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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 264

[FRL-3356-2]

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

AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA regulations, promulgated under the Resource Conservation and Recovery Act (RCRA), require ground-water monitoring to detect contamination of ground water at permitted hazardous waste land disposal facilities (40 CFR § 264.90 et seq. Part 264 Subpart F). These regulations specify that a statistical method must be used to evaluate the presence or increase of contamination. Due to problems associated with the use of Cochran's Approximation to the Behrens–Fisher Student's t-test (CABF) as such as statistical method, EPA proposed amendments to the Part 264 Subpart F regulations on August 24, 1987 (52 FR 31948). These amendments, which EPA is today finalizing, specify five different statistical methods that are more appropriate to ground-water monitoring than the CABF method. The amendments finalized today also outline sampling procedures and performance standards that are designed to help minimize the event that a statistical method will indicate contamination when it is not present (Type I error), and fail to detect contamination when it is present (Type II error).

DATE: These final regulations become effective April 11, 1989, pursuant to RCRA section 3010(b).

ADDRESSES: The official docket for this rulemaking (Docket No. F–88–SGWF–FFFFF) is located in Room MLG100, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, and is available for viewing from 9:30 a.m. to 3:30 p.m., Monday through Friday, excluding legal holidays. The public must make an appointment to review docket materials. Call (202) 475–9327 for appointments. The public may copy a maximum of 100 pages of docket materials at no cost. Additional copies cost $.15/page.

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 Jim Brown, (202) 382–4658.

SUPPLEMENTARY INFORMATION:

Preamble Outline

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 USC 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 certain land-based interim status facilities in 1980 (45 FR 33232, May 19, 1980), codified in 40 CFR Part 265, Subpart F, and 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 certain landfills, surface impoundments, and land treatment units, and, in the case of permitting standards, to waste piles as well. (See 40 CFR 264.90(a)(2) and 265.90(a)). 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 these units are contaminating ground water. As explained in more detail below, the Subpart F regulations regarding statistical methods used in evaluating ground-water monitoring data have generated criticism. EPA is today finalizing amendments to the Part 264 Subpart F regulations governing statistical methods for RCRA permitted facilities proposed August 24, 1987 (52 FR 31948) to respond to these concerns. Due to the fact that most interim status land disposal facilities are expected to receive RCRA permits by November 1988, EPA is not amending the Part 265 Subpart F regulations governing statistical methods at interim status facilities.

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 alternate 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 chemical parameters and 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 to ground-water monitoring. It has been pointed out that: (1) The replicate sampling method required under the current Part 264 Subpart F regulations is not appropriate for the CABF procedure, (2) the CABF procedure does not adequately consider the number of comparisons that must be made under these regulations, 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), instances where contamination is falsely indicated at the site. False positives may require an owner or operator unnecessarily to collect additional ground-water samples, to

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further characterize ground-water quality, and to apply for a permit modification to begin more comprehensive monitoring or corrective action. This permit modification is then subject to EPA review. In addition, there is concern that the CABF procedure may result in "false negatives" (Type II error), i.e., instances where actual contamination goes undetected. The CABF procedure may result in false negatives when the background data, which are often used as the basis of the statistical comparisons, are highly variable due to temporal, spatial, analytical, and sampling effects.

B. Suggested Changes Published in NPRM

As a result of these concerns, EPA is amending both the statistical method and the sampling procedures of the regulations, by requiring (if necessary) that owners or operators more accurately characterize the hydrogeology and potential contaminants at the facility, and by including in the regulations performance standards which all the statistical methods and sampling procedures must meet. Statistical methods and sampling procedures meeting these performance standards should have a low probability of indicating contamination when it is not present and of failing to detect contamination that actually is present.

III. Public Comments on the NPRM

A. Comments Solicited by EPA

In a notice of proposed rulemaking (NPRM) issued on August 24, 1987 (52 FR 31948), EPA solicited comments on alternative statistical methods to the CABF method as well as general information that would help evaluate approaches to determining if a facility is contaminating the ground water.

1. Power of a Statistical Test

EPA first invited comments on the issue of whether the power of a statistical test should be specified numerically. In the NPRM, however, EPA stated that it was its view that a set of specific numerical performance standards that would achieve the proper balance between false positives and false negatives is not possible because it would involve specifying every possible minimum magnitude of difference for each contaminant at each site. This requires specifying concentration level changes at each site to which the statistical test must be sensitive. This is not possible due to the current state of knowledge about ground-water contamination.

A consensus of the commenters acknowledged this difficulty. Once commenter offered an excellent summary of the problems associated with setting a numerical performance standard: "The power of a statistical test is not a value, but a function involving sample sizes, sampling plans, the statistical models on which the test is based, the Type I error level, the inherent variability and correlation structure of the measurements, and the amount of increase in the level of the constituent at which the power is evaluated."

However difficult to quantify, the Agency agrees with the consensus of the respondents that the power of a statistical test can be improved by a variety of methods, such as adequately characterizing the hydrogeology and the fate and transport characteristics of potential contaminants at the site, properly locating monitoring wells, increasing sample sizes, and reducing measurement variability by using proper analytical, quality control, and quality assurance procedures. Therefore, rather than endorsing a set of specific numeric standards that specify the power of a statistical test, EPA is encouraging a systems approach to ground-water monitoring as reflected in the performance standards (§ 264.97(i)) and other components of today's final rule.

2. Methods to Analyze Below Detection Limit Data

EPA also invited public comment on the methods available for analyzing data where the background level of a constituent is either below the detection limit of the analytical method used or is recorded as a trace level of the constituent. This problem is often encountered with (although not limited to) synthetic organic compounds (e.g., volatile and semivolatile organic compounds). Many of these compounds do not occur naturally in ground water, and therefore are not detected during background sampling. This makes comparing downgradient (compliance well) concentrations with background levels of these compounds especially dificult.

