoring methodology to protect human health and the environment. Several commenters felt that the last performance standard, pertaining to seasonal and spatial variability, should be considered in developing the statistical procedures and not just during the data analysis. Consequently, EPA feels that a performance standard must incorporate aspects of ground-water monitoring in addition to the statistical techniques.

While some respondents called for the performance standards to specify requirements, few suggested what those specific requirements should be. The only specific suggestion made was that the Type I error should be set at 0.01. However, the context of that comment made it clear that 0.01 was merely in preference to 0.05, and that selection was based on the desire to keep the false positive rate as low as possible.

One suggestion was that risk be considered in setting performance standards and that the cost of meeting the performance requirements should be taken into account. It was also suggested that the level of performance to be required was a matter for policy decision by EPA. The required level of performance should be based on what is perceived as technically achievable, and which would result in an acceptable risk level. The achievement of zero risk was thought to be an unattainable, idealized goal.

In general, the respondents endorsed the concept of a performance standard, but they provided little in the way of concrete suggestions as to what the

performance standards should be. They raised many concerns, but suggested few answers. Some of the requests contradict others, making it evident that no single standard can satisfy all of the comments.

III. Today's Proposal

In today's proposal, EPA has elected to retain the idea of general performance requirements that the regulated community must meet. This proposal allows for flexibility in designing statistical procedures to site-specific considerations.

EPA has tried to bring a measure of certainty to today's regulations while accommodating the unique nature of many of the regulated units in question. Consistent with this general strategy, the Agency is establishing several options for the sampling schemes and statistical tests to be used in detection monitoring and, where appropriate, in compliance monitoring.

The Regional Administrator will specify for each of the hazardous constituents one or more of the statistical tests and sampling schemes described in today's regulations. In deciding which statistical test is appropriate, he will consider the theoretical properties of the test, the data available, and the hydrogeology of the site.

The Agency recognizes that there may be situations where the statistical tests and sampling schemes specified may not be appropriate. In such cases, it is necessary to develop procedures that are tailored to the specific performance standards that every procedure must meet. Thus, today's regulations establish performance standards for use by the Regional Administrator in determining whether an alternative procedure or scheme will be sufficiently protective of human health and the environment.

A. General Performance Standards

EPA's basic concern in establishing today's performance standards for statistical procedures is to achieve a proper balance between the risk that the procedures will falsely indicate that a regulated unit is causing background values or concentration limits to be exceeded (false positives) and the risk that the procedures will fail to indicate that background values or concentration limits are being exceeded (false negatives). Today's proposal is designed to address that concern directly. Thus, any statistical test or sampling scheme, whether specified in today's regulations or an alternative to those specified, should meet the following performance standards:

1. If the distributions differ among constituents, more than one procedure may be needed. The owner or operator must show that the normal distribution is not appropriate if using a statistical procedure which assumes the data are not normally distributed. A "goodness of fit" test should be used to demonstrate that the distribution assumptions are not violated.

2. The statistical test is to be conducted separately for each hazardous constituent. At each time that a test is done, the test for individual constituents shall be done at a Type I error level no less than 0.01. A multiple comparisons procedure may be used to control the experimentwise error rate at a level no less than 0.05. However, the individual well comparisons must have a Type I error no less than 0.01, which may make the experimentwise error rate greater than 0.05. The owner or operator must evaluate the power and may be required to increase the sample size to achieve an acceptable power level. The sample size and sampling procedure shall be appropriate to the level of the Type I and Type II errors and the decision criteria.

3. The monitoring well system should be in accordance with the natural features of the site. The owner or operator must ensure that the number, locations, and depths of wells will detect hazardous waste constituents that migrate from the waste management area to the uppermost aquifer at the first sampling period after such migration occurs.

4. The statistical procedure should be appropriate for the behavior of the parameters involved. It should include methods for handling data below the limit of detection. In cases where there is a high proportion of values below limits of detection, the owner or operator may demonstrate that an alternative procedure is more appropriate.

5. The statistical procedure should consider, and if necessary control or correct for, seasonal and spatial variability and temporal correlation in the data.

