

Method TO-15A June 3, 2020 Webinar Comments/Questions

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
1	Maisha Brown – Philadelphia Air Management Services	General	Is the webinar being recorded? We have staff that were not able to attend and would benefit from this presentation.	<p>The slide deck was posted to the EPA AMTIC website here: https://www.epa.gov/sites/production/files/2020-06/documents/to-15a_webinar_slidedeck.pdf</p> <p>EPA will also be distributing this table of comments and questions to webinar attendees. EPA does not intend to publish the video of the webinar.</p>
2	Lorraine Kimball - EPA	Various	Instrument qualification – will instruments already being used be allowed to be grandfathered in?	<p>The purpose of the instrument qualification is to demonstrate that instruments do not show chromatographic artifacts or interferences, or enhancement or suppression of analyte responses. Instruments already in use should meet qualification criteria by demonstrating acceptable performance on blanks and ongoing positive QC samples, e.g., CCVs. Instruments in use typically meet these criteria on an ongoing basis.</p>
3	Ray Merrill - EPA	Various	Will known standard challenges be required in humidified air or could they be done in humidified nitrogen?	<p>For instances where nitrogen is forbidden for qualification (zero and known standard challenges), it is forbidden since nitrogen creates an inert environment. The inert nitrogen environment does not represent ambient air and does not permit oxidation of organic matter and potential increases in target VOCs that can occur in oxygenated environments such as ambient and hydrocarbon-free (HCF) air.</p> <p>The permitted humidified diluent gases for known standard challenges are as follows (note that all zero challenges are to be with HCF air):</p> <ul style="list-style-type: none"> - Canisters: HCF air only - Sampling instruments: HCF air or N₂ - Analytical instruments: HCF air or N₂ - Autosamplers: HCF air or N₂

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4	Nick Gannon - EPA	Various	Is there any method discussion regarding high level air samples – e.g., samples with ppm results?	Method TO-15A focuses on ambient level measurements, which typically fall within the 20 to 5000 pptv range cited in the method. Briefly described are considerations for canister cleanliness criteria and blank samples for higher level (e.g., ppm-level) measurements. Such blanks need not meet the ≤ 20 pptv requirement, rather, they should not exceed 5% of the expected measured sample concentrations. This criterion (< 5% of the expected sample concentration) would similarly apply to other blank criteria (method blanks, zero challenges, diluent gas, etc.) associated with ppm measurements.
5	John Lee - Chubb	18	Regarding the ppm question, can we simply apply a multiplier to Section 18 values?	Modifications to the method to address ppm level measurements should involve altering the blank criteria as mentioned above in comment 4 and will likely result in a different calibration concentration range. Other considerations for ongoing QC, such as SSCV, CCV, and precision measurements are based on relative percentages of the theoretical concentration or sample measurements, and while the absolute concentrations would be different (ppmv as opposed to ppbv or pptv), the acceptance criteria percentages would remain as listed in Table 18-1.
6	Ben Peters – Markes International	General	Can you please provide more information/guidance on the 1-year transition?	The one-year transition period applies to NATTS Program analytical support laboratories (ASLs). NATTS ASLs have been complying with the 2016 NATTS Technical Assistance Document (TAD) and will have one year to enact changes to comply with the updated criteria in TO-15A once the NATTS TAD is updated.
7	Ralph Schulz – Georgia EPD Laboratory	14.4	No BFB? No tune?	Operators of GC/MS instruments should tune the MS per manufacturer recommendations for detecting m/z in the 30-270 amu (or wider) range. Bromofluorobenzene (BFB) is useful for tuning GC/MS instruments with linear quadrupole detectors, particularly those operating in SCAN mode; however, BFB tuning is no longer required. BFB tuning criteria are detailed in Section 14.4.2.
8	Stephen Blaze - EPA	14.3.2	At what level standard is the 10 scans/peak requirement supposed to be verified? At low/mid or high-level standard?	Each positively identified chromatographic peak regardless of concentration should include a minimum of 10 scans across the width of the peak and will preferably have 12 or more scans.
9	Karna Holquist – Texas CEQ	15.2.1	Are the 8 concentration levels a requirement?	A minimum of five non-zero calibration levels must be included in the calibration, and more levels are recommended. For quadratic curves, a minimum of eight levels is strongly recommended, but not required.

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10	Jennifer McGee – Virginia DEQ	15.2.1	Does the zero concentration count as 1 of the minimum 5 levels?	No, the zero concentration level does not count as one of the required calibration levels.
11	Nicole Marz – Oregon DEQ	Not applicable	Will the NATTS TAD be revised for the TO-15A criteria?	EPA plans to revise the 2016 NATTS TAD to incorporate the acceptance criteria changes in TO-15A as well as to make other updates and clarifications. Our best guess for publishing a revision to the NATTS TAD would be 6 months from now (approximately December 2020).
12	Bryce Stearns - Eurofins Test America (ETA)	15.2.1	How would one provide traceability for a zero calibration level standard?	When employed, the zero concentration point is prepared from the humidified diluent gas employed for preparing calibration standard dilutions. The source gas for and filling of the zero calibration level canister should be recorded in the laboratory records.
13	Ralph Schulz – Georgia EPD Laboratory	8.1 and 17	If std cylinders are only certified for 1 year, how do we perform new EPA MDL study method update rule if EPA requires 2 years of data? The 1st year amount will not match 2nd year amount of spike level for MDL, so MDL results will not be valid. Our MDL math program will crash as the amount between the 2 years are different and this is considered an error by the program. EPA auditors for drinking water were just here and require 2 years for MDL study data.	The method detection limit (MDL) Method Update Rule (MUR) described within TO-15A requires many of the same aspects but does not strictly follow the MUR requirements in the Code of Federal Regulations (CFR). The MUR listed in TO-15A requires a minimum of seven separate method blanks and seven separate standard spikes for determining the MDL and does not require one or more years' worth of data. Method users are encouraged to include additional spikes and blanks in the MDL determinations and there are instructions for calculations and data handling when there are greater than seven spikes and/or blanks in the dataset.
14	Lorraine Kimball - EPA	Various	With all the new requirements (can cleanliness, each autosampler port verification, can bias/accuracy, 8 cal levels in triplicate, using one can per cal level) when would an analyst have time to analyze actual field samples?	The requirements to perform bias verifications/qualifications are designed to demonstrate that sampling media, clean gases, and sampling and analysis instruments do not unacceptably bias the collected sample measurements. In general, once the analysis instrument and autosampler are qualified, the continued meeting of QC acceptance criteria will demonstrate the analysis system remains in control. For sampling instruments and canisters, repeated sampling can result in build-up of contaminants over time which are not apparent through routine analysis, hence the periodic requalification requirements. The method makes recommendations but does not require 8 calibration levels, that calibration standards be analyzed in triplicate, nor that each calibration level be prepared in its own canister. For laboratories that choose not to perform the indicated equipment (canister, sampling instrument, etc.) qualifications, the associated sample data should be flagged accordingly to indicate the measurement system bias has not been characterized.

