Texas Natural Resource Conservation Commission INTEROFFICE MEMORANDUM

To. X	Remediation Division Staff	Date	August 9, 2001
From	Jacqueline Hardee, Director Remediation Division		
Subject:	Acceptability of using a statistically-derived background value as a cleanup standard when it exceeds a human health-based criteria under the 1993 Risk Reduction Rule		

## **Purpose:**

The background concentration of a contaminant may be used on a site-specific basis as the cleanup level under all three standards of the 1993 Risk Reduction Rule (Chapter 335). Under Standard 1, background serves as the cleanup level unless the practical quantitation limit exceeds background (§335.554(d)). For Standards 2 (§335.555(d)(1)) and 3 (§335.563(j)(1)), background may also be used as the final cleanup level in cases where the background concentration of a contaminant is greater than a health-based cleanup level (e.g., medium-specific concentration (MSC) under Standard 2), or federally promulgated standard (e.g., MCL). However, while the rule states that background samples must be collected from areas unaffected by waste management or industrial activities, it does not specify the statistic that should be used to represent background. This memorandum is, therefore, intended to provide clarification on the process that a TNRCC project manager should follow to ensure that considerations for site-specific background are appropriately incorporated in remedial decisions under Chapter 335.

## **Background Considerations:**

In some cases, site-specific background concentrations can be high enough to exceed a health-based cleanup level. For example, the health-based soil MSC for a metal may fall within the natural distribution of that metal for a given soil type. In these situations, the rule allows a responsible party to remediate to the background level rather than requiring that they pursue a health-based level that may not be achievable even in the absence of the facility operations.

Although the need to consider site-specific background is clear, the difficulty lies in attempting to label a specific concentration as "background", since background is inherently a distribution of concentrations. Responsible parties typically prefer to use an upper-end statistic, such as the 95% upper tolerance limit (95% UTL), to represent background. While certain EPA guidance documents have described specific situations where the 95% UTL may be useful (e.g., identifying whether a release from a unit has occurred), these documents do not state that this statistic should be used as a basis for a background-based media cleanup level. The 95% UTL represents the upper limit of an interval that is intended to contain the 95<sup>th</sup> percentile of a background distribution with 95% confidence. In practice, the 95% UTL can be at or above the maximum measured value in a set of background samples, and it is not at all representative of typical background. This is especially true when extreme values are present within a background data set, as evidenced by the following example:

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Example 1: Eight background soil samples are analyzed for lead, with the following sampling results in parts per million (50, 100, 125, 200, 225, 250, 300, 700). Although the arithmetic mean is only 243 ppm, the presence of the one extreme sample results in a 95% UTL of 648 ppm. If accepted, this concentration would exceed the residential health-based soil MSC (500 ppm) and become the default soil cleanup level for lead at the site. Without the one extreme sample, the 95% UTL would drop to only 364 ppm.

In the above example, the sample that contained lead at 700 ppm may actually be a sample from a contaminated area, or a sample that is only representative of a very limited portion of the background sampling area (e.g., an isolated area where fill material is present). However, the presence of this single high background sample might be erroneously used to justify not remediating an entire site to a health-based level.

## Guidelines for Staff Review:

TNRCC project managers should observe the following general process in <u>approving</u> a site-specific background determination submitted under any of the three risk reduction standards of Chapter 335:

A determination as to whether background is being applied as a cleanup level for any contaminant should be made by the TNRCC project manager. The project manager is also responsible for making an initial determination as to whether all samples in the background data set are appropriately representative of site conditions (e.g., similar geology, depth, etc.).

Under any risk reduction standard, before a TNRCC project manager approves a cleanup level based on a background estimate that exceeds human health-based limits or Standard 2 MSCs (e.g, MCL, SAI-Res), they should consult with the Toxicology & Risk Assessment (TARA) Section. TARA will then coordinate further review with the Remedial Technical Support Section, the project manager, and other program area statistical experts. However, specific consultation with TARA is not necessary when a background value solely exceeds the soil-to-groundwater MSC (i.e., Standard 2 GWP-Res or GWP-Ind for Standard 1 or 2), or other alternative soil-to-groundwater cleanup level established under risk reduction standard 2 or 3 (as described in §335.559(f)(2) and §335.563(i)(2), respectively). In these situations, the program area should evaluate the potential for soil-to-groundwater contamination on a case-by-case basis in determining an appropriate value for use in representing background. This process should be followed regardless of the statistical approach employed, although the use of a 95% UTL or other upper-end statistic may increase the likelihood that background will exceed a health-based limit. In following this process, Standard 2 MSCs will essentially serve as indicators for when approaches for defining background should be more carefully examined.

In determining whether there is sufficient evidence to warrant basing a final cleanup level on background when background exceeds a health-based limit or MSC, the agency will maintain

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> a high bar. Those designated TNRCC staff will scrutinize the submittal by (1) verifying that the assumptions of the statistical approach used to develop background have been adequately met, (2) conferring with the TNRCC project manager to ensure that the samples were collected from an appropriate location, (3) evaluating the presence of potential outliers, and (4) ensuring that the proposed background value can be practically defended by the agency as a valid rationale for not restoring soil, water and other media to health-based criteria. It is anticipated that there will be situations where a specific background value has already been applied at a site for investigation purposes. Due to the complexities and site-specific nature of these issues, a determination on how to address potential differences between a background estimate approved for investigation purposes and a background estimate used to establish the final cleanup level at a site will be handled on a case-by-case basis.

The project manager should be aware that other aspects of the remedial process may be affected by the statistical estimate of background that is employed. For instance, if a 95% UTL is the basis for a soil cleanup level, it would be inappropriate to average concentrations across an affected property and compare that average with the cleanup level. Rather, as the 95% UTL approximates the upper-end of the background distribution, all soil samples at an affected property would need to be individually compared to the cleanup level.

Through this process, it is anticipated that TNRCC will be able to maintain consistency and defensibility in applying background as a cleanup level when warranted by site-specific conditions.