

ADVANCED MANUFACTURING

1. SUMMARY OF CONTENT: This directive defines national standards and responsibilities for integrating Advanced Manufacturing (AM) into Veterans Health Administration (VHA) operations and establishes VHA policy for the development, manufacture, and distribution of healthcare-related products using AM technology. It designates several VHA leadership offices, program offices, Veterans Integrated Services Networks, and Department of Veterans Affairs (VA) medical facilities that have responsibilities and duties related to AM. The VHA AM program refers specifically to AM activities supporting health care delivery and does not cover AM activities for non-health care related functions such as facility maintenance nor does it cover research-related activities.

2. RELATED ISSUES: None.

3. POLICY OWNER: The Office of Advanced Manufacturing (OAM) (14HIL) is responsible for the content of this directive. Questions may be addressed to OAM at VAOfficeofAdvancedManufacturing@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local document creation requirements in this directive.

5. RESCISSIONS: VHA Notice 2024-15, Delegation of Authority and Oversight for VHA Advanced Manufacturing, dated October 16, 2024, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of September 2030. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Carolyn M. Clancy, MD
Assistant Under Secretary for Health
for Discovery, Education, and Affiliate Networks

DISTRIBUTION: Emailed to the VHA Publications Distribution List on September 10, 2025.

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

CONTENTS

ADVANCED MANUFACTURING

1. POLICY 1

2. RESPONSIBILITIES 1

3. ADVANCED MANUFACTURING SITE REQUIREMENTS 8

4. RELATION TO TELEHEALTH AND TELERADIOLOGY PROGRAMS 10

5. TRAINING 10

6. RECORDS MANAGEMENT 10

7. BACKGROUND 10

8. DEFINITIONS 11

9. REFERENCES 13

APPENDIX A

ADVANCED MANUFACTURING AND SUPPLY CHAIN RESILIENCYA-1

APPENDIX B

ACCESSING ADVANCED MANUFACTURING PRODUCTSB-1

ADVANCED MANUFACTURING

1. POLICY

It is Veterans Health Administration (VHA) policy to use Advanced Manufacturing (AM) in accordance with the United States Food and Drug Administration (FDA) Quality System Regulation and the quality management system (QMS) established by the VHA Office of Discovery, Education and Affiliate Networks (DEAN) for medical devices furnished to Veterans for clinical care and service to ensure access to patient-matched medical devices (PMMD), empower frontline clinicians to invent and implement product-based solutions to clinical challenges and strengthen supply chain resiliency in times of emergency. **AUTHORITY:** 38 U.S.C. §§ 1706 and 7303.

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Reviewing, concurring and non-concurring on oversight actions taken by the Office of Advanced Manufacturing (OAM), if requested by the Executive Director, OAM, for sites engaging in unsafe, unauthorized, or inappropriate AM activities.

b. **Chief Operating Officer.** The Chief Operating Officer is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Overseeing VISNs to ensure the effectiveness of and compliance with this directive.

c. **Assistant Under Secretary for Health for Discovery, Education, and Affiliate Networks.** The Assistant Under Secretary for Health for Discovery, Education, and Affiliate Networks is responsible for:

(1) Supporting OAM with implementation and oversight of this directive.

(2) Providing signature, oversight, and decisional authority for VHA AM, innovation, and discovery activities, with the exception of Service-Specific AM Cells (see paragraph 3) and those functions and duties which, by statute, may not be delegated.

(3) Ensuring VHA AM activities comply with the Office of Management and Budget Circular A-76, Performance of Commercial Activities, dated August 4, 1983 (revised 1999).

(4) Supporting the Executive Director, OAM to maintain supply chain resiliency for AM (see Appendix A).

(5) In collaboration with OAM, giving final approval for Federated AM Sites to act as an OAM Site during emergency responses or during times of supply chain disruption. **NOTE: Independent AM Sites and Service-Specific AM Cell capabilities are established through the authority of their VA medical facility Director in an MOU. (For details, see paragraph 3.b.)**

d. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health for Patient Care Services is responsible for integrating AM as an enabling capability in patient care services where appropriate.

e. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for integrating AM as an enabling capability in clinical services where appropriate. This includes ensuring those clinical services collaborate with OAM when their Service-Specific AM Sites wish to use the digital workflow or 3D printing (3DP) products off-label from FDA-cleared indications and labeling (for details, see paragraph 3.b.).

f. **Assistant Under Secretary for Health for Dentistry.** The Assistant Under Secretary for Health for Dentistry is responsible for:

(1) Developing and implementing service-specific AM technologies and Cells that advance VHA digital dentistry and create value for Veterans in on-site dental laboratories.