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15	Ray Merrill - EPA	15.2.1	Typical quad MS show linear calibration when the source has just been cleaned but go quadratic after the first 6 or 7 samples. What should a lab do if they know this is the performance of their system?	In such situations where the laboratory is aware that an ion source requires a level of burn-in or conditioning after cleaning, the laboratory should complete the burn-in/conditioning prior to establishing calibration. Similarly, laboratories should ensure conditioning is completed when performing MDL studies, as it is preferable to characterize the typical instrument performance when determining MDLs than to attempt to establish MDLs under ideal instrument conditions.
16	Bryce Stearns - ETA	16.2	Does S:N apply to all ions monitored?	The S:N criterion applies to the quantitation, or target, ion for a given VOC as well as for at least one qualifier ion. Typically, the quantitation ion will be the base peak – the most abundant ion for that compound.
17	Kristen Leckrone - EPA	16.2	is it sufficient to document s/n at the RL rather than for every sample, provided samples are > RL?	The method does not require documenting S:N with every sample. The S:N will typically exceed 5:1 at concentrations greater than the MDL. Once concentrations rise to the reporting limit (RL) (which is often set above the practical quantitation limit [PQL]) the S:N should be substantially greater than 5:1. The method makes allowance that not every peak S:N needs to be measured, and the analyst's opinion weighs heavily on S:N interpretation. Demonstration of the S:N at the RL should be sufficient provided the S:N exceeds a S:N of 5:1 and there aren't substantial interferences that increase the noise or result in coelutions. Documentation of the S:N should be retained in the laboratory records for the specific method settings.
18	Don Dawicki - ETA	General	If we are a lab that generally does not support much ambient air analysis but supports mainly vapor intrusion/soil vapor monitoring, are we able to modify the method (higher calibration range) and still call the method TO-15A?	Method TO-15A is a guidance document for VOCs measurements and is focused on ambient air; however, method users can modify the calibration range and blank acceptance criteria to relate the criteria to the measured concentrations (e.g., ppm levels of VOCs). When modified, laboratories should cite "modified Method TO-15A" or similar to indicate that the method is not performed as written.
19	Nick Gannon - EPA	14.4	@ BFB question - The Sept 2019 TO-15A pub has BFB criteria (pg 63). If there is no BFB/tune criteria, how long can a run go?	TO-15A does not require tuning with BFB; however, it does require tuning the MS instrument and verifying the tune each day of use according to the manufacturer specifications. An analytical sequence must begin and end with a passing CCV; where a sequence is defined as the samples and standards analyzed in one calendar day or a 24-hour period. A CCV is recommended after every 10 samples to minimize the risk of losing (invalidating) sample data should the concluding CCV fail acceptance criteria.

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20	Brooke Slepanki - Canada	9.4	In our lab, we have about 1500 canisters. With all the new can cleanliness requirements, it would add around 500 cans to be tested (with 2 test runs per can) per year if they need to all be done every 3 years. That would add a significant amount of work on top of the 2600 samples we already get. Do you have suggestions as to how a lab could accommodate that if additional staffing is not an option? We are worried that this amount of testing is not feasible.	The method does not address the manner in which laboratories qualify their canisters; however, laboratories should develop a canister tracking system such that the use of canisters is documented and traceable. Such a tracking system allows laboratories to segregate ambient (pptv and ppbv level) canisters from vapor intrusion and/or source-level (hundreds of ppbv to ppm). This would reduce the number of canisters requiring ambient level qualification, and permit canisters that routinely serve as QC check (CCV or SSCV) or ICAL standard canisters to be bias checked as part of routine analyses. Measured sample data associated with canisters that have not been qualified should be flagged as described in comment 14.
21	Kristen Leckrone - EPA	17	MDLs: Appendix B does not require spike level to be between MDL _{sp} and 10MDL _{sp} . Is this a firm requirement for TO-15A?	TO-15A requires that the determined MDL _{sp} be between 10% and 100% of the spiking level or the MDL _{sp} process must be repeated as listed in Section 17.6. Described another way, MDL _{sp} < spike level < 10·MDL _{sp} .
22	Dan Cardin – Entech Instruments	9.5	For challenging canister sampling systems using pumps, what is the recommended way of doing this, as pumps tend to draw far more gas than what is delivered into the canister, and that will exhaust a cylinder standard very rapidly?	This is an area in which manufacturers may decide to provide guidance to their customers on their particular sampling units as the design and configuration are unique to the sampler. If practical, the sampling unit pump may be disabled to perform the challenge, or it may be necessary to challenge canister sampling systems with pumps over a shorter duration (e.g., 4 hours). Alternatively, If the known standard check is not feasible due to gas consumption factors, the zero-air challenge will minimally need to be performed.
23	Karna Holquist – Texas CEQ	17	I couldn't find the MDL _{sp} and 10MDL _{sp} requirement either	Refer to comment 21.
24	Ralph Schulz – Georgia EPD Laboratory	Various	This is all very good for a research lab. As a production lab I agree with previous comments that there isn't enough time or personnel to meet all the criteria required.	Refer to comment 20.

