SCIENCE AND TECHNOLOGY POLICY INSTITUTE

Occupational Safety and Health Considerations in the Advanced Manufacturing Setting

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April 2017

1. Introduction

The National Institute for Occupational Health and Safety (NIOSH), in fulfillment of its mission to "develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice,"[1] works with manufacturing industries to evaluate workplace hazards and risks and to incorporate health and safety practices into its business plans. While NIOSH's efforts remain valid for standard manufacturing endeavors, emerging materials and technologies and new capabilities within existing technologies may change the way that occupational and environmental safety and health is practiced.

NIOSH asked IDA's Science and Technology Policy Institute (STPI) to develop a white paper that can be used by NIOSH as an element of a strategic approach to ensure that NIOSH is prepared to identify potential worker health and safety issues associated with advanced materials and advanced manufacturing technologies. The white paper is intended to assist NIOSH in addressing issues arising from the major categories of occupational hazards—physical, chemical, biological, radiological, ergonomic, and psychosocial hazards—as they arise in advanced manufacturing settings.[2] To that end, the STPI team constructed a definition of advanced manufacturing, tested the definition against research occurring in the Manufacturing USA Institutes, and proposed an approach for recognizing advanced manufacturing. The STPI team then developed a tool for identifying concerns in the workplace and outlined implications and considerations for advanced manufacturing settings.

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1 The National Institute for Occupational Safety and Health (NIOSH), "About NIOSH," https://www.cdc.gov/niosh/about/.

2 D. C. Breeding, "What Is Hazardous?," Occupational Health and Safety, https://ohsonline.com/articles/2011/07/01/what-is-hazardous.aspx.

2. Focusing the Definition of Advanced Manufacturing

A. Methods

In developing a definition of advanced manufacturing for this white paper, the STPI team gathered definitions from various Federal and industry organizations by consulting publicly available information through online searches for the key phrase *advanced manufacturing.* The list of definitions STPI identified is located in Appendix A. The team 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. A list of interviewees and a copy of the interview guide can be found in Appendix B. By identifying common themes across information acquired through online searches and interviews, the STPI team developed a working definition of advanced manufacturing.

This working definition was then compared to initiatives set forth through the Manufacturing USA Institutes. According to Manufacturing.gov, Manufacturing USA (manufacturingUSA.com) is a network of organizations, termed Institutes, that bring together industry, academia, and Federal partners to promote American competitiveness and sustainable development in the manufacturing sector.[3] The Institutes serve as a proxy for Federal priorities within the advanced manufacturing field. Thus, evaluating the extent to which STPI's definition aligns with the Institutes serves as a check on its utility and relevance.

B. Definition

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" or the "use of cutting edge materials and emerging capabilities enabled by the physical and

[3] Advanced Manufacturing National Program Office (AMNPO), "Highlighting Manufacturing USA," https://www.manufacturing.gov/.

biological sciences."[4] NIOSH's mission is particularly challenging when applied to industrial sectors that use novel, cutting edge materials, technologies, and processes and are prone to fast and frequent changes in manufacturing methods.

To focus on the intersection between advanced manufacturing and the NIOSH mission, the STPI team has identified *state of the art* as a critical aspect of the concept of advanced manufacturing and, for the purposes of this white 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, the STPI team 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. Manufacturing of materials (nonbiological and biological materials[5]) with novel or optimized properties

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[4] President's Council of Advisors on Science and Technology (PCAST), *Report to the President on Ensuring American Leadership in Advanced Manufacturing* (Washington, D.C.: PCAST, 2011).

[5] Here, the manufacture of biological materials is meant to include the products and processes associated with synthetic biology as well as other biological materials. According to the European Commission, "Synthetic biology is the engineering of biology: the synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature. This engineering perspective may be applied at all levels of the hierarchy of biological structures—from individual molecules to whole cells, tissues and organisms. In essence, synthetic biology will enable the design of 'biological systems'

b. Manufacturing of products that use or incorporate materials with novel or optimized properties

c. Manufacturing of products from novel combinations of materials that provide new or optimized state-of-the-art performance

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.

1. Process-Centered State-of-the-Art Manufacturing

Process-centered state-of-the-art manufacturing is defined 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. The STPI team appreciates that networking for IT purposes refers to the networking of computers through servers; within subcategory 1.b, however, networking refers to the amalgamation of data for process-, product-, and supply chain-control.[6]

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in a rational and systematic way." European Commission, *Synthetic Biology Applying Engineering to Biology* (Luxembourg: Office for Official Publications of the European Communities, 2005).

[6] According to the Council of Supply Chain Management Professionals, "supply management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies." Council of Supply Chain Management Professionals (CSCMP), "CSCMP Supply Chain Management Definitions and Glossary," http://cscmp.org/imis0/CSCMP/Educate/SCM_Definitions_and_Glossary_of_Terms/CSCMP/Educate/SCM_Definitions_and_Glossary_of_Terms.aspx?hkey=60879588-f65f-4ab5-8c4b-6878815ef921. Increasingly, process-centered state-of-the-art manufacturing elements have been used to improve supply chain management, creating what is known as *smarter supply chains*. These supply chains are instrumented, interconnected and intelligent: *instrumented* refers to the use of machine-generated

The Manufacturing USA network of Institutes, as described previously in section A of this chapter, lends credibility to the process-centered state-of-the-art manufacturing framework set forth here. Three of the Institutes, described in the subsections that follow, are particularly good examples of current process-centered state-of-the-art manufacturing. This does not mean that other Institutes do not incorporate category 1 elements or that these three Institutes bear no relationship to elements set forth in category 2; instead, these three Institutes were selected because their primary purpose is to support the development and application of processes and technologies that fall under the purview of category 1. Within these examples, only those aspects related to category 1 of the framework are discussed. Appendix C provides additional details on the Institutes and their relationship to the entire state-of-the-art manufacturing framework.

a. Digital Manufacturing and Design Innovation Institute (DMDII)

DMDII aims "to demonstrate and apply digital manufacturing technologies to increase the competitiveness of American manufacturing."[7] Manufacturing.gov defines digital manufacturing as manufacturing that "focuses on reducing the time and cost of manufacturing by integrating and using data from design, production, and product use; [on] digitizing manufacturing operations to improve product, process, and enterprise performance; [and on applying] tools for modeling and advanced analytics, throughout the product life cycle."[8] DMDII achieves its goal of promoting digital manufacturing practices by supporting technology development and application in five main areas, defined by DMDII as follows:[9]

- Advanced Analysis (AA) involves the "the collection and analysis of data over sustained periods of time which enable manufacturing design."
- Advanced Manufacturing Enterprise (AME) is "the aggregation and integration of data throughout the manufacturing supply chain and product lifecycle."

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information collected via tools such as tags and sensors to improve supply chain management; *interconnected* indicates that the smarter supply chain is networked and monitored using IT; and *intelligent* refers to the use of advanced analytics and modeling to improve supply chain-related decision making. IBM, *The Smarter Supply Chain of the Future: Global Chief Supply Chain Officer Study* (Somers, New York: IBM., 2010).

7 UI Labs, "DMDII Projects," http://www.uilabs.org/innovation-platforms/manufacturing/projects/.

8 Advanced Manufacturing National Program Office (AMNPO), "Glossary of Advanced Manufacturing Terms," https://www.manufacturing.gov/news-2/news/glossary-of-advanced-manufacturing-terms/.

9 Digital Manufacturing and Design Innovation Institute (DMDII), "Project Call 15-08 Course Content Expectations," http://www.uilabs.org/wp-content/uploads/2017/02/DMDII-WFD-15_08-Workshop-Course-Content.pdf.

- Intelligent Machining (IM) is the "integration of smart sensors and controls to enable equipment to automatically sense and understand the current production environment in order to conduct self-aware machining."
- Digital Manufacturing Commons (DMC), is "an open source platform that enables data aggregation, analysis, and action."
- Digital Manufacturing Security encompasses "how to secure all aspects of a digital manufacturing operation and protect operational technologies, systems, and resources."

These topic areas underscore the utility of both process-centered state-of-the-art manufacturing subcategories. AA, AME, and DMC provide evidence of the relevance of subcategory 1.a. Subcategory 1.b is demonstrated within the concept of IM, which involves the use of automating technology, including sensors and controls.

b. Advanced Robotics Manufacturing Institute (ARM)

Established in 2017, ARM is one of the newest Institutes in the Manufacturing USA network. According to the press release announcing its establishment, ARM aims "to create and then deploy robotic technology by integrating the diverse collection of industry practices and institutional knowledge across many disciplines—sensor technologies, end-effector development, software and artificial intelligence, materials sciences, human and machine behavior modeling and quality assurance—to realize the promises of a robust manufacturing innovation ecosystem."[10] Although few specifics were publicly available at the time of this writing, ARM intends to promote the use of robotics in manufacturing, particularly within the automotive, aerospace, electronics, and textiles industries. Technologies of interest include collaborative robotics; robotic learning and control; robotic dexterity and mobility; robotic perception and sensing; and verification and validation.[11] The establishment of this Institute lends credibility to the inclusion of subcategory 1.b within the state-of-the-art manufacturing framework.

c. Clean Energy Smart Manufacturing Innovation Institute (CESMII)

CESMII emphasizes smart manufacturing, which Manufacturing.gov defines as manufacturing that "aims to reduce manufacturing costs from the perspective of real-time energy management, energy productivity, and process energy efficiency. [Smart manufacturing] initiatives will create a networked data driven process platform that combines innovative modeling and simulation and advanced sensing and control. [Smart

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10 U.S. Department of Defense (DOD), "DoD Announces Award of New Advanced Robotics Manufacturing (ARM) Innovation Hub in Pittsburgh, Pennsylvania," (2017).

