PEER REVIEW SUMMARY REPORT

Independent External Peer Review of the Preliminary Draft Report *Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals*

Prepared for:
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Acknowledgments

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1. INTRODUCTION

Coal combustion residuals (CCRs) are the byproducts resulting from coal combustion that are captured from plant effluent and flue gases prior to discharge to the environment. Over a hundred million tons of CCRs are generated each year in the United States alone. Once generated, CCRs may either be disposed of or beneficially used. Beneficial use is the reuse of CCRs in a product that provides a functional benefit; that replaces a product made from virgin raw materials (referred to as an 'analogous product') on the market, conserving natural resources that would otherwise need to be obtained through practices, such as extraction; and that meets relevant product specifications and regulatory standards. Beneficial use of these CCRs can contribute to a sustainable future by reducing production costs, reducing energy consumption and reducing greenhouse gas emissions, and the amount of natural resources consumed. The U.S. Environmental Protection Agency (EPA), in line with its mission to protect human health and the environment, supports the beneficial use of CCRs in a safe and protective manner.

In response to a recommendation from the Office of the Inspector General (OIG), EPA has developed a preliminary draft report entitled, *Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals*, that describes a methodology developed by EPA to determine the comparability of encapsulated beneficial products made with CCRs and analogous products, which do not contain CCRs, during use by the consumer.[1] Encapsulated beneficial uses are those that chemically bind or physically isolate CCRs in a solid matrix that prevents mobilization of the CCRs into the surrounding environment. Evaluation of unencapsulated uses often requires additional, site-specific considerations and is not addressed in this methodology. Furthermore, this methodology does not address any phase of the product lifecycle other than use by the consumer. Other stages of the product lifecycle either fall under the purview of other regulatory bodies or are already sufficiently addressed by existing regulations.

Versar, Inc. conducted an independent external peer review of this document, using quality assurance procedures to ensure that qualified individuals, free from conflict of interest, were selected to participate. Versar's approach to the selection of the technical expert reviewers consisted of four key steps: (1) development of selection criteria, (2) creation of a source list of external reviewers, (3) screening for conflict of interest, and (4) confirmation of external reviewer participation.

The experts that participated in this review were identified by literature searches of scientific journals, professional societies, and scientific meetings, as well as searches of Versar's internal peer review database of more than 2,000 scientists. As a result of this search, Versar identified 25 scientific experts to contact as potential candidates. Interested candidates provided a current *curriculum vitae* which was reviewed by two Versar staff members to ensure that each candidate had the appropriate scientific credentials and evidence of expertise through a listing of their publications and professional affiliations. The areas of expertise related to groundwater hydrology, construction engineering with knowledge of beneficial use of industrial materials,

[1] While this methodology can be used to evaluate encapsulated beneficial uses of other non-hazardous industrial residuals, the focus of this document is CCRs.

knowledge of coal combustion residues, and general knowledge of the underlying principles of risk screening analyses.

Versar also conducted conflict of interest (COI) screening to obtain unbiased, objective scientific input. This screening involved sending the potential candidates a series of COI screening questions that helped us to determine if they were involved with any other work and/or organizations that might create a real or perceived conflict of interest for the current task. Additionally, each expert signed forms certifying that, to the best of their knowledge, they did not have any conflict of interest related to the task. Upon completion of the COI screening, Versar selected four experts, based on their credentials, to conduct the review. These four experts are recognized within the scientific community for their knowledge and publications related to the topics addressed in the preliminary draft document "Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals."

Peer Reviewers:

Nicholas T. Basta, Ph.D.

Dr. Basta is a Professor at The Ohio State University, School of Environment and Natural Resources. He received his Ph.D. in 1989 from Iowa State University in Soil Chemistry with a minor in Analytical Chemistry. Some of his current research focuses on beneficial use of agricultural, industrial, and municipal by-products in agronomic/environmental systems with emphasis on their risk and environmental impact. He has published over 300 articles, books, bulletins, reports, etc. on environmental soil chemistry and fate/transport of chemicals. He is currently working with the Virginia Center for Coal & Energy Research at Virginia Tech, Appalachian Research Initiative for Environmental Science (ARIES), studying potential exposure pathways and health effects of coal mining. He is also working with the American Water Works Research Foundation examining beneficial use of drinking water treatment residuals to reduce phosphorus loss from agricultural land and to protect surface water quality. He has published papers on the beneficial uses of foundry sand, as well as papers on beneficial uses in soil applications.

Tuncer B. Edil, Ph.D., PE

Dr. Edil is the Research Director of the Recycled Materials Resource Center and Chairman of the Geological Engineering Program at the University of Wisconsin-Madison, Department of Civil and Environmental Engineering. He received his Ph.D. from Northwestern University in 1973 in Civil Engineering. He has published well over 300 papers, including several on groundwater and environmental impacts from coal ash and fly ash in pavement. He has also published on beneficial use of recycled materials in transportation applications. His current research focuses on construction of highways over poor subgrades and the use of industrial by-products and geosynthetics in highway construction. Much of his research focuses on industrial by-products such as shredded automobile tires, foundry by-products, and coal combustion fly ash, as well as compatibility of geosynthetic clay liners and other geosynthetics with acidic mine waste.

Kevin H. Gardner, Ph.D., PE

Dr. Gardner is the Director of the Recycled Materials Resource Center and Professor of Environmental and Civil Engineering at the University of New Hampshire (UNH). He received his Ph.D. from Clarkson University in 1996 in Civil and Environmental Engineering. Currently, his research spans a wide range of environmental processes with the common theme of environmental chemistry, particularly related to environmentally significant surfaces and particles. He also serves as the Director of UNH's Contaminated Sediments Center, with a focus on beneficial use of dredged sediments (including risk assessment for beneficial uses), and in-situ treatment methods. He has published numerous papers including papers on beneficial use of recycled materials and long-term implications for beneficial use. He has also published papers on coal fly ash and long-term weathering of coal fly ash.

Agnes B. Lobscheid, Ph.D.

Dr. Lobscheid is a Principal Scientific Engineering Associate for the Environmental Energy Technologies Division, Indoor Air Department, at the Lawrence Berkeley National Laboratory. She received her Ph.D. from the University of California, Berkeley, in 2004 in Environmental Health Science. Her current research includes life cycle impact assessment for ecological and human health impact analysis using novel exposure modeling to characterize the life cycle impacts from chemical emissions from agricultural, processing, transportation, storage, distribution, and use stages of biofuels. She is also researching the exposure and risk assessment component of a population-based study to understand health impacts from gas cooking burners in California households. She has written papers on air pollution from coal fired stoves and numerous papers on environmental and human health exposure and risk assessment.

The remainder of this document presents the charge questions, which guided and focused the review (Section 2). In Section 3, a summary of the reviewers' comments is provided, highlighting the major suggestions for improving the methodology and document. This section is organized by charge question. Section 4 presents the reviewer comments, as submitted, also organized by charge question.

2. CHARGE TO REVIEWERS

EPA believes that reuse of industrial materials, when performed properly and in an environmentally sound manner, is preferable to the disposal of these materials as it can provide significant environmental, economic, and/or product advantages. In a March 23, 2011 report, the Office of Inspector General (OIG) found that EPA did not follow accepted and standard practices in determining the safety of the 15 categories of coal combustion residuals (CCR) beneficial uses. The OIG recommended that "…EPA define and implement risk evaluation practices to determine the safety of the CCR beneficial uses EPA promotes." In response, the Office of Solid Waste and Emergency Response (OSWER) agreed to "…develop a process or evaluation hierarchy to evaluate the potential risk of beneficial uses of CCRs." In addition, OSWER agreed "… to use common evaluation techniques in a hierarchy to accommodate different levels of evaluation needed considering materials, nature, use, and the necessity for site-specific evaluation, for example." In that response, OSWER also noted that encapsulated uses and unencapsulated uses present different challenges and issues and decided to issue two evaluation approaches in recognition of that fact. The attached draft methodology is OSWER's response to develop an evaluation hierarchy for encapsulated uses of CCRs. It is designed to evaluate the risk that may be posed by substituting CCRs for a non-CCR material(s) in a product, or substituting a CCR-containing product for an analogous, non-CCR product. The purpose of the encapsulated use methodology is solely to conduct comparative risk screening of having CCRs in the product as used. It is not meant to evaluate the inherent risk of the non-CCR product or the full cradle-to-grave risks (i.e., from manufacture to disposal).

A conceptual model will be developed by the second quarter of 2014 for unencapsulated uses of CCRs in recognition of the fact that additional factors may need to be considered given additional potential exposure routes for such uses and relevance of site-specific considerations.

