NIOSH EXPOSURE ASSESSMENT PROGRAM REVIEW

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ABBREVIATIONS

CDC = Centers for Disease Control and Prevention

DGUV/IFA = Deutschen Gesetzlichen Unfallversicherung/Institut für Arbeitsschutz

DFG = Deutsche Forschungsgemeinschaft

DREAM = Direct Reading Exposure Assessment Methods

EPA = Environmental Protection Agency

EXA = Exposure Assessment

GPRA = Government Performance and Results Act

HHE = Health Hazard Evaluation Reports

ICP-MS = inductively coupled plasma-mass spectrometry

ME = Development and Evaluation of Methods chapter in the NMAM

MSHA = Mine Safety and Health Administration

NIOSH = National Institute for Occupational Safety and Health

NIST = National Institute of Standards and Technology

NMAM = NIOSH Manual of Analytical Methods

OSHA = Occupational Safety and Health Administration

PEL = Permissible Exposure Limit (OSHA)

PS = Purpose, Scope and Use of NIOSH Methods chapter in NMAM

REL = Recommended Exposure Limit (NIOSH)

SBIR = Small Business Innovation Research

SRM = standard reference material

UA = Measurement Uncertainty and NIOSH Method Accuracy Range

ACKNOWLEDGEMENTS

The panel members would like to acknowledge the written and verbal contributions of Dr. Philip Smith, CIH. Dr. Smith is the Director of the Industrial Hygiene Chemistry Division at the Occupational Health and Safety Administration (OSHA) who has worked for over 28 years as industrial hygienist. Dr. Smith contributed significantly to the discussion of the evidence package and in the in-person meeting but

was not available to complete the review. In addition, we thank David Frye and Mary Dawson for their logistic support.

OVERVIEW

The National Institute for Occupational Safety and Health (NIOSH), a component of the Centers for Disease Control and Prevention (CDC), sought an independent, expert, external peer review to evaluate both the impact and relevance of their Exposure Assessment (EXA) Program. . The review was intended to ensure that NIOSH was sufficiently protecting the health and safety of the worker population base and properly using taxpayer funds. The review would offer an accountability that would assist in meeting NIOSH Director's goals and responding to Government Performance and Results Act (GPRA).

NIOSH's program review contractor was tasked with selecting an EXA Program review panel chair. The chair, with the support of the program review contractor, would then help select 4-5 additional panel members consisting of 2-3 exposure scientists, 1 evaluation expert and 1 translation expert.

On October 25, 2016, Dana Boyd Barr, an exposure scientist, was selected as the review panel chair. On November 10, 2016, Dr. Barr met with NIOSH evaluators at NIOSH offices in Atlanta, GA, to be given the charge of the panel and an overview of NIOSH and the review process. By January 2017, the other panel members had been selected. (The panel members are listed below). On February 28, 2017, the panel met via an Adobe Connect webinar to be given the charge and an overview of NIOSH and the review process. On April 7, 2017, the evidence package detailing NIOSH programs, activities, and research was provided to panel members for review. On May 10, 2017, NIOSH scientists provided an in-person overview of the EXA program at NIOSH-Atlanta and allowed panel members to ask questions and seek clarification. On the following day, panel members met to discuss the relevance and impact of the NIOSH EXA program. This report is a synthesis of panel members written reviews and discussion of the evidence package, EXA program presentations and ancillary information provided. All panel members have reviewed and edited the report and have provided individual scores for relevance and impact.

PANEL MEMBERS

Dana Boyd Barr, PhD (Chair; exposure scientist) is a Professor of Environmental Health at Emory University's Rollins School of Environmental Health. She has a PhD in analytical chemistry and over 30 years of experience in exposure science and analytical methods development in support of occupational and environmental health studies. She has over 300 publications on analytical methods, exposure assessment, and epidemiologic studies.

Doug Brugge, PhD (translation expert) is a Professor in the Department of Public Health and Community Medicine at Tufts University School of Medicine. Most of his work uses a community-based participatory research approach. He has over 150 publications and has a deep commitment to seeing research translated into policy and practice.