11 Advanced Robotics Manufacturing Institute (ARM), "Ecosystem for Techo-Economic Impact," http://www.arminstitute.org/#text-16.

manufacturing] integrates efficiency intelligence in real-time across an entire production operation with primary emphasis on minimizing energy and material use [and is] particularly relevant for energy-intensive manufacturing sectors."[12] Because smart manufacturing focuses on networking various forms of IT in the design and manufacturing processes (subcategory 1.a), it, too, is a prime example of process-centered manufacturing as of the first quarter of the 21st century.

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. For example, the composition of a light element alloy can be formulated to obtain a material with an optimized density-to-strength ratio. Phase transformations of materials can provide novel properties such as those exhibited by shape-memory alloys or piezoelectric ceramics. 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. Functionalizing—modifying the surface chemistry—of nanomaterials can result in novel properties that enable, for example, cancer cell targeting and 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. This white paper places special emphasis on nanoscale materials because of their continuing relevance to the marketplace.

Several of the Manufacturing USA Network Institutes are illustrative of the materials-centered state-of-the-art manufacturing framework described above. Three of the Institutes, described in the following subsections, are good examples of current materials-centered state-of-the-art manufacturing. These Institutes were selected because their primary purpose is to support the development and application of materials and products that fall under the purview of category 2 of the state-of-the-art manufacturing framework. Although the work associated with these Institutes may incorporate elements of process-centered state-of-the-art manufacturing, only those aspects related to category 2 of the framework are detailed in the examples below.

a. Lightweight Innovations for Tomorrow (LIFT)

The vision of LIFT is to establish the United States as a world leader in lightweighting innovation by accelerating the development and application of innovative lightweight metal production and manufacturing technologies to the benefit of the U.S. transportation,

[12] Advanced Manufacturing National Program Office (AMNPO), "Glossary of Advanced Manufacturing Terms".

aerospace, and defense markets. The mission of LIFT is to speed the development of new lightweight metal manufacturing processes for products using lightweight metals, including aluminum, magnesium, titanium, and advanced high-strength steel alloys.[13] LIFT projects support two of the three materials-centered subcategories in the state-of-the-art manufacturing framework. Wrought metal alloys are manufactured (subcategory 2.a) in the form of sheets, and products, such as automotive body parts, are subsequently manufactured by stamping the metal sheets into desired shapes (category 2.b). For lightweight alloys containing magnesium, products are manufactured by casting the alloys directly into final form (category 2.b). High-strength steel parts for transportation applications are manufactured using additive processes that are capable of creating complex shapes (category 2.b).

b. Advanced Functional Fabrics of America (AFFOA)

The mission of AFFOA is to enable a manufacturing-based revolution by transforming traditional fibers, yarns, and fabrics into highly sophisticated, integrated, and networked devices and systems.[14] AFFOA is poised to deliver revolutionary advances across the entire fabric supply chain, from multifunctional fibers to advanced nonwovens and yarn production to sophisticated weaving and knitting capabilities and end-product fabrication for first-to-market manufacturing opportunities.[15] According to a press release from the Institute: "Recent breakthroughs in fiber materials and manufacturing processes will soon allow us to design and produce fabrics that see, hear, sense, communicate, store and convert energy, regulate temperature, monitor health and change color—the dawn of a 'fabric revolution.'"[16] Planned AFFOA capabilities and projects will encompass all three of the materials-centered state-of-the-art manufacturing subcategories. Innovations in fabric science will create fibers and yarns with novel properties such as exceptional strength, flame resistance, reduced weight and electrical conductivity[17] (category 2.a). Many materials and complex functional structures will be integrated into a fabric's very fibers (category 2.a); manufacturing processes and technologies will be developed to integrate such fibers with integrated circuits, LEDs, solar cells, and other capabilities (categories 2.b and 2.c). Such materials and products will enable revolutionary defense and

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[13] Lightweight Innovations for Tomorrow (LIFT), "Lightweight Innovations for Tomorrow," https://lift.technology/.

[14] Advanced Functional Fabrics of America (AFFOA), "Advanced Functional Fabrics of America," (2017).

[15] Massachusetts Institute of Technology (MIT), "Advanced Functional Fabrics of America."

[16] U.S. Department of Defense (DOD), "DoD Announces Award of New Revolutionary Fibers and Textiles Manufacturing Innovation Hub Lead in Cambridge, Massachusetts," https://www.defense.gov/News/News-Releases/News-Release-View/Article/710462/dod-announces-award-of-new-revolutionary-fibers-and-textiles-manufacturing-inno.

[17] Ibid.

commercial applications, such as shelters with power generation and storage capacity built into the fabric, ultra-efficient energy-saving filters for vehicles, and uniforms that can regulate temperature and detect threats like chemical and radioactive elements in order to warn warfighters and first responders.[18]

c. Flexible Hybrid Electronics Institute (NextFlex)

This Institute is focused on building an entirely new ecosystem for flexible hybrid electronics, giving everyday products the power of silicon integrated circuits by combining them with new and unique printing processes and new materials to manufacture lightweight, low-cost, flexible, comfortable, stretchable, and highly efficient smart products.[19] Novel commercial and defense products envisioned to be manufactured by NextFlex include wearable health monitoring systems for lifestyle and fitness; medical health monitoring systems to improve the way health care is managed; soft robotics for the elderly or wounded soldiers; sensor monitoring systems for structures, aircraft, and vehicles; and lightweight rugged sensors for harsh environments. All three of the materials-centered state-of-the-art manufacturing subcategories will be represented in NextFlex capabilities and technologies.[20] Materials with novel elasticity properties will need to be manufactured for flexible substrates (category 2.a). A variety of components—substrates, thinned silicon logic and computation devices, interconnects manufactured from nanoparticle-containing inks, gallium phosphate-based communications devices, and batteries—will need to be used, integrated, and combined (categories 2.b and 2.c) for flexible hybrid electronics applications.

3. Crosscutting State-of-the-Art Manufacturing

The state-of-the-art manufacturing categories and subcategories are not conceptualized as mutually exclusive groupings, and it is possible that some advanced manufacturing efforts will encompass more than one subcategory. Notable among these is additive manufacturing. As defined by Manufacturing.gov, which derives its definition from the CIRP *Encyclopedia of Production Engineering*, *additive manufacturing* is "the construction of complex three-dimensional parts from 3D digital model data by depositing successive layers of material."[21] It is also frequently referred to as three-dimensional (3D) printing.

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[18] Massachusetts Institute of Technology (MIT), "Advanced Functional Fabrics of America."

[19] NextFlex, "About Us," http://www.nextflex.us/about-us/.

[20] U.S. Department of Defense (DOD) Manufacturing Technology Program, "Nextflex, the Flexible Hybrid Electronics Manufacturing Innovation Institute," https://www.dodmantech.com/Institutes/NextFlex.

[21] Advanced Manufacturing National Program Office (AMNPO), "Glossary of Advanced Manufacturing Terms".

Additive manufacturing includes elements that span several of the state-of-the-art manufacturing framework subcategories. For example, additive manufacturing frequently incorporates computer-aided design (CAD),[22] a form of data-integration that falls under subcategory 1.a. The 3D printing process itself generally utilizes elements of subcategory 1.b, including novel material processing hardware, robotics, sensors, and other automating technologies. Finally, additive manufacturing often involves the use of materials with novel or optimized properties (subcategory 2.b), particularly those with features at the submicron or nanoscale.

Within the Manufacturing USA network, additive manufacturing is promoted by America Makes, the flagship Institute for Manufacturing USA. The mission of America Makes is "to accelerate the adoption of additive manufacturing technologies in the U.S. manufacturing sector and to increase domestic manufacturing competitiveness"[23] through a number of goals related to additive manufacturing. Within its technology roadmap, America Makes identifies five technical focus areas: design, material, process, value chain, and the additive manufacturing genome.[24] The design, process, and value chain areas each relate to process-centered state-of-the-art manufacturing, focusing on technological advancements in design methods and tools, technological advancements in additive manufacturing machines, and technological advancements that "enable step change improvements in end-to-end value chain cost and time to market for additive manufacturing produced products,"[25] respectively. The materials and additive manufacturing genome focus areas relate to materials-centered state-of-the-art manufacturing by "building the body of knowledge for benchmark additive manufacturing property characterization data and eliminating variability in 'as-built' material properties"[26] and by "accelerating technological advancements that enable step change improvements in the time and cost required to design, develop, and qualify new materials for additive manufacturing,"[27] respectively.