Charge Questions:

Based on your knowledge of the beneficial use of industrial recycled materials and the current CCR encapsulated beneficial uses, please provide comments on the methodology in response to the following:

1. Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?

2. Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

3. Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

4. Are you aware of additional references or other resources that could improve this methodology?

3. SUMMARY OF PEER REVIEW COMMENTS

3.1 GENERAL IMPRESSIONS

The reviewers were generally positive in their overall impressions of the document. One reviewer commented that the methodology consisted of logical steps and that the report was clearly written. Another reviewer stated that the methodology presented a flexible approach for evaluating encapsulated beneficial uses of CCRs. A third reviewer found the methodology to be comprehensive and a scientifically-sound evaluation of risks associated with select beneficial uses. However, areas of improvement were also noted by the reviewers. In contrast to the one reviewer who found the report clearly written, two reviewers pointed out the need to improve the clarity of the document in several areas, including clarifying the definition of various terms (e.g., encapsulated, analogous material, constituents), intended use of the methodology (generic for a beneficial use and class of CCR or specific for each type of material), and specification of the origin of the CCR . Two reviewers suggested adding a list of major beneficial uses of encapsulated CCRs. One of these reviewers also suggested listing the specific COPC/exposure pathways of concern associated with the beneficial uses.

3.2 RESPONSE TO CHARGE QUESTIONS

1. Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?

All of the reviewers had at least one issue with how the methodology was presented in the report or with the methodology itself. One reviewer stated that, generally, the report was written in a clear, robust, transparent, and flexible manner, and did have concerns with the flexibility of the methodology in terms of the risk assessment. This reviewer suggested that the methodology consider natural background levels of those COPCs where the maximum allowable concentrations are below background levels to determine if additional significant risk is added from the encapsulated CCR. Another reviewer, while finding the methodology clear, transparent and flexible, questioned the robustness of the methodology because the general framework of the approach leaves the assessment of a potential decision largely up to the individual reviewing the evaluation. The reviewer added that the methodology should indicate whether or when collection of additional data is warranted for a CCR-based, substitute, or analogous material. Two of the reviewers questioned the clarity and/or the transparency of the report. Suggestions for improvement included adding a flowchart or diagram summarizing development of the methodology, revisions to figures in the report, clarifying who is the "party" conducting the evaluation and making the final decision, consistent use of terms, and clarifying the definitions of terms.

2. Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

The reviewers found the methodology to be applicable to the range of potential encapsulated beneficial uses of CCRs. One reviewer commented that the nature of the methodology makes it widely applicable for non-encapsulated uses of CCRs and uses of other types of byproducts as well. Another reviewer focused on the need to better define the role and use of the weight-of-

evidence approach in the methodology. This same reviewer commented on the need for the methodology to distinguish between the comparison of environmental releases or human exposures to screening levels and health-based thresholds. Similarly, the methodology should explicitly address how mixtures of chemicals could be addressed.

3. Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

Three of the reviewers had suggestions on additional steps or considerations to be included in the methodology besides those mentioned in earlier responses. One reviewer noted that the dust ingestion pathway is mentioned in the text, but is absent from the conceptual model (Figure 2-1). Another reviewer suggested including more discussion on the sufficiency of existing or newly collected data in the methodology. Over 13 additional steps/considerations were received from a third reviewer relating to characterizing the exposure levels, chemical hazard screening, defining terms, statistical analysis, and sensitivity analysis. One reviewer suggested additional guidance on evaluating potential impacts to ecological receptors.

4. Are you aware of additional references or other resources that could improve this methodology?

One of the reviewers responded that while there is a large amount of literature relating to the performance of encapsulated CCRs, leaching methods and evaluation frameworks, inclusion of such literature is not necessary and would complicate the general nature of the methodology. The reviewers did suggest nine additional references (addressing uncertainty and variability in fate and exposure models, WOE, exposure factors, and bioavailability in soils) that would improve the methodology:

Burton, GA, PM Chapman, EP Smith. (2010). Weight-of-Evidence Approaches for Assessing Ecosystem Impairment. Human and Ecological Risk Assessment: An International Journal 8 (7): 1657-1673. http://www.tandfonline.com/doi/abs/10.1080/20028091057547

Hertwich, EG, TE McKone, and WS Pease (1999). Parameter uncertainty and variability in evaluate fate and exposure models. Risk Analysis 19(6): 1193-1204.

Hertwich, EG, TE McKone , and WS Pease (2000). A systematic uncertainty analysis of an evaluate fate and exposure model. Risk Analysis 20(4): 439-454.

Linkov, I, D Loney, S Cormier, and T Bridges (2009). Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches. Science of the Total Environment 407(19): 5199-5205.

Mumtaz, MM and PR Durkin (1992). A weight-of-evidence approach for assessing interactions in chemical mixtures. Toxicology and Industrial Health 8(6); 377-406.

Paté-Cornell, ME (1996). Uncertainties in risk analysis: Six levels of treatment, Reliability Engineering and System Safety 54(2–3): 95-111.

Scheckel, K.G., R.L. Chaney, N.T. Basta and J.A. Ryan. 2009. Advances in Assessing Bioavailability of metal(loid)s in Contaminated Soils. Adv. Agron. 107:10-52.

U.S. EPA (2011). Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F.

Weed, D (2005). Weight of Evidence: A Review of Concept and Methods. Risk Analysis 25(6): 1545- 1557. http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.2005.00699.x/full

4. REVIEWER COMMENTS

4.1 GENERAL IMPRESSIONS

Nicholas Basta, Ph.D.

The methodology described in the preliminary draft is comprehensive and offers a scientifically sound quantitative evaluation of environmental human and ecological risk associated with select beneficial use of encapsulated CCRs. The draft can be improved by listing expected major beneficial uses of encapsulated CCRs and specific COPC/exposure pathways of concern associated with that use.

Tuncer Edil, Ph.D., PE

The methodology presented is intended to provide an evaluation approach for beneficial use of CCRs for encapsulated uses. The introduction rightfully states the EPA's policy of supporting beneficial use of CCRs, balanced with its mission of protecting human health and the environment. The purpose given on page 1-1 makes reference to the EPA's C^2P^2 program and describes the motivation for developing the methodology. The seven damage cases that were not made accessible by the C^2P^2 Website, I believe, did not involve any "encapsulated beneficial use." Therefore, this phase of the methodology is probably not rooted in a real demonstrated damage, thus it should not be unnecessarily cumbersome and extensive but needs to be in place to bring everything, including new encapsulated uses, to the EPA's accepted and standard practice.

Overall, the methodology provides an approach with flexibility to evaluate the beneficial uses. I believe there is a deliberate effort not to invent the wheel again by taking advantage of historical information through the literature survey and employing the methodology with proper exits as shown on the flowchart, avoiding unnecessary extra unneeded steps.

However, there are ambiguities when you look at it as a user that should be improved. More specifically:

- The definition of "encapsulated" is not clear enough. I think some examples in an "including, but not limited to, type of list" would be helpful. For instance, the Ireland EPA lists the following for "bound" applications, meaning encapsulated applications (use of the word "bound" in the US context is not appropriate):

    - Type I addition in concrete, e.g. as filler or lightweight filler aggregate.
    - Type II addition in concrete, e.g. cementitious component in concrete.
    - Cement manufacture, e.g. added as a raw material into kiln feed or added to Portland cement.
    - Ceramic tiles and brick-making.
    - Paints, plastics, rubber and similar.
    - Lightweight filler in bitumen-bound materials, e.g. foamed bitumen or asphalt.

- Hydraulically bound mixtures in pavement construction, e.g. capping, sub-base and road base, and ground stabilization.

This list clearly indicates that soil stabilization is included in "encapsulated." Perhaps, addition of the word "hydraulically bound" is a useful one (as mixtures that set and harden by hydraulic reactions); as it would clearly allow beneficial use of self-cementing fly ash in stabilization of soil and road base materials. I was not sure if soil stabilization was considered in "encapsulated" use reading the definition given in the methodology. There are some other uses that may or may not be interpreted to be within the given definition. For instance, embankment in which fly ash is hydraulically bound to some analogous material or itself hydraulically bound like self-cementing fly ash as opposed to non-reactive fly ash.

- It is not clear whether the methodology is intended in a generic sense for a given beneficial use, e.g. cement replacement in concrete and a class of CCR, e.g. fly ash or specifically for each fly ash produced by a power plant and for each percentage replacing the analogous material. Furthermore, who makes the final determination that the use is acceptable at the end of this methodology?

- If Step 1, Literature Survey demonstrates that no case to be found where the specific beneficial use resulted in damage to human health or the environment, would this be a basis to determine that the use of CCR is comparable to analogous product?

