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APPENDICES

APPENDIX 33

**Notes for the Validation of Semivolatile Organic Data
Generated by SW-846 Method 8270C**

1.0 OBJECTIVES

This standard operating procedure (SOP) describes procedures that Environmental Standards data reviewers will use to validate semivolatile organic data generated by SW-846 Method 8270C for the General Electric Company's Hudson River Design Support Sediment Sampling and Analysis Program. Validation will be performed to assess the compliance of the sample data to SW-846 Method 8270C and/or other reference documents (*e.g.*, analytical SOPs), as applicable to the General Electric Company's Hudson River Design Support Sediment Sampling and Analysis Program. In addition, the usability of the semivolatile organic data provided by the analytical laboratories will be determined based on the general guidance provided in the "US EPA Contract Laboratory Program National Functional Guidelines for Organic Data Review" (10/99; National Functional Guidelines). It should be noted that the National Functional Guidelines apply strictly to data generated by Contract Laboratory Program (CLP) protocol and it is not directly applicable to validation of data generated by SW-846 Method 8270C; this SOP presents the specific data qualification actions that will be used for validation.

The validation findings will be presented in a quality assurance review (QAR) that will be prepared for one or more sample delivery groups (SDGs). Copies of annotated analytical results summaries (Form I's), including any changes to the analytical results and data qualifier codes, or a data summary spreadsheet of the qualified analytical results will be included in the analytical results section of the QAR.

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2.0 EVALUATION TOOLS

Excel forms available in R:/Templates/Chemistry/XCELforms:

- Organic field duplicate comparison Rev 1-01.xls
- Organic field quadruplicate comparison Rev 1-01.xls
- Organic field triplicate comparison Rev 1-01.xls

Chemistry Applications:

- FIT
- Mass Spec Database
- Methods Database
- Target Version 4.1 data processing software

3.0 REFERENCE DOCUMENTS

- US EPA Contract Laboratory Program National Functional Guidelines for Organic Data Review (10/99).
- SW-846 Method 8270C.

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- Region I, EPA – New England Data Validation Functional Guidelines for Evaluating Environmental Analyses (12/96).
- Region II, EPA – SOP for Data Validation for SW-846 Method 8270C.
- Region III – Modifications to National Functional Guidelines for Organic Data Review (9/94).

4.0 PROCEDURE

4.1 EVALUATION OF METHOD COMPLIANCE

The data reviewer will assess the method compliance of the semivolatile data based on evaluation of information presented in the data package deliverables. Compliance with SW-846 Method 8270C and/or other reference documents (*e.g.*, analytical SOPs or QAPjPs) as applicable to General Electric Company's Hudson River Design Support Sediment Sampling and Analysis Program (as directed by the Project Manager) will be evaluated as part of the assessment. In addition, the deliverables will be evaluated for reporting errors and inconsistencies. The findings of the method compliance assessment will be described in terms of deficiencies and comments about the data/deliverables. The deficiencies/comments will be presented in three subdivisions (*i.e.*, correctable deficiencies, noncorrectable deficiencies, and comments) of the Organic Data Evaluation Section of the QAR. Each deficiency and comment discussed in the QAR will indicate

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any subsequent impact on the usability of the data or will identify aspect(s) of the data that could not be evaluated due to the deficiency.

The data reviewer should contact the project laboratory(ies) to request the correction of deficiencies prior to submittal of the QAR (if feasible and sanctioned by General Electric Company). At a minimum, corrections required to allow for a full evaluation of the usability of the data should be requested. Such correctable deficiencies may include sample result errors, missing data deliverables, or calculation errors that would require a significant amount of the data reviewer's time to correct. Any laboratory resubmittals as a result of such requests will be discussed in the comments subsection of the QAR and will be included as an attachment to the QAR.