(2) Overseeing, through the Dental Laboratory Operations Directorate (co-located at the Central Dental Laboratory (CDL)), prescription-based operations and budget for CDL and nationally contracted dental laboratory services and processes. **NOTE: CDL uses AM technology to fulfill prescriptions as needed at their discretion.**

(3) Providing AM subject matter expertise, collaboration, information sharing, and support planning, as needed, to the Executive Director, OAM through the Dental Laboratory Operations Directorate.

(4) Collaborating with OAM Portfolio Directors through the Dental Laboratory Operations Directorate to utilize appropriate cost-effective AM laboratories that meet dental clinician or patient needs and enhance product quality and fabrication workflow.

(5) Collaborating with OAM when their service wishes to use the dental digital workflow or dental 3DP product off-label from FDA-cleared indications and labeling.

g. **Chief, Office of Healthcare Innovation and Learning.** The Chief, Office of Healthcare Innovation and Learning (OHIL), aligned under the Office of Discovery, Education and Affiliate Networks, is responsible for:

(1) Providing executive-level leadership and oversight to OAM.

(2) Ensuring relevant OHIL initiatives as described by this directive comply with the VHA DEAN QMS documented in the Quality Plan on the [OAM SharePoint](#). **NOTE:** *This is an internal VA website that is not available to the public.*

h. **Deputy Chief, Office of Healthcare Innovation and Learning.** The Deputy Chief, OHIL is responsible for:

(1) Developing, implementing, and supporting the VHA DEAN QMS documented in the [Quality Plan](#). **NOTE:** *This is an internal VA website that is not available to the public.*

(2) Overseeing and ensuring OAM Sites and Federated AM Sites that are activated as OAM Sites into the VHA DEAN QMS, are registered with FDA as medical device manufacturers of specific devices and that machines at each Federated AM Site have Installation Qualification and Performance Qualification performed during “downtime” to prepare for an emergency. For details, see Appendix A.

i. **Executive Director, Office of Advanced Manufacturing.** The Executive Director, OAM is responsible for:

(1) Developing and implementing AM initiatives that enhance VHA’s ability to ensure access to patient-matched medical devices, empower frontline clinicians to design and implement product-based solutions to clinical challenges, and strengthen supply chain resiliency by providing in-house VHA manufacturing capability. **NOTE:** *OAM has oversight of the clinical AM program but does not provide oversight or direct AM operations for any non-healthcare activities (e.g., VA medical facilities employing AM to produce nameplates).* For oversight regarding AM as related to non-healthcare activities, please contact local VA leadership.

(2) Developing VHA policies and standards for clinical AM.

(3) Managing memoranda of understanding (MOUs) between OAM and VHA program offices, as well as between OAM and sponsoring VA medical facilities for designations as OAM Sites and Federated AM Sites. **NOTE:** *The purpose of MOUs is to define and mutually acknowledge the mechanisms for interaction, expectations, applicable reimbursement, and support between OAM and the other entity. MOU templates can be found on the [OAM SharePoint](#). This is an internal VA website that is not available to the public.*

(4) Developing and executing the OAM annual plan.

(5) Developing the annual OAM summary which includes a description of OAM activities and currently available products and disseminating the summary to VISN Directors and VHA program office Directors as appropriate.

(6) Managing the OAM annual budget and ensuring the financial viability of AM programs within VHA. OAM uses standard obligation and invoicing procedures. Reimbursement of costs for AM products aligns with agreements between customers and OAM.

(7) Chartering and overseeing OAM standing and ad-hoc working groups, committees, and councils.

(8) Setting production resource allocations, delivery dates, and priorities for OAM Portfolio Directors. **NOTE: Non-VA employees such as contracted employees, may be involved in AM activities and production. Separate contracts are in place with non-VA employees addressing IP ownership.**

(9) Ensuring authorized AM machines and supplies are communicated and used for the various products as indicated by product Device Master Records or equivalent.