[22] Manufacturing.gov relies on *CIRP Encyclopedia of Production Engineering*'s definition of CAD: "the use of a wide range of computer-based tools that assist engineers, architects, and other design professionals in their design activities. It is the main geometry authoring tool within the Product Lifecycle Management process and involves both software and sometimes special-purpose hardware." L. Laperriere and G. Reinhart, eds., *CIRP Encyclopedia of Production Engineering* (Paris, France: CIRP, 2014); Advanced Manufacturing National Program Office (AMNPO), "Glossary of Advanced Manufacturing Terms".

[23] America Makes, "Mission Statement," https://www.americamakes.us/mission-statement.

[24] America Makes, "Technology Roadmap," https://www.americamakes.us/projects/techroadmap.

[25] Ibid.

[26] Ibid.

[27] Ibid.

C. Recognizing State-of-the-Art Manufacturing

The complexity of advanced manufacturing makes identification of new advanced manufacturing activities challenging. One aspect of this complexity is the wide array of terminology used to refer to advanced manufacturing or related concepts. In describing the difficulties in assigning a single definition to the term, *The Handbook of Manufacturing Industries in the World Economy* points out that "a number of terms have been used not as synonyms but in some fashion interchangeably by researchers, policy-makers and commentators over the past 10 to 20 years."[28] For example, the terms *advanced manufacturing* and *next-generation manufacturing* have both been used to capture activities related to what is referred to as *state-of-the-art manufacturing* for the purposes of this white paper.

Similarly, a range of terminology is used to refer to subsets of activities related to the concept of state-of-the-art manufacturing. To determine the relationship between different aspects of advanced manufacturing, such as smart and digital manufacturing, and the state-of-the-art manufacturing definition, the STPI team researched these definitions to determine if they were inherent in, tangential to, or distinct from the state-of-the-art manufacturing categories (Table 1). From this exercise, the STPI team was able to determine that the activities described by these terms are captured within the state-of-the-art manufacturing framework. In addition, most describe activities related to the use of new applications of information technology (IT) or new tools (modeling, computation, and simulation) for data integration (subcategory 1.a). The activities described by these terms differ primarily in their desired outcome. For example, smart manufacturing focuses on the use of data integration for energy management, productivity, and efficiency, while digital manufacturing emphasizes using similar tools for time and cost efficiency more generally. Because the state-of-the-art manufacturing framework is an identification tool, it does not need to distinguish between nuances in desired outcomes. Rather it captures the general goal (data organization and integration) and focuses instead on how that goal is achieved (through new uses of IT and data integration tools such as modeling, computation, and simulation), which is a more relevant metric for identification purposes.

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[28] J. R. Bryson, J. Clark, and V. Vanchan, *Handbook of Manufacturing Industries in the World Economy* (Cheltenham, UK: Edward Elgar Publishing, 2015).

Table 1. Terms Relevant to State-of-the-Art Manufacturing

Manufacturing Terms	Definition	Relationship to state-of-the-art manufacturing
Additive manufacturing 3D printing Layered manufacturing Solid freeform manufacturing Direct digital manufacturing Rapid prototyping	Manufacturing.gov relies on the CIRP *Encyclopedia of Production Engineering*'s definition of *additive manufacturing*, which indicates that additive manufacturing is "the construction of complex three-dimensional parts from 3D digital model data by depositing successive layers of material."[1, 2] Additive manufacturing may also be referred to as *3D printing*, *layered manufacturing*, *solid freeform manufacturing*, *direct digital manufacturing*, and *rapid prototyping*.[1, 2]	1a,1b, 2b
Agile manufacturing	Manufacturing.gov adopts concepts from Gunasekaran and Suri to conclude that *agile manufacturing* includes "tools, techniques, and initiatives (such as lean and flexible manufacturing) to help a plant and/or organization rapidly respond to their customers, the market, and innovations. It can also incorporate 'mass customization' concepts to meet unique customer needs as well as 'quick response manufacturing' to reduce lead times across an enterprise."[1, 3, 4]	May be achieved using tools for data integration (1a)
Cybermanufacturing Computer-aided manufacturing Computer-assisted manufacturing	*Cybermanufacturing* can be defined as a "transformative concept that involves the translation of data from interconnected systems into predictive and prescriptive operations to achieve resilient performance. It intertwines industrial big data and smart analytics to discover and comprehend invisible issues for decision making."[5] Similar concepts are captured by the terms *computer-aided manufacturing*, *computer-assisted manufacturing*, and *computer-integrated manufacturing*.[1]	1a
Digital manufacturing	Manufacturing.gov defines *digital manufacturing* as manufacturing that "focuses on reducing the time and cost of manufacturing by integrating and using data from design, production, and product use; [on] digitizing manufacturing operations to improve product, process, and enterprise performance; [and on applying] tools for modeling and advanced analytics, throughout the product life cycle."[1]	1a
Flexible manufacturing	Relying on the definition found in the CIRP *Encyclopedia of Production Engineering*, Manufacturing.gov indicates that *flexible manufacturing* can refer to "an integrated group of manufacturing equipment and/or cross-trained work teams that can produce a variety of parts in the mid-volume production range. Flexible refers to the system's capability to manufacture different part variants [and the fact that] production quantity can be adjusted in response to changing demand."[1, 2]	May be achieved using tools for data integration (1a)

Lean manufacturing Just-in-Time Six Sigma Total quality management Kaizen	Manufacturing.gov defines *lean manufacturing* as "a manufacturing practice that aims to reduce wasted time, effort or other resources in the production process." Related concepts include *Just-in-Time*, *Six Sigma*, *Kanban*, *total quality management*, and *kaizen*.[1]	May be achieved using tools for data integration (1a) or robotics/ automated processes (1b)
Nanomanufacturing	The National Nanotechnology Initiative defines *nanomanufacturing* as "manufacturing at the nanoscale…nanomanufacturing involves scaled-up, reliable, and cost-effective manufacturing of nanoscale materials, structures, devices, and systems. It also includes research, development, and integration of top-down processes and increasingly complex bottom-up or self-assembly processes."[6]	2a, 2b
Smart manufacturing Industry 4.0	Manufacturing.gov defines *smart manufacturing* as manufacturing that "aims to reduce manufacturing costs from the perspective of real-time energy management, energy productivity, and process energy efficiency. [Smart manufacturing] initiatives will create a networked data driven process platform that combines innovative modeling and simulation and advanced sensing and control. [Smart manufacturing] integrates efficiency intelligence in real-time across an entire production operation with primary emphasis on minimizing energy and material use [and is] particularly relevant for energy-intensive manufacturing sectors."[1] *Industry 4.0* is a term commonly used in Europe to refer to similar concepts.	1a

[1] Advanced Manufacturing National Program Office (AMNPO), "Glossary of Advanced Manufacturing Terms."

[2] L. Laperriere and G. Reinhart, eds., *CIRP Encyclopedia of Production Engineering* (Paris, France: CIRP, 2014).

[3] A. Gunasekaran, *Agile Manufacturing: The 21st Century Competitive Strategy* (Oxford, UK: Elsevier Science Ltd, 2001).

[4] R. Suri, *It's About Time: The Competitive Advantage of Quick Response Manufacturing* (New York, NY: CRC Press, 2010).

[5] J. Lee, B. Bagheri, and J. Chao, "Introduction to Cyber Manufacturing," *Manufacturing Letters* 8(2016).

[6] National Nanotechnology Initiative, "Manufacturing at the Nanoscale," https://www.nano.gov/nanotech-101/what/manufacturing.

Because the complexity of the state-of-the-art manufacturing concept makes its identification challenging, the STPI team established cases in which process and materials could be classified as *state of the art* (SOTA) or *standard*. For these cases, a manufacturing element is understood to be either a manufacturing process or approach, or a material used within a manufacturing effort. There are four possible combinations of state-of-the-art and non-state-of-the-art manufacturing elements, three of which fall under the purview of state-of-the-art manufacturing (Table 2).

Table 2. Four Cases for Manufacturing Process and Materials

Description of Manufacturing Elements	Process/Material Status	Manufacturing Classification	Example
Manufacturing effort uses a **state-of-the-art process or approach** to produce or incorporate a **state-of-the-art material or material combination**	SOTA/SOTA	SOTA Manufacturing	3D printing of nanotechnology-enabled composites using carbon nanotubes
Manufacturing effort uses a **state-of-the-art process or approach** but **does not produce or incorporate a state-of-the-art material or material combination**	SOTA/Standard	SOTA Manufacturing	3D printing of manufacturing tools from nylon
Manufacturing effort uses a **non-state-of-the-art process or approach** to produce or incorporate a **state-of-the-art material or material combination**	Standard/SOTA	SOTA Manufacturing	Casting of automotive parts from lightweight alloys
Manufacturing effort uses a **non-state-of-the-art process or approach** and **does not produce or incorporate a state-of-the-art material or material combination**	Standard/Standard	Standard Manufacturing	Drawing fiber optic cables from glass

The STPI team acknowledges that the identification of state-of-the-art manufacturing, or the determination that a manufacturing process or product cycles into, *or out of*, state-of-the-art manufacturing status, is a judgement call informed by standard manufacturing practice in a given industrial sector as well as knowledge of the specific manufacturing materials, processes, and products.

