

**BY ORDER OF THE COMMANDER  
59TH MEDICAL WING**

**59TH MEDICAL WING INSTRUCTION  
41-205**



**13 MAY 2016**

**Health Services**

**USER TESTS OF SUPPLIES AND  
EQUIPMENT**

**COMPLIANCE WITH THIS PUBLICATION IS MANDATORY**

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(Lt Col Stephanie Dusza)

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This instruction implements Air Force Policy Directive 41-2, *Medical Support*. This instruction establishes policies and procedures for obtaining approval for and conducting user tests of medical supplies and equipment. By following these guidelines, the 59th Medical Wing (59 MDW) activities interested in conducting user tests will avoid violating the Federal Acquisition Regulation, provide for adequate in-servicing of the products under evaluation, and protect 59 MDW from product liability during the test. This publication applies to all personnel assigned, attached or under contract to the 59 MDW, with the exception of 959th personnel. This instruction does not apply to the Air National Guard or Air Force Reserve. The authority to waive requirements is the publication approval authority. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with (IAW) Air Force Manual 33-363, *Management of Records*, and disposed of IAW Air Force Records Information Management System Records Disposition Schedule.

**SUMMARY OF CHANGES**

This publication has been revised. This rewrite of 59 MDWI 41-205 includes changing the Safe Medical Device Act of 1990 to the FDA Modernization Act (FDAMA) of 1997.

## **1. General.**

1.1. User tests are meant to determine whether an item meets the needs of a specific activity. Often, it is difficult to ascertain the effectiveness and functionality of an item based solely on the product literature. In those instances, it is necessary to conduct a user test.

1.2. User tests are often time consuming and expensive. Consequently, their use should be reserved for equipment and supply acquisitions involving multiple users, extensive operating and maintenance expenditures, or complex products requiring detailed training and in-servicing.

## **2. Exclusions.**

2.1. Products under development by a manufacturer and not available for purchase are prohibited from being user tested unless the test is a part of a research project approved by the Office of the Surgeon General.

2.2. Arrangements established with vendors in which equipment is provided to the hospital at no cost when we agree to purchase consumable supplies with the equipment, are not user tests. Such agreements are established only by contracting officers authorized to act on behalf of the government. Refer these types of requests to the Acquisitions Section of Medical Materiel Flight.

## **3. Statement of Understanding (SOU) ([Attachment 3](#)).**

3.1. The SOU must be completed before taking possession of equipment or supplies for a user test. It may be possible to preclude a user test by reviewing the manufacturer's literature on equipment models to determine whether they meet the user's minimum essential characteristics. Care should be taken to ensure that informal user tests are not abused. User tests are not a convenient or rapid means to circumvent the acquisition process. These tests should be used only on a temporary basis (generally 30 days or less and should not exceed 90 days).

## **4. Testing.**

4.1. In order for a user test to be valid the user must submit the request to the respective Group Medical Equipment Management Office (MEMO) for it to be routed and approved by Medical Equipment Repair Center before the delivery and start date of the test can be arranged with the vendor.

4.2. If equipment is to be tested, MEMO notifies Biomedical Equipment Maintenance about when the vendor will deliver the equipment. Upon arrival, and prior to beginning the user test, a biomedical equipment maintenance technician inspects the equipment and signs the SOU. During the initial inspection, the biomedical equipment maintenance technician will identify whether the item to be tested is covered by the FDAMA of 1997 and any implementation guidance. If so, the vendor will be responsible for making appropriate notifications to ensure compliance with the act and will provide Logistics with copies of the notification letters.

4.3. The vendor is responsible for training all test site users on the operation of the equipment. The coordinator maintains a list of attendees.

4.4. The test is conducted with the product evaluation documentation annotated during the test.

4.5. If equipment or a durable supply has been tested, the coordinator arranges for return of the item or items to the vendor, and prepares a return document following each test (Attachment 2). The coordinator delivers the return document to MEMO.

**5. Purchase.**

5.1. If a decision is made to purchase the equipment or supply item after the user test, the designated custodian works with MEMO to prepare a complete equipment request package.

