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A Statistician's View of the U.S. Primary Drinking Water Regulation on Coliform Contamination

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The new U.S. regulation for monitoring possible coliform contamination of drinking water is based on a presence–absence assay, in contrast to the previous regulation that was based on coliform density assays. A water is said to be in compliance if the fraction of 100-mL sample volumes that contain coliforms is judged to be less than 0.05. The rule is designed to allow only a small chance that the water will pass the test when, in fact, the fraction is greater than the so-called "protection reliability standard" of 0.10. Statistical analysis of the compliance criterion shows that the false pass rate is higher than intended and/or the protection reliability standard is higher than intended, and the false fail rate can be as high as 0.5. For purposes of comparison with the previous regulation, the new criteria are converted into corresponding coliform density values.

Introduction

In 1989, the U.S. Environmental Protection Agency (EPA) published new regulations for monitoring drinking water for total coliform contamination (*1*). Coliforms make up one of 83 types of contamination for which the EPA is required to promulgate National Primary Drinking Water Regulations under the 1986 amendments to the Safe Drinking Water Act. The new regulations were the result of extensive study, including comments from the public. Under the new rules, 100-mL samples are drawn in a specified manner from a drinking water system, and each sample is assayed for coliform presence. If coliforms are present in a small percentage of the samples (usually 5% or less, except for systems that serve few people), then the water system is in compliance. The *Federal Register* (*1*) contains a complete description of the monitoring protocol and compliance rules.

The purposes of this paper are to (i) define and discuss statistical characteristics useful in providing a practical interpretation of the new compliance rules, (ii) furnish exact values for quantities that are calculated only approximately in documents cited by the EPA in its discussion of the new regulations, (iii) bring attention to the exact calculations of Borup (*2*), and (iv) show the relationship between the new criterion, based on the percentage of samples in which coliforms are present, and the previous criterion, based on the density of organisms.

Statistical Foundations

The EPA views the water volume in a distribution system as being partitioned into a large number of 100-mL volumes. In each of those 100-mL volumes, coliforms are either present or absent. Let P denote the (conceptual, unknown) proportion of the 100-mL volumes where coliforms are present; P is the fraction of water contaminated. Let n denote the number of 100-mL volumes to be sampled, and let X be a random variable denoting the number of the sampled volumes containing coliforms. The potential values for X are 0, 1, 2, ..., n. Finally, let $p = X/n$ denote the estimator of P based on the random sample. If p is a reliable estimator of P, then a small observed p indicates that P is small enough for the system to be in compliance. The estimator p becomes more reliable as n increases. Statistical analyses can determine how large n must be for p to attain some specified reliability.

Borup (*2*) has summarized those aspects of the regulations that are important to this statistical discussion. He lists the assumptions upon which the EPA's statistical calculations are based. Under those assumptions, the random variable X follows a binomial probability distribution with mean $n \cdot P$ (*3*).

Maximum Contaminant Level

The regulations establish a maximum contaminant level goal of $P = 0$; i.e., no coliforms in the system. The justification is that "conceptually, coliforms should not be present in drinking water, because they may indicate the presence of pathogenic organisms in the water" (*1*). If the maximum contaminant level goal were strictly used as a criterion, the compliance rule would be violated any time $p > 0$; i.e., any time one or more sample(s) contain coliforms. The compliance rules are not this strict. According to the regulations, if all 100-mL portions of the system were tested and 5% or fewer contained coliforms, then the system would be in compliance. As is pointed out in Borup (*2*), this compliance rule implies a *de facto* criterion of $P \leq 0.05$. For the statistical calculations of this article, I will assume the criterion for a water to be in compliance is $P \leq 0.05$.

One might reasonably ask "Is $P = 0.051$ enough larger than the criterion 0.05 to be of practical importance?" and "If 0.051 is not significantly above 0.05 in a practical sense, what value is?". Contemplation of such issues led the EPA to determine that the value $P = 0.1$ deserved special attention: "The expert panel recommended this level, at which at least 90 percent of the water is coliform-free, be accepted as a 'protection reliability standard'" (*4*). Let P_0 denote the largest value of P consistent with compliance, and let P_1 denote the smallest noncompliant value of practical importance. The protection reliability standard equals $100(1 - P_1)\%$. For the new monitoring regulations, $P_0 = 0.05$ and $P_1 = 0.1$.