3. Assessing the Implications of State-of-the-Art Manufacturing for Occupational and Environmental Safety and Health

Standard occupational and environmental safety and health (OESH) paradigms manage risk primarily through measures that control the magnitude of exposure to workplace hazards. To understand how OESH might differ for state-of-the-art manufacturing, STPI (1) examined relevant documents, interviewed subject matter experts, (2) developed a tool to assist NIOSH staff in identifying state-of-the-art manufacturing settings and OESH risks in those settings, and (3) explored the OESH risks and benefits associated with several state-of-the-art manufacturing technologies and materials, that is, modeling and simulation; automation, robotics, and sensors; and production or use of materials with novel or optimized properties.

A. Assessment Tool

STPI first reviewed three well-established approaches to standard occupational risk management: the NIOSH Prevention through Design[29] program, the Good Nano Guide's Occupational Health and Safety Reference Guide,[30] and the American National Standards Institute (ASTI)'s Z10-2012 Occupational Health and Safety Management Systems Standard;[31] and then consulted a Schulte et al. paper on risk management of engineered nanomaterials[32] to establish a generalized manufacturing process that is applicable to both process-centered and materials-centered state-of-the-art manufacturing). STPI then linked an OESH risk-assessment approach to the manufacturing process to create a flow chart (Figure 1) that could serve as an organizing tool to assist NIOSH in determining (1) if a manufacturing process aligns with the definition of state-of-the-art manufacturing, and (2) the location and type of potential exposures (standard vs new) in the manufacturing setting.

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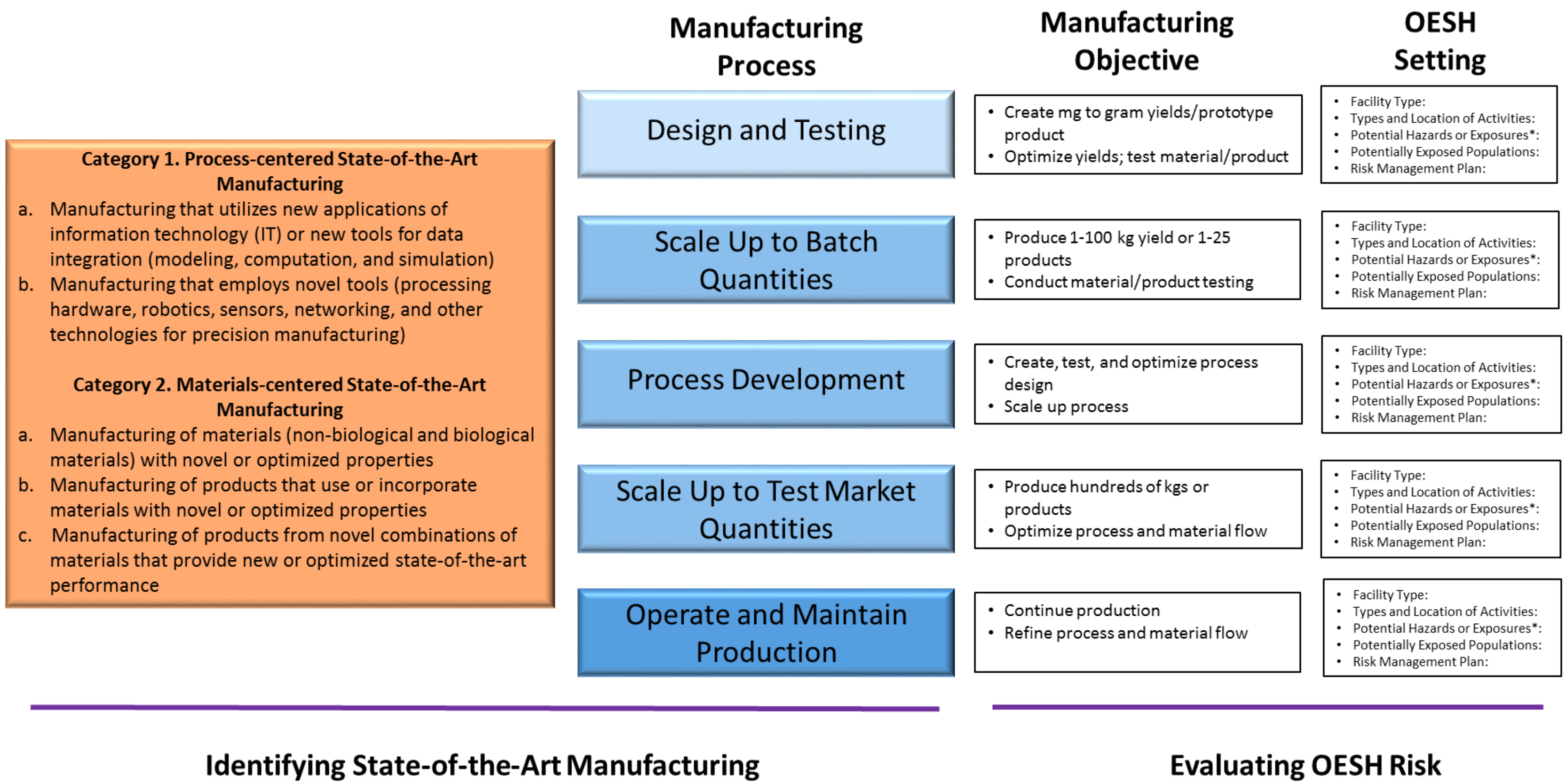
29 P. A. Schulte, R. Rinehart, A. Okun, C. L. Geraci, and D. S. Heidel, "National Prevention through Design (PtD) Initiative," *Journal of Safety Research* 39(2008).

30 Good Nano Guide, "OHS Reference Manual," https://nanohub.org/groups/gng/ohs_reference_manual.

31 American National Standards Institute (ANSI), "Z10-2012 Occupational Health and Safety Management Systems Standard," (2012).

32 P. Schulte, C. Geraci, R. Zumwalde, M. Hoover, and E. Kuempel, "Occupational Risk Management of Engineered Nanoparticles," *Journal of Occupational and Environmental Hygiene* 5(2008).



Source. Content under the Manufacturing Process and Manufacturing Objective headings was adapted from P. Schulte, C. Geraci, R. Zumwalde, M. Hoover, and E. Kuempel, "Occupational Risk Management of Engineered Nanoparticles," *Journal of Occupational and Environmental Hygiene* 5(2008), Figure 2, which is reproduced in Appendix E of this white paper. Content under the Setting heading was adapted from Good Nano Guide, "OHS Reference Manual."

* Physical, chemical, biological, radiological, ergonomic, and psychosocial hazards or exposures.

Figure 1. Tool for Identifying State-of-the-Art Manufacturing and Evaluating Related Risk

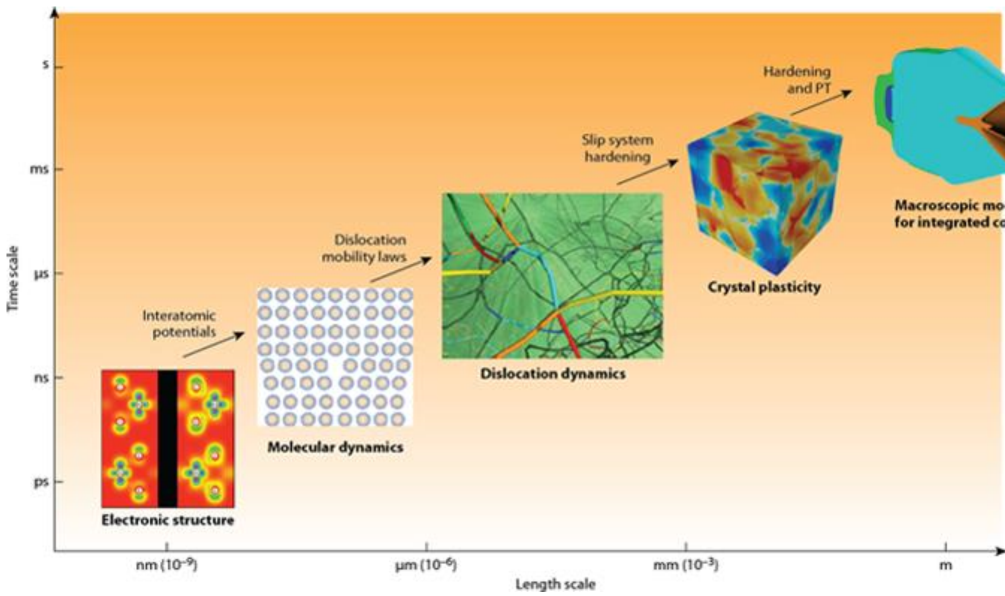
The STPI team recognized that many state-of-the-art manufacturing technologies—such as CAD, modeling and simulation, and automation—will provide an opportunity to control the magnitude and type of hazard, as well as the number of people exposed. Therefore, the team added location of the manufacturing activity to its OESH risk assessment component in Figure 1 to reflect the potential for distributed manufacturing practices and added hazard as *potential hazards and exposures* to capture the possibility of controlling the magnitude and types of hazards in a workplace. It should be noted that these changes reflect lessons learned and best practices developed for nanomaterials and nanomanufacturing and provide a basis for risk assessment in state-of-the-art manufacturing work sites.

