



# THE AFMLL

## The Air Force Medical Logistics Letter *Leading Focused, Full Spectrum, Integrated Logistics - Worldwide*



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Air Force Medical Logistics Office  
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### WEB CORNER

*The AFML Web Corner is designed to inform our customers of information available on the AFMLO home page. Check out our home page and contact us with any questions and/or suggestions.*

### Commander's War Reserve Materiel (WRM) Enabling Guide

The Commander's War Reserve Materiel (WRM) Enabling Guide was developed by AFMLO/FOC-A to address recent audit and inspection findings and to provide information on the important logistics tasks associated with maintaining readiness capabilities. Findings indicate that our WRM may not be receiving the attention it should in the areas of quality control, capability, and accountability. The complete guide can be found on the AFMLO web site at <https://afml.ft-detrick.af.mil/afmlo/Readiness.htm>. Contact Mr. Dale Lyons at DSN 343-4017 with any questions. (AFMLO/FOC-A, Mr. Dale Lyons, DSN 343-4017, commercial 301-619-4017, [dale.lyons@ft-detrick.af.mil](mailto:dale.lyons@ft-detrick.af.mil))

Web site point of contact: Mr. Lynn Elspas  
Commercial: 301-619-4130  
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E-mail: [Webmaster@ft-detrick.af.mil](mailto:Webmaster@ft-detrick.af.mil)

### From the Log Chief...A Personal Message To Supervisors And Subordinates.

Being responsible for one or more people makes you a supervisor. Being a supervisor makes you one of the most important people in the Air Force. Being a subordinate just means you have a boss, and who doesn't fit in that category? It also means you are responsible for getting the job done, making you one of the most important people in the Air Force. Whether supervisor or subordinate,

you are charged with getting the mission accomplished, and that is an awesome responsibility. While I originally aimed this article at first-line supervisors, it really applies at all levels: airman, NCO, officer and civilian equivalents.

As a supervisor, you are constantly in the spotlight. Your subordinates look up to you, your superiors expect results from you, and your peers are curious to see what works for you that they might apply to their work setting.

Your daily actions have both long and short-term implications for your duty section and the Air Force. The example you set will not only impact what goes on in your work area now, but will be the basis for the developing supervisory skills of your troops.

I talk to a broad cross-section of people when I visit logistics activities around the world. I meet with airmen, NCOs and officers in separate groups to get some first-hand feedback on how they perceive the world. Every place I go, I hear about and see all the great work you are doing. While most of what I hear is positive, there are some common themes I hear about that we need to work on together.

Many officers and NCOs tell me they are overworked, under appreciated, and are unhappy with the quality of their airmen. Many airmen (and we are all airmen) tell me they are not being sufficiently trained, are under appreciated, and want to contribute more. Seems like there might be some common ground to exploit here.

Knowing there are two sides to every story, I asked one of the airmen to get me his training record. There wasn't a single entry in it from his current supervisor! When I asked the supervisor about it, he was obviously embarrassed, but said quite frankly that while training had been done, he hadn't had time to document it.

The result: two people who were working at less than full potential. And, given the possibility that an untrained or insufficiently trained airman might check in a damaged hazardous item, the possibility for multiple dangerous scenarios was apparent.

Back to that in a minute. Meantime, consider this...everybody has a boss. I know I am more effective and more productive when my boss tells me what he expects and gives me feedback on how I am doing. I doubt any of you would disagree that you want to know what your boss expects and want to know how he or she perceives your performance. Your airmen tell me they are no different. They want to know what you expect and how they are doing.

Trust me...no matter how busy you are, it is worth the time to provide them with both training and feedback. It is worth both your time and theirs. In some cases, supervisors might not feel up to the task. They might not feel like they know enough to train their team members. Again, trust me...in almost every case you know more than they do and what you don't know, you can learn together. Even if you have retrained into a Logistics specialty or are returning after a lengthy absence, you bring experience to the table your subordinates do not have. And for what you don't know, there is a wealth of experience out there. Your supervisory chain, MAJCOM staffs, AFMLO, the Air Staff, subordinates, peers and superiors in other accounts, are all resources at your disposal...most of whom would be flattered to be asked for help!

So...carve out the time, pull out those training records, sit down with each of the people on your team, and go over the tasks in the CFETP they are expected to perform. Ensure they understand and are trained to do each one. If they aren't, identify each "task for training" and follow it through certification. If nothing else happens, you will at least have opened the door for some healthy dialogue. Encourage feedback from your team members.

If you are reading this and are not a supervisor, consider this. Training is a two-way street. Show some interest by asking your boss to go over your training record with you. If nothing else happens, you will at least have opened the door for some healthy dialogue. Ask your boss how he or she thinks you are doing and what you could do better.

Bet you can see some common ground here whether you are a supervisor or a subordinate.

The stock market may not be doing much these days, but an investment in your troops and their training will result in phenomenal returns! Try it, and drop me a note about what happens. And believe this...the career field managers and I will ask when we come to visit. (Colonel Moreland, HQ USAF/SGML, DSN 343-2005, commercial 301-619-2005, jim.moreland@ft-detrick.af.mil)

## MEDICAL MATERIEL

### Allowance Standard (AS) Updates

**Attachment 4** contains AS updates. Changes are the result of cataloging actions to replace Acquisition Advice Code "V" and "Y" NSNs and changes generated by the OPR. These changes are provided to update your WRM records. Remember to establish prime-sub relationships when applicable. Use the information in the "Add" and "Replaced" portion of the change document to determine the need for prime-sub relationships. If an NSN is replaced and there are on-hand balances, a prime-sub relationship should be established. Adjust WRM levels on NSNs listed as "Add" or "Delete." If you have any questions or concerns, contact the appropriate AS manager. A list of the AS managers and the current version of each AS is available on the AFMLO web site at <https://afml.ft-detrick.af.mil>. Only minor changes are contained in this attachment and no SORTS reporting option is required. Any SORTS reporting option required as a result of a major AS change will be provided in the Transition Plan coordinated between the Pilot Unit, MEFPAK, and HQ USAF/SGXR. Additionally, you may sign up to receive

electronic notification of changes to AS maintained at your account. To do so, click on the Medical Readiness and subscribe to List Server for AS Changes options on the AFMLO web site at <https://afml.ft-detrick.af.mil>. (AFMLO/FOC-D, Ms. Anne Newcomer, DSN 343-4118, commercial 301-619-4118, anne.newcomer@ft-detrick.af.mil)

### Electronic Catalog (ECAT) Program Correction

Reference article published in AFMLL 12-00, "Electronic Catalog (ECAT) Program," there is a correction to the first paragraph. Delete sentence beginning with "you will need a login ID and password before access is granted." (AFMLO/FOM-P, Ms. Charlotte Christian, DSN 343-4164, commercial 301-619-4164, charlotte.christian@ft-detrick.af.mil)

### Electronic Catalog (ECAT) Status List

Once you begin ordering through the Electronic Catalog (ECAT), it is important to verify that status has been received and posted for your ECAT requisition(s). Since MEDLOG processes ECAT requisitions the same way as depot MILSTRIP requisitions, status supply codes will be similar. The Defense Supply Center Philadelphia (DSCP) will furnish either "BD" or "BV" confirmation in the form of an "AB1" status image when the materiel is under contract for direct vendor delivery. As a result of processing, MEDLOG generates the ECAT Receiving Report (PCN SI008-W21). This report lists those items that have a contract/call number assigned. DSCP can also provide cancellation status, i.e., CB, CG, or CX. Cancellation actions will be reflected on

The AFMLL is a specialized newsletter published by the Air Force Medical Logistics Office. The AFMLL is published monthly to provide medical logistics information to Air Force medical activities worldwide. Our mission is to ensure all Air Force medical treatment facilities receive the highest level of medical logistics support. In that regard, we solicit your articles for inclusion in the AFMLL to relay information for use by other activities. For additional information concerning this publication, call (301) 619-4182/DSN 343-4182 or write to the AIR FORCE MEDICAL LOGISTICS OFFICE/FOA, ATTN: Donna Poffinberger, 1423 SULTAN DRIVE, SUITE 200, FORT DETRICK, MARYLAND 21702-5006. Articles may be faxed to (301) 619-2557 or DSN 343-2557, or e-mailed to: donna.poffinberger@ft-detrick.af.mil

The use of a name of any specific manufacturer, commercial product, commodity, or service in this publication does not imply endorsement by the Air Force.

Matters requiring AFMLO action after normal duty hours may be referred to the AFMLO Staff Duty Officer. The Staff Duty Officer may be reached at DSN 343-2400 or (301) 619-2400 between the hours of 1630 and 0700 weekdays, and anytime on weekends and holidays.

the Status Action List, Part I (PCN SI008-22). Status can also be viewed on the DSCP web site [medweb.dscp.dla.mil/ecat.html](http://medweb.dscp.dla.mil/ecat.html). To view status from the DSCP web site, click on the status button at the top of the screen. Next, click on the contract number you wish to review. This will bring up a "Summary for Order" screen. For a line-by-line summary of items ordered with current status, go to the bottom of the screen. If you did not receive status and need to follow-up on an ECAT order, contact the DSCP ECAT Help Desk at DSN 444-2443, toll free 800-290-8201 or 800-441-1837, [ecathelp@dscp.dla.mil](mailto:ecathelp@dscp.dla.mil) (AFMLO/FOM-P, Ms. Charlotte Christian, DSN 343-4164, commercial 301-619-4164, [charlotte.christian@ft-detrick.af.mil](mailto:charlotte.christian@ft-detrick.af.mil))

### **Chemically Hardened Air Transportable Hospital (CHATH) Training Aides**

Looking for Chemically Hardened Air Transportable Hospital (CHATH) training aides? The draft CHATH Technical Manual is currently being validated and verified at Warner Robins. There are other CHATH training aides available, including a CHATH training video produced for the 311<sup>th</sup> Health Services Wing by the Lackland Multimedia Production Center at Lackland AFB, TX. To order, log on to the Defense Automated Visual Information System (DAVIS) at <http://dodimagery.afis.osd.mil> or call the Air Force POC at DAVIS, Marie Digenova, DSN 795-6543, FAX 795-6106, or [madigeno@hq.afis.osd.mil](mailto:madigeno@hq.afis.osd.mil). The title of the video is "CHATH USER FAMILIARIZATION," and the Production Identification Number is 613941.

