Message

From: Williamson, Laura [LWilliamson@mt.gov]
Sent: 1/15/2020 9:09:10 PM
To: Greene, Nikia [Greene.Nikia@epa.gov]; Partridge, Charles [Partridge.Charles@epa.gov]
CC: Harwell, Todd [tharwell@mt.gov]; Ferguson, Matthew [Matthew.Ferguson@mt.gov]; Reed, Daryl [dreed@mt.gov]
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019
Attachments: Assessment of Butte Meconium Data_LW notes_1.15.2020.docx; Meconium Data2.xlsx; Meconium Data.xlsx; Example of interference_DPHHS.pdf

Hi Nikia and Charlie,

Thank you for following up with Dr. Hailer to get additional information on the ICP-MS run for the Butte data.

The Environmental Lab at DPHHS has the same (or very similar) instrumentation as that used in the study. DPHHS's Metals Chemist in the Environmental Lab has reviewed the output and supporting materials submitted by Dr. Hailer. Attached is her assessment of the ICP-MS analysis. Todd, Matt and I met with her this morning to review her assessment. The take home message from her assessment is: Several issues were identified in the QC methods, therefore we have concerns about the accuracy of the reported results.

After you've had time to review, let me know if you've got questions. We can arrange for a meeting with our chemist and she can talk you through her assessment.

Laura

From: Greene, Nikia
Sent: Monday, January 6, 2020 3:05 PM
To: Williamson, Laura ; Ferguson, Matthew
Cc: Partridge, Charles ; Reed, Daryl ; Lynn Woodbury
Subject: [EXTERNAL] FW: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

FYI: Also, I wanted to let you know EPA will be presenting at the Board of Health meeting on February 5th, 2020 to present our review and findings of the meconium study. We also may present at the Council of Commissioners meeting that evening.

Laura, I have many stakeholders asking about plans for the recent McDermott Brain Cancer Study. Can you please keep me updated on DPHHS's plan/process for that study?

Thanks,

Nikia Greene
Remedial Project Manager
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(406)-457-5019
greene.nikia@epa.gov

From: Hailer, Katie <KHailer@mtech.edu>
Sent: Monday, January 06, 2020 2:34 PM
To: Greene, Nikia <Greene.Nikia@epa.gov>; LEAD, JAMIE <JLEAD@mailbox.sc.edu>; MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>

Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>; Hartline, Beverly <BHartline@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Nikia,

Attached and below is the additional information you have requested for the MT samples. The meconium sample collection and digestion document is the same for both sites, Butte and Columbia. The rest of the information provided is specific to the Butte samples.

1. What is the individual calibration standard values that were used to set up the calibration curve?
   The calibration values for the meconium analysis are as follows:
   As, Sr, Mo, Cd, Pb, and U were calibrated using 0, 0.1, 1, and 10ug/L standards.
   Mn and Se were calibrated using 0, 1, 10, and 100ug/L standards.
   Cu was calibrated using 0, 10, 100, and 250ug/L standards.
   Zn was calibrated using 0,10, 100, and 500ug/L standards.
   Al was calibrated using 0 and 10ug/L standards.
2. The Instrument Quantitative Data report for the calibration standards to show the intensity and counts of the internal standards.
   See attached excel document
3. The spiking levels of the individual analytes for the Lab Fortified Blank and the sample spikes.
   The spiking levels used in the LFBs and sample spikes are as follows:
   Mn: 5ug/L
   Cu: 20ug/L
   Zn: 50ug/L
   As: 5ug/L
   Cd: 5ug/L
4. The certified values for sample T- 231. Was it carried through the digestion process?
   The certified values for sample T-231 can be found here:
https://bqs.usgs.gov/srs_study/reports/analyte_report.php [bqs.usgs.gov]
   The T-231 was not carried through the digestion process
5. Were the sample digests diluted prior to analysis or analyzed direct?
   They were diluted to 50mL after digestion. They were not further diluted prior to ICP-MS analysis. See attached protocol
6. What were the initial sample weights used in the digestion process and the final volume.
   See attached protocol
7. Were the samples dried, ground and weighed, or weighed as received? Were final values expressed as dry weight basis or as Received basis?
   Wet weight, weighed as received
8. What was the instrument rinse time between samples? (Possible carryover from high to low)
   The rinse time between sample analysis includes a 40 second wash in 1% TMG HNO3 at a pump speed of 35rpm, then a 35 second sample flush time after the autosampler has moved to the sample at 35 rpm, and finally a 10 second read delay of the sample at 20rpm prior to the analysis, which is also performed at 20rpm.
9. Was a digestion Blank carried through the process? If so, what are the values of the analytes? On the instrument printout, is Sample ID LBlank following the CV a digestion blank or a continuing calibration blank?
   The sample "MBLANK," which was run #36, is the digestion blank carried through the procedure. The LBLANK samples following the CVs are laboratory blanks, which would also function as continuing calibration blanks. The EPA may call them something different than I do. They are not digestion blanks.
10. Data calculations from the instrument data to the final reported values.
    Do your own math

Katie

From: Greene, Nikia <Greene.Nikia@epa.gov>
Sent: Wednesday, December 18, 2019 5:33 PM
To: LEAD, JAMIE <JLEAD@mailbox.sc.edu>; MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>; Hailer, Katie <KHailer@mtech.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Professors Lead, McDermott, and Hailer,

Thank you for all the responses. I understand everyone has much going on as does EPA and others. In order to fully evaluate the results that Professor Hailer sent, the minimal additional information that is necessary is as follows:

The minimum additional information that is necessary to assess the Elan DRC II meconium data:

1. What is the individual calibration standard values that were used to set up the calibration curve?
2. The Instrument Quantitative Data report for the calibration standards to show the intensity and counts of the internal standards.
3. The spiking levels of the individual analytes for the Lab Fortified Blank and the sample spikes.
4. The certified values for sample T- 231. Was it carried through the digestion process?
5. Were the sample digests diluted prior to analysis or analyzed direct?
6. What were the initial sample weights used in the digestion process and the final volume.
7. Were the samples dried, ground and weighed, or weighed as received? Were final values expressed as dry weight basis or as Received basis?
8. What was the instrument rinse time between samples? (Possible carryover from high to low)
9. Was a digestion Blank carried through the process? If so, what are the values of the analytes? On the instrument printout, is Sample ID LBlank following the CV a digestion blank or a continuing calibration blank?
10. Data calculations from the instrument data to the final reported values.

Additionally, If Professor Lead and McDermott decide to share the data I have requested below, EPA and others would need similar additional data, to fully evaluate the Columbia data.

Thanks,

Nikia Greene
Remedial Project Manager
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greene.nikia@epa.gov

From: LEAD, JAMIE <JLEAD@mailbox.sc.edu>
Sent: Wednesday, December 18, 2019 2:24 AM
To: MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>
Cc: Greene, Nikia <Greene.Nikia@epa.gov>; Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>; Hailer, Katie <KHailer@mtech.edu>
Subject: Re: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Dear all

I am overseas travelling, will be taking time off for the holiday and then travelling in the US in early-mid January for other work. My internet connections and computer are very poor at the moment for some reason and only my iPhone is working. I aim to get to your comments and questions by mid January as soon as I am back in office. I'll review all extra information then and respond as soon as possible. I'll have a better idea of dates once I am in the office. I simply haven't had access to look at.
Apologies
Jamie

Sent from my iPhone

On 17 Dec 2019, at 18:39, MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu> wrote:

> Dear Mr. Greene,
> I am the epidemiologist on the team so I will defer to Dr. Lead regarding your request for the laboratory data. I must say we had an extensive QA protocol that was followed during the collection of the samples, since I managed that aspect of the Columbia project. Dr. Lead is planning to do a comparative analysis of the literature at some point next semester but we are currently involved in another project that is taking all our attention. This is important work and we are taking it very seriously.
> Regards,
> Suzanne McDermott
>
> Suzanne McDermott, PhD
> Professor
> Department of Epidemiology and Biostatistics
> University of South Carolina
> Arnold School of Public Health
> Columbia SC 29208
> 803 777-7225

From: "Greene, Nikia" <Greene.Nikia@epa.gov>
Date: Tuesday, December 17, 2019 at 1:19 PM
To: "LEAD, JAMIE" <JLEAD@mailbox.sc.edu>, "MCDERMOTT, SUZANNE" <SMCDERMO@mailbox.sc.edu>
Cc: "Partridge, Charles" <Partridge.Charles@epa.gov>, "Wall, Dan" <wall.dan@epa.gov>, "Sullivan, Karen" <ksullivan@bsb.mt.gov>, "Hutchins, David" <DHutchins@mtech.edu>, "Hailer, Katie" <KHailer@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Professors McDermott and Lead,

Professor Hailer has shared the Butte laboratory data with me and others and I am wondering if I can expect that you will send me the data from Columbia.

If so, please let me know when I might receive the lab data and a response to my other request below.

Thanks,

Nikia Greene
Remedial Project Manager

U.S. EPA, Region 8
(406)-457-5019
greene.nikia@epa.gov

From: Greene, Nikia
Sent: Wednesday, December 11, 2019 9:40 AM
To: LEAD, JAMIE <JLEAD@mailbox.sc.edu>; Hailer, Katie <KHailer@mtech.edu>; MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Professor Lead,

Thank you for the response to my data request. At this time, EPA is not in a position to commit to the development of a new program of study in the area of meconium. However, I am thankful that you would be able to share data from your study. The reasons why I am requesting the data are as followed:

1. A "potential public health emergency" was announced in Butte (as referenced in the Montana Standard November 26, 2019)
2. EPA is tasked with protection of human health and the environment and most all of the city of Butte falls under EPA's Superfund authority.
3. For EPA to validate the data we need the original data/outputs, and QC information from the ICP-MS analysis.
4. The archived data (physical samples) will be challenging to analyze as you discuss below; however, EPA would like the opportunity to perform an independent analysis to confirm the results.

Furthermore, I would like to make a few additional requests from you:

1. You had mention below that "limited literature data in general agrees with our data and interpretation". Could you please point me to the literature you are referring to. EPA's initial review of the literature referenced in your cross-sectional study and others produces the table below.
2. Please let me know if the meconium for your study was sampled under a Quality Assurance Project Plan or a Sampling and Analysis Plan. If so, could you please share the study planning document(s)?

Table

Lastly, your cross-sectional pilot study on metals concentrations was surprising to me as the EPA Remedial Project Manager for the Butte Priority Soils Operable Unit and was alarming to the public. Extensive investigations have been conducted in Butte since the early 1980's and EPA has determined that lead, arsenic, and mercury are the primary human health risk drivers and copper, manganese, and zinc were not identified as important contributors to exposure. Thus, the identification of these metals as contaminants of interest in your pilot study is unexpected. After the EPA has had an opportunity to further review the results from your study, the EPA will take the appropriate steps to investigate the concerns or conduct an additional study. Until EPA has had the opportunity to review your original and archived data, we can only make limited statements and assumptions about the content of the 4-page journal article summarizing your study results. Moving forward, the EPA needs to validate and independently confirm the results and conclusions from your study. As a researcher, I am sure that you

appreciate and understand that the EPA will follow a scientific process for verifying the results from these types of studies and make data-driven decisions on how to protect human health and the environment.

If you have any questions on my original requests and the requests listed above, please do not hesitate to contact me. Again, I really appreciate your willingness to help the EPA verify the results from your study.

Thanks,

Nikia Greene
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From: LEAD, JAMIE <JLEAD@mailbox.sc.edu>
Sent: Tuesday, December 10, 2019 4:23 AM
To: Hailer, Katie <KHailer@mtech.edu>; Greene, Nikia <Greene.Nikia@epa.gov>; MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Dear Nikia, all,

I completely agree with Dr Hailer. On the matter of existing samples, in some cases we do not have remaining samples and, where we do, the samples will not provide accurate metal data for a number of reasons. I see no advantage and several problems with attempting to re-analyze any remaining samples. I also encourage you to perform you own study, including importantly any effects, which we have not looked at yet. We have quantified an exposure biomarker and it is more important to investigate possible human health effects.

I'm happy to share disaggregated data as is standard. Although your request for raw data is unusual, I am in principle happy to share but several things give me pause. First, I didn't realize that you had already seen Dr Hailer's data, partly discounted it and also would not or could not quantify the metals which we found to be potentially problematic. Secondly, as mentioned, I have shared data before with colleagues and it is generally disaggregated, but not raw data, for modelling, data comparison etc.. In this case you want raw data and the purpose is not clear. The request for data and samples appears to carry an implicit criticism of our professional capability; either our competence or our honesty. For the SC study, Drs Hailer, McDermott and myself supervised the research and design. Samples were handled and data analyzed by several very experienced PhD students (published and graduated), the analysis was performed by a dedicated university ICP-MS facility with a very experienced laboratory manager. The data was interpreted by the students under my direction and checked by me several times. Thirdly, I think you should have been aware of the issues of re-analysis of archived samples. Now that you are, and given the potential problems for human health, it does seem to the most appropriate way forward is to perform a new and more detailed study building on our preliminary data, including more samples and an assessment of potential health effects rather than re-checking peer-reviewed data. Fourthly, limited literature data in general agrees with our data and interpretation. However, there is clearly a need for more data because of the limited nature of literature data and the preliminary nature of our study. Taken together, the request for raw data does not seem to be scientifically justified and the

logical next step is a more detailed study. If you have concerns about the data quality, I suggest you perform another independent preliminary study.

So, although happy to share data, I would like to know the reason for the request and, more importantly, a commitment to develop a program of study in this area. This does seem the best way forward and I would be happy to discuss.

Best,

Jamie Lead,
Endowed Professor of Environmental Nanoscience and Risk,
Director of the SmartState Center for Environmental Nanoscience and Risk (CENR),
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Sent from Mail [protect2.fireeye.com] for Windows 10

From: Hailer, Katie
Sent: Friday, December 6, 2019 3:49 PM
To: Greene, Nikia; MCDERMOTT, SUZANNE; LEAD, JAMIE
Cc: Partridge, Charles; Wall, Dan; Sullivan, Karen; Hutchins, David
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Dear Nikia,

I am happy to provide you with my raw data from the ICP-MS work. I should have that information to you early next week. I have been in contact with Dr. Jamie Lead from S.C. He is the chemist (who is also in the top 1% of cited scientists worldwide for 2019) that performed the sample analysis in Columbia. He is copied in on this email. He is currently out of the country and only has access to some of his raw data at the moment. He will send you the full set of raw data as soon as possible, once he returns to the US.

I'd like some clarification regarding your request of our remaining physical samples. There are many potential issues with re-analyzing these samples. First off, these samples have been sitting in a freezer for over a year. Most of the remaining samples do not contain sufficient amounts to perform an identical analysis (less than 1g of sample present) which means that methods will need to be cut by ½ or a 1/4 . With concentrations in the low ppb for some metals (especially the samples from Columbia), cutting the method in half or more, you run the risk of not detecting any metals, giving you false negatives on the results. In addition, while sitting in the freezer for over a year, there could be sorptive metal loss or even microbial degradation. Conversely, loss of water from the samples could actually concentration metal levels, giving higher concentrations. Having not conducted time lapse studies on meconium samples myself, I can only speculate as to how the sample might degrade or change over time. Instead of trying to re-analyze old samples with a potential myriad of unknown issues, why don't you collect some new samples from Butte and analyze them? Once you get approval, sample collection

is essentially free and working with fresh samples will eliminate the concerns listed above. I would be happy to work with you to make the correct connections within St. James to gain approval to verbally consent mothers and gather additional samples.

My second point of clarification is regarding your statement of "contaminates of concern". When I met with you, Charlie, and Chris in March 2019, I shared this data with you. Granted in hadn't been published, but the numbers were the same. At that point in time, all of you indicated that you did not have the ability to look at any metals except for the contaminates of concern, and you seemed largely unconcerned with the data because of the lack of lead (Pb) in the samples. My samples were analyzed for Pb, As, and Cd. Only 1 baby had detectable Pb in the Butte set (low ppb concentrations). All samples had detectable As. Cadmium was not detected in any of the samples. What metals will you be able to analyze for? Specifically will you be looking at Cu, Mn, and Zn levels? I'm curious what has changed between March and now that allows you to analyze for these other metals.

Both Jamie and I have been through our own data a number of times and are sure that the units are correct. Parts per billion or ug/kg is a very common unit to express data from ICP-MS analysis and it is also a unit commonly used in other publications using meconium as a sampling matrix. Columbia's numbers with low ppb to below detection for various metals seems to be similar to other published meconium studies from non-exposed populations. Again, I really wonder why time and resources are being spent on trying to find mistakes in our data rather than collecting additional samples and analyzing them for metals?

I'll have my raw data files to you next week. Dr. Lead will have his sent to you once he is back in the US.

Thanks,
Katie

From: Greene, Nikia <Greene.Nikia@epa.gov>
Sent: Thursday, December 5, 2019 2:32 PM
To: smcdermo@mailbox.sc.edu; Hailer, Katie <KHailer@mtech.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>
Subject: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Professors McDermott and Hailer,

I was made aware of the accepted journal (November 13, 2019) of your cross-sectional pilot study performed in Butte and Columbia on November 25th 2019. Also, on November 26th 2019 the Montana Standard published an article "Health study shows startling levels of metals in Butte babies' meconium".

I work with the community of Butte on a daily basis as a Remedial Project Manager for EPA. The main objective of my position is to make sure that the cleanup in Butte is protective of human health and the environment. So when I come across a new study that has metals associated with public health and statements like "potential public health emergency" I am responsible to provide a due diligence review of those possible health issues that may be associated with contaminants of concern that are associated with my site. To ensure that my review is thorough and accurate I am making the following request:

My request is for the original laboratory report from the cross-sectional pilot study. If the report was developed through a commercial laboratory I would like to request the ICP-MS instrument output in Form 1. If the report was developed through a University Laboratory I would like to request the raw output for the laboratory instrumentation. Additionally, if there are any physical samples that have been preserved, I would like to request them from Butte and Columbia or both. I am particularly interested in the physical samples from Columbia.

Thank you for the consideration.

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