January 28, 2020

The Honorable Patrick McDonnell
Department of Environmental Protection
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Harrisburg, PA 17101

Mr. Michael Kutney, P.G. Chief, Permits and Technical Section
Department of Environmental Protection
Pottsville District Mining Office
5 West Laurel Boulevard
Pottsville, PA 17901

Mr. John Stefanko, Deputy Secretary
Active and Abandoned Mine Operations
Department of Environmental Protection
Rachel Carson State Office Building
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Mr. Gary Latsha, Inspector Supervisor
Department of Environmental Protection
Pottsville District Mining Office
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Pottsville, PA 17901

Re: - EEC Comments, January 21, 2020 re: Response by the RJ Lee Group Regarding the Inquiry for an SOP Used for Differential Counting (Transmittal of RJ Lee Group January 14, 2020 Letter, Rock Hill Quarry, Hanson Aggregates Pennsylvania LLC, SMP # 7974SM1, East Rockhill Twp., Bucks Co., PA, dated January 15, 2020)

- EEC Comments, January 20, 2020 re: Response by the EMSL Laboratories Regarding the Inquiry for an SOP Used for Differential Counting (Email from Benjamin Ellis to Gary Latsha, dated January 8, 2020).

- REPA Comments re: January 16, 2020 Community Update from PADEP, John J. Stefanko, Deputy Secretary

On behalf of Rockhill Environmental Preservation Alliance, Inc. (REPA), enclosed please find two January 2020 reports prepared by Erskine Environmental Consulting on the above subject matters. The reports are supplementary to and augment comments provided in previous memoranda prepared by Erskine Environmental Consulting (EEC) already in your possession. REPA comments on PADEP January 16, 2020 Community Update are also included in this cover letter.

Comments on PADEP Community Update for Rockhill Quarry, January 16, 2020:

EEC's most recent reviews and the above PADEP Community update increases alarming concerns regarding how PADEP continues to address asbestos issues at the Rockhill quarry. On behalf of residents, REPA has repeatedly attempted to present to PADEP credible reports from a highly reputable and experienced Geologist who, time after time, has uncovered misleading conclusions from Rockhill Quarry consultants and vendors regarding asbestos levels. Despite those efforts PADEP persists in allowing self-monitoring and self-reporting through the same consulting laboratories used by the Quarry to employ methods that misrepresent and under report asbestos levels.

EEC has completed numerous reviews to support these conclusions such as:

- **[QGSR] … dismisses by implication that the results are not actionable by regulators when the opposite is true: asbestos is present in concentrations that may produce an adverse exposure to the public who live off of the site.**
- **The survey was not designed with the health and safety of the public nor general regulatory and testing standards in mind.**
- **Considering that the original results were likely under reported, the final averaged result is highly misleading.**
- **The result is a significant under-reporting of asbestos that would normally be reported.**
- **The representation that the concentrations at the Rockhill site are below these thresholds [regulatory - OSHA, EPA] are not actionable or worse, not a potential adverse exposure impact, is dangerously misleading.**

On behalf of residents, REPA requests answers for the following questions posed to PADEP and all who are involved in making decisions regarding mining operations at the Rockhill Quarry:

1. *Why is PADEP considering allowing mining operations when veins of asbestos have been confirmed at the site and airborne asbestos particles from blasting and mining operations cannot be completely contained?*
2. *Why is PADEP going to such great lengths to determine asbestos levels when there is NO SAFE LEVEL of ASBESTOS?*
3. *How can PADEP independently and accurately assess exposure risks from asbestos in the Rockhill Quarry if they continue to utilize the same laboratories used by the Quarry Operators that have repeatedly presented misleading information?*
4. *Why is PADEP even considering potentially putting thousands of residents and school children at risk for exposure to a deadly carcinogen that sickens and kills people?*

Given these indisputable facts we are asking that PADEP seriously consider possible ramifications for their actions and amend their approach accordingly.

Respectfully yours,

Rockhill Environmental Preservation Alliance, Inc.

cc: The Honorable Thomas Wolf, Governor of Pennsylvania
The Honorable Brian Fitzpatrick, U.S. Representative PA 01
The Honorable Steven Santarsiero, 10th Senatorial District
The Honorable Robert Mensch, 24th Senatorial District
The Honorable Craig Staats, PA's 145th Legislative District
Steven Baluh, P.E
Marianne Morano, East Rockhill Township Manager
Amiee Bollinger PADEP
Virginia Cain, PADEP
Robert Fogel, PADEP
Erika Furlong, PADEP
Craig Lambeth, PADEP
Shawn Mountain, PADEP
Patrick Patterson, PADEP
James Rebarchak, PADEP
Daniel Sammarco, PADEP
Sachin Shankar, PADEP
Richard Tallman PADEP
Doug White, PADEP

ATTACHMENT LINKS:

1. EEC Comments, January 21, 2020 re: Response by the RJ Lee Group Regarding the Inquiry for an SOP Used for Differential Counting (Transmittal of RJ Lee Group January 14, 2020 Letter, Rock Hill Quarry, Hanson Aggregates Pennsylvania LLC, SMP # 7974SM1, East Rockhill Twp., Bucks Co., PA, dated January 15, 2020)
2. EEC Comments, January 20, 2020 re: Response by the EMSL Laboratories Regarding the Inquiry for an SOP Used for Differential Counting (Email from Benjamin Ellis to Gary Latsha, dated January 8, 2020)
3. January 16, 2020 Community Update from John J. Stefanko, Deputy Secretary of Active and Abandoned Mine Operations for the PADEP

Erskine Environmental Consulting

Geologic Investigations Hazardous Materials Naturally Occurring Asbestos

TECHNICAL MEMORANDUM

January 21, 2020

Subject: Comments: Response by the RJ Lee Group Regarding the Inquiry for an SOP Used for Differential Counting (Transmittal of RJ Lee Group January 14, 2020 Letter, Rock Hill Quarry, Hanson Aggregates Pennsylvania LLC, SMP # 7974SM1, East Rockhill Twp., Bucks Co., PA, dated January 15, 2020).

The following is a response to the RJ Lee group (RJLG) document referenced above that responds to PA DEP's request for the Standard Operating Procedures (SOPs) used to differentiate particles that originally crystallized in the asbestiform habit (termed "asbestos" by RJLG) and the non-asbestiform habit (termed "cleavage fragments" by RJLG). The review encompasses three items:

1. The absence of an SOP used to differentiate particles on the basis of particle morphology and dimensions,
2. Reference by RJLG to a previous project with a claim that an RJLG differential counting procedure was approved by EPA, and
3. Standard of practice as illustrated in recent report by an Interagency Working Group tasked to recommend test methodology for NOA and commercial products with asbestos present as a natural constituent (in this case, talc mines and talc products).

Much of the RJLG response document describes the basis of RJLG's position using definitions and descriptions in regulations and test methods. Much of this was described in a previous submittal by RJLG, and comments have previously been submitted by EEC in a memorandum dates January 15, 2020. This subject is not revisited here.

Summary and Conclusions.

