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To: Asbestos Coordination Team

From: Christopher P. Weis, Ph.D., DABT
National Enforcement Investigation Center
Office of Criminal Enforcement, Forensics and Training
Office of Enforcement and Compliance Assurance

RE: Review of *Quality Assurance Project Plan (QAPP), Ambient Air Monitoring for Asbestos During Demolition of Substandard Structures in City of Fort Worth, Texas, Phase 2 – Cowtown Inn Site*

General Comments:

1) The risk criterion presented in the Phase II QAPP of 0.01 S/cc would allow for unacceptable exposures to the community. This criterion underestimates the potential risk due to several questionable assumptions. It incorrectly assumes that dose rate (the amount of asbestos exposure per unit time) is linearly proportional to adverse health effects caused by asbestos. This incorrect assumption would fail to adequately provide for health protection of workers and the public during the implementation of the Cowtown Demonstration Project. Existing occupational standards recognize dose non-linearity by requiring the establishment of Short Term Exposure Limits (STEL) for asbestos and many other hazardous substances. The proposed residential exposure limit of 0.01 fibers per cubic centimeter of air ignores dose rate effects and represents an asbestos exposure level commonly considered to require emergency response on behalf of the U.S. EPA.

   The risk evaluation in the Phase II QAPP does not consider cumulative exposure to asbestos or other environmental contaminants. EPA initiatives to consider cumulative environmental exposure[1], particularly important for communities with potential for multiple source exposures such as the neighborhood near the Cowtown Inn, are not adequately addressed in the document. Consideration must be given to possible multiple sources of asbestos exposure, as well as possible exposure to other environmental contaminants, for the community near the project.

   The risk evaluation in the Phase II QAPP incorrectly assumes that NESHAP's regulation of ACM is health-based[2]. For example, the assumption that the NESHAPS cutoff for 1%

[1]EPA Science Policy Council Cumulative Risk Assessment Program, http://www.epa.gov/osp/spc/2cumrisk.htm
[2]FR 54, no 6, Tues, Jan 10, 1989, p. 922

asbestos in ACM is a health-based limit is not correct. EPA[3] and independent investigations[4] have demonstrated that bulk ACM concentrations below the PLM limit of detection can create elevated airborne asbestos concentrations.

2) The Phase II QAPP attempts to justify its risk criterion by comparing it to the level of 70 S/mm^2 mentioned in the TEM method in the AHERA regulations[5]. It is incorrectly stated in the Phase II QAPP that this is a clearance criterion and in the Phase I report that it represents "clean air in the building." This level was proposed in 1980 as an upper limit on the filter blank contaminant level. It should never be used as a risk comparison. Furthermore, current levels of filter blank contamination are now far below this level, and therefore the 70 S/mm^2 level is no longer relevant.

3) Due to the potential for human exposure coupled with the experimental nature of the Project, the study design for the Phase II Project (Project) must be submitted for review by the Western Institutional Review Board or other appropriate IRB prior to initiation of the project. The Project constitutes research involving actual or possible human exposures to hazardous materials. The Project evaluates changes in or alternatives to existing programs (NESHAPS) and procedures of the U.S. Environmental Protection Agency and is subject to the approval of the EPA Administrator. The Project represents "...research activities for which a Federal Department or Agency has specific responsibility for regulating ..." (45 CFR, Part 46, Subpart A, Sec. 46.102(e)). As such, the Project is subject to federal regulatory policy for the protection of human subjects as outlined in 45 CFR Part 46 Subpart A. Therefore, if the federal government (ie. the EPA) is participating in and/or supporting research that exposes or may expose humans to hazardous materials, federal policy requires Institutional Review Board review and prior approval.

4) The primary objectives and the primary goal of the Phase II QAPP should be rewritten so that they do not imply that the results from the Project can be generalized to "buildings containing in-place RACM". Even assuming that all the deficiencies in the QAPP were addressed, the findings from demolition of a single building will not provide sufficient data for extrapolation.

5) The Phase II QAPP proposes several criteria for removal of Releasable Asbestos Containing Material (RACM) that, if satisfied, would cause the material to be removed prior to demolition. There is no justification or explanation for how these removal amounts and material types were chosen. Furthermore, it is unclear whether or not any RACM will be removed from the Cowtown Inn before demolition.

6) We are particularly concerned that there is no consideration for the identification, assessment or removal of materials such as vermiculite attic insulation, Monokote fireproofing, vermululite-containing ceiling tile etc. that might have been previously missclassified as non-asbestos but for which the Agency now has renewed concern.

