

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HHS 99-01)**

<p><u>Title and Description of Material Weakness:</u> Financial Systems and Reporting: Departmentwide routine periodic reconciliations and account analyses were not done throughout the year which resulted in various problems including:</p> <p>a) Departmentwide: Numerous material adjustments were needed to financial statements at year-end before reliable financial statements could be produced and provided to the auditors. These included instances of: adjusting financial statement amounts, but not the underlying general ledger; using accounts not prescribed by the U.S. Standard General Ledger (SGL); and not posting accounts in accordance with prescribed SGL rules.</p> <p>b) HCFA: Lack of account analysis and validation led to inaccurate balances in the Hospital Insurance/Supplemental Medical Insurance (HI/SMI) Trust Funds and missing Medicare benefit claims data. HCFA did not independently verify the Medicare Hospital Insurance/Supplemental Medical Insurance Trust Fund balances, did not reconcile these accounts at a sufficiently detailed level and used ineffective methodologies to calculate HI and SMI transfers. HCFA also did not periodically validate the National Claims history file to ensure the existence and completeness of the data. However, the National Claims History File problem has been resolved and internal controls have been strengthened to ensure the accuracy of trust fund balances.</p>	
<p><u>Pace of Corrective Action</u> Year Identified: 1999 Original Targeted Correction Date: N/A Correction Date in Last Report: NA Current Correction Date: FY 2000</p>	<p>Lead Managerial Contact: Department: Sue Mundstuk, Director, Division of Accounting and Fiscal Policy</p> <p>HCFA: Jeff Chaney, Director, Division of Accounting, Financial Service Group, Office of Financial Management</p> <p>Source of Discovery: FY 1999 financial statement audit by OIG and other sources.</p> <p>Appropriation/Account #:</p>
<p><u>For Corrected Items Only</u> Validation Process Used:</p> <p>Results Indicators:</p>	

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
(HHS 99-01)****Description of Material Weakness (Continued)****a) Financial Systems and Reporting, Department-wide:**

To address the problem that routine analyses and reconciliations were not being done throughout the year, the Department revised its procedures in guidance issued July 29, 1999 to strengthen requirements for periodic analyses and reconciliations. Various reconciliation/account analysis problems were identified in several OPDIVs which were most material in HCFA as noted below.

b) Financial Reporting, HCFA**Trust Fund Reconciliation:**

During fiscal year (FY) 1999, a series of bookkeeping errors caused the Medicare Hospital Insurance (HI) Trust Fund to be overfunded by \$14 billion and the Supplemental Medical Insurance (SMI) Trust Fund to be underfunded by \$18 billion. As a result of these errors, the HI Trust Fund earned excess interest in the amount of about \$154 million and the SMI Trust Funds lost interest earnings in the amount of about \$237 million for FY 1999. The net total loss of interest to the Medicare Trust Funds is approximately \$83 million. The Office of the Actuary is reviewing and finalizing these amounts.

During the last 9 months of FY 1999, the monthly adjustments that were made between the estimated amount deposited into the transfer accounts during the month and the actual Medicare benefit outlays were made in error. For example, if funds remained in the transfer accounts at month end, and funds were to be returned to the Medicare Trust Funds, the actual adjustment that was made had the effect of transferring additional funds to the transfer accounts. In addition, the adjustments were not reconciled to month-end transfer account balances shown on the Undisbursed Appropriation Account Ledger (FMS-6653) report, which the Department of the Treasury's Financial Management Service supplies to agencies monthly. Finally, it appears that, because of insufficient training, staff did not understand that the large month-end transfer account balances on the FMS-6653 (positive or negative amounts) were indicative of problems in the adjustment process. It is evident that the checks and balances designed to prevent these kinds of errors from occurring were not effective, and supervision was not adequate. A CAP has been developed to address this situation and to prevent these problems from occurring again.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HHS 99-01)**

Briefly define (purpose, scope, methodology, resources) the corrective action plan (CAP) that corrects/improves this material weakness

Department: Working with the Office of Inspector general, evaluation teams will be formed consisting of Department and OIG staff. The teams will focus on critical reconciliation issues in the OPDIVs to resolve audit findings and avoid future audit findings. Specific tasks include: 1) determine if OPDIVs have proper internal control procedures in place; 2) if so, determine that proper financial reporting procedures are being followed; and 3) test the procedures to see if they are effective. OIG will also test the Medicare National Claims History file.