Brian Buckley, PhD (exposure scientist) is Executive Director of Laboratories and Associate Director of Administration at Rutgers University's Environmental and Occupational Health Science Institute. He has a PhD in analytical chemistry and has over 30 years of experience in exposure science and toxicology.

Nicole Deziel, PhD (exposure scientist) an Assistant Professor of Epidemiology at Yale University's School of Public Health. Her research is focused on evaluating, improving, and developing exposure estimates for application in environmental epidemiologic studies.

Cora Roelofs, ScD (evaluation expert) is an independent research consultant at CR Research/Consulting Services. She has an ScD in work environment and an MS in environmental and occupational health science and has expertise in worker health and safety management through collaborative research, best practices integration and evaluation.

EXECUTIVE SUMMARY

NIOSH's intramural Exposure Assessment Program has been productive, engaged, responsive, and impactful during the 10 years evaluated (2006-2016) by the panel. NIOSH extramural funding has also resulted in important scientific and practical advances, making significant achievements in underrepresented areas.

A signature product for NIOSH methods development efforts is the NIOSH Manual of Analytical Methods (NMAM). NMAM is a heavily-used industrial hygiene analytical methods compendium which has included 235 new methods, updates or publications over the past 10 years. NMAM serves as a default source for analytical methods in the occupational health and safety arena because of its historical acceptance, ease of access, and validation process. Over 150 laboratories, including private and government laboratories, are accredited in the use of the methods with the largest number of those accreditations in particulate air monitoring methods. The NMAM has received about 300,000 downloads yearly and is recommended for use by professional organizations. The large number of downloads and citations NIOSH methods receive, the large number of laboratories accredited to perform NMAM methods, and the acceptance of NMAM methods as an industry standard are a testament to the high impact of methods development in the EXA program at NIOSH.

The relevance of the NMAM methods has been improved by efforts to update the technology and validation parameters of NMAM methods. These efforts resulted in a 5th Edition of the NMAM that contains 19 new methods and 40 updated methods. While these methods are important and widely used, many are often modified by individual laboratories to meet their analytical needs and much of the instrumentation used in the analytical methods is outdated. Currently, most of the validation work is contracted out to external laboratories which is a shift in paradigm from the internal validation of methods that previously took place. As a result, some of the methods lack rigorous validation or the validation data are insufficiently documented or difficult to find. To maintain a high relevance, NIOSH should update methods to analytic platforms that are available in most laboratories (e.g., ICP-MS for elemental analysis) and maintain a set of robust validation parameters that are published with each analytical method in a standard format. Of particular note, the addition of guidance documents in the NMAM is highly relevant and impactful as sampling considerations should accompany the methods to ensure the entire analytical system is robust.

NIOSH has demonstrated a profound impact in sensors and direct reading methods, particularly in technology developed for the mining industry. The direct reading and sensor program had notable achievements in developing and disseminating exposure assessment methods as well as advancing the use of direct reading instruments. While the sensor and direct reading technology is impactful, NIOSH impact may be improved by solving fundamental performance issues for sensor technologies that are currently heavily used in multiple industries rather than funding relatively high-risk or one-of-a-kind sensors that may only impact a narrow segment of the working population, exhibiting limited overall impact on worker health. In particular, data on use and impact of sensor and direct readings Small Business Innovation Research (SBIR) grants have not been adequately captured, so although the end-products appear valuable, it is difficult to properly evaluate relevance or impact of this grant program. This is a lost opportunity for NIOSH to capitalize on the obvious successes of the devices developed under SBIRs grants.