The following is a summary of conclusions and opinions based on the review of the documents specified above:

- The RJLG laboratory does not have a Standard Operating Procedure (SOP) for the differential analysis of asbestos intended to separate particles based on morphology and crystallization habit. A written SOP would normally and necessarily provide quality assurance procedures that ensure precision, accuracy

and reproducibility of a reported concentration. The SOP would specify quality assurance procedures such as intra-laboratory and inter-laboratory sample exchanges designed to assure consistency. Therefore, the test results submitted by RJLG that were analyzed by differential counting procedures, or tested by procedures that are not in conformance with the standards established through the NVLAP accreditation program, are highly suspect and not verifiable as being accurate, precise or reproducible.

- However, RJLG has a procedure for differential counting by Transmission Electron Microscopy (TEM). The procedure that is outlined is not consistent with standard test methods, and its application under-reports asbestos concentrations as would be reported by the vast majority of asbestos testing laboratories and in accordance with current Standard of Practice. The report cited by RJLG to justify its protocol (Berman, 2003) that includes this protocol on pages 52 and 53 may be accessed by a Google search[1] or direct access at:

  https://www.state.nj.us/dep/dsr/sparta/Core%20final%20report.pdf

- RJLG claims that it's differential counting protocol has been approved by EPA, and cites the Berman (2001) study as a reference. A review of the Berman study indicates that the method was not the EPA approved method.

- The results of the Berman study where the RJLG differential counting protocol was formally tested shows that its application significantly under-estimated risk as compared to risk derived by standard EPA protocol. The study indicates that the calculated risk using the data set produced by RJLG's protocols were significantly lower than the risk calculated using EPA protocol by a factor of six. Therefore, the application of the RJLG protocol will severely under-estimate risk when applied to standard EPA risk assessment protocols.

- A recent release of findings by an interagency working group, including EPA, OSHA, NIOSH and USGS, provides a clear framework for the Standard of Practice for asbestos testing protocol. The report formally documents the Standard of Practice that has been observed by experienced and informed consultants and laboratories for many years. The differential counting protocols advocated by RJLG are not included and dismissed. The report is attached as Appendix A of this memorandum.

[1] D. W. Berman (2003). "Analysis and interpretation of measurements for the determination of asbestos in core samples collected at the Southdown Quarry in Sparta, New Jersey", Report of analysis, Aeolus, Inc., November 12, 2003.

Comment 1: The RJLG does not have a laboratory SOP for differential counting.

Following a review of terminology in some regulations and test methods that apparently were used to justify differential counting, RJLG states, on page 3: *"RJLG does not have a formal SOP for this action but relies on more than 40 years of experience analyzing amphibole minerals."*

The absence of a formal SOP within a laboratory that performs testing and reporting of a listed carcinogen is concerning for several reasons:

1. RGLG provided to PA DEP its certification of accreditation under the National Voluntary Laboratory Accreditation Program (NVLAP) for the testing of asbestos, presumably to document its qualification to perform asbestos testing services. An SOP for the methodology employed to perform asbestos testing is required under the NVLAP accreditation. The document also stated: "*RJLG used the EPA 600/R-93/116 procedure to analyze various bulk (rock) samples."* The NVLAP accreditation is designed to assure that EPA test methods are correctly adhered to so that a test result will be accurate, precise, and reproducible. The accreditation includes participation in the proficiency testing program designed by the National Institute of Standards and Technology (NIST).

   Apparently RJLG has two procedures: one following the NVLAP-required SOP for building materials where procedures under the NVLAP accreditation is legally required and assures validation of a test result, and a separate procedure where the NVLAP accreditation is not legally required (such as for NOA). It is not acceptable to arbitrarily modify a test method and report a result that would differ from the result had the method been implemented as designed, particularly if the deviation is designed to achieve a desired outcome.

2. The primary purpose of a written SOP is to assure that procedures conducted by laboratories produce results that are precise, accurate and reproducible. One of the key components of an SOP are the procedures for the verification of results between analysts within a laboratory (intra-laboratory results) and across laboratories (inter-laboratory results), a requirement specified under the NVLAP accreditation. Participation in the NVLAP program requires intra- and inter-laboratory sample exchange as a method of calibration. A precise, accurate and reproducible result is not possible without a sound quality assurance program designed within an SOP. The absence of an SOP for asbestos analysis that would normally include a sound quality assurance program suggests that the results from the Rockhill quarry are not precise, accurate, and reproducible, and therefore cannot be validated.

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Comment 2: RJLG utilizes a non-standardized procedure for differential counting by Transmission Electron Microcopy (TEM) that selectively, methodically, and improperly eliminates particles reportable as asbestos on a particle by particle basis.

While RJLG does not have a Standardized Operating Procedure designed to assure precision, accuracy and reproducibility, it apparently does have a written procedure marked "draft" that has been used for "cleavage/asbestiform" differentiation by TEM. RJLG cites a paper[2] authored by Dr. Wayne Berman (Berman, 2003), a highly respected scientist in the field of asbestos risk assessment, where differential counting procedures conducted by RJLG were applied and tested against other protocols that calculate cancer risk. The results of this study showing how the RJLG procedure contributes to an underestimation of risk are discussed later in this memorandum.

This differentiation protocol may be found in an appendix of the Berman study on pages 52 and 53, and may be accessed by a Google search using the reference footnoted below, or accessed directly at:

https://www.state.nj.us/dep/dsr/sparta/Core%20final%20report.pdf

The procedure selectively, methodically, and improperly eliminates particles on a particle by particle basis (as opposed to a population of particles) using length and morphological criteria. It relies on the general characteristics of commercial asbestos that are described in test methods and regulations for building materials. The EPA Method, however, states that *"the asbestiform habit is generally recognized"* by these characteristics and *"These characteristics refer to the population of fibers as observed in a bulk sample".* The elimination of individual particles on the basis of having stepped sides (such as are present in asbestos bundles) and non-perpendicular ends (which are common on asbestos fibers) are not prescribed in the TEM protocol by EPA 600/R-93/116, the AHERA, and other TEM methods. The RJLG protocol eliminates biologically active fibers from reporting and under-estimate potential risk, as will be documented later in this memorandum.

Comment 3: RJLG incorrectly claims that its differential counting procedure has been approved by EPA.

On page 4 of its response, RJLG states: *"Such procedures were approved by the EPA for use in differentiating "asbestos" from "non-asbestos" during the investigation into the possible contamination at the Southdown quarry in New Jersey"* and cites the report prepared by Dr. Berman.

[2] D. W. Berman (2003). "Analysis and interpretation of measurements for the determination of asbestos in core samples collected at the Southdown Quarry in Sparta, New Jersey", Report of analysis, Aeolus, Inc., November 12, 2003.

In this report, cited as a footnote, Dr. Berman writes:

- *"The issues to be addressed and the general approach to be adopted for the study of Southdown Quarry were first described in a detailed framework prepared by an expert panel assembled to oversee the study (Expert Panel-Commissioned by NJDEP/EPA 2000). For risk assessment, the approach proposed in a new protocol (Berman and Crump 2001) was adopted for this study".*

The Berman and Crump protocol, which does not apply differential counting procedures, was the only method approved by EPA for the risk assessment. Therefore, the differential counting protocol was not an EPA approved method.