Several commenters requested EPA to consider establishing national baseline values for compounds that do not occur naturally in ground water, and as a result are frequently recorded as below the limit of analytical detection in background monitoring wells. Specifically, the commenters suggested that EPA conduct a round-robin study involving several different certified chemical laboratories to establish national baseline values for these compounds.

The Appendix IX rule (52 FR 25942, July 9, 1987) listed practical quantification limits (pql's) that were established from "Test Methods for Evaluating Solid Waste" (SW-846). SW-846 is the general RCRA analytical methods manual, currently in its third edition. The pql's listed were EPA's best estimate of the practical sensitivity of the applicable method for RCRA ground-water monitoring purposes. However, some of the pql's may be unattainable because they are based on general estimates for the specific substance. Furthermore, due to site-specific factors, these limits may not be reached. For these reasons the Agency feels that the pql's listed in Appendix IX are not appropriate for establishing a national baseline value for each constituent for determining whether a release to ground water has occurred. Instead, the pql's are viewed as target levels that chemical laboratories should try to achieve in their analyses of ground water. In the event that a laboratory cannot achieve the suggested pql, the owner or operator may submit a justification stating the reasons why these values cannot be achieved (e.g., specific instrument limitations). After reviewing this justification, the Regional Administrator may choose to establish facility-specific pql's based on the technical limitations of the contracting laboratory.

Thus EPA is today clarifying § 264.97(h) to allow owners or operators to propose facility-specific pql's. These pql's may be used with the statistical methods listed in § 264.97(h) (e.g., nonparametric ANOVA), to comply with § 264.97(i)(5) upon approval of the Regional Administrator. In addition, EPA is also adding language to § 264.97(i)(5) to state that any pql approved by the Regional Administrator must be the lowest concentration level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions that are available to the facility.

EPA believes it to be necessary that the owner or operator utilize a statistical method to account for data below the detection limit of the analytical method used. Although several commenters submitted methods which could be specified in the regulations, EPA believes that no single method is appropriate at all facilities. Accordingly, EPA believes it is necessary to evaluate the appropriateness of each method on a case-by-case basis. The fifth performance standard of today's final rule, found at § 264.97(i)(5), reflects this belief by requiring that the statistical

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method chosen include procedures to evaluate data that is below the limit of analytical detection. Statistical methods that are commonly applied use tests of proportions, prediction and tolerance intervals, and procedures which characterize censored data distributions. Examples of these methods will be provided in a guidance document which will be available later this year.

3. Establishing Background Concentrations With Downgradient Wells

EPA also sought comments on the utility of allowing the use of samples from downgradient wells to establish background concentrations at newer units that have had no opportunity to contaminate the ground water and that are located in areas with little potential to be influenced by external sources unrelated to the unit. Four commenters addressed this issue and supported the Agency's proposal to use downgradient wells to establish background concentrations of constituents in selected circumstances.

EPA realizes that this option is not a new feature of the Part 264 Subpart F regulations (see previous § 264.97(g)(3)). EPA believes that discussion of this option in this rulemaking is appropriate because of the emphasis in today's regulations on choosing statistical methods and sampling procedures appropriate for individual facilites. Using downgradient wells to establish background concentrations reduces some of the components of spatial variability for any statistical method employed. In addition, unlike the CABF method, the control chart statistical method specified in today's amendments can accommodate intra-well comparisons. An intra-well comparison is a method that establishes background concentrations from an individual well, and compares future monitoring data obtained from the well to its own background concentration. An intra-well comparison method is necessary if downgradient wells are to be used to establish background concentrations.

B. Other Issues

Other comments on the NPRM were received from the public on a wide variety of issues raised by the proposal, some of which are discussed below. These comments and the Agency's formal responses are available through the official docket for this rulemaking.

1. Guidance Document

Many commenters addressed the fact that the Agency did not make available its planned guidance document on statistical methods during the comment period on the NPRM. The respondents stated that more details on the proposed statistical methods and procedures for handling censored data, correlations, and seasonal variation were needed before complete comments could be given. However, EPA requested comments on the regulation and not on specific protocols of the statistical methods. Therefore, a guidance document detailing the statistical methods should not have been necessary to review the NPRM. However, a draft guidance document addressing these concerns will be issued after finalization of this rule.

2. Data Distribution Assumptions

Commenters also addressed the assumptions made in the first performance standard, or § 264.97(i)(1) of the proposed rule, concerning the distribution of data. As written, this proposed performance standard assumed that the data obtained through ground-water monitoring are normally distributed at all sites. Proposed § 264.97(i)(1) required that a goodness of fit test be conducted to demonstrate that the normal distribution assumption is not appropriate to the data. Some respondents suggested that owners and operators be required to justify the normal distribution of their data, just as they are required to justify a different data distribution (e.g., lognormal, non-normal, etc.) under the proposed performance standard. Others commented that it would be more reasonable to assume a lognormal distribution. Still others suggested that EPA should replace the assumption of normality with a requirement that the statistical method, including any preliminary transformations, be appropriate for the background data or data expected on the basis literature.

EPA is retaining the assumption of normality in the data distribution in today's final rule (§ 264.97(i)(1)) because many of the statistical procedures cited in the regulation are robust for data that, while not normally distributed, do not significantly violate the normal distribution assumption. Thus EPA believes it is reasonable to assume normality of data and to only require demonstrations where the owner or operator wishes to use a distribution-free theory test. The statistical test will be appropriate for most data under this assumption and the owner or operator will not in all cases be required to go through the extra step of determining the distribution of ground-water data. The regulation's first performance standard provides that the owner or operator may use a distribution-free theory test or a transformation, provided he or she demonstrates that the data are inappropriate for a normal theory test. EPA requires this showing to prevent increases in the Type II error rate, a possible result of using distribution-free theory tests or transformations in inappropriate circumstances. When the Type II error rate increases, environmentally significant contamination may go undetected. A demonstration of a data distribution may include both graphics and literature as well as the conventionally used statistical methods.