NIOSH has considered both evaluation and translation in their EXA program, but opportunities for more thorough evaluation and translation exist. The contribution analysis is a valuable tool for evaluating the performance of the EXA program using metrics such as number of citations, methods generated, laboratories accredited, and downloads or websites views. Similarly, the logic model and its documented intermediate outcomes assisted in evaluating the impact of NIOSH EXA activities. NIOSH could, however, exploit innovative evaluation techniques, developed and implemented with the activity so that clear, activity-specific evaluation criteria are in place. In addition, NIOSH should be more proactive in working with the Occupational Safety and Health Administration (OSHA) to assist in translating non-regulatory Recommended Exposure Limits (RELs) developed by NIOSH to regulatory Permissible Exposure Limits (PELs). Although this is not a mandate of NIOSH, it would align with their overall goal of protecting workers' health. NIOSH should also look to achieve greater utilization of both their methods and sensors by continuing to adapt current capabilities to include a larger suite of analytes or matrices.

Lastly, NIOSH should strive for objective, transparent and strategic prioritization of research efforts in both methods development and direct reading/sensors in the EXA program. Currently, decision-making processes for both appear to be more subjective based upon requests or perceived needs of senior management rather than by strategic design to address the needs and burdens of the occupational health community. By allowing a more strategic process, NIOSH research will remain highly impactful and relevant.

RELEVANCE, IMPACT, AND EXA PROGRAM SCORES

The NIOSH EXA review panel provided final scores of relevance and impact reflective of their overall evaluation of the EXA Program including intramural and extramural and methods development and direct reading/sensors. Scores are presented on a 5-point scale with a 5 being the most impactful or most relevant. The total EXA Program score is the sum of the relevance and impact scores with a maximum possible score of 10. These scores took into consideration the contribution analysis and LOGIC model's intermediate outcomes along with the panel's independent assessment of the Evidence Package. A composite scoresheet is provided in Appendix 1.

Relevance Score: 4.0

Impact Score: 4.0

Total EXA Program Score: 8.0

METHODS DEVELOPMENT

NIOSH is globally recognized for its research and development in support of protecting workers' health. NIOSH has exhibited leadership and innovation in the programs for each sector or occupational grouping. In addition, NIOSH has pioneered "cross-sector" research focusing on elements of workers' exposure and safety that span the various sectors and improve overall impact of their programs.

NIOSH has contributed research to industrial communities that have enabled better compliance with OSHA regulations although its successes clearly extend beyond facilitating OSHA compliance. For example, NIOSH recognized a need for particle sampling technology development and their adaptation of cyclone sampling devices to include multiple particle sizes and characteristics was successful. In addition, the development of the sidewall collection device was innovative and impactful. Many of the NIOSH sampling projects created new sampling devices not being developed by other agencies. NIOSH has developed a significant reputation in particulate sampling technology excellence, especially in the workplace. In addition, the effort in bioaerosol sampling and preservation was an almost completely unexplored area of research prior to NIOSH initiatives in this area. They created excellent environments for testing these technologies. However, a 2002 NIOSH document Exposure Assessment Methods: Research Needs and Priorities noted that exposure assessment field methods and sampling strategies were overdue for revision. Although novel and innovative sampling techniques have been developed, clear evidence of revision of other techniques identified in the 2002 report was not provided.

Clearly, the largest output of methods development and a signature product of the NIOSH EXA program is the NIOSH Manual of Analytical Methods (NMAM). This industrial hygiene analytical method compendium is available in downloadable PDF format on the NIOSH website. The NMAM 5th Edition contains 19 new methods and 40 updated methods. NMAM is regarded as the "gold-standard" source for analytical methods in the occupational health and safety arena largely because of their reputation for developing and validating relevant methods for exposure assessment. Over 150 laboratories are certified in the use of the NMAM methods. The NMAM has received about 300,000 downloads yearly and is recommended for use by professional organizations. Many metrics such as the number of downloads of methods and laboratory accreditations demonstrate the high impact of methods development in the EXA program at NIOSH.