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25	Dan Cardin – Entech Instruments	17	MDL concentrations of 3:1 or 5:1 SN are recommended, but new GCMS systems in full scan can provide a 20:1 or higher SN at 0.02PPB concentrations using 250cc sample sizes, allowing an MDL of as low as 2 ppt to be determined. Why would it be necessary in that case to go down to 5:1 SN, which may be a 5 ppt standard (very difficult to even make!!!)	Concentrations equivalent to S:N of 5:1 are approximate appropriate spiking concentrations determining MDL_{sp} . For most analytes for many systems, preparing spiked canisters at approximately 10 pptv may be sufficient to determine MDL_{sp} . Laboratories may prepare further static dilutions to achieve a 5 pptv standard to prepare the ≥ 7 spiked canisters. The goal of the MDL process is to simulate the variability in instrument response in the region where the signal becomes difficult to distinguish from noise. Such is performed via analysis of low-concentration standards, and the absolute accuracy of the low concentration standards is not critical.
26	Ana Suarez – Broward County Florida	Not applicable	Has any lab made this transition yet? EPA? ERG?	EPA ORD has been analyzing samples following the criteria in TO-15A. It is unclear whether other laboratories have adopted the acceptance criteria in TO-15A since TO-15A has just been rolled out in March 2020.
27	John Lee – Chubb	Not applicable	Is it acceptable to heat canisters for compounds with BP's higher than 220 C or VP's lower than 0.1 mm Hg (i.e. Naphthalene) as long as all QC samples are also heated?	TO-15A does not specifically address this topic of heating canisters for analysis. Canister manufacturer recommendations should be followed for determining whether heating to such a degree is acceptable. Silicon-ceramic linings will likely be damaged by such high heat. Heating during analysis is not discussed in the method; however, handling - in this case heating - sample and QC samples identically is acceptable.
28	Kyristin Fornace – South Coast AQMD	Not applicable	Adding on to Ana Suarez's question: if there is a lab that has successfully implemented TO-15A with all QC requirements, we would be interested to hear what the major challenges were and how they were addressed.	The various components of the method have been implemented and vetted by various laboratories. TO-15A has just been released in Spring 2020 and we expect that further information will be presented by individual laboratories implementing the method at the San Diego Measurements meeting in December 2020.
29	Dan Cardin – Entech Instruments	15.2	Quadratic Curve allowance may not be a good idea, as if the response is not linear with concentration, it's very likely that a bias will occur if there are co-elutions with other high concentration compounds. We generally don't see the need for quadratic curve fits for dynamic ranges of less than 1000x, and 20-5000 ppt is only a 250x range	As quadratic behavior can occur due to a number of factors, the method cautions the user to ensure that quadratic behavior is attributable to the system's response to the compound and not due to standards preparation errors or system background resulting in enhancement or suppression at the limits of the calibration concentration range. The method leaves it up to the user to determine if a quadratic regression model best represents the response behavior of a given compound on the user's analytical system.

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30	Ralph Schulz (Georgia EPA Laboratory) and Kevin Bradley (San Diego APCD)	16.2	If the secondary ions are not present...should we NOT report the compound? This applies more to <MDL detects with primary ion present.	At least one qualifier (secondary) ion must be present with > 3:1 S/N and at the defined relative abundance to positively identify (report) the compound. There is a single exception to this, which is when analyzing MDL spike samples, as the presence of the compound is presumed; in this instance, the MDL_{sp} concentration may be of such low magnitude that the qualifier ion(s) may not be present in sufficient abundance to meet S/N requirements for qualitative peak identification
31	Donna Tedder (Eastern Research Group)	16.2	Please confirm the Method TO-15A RT criteria for the target VOCs is actually 2 seconds from the mean ICAL RTs, and not 20 seconds.	The RT of all compounds (internal standards and target analytes) must be within ± 2 seconds of the average RT from the most recent initial calibration. This change of RT window assignment from those in TO-15 (1999), ± 0.33 minutes for internal standards and ± 0.06 RRT units for target analytes, was made since modern GC systems operate by computer with precise flow and pressure control, improving on the performance of earlier instruments that required operators to employ hand-actuated valves to inject on the GC column.

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32	Viviane Aparecida – Environmental Agency of Sao Paulo, Brazil, CETESB	11.1.2	<p>I have one question about ending pressure. I usually use a Restek sampling train for subambient sample collection and the Restek Guide to Whole Air Canister Sampling says:</p> <p>There are four possible scenarios:</p> <p>A. Ideally there will be a vacuum of -7" to -4" Hg in the canister.</p> <p>B. If more than -7" Hg vacuum remains, less sample was collected than initially anticipated. The sample will be valid, but the detection limit may be higher than expected. You might have to pressurize the canister prior to the analysis, which will dilute the sample and require you to use a dilution factor to determine final concentrations of target compounds.</p> <p>C. A vacuum of less than -4" Hg indicates the sample might be skewed toward the initial part of the sampling period. This assumption usually is valid because the flow rate through the flow controller will fall once the vacuum falls below -5" Hg (Figure 6, page 4), when the change in pressure across the flow controller diaphragm becomes too small and the flow controller is unable to maintain a constant flow. Although flow was not constant over the entire sampling period, the sample may be usable because the sample was collected over the entire interval.</p> <p>D. If the ending vacuum is less than -1" Hg the sample should be considered invalid because it will be impossible to tell when the sample flow stopped.</p> <p>Now in the Method TO-15A says: Subambient sample collection • Ending pressure should be 1.5 to 3 psi below ambient pressure to ensure a constant sampling rate over the 24-hour period What I should do?</p>	<p>The guidance in TO-15A for subambient sample collection appears in Table 11-2 and lists typical subambient sampling pressure ranges at completion of -11 to -4 inches Hg gauge based on the flow curves shown in Figure 9-2. The ending sample vacuum/pressure is dependent on the ability of the specific flow controller to maintain a constant sampling rate at a given canister pressure in relation to ambient pressure. Users should at a minimum follow manufacturer recommendations and are strongly encouraged to characterize the MFCD flow characteristics to ensure constant flow over the collection duration (Section 9.1). Flow controller manufacturer and type vary in their ability to maintain a constant flow as the canister pressure approaches ambient pressure; as such, the user should determine the pressure range over which the flow rate is constant and not exceed this range, thereby ensuring constant flow. Manufacturer instructions for the flow controllers can be referenced if method users cannot independently verify the constant flow rate pressure range; however, the user cannot confirm constant sampling rate for the sampling duration. The discussion provided in the Restek <i>Guide to Whole Air Canister Sampling</i> describes operation of their mechanical flow control device (MFCD). The Restek guidance provides a hierarchy for how to handle data based on the ending sample canister pressure for their MFCD, specifically describing sample validity as it relates to constant flow rate and ending sample pressure.</p>