3. Obligation of Owner/Operator to Propose Statistical Methods and Sampling Procedures

Some commenters opposed a provision in the proposed rule stating that the Regional Administrator is responsible for specifying the sampling procedures and frequencies, and the statistical methods that are required under § 264.97 (General Ground-Water Monitoring Requirements). The commenters stated that the regulated party, not the Regional Administrator, should be responsible for designing and proposing the statistical methods and sampling procedures. EPA agrees that it would be more effective to ask the owner or operator to undertake initial design of methods and procedures. Therefore, EPA has changed the language of §§ 264.97 (g) and (h) to require the owner or operator to propose a respective sampling procedure and statistical method which must then be approved by the Regional Administrator.

4. Data Variability and Sampling Procedures

Commenters also addressed the need for specific methods to handle correlated data (see autocorrelation in glossary) and the problems caused by temporal and spatial variation. EPA recognizes the possibility of the correlation of errors, and temporal and spatial variation affecting the data sets and believes that certain provisions in today's final rule enable owners and operators to reduce these sources of errors and control for data variability. Choosing an appropriate sampling interval that spans a sufficient amount of time to allow one to obtain an independent ground-water sample will help reduce the effects of autocorrelation. Under § 264.98(d) and § 264.99(f), owners and operators have the latitude to choose such an interval, provided that four samples are taken from each well at least semiannually.

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Also, sampling both background and compliance wells at the same-point-in-time should reduce temporal effects. One-point-in-time comparison sampling is also allowed under § 264.98(d) and § 264.99(f), which require that all wells, background and compliance, be sampled during the specified sampling interval. The current regulations prevented owners and operators from performing one-point-in-time comparisons by requiring that background concentrations be established prior to the monitoring of compliance wells in detection and compliance monitoring. (See § 264.97(g).) To better characterize spatial variability, an owner or operator may wish to install and sample from multiple background and compliance wells. Additionally, if sufficient data are available, statistical procedures such as moving averages, in which a background value is established by continually updating the data, and trend analysis may be used to reduce seasonal and temporal effects.

5. Procedures at Interim Status Facilities

Some respondents requested that the same regulatory changes should be made in the Part 265 ground-water monitoring regulations for interim status facilities as were made for permitted facilities. They added that all the reasons for replacing the Student's t-test at a permitted facility apply with equal force at an interim status facility.

As discussed above this rule is expected to be finalized by September 1988, and to become effective six months after the date of promulgation, or March 1989. By November 1988, the majority of interim status land disposal facilities are expected to be either permitted or closed. In the event that a significant number of facilities are still operating after this date, EPA will assess the need to amend 40 CFR 265 as appropriate. The Agency recognizes that some facilities may be subject to interim status due to new listings of RCRA hazardous wastes. EPA intends to move expeditiously to permit these facilities so that they may take advantage of today's amendments to the statistical procedures at permitted facilities under Part 264.

6. Determining Background Concentrations

Determining the background concentration of constituents was another topic addressed by commenters. These commenters argued that the current regulation, which limits background determinations to data collected during a single year, is too restrictive. Section 264.97(g)(1) of the current regulations states that background ground-water quality for a monitoring parameter or constituent in detection monitoring must be based on data from quarterly sampling of background (or, in certain circumstances, compliance wells) for one year. EPA agrees with this position. As discussed above, EPA is therefore requiring that monitoring under § 264.98(d) and § 264.99(f) be performed at all wells, including background and compliance wells. Thus the background determination will not be limited to data collected during a single year prior to monitoring compliance wells as is currently set forth in § 264.98(g)(2). This will allow the mean concentration of a constituent to be used in one-point-in-time comparisons between background and compliance wells, or to be used to establish a "moving average" in the background well data base for comparison to the compliance well values at a frequency required in the facility permit.

EPA encourages owners and operators to determine the concentrations of a constituent in these samples through the use of one-point-in-time comparisons between background and compliance wells. Some facility owners or operators may want to use the concentrations to establish a "moving average" in the background well data base for comparison to the compliance well values at the frequency required in the facility permit. While using several background values to establish a "moving average" is an acceptable method of analysis, it increases the number of degrees of freedom, making this method more sensitive to changes in constituent concentrations. Further, this method does not account for seasonal variation as effectively as one-point-in-time comparison procedures. Therefore, most owners or operators should find one-point-in-time comparisons to be a preferred method of analysis. This approach will help reduce the components of seasonal variation by providing for simultaneous comparisons between background well and compliance well monitoring data.

7. Sampling Required by Proposed § 264.98(g)(2)

Many commenters were opposed to the provisions in proposed § 264.98(g)(2) for detection monitoring which required the owner or operator to, upon obtaining statistically significant evidence of contamination," 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." The respondent's primary point of concern was that this provision would require extensive sampling and statistical analysis to determine background concentrations for all of the Appendix IX compounds prior to obtaining statistically significant evidence of contamination at a facility. Under the current regulation an owner or operator is required only to determine whether any Part 264 Appendix IX constituent is present, and at what concentration (§ 264.98(h)(2)). EPA has reviewed this requirement and has found it to be one of technical oversight. Therefore, acting in accordance with the comments received on this matter, EPA is replacing the proposed sections with the previously existing language of § 264.98(h)(2); that is "immediately sample the ground water in all monitoring wells and determine whether constituents identified in the list in Appendix IX of Part 264 are present and, if so, at what concentration."

