

INFORMATION PAPER

MCMR-MMO-A
10 Dec 09

SUBJECT: Department of Defense Unique Identification (UID) Program

PURPOSE: To provide an overview of the UID program and the USAMMA's implementation plan

BACKGROUND: The Draft Army UID Strategy, Jul 08, and the memorandum from the Acting USD (AT&L) dated 29 July 2003, entitled Policy for Unique Identification (UID) of Tangible Items – New Equipment, Major Modifications, and Re-procurements of Equipment and Spares, requires the implementation of an Item Unique Identification (IUID) program that assigns a set of data elements to be marked on equipment that are globally unique and unambiguous. On 23 Dec 04, the policy was extended to legacy items in inventory and operational use, including government property in the possession of contractors (PIPC). On 10 Jul 08, we received copy of a letter from Ms. Embrey of the Office of the Assistant Secretary of Defense for Force Health Protection & Readiness offering her support of the Food & Drug Administration's (FDA) efforts to establish the Unique Device Identification (UDI) program for medical devices and materials. See attachment.

DISCUSSION.

1. The UAMMA has established a working group to utilize a team approach in coordinating related activities for the implementation of the program. The working group includes but is not limited to members of FSD, FPD, DCO, PMOs Medical Devices and ICS. An Initial group planning meeting held on 9 Jul 08 included DSCP and USAMRAA along with the USAMMA members.
2. Topics discussed were UID requirements in the contract for new equipment procurement, planning for legacy equipment in the inventory, personnel requirements, and funding.
3. Items will require a DoD compliant UII for all tangible items delivered to the Government under contract or in inventory or use, if one or more of the following applies:
 - a. All items for which the Government's unit acquisition cost is \$5,000 or more;
 - b. Items for which the Government's unit acquisition cost is less than \$5,000, when identified by the requiring activity as serially managed, mission essential or controlled inventory;
 - c. When the Government's unit acquisition cost is less than \$5,000 and the requiring activity determines that permanent identification is required;
 - d. Regardless of value
 - 1) any DoD serially managed subassembly, component, or part embedded within the end item
 - 2) the parent end item that contains the embedded subassembly, component or part.
4. The enclosed position paper by the Joint Federal Data Synchronization Work Group basically states that the data in the medical surgical industry is disorganized, redundant, and highly inaccurate. DoD, including Military Health Care System and Defense Supply Center Philadelphia, has partnered with FDA and VA to establish and promote standardized and synchronized data with centralized data utility for

INFORMATION PAPER

medical surgical items. It goes on to say that the DoD IUID program spans all commodities and is not healthcare specific. The DoD IUID Program Office will respond to this initiative. In the meantime DSCP/DLA has put on hold the DoD UID requirement for new equipment procurement at least until the FDA's UDI is mandated or guidance published with anticipated publication date of early FY 2011.

5. USAMMA's procuring products regulated under the Federal Food, Drug, and Cosmetic Act (FFD&CA) will ensure that the products comply with the act's legal requirements and the US Food & Drug Administration's (FDA) regulatory guidance for additions / changes to labels on medical drugs, biologics, and devices. Where there is a conflict between DoD's UID guidance and the FFD&CA / FDA regulatory guidance, the FFD&CA and FDA guidance shall take precedence.

RECOMMENDATION: It is clear that UDI will provide a path to medical surgical data synchronization and standardization which will be based on healthcare industry and or global standards enabling product managers to differentiate an individual item from all other like and unlike items throughout the supply chain, from acquisition through disposal or destruction. Recommended course of action is to continue with the DoD UID initiative, following the DFARS regulation and procure new equipment with UID labeling. Continue to plan and mark legacy medical equipment with UID labels. When the FDA UDI guidance is published make the necessary changes as needed for the legacy equipment.

POC: PMO Medical Devices, USAMMA, DSN 343-4382.