Error Rates for Compliance Rule

Because of chance events in the sampling process, it is possible that many of the n sampled 100-mL portions could be completely free of coliforms, even if P is not small. It is also possible that many of the samples could contain coliforms, even if P is small. Although such misleading samples are improbable, they prevent the compliance rule

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from being perfect. It is of interest to determine (i) the chance that the compliance rule will incorrectly claim a violation for a water having $P = P_0 = 0.05$ and (ii) the chance that the compliance rule will incorrectly claim compliance for a water having $P = P_1 = 0.1$. The former error rate is the **false fail rate**, denoted by R_{ff}; the latter error rate is the **false pass rate**, denoted by R_{fp}. It is important for producers and consumers to know the error rates attached to the compliance rule. If the false pass rate is large, then the compliance rule often fails to discover coliform contamination. If the false fail rate is large, then the compliance rule is expensive to implement because producers may expend time and resources mistakenly doing repeat monitoring of water that actually is already in compliance.

Although the new compliance rules do not mention false pass and false fail rates, the rules implicitly establish a false pass rate of 0.05. The basis for this claim is the stated justification for requiring $n \geq 60$: "The primary reason for requiring a contaminated small system to collect at least 10 samples during a two-month period is based on the statistical analysis described in the November 3, 1987, notice which indicates that, for example, if 60 or more samples are collected and 95 percent or more are total coliform-negative, there is 95 percent confidence that the fraction of water with coliforms present is less than 10 percent" (*1*). The reasoning is clearly based on confidence intervals, and the confidence percentage provides an alternative way to view the false pass rate, R_{fp}. The quoted confidence statement can be rewritten using notation: "If $n = 60$, observed $p = 0.05$, and the upper, one-sided confidence interval end point for P is P_1 (=0.1), then the confidence level for that interval is $100(1 - R_{fp})\%$". An approximate confidence level of 95% is equivalent to setting R_{fp} to an approximate value of 0.05. Apparently, the regulations are designed for an upper bound of 5% on the false pass rate; i.e., to require that $R_{fp} \leq 0.05$. (The reasoning is clear, but the value of 0.05 used when writing the regulations is inaccurate. As is discussed below, the exact R_{fp} actually is 0.137 for $n = 60$ and observed $p = 0.05$.)

Exact versus Approximate Statistical Calculations

When formulating the new regulations, the EPA relied on approximate statistical calculations. A Student's t probability distribution was used to approximate binomial probabilities. Such an approximation is valid if n is large and P is not small. Statisticians (*5*) do not advocate the use of the approximation when $n{\cdot}P < 5$, as is the case, for example, when $n = 60$, $P = 0.05$, and $n{\cdot}P = 3$. In any case, approximations are not necessary, because the exact calculations can easily be done using a computer.

Table 1 reproduces a portion of the table shown in the Appendix of the November 3, 1987, *Federal Register* notice (*4*), with an extra column added to show the exact values. Let L_u denote the 95% upper, one-sided confidence limit for P. (For such one-sided confidence intervals, the lower limit is zero.) An exact upper limit was found by solving the following equation for L_u:

$$\sum_{k=0}^{X} \binom{60}{k} L_u^{\,k} (1 - L_u)^{n-k} = 0.05 \qquad (1)$$

The solution to eq 1 can be found by iteration on a computer or by using tables of the F distribution (*6*). Based on the approximate upper limit recommended by the EPA (*1*), it appears that $X = 3$ samples containing coliforms among $n = 60$ samples leads to an L_u no larger than $P_1 = 0.1$. It turns out, however, that the exact L_u is 0.124. If the number of samples with coliforms present is only $X = 2$, the exact L_u is 0.101, only slightly above P_1. In order to adhere to a 90% protection reliability standard and a false pass rate of $R_{fp} = 0.05$, the compliance rule should be *2 or fewer* of 60 samples with coliforms present. The established compliance rule, which allows *3 or fewer* of 60 samples to have coliforms present, has an exact protection reliability standard of only 86.6%, which corresponds to a *de facto* P_1 of 0.134.