In referring to "statistical procedures", EPA means to emphasize that the concept of "statistical significance" must be reflected in several aspects of the monitoring program. This involves not only the choice of a level of significance, but also the choice of a statistical test, the sampling requirements, the number of samples, and the frequency of sampling. Since all of these interact to determine the ability of the procedure to detect contamination, the statistical procedures

must be evaluated in their entirety, not by individual components.

A set of specific numerical performance standards that would achieve the proper balance between false positives and false negatives is not possible due to site specific differences. The probability of correctly deciding that a regulated unit is contaminating ground water (often expressed as the power of a statistical test) cannot easily be summarized by a single number because the power of a test is related to the magnitude of the difference between two populations. Today's regulations do not attempt to express the idea of "exceeding background values or concentration limits" in terms of any minimum magnitude. This is because any statistically significant increase is a cause for concern. A performance standard related to the power of a statistical test would have to be specified for every possible minimum magnitude that might be of concern. This is not feasible given the current state of knowledge about ground-water contamination.

An alternative would be for EPA to decide what magnitude of increase it is concerned about and to specify how powerful the test would be for that magnitude of difference. However, the Agency does not believe it is appropriate to determine an amount of contamination that is acceptable for each contaminant at each site. Also, there would remain the problem of having to specify how powerful the test should be for values above the minimum difference of concern. EPA invites comment on this issue.

B. Basic Statistical Procedures and Sampling Schemes

Today's proposed regulations specify four types of statistical procedures to detect contamination in ground water. EPA believes that at least one of these types of procedures will be appropriate for a wide variety of situations. To address situations where these procedures may not be appropriate, EPA has placed a provision in today's proposed regulations for the Regional Administrator to select an alternate procedure. The suggested procedures are based in part on suggestions received in public comments.

1. A parametric analysis of variance (ANOVA) followed by multiple comparison procedures to identify specific sources of difference. The procedures will include estimation and testing of the contrasts between the mean of each downgradient well and the upgradient mean for each constituent.

2. An analysis of variance (ANOVA) based on ranks followed by multiple comparison procedures to identify specific sources of difference. The procedure will include estimation and testing of the contrasts between the median of each downgradient well and the median upgradient levels for each constituent.

3. A procedure in which a tolerance or prediction interval is established from the background (upgradient well) data, and the level of each constituent in each downgradient well is compared to its upper tolerance or prediction limit.

4. A control chart approach which would give control limits for each constituent. If any downgradient well has a value outside the control limits for that constituent, that would constitute statistically significant evidence of contamination.

5. Another statistical test procedure specified by the Regional Administrator, provided that it is protective of human health and the environment and meets the performance standards specified.

EPA has specified multiple statistical and sampling procedures and has allowed for alternatives because no one procedure is appropriate for all circumstances. EPA believes that the suggested procedures are appropriate for the site-specific design and analysis of data from ground-water monitoring systems, and they can account for more of the site-specific factors than Cochran's Approximation to the Behrens Fisher Student's t-test (CABF) and the accompanying sampling procedures in the current regulation. The statistical procedures specified in today's regulations address the multiple comparison problems and provide for documenting and accounting for sources of natural variation.

EPA believes that the specified tests consider and control for natural temporal and spatial variation. Technical details and examples for each specified procedure will be included in a draft guidance document which is anticipated to be available by September, 1987. The decision on the number of wells needed in a monitoring system will be made on a site-specific basis by the Regional Administrator and will consider the statistical method being used, the natural hydrogeology, and the sampling scheme. The number of wells must be sufficient to ensure a high probability of detecting contamination when it is present. To determine which sampling scheme should be used, the Regional Administrator should consider existing data and site characteristics including the possibility of trends and seasonality. The regulations establish three sampling

schemes and a provision for an alternative for use in detection and compliance monitoring systems. These sampling schemes are:

1. Obtain a sequence of daily (or nearly daily) observations at least twice a year unless it is found that this frequency of sampling results in autocorrelation of the observations.

2. Obtain a sequence of weekly observations at least twice a year, provided that weekly observations are not autocorrelated and that no seasonal effects are present in the data.