For context: A common practice of Dr. Berman is to compare risk derived by several methods[3]. In this case, he compared the risk calculated for the study by the Berman and Crump method to 1) risk calculated using EPA methodology, and 2) risk derived using data derived from the procedure of differential counting advocated by RJLG. Thus, the risks calculated using the EPA and RJLG protocols were presented for comparative purposes only, and only the Berman and Crump protocol was approved for the establishment of risk for the project.

Neither the Berman and Crump method nor the EPA method utilizes particle differentiation. A reluctance by Dr. Berman to apply the RJLG protocol is indicated in his statement:

- *"Although the procedure defined by RJ Lee for distinguishing true asbestos structures from cleavage fragments was employed in this study to delineate between such structures, this (and similar procedures proposed by others) is not without controversy"* (see page 33 of Berman, 2003).

The basis for Dr. Berman's concern regarding the use of differential counting is found in references throughout the document, including:

- *"…studies that definitively separate effects of dimensions from effects of crystalline habit appear to be lacking. Thus, it is not clear whether the distinction between the crystalline habits of true fibers and cleavage fragments precisely map distinctions in health effects so that questions concerning the biological activity of*

[3] Dr. Berman designed the perimeter air monitoring program for the Calaveras Dam Replacement Project (CDRP), in accordance with the procedures that were employed in the Berman (2003) document. Risk was calculated using five metrics: Berman and Crump, thin metric; Berman and Crump, all widths metric; standard EPA method; enhanced EPA method with amphiboles were assigned a higher potency than chrysotile; and the California Air Resource Board (CARB) metric. None of the protocols applied the differential counting methods that are advocated by RJLG, and all amphibole compositions were included in the calculation of risk. The protocol chosen was the one that was considered to be the most protective to the public. It is consistent with the interagency working group recommendations, attached as Appendix B.

cleavage fragments have not been entirely resolved" (bottom of page 7 of Berman, 2003).

- *"Unfortunately, procedures proposed for distinguishing fibers from cleavage fragments… are controversial and have not been codified. Thus, no formal procedure has been established for determining whether fibrous structures of unknown origin or structures from mixed environments should be counted or excluded when addressing health effects"* (page 8 of Berman, 2003).

These reservations are consistent with EPA's position, documented in previous memoranda by EEC, and reiterated in a recent document by an interagency working group for talc methodology for talc-bearing rocks and products (this is discussed later in this memorandum, and attached as Appendix A).

Comment 4: Dr. Berman's concerns regarding the application of the RJLG protocol for the purpose of risk assessments have not changed.

EEC contacted Dr. Berman to review the results of his study and obtain his current viewpoint regarding the application of the RJLG protocol to risk assessments[4]. The following are a summary of his comments and position that are relevant to the application of the RJLG protocol:

1. The calculation of risk using the RJLG differential counting procedures was not part of the central purpose of the study, rather, the calculation of risk using the RJLG data set was conducted by request. Dr. Berman could not recall exactly who made the request, but pointed out that he reported to EPA and the New Jersey DEP.

2. The procedures for differential counting remain controversial, largely because they have not been adequately tested against other data sets. There are insufficient studies that correlate fiber data derived by the RJLG method and fibers that are biologically active (in other words, those that contribute to cancer risk). Also, because the data have not been verified, the data produced by these methods have not been shown to be accurate and are not reliable.

3. The RJLG protocols may substantially exclude cleavage fragments from a population, but as his study indicates, the methodology excludes fibers that are biologically active (contribute to cancer risk).

[4] Personal communication with Dr. Wayne Berman, January 20, 2020.

Comment 5: The application of the RJLG differential counting protocol to risk analysis lead to a significant underestimation of the risk of contracting mesothelioma and other asbestos-related disease.

The Berman (2003) report cited by RJLG as an example compares the risk of asbestos-related disease as calculated by the three metrics (Berman and Crump; EPA, and both protocols using an RJLG data set). The key fiber counting protocol of each method is described briefly below:

EPA Method.

The EPA method includes fibers that are referred to as "PCM" fibers (if analyzed by Phase Contrast Microscopy) or 7402 fibers (if measured by TEM using the NIOSH 7402 method). These fibers are restricted to those with lengths that are greater than or equal to 5 microns, and widths that are greater than or equal to 0.25 microns. Exposures to asbestos as measured in air samples have been correlated with excess cancer in human populations. The potency of each fiber is equivalent: there is no distinction between chrysotile and amphibole, and no accounting for the potential higher potency of very long and very thin fibers. Thus, the PCM and 7402 fiber population is a surrogate for the biologically active (long and thin fibers) that are also present in the air samples, but not included in the count. The fibers that were selected are referred to as "7402 fibers" in the Dr. Berman report.

Berman and Crump Method.

Rather than use a surrogate, the Berman and Crump method includes the fibers in a population that he has determined to be biologically active. Based on his review and analysis of past data, Dr. Berman assigns a higher potency for amphibole and a higher potency for very long and very thin fibers. As a result, the risk calculated using this method is often higher than the risk calculated by the standard EPA method. The fibers that were selected are referred to as "Protocol Fibers" in the Dr. Berman report.

RJLG Method

The RJLG method applies fibers counted following the RJLG differential counting procedure. Dr. Berman estimated risk using this fiber count using both the EPA and Berman and Crump methods. The fibers that were selected are referred to as "true asbestos fibers only" in the Dr. Berman report.

Comparison of Risk Calculations.

Figure 1 shows a photomicrograph of tremolite asbestos extracted from marble by RJLG using chemical dissolution methods. A question emerges: Does the differentiation protocol employed by RJLG remove only non-asbestos fibers ("cleavage fragments"),

and if so, did the method also differentiate fibers that are biologically from those that are not? If the answer is yes, then there should be a high correlation between the risk calculated using the RJLG fiber population and the Berman and Crump and EPA methodology. If the answer is no, then the method eliminated fibers that are biologically active and contribute to cancer risk.

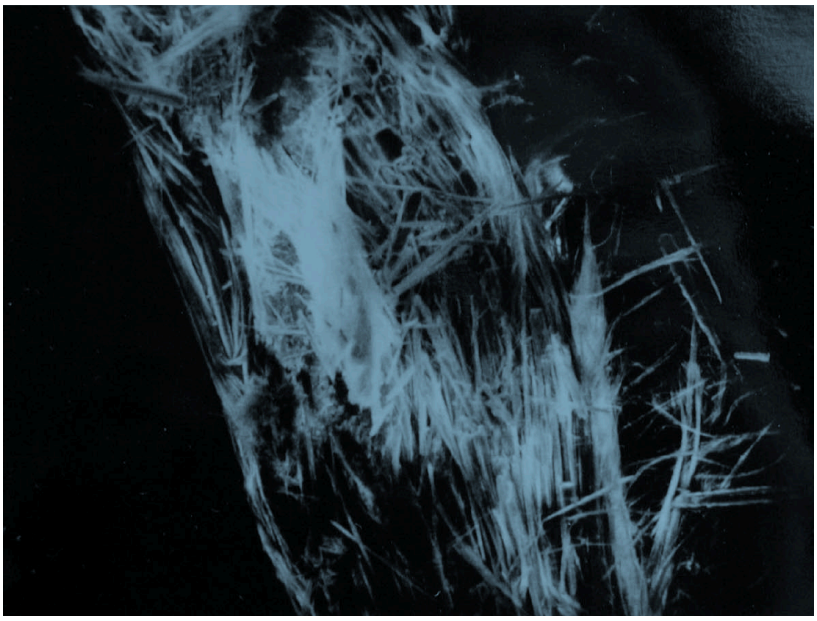

Figure 1: Photomicrograph of tremolite asbestos from Southdown Quarry, prior to particle differentiation by RJLG methodology (from: Berman, 2003).