(10) Managing VHA's catalog of approved AM product designs and files.

(11) Collaborating with other VHA program office Directors to integrate AM as a capability supporting their program goal.

(12) Managing Federated AM Sites and enrolling them into the VHA DEAN QMS when directed by the Chief Operating Officer to fulfill supply chain resiliency needs.

(13) Complying with FDA and VHA regulations and guidelines related to medical device manufacturer responsibilities for product safety and recalls. **NOTE: OAM is considered both a "firm" and "program office" as found in VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.** In accordance with VHA Directive 1068, the Executive Director of OAM must appoint a Designated Service Area Specialist (DSAS) who is responsible for informational requests submitted by the National Center for Patient Safety (NCPS) and must inform NCPS if additional actions beyond a product recall are deemed necessary.

(14) Assigning primary and alternate Designated Service Area Specialists (DSAS) for OAM, in accordance with VHA Directive 1068 and supporting them in all their responsibilities. **NOTE: For further information on product recalls and program office DSAS responsibilities, see VHA Directive 1068.**

(15) Providing AM expertise (either from OAM Staff or OAM Sites) to other VHA program offices, VISNs, and VA medical facilities to assist in studies, reviews, working groups, reports, or similar efforts as requested. **NOTE: Any participation in such efforts falls under the guidelines of their sponsoring organizations (e.g., OAM participation in NCPS-led root cause analysis falls under the purview of VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023).**

(16) Working closely with the National Office of Sterile Processing (OSP) and Sterile Processing Services to ensure understanding and compliance around 3D-printed devices requiring cleaning and sterilization. 3D-printed implantable devices must follow the same pathways as other implantable devices in the Department of Veterans Affairs (VA). **NOTE:** See VHA Directive 1116(2), *Management of Critical and Semi-Critical Reusable Medical Devices*, dated July 17, 2023.

(17) Exercising signature, oversight, and decisional authority over all VHA AM activities with the exception of those functions and duties which, by statute or regulation, may not be delegated or reside within other VHA program offices. The Executive Director, OAM, may issue instructions, warnings or cease operations mandates to sites engaged in unsafe, unauthorized, or inappropriate AM activities, such as those involving uncleared medical devices, unauthorized human tissue, weapons, or other such objects as may be deemed unsafe or inappropriate for ethical, regulatory, or legal reasons. **NOTE:** The Executive Director, OAM notifies the relevant Assistant Under Secretary for Health when a warning or similar action is issued by OAM, and requests review and concurrence from the Under Secretary for Health or relevant Assistant Under Secretary for Health for cease-and-desist orders.

(18) Ensuring all personnel actively assigned to an OAM Site developing or producing medical devices complete Quality System role and device-specific training in accordance with the VHA DEAN QMS. See the Job Function Training Matrix (QMS Form 09-001224) [on the OAM SharePoint](#) for specific training requirements by role. **NOTE:** This is an internal VA website that is not available to the public.

(19) Collaborating with the VA Office of Acquisition and Logistics to add AM products to the Item Master File and allow ordering through VHA standard supply processes. **NOTE:** For more information, see paragraph 2.c. in Appendix B.

j. **Office of Advanced Manufacturing Portfolio Directors.** OAM Portfolio Directors are responsible for:

(1) Managing a portfolio of AM products (including medical devices) that support improved patient care (e.g., effectiveness, safety, or efficiency).

(2) Working with clinical subject matter experts (SMEs) and the Directors of VHA program offices to identify clinician and patient needs that could be addressed with AM or AM products.

(3) Developing and executing an education and outreach program to raise awareness of the potential benefits of AM products among clinicians, patients, and support staff.

(4) Coordinating a network of manufacturing capacity to fill demands, including OAM Sites, Federated AM Sites, and external vendors. Per this directive, it is not intended for external vendors to receive the OAM final manufactured product.

(5) Collaborating with the Department of Defense (DoD) to identify AM opportunities to support DoD requirements and enhance continuity of care as Service members transition from DoD's to VA's health care system.