3. Obtain monthly observations provided the data exhibit no seasonal effects.

4. Use another sampling schedule appropriate to an alternative statistical procedure specified by the Regional Administrator. The alternative procedure must be protective of human health and the environment.

EPA believes that the above sampling schemes will allow the use of statistical procedures that will accurately detect contamination. These different sampling scenarios were chosen to allow for the unique nature of the ground-water systems beneath hazardous waste sites. These sampling schemes will give proper consideration to the temporal variation of and correlation among the ground-water constituents. The specified procedures require sampling data from upgradient wells, at the compliance point, and according to a specific test protocol. The owner or operator should use a background value determined from data collected under one of these scenarios if a test specified by the Regional Administrator requires it, or if a concentration limit in compliance monitoring is to be based upon background data. A guidance document under development includes scenarios for which each sampling scheme would be appropriate.

If the owner or operator uses a statistical method based on a distribution other than the normal, he must show the normal distribution is not appropriate. The same applies to transformations of the data. If the owner or operator desires to use a transformation, it must first be shown that the untransformed data are inappropriate for a normal theory test. There are several procedures for doing this, some of which will be detailed in the draft guidance document. If contamination is detected by one of these tests and the owner or operator suspects that the detection is an artifact caused by some feature of the data other than contamination, the Regional Administrator may specify that statistical tests of trend, seasonal variation, autocorrelation, or other

interfering aspects of the data be performed in order to establish whether the result indicates genuine contamination or whether the result arose from natural variation.

EPA recognizes that even where the distribution of a constituent is expected to be normally distributed, there may be situations where the owner or operator can devise sampling procedures that are more appropriate to the facility and which will provide reliable results. Therefore, today's regulations allow the Regional Administrator to approve such procedures if he finds that the procedures balance the risk of false positives and false negatives in a manner comparable to that provided by the above specified tests and that they meet the specified performance standards. In examining the comparability of the suggested procedure, the Regional Administrator will examine the ability of the procedure to provide a reasonable balance between the risk of false positives and false negatives. The Regional Administrator will specify in the permit such things as the sampling frequency and the sample size for the alternative statistical procedure.

The regulations indicate that the procedure must provide reasonable confidence that the migration of hazardous constituents from a regulated unit into and through the aquifer will be detected. (The reference to hazardous constituents does not mean that this option applies only to compliance monitoring; the test also applies to monitoring parameters and constituents in the detection monitoring program since they are surrogates indicating the presence of hazardous constituents.) The protocols for the specific tests, however, will be used as a general benchmark to define "reasonable confidence" in the proposed procedure. If the owner or operator shows that his suggested test is comparable in its results to one of the specified tests, then it is likely to be acceptable under the "reasonable confidence" test. There may be situations, however, where it will be difficult to directly compare the performance of an alternative test to the protocols for the specified tests. In such cases the alternative test will have to be evaluated on its own merits.

A situation that will probably require the crafting of a specialized procedure is the one in which the background level of a constituent either is below the detection limit of the analytical methods used or is recorded as a trace level of the constituent. EPA believes that appropriate statistical procedures can be developed in such cases. EPA seeks

comments from the public on what methods are available that rely on facility-specific data and properly applied statistical methodologies.

C. Effects of Proposed Changes on Existing Monitoring Programs

1. Detection Monitoring

The detection monitoring program relies on the finding of increases over background levels to define when a regulated unit is leaking. In addition, in many situations, the concentration limit for a particular hazardous constituent may be set at the background concentration. Today's proposed regulations are designed to ensure that reasonable methods are available for the analysis of background ground water quality and for determining if a specific ground water standard is exceeded.

The concentration of chemical constituents in ground water may fluctuate substantially over time. During different times of the year the recharge rates to ground water will vary, reflecting the differences in climate, rainfall, and other factors. Differing recharge rates or other factors may cause seasonal variation in the concentrations of chemical constituents in ground water.

EPA believes that such variation in background concentrations should be documented and considered in the statistical test if it occurs. If such natural variation in background concentrations can be documented, a statistical technique that accounts for such variation should be used, provided that this can be done without compromising other regulatory objectives.