The majority of the methods in the NMAM are unique, needs-driven and do not represent efforts duplicated by other agencies or organizations which demonstrates good stewardship of NIOSH research funds. However, many of the methods are overly prescriptive and inflexible which may result in laboratories modifying them to render them more robust and usable. For example, if a specific solvent is used for extraction in the NMAM method and that solvent is not available or is prohibitively expensive (as acetonitrile was several years back) or an eco-friendly alternative solvent is available, the end user may opt to change the method. Although NIOSH is aware that modifications occur to methods in practice, they should be more explicit and make it more widely known that modifications are allowed if the performance metrics of the original method can be achieved. One potential way to achieve this is to include this information which states the minimum performance standards for each method in the chapter "Purpose, Scope and Use of the NMAM." For example, in Method 1453 for Vinyl Acetate, performance data provided include range, bias, precision and accuracy. In the "Purpose, Scope and Use of NMAM," NIOSH could state that the method, which is gas chromatography-flame ionization detection could be modified using any detector that gives similar or greater selectivity and

the preparation can be modified as long as the range, bias, precision and accuracy are comparable to or better than the metrics provided. By recognizing and clearly stating that the methods are really performance-based and less rigid, laboratories modifying methods would be compelled to meet the performance metrics of the method.

The methods in the NMAM, while generally very sound, are also somewhat dated both in approach and technology employed. Most methods are not optimized to include multiple chemicals thus limiting the efficiency of these methods in the laboratories employing them. Many of the methods require outdated equipment and technology when most laboratories using these methods possess newer equipment. Currently, most of the development and validation work is contracted out to external laboratories which is a shift in paradigm from the internal development and validation previously used. This shift in approach is largely because of budgetary constraints and a decrease in the number of NIOSH chemists that can effectively perform these tasks which is likely beyond the control of the EXA program. However, as a result, NIOSH has retained less control over the quality of the methods. This is evidenced by the publication and subsequent withdrawal during this evaluation period of the diacetyl method (https://www.cdc.gov/niosh/docs/2003-154/pdfs/2557.pdf) which did not adequately consider water vapor content of air sampled when the method was initially developed and published. Many of the outsourced methods lack the rigorous validation intended for the methods. Also, the validation or back-up data are not documented or are difficult to find. For instance, ICP analysis backup data (compiled by a contract laboratory) do not specify if the metals analyzed during validation were soluble species (e.g., nitrate salts) or otherwise, while the backup data for vinyl acetate (data collected in-house) appear to cover most of the needed sample stability and recovery details. Admittedly these are probably not fair comparisons as one method must apply to a wide range of potential forms of various metals, while the other applies to a single organic vapor analyte, but the lack of detail in the ICP metals backup data demonstrates a significant gap for those who will need to rely upon the data. Backup data should be publicly available for all adopted methods. To maintain a high relevance, NIOSH should update methods to platforms that are available in most laboratories (e.g., ICP-MS for elemental analysis) and maintain a set of robust validation parameters and backup data that are published with each analytical method in a standard format.

Approaches to updating methods could be to first update those methods that are used most often or those that require the fewest changes. Arguably, the most "popular" or most-used methods should be the ones given first consideration as those changes would have the widest impact. However, while those most-used methods are being updated, it may be possible to concurrently modify methods that require the fewest updates. For the most part, the "low-hanging fruit" or methods with the fewest updates will be those that just require a platform change (e.g., atomic absorption spectrometry to ICP-MS) or clarification of some of the components of the methods (e.g., whether soluble metals are analyzed). The methods that will require the most input will be those that may require the combination of multiple analytes into a single method.

For most methods, the most time-consuming part of the modifications will be generating the validation or backup data which should be streamlined so the same metrics are used for similar chemicals (e.g., all organics should have the same validation criteria) or matrices. NIOSH discusses method metrics, validation and error in multiple introductory chapters (i.e., PS, ME, UA) in the NMAM. To be more concise, validation parameters should be listed alone in a separate chapter with clear definitions of required and optional metrics for each method/matrix combination. Minimum validation parameters should include extraction recovery (where applicable), limit of detection, limit of quantification, precision, accuracy and bias.

Recognizing that methods and resulting data need to be 508 compliant, NIOSH could develop a standard template for reporting or recording backup data which would include the common location of all data. Previous backup data could be put in a 508-compliant format by a contractor or NIOSH should clearly indicate that backup data are not available because of non-compliance and those methods should be retired or updated. NIOSH could evaluate NIST and EPA formats for standardizing method to see if elements would be suitable for NIOSH to use.

