Advanced Manufacturing Implications for Occupational Safety and Health

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ABSTRACT

The term *advanced manufacturing* has been used to capture recent technology-enabled changes in manufacturing, including the use of novel, cutting edge materials, technologies, and processes, and manufacturing methods that are prone to fast and frequent modifications. Establishing occupational safety and health (OSH) practices may be particularly challenging in such environments. To assist advanced manufacturing stakeholders in identifying potential worker health and safety issues associated with advanced materials and advanced manufacturing technologies, we researched the scope of advanced manufacturing and explored the implications of that scope for OSH. Using literature reviews and interviews with subject matter experts, we (1) constructed a definition of advanced manufacturing, (2) proposed a framework that operationalizes that definition, and (3) outlined an initial set of OSH implications for advanced manufacturing settings.

Keywords: advanced manufacturing, occupational safety and health

1 INTRODUCTION

Manufacturing processes are designed to efficiently, precisely, and reproducibly generate a product. The term *advanced manufacturing* has been used to capture recent technology-enabled changes in manufacturing, incorporating elements such as "the use and coordination of information, automation, computation, software, sensing, and networking" and the "use of cutting edge materials and emerging capabilities enabled by the physical and biological sciences" [1]. Practicing occupational safety and health (OSH) may be challenging in rapidly evolving advanced manufacturing environments in which novel materials, technologies, and processes are often employed. Identifying and managing potential OSH challenges in advanced manufacturing settings requires a clearly scoped definition of the advanced manufacturing concept and exploration of the potential OSH implications associated with that concept.

2 METHODS

To develop a definition of *advanced manufacturing*, we gathered definitions from various Federal and industry organizations by consulting publicly available information through online searches for the key phrase *advanced manufacturing*. We subsequently conducted semi-structured interviews with twelve individuals in Federal, academic, and industry positions related to advanced manufacturing to confirm the currency of official definitions and provide additional perspective. By identifying common themes across information acquired through online searches and interviews, we developed a working definition of *advanced manufacturing* and a framework that operationalizes that definition. We also asked interviewees to consider how the characteristics, processes, and materials that they identified as part of the advanced manufacturing landscape might affect workforce safety, change worker exposures and potential health impacts, or alter the traditional OSH approaches.

3 DEFINING AND OPERATIONALIZING ADVANCED MANUFACTURING

We identified *state of the art* as a critical aspect of the concept of advanced manufacturing, and, for the purposes of this paper, defined *state-of-the-art manufacturing* as the process of making products or materials using the newest or most sophisticated ideas, science, and technology available at that time. Manufacturing is characterized as advanced when it (1) uses a state-of-the-art manufacturing process; (2) produces or incorporates state-of-the-art materials or material combinations; or (3) uses a state-of-the-art manufacturing process to produce or incorporate state-of-the-art materials or material combinations. It is important to note that, as science-based capabilities continue to evolve, the materials, equipment, and processes that constitute state of the art will change. Thus, understanding the state-of-the-art manufacturing landscape requires not only keeping pace with scientific and technological innovation but also a flexible conceptualization of what activities comprise state-of-the art manufacturing.

To provide greater clarity on the types of manufacturing activities that might use state-of-the-art processes or materials, we operationalized the state-of-the-art manufacturing definition as process-centered and materials-centered. Each of those categories is further subdivided, creating the following framework:

1. Process-centered state-of-the-art manufacturing
   a. Manufacturing that utilizes new applications of information technology (IT) or new tools for data integration (modeling, computation, and simulation)
   b. Manufacturing that employs new or cutting edge tools (processing hardware, automating technology, robotics, sensors, networking, and other technologies for precision manufacturing)
2. Materials-centered state-of-the-art manufacturing
   a. Manufacture of materials (nonbiological and biological materials) with novel or optimized properties
   b. Manufacture of products that use or incorporate materials with novel or optimized properties
   c. Manufacture of products from novel combinations of materials that provide new or state-of-the-art performance

In our framework, alignment of a manufacturing practice with one subcategory is sufficient for an activity to be considered state-of-the-art manufacturing; however, the categories and subcategories are not mutually exclusive. For example, a manufacturing effort may use novel automating technology (category 1.b) to manufacture a material with novel properties (category 2.a).

The following sections discuss the two categories of state-of-the-art manufacturing in greater detail, placing special emphasis on current science and technology capabilities that meet the working definition of state-of-the-art manufacturing.

3.1 Process-centered state-of-the-art manufacturing

We defined process-centered state-of-the-art manufacturing as a systematic series of actions that involve the use of novel or emerging capabilities and technologies or the novel application of existing capabilities or technologies to make a product. The incorporation of these capabilities and technologies generally enables enhanced precision, integration, or control of the manufacturing process, or improved use or coordination of information within the manufacturing effort. Currently, this category encompasses manufacturing that utilizes new applications of IT or new tools for data integration, including modeling, computation, and simulation; and manufacturing that employs novel tools, such as processing hardware, automating technology, robotics, sensors, networking, and other technologies for precision manufacturing.