For detection monitoring, and, where appropriate, for compliance monitoring, today's regulations provide three different sampling schemes for gathering ground water data. The Regional Administrator will specify which sampling scheme is to be used after considering the data, the statistical test to be used, the presence of trends, and natural temporal variation. The sampling scheme should be designed so that the major components of temporal variability can be characterized.

The different sampling procedures included in today's regulations enable the Regional Administrator to specify a sampling scheme that will allow for documentation of and adjustment for natural temporal variabilities. In the past, the tendency has been to abandon the sampling scheme and to use an alternate statistical approach when data exhibited temporal variability. EPA believes that in most cases one of the listed sampling schemes will still be

appropriate in this situation if a correction factor or data transformation is applied.

It is possible that hazardous constituents could already be migrating downgradient before a facility has received a permit. EPA does not believe it is generally appropriate to allow such contamination to continue to migrate while the owner or operator collects background data for one year. Therefore, EPA will, whenever possible, rely on whatever reliable background data is available to establish background values for the compliance monitoring program. Our concern is that data collection should not cause a delay in characterizing background. Possible methods which would avoid delays in characterizing the site would be sampling schemes 1 or 2.

Occasionally, additional background sampling and analysis over time may be appropriate even where compliance point concentrations exceed upgradient concentrations, at a given point in time, if the Regional Administrator believes it reasonably possible that this difference is due to seasonal or spatial variation in ground water quality. In this case, the Regional Administrator would consider whether the rate of ground water flow (and any contamination) was sufficiently slow that additional time for collection of ground water quality data would not jeopardize the potential for successful corrective action if it is determined to be necessary. The Regional Administrator would not, however, allow time for additional data gathering in cases where the initial difference in compliance point and upgradient constituent concentration is above potential seasonal variation.

The owner or operator who wants to account for seasonal variations in the background values has at least three additional options. One, he can anticipate the need for such data by collecting upgradient data on Appendix IX constituents likely to be in leachate before the detection monitoring program indicates that leakage has occurred. Two, he may continue to collect background data after the compliance monitoring program permit is issued. Three, he may use that data in making a demonstration that an apparent increase over concentration limits in the ground water protection standard was caused by contamination from other sources. He may also use the data in seeking a permit modification to change the background values contained in the compliance monitoring program.

Another issue in the establishment of background for a constituent is the question of which wells should be used in the data base. In evaluating temporal

variability, the frequency of sampling and the statistical method used to analyze the sampling data should be designed and considered simultaneously.

One option, which EPA is considering for detection monitoring programs at new facilities and possibly also at facilities where it is known that ground water is not contaminated, is to collect background data by monitoring downgradient wells. In each downgradient well, ground-water concentration levels would be monitored and the resulting data would be used to establish a background limit that would be unique to each downgradient well. The advantages of this approach are that first, the influence of spatial variability would be removed; second, a control chart class of statistical thresholds could be developed for each downgradient well; and third, upgradient wells may not be required. The disadvantages are that first, there must be assurance that contamination from the unit is not being factored into establishment of the background data base, and; second, if this method is used and contamination unrelated to the regulated unit flows under the downgradient side of the unit after establishment of the background limits, a false positive may result.

EPA believes that this method best applies to newer units that have had no opportunity to contaminate the ground water and that are located in areas with little potential to be influenced from external sources unrelated to the unit. It is also clear that this method can only be applied the first time a facility is in detection monitoring. A facility which begins compliance monitoring and subsequently returns to detection monitoring will not be allowed to establish or reestablish background limits based on data collected in the downgradient wells. EPA seeks comment on the utility of allowing downgradient wells to serve as background in these situations.

A second option, which EPA believes is preferable in most situations, and which corresponds to the current regulatory approach, is to base background data on upgradient wells. Assuming these wells are properly placed and unaffected by the unit, they should produce data that are not biased by contamination from the unit.