Additionally, the Signal Corporation of Virginia Beach, VA, produced a CHATH training package on CD-ROM. This CD-ROM can be obtained by contacting Capt Randy Smith at ACC/SG, DSN 574-1284, commercial 747-764-1284, [randy.smith@langley.af.mil](mailto:randy.smith@langley.af.mil) (AFMLO/FOC-D, Maj Jerry Roberts, DSN 343-4117, commercial 301-619-4117, [jerry.roberts@ft-detrick.af.mil](mailto:jerry.roberts@ft-detrick.af.mil))

### **Medical Materiel Management Series**

In an effort to expand the knowledge of Air Force Medical Materiel Managers, AFMLO/FOC-A will be generating a series of Medical Logistics Management articles that will be published in the AFMLL beginning this issue. While the information provided is directed to Medical Logistics Flight Chiefs, Superintendents, and NCOICs, this information can benefit all 4A1 career field personnel. Medical Materiel Management articles previously published in the Air Force Medical Logistics Letter tended to be reactive in nature. In an effort to be more proactive, we are offering all medical logistics personnel the opportunity to suggest management topics to be covered. Submit your suggestions to AFMLO/FOC-A, Mr. Dale Lyons, [dale.lyons@ft-detrick.af.mil](mailto:dale.lyons@ft-detrick.af.mil), Mr. Rich Prout, [rich.prout@ft-detrick.af.mil](mailto:rich.prout@ft-detrick.af.mil), MSgt Clif Green, [clifton.green@ft-detrick.af.mil](mailto:clifton.green@ft-detrick.af.mil), or TSgt Waymond Hughes, [waymond.hughes@ft-detrick.af.mil](mailto:waymond.hughes@ft-detrick.af.mil). (AFMLO-FOC-A, TSgt David Harmon, DSN 343-4050, commercial 301-619-4050, [david.harmon@ft-detrick.af.mil](mailto:david.harmon@ft-detrick.af.mil))

#### **Article No. 1: BMSO/BAFO Financial Reconciliation Negative On-Hand Balances**

AFMLO/FOC-A is receiving BMSO/BAFO Financial Reconciliation Lists that reflect negative operating (expendability code 1) inventory balances. These negative balances are caused by Prime Vendor (PV) receipts that have PND (Prime Vendor Summary Receipt) actions pending. To aid in managing delinquent PV due-ins and PND's, MEDLOG provides a PV trouble list, Parts I and II. Part I lists PV due-ins over 3 days old, and Part II lists PV receipts with incomplete PND action. DSCP is required to make payment within 15 days of your receipt of delivery. Payment cannot be made until the PND action is complete and, therefore, it is important that the PND action be completed promptly. Late payments are subject to interest penalties. Logistics Flight Chiefs and Superintendents should be especially vigilant to ensure all PV deliveries are received and summary receipts processed. References for the above information are: AFMAN 23-110, Vol. 5, Chapter 16; AFCSM 41-230, Vol. 2, Section 8.35, 9.22 and 9.23; and

CONUS and OCONUS Prime Vendor Desk References located on the AFMLO web site. (TSgt David Harmon, AFMLO/FOC-A, DSN 343-4050, commercial 301-619-4050, david.harmon@ft-detrick.af.mil)

## Memorandums Of Agreement

In continuing support of the Medical Logisticians in the field, we would like to offer examples of Memorandums of Agreement (MOA) for base support of nonmedical WRM equipment in medical WRM programs. MOAs are suggested for major nonmedical WRM equipment that is inspected and maintained by a base organization per AFMAN 23-110, Vol 5, Ch 15.16.2. Medical logistics retains responsibility for managing medical WRM programs, regardless of the activity servicing the WRM equipment.

Recently, we contacted the MAJCOMs to solicit sample MOAs currently in use at their accounts. We would like to thank the MAJCOMs and bases that responded for their assistance. A special thanks to SSgt Jennifer Ottem and the Kadena AFB logistics staff for their assistance in putting this information together.

The MOA samples are available through the Medical Readiness and CME Documents and Products options on the AFMLO web site at <https://afml.ft-detrick.af.mil>. (AFMLO/FOC-O, TSgt Waymond Hughes, DSN 343-6854, commercial 301-619-6854, waymond.hughes@ft-detrick.af.mil)

## USAF Medical Logistics Directory *January 2001 Edition*

**Attachment 6** is the January 2001 issue of the USAF Medical Logistics Directory (Bluebook). It is also available on the AFMLO web site, <https://www.afml.ft-detrick.af.mil>. (AFMLO/FOA, Mrs. Sarah Ring, DSN 343-4153, commercial 301-619-4153, sarah.ring@ft-detrick.af.mil)

## Current Status of Decentralized Blanket Purchase Agreements (DBPAs)

Pages 1 through 81 of **Attachment 3** contain the quarterly updated list of DBPAs. Pages 82 through 84 contain an alphabetic cross-reference for the current DBPAs, while pages 85 through 88 provide a category reference. A Routing Identifier Code (RIC) is included as pages 89 through 91. The DBPA Program includes DBPAs negotiated by DSCP, the Veterans Affairs (VA), National Acquisition Center, and the AFMLO/VA Special Services (VASS).

### DBPA Purchases for FY 00

The annual DBPA Survey Report for FY 00 was completed. There were 388 active DBPAs: 217 DSCP DBPAs, 152 VANAC DBPAs, and 19 AFMLO VASS DBPAs. We received 100 percent response to this survey from 86 Medical Logistics facilities authorized to use the DBPAs. There were 23 facilities that reported zero usage against the DBPAs. The DBPA purchases dropped approximately \$2.9M compared to FY 99. This was mainly due to increase in Prime Vendor sales and more usage of the IMPAC credit card. We could see a further drop in DBPA usage in FY 01 due to the implementation of ECAT. A summary of the DBPA purchases for FY 00 is listed below.

#### Purchases Made By Medical Logistics Facilities

	Total Calls	Total Dollars
DSCP	12,958	\$16,589,249.09
VANAC	7,940	8,567,725.60
AFMLO VASS	10	27,194.83
TOTAL	20,908	\$25,184,169.52

Purchases made by the AFMLO VASS Contracting Office:

\$16,041,000.00

Total DBPA purchases for FY 00:

\$41,225,169.52

## New Agreements

The DBPAs listed below were negotiated by DSCP. A copy has been forwarded to the Defense Logistics Information Service (DLIS) for publication in the Universal Data Repository (UDR).

(SP0200-01-A) <u>DLA120-01-A-</u>	<u>Vendor:</u>	<u>RID:</u>
8549	Kreiser's Inc.	LKM
9303	Lensco	LLM

## Agreement Modifications

The DBPA modifications listed below were issued by DSCP. Copies of these modifications were forwarded to DLIS for inclusion in the UDR.

(SP0200-01-A) <u>DLA120-01-A-</u>	<u>Vendor:</u>	<u>MOD To:</u>
8547	Di-Verse Medical Services, Inc.	Cancel DBPA

The DBPA modifications listed below were issued by the VANAC. Copies of these modifications were forwarded to DLIS for inclusion in the UDR.

<u>VA0200-01-A-</u>	<u>Vendor:</u>	<u>MOD To:</u>
9237	Columbia Diagnostics, Inc.	Change vendor's address
9493	Smith & Nephew, Inc.	Change vendor's name

## AFMLO VASS DBPAs Awarded to Date

### VAO797-98/ 99/00-:

A0011	Getinge/Castle Inc	LGX
A0012	Hewlett Packard Heartstream, Inc.	LIV
A0016	Science Application Int'l Corp.	LJN
A0017	Northrop Grumman Corp.	LXY
A0019	Protocol Systems, Inc.	LNY
A0020	Dynanet Corp	LUP
A0021	Computer Technology Associates, Inc.	LKO
A0023	Management Systems Designers, Inc.	LVI
A0031	Comteq Federal, Inc.	LWZ
A0032	Swank Healthcare Services	LJM
A0033	IGov.com	LVL
A0037	McAdams Technologies, Inc.	LXD
A0039	Primedia Workplace Learning , Health & Sciences	LNO
A0041	Sherikon, Inc.	LX
A0042	Essex Cryogenics of Mo., Inc.	LXG

A0043	Telescience Int'l, Inc.	LXJ
A0044	Aseptico, Inc.	LXH
A0045	Jahn Corporation	LXI
A0046	Government Marketing Int'l	LXK

## FY 01 Expired or Cancelled DBPAs

<u>DBPA #:</u>	<u>Vendor:</u>	<u>Eff Date</u>
VA0200-01-A-4004	Creighton Pharm., Corp.	17 Oct 00
SP0200-01-A-9314	FIC Corp.	20 Oct 00
SP0200-01-A-8544	TP Orthodontics, Inc.	4 Nov 00
SP0200-01-A-8547	Di-Verse Medical Services, Inc.	1 Dec 00

## Active SPO Agreements

Agreements converted to SPO200-01-A are listed numerically below.

8501	8502	8503	8505	8506	8510	8511	8513	8514
8516	8517	8518	8520	8526	8532	8533	8539	8540
8542	8545	8548	8549	8552	8553	8555	8557	8558
8559	8560	8563	8565	8567	8569	8570	8572	8573
8574	8575	8583	8584	8587	8588	8589	8590	8591
8592	8595	8596	8597	8598	8600	8601	8602	8603
8604	8606	8607	8608	8609	8611	8613	8614	8615
8616	8617	8618	8619	8620	8621	8622	8623	9013
9018	9019	9022	9026	9027	9028	9029	9030	9038
9048	9052	9056	9057	9061	9068	9073	9074	9077
9081	9084	9085	9086	9094	9095	9099	9114	9125
9129	9133	9138	9139	9141	9145	9146	9147	9149
9158	9159	9166	9169	9172	9184	9189	9209	9217
9224	9227	9232	9233	9235	9236	9238	9242	9243
9244	9245	9246	9250	9252	9255	9259	9266	9274
9275	9276	9281	9284	9287	9288	9289	9299	9300
9303	9304	9319	9321	9322	9329	9331	9353	9360
9363	9369	9370	9377	9380	9383	9385	9390	9391
9411	9416	9420	9425	9444	9453	9465	9469	9485
9487	9488	9497	9499	9500				

## Active VA0 Agreements

VA0 Agreements are listed numerically below as VA0200-01-A-

4000	4003	4005	4006	4011	4013	4014	4017	4018
4019	4021	4022	4023	4024	4025	4026	4027	4028
4029	4030	4031	4032	4033	4034	4038	4044	4049
4051	4052	4053	4057	8507	8508	8509	8528	8535
8536	8537	8543	8546	8562	9002	9005	9006	9009
9014	9017	9020	9021	9032	9035	9042	9049	9052
9059	9072	9090	9104	9108	9111	9122	9132	9134
9136	9152	9155	9156	9160	9161	9162	9164	9167
9170	9175	9182	9185	9186	9187	9195	9198	9202
9204	9207	9210	9211	9212	9215	9219	9220	9221
9225	9228	9237	9239	9247	9253	9256	9269	9271
9278	9285	9290	9293	9296	9309	9311	9316	9317

9318 9320 9323 9325 9327 9338 9343 9350 9356  
9357 9364 9378 9385 9388 9397 9402 9405 9409  
9413 9414 9419 9423 9427 9430 9434 9435 9436  
9437 9438 9439 9440 9441 9448 9452 9484 9492  
9493 9494 9496

(AFMLO/FOM-P, Ms. Charlotte Christian, DSN  
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## Information

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### Medical Logistics in Action

Headquarters, Air Force Medical Support Agency (HQ AFMSA) and the Air Force Medical Logistics Office (AFMLO) extend sincere congratulations to the personnel named below for their outstanding achievements.