8. Type I Experimentwise Error Rate

Many commenters addressed the second performance standard finalized in today's rule as § 264.97(i)(2). For individual well comparisons in which a compliance well is compared with background, § 264.97(i)(2) specified that the Type I error level shall be no less than 0.01 for each testing period. In other words, the probability of the test resulting in a false positive is no less than 1 in 100. EPA believes that this significance level will sufficiently limit the false positive rate and has retained this provision of the second performance standard in today's rule. Section 264.97(i)(2) also accounted for those owners and operators of facilities that have an extensive network of ground-water monitoring wells who find it more convenient to use a multiple well comparisons procedure. Multiple comparisons procedures control the experimentwise error rate for comparisons involving multiple background and compliance wells. Under today's final version of the second performance standard, if this method is used, the Type I experiment-wise error rate for each constituent shall be no less than 0.05 for each testing period. Here, the probability of the test resulting in a false positive is no less than 5 in 100. Again, EPA is limiting the Type I error rate for the purpose of controlling the Type II error rate. In the multiple well comparisons procedure, if the overall test is shown to be significant, then individual well contrasts are performed to identify

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which differences are statistically significant. In conducting a multiple well comparisons procedure, if the owner or operator chooses to use a t-statistic rather than an F–statistic, the individual well Type I error level of no less than 0.01 must be maintained. This provision should be considered if a facility owner or operator wishes to use a procedure that distributes the risk of a false positive evenly among all monitoring wells and monitoring parameters at the facility. This is reflected in the second performance standard which requires that if a multiple comparisons procedure is used, the Type I error of no less than 0.01 for individual well comparisons must be maintained.

Several commenters expressed concern that in prescribing a Type I error rate of no less than 0.01 (0.05 for multiple well comparisons) this second performance standard would lead to high false positive rates. Owners and operators should note, however, changes in the language of § 264.97(i)(2) of today's final rule which specifies that this Type I error level applies per single testing period, not for the entire operating life of the facility. Multiple-unit facility owners and operators may generate a large number of comparisons due to the large number of wells at their facilities, and may potentially face a large number of false positives in their data evaluation. These owners and operators are encouraged to implement a unit-specific data evaluation approach if they wish to keep the overall false positive rate down to a lower level.

EPA realizes, however, that there still may be situations where facilities will generate large false positive rates, especially those that monitor for a large number of constituents over several monitoring wells. Here, if the owner or operator suspects that a detection is a false positive, he or she may wish to make a demonstration under § 264.98(g)(6) or § 264.99(i) of today's final rule.

In these cases, a determination of whether a leak has occurred may in many cases be based on the Regional Administrator's evaluation of the hydrogeology, geochemistry, climatic factors, and the relative magnitude of the concentration of the constituents along with the results of the statistical test. In evaluating the relative magnitude of the concentration of the constituents, for example, if the exceedance is based on an observed compliance well value that has the same relative magnitude as the practical quantification limits (pql) or the background level, the exceedance is more likely a false positive and further sampling and testing may be appropriate. If, however, the background or an action level is exceeded by an order of magnitude in any sample, then the exceedance may indicate a release from the facility.

Many commenters stated that it was hard to understand how to apply this second performance standard (especially the Type I error level of 0.01 for individual well comparisons) to control charts, tolerance intervals, and prediction intervals. Several commenters suggested that, in setting a Type I error level for control charts, EPA should be consistent with the research projects that were conducted by the Agency's laboratories. Specifically, the commenters requested that EPA utilize a combined Shewhart-CUSUM control chart scheme to evaluate ground-water monitoring data.

EPA agrees that § 264.97(i)(2), or the second performance standard, is not directly applicable to control charts, tolerance intervals and prediction intervals. Accordingly, the Agency is specifying in § 264.97(i)(2) that this performance standard does not apply to these three statistical methods. EPA would nevertheless like to retain these statistical methods and has therefore attempted to specify, in today's final rule, when their use is appropriate as well as applicable performance standards.

Control charts have been employed by industry for many quality control applications. Because of their widespread use, EPA is generally allowing their use as a statistical method for ground-water monitoring under § 264.97(h)(4), so long as they comply with the performance standard specified in § 264.97(i)(3). There are a variety of control charts available for applications to ground-water monitoring. Each procedure has different parameters that need to be specified based on various features of the data such as the mean, variance, sample size, decision interval value (h), reference value (k), and control limits. EPA does not believe it to be appropriate to specify numerical values for these parameters in a performance standard in today's final rule, because they are dependent on site-specific factors such as the constituents being monitored for and the facility's hydrogeology. Therefore, the Agency is requiring the owner or operator to propose values for these parameters that are appropriate for the type of control chart used. If the Regional Administrator finds the type of control chart and the associated parameters to be appropriate for the facility that proposed them and protective of human health and the environment, then he or she will approve and include them in the facility's operating permit. This is reflected in the third performance standard of today's final rule.

In evaluating the control chart, the owner or operator should also consider ther average run lengths, in and out of control, before a decision regarding a suspected release is made. Guidance addressing control charts will be issued after finalization of this rule.

Tolerance intervals and prediction intervals have not been widely used by the Agency to evaluate ground-water monitoring data. However, the Agency is aware of recent publications that have employed these statistical methods to evaluate ground-water monitoring data, especially in evaluating certain classes of chemical compounds (e.g., volatile organic compounds). Several commenters suggested that the Agency incorporate this research into today's final rule, noting that these procedures may be the best way to evaluate data that is below the limit of analytical detection.

While EPA does not believe it appropriate to specify the confidence levels for prediction and tolerance intervals (or in the case of tolerance intervals the percentage of the population that the interval must contain) in today's final rule, the Agency is nevertheless adding a performance standard relating to the use of these procedures in today's final rule. Because the parameters of confidence levels and population percentages may vary due to site-specific factors, § 264.97(i)(4) states that the facility owner or operator must submit parameters that are protective of human health and the environment to the Regional Administrator for approval. In evaluating these parameters, the Regional Administrator may consider the number of samples in the background data base and the range of the concentration values for each constituent of concern.