   While airborne release from some ACM may be adequately controlled by wetting, releases from other ACM may not. Differences in the age, quality, and type of asbestos materials found in other structures may have an affect on the propensity for airborne release. EPA

[3]Pilot Study to Estimate Asbestos Exposure from Vermiculite Attic Insulation, Final Draft, May 21, 2003, http://www.epa.gov/asbestos/insulationreport.pdf

[4]Addison, J. *Vermiculite*, Reg. Tox & Pharm, 21:397-405 (1995)

[5]40 CFR 763, Subpart E, Appendix A

has demonstrated that airborne release from certain ACM is only minimally controlled by wetting. This is clearly demonstrated in the case of vermiculite attic insulation and may also be true of other vermiculite containing materials such as wall board, ceiling tile, concrete decking and Monokote spray-on fireproofing.

7) The draft charge for peer review of the Project, should be modified to focus on the scientific and technical aspects of the QAPP. Statements in the charge related to the cost and benefit of the project or demolition of asbestos-containing building in general must be removed. We suggest a strict adherence to the Science Policy Council guidelines[6] and the involvement of the Science Advisory Board.

8) Since the table containing details of the TEM analytical protocol (the number of grid areas and approximate area examined, Table B-2 in Phase I) is missing, the Phase II QAPP does not include the information that is necessary to evaluate the analytical sensitivity and thus many of the quality assurance aspects of the Project. In the Phase I QAPP, Table B-2 specified the use of 26 grid openings, a 0.01 mm^2 grid area and an air volume of 3000 L and stated (correctly) that these parameters would achieve an analytical sensitivity of 0.0005 S/cc; however, the same table incorrectly states that the protocol would produce a sensitivity of 0.0001 S/cc for asbestos structures greater than 5 um. The basis for this difference in sensitivities must be provided. Since the same values for analytical sensitivity are claimed in the Phase II QAPP as in Phase I QAPP, but the air volume is decreased, the number of grid openings must be correspondingly increased to maintain a given sensitivity.

9) The analytical protocol in the Phase II QAPP is unclear on several key aspects related to the identification of structures during analysis. It is unclear on whether all TEM-observable structures or only PCM-equivalent structures will be counted. The use of the ISO 10312 method would suggest that all TEM-observable structures will be counted; however, the section of the QAPP entitled "Comparability" on page 25 states "counting structures longer than 5 um in length," which could imply that not all structures will be counted . The analogous section in the Project XL QAPP[7], on the other hand, specifies counting structures longer and shorter than 5 um in length. This is inconsistent. Furthermore, the QAPP mixes methods, fiber definitions and analytical sensitivities for 3 different analytical techniques (PCME measurement; ISO 10312, and AHERA). Each of these analytical methods measures fibers with different morphological characteristics. In various places, the QAPP refers to asbestos structures and asbestos fibers interchangeably, but these are not equivalent. We strongly recommend a more clear explanation of the technique to be employed to analyze and classify the different types of asbestos structures.

   It appears from the Phase I data that only structures greater than 5 um were reported. Generally, the number of structures less than 5 um are far more numerous yet the only 2 asbsestos structures reported were greater than 5 um. Since both high and low magnifications were reported, we assume that attempts were made to observe smaller structures, yet none were reported. Given the greater number of small structures found in nearly all fiber populations, we would expect the higher magnfication to detect more structures.

[6]Science Policy Council Handbook, EPA 100-B-98-001
[7]Quality Assurance Project Plan, Project XL, August 17, 2000, http://www.epa.gov/ProjectXL/fortwor/fw-qapp.pdf

10) The sampling and analytical protocol used in Phase I was insufficient to detect background[8] and, thus, the analytical sensitivity should be increased for Phase II to meet the stated objectives. In the Phase I report, there were 24 samples collected upwind of the demolition and disposal site, and no structures were detected. This translates to a detection limit for background air of 0.000061 S/cc. Since 3 times the analytical sensitivity gives the detection limit, an analytical sensitivity of 0.00002 S/cc would be necessary to detect a background of 0.00006, and most likely an even lower value would be required. Despite this, page 26 of the QAPP states that an analytical sensitivity of 0.0005 S/cc is sufficiently low so that the number of measurements where asbestos structures are not observed or not detected is minimal. To achieve the required low sensitivities it may be necessary to move to an indirect analytical preparation technique, such as ISO 13794. The report by Berman and Chatfield[9] cited in the QAPP concluded that direct analytical techniques were usually insufficient to detect background levels in rural settings, and this seems to hold true in Ft. Worth as well.

