Published in final edited form as:
J Occup Environ Hyg. 2018 June ; 15(6): D45–D50. doi:10.1080/15459624.2018.1457221.

Launching the Dialogue: Safety and Innovation as Partners for Success in Advanced Manufacturing

CL Geraci[1], **SS Tinkle**[2], **SA Brenner**[3], **LL Hodson**[1a], **CA Pomeroy-Carter**[2], and **N Neu-Baker**[3]

[1]National Institute for Occupational Safety and Health

[2]IDA/Science and Technology Policy Institute

[3]SUNY Polytechnic Institute Colleges of Nanoscale Science & Engineering

Keywords

Advanced manufacturing; safety; innovation; partnerships

INTRODUCTION

Emerging and novel technologies, materials, and information integrated into increasingly automated and networked manufacturing processes or into traditional manufacturing settings are enhancing the efficiency and productivity of manufacturing. Globally, there is a move toward a new era in manufacturing that is characterized by the ability to create and deliver more complex designs of products; the creation and use of materials with new properties that meet a design need; the employment of new technologies, such as additive and digital techniques that improve on conventional manufacturing processes; and a compression of the time from initial design concept to the creation of a final product. Globally, this movement has many names, but advanced manufacturing has become the shorthand for this complex integration of material and technology elements that enable new ways to manufacture existing products, as well as new products emerging from new technologies and new design methods. As the breadth of activities associated with advanced manufacturing suggests, there is no single advanced manufacturing industry. Instead, aspects of advanced manufacturing can be identified across a diverse set of business sectors that use manufacturing technologies, ranging from the semiconductors and electronics to the automotive and pharmaceutical industries. The breadth and diversity of advanced manufacturing may change the occupational and environmental risk profile, challenge the basic elements of comprehensive health and safety (material, process, worker, environment, product, and general public health and safety), and provide an opportunity for development and dissemination of occupational and environmental health and safety (OEHS) guidance and best practices. It is unknown how much the risk profile of different elements of OEHS will change, thus requiring an evolution of health and safety practices. These changes may

[1a]Corresponding author lhodson@cdc.gov.

DISCLAIMER

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the National Institute for Occupational Safety and Health.

be accomplished most effectively through multi-disciplinary, multi-sector, public-private dialogue that identifies issues and offers solutions.

FRAMING THE DIALOGUE

The success of advanced manufacturing in the United States requires the active participation of communities, educators, workers, and businesses, as well as Federal, State, and local governments. The Advanced Manufacturing Innovation Symposium at the 2017 TechConnect World Innovation Conference and Expo in Washington, DC provided a unique forum to engage experts from all levels of industry, government, and academia to explore how innovations in advanced manufacturing have created challenges and opportunities in the field of OEHS. The session, *Safety and Innovation as Partners for Success in Advanced Manufacturing*, was framed by an inclusive definition of advanced manufacturing that incorporated advanced materials (e.g., manufacturing with materials specifically designed for an application or developed from nanomaterials or biomaterials), advanced equipment (e.g., highly integrated digital systems or robotics-enabled manufacturing), and advanced processes (e.g., additive manufacturing, biomanufacturing) and was organized through a panel and guided discussion. OEHS practitioners, technology leaders, manufacturing operations professionals, and partnership experts from start-ups, small and large companies, academia, and government who have experience with advanced manufacturing addressed theoretical and practical questions in OEHS management in advanced manufacturing settings. The discussion focused on: (1) potential advanced manufacturing occupational and environmental health and safety management challenges, (2) changes to hazard and risk profiles and assessment tools, (3) best practices for risk mitigation, guidance documents and other resources, and (4) partnerships. The session participants considered the value of OEHS in their advanced manufacturing settings; that is, how OEHS is incorporated into their business practices and how it supports the business's manufacturing policies and practices. Discussion of effective management practices included OEHS practices that were created or adopted to accommodate the company's transition into advanced manufacturing and the challenges to making these changes. Additional discussions focused on the types of information resources—government, academic, or industrial—that inform decision making, and the role of partnerships in developing and implementing OEHS practices and guidelines that address unique workplace challenges in advanced manufacturing.

