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Ms. Michele Peterson  
Defense Acquisition Regulations Council  
OUSD(AT&L)DPAP(DAR)  
IMD 3C132  
3062 Defense Pentagon  
Washington, DC 20301-3062

Ref: DFARS Case 2004-D011 – Defense Federal Acquisition Regulation Supplement; Radio Frequency Identification

Ms. Peterson:

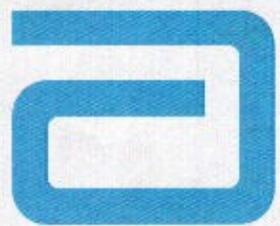
Abbott is very pleased to have the opportunity to provide comments on the Defense Federal Acquisition Regulation Supplement; Radio Frequency Identification published on April 21, 2005 in the *Federal Register*.

We thank the Department of Defense for your consideration of our comments. We recognize that pharmaceuticals and medical devices are not included in the scope of this proposed rule. However in anticipation of future requirements for products that impact our business we took the opportunity to provide feedback on the five questions posed in the Federal Register notice as well as included a few general remarks. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,

Richard M. Johnson  
Director, Quality Center of Excellence  
Corporate Regulatory & Quality Science

Encl: Comments



**COMMENTS:**

Below are Abbott's responses to the five questions of particular interest to the DoD:

**1. The definitions of the terms "case" and "palletized unit load" and their use throughout the rule.**

Abbott proposes the following clarifications of definition of case and pallet:

Case: A single package or container that contains a pre- determined quantity of a specific item or multiple items associated with an order packaged together. The RFID tag applied to the single unit will associate the EPC code to the list of items inside the case.

Pallet: A carrier, skid or other portable platform that contains multiple cases that is distributed as a unit. The RFID tag affixed to the pallet will associate the EPC code to the case RFID tags contained on the palletized unit.

**2. The impact of providing electronic advance shipment notice (ASN) information.**

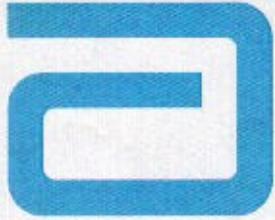
a) There is considerable anxiety about the ability to meet the requirements of the ASN.

- Most of the data included in the ASN is not RFID tag data.
- The Wide Area Work Flow Interface Control Document – Appendix R – 856 – WAWF EDI Implementation Guide is asking for information that is not currently retained in our system. This will require significant additional systems changes, as well as Customer Service process changes to enter a DoD order.
- This specification document implies that the RFID tagging and reporting is done at the catalog number level (i.e., the part number listed on the Government Delivery Order against one of the contracts). Some packaging occurs at the pickable level. All the components of the same catalog number may not be in the same case. The Wide Area Work Flow Interface Control Document – Appendix R – 856 – WAWF EDI Implementation Guide only seems to allow for tags reported at the catalog part number level.

Proposed Change: This needs further clarification to allow for data to be submitted at the pickable level.

b) All DoD Purchase Orders are not sent via EDI today to Abbott. Sending an EDI MIRR would be much simpler if all DoD orders were submitted EDI. Many of the MIRR fields would already exist from an EDI submission of the Purchase Order/Government Delivery Order. The MIRR would be a return of that Purchase Order/Government Delivery Order information plus the RFID tag data.

Proposed Change: Convert DoD orders to EDI submissions only.



c) Currently in WAWF, an entire ASN MIRR will be rejected if any required field value is not what is expected. The rejection of the entire ASN for any data field issue may prevent the ASN from being received prior to the receipt of the material.

Proposed Change: Reject only affected lines.

d) Through review of some contracts, the DoD provides their own set of line numbers for vendor products as specified in the contract and not those established by the vendor. This may be an issue in the development of the ASN and providing the correct data.

Proposed Change: Use of common line numbers that are designated by the vendor.

e) Direct shipment of pharmaceutical products to the DoD is not always provided by the drug manufacturer's distribution center. Drug distribution may be facilitated through a pharmaceutical distribution entity. The relationship between the drug distributor and the drug manufacturer must be considered during contract negotiations. If distribution of pharmaceuticals is changed by the use of RFID systems, manufacturers without current systems for supplying DoD with ASN notification will require internal system modifications to assure compliance with the requirements (if direct shipments to the DoD are incurred).