11) Several aspects of public and environmental health protection have been omitted from the QAPP and should be included prior to proceeding with the project. These include, 1) demonstration of informed consent from the affected public, 2) public involvement in the design process and 3) identification of critical characteristics of the affected public (e.g. demographics, health status, socio-economics, etc.), 4) worker protection and occupational monitoring. Some of these aspects are covered in a document entitled "The Fort Worth Method: Phase 2 Demolitions". However, all of the specific information on the aspects of the project specific to the Cowtown Inn should be in the QAPP to allow a full assessment of the project.

12) Active and/or passive sampling for deposition should be included in the project plan. A number of techniques are available for this purpose. Exclusive reliance on soil sampling will not necessarily achieve sufficient sensitivity. Secondary entrainment of dust following demolition might provide a significant and ongoing source of exposure following completion of the project.

13) It is clear from the Project XL submittal that data evaluation and validation must be improved and/or included for the Phase II project. Our review of the TEM data that was submitted for Project XL found a number of mistakes. Both sets of Hemphill samples miscalculated the analytical sensitivity and detection limits by using the recorded stopping time as the air volume rather than the volume of air collected. By doing this the analytical sensitivity was erroneously reported. Both Hemphill datasets claim an analytical sensitivity of 0.005 S/cc, while the actual sensitivities were 0.01 and 0.0086 S/cc. All analyses report concentrations less than the analytical sensitivity, not the detection limit, in contradiction to ISO 10312. The figures prepared for the Hemphill and East Berry demolitions show distances in feet but the sampling records show these distances as yards. The TEM analytical bench sheets for the Phase I demolition were not available, but these should be reviewed to determine if similar errors were made. As a result of these errors, a thorough quality assurance audit on the contract laboratory is warranted prior to initiating the work.

[8]Report, Project XL-Phase I, October 17, 2001, http://ci.fort-worth.tx.us/DEM/xl/phase1_report.pdf

[9]Environmental Asbestos Assessment Manual, Part 2: Technical Background Document, EPA/540/2-90/005b, p. 31-39

14) NEIC was unable to thoroughly evaluate the QAPP without more detailed information on sample collection, handling and transport. If this information is available in a SOP, this should be provided for review. All raw data including bench sheets was requested by NEIC on March 18, 2004.

Specific Comments:

15) Page 7, Section A.2.2. The primary objectives of the demonstration project for the Fort Worth method are phrased in such a way as to imply that the results of a single experiment will be used to extrapolate to a much larger population. The QAPP states:

a) Determine whether asbestos airborne concentrations upwind during demolition of buildings containing in-place RACM are statistically significantly different than those concentrations downwind.
b) Determine whether asbestos airborne concentrations upwind (comparative environmental background) during uploading and disposal of demolition debris characterized as RACM are statistically significantly different than those concentrations downwind.
c) Determine if there is a statistically significant difference between the downwind asbestos airborne concentrations comparing the Fort Worth method with the traditional NESHAP method that requires prior removal of RACM for facilities not in danger of imminent collapse.

The wording of these objectives implies that the extrapolation is from the single proposed demonstration (The Cowtown Inn) to "buildings containing in-place RACM". These overly broad objectives should be replaced with a more modest and attainable goals, such as:

a) determine asbestos airborne concentrations upwind and downwind during demolition of the Cowtown Inn using the Fort Worth and NESHAP methods.
b) Determine asbestos airborne concentrations upwind and downwind during uploading and disposal of demolition debris from the Cowtown Inn generated from the Fort Worth and NESHAP methods.

16) Page 12, Section A.3.1.1: The QAPP states that it is most safety conscious to demolish Building 4 first since it is closest to the church and school. However, high resolution satellite images reveal that Building 4 is actually closer to residential homes on both the West and East. Residents in these homes are at highest risk due to possible long-term exposure to contaminated soil and dust from the demolition.

17) Page 13, footnote 6: The QAPP states that storm water will be collected on site. Provisions should be made to provide sand filtration for demolition storm water that may be contaminated with asbestos.

18) Page 14, Section A.3.1.3: Air sampling density and frequency is insufficient to provide adequate protection for workers and residents. No provision is made for excursion sampling. No provision is made for personal air monitoring. No provision is made for opportunistic monitoring during visible dust emission. No provision is made for analysis by indirect ISO methodology in cases where filters may be overloaded. No discussion of treatment for overloaded filters is included in the QAPP. Please include such provisions

prior to proceeding with the project.