RESULTING DISCUSSION

As the use of advanced materials, equipment, and processes proliferates in manufacturing settings, there was recognition across all sectors represented by the session participants (panelists and audience) that, although some occupational hazards and risks will change, the basic concepts of OEHS and sustainability are valued by the advanced manufacturing community. Because of the technical precision involved in both advanced materials and process development, the widely accepted hierarchy of controls—designing-out hazards to minimize risk—remains highly applicable.[1] These control measures contribute to the business case for advanced manufacturing through improvements in product development and manufacture (improved product quality, less hazardous materials, greater operational efficiency, improved time to market, increased market share) and workplace safety and employee wellness, both in the short and long term (improved worker health, reductions in workers' compensation rates, reduced health care costs for workers who are injured or develop chronic diseases, enhanced employee morale, and decreased employee absenteeism and turnover).[2]

The panelists stated that OEHS is considered an essential component of a corporate sustainability program and a logical starting point for good material and product stewardship. Larger organizations are able to leverage existing OEHS practices to manage the introduction of new materials and technologies, and smaller companies may use their sustainability record to improve relations with larger companies and customers.[3] Customers have become increasingly concerned with human health and environmental issues related to product manufacturing, consumer use, and recycling/re-use. Similarly, many companies are more receptive to proactively addressing OEHS concerns if those concerns improve product quality, safety, and consumer acceptance while simultaneously lowering costs or at least remaining cost-neutral. For example, reducing or minimizing emissions of airborne particulates during manufacturing using advanced technologies, such as additive manufacturing, may promote worker respiratory health and prevent the loss of valuable materials, thus improving production efficiency. Reduced airborne particulate emissions from manufacturing plants may also decrease the local community's particulate exposure and improve public perception of that manufacturing site. Depending on product design, consumer exposures during product use could also be reduced. An effective OEHS strategy that engenders a safer product for workers and consumers could be leveraged as a marketing tool, which may be viewed as value added to sustainable product development.

The case for implementing OEHS measures is especially persuasive when OEHS practices directly enhance operational performance or brand identity; however, there are other benefits not as readily apparent. In some business cases, OEHS value may be better expressed in terms of future costs that are the consequence of decisions not to invest in health and safety practices. These future factors may include lagging or trailing compensation claims, the potential for legal claims of harm or injury, fines, or other financially detrimental outcomes. In addition, regulatory uncertainty may develop due, in part, to a paucity of information about new or novel advanced manufacturing materials and processes that will have widespread commercial deployment, and failure to comply with regulations could engender higher late-stage development costs. Projecting the consequences of establishing—or not establishing—appropriate OEHS measures and the related cost of that decision is challenging as data on the long-term benefits and risks evolve slowly.

EVALUATING OEHS MANAGEMENT CHALLENGES

Despite the general recognition by the panelists that OEHS, as an element of overall corporate sustainability, adds value to product development and commercialization, comprehensive integration of OEHS considerations into business plans is not a widespread practice. While there are many reasons underlying this lack of integration, participants cited the criteria used by senior management to make product design and budget decisions as frequently not giving OEHS considerations the same emphasis as other elements of a sustainability program. Participants also noted that OEHS managers are generally not included in the meetings at which product business decisions are made and that, when budgets are constrained, the high cost of advanced materials, processes, and manufacturing equipment may preclude the funding of OEHS safety measures. Potential remedies for this disconnect between the value of OEHS and product decisions could include the addition of OEHS decision-making criteria to a Return on Investment (ROI) analysis. These ROI-related OEHS criteria could include comparison of the cost of OEHS policies to the reductions in costs associated with employee injuries and illnesses, corporate insurance, energy and water consumption, and waste management and removal. Limited business acumen among OEHS professionals, and a lack of business manager training in, and knowledge of, the basic elements and importance of OEHS are also cited as contributing factors. Formal or informal dialogue at gatherings for OEHS practitioners, technology leaders, manufacturing operations professionals, the insurance industry, and partnership experts—whether within or external to a company—are examples of mechanisms through which to bridge the business manager-OEHS professional knowledge gap.

The technical complexity of the advanced manufacturing workplace may require an OEHS professional to develop a combination of traditional, modified, and new practices to optimize and manage workplace health and safety. Established companies transitioning into advanced manufacturing will be challenged to adapt and adopt appropriate OEHS practices, and new companies may lack the resources and institutional knowledge to implement effective OEHS programs, especially start-up, small, and medium enterprises. Furthermore, an OEHS management policy or practice may apply to a specific material, tool, or product, or to an integrated program of policies and practices across a product line or an entire organization. Companies that develop or adopt new technologies often do so in an environment of subjective guidance. Historically, many OEHS practices were developed in response to a regulatory or policy requirement, and new materials and technologies generally do not have an incident-driven regulatory response that can provide part of the OEHS framework for a business case. Developing and implementing an effective OEHS plan within a business case will require a balance of historical knowledge and experience as it reasonably applies to the new business. Often, the communications needed to establish new OEHS practices will need to be proactive and emphasize prevention as a way to avoid future costs and liabilities.