9. Time Intervals for Ground-Water Sampling

There was some confusion expressed in the comments regarding the time intervals within which ground-water samples are to be collected (i.e., sampling procedures). EPA proposed in § 264.97(g) that a sequence of samples be taken at either daily, weekly, or monthly intervals. Providing the owner or operator with a flexible sampling schedule will allow him or her to choose a sampling procedure that will reflect site-specific concerns. The intent was to set a sampling frequency that allows

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sufficient time to pass between sampling events to assure, to the greatest extent technically feasible, that an independent sample is taken from each well. In this final rule, the language of § 264.97(g) (1)–(4) has been consolidated into one provision, § 264.97(g), which specifes that the owner or operator shall obtain a sequence of at least four samples from each well, based on an interval that is determined after evaluating the aquifer's effective porosity, hydraulic conductivity and hydraulic gradient (which govern rates of flow), and the fate and transport characteristics of the potential contaminants.

The minimum number of samples that are to be collected each testing period is four. This minimum number was selected by the Agency to maintain consistency with the prior requirements that specified that the owner or operator collect one sample from each well and divide it into four replicate samples for laboratory analysis. Therefore, requiring the owner or operator to collect four samples from each well for laboratory analysis should not impose an increase in the number of analyses. There may, however, be an increase in field sampling efforts associated with this sampling procedure. However, the quality of the ground-water monitoring data will be significantly improved.

In order to maintain a complete annual record of ground-water data, the facility owner or operator may find it desirable to obtain a sample each month of the year. This will help identify seasonal trends in the data and permit evaluation of the effects of autocorrelation and seasonal variation if present in the samples.

Several commenters noted that the number and kinds of samples collected to establish background should be appropriate to the form of statistical test employed, following generally accepted statistical principles. EPA agrees. Thus, for example, the use of control charts presumes a well defined background of perhaps 16 to 30 samples. By contrast, ANOVA alternatives might require only 4 to 6 samples. A performance standard stating that the number and kinds of samples collected to establish background be appropriate for the form of statistical test employed was incorporated into § 264.97(g) of today's final rule. In addition, a guidance document under development includes scenarios for which each sampling procedure would be most appropriate.

IV. Implementation

In addition to changes made in this final rule pursuant to public comments, the Agency is also promulgating a series of changes to clarify the implementation of these regulations. The Agency recognizes that some discussion of the implementation of these changes may be beneficial prior to the issuance of the guidance document. However, additional information concerning implementation will be addressed in the guidance document.

Because today's amendments to the statistical methods and sampling procedures require that an owner or operator institute methods that conform to the unit's site-specific characteristics and eliminate the CABF method as the default method, compliance with today's regulations requires detailed knowledge of the site. Thus, an important implementation issue concerns the source of this site-specific information. Such information should be available to owners or operators at a sufficient level of specificity to allow these regulations to easily be implemented at all regulated units subject to these regulations. For new units, or units operating under interim status, the gathering of the applicable site-specific data is a requirement of Part B of a RCRA permit application under § 270.14(c)(2). Under this provision, owners and operators of hazardous waste surface impoundments, waste piles, land treatment units, and landfills must identify the uppermost aquifer and aquifers hydraulically interconnected beneath the facility property, including ground-water flow direction and rate, and the basis for that identification. Units currently operating with a RCRA permit should also have site-specific data, obtained either from on-going ground-water monitoring or to fulfill the § 270.14(c)(2) requirement for the Part B permit application.

The second major implementation issue concerns when and how the sampling frequency and statistical method will be specified in the facility's RCRA permit. Under § 270.14(c)(7)(vi), owners and operators must submit a description of their proposed sampling, analysis and statistical comparison procedures to be used in evaluating ground-water monitoring data as a requirement of their Part B permit application. While most new units or units operating under interim status should have the data necessary to propose a sampling frequency, they may not have sufficient data to propose a statistical comparison procedure. The Agency does not believe this will pose an implementation problem, however. Where this is the case, the owner or operator shall propose a contingency plan under § 270.14(c)(7)(vi) in which several statistical methods and the conditions under which the method would be appropriate at the site is specified. The Agency notes that the ANOVA statistical method specified in § 264.97(h)(1) can be performed with six months of ground-water monitoring data, and thus owners and operators with this amount of data would not need to propose a contingency plan under § 270.14(c)(7)(vi), but could propose use of the ANOVA statistical method. Should an owner or operator who incorporates a contingency plan into his or her permit wish to use a statistical method not specified in the contingency plan at a later date, he or she may propose a permit modification to incorporate this method in their RCRA permit under § 270.1(a)(3). Owners and operators currently operating under a RCRA permit and employing the CABF method or another statistical method or sampling procedure not appropriate at their unit may of course also apply for a permit modification under § 270.41(a)(3) to institute an appropriate sampling procedure and statistical method.

V. Miscellaneous

A. Deletion of Proposed § 264.97(i)(3)

The third performance standard that appeared in § 264.97(i)(3) of the proposed rule required that the monitoring well system be in accordance with the natural features of the site. Although this requirement is a very important component of a ground-water monitoring system, it was out of place as a performance standard in that it does not describe requirements that are directly related to the statistical methods or sampling procedures. Further, it is redundant with § 264.97(a) of the regulations. For these reasons it does not appear as a performance standard in today's final rule.