HCFA: As part of HCFA’s CAP to correct the trust fund error, HCFA has taken steps to correct the error by making the necessary transactions to decrease the balance of the HI Trust Fund and to increase the balance of the SMI Trust Fund. HCFA is in the process of seeking approval/authority to reduce the HI Trust Fund interest revenue and to increase the SMI Trust fund interest revenue. HCFA has performed a detailed analysis of the Medicare Trust Funds account activity and processes affecting this account to determine the reason for these internal control weaknesses and to eliminate them in the future. Consequently, we have implemented procedures that will ensure that employees involved in the process have the appropriate level of expertise and that each person involved in the process fully understands his/her assigned duties.

HCFA has instituted protocols to provide qualified and continuous supervision to ensure that employees adequately perform their assigned duties, and has established a formal system of monthly reconciliations and analyses of key financial data that includes readily available supporting documentation and senior management approval.

5) CAP Milestones for FY 2000

Scheduled Due Dates

Financial Reporting HHS-wide

Form evaluation teams of Department and OIG staff

June, 2000

Build an efficient process for producing financial statements in the PSC and NIH financial systems

June, 2000 (start date)

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HHS 99-01)**

CAP Milestones for FY 2000

Scheduled Due Dates

HCFA – Trust Fund Reconciliation

A. Analyze the condition of the Trust Funds Account as of October 1999 and determine the corrective action necessary to eliminate the cause and internal control weaknesses of the inappropriate account balances and to correct the error.

October 1999

Milestone status: Completed

B. Determine the impact on the interest earnings on the Trust Funds account

October 21, 1999

Milestone status: Completed

C. OMB, Treasury and HHS are in negotiations to determine the appropriate actions to correct the interest earnings in the HI and SMI Trust Fund accounts.

ASAP

Milestone status: In process

D. Strengthen internal controls to prevent future errors by making the adjustment to the Trust Fund Accounts on the 6th day of the month, which is the next day after the required source documents are received in the Division of Accounting.

November, 1999

Milestone Status: Completed.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HHS 99-01)**

CAP Milestones for FY 2000

Scheduled Due Dates

HCFA (Continued)

E. Implement monthly use of the Benefit Adjustment spreadsheet for use in performing analyses, calculations and verification of the monthly Trust Fund Account adjustment.

November 18, 1999

Milestone status: Completed.

F. Develop written, detailed procedures on the use of the Benefit Adjustment spreadsheet and the preparation of the Statements of Non expenditure Transfers (SF-1151's and current Month's Statement of transactions (SF-224's).

March 15, 2000

Milestone Status: In process. Procedures have been drafted

G. Staff responsible for preparing the SF-1151 and the SF-224 received detailed training for the preparation of these forms and the use of the Benefit Adjustment spreadsheet.

November 18, 1999

Milestone Status: Completed

H. All supporting documentation will be reviewed and approved at least monthly by an Accountant, the Accounting Systems Management Branch Chief, Division of Accounting Director, and the Deputy Director of the Financial Services Group. The package will contain the transmittal letter to Treasury, the required SF-1151, the Benefit Adjustment spreadsheet and the source documents to support the adjustment. The signature on the letter and any SF-1151 returning funds to the Trust Funds will be that of the Director, Division of Accounting.

November 18, 1999

Milestone Status: Completed.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
(HHS 99-01)**

ADDITIONAL BACKGROUND INFORMATION ON TRUST FUNDS

The Medicare Trust Funds are invested in interest-bearing securities managed by the Department of the Treasury. Medicare benefit payments are paid out of non-interest bearing accounts commonly referred to as transfer accounts. There are two separate transfer accounts, one for HI and one for SMI. Each week, based on estimated Medicare benefit outlays, the Department of the Treasury transfers (deposits) funds from the Medicare Trust Funds into the Medicare transfer accounts. Then, as Medicare benefits are paid throughout the month by our contractors, the outlays are charged to the transfer accounts.