(6) Collaborating with the Technology Transfer Program to identify inventions that could become candidates for OAM management and production.

k. **Director, Technology Transfer Program.** The Director, Technology Transfer Program in the VHA Office of Research and Development is responsible for:

(1) Collaborating with OAM staff and contracted staff to identify inventions that could be a prospect for an OAM project that is subject to OAM management and production.

(2) Fulfilling responsibilities assigned in VHA Directive 1200.18, Determination of Rights for Inventions and Discoveries, dated October 6, 2023, related to the determination of rights to inventions by VA employees, and working with OAM to determine whether disclosed inventions are appropriate for AM. Separate contracts are in place with non-VA employees addressing IP ownership.

l. **VHA Program Office Directors.** VHA program office Directors are responsible for:

(1) Providing input to AM programs related to their program office areas of responsibility (e.g., rehabilitative care or dentistry).

(2) Collaborating with OAM Portfolio Directors to identify clinician and patient needs that could be addressed with AM or AM products.

(3) Engaging with OAM to establish and execute MOUs.

(4) Reviewing the annual OAM summary report disseminated by OAM.

m. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Reviewing annual OAM summary report disseminated by OAM.

n. **VA Medical Facility Director.** The VA medical facility Director of a VA medical facility hosting an AM Site is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive, including the VHA DEAN QMS, and ensuring that appropriate corrective action is taken if noncompliance is identified. See the VHA DEAN Quality Plan on the [OAM SharePoint](#) for an overview of the VHA DEAN QMS. **NOTE:** *This is an internal VA website that is not available to the public.*

(2) Authorizing purchase requisitions only for AM machines and supplies from the list of authorized materials published by the OAM Executive Director, based on the type of product being produced and that product's Device Master Record or equivalent.

(3) Ensuring compliance with the requirements of MOU agreements. MOU templates can be found on the [OAM SharePoint](#). **NOTE:** *This is an internal VA website that is not available to the public.*

(4) Ensuring VA medical facility staff use appropriate Current Procedural Terminology (CPT) codes to capture AM workload. OAM provides up-to-date information on [AM-specific CPT coding](#). **NOTE:** *This is an internal VA website that is not available to the public.* Funding OAM Site operations, contingent on reimbursement from OAM, if hosting an OAM Site.

(5) Including OAM products in safety and product-related event reporting procedures, including adverse event reporting. **NOTE:** *This directive is not intended to modify existing safety and patient safety reporting processes, but rather to clarify that OAM products are included in existing processes and procedures. For further information on adverse events and reporting, see VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.*

o. VA Medical Facility Chief of Staff and Associate Director of Patient Care Services. The VA medical facility Chief of Staff (CoS) and Associate Director of Patient Care Services (ADPCS) are responsible for:

(1) For VA medical facilities with Service-Specific AM Cells, ensuring safe and effective integration of AM capabilities into clinical care. OAM is available to provide advice, expertise, and training related to AM capabilities.

(2) For AM Site sponsoring facilities, providing clinician SMEs for input into AM product development and AM Site operations.

p. Director, Office of Advanced Manufacturing Site. The Director, OAM Site is responsible for:

(1) Allocating production resources to meet required delivery dates and priorities in line with the established agreements with the OAM sites captured in MOUs and charter documents. **NOTE:** *Charter documents include project charters that capture information used to assess whether OAM can take on a new development project. OAM project charter template located on the [OAM SharePoint](#). This is an internal VA website that is not available to the public.*

(2) Managing product development projects through established agreements with the OAM sites captured in MOUs and charter documents.

(3) Participating in OAM working groups, integrated product teams, committees, and councils in line with the established agreements with the OAM sites captured in MOUs and charter documents.

(4) Participating in High Reliability Organization (HRO) and emergency management efforts in line with the established agreements with the OAM sites captured in MOUs and charter documents.

q. **Director, Federated AM Site.** The Director, Federated AM Site, is responsible for:

(1) Taking OAM consultation under consideration. When changes to FDA regulatory guidance and policy are introduced, Federated AM Site must comply with the VHA DEAN QMS.

(2) Allocating production resources to meet required delivery dates agreed upon with customers and priorities as set by the sponsoring VA medical facility's leadership.

(3) Participating in OAM working groups, integrated product teams, committees, and councils as required by the Executive Director, OAM.