ILLUSTRATING ADVANCED MANUFACTURING CHALLENGES TO RISK PERSPECTIVES AND HAZARD ANALYSIS

Case studies provide a useful tool to understand potential changes in advanced manufacturing OEHS practices. One example of advanced manufacturing is the use of metal powder bed additive manufacturing processes (also referred to as 3D printing), which may demand consideration of worker exposure to fine and nanoscale metal powders, the handling of more active forms of sensitizing metals, the potential for metal emissions, and the possible presence of combustible dust in the workplace. Environmental considerations, such as policies related to metal powder reuse and proper waste disposal practices, must also be taken into account. Understanding the actual risks associated with these advanced processes will require careful evaluation and assessment of potential process emissions and worker exposure. Good OEHS practices for managing and controlling fine powders in the additive manufacturing process, whether metal or organic, are known ; however, communicating those practices to businesses adopting additive manufacturing that are not familiar with them or may not have experience in OEHS is an ongoing challenge. Until good process and task-based emission and exposure information can be generated for additive manufacturing, there are some fundamental, proactive risk management practices that can be followed.

Robots are another example of the change in how manufacturing tasks are performed that could introduce new ergonomic and other workplace hazards and new elements to risk management strategies. While robots and robotics have been used in manufacturing for over 30 years, their level of sophistication is increasing dramatically to keep pace with and accelerate advanced manufacturing processes. Already workers are equipped with performance-enhancing robotic devices, such as robotic prostheses and exoskeletons (also known as exosuits). New classes of robots are being designed to work alongside human workers, and robots that can collaborate with humans or function autonomously, potentially in dangerous environments, are being developed. The potential benefits for robotic manufacture to prevent worker injuries and fatalities are substantial; however, assessment of their functions and potential hazards will be essential to understand OEHS considerations of robot-human interactions. The advanced manufacturing community that employs robots can build on the foundational work of the American National Standards Association (ANSI) and the Robotics Industry Association who have established voluntary consensus standards for human safety when working with or near robots performing a single repetitive task. The complexity of collaborative and autonomous robots will further challenge these standards and current OEHS practices.

RECOMMENDING A BEST PRACTICES APPROACH

In the absence of specific regulatory guidance or data that provide for a well-characterized hazard and risk profile of an advanced manufacturing material and/or process, companies often rely on the use of “best practices” or “current best approaches” to guide their OEHS programs. Some companies have attempted to benchmark their OEHS practices against those of other companies in related industries. Others have developed models that account for the latest OEHS research and have attempted to predict risks and hazards associated with manufacturing practices. Still others have relied on third party experts to assist with developing, evaluating, and modifying OEHS practices and management tools.

The utility of each of these approaches in isolation is constrained and in combination, compounded. Benchmarking efforts often reveal that industries using similar advanced manufacturing materials and processes do not have a unified OEHS approach. Modeling and simulation of processes, emissions, and exposure, while theoretically attractive, can be limited by the amount of available data for a new manufacturing endeavor, especially if the data were not collected in a scenario that reflects actual advanced manufacturing conditions. The available data may also be biased toward adverse health impacts because they are more likely to be accepted for publication, and with limited data, the predictive value of modeling is often limited to near-term effects. Companies may rely on third party experts to provide guidance in areas where there may not be internal capability, or if an un-biased, independent approach is needed. Often, this involves the use of OEHS consultants, insurance risk managers, or law firms conducting evaluations of operations and comparing findings to known or existing guidelines. However, these third party experts may also lack the tools and information needed to effectively address OEHS for new or emerging technologies, or it may be too expensive for small or start-up companies to purchase their services. Ultimately, the data and information needed will come from the organizations developing and deploying the technology, either directly or in collaboration with research partners. Nanotechnology provides an example of early and successful interactions between materials developers, OEHS researchers, and government. Often cited are NIOSH's workplace guidance "Approaches to Safe Nanotechnology" and the National Science Foundation's nanoHUB.org which hosts the "Good Nano Guide.[4,5] Advanced manufacturers might consider opening a dialogue among appropriate experts in their manufacturing operations, their OEHS specialists, and the OEHS research community as part of a company's OEHS management plan. Ultimately, collaboration across these public-private lines could engender science-based data and guidance for policymakers and regulatory agencies. This approach would allow for early consideration of existing regulatory policy as it might apply to the product under development, policy creation for emerging technologies, policy redesign to avoid regulatory entanglement, identification of challenges that advanced manufacturing might pose for existing regulatory policy, and development of collaborative solutions.