B. OESH Implications

The STPI team asked the twelve interviewees to consider how the characteristics, processes, and materials that they identified as part of the state-of-the-art manufacturing landscape might affect workforce safety, change worker exposures and potential health impacts, or alter the traditional OESH approaches. The list of interviewees and the interview protocol is included in Appendix B. The STPI team reviewed the responses, identified common themes, and, where necessary, supplemented the interview information with pertinent information from published literature. Using these sources and subject matter expertise, the team then examined the potential OESH ramifications of three major technologies impacting state-of-the-art manufacturing—modeling and simulation; automation, robotics, and sensors; and production or use of materials with novel or optimized properties. Interviewees also provided several high-level considerations for a state-of-the-art manufacturing workplace, and those are provided in section C of this chapter.

1. Modeling and Simulation (Category 1.a)

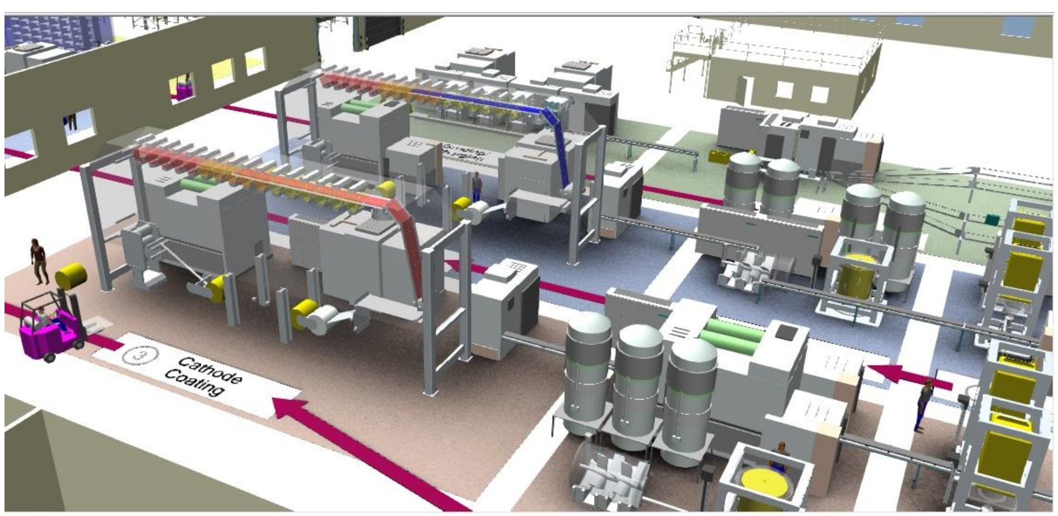
Modeling and simulation are used across the state-of-the-art manufacturing process, in the manufacture of materials with novel or optimized properties and in the manufacture of products that use, incorporate, or combine materials with novel or optimized properties. Modeling and simulation of *materials and products* entail the use of advanced computing technologies for engineering, testing, or design purposes (Figure 2). 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. Some of the potential benefits are safer products, improved product quality, shorter time to market, and reduced manufacturing costs.



Source. Lawrence Livermore National Laboratory, “Modeling and Simulation,” https://manufacturing.llnl.gov/modeling-and-simulation.

Figure 2. Modeling and Simulation of Materials and Products for State-of-the-Art Manufacturing

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 (Figure 3).



Source. http://community.plm.automation.siemens.com/legacyfs/online/wordpress/images/2014/10/Tecnomatix-Plant-Simulation.png.

Figure 3. Modeling and Simulation of a State-of-the-Art Manufacturing Process

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. For example, when virtually designing a material with novel or optimized properties, it may be possible to draw conclusions about the potential hazard of the material by comparing it structurally or chemically to a material with known hazards; however, the utility of modeling and simulation in the materials design process is limited by a reliance on inference: if the proposed material cannot be related to a known material, it may not be possible to draw conclusions about its hazard or exposure potential.

Modeling and simulation could also 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. Elimination and substitution are near the top of the Prevention through Design hierarchy of controls,[33] but if not feasible or practical, other Prevention through Design controls, such as engineering or administrative controls, may be applied.

Additional benefits of modeling and simulation include the development of generalizable models of state-of-the-art manufacturing that could streamline identification of potential workplace hazards and exposures within proposed manufacturing processes before, rather than after, their implementation. Although not an example specifically focused on state-of-the-art manufacturing, the Reusable Abstractions of Manufacturing Processes (RAMP) Challenge sponsored by the National Institute of Standards and Technology (NIST), in partnership with the National Science Foundation, ASTM International, and the American Society of Mechanical Engineers, funds research to create generalized models of manufacturing processes for potential application in a variety of industries.[34]

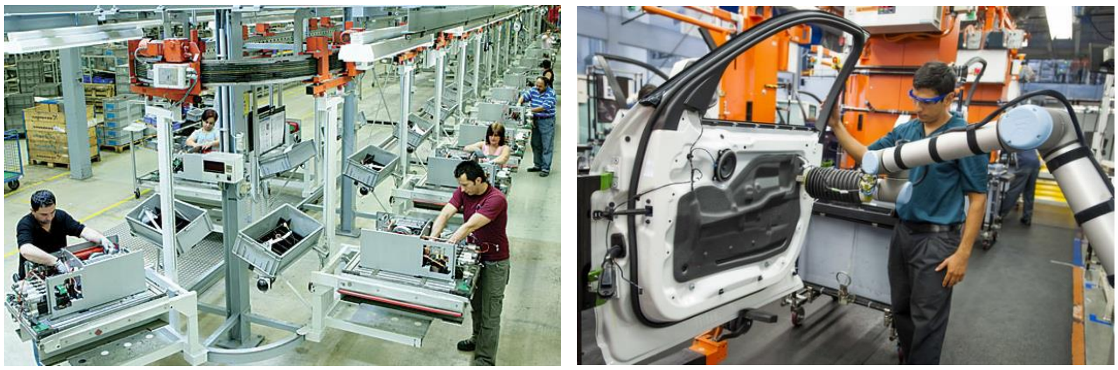
2. Automation, Robotics, and Sensors (Category 1.b)

Automation and robotics are valued in manufacturing processes because of their precision, speed, and reliability, as well as their ability to complete tasks that may be ill-suited for human workers because they are too dangerous or require physical abilities beyond those of humans. In modern manufacturing environments, robots and automated machines may operate in isolated settings, separated from human workers, or in the vicinity of those workers. In other situations, human workers may be expected to work

[33] J. Peterson, "Principles of Controlling the Industrial Environment," in *The Industrial Enviornment—Its Evaluation and Control* (Washington, D.C.: NIOSH. https://www.cdc.gov/niosh/pdfs/74-177-t.pdf, 1973).

[34] National Institute of Standards and Technology (NIST), "Reuseable Abstractions of Manufacturing Processes Challenge," http://www.internano.org/node/4591?utm_source=newsletter&utm_medium=email&utm_campaign=nmw20170310.

collaboratively with robots (Figure 4). While both robots and automated machines are generally considered machines that are "programmable by computer algorithms to perform simple and complex tasks," robots can be distinguished from automated machines based on their ability to "modify tasks in response to changes in the […] external environment."[35]



Sources. Left image: http://www.assemblymag.com/ext/resources/Issues/March2012/asb0312layout11.jpg
Right image: http://zdnet3.cbsistatic.com/hub/i/2015/07/07/042d1f56-9a34-4e95-965e-e9d43589ae2d/6c01c26102b200696e433e82a24a328a/upload3480.jpg.

Figure 4. Automated Workplace (left panel) and Collaborative Workspace Robot (right panel)

Increased use of automation and robotics within manufacturing processes offers one potential benefit: the number of human workers on production floors will decrease, thereby reducing the total number of workers exposed to potential hazards; however, risk of injury may be increased for individuals working nearby automated processes and robots. This risk may be especially great for individuals that work collaboratively with robots, particularly those who work within the robot's spatial envelop.[36] In their paper on robots in the workplace, Murashov et al. summarize statements made by the International Organization for Standardization in its Safety Requirements for Industrial Robots, indicating that robots generally lack awareness of their surroundings and may expose nearby workers to mechanical, electrical, thermal, or noise-related hazards. Other potential hazards include vibrations, radiation, and chemical hazards.[37] In 1984, NIOSH provided formal risk management recommendations that address the design of robotic systems and best practices for training and supervision for workers that work with or around robots; however, these guidelines may not fully address the complexity of today's more

[35] V. Murashov, F. Hearl, and J. Howard, "Working Safely with Robot Workers: Recommendations for the New Workplace," *Journal of Occupational and Environmental Hygiene* 13, 3 (2016).

[36] Ibid.