B. Demonstrations of Error Caused by Data Variability

Section 264.97(k) of the proposed regulations included a provision allowing the Regional Administrator to specify statistical tests of trend, seasonal variation and autocorrelation should the owner or operator suspect that the contamination detected by any of the statistical tests was caused by some feature of the data other than contamination. The Agency is retaining the substance of this provision in the final rule. However, because § 264.98(i) and § 264.99(j) of the regulation currently provide for demonstrations of error by owners and operators pursuant to a detection of contamination suspected to be caused by some other feature, this final rule amends these sections to incorporate the substance of the proposed § 264.97(k). Thus, under today's final rule, as part of a

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demonstration that the detection of contamination at a unit during detection monitoring (§ 264.98(g)(6)) or during compliance monitoring (§ 264.99(i)) was an error or caused by another source, the owner or operator may perform statistical tests to evaluate trends, seasonal variation, or autocorrelation.

VI. General Description of Statistical Methods

A. Analysis-of-Variance

The analysis-of-variance (ANOVA) is a statistical method for analyzing data from ground-water monitoring wells. It is a special case of a more general procedure referred to as a general linear model (GLM) and as such is a very flexible analysis system.

Analysis-of-variance is a method for partitioning the total variation in a set of data into the different sources of variation that are present. It results in a summary table that provides a convenient form for summarizing and presenting information contained in a set of data. Analysis-of-variance models are used to analyze the effects of the independent variable or variables under study on the dependent variable. In the context of ground-water monitoring, wells or groups of wells represent the independent variables. The concentration of hazardous constituents is the dependent variable. The analysis-of-variance would determine whether different wells (or groups of wells) had significantly different concentrations of the hazardous constituents.

Contrasts are used to investigate where any differences occur. In this case the contrasts of interest are the pairwise contrasts between the background wells and the compliance wells. In a parametric analysis-of-variance, the contrasts of interest is the comparison between the mean concentration of the background wells and the mean concentration of each compliance well.

In ground-water monitoring, the analysis of variance is generally appropriate in situations where a background concentration for a particular constituent can be established. If there are data from several wells for one or more time periods for a water quality parameter that are not normally distributed, and not transformable to normality, then an analysis-of-variance based upon ranks (nonparametric ANOVA) may be appropriate.

B. Tolerance Intervals

Tolerance intervals define, with a specified probability, a range of values that contain a discrete percentage of the population. Tolerance intervals are simple to construct, requiring a calculator and a table of tolerance factors. Because of their simple construction, tolerance intervals are easy to understand and apply to a ground-water monitoring scenario.

Tolerance intervals can be used in a detection monitoring program when individual compliance wells are compared to a group of background wells in order to detect ground-water contamination. Tolerance intervals can be constructed from the background well concentrations and expressed as an interval centered at the mean background well concentration. Compliance well hazardous constituent concentrations found to fall outside of the tolerance interval limits signal possible ground-water contamination.

Tolerance intervals may also be applied to a hazardous waste site in a compliance montoring program. Tolerance intervals can be constructed from the compliance well hazardous constituent concentrations, starting when the facility entered the compliance monitoring program. The objective of this procedure is to construct a tolerance interval based on the background well constituent concentrations, testing each compliance well concentration to determine if it lies within the tolerance interval. If the present concentration of a compliance well hazardous constituent is greater than the historical tolerance interval limits, it indicates that the ground-water quality has deteriorated to such a point that further action may be warranted.

C. Prediction Intervals

A prediction interval is an interval in which one is confident at a specified percentage that the next observation will lie within the interval. Like tolerance intervals, prediction intervals are simple to construct, requiring only a calculator and a table of prediction factors.

Parametric prediction intervals can be constructed for constituents that follow a normal distribution. In some cases, prediction intervals can be constructed for constituents that have non-normal distributions (e.g., Poisson or binomial distributions). It should be noted, however, that most other distribution-free prediction intervals cannot be constructed with a specified probability, and therefore their use is not recommended.

Prediction intervals are used in a detection monitoring program when individual compliance well concentrations are compared to one or more background wells. The mean concentration and standard deviation are estimated from the background well sample, and prediction intervals are constructed on the basis of the number of previous observations, the number of new measurements, and the levels of confidence that one wishes to obtain. Future compliance well hazardous constituent concentrations found to fall outside of the prediction limit(s) signal possible ground-water contamination.

In a compliance monitoring program, prediction intervals are constructed from compliance well concentrations, starting when the facility entered the compliance monitoring program. Each future compliance well observation is tested to determine if it lies within the prediction interval. If the present concentration of a compliance well hazardous constituent is greater than the historical prediction limits, it indicates that the ground-water quality has deteriorated to such a point that further action may be warranted.

D. Control Charts

Control charts are widely used as a statistical tool in industry as well as reasearch and development laboratories. From the population distribution of a given variable, such as concentrations of a given constituent, repeated random samples are taken at intervals over time. Statistics, for example the mean of replicate values at a point in time, are computed and plotted together with upper and/or lower predetermined limits on a chart, where the X-axis represents time. If a result falls outside these boundaries, then the process is declared to be "out of control"; otherwise, the process is declared to be "in control." The widespread use of control charts is due to their ease of construction and the fact that they can provide a quick visual evaluation of a situation.

In the context of ground-water monitoring, control charts can be used to monitor the inherent statistical variation of the data collected and to flag anomalous results. Further investigation of data points lying outside the established boundaries will be necessary before any direct action is taken.

Control charts, when applied to the properly adjusted and/or transformed data, can be used to evaluate ground-water monitoring data. A control chart can be constructed for each consitituent in each well to monitor the concentration of a constituent in a well over time. A new sample for a given well can be compared to the historical data from that well, and conclusions can be drawn on whether the well is in control. This specific use of control charts should be encouraged regardless

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of the objectives of more refined data analysis. It provides a quick and easy means of checking the data for possible outliners, quality control problems, or data entry errors.

VII. Glossary

Autocorrelation

A measure of the relationship among members of a series of observations typically ordered in time or across space.