4.2 DETERMINATION OF DATA USABILITY

The data reviewer will determine the usability of the semivolatile organic data based on an evaluation of the information presented in the data package deliverables. The findings of the semivolatile organic data usability assessment will be presented in terms data qualifications that the project team should consider in order to best utilize the data; these qualifications will be presented in the Organic Data Qualifier subsection of the QAR. Each qualification will indicate that the affected sample result(s) has been flagged with a representative qualifier code(s) in the General Electric Company's database to provide, at a glance, an indication of the quantitative and qualitative reliability of each analytical result. In general, the qualifier statements will be presented in the QAR in the following

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order: blank qualification, common contaminants that were not qualified, unusable results (R/UR), tentative identifications of targets (N), estimated results (J/UJ), tentatively identified compounds (TICs), field duplicate comparison, and a general qualifier for all results reported below the quantitation limit (if applicable to General Electric Company's Hudson River Design Support Sediment Sampling and Analysis Program).

The data reviewer's criteria for evaluating the usability of the semivolatile organic data and the resulting qualifications will be as stated on the attached Table for the Validation of Semivolatile Organic Data Generated by SW-846 Method 8270C. It should be noted that the Project Manager should be consulted when the use of "professional judgement" is indicated on the attached table.

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**Notes for the Validation of Semivolatile Organic Data
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Quality Control Item	Usability Criteria	Action
Temperature Upon Receipt	4±2°C.	<p>If temperature is >6°C but ≤10°C, no action is required.</p> <p>If temperature is >10°C but ≤20°C, qualify positive results as estimated (“J”) and qualify “not-detected” results as estimated (“UJ”).</p> <p>If temperature is >20°C, qualify positive results as estimated (“J”) and qualify “not-detected” results unusable (“UR”).</p> <p>Note time of sample collection relative to receipt at laboratory; use professional judgment if < 8 hours has elapsed from collection to receipt to determine if the qualification for elevated temperature applies.</p>
Technical Holding Time	<p>Aqueous samples should be extracted within 7 days of sample collection.</p> <p>Solid/soil samples should be extracted within 14 days of sample collection.</p> <p>All matrices should be analyzed within 40 days after extraction.</p>	<p>If a holding time is exceeded, qualify positive results as estimated (“J”) and qualify “not-detected” results as estimated (“UJ”). If a holding time is grossly exceeded (<i>i.e.</i>, >twice the holding time), qualify positive results as estimated (“J”) and qualify “not-detected” results as unusable (“UR”).</p>
GC/MS Tuning (DFTPP) (See Note #1 for additional information.)	Ion abundances should meet the method acceptance criteria.	<p>If mass calibration was not performed, qualify all associated data as unusable (“R”/“UR”).</p> <p>If mass assignment is in error, qualify all associated data as unusable (“R”/“UR”).</p> <p>Use professional judgement if abundance criteria are not met. (See Note #1.)</p> <p>Use professional judgement if samples are analyzed more than 12 hours after a compliant tune and there is no evidence of a compliant tune following the samples.</p>

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**Notes for the Validation of Semivolatile Organic Data
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Quality Control Item	Usability Criteria	Action
Initial Calibration (See Note #2 for additional information.)	Average RRF for each compound should be ≥ 0.050 . %RSD should be $\leq 15\%$ or a calibration curve should be generated. If a curve is generated, r (linear) or coefficient of determination (COD; quadratic) should be ≥ 0.99 .	If a target compound has an average RRF < 0.050 , qualify positive results as estimated ("J") and qualify "not-detected" results as unusable ("UR"). Compounds with $15\% < \%RSD \leq 50\%$, qualify positive results as estimated ("J") and do not qualify "not-detected" results. Compounds with $50\% < \%RSD \leq 90\%$, qualify positive results as estimated ("J") and use professional judgement to qualify "not-detected" results. Compounds with $\%RSD > 90\%$, qualify positive results as estimated ("J") and qualify "not-detected" results as unusable ("UR"). Use professional judgment when evaluating correlation coefficients (r) and coefficients of determination (COD). If r (linear) or COD (quadratic) is < 0.99 but ≥ 0.85 , qualify positive results as estimated ("J") and do not qualify "not-detected" results. If r or COD is < 0.85 , qualify positive results as estimated ("J") and qualify "not-detected" results as unusable ("UR").
Continuing Calibration Verification (CCV) (See Note #3 for additional information.)	CCV RRFs for target compounds should be ≥ 0.050 . %drift or %difference should be $\leq 20\%$.	If target compounds have an RRF < 0.050 , qualify positive results as estimated ("J") and qualify "not-detected" results as unusable ("UR"). If target compounds have $20\% < \%D \leq 90\%$ with the response indicating a sensitivity decrease, qualify positive results as estimated ("J") and qualify "not-detected" results as estimated ("UJ"). If target compounds have $\%D > 20\%$ with a response indicating a sensitivity increase, qualify positive results as estimated ("J") and use professional judgement to qualify "not-detected" results. If target compounds have $\%D > 90\%$ with the response indicating a sensitivity decrease, qualify positive results as estimated ("J") and qualify "not-detected" results as unusable ("UR").