[37] Ibid.

sophisticated robotic systems.[38] The review by Murashov et al., all NIOSH authors, can serve as the basis to update NIOSH robotics recommendations.[39]

In addition to the physical safety hazards, increased use of robotics and automation within manufacturing processes will necessitate workforce reorganization, restructuring, and downsizing, factors that could have negative psychosocial consequences for workers. Displacement of workers by automated processes and robots could cause job insecurity and create isolated work environments for the remaining workers. In addition, increased use of automation and robotics is expected to result in flexible, possibly unpredictable, production flow; decentralized task management and an associated loss of control for many workers; limited opportunities for interesting job content and advancement; and task-shifting, which may include deskilling or necessitate upskilling[40] and frequent retraining. Automation also provides opportunity to increase worker performance monitoring and intensifies demands on workers to operate efficiently, handle complex decision-making, perform multiple types of tasks, or step in if equipment malfunctions.[41] All of these changes have been associated with negative workplace impacts,[42] and many are listed as job conditions that may lead to worker stress in NIOSH's report "Stress at Work."[43] In its 2002 report, *The Changing Organization of Work and the Safety and Health of Working People*, NIOSH emphasized the need for more research to understanding how changes in workforce organization might influence worker health."[44] Although not explicitly related to advanced manufacturing or automation and robotics, many of the concerns outlined in the report are relevant to implementation of these manufacturing technologies.

Complex equipment, automated processing, and robotics may also shift the location of a hazard or an exposure in a manufacturing process, thus changing the population of workers at risk. For example, in a semi-conductor fabrication facility, line workers are generally protected from exposure to materials because the process is automated or specific engineering controls have been developed. This situation could shift the potential for

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38 National Institute for Occupational Safety and Health (NIOSH), "Preventing the Injury of Workers by Robots," https://www.cdc.gov/niosh/docs/85-103/.

39 Murashov, Hearl, and Howard, "Working Safely with Robot Workers: Recommendations for the New Workplace."

40 Deskilling refers to the reduction of skills among workers as a consequence of technological development, while upskilling refers to acquisition of new skills by workers in an environment of technological change.

41 M. J. Smith and P. Carayon, "New Technology, Automation, and Work Organization: Stress Problems and Improved Technology Implementation Strategies," *The International Journal of Human Factors in Manufacturing,* 5, 1 (1995).

42 Ibid.

43 National Institute for Occupational Safety and Health (NIOSH), "Stress at Work," (1999).

44 National Institute for Occupational Safety and Health (NIOSH), "The Changing Organization of Work and the Safety and Health of Working People," (2002).

hazardous exposures to equipment maintenance workers who are not protected by these controls or for whom the engineering controls are disabled during cleaning and upkeep. This risk may be compounded for maintenance workers who are employed through a nonstandard work arrangement, such as contract work. In this case, it may be unclear which party, the manufacturer or the contracting agency, is responsible for worker safety and ensuring compliance with safety laws and practices. This gap may leave contract maintenance workers under-protected.[45]

Some of the technologies produced by or for state-of-the-art manufacturing will have *applications* in addition to *implications*. Notable among these is sensor technology. Advanced sensors are being developed for use within manufacturing processes and may be produced using state-of-the-art manufacturing methods. Sensors can be integrated into the manufacturing environment and provide valuable information on the state of the manufacturing environment by monitoring potential hazards (e.g., electrochemical or noise hazards), including early detection of dangerous exposure levels. In the case of wearable technology, sensors can be used to monitor physiological and biomechanical status to detect anomalies or track personal exposures to hazardous environmental conditions. NIOSH facilitates the development and use of sensors through its Center for Direct Reading and Sensor Technologies.[46]

3. Production or Use of Materials with Novel or Optimized Properties (Category 2)

Materials (nonbiological and biological materials) with novel or optimized properties, and the manufacture of products that incorporate such materials, may have an inherently greater risk than the manufacturing processes that produce or incorporate them into products. Engineered nanomaterials are especially relevant to state-of-the-art manufacturing, and NIOSH and others have produced seminal guidance documents to manage risk in nanomanufacturing. These documents include "Perspectives on the Design of Safer Nanomaterials and Manufacturing Processes,"[47] "Occupational Risk Management of Engineered Nanoparticles,"[48] and resources to encourage best risk-management practices, such as the Good Nano Guide[49] and NIOSH's reports on the subject, including "Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small

[45] J. Howard, "Nonstandard Work Arrangements and Worker Health and Safety," *American Journal of Industrial Medicine* (2016).

[46] National Institute for Occupational Safety and Health (NIOSH), "Direct Reading and Sensor Technolgies," https://www.cdc.gov/niosh/topics/drst/.

[47] C. Geraci, D. Heidel, C. Sayes, L. Hodson, P. Schulte, A. Eastlake, and S. Brenner, "Perspectives on the Design of Safer Nanomaterials and Manufacturing Processes," *Journal of Nanoparticle Research* 17(2015).

[48] Schulte, Geraci, Zumwalde, Hoover, and Kuempel, "Occupational Risk Management of Engineered Nanoparticles."

[49] Good Nano Guide, "OHS Reference Manual".

to Medium-Sized Enterprises"[50] and "Approaches to Safe Nanotechnology, Managing the Health and Safety Concerns Associated with Engineered Nanomaterials,"[51] among others.

Nanomanufacturing guidance documents can serve as a model for the handling of synthesized, often nanoscale, biological materials. Synthetic biology is an emerging field, and biologics are being developed for use across several industries. In addition to nanomedical products, agricultural biotechnology, computer technology, and information storage are formulating standard and novel RNA and DNA molecules to incorporate into devices and processes. Biological processes are also being altered to serve as production systems for both biological and nonbiological materials. While best practices for handling these materials and working with related processes, such as gene editing, have been well-defined for the laboratory setting, less guidance exists for the safe use of these materials as they scale-up for use within the larger bioeconomy.[52]

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, contributes to a heightened perception of risk. Some experts have advocated for alternative solutions to synthetic biology, which minimizes risk in a cost-effective manner;[53] 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 risk management include increased health surveillance of workers exposed to synthetic biologics; proactive risk assessment and management; the application of Prevention through Design principles; improved risk assessment and management guidance related to synthetic biology; development of post-exposure prevention procedures for synthetic biologics; and encouragement of greater awareness of and involvement in synthetic biology risk assessment and management within the community.[54] 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

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50 National Institute for Occupational Safety and Health (NIOSH), "Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises," (2016).

51 National Institute for Occupational Safety and Health (NIOSH), "Approaches to Safe Nanotechnology," (2009).

52 J. Howard, V. Murashov, and P. Schulte, "Synthetic Biology and Occupational Risk," *Journal of Occupational and Environmental Hygiene* 14, 3 (2016).

53 A. M. Finkel, "Channeling Synthetic Biology through 'Solution-Focused Risk Assessment'," (2014). ''

54 Howard, Murashov, and Schulte, "Synthetic Biology and Occupational Risk."

correct risk-management questions; exploring new ways to integrate risk assessment and management; and encouraging creative solutions.[55]

C. Other Considerations

From its analysis, the STPI team catalogued several overarching or longer term factors that are relevant to state-of-the-art manufacturing.

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 to 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 as well as manage issues and the role of NIOSH 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 maintenance of 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. The semi-conductor fabrication facilities are examples of this condition.

Complexity of state-of-the-art manufacturing management. With increased use of materials with novel or optimized properties, especially nanoscale materials, and incorporation of automated processes into product production, an increasing number of persons and types of expertise and equipment are critical to a safety decision. 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

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[55] A. D. Maynard, *Innovative Approaches to Emergent Risk* (Ann Arbor, Michigan: University of Michigan School of Public Health, 2014).

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.

Trust of government. Industries continue to express concerns about government involvement in partnerships that involve intellectual property and compliance with Federal regulations. As NIOSH continues to develop state-of-the-art manufacturing industry partnerships and its research mission, personal relationships will be needed to build the trust necessary for industry to partner fully with government and disclose its materials, products, and processes.

4. Summary and Conclusions

Identification of occupational hazards is particularly challenging in industrial sectors that use novel, cutting-edge materials, technologies, and processes, and are prone to fast and frequent changes in manufacturing methods. At the request of NIOSH, the STPI team developed a strategic approach to identifying occupational hazards—physical, chemical, biological, radiological, ergonomic, and psychosocial hazards—in advanced manufacturing settings that display these manufacturing characteristics. The team (1) conducted interviews with subject matter experts and performed internet research and literature reviews to construct a NIOSH-centric working definition of advanced manufacturing; (2) evaluated the utility of that definition against initiatives set forth in Manufacturing USA Institutes; and (3) provided guidance on use of the definition to recognize advanced manufacturing workplaces and changes in OESH practice.

To align STPI's working definition of advanced manufacturing with NIOSH needs, the team focused on the concept of *state of the art* and its place within the advanced manufacturing construct. The STPI team 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 the time. State-of-the-art manufacturing can be related to advanced manufacturing as manufacturing which (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.

The STPI team operationalized this definition of state-of-the-art manufacturing by creating the following framework:

1. Process-centered state-of-the-art manufacturing
    d. Manufacturing that utilizes new applications of information technology (IT) or new tools for data integration (modeling, computation, and simulation)
    e. Manufacturing that employs novel tools (processing hardware, automating technology, robotics, sensors, networking, and other technologies for precision manufacturing)
2. Materials-centered state-of-the-art manufacturing
    f. Manufacturing of materials (nonbiological and biological materials) with novel or optimized properties

g. Manufacturing of products that use or incorporate materials with novel or optimized properties

h. Manufacturing of products from novel combinations of materials that provide new or optimized state-of-the-art performance

The team verified the utility and relevance of this definitional framework using activities and research occurring within the Manufacturing USA innovation institutes and found examples for all five state-of-the-art subcategories.