The results of the comparison of the three methods are presented in Tables 8 and 9 of the Berman study, and summarized below in Tables 1 and 2 and Figures 2 and 3.

Table 1 presents the risk that was calculated at three locations by the Berman and Crump method and the Berman and Crump method using the RJLG differentiated fiber data (note: a risk of 5.00E-4 means that there is an elevation in lifetime cancer risk of five-in-a-ten thousand for area residents). Figure 2 graphically presents the data from Table 1. Of importance here is not the risk that was calculated for this specific project, but the difference between the calculated risk among the two protocols. The risk that was calculated using the RJLG protocol is lower for all three locations, averaging a factor of 2.1 higher. Dr. Berman states that he does not consider a factor of 2 as being statistically significant, however, because the difference is consistent at each location, the measurable decrease in calculated risk at each location would be considered significant by many.

TABLE 1
Comparison of Risk
Berman and Crump vs. RJLG protocol

	Berman & Crump	RJLG	Difference
Point of Maximum Impact	5.00E-04	3.00E-04	1.7
North Facility Boundary	2.00E-04	9.00E-05	2.2
South FacilityBoundary	5.00E-05	2.00E-05	2.5
		Average	2.1

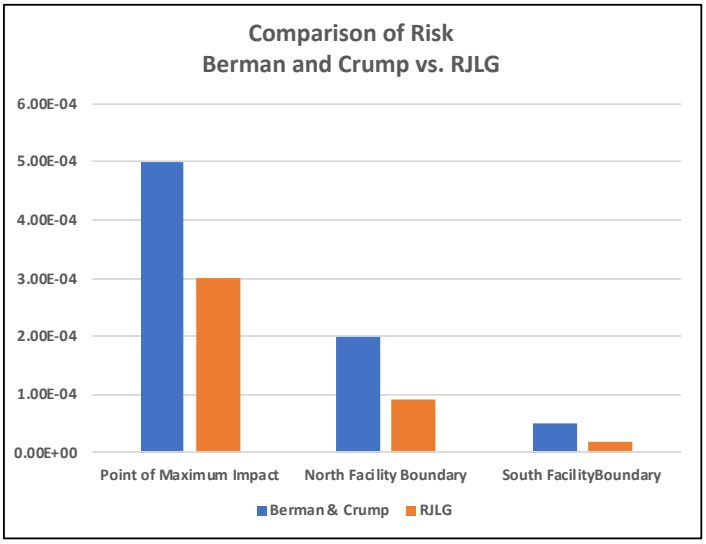

Figure 2: Comparison of calculated risk between the Berman and Crump protocol and Berman and Crump protocol using RJLG differential counting.

Table 2 presents the risk that was calculated at the three locations by the EPA method and the EPA method using the RJLG differentiated fiber data. Figure 3 graphically presents the data from Table2. The risk using the RJLG differentiated data set is much lower at all locations, differing by a factor of 5.8 lower on average. Dr. Berman states that he considers this difference statistically "moderate". Considering that the EPA method is the standard method used by risk assessors and is required under EPA regulations, this nearly six-fold underestimation of risk would be considered significant by most.

TABLE 2
Comparison of Risk
EPA vs. RJLG protocol

	EPA	RJLG	Difference
Point of Maximum Impact	3.00E-05	4.00E-06	6.5
North Facility Boundary	8.00E-06	1.00E-06	7.0
South FacilityBoundary	2.00E-06	4.00E-07	4.0
		Average	5.8

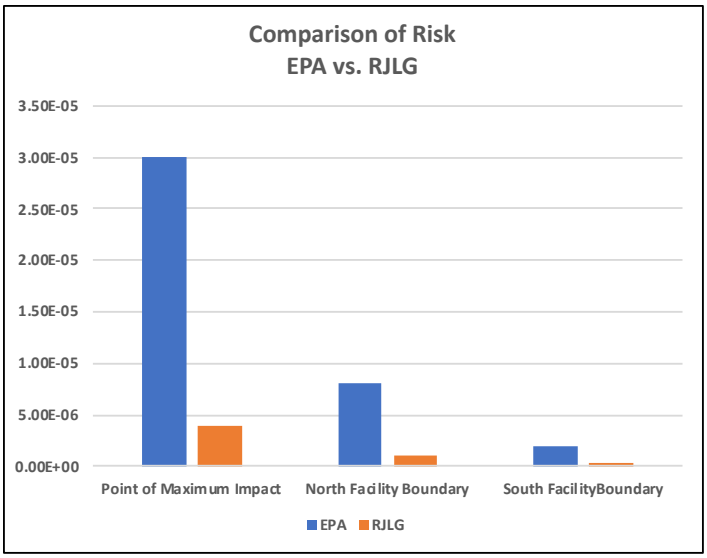

Figure 3: Comparison of calculated risk between the EPA protocol and EPA protocol using RJLG differential counting.

Comment 6: Recent clarification by an Interagency Working Group Indicates that the RJLG Protocol is Outside of the Standard of Practice for the analysis of asbestos in NOA.

On January 6, 2020, the Interagency Working Group on Asbestos in Consumer Products (IWGACP) released an executive summary of its review of test methodologies as they apply to the analysis of naturally occurring asbestos to support the development of standardized testing methods for asbestos and other mineral particles of health concern in talc that could potentially affect consumer product safety (see Attachment A)[5]. The working group included representatives of EPA, OSHA, NIOSH, the USGS and other Federal agencies[6].

Although the working group was tasked with proposed methodologies for natural occurrences of rocks containing talc and talc products, it is applicable to all asbestos that is naturally occurring in rocks and soil, as well as products where the asbestos is present as a naturally occurring byproduct. It is distinct from testing of commercial products such as building materials where asbestos was mined, processed, and applied.

Several of the memoranda previously submitted by EEC included rebuttals to procedures apparently followed by RJLG. In particular, deviations from test methods eliminated the

[5] Executive Summary: Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc, dated January 6, 2020.

[6] Food and Drug Administration (FDA), National Institute for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the U.S. Geological Survey (USGS).

reporting of asbestos particles that would normally be reported in accordance with the reporting requirements of individual methods and Standard of Practice. The IWGACP provides the viewpoint of key regulatory agencies, particularly EPA, OSHA, NIOSH and USGS, and supports many of the concerns that were raised in EEC's memoranda.

Key and Relevant Findings

It is instructive to read the entire document for context and details, and EEC encourages the PA DEP to review it and compare the findings with the opinions expressed in EEC's memoranda. The following is a summary of some key findings and recommendations that support EEC's findings and opinions.

1. *"Both types of elongate minerals (asbestiform habit and non-asbestiform habit) are suspected of having biological activity with similar pathological outcomes. Therefore, the distinction is irrelevant".*

In essence, this finding rebuts the use of differential counting procedures that eliminate particles that were not applied to building materials.

2. *"Covered (applicable) minerals include chrysotile (but not other serpentine minerals) and members of the amphibole group (inclusive; not restricted to the five amphiboles used commercially). Test methods should specify reportable Elongate Mineral Particles (EMPs) identified as amphibole or chrysotile particles as covered minerals".*

This recommendation is stating that all amphibole compositions should be included in the testing and reporting procedures, and not restricted to the narrow range of amphibole compositions found in building materials. In essence, all amphiboles, not only the five regulated amphiboles applied to building materials, are considered to have similar potency, and none should be eliminated from reporting.

3. *"Countable EMPs have an aspect ratio (AR) of >3:1 and a length of > 0.5 µm using the most inclusive criteria for length and AR from among the "asbestos" counting rules in established testing protocols. Testing laboratories should report all EMPs having length ≥ 0.5 µm (500 nm)".*

This recommendation is providing the definition of asbestos for reporting purposes, which is consistent with AHERA protocol. It does not allow for the differential exclusion of particles based on width or crystallization habit. It is inconsistent with RJLG's definition that was selectively culled by RJLG to develop the differential counting protocol.

4. *"IWGACP strongly recommends using TEM with energy dispersive X-ray spectroscopy (EDS) and selected area electron diffraction (SAED) analyses to*

reliably detect and identify chrysotile and asbestiform and non-asbestiform amphibole minerals, including EMPs whose narrowest width is <200 nm (the limit of resolution for light microscopy)".

This recommendation eliminates the false negatives or under-reported concentrations that are common by PLM analysis.

5. *"Adoption of the term EMP as "any mineral particle with a minimum aspect ratio of 3:1", consistent with how this term is defined in the NIOSH Bulletin 62, to resolve ambiguity and disagreement in mineral (asbestos versus non-asbestos) identification."*

This recommendation eliminates the differentiation of particles based on particle morphology or crystallization habit. As was noted above, the IWGACP established that there is no evidence that "asbestos" and "non-asbestos" fibers with similar lengths, widths or aspect ratios have different toxicities based on crystal morphology or crystallization habit.

6. *"Although IWGACP concludes that criteria for differential counting and classification of EMPs would be beneficial, no specific recommendations were agreed upon during deliberations. Therefore, at this time the IWGACP recommends reporting and counting all EMPs of covered minerals under a single classification with additional information that would allow further classification based on measurements such as mineral type and dimensions in the future".*

Again, the recommendation states that while differential counting may be useful for some purposes, it should not be employed as a method to eliminate particles from reporting or risk assessment.

Actually, there is nothing new in the IWGACP findings. It is based on several decades of research in the field of NOA that have been reported during many scientific meetings and journal articles. As such, these recommendations have been considered the Standard of Practice for many years. It is important that the key regulatory agencies have now established this fact in the written record.

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The comments and conclusions provided in this memorandum represents the opinion of the author, and is based on more than 33 years of experience in the fields of asbestos consulting and testing. It is suggested that the RJLG and others review this document, and offer their opinions or rebuttal to the material provided herein. EEC will be happy to review and comment on any submittals.

Please contact me if you have any questions.

Bradley G. Erskine, Ph.D., CEG
Erskine Environmental Consulting

APPENDIX A

Executive Summary: Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc, dated January 6, 2020.

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EXECUTIVE SUMMARY[1]

PRELIMINARY RECOMMENDATIONS ON TESTING METHODS FOR ASBESTOS IN TALC AND CONSUMER PRODUCTS CONTAINING TALC

January 6, 2020

In the fall of 2018, the United States Food and Drug Administration (US FDA) formed the Interagency Working Group on Asbestos in Consumer Products (IWGACP), with representatives from eight federal agencies[2], to support the development of standardized testing methods for asbestos and other mineral particles of health concern in talc that could potentially affect consumer product safety.[3] The IWGACP was formed in response to reports of the presence of asbestos in talc-containing cosmetic products, with talc being the presumptive source of asbestos. Since 2017, there have been several voluntary recalls of cosmetic products by retailers in the US and globally (Canada, Netherlands, Taiwan) due to the presence of asbestos.

Talc is a hydrated magnesium silicate mineral that is used in a wide variety of consumer products including cosmetics, foods, dietary supplements, drugs, medical devices, ceramics, and art materials. Raw material talc is obtained from mines that may also contain asbestos and related minerals. Removal of asbestos by purification of talc ores is extremely difficult. Thus, judicious selection of talc deposits and mining locations within the deposits is necessary to avoid contamination with asbestos and similar biologically active mineral particles. It is imperative that appropriate monitoring methods are available to detect asbestos in talc to ensure its suitability as a raw material for use as an ingredient in consumer products.

The health hazards associated with asbestos are well documented. There is general agreement among US federal agencies, most developed nations, and the World Health Organization (WHO) that there is no known safe level of asbestos exposure. Inhalation of asbestos, from any source, is a safety concern because it can cause the formation of scar-like tissue in the lung, resulting in

[1] The recommendations and opinions expressed in this document are based on discussions on matters of "scientific debate" (contentious issues that have not been completely resolved or finalized in the ongoing debate) among subject matter experts on the IWGACP and do not necessarily reflect the opinions or policies of their agencies. These recommendations do not represent proposed changes to any regulations of the U.S. Government. The use of the terms "IWGACP" or "we" refers to the consensus opinion of the working group scientists and not the individual experts or the agencies they represent.

[2] Food and Drug Administration (FDA), National Institutes for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the Department of Interior's U.S. Geological Survey (USGS). The participating federal agencies have expertise in asbestos-testing and/or asbestos-related issues (e.g., from a health perspective), or because they regulate some of the consumer products that contain talc as an ingredient.

[3] By "consumer products", we are referring to products used by consumers, which are regulated by a variety of federal agencies. This includes, but is not limited to, "consumer products" as defined under the Consumer Product Safety Act.

asbestosis or pleural plaques, or it may lead to the development of lung cancers and mesothelioma. Exposure to asbestos may also lead to the development of other cancers.[4]

Concern about the purity of talc used as a raw material was heightened in the early 1970s when numerous cosmetic products tested positive for asbestos. However, at that time the development of asbestos testing methods was still in its infancy. In 1976, the cosmetics industry implemented voluntary asbestos testing of talc raw materials using the Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 method. Talc suppliers to the pharmaceutical industry use a similar method to certify that talc meets the United States Pharmacopeia's (USP's) requirement for "Absence of Asbestos." To date, both methods rely on the use of X-ray diffraction (XRD) or infrared (IR) spectroscopy followed by polarized light microscopy (PLM) only if XRD or IR is positive for amphibole or serpentine minerals in talc. The CTFA J4-1 and USP methods remain standard test methods despite long-recognized shortcomings in specificity and sensitivity compared with electron microscopy-based methods.

In 2010, FDA asked the USP to consider revising the current tests for asbestos in talc to ensure adequate specificity, and in 2014 the Talc USP expert panel recommended an update of the Talc USP monograph to require an electron microscopy method for the measurement of asbestos in talc (Woodcock, 2010[5]; Block et al. 2014[6]). Recent reports from testing of cosmetic products indicate that because of shortcomings in sensitivity, light microscopy (polarized light microscopy; PLM) sometimes fails to detect finely-sized particles of asbestos and similar minerals even when they are present in talc. Moreover, modern laboratories with expertise in asbestos testing, when asked to test talc-containing consumer products, routinely perform electron microscopy and do not rely solely on PLM. These findings provide support to recommendations from many scientific experts, including those on this Working Group, that transmission electron microscopy (TEM) should be used for asbestos-testing of talc, even if the findings of PLM are negative. (See, for example, Rohl and Langer, 1974[7], Millette 2015[8], Block et al. 2014[5]).

There are many definitions of "asbestos" used in the commercial, geological, and legal domains. As a commercial term, asbestos refers to a group of six mined minerals that have commercially useful properties including flexibility, durability, and heat-resistance. Mineralogists define "asbestos" as those silicate minerals belonging to the serpentine and amphibole groups which have an unusual fibrous (asbestiform) crystal growth habit as opposed to non-asbestiform crystal

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[4] *Asbestos: Selected Cancers*, 2006, Institute of Medicine of the National Academy, Committee on Asbestos; International Agency for Research on Cancer (IARC), 2012, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Monograph 100C. A Review of Human Carcinogens: Arsenic, Metals, Fibres, and Dusts.

[5]Woodcock, J. (2010) Letter to Roger L. Williams, CEO of USP (October 12, 2010). See https://www.usp.org/sites/default/files/usp/document/get-involved/monograph-modernization/2010-10-12-letter-from-dr-janet-woodcock.pdf

[6] Block LH, Beckers D, Ferret J, Meeker GP, Miller A, Osterberg RE, Patil DM, Pier JW, Riseman S, Rutstein MS, Tomaino GP, Van Orden DR, Webber JS, Medwid J, Wolfgang S, and Moore K (2014) Stimuli to the Revision Process, Modernization of Asbestos Testing in USP Talc USP-PF 40(4) https://www.fairwarning.org/wp-content/uploads/2017/12/11TalcDoc.pdf

6 Rohl AN and Langer AM. (1974) Identification and quantitation of asbestos in talc. Environ Health Perspect. 9: 95-109.

[8] Millette JR (2015) Procedure for the Analysis of Talc for Asbestos. The Microscope 63(1): 11-20.

growth. US asbestos regulations and the test methods required to establish regulatory compliance specify each regulated type of asbestos using mineral and commercial nomenclature. Most US regulations specify the six asbestos minerals historically used commercially: chrysotile (a member of the serpentine group) and asbestiform riebeckite (commercially called "crocidolite"), asbestiform grunerite-cummingtonite (commercially called "amosite"), tremolite asbestos, anthophyllite asbestos, and actinolite asbestos (with the latter five being members of the amphibole group).

Asbestos regulations and standard methods for analysis contain a wide variety of "counting rules" designating how to quantify asbestos in occupational or environmental settings using various microscopic methods. Rules were tailored to simplify counting, to improve statistical analysis, and to provide a threshold for mitigating risk when asbestos is known to be present. To date, counting rules have not specifically considered biological activity, overt toxicity, or epidemiology of the kinds of chrysotile and amphibole particles being detected and counted. That is, all mineral particles meeting specified criteria for mineral type and dimensions are expected to be reported and counted.

Importantly, testing methods pertaining to asbestos in articles of commerce were developed for analyzing "bulk materials" containing at least 1% asbestos as an intentional ingredient by weight or in settings where asbestos was known to be present (*e.g.* mines, mills, factories, schools, and other settings). Published methods for analysis of bulk materials were not intended to determine the presence of asbestos in products at less than 1% concentration. In contrast, the likely amount present when asbestos is a contaminant or impurity in talc or talc-containing consumer products might be orders of magnitude below 1%.

Because no single published testing method can be followed, as written, for the analysis of asbestos in talc and talc-containing consumer products, analytical laboratories appear to be adapting published testing methods that were intended for analysis of asbestos in air or building materials. Thus, to help reconcile potential discrepancies in reports of analysis, IWGACP recommends the development of a standardized method specifically for the analysis of asbestos and other biologically active EMPs in talc and talc-containing consumer products for use by government regulatory authorities, industry, and contracting laboratories. Rigorous training requirements, quality assurance, and quality control would need to accompany the implementation of these methods to maintain consistency of results across the field.

The difficulty of identifying and quantifying individual asbestos or other mineral particles present at low concentrations in talc is compounded by the presence of non-asbestiform analogs with the same elemental composition and crystal structure, but different growth habit. Using TEM, differentiation of chrysotile from non-asbestiform serpentine analogs is relatively straightforward; however, each of the non-asbestiform amphiboles can disaggregate into particles resembling asbestiform fibers, giving rise to disputes between laboratories over whether elongate amphibole particles are truly asbestos, or are particles resulting from attrition of larger particles of a non-asbestiform analog. Because both types of elongate minerals are suspected of having biological activity with similar pathological outcomes, the distinction is irrelevant. Lack of consensus concerning what should be called "asbestos" has persisted since the first reports indicating that asbestos might be present in talc used in cosmetics and has inhibited thorough toxicological and epidemiological investigations of disease attributable to talc that contains asbestos.

In light of this lack of consensus, the IWGACP considered applicable published asbestos test methods[9] and other published documents in developing recommendations for terminology, analytical techniques, and criteria for qualitative and quantitative measurement of asbestos in talc and talc-containing consumer products. Based on its review, the IWGACP agrees with the recommendations and rationale provided in the peer reviewed NIOSH Bulletin 62[10] regarding adopting the term "elongate mineral particle" or "EMP" that is defined as "*any mineral particle with a minimum aspect ratio* [*i.e.*, length: width ratio] *of 3:1.*" Thus, an EMP encompasses both asbestiform and non-asbestiform particles that have dimensions that enable them to be respirable. NIOSH Bulletin 62 also introduced two terms "covered mineral" and "countable EMP," that appear to be applicable to the analysis of talc and talc-containing products. A "covered mineral" is defined as "*a mineral encompassed by a specified regulation or recommended standard*" and a "countable EMP" as "*a particle that meets specified dimensional criteria and is to be counted according to an established protocol*." However, for talc and talc-containing products, the recommendations for covered minerals and countable EMP dimensions differ from those discussed in Bulletin 62 for the NIOSH recommended exposure limit (REL). For talc and talc-containing products:

- Covered minerals include chrysotile (but not other serpentine minerals) and members of the amphibole group (inclusive; not restricted to the five amphiboles used commercially).
- Countable EMPs have an aspect ratio (AR) of $\geq$3:1 and a length of > 0.5 µm using the most inclusive criteria for length and AR from among the "asbestos" counting rules in established testing protocols. The specified minimum length of 0.5 µm is consistent with the counting rules for fibers established by the global standard for TEM sampling and analysis, ISO 10312:2019 (Appendix C) and is supported by studies that indicate asbestos particles and EMPs of these dimensions could pose a health concern.[11]

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[9] The Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 Method (1976): http://www.asbestosandtalc.com/EMP%20Detection%20Limits%20ASTM/PCPC000960.pdf ; United States Pharmacopeia (USP) standard for talc (2011): http://ftp.uspbpep.com/v29240/usp29nf24s0_m80360.html; https://www.astm.org/Standard/standards-and-publications.html; USP Food Chemicals Codex (2019): https://www.foodchemicalscodex.org/ ; various ASTM, ISO, EPA, and NIOSH standards: https://www.astm.org/Standard/standards-and-publications.html; https://www.iso.org/standards.html; https://www.epa.gov/asbestos/asbestos-laws-and-regulations; https://www.cdc.gov/niosh/pubs/all_date_desc_nopubnumbers.html

[10] NIOSH (2011) "Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research" *Current Intelligence Bulletin 62*. Department of Health and Human Services. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Publication No. 2011-159 (March 2011). http://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf.

[11] For example, see Suzuki and Yuen (2002) Asbestos fibers contributing to the induction of human malignant mesothelioma. Ann NY Acad Sci 982: 160-176: https://www.ncbi.nlm.nih.gov/pubmed/12562635; Dodson et al. (2003) Asbestos fiber length as related to potential pathogenicity: a critical review. Am J. Ind. Med. 44: 291-297: https://www.ncbi.nlm.nih.gov/pubmed/12929149; Suzuki et al. (2005) Short, thin, asbestos fibers contribute to the development of human malignant mesothelioma: pathological evidence. Int. J. Hyg. Environ. Health 208(3): 201-210: https://www.ncbi.nlm.nih.gov/pubmed/15971859; Boulanger et al. (2014) Quantification of short and long asbestos fibers to assess asbestos exposure: a review of fiber size toxicity. Environmental Health 13:59: https://www.ncbi.nlm.nih.gov/pubmed/25043725; ANSES (2015) Opinion of the French Agency for Food, Environmental and Occupational Health and Safety on "Health effects and the identification of cleavage fragments of amphiboles from quarried minerals": https://www.anses.fr/en/system/files/AIR2014sa0196RaEN.pdf .

The optimal analytical approach should address potential interference by sample matrices and thereby ensure sensitivity at levels or concentrations that are protective of public health. In addition, multiple sampling and analysis methods will be required to provide all the information that is needed to make health protective identification and classification of asbestos and other EMPs of potential concern. To improve agreement in data interpretation among stakeholders and resolve inconsistencies in applying published methods and counting criteria, IWGACP recommends minimum content and format for analytical reports. IWGACP also suggests written protocols that specify appropriate instruments, methods, and counting rules for the detection, quantification, and classification of EMPs. In conclusion, the IWGACP recommends:

1. Adoption of the term EMP as *"any mineral particle with a minimum aspect ratio of 3:1"*, consistent with how this term is defined in the NIOSH Bulletin 62, to resolve ambiguity and disagreement in mineral (asbestos versus non-asbestos) identification.

2. Testing laboratories report all EMPs having length ≥ 0.5 µm (500 nm).

3. That test methods specify reportable EMPs identified as amphibole or chrysotile particles as covered minerals.

4. Test methods require the counting and reporting of covered EMPs as a function of sample mass. When counting, IWGACP recommends referring to guidelines such as ISO 10312 to classify primary and secondary structures. Individual fibers in secondary structures can be counted recording the dimensions of each fiber.

5. Use of TEM at nominally 20,000x magnification, in addition to PLM, to resolve the issues of sensitivity that cause reporting of false negatives for covered EMPs. IWGACP strongly recommends using TEM with energy dispersive X-ray spectroscopy (EDS) and selected area electron diffraction (SAED) analyses to reliably detect and identify chrysotile and asbestiform and non-asbestiform amphibole minerals, including EMPs whose narrowest width is <200 nm (the limit of resolution for light microscopy). SEM might be useful as a complementary method but has significant shortcomings for identification of chrysotile and visualization of the narrowest particles in the population that can only be overcome by using TEM.

6. That "mass percent," a unit that is frequently used to express content of asbestos in commercial bulk materials, is not appropriate for measurement of EMPs in talc and consumer products containing talc because weight percent does not correlate with the number of fibers, and one large fiber could dominate the mass percent value.

7. Although IWGACP concludes that criteria for differential counting and classification of EMPs meeting criteria in #2 would be beneficial, no specific recommendations were agreed upon during deliberations. Therefore, at this time the IWGACP recommends reporting and counting all EMPs of covered minerals under a single classification with additional information that would allow further classification based on measurements such as mineral type and dimensions in the future.

In addition, the IWGACP has identified the following as areas for directing efforts to promote reliability of the analytical methods for asbestos and other EMPs of health concern in talc and talc-containing consumer products:

- Validation of analytical methods (XRD, PLM, TEM) specific to talc and consumer products containing talc that minimize false positive and false negative results.
- Research and validation of methods of sampling that maximize sample representativeness and minimize error and false positives and false negatives.
- Research on methods for sample preparation, in particular, treatments (e.g. "concentration methods") that improve sensitivity while leaving covered minerals unchanged with respect to identity and dimensions.
- Development of talc-specific reference standards with known concentrations of specific EMPs that can be used to assess laboratory and analyst proficiency, increase inter-laboratory concurrence in method validation, minimize reporting errors, and potentially provide for improved reliability of quantitative analysis.

Erskine Environmental Consulting

Geologic Investigations Hazardous Materials Naturally Occurring Asbestos

TECHNICAL MEMORANDUM

January 22, 2020

Subject: Comments: Response by the EMSL Laboratories Regarding the Inquiry for an SOP Used for Differential Counting (Email from Benjamin Ellis to Gary Latsha, dated January 8, 2020).

The following is a response to the EMSL Laboratories (EMSL) email that "provided background information on what constitutes asbestiform structures and the decision making process used by EMSL during analysis on samples analyzed" for PA DEP.

Based on the information provided, it can be concluded that:

- EMSL does not have an SOP for differential counting, and therefore, the differential counting procedures are not incorporated into its SOP for asbestos testing as required by the NVLAP accreditation.

- EMSL offers differential counting only upon request, and therefore, is not conducted during routine testing that rely on standardized test methodologies and in accordance with protocols established through the NVLAP accreditation program. EMSL apparently has two independent procedures: one that conforms to test methods and protocols established under the NVLAP accreditation, and another, modified under request, that is applied in select cases.

- EMSL acknowledges that criteria used for differential counting is subjective, and not included within recognized test methods. As a result, its test results that used these methods cannot be verified as precise, accurate or reproducible, and therefore, cannot be validated.

The following is a brief summary of the email using specific passages to illustrate where EMSL is in agreement with conclusions in previous memoranda submitted by Erskine Environmental Consulting (EEC), and where EEC disagrees with EMSL's protocols.

EEC is in agreement with EMSL on the following topics:

EMSL Statement: *"Unfortunately, the distinction between asbestiform and non-asbestiform on a fiber by fiber basis is difficult at best and is often based on subjective morphological observations. Even the importance of the distinction between asbestiform and other fibers with similar dimensions is subjective and highly debated".*

EEC Response: This statement is true: the differentiation is difficult at best, highly subjective, and highly debated. Conformance with the standard procedures used to test asbestos using standardized test methods is neither difficult, subjective, nor debated.

EMSL Statement: *"…it should be recognized that the distinction can be subjective. It is important that the client and the laboratory have a discussion prior to analysis, about the specific criteria to be applied".*

EEC Response: Normally a client expects that a test method be followed correctly and the results are accurate, precise and reproducible. Otherwise, the test result cannot be relied upon. When deviating from a test method, or implementing a new testing protocol that is not standard, it is critically important that the laboratory discuss the pros and cons with the client, and explain in writing how the test methodology deviates from Standard of Practice. In this case, the client should be aware that the test methodology is not in conformance with standard test methods, and the result can deviate considerably from a result that would normally be produced by applying the test method correctly.

EMSL Statement*: "Since the asbestiform and non-asbestiform manifestations of a particular mineral can have identical chemistry and crystallography at the microscopic level, the primary distinctions are made by morphology (size and shape) of the elongate mineral particles (EMPs) in question. Because of this, it is extremely important to recognize that the preparation steps that the laboratory employs can have a profound impact on the size and shape of the fibers observed during analysis".*

EEC Response: Minerals that have crystallized within a rock are crushed and pulverized to a finely comminuted powder. Therefore, the morphology of the original fibers may be severely altered. This is only one reason why the shape of the fiber tips, for example, cannot be used as a method to positively identify asbestos. Many fibers will be omitted from reporting because of morphological alteration during the pulverization process.

EMSL Comment: *"The specific criteria outlined in the analytical methods significantly affect the final results that are reported. These criteria typically do not address distinguishing asbestiform from non-asbestiform EMPs".*

EEC Response: This is a correct statement. Test methods do not provide criteria for differential counting. It is not part of the test methods. Therefore, if differential counting protocols are used, the laboratory cannot claim to be following a specific method.

EMSL Statement: *"The asbestiform habit is best defined at the macro scale on hand samples and not the micro scale on individual fibers".*

EEC Response: The general definitions and descriptions of asbestos cited in regulations and by both RJLG and EMSL are derived from observations of commercial-grade asbestos deposits that can be observed without the aid of a hand lense. These descriptions and characteristics include: long curved fibers; high aspect ratios; matted masses, etc. However, the overwhelming majority of asbestos in rocks is too fine to observe macroscopically or with a hand lense. Asbestos is defined on the micro scale by the counting rules established in the test methods, and not by a general description of commercial grade asbestos. It is not acceptable to apply these descriptions during microscopic analysis and overturn the positive identification of asbestos.

EMSL Statement: *"None of the current asbestos methods can unambiguously classify a countable fiber as asbestiform vs. cleavage fragment in all cases. Furthermore, it cannot be unambiguously stated that non-asbestiform fibers can be dismissed as non-contributors to asbestos related diseases".*

EEC Response: This is precisely why the test methods do not include protocols for particle differentiation.

EMSL Statement: *"Cleavage fragments have the potential to be elongate, and if they have the same chemistry as the asbestiform variety of a specific mineral, they will be counted as a fiber during analysis".*

EEC Response: Correct- EPA and other test methods do not allow for particle differentiation. Any additional analysis involving differentiation is not in conformance with the test methods.

EMSL Statement: *"Below are some common definitions…"*

EEC Response: As stated above, these "definitions" rose from massive commercial-grade deposits, and are not incorporated into the test methodologies.

EEC is in disagreement with EMSL on the following topics:

EMSL Statement: *"TEM analysis involves more analysis and decisions on a fiber by fiber basis. The lab can characterize the fibers present in the sample with a particle size distribution that includes average length, width, aspect ratio etc. However, on a fiber by fiber basis subjective decisions need to be made on the basis of morphology as to whether the particle is to be included in the overall count".*

EEC Response: TEM analysis following the test methods do not involve "more analysis and decisions on a fiber by fiber basis". It involves an analysis that is specified in the test method itself. There are no procedures within test methods to conduct such an analysis, and no criteria to apply the results. EMSL states that subjective criteria are needed for the analysis of individual fibers, and acknowledged that the sample preparation procedure can seriously affect a sample. A subjective analysis produces a qualitative result at best, and perhaps this is one reason why the field sampling report is titled: "Qualitative Geologic Survey".

EMSL Statement: *"In a scientific approach to this technical challenge, EMSL has adopted the following criteria for differentiation of asbestos vs. non-asbestos elongate particles".*

- *Elongate mineral fibers of amphiboles with pointed terminations (acicular), Rounded or cleft sides or ends, or do not meet aspect ratio will be counted as non countable elongate mineral fibers (Non- Asbestiform)*

EEC Response: There is nothing scientific about using these protocols to eliminate fibers from reporting. The scientific approach is to test the use of the criteria against other test data, and conduct an analysis assuring that fibers that contribute to a cancer risk are not inadvertently removed. Quality assurance testing has not been conducted, and at least one major study has shown that the application of these untested and subjective protocols significantly under estimate risk (see EEC's response to RJLG, dated January 21, 2020).

These applications are subjective, and are not recognized in test methods. Asbestos fibers often have rounded and cleft ends, as well as sides that are cleft (indented) and not wholly parallel. See Figure 1 on the following page as an example.

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Figure 1: Scanning Electron Microscopy (SEM) photomicrograph of tremolite asbestos rock fragment collected within the Franciscan Complex in the San Francisco Bay Area region of California. Note the numerous fibers with rounded, pointed and cleft ends, non-parallel sides, and non-perpendicular ends, all of which would be eliminated using EMSL's and RJLG's differential counting criteria.

The comments and conclusions provided in this memorandum represents the opinion of the author, and is based on more than 33 years of experience in the fields of asbestos consulting and testing. It is suggested that the RJLG and others review this document, and offer their opinions or rebuttal to the material provided herein. EEC will be happy to review and comment on any submittals.

Please contact me if you have any questions.

Bradley G. Erskine

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1/16/20 Email:

Hello,

You are receiving this email from the Pennsylvania Department of Environmental Protection (DEP) because you have expressed interest in the Rock Hill Quarry in East Rockhill Township, Bucks County.

As of January 16, 2020, mining and related activities remain under a cessation order.

Since the last community update, sent on December 23, 2019:

- Hanson requested an extension on the January 20th deadline from DEP to respond to requests for additional testing and analysis for asbestos in aggregate and water at the quarry. The purpose of the extension request is to address comments that DEP is preparing in response to the Qualitative Geologic Survey report, submitted on Nov 15, and East Rockhill Township's review on this report, submitted on Dec. 23. DEP will be granting this extension.
- DEP requested and received Standard Operating Procedures (SOPs) from ESML and RJ Lee Group, the two laboratories that tested for asbestos on behalf of DEP and Hanson, respectively. DEP requested these two SOPs to compare the different methods used for testing the samples and the research supporting those methods. Both SOPs have been posted to the webpage.
- DEP has not yet received a final response from the PA Department of Health in response to questions asked by DEP regarding asbestos. Once received, those responses will be shared publicly and posted to the webpage.

DEP continues to update its webpage for this project, available at:https://www.dep.pa.gov/About/Regional/SoutheastRegion/Community%20Information/Pages/Rock-Hill-Quarry-.aspx

If you received this message from a friend and would like to be added to the list, please contactRA-EPmining@pa.gov to be added.

Thank you for your continued interest in DEP's oversight of the Rock Hill Quarry.
Sincerely,
John J. Stefanko | Deputy Secretary
Active and Abandoned Mine Operations
Department of Environmental Protection