NIOSH has established a memorandum of understanding with the German Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung/Institut für Arbeitsschutz (DGUV/IFA) to enable method developments through outside partnerships. This approach is more favorable than using industrial contract laboratories to perform the methods development and validation. As NIOSH acknowledges, their partnership with DGUV/IFA is cost-effective and saves NIOSH resources and promotes global harmonization. The DGUV/IFA also participates in the German Research Foundation's (Deutsche Forschungsgemeinschaft or DFG) development of compendiums similar to NMAM for German occupational and environmental health. The DFG compendium development involves a panel of experts that volunteer to develop or "prove" proposed methods, largely because these methods are of keen interest to them as well. NIOSH may want to consider a similar approach as it is cost-effective, provides performance-based standards allowing method modifications as needed (e.g., if a laboratory doesn't have tandem mass spectrometry, they may adapt to single stage mass spectrometry as long as the performance standards are met) and the validation or back-up data are standardized and provided by experts in the field instead of one single contract laboratory. NIOSH should also consider National Institute of Standards and Technology (NIST) strategies for standard reference material (SRM) validation or the Environmental Protection Agency's (EPA's) validation of analytical methods which are often carried out in the very labs that will eventually be required to perform the assay to ensure regulatory compliance.

NIOSH has been involved in many other methods development endeavors outside the NMAM that include development of new validated methods in response to emerging threats from biohazards, nanomaterials, and legal and illegal drugs. These methods are quite novel, however, many of them appear to be opportunistic rather than needs-driven. Prioritization of research with a limited budget should involve a strategic process that is need- and burden-driven (OVERARCHING ISSUES *vide infra*).

Translation of research and methods into worker-protective occupational limits or regulatory processes is an important and impactful part of NIOSH's overall mission. Although NIOSH methods are translated into workplace use, it occurs slowly. While NIOSH does not regulate standards, their research may result in recommendations for new or improved standards[1]. NIOSH has several means of developing and publicizing "Best Practices" including the development of Recommended Exposure Limits (RELs) and the NIOSH Criteria Documents, as well as Research to Practice program and the Training and Education branch. Health Hazard Evaluation reports (HHE) could also be "mined" for best practice recommendations and/or HHEs could be a venue for testing exposure assessment strategies, instruments and methods. Both intramural and extramural research funding, particularly those that involve partnerships with employers or associations could incorporate a goal of developing a best practices industry standard across many categories of exposure assessment. For instance, a NIOSH partnership for research in the hospitality industry could establish best practices for assessment of musculoskeletal hazards (as well as their reduction) as a strategic aim of the partnership. Given that what constitutes the "best practice" must evolve with the available science, this effort will take monitoring and updating. In addition to developing its own expanded set of best practices, NIOSH could be more proactive in working with the Occupational Safety and Health Administration (OSHA) to

assist in translating non-regulatory (RELs) developed by NIOSH into regulatory Permissible Exposure Limits (PELs). Although this is not a mandate of NIOSH, it would align with their overall goal of protecting workers' health.

NIOSH has strived to incorporate impact assessment into the industrial hygiene paradigm which is commendable. Web downloads of the methods manual have remained steady and relatively high. Similarly, citations are a useful metric although they may also capture legacy methods as well as 2006-2016 methods. A simple Google Scholar search returned a similar number of pages of citations as did EPA methods which suggests NIOSH methods are impactful. These are informative metrics, however, additional metrics could be included during the onset of an activity to record information on impact and relevance as it is being generated.

While such metrics play a role, they cannot be the only metrics used in evaluating impact. NIOSH EXA program research has filled critical knowledge gaps and created "niche" areas in sampling (e.g., bioaerosols) and measurement of unique workplace hazardous chemicals (e.g., beryllium). The research initiatives in protection of coal miners are unparalleled possibly at the expense of other industries (e.g., farming). The methods within NMAM are generally unique for exposures that cause occupational risk. However, the real impact is realized when worker protection is measured either as a decrease in work days lost, or fewer fatalities or less money paid out in workmen's compensation claims. A great need exists to capture and characterize more intermediate data to better demonstrate the ultimate impact of reduced exposure/improved worker health.