2. Compliance Monitoring

The statistical procedure(s) that will be used in compliance monitoring will be contingent upon the type of concentration limit used. If the concentration limit is based upon the

background values, then one of the statistical procedures specified in the regulations may be used. If the concentration limit is based upon a maximum concentration limit or an alternate concentration limit, then the Regional Administrator will require an appropriate test. In many cases this is the tolerance interval procedure specified in the proposed regulations.

IV. Regulatory Analysis

A. State Authority

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce their State hazardous waste management programs in lieu of EPA operating the Federal program in those States. Authorization, either interim or final, may be granted to State programs that regulate the identification, generation, transportation, or operation of facilities that treat, store, or dispose of hazardous waste. Upon authorization of the State program, EPA suspends operation within the States of those parts to the ground-water monitoring requirements for land-based hazardous waste management facilities applying for and operating under permits. Since the ground-water monitoring requirements are not imposed under any of the amendments made by the Hazardous and Solid Waste Amendments of 1984, final rules modifying the statistical procedures would not take effect directly in all States under section 3006(g). Rather, if EPA promulgates this proposal, States that have been granted final authorization will have to revise their programs to cover the additional requirements in today's announcement. Generally, these authorized State programs must be revised within one year of the date of promulgation of such standards, or within two years if the State must amend or enact a statute in order to make the required revision. See 40 CFR 271.21. However, States may always impose requirements which are more stringent or have greater coverage than EPA's programs.

Regulations which are broader in scope, however, may not be enforced as part of the federally-authorized RCRA program.

B. Regulatory Impact Analysis

Executive Order 12291 (46 FR 13191, February 9, 1981) requires that a regulatory agency determine whether a new regulation will be "major" and if so, that a Regulatory Impact Analysis be conducted. A major rule is defined as a regulation that is likely to result in:

1. An annual effect on the economy of \$100 million or more;

2. A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or

3. Significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Therefore, the Agency has determined that today's proposal is not a major rule. Today's action should produce a net decrease in the cost of ground-water monitoring at each facility. This proposal has been submitted to the Office of Management and Budget (OMB) for review in accordance with Executive Order 12291.

C. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities. As stated above, this proposal will have no adverse impacts on businesses of any size. Accordingly, I hereby certify that this proposed regulation will not have a significant economic impact on a substantial number of small entities. This regulation therefore does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 264

Hazardous material, Reporting and recordkeeping requirements, Waste treatment and disposal, Ground water, Environmental monitoring.

Date: August 14, 1987.

Lee M. Thomas,
Administrator.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for Part 264 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as Amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

2. In § 264.91 by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 264.91 Required programs.

(a) * * *

(1) Whenever hazardous constituents under § 264.93 from a regulated unit are detected at the compliance point under § 264.95, the owner or operator must institute a compliance monitoring program under § 264.99. Detected is defined as statistically significant evidence of contamination as described in § 264.98(e);

(2) Whenever the ground-water protection standard under § 264.92 is exceeded, the owner or operator must institute a corrective action program under § 264.100. Exceeded is defined as statistically significant evidence of increased contamination as described in § 264.99(d);

* * *

3. Section 264.92 is revised to read as follows:

§ 264.92 Ground-water protection standard.

The owner or operator must comply with conditions specified in the facility permit that are designed to ensure that hazardous constituents under § 264.93 detected in the ground water from a regulated unit do not exceed the concentration limits under § 264.94 in the uppermost aquifer underlying the waste management area beyond the point of compliance under § 264.95 during the compliance period under § 264.96. The Regional Administrator will establish this ground-water protection standard in the facility permit when hazardous constituents have been detected in the ground water.

4. In § 264.97 by removing the word "and" from the end of (a)(1), adding (a)(1)(i) and (a)(3), revising paragraphs (g) and (h), and adding (i), (j), and (k) to read as follows:

§ 264.97 General ground-water monitoring requirements.

(a) * *

(1) * * *

(i) A determination of background quality may include sampling of wells that are not upgradient from the waste management area where:

(A) Hydrologic conditions do not allow the owner or operator to determine what wells are upgradient; and

(B) Sampling at other wells will provide an indication of background ground-water quality that is representative or more representative

than that provided by the upgradient wells; and

* * *

(3) Provide statistically significant evidence that hazardous waste or hazardous constituents that migrate from the waste management area to the uppermost aquifer will be detected.