19) Page 15, Section A.3.1.5: The QAPP provides no discussion of risk-based analytical reporting limits for asbestos in runoff water. Estimates of analytical sensitivity for asbestos measurements in water should be provided.

20) Page 19-21, Section A.4.1: The proposed statistical approach can be refined to handle zero structure counts on the TEM analysis through the use of a binomial or a Poisson general linear mixed model, which is a generalization of the analysis of variance approach outlined in this section to a variety of outcome data, including the count data obtained in TEM, in the presence of correlation such as repeated measures. This statistical approach will give improved statistical power for detecting differences between upwind and downwind monitoring locations.

21) Page 22, Section A.4.2.1: Adjustment of an exposure duration from a lifetime to one month is inappropriate, breaks several basic principles of toxicology, and is contrary to Agency cumulative exposure initiatives. This approach ignores the effect of dose-rate on physiological clearance mechanisms in the pulmonary compartment, is presented without supporting scientific basis, and prescribes identical physiological clearance and toxicological susceptibility to all exposed individuals regardless of age, health status, and alternative sources of exposure. Note that the proposed health-based cutoff of 0.01 f/cc is equivalent of the Agency's emergency response trigger level.

22) Page 23, Section A.4.3: This section proposed two criteria for "acceptance of equivalency" of the Fort Worth Method and the existing Asbestos NESHAP method. The Cowtown Inn project cannot provide data to demonstrate the equivalency of the NESHAP and Fort Worth method in a global way, and should be modified to state "for this project". Furthermore, the difference in emissions or air concentration that could be detected between the two methods is not discussed even for the local question of equivalency.

    The first criteria is statistical and compares upwind and downwind locations for both the disposal and landfilling stage for the Fort Worth method. The second criteria compares the average concentration of downwind filters to the proposed 0.01 S/cc level. The first criteria states that this will be the primary criteria, but if the background samples are all non-detect, then the statistical approach will not work and the second criteria will work. This last claim is a result of using inappropriate statistical methods; if more correct methods are used then the non-detect values do not pose a problem, and there is a wide range of concentrations less than the proposed 0.01 S/cc criteria that would be statistically greater than background.

    For low-level asbestos work, the TEM analytical results can be modeled as a binomial variable that scores as one if a grid area has one or more asbestos structures and zero otherwise.[10] The probability that a grid has a structure can be modeled as the number of structures on the filter divided by the number of grids on the filter, i.e.

    $$p = C_a V_a 1000 / A_f A_g,$$

[10]For low-level work, the probability of multiple fibers per grid is small; as the concentration increases this assumption is no longer valid and the number of structures on each grid area must be modeled as a Poisson process; this adds complexity but no essential difficulty.

where C_a is the air concentration in S/mL, V_a is the sampled air volume in liters, A_f is the area of the filter, and A_g is the area of each grid. If the air concentration is homogenous, then the likelihood function

$$L = Binomial(N_f N_g, X, p)$$

where N_f is the number of filters, N_g is the number of grids examined per filter, and X is the sum of all structures observed for all filters.

The greatest ability to detect differences between upwind and downwind locations can be achieved by using all TEM structures, not only (Phase Contrast Microscopy) PCM-equivalent structures, for comparisons with background. From the Phase I study, the detection limit for background based on upwind samples is 60 S/m^3 for all TEM-detectable structures. Suppose the actual background is 20 S/m^3. For a sample volume of 1500 L, a grid size of 0.0085 mm^2, and the minimum of 4 grids examined per filter, there is a probability that a grid has an asbestos structure of 0.0331%. The probability of observing a total of 1 or more structures on all 27 upwind samples is about 5%. Suppose that a criterion of 1 or more total structures in all filters is used as a criteria to distinguish between upwind and downwind. If the downwind air concentration is 830 S/ m^3 (42 times background) then there is about a 5% probability of obtaining 0 total structures. In other words, the use of the criterion of 0 total structures to distinguish between upwind and downwind samples would have a 5% false positive rate and at a concentration of 830 S/m^3 the false negative rate is less than 5%. This means that the statistical criteria can distinguish between upwind and downwind locations at a concentration that is 1/12 the proposed criteria of 0.01 S/cc.