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Quality Control Item	Usability Criteria	Action
Internal Standards	<p>Area counts of the internal standard peaks should be 50-200% of the internal standard area observed in the associated CCV.</p> <p>Retention time (RT) of the internal standard should not vary more than ± 30 seconds from the RT of the internal standards observed in associated CCV standard.</p>	<p>If a sample area count is outside of the criteria (50-200% of associated CCV), qualify positive results for compounds quantitated using that internal standard as estimated (“J”) and qualify “not-detected” results for compounds quantitated using that internal standard as estimated (“UJ”).</p> <p>If extremely low sample area counts (<25%) are reported, qualify positive results for compounds quantitated using that internal standard as estimated (“J”) and qualify “not-detected” results for compounds quantitated using that internal standard as unusable (“UR”).</p> <p>If an internal standard RT varies by more than 30 seconds and no peaks are observed in the sample chromatogram, qualification of data is not necessary. Use professional judgment if peaks are observed in the sample chromatogram.</p>
Blanks (See Notes #4 and #10 for additional information)	Summarize all results greater than the method detection limit (MDL) in the blanks. The highest positive result associated with a sample should be utilized for evaluation of contamination.	<p>If a target compound is detected in the blank but not in the associated sample(s), no action is required.</p> <p>If a sample result is $\leq 5\times$ ($10\times$ for common contaminants) blank result, qualify the positive result as “not-detected” (“U*”).</p> <p>If the positive result qualified “U*” is $< RL$, the RL should be used as reported. If the positive result qualified “U” is $\geq RL$, the value of the positive result should be used as the revised RL.</p> <p>If a sample result is $> 5\times$ (or $10\times$) blank result, qualification is not required. If gross contamination exists (<i>i.e.</i>, saturated peaks by GC/MS), qualify the positive results as unusable (“R”) due to interference.</p> <p>If a TIC is observed in blank and sample or if the TIC is a known laboratory artifact, qualify as unusable (“R”) due to interference.</p>

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Quality Control Item	Usability Criteria	Action
Surrogate Recovery (See Note #5 for additional information.)	Use laboratory acceptance limits. Use default limits of 20-150% if laboratory limits are unreasonable.	<p>If the recoveries of one or more surrogate in either fraction (acid or base) are > upper limit, qualify positive results for that fraction as estimated (“J”) and do not qualify “not-detected” results.</p> <p>If the recoveries of one or more surrogate in either fraction (acid or base) are < lower limit but ≥10%, qualify positive results for that fraction as estimated (“J”) and qualify “not-detected” results as estimated (“UJ”).</p> <p>If the recoveries of one or more surrogate in either fraction (acid or base) are < 10%, qualify positive results for that fraction as estimated (“J”) and qualify “not-detected” results as unusable (“UR”).</p>