(4) Participating in HRO and emergency management efforts as directed by the Executive Director, OAM.

3. ADVANCED MANUFACTURING SITE REQUIREMENTS

a. VHA AM Sites may be designated as one of the following through an MOU established between the sponsoring VA medical facility and OAM. Details regarding MOUs can be found on the [OAM SharePoint](#). **NOTE:** *This is an internal VA website that is not available to the public.*

(1) **Office of Advanced Manufacturing Site.** An AM site operating under the guidelines of OAM located within a VA medical facility or VA designated space to (1) develop new products and AM processes, and (2) use AM to manufacture medical devices and non-medical device products. OAM sites may operate under the VHA DEAN QMS (for OAM Sites that develop and produce medical devices subject to Good Manufacturing Practices (GMP), referred to as OAM Registered Sites) or may not (for OAM Sites that develop and produce GMP-exempt or otherwise very low-risk medical devices and non-medical device products, referred to as OAM Non-registered Sites). OAM Sites can fulfill orders from any VA medical facility that has a service-level agreement with OAM. An OAM Site is located within a VA medical facility (health care system, VA medical center, or clinic). Funding for AM Site support (credentialing, facilities space, utilities, facilities, biomedical engineering, Information Management/Information Technology, Human Resources, security, and other support functions for the AM Site) comes from OAM for work related to OAM products, initiatives, and operations. Costs associated with VA medical facility-specific products, initiatives, and operations that are not OAM-approved are not reimbursed and are the responsibility of the VA medical facility. While VA medical facilities are not registered with FDA, an OAM Site residing at a VA medical facility may be registered depending on the devices manufactured. **NOTE:** *FDA guidance is available on the [FDA website](#). This is an internal VA website that is not available to the public.*

(2) **Federated Advanced Manufacturing Site.** A Federated AM Site is a VHA entity operating as an AM Site in a VA medical facility to manufacture non-medical device products or GMP-exempt or otherwise very low-risk medical devices. As a risk control measure, Federated AM Sites can only fulfill orders from within their VISN unless further restricted by the sponsoring VA medical facility. Federated AM Sites pay a fee to OAM in exchange for access to OAM training, consultation, technical support, enterprise contracts, enterprise systems, enterprise catalogs and production instructions, and other enterprise support. Federated AM Sites may be activated as OAM Sites by the Executive Director, OAM with approval from the Assistant Under Secretary for Health for DEAN to support supply chain resiliency, at which point the restriction to fulfill orders only within the VISN may be temporarily waived for items deemed necessary for supply chain resiliency. A Federated AM Site is located within a VA medical facility and is operated by VA staff and may include non-VA employees such as contracted staff. Separate contracts are in place with non-VA employees addressing IP ownership. The VISN or VA medical facility funds all operations of a Federated AM Site unless activated to support supply chain resiliency. If a Federated AM site is activated to support supply chain resiliency, OAM uses standard obligation and invoicing procedures. Reimbursement costs for AM products align with agreements between customers and OAM.

b. There are two other types of AM Sites which are established through the authority of the VA medical facility Director:

(1) **Independent AM Site.** An Independent AM Site is an AM Site operating under the guidance of and located within a VA medical facility to manufacture non-medical device products or GMP-exempt or otherwise very low risk medical devices. As a risk control measure, Independent AM Sites can only fulfill orders from within their VA medical facility unless further restricted by the sponsoring VA medical facility. Independent AM Sites do not pay a fee to OAM and so do not have access to training from OAM, consultation, technical support, enterprise contracts, enterprise systems, enterprise catalogs and production instructions, and other enterprise support. However, as VHA entities, Independent AM Sites are subject to this directive and must not operate in violation of this directive, the VHA DEAN QMS, or other related policies and standards. The VA medical facility funds all Independent AM Site operations.

(2) **Service-Specific AM Cell.** A Service-Specific AM Cell is not a standalone AM Site, but rather a section of an existing individual service line where an individual clinician uses AM to provide care for their patients in their scope of practice (e.g., a hand therapist might use a 3D printer as a tool in their scope of practice to provide hand splints, an existing dental laboratory may use AM machines operated by a dental technician and a prosthetics fabrication laboratory may use AM machines operated by prosthetists or prosthetic technicians). Service-Specific AM Cells operate under the VA medical facility's policies and guidelines rather than this directive. Service-specific AM Cells may become Federated AM Sites through an MOU with OAM and receive access to OAM's platform, training, consultation, and product lines. Service lines must collaborate with OAM when their service wishes to use the digital workflow or AM system off-label from FDA-cleared indications and labeling.