#### 17<sup>th</sup> MDG Goodfellow AFB, TX

**MSgt Alan Long** was selected the 17<sup>th</sup> MDG Senior Noncommissioned Officer of the Quarter, Jul-Sep 00. **TSgt Armando Oakes** was selected the Quality Assurance Evaluator of the Year for the 17<sup>th</sup> TRW and Goodfellow AFB, TX. **Mr. Wayne Jones** was selected the 17<sup>th</sup> MDG Civilian of the Quarter, Jul-Sep 00.

#### 27<sup>th</sup> MDG Cannon AFB, NM

**Ashley Worthy** was promoted to **Airman** and **Rose Norcisa** was promoted to **Airman 1<sup>st</sup> Class**. **AIC Arturo Macabalitao** was selected the 27<sup>th</sup> MDSS Airman of the Quarter, Jul-Sep 00. **SSgt Kathy Smith** was selected the 27<sup>th</sup> MDSS and 27<sup>th</sup> MDG Noncommissioned Officer of the Quarter, Jul-Sep 00. **Mr. Larry Claypoole** was selected the 27<sup>th</sup> MDG Civilian of the Quarter, Category II, Jul-Sep 00. **1Lt Victor Weeden** was selected the

27<sup>th</sup> MDSS and 27<sup>th</sup> MDG Company Grade Officer of the Quarter, Jul-Sep 00. The 27<sup>th</sup> MDG Logistics Flight was selected as the Air Combat Command Category III Account of the Year for 2000.

#### 28<sup>th</sup> MDSS Ellsworth AFB, SD

**Charles S. Yates** was promoted to **Technical Sergeant**.

#### 49<sup>th</sup> MDG Holloman AFB, NM

**Crystal Nelson** was promoted to **Airman 1<sup>st</sup> Class**.

#### 60<sup>th</sup> MDSS Travis AFB, CA

**Stephen M. Wright** was promoted to **Chief Master Sergeant**. **Shannondoah A. Rodriguez** was promoted to **Staff Sergeant**. **Maxwell B. Tinsley** and **Consueloannette M. Vazquez** were promoted to **Senior Airman**. **Holly J. Edwards** was promoted to **Airman**. **Mr. Dan Andersen** was selected the 60<sup>th</sup> MDSS Civilian Manager of the Quarter, Oct-Dec 00. **SrA Darrell C. Buckalew** was awarded certification by the International Certification Commission as Biomedical Equipment Technician.

#### 86<sup>th</sup> MDSS Ramstein AB, GE

**Marygail Harris** and **Gene Goodson** were promoted to **Staff Sergeant**. **Okokon Ubong** was promoted to **Airman 1<sup>st</sup> Class** and **Aimee J. Robson** was promoted to **Senior Airman**. **Rosemarie Spiel** was selected as the 86<sup>th</sup> MDG Civilian of the Year, 2000

**MSgt Jose G. Alfaro** and **SSgt David Bethune** were awarded the Air Force Commendation Medal for outstanding achievement in support of MEDFLAG 00-1, Operation BRILLIANT

LION/NJAMOU Cameroon 2000. **SSgt Gene C. Goodson, SrA Kevin J. Hutcherson, SrA Stephen W. Rushing II, and SrA Rowanna L. Loveless** were awarded the Air Force Achievement Medal for outstanding achievement in support of MEDFLAG 00-1, Operation BRILLIANT LION/NJAMOU Cameroon 2000. **MSgt Jose G. Alfaro, SSgt David Bethune, SSgt Margaret McHugh, SSgt Jeffrey N. Thompson, SSgt Leo P. De Los Santos, SSgt Gene C. Goodson, and SrA Marygail Harris** were awarded the Air Force Achievement Medal for outstanding achievement in support of Operation ALLIED FORCE.

**51<sup>st</sup> Contingency Hospital  
Kimhae AB, KO**

**James Brown** was promoted to **Staff Sergeant**.

**384<sup>th</sup> Training Squadron  
Sheppard AFB, TX**

The following personnel graduated from the Medical Materiel Apprentice Course, J3ABR4A131 002. Top graduate is denoted by an asterisk (\*). Distinguished graduate is denoted by a plus sign (+).

Class: 06 Nov 00  
Graduation Date: 12 Dec 00  
Instructor: SSgt Shannon Breeden

NAME	RANK	ASSIGNMENT
Balsamo, Gabriela	AB	Lackland AFB, TX
Dawkins, Nakeisha	AB	Lackland AFB, TX
Estrella, Juan M.	AB	Andrews AFB, MD
Foster, Stacy L. *	SrA	Minneapolis-St. Paul IAP, MN AFRES
Gratz, Ivory B.	AB	Lackland AFB, TX
Johnson, Siobhan S.	A1C	Kadena AB, JA
Puente, Mary J. +	TSgt	Kelly AFB, TX AFRES
Rodriguez, Rolando	Amn	Patrick AFB, FL AFRES
Rosen, Tiffany S.	AB	Lackland AFB, TX
Samuels, William J.	A1C	New York ANG
Stevens, George C.	TSgt	Michigan ANG
Villanueva, Johnryan	AB	Sheppard AFB, TX
Webster, Adam W.	AB	Sheppard AFB, TX

The following personnel graduated from the Medical Materiel Craftsman Course, J3ACR4A171 002. Top graduate is denoted by a plus sign (+).

Class: 27 Nov 00  
Graduation Date: 8 Dec 00  
Instructor: MSgt Priscilla Street

NAME	RANK	ASSIGNMENT
Crouch, Samuel	SSgt	MacDill AFB, FL
Fisher, Marcus	TSgt	Luke AFB, AZ AFRES
Green, Tommy	SSgt	Davis-Monthan AFB, AZ
Hodge, Davita	SSgt	Offutt AFB, NE
Howell, Jennifer	SSgt	Sheppard AFB, TX
Miller, Dax	SSgt	Hickam AFB, HI
Preston, Linda +	SSgt	Wright-Patterson AFB, OH
Quesenberry, Stephen	SSgt	Sheppard AFB, TX
Shaw, Parrish	SSgt	Brooks AFB, TX
Taylor, Anthony	SSgt	Tinker AFB, OK AFRES
Young, William	SSgt	Ramstein AB, GE

**821<sup>st</sup> MDSS  
Buckley AFB, CO**

**Jerry L. Peguese** was promoted to **Master Sergeant**.

(AFMLO/FOA, Ms. Donna J. Poffinberger, DSN 343-4182, commercial (301) 619-4182, donna.poffinberger@ft-detrick.af.mil)

## AFMLO Messages/Listings

<u>Category</u>	<u>Last Published</u>	<u>Date</u>	<u>AFMLO OPR</u>
DoDMMQC	00-1442	21 Dec 00	FOM-P
Last 2000 DoDMMQC Message	00-1442	21 Dec 00	FOM-P
SLEP MMQC	00-5104	29 Dec 00	FOM-P
Last 2000 SLEP MMQC	00-5104	29 Dec 00	FOM-P
QA Message	0313-0006	29 Dec 00	FOM-P
Last 2000 QA Message	0313-0006	29 Dec 00	FOM-P
DBPA Consolidated List	AFMLL 01-2001	9 Jan 01	FOM-P
DBPA Message	281218Z	Dec 00	FOM-P

# CLINICAL ENGINEERING

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## Facilities Management

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### Energy Savings Performance Contracts – Is It The Right Choice For Your Facility?

While budgets are tight for maintenance and repair of our facilities, Energy Savings Performance Contracts (ESPC) may offer facility managers an alternative funds source for infrastructure improvements. Under this concept, an ESPC contractor finances the equipment, design, and construction of energy efficiency projects. In return, the using agency amortizes the debt and repays the contractor using savings from reduced energy costs. While ESPCs offer some interesting possibilities, these contracts can be very complicated and may result in unforeseen consequences. Are ESPCs a viable remedy for Real Property Maintenance (RPM) budget shortfalls or an expensive commitment that exposes medical groups to long-term contract risks?

As a result of congressional mandates to reduce federal energy consumption, Base Civil Engineering (BCE) is a strong advocate of ESPCs for Air Force facilities. Until recently, ESPCs have been on the fringe of medical facility management partly because of the complexity in executing these contracts in non-line buildings. Our medical facilities are considered appealing energy saving targets because of their extended hours of operation and high energy consumption. BCE may have approached some of you about implementing an ESPC in your facility, which may be tempting since it appears to be “free money.”

After all, under the ESPC concept, infrastructure improvements should be fully paid for by future energy savings.

However, buyers should beware. What appears at first glance to be a very good deal may contain hidden liabilities. The true cost of an ESPC is not always clearly defined and finance charges can greatly multiply contract payback beyond projected energy savings. ESPCs may contain contractual obligations that will limit your flexibility in determining facility project and maintenance strategies. Complex energy saving projects may significantly compromise a building's original mechanical and electrical design schemes. Finally, the basis of these contracts is energy savings benefits that can be very difficult to measure and validate, especially after facility changes occur.

Don't discount ESPCs altogether. With the right application and vigilant oversight, ESPCs can be an important source of funds for infrastructure improvements. Given a tight RPM budget, facility managers can take advantage of contractor financing to repair or replace obsolete real property components. If an ESPC is used judiciously, facility managers can upgrade facility infrastructure and reduce utility costs without tying themselves to a problematic long-term contract. The key in deciding whether an ESPC is a good fit for your facility is a comprehensive evaluation of the contract proposal in light of your building engineering, mission support plan, and RPM funding environment.

If considering an ESPC, contact your Regional Health Facilities Office for assistance. **Attachment 1** is a bullet background paper that explains the ESPC program in more detail. If you have any questions, please contact Capt Richard Cutts at 404-562-4243, or richard.cutts@usafsg.brooks.af.mil. (AFMSA/SGSFS, Maj Dan Morgan, DSN 240-4147, commercial 210-536-4147, dan.morgan@usafsg.brooks.af.mil)

## Test Your Knowledge About Regulated Medical Waste

*Q1. Is a properly disposed, unused syringe in a medical facility considered regular or regulated medical waste?*

A1. Although a syringe may be unused and clean during time of disposal, the Environmental Protection Agency (EPA) considers any discarded sharps, including blades, hypodermic needles, and syringes, to be regulated medical waste. Located under Title 40 CFR 261, the purpose for the classification was twofold. First, it was intended to discourage the general public from sorting through trash and obtaining the objects for personal use. Second, treating all sharps as infectious materials removes doubt as to whether certain items contain infectious material.