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33	New York State DEC	9.4 and 9.5	It is not appropriate to use zero air for canister qualification and sampler certification. This is not appropriate as we have observed acrolein growth when using zero air and that the method is unworkable if acrolein is to be measured due to growth. We feel that N ₂ should be used here.	The exclusion of nitrogen for canister zero air challenges and known standard challenges is intentional to evaluate the potential for increases in concentration of target analytes which may occur in the sampled air matrix. The ambient air matrix is not well-represented by the inert N ₂ atmosphere as it does not permit such reactions; rather, ambient air is best represented by HCF zero air as the latter allows interactions and behavior similar to that which is expected to occur in a canister filled with ambient air. The increase or “growth” of acrolein in canisters is widely reported to occur in oxygenated environments and should be characterized by assessing concentration increases over time by use of HCF zero air. Use of N ₂ for this purpose ignores the potential increase in concentration of oxygenated compounds like acrolein, ketones, and aldehydes. Use of N ₂ for other purposes (such as diluent gas for standards preparation) is permitted. See above comment 3.
34	New York State DEC	10.1	Manufacturers recommend against the use of the combination of zero air and heat for cleaning as it destroys the canister lining.	Manufacturer literature cautions against the combination of using zero air with high heat (> 80°C) for silicon ceramic lined canisters due to lining degradation. ORD is not aware of manufacturer recommendations against use of zero air for cleaning gas.
35	Pam Foy-Gilmore (Wisconsin DNR)	8.5	What is the reasoning behind moving away from nitrogen gas?	Rationale for limitations on use of N ₂ is described in more detail in responses to comments 3 and 33.
36	Pam Foy-Gilmore (Wisconsin DNR)	Appendix A	Would it be possible to get a unit converter? There's multiple units with different reference points (vacuum, ambient).	Vacuum and pressure unit conversions are shown in TO-15A Appendix A on page 95.

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
37	Bryce Stearns - ETA	17	MDLs - Have participating laboratories routinely obtained valid calibrations incorporating a low calibration point <u>at or below 20 pptv</u> for <u>all analytes</u> listed in Table 1-1 meeting all the criteria of TO-15A using a quadrupole GCMS operating in full scan mode?	MSs operating in SCAN mode only (and not simultaneous SIM/SCAN) may not be able to include a low calibration concentration level of 20 pptv for many of the analytes in Table 1-1. The instrument sensitivity at this concentration range in SCAN mode is analyte dependent and users may not achieve sufficient sensitivity at such low concentrations for proper compound identification (likely due to insufficient S:N or absence of qualifier ions). If there is insufficient sensitivity at such a low concentration such that the compound cannot be properly identified, the affected calibration levels should not be included in the calibration curve. EPA ORD is not aware of laboratories obtaining a valid calibration curve for all analytes including 20 pptv using a quadrupole MS in full SCAN mode.
38	Bryce Stearns - ETA	17	MDLs - If so [if labs have routinely obtained valid calibrations at or below 20 pptv], have they also obtained valid MDLs below 20 ppt following the requirements of TO-15A for all analytes listed in Table 1-1 using full scan quadrupole GCMS?	The MDLs shown in Table 17-2 were generated with a linear quadrupole MS in SIM. EPA ORD is not aware of laboratories obtaining MDLs below 20 pptv for all analytes in Table 1-1 using a linear quadrupole in full SCAN mode.
39	Scott Winters (Virginia DCLS)	13.2.1	<p>How do you recommend calibration of the Mass Flow Controllers in the (Entech) 4600 dynamic diluter?</p> <p>What flow controller/instrument do you recommend purchasing for this calibration? We have 4 MFCs up to 50cc and 1 up to 5000cc.</p>	<p>The manufacturer should be consulted as to their recommendations for this procedure. In general, calibration of the mass flow controllers (MFCs) can be accomplished by measuring the flows of the MFCs with a NIST-traceable certified flow meter such as a dry graphite piston-type flow meter (these are available from Mesa Labs, for example) or a mass flow meter (these are available from Sierra Instruments, Omega Instruments, and Alicat Scientific, for example). <i>Note that EPA's mention of these tradenames does not constitute endorsement of these products.</i> The gas employed for flow calibration must be the gas to be metered by the MFC (zero air, nitrogen, etc.) to ensure accurate gas flow metering. The measured flows are plotted against the MFC settings and an external calibration curve generated by linear regression. Once the calibration curve is generated for each MFC, the user inputs the flow setting corresponding to the desired flow rate according to the linear regression to achieve the actual desired flow rate.</p>

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40	Praveen Srirama (Carlsbad EMRC)	10.2	<p>You said during that the TO-15A talks about high level VOC measurement and blank qualification. I couldn't find that, could you please direct me to that section?</p> <p>Also, will the TO-15 method be revoked by EPA? We have two types of samples, one is from source (ppm), and the other ambient (ppt), and it will be very tough to do the analysis of these source samples with TO-15A.</p>	<p>High-level (e.g., ppm level) VOCs measurements are not specifically addressed within the method; however, the method modifications for conducting higher level measurements are discussed in comments 4 and 5. Pertinent blank acceptance is discussed in Section 10.2 on page 40.</p> <p>EPA does not intend to revoke TO-15 as many labs will continue to employ TO-15 in their laboratories. Additionally, other methods, such as EPA Compendium Method TO-17, reference TO-15 and for this reason laboratories should maintain access to TO-15.</p>
41	Steven Walters (North Carolina DENR)	15.2.3	When evaluating the ICAL for VOC analysis, can I choose to use %RSD of response factors or R ² ? I know I have to evaluate the % recovery of each level against nominal, but I interpreted the TAD as giving the user a choice on the RSD or R-squared but a must on the % recovery.	For calibration curves, either the %RSD of response factors or a linear (or quadratic) regression may be employed for each target analyte and may include weighting schema to better characterize the lowest third of the calibration curve concentration range. The user must still evaluate the response of each calibration standard level against the generated curve and the concentration of each level must be within ±30% of the theoretical concentration.
42	Ned Fairchild (Oregon DEQ)	15.3.2	I don't recall any discussion during the presentation around the additional CCV requirements in TO-15A. Since an additional closing (and/or ongoing) CCV(s) is a pretty significant departure from the TAD (and TO-15 2 nd ed.) requirements of a passing CCV per 24 hour tune window, and GC/MS vols/semi-vols analysis in general, I would like to see it called out. More specifically the 2 nd edition says a passing CCV is necessary to proceed with analysis, and TO-15A more or less says: "CCVs should be within 30% of the theoretical concentrations....corrective action should be taken to investigate and address CCV failures" which I find a little short on specifics, considering that each sample will now have 2 CCVs associated with it.	Refer to response above in comment 19. A passing CCV is required to begin and conclude an analytical sequence, which is defined as the samples analyzed on one day (e.g., a 24-hour period). Failures of CCV acceptance criteria require corrective action which may include instrument recalibration and reanalysis of the samples analyzed in the part of the sequence bracketed by the failing CCVs. The inclusion of an additional CCV after every 10 samples is to provide more QC which reduces the number of samples requiring reanalysis should a CCV fail criteria.
43	ETA	General	Is it the agency's plan to phase out TO-15 and replace with TO-15A?	Refer to comment 40.