4. RELATION TO TELEHEALTH AND TELERADIOLOGY PROGRAMS

a. Sponsoring VA medical facilities must use AM consults to initiate patient-matched medical device orders and must cover patient-matched medical device workflow. Any clinical interaction to impact patient care is covered under existing VHA directives (e.g., VHA Directive 1914(1), Telehealth Clinical Resource Sharing Between VA Facilities and Telehealth from Approved Alternative Worksites, dated April 27, 2020, or VHA Directive 1916, VHA Teleradiology Programs, dated June 10, 2021) rather than this directive.

b. AM consults may result in clinician-to-clinician dialogue. This collaboration is only for the design, production, and modification of products. If the customer requires a consult to inform diagnostic or treatment decisions, they must initiate a consult to the appropriate service. Providing consultations related to identifying and diagnosing a Veteran's medical condition and defining medical management, falls outside the scope of this directive.

5. TRAINING

The following training is **recommended** for the VA medical facility Director, CoS, and ADPCS: Talent Management System (TMS) Course VA 45343, 3D Printing in the VA Healthcare System: Building the Hospital of the Future.

6. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer at the VA medical facility.

7. BACKGROUND

a. VHA has used 3DP in the clinical environment for over 10 years and has been a pioneer in establishing point-of-care AM facilities to bring medical device fabrication to the hospital campus. VHA 3DP capabilities exist at more than 90 VA sites with a range of clinical capabilities.

b. VHA's goal is for every VA medical facility to be able to access AM capacity, providing all Veterans access to high-quality, accessible, integrated, and personalized care within VHA. This includes patient-matched and personalized products, as well as serial products that are made in the hospital using AM technologies (e.g., digital manufacturing and additive manufacturing (AddM)/3DP).

c. OAM guides the use of AM technologies in health care applications; integrates the functions of quality, safety, and high reliability to achieve value for Veterans; recognizes current and emerging Veteran needs; aligns with VHA strategic guidance and resource allocation; and consistently performs with VA Core Values of Integrity, Commitment, Advocacy, Respect, and Excellence.

8. DEFINITIONS

a. **3D Printing.** 3DP, often synonymous with AddM, is the fabrication of objects through the deposition of a material using a print head, nozzle, or another printer technology. 3DP is a type of AM.

b. **Additive Manufacturing.** AddM is the process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies.

c. **Advanced Manufacturing.** AM is the use of innovative technologies to create products and often utilizes digital blueprints as the input to these manufacturing technologies. AM can include production activities that depend on information, automation, computation, software, sensing, and networking. AM technologies are not limited to production methods and include nanotechnology, advanced ceramics, photonics and optics, composites, biobased and advanced materials, flexible hybrid technologies, and tool development for microelectronics. Additional healthcare-specific technologies include pharmaceuticals and programmable matter.

d. **Advanced Manufacturing Consult.** An AM consult is a request for AM services on behalf of a clinician in support of patient care. In VHA, consult requests are made through the Electronic Health Record (EHR) to communicate service requests or results. AM consults are between a customer clinician and an AM Site. Any patient interaction is limited to informing the AM product design and performance, not for patient diagnosis or treatment planning. ***NOTE: For further information on consults, see VHA Directive 1232, Consult Management, dated November 22, 2024.***

e. **Advanced Manufacturing Product.** An AM product is the output of a manufacturing process, converting raw materials into a finished physical object. AM products include medical devices (e.g., surgical guide), non-medical device healthcare items (e.g., iPad grips for nursing staff), and non-health care items (e.g., door stops).

f. **Custom Device.** A device qualifies as a “custom device” by meeting statutory requirements, including, among others, the following for each device:

(1) Is created or modified in order to comply with the order of an individual physician, nurse, or dentist (or other specially qualified person);

(2) Necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515 of the Federal Food, Drug, and Cosmetics Act (Title 21, U.S.C. Chapter 9; FD&C Act);