The STPI team then developed a tool and guidance for NIOSH to determine if the definition of advanced manufacturing applies to a manufacturing setting, that is, if a manufacturing effort uses a state-of-the-art process or approach, or it produces or incorporates a state-of-the-art material or material combination, or both. While this approach simplifies classification of manufacturing as state-of-the-art, the team also acknowledges that the identification of state-of-the-art manufacturing, or the determination that a manufacturing process or product cycles into, *or out of*, state-of-the-art manufacturing status, is a judgement call informed by standard manufacturing practice in a given industrial sector, as well as knowledge of the specific manufacturing materials, processes, and products.

The STPI team outlined OESH implications related to three technology areas integral to many state-of-the-art manufacturing settings—modeling and simulation; automation, robotics, and sensors; and production or use of materials with novel or optimized properties—and general OESH considerations related to them. STPI noted benefits, such as reduced magnitude of exposure, fewer exposed workers, or design of less hazardous materials, as well as novel risks associated with injury from colliding with a robot, automation-induced psychosocial stress, and potentially more hazardous synthetic biology materials.

In conclusion, the STPI team provides this white paper as an element of a strategic approach to ensure that NIOSH has the capability to identify potential worker health and safety issues associated with advanced materials and advanced manufacturing technologies. The team also recognizes that the framework, implications, and considerations presented herein will need to evolve as today's state of the art becomes tomorrow's routine and new materials and processes emerge. At the point of reconsideration, this analysis can serve as the foundation for evaluating changes in state-of-the-art manufacturing and its associated implications.

Appendix A.
Definitions of Advanced Manufacturing

Table A-1. Definitions of Advanced Manufacturing

Source	Definition
President’s Council of Advisors on Science and Technology	Advanced manufacturing is “a family of activities that (a) depend on the use and coordination of information, automation, computation, software, sensing, and networking, and/or (b) make use of cutting edge materials and emerging capabilities enabled by the physical and biological sciences, for example nanotechnology, chemistry, and biology. This involves both new ways to manufacture existing products, and especially the manufacture of new products emerging from new advanced technologies.”[1][56]
Center for Advanced Manufacturing Puget Sound	Advanced manufacturing is “the integration of technology based systems and processes in the production of products (fit, form, and function) to the highest level of quality and in compliance with industry specific certification standards. Products and processes are often innovative, made from advanced materials and components, and produced on technology driven equipment and processes. Paramount to Advanced Manufacturing is a highly skilled workforce operating in lean and continuous improvement cultures. The goal of Advanced Manufacturing companies is to continue to strive to be the “best in class”, focused on high performance, with constant awareness of customer expectations.”[2][57]
National Association of Advanced Manufacturing	“The Advanced Manufacturing entity makes extensive use of computer, high precision, and information technologies integrated with a high performance workforce in a production system capable of furnishing a heterogeneous mix of products in small or large volumes with both the efficiency of mass production and the flexibility of custom manufacturing in order to respond quickly to customer demands.” [3][58]
National Defense University	Advanced manufacturing is “the insertion of new technology, improved processes, and management methods to improve the manufacturing of products.”[4][59]

[56] President’s Council of Advisors on Science and Technology (PCAST), *Report to the President on Ensuring American Leadership in Advanced Manufacturing*.

[57] Center for Advanced Manufacturing Puget Sound (CAMPS), “Camps Wiki,” (Central Washington University, Des Moines Campus: Group 1, Supply Chain 480. CAMPS-Wiki-Terms-and-Content-06-02-16.docx 2016).

[58] IDA Science and Technology Policy Institute (STPI), *White Papers on Advanced Manufacturing Questions* (Washington, D.C.: STPI, 2010).

[59] National Defense University, *2002 Industry Study: Advanced Manufacturing* (Washington, D.C.: National Defense University. file:///C:/Users/lgarlet/Downloads/ADA426501.pdf, 2002).

Source	Definition
Department of Labor	Advanced manufacturing involves “implementing process improvements, increasing quality controls, and installing advanced robotics and other intelligent production systems.”[5] [60]

[1] President’s Council of Advisors on Science and Technology (PCAST), *Report to the President on Ensuring American Leadership in Advanced Manufacturing*.

[2] Center for Advanced Manufacturing Puget Sound (CAMPS), “Camps Wiki” (Central Washington University, Des Moines Campus: Group 1, Supply Chain 480. CAMPS-Wiki-Terms-and-Content-06-02-16.docx 2016).

[3] IDA Science and Technology Policy Institute (STPI), *White Papers on Advanced Manufacturing Questions* (Washington, D.C.: STPI, 2010).

[4] National Defense University, *2002 Industry Study: Advanced Manufacturing* (Washington, D.C.: National Defense University. file:///C:/Users/lgarlet/Downloads/ADA426501.pdf, 2002).

[5] U.S. Department of Labor; Employment and Training Administration (ETA), *Advanced Manufacturing Industry: Addressing the Workforce Challenges of America’s Advanced Manufacturing Workforce* (Washington, D.C.: ETA).

[60] U.S. Department of Labor; Employment and Training Administration (ETA), *Advanced Manufacturing Industry: Addressing the Workforce Challenges of America’s Advanced Manufacturing Workforce* (Washington, D.C.: ETA).

Appendix B.
Interviewees and Interview Guide

STPI conducted interviews with twelve subject matter experts in Federal, academic, and industry positions related to advanced manufacturing. A list of interviewees can be found in Table B-1, followed by the interview guide.

Table B-1. Interviewees

Name	Position
Castracane, James	Professor and Head of the Nanobioscience Constellation at CNSE*
Cooper, Khershed	Program Director for the Nanomanufacturing Program at the National Science Foundation
Diamond, Thomas	Vice President of Environmental Health and Safety at CNSE
Diebold, Alain	Interim Dean of the College of Nanoscale Science at CNSE
Eisenbraun, Eric**	Associate Professor of Nanoscience at CNSE
Fancher, Michael**	Director of New York State's Center for Advanced Technology in Nanomaterials and Nanoelectronics
Gayle, Frank	Deputy Director of the interagency Advanced Manufacturing National Program Office (headquartered at the National Institute of Standards and Technology)
Liehr, Michael	CEO of AIM Photonics and Vice President for Research at CNSE
McKittrick, Mike	Technology Manager at the U.S. Department of Energy's Critical Materials Institute for the Advanced Manufacturing Office
Morse, Jeff***	Managing Director of the National Nanomanufacturing Network
Roth, Gary	Health Research Scientist at the National Institute of Occupational Health and Safety
Tuominen, Mark***	Director of the National Nanomanufacturing Network and Co-Director of the National Science Foundation's Center for Hierarchical Manufacturing
Whitman, Lloyd	Assistant Director for Nanotechnology and Advanced Materials for the White House Office of Science and Technology Policy

*CNSE refers to SUNY Polytechnic Institute's Colleges of Nanoscale Science and Engineering.

**Eric Eisenbraun and Michael Fancher were interviewed together.

***Jeff Morse and Mark Tuominen were interviewed together.

Interview Guide

Purpose of the interviews: (1) vet the definition/characteristics of advanced manufacturing, (2) determine the descriptive utility of "advanced" for near and midterm changes in the field of manufacturing, and (3) consider changes in consequent to near and midterm changes in manufacturing.

Questions

3. Context: How are you involved in manufacturing or research that informs manufacturing?
4. How would you define or scope what advanced manufacturing is? Is it different from manufacturing in general? Are there specific characteristics of advanced manufacturing that make it "advanced"? Does the definition differ depending on the scale of manufacturing?
5. What is your view of the manufacturing ecosystem with regard to this list of possible manufacturing elements for the next 5 years? 10–15 years?
    - i. Advanced materials
    - j. Advanced processes and methods
    - k. Advanced technologies
    - l. New ways to apply existing technology
6. Are there different materials, methods, and instruments needed for small scale manufacturing vs large scale manufacturing?
7. Based on our discussion, would you make any changes to your definition of advanced manufacturing?
8. As the aspects of advanced manufacturing you describe become part of the U.S. manufacturing ecosystem, how will this affect the safety of the workforce? Will it change worker exposures and potential health impacts? Change the traditional occupational health and safety approaches?