The deposits into the transfer accounts are based on estimates. At the end of the month, the actual Medicare benefit outlays are determined by HCFA's Division of Accounting (DA), and an adjustment is made between the estimated amounts that have been deposited into the transfer accounts and the actual Medicare benefit outlays that have occurred. If the estimate was too high during the month, and excess funds were deposited into the transfer accounts, funds are returned from the transfer accounts to the Medicare Trust Funds. However, if the estimate was too low, and insufficient funds were deposited into the transfer accounts, then additional funds are transferred from the Medicare Trust Funds into the transfer accounts.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (ACF-90-05)**

<p>Title and Description of Material Weakness: Increase Office of Child Support Enforcement (OCSE) Internal Control Efforts to Promote Improvements in State Financial Controls Over Child Support Collections and Expenditures - ACF-90-05.</p> <p>Increased federal stewardship is needed to promote adequate internal controls and cash management practices states establish to guarantee that child support collections are safeguarded and distributed properly, that unidentified collections are reconciled, and that interest on collections is offset against program expenditures.</p>	
<p>Pace of Corrective Action Year Identified: 1990 Original Targeted Correction Date: FY 1999 Correction Date In Last Year's Report: FY 2000 Current Correction Date: FY 2005 Reason for Change in Dates:</p>	<p>Name of Responsible Program Manager: David Ross Source of Discovery: Management assessment report dated August 1990; and recent management reviews by OCSE Audit Division Lead Managerial Contact: Keith Bassett Appropriation/Account #: 75XI501</p>
<p>Validation Process Used: Upon request, managers will be held accountable for providing appropriate documentation to the Agency or Department to validate the correction of the material weakness.</p> <p>Results Indicators:</p> <ol style="list-style-type: none"> 1. Staffs in both the ACF Regional Offices and the States should be trained in the area of internal controls and cash collection responsibilities. 2. Potentially inappropriate financial reporting of Child Support Collections and interest earned on these collections should be identified in a more timely manner. 	

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-97-02)**

Title and Description of Material Weakness: Improved financial reporting to properly account for Medicare Accounts Receivable and other financial information.

The HHS Office of Inspector General (OIG) has not been able to provide assurance as to the reasonableness and accuracy of the AR in the Health Care Financing Administration's (HCFA) financial statement reported by the Medicare contractors due to the lack of documentation to support AR activity. A revised corrective action plan (CAP) was implemented during FY 1999 to address this issue. In FY 1999, HCFA worked diligently to improve the financial reporting of its accounts receivable and other financial information at contractor sites. As a result, we have achieved many of our goals including: the issuance to all contractors of revised Financial Reporting Policies, the development and issuance of clear policies on write-offs and adjustments, and the development of a revised policy for identifying and reporting Medicare Secondary Payor receivables. However, many Medicare contractors remain limited in their financial reporting because they still lack general ledger systems that incorporate double entry book keeping. As a result, some Medicare contractors are still unable to adequately and consistently support their financial reporting activities in accordance with HCFA policies. For this reason HCFA believes this issue will still be considered a material weakness in FY 1999.

Pace of Corrective Action

Year Identified: FY 1997

Original Targeted Correction Date: FY 1999

Correction Date in Last Report: N/A

Current Correction Date: 1999

Name of Responsible Program Manager: G. Jeff Chaney, Director,
 Division of Accounting, FSG/OFM

Source of Discovery:

Appropriation/Account #:

For Corrected Items Only

Validation Process Used:

Results Indicators:

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-97-02)**

Briefly define (purpose, scope, methodology, resources) the corrective action plan (CAP) that corrects/improves this MW:

HCFA continues to provide instructions/guidance to the Medicare contractors on reconciling their quarterly financial reports to existing HCFA data to ensure accurate reporting. As HCFA progresses toward its long-term goal of developing an integrated financial management system, we continue to provide training and guidance to Medicare contractors regarding good financial reporting through educational activities, internal audits and self-assessments. HCFA will continue to use consultants to evaluate the validity and completeness of the Medicare accounts receivable.