(3) Is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(4) Is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(5) Either (a) is intended to meet the special needs of such physician, certified registered nurse anesthetist, certified nurse midwife, clinical nurse specialist, certified nurse practitioner, registered nurse, or dentist in the course of their professional practice (or other specially qualified person as designated) or (b) is intended for use by an individual patient named in the order of a physician, advanced practice nurse or dentist (or other specially qualified person as designated);

(6) Is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals, physician, or dentist; and

(7) May have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices. (21 U.S.C. § 360j(b)). **NOTE:** For further information, see [“Custom Device Exemption, Guidance for Industry and Food and Drug Administration Staff”](#).

g. **Customer.** For purposes of this directive, a customer is an individual who places an order for an AM product. The customer may be a clinician, supply technician, or other person authorized to order medical devices or other supplies. The customer may be different from the end user of an AM product.

h. **Firm.** A firm, as used in this directive, is a manufacturer, wholesaler, distributor or marketer of a product or device.

i. **Medical Device.** Section 201(h) of the Food, Drug & Cosmetic Act (FD&C Act) defines a device as: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

(1) Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

(3) And does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(4) The term “device” does not include software functions excluded pursuant to section 520 (0).

j. **Medical Device Manufacturer.** A medical device manufacturer is any organization or individual that makes by chemical, physical, biological, or other procedures, any article that meets the definition of “device” in 21 U.S.C. § 321(h).

k. **Patient-Matched Medical Devices.** PMMDs are medical devices with a range of different specifications that have been approved or cleared to treat patient populations that can be studied clinically and include anatomically matched devices and surgical instrumentation created by using a patient's own medical imaging. **NOTE:** *While patient-matched or patient-specific devices are sometimes colloquially referred to as "customized" devices, they are not custom devices meeting the FD&C Act custom device exemption requirements unless they comply with all of the criteria of 21 U.S.C. § 360j(b). For further information, see the [Custom Device Exemption Guidance for Industry and Food and Drug Administration Staff.](#)*

l. **Product.** The FDA considers a product to be a device, and subject to FDA regulation if it meets the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act.

m. **Product Recall.** A product recall is a method for removing products from sue that are in violation of laws administered by the FDA or otherwise deemed defective or potentially harmful to patients. Product recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

n. **Sponsoring VA Medical Facility.** A sponsoring VA medical facility is the VA health care system or VA medical facility which hosts the user of the OAM product. This is normally the site through which a patient receives clinical care.

9. REFERENCES

- a. 21 U.S.C. §§ 321(h), 360j(b).
- b. 21 U.S.C. Chapter 9.
- c. 38 U.S.C. §§ 1706, 7303.
- d. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.
- e. VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.
- f. VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.
- g. VHA Directive 1116(2), Management of Critical and Semi-Critical Reusable Medical Devices, dated July 17, 2023.
- h. VHA Directive 1200.18, Determination of Rights for Inventions and Discoveries, dated October 6, 2023.
- i. VHA Directive 1232, Consult Management, dated November 22, 2024.

j. VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020.

k. VHA Directive 1914(1), Telehealth Clinical Resource Sharing Between VA Facilities and Telehealth from Approved Alternative Worksites, dated April 27, 2020.

l. VHA Directive 1916, VHA Teleradiology Programs., dated June 10, 2021.

m. [VA Financial Policy Volume II -Appropriations, Funds and Related Information.](#)

n. [VA OAM SharePoint site.](#) **NOTE:** *This is an internal VA website that is not available to the public.*

o. VA OAM information on [AM-specific CPT coding.](#) **NOTE:** *This is an internal VA website that is not available to the public.*

p. [VA OAM Job Function Training Matrix \(QMS Form 09-001224\).](#) **NOTE:** *This is an internal VA website that is not available to the public.*

q. [VHA Office of Discovery, Education and Affiliate Networks \(DEAN\) Quality Management System \(QMS\) Quality Plan.](#) **NOTE:** *This is an internal VA website that is not available to the public.*

r. FDA. [Custom Device Exemption, Guidance for Industry and Food and Drug Administration Staff.](#) 2014.