* * *

(g) In detection monitoring or where appropriate in compliance monitoring, data on each hazardous constituent specified in the permit will be collected from background wells and wells at the compliance point(s). The sampling procedures and frequency must be protective of human health and the environment. The sampling requirements must ensure that the statistical procedure has an acceptably low probability of failing to detect contamination. The Regional Administrator will specify one or more of the following requirements in the permit for each hazardous constituent to be monitored for:

(1) Obtain a sequence of daily (or near daily) samples at least twice a year, unless it is found that this frequency of sampling results in autocorrelation of the observations that cannot be corrected by the statistical procedure used.

(2) Obtain a sequence of weekly samples at least twice a year, provided that weekly observations are not autocorrelated and that no seasonal effects are present in the data used in each periodic comparison.

(3) Obtain monthly samples provided the data exhibit no seasonal effects.

(4) Use an alternate sampling procedure specified by the Regional Administrator under paragraph (i) of this section.

(h) Based on the factors in § 264.97(i), the Regional Administrator will specify one of the following statistical procedures to be used in combination with the sampling requirements for each hazardous constituent:

(1) A parametric analysis of variance (ANOVA) followed by multiple comparisons procedures to identify statistically significant evidence of contamination. The procedure must include estimation and testing of the contrasts between each downgradient well's mean and the upgradient mean levels for each constituent.

(2) An analysis of variance (ANOVA) based on ranks followed by multiple comparisons procedures to identify statistically significant evidence of contamination. The procedure must include estimation and testing of the contrasts between each downgradient

well's median and the background median levels for each constituent.

(3) A tolerance or prediction interval procedure in which a tolerance interval for each constituent is established from the distribution of the background data, and the level of each constituent in each downgradient well is compared to the upper tolerance or prediction limit.

(4) A control chart approach that gives control limits for each constituent.

(5) Another statistical test procedure that is protective of human health and the environment and meets the performance standards specified in § 264.97(i).

(i) The Regional Administrator can establish an alternative sampling procedure and statistical test for hazardous constituents that he finds will be protective of human health and the environment. In establishing that procedure, the Regional Administrator will consider the following factors:

(1) If the distributions for different constituents differ, more than one procedure may be needed. The owner or operator must show that the normal distribution is not appropriate if using a nonparametric or other methodology not requiring an assumption of normality. For any statistic not based on a normal distribution, a goodness of fit test shall be conducted to demonstrate that the normal distribution is not appropriate. Other tests shall be conducted to demonstrate that the assumptions of the statistic or distribution are not grossly violated.

(2) Each hazardous constituent is to be tested for separately. At each time that a test is done, the test for individual constituents shall be done at a Type I error level no less than 0.01. A multiple comparisons procedure may be used at a Type I experimentwise error rate no less than 0.05. The owner or operator must evaluate the ability of the method to detect contamination that is actually present and may be required to increase the sample size to achieve an acceptable power level.

(3) The monitoring well system should be consistent with § 264.97(a). The owner or operator must ensure that the number, locations, and depths of monitoring wells will detect hazardous constituents that migrate from the waste management area to the uppermost aquifer.

(4) The statistical procedure should be appropriate for the behavior of the parameters involved. It should include methods for handling data below the limit of detection. The owner or operator should evaluate different ways of dealing with values below the limit of detection and choose the one that is most protective of human health and the

environment. In cases where there is a high proportion of values below limits of detection, the owner or operator may demonstrate that an alternative procedure is more appropriate.

(5) The statistical procedure used should control for seasonal and spatial variability and temporal correlation.

(j) Ground-water monitoring data collected in accordance with paragraph (g) of this section including actual levels of constituents must be maintained in the facility operating record. The Regional Administrator will specify in the permit when the data must be submitted for review.

(k) If contamination is detected by any of the statistical tests, and the Regional Administrator or the owner or operator suspects that the detection is an artifact caused by some feature of the data other than contamination, the Regional Administrator may specify that statistical tests of trend, seasonal variation, autocorrelation, or other interfering aspects of the data be done to establish whether the significant result is indicative of detection of contamination or resulted from natural variation.