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Quality Control Item	Usability Criteria	Action
Matrix Spike/Matrix Spike Duplicate (MS/MSD)	Use 50-135% as recovery limits. For precision, use RPD limits of 20% for aqueous samples and 40% for solid samples.	<p>Data should not be qualified due to %Rs (or RPDs calculated on %Rs) that are outside of criteria if the original concentration of a compound is > 4× spiking level for that compound. RPDs calculated using MS/MSD results can be used to evaluate precision.</p> <p>If the recovery is > 135%, qualify the positive result in the native sample as estimated (“J”) and do not qualify the “not-detected” result.</p> <p>If the recovery is <50% but ≥10%, qualify the positive result in the native sample as estimated (“J”) and qualify the “not-detected” result in the native sample as estimated (“UJ”).</p> <p>If the recovery is <10%, qualify the positive result in the native sample as estimated (“J”) and qualify the “not-detected” result in the native samples as unusable (“UR”).</p> <p>If the precision exceeds the RPD criterion, qualify the positive result in the native sample as estimated (“J”) and do not qualify “not-detected” result.</p> <p>If the precision criteria (see field duplicate usability criteria) for non-spiked compounds are not met, qualify positive results in the native sample as estimated (“J”) and qualify “not-detected” results in the native sample as estimated (“UJ”).</p> <p>If a field duplicate of the native sample was collected and analyzed, the field duplicate should also be qualified if the MS/MSD %Rs or RPD are outside of the criteria (as stated above for the native sample).</p>

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Quality Control Item	Usability Criteria	Action
Laboratory Control Sample/Laboratory Control Sample Duplicate (LCS/LCSD)	Use 50-135% as recovery limits. For precision, use RPD limits of 20% for aqueous samples and 40% for solid samples.	<p>If the recovery is >135%, qualify all positive results in all associated samples as estimated (“J”) and do not qualify “not-detected” results.</p> <p>If the recovery is <50% but ≥10%, qualify all positive results in all associated samples as estimated (“J”) and qualify “not-detected” results as estimated (“UJ”).</p> <p>If the recovery is <10%, qualify all positive results in all associated samples as estimated (“J”) and qualify “not-detected” results as unusable (“UR”).</p> <p>If the precision exceeds the RPD criterion, qualify positive results as estimated (“J”) and do not qualify “not-detected” results.</p>
Field Duplicate (See Note #6 for additional information.)	Use precision limits of 20% RPD (%RSD for triplicate and quadruplicate analyses) for aqueous samples and 40% RPD (%RSD for triplicate and quadruplicate analyses) for solid samples when sample results are ≥5× RL. Use limit of ± RL (±2× RL for solids) when at least one sample value is <5× RL. (Use one-half the RL as a numerical value for any “not-detected” results in the RPD calculations).	If the criteria are not met, qualify positive results for noncompliant compounds in original sample and its duplicate as estimated (“J”) and qualify “not-detected” results as estimated (“UJ”).

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Quality Control Item	Usability Criteria	Action
Target Compound Identification (See Note #7 for additional information.)	Relative Retention Time (RRT) should be ± 0.06 RRT units of the standard RRT. Mass spectra of sample and current laboratory-generated standard should match.	Use professional judgement when applying the qualitative criteria for GC/MS analysis of target compounds. If it is determined that incorrect identifications were made or positive results were not reported, professional judgement should be used to determine which of the following options should be used: (1) qualify affected results as unusable ("R"); (2) correct reported results based on the raw data; or (3) contact laboratory for clarification. If a positive result meets some qualitative criteria but an evaluation of all qualitative criteria is inconclusive (possibly due to mass spectral interferences), use professional judgment to determine if result should be qualified "N".
Percent Solids	Solid samples with less than 50% solid content require qualification.	If a solid sample has a percent solid content $< 50\%$ but $\geq 10\%$, qualify positive results as estimated ("J") and qualify "not-detected" results as estimated ("UJ"). Use professional judgement if a solid sample has a percent solid content $< 10\%$.
Compound Quantitation (See Note #8 for additional information.)	Samples with results that exceed the instrument calibration range should be reanalyzed at a dilution.	If a target compound result exceeds the instrument calibration range, qualify the positive result as estimated ("J"). If a target compound result is $< RL$ but $\geq MDL$, qualify positive results as estimated ("J"). Use professional judgement to determine whether sample reanalyses and dilutions should be compared to the original analyses. If the precision criteria (see field duplicate usability) between the original sample result and the reanalysis sample result are not met, qualify positive results as estimated ("J") and qualify "not-detected" results as estimated ("UJ"). If a target compound result is $< RL$ but $\geq MDL$, qualify positive results as estimated ("J").
System Performance (See Note #9 for additional information.)	Professional judgement should be used when assessing the degradation of the system performance during analyses.	Use professional judgement to qualify the data if it is determined that system performance degraded during sample analysis.