IDENTIFYING RESOURCES AND PARTNERSHIPS

The participants suggested that developing and disseminating knowledge and best practices related to OEHS in advanced manufacturing has great value and may be most effectively achieved through the creation of a convening body of experts (which would include advanced manufacturing stakeholders, made up of government, industry, academia, and others, such as, insurance providers) and a centralized information repository. The ultimate goal would be to drive both advanced manufacturing technologies and OEHS research fields forward in a collaborative manner, in contrast to the historical model of one lagging behind the other. Ideally, the body would be non-regulatory and have as its primary purpose the creation of a forum for cultural exchange of information and the development of practices based on the experience and expertise of all stakeholders.

There is a need for an array of functioning partnerships to address how governmental agencies and private sector companies can collaborate to offset the concerns of potential investors about unforeseen risks and potential regulatory roadblocks. Construction of and adherence to relevant occupational safety practice and policy should be incorporated at the beginning of product development and manufacture rather than implemented later as a reaction to unsafe conditions.

The panel stated that although companies may be eager to work with experts and to explore the use of a unified approach to OEHS in advanced manufacturing, there are several potential barriers to information-sharing among stakeholders.

1. *Liability issues*. Companies may be hesitant to promote their internal OEHS practices for fear that doing so may introduce liability issues; however, they

might be more open within a forum for information-sharing that promotes broad input to the development of practices and serves as a source for dissemination.

2. *Concerns about intellectual property (IP)*. Although OEHS practices themselves are usually not proprietary, some companies may consider them an element of their competitive advantage. Others may be reluctant to share OEHS information on the basis of IP protection, particularly if doing so necessitates sharing information about production processes or other potentially sensitive information. Several models for developing and sharing OEHS information in highly competitive industries exist and could be copied (e.g., the semiconductor industry).

3. *Need to incentivize information-sharing*. Because companies may perceive limited potential gains in competitive advantage from sharing OEHS information, promoting a culture of information-sharing may be impeded by a lack of incentive. Demonstrating true return on investment and support for accelerated commercialization is a tangible activity that a forum or consortium would be better positioned to address. Making and delivering on the business case for OEHS is critical in order to gain buy-in and resources from company decision-makers.

4. *Need for trust among stakeholders*. Stakeholders may be unwilling to engage in information-sharing without a high degree of trust among all participants. Open information sharing, a high degree of collaboration, and a structure that includes all stakeholders in the operation of the forum will be needed. Identifying 'trusted partners' early in the process was identified as critical.

5. *Lack of cohesiveness among the advanced manufacturing industries*. Industry-specific OEHS issues may be difficult to address in a forum focused on cross-sectorial OEHS knowledge in advanced manufacturing. A potential solution rests in addressing advanced manufacturing OEHS in terms of materials, processes, and ancillary activities. Additionally, the definition of advanced manufacturing continues to evolve, making it challenging for stakeholders to identify themselves or others as part of the advanced manufacturing community. A convening body would help in identifying commonalities, shared challenges, and definitions as technologies and processes evolve rapidly.

While liability and intellectual property issues must be considered and addressed while making the business case for OEHS; information-sharing, trust, and cohesiveness are particularly challenging in a fledgling manufacturing ecosystem. Based on these findings, a successful convening body would need to be viewed as a trusted, independent partner. The semiconductor industry, wherein consortia have aided industry in managing risk and proactively tackling OEHS issues, provides an example of a successful model. In particular, the New York State NanoHealth and Safety Center (NSC), was an effective convening authority: the NSC, launched in 2011, was a $10M, 5-year collaborative effort between SEMATECH Consortium semiconductor member companies, New York State, and SUNY Polytechnic Institute in Albany, New York. This public-private model was a first-of-its-kind effort to address emerging OEHS issues in order to reduce cost and risk, solve manufacturing problems, and leverage resources among participating parties. NSC successfully utilized non-disclosure agreements to protect IP, thereby increasing trust and cooperation among the participating companies. Research projects were proposed by industry members in collaboration with researchers, and teams were formed of individuals with the skills and expertise needed to obtain data, interpret results, and contribute to best-practice recommendations in real-time. Project selection each year occurred through a voting process, allowing each member to have a voice in the direction of the group. Working group updates were provided at least quarterly and technical transfer reports were prepared and shared with all NSC members annually. Active participants included not only semiconductor (chip) makers, but also tool makers and supply chain companies; therefore, a large ecosystem of diverse companies was able to contribute and benefit. Some were exclusively dedicated to nanoelectronics, while others had diverse company portfolios, including business and products in related sectors (e.g., photovoltaic) or completely different markets (e.g., health care). Many companies were direct head-to-head international competitors, while others existed to support the function of the industry as a whole.