- There seems to be an implication of substituting CCR for an analogous material such as fly ash for cement in concrete production. However, certain uses do not result in substitution but addition, such as adding fly ash to soil for stabilization. Meaning of "comparable to analogous material" can be clarified to cover both cases. It is also not clear what "analogous material" is. Is it the component being substituted, e.g. cement or is it final product, e.g. concrete without CCR? This should be clarified.

Kevin Gardner, Ph.D., PE

The "Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals" presents a hierarchical method that can be used for assessing potential risks associated with CCR beneficial use, specific only to encapsulated forms. The methodology consists of very logical steps that one would fully expect to use to conduct such an evaluation, in particular a comparative analysis with the analogous product not containing CCRs. In general terms, this amounts to:

- Find out if it's already been done (by searching literature);
- If not, use available data to make your own comparison;
- If some concerns are raised from the second step, evaluate potential exposure;
- If potential exposures are greater in the CCR product, conduct screening-level assessment; and
- Screening level exceedances are carried through to a risk assessment.

Included in each step of the methodology are examples to clarify the text of the document. The document is clearly written and presented. There is essentially no chance of misunderstanding from the reading of this document. The methodology presented is very general, but also logical and straightforward. There is scant room for inaccurate information given the general nature of the methodology presented.

Agnes B. Lobscheid, Ph.D.

The preliminary draft Methodology encompasses a traditional risk assessment paradigm, with the main objective to compare end-use or consumer risks between potential COPC and the analogous product. Overall, this document has most of the elements of a traditional risk assessment, i.e., hazard identification, exposure assessment, and risk evaluation. Dose response is not explicitly considered though but taken into account in the health-based screening level. While the HEI is considered as the human receptor, it is recommended that there be additional guidance provided on how to deal with sensitive ecological receptors

I recommend that the origin of the coal combustion residues be specified in the document (e.g., in Section 1.1, Background). For instance, is this method applicable to CCRs originating from plant effluents and flue gases from electrical utilities and independent power plants, or are there other sources of CCRs? It would also be worthwhile to provide a few examples of materials or products where the beneficial use of an encapsulated CCR can be used to replace an analogous product. For example, can encapsulated CCRs be used to manufacture underground storage containers? That would make the soil leaching route the most critical human and ecological exposure pathway.

There are a few instances where the methodology is unclear, and additional explanation or material can be included to resolve this issue. I've provided some suggestions for making the methodology more clear, in my responses to charge questions 1-3. It is also unclear how mixtures are treated in this method? Certainly, the presence or absence of other chemicals within the encapsulated CCR matrix can influence the fate and exposure of a given COPC. But whether "constituents" includes mixtures or specific chemicals should be made explicit in the method documentation.

Once the issues addressing the clarity of the document are addressed, I believe that the methodology will satisfactorily address the OIG's comments to "define and implement risk evaluation practices to determine the safety of the CCR beneficial uses EPA promotes."

4.2 RESPONSE TO CHARGE QUESTIONS BY REVIEWER

Question 1.
Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?

Nicholas Basta, Ph.D.

In general, yes. I do have concerns re: Step 5-Risk Assessment. Specially, maximum allowable concentrations of COPC that are below natural environmental media background such as arsenic. The methodology should be flexible by consideration of natural background levels of these COPC to determine if *additional* significant risk is added to natural background from the encapsulated CCR.

Tuncer Edil, Ph.D., PE

The evaluation method proposed is robust and transparent and based on proven methods EPA has; however, it is not totally clear to a reader. Some aspects can be made clearer. Please see the general comments above.

Kevin Gardner, Ph.D., PE

The methodology is clear, transparent and flexible and is appropriate for the intended purpose. The robustness of the methodology remains a question in my mind. In one sense, the methodology is robust in that a very general set of principles for how one would approach evaluating a beneficial use of CCRs. In fact, it is general enough that it would extend far beyond beneficial uses of CCRs. In a second sense, the robustness is questionable because its general framework nature leaves the assessment of a potential decision made with this approach largely up to the individual reviewing the evaluation. For example, lack of data on both CCR-containing product and non-CCR-containing product could lead to high uncertainty of exposures for both materials resulting in an inability to say that they are different. The methodology and flow chart do not indicate whether or when collection of additional data is warranted.

Agnes B. Lobscheid, Ph.D.

I have a few suggestions for making the evaluation methodology more transparent with the use of figures:

1. In Section 1.2 - Purpose, consider presenting a flowchart or diagram summarizing the history (timeline) of the development of a methodology for evaluating the beneficial use of encapsulated CCRs. This diagram could include the EPA agencies, and other government agencies and programs that have been associated with the development of guidelines and methodology for evaluating the encapsulated (and unencapsulated) use of CCRs. This would provide a useful summary of how this methodology evolved and how stakeholders interact.

2. In Figure A-1, the arrows are confusing and it is hard to follow where the right and left

arrows are pointing to.

I have a few suggestions for making the evaluation methodology more clear, with respect to who is in charge or who conducts this evaluation (who is the "party conducting the evaluation"):

1. In the "Purpose," who is in charge or manages each step of the evaluation methodology? Is this all handled by/at EPA? Which agencies? Or by local or state governments or agencies?

2. In "Step 5 - Risk Assessment," paragraph 3, please specify who judges, and how the determination is made, as to whether the "existing data gaps and uncertainties are too great to reach a final conclusion, and then additional data and evaluation may be needed."

3. In Section 2, Methodology, the second paragraph states that "…is encouraged to engage with the appropriate regulatory organizations to ensure that all assumptions, models, and calculations used are valid and appropriate." It appears that further clarification needs to be provided as to who the (initial) contact agencies should be so that "the party conducting the evaluation" will know who or what agency to contact. Is the Office of Resource Conservation and Recovery the only EPA Agency involved with implementing this methodology? What is the role of OSWR? If a figure such as that suggested above in Section 1.2 would be included, then the agencies and regulatory organizations involved with the evaluation for encapsulated use of CCRs would be easily identified.

For clarity, the use of the word "surrogate" should be consistent and clearly stated e.g.:

1. In Section 2.2, Comparison of Available Data, the discussion of surrogate COPC needs to be more clearly presented (i.e., in the third paragraph of Section 2.2). It is unclear whether the surrogate is a product or chemical, or a chemical mixture in the product containing encapsulated CCR. How is the surrogate selected? What are some criteria for establishing an appropriate surrogate?

2. In "Step 4 - Screening assessment, it is confusing to use "surrogate for exposure" in paragraph 3 and also "surrogate in place of releases" in Section 2.2, paragraph 3. A consistent use of the word "surrogate" is needed.

For clarity, the following comments and suggestions are made on Figure 2-1:

1. Revise caption to indicate: "Generic Conceptual Exposure model for Human and Ecological Receptors"

2. The releases can be divided by media, i.e., air, soil, water, therefore change:
   "than volatilization" to "emission to ambient air,"
   "dust generation" to "contaminated soil"
   "leaching" to "leaching to ground or surface water"

3. Suggest dividing exposures by indirect and direct exposures, i.e. all of the exposures in the exposure category are direct exposures, i.e., inhalation of ambient air; ingestion of

contaminated ground water. However, contaminated soil can also have both direct (dermal) and ingestion (soil pica), as well as inadvertent ingestion due to hand-to-mouth activity in young children. Consider including the dermal soil and direct and inadvertent soil ingestion pathways in this conceptual model (maybe with a dashed line between dust or contaminated soil to a new box for "ingestion of soil" under "exposure" and then a dashed line to the "residential adult/child" box). It is unclear whether human dermal exposures are accounted for in this evaluation model framework (screening levels for dermal exposures are lacking, however, e.g., the ATSDR does not have MRLs for hazardous substances for the dermal exposure route).

4. Is there an exposure model that takes into account HEI and separately the ecological receptor? Figure 2-1 seems to indicate that there is. If there is not, then it would be useful to suggest or recommend exposure models that characterize the exposure pathways and resulting exposure concentrations for each for each of the receptors in Figure 2-1.

Additional comments regarding clarity:

1. I recommend re-defining "COPC" from "constituents of potential concern" to 'chemicals of potential concern." Also, please clearly state whether mixtures or specific chemicals are taken into account in the comparative risk assessment.

   It is unclear whether a comparison of health-based risks (noncancer and carcinogenic) risks are taken into account in the final step.

Question 2.
Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

Nicholas Basta, Ph.D.

The methodology is robust and covers most of the critical exposure scenarios for encapulsated CCR such as wallboard, concrete, roofing materials and bricks.