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Quality Control Item	Usability Criteria	Action
Overall Assessment of Data	Assess overall quality of the data. Review available materials to assess the quality, keeping in mind the additive nature of the analytical problems.	Use professional judgment to determine the need to qualify data not qualified based on the QC previously addressed. Write a brief narrative to give the user an indication of the analytical limitation of the data. If sufficient information on the intended use and required quality of the data is available, include the assessment of the usability of the data within the given context.

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1. GC/MS Tuning Criteria (Alternate tuning criteria may be used by the laboratory [e.g., CLP, Methods 525, or manufacturer instructions], provided that method performance is not adversely affected.)

<u>m/z</u>	<u>ion abundance criteria</u>
51	30-60% of m/z 198
68	less than 2% of m/z 69
70	less than 2% of m/z 69
127	40-60% of m/z 198
197	less than 1% of mass 198
198	base peak, 100% relative abundance
199	5-9% of m/z 198
275	10-30% of m/z 198
365	greater than 1% of m/z 198
441	present, but less than m/z 443
442	greater than 40% of m/z 198
443	17-23% of m/z 442

If using professional judgement to determine impact when ion abundance criteria are not met, some of the most critical factors in the DFTPP criteria are the non-instrument specific requirements that are also unduly affected by the location of the spectrum on the chromatographic profile. The m/z ratios for 198/199 and 442/443 are critical. These ratios are based on the natural abundances of C¹² and C¹³ and should always be met. Similarly, the relative abundances for m/z 68, 70, 197, and 441 indicate the condition of

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the instrument and the suitability of the resolution adjustment and are very important. For the ions at m/z 51, 127, and 275, the actual relative abundance is not as critical. The relative abundance of m/z 365 is an indicator of suitable instrument zero adjustment. If relative abundance of m/z 365 is zero, MDLs may be affected.

2. If the initial calibration %RSD is >50%, the linearity of the first three initial calibration standards for the compound should be evaluated. If the first three initial calibration standards for the compound are linear (*i.e.*, $r \geq 0.99$), do not qualify “not-detected” results. If the first three initial calibration standards for the compound are not linear, qualify “not-detected” results as estimated (“UJ”).

Use professional judgement when evaluating the concentration intercept of a calibration curve. If the concentration intercept is positive, the samples should be evaluated for false positives. If the concentration intercept is negative, the samples should be evaluated for false negatives.

3. If instrument instability (*i.e.*, several continuing calibration standards with compounds exhibiting both increasing and decreasing sensitivity throughout an analytical sequence) is observed in the analysis of sequential continuing calibration standards, “not-detected” results may be qualified as estimated (“UJ”) due to instrument sensitivity of a continuing calibration standard response that is greater than the initial calibration standard response (increase in instrument sensitivity).

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If the continuing calibration standard is %D>15% in the direction of increased instrument sensitivity and it is determined that “not-detected” results should not be qualified, the data reviewer should note this in the QAR support documentation.

4. The frequency of equipment/rinse blanks is determined during the sampling event. The results of a equipment/rinse blank should be applied to all samples collected using the same equipment (equipment/rinse blanks only) on the same day; unless, if only one was collected for a several-day sampling event. In instances when more than one blank is associated with a given sample, qualification should be based upon a comparison with the associated blank having the highest concentration for a contaminant.

The following compounds are considered common laboratory contaminants/artifacts. If these compounds are reported as target compounds, the 10× rule applies for the evaluation of blank contamination. If these compounds are reported as TICs, the compounds should be considered laboratory artifacts.