Consider the approximate L_u values cited in the official notices (Table 7 of ref 7) where a t-distribution calculation was used to approximate the L_u associated with each of many selected n and X combinations. For a representative subset of the same n and X combinations, Table 2 shows the exact 95% upper confidence limits. Table 2 can be used to find the associated protection reliability standard, which is $100(1 - L_u)\%$. For example, if the compliance rule were 3 or fewer coliform-positive samples out of 50 samples and the false pass rate is set at 0.05, then the associated protection reliability standard would be 85.2%.

Table 1. Upper 95% Confidence Limit (Approximate and Exact) for Fraction of Water Contaminated when X of n = 60 Samples Show Coliforms Present[a]

no. of samples positive (X)	% positive 100 (X/60)	approx $L_u^{\dagger}$	exact $L_u^{\ddagger}$
0	0.0	NC	0.049
1	1.7	NC	0.077
2	3.3	0.072	0.101
3	5.0	0.097	0.124
4	6.7	0.121	0.146
5	8.3	0.143	0.167
6	10.0	0.165	0.188
7	11.7	0.186	0.201
8	13.3	0.206	0.228

[a] The abbreviations used in this table are as follows: L_u, upper, one-sided 95% confidence limit for P; $L_u^{\dagger}$, approximate value of L_u given in ref 1; $L_u^{\ddagger}$, exact value of L_u given by eq 1; NC, not calculated.

Table 2. Upper 95% Confidence Limit (Approximate and Exact) for Fraction of Water Contaminated when X of n Samples Show Coliforms Present[a]

n	X	approx $L_u^{\dagger}$	exact $L_u^{\ddagger}$	r_{fp}	X	aprox $L_u^{\dagger}$	exact $L_u^{\ddagger}$	r_{fp}
32	1	0.140	0.140	0.050	2	0.181	0.184	0.054
34	1	0.131	0.132	0.052	2	0.167	0.174	0.061
36	1	0.121	0.125	0.057	2	0.155	0.165	0.067
38	1	0.111	0.119	0.066	2	0.143	0.157	0.076
40	1	0.103	0.113	0.072	2	0.131	0.149	0.090
42	1	0.095	0.108	0.082	2	0.123	0.142	0.096
44	1	0.087	0.103	0.095	2	0.115	0.136	0.105
46	1	0.079	0.099	0.112	2	0.109	0.131	0.109
48	1	0.071	0.095	0.136	2	0.103	0.125	0.116
50	2	0.097	0.121	0.125	3	0.117	0.148	0.148
52	2	0.091	0.116	0.136	3	0.113	0.142	0.147
54	2	0.085	0.112	0.152	3	0.109	0.137	0.146
56	2	0.080	0.108	0.164	3	0.105	0.133	0.147
58	2	0.076	0.105	0.173	3	0.101	0.128	0.150
60	3	0.098	0.124	0.148	4	0.121	0.146	0.134

[a] The nominal false pass rate is $R_{fp} = 0.05$. The abbreviations used in this table are as follow: L_u, upper, one-sided 95% confidence limit for P; $L_u^{\dagger}$, approximate value of L_u given in ref (*1*); $L_u^{\ddagger}$, exact value of L_u given by eq 1 (for which the associated false pass rate is $R_{fp} = 0.05$); r_{fp}, false pass rate for the approximate value $L_u^{\dagger}$.

The calculations for Table 2 fix the false pass rate at 0.05 and show the discrepancies between the approximate and exact confidence interval end points. If one used the approximate end point to set the protection reliability standard, however, then the exact false pass rate is different from 0.05. Table 2 also shows how much the exact false pass rate differs from 0.05 if the protection reliability standard were held to the value associated with the approximate L_u. The calculations amounted to finding what confidence coefficient can really be attached to each approximate confidence limit. As an example, consider a compliance rule of 3 or fewer coliform-present samples out of 50 samples. Suppose we want a protection reliability standard of 88.3%, which is 100[1 − 0.117]%, 0.117 being the approximate L_u. Then the actual false pass rate is 0.148.