3.2 Materials-centered state-of-the-art manufacturing

The second state-of-the-art manufacturing category encompasses the manufacture of materials (nonbiological materials and biological materials) with novel or optimized properties and the manufacture of products that use, incorporate or combine such materials. Subject matter experts provided examples of such conditions: (1) the composition of a light element alloy can be formulated to obtain a material with an optimized density-to-strength ratio; (2) phase transformations of materials can provide novel properties such as those exhibited by shape-memory alloys or piezoelectric ceramics; (3) the design or re-design of genetic material is driving the construct of new genomes and life forms and new processes to manufacture chemicals and therapeutics; and (4) functionalizing—modifying the surface chemistry—of nanomaterials can result in novel properties that enable, for example, cancer cell targeting or water purification. Identification of manufacturing efforts that fall under the purview of this category requires an understanding of the current state of materials science and engineering fields.

4 OSH IMPLICATIONS

We considered how the characteristics, processes, and materials identified as part of the state-of-the-art manufacturing landscape might affect workforce safety, change worker exposures and potential health impacts, or alter traditional OSH approaches. Using interview responses and supplementing with peer-reviewed literature, we examined some of the potential OSH ramifications of two major technologies impacting state-of-the-art manufacturing—modeling and simulation (process-centered) and the use of synthetic biology (materials-centered)—and identified several high-level considerations for the state-of-the-art manufacturing workplace.

4.1 Modeling and simulation

Modeling and simulation of materials and products entail the use of advanced computing technologies for engineering, testing, or design purposes. By creating a digital model of a material or product, a manufacturer can perform a wide range of tests, such as hazard analysis, manufacturability analysis, or performance testing, before physically making the material or product. According to interviewees, some of the potential benefits are safer products, improved product quality, shorter time to market, and reduced manufacturing costs. The ability to model a material or product before it is physically produced allows virtual experimentation that may help clarify the potential hazards and health risks for the workforce, though the utility of modeling and simulation is limited by a reliance on inference: if the proposed material or product cannot be related to a known material or product, it may not be possible to draw conclusions about its hazard or exposure potential.

Similarly, simulation of a state-of-the art manufacturing process before scale-up to market quantities can identify methods to optimize use of materials and types of manufacturing processes and equipment, analyze process-induced changes in materials used in manufacturing, increase product yield, and reduce waste—all changes that could have implications for the magnitude and type of worker hazard and exposure. Modeling and simulation can be used to identify hotspots for hazard and exposure in a state-of-the-art manufacturing process, thus providing early opportunities for elimination or substitution of particularly hazardous processes.

4.2 Synthetic biology

The rapid rate of synthetic biology technology development, combined with an uncertain regulatory environment, the potential for malicious or misguided use of synthetic biology technologies, and limited understanding of the potential consequences of altering biological (and potentially self-replicating) systems, contribute to a heightened perception of risk. Some experts have advocated for alternative solutions to synthetic biology, which minimizes risk in a cost-effective manner [2]; however, when synthetic biology is selected for use in a manufacturing setting, risk assessment, including risk management, is essential. Risk management measures that have been identified as relevant to synthetic biology include increased health surveillance of workers; proactive risk assessment and management; the application of Prevention through Design principles; improved guidance; development of post-exposure prevention procedures; and encouragement of greater awareness of and involvement in synthetic biology risk assessment and management within the community [3]. Other experts have emphasized the importance of identifying the synthetic biology challenges in terms of science, outcomes, desired and undesired endpoints, and potential alternative paths; asking the correct risk-management questions; exploring new ways to integrate risk assessment and management; and encouraging creative solutions [4].

4.3 Other considerations

Other overarching or longer term factors with relevance to state-of-the-art manufacturing identified by interviewees include:

Changes in workforce organization. State-of-the-art manufacturing is expected to shift some industries toward distributed, as opposed to centralized, manufacturing models. Because collocation can simplify management challenges, geographically dispersed manufacturing efforts may increase the challenge of risk management across a given manufacturing enterprise.

Supply chain management. The scope of management—the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities—may be complex for state-of-the-art manufacturing. These activities may contain their own hazards and exposures. Consideration of the supply chain will be important for effective risk management in such situations.

Democratization of manufacturing. Increased access to and reduced cost of several manufacturing technologies, such as 3D printing, are democratizing manufacturing and enabling smaller scale state-of-the-art manufacturing by citizen scientists and small businesses. Whether small manufacturers have the financial and logistical ability to design safe manufacturing environments in these settings is unclear.

Rapid rate of manufacturing process iteration. A subset of the state-of-the-art manufacturing industries cycle through a manufacturing process—from research and design to production and back to research and design for the next-generation product—at a rapid pace. This rapid cycling may hinder the ability to identify and manage issues through a proactive, coordinated, comprehensive approach.

Complexity of state-of-the-art manufacturing management. With increased use of materials with novel or optimized properties and incorporation of automated processes into product manufacturing, an increasing number of persons and types of expertise and equipment are critical to safety decisions. This team might include—in addition to industrial hygienists and safety engineers—industrial and mechanical engineers, physicists and chemists, physician scientists, and social scientists. As the complexity of workforce management increases, so, too, will the importance of developing and fostering a positive safety culture.

Re-examination of Material Composition Disclosure. The definition of full disclosure may need to expand to include disclosure of all components in a material or product, even those components below the 1% component regulatory threshold. Nanoscale nonbiological and biological materials may be present at low concentrations but engender high hazard.

While our conclusions align with the needs of today's advanced manufacturing environment, we recognize that the field of advanced manufacturing will continue to evolve, and that the framework, implications, and considerations presented herein will need to be adapted as today's state of the art becomes tomorrow's routine, and new materials and processes arise. This evolution will occur most effectively through an ongoing public-private dialogue that balances the needs of the advanced manufacturing workforce with the realities of advanced manufacturing.

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