- Common phthalate contaminants.
- Other common laboratory contaminants: CO₂ (m/z 44), siloxanes (m/z 73), diethyl ether, hexane, and certain freons.
- Solvent preservatives, such as cyclohexene, which is a methylene chloride preservative. Related by-products include cyclohexanone, cyclohexenone, cyclohexanol, cyclohexenol, chlorocyclohexene, and chlorocyclohexanone.

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- Aldol reaction products of acetone include: 4-hydroxy-4-methyl-2-pentanone, 4-methyl-2-penten-2-one, and 5,5-dimethyl-2(5H)-furanone.
- Silicon containing compounds (*e.g.*, trimethylsilanol)

If a sample result qualified “U*” is <RL and the laboratory did not report the RL on the data tables or Form I the positive result (*e.g.*, 8 µg/L) should be replaced with the RL (*e.g.*, 10 µg/L).

5. The surrogate recovery limits do not apply to samples analyzed at dilutions greater than five-fold. Qualification of the data is not necessary if the surrogate is diluted beyond detection. Generally, greater than a five-fold dilution will affect the ability to even detect the surrogate. If a sample was analyzed at a five-fold dilution or less and the surrogates were not detected in the sample, qualify positive results as estimated (“J”) and “not-detected” results estimated (“UJ”).
6. Duplicate samples may be collected and analyzed as an indication of overall precision. Field duplicate analyses measure both field and laboratory precision; therefore, the results may have more variability than laboratory duplicates that measure only laboratory performance. It is also expected that soil duplicate results will have a greater variance than aqueous duplicate results.
7. Generally, all ions present in the standard mass spectrum at relative intensity >10% should be present in the sample mass spectrum; however, the concentration of the

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compound should be considered when evaluating ions with a relative intensity of $\leq 30\%$ in the standard mass spectrum. In addition, data for ions with a m/z of ≤ 40 are often not collected and generally are not used for evaluation purposes.

Characteristic ions from reference mass spectrum (three ions of greatest relative intensity or any ions over 30% relative intensity if less than three such ions occur in the reference spectrum) should maximize in the same scan or within one scan of each other. Relative intensities of these characteristic ions should be within $\pm 30\%$ between the standard and sample spectra.

Ions that are not present in the standard mass spectrum may be present in the sample mass spectrum without impacting the qualitative identification of the target compound. The presence of such ions at relative intensity greater than 10% may be indicative of a coeluting compound. If feasible, the coeluting compound should be tentatively identified in order to evaluate whether the coeluting compound's mass spectrum contains any of the characteristic ions of the target compound. If a coeluting compound that has a mass spectrum containing the characteristic ions of the target compound, use professional judgment to evaluate the impact on the sample result is tentatively identified.

N-nitrosodiphenylamine (TCL, PPL, App IX) cannot be distinguished from diphenylamine (App IX) because *N*-nitrosodiphenylamine degrades to diphenylamine in the injection port. A note to this effect should be included in the qualifier section if these compounds are detected. In addition, benzo(b)fluoranthene and benzo(k)fluoranthene

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sometimes coelute and have similar mass spectra; therefore, if either of these compounds is detected in samples, the chromatograms of the samples and standards should be evaluated for separation. If coelution is observed, qualify “J” and/or “N” using professional judgment.

8. If a sample result exceeds the instrument calibration range (lower dilution analysis) or is less than the RL (secondary dilution), do not utilize this result when comparing an original analysis to a diluted reanalysis.
9. Poor chromatographic performance affects both qualitative and quantitative results. Indications of substandard performance include:
 - high background levels or shifts in absolute retention times of internal standards
 - excessive baseline rise at elevated temperatures
 - extraneous peaks
 - loss of resolution
 - peak tailing or peak splitting that may result in inaccurate quantitation
10. The RL will be defined on a project-specific basis. If the project-required RL is lower than the low initial calibration standard concentration, the Project Manager should be consulted for instructions on how to apply qualification related to the RL.

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