Appendix C.
Key Federal Funding Partners

Table C-1. Key Federal Funding Partners

Department or Agency	Key Office or Program
Department of Agriculture	No general advanced manufacturing office but supports advanced biofuel development through its Foreign Agricultural Service and supports nanocellulose production at the Forest Product's Laboratory's Nanocellulose Pilot Plant
Department of Commerce (NIST)	Office of Advanced Manufacturing; Manufacturing Extension Partnership
Department of Defense	Manufacturing Technology Program
Department of Energy	Advanced Manufacturing Office
National Aeronautics and Space Administration	National Center for Advanced Manufacturing
National Institutes of Health	No general advanced manufacturing office but supports advanced material and technology development for biomedical applications
National Science Foundation	Advanced Manufacturing Cluster within the Division of Civil, Mechanical, and Manufacturing Innovation
Small Business Administration	No general advanced manufacturing office but supports small businesses, including those engaging in advanced manufacturing

Appendix D.
Manufacturing USA Institutes

Table D-1 displays each Manufacturing USA Institute, along with its year of establishment, its primary focus, the relationship of its primary focus to the state-of-the-art manufacturing framework, and more information about the use of nanomaterials within the Institute. For ease of reference, the state-of-the-art manufacturing framework is reproduced here:

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 novel tools (processing hardware, automating technology, robotics, sensors, networking, and other technologies for precision manufacturing)
2. Materials-centered state-of-the-art manufacturing
    a. Manufacturing of materials (nonbiological and biological materials) with novel or optimized properties
    b. Manufacturing of products that use or incorporate materials with novel or optimized properties
    c. Manufacturing of products from novel combinations of materials that provide new or optimized state-of-the-art performance

Table D-1. Manufacturing USA Institutes

Institute	Year of Announcement	Primary Focus	Relationship to State-of-the-Art Manufacturing Framework	Nanomaterial Use*
Advanced Tissue Biofabrication Manufacturing Innovation Institute (ATBMII)	2016	Biofabrication	2	ATBMII has not yet released a technology roadmap or other information that would allow for a complete evaluation of nanomaterial use. Nevertheless, the Institute's focus on biofabrication and the role of nanomaterials within that field to date makes nanomaterial use possible.
Advanced Functional Fabrics of America (AFFOA)	2016	Fibers and textiles manufacturing	2	The Institute's goal of :transforming traditional fibers, yarns, and fabrics into highly sophisticated, integrated and networked devices and systems: may be accomplished through the use of nanomaterials or functionalized nanomaterials.
American Institute for Manufacturing Integrated Photonics (AIM Photonics)	2015	Optics and photonics	1, 2	Interviews revealed the use of thin films, some of nanometer thickness, within the Institute.
America Makes	2012	Additive manufacturing	1, 2	Additive manufacturing frequently makes use of materials with nanoscale features. America Makes' technology roadmap includes two relevant focus areas: The Material focus and the Additive Manufacturing Genome. Given the use of nanomaterials in additive manufacturing, it is possible that past, present, and future projects related to these areas may include the use of nanomaterials.
Advanced Robotics Manufacturing Institute (ARMI)	2017	Robotics manufacturing	1	The Institute's primary focus on robotics makes the use of nanomaterials unlikely.

Institute	Year of Announcement	Primary Focus	Relationship to State-of-the-Art Manufacturing Framework	Nanomaterial Use*
Digital Manufacturing and Design Innovation Institute (DMDII)	2014	Digital manufacturing	1	The primary focus of the Institute is on process-related state-of-the-art manufacturing, but DMDII's demonstration facility does include a micro-/nano-technology cell to address digital manufacturing issues related to difficult-to-machine material equipment.
Institute for Advanced Composites Manufacturing Innovation (IACMI)	2015	Composite materials manufacturing	2	IACMI's Preliminary Technology Roadmap includes the development of novel glass fibers, including those at the nanoscale. This and the Institute's focus on materials production makes the use of nanomaterials in future projects likely.
Lightweight Innovations for Tomorrow (LIFT)	2014	Lightweight metals manufacturing	2	Lift's focus on development of lightweight metals could involve the use of nanomaterials. In addition, surveying LIFT's historical newsletters revealed that Institute members conduct work at the nanoscale.
NextFlex	2015	Flexible hybrid electronics	1, 2	Interviews revealed the use of nanoparticles, thin films, and multilayers within NextFlex.
National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)	2016	Biopharmaceutical manufacturing	2	The use of nanomaterials within the biopharmaceutical industry to date makes future nanomaterial use within NIIMBL possible.
Power America	2014	Wide bandgap semiconductor manufacturing	1, 2	Interviews with Power America subject matter experts indicate that nanomaterials are used in silicon-based semiconductor device production. Thus, it is possible that nanomaterials may be used for wide bandgap semiconductors.

Institute	Year of Announcement	Primary Focus	Relationship to State-of-the-Art Manufacturing Framework	Nanomaterial Use*
Rapid Advancement in Process Intensification Deployment Institute (RAPID)	2016	Process Intensification	1	RAPID's focus on process intensification makes the use of nanomaterials as a primary focus of the Institute unlikely.
Reducing Embodied-Energy and Decreasing Emissions (REMADE)	2017	Reuse, recycling, and remanufacturing	1	REMADE's focus on reuse, recycling, and remanufacturing makes the use of nanomaterials as a primary focus of the Institute unlikely.
Clean Energy Smart Manufacturing Innovation Institute (CESMII)	2016	Smart manufacturing	1	CESMII's focus on smart manufacturing indicates that material use, including nanomaterial use, is not the primary focus of the Institute.

* Found in the Institute's publicly available information or in a nonpublic source (noted when applicable); other comments reflect the views of the white paper's authors.

Appendix E. Source Figure for Figure 1 of This White Paper

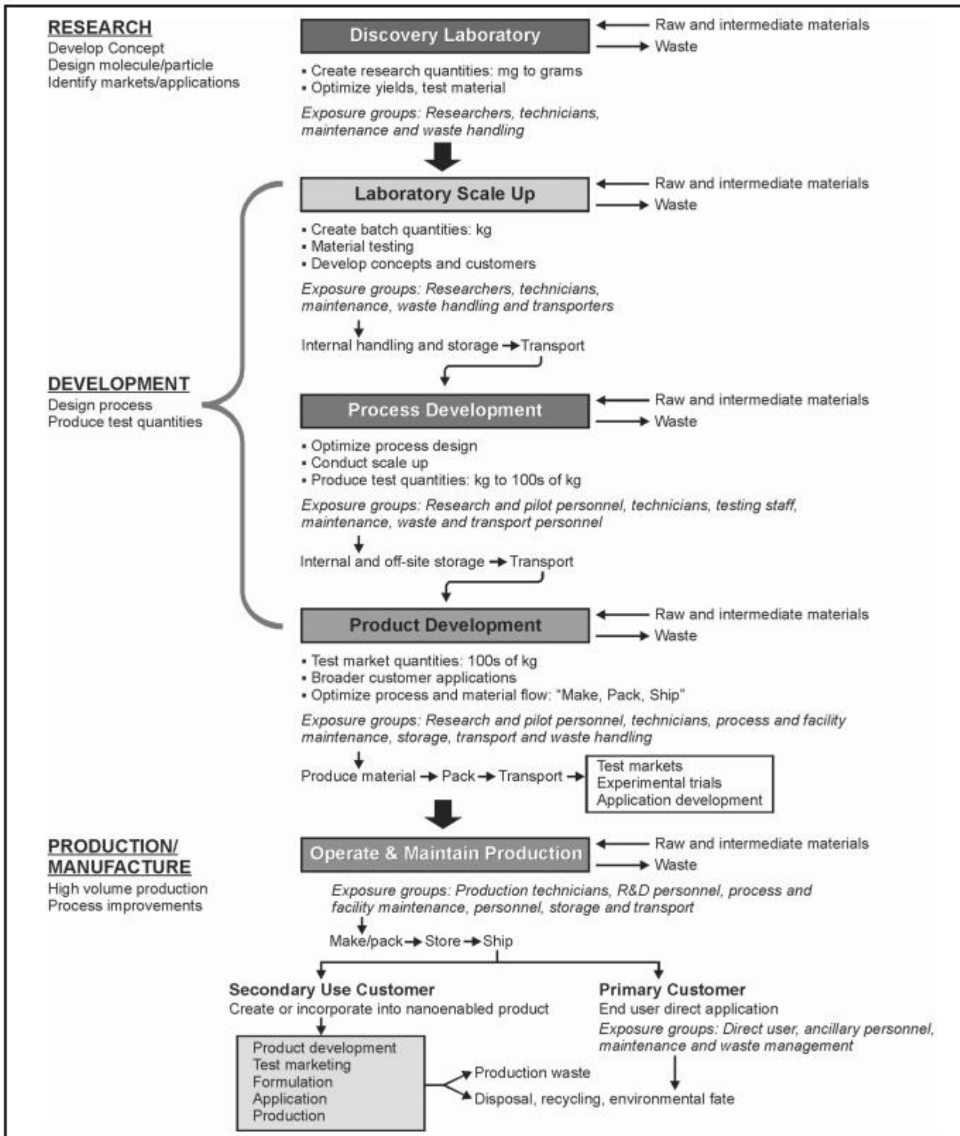

FIGURE 2. Workplaces with potential for occupational exposure to engineered nanoparticles. The figure illustrates the life cycle of nanomaterials from laboratory research development through product development, use, and disposal. Each step of the life cycle represents opportunities for potential worker exposure to nanoparticles.

Source. Schulte, Geraci, Zumwalde, Hoover, and Kuempel, "Occupational Risk Management of Engineered Nanoparticles." Reproduced with author permission. [61]

Figure E-1. Source Figure for Material in Figure 1 of This White Paper

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