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44	ETA	General	Is the agency open to issuing an addendum to the method as they receive feedback and comments from laboratories on the feasibility of the method?	EPA plans to issue an addendum to TO-15A to address analysis of ethylene oxide. There are currently no plans to amend TO-15A.
45	ETA	General	While described as a performance-based method, EPA TO-15A defines narrow criteria relevant to the NATTS ambient air monitoring program, leaving little flexibility to extend the method to vapor intrusion investigations and other special studies without significant modifications to table 18-1. Incorporating performance criteria relative to an investigation's data quality objectives would provide a more adaptable method for commercial laboratories without compromising data usability. For example, whereas an appropriate cleanliness criterion for the NATTS program is <20 pptv, a relative cleanliness criterion such as less than ½ the LOQ would be appropriate for the variety of programs commonly performed by commercial air laboratories.	Refer to comments 4 and 5. Method authors limited the scope of TO-15A to the ambient air measurements, as to increase the scope to cover vapor intrusion and source-level (e.g., ppm level) measurements would have required development of acceptance criteria tailored to these specific measurement purpose(s). TO-15A, as written, states that the user may tailor calibration ranges and establish blank criteria relative to the expected sample measurement concentration range.
46	ETA	3	<p>States: "The target VOCs may also be measured in soil gas during vapor intrusion investigations and in indoor air, both of which are outside the scope of this method."</p> <p>What would be the appropriate TO method be for these matrices? Can I report data for soil gas/indoor air using method TO-15A?</p>	Refer to comments 4 and 5. Analysis of soil gas samples and indoor air investigations are outside the scope of TO-15A. However, once sampling practices are established and shown to be non-biasing, instrumental analysis practices can be tailored to measure the collected samples with appropriate data quality as described in the method. Provided the measured blank values do not exceed 5% of the measured sample concentrations, calibration curves bracket the measured concentrations, compound identification criteria are met, and QC acceptance criteria for QC samples ($\pm 30\%$ of theoretical) and internal standards (relative area response change less than 40% from the ICAL) are met, the analyzed data are suitable for reporting.

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47	ETA	General	<p>Regarding the reference to “Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program, USEPA, EPA-454/B-17-001, January 2017.”</p> <p>The referenced document defines the usage of terms like “should” and “may” as optional or discretionary and do not require adherence to the element. The term “should” is used extensively throughout the document and at times runs contrary to specifications found elsewhere. Unless superseded elsewhere in the document, do laboratories have the discretion to treat elements as optional if they are precluded by the terms “should”, “may”, or “recommended”?</p>	<p>Method TO-15A is a guidance document. The wording chosen (e.g., should, may, recommended) helps to rank the authors’ opinions of relative importance to help ensure successful results and high quality data. Use of the term “should” indicates a recommended practice or procedure and users should prepare technical justification for the omission of the practice or procedure.</p>
48	ETA	7.3.3.2	Is it expected that laboratories will generate flow profile data for any and all flow controller used for method TO-15A?	Method users should determine the flow characteristics of sampling devices, particularly those that result in subambient pressure samples. Entities responsible for collecting samples should be able to justify that integrated sampling does not bias the sample for any given portion of the sampling period.
49	ETA	7.4	<p>The requirement to use high quality, calibrated vacuum gauges with accuracy of +/-0.25% in the field to measure initial and post-sample vacuum is not practical given that very few of the projects supported by commercial laboratories fall into the category of existing air monitoring shelters where gauges can be stored at the sampling location. In our experience, these expensive, accurate gauges are easily compromised with repeated shipping back and forth between the field and the lab. Maintaining a large operable and accurate fleet of these gauges in order to meet this requirement is not feasible.</p>	<p>As discussed previously, TO-15A is a guidance document, and does not necessarily require that users follow specific practices or procedures; however, the specified performance criteria must be met. Practices and procedures offered are recommended to provide potential solutions to establish good QA/QC practices. However, unless the starting canister vacuum and ending canister pressure are verified, the integrity of the collected sample is not known. The rationale for employing a calibrated pressure transducer/gauge is to verify that a canister’s beginning vacuum is sufficiently low (to avoid unacceptable levels of contamination) and that retrieved canisters have not leaked after collection until received at the laboratory.</p>

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
50	ETA	7.6.3.1	"The GC must allow temperature programming with quick and accurate temperature ramping. If needed for separation of very light VOCs (such as ethane), the GC should be capable of subambient cooling (e.g., -50 °C)." Is it expected that laboratories will support very light hydrocarbons by TO-15A? Are those compounds considered within the scope of the method?	The discussion of light hydrocarbons in this instance is intended to guide the user on how to separate VOCs that elute in the early part of the chromatogram, even if they are not analytes to be quantitated, as they may interfere with the quantitation of other early eluting compounds.
51	ETA	8.1	"Gas vendors or third-party certification laboratories may offer recertification services of the target compound concentrations and extend the expiration of the cylinder contents." Does cylinder re-certification need to adhere to ISO 17025 requirements as specific in the TNI standards? Our experience is that most entities will not re-certify to 17025.	Method TO-15A does not indicate the level of quality assurance to which gas providers and certification laboratories must adhere. When available, standard gases should be traceably certified to a NIST Standard Reference Material or to a NIST/EPA-approved Certified Reference Material. Such should be prescribed within quality documents and policies specific to the entity performing the analysis.
52	ETA	9.1	"...the sampling device may be characterized by assembling an evacuated canister, a calibrated vacuum/pressure gauge, the flow controlling device to be tested, a particulate filter, and a certified flow meter..." Is it expected that each sampling set-up be characterized in this fashion? It is our experience that accomplishing this characterization for each combination of sampling system would not be practical.	The sampling apparatus for integrated sampling should be qualified to ensure that the ending canister pressure does not exceed the pressure at which the flow controller ceases to maintain constant flow. If this pressure cannot be determined experimentally, users should estimate this pressure and collect samples in such a manner that the likelihood of exceeding this pressure is minimized. Typically, MFCDs maintain established flow settings if the flow controller is not adjusted (intentionally or through rough handling) or does not ingest dirt or particulate matter that obstructs the flow path. Performance of this procedure provides evidence that the flow characteristics are established and documented such that sample collections exhibit constant flow over the collection duration.