Overall Status of Material Weakness at the Close of FY 1999 (global progress toward correcting/improving this weakness over this fiscal year).

All short term corrective actions for FY 1999 have been completed. In addition to our revised policies, HCFA entered into an agreement with the OIG to hire independent public accountants to provide consulting services to assist the agency in validating the accuracy and completeness of its accounts receivable. The consultants performed work at contractor locations that accounts for approximately 81 percent of the outstanding AR balance reflected in the agency's financial statement. Additionally, OIG performed similar work to validate AR at HCFA CO and RO.

The implementation of the revised policies and other initiatives undertaken in this FY have resulted in significant adjustments and write-offs made to HCFA's AR balance. HCFA identified about \$4.3 billion of AR that were corrected in our financial statements this year. This \$4.3 billion is made up of three segments: (1) \$2.7 billion referred to as currently not reportable, (2) \$1.3 billion in adjustments and (3) \$.3 billion written off primarily due to the expiration of the statute of limitations. The \$1.3 billion (principal and interest) reflected in HCFA's financial reporting, resulted from the validation effort performed by the OIG and the consultants, and revised policies and supplemental guidance provided by HCFA to the Medicare contractors.

CAP Milestones for FY 2000

Scheduled Due Dates

Identify CAP Milestones for FY 2000

Scheduled Due Dates

A. HCFA will continue to provide general and specific guidance to Medicare contractors regarding financial reporting activities, specifically in reconciling their financial data to HCFA records.	Ongoing
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Milestone status: Ongoing

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-97-02)**

CAP Milestones for FY 2000

Scheduled Due Dates

B. HCFA will continue monitoring contractors' AR data and supporting documentation particularly regarding write-offs and the identification and adjustment of MSP receivables. Ongoing

Milestone status: Ongoing

C. HCFA will continue using consultant firms to support and review AR balances. March 31, 2000

Milestone status: In the planning phase.

D. HCFA will test financial management internal controls at about 25 Medicare contractors using Certified Public Accounting Firms. FY 2000

Milestone status: In Progress.

E. Long-Range Plan Milestone

Develop, an integrated general ledger system for all Medicare contractors. FY 2004

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-98-01a)**

Title and Description of Material Weakness: Medicare EDP Controls. Note: This material weakness is in two parts as reported by the auditors in the HCFA FY 1999 financial statement audit: a) Improve Systems Application Controls for Medicare Contractors (HCFA 98-01a); and b) System Access Controls in HCFA Central Office (HCFA 98-01b). Following is a description and corrective action plan (CAP) for (a) Improving Systems Application Controls for Medicare Contractors. (Note: The CAP for the second part can be found at exhibit HCFA 98-01b immediately following this exhibit.)

There are three parts to this material weakness: 1) One fiscal intermediary had developed and implemented an override library that gave locally changed programs higher execution priority over the standard Fiscal Intermediary Shared System (FISS) Programs provided by the FISS maintainer; 2) At one fiscal intermediary, the programmers made local changes to the FISS programs outside of the Program Assistance request (PAR) process. Program changes performed locally are not subjected to the same documentation, authorization, testing, quality assurance, and other requirements present in the standard PAR process; and 3) The Medicare Carrier System (MCS) is the carrier shared system and the MCS application contains numerous edits and audits. Although the carriers do not have MCS source code, the application, by design, allows them to deactivate almost all of the edits in the application, including mandatory HCFA edits.

Pace of Corrective Action

Year Identified: 1998

Original Targeted Correction Date: FY 1999

Correction Date in Last Report: NA

Current Correction Date: FY 2000

Lead Managerial Contact: Edward King, Director, Business Systems Operations Group, Office of Information Services

Source of Discovery: FY 1997 financial statement audit by OIG

Appropriation/Account #: Bureau of Program Operations, HCFA

For Corrected Items Only

Validation Process Used:

Results Indicators:

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
(HCFA-98-01a)****Briefly define (purpose, scope, methodology, resources) the corrective action plan (CAP) that corrects/improves this material weakness**

The identified weaknesses related to the FISS and the MCS are currently being addressed. The specific local site that made the changes to the FISS code took actions to formally document the changes. The finding identified for the NCS system related to the exact duplicate edits was fixed in April 1998. As a long term solution, the process will be enhanced to limit overrides and to provide reasonable assurance that only authorized access to source code and programs is permitted. The will require the development and implementation of policies and procedures for safeguarding programs/systems that support claims processing and financial functions. Suggested control objectives have been provided to Medicare contractors for consideration as part of their internal control certification process for FY 2000.