Tuncer Edil, Ph.D., PE

Because of the uncertainty what encapsulated beneficial uses cover, it is difficult to answer. But considering some of these uses individually as listed under the general comments above, it appears to be applicable. However, the pathways and critical aspects are different for different uses.

Kevin Gardner, Ph.D., PE

The methodology is entirely applicable. In fact, it seems just as appropriate for non-encapsulated uses and uses of other types of byproducts in addition to CCRs. Its general nature makes it quite widely applicable.

Agnes B. Lobscheid, Ph.D.

My comments to this charge question are focused on incorporating the weight of evidence approach and using comparisons of environmental releases or human exposures to screening levels and health-based thresholds.

It is unclear how a WOE approach will be incorporated into this methodology. In the introductory paragraph to Section 2 - Methodology, it is stated that "this methodology is intended to be broad and flexible to allow a weight of evidence approach to the evaluation of beneficial use of CCRs." The WOE approach is not brought up again until Section 2.4 - Screening Assessment (page 2-7). But, how will the WOE approach aid in making decisions with respect to conflicting data in Step 2? I also suggest that in Section 2.1, Step 1- Literature Review, the first paragraph could end with whether and how the WOE approach fits in with this stage of the evaluation. Please consider incorporating the findings from the four references under my response to Charge Question 4, which may help with defining the role and use of the WOE approach in this methodology.

Also, in Section 2.2, Comparison of Available Data, it is important to distinguish b/w whether emissions to the environment or human exposure concentrations are being assessed with respect to screening levels and health-based thresholds. For ecological endpoints and possibly direct exposure pathways to humans, the former may be sufficient, but for human receptors the comparison should ideally be made on an exposure basis, using fate and transport modeling to characterize direct and indirect exposure routes.

Question 3.
Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

Nicholas Basta, Ph.D.

The dust ingestion pathway must be considered. This pathway is mentioned on page 2-5 but is absent in Figure 2-1.

Tuncer Edil, Ph.D., PE

Additional considerations can be incorporated in response to the general comments given above.

Kevin Gardner, Ph.D., PE

I would like to see data sufficiency be incorporated more clearly. I don't know that this is easily done at this general level, but it should be addressed clearly in the methodology. The first step of the methodology briefly mentions that additional data may be collected, but this is a different issue than the sufficiency of existing (or even newly collected) data.

Agnes B. Lobscheid, Ph.D.

I have several additional considerations or steps and they are grouped according to a common theme here.

Additional Considerations for characterizing exposure levels:

1. In Section 2.2, Comparison of Available Data, it is unclear whether dermal exposures are considered, e.g., through direct handling of the end product? Depending on the type of encapsulated CCR beneficial use product, there may be a potential for dermal contact and human exposure.

2. The draft states that both human and ecological receptors will be considered for the exposure modeling. What are some of the analogous HEIs considered for ecological receptors? As pointed out in "Step 3 - Exposure Review," identifying the appropriate receptor is key and although a comprehensive description of human receptor types is provided, relatively little discussion of ecological receptor types is provided (beyond phylogenic class). It is suggested that additional references be provided for additional information on characterizing ecological receptor, e.g., providing a link to tools that the EPA has developed to screen for ecological risks, e.g.
   http://www.epa.gov/oswer/riskassessment/tooleco.htm

Additional Steps or Considerations for chemical hazard screening:

1. A key hazard screening criteria is the chemical persistence in the air, soil, or water media. But, persistence is not mentioned anywhere in the document. This might be a useful fate

parameter to use to make comparisons between the COPC associated with the encapsulated CCR beneficial use product, and the COPC from the analogous product made of virgin material. The US EPA's EPI Suite screening level tool may be useful to include in the assessment in order to characterize the overall persistence in environmental media (http://www.epa.gov/oppt/exposure/pubs/episuite.htm).

2. Based on the material in "Step 4 - Screening Assessment": Is the RSL officially recommended for use in the evaluation? Please specify in the evaluation report. Also, please consider providing an (example or recommended) Ecological screening level tool.

3. In "Step 4- Screening assessment," in the first sentence of the second paragraph, what does "potential adverse effect" refer to specifically? I assume that it is a health-based endpoint for the human receptor, so a carcinogenic or non-carcinogenic effect (this should be explicitly stated somewhere in the document though).

4. "Step 4 - Screening assessment," paragraph 4, presents the first mention of "fate and exposure modeling." I think some background on fate and exposure modeling is needed, beyond a reference to the "Protecting Air" and "Assessing Risk" chapters of the Guide for Industrial Waste Management (US EPA, 2003). Perhaps a summary of some commonly used and agency-approved fate and transport and exposure models in the Appendix. See, for example, the following EPA screening-level models:

   EMSOFT for chemical volatilization from soil to air (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2862)

   MMSOILS for modeling the chemical transport across multi-media environments, and the direct and indirect human exposure pathways (http://www.epa.gov/ceampubl/mmedia/mmsoils/).

Additional Considerations for defining "sufficient," "quality," and "adequately addressed," as well as "no significant data gaps or other concerns" and "inherent variability":

1. In Section 2.1, Step 1- Literature Review, it is recommended that additional guidance be provided in terms of determining the "sufficient application and quality to demonstrate the potential beneficial use is comparable to the analogous non-CCR product." What are some/the criteria for defining "sufficient" and "quality"? Also, along these lines, what is the definition of "sufficient" in paragraph 5? Or the definition of "adequately addressed" in Paragraph 6? Is this based on expert judgment or review by the ORCR? Please specify in the report.

2. In addition, in the Hypothetical Application of Step 1, what party makes the conclusion that there are "no significant data gaps or other concerns." Is this based on expert judgment and/or EPA determination or by implementing a WOE approach?

3. In Section 2.2 - Comparison of Available Data, Paragraph 4**,** Additional clarification on the material presented here is needed. How is inherent variability defined? Three references are suggested and listed under my response to Charge Question 4, in order to characterize and assess the true uncertainty and variability in the evaluation.

Additional Considerations for statistical analysis:

1. In Section 2.2, Paragraph 4; please clarify what is meant by "if data are available, this may be accomplished using statistical analysis or another appropriate comparison method"? What type of statistical analysis is referred to? Is this a t-test to compare the means of the distributions of the emission rates from the encapsulated CCR beneficial use product with the analogous product? Also, in the hypothetical Application of Step 2, what does the "statistical test conducted" indicate, e.g., is that also a t-test? Clarification and specific guidance would be useful in terms of recommended (or required) statistical tests.

Additional Considerations for sensitivity analysis:

1. The second sentence of "Hypothetical Application of Step 5," i.e. "The fifth step begins by reevaluating the conservative assumptions used in the previous screening step to generate a more realistic exposure scenario."

   Seems to be referring to conducting a sensitivity analysis on the output of the fate and exposure model by varying the assumptions/inputs. Are there any guidelines by which a "more realistic exposure scenario" is generated? Seems that a probabilistic or Monte Carlo assessment of risk is needed, and central tendencies need to be evaluated as well as the 75^{th} or 95^{th} (for a HEI) and then presented for each scenario, i.e., based on which model input(s) were adjusted.

Question 4.
Are you aware of additional references or other resources that could improve this methodology?

Nicholas Basta, Ph.D.

Scheckel, K.G., R.L. Chaney, N.T. Basta and J.A. Ryan. 2009. Advances in Assessing Bioavailability of metal(loid)s in Contaminated Soils. Adv. Agron. 107:10-52.

Tuncer Edil, Ph.D., PE

No.

Kevin Gardner, Ph.D., PE

There are loads of references and resources that are available about the performance of encapsulated CCRs, about leaching methods and evaluation frameworks, that would be appropriate to reference. However, the methodology as presented in not reliant on such sources and inclusion would complicate what is a Spartan approach to presentation of a very general methodology.

Agnes B. Lobscheid, Ph.D.

I have grouped additional references into three categories.

1. **Addressing uncertainty and variability in fate and exposure models:**

   Hertwich, EG, TE McKone, and WS Pease (1999). Parameter uncertainty and variability in evaluate fate and exposure models. Risk Analysis 19(6): 1193-1204.
   Hertwich, EG, TE McKone , and WS Pease (2000). A systematic uncertainty analysis of an evaluate fate and exposure model. Risk Analysis 20(4): 439-454.
   Paté-Cornell, ME (1996). Uncertainties in risk analysis: Six levels of treatment, Reliability Engineering and System Safety 54(2–3): 95-111.