Unused sharps in storage and supply areas, however, are classified as supply items. Hence, sharps are not considered to be regulated medical waste until either used or disposed of as waste.

*Q2. True or False: After your medical waste is collected by a contractor, the contractor then assumes full responsibility for your waste disposal?*

A2. False – A tracking form must follow the waste until it reaches its final destination. However, if there are any discrepancies due to mishandled or mismanaged shipments, the contractor may not necessarily be found at fault. Depending upon the situation, the waste generating facilities can also be held liable. Therefore, it is imperative that preventive measures be considered. Examples may include performing an extensive background and reference check of the contractor or by randomly following the disposal truck until it reaches the disposal facility. An appointed Contract Quality Assurance Evaluator (QAE) usually performs these duties. Proper documentation is the key to a successful program. Remember, the waste generating facility always has overall cradle-to-grave responsibility.

More information about medical waste management can be found in Air Force Instruction 41-201, Chapter 4, and in Environmental Protection Agency Titles 40 CFR and 49 CFR. (AFMLO/FOM-F, 1LT Robert Foote, DSN 343-2117, commercial 301-619-2117, robert.foote@ft-detrick.af.mil)

## Odyssey Inspection System Revised

The joint venture program between the Joint Commission on the Accreditation for Healthcare Organizations (JCAHO) and the Air Force Inspection Agency (AFIA) is in full swing. The system, called Odyssey, combines the efforts of the two organizations, thereby allowing medical treatment facilities to prepare for one series of inspections rather than having to prepare for two.

Effective 1 January 2001, the combined JCAHO survey and Health Services Inspection (HSI) will occur within a 36-month window (12-48 months since the last inspection) rather than the present system of regularly scheduled triennial inspections. Inspection visit announcements will occur only 2-4 weeks before an upcoming inspection. When scheduling inspections, prior performance factors such as previous JCAHO scores and sentinel events will be taken into consideration.

Why the change? According to Col Geeze from the AFIA, preparing for past inspections became an end in itself, "Emphasis on mission performance was being supplanted by emphasis on HSI/JCAHO performance, and resources were being inappropriately allocated to prepare for inspections. The cart was pulling the horse." He continues by saying, "We have adopted the short-notice inspection paradigm to minimize any negative impact we might have on the AFMS, and provide leadership with the most accurate assessments possible."

For more information, refer to "IG Crosstalk" on the AFIA Medical Operations web site at [https://www-4afia.saia.af.mil/medical\\_operations/](https://www-4afia.saia.af.mil/medical_operations/)

SG\_Home.htm. (AFMLO/FOM-F, Maj Gil Weston, DSN 343-4972, commercial 301-619-4972, gil.weston@ft-detrick.af.mil)

of medical equipment. (AFMLO/FOM-E, Capt P.J. Toth, DSN 343-7445, commercial 301-619-7445, paul.toth@ft-detrick.af.mil)

## **Facilities Management Position Description Templates**

Through a lot of hard work, the folks at Elmendorf Air Force Base were able to get the grade revised for their Facility Manager position to a Hospital Engineer. The position description they developed thoroughly captures the duties and skill requirements of today's medical facility manager. In addition, they developed an equally impressive and accurate Hospital Safety Officer position description. So that others can download and use these position descriptions as templates, Capt Vanderhoof and Maj Faust were gracious enough to share their efforts. These documents are available on the AFMLO web site at <https://afml.ft-detrick.af.mil/afmlo/facilities.htm>. Click on "General Information." (AFMLO/FOM-F, 1LT Robert Foote, DSN 343-2117, commercial 301-619-2117, robert.foote@ft-detrick.af.mil)

WILLIAM H. HILL  
Deputy Chief, Air Force Medical Logistics Office

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## **Quality Assurance**

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### **Food and Drug Administration (FDA) Recalls/Alert Notices**

**Attachment 2**, paragraph 1, provides information on FDA medical equipment recalls and alerts. Personnel from clinical engineering, biomedical equipment maintenance, quality assurance, and safety should follow the guidance provided to ensure the effective maintenance and management

**BACKGROUND PAPER**  
**ON**  
**ENERGY SAVINGS PERFORMANCE CONTRACTS (ESPC)**

**Purpose:** To explain the Energy Savings Performance Contracts (ESPC) Program and provide some basic guidance on evaluating proposals

**Background:**

- The Energy Policy Act of 1992 and Executive Order 13123 mandate energy reduction measures in government facilities
  - The Air Force has implemented an aggressive facility energy management program to meet the mandates
- AF Civil Engineering (AFCEA/CESM) is the program manager and is using ESPCs as a primary means of achieving the reductions
- ESPCs provide services for the design, acquisition, financing, installation, testing, operation, and where appropriate, the maintenance and repair of identified energy or water conservation measures
  - An Energy Saving Company (ESCO) contractor finances the equipment, design, and construction of these energy conservation measures (ECM) and is paid back with savings from reduced energy and maintenance costs
  - The using agency amortizes the debt and repays the ESCO from the subsequent energy cost savings in a payment plan lasting up to 20 years
  - An ESPC must produce more savings than it costs using a "simple payback" formula where costs include all equipment, installation, design, and construction required for the implementation of the ECM
    - "Simple payback" (ECM project costs divided by ECM's annual savings) must be 10 years or less
  - ECM financing and O&M tails are valid ESPC costs that are not included in the "simple payback" formula and can substantially increase the final contract cost
- The ESPC program is a three-phase process
  - Phase I: The ESCO performs a feasibility study to identify a facility's ESPC potential after which the using agency decides whether or not to move forward with the contract
  - Phase II: The ESCO performs an investment grade audit of ESPC potential and provides a detailed proposal with specifics on ECM project design, energy savings, measurement and validation methodology, financing, payback schedules, etc.
    - The decision to move to Phase II deepens the government commitment to execute the ESPC; contract modifications or cancellation must be completely justified
  - Phase III: The ESPC is executed; ECM project construction begins; repayments to the ESCO start the first month following ECM project completion

- Benefits of the ESPC program
  - Does not require up-front Defense Health Program (DHP) funding to upgrade medical facility infrastructure
  - Less energy consumption results in decreased utility costs, less pollution, and possibly reduced maintenance requirements
  - Eliminates excessive maintenance and repair costs of aging or obsolete energy consuming equipment
  - Provides a single POC for the audit, design, construction, and maintenance of ECM projects
- Pitfalls of the ESPC program
  - Total costs of an ESPC may be more than the benefits gained due to added "soft" costs such as financing and O&M tails, which are not included in simple payback calculations but are factored into total contract payout
  - Contractor is allotted a risk factor that builds in additional government costs to cover their risk
  - The medical group may become the agency responsible for enforcing contractual aspects of maintenance and repair, measurement, and validation
  - The medical group may be locked into contractual obligations for repayment even if future facility modifications (such as additions, alterations, system replacements, etc.) occur that eliminate or reduce the energy cost savings
  - Early contract repayment options are limited as total capital costs must be paid and O&M tails may become locked in at contract start

**Recommendations:**

- Contact your Regional Health Facilities Office for assistance during an ESPC evaluation
- Medical groups must fully appreciate the cost, benefit, infrastructure impact, and roles and responsibilities involved in ESPCs
- Ensure costs, especially finance and O&M tails, are fully understood
- When simple payback on a particular project is over 10 years, highly scrutinize it
- Ensure measurement and validation plans are appropriate and realistic
- The ESPC savings cannot be used to finance non-energy savings work; all general repair work done in conjunction with the ESPC must be funded with current fiscal year O&M funds
- If possible, accomplish energy saving projects using O&M funds (versus ESPCs) so that the medical group will receive 100% of the energy cost reduction benefit
- If possible, avoid base-wide contracts; limit the task order to medical facilities
- Factor in the impact of ESPC contractual obligations on future facility project and maintenance strategies
- Additional information may be found at <http://www.eren.doe.gov/femp/financing/esp.intro.html>

**FDA MEDICAL EQUIPMENT RECALLS AND ALERTS**. The following recalls are reported in Accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM-P, Capt Paul J. Toth, DSN 343-7445)

**CLASS I RECALLS:** None

**CLASS II RECALLS:**

**6515 NS  
MDC 13845  
PRODUCT**

**Aspirators/Suction Apparatus**

Various models of SSCOR powered suction pumps used exclusively by professional personnel trained in the techniques of constant suctioning to clear the airway by removing bodily fluids and particulate matter:

- a) Suction Unit, Model No. 10552;
  - b) Suction Unit, Model No. 15002;
  - c) Suction Unit, Model No. 2500;
  - d) Suction Unit, Model No. 40014;
  - e) Suction Unit, Model No. 45000;
  - f) Suction Unit, Model No. 64000;
  - g) Suction Unit, Model No. 64000-220;
  - h) Suction Unit, Model No. 90024;
  - i) Suction Unit, Model No. 90032. Recall #Z-050/058-1.
- a) Serial Nos. 2655 - 3152; b) Serial Nos. 628 - 3603;  
 c) Serial Nos. 250 - 887; d) Serial Nos. 5802 - 6499;  
 e) Serial Nos. 1094 - 1142; f) Serial Nos. 4881 - 8381;  
 g) Serial Nos. 1008 - 1128; h) Serial Nos. 1854 - 2290;  
 i) Serial Nos. 2216 - 2388.

CODE

MANUFACTURER  
RECALLED BY

SSCOR, Inc., Sun Valley, California.  
 Manufacturer, by letters beginning on June 28, 2000.  
 Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide, Mexico, Canada, Philippines, Chili.  
 6,354 units were distributed.  
 Presence of hairline cracks in the plastic fuse holders which house a fuse required to recharge the suction unit.

- None Present
- Action Taken \_\_\_\_\_

**6515 NS  
MDC 12636  
PRODUCT**

**Monitor Systems, Physiologic**

Escort E300 Series Patient Monitor, intended use is as an electrocardiograph and respiration monitor.  
 Recall #Z-030-1.

CODE

Serial numbers are non-sequential (there are gaps), are four digits long and include: 1001 to 4086.

MANUFACTURER

Medical Data Electronics, Arleta, Georgia.