Summarize status of Material Weakness corrective action plan at the close of FY 1999 (identify progress in correcting/improving this weakness, explain any missed milestones, etc.):

HCFA has made notable progress regarding EDP. All short term corrective actions for 1999 have been implemented. Other corrective actions have begun, but the end results are not yet evident.

Contractors have access to source codes to allow them to take immediate action in emergency situations to resolve abnormal program ends that would otherwise potentially cause serious payment to processing delays and to accommodate individual intermediary requirements such as writing special printing hardware interfaces to handle print utilities. After all Y2K activities are completed, HCFA will begin development of EDP strategies that do not require HCFA to release source codes but continue to allow contractors to take immediate action to resolve processing problems.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-98-01a)**

CAP Milestones for FY 2000

Scheduled Due Dates

A. FISS - Local contractor(s) review and document local changes to the PAR.

Ongoing

Milestone status: Ongoing.

B. Develop procedures which allow contractors to resolve processing problems without requiring use of the source code.

FY 2000

Milestone status: Will begin after completion of Y2K activities.

C. Implement system changes to establish internal controls:
 a) hard code HCFA mandated payment edits into standard systems or local contractor systems. b) implement access control to production program libraries.

FY 2000

Milestone status: Will begin after completion of Y2K activities.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-98-01b)**

<p>Title and Description of Material Weakness: Medicare EDP Controls. This is the second part of the material weakness called Medicare EDP Controls as reported by the auditors in the HCFA FY 1999 financial statement audit: System Access Controls in HCFA Central Office (HCFA 98-01b). Following is a description and corrective action plan (CAP) for Systems Access Controls in the HCFA Central Office.</p> <p>Direct command-line access to the M204 database has been granted to approximately 150 applications developers and Data Base Administrators (DBAs). With the knowledge of file names and database update passwords, these developers can intentionally or inadvertently modify or update the data structures within specific regions of the M204 database. The M204 database product is used to store data for many of HCFA's sensitive applications, including, but not limited to, the Automated Payment Plan System, Enrollment Database and Group Health Plan Applications.</p>	
<p><u>Pace of Corrective Action</u> Year Identified: 1998 Original Targeted Correction Date: 1999 Correction Date in Last Report: FY 2000 Current Correction Date: FY 2000</p>	<p>Lead Managerial Contact: Dennis Read – Director, Technology Infrastructure Group, Office of Information Services</p> <p>Source of Discovery: FY 1997/FY 1998 financial statement audits by OIG</p> <p>Appropriation/Account #:</p>
<p><u>For Corrected Items Only</u> Validation Process Used:</p> <p>Results Indicators:</p>	

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-98-01b)**

Briefly define (purpose, scope, methodology, resources) the corrective action plan (CAP) that corrects/improves this material weakness

HCFA will use the utility product SIRSAFE to enhance M204 security controls. HCFA workgroup developed and provided training on SIRSAFE to the Group Health Plans system developers and owners in November 1999. Because of Y2K priorities and deadlines, HCFA was unable to meet its December 1999 implementation target date. The implementation process for SIRSAFE is now scheduled to begin in January 2000. Training for the other M204 developers and owners will be held the week of January 10, 2000. A detailed project plan has been developed for this effort. Also activities have been planned for intensifying training, awareness and Medicare contractor oversight in the year 2000.

Summarize status of Material Weakness corrective action at the close of FY 1999 (progress in correcting/improving this weakness, explanation of any missed milestones, etc.):

Much of our energy during 1999 was spent ensuring that our systems meet the Y2K requirement. We have made progress in addressing some of the EDP concerns addressed in the 1998 audit. Many of the corrective actions have been implemented but the end results are not yet evident.