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53	ETA	9.2.2	<p>“... it is strongly recommended that flow rates be verified at the sampling location at the time of deployment. If the flow rate has changed and is outside the desired range, the controller will need to be adjusted.” ETA does not recommend that flow controller be adjusted in the field. Flow controller settings need to be very precise and need to be performed in controlled settings (i.e., the laboratory). Measuring canister pressures in the laboratory prior and subsequent to sampling is our recommended approach for determining the validity of sample collection.</p>	<p>The method states that the flow controller device flow rate should be verified at the sampling location and adjusted to the desired rate if the setting has changed. If the flow rate is as expected upon verification in the field, no change is needed. Mechanical flow control device settings may be perturbed by rough handling during transport and differing atmospheric conditions (temperature and barometric pressure) between the lab and field location may alter flow characteristics of the MFCD; therefore, verification of flow characteristics at the time of setup provides additional assurance that the proper flow rate is attained. As the commenter mentions, measurement of the starting and ending canister pressure provides additional assurance that the sample collection occurred as intended.</p>
54	ETA	9.2.2	<p>“A simple technique can be used to verify that the MFCD is properly set at time of deployment.” This technique would require deployment of additional sample canisters and certified mass flow controllers to the field. A recommendation would be for field personnel to return to the sampling locations at a prescribed time to verify that sample collection was proceeding.</p>	<p>The technique described in TO-15A requires an evacuated canister which is the sample canister, a vacuum/pressure gauge which is generally located on the sampling device, and a stopwatch like that on a wristwatch or cell phone; however, it does not require additional sample canisters or an additional flow control device. At the time of deployment this check is performed and takes a few minutes. This procedure is optional and provides additional assurance that the flow setting is set as intended.</p>
55	ETA	9.4	<p>What type of supporting documentation will the laboratories need to retain for instrument and canister qualifications?</p>	<p>Documentation to support the canister qualification would include those detailing canister cleaning, filling with humidified zero air (zero air qualification) and standard gases (including standard dilution and COA records for known standard qualifications), analysis records (including associated calibration and QC samples), and calculations for determining criteria were met for the canisters undergoing qualification.</p>

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
56	ETA	9.3.3	"Each target VOC's concentration should be within $\pm 15\%$ of theoretical concentration." Given that the method specifies quantification using the average response from the initial calibration and the CCV acceptance criteria is $\pm 30\%$, $\pm 15\%$ for the spike challenge is overly restrictive. In addition, the last sentence in Section 9.4.3 specifies utilization of a $\pm 30\%$ for just that reason. Can the laboratories evaluate using either; the CCV acceptance criteria or %difference of the challenge results versus the concentrations measured in the CCV?	The method prescribes that autosamplers must meet the $\pm 15\%$ of theoretical for successful qualification. This specification is separate from the CCV acceptance criterion, which permits instrument calibration drift of up to $\pm 30\%$ - which is the rationale for its mention in Section 9.4.3. The autosampler verification is a discrete check which does not require evaluation over time, and therefore does not need to take into account the calibration drift or concentration changes of the canister contents.
57	ETA	9.4.1	Regarding canister leak check "... until the next pressure reading several days later." What would the agency define as the minimum number of days necessary to critically evaluate the leak rate?	In this instance, "several days" refers to approximately 3 or more days. Practically, this should be driven by the resolution of the vacuum/pressure gauge/transducer to ascertain that a pressure change is registered. For example, if the gauge/transducer is graduated in tenths of psi, minimally two days would be needed to ensure that a pressure change of 0.1 psi/day was exceeded.

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
58	ETA	9.4.2	<p>Sections 9.4.2 and 9.4.3 describe aspects of the zero air and known standard canister qualification procedures as recommended, not required, yet these recommendations are included in Table 18-1 outlining TO-15A performance specifications. The procedures described in sections 9.4 and 9.5 for canisters and MFCDs cannot be accomplished without significant resources in media inventory, labor, and analytical instrumentation given the large existing canister and MFCD inventories of the major air testing laboratories. Strictly following the recommended procedures in addition to required procedures cannot be accommodated without severe financial impact to air testing laboratories which have thousands of canisters in their inventories. Please clarify intent regarding these recommended procedures. For example: the laboratory does not feel a 30 day assessment of the zero-air challenge is practical. Could laboratories rely solely on the 24 hour cleanliness check?</p>	<p>Method TO-15A addresses procedures for demonstrating that biases imparted in the sampling and analysis phases are acceptably low for the measurement of VOCs at trace (pptv) levels in ambient air. Without performing these qualifications of canisters (and qualifications of sampling instruments and analysis instruments) measurements cannot reliably be attributed to the sampled atmosphere and may instead be a result of unknown bias in an aspect of the sample collection or analysis process.</p> <p>New canisters may not perform appropriately due to manufacturing defects and older canisters can exhibit degraded performance due to poor hygiene practices, imparting a bias to the measurements.</p> <p>Laboratories will not be able to attest that the reported measured sample concentrations are attributable to the sampled atmosphere without performing qualification of sampling media (as well as the sampling and analysis systems).</p> <p>The 30-day period for qualifying canisters is designed to evaluate the bias that may be imparted to canister contents (e.g., a collected ambient air sample) over the duration of sample holding time, nominally 30 days. Laboratories may evaluate canisters' performance over shorter periods, typical of routine sample holding periods, if samples are not routinely maintained (or analyzed) after 30 days.</p> <p>Analysis at earlier timepoints (e.g., 7 or 14 days after filling) may demonstrate unacceptable concentration changes and obviate longer evaluation periods. While concentration changes may be evident after 24 hours from filling, it is not realistic to expect that 24 hours of aging is sufficient to characterize canister behavior that may occur at later timepoints such as 30 days after filling. (Note: One reason for the 24-hour timepoint is to allow an early determination of canisters that may fail right out of the starting gate.)</p> <p>The canister cleanliness check performed to verify effective canister cleaning does not replace the canister qualification process.</p>

