DELEGATION OF AUTHORITY AND OVERSIGHT FOR VHA ADVANCED MANUFACTURING

1. By the direction of the Office of the Under Secretary for Health, Veterans Health Administration (VHA), in accordance with 38 C.F.R. § 2.6(a)(1) this VHA notice delegates to the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks the interim authority for signature, oversight, and decisional authority over all VHA Advanced Manufacturing activities while a directive is being prepared, with the exception of those functions and duties which, by statute, may not be delegated.

2. The Office of Healthcare Innovation and Learning oversees VHA Advanced Manufacturing activities (e.g., 3D printing, injection molding and vacuum forming) for medical devices furnished for clinical care and service in accordance with VHA-DEAN's Food and Drug Administration (FDA) Registration and Quality Management System (QMS) to ensure compliance with FDA Quality System Regulation (21 C.F.R. § 820).

3. The Office of Healthcare Innovation and Learning will coordinate with the National Program Office for Sterile Processing to ensure necessary adherence to standards and policies for sterile processing as well as those related to reusable medical devices, where applicable.

4. The Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks is responsible for the content in this notice. All inquiries concerning this notice should be addressed to VHA Office of Regulations, Appeals and Policy (10BRAP) at VHA10BRAPPolicy@va.gov.

5. This VHA notice will expire and be archived on July 31, 2022.

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

/s/ Steven L. Lieberman, M.D.
Deputy to the Deputy Under Secretary for Health
Performing the Delegable Duties of the Under Secretary for Health