NIOSH should expend time and energy in developing interpretable and creative metrics that can be integrated into programs or research priorities. Evaluation scientists can work with exposure assessment methods development scientists to populate logic models with agreed upon measurable process and outcome metrics of impact and significance *a priori*. This would allow for evaluation data to be built into the project and provide for data to be collected before, during and after the development of a method or direct reading instrument. An example of process evaluation data would be "the number of diverse stakeholders consulted regarding design criteria." Outcome data could include "percent of users reporting success with the method." These data could complement more traditional strategies currently employed by NIOSH, for example, when evaluating the new side-wall capsule for metals sampling, a comparison to the traditional method was used to demonstrate the improved method[2]. Simulation or prediction analyses could be conducted to better estimate the ultimate impact on worker exposure and health. Evaluators should also include survey and qualitative or "perspective" data from key informants as data. Collection of these data may be underway, and if so, can be used to better demonstrate impact.

More cross-disciplinary integration on developing metrics and assessing impact is needed. Program evaluation need not be resource intensive; it could be built into the method validation process. For example, if in the process of validating a new method, an improvement in sensitivity or reproducibility is identified or another analyte is validated, it should be documented and highlighted. In addition to using simulation or epidemiologic type approaches to estimate impact on exposure or health, other metrics for consideration could include: number of accredited labs for NIOSH methods, time between new method publication and adoption by laboratories or a cost evaluation (dollars spent developing/validating methods divided by the number of labs using methods).

DIRECT-READING METHODS AND SENSORS

Direct-reading monitors and sensors enable continuous and/or real-time exposure and hazard evaluations in the workplace. These devices are needed in industrial applications where chemical and/or particulate exposures are likely and strict adherence to industry limits is needed to ensure the protection of worker's health. Because of their use in regulatory adherence, these devices also need to have robust performance characteristics.

NIOSH's direct-reading and sensor program is strong and it has notable achievements in advancing the use of direct-reading instruments. In particular, NIOSH has had obvious successes in sensor technology developed for the mining industry. Examples include the development, commercialization, and subsequent employment of several technologies in the mining sector such as the Continuous Personal Dust Monitor whose use was mandated by the Mining Safety and Health Administration (MSHA). This sensor-based technology allows miners to either move away from areas of high airborne dust or to direct engineering controls at problems in near real-time, fulfilling of one of the primary promises of real-time detection systems. In addition, NIOSH's "life cycle" approach to testing, implementing, translating and evaluating methods is robust, relevant and cost-effective. In addition, NIOSH has engaged with professional associations and other government agencies in an active and beneficial way to provide valuable input for new sensor development needs and current capabilities.

Although NIOSH has an active past in evaluating and deploying direct-reading monitors and sensors, they established the Direct Reading Exposure Assessment Methods (DREAM) initiative which dedicates intramural resources to coordinate NIOSH-wide direct-reading and sensor activities. In turn, the DREAM initiative led to the development of the virtual NIOSH Center for Direct Reading and Sensor Technologies in 2014. This virtual center coordinates national efforts to guide development and validation of exposure sensing tools, offers training and education about the proper use of tools and fosters outreach and understanding about the needs and uses of direct-reading monitors and sensing. The development of the DREAM program helped coordinate activities in a cost-effective manner.