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59	ETA	9.5	What type of supporting documentation will the laboratories need to retain for sampling device qualifications?	Documentation to support the sampling device qualification would include records detailing: flow calibration, canister qualification for canisters employed in collecting reference and challenge samples, sources and preparation of humidified zero air and standard gases (including standard dilution and COA records), analysis records (including associated calibration and QC samples), and calculations demonstrating criteria for the sampling systems undergoing qualification were met.
60	ETA	9.5	This section references an “...annual calibration...” of sampling devices that is not defined elsewhere in the document. Is there a specific calibration procedure to be followed for sampling devices and systems?	This “annual calibration and maintenance” refers to sampling systems that are operated routinely year-round – typically those installed in fixed monitoring stations. The method does not describe annual maintenance of these sampling units; however, the statement that qualification be performed after “calibration and maintenance” is to ensure that no alterations (e.g., components replaced or maintenance conducted) are made after qualification. Such calibration would include setting/demonstrating flow characteristics and calibrating on-board vacuum/pressure gauges. Maintenance would include replacing pump seals, particulate filters, and other cleaning or adjustments as recommended by the manufacturer. Flushing with humidified zero air or nitrogen after maintenance is recommended to purge contaminants from the sampling unit prior to performing qualification.
61	ETA	9.5.1	The procedure described in this section for leak checking a sampling device relies on the use of an additional evacuated canister that is not ultimately used for sample collection. Our experience is that most “leaks” occur when the sampling device (flow controller) is not correctly affixed to the sampling canister and this process would not necessarily validate that the sampling device/canister interface with the sampling canister is leak free.	The intent is that this leak check be performed prior to qualification of sampling devices and sampling systems to ensure that the sampled gases are not contaminated due to leaks. This leak-check procedure is intended to demonstrate the sampling apparatus is acceptably leak-free – that components (stainless frits, connecting tubing, etc.) and seals are properly and securely installed and adjusted. This leak-check is separate from the leak check procedure described in Section 11 that should be performed upon sample deployment.
62	ETA	9.5.2	Can the sampling device zero-air challenge be combined with the canister zero-air challenge?	Users should employ canisters that have successfully undergone qualification in order to subsequently qualify sampling systems. If the user attempts to qualify both a sampling system and a canister in the same process, it will not be clear to the user whether the canister, sampling system, or both is responsible for any failures of acceptance criteria.

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63	ETA	9.5.3	Similarly, can the sampling device known-standard challenge be combined with the canister known-standard challenge?	For the same reasons as listed in comment 62, this is not recommended.
64	ETA	11.1.2	ETA does not recommend field adjustment of sampling devices. Verification of device flow in the field would require the use of sensitive and costly instrumentation <u>not designed for field use</u> .	Refer to responses in comments 53 and 54.
65	ETA	12.1	Invalidating a sample when the receipt pressure measured in the lab differs by more than 0.5 psi from the field reading is not practical, even assuming that a +/-0.25% gauge is used in the field for vacuum readings. As recognized in the method, differences in temperature and pressure between the lab and the field can easily account for real differences unrelated to leaking cans; however, if field temperature and pressure readings are not recorded by the field sampler, the lab is not able to evaluate this situation. Additionally, many samples collected are special events without an opportunity for resampling. From our experience, a less stringent criterion for the pressure difference is warranted with little impact on project objectives which allows for the use of field rugged gauges for the field readings. Rather than invalidating a sample based on a minor apparent difference in pressure without consideration of the data quality objectives, is it a modification to the method for the lab to document the discrepancy and continue with analysis with the decision to "invalidate" left to the end data user and acceptance criterion outlined in the project's Statement of Work?	<p>The method makes allowances for justifying pressure differences between sample retrieval and laboratory receipt. Atmospheric pressure differences from the sampling site to the laboratory will not impact absolute pressure readings (laboratories should employ gauges displaying absolute pressure as opposed to gauge pressure). Temperature differences of greater than $\pm 11^{\circ}\text{C}$ between sample retrieval and receipt at the laboratory will result in observed pressure changes of > 0.5 psi, assuming the canister has not leaked. Samples retrieved at lower and higher temperatures than the receipt temperature are expected to show increases and decreases, respectively, in measured absolute pressures when received compared to when retrieved.</p> <p>Laboratories may opt to analyze samples and flag data to state that canister receipt pressures indicate a leak may have occurred, potentially contaminating the collected sample. Such flagging is appropriate and may be preferable to invalidation when reporting measured concentrations to be assessed against a not-to-exceed threshold. Ultimately, the end user of any data is responsible for the decision to report a measured concentration, and the process by which this decision is made is indeed described in a project's statement of work or quality/test plan.</p>

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
66	ETA	13.4	Section specifies standard storage times of not greater than 30 days. Can longer storage time be used if supported by appropriate validation (recovery) studies?	<p>Such storage stability validation studies should be supported by canister qualifications indicating canister contents at the concentrations in question do not appreciably change (e.g., exceed $\pm 30\%$ change) over the tested duration. Note that such studies would require matching the sample matrix as closely as possible (and not employing an inert matrix such as dry nitrogen). Conditions such as sample humidity and compound constituents (e.g., reactive species such as nitrogen oxides) impact analyte stability; therefore, users are cautioned to document the sample matrix and associated characteristics that may impact stability of the target VOCs under investigation.</p> <p>EPA ORD would certainly welcome those studies being published in order to benefit the user community.</p>
67	ETA	14.4.1	What type of supportive tune documentation will the laboratories need to retain and/or provide?	In the past, analysts would maintain a copy (printout or electronic) of the BFB tune report demonstrating passing criteria for all required ions for each tune check. To demonstrate tuning criteria for TO-15A, analysts will need to include the manufacturer-recommended/required tuning procedures and their frequency in the standard operating procedure (SOP) document and will need to produce/retain documentation that the criteria were met at the proper frequency (presumed to be each day, or 24 hours of analysis time).
68	ETA	14.4.1	Section specifies tune verification “each day of use”. Does this constitute the maximum length of an analytical sequence (i.e., 24 hr)?	The language specifying “day of use” was to indicate that the instrument need not continually remain in tune over periods (e.g., weekend days) when the instrument is not in use. A “day” of use is to be interpreted as each 24 hours of use.