2. **Weight of Evidence Papers:**

   Mumtaz, MM and PR Durkin (1992). A weight-of-evidence approach for assessing interactions in chemical mixtures. Toxicology and Industrial Health 8(6); 377-406.
   Weed, D (2005). Weight of Evidence: A Review of Concept and Methods. Risk Analysis 25(6): 1545- 1557. http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.2005.00699.x/full
   Burton, GA, PM Chapman, EP Smith. (2010). Weight-of-Evidence Approaches for Assessing Ecosystem Impairment. Human and Ecological Risk Assessment: An International Journal 8 (7): 1657-1673. http://www.tandfonline.com/doi/abs/10.1080/20028091057547

Linkov, I, D Loney, S Cormier, and T Bridges (2009). Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches. Science of the Total Environment 407(19): 5199-5205.

3. **In the "Hypothetical Application of Step 4," it is recommended that EPA's Exposure Factors Handbook be cited following " exposure factors" in the fourth sentence, i.e.**

" Health based screening levels are characterized based on the relevant human exposure factors (EPA, 2011)."

U.S. EPA (2011). Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F.

4.3 SPECIFIC OBSERVATIONS

Nicholas Basta, Ph.D.

Page	Line	Comment
2-6	Fig 2-1	Add ingestion as an exposure pathway to dust generation release.

Tuncer Edil, Ph.D., PE

Page	Line	Comment
1-1	Line 9	Should add "cost savings" as a benefit.
1-2	Lines 3-6	It is not clear what "encapsulated" covers based merely on the definition. Perhaps examples, including but not limited to, can be provided to clarify.
2-1	Paragraph 2	Who is the intended party conducting this evaluation?
2-1	Paragraph 3	Is this literature search to be conducted for every individual CCR produced by a plant during a period when various factors kept constant and for a specific beneficial use application or for a class of CCR, say fly ash or a more specified fly ash defined in terms of e.g., source of coal, combustion process, etc.? The question is about how often this search needs to be done.
2-2	Paragraph 2	Identification of COPC is achievable in the literature survey irrespective of the laboratory leaching method employed and through field leachate data. However, there is not unanimity regarding what method to be used to determine COPC release concentration. So the literature survey may result in ambiguous results regarding concentration as single pH is used mostly and the LEAF method is not used widely yet as it is still under development. This issue needs to be addressed.
2-3	Last paragraph	There is some ambiguity here. For instance, mixing fly ash may change pH and cause releases from the remaining raw materials. Perhaps can be simplified as stated in the last sentence of the paragraph: "compare releases from the products as a whole."
2-8	Last paragraph	In this hypothetical example, if concentration of a COPC at the point of exposure were determined to be below the maximum contaminant level (MCL) for the COPC, would it not be the point to stop? Because MCLs are already based on a risk assessment exercise.

Kevin Gardner, Ph.D., PE

Page	Line	Comment
1-2	Line 4	."..solid matrix that prevents mobilization.." If it prevented mobilization, there would be no need for this methodology. This should be re-phrased (perhaps to 'minimizes' or 'reduces' mobilization).

Page	Line	Comment
2-8	First Paragraph	It's not clear in this paragraph that the approach described is comparative in nature. One of the very positive elements of the entire methodology is the clarity of this aspect: that the CCR-containing product is being compared with the non-CCR product. As this paragraph starts out, it is not clear this is the case ("…evaluation of risks associated with COPC exposures carried forward from previous steps." And, "the purpose of this step is to determine whether the beneficial use product may result in unacceptable risk to human or ecological receptors." This is a very different tone compared to the rest of the document which clearly focuses on the comparison between products. Indeed, later in this section (3rd paragraph), it says, "If the identified risks and associated uncertainties are found to be comparable.." While it's not very clear (it could be inferred that the risks and uncertainties are comparable) I believe it to mean the risks and uncertainties of the two products are comparable). This section should be edited to make the intent more clear throughout and focus on the comparative risk.

Agnes B. Lobscheid, Ph.D.

Page	Line	Comment
1-1	Paragraph 1	Gasses should be gases.
2-3	Paragraph 2	Change "However, any other routes through which these…" to "However, any other <u>exposure</u> routes through which these…"
2-3	Paragraph 3	Considering revising "The previous step of the methodology identified the COPCs…" to "Step 1 of the methodology identified…"
2-1	Paragraph 3	Consider revising "collecting and reviewing available literature on the beneficial use of a CCR" to specify "collecting and reviewing <u>peer-reviewed literature and agency and other government reports and databases</u> on the beneficial use of a CCR."
2-3	Paragraph 3	The third sentence of this paragraph is confusing. Consider revising "The purpose of this step is to determine if the potential exists for higher COPC concentrations to be released from the beneficial use product than from the analogous product." To: "The purpose of this step is to determine if there is a potential for increased emissions and higher exposure levels resulting from the release of a COPC from the beneficial use product relative to the analogous product."

Page	Line	Comment
2-4	Paragraph 3	Consider revising the first three sentences from: "A beneficial use product under evaluation contain a COPC that can vaporize and enter the ambient air. The same COPC and release route is present in the analogous product as well. Available literature shows a strong relationship between the concentration of this COPC in the products and the rate of emanation from the product." To: "A beneficial use product under evaluation contains a COPC that can volatilize to the ambient air. … Available literature shows a strong relationship between the COPC concentration in the product and the emissions rate from the product." Please consider changing "rate of emanation" to "emission rate."
2-7	Paragraph 4	Recommend inserting paragraph break between the 4th and 5th sentence. (5th sentence should be the first sentence of the new paragraph).
2-7	Paragraph 4, Sentence 6-7	Suggest revising the following: "For conservatism, assumptions are made that the soil is highly permeable and that the closest residential receptors live directly adjacent to the source of the groundwater contamination. These assumptions feed into IWEM, which models new COPC concentrations adjusted for dilution-attenuation at the point of exposure." To: "As a conservative assumption, the soil is assumed to be highly permeable and that the nearest residential receptors live directly adjacent to the source of the groundwater contamination. These assumptions are incorporated into the IWEM, generating tap-water COPC concentrations adjusted for dilution-attenuation at the point of exposure."
2-7	Paragraph 3, Sentence 1	Revise from: "Each exposure found to exceed screening levels…" To: "Each exposure level found to exceed screening levels…"

Page	Line	Comment
2-7	Paragraph 3, Sentence 5-6	Revise from: "If a conservative exposure is found to be below screening levels after adjustment for dilution and attenuation, then no additional evaluation is necessary for that exposure. However, if one or more exposures still exceed the screening levels, then evaluation of those exposures should proceed…." To: If an exposure level based on conservative assumptions is found to be below screening levels after adjustment for dilution and attenuation, then no additional evaluation is necessary for that exposure route. However, if any other exposure routes lead to exposure levels that exceed the screening levels, then evaluation of those exposure routes should proceed….."

APPENDIX A

ORIGINAL COMMENTS FROM PEER REVIEWERS

Peer Review Comments on EPA's Preliminary Draft Document
Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals

April 2, 2012

Nicholas T. Basta, Ph.D.
The Ohio State University

I. GENERAL IMPRESSIONS

The methodology described in the preliminary draft is comprehensive and offers a scientifically sound quantitative evaluation of environmental human and ecological risk associated with select beneficial use of encapsulated CCR. The draft can be improved by listing expected major beneficial uses of encapsulated CCR and specific COPC / exposure pathways of concern associated with that use.

II. RESPONSE TO CHARGE QUESTIONS

Provide narrative responses to each of the four charge questions below.

1. Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?

In general, yes. I do have concerns re: Step 5-Risk Assessment. Specially, maximum allowable concentrations of COPC that are below natural environmental media background such as arsenic. The methodology should be flexible by consideration of natural background levels of these COPC to determine if *additional* significant risk is added to natural background from the encapsulated CCR.

2. Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

The methodology is robust and covers most of the critical exposure scenarios for encapulsated CCR such as wallboard, concrete, roofing materials and bricks.

3. Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

The dust ingestion pathway must be considered. This pathway is mentioned on page 2-5 but is absent in Figure 2-1.

4. Are you aware of additional references or other resources that could improve this methodology?

Scheckel, K.G., R.L. Chaney, N.T. Basta and J.A. Ryan. 2009. Advances in Assessing Bioavailability of metal(loid)s in Contaminated Soils. Adv. Agron. 107:10-52.

III. SPECIFIC OBSERVATIONS

Please provide specific observations, or comments on the document, mentioning page, paragraph, and/or line number.

Page	Line	Comment
2-6	Fig 2-1	Add ingestion as an exposure pathway to dust generation release.