CAP Milestones for FY 2000

Scheduled Date

A. Provide training to GHP system Developers and owners on implementing SIRSAFE security utility.

November, 1999

Milestone status: Complete

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (HCFA-98-01b)**

CAP Milestones for FY 2000

Scheduled Date

B. Provide training on SIRSAFE security utility to other M204 developers and owners.

February 2000

Milestone status: Complete.

C. Improve the process to control M204 access via a commercial product that should be in place by January 2000.

September 2000

Milestone status: In process.

D. Continue to enhance access controls through improvements in training, risk assessments, system administration, and internal audits.

Ongoing

Milestone status: HCFA has contracted the services of experienced personnel to provide assistance in the areas of Security Training & Awareness; Security WEB Site Development; Network Security Testing; Security Plan Development; Systems Accreditation; Security Engineering; Security Architecture; Technology Assessment; Physical Security; Disaster Recovery; and Emergency Response.

These efforts are an integral part of the HCFA Enterprise Systems Security initiative.

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (FDA-89-02)**

<p>Title and Description of Material Weakness: Weakness in the Enforcement Program for Imported Foods in the Food and Drug Administration (FDA) - (FDA-89-02). The Office of Inspector General reported that FDA did not inspect a large enough sample of imported foods to ensure the safety of the public health.</p>	
<p><u>Pace of Corrective Action</u> Year Identified: 1989 Original Targeted Correction Date: 1990 Correction Date in Last Year's Report: FY 1999 Current Correction Date: FY 1999 Reason for Change in Dates:</p>	<p>Name of Responsible Program Manager: Dennis Baker Source of Discovery: OIG (Report A-15-90-00001) and internal FDA management reviews. Appropriation/Account # 7520600</p>
<p>Validation Process Used: A corrective action review will be completed following correction of the material weakness.</p> <p>Results Indicators:</p> <p>FDA determined that a 20 percent minimum inspection rate to assure the safety of the imported foods was unrealistic. As a result, a revised strategy for how the Agency will deal with imported foods has been prepared. FDA's new approach will focus on products and problems which present a high risk to the American public, or firms and countries of origin which have a history of noncompliance.</p>	

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (FDA-89-02)**

Title and Description of Material Weakness: Weakness in the Enforcement Program for Imported Foods in the Food and Drug Administration (FDA)

Major Milestones	Milestone Dates		
	Original Plan	Revised Plan	Actual Date
<p><u>(a) Completed actions/events:</u> FDA uses a structural and selective sampling method, based on both the entry level and product intelligence to provide an effective level of examination coverage. This assessment is supported by historical data covering the period of 1972-1992.</p> <p>FDA developed a Revised Imports Strategy which embodies intelligence based sampling of imports to provide an effective level of coverage, and includes performance indicators. With this new approach, FDA focuses its import activities on products and problems presenting a high health risk to the American public, or firms and countries of origin which has a history of non-compliance. Electronic screening, improved strategic alliances and improved premarket and postmarket surveillance are key components of the revised strategy.</p> <p>FDA has expanded the use of an electronic entry processing system (EEPS) for imports using the Custom's Automated Commercial System. EEPS enables FDA to screen import entries and electronically make "May Proceed" decisions on products of low risk and high compliance rates. At this time, EEPS has been implemented at all major ports where electronic entry of imports is available.</p> <p>FDA plans to maintain its pre-market surveillance through a vigorous foreign inspection program designed to identify problems at their source. FDA completed 866 foreign inspections during FY 1995. This represents an increase of 16.7% from FY 1994 accomplishments. This total includes inspection of 65 food firms.</p> <p>DIOP received approval from CDER to expand ACS screening criteria for drug products. This should increase the "May Proceed" level from the current rate of 60%. FDA completed 829 foreign inspections during FY 1996. The number of foreign inspections planned in FY 96 was 1418. This represents a decrease of 4.3% from FY 1995 accomplishments.</p> <p>The number of foreign inspections planned for FY 1997 was 997. This total includes inspection of 40 food firms. FDA completed 811 foreign inspections during FY 1997. This represents a decrease of 2.2% from FY 1996 accomplishments.</p>			<p align="center">1992/93</p> <p align="center">FY 1994</p> <p align="center">FY 1995</p> <p align="center">FY 1996</p> <p align="center">FY 1997</p>