RECALLED BY Manufacturer, by letter dated July 7, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide, Belgium, Canada, Czech Republic, England, Finland, France, Greece, Hong Kong, India, Italy, Korea, Kuwait, Netherlands, Norway, Russia, South Africa, Sweden, Switzerland, Taiwan, ROC, Turkey, United Arab Emirates, United Kingdom.  
QUANTITY 483 units were distributed.  
REASON It is possible for the High Breath Rate Alarm to function incorrectly under certain conditions.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6515 NS**  
**MDC 13215**  
PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY

**Infusion Pumps**  
GemStar Ambulatory PCA Infusion Pump. Recall #Z-047-1.  
List #13000.  
Abbott Laboratories, San Diego, California.  
Manufacturer, by letter September 6, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
Approximately 500 units were distributed.  
The devices have a dimensional problem in the latch retaining pin for the battery door that can work its way out of the door and then the door cannot be closed.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6515 NS**  
**MDC 14361, 14360**

PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY

**Ventilators, Intensive Care, Neonatal/Pediatric (Pressure Cycled)**  
Esprit Ventilator with 10.4-inch Display, color capable.  
Recall #Z-067-1.  
Various serial numbers.  
Respironics, Inc., Vista, California.  
Manufacturer, by telephone on or about September 21, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and Japan.  
53 units were distributed.  
There is a design deficiency and the backlight inverter PCB needs to be insulated.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6515 NS**  
**MDC 13775**  
PRODUCT  
  
CODE  
MANUFACTURER  
RECALLED BY  
  
DISTRIBUTION  
  
QUANTITY  
REASON

**Stimulator, Neuromuscular**  
Belisle brand Advanced Facial Muscular Therapy, an electrical muscle stimulator system. Recall #Z-075-1.  
All units.  
Belisle Systems , Inc., Clearwater, Florida.  
Manufacturer, by letter on July 19, 2000. Firm-initiated recall ongoing.  
Texas, New York, California, Kansas, Oklahoma, Georgia, Virginia, Oklahoma, Florida, North Dakota, Louisiana.  
30 units.  
Device was marketed without a 510(k) or PMA

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6525 NS**  
**MDC 11758**  
PRODUCT  
  
CODE  
MANUFACTURER  
RECALLED BY  
  
DISTRIBUTION  
QUANTITY  
REASON

**X-Ray Rad/Fluoro Units, Mobile (C-Arm)**  
Mobile Digital Imaging Systems, C-Arm fluoroscopic x-rays:  
a) Series 7700; b) Compact 7700. Recall #Z-005/006-1.  
None.  
GE OEC Medical Systems, Inc., Salt Lake City, Utah.  
Manufacturer. FDA approved the firm's corrective action plan letter on October 26, 2000. Firm-initiated field correction ongoing.  
Nationwide and international.  
218 units were distributed.  
The diagnostic x-ray devices were found defective under 21 CFR 1003.10 and failed to comply with the performance standard in 21 CFR 1020.32(c). The defect occurs as a result of the emission of electronic product radiation that is unnecessary to the accomplishment of its primary purpose and which creates a risk of injury to the perator and patient. The system also failed to meet the fluoroscopic performance standard 21 CFR 1020.32(c) "X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure".

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6525 NS**  
**MDC 11758**  
PRODUCT  
  
CODE  
MANUFACTURER

**X-Ray Rad/Fluoro Units, Mobile (C-Arm)**  
Series 9800 Mobile Digital Imaging Systems, C-Arm Fluoroscopic x-rays. Recall #Z-007-1.  
Series 9800.  
GE OEC Medical Systems, Inc., Salt Lake City, Utah.

RECALLED BY Manufacturer. FDA approved the firm's corrective action plan letter on October 26, 2000. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 795 units were distributed.

REASON The diagnostic x-ray devices were found defective under 21 CFR 1003.10. The defect occurs as a result of the emission of electronic product radiation that is necessary to the accomplishment of its primary purpose and which creates a risk of injury to the operator and patient.

None Present  
 Action Taken \_\_\_\_\_

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**6530 NS**  
**MDC 12296**  
**PRODUCT**

**Lasers**  
a) SDL-FL-10/20 Series Fiber Laser; b) SDL-FD-25 Fiber Coupled Laser Systems, diode laser systems used as laser marking systems. Recall #Z-048/049-1.  
Model SDL-FL10/20 and SDL-FD25.

CODE SDL Inc., San Jose, California.

MANUFACTURER Manufacturer. FDA approved the firm's corrective action plan on November 2, 2000. Firm-initiated field correction ongoing.

RECALLED BY Nationwide and international.

DISTRIBUTION a) 293 units; b) 40 units were distributed.

QUANTITY The laser product failed to comply with the Federal laser product performance standard, 21 CFR 10 40.10(f)(4). The key could be removed

REASON from the key control of the laser systems when the key was in the "On" position.

None Present  
 Action Taken \_\_\_\_\_

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**6530 NS**  
**MDC 13969**  
**PRODUCT**

**Tables, Urological**  
Hydrajust IV Urological Table. Recall #Z-001-1.  
All Serial Numbers are affected for Part Numbers: 400001, 400002, 400005, 400006, 400007, 400008, 400011, 400012, 400015, 400016, and 400017.  
The Serial Numbers affected for Part Number 400025 are: 3496-0503, 3496-0504, 3596-0506, 3596-0507, 3896-0510, 4596-0512, 4796-0513, 4796-0514, 5196-0516, 5196-0517, 5196-0518, 5296-0519, 0397-0522, and 0397-0524.  
The Serial Numbers affected for Part Number 400026 are: 0797-0501, 1196-0502, 3496-0505, 3596-0508, 3996-0511, 4796-0515, 0297-0520, 0397-0521, and 0397-0523

CODE

MANUFACTURER Mallinckrodt, Inc., Liebel-Flarsheim Business,  
Cincinnati, Ohio.  
RECALLED BY Mallinckrodt, Inc., Liebel-Flarsheim Business,  
Cincinnati, Ohio, by Certified Mail on June 12, 2000.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 450 units were distributed.  
REASON A mechanical failure may allow the table and tube arm to  
freely rotate downward and injure a patient.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6630 NS**  
**MDC 15107**  
PRODUCT

**Glucose Analyzers**

CODE  
MANUFACTURER  
RECALLED BY

Accu-Chek Voicemate System, Catalog #2030802, designed  
for testing glucose in whole blood by visually impaired  
persons with diabetes. Recall #Z-066-1.  
Lot #119164 and serial number on meter 7674342975.  
SCI Systems, Inc., Huntsville, Alabama.  
Roche Diagnostics Corporation, Indianapolis, Indiana, by  
telephone on or about October 18, 2000. Firm-initiated  
recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide.  
200 units were distributed.  
The Advantage blood glucose meter placed in one system  
reports results in mmol/L instead of mg/Dl, which may  
result in an 18-fold difference in the numbers reported  
out to the patient over the voice readout of the device.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**6630 NS**  
**MDC 15551**  
PRODUCT

**Clinical Chemistry Analyzer**

CODE  
MANUFACTURER  
RECALLED BY

Vitros Calibration Diskette DRV 5285, for use with  
Vitros 250 and 950 Chemistry Systems, when used in  
conjunction with Generation 48 Digoxin Slides:  
Catalog #825 1878 Vitros 250 Chemistry System;  
Catalog #871 6607 Vitros 950 Chemistry System.  
Recall #Z-018/019-1.  
Data Release Version 5825.  
Ortho-Clinical Diagnostics, Inc., Rochester, New York.  
Manufacturer, by telephone on or about November 13, 1998.  
Firm-initiated field correction complete.  
Nationwide, England, France, Germany, Italy.  
1,643 diskettes, affecting over 1,902 Digoxin Gen 48  
packs.

DISTRIBUTION  
QUANTITY

REASON

The Vitros Calibration Diskette DRV 5285 contained revised parameters that affected the time during which readings were taken by the instrument to calculate reaction rates. This resulted in a shift in digoxin predicted concentration. For customers who received Digoxin GEN 48 Slides and calibrated using an earlier release of the calibration diskette, loading of DRV 5285 without recalibration of Digoxin GEN 48 slides resulted in a negative shift in digoxin results by approximately 1.5 ng/ml.

None Present

Action Taken \_\_\_\_\_

\_\_\_\_\_

2. **DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION**. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

**CLASS I:** A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

**CLASS II:** A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**CLASS III:** A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to **AFMLO/FOM-P** no later than **02 FEB 01** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP purchase order number, contract number, and stock record account number (SRAN).  
**(FOM-P), Bonnie Phillips DSN (343-4170)**

**CLASS I RECALLS:**

NSN	6505 Nonstandard
PRODUCT	Rich's MSM Eye and Ear Drops (Methylsulfonylmethane), in 1-ounce bottles. Recall #D-026-1.
CODE	All product (Product not coded).
MANUFACTURER	Rich Distributing, Portland, Oregon.
RECALLED BY	Manufacturer, by e-mail and mail on August 1, 2000, and by a mass mailing to be completed by September 6, 2000. Firm-initiated recall ongoing. See also FDA press release P00-16, August 11, 2000.
DISTRIBUTION	Nationwide and international.
QUANTITY	Undetermined.
REASON	Microbial contamination (Pseudomonas fluorescens).

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

NSN	6505 Nonstandard
PRODUCT	Sterile Talc Powder, in 100 mL vials, used to treat Malignant Pleural Effusion (MPE). Recall #D-028-1.
CODE	All lot numbers as follows: Non-sterile lot numbers: 9H010 and 9K012 Unapproved New Drug lot Numbers:
	Distribution Began      Lot Number
	10/14/97 (2 yr.exp.date)      7I008
	03/27/98                      8B004
	07/31/98                      8E005
	11/18/98)                     8I007
	+/3/99                         9B003

	6/4/99	9D004
	3/30/00	0A002
	6/5/00	0E006.
MANUFACTURER RECALLED BY	Sciarra Laboratories, Hicksville, New York. Bryan Corporation, Woburn, Massachusetts, by letter dated September 11, 2000. Firm-initiated recall ongoing.	
DISTRIBUTION QUANTITY	Nationwide and Canada. Lot 9H010= 545 Cases (10 each) + 4 each Lot 9K012= 847 Cases (10 each) + 119 each Estimated at approximately 5,568 cases of the remaining 8 lots were distributed.	
REASON	Non-sterile product.	
	[ ] None Present	
	[ ] Action Taken _____	