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Comment #	Commenter	TO-15A Section	Comment/Question	Response
69	ETA	15.2.2	The TO-15A method describes analyzing the Method Blank prior to the daily CCV which is inconsistent with laboratory convention and the TO-15 analytical sequence in which the blank is analyzed after the daily CCV and immediately prior to the field samples in order to demonstrate the system is free of target compounds after running the standard. Is there an expected increase in quality by running the Method Blank prior to the CCV instead of after the CCV?	<p>The rationale for analyzing the method blank (MB) before the CCV is to demonstrate that the instrument is sufficiently clean so that CCV recoveries are not influenced by interferences, contamination, or carryover in the system after sitting idle. With the CCV concentrations in the lower 1/3 of the calibration curve, there is little concern that there will be carryover contamination following the CCV that would impact subsequent MB or samples.</p> <p>If contamination from the CCV is a concern, laboratories are encouraged to perform a study to demonstrate lack of carryover following standards (such as the high-level calibration standard). If carryover is found, preconcentrator settings should be adjusted to improve cleanliness and to reduce carryover to acceptable levels. In general, the order in which the MB and CCV are analyzed is not critical in this specific instance, as both QC checks must meet criteria to demonstrate the calibration remains valid and the system is sufficiently clean in order to continue with the analysis sequence.</p>
70	ETA	15.2.3	Calibration Curve Models lists a requirement that the r^2 for linear or quadratic curves should be > 0.995 . However typical EPA method requirements for coefficient of determinations (r^2) and coefficient of correlation (r) are usually $r > 0.995$ and $r^2 > 0.990$ respectively. Should the r^2 value be 0.990 or 0.995 as stated?	The reference to r^2 (the coefficient of determination) ≥ 0.995 is intentional. Of utmost importance is that the backcalculated concentration of each standard's concentration be within $\pm 30\%$ of nominal.
71	ETA	15.3.2	Section states: "At a minimum, a CCV standard is analyzed at the beginning and end of the analytical sequence unless the sequence begins with an ICAL.". Is it appropriate to interpret the analytical sequence as being 24 hours in length? (See 14.4.1).	Refer to comment 19. The "analytical sequence" should be interpreted as the QC samples and field samples analyzed within a single day, which may be interpreted as a 24-hour period.
72	ETA	15.3.2	Section states: "At a minimum, a CCV standard is analyzed at the beginning and end of the analytical sequence.....". What is the acceptance criterion for the closing CCV?	The concluding CCV must meet the same criterion as the starting CCV, $\pm 30\%$ of the theoretical concentration(s).

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73	ETA	15.3.2	ETA would not necessarily run a new ICAL after clipping the analytical column if a subsequent CCV meets the acceptance criteria. Is it necessary to run a new ICAL after routine column maintenance (i.e., clipping the column) as described in this section?	Trimming of the analytical column is typically performed to reduce/remove contaminant build-up or damaged stationary phase (active sites) at/near the GC inlet. In so doing, the instrument performance is expected to change (improved sensitivity, reduced peak tailing, reduced contamination/co-eluting substances, etc.) as are the compound retention windows. Therefore, it is expected that a new ICAL be established to account for the change in sensitivity and to reset RT windows.
74	ETA	15.3.3.1 & 15.3.3.2	Are both an instrument blank (IB) and Method blank (MB) required to be run before each analytical sequence?	The method requires an IB and MB prior to each ICAL and analytical sequence.
75	ETA	15.3.3.3	Is the calibration blank (CB) to be reported as part of the data package if not used in the calibration curve?	The reporting of QC data such as CB, MB, SSCV, CCV, etc., is per the laboratory's discretion; however, compounds exceeding 20 pptv in the CB will impact the calibration and subsequent sample data quality and such should be noted in the associated data report(s).
76	ETA	17.9	Section describes the reporting of values below the MDL. Does the agency expect laboratories to report values below the MDL?	Reporting of concentrations < MDL is a requirement of some air monitoring programs, one of which is the NATTS Program, which is concerned with monitoring concentration trends over time. For this program, concentrations less than the MDL, even though they may have larger associated uncertainties, are preferable to reporting non-numerical results (non-detects) or detection limit-substituted results (1/2 MDL, or similar). Unless required by the project or program, TO-15A does not require reporting measured concentrations < MDL.

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77	Bryce Stearns - ETA	General	<p>If I recall correctly, during the presentation you offered to discuss possible strategies for accomplishing the rather extensive task of canister and flow controller qualifications.</p> <p>Do you anticipate conducting calls or sessions with interested parties, or is this something you would be willing to discuss one-on-one? Either way, we are keenly interested in learning all we can about the possible best practices for accomplishing, what will ultimately be, this very extensive task.</p>	<p>EPA tailored the discussion on June 3, 2020 for the NATTS, UATMP, and other similar ambient air monitoring network monitoring agencies and ASLs. While it is expected that commercial laboratories will also follow the method, EPA does not currently have plans to offer guidance (calls or sessions) and strategies on handling the logistics for qualification of large fleets of canisters. We have provided recommendations in the response to comment 20.</p> <p>It is up to the individual laboratory to determine the most practical way to accomplish qualification of canister media and/or flow controllers. As a preliminary step for canister qualification, we would recommend maintaining a database of each canister in the fleet and its history – sample type, associated high concentration(s) of noteworthy compounds, cleaning dates, maintenance (e.g., valve replacement), and other pertinent details such as qualification date(s). This will allow categorizing and reserving canisters for various purposes (ambient air, vapor intrusion, source level sampling, etc.) so that the number of canisters to qualify could be limited or reduced to only those needed for ambient air sampling and analysis. Recall that the reason for qualification is to ensure that the compounds measured were in the sampled air, and not an artifact of the sample collection or analysis procedure and equipment. We would not recommend qualifying canisters as rigorously for source sampling, as the level of contamination is likely minuscule in comparison to the concentrations in the collected sample. To confidently report ambient air measurements, canisters must be qualified to demonstrate they do not unacceptably bias the measurements.</p>