Trust amongst members was established over many years (in some cases, predating the formation of the NSC) and strengthened through appropriate handling of IP and other confidentiality issues by the neutral-territory stakeholder (academia). For the most part, OEHS activities were seen as largely pre-competitive; a necessary component of all companies that was vital to their long-term success. Participants were also aware of the liabilities associated with failing to invest in OEHS. While there were many differences between participating companies (e.g., size, array of products and services, sector, business model), common ground was identified and projects were scoped to maximize value for those investing time and resources. In some cases, a handful of companies with a unique common interest undertook a specific project of high-value to them, while other projects were of broad interest to nearly the entire membership. Members were enthusiastic about the value and outputs of the NSC for their companies as well as their own professional development, and industry representatives were lively participants in the collaborative forums hosted by the NSC (working group calls, in-person meetings, research presentations, etc.). Gains for each company through this collective approach were greater than if each individual company had attempted to undertake comprehensive OEHS research themselves. For the semiconductor industry and its suppliers alike, there was a keen advantage in proactively incorporating OEHS all the way from R&D to procurement to manufacturing. This public-private consortium approach helped companies both in the short and long term; immediate OEHS best practices were developed and deployed for specific scenarios, and forward-thinking decisions could be made with regard to the semiconductor roadmap, which charts the industry-wide course five to ten years into the future.

CHARTING A PATH FORWARD

The breadth, diversity, and pace of advanced manufacturing present new and continuing challenges and opportunities to the OEHS community. The proactive incorporation of OEHS along product pipelines and AM processes will enable and accelerate economic vitality and competitiveness. The establishment of a convening body or clearinghouse that serves to not only assist companies and industries in addressing advanced manufacturing OEHS concerns, but that also mitigates risk and safeguards IP, would greatly benefit OEHS efforts. The pace of innovation, including development and use new materials, tools, technologies, and processes, makes it nearly impossible for OEHS professionals to keep pace with AM advances if they do not work together. Resources can be effectively pooled and shared among participating parties, providing collective value that far exceeds their individual financial contributions. Precompetitive information to address shared concerns, knowledge gaps, and immediate OEHS needs; best practices; and risk mitigation strategies could be easily shared and disseminated via a consortium model and could facilitate compliance and expedite health and safety recommendations. Concerns regarding liability and IP could be addressed and protected through agreements that meet each participant's requirements. With sufficient nondisclosure agreements and other legal protections in place, as well as an emphasis on the many and varied OEHS returns on investment, contributors and users could be incentivized to cooperate and participate in an advanced manufacturing OEHS consortium. In sum, companies and OEHS practitioners should be encouraged by this array of options to meet the challenges and opportunities presented by advanced manufacturing and by the elements of a business case for pro-active adoption of OEHS practices that they represent.

Acknowledgments

Session co-chairs were: Chuck Geraci, PhD, CIH, National Institute for Occupational Safety and Health; Sally Tinkle, PhD, IDA/Science and Technology Policy Institute; and Sara Brenner, MD, MPH, SUNY Polytechnic Institute. Panel members included: Thomas Diamond, CIH, SUNY Polytechnic Institute; Doyle Edwards, Brewer Science; John Howard, MD, National Institute for Occupational Safety and Health; Roger Martella, General Electric; Kim Nelson, PhD, American Process, Inc.; Peter Scheuer, Honeywell - F&MT; and Mark Tuominen, PhD, University of Massachusetts, Amherst.

CONFLICTS OF INTEREST

Brenner SA and Neu-Baker N conduct research supported by CDC-NIOSH.

Tinkle SS and Pomeroy-Carter, CA performed contract work for CDC-NIOSH.

References

1. Peterson J. Principles for controlling the occupational environment. The industrial environment—its evaluation and control. 1973:74–117.
2. AIHA. American Industrial Hygiene Association, Demonstrating the business value of industrial hygiene. 2008. (https://www.aiha.org/votp_new/pdf/votp_report.pdf) Retrieved May 30, 2017
3. MIT Sloan Management Review. Fall;2009 51(1) https://www.bcg.com/documents/file32201.pdf.
4. NIOSH. Approaches to safe nanotechnology: managing the health and safety concerns associated with engineered nanomaterials. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH); Cincinnati: 2009. NIOSH Pub No. 2009-125
5. nanoHUB.org https://nanohub.org/