Peer Review Comments on EPA's Preliminary Draft Document
Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals

April 3, 2012

Tuncer B. Edil Ph.D., PE
University of Wisconsin-Madison

I. GENERAL IMPRESSIONS

The methodology presented is intended to provide an evaluation approach for beneficial use of CCRs for encapsulated uses. The introduction rightfully states the EPA's policy of supporting beneficial use of CCRs, balanced with its mission of protecting human health and the environment. The purpose given on page 1-1 makes reference to the EPA's C^2P^2 program and describes the motivation for developing the methodology. The seven damage cases that were not made accessible by the C^2P^2 Website, I believe, did not involve any "encapsulated beneficial use." Therefore, this phase of the methodology is probably not rooted in a real demonstrated damage, thus it should not be unnecessarily cumbersome and extensive but needs to be in place to bring everything, including new encapsulated uses, to the EPA's accepted and standard practice.

Overall, the methodology provides an approach with flexibility to evaluate the beneficial uses. I believe there is a deliberate effort not to invent the wheel again by taking advantage of historical information through the literature survey and employing the methodology with proper exits as shown on the flowchart, avoiding unnecessary extra unneeded steps.

However, there are ambiguities when you look at it as a user that should be improved. More specifically:

- The definition of "encapsulated" is not clear enough. I think some examples in an "including, but not limited to, type of list" would be helpful. For instance, the Ireland EPA lists the following for "bound" applications, meaning encapsulated applications (use of the word "bound" in the US context is not appropriate):

  - Type I addition in concrete, e.g. as filler or lightweight filler aggregate.
  - Type II addition in concrete, e.g. cementitious component in concrete.
  - Cement manufacture, e.g. added as a raw material into kiln feed or added to Portland cement.
  - Ceramic tiles and brick-making.
  - Paints, plastics, rubber and similar.
  - Lightweight filler in bitumen-bound materials, e.g. foamed bitumen or asphalt.

  - Hydraulically bound mixtures in pavement construction, e.g. capping, sub-base and road base, and ground stabilization.

This list clearly indicates that soil stabilization is included in "encapsulated." Perhaps, addition of the word "hydraulically bound" is a useful one (as mixtures that set and harden by hydraulic reactions); as it would clearly allow beneficial use of self-cementing fly ash in stabilization of soil and road base materials. I was not sure if soil stabilization was considered in "encapsulated" use reading the definition given in the methodology. There are some other uses that may or may not be interpreted to be within the given definition. For instance, embankment in which fly ash is hydraulically bound to some analogous material or itself hydraulically bound like self-cementing fly ash as opposed to non-reactive fly ash.

- It is not clear whether the methodology is intended in a generic sense for a given beneficial use, e.g. cement replacement in concrete and a class of CCR, e.g. fly ash or specifically for each fly ash produced by a power plant and for each percentage replacing the analogous material. Furthermore, who makes the final determination that the use is acceptable at the end of this methodology?

- If Step 1, Literature Survey demonstrates that no case to be found where the specific beneficial use resulted in damage to human health or the environment, would this be a basis to determine that the use of CCR is comparable to analogous product?

- There seems to be an implication of substituting CCR for an analogous material such as fly ash for cement in concrete production. However, certain uses do not result in substitution but addition, such as adding fly ash to soil for stabilization. Meaning of "comparable to analogous material" can be clarified to cover both cases. It is also not clear what "analogous material" is. Is it the component being substituted, e.g. cement or is it final product, e.g. concrete without CCR? This should be clarified.

II. RESPONSE TO CHARGE QUESTIONS

Provide narrative responses to each of the four charge questions below.

1. Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?

The evaluation method proposed is robust and transparent and based on proven methods EPA has; however, it is not totally clear to a reader. Some aspects can be made clearer. Please see the general comments above.

2. Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

Because of the uncertainty what encapsulated beneficial uses cover, it is difficult to answer. But considering some of these uses individually as listed under the general comments above, it appears to be applicable. However, the pathways and critical aspects are different for different uses.

3. Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

Additional considerations can be incorporated in response to the general comments given above.

4. Are you aware of additional references or other resources that could improve this methodology?

No.

III. SPECIFIC OBSERVATIONS

Please provide specific observations, or comments on the document, mentioning page, paragraph, and/or line number.

Page	Line	Comment
1-1	Line 9	Should add "cost savings" as a benefit.
1-2	Lines 3-6	It is not clear what "encapsulated" covers based merely on the definition. Perhaps examples, including but not limited to, can be provided to clarify.
2-1	Paragraph 2	Who is the intended party conducting this evaluation?
2-1	Paragraph 3	Is this literature search to be conducted for every individual CCR produced by a plant during a period when various factors kept constant and for a specific beneficial use application or for a class of CCR, say fly ash or a more specified fly ash defined in terms of e.g., source of coal, combustion process, etc.? The question is about how often this search needs to be done.
2-2	Paragraph 2	Identification of COPC is achievable in the literature survey irrespective of the laboratory leaching method employed and through field leachate data. However, there is not unanimity regarding what method to be used to determine COPC release concentration. So the literature survey may result in ambiguous results regarding concentration as single pH is used mostly and the LEAF method is not used widely yet as it is still under development. This issue needs to be addressed.
2-3	Last paragraph	There is some ambiguity here. For instance, mixing fly ash may change pH and cause releases from the remaining raw materials. Perhaps can be simplified as stated in the last sentence of the paragraph: "compare releases from the products as a whole."
2-8	Last paragraph	In this hypothetical example, if concentration of a COPC at the point of exposure were determined to be below the maximum contaminant level (MCL) for the COPC, would it not be the point to stop? Because MCLs are already based on a risk assessment exercise.

Peer Review Comments on EPA's Preliminary Draft Document
Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals

April 3, 2012

Dr. Kevin H. Gardner, Ph.D., PE
University of New Hampshire

I. GENERAL IMPRESSIONS

The "Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals" presents a hierarchical method that can be used for assessing potential risks associated with CCR beneficial use, specific only to encapsulated forms. The methodology consists of very logical steps that one would fully expect to use to conduct such an evaluation, in particular a comparative analysis with the analogous product not containing CCRs. In general terms, this amounts to:

- Find out if it's already been done (by searching literature);
- If not, use available data to make your own comparison;
- If some concerns are raised from the second step, evaluate potential exposure;
- If potential exposures are greater in the CCR product, conduct screening-level assessment; and
- Screening level exceedances are carried through to a risk assessment.

Included in each step of the methodology are examples to clarify the text of the document. The document is clearly written and presented. There is essentially no chance of misunderstanding from the reading of this document. The methodology presented is very general, but also logical and straightforward. There is scant room for inaccurate information given the general nature of the methodology presented.

II. RESPONSE TO CHARGE QUESTIONS

Provide narrative responses to each of the four charge questions below.

1. Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?

The methodology is clear, transparent and flexible and is appropriate for the intended purpose. The robustness of the methodology remains a question in my mind. In one sense, the methodology is robust in that a very general set of principles for how one would approach evaluating a beneficial use of CCRs. In fact, it is general enough that it would extend far beyond beneficial uses of CCRs. In a second sense, the robustness is questionable because its general framework nature leaves the assessment of a potential decision made with this approach largely up to the individual reviewing the evaluation. For example, lack of data on both CCR-containing product and non-CCR-containing product could lead to high uncertainty of exposures for both

materials resulting in an inability to say that they are different. The methodology and flow chart do not indicate whether or when collection of additional data is warranted.

2. Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

The methodology is entirely applicable. In fact, it seems just as appropriate for non-encapsulated uses and uses of other types of byproducts in addition to CCRs. Its general nature makes it quite widely applicable.

3. Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

I would like to see data sufficiency be incorporated more clearly. I don't know that this is easily done at this general level, but it should be addressed clearly in the methodology. The first step of the methodology briefly mentions that additional data may be collected, but this is a different issue than the sufficiency of existing (or even newly collected) data.

4. Are you aware of additional references or other resources that could improve this methodology?

There are loads of references and resources that are available about the performance of encapsulated CCRs, about leaching methods and evaluation frameworks, that would be appropriate to reference. However, the methodology as presented in not reliant on such sources and inclusion would complicate what is a Spartan approach to presentation of a very general methodology.

III. SPECIFIC OBSERVATIONS

Please provide specific observations, or comments on the document, mentioning page, paragraph, and/or line number.

Page	Line	Comment
1-2	Line 4	.”..solid matrix that prevents mobilization..” If it prevented mobilization, there would be no need for this methodology. This should be re-phrased (perhaps to ‘minimizes’ or ‘reduces’ mobilization).