NSN PRODUCT	6505 Nonstandard a) Eyewash, Emergency Eye/Face Body Wash, Eyewash Concentrate and Normal Saline as follows: Lavoptik Brand manufactured by H.L. Bouton, Buzzards Bay, MA: Lavoptik Emergency Eye/Face/Body Wash in 16 oz. and 32 oz. Lavoptik Eye Wash in 6 oz. Lavoptik Eye Wash Concentrate For use in Portable Eye Wash Stations in 70 oz. and 180 oz. Rapid-Clear Brand distributed by Sellstrom, Palatine, IL: Rapid-Clear Eye Wash 16 oz., and 32 oz. and 128 oz Rapid-Clear Eye Wash Concentrate For Use in Portable Eye Wash Stations 180 oz. Zee Brand distributed by Zee Medical, Irvine CA Zee Protector II Refill Sterile Eye Wash Solution for Use in ZEE Protector II Eye Wash Station , 5 Qt b) Normal Saline Solution 16 oz. Recall #D-029/030-1. All lots.	
CODE MANUFACTURER RECALLED BY	H.L. Bouton Company, Inc., Buzzards Bay, Massachusetts. Manufacturer, by letter on or about September 28, 2000, and by press release on September 26, 2000. Firm-nitiated recall ongoing.	
DISTRIBUTION QUANTITY	Nationwide. 40,000-50,000 units were distributed.	
REASON	Microbial contamination (Bulkholderia cepacia).	
	[ ] None Present	
	[ ] Action Taken _____	

**CLASS II RECALLS:**

NSN PRODUCT	6505 Nonstandard a) Qualitest brand Prednisone Tablets, 10 mg, in 21 and 48 count, unit dose pack, NDC #0603-5333-31 and 0603-5333-15; b) Dexamethasone Tablets,	
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USP, 0.75 mg, 12 count, unit dose pack, under the Qualitest and Vintage labels.  
 Recall #D-011/012-1.  
 CODE Lot Numbers: a) 071F0A and 071F0B;  
 b) Qualitest Dexamethasone Tablets, USP, 0.75mg, NDC #0603-3191-11, Lot numbers: 022D9A, 022D9B, 022D9C, 022D9D, 022D9E, 014E9A, 014E9C, 014E9D, 053F9A, 052L9B, 052L9C Dexamethasone Tablets, USP, 0.75mg, NDC #0254-2667-06, Lot numbers: 022D9F, 014E9B, 014E9E, 052L9A  
 Vintage Dexamethasone Tablets, USP, 0.75mg, Rx, NDC #0254-2667-06, Lot numbers: 014E9B, 014E9E, 052L9A, 022D9F.  
 MANUFACTURER Vintage Pharmaceuticals, Inc., Huntsville, Alabama.  
 RECALLED BY Manufacturer, by telephone followed by letter dated August 17, 2000.  
 DISTRIBUTION Firm-initiated recall ongoing.  
 QUANTITY (a) Nationwide; b) Nationwide and Puerto Rico.  
 REASON a) 4,483 packages; b) 179,728 packages were distributed. Lack of data to support labeled expiration date.

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Red Blood Cells. Recall #B-322-1.  
 CODE Unit #8507209.  
 MANUFACTURER Poudre Valley Health Systems Blood Bank, Fort Collins, Colorado.  
 RECALLED BY Manufacturer, by telephone and fax on January 20, 1999.  
 DISTRIBUTION Firm-initiated recall ongoing.  
 QUANTITY Colorado.  
 REASON 1 unit was distributed. Blood product was collected from a donor who reported travel to an area designated as endemic for malaria.

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Heparin Sodium Injection, USP, 5000 USP units per 0.5 mL in 1 mL tubex per 10,000 USP units, Rx.  
 CODE NDC #0008-0277-02. Recall #D-015-1.  
 MANUFACTURER Lot Numbers: 10945 EXP 02/01 and 10962 EXP 02/01. Wyeth-Ayerst Laboratories, Philadelphia, Pennsylvania (responsible firm).  
 RECALLED BY AmeriSource Health Services Corporation, doing business as American Health Packaging (AHP), Columbus, Ohio (repacker/relabeler/distributor), by letter mailed on September 26, 2000. Firm-initiated recall ongoing.  
 DISTRIBUTION Ohio, New Jersey, Tennessee, Florida, Minnesota,

QUANTITY  
REASON  
Kentucky.  
60 bags (1,500 vials) were distributed.  
Lack of assurance of sterility.  
  
 None Present  
 Action Taken \_\_\_\_\_  
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NSN  
PRODUCT  
6505 Nonstandard  
a) Meperidine HCL Injection, USP, 75 mg per mL, 1 mL fill in 2 mL size, used for the relief of moderate to severe pain, preoperative medication, support of anesthesia, and obstetrical analgesia. NDC #0008-0605-2 and NDC #0008-0605-50; b) Heparin Sodium Injection, USP, 5,000 USP units per 0.5 mL fill in 1 mL tubex(r) 10,000 USP units per mL, Rx indicated for anticoagulant therapy. NDC #0008-0277-02. Recall #D-018/019-1.  
CODE  
Lot Numbers: a) 2990430 EXP 1/01 and 2990431 EXP 1/01; b) 2991816 EXP 2/01.  
MANUFACTURER  
RECALLED BY  
Wyeth Ayerst Laboratories, West Chester, Pennsylvania.  
Manufacturer, by letter on September 18, 2000.  
Firm-initiated recall ongoing.  
DISTRIBUTION  
QUANTITY  
REASON  
Nationwide.  
a) 350,490 tubexes; b) 186,390 tubexes were distributed.  
Current good manufacturing practice deviations (lack of assurance of sterility).  
  
 None Present  
 Action Taken \_\_\_\_\_  
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NSN  
PRODUCT  
6505 Nonstandard  
Touro brand Rx (cough and cold; allergy), in unit dose packages of physician samples as follows:  
TOURO ALLERGY Capsule, (Brompheniramine Maleate 5.75 mg and Pseudoephedrine 60 mg), Physician sample,  
TOURO CC Caplets, (Dextromethorphan hydrobromide 30 mg, Pseudoephedrine 60 mg and Guaifensin 575 mg), Physician sample,  
TOURO DM Caplets, (Dextromethorphan hydrobromide 30 mg and Guaifensin 575 mg), Physician sample,  
TOURO EX Caplets, (Guaifensin 575 mg), Physician sample,  
TOURO LA Caplets, (Pseudoephedrine HCL 120 mg and Guaifensin 575 mg), Physician sample.  
Recall #D-031/035-1.  
CODE  
LOT Numbers: a) 419; b) 772; c) 471; d) 394C01; e) 699.  
MANUFACTURER  
RECALLED BY  
PharmaFab, Grand Prairie, Texas.  
Darthmouth Pharmaceuticals, Inc., Wareham, Massachusetts (repacker), by letter beginning on October 18, 2000.  
Firm-initiated recall ongoing.  
DISTRIBUTION  
QUANTITY  
Connecticut, Massachusetts, Rhode Island.  
The amount of product in commerce is approximately as follows:

REASON Touro Allergy 966 boxes of 30 UDPs;  
Touro CC 1004 boxes of 30 UDPs;  
Touro DM 888 boxes of 30 UDPs;  
Touro EX 546 boxes of 30 UDPs;  
Touro LA 670 boxes of 30 UDPs.  
Lack of data to support labeled expiration date.

None Present  
 Action Taken \_\_\_\_\_  
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NSN 6505 Nonstandard  
PRODUCT ALLERx(tm) Tablets, Pseudoephedrine HCL 120 mg,  
Methscopolamine Nitrate 2.5 mg, Chlorpheniramine Maleate  
8 mg), 10 day trade pack, Rx. Recall #D-036-1.  
CODE Lot #0G06701.  
MANUFACTURER Adams Laboratories, Inc., Fort Worth, Texas.  
RECALLED BY Manufacturer, by telephone beginning October 10, 2000,  
followed by letter on October 11, 2000. Firm-initiated  
recall ongoing.  
DISTRIBUTION Nationwide and Puerto Rico.  
QUANTITY 7,678 individual units were distributed; firm estimated  
that less than 5 percent of product remained on market  
at time of recall initiation.  
REASON Tablets in reverse order for AM and PM dispensing.

None Present  
 Action Taken \_\_\_\_\_  
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NSN 6515 Nonstandard  
PRODUCT Electrodes intended for use during electrocardiographic  
procedures:  
a) InvisaTrace 1680, Radiotranslucent Clear Tape ECG Electrode, sold as  
follows: Catalog #1680-001, 1 per pouch, 30 per box, 600 per case  
Catalog #1680-005, 5 per pouch, 50 per box, 600 per case, Cat. #1680-  
030, 30 per pouch, 600 per case; b) UltraTrace 1690, Clear Tape ECG  
Electrode, multi-purpose for short or long term use. The product insert  
identifies this as an adult long-term monitoring electrode and describes  
long term use as 5-7 days. Sold as follows: Catalog #1690-001, 1 per  
pouch, 30 per box, 600 per case, Catalog #1690-003, 3 per pouch, 30 per  
box, 600 per case, Catalog #1690-005, 5 per pouch, 30 per box, 600 per  
case, Catalog #1690-010, 10 per pouch, 50 per box, 1000 per case, Cat.  
#1690-030, 30 per pouch, 600 per case. Recall #Z-028/029-1.  
CODE a) InvisaTrace Model No. 1680 Series, Radiotranslucent Clear Tape ECG  
Electrode; Catalog No. 1680-001, Lot Codes 9909211, 9910071, 9910081;  
Catalog No. 1680-005, Lot Codes 9909181, 9909231, 9910081; Catalog No.  
1680-030, Lot Codes 9909231, 9909232, 9909271, 9909272, 9909291, 9909292,  
9910011, 9910012, 9910052, 9910061, 9910082, 9910131;  
b) UltraTrace Model 1690 Series, Clear Tape ECG Electrode, Catalog No.  
1690-001, Lot Codes 9909301, 9910261, 9910262; Catalog No. 1690-003, Lot  
Codes 9909201, 9909202, 9911011; Catalog No. 1690-005, Lot Codes 9909131,  
9910121, 9910122, 9910132, 9910141, 9910142, 9910192, 9910221; Catalog

MANUFACTURER  
RECALLED BY

No. 1690-010, Lot Codes 9909071, 9910051, 9909211, 9909231, 9909241, 9910261, 9910262, 9910291; Catalog No. 1690-030, Lot Codes 9909141, 9909141, 9909152, 9909161, 9909252, 9909291, 9910041, 9910052, 9910071, 9910081, 9910151, 9910202, 9910262, 9910271, 9911031, 9911041.  
Conmed Corporation, Rome, New York.

Conmed Corporation, Utica, New York, by letters dated September 20, 2000, and by fax on September 21-22, 2000.  
Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide, Australia, Canada, Germany, Japan, The Netherlands, Spain, Taiwan.

QUANTITY  
REASON

a) 737 cases; b) 1,911 cases.  
Some electrodes in these lots may exhibit a separation of the sensing element from the body of the electrode, causing the electrode not to function.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

6515 Nonstandard  
Pulse Generators, intended for the treatment of Bradycardia:  
a) META DDR, Model No. 1256D Pulse Generator;  
b) TEMPO VR, Model No. 1102 Pulse Generator;  
c) TEMPO V, Model No. 1902 Pulse Generator;  
d) TEMPO DR, Model No. 2102 Pulse Generator;  
e) TEMPO D, Model No. 2902 Pulse Generator.  
Recall #Z-031/035-1.