The performance of the comparison can be improved by the use of the Phase I analytical protocol (3000 L, 26 grid areas per filter, 0.01 mm^2 grid area). This protocol would allow a downwind concentration of 180 S/m^3 to be distinguished with a false positive and false negative rate of 1%.

For the actual data, the likelihood ratio can be used for comparing upwind and downwind locations. If the air concentration is identical between the two, then the likelihood function is:

$$L(p) = Binomial(2 N_f N_g, X1 + X2, p)$$

If the air concentration differs between upwind and downwind, the likelihood is:

$$L(p1, p2) = Binomial(N_f N_g, X1, p_1)\, Binomial(N_f N_g, X2, p_2)$$

The log of this ratio follows approximately the chi-square distribution, which can be used to test the hypothesis that upwind and downwind locations are the same.

More complicated models can be fit that allow for heterogeneity between filter locations and times can be developed if the data warrant. These models involve modeling air concentration as a random variable that varies over sampling location and collection times. The statistical techniques for analyzing models of this sort are called general linear mixed

models.

23) Page 25, Section A.4.7: The QAPP indicates that the ISO 10312 procedure will be used but that only structures greater than 5 microns will be counted. The QAPP goes on to state that "*all fibrous minerals observed will be identified and counted, including....cleavage fragments*". It is not clear from this statement whether the primary objectives will be met by the former (PCME) definition or the latter (ISO 10312) definition. This issue will have significant impact on the decision control limits used to support the primary objectives of the QAPP. i.e. if the upwind and down wind averages are based upon structures longer than 5 microns vs. "all fibrous minerals" significantly more grid openings will need to be counted (or much more air filtered) to meet the desired statistical power.

24) Page 28, Section A.5.1: A detailed explanation for occupational monitoring for field personnel should be added to the this section.

25) Page 31, Section A.6.3.2: It is not clear why the QAPP requires reporting structure dimensions in units of millimeters observed at the counting magnification. The reported data should also include a conversion factor to allow interpretation of millimeters observed to actual structure dimensions in microns.

26) Page 32, Section B.1.1: The QAPP states that sampling will be terminated should wind speeds change direction or exceed 30 mph. It seems logical that sampling should proceed to assure protection of human health under uncontrolled or unanticipated environmental conditions. Provisions should be made for indirect analysis of filters by ISO 13794 in the event that they might be overloaded by blowing dust.

27) Page 33, Section B.1.2: The QAPP defines overloaded samples as those having an non-asbestos particulate load greater than 10 percent. It is implied, but not stated, that such samples will not be analyzed. However, such samples may contain information which is very relevant to human health. They could and should be analyzed by indirect preparation procedures described in ISO 13794. Additionally, asbestos analysts could easily analyze samples using direct observation with non-asbestos particulate load as high as 25%. The QAPP should be changed to allow analysis of such samples.

28) Page 34, Section B.1.5: Areas of the Cowtown site which are covered by impervious asphalt should be sampled by using microvacuum or vacuum sock techniques coupled with indirect sample preparation or elutriation methods for analysis.

29) Page 34, Section B.1.5: Soil samples should be analyzed for releasable asbestos. It is well documented that soils contaminated with asbestos far below the analytical sensitivity of the Polarized Light Microscope (PLM) can release unacceptable levels of asbestos into the air when disturbed. Soils contaminated by the procedures outlined in the QAPP may provide an ongoing source of contamination to the residential community. In order to determine the potential for ongoing exposure, measures of releasable asbestos should be made by elutriator techniques or more simple glove-box measurements for releasable asbestos.

30) Page 35, Section B.2.1: The QAPP proposes the use of 25-mm cassettes with a 0.45 micron pore size MCE filters. Studies by EPA's Office of Research and Development indicate that MCE filters may underestimate airborne asbestos concentrations by 30 to 50%. Consideration should be given to employing 0.2 micron pore size MCE filters or nucleopore filters.

31) Page 38, Section B.2.3: No rationale is provided to justify the collection of 800 ml of water for runoff analysis. The QAPP should include a more detailed discussion of the decision criteria and control limits (precision and accuracy) for analysis of runoff water.

32) Page 42, Section B.4.1.2: The QAPP states here that the anticipated air volume to be collected is 3000 liters. While this is a much more reasonable target air volume and is consistent with the air volumes collected in the Phase I pilot project, it is inconsistent with previous references to target air collection volumes in the QAPP.

33) Page 56, Section B.10.3: The proposal to use a detection limit of one-half the analytical sensitivity is at odds with the ISO method. The ISO detection limit is 3 times the analytical sensitivity.