Tables 1 and 2 suggest that (i) the protection reliability standard can be lower than the 90% intended and/or (ii) the true false pass rate for the new compliance rule can be substantially higher than the 0.05 intended.

Coliform Density Calculations

Those who are experienced in measuring coliform densities may be curious about the relationship of the new criteria to density values. I have tried two approaches for converting the present criteria for compliance ($P_0 = 0.05$; $P_1 = 0.1$) into corresponding coliform densities. The results are densities between 0.05 and 0.42 coliform/100 mL. The first approach is based on the assumptions (*8*) underlying the most probable number (MPN) method. Let the random variable C be the number of coliforms in a 100-mL sample. The possible values of C are the nonnegative integers, 0, 1, 2, ... Let λ denote the true density (coliforms/100 mL) in the water. Under the usual assumptions, C follows a Poisson probability distribution (*3*); that is, the probability that c is the realized value of C is given by

$$\text{prob}[C = c] = (\lambda^c e^{-\lambda})/c! \qquad (2)$$

The Poisson distribution has long been the conventional model for describing the number of bacteria in samples from drinking water systems. Equation 2 yields prob[$C = 0$] = $e^{-\lambda}$. Now prob[$C = 0$] is the fraction of water that is uncontaminated; i.e., $1 - P$. Setting $1 - P = e^{-\lambda}$ and solving for λ, we find $\lambda = -\log_e (1 - P)$. This equation yields $\lambda = 0.051$ when $P = P_0 = 0.05$, and $\lambda = 0.105$ when $P = P_1 = 0.1$. Based on this reasoning, the presence–absence compliance criterion is equivalent to a coliform density of 0.051 coliform/100 mL. The 90% protection reliability standard is equivalent to a density of 0.105 coliform/100 mL.

Research cited in the EPA notices (*4, 1*) demonstrated that the random variable C could follow a negative binomial probability distribution rather than the Poisson probability distribution (*9*). The Poisson distribution may not provide the most accurate basis for converting the criterion value P into a corresponding density of coliforms. Nevertheless, an MPN analysis based on the Poisson model was an approved technique under the old regulations, and it is instructive to use the Poisson model when relating coliform density values to the new criterion.

The second approach is to use the results of Christian and Pipes (*9*) and base the calculations on the negative binomial distribution. The mathematics are more complicated than for the Poisson model because, in addition to the density parameter λ, the negative binomial distribution depends on an excess variance parameter denoted by δ. For the negative binomial distribution, the random variable C has mean λ and variance $\lambda(1 + \delta\lambda)$. The formula for the well-known negative binomial probability function (*3*) is

$$\text{prob}[C = c] = \frac{\Gamma(c + \delta^{-1})}{c!\Gamma(\delta^{-1})}\left(\frac{\delta\lambda}{1 + \delta\lambda}\right)^c\left(\frac{1}{1 + \delta\lambda}\right)^{1/\delta} \qquad (3)$$

An interesting property of eq 3 is that it becomes exactly the Poisson probability distribution of eq 2 when δ approaches zero. According to eq 3, prob[$C = 0$] = $[1/(1 + \delta\lambda)]^{1/\delta}$. Setting prob[$C = 0$] = $1 - P$ and solving for λ, we find $\lambda = [(1 - P)^{-\delta} - 1]/\delta$.

In order to convert the criterion value for P into a corresponding coliform density value, the excess variance parameter δ must be specified. Christian and Pipes (*9*) have intensively sampled small water distribution systems to observe the density of coliforms (count per 100 mL). I have calculated the method-of-moments estimate of δ for each of the 15 data sets presented by Christian and Pipes. The median of those 15 δ values is 22. For $\delta = 22$, the coliform density is $\lambda = 0.10$ when $P = P_0 = 0.05$ and $\lambda = 0.42$ when $P = P_1 = 0.1$. In summary, calculations based on the negative binomial distribution and a typical excess variance parameter of 22 show that the presence–absence compliance criterion is equivalent to a coliform density of 0.1 coliform/100 mL. The 90% protection reliability standard is equivalent to a density of 0.42 coliform/100 mL.