CODE  
MANUFACTURER  
RECALLED BY

Serial numbers from U6100663 to U6227334.  
Teletronics Pacing Systems, Miami Lakes, Florida.  
St. Jude Medical, Cardiac Rhythm Management Division, Sylmar, California.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
10,345 devices were distributed.  
Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

6515 Nonstandard  
Thoracentesis/Paracentesis Kits (Sterile), Catalog #TPK1001, intended use is to perform Thoracentesis and Paracentesis procedures using a needle to remove thoracic fluid. Recall #Z-038-1.  
Lot #L0B070.

CODE  
MANUFACTURER  
RECALLED BY

Allegiance Healthcare Corporation, El Paso, Texas.  
Manufacturer, by letter on September 8, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

Nationwide.  
156 kits were distributed.

REASON Unsterilized kits labeled as sterile.  
  
 None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6520 Nonstandard  
PRODUCT Steri-Oss brand, Non-Hexed Cylindrical Implants (Endosseous Implants), HA Coated, 3.25D by 12mm, Catalog #2612H, devices that are surgically placed in the upper or lower jaw arches to provide support for a prosthetic device, such as artificial teeth and to restore the patients chewing function. Recall #Z-027-1. Lot #993683.  
CODE  
MANUFACTURER RECALLED BY Nobel Biocare USA, Inc., Yorba Linda, California. Manufacturer, by letter dated August 16, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION California, Florida, Kentucky, Louisiana, Ohio, New Jersey, New York, Utah.  
QUANTITY 59 units were distributed.  
REASON Some of the inner vial labels were incorrectly placed on the 3.25 x 14mm implants, catalog #3214TPS, lot 993719.  
  
 None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6520 Nonstandard  
PRODUCT Steri-Oss brand HL Cylindrical Implants (Endosseous Implants), TPS Coated, 3.25D by 14mm, Catalog #3214TPS, device that are surgically placed in the upper or lower jaw to provide support for a prosthetic device, such as artificial teeth and to restore the patients chewing function. Recall #Z-026-1. Lot #993719.  
CODE  
MANUFACTURER RECALLED BY Nobel Biocare USA, Inc., Yorba Linda, California. Manufacturer, by letter dated August 16, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Arizona, California, Connecticut, Georgia, Kentucky, Massachusetts, New York, Oregon, Texas, Israel, Japan.  
QUANTITY 59 units were distributed.  
REASON The inner vial label and the vial cap were mislabeled as 12 mm and not 14 mm.  
  
 None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT META Pulse Generators. Recall #Z-036-1.  
CODE Model 1256.

MANUFACTURER Teletronics Pacing Systems, Miami Lakes, Florida.  
 RECALLED BY St. Jude Medical, Cardiac Rhythm Management Division,  
 Sylmar, California, by letter June 6, 2000. Firm-  
 initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 1,848 were implanted.

REASON These devices have shown an increased risk of failure of  
 the pacemaker processing integrated circuits (IC) that  
 controls the pulse generator. This failure is most  
 commonly characterized by sensing or output anomalies,  
 including the possibility of no output. Extensive  
 analysis has shown that the IC failure is due to  
 electrostatic discharge (ESD) during manufacturing.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

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**CLASS III RECALLS:**

NSN 6505 Nonstandard

PRODUCT Morphine Sulfate Injection, USP (with additive), Rx for  
 the relief of severe pain:  
 a) 1 MG/ML, NDC 61703-219-75 (30 ML (LONG) X 1 VIAL)  
 NDC 61703-219-80 (10 ML X 1 VIAL)  
 NDC 61703-219-85 (30 ML (SHORT) X 1 VIAL)  
 b) 5 MG/ML NDC 61703-221-75 (30 ML (LONG) X 1 VIAL)  
 NDC 61703-221-85 (30 ML (SHORT) X 1 VIAL)  
 c) 10MG/ML NDC 61703-231-32 (10 ML X 10 VIALS)  
 d) 25 MG/ML NDC 61703-223-21 (20 ML X 10 VIALS)  
 NDC 61703-223-43 (40 ML X 10 VIALS)  
 e) 50 MG/ML NDC 61703-225-21 (20 ML X 10 VIALS)  
 NDC 61703-225-43 (40 ML X 10 VIALS).

Recall #D-003/007-1.

CODE	LOT NO.	EXP. DATE
	8151	9/00
	8151039	11/00
	8152-33, 36, 37	10/00
	8152-38	11/00
	8153-29, 32	9/00
	8153-35	10/00
	81510-31	9/00
	9151-1, 1A	12/00
	9151-9	3/01
	9151-15, 21, 25	4/01
	9151-26	7/01
	9151-32, 35	8/01
	9151-46, 56	10/01
	9151-57, 59	11/01
	9152-4, 7	2/01
	9152-11, 12, 13	3/01
	9152-23, 24	4/01
	9152-34, 36	8/01
	9152-48	10/01

9152-62	11/01
9153-3	1/01
9153-10, 14	3/01
9154-8	3/01
9154-50	10/01
9156-42	9/01
9157-33	8/01
9157-43	10/01
9157-58	11/01
9158-18	4/01
9159-5	2/01
9159-16, 20	4/01
9159-22	5/01
9159-28	7/01
9159-31	8/01
9159-38, 39, 40	9/01
9159-49	10/01
9159-51, 52, 61	11/01
91510-2, 6	1/01
91510-17, 19	4/01
91510-29	6/01
91510-30	8/01
91510-37, 41, 44, 4	9/01
91510-53, 54	10/01
91519-55	11/01
0151-4, 5	12/01
0151-21, 23, 24	2/02
0152-9, 10, 16	1/02
0152-25	2/02
0152-28, 31	3/02
0153-1	12/01
0153-12	1/02
0155-22	2/02
0156-2	12/01
0156-17	1/02
0157-6	12/01
0157-29	3/02
0158-7	12/01
0159-3, 8	12/01
0159-11, 13	1/02
0159-32, 33	4/02
01510-19, 20	2/02.

MANUFACTURER

Faulding Pharmaceutical PR, Inc., Aguadilla, Puerto Rico.

RECALLED BY

Manufacturer, by letter mailed on September 12, 2000, followed by telephone. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

Approximately 285,343 units were distributed.

REASON

Misbranding - Product labeled to contain 0.1% sodium bisulfite rather than the actual amount of 0.2%.

None Present

Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Indicator Red Cells. Recall #B-299-1.  
 CODE Lot number 20549, included with Capture-CMV (Lots 20585, 20586, and 20587) and Capture-S Test Kits (Lots 20588 and 20589).

MANUFACTURER Immucor, Inc., Norcross, Georgia.  
 RECALLED BY Manufacturer, by telephone and fax on May 12, 2000.  
 Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Canada, Italy, Spain.  
 QUANTITY 405 test kits were distributed.  
 REASON Indicator red cells exhibited loss of anti-IgM activity.

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT a) Doxycycline Hyclate Capsules, USP, 50 mg, in bottles of 50, NDC #0364-2023-50; b) Doxycycline Hyclate Capsules, 100 mg, in bottles of 50 and 500, NDC #0364-2033-05, Schein Pharmaceutical label.  
 CODE Lot Numbers: P9H0299 EXP AUG 01 and P9E0179 EXP MAY 01.  
 MANUFACTURER Danbury Pharmacal of Puerto Rico, Inc., Subsidiary of Schein Pharmaceutical, Inc., Humacao, Puerto Rico.  
 RECALLED BY Manufacturer, by mail on August 16, 2000.  
 Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.  
 QUANTITY 7,590 bottles of 50 (lot P9H0299); 28,205 bottles of 50 (lot P9E0179) and 2,888 bottles of 500 (lot P9E0179) were distributed.

REASON Product exceeds USP limit for water content.

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Allegra(r) Tablets (fexofenadine HCL), 60 mg, physician sample units, Rx for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older, and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older. Recall #D-010-1.

CODE Lot #1021570 EXP 032002 Lot #1022502 EXP 102102  
 Lot #1021572 EXP 101802 Lot #1023169 EXP 110602  
 Lot #1021573 EXP 102002 Lot #1022714 EXP 032002  
 Lot #1022501 EXP 102102.

MANUFACTURER Aventis Pharmaceuticals, Inc., Kansas City, Missouri.  
 RECALLED BY Manufacturer, by voice mail on June 28, 2000, and by E-mail letters on June 30, 2000, and July 13, 2000.  
 Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.  
QUANTITY 207,878/30 2-tablet card boxes were distributed.  
REASON Mislabeling - The label bears unapproved dosage instructions for patients other than adults.

None Present  
 Action Taken \_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT Estratab(r) Tablets (Esterified Estrogens Tablets, USP), 2.5 mg, in 100-count bottles. NDC #0032-1025-01. Recall #D-014-1.

CODE All lots.  
MANUFACTURER Solvay Pharmaceuticals, Baudette, Minnesota.  
RECALLED BY Solvay Pharmaceuticals, Marietta, Georgia, by letter on August 23, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.  
QUANTITY 16,418 units were distributed.  
REASON Firm withdrawal of application (stability data).

None Present  
 Action Taken \_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT Nortriptyline Hydrochloride Capsules, USP 25 mg, in 500-count bottles, Rx. NDC #0364-2509-02. Recall #D-017-1.

CODE Lot #P9E0175 EXP 5/01.  
MANUFACTURER Danbury Pharmacal of Puerto Rico, Inc., Subsidiary of Schein Pharmaceutical, Inc., Humacao, Puerto Rico.  
RECALLED BY Manufacturer, by priority mail on September 12, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.  
QUANTITY 6,756 bottles were distributed.  
REASON Dis solution failure (stability).

None Present  
 Action Taken \_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT Pipracil, Rx indicated for the treatment of serious infections caused by susceptible strains of designated organisms; Zosyn 3 gram/0.375 gram: indicated for the treatment of patients with moderate to severe infections caused by piperacillin-resistant, piperacillin/tazobactam-susceptible, beta-lactamase producing strains of designated microorganisms:  
a) Pipracil(r) 3 gram ADD-Vantage(r) vials (Piperacillin Sodium), For IV Use;

b) Pipracil(r) 4 gram ADD-Vantage(r) vials (Piperacillin Sodium), For IV Use;  
c) Zosyn(r) 3.375 gram ADD-Vantage(r) vials (Sterile Piperacillin and Sodium Tazobactam Sodium), For IV Use.  
Recall #D-020/022-1.