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (FDA-89-02)**

	Original Plan	Revised Plan	Actual Date
<p>FDA completed 938 foreign inspections during FY 1998. The number of foreign inspections planned was 976. This represents a 15.6% increase over FY 1997 accomplishments.</p>	FY 1998		1998
<p>Complete the full roll-out of OASIS version 2 to all district offices.</p>	FY 1998		1998
<p>The default "May proceed" rate for all food commodities has been set at 70% or greater. However, the "May proceed" rate measured at any particular time may be lower as FDA intensifies a problem with a firm, country or product. These adjustments are considered essential to FDA surveillance activities.</p>	FY 1998		
<p><u>(b) Actions Completed During FY 1999:</u> The number of foreign inspections planned for FY 1999 is 987. This included inspection of 40 food firms. FDA completed 810 foreign inspections during FY 1999. This total includes the inspection of 87 foreign food firms.</p>	FY 1999		1999
<p><u>c) Planned/continuing agency actions:</u> All facets of the Revised Imports Strategy will continue to be implemented and evaluated.</p> <p>The number of foreign inspections planned for FY 2000 is 942. This included inspection of 175 food firms.</p> <p>FDA continues to develop and evaluate agreements with foreign governments whose requirements and regulatory infrastructure are equivalent to FDA's. As these agreements are developed and finalized, surveillance resources can be targeted toward countries whose internal requirements supply less assurance of compliance with U.S. requirements.</p> <p>The rate of increase in imported entries has been too rapid to maintain the 4% examination rate. In FY 1997, the agency processed 2,765,548 line items of food and performed 47,478 physical examinations. This represents an examination rate of 2%. Further, based on projections from entry data for the first 9 months of FY 1998, there will be approximately 3,348,000 line items of food offered for entry, a 21% increase in entry lines over FY 1997 data.</p> <p>Since maintaining the 4% examination rate is not realistic, FDA believes that identifying forms and countries with inspection systems comparable to those in the United States and in accordance with the Food Safety Initiative is a viable alternative to increasing the point of entry examination of FDA regulated products.</p>	FY 2000		

**1999 FMFIA MATERIAL WEAKNESSES: SCHEDULE OF CORRECTIVE ACTIONS
 (PHS-93-02)**

<p>Title and Description of Material Weakness: Deficiencies in the Public Health Service Technology Transfer Activities</p> <p>Deficiencies were noted in the PHS technology transfer activities. The technology transfer deficiencies include: (1) the management information systems are inadequate; (2) the processes to ensure that royalties and other payments are received are inadequate.</p>	
<p><u>Pace of Corrective Action</u> Year Identified: 1993 Original Targeted Correction Date: 1994 Correction Date in Last Year's Report: FY 1999 Current Correction Date: FY 2001 Reason for Change in Dates: Contractor failed to provide system in accordance with contract terms and budget. Program is seeking new contract to complete the work or develop a new system to replace the current system.</p>	<p>Name of Responsible Program Manager: Dr. Maria Freire Source of Discovery: NIH Alternative Management Control Review Appropriation/Account #: 7530846</p>
<p>Validation Process Used: NIH management will be required to demonstrate to the Department that corrective actions have been completed. This will be followed by a Corrective Action Review within one year to demonstrate that corrective actions taken remain effective.</p> <p>Results Indicators: Existence of policies, procedures,, and information system.</p>	

**1999 FMFIA MATERIAL WEAKNESS: SCHEDULE OF CORRECTIVE ACTIONS
 (PHS-93-02)**

Title of Material Weakness: Deficiencies in the Public Health Service Technology Transfer Activities

Major Milestones	Milestone Dates		
	Original Plan	Revised Plan	Actual Date
1. OTT will improve its information systems so its staff can more easily determine what costs have been incurred, billed and collected.	Oct. 98	June, 2001	
2. OTT will revise the current model license agreements used by NIH to include standard language on auditing; develop criteria for use in determining whether or not an audit should be requested by NIH; and obtain ICD approval to enter into contracts to conduct audits as required.	