Page	Line	Comment
2-8	First Paragraph	It's not clear in this paragraph that the approach described is comparative in nature. One of the very positive elements of the entire methodology is the clarity of this aspect: that the CCR-containing product is being compared with the non-CCR product. As this paragraph starts out, it is not clear this is the case ("…evaluation of risks associated with COPC exposures carried forward from previous steps." And, "the purpose of this step is to determine whether the beneficial use product may result in unacceptable risk to human or ecological receptors." This is a very different tone compared to the rest of the document which clearly focuses on the comparison between products. Indeed, later in this section (3rd paragraph), it says, "If the identified risks and associated uncertainties are found to be comparable.." While it's not very clear (it could be inferred that the risks and uncertainties are comparable) I believe it to mean the risks and uncertainties of the two products are comparable). This section should be edited to make the intent more clear throughout and focus on the comparative risk.

Peer Review Comments on EPA's Preliminary Draft Document
Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals

April 3, 2012

Agnes Lobscheid
Environmental Energy Technologies Division
Lawrence Berkeley National Laboratory

I. GENERAL IMPRESSIONS

The preliminary draft Methodology encompasses a traditional risk assessment paradigm, with the main objective to compare end-use or consumer risks between potential COPC and the analogous product. Overall, this document has most of the elements of a traditional risk assessment, i.e., hazard identification, exposure assessment, and risk evaluation. Dose response is not explicitly considered though but taken into account in the health-based screening level. While the HEI is considered as the human receptor, it is recommended that there be additional guidance provided on how to deal with sensitive ecological receptors

I recommend that the origin of the coal combustion residues be specified in the document (e.g., in Section 1.1, Background). For instance, is this method applicable to CCRs originating from plant effluents and flue gases from electrical utilities and independent power plants, or are there other sources of CCRs? It would also be worthwhile to provide a few examples of materials or products where the beneficial use of an encapsulated CCR can be used to replace an analogous product. For example, can encapsulated CCRs be used to manufacture underground storage containers? That would make the soil leaching route the most critical human and ecological exposure pathway.

There are a few instances where the methodology is unclear, and additional explanation or material can be included to resolve this issue. I've provided some suggestions for making the methodology more clear, in my responses to charge questions 1-3. It is also unclear how mixtures are treated in this method? Certainly, the presence or absence of other chemicals within the encapsulated CCR matrix can influence the fate and exposure of a given COPC. But whether "constituents" includes mixtures or specific chemicals should be made explicit in the method documentation.

Once the issues addressing the clarity of the document are addressed, I believe that the methodology will satisfactorily address the OIG's comments to "define and implement risk evaluation practices to determine the safety of the CCR beneficial uses EPA promotes."

II. RESPONSE TO CHARGE QUESTIONS

Provide narrative responses to each of the four charge questions below.

1. ***Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?***

I have a few suggestions for making the evaluation methodology more transparent with the use of figures:

1. In Section 1.2 - Purpose, consider presenting a flowchart or diagram summarizing the history (timeline) of the development of a methodology for evaluating the beneficial use of encapsulated CCRs. This diagram could include the EPA agencies, and other government agencies and programs that have been associated with the development of guidelines and methodology for evaluating the encapsulated (and unencapsulated) use of CCRs. This would provide a useful summary of how this methodology evolved and how stakeholders interact.

2. In Figure A-1, the arrows are confusing and it is hard to follow where the right and left arrows are pointing to.

I have a few suggestions for making the evaluation methodology more clear, with respect to who is in charge or who conducts this evaluation (who is the "party conducting the evaluation"):

1. In the "Purpose," who is in charge or manages each step of the evaluation methodology? Is this all handled by/at EPA? Which agencies? Or by local or state governments or agencies?

2. In "Step 5 - Risk Assessment," paragraph 3, please specify who judges, and how the determination is made, as to whether the "existing data gaps and uncertainties are too great to reach a final conclusion, and then additional data and evaluation may be needed."

3. In Section 2, Methodology, the second paragraph states that "…is encouraged to engage with the appropriate regulatory organizations to ensure that all assumptions, models, and calculations used are valid and appropriate." It appears that further clarification needs to be provided as to who the (initial) contact agencies should be so that "the party conducting the evaluation" will know who or what agency to contact. Is the Office of Resource Conservation and Recovery the only EPA Agency involved with implementing this methodology? What is the role of OSWR? If a figure such as that suggested above in Section 1.2 would be included, then the agencies and regulatory organizations involved with the evaluation for encapsulated use of CCRs would be easily identified.

For clarity, the use of the word "surrogate" should be consistent and clearly stated e.g.:

1. In Section 2.2, Comparison of Available Data, the discussion of surrogate COPC needs to be more clearly presented (i.e., in the third paragraph of Section 2.2). It is unclear whether the surrogate is a product or chemical, or a chemical mixture in the product containing encapsulated CCR. How is the surrogate selected? What are some criteria for establishing an appropriate surrogate?

2. In "Step 4 - Screening assessment, it is confusing to use "surrogate for exposure" in paragraph 3 and also "surrogate in place of releases" in Section 2.2, paragraph 3. A consistent use of the word "surrogate" is needed.

For clarity, the following comments and suggestions are made on Figure 2-1:

1. Revise caption to indicate: "Generic Conceptual Exposure model for Human and Ecological Receptors"

2. The releases can be divided by media, i.e., air, soil, water, therefore change:
   "than volatilization" to "emission to ambient air,"
   "dust generation" to "contaminated soil"
   "leaching" to "leaching to ground or surface water"

3. Suggest dividing exposures by indirect and direct exposures, i.e. all of the exposures in the exposure category are direct exposures, i.e., inhalation of ambient air; ingestion of contaminated ground water. However, contaminated soil can also have both direct (dermal) and ingestion (soil pica), as well as inadvertent ingestion due to hand-to-mouth activity in young children. Consider including the dermal soil and direct and inadvertent soil ingestion pathways in this conceptual model (maybe with a dashed line between dust or contaminated soil to a new box for "ingestion of soil" under "exposure" and then a dashed line to the "residential adult/child" box). It is unclear whether human dermal exposures are accounted for in this evaluation model framework (screening levels for dermal exposures are lacking, however, e.g., the ATSDR does not have MRLs for hazardous substances for the dermal exposure route).

4. Is there an exposure model that takes into account HEI and separately the ecological receptor? Figure 2-1 seems to indicate that there is. If there is not, then it would be useful to suggest or recommend exposure models that characterize the exposure pathways and resulting exposure concentrations for each for each of the receptors in Figure 2-1.

Additional comments regarding clarity:

1. I recommend re-defining "COPC" from "constituents of potential concern" to 'chemicals of potential concern." Also, please clearly state whether mixtures or specific chemicals are taken into account in the comparative risk assessment.

   It is unclear whether a comparison of health-based risks (noncancer and carcinogenic) risks are taken into account in the final step.

2. Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

My comments to this charge question are focused on incorporating the weight of evidence approach and using comparisons of environmental releases or human exposures to screening levels and health-based thresholds.

It is unclear how a WOE approach will be incorporated into this methodology. In the introductory paragraph to Section 2 - Methodology, it is stated that "this methodology is intended to be broad and flexible to allow a weight of evidence approach to the evaluation of

beneficial use of CCRs." The WOE approach is not brought up again until Section 2.4 - Screening Assessment (page 2-7). But, how will the WOE approach aid in making decisions with respect to conflicting data in Step 2? I also suggest that in Section 2.1, Step 1- Literature Review, the first paragraph could end with whether and how the WOE approach fits in with this stage of the evaluation. Please consider incorporating the findings from the four references under my response to Charge Question 4, which may help with defining the role and use of the WOE approach in this methodology.

Also, in Section 2.2, Comparison of Available Data, it is important to distinguish b/w whether emissions to the environment or human exposure concentrations are being assessed with respect to screening levels and health-based thresholds. For ecological endpoints and possibly direct exposure pathways to humans, the former may be sufficient, but for human receptors the comparison should ideally be made on an exposure basis, using fate and transport modeling to characterize direct and indirect exposure routes.

3. Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

I have several additional considerations or steps and they are grouped according to a common theme here.

Additional Considerations for characterizing exposure levels:

1. In Section 2.2, Comparison of Available Data, it is unclear whether dermal exposures are considered, e.g., through direct handling of the end product? Depending on the type of encapsulated CCR beneficial use product, there may be a potential for dermal contact and human exposure.

2. The draft states that both human and ecological receptors will be considered for the exposure modeling. What are some of the analogous HEIs considered for ecological receptors? As pointed out in "Step 3 - Exposure Review," identifying the appropriate receptor is key and although a comprehensive description of human receptor types is provided, relatively little discussion of ecological receptor types is provided (beyond phylogenic class). It is suggested that additional references be provided for additional information on characterizing ecological receptor, e.g., providing a link to tools that the EPA has developed to screen for ecological risks, e.g.
   http://www.epa.gov/oswer/riskassessment/tooleco.htm

Additional Steps or Considerations for chemical hazard screening:

1. A key hazard screening criteria is the chemical persistence in the air, soil, or water media. But, persistence is not mentioned anywhere in the document. This might be a useful fate parameter to use to make comparisons between the COPC associated with the encapsulated CCR beneficial use product, and the COPC from the analogous product made of virgin material. The US EPA's EPI Suite screening level tool may be useful to include in the assessment in order to characterize the overall persistence in environmental media

(http://www.epa.gov/oppt/exposure/pubs/episuite.htm).