(5). In § 264.98 by removing paragraphs (i), (j) and (k), and by revising paragraphs (c), (d), (f), (g), and (h) to read as follows:

§ 264.98 Detection monitoring program.

* * *

(c) The owner or operator must conduct a ground-water monitoring program for each parameter or constituent in accordance with § 264.97(g). The owner or operator must maintain a record of ground-water analytical data as measured and in a form necessary for the determination of statistical significance under § 264.97(h) for the active life and post-closure care period of the facility.

(d) The Regional Administrator will specify how often the owner or operator must collect samples and conduct statistical tests to detect contamination. The frequencies for both will be at least semi-annually and will be consistent with § 264.97(g) considering the size of the Type I or Type II errors. Where appropriate, the comparison will be made between background wells and wells at the point(s) of compliance.

* * *

(f) The owner or operator must determine whether there is statistically significant evidence of contamination for any parameter or constituent specified in the permit pursuant to paragraph (a) of this section at a

frequency specified under paragraph (d) of this section.

(1) In determining whether statistically significant evidence of contamination exists, the owner or operator must use the procedure(s) specified in the permit under § 264.97(h). This procedure(s) must compare data collected at the compliance point(s) to the background water quality data.

(2) The owner or operator must determine whether there is statistically significant evidence of contamination at each monitoring well at the compliance point within a reasonable period of time after completion of sampling. The Regional Administrator will specify in the facility permit what period of time is reasonable, after considering the complexity of the statistical test and the availability of laboratory facilities to perform the analysis of ground-water samples.

(g) If the owner or operator determines pursuant to paragraph (f) of this section that there is statistically significant evidence of contamination for parameters or constituents specified pursuant to paragraph (a) of this section at any monitoring well at the compliance point, he must:

(1) Notify the Regional Administrator of this finding in writing within seven days. The notification must indicate what parameters or constituents have shown statistically significant evidence of contamination.

(2) Immediately sample the ground-water in all monitoring wells at the waste management area of concern and determine if there is a statistically significant difference between the compliance and background levels for concentration of all constituents identified in Appendix IX of Part 264.

(3) For any Appendix IX compounds for which there is a significant difference, the owner or operator may resample within one month and repeat the Appendix IX analysis for those compounds detected. If the results of the second analysis confirm the initial results then these constituents will form the basis for compliance monitoring. If they do not resample, the hazardous constituents found during the initial Appendix IX analysis will form the basis for compliance monitoring.

(4) Within 90 days, submit to the Regional Administrator an application for a permit modification to establish a compliance monitoring program meeting the requirements of § 264.99. The application must include the following information:

(i) An identification of the concentration of any Appendix IX constituent detected in the ground water

at each monitoring well at the compliance point;

(ii) Any proposed changes to the ground-water monitoring system at the facility necessary to meet the requirements of § 264.99;

(iii) Any proposed additions or changes to the monitoring frequency, sampling and analysis procedures or methods, or statistical procedures used at the facility necessary to meet the requirements of § 264.99;

(iv) For each hazardous constituent detected at the compliance point, a proposed concentration limit under § 264.94(a) (1) or (2), or a notice of intent to seek a variance under § 264.94(b); and

(5) Within 180 days, submit to the Regional Administrator:

(i) All data necessary to justify any variance sought under § 264.94(b); and

(ii) An engineering feasibility plan for a corrective action program necessary to meet the requirements of § 264.100, unless:

(A) All hazardous constituents identified under paragraph (g)(2) of this section are listed in Table 1 of § 264.94 and their concentrations do not exceed the respective values given in that Table; or

(B) The owner or operator has sought a variance under § 264.94(b) for every hazardous constituent identified under paragraph (g)(2) of this section.

(6) If the owner or operator determines, pursuant to paragraph (f) of this section, that there is a statistically significant difference for parameters or constituents specified pursuant to paragraph (a) of this section at any monitoring well at the compliance point, he may demonstrate that a source other than a regulated unit caused the contamination or that the contamination resulted from error in sampling, analysis, or evaluation. While the owner or operator may make a demonstration under this paragraph in addition to, or in lieu of, submitting a permit modification application under paragraph (g)(3) of this section, he is not relieved of the requirement to submit a permit modification application within the time specified in paragraph (g)(3) of this section unless the demonstration made under this paragraph successfully shows that a source other than a regulated unit caused the increase, or that the increase resulted from error in sampling, analysis, or evaluation. In making a demonstration under this paragraph, the owner or operator must:

(i) Notify the Regional Administrator in writing within seven days of determining statistically significant evidence of contamination at the compliance point that he intends to

make a demonstration under this paragraph;

(ii) Within 90 days, submit a report to the Regional Administrator which demonstrates that a source other than a regulated unit caused the contamination or that the contamination resulted from error in sampling, analysis or evaluation;

(iii) Within 90 days, submit to the Regional Administrator an application for a permit modification to make any appropriate changes to the detection monitoring program at the facility; and

(iv) Continue to monitor in accordance with the detection monitoring program established under this section.

(h) If the owner or operator determines that the detection monitoring program no longer satisfies the requirements of this section, he must, within 90 days, submit an application for a permit modification to make any appropriate changes to the program.

6. In § 264.99 by revising paragraph (c), revising paragraphs (d), (f), and (g), removing paragraph (h), redesignating paragraph (i) as (h), (j) as (i), and (k) as (j), revising the redesignated paragraphs (h) introductory text and (i) introductory text, and removing paragraph (l) to read as follows:

§ 264.99 Compliance monitoring program.

* * * * *

(c) The Regional Administrator will specify the sampling requirements and statistical procedures appropriate for the constituents and site, consistent with § 264.97 (g) and (h).

(1) The owner or operator must conduct a sampling program for each parameter or constituent in accordance with § 264.97(h).

(2) The owner or operator must record ground-water analytical data as measured and in a form necessary for the determination of statistical significance under § 264.97(h) for the active life and post-closure care period of the facility.

(d) The owner or operator must determine whether there is statistically significant evidence of increased contamination for any parameter or constituent specified in the permit, pursuant to paragraph (a) of this section, at a frequency specified under paragraph (f) of this section.

(1) In determining whether statistically significant evidence of increased contamination exists, the owner or operator must use the procedure(s) specified in the permit under § 264.97(h). This procedure must compare data collected at the compliance point(s) to a concentration

limit developed in accordance with § 264.94.

(2) The owner or operator must determine whether there is statistically significant evidence of increased contamination at each monitoring well at the compliance point within a reasonable time period after completion of sampling. The Regional Administrator will specify that time period in the facility permit, after considering the complexity of the statistical test and the availability of laboratory facilities to perform the analysis of ground-water samples.

(f) The Regional Administrator will specify the frequencies for conducting statistical tests to determine statistically significant evidence of increased contamination. The frequencies will be at least semi-annually and will be consistent with § 264.97(g) considering the size of the Type I and Type II errors.

(g) The owner or operator must analyze samples from all wells at the compliance point of a regulated unit for all constituents contained in Appendix IX of Part 264 at least annually to determine whether additional hazardous constituents are present in the uppermost aquifer, pursuant to procedures in § 264.98(f). If the owner or operator finds Appendix IX constituents in the ground-water that are not identified in the permit, the owner or operator may resample within one month and repeat the Appendix IX analysis.

If the second analysis confirms the presence of new constituents, the owner or operator must report the concentration of these additional constituents to the Regional Administrator within seven days after completion of the second analysis and add them to the monitoring list.

(h) If the owner or operator determines pursuant to paragraph (d) of

this section that any concentration limits under § 264.94 are being exceeded at any monitoring well at the point of compliance, he must:

(i) If the owner or operator determines, pursuant to paragraph (d) of this section that the ground-water concentration limits under this section are being exceeded at any monitoring well at the point of compliance, he may demonstrate that a source other than a regulated unit caused the contamination or that the contamination resulted from error in sampling, analysis, or evaluation. In making a demonstration under this paragraph, the owner or operator must:

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