Proposal: More time is needed to research and clearly understand the content of the ASN requirements (notification timing, method of notification, system integration requirements, ensuring precise data is submitted, vendor/distributor involvement, remediation for when the ASN may differ from the shipment, etc.).

### **3. Whether small business considerations have been fully addressed in the regulatory flexibility analysis.**

Not applicable.

### **4. Scientific, industry, or manufacturing based evidence from changes or additions to packaging or package systems in order to assess the possible impact, if any, on the environment and materials recycling, including corrugated, metal, and plastic shipping containers and pallets.**

Even though industry has somewhat embraced this technology there are still questions regarding the long-term effect of RF. Current data suggests there are less concerns with RF than with microwave. However, agencies such as the FDA have not yet taken a stand on the effects of RF on biologics and medical products, therefore the burden of proof is left upon each individual vendor.

It is intended that non-removable, passive tag RFID label stock (with embedded antenna) will be affixed to shipped pallets and individual cases similar as is done today with bar-coded labels. Recycling of passive RFID tags with metallic based antenna labels affixed to pallet units or item case is not intended based on initial packaging evaluation studies (specifically, silver based antenna). It is recognized that based on passive RFID tag antenna materials and accumulated quantities, special handling at the end use point may be required. Direction may be needed to address newer packaging impact on the environment.

Proposal: More guidance needs to be given on the effects, if any, on medical products, environment and other areas that use this technology as well as the handling of this material throughout the supply chain.



## **5. What are the options for minimizing and mitigating the impacts on the materials recycling process from the use of RFID tags on shipping containers and pallets?**

As previously stated, recycling of passive RFID tags with metallic based antenna labels, which are affixed to pallet units or item cases, is not intended based on initial packaging evaluation studies (specifically, silver based antenna). As a product supplier, we would not intend to facilitate material recycling through the return of passive case and pallet RFID tags.

Guidance needs to be provided to the end user on the ability and method to recycle these materials.

### **GENERAL COMMENTS:**

Readability distance may vary based on equipment used, type of material and other factors that effect RF. MIL-STD-129 has defined requirements for placement of tags on the pallet and case. This requirement may not be met for certain types of materials, liquids, metals, etc. We recommend the DoD make allowances for tag placement that best suits the material being tagged.

MIL-STD-129 also states a requirement for the tag to be readable at the time of shipment. Guidance is needed if the tag is damaged in transit or just simply not readable at the time of receipt.

The destruction of the RFID label after product delivery is a concern. Clear guidance has not been given on killing tags to ensure they do not resurface or are used to transport material other than the intended product. There needs to be assurance for when shipping materials are recycled or discarded, that previously assigned RFID information not be mistakenly re-used to identify another shipment or configuration of materials. An understanding of the DoD approach to handling passive RFID tags would be needed to assure systems support the intended post use handling of the tags.

It is not clearly outlined if (or which) pharmaceutical drug product(s) may require UID numbers affixed to the unit containers (bottles of tablets, solution, capsules, etc). The addition of an RFID tag on a small bottle containing a serialized identifier would be difficult at a local distribution center and may need consideration at the manufacturer.

Clear understanding of pharmaceutical product flow from the product manufacturer, to an authorized pharmaceutical distribution center, and finally to a DoD depot or warehouse must be considered in order to manage the impact of RFID tagging of cases and pallets when product is not directly shipped to DoD facilities. At this time, there are no clear contractual requirements between pharmaceutical DC centers and manufacturers regarding RFID tagging needs. The responsibility of providing ASN's and case/pallet RFID tags would reside with the pharmaceutical distribution entity. Original packaging of cases and pallets from the manufacturer may change at the DC since these deliveries are not dedicated for DoD orders but are stocking orders for multiple customers.

Very limited guidance has been made available regarding the impact analysis requirements for pharmaceutical and medical materials (products). It is currently understood from FDA guidance that biological pharmaceutical materials are not to be included in RFID pilot studies until further regulatory review is completed and further guidance is provided. Would the DoD guidance provide similar concerns?