The rationale for the activities completed by the program in direct-reading and sensors are moderately justified. This program area coalesced as a virtual center in 2014, towards the end of the program years we are evaluating, and the area of "sensors" is not mentioned per se in the NIOSH Program Portfolio until 2016. The early efforts in this area appear to have been unfocused (ranging from intramural work to measure accuracy and precision of handheld sensors, to extramural funding for development of very small micro-GC instruments), perhaps due in part to the lack of an administrative core. For sensors to be used in general industry, a steady focus on fundamentals of sensor technology and well-resourced determination of fundamental sensor performance parameters would be a more appropriate focus. The relevance of the virtual center on direct-reading and sensor technologies will likely increase substantially; the full potential relevance of the virtual center has not been realized yet likely because of the newness of this potential as a high-level stand-alone effort within NIOSH.

Extramural funding on sensor and direct reading monitors was primarily administered through Small Business Innovation Research (SBIR) grants. The performance and use metrics of the SBIR grants have not been adequately recorded thus prohibiting their proper evaluation of relevance and impact. This seems to be a lost opportunity for NIOSH to capitalize on instrumentation development that could be potentially impactful. For example, a review of NIH RePORTER shows no patents, papers, presentations, awards, or commercialized devices. If external funding did lead to these products, they

do not appear to be adequately captured by NIH RePORTER and/or NIOSH. It appears also that results from these grants do not have to be reported. It is not clear how much NIOSH actually spends on SBIRs (as compared to administrating them) and virtually no data on successful output have been collected. NIOSH should implement a better reporting system for SBIR grantees so the full impact of this program can be adequately evaluated.

Sensors obviously have great potential impact, though the impact may not yet to be fully realized or documented for the time period being evaluated. The Evidence Package repeatedly stated "no metrics available" to evaluate the ultimate goal of improving worker health. NIOSH cited the lack of resources for conducting longitudinal studies or randomized control trials as well as employers' reluctance to participate in health studies as barriers to fully evaluate impacts on occupational health. While impact is challenging to quantify, potential and actual impacts on health can be assessed without these "gold standard" methods. Given the fiscal constraints, a cost-effective means by which NIOSH could improve the impact of its work and address critical, underserved worker populations is by extending or modifying their new methods and sensors developed to other populations/sectors.

Cost-effective tools for measuring impact could include tabulating and describing case studies for which NIOSH methods or sensors were incorporated into regulations or changes in policies. In addition, studies comparing exposures or adverse events in workers utilizing newly developed real-time sensors to those using the older methodology could provide critical insights into the efficacy of the new sensors. The principal function of a real-time sensor is to alert the worker when they have entered a dangerous work environment so they can quickly take corrective action. Measuring the potentially hazardous agent or a biomarker of exposure in populations with the new versus old methodology would provide quantitative evidence of an exposure reduction or a true protective effect (or not) of real time sensors. Inexpensive surrogate measures (e.g., diaries of time spent in a hazardous environment vs. outside of the environment) can also be used to identify whether a true change in behavior was occurring in those wearing a monitor. NIOSH should be encouraged to track the impact of its monitors through worker exposure studies of those who use the monitors and those who do not.

Another metric of impact is the commercialization of the monitor created. A commercial instrument demonstrates both need and potential impact. Impact would include development costs which can be factored in based on potential users vs. dollars expended to produce. It appears that NIOSH did very well in its ability to find buyers for their sensors.

Impact can also be judged on the cost of the project. A more expensive project would have less overall impact than one that was able to achieve the same overall goal with less funding. For example, to change the behavior of a worker potentially exposed to a hazardous chemical the following procedure might take place: an evaluation of exposure route, estimated/measured amount (concentration x time), installation of preventative measures (PPE and administrative controls), follow-up with bio-monitoring (including sample collection and laboratory analysis), and tracking the number of days lost to exposure incidents. Alternatively, a new real-time sensor could be worn and a case-control study performed to determine efficacy. Assuming sensor development costs do not dramatically exceed the cost of the first procedure, the real-time sensor had a greater impact because the feedback and response occurred in real time. This effect is demonstrated on a national level with devices like a FitBit© that provide instant or near instant feedback to the wearer. Conversely, the method developed to measure manganese in bone using neutron activation analysis is intriguing but its utility is questionable. Unless the technique's energy source can be adapted, it is a method that is neither real time nor practical to bring subjects to accelerators.