MICHAEL W. GLASS, Colonel, MSC, USAF  
Administrator, 59th Medical Wing

**Attachment 1****GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION*****References***

AFPD 41-2, *Medical Support*, 28 June 2013

AFI 41-209, *Medical Logistics Support*, 6 October 2014

*FDA Modernization Act (FDAMA) of 1997*

***Adopted Form***

AF Form 847, *Recommendation for Change of Publication*

***Abbreviations and Acronyms***

**FDAMA**—FDA Modernization Act

**IAW**—In Accordance With

**MDW**—Medical Wing

**MEMO**—Medical Equipment Management Office

**SOU**—Statement of Understanding

***Terms***

**Medical Equipment**—A medical item that has a life expectancy of five years or more, maintains its identity when in use, and costs more than \$2,500.

**Medical Supplies**—Medical items consumed through normal use and durable medical items costing \$2,500 or less.

**Attachment 2**  
**LOANED EQUIPMENT**

**Figure A2.1. Statement of Understanding Return Documentation.**

(Company/Source Name - Address -- Phone #)

Acknowledges return of: \_\_\_\_\_

(List the equipment to be returned)

\*Which was provided to 59 MDW for the purpose as states in agreement dated \_\_\_\_\_.

"Attach copy of original Product Evaluation-Statement of Understanding".

\_\_\_\_\_  
(Vendor's Authorized Representative)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Using Activity Representative)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Medical Logistics Representative)

\_\_\_\_\_  
(Date)

Attachment 3

WILFORD HALL AMBULATORY SURGICAL CENTER PRODUCT EVALUATION

Figure A3.1. Statement of Understanding.

The \_\_\_\_\_ (Name and Address of Manufacturer), hereinafter called Vendor, shall provide to 59 MDW, hereinafter called the Government, for the purpose of an informal user evaluation of the property:

\_\_\_\_\_  
(Name of property to be evaluated)

The Vendor shall provide the property at no cost to the Government. Vendor shall bear all expenses for transportation, installation, removal, operational supplies, and repair parts. The Vendor shall be responsible for scheduled and unscheduled maintenance of the property. If repair service is unavailable or inconvenient, Vendor may authorize Air Force biomedical equipment technicians perform the maintenance. Vendor understands that this evaluation is without monetary consideration for the use of the property. It is for evaluation only and does not obligate the Government to purchase the property or any other products or services at the present or any future time.

Vendor will deliver the property on or about \_\_\_\_\_. The Government may evaluate the property for a period of \_\_\_\_\_ days. (90 day limit). The Government agrees to use the property for evaluation only and to use the property in an environment and under circumstances consistent with the property’s design and intended use. The Government further agrees to provide reasonable care and safeguard of the property while it is in the Government’s possession. Vendor and the Government understand that the results of the evaluation may not be used as an endorsement by the Government of the property or the Vendor and may not be used for promotional purposes.

Vendor will indemnify, save harmless, and forever defend the Government from and against any and all claims, actions, debts, liabilities and attorney’s fees arising out of, claimed on account of, or in any manner predicated upon loss of, or damage to the property of, or injuries to, or death of any and all persons whatsoever, in any manner caused by or attributed to Vendor, his agents, servants, or employees while in, on or about the 59 MDW or attributed to the failure or malfunction of the property provided by Vendor during the period of the Government’s use, test, or evaluation of the property.

Endorsements of Authorized Representatives: (Print Name, Sign, and Date)

\_\_\_\_\_  
(Vendor’s Authorized Representative)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Using Activity Representative – Account # - Phone #)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Legal Office Representative, 292-7808, WHASC, 7th floor, Rm 7A65)

\_\_\_\_\_  
(Date)

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(Contracting Representative, 671-0929, 1655 Selfridge Ave, LAFB)

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(Date)

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(Medical Logistics Representative, 292-6405, WHASC, Basement Rm BM10)

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(Date)

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(Medical Maintenance Representative, 292-5103, WHASC, Basement Rm BM10)  
(For equipment only)

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(Date)