F-Statistic

A statistic calculated on the basis of the F-distribution. The F-statistic is used in an analysis-of-variance to determine if there is a relationship between factors of interest. The F-distribution is also used to check the equality of variance assumption in certain statistical tests.

Frequency Distribution

Used to described a set of measurements and often expressed in a graphical or tabular form. Several arbitrary non-overlapping intervals are established, the number of intervals is based on the range and units of measure of the data, and the number of measurements falling within each interval are recorded or plotted in sequence. The resulting plot or table describes the frequency distribution.

Lognormal Distribution

If the logarithms (to any base) of a set of measurements are distributed according to the normal distribution, the original measurements, prior to the logarithmic transformation, are said to follow a lognormal distribution. A lognormal frequency distribution typically has a long narrow tail and is often used to describe sets of environmental data such as ground-water concentration measurements.

Mean

The most common mean is the arithmetic mean, which refers to the center or average of a set of measurements. The arithmetic mean is defined as equal to the sum of all the observations divided by the number of observations.

Non-Normal Distribution

A non-normal distribution refers to any of the many distributions other than the normal distribution. The lognormal and exponential are examples of non-normal distributions. Many parametric statistical procedures require that the data be selected from a population following a normal distribution.

Nonparametric

Refers to statistical procedures which do not necessitate the use of as many assumptions, for example, that the data be selected from a specific distribution, as an equivalent parametric statistical procedure. Nonparametric tests are often called distribution-free tests.

Normal Distribution

A widely used, continuous frequency distribution that approximates a symmetrical bell-shaped curve in appearance. Parametric statistical procedures often require that data approximate a normal distribution.

Parametric

The mean and variance of an normal distribution are examples of parameters. Parametric statistical procedures rely on estimates of the mean and variance and often assume that the data were selected from a population which follows a normal distribution.

Power

The power of the statistical procedures used in detection and compliance monitoring is the probability that contamination will be detected (rejection of the null hypothesis of no contamination) by the statistical procedure when contamination is really present. For a given sampling protocol, the power is greatest when the downgradient concentrations are much larger than background and the power is least when downgradient concentrations are only slightly larger than background. The concept of power does not apply when downgradient concentrations are less than or equal to background concentrations.

Practical Quantification Limits (pql's)

The lowest concentration level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions.

Robust

A testing procedure is robust in the sense that small or moderate departures from the assumptions required for a test, such as normality or constant variance, do not markedly affect its performance.

Seasonal Variation

A series of ground-water measurements collected over time exhibit seasonal variation when the measurements vary across sampling events in a periodic or cyclical fashion that can be explained by seasonal effects such as the annual cycle of ground-water recharge.

Spatial Variation

The variation among a group of measurements from samples obtained at the same time from different horizontal or vertical locations.

Standard Deviation

A measure of the dispersion, spread or deviation of a set of observations around the mean. It is the positive square root to the variance and is expressed in the same units of measure as the original observations.

t-Statistic

A statistic calculated on the basis of the t-distribution. The shape of the curve for a t-distribution changes with the number of observations in the sample that are used to estimate the sample populations. As the number of observations in the sample approach infinity, the t-distribution becomes identical to the normal distribution.

Temporal Variation

The variation among a series of measurements from samples obtained at the same location but over time.

Variance

A measure of the dispersion, spread, deviation or variability of a set of observations around the mean. The sum of the squared deviations of the observations from the arithmetic mean divided by one less than the total number of observations.

VIII. 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 of 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). States that have been granted

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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.

The Agency has determined that today's regulation is not a major rule because it does not meet the above criteria. Today's action should produce a net decrease in the cost of ground-water monitoring at each facility. This final rule has been submitted to the Office of Management and Budget (OMB) for review in accordance with Executive Order 12291. OMB has concurred with this final rule.

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 (e.g., 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 final rule will have no adverse impacts on businesses of any size. Accordingly, I hereby certify that this regulation will not have a significant economic impact on a substantial number of small entities. This final rule, 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: September 28, 1988.

Lee M. Thomas,

Administrator.

Therefore, 40 CFR Chapter I is 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 a 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(f);

(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), redesignating and revising (g)(3) as (a)(1)(i), adding (a)(3), revising paragraphs (g) and (h), and adding (i) and (j), 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 hydraulically upgradient of the waste management area where:

(A) Hydrogeologic conditions do not allow the owner or operator to determine what wells are hydraulically 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) Allow for the detection of contamination when hazardous waste or hazardous constituents have migrated from the waste management area to the uppermost aquifer.

* * * * *

(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 number and kinds of samples collected to establish background shall be appropriate for the form of statistical test employed, following generally accepted statistical principles. The sample size shall be as large as necessary to ensure with reasonable confidence that a contaminant release to ground water from a facility will be detected. The owner or operator will determine an appropriate sampling procedure and interval for each hazardous constituent listed in the facility permit which shall be specified in the unit permit upon approval by the Regional Administrator. This sampling procedure shall be:

(1) A sequence of at least four samples, taken at an interval that assures, to the greatest extent technically feasible, that an independent sample is obtained, by reference to the uppermost aquifer's effective porosity, hydraulic conductivity, and hydraulic gradient, and the fate and transport

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characteristics of the potential contaminants, or

(2) an alternate sampling procedure proposed by the owner or operator and approved by the Regional Administrator.

(h) The owner or operator will specify one of the following statistical methods to be used in evaluating ground-water monitoring data for each hazardous constituent which, upon approval by the Regional Administrator, will be specified in the unit permit. The statistical test chosen shall be conducted separately for each hazardous constituent in each well. Where practical quantification limits (pql's) are used in any of the following statistical procedures to comply with § 264.97(i)(5), the pql must be proposed by the owner or operator and approved by the Regional Administrator. Use of any of the following statistical methods must be protective of human health and the environment and must comply with the performance standards outlined in paragraph (i) of this section.

