

SUBJECT: Department of Defense Unique Identification (IUID) Program

PURPOSE: This information paper prescribes Department of the Army policy and responsibilities for Item Unique Identification (IUID) which includes planning, acquiring, and sustaining IUID for Army managed items. This policy implements key provisions of Department of Defense Directive (DODD) 8320.03 and Department of Defense Instruction (DODI) 8320.04.

BACKGROUND: The Draft Army IUID Strategy, Jul 08, and the memorandum from the Acting USD (AT&L) dated 29 July 2003, entitled Policy for Unique Identification (IUID) 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 USAMMA has established a working group to utilize a team approach in coordinating related activities for the implementation of the program in TEWELS. 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 IUID 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 IUID 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;
 - a. 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;
 - b. When the Government's unit acquisition cost is less than \$5,000 and the requiring activity determines that permanent identification is required;
 - c. 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. 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 IUID guidance and the FFD&CA / FDA regulatory guidance, the FFD&CA and FDA guidance shall take precedence.

RECOMMENDATION: It is clear that IUDI 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 IUID initiative, following the DFARS regulation and procure new equipment with IUID labeling. Continue to plan and mark legacy medical equipment with IUID labels. When the FDA UDI guidance is published make the necessary changes as needed for the legacy equipment. The following procedures must be followed for marking any original data labeled item under these guidelines:

a. If the non-critical item being procured or repaired includes a data label as a part of its design, the procurement or maintenance activity shall require that the data label conforms to the technical requirements for generating and affixing data labels for that item in accordance with the IUID requirements of MIL-STD-130N (or later version). "Label" (also known as a "data plate," "name plate," "identification plate," etc.) is defined in subparagraph 3.34 of MIL-STD-130N.

b. A new data label to replace the original data label is not required when sufficient space exists on the original data label to add a compliant IUID data matrix provided that the following requirements are met:

(1) The method(s) to incorporate the compliant IUID data matrix on the original data label shall meet the requirements of MIL-STD-130N (or later version), paragraphs 4.1 thru 4.7, conform to the appropriate recommended marking method(s) in Table II, and be consistent with the selection criteria in Table III of the standard.

(2) If an additive data label is to be used to apply the 2-D data matrix mark to the original data label, then any such addition shall also meet the requirements of MIL-STD-130N (or later version), paragraphs 4.1 thru 4.7, conform to the appropriate recommended marking method(s) in Table II, and be consistent with the selection criteria in Table III of the standard.

c. When an IUID-compliant new data label is necessary to replace the original data label, the following requirements apply:

(1) The original data label and any associated adhesive or hardware shall be completely removed.

(2) The new data label shall meet the following criteria:

(a) To accommodate the addition of the IUID data matrix in accordance with MIL-STD-130N (or later version), information on the new replacement data label may be re-sized

and/or repositioned anywhere on the new data label provided that the permanency and legibility requirements of paragraph 4.3 of MIL-STD-130N (or later version) are met.

(b) The new data label shall have the same dimensions as the original data label.

(c) The new data label shall be placed in the same location as the original data label.

(d) The new data label shall be made of the same material as the original data label.

(e) The new data label shall be marked and affixed on the item to meet the requirements of 577 MIL-STD-130N (or later version), paragraphs 4.1 thru 4.7, conform to the appropriate recommended marking method(s) in Table II, and be consistent with the selection criteria in Table III of the standard 580

d. The addition of data labels outside the original data label footprint on the item is not authorized.

POC: PMO Medical Devices, USAMMA, DSN 343-1891.