s. [FDA guidance.](#) **NOTE:** *This is an internal VA website that is not available to the public.*

t. [OAM project charter template.](#) **NOTE:** *This is an internal VA website that is not available to the public.*

ADVANCED MANUFACTURING AND SUPPLY CHAIN RESILIENCY

1. EMERGENCY SUPPLY CHAIN RESILIENCY RELATED COLLABORATION

a. The Office of Advanced Manufacturing (OAM) works with the Department of Veterans Affairs (VA) Office of Acquisition and Logistics, to identify supply chain resiliency requirements that may be met by Veterans Health Administration's (VHA's) Advanced Manufacturing (AM) capability.

b. OAM may recommend Federated AM Sites as acting OAM Sites during emergency responses or during times of supply chain disruption with final approval from the Assistant Under Secretary for Health for Discovery, Education, and Affiliate Networks.

c. The activated Federated AM Sites transition to control by OAM to meet national VA production requirements.

d. Federated AM Sites are not authorized to produce non-Good Manufacturing Practices (GMP) exempt medical devices. However, it is likely that in a national emergency, VHA would need to increase supplies of non-GMP-exempt medical devices. The Executive Director, OAM has the authority to enroll Federated AM Sites that have been activated as OAM Sites into the VHA Discovery, Education and Affiliate Network (DEAN) Quality Management System (QMS) and register them with FDA as medical device manufacturers of specific devices. Select machines at each Federated AM Site have Installation Qualification and Performance Qualification performed during "downtime" to prepare for an emergency situation. When activated, QMS-trained OAM personnel deploy to designated sites to oversee regulated production using a MOU to outline specific details. After they have been certified as compliant and registered with FDA, these AM Sites are available to produce assigned devices for national requirements. See the VHA DEAN QMS documented in the Quality Plan on [the OAM SharePoint](#) for more information. **NOTE:** *This is an internal VA website that is not available to the public.*

e. When the emergency or supply chain disruption no longer exists, the Chief Operating Officer returns the activated AM Sites to the control of their sponsoring VA medical facility. At this time, the Executive Director, OAM disenrolls the Federated AM Sites from the VHA DEAN QMS and de-registers them as manufacturing sites with FDA.

ACCESSING ADVANCED MANUFACTURING PRODUCTS

1. PATIENT-MATCHED MEDICAL DEVICES

a. Clinicians may order patient-matched medical devices (PMMD) by creating an Advanced Manufacturing (AM) consult in the Veterans Health Administration (VHA) standard system (e.g., Computerized Patient Record System, Cerner). The AM consult routes to the Office of Advanced Manufacturing (OAM), which assesses the AM consult request and designates the appropriate production source. Executive Director, OAM or designee discusses any production concerns with the customer before accepting the consult as an order. **NOTE:** *For further information on consults, see VHA Directive 1232, Consult Management, dated November 22, 2024.*

b. The AM consult process is available on the internal [VHA OAM SharePoint site](#) is used for PMMD because production of PMMD requires clinician engagement. **NOTE:** *This is an internal Department of Veterans Affairs (VA) website that is not available to the public.*

c. In the case where new products are released before they can be incorporated into the AM consult process, they must be made available to the VHA network through the OAM SharePoint or by other means of direct order submission to OAM.

2. SERIAL MEDICAL DEVICES

a. OAM may also make available serial (i.e., non-custom or non-patient matched) medical devices and products. Serial production medical devices (generic device types) are a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness. These devices include the most common medical-surgical products which are mass-produced.

b. Customers must not use the AM consult process for these devices. Instead, customers can identify available items on the OAM SharePoint and order the item by contacting OAM.

c. OAM must work with the VA Office of Acquisition and Logistics to add AM products to the Item Master File and allow ordering through VHA standard supply processes. OAM must fulfill the order just as with any other source of supply. **NOTE:** *For further information on VHA standard supply chain processes, see VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020.*

3. PAYMENT

OAM uses a fully burdened cost model to assign the price of each AM product. This model captures all applicable costs as directed by Federal financial and revolving fund

September 10, 2025

VHA DIRECTIVE 1764
APPENDIX B

regulations and guidelines. Prices for each product line must be updated on all applicable systems, including the [OAM SharePoint](#). **NOTE:** *This is an internal VA website that is not available to the public.*