OVERARCHING ISSUES

DECISION MAKING PROCESS

NIOSH should ensure objective, transparent and strategic prioritization of research efforts in in the EXA program. The current decision paradigm appears more subjective or reactive rather than a well-thought strategic process that considers the needs and burdens of the occupational health community. By allowing a more strategic process, NIOSH research will remain highly impactful and relevant.

EVALUATION AND TRANSLATION

NIOSH has incorporated both evaluation and translation components in their EXA program but opportunities to augment these components exist. The contribution analysis and logic model were both useful tools for evaluating the programs. In particular, the intermediate outcomes in the logic model that are readily available likely led to a larger impact of the program. Multiple metrics such as numbers of citations, methods, certified laboratories, downloads and website views demonstrate the wide reach of NIOSH activities and likely impactful result. Intermediate outcomes such as commercialization and use of technologies/methods by industry are certainly good predictors of outcome and impact. Although NIOSH has made great strides in evaluating the EXA program, they could also consider adding cost-effective evaluation techniques at the outset of the activity that may better track their success and impact. In addition, NIOSH should continue to actively advocate for the translation of their outputs by working with the OSHA to assist in translating non-regulatory RELs developed by NIOSH to regulatory PELs. In addition, commercialization of sensors and samplers, especially those developed with the SBIR grant mechanism would offer another avenue of translation of NIOSH research.

CONCLUSIONS

NIOSH has developed a robust and productive EXA program that is internationally recognized. They have realized several ground-breaking successes and have demonstrated a high relevance and impact of their program despite continued budgetary constraints. In particular, the NMAM and the intramural sensor program have produced output that is far-reaching and widely used. The portfolio of research and activities of NIOSH's EXA program was impressive and impactful. NIOSH could improve the relevance and impact of its program by implementing several specific modifications or adaptations of their activities as mentioned *vide supra*. Overarching changes that would also improve relevance and impact would be the implementation of a strategic, need-driven, transparent prioritization of research activities, inclusion of evaluation metrics in the development process that would enable NIOSH to more easily capture relevance and impact, and a more proactive approach to ensuring implementation of their outputs in industry and among other agencies such as OSHA.

APPENDIX 1

NIOSH Exposure Assessment Program Scoresheet

Relevance

Did the EXA Program appropriately set priorities based on burden and need?

5 = The rationale for the activities completed by the program are highly justified.

4 = The rationale for the activities completed by the program are justified.

3 = The rationale for the activities completed by the program are moderately justified.

2 = The rationale for the activities completed by the program are minimally justified.

1 = The rationale for the activities completed by the program are not justified.

__4.0_____ **Relevance Score**

Impact

How engaged was the EXA Program in transferring research into the workplace? Has (or is it likely in the future) that the EXA Program's activities and outputs will directly or indirectly lead to improvements in workplace safety and health?

5 = Research program has made major contribution(s) to worker health and safety on the basis of end outcomes or well-accepted intermediate outcomes.

4 = Research program has made some contributions and/or demonstrates great potential to contribute to end outcomes or well-accepted intermediate outcomes.

3 = Research program activities are ongoing and outputs are produced that are likely to result in improvements in worker safety and health. Well-accepted outcomes have not been recorded, but potential for well-accepted outcomes has been demonstrated.

2 = Research program activities are ongoing and outputs are produced that may result in new knowledge or technology, but only limited application is expected. Well-accepted outcomes have not been recorded and the potential for well-accepted outcomes is limited.

1 = Research activities and outputs do not result in or are not likely to have any application.

_4.0_____ **Impact Score**

Average Panel Relevance Score + Average Panel Impact Score = Total EXA Program Score

__8.0_____ **Total EXA Program Score**

REFERENCES

1. The Occupational Safety and Health Act. (1970).

2. Chisholm, W.P., Lee, T., Slaven, J.E., Nelson, J. & Harper, M. Comparison of filter and wall deposits from samplers used to collect airborne lead-containing dusts at field sites. *Aerosol Sci Technol* **46**, 411-418 (2012).