2. Based on the material in "Step 4 - Screening Assessment": Is the RSL officially recommended for use in the evaluation? Please specify in the evaluation report. Also, please consider providing an (example or recommended) Ecological screening level tool.

3. In "Step 4- Screening assessment," in the first sentence of the second paragraph, what does "potential adverse effect" refer to specifically? I assume that it is a health-based endpoint for the human receptor, so a carcinogenic or non-carcinogenic effect (this should be explicitly stated somewhere in the document though).

4. "Step 4 - Screening assessment," paragraph 4, presents the first mention of "fate and exposure modeling." I think some background on fate and exposure modeling is needed, beyond a reference to the "Protecting Air" and "Assessing Risk" chapters of the Guide for Industrial Waste Management (US EPA, 2003). Perhaps a summary of some commonly used and agency-approved fate and transport and exposure models in the Appendix. See, for example, the following EPA screening-level models:

   EMSOFT for chemical volatilization from soil to air (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2862)

   MMSOILS for modeling the chemical transport across multi-media environments, and the direct and indirect human exposure pathways (http://www.epa.gov/ceampubl/mmedia/mmsoils/).

Additional Considerations for defining "sufficient," "quality," and "adequately addressed," as well as "no significant data gaps or other concerns" and "inherent variability":

1. In Section 2.1, Step 1- Literature Review, it is recommended that additional guidance be provided in terms of determining the "sufficient application and quality to demonstrate the potential beneficial use is comparable to the analogous non-CCR product." What are some/the criteria for defining "sufficient" and "quality"? Also, along these lines, what is the definition of "sufficient" in paragraph 5? Or the definition of "adequately addressed" in Paragraph 6? Is this based on expert judgment or review by the ORCR? Please specify in the report.

2. In addition, in the Hypothetical Application of Step 1, what party makes the conclusion that there are "no significant data gaps or other concerns." Is this based on expert judgment and/or EPA determination or by implementing a WOE approach?

3. In Section 2.2 - Comparison of Available Data, Paragraph 4**,** Additional clarification on the material presented here is needed. How is inherent variability defined? Three references are suggested and listed under my response to Charge Question 4, in order to characterize and assess the true uncertainty and variability in the evaluation.

Additional Considerations for statistical analysis:

1. In Section 2.2, Paragraph 4; please clarify what is meant by "if data are available, this may be accomplished using statistical analysis or another appropriate comparison method"? What type of statistical analysis is referred to? Is this a t-test to compare the means of the distributions of the emission rates from the encapsulated CCR beneficial use product with the analogous product? Also, in the hypothetical Application of Step 2, what does the "statistical test conducted" indicate, e.g., is that also a t-test? Clarification and specific guidance would be useful in terms of recommended (or required) statistical tests.

Additional Considerations for sensitivity analysis:

1. The second sentence of "Hypothetical Application of Step 5," i.e. "The fifth step begins by reevaluating the conservative assumptions used in the previous screening step to generate a more realistic exposure scenario."

   Seems to be referring to conducting a sensitivity analysis on the output of the fate and exposure model by varying the assumptions/inputs. Are there any guidelines by which a "more realistic exposure scenario" is generated? Seems that a probabilistic or Monte Carlo assessment of risk is needed, and central tendencies need to be evaluated as well as the 75th or 95th (for a HEI) and then presented for each scenario, i.e., based on which model input(s) were adjusted.

4. Are you aware of additional references or other resources that could improve this methodology?

I have grouped additional references into three categories.

1. Addressing uncertainty and variability in fate and exposure models:

Hertwich, EG, TE McKone, and WS Pease (1999). Parameter uncertainty and variability in evaluate fate and exposure models. Risk Analysis 19(6): 1193-1204.

Hertwich, EG, TE McKone , and WS Pease (2000). A systematic uncertainty analysis of an evaluate fate and exposure model. Risk Analysis 20(4): 439-454.

Paté-Cornell, ME (1996). Uncertainties in risk analysis: Six levels of treatment, Reliability Engineering and System Safety 54(2–3): 95-111.

2. Weight of Evidence Papers:

Mumtaz, MM and PR Durkin (1992). A weight-of-evidence approach for assessing interactions in chemical mixtures. Toxicology and Industrial Health 8(6); 377-406.

Weed, D (2005). Weight of Evidence: A Review of Concept and Methods. Risk Analysis 25(6): 1545- 1557. http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.2005.00699.x/full

Burton, GA, PM Chapman, EP Smith. (2010). Weight-of-Evidence Approaches for Assessing Ecosystem Impairment. Human and Ecological Risk Assessment: An

International Journal 8 (7): 1657-1673.
http://www.tandfonline.com/doi/abs/10.1080/20028091057547

Linkov, I, D Loney, S Cormier, and T Bridges (2009). Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches. Science of the Total Environment 407(19): 5199-5205.

3. In the "Hypothetical Application of Step 4," it is recommended that EPA's Exposure Factors Handbook be cited following " exposure factors" in the fourth sentence, i.e.

" Health based screening levels are characterized based on the relevant human exposure factors (EPA, 2011)."

U.S. EPA (2011). Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F.

III. SPECIFIC OBSERVATIONS

Please provide specific observations, or comments on the document, mentioning page, paragraph, and/or line number.

Page	Line	Comment
1-1	Paragraph 1	Gasses should be gases.
2-3	Paragraph 2	Change "However, any other routes through which these…" to "However, any other exposure routes through which these…"
2-3	Paragraph 3	Considering revising "The previous step of the methodology identified the COPCs…" to "Step 1 of the methodology identified…"
2-1	Paragraph 3	Consider revising "collecting and reviewing available literature on the beneficial use of a CCR" to specify "collecting and reviewing peer-reviewed literature and agency and other government reports and databases on the beneficial use of a CCR."
2-3	Paragraph 3	The third sentence of this paragraph is confusing. Consider revising "The purpose of this step is to determine if the potential exists for higher COPC concentrations to be released from the beneficial use product than from the analogous product." To: "The purpose of this step is to determine if there is a potential for increased emissions and higher exposure levels resulting from the release of a COPC from the beneficial use product relative to the analogous product."

Page	Line	Comment
2-4	Paragraph 3	Consider revising the first three sentences from: "A beneficial use product under evaluation contain a COPC that can vaporize and enter the ambient air. The same COPC and release route is present in the analogous product as well. Available literature shows a strong relationship between the concentration of this COPC in the products and the rate of emanation from the product." To: "A beneficial use product under evaluation contains a COPC that can <u>volatilize</u> to the ambient air. … Available literature shows a strong relationship between <u>the COPC concentration in the product and the emissions rate from the product</u>." Please consider changing "rate of emanation" to "emission rate."
2-7	Paragraph 4	Recommend inserting paragraph break between the 4th and 5th sentence. (5th sentence should be the first sentence of the new paragraph).
2-7	Paragraph 4, Sentence 6-7	Suggest revising the following: "For conservatism, assumptions are made that the soil is highly permeable and that the closest residential receptors live directly adjacent to the source of the groundwater contamination. These assumptions feed into IWEM, which models new COPC concentrations adjusted for dilution-attenuation at the point of exposure." To: "As a conservative assumption, the soil is assumed to be highly permeable and that the nearest residential receptors live directly adjacent to the source of the groundwater contamination. These assumptions are incorporated into the IWEM, generating tap-water COPC concentrations adjusted for dilution-attenuation at the point of exposure."
2-7	Paragraph 3, Sentence 1	Revise from: "Each exposure found to exceed screening levels…" To: "Each exposure level found to exceed screening levels…"

Page	Line	Comment
2-7	Paragraph 3, Sentence 5-6	Revise from: "If a conservative exposure is found to be below screening levels after adjustment for dilution and attenuation, then no additional evaluation is necessary for that exposure. However, if one or more exposures still exceed the screening levels, then evaluation of those exposures should proceed…." To: If an exposure level based on conservative assumptions is found to be below screening levels after adjustment for dilution and attenuation, then no additional evaluation is necessary for that exposure route. However, if any other exposure routes lead to exposure levels that exceed the screening levels, then evaluation of those exposure routes should proceed….."