CODE Lot Numbers: a) 426-116 EXP 4/01; b) 426-149 EXP 6/01, 464-675 EXP 2/02, 800-118 EXP 6/02; c) 800-048 EXP 4/03.  
MANUFACTURER Lederle Piperacillin, Inc., Carolina, Puerto Rico.  
RECALLED BY Wyeth-Ayerst Laboratories, Philadelphia, Pennsylvania, by letter on October 13, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY Approximately 21,422 units were distributed between July 1999 - September 2000. (Pipracil 3 gram 5,022 units, Pipracil 4 gram 15,566 units and Zosyn 5, 424 units).  
REASON Vial breakage.

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT Pueblo Xtra brand Isopropyl Alcohol, 70% Rubbing Alcohol, in 16-fluid ounce bottles. Recall #D-023-1.  
CODE Lot Numbers: B125 and B143.  
MANUFACTURER Omega, Inc., Carolina, Puerto Rico.  
RECALLED BY Manufacturer, on October 3, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Puerto Rico.  
QUANTITY 7,200 units were distributed.  
REASON Mislabeling - Product bears both the correct label strength of 70% and an incorrect label declaration of 50%.

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT a) Duphalac(r) (Lactulose Solution, USP), 10 g/15mL, in 8, 16, and 32-fluid ounce units; b) Duphalac(r) (Lactulose Solution, USP), 20 g/30mL, in 30mL unit dose cups. Recall #D-024/025-1.  
CODE All lots within expiration date.  
MANUFACTURER Solvay Pharmaceuticals, Inc., Baudette, Minnesota.  
RECALLED BY Solvay Pharmaceuticals, Inc., Marietta, Georgia, by letter on August 23, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.

QUANTITY 1,814,103 units were distributed.  
REASON Firm withdrawal of application (stability data).  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
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NSN 6550 Nonstandard  
PRODUCT Vitros Eci Immunodiagnostic Estradiol Reagent Packs,  
Catalog #855 2360, for in vitro quantitative measurement  
of estradiol in human serum and plasma.  
Recall #Z-017-1.  
CODE Lot #134 EXP 07/03/00.  
MANUFACTURER Ortho-Clinical Diagnostics, Inc., Forest Farm Estate  
Whitchurch Cardiff, UK.  
RECALLED BY Ortho-Clinical Diagnostics, Inc., Rochester, New York,  
by E-mail and/or fax and by letter dated April 25, 2000,  
Firm-initiated recall ongoing.  
DISTRIBUTION Connecticut, Indiana, Michigan, New York, Ohio, Texas,  
Utah, Argentina, Australia, Brazil, Canada, Chile,  
Colombia, England, Germany, India, Italy, Japan, Mexico,  
Puerto Rico, Panama, Singapore, Spain and Venezuela.  
QUANTITY 938 kits were distributed.  
REASON A positive bias was observed on controls and patient  
samples when using the above product.  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
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NSN 6550 Nonstandard  
PRODUCT Vitros Chemistry Products Testosterone Reagent, Catalog  
#143-5205, for in-vitro quantitative measurement of  
testosterone in human serum and plasma.  
Recall #Z-021-1.  
CODE Lot Numbers: 90 EXP 4 May 2000 Previous EXP 15 Oct 2000,  
Lot 100, Revised EXP 17 May 2000, Previous EXP 18 Oct  
2000.  
MANUFACTURER Ortho-Clinical Diagnostics, Inc., Cardiff, Wales, UK.  
RECALLED BY Ortho-Clinical Diagnostics, Inc., Rochester, New York,  
by letter dated May 1, 2000. Firm-initiated recall  
ongoing.  
DISTRIBUTION Nationwide, Argentina, Australia, Brazil, Canada, Chile,  
Colombia, India, Japan, Mexico, Puerto Rico, Panama,  
Singapore, Venezuela, England, France, Germany, Italy  
and Spain.  
QUANTITY 960 packs were distributed.  
REASON Products were assigned the wrong expiration dates. EXP  
dates were too long.  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
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NSN 6550 Nonstandard  
 PRODUCT Automated Slide Stainer (Dispenser), intended to stain samples collected to aid in the diagnosis of disease:  
 a) Part #1362303; b) Part #1362304; c) Part #1362305.  
 Recall #Z-023/025-1.

CODE a) Part Number 1362303: A dispenser that is filled by Ventana Medical Systems and is used in the production of 87 different products with unique catalog numbers. Each of these products are for single use only and have no expiration dating except for that which applies to the reagent in the dispenser. 114,782 units of 119 dispenser lots are affected.  
 b) Part Number 1362304: An unfilled dispenser for customer use and is used in 62-65 other products. 8,167 units of 13 dispenser lots are affected.  
 c) Part Number 1362305: A dispenser for light sensitive reagents. it contains 36 reagents which are for single use and bear expiration dates relevant to the reagent. 19, 181 units of 22 dispenser lots are affected.

MANUFACTURER Ventana Medical Systems, Inc., Tucson, Arizona.  
 RECALLED BY Manufacturer, by letter dated June 30, 2000.  
 DISTRIBUTION Firm-initiated recall ongoing.  
 Nationwide, Argentina, Australia, Austria, Belgium, Brazil, Chile, Czech Republic, Finland, France, Germany, Hong Kong, Hungary, India, Italy, Korea, Luxembourg, Malaysia, Mexico, New Zealand, Norway, Panama, Philippines, Portugal, Scotland, Singapore, Slovenia, Spain, Sweden, Switzerland, Taiwan ROC, Thailand, The Netherlands, Turkey, United Kingdom, Wales.

QUANTITY 269,498 kits were distributed.  
 REASON Leaking dispensers were attributed to the vent in the cap of the dispenser, the interface of the cap and the barrel or from the nozzle.

None Present  
 Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
 UPDATE Vitros Chemistry Products Testosterone Reagent Pack, Catalog #143 5205 (Ortho-Clinical Diagnostics, Inc., Rochester, New York), Recall #Z-920-0, which appeared in the September 20, 2000 Enforcement Report is a Class III recall.

None Present  
 Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
 PRODUCT Cardiac T Rapid Assay, Catalog #5740200, intended for

use in the qualitative determination of cardiac troponin T in anticoagulated venous or arterial whole blood.  
 Recall #Z-037-1.  
 CODE All lot numbers.  
 MANUFACTURER Roche Diagnostics, GmbH, Mannheim, Germany.  
 RECALLED BY Roche Diagnostics Corporation, Indianapolis, Indiana, by letter on September 29, 2000. Firm-initiated field correction ongoing.  
 DISTRIBUTION Nationwide.  
 QUANTITY Undetermined.  
 REASON Sodium fluoride interferes with the assay and results in falsely low values.  
  
 None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6550 Nonstandard  
 PRODUCT a) Cardiac M Assay, Catalog #1893840, intended for use with the cardiac reader analyzer to provide rapid and quantitative measurements of cardiac troponin T;  
 b) Cardiac T Quantitative Assay, Catalog #1894307, for use with the cardiac reader analyzer to provide rapid and quantitative measurements of cardiac troponin T.  
 Recall #Z-042/043-1.

CODE All lots.  
 MANUFACTURER Roche Diagnostics, GmbH, Mannheim, Germany.  
 RECALLED BY Roche Diagnostics Corporation, Indianapolis, Indiana, by issuing an urgent product correction on September 29, 2000. Firm-initiated field correction.  
 DISTRIBUTION Massachusetts.  
 QUANTITY Undetermined.  
 REASON The use of blood collection devices containing sodium fluoride cause falsely low results.  
  
 None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6550 Nonstandard  
 PRODUCT a) Precical, Catalog Nos. 620213 and 917213, a lyophilized preparation of pooled human sera for use as a calibrator of clinical chemistry assays;  
 b) Precitrol A, Catalog Nos. 620211 and 917211;  
 c) Precitrol N, Catalog Nos. 620212 and 917212, lyophilized preparations of pooled human sera for use as a control of clinical chemistry assays.  
 Recall #Z-044/046-1.

CODE Lot Numbers: a) 750001 and 750002; b) 770001, 770002, and 770003; c) 760001, 760002, and 760003.  
 MANUFACTURER Roche Diagnostics Corporation, Indianapolis, Indiana.  
 RECALLED BY Manufacturer, by customer bulletin on May 15, 2000 and

DISTRIBUTION  
QUANTITY  
REASON

August 15, 2000. Firm-initiated recall ongoing.  
Nationwide.  
58,086 Precial and 878,692 Precitrol A and N.  
A negative bias was observed when using the calcium  
setpoint associated with these lots of calibrators.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

6550 Nonstandard  
Roche Control Serum N (Human), Catalog #0737119,  
intended as an assayed quality control material to  
monitor the accuracy and precision at normal  
concentration levels in quantitative clinical chemistry  
assays. Recall #Z-061-1.

CODE  
MANUFACTURER  
RECALLED BY

Lot #U0434 EXP 1/31/02.  
Roche Diagnostics Corporation, Indianapolis, Indiana.  
Manufacturer, by customer bulletin sent on September 18,  
2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide.  
750 kits with 20 vials each were distributed.  
The normal control show a significant decrease in  
recovery of Direct Bilirubin. The Direct Bilirubin  
recovery shows bottle-to-bottle inconsistencies within  
the affected lot.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

6550 Nonstandard  
Roche Creatinine Enzymatic Reagent, COBAS Integra 400  
and 700 Analyzer Operators, Catalog #0763144, reagent  
intended for use on the COBAS Integra analyzer for the  
kinetic quantitative determination of creatinine  
concentration in serum, plasma or urine.

CODE  
MANUFACTURER  
RECALLED BY

Recall #Z-062-1.  
All lot numbers.  
Roche Diagnostics, Mannheim, Germany.  
Roche Diagnostics, Corporation, Indianapolis, Indiana,  
by letter on September 19, 2000. Firm-initiated recall  
ongoing.

DISTRIBUTION

Nationwide.

QUANTITY  
REASON

2,010 units were distributed.  
Device may give falsely negative results due to hemoglobin interference. The firm's medical expert determined that this negative interference can be clinically significant, especially in neonates and children because their creatinine levels are lower in general.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN  
PRODUCT

6550 Nonstandard  
Elecys Estradiol Assay, Catalog #1776002, an in-vitro quantitative determination of estradiol in human serum and plasma. Recall #Z-063-1.

CODE  
MANUFACTURER  
RECALLED BY

Lot #199871.  
Roche Diagnostics, GmbH, Mannheim, Germany.  
Roche Diagnostics Corporation, Indianapolis, Indiana, by customer bulletin issued on April 12, 2000, and an urgent product correction notice issued on September 28, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide.  
2,636 kits were distributed.  
A shift in recovery was identified for this lot in comparison to the previous lot manufactured. This shift primarily affects samples from males, post menopausal women and IVF patient.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_