Discussion

It seems logical to use the following strategy when creating monitoring regulations. The regulatory authority (i) specifies a compliance criterion in terms of a maximum contaminant level (e.g., $P_0 = 0.05$), (ii) specifies a protection reliability standard (e.g., $P_1 = 0.1$), (iii) defines a compliance rule (e.g., take 60 samples and claim compliance if 5% or fewer contain coliforms), and (iv) calculates the false pass and false fail rates attached to that protocol (e.g., $R_{fp} = 0.13$ and $R_{ff} = 0.50$). The regulations then hinge on a few easily interpretable quantities: the criteria, the number of samples, and the two error rates. These quantities can be embedded in a cost–benefit analysis of proposed regulatory changes.

The new regulations have some interesting properties. They are designed for a compliance criterion of $P_0 = 0.05$ and a protection reliability standard of 90%. They are flawed by some inaccuracies; e.g., when 60 samples are taken, the compliance rule should be $X \leq 2$ (2 or fewer with coliforms present). For $n = 60$ samples, using the official compliance rule of $X \leq 3$, the false pass rate is 13.7% and the false fail rate is 35%. For a large number of samples ($n > 200$), the compliance rules lead to a false pass rate less than 1% and a false fail rate between 40% and 50%. [The preceding rates were found using a computer program for the binomial distribution; alternatively, they can be read from the graphs published by Borup (*2*).]

One disconcerting aspect of the new rules is that as the number of routine samples increases, the false pass rate approaches zero and the false fail rate stays near 0.5. Because the new rules imply that a true P between 0.05

and 0.1 represents minor contamination of no practical significance, it seems reasonable to relax the protocol when n is large so that compliance can be achieved even if more than 5% of the observed samples have coliforms present. It would then be possible to maintain a low R_{fp} while reducing R_{ff}. For example, suppose the water is sampled daily so that over a 1-year period $n = 365$ samples are taken. The exact error rates are $R_{fp} = 0.028$ and $R_{ff} = 0.046$ for the protocol that claims compliance if and only if no more than 25 (6.8%) of the 365 samples contain coliforms. Similar examples are shown in Borup (*2*).

The error rate calculations assume that the number of positive samples follows the binomial distribution, the same assumptions used by all others who have studied these issues. The error rates calculated in this manner shed the best possible light on the compliance rule. The calculations ignore inherent uncertainties (such as due to the sampling mechanisms, storage, transport, etc.). The calculations ignore the possibility that the microbial assay method is not perfect; e.g., it might not always detect coliforms that are present (*10*). If there are uncertainties due to sources other than the random sampling, then the correct error rates are higher than the values discussed in this article. Borup (*2*) listed reasons why the binomial probability model might not always be appropriate for drinking water systems.

The statistical calculations emphasized in this paper are based also on the assumption that the number of samples n is fixed. The new regulations require repeat monitoring when one or more samples have coliforms present. This means that the total number of samples is a random variable. The minimum and maximum number of samples are known, but the actual number depends on what happens during monitoring. It appears that only fixed sample size calculations were conducted when the protocol was being developed. Borup (*2*), however, calculated probabilities in a way that took into account the sequential decision process imbedded in the monitoring protocol.

There are other statistical aspects that could be investigated but are beyond the purposes of this paper. One example is that, for any specified value for P, it is possible to calculate the average number of days before monitoring first uncovers a violation. If $P = P_0$, that average should be high, and if $P = P_1$, that average should be low. Instead of just the average, one could derive the whole probability distribution of the waiting time until a violation occurs.

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Nomenclature

C	number of coliforms in a 100-mL sample
L_u	95% upper, one-sided confidence end point for P
n	number of sampled 100-mL volumes
P	true (unknown) fraction of water contaminated
P_0	largest value of P consistent with compliance
P_1	smallest noncompliant value of practical importance; the protection reliability standard equals $100(1 - P_1)\%$
p	X/n, the estimator of P
R_{ff}	false fail rate
R_{fp}	false pass rate
X	number of the sampled volumes that contain coliforms
δ	excess variance parameter of the negative binomial distribution
λ	true coliform density (mean number of coliforms/100 mL)

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