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

(3) A tolerance or prediction interval procedure in which an interval for each constituent is established from the distribution of the background data, and the level of each constituent in each compliance 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 method submitted by the owner or operator and approved by the Regional Administrator.

(i) Any statistical method chosen under § 264.97(h) for specification in the unit permit shall comply with the following performance standards, as appropriate:

(1) The statistical method used to evaluate ground-water monitoring data shall be appropriate for the distribution of chemical parameters or hazardous constituents. If the distribution of the chemical parameters or hazardous constituents is shown by the owner or operator to be inappropriate for a normal theory test, then the data should be transformed or a distribution-free theory test should be used. If the distributions for the constituents differ, more than one statistical method may be needed.

(2) If an individual well comparison procedure is used to compare an individual compliance well constituent concentration with background constituent concentrations or a ground-water protection standard, the test shall be done at a Type I error level no less than 0.01 for each testing period. If a multiple comparisons procedure is used, the Type I experimentwise error rate for each testing period shall be no less than 0.05; however, the Type I error of no less than 0.01 for individual well comparisons must be maintained. This performance standard does not apply to tolerance intervals, prediction intervals or control charts.

(3) If a control chart approach is used to evaluate ground-water monitoring data, the specific type of control chart and its associated parameter values shall be proposed by the owner or operator and approved by the Regional Administrator if he or she finds it to be protective of human health and the environment.

(4) If a tolerance interval or a prediction interval is used to evaluate groundwater monitoring data, the levels of confidence and, for tolerance intervals, the percentage of the population that the interval must contain, shall be proposed by the owner or operator and approved by the Regional Administrator if he or she finds these parameters to be protective of human health and the environment. These parameters will be determined after considering the number of samples in the background data base, the data distribution, and the range of the concentration values for each constituent of concern.

(5) The statistical method shall account for data below the limit of detection with one or more statistical procedures that are protective of human health and the environment. Any practical quantification limit (pql) approved by the Regional Administrator under § 264.97(h) that is used in the statistical method shall be the lowest concentration level tha can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions that are available to the facility.

(6) If necessary, the statistical method shall include procedures to control or correct for seasonal and spatial variability as well as temporal correlation in the data.

(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.

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 chemical parameter and hazardous constituent specified in the permit pursuant to paragraph (a) of this section 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).

(d) The Regional Administrator will specify the frequencies for collecting samples and conducting statistical tests to determine whether there is statistically significant evidence of contamination for any parameter or hazardous constituent specified in the permit under paragraph (a) of this section in accordance with § 264.97(g). A sequence of at least four samples from each well (background and compliance wells) must be collected at least semi-annually during detection monitoring.

* * * * *

(f) The owner or operator must determine whether there is statistically significant evidence of contamination for any chemical parameter of hazardous 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 method(s) specified in the permit under § 264.97(h). These method(s) must compare data collected at the compliance point(s) to the background ground-water quality data.

(2) The owner or operator must determine whether there is statistically significant evidence of contamination at each monitoring well as 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

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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 chemical parameters or hazardous constituents specified pursuant to paragraph (a) of this section at any monitoring well at the compliance point, he or she must:

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

(2) Immediately sample the ground water in all monitoring wells and determine whether constituents in the list of Appendix IX of Part 264 are present, and if so, in what concentration.

(3) For any Appendix IX compounds found in the analysis pursuant to paragraph (g)(2) of this section, the owner or operator may resample within one month and repeat the 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 the owner or operator does not resample for the compounds found pursuant to paragraph (g)(2) of this section, the hazardous constituents found during this 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 or 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 methods 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 an alternate concentration limit under § 264.94(b); and

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

(i) All data necessary to justify an alternate concentration limit sought under § 264.94(b); and

(ii) An engineering feasibility plan for a corrective action program necessary to meet the requirement 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 an alternate concentration limit 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 chemical parameters or hazardous constituents specified pursuant to paragraph (a) of this section at any monitoring well at the compliance point, he or she may demonstrate that a source other than a regulated unit caused the contamination or that the detection is an artifact caused by an error in sampling, analysis, or statistical evaluation or natural variation in the ground water. The owner operator may make a demonstration under this paragraph in addition to, or in lieu of, submitting a permit modification application under paragraph (g)(4) of this section; however, the owner or operator is not relieved of the requirement to submit a permit modification application within the time specified in paragraph (g)(4) 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 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 or she 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 procedures and statistical methods appropriate for the constituents and the facility, consistent with § 264.97 (g) and (h).

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

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

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

(1) In determining whether statistically significant evidence of increased contamination exists, the owner or operator must use the method(s) specified in the permit under § 264.97(h). The methods(s) 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

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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 collecting samples and conducting statistical tests to determine statistically significant evidence of increased contamination in accordance with § 264.97(g). A sequence of at least four samples from each well (background and compliance wells) must be collected at least semi-annually during the compliance period of the facility.

(g) The owner or operator must analyze samples from all monitoring wells at the compliance point 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 and, if so, at what concentration, pursuant to procedures in § 264.98(f). If the owner or operator finds Appendix IX constituents in the ground water that are not already identified in the permit as monitoring constituents, 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 the completion of the second analysis and add them to the monitoring list. If the owner or operator chooses not to resample, then he or she must report the concentrations of these additional constituents to the Regional Administrator within seven days after completion of the intiial 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 or she 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 or she may demonstrate that a source other than a regulated unit caused the contamination or that the detection is an artifact caused by an error in sampling, analysis, or statistical evaluation or natural variation in the ground water. In making a demonstration under this paragraph, the owner or operator must:

* * * * *

[FR Doc. 88-22913 Filed 10-7-88; 8:45 am]

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