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Medical Monitoring Working Group Focused Call Summary Amendment

Mike McAnulty

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February 26, 2024

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RE: Medical Monitoring Working Group Focused Call Summary Amendment

Agency Representatives:

I am writing to you on behalf of Atlantic Richfield Company and Butte-Silver Bow to submit the minutes from the Medical Monitoring Working Group topic-focused call held December 19 of 2023. The minutes, previously submitted on January 10, 2024, have been amended to correct an omission from the list of participants. There are no other changes. The minutes document the discussion highlights from this meeting, which focused on advancing the topic of blood lead data treatment during the period between regular Working Group meetings to support planning for the Phase 3 health study. The amended meeting minutes may be downloaded at the following link:

<https://pioneertechnicalservices.sharepoint.com/:f/s/submitted/EuAV2L1J9FRDq6qPT7jFkdUBqRm vF3UBrfhgd9EPaOuELQ>.

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If you have any questions or comments, please call me at (907) 355-3914 or Eric Hassler at (406) 497-5042.

Sincerely,



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An affiliate of **Atlantic Richfield Company**

Eric Hassler, Director
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TOPIC: TREATMENT OF MULTIPLE BLOOD LEAD RECORDS**DATE: DECEMBER 19, 2023**

PARTICIPANTS: Dr. Charlie Partridge (**USEPA**); Dr. Michelle Zeager (**ATSDR**); Daryl Reed (**MDEQ**); Brandon Warner, Abby Peltomaa, and Kayla Harvey (**BSBHD**); David Dobrinen (**BSB Environmental Database Consultant**); Dr. Seth Cornell (**BSB Board of Health**); Joe Griffin (**CTEC Representative**); Dr. Rosalind Schoof and Amanda Bailey (**AR Technical Consultants**)

OVERVIEW: A subset of Working Group members participated in a call to discuss the process for handling cases of multiple blood lead results for a single patient in the same year, when selecting the Phase 3 study trend analysis BLL dataset. Initial recommendations were included in Section 2.1.2 of the draft Phase 3 Health Study Plan circulated to the Working Group on October 12, 2023, and on slide 23 from the October 24, 2023 Working Group meeting. The plan will be updated to incorporate recommendations discussed during this call and additional information from EPA, when available. The group also briefly discussed arsenic biomonitoring.

Arsenic Biomonitoring:

- EPA raised the topic of arsenic urinary biomonitoring, noting ATSDR's decision to decline, for the time being, EPA's request to complete another arsenic exposure study in Butte
- Currently, reactive arsenic biomonitoring is offered in response to environmental data; not proactively offered to the general public
- Some processes (laboratory, price points, etc.) are in place to implement a monitoring program
- BSB and ARC will need to discuss details and funding prior to Working Group involvement
- Questionnaires and commitments to avoid certain foods/activities prior to testing are recommended

BLL Data Treatment:**Issue:**

- In some cases, a child has more than one BLL test in a given year, referred to herein for simplicity as duplicates (though there may be more than two results for one person)
- For trend analyses, need to select one result per child that will be counted as above or below the specified reference value
- Duplicates can occur for a variety of reasons and may represent multiple results of the same type (capillary or venous) or a combination of types
- Reasons for duplicates may include:
 - Starting in 2022 with implementation of regular confirmation testing, most capillary results >3.5 µg/dL will have a "duplicate", the venous confirmation sample
 - In some cases a second capillary test is completed instead of collecting a venous sample, and may serve as a confirmation sample
 - Follow-up monitoring may be completed in EBLL cases
 - Various other case-specific occurrences

Resolution:

- The group generally agrees with the suggested protocol for treatment of multiple BLL results outlined in Section 2.1.2 (Data Treatment) of the current draft Phase 3 Study Plan (circulated October 12, 2023), extrapolated from CDC protocol for same-day duplicate tests

- Language in Section 2.1.2 will be modified to:
 - Change the last bullet to apply to both capillary and venous results, rather than just capillary (multiple results 15 or more days apart: use initial result)
 - Caveat that the general protocol will be applied, with case-by-case review to determine if the general approach is appropriate and/or identify cases where different treatment may be warranted
- Ramboll and BSB will also look into the question of how past data analyses may have been affected by the occurrence of duplicates, starting with 2018-2019 data
 - Prior to establishment of the Environmental Health Nurse position and regular venous confirmation testing, data were not provided in a way that identified duplicate occurrences
 - Initial evaluation will inform the need to re-evaluate older data
 - BSB will also evaluate if/how far back duplicate identification is feasible for earlier datasets
- In 2023 there were 37 BSB residents aged 6 years or less with more than one BLL record (capillary, venous, or both), with the majority of duplicates being cases of capillary + venous confirmation/follow-up samples
- Charlie will share some work he's done with IEUBK modeling to inform the question of blood lead clearance rates and an appropriate timeframe within which a second BLL test can be treated similar to a same-day test
 - The 10 – 14 day and ≥ 15 day timeframes currently specified in Study Plan (as placeholders) will be updated as applicable based on review of this information
- In response to a question from ATSDR, noted that for BLL data analyses, exposure sources are not factored in and we don't have a way to analyze that based on available information

Additional Notes on BLL Testing/Reporting Processes:

- Immediate venous confirmation testing is recommended any time there is a BLL > 3.5 $\mu\text{g}/\text{dL}$
- When a venous sample is refused at BSBHD, a second capillary test or, if denied, follow up with primary care physician is recommended
- Results of capillary tests taken at WIC and venous samples collected at BSBHD are always provided to the patient's primary care physician, unless the patient or parent requests otherwise or they don't have a primary care physician
- In Montana, results reportable to the State (MDPHHS) include:
 - All venous results, regardless of concentration
 - Capillary results ≥ 3.5 $\mu\text{g}/\text{dL}$ in patients aged < 16 years
 - Results of subsequent tests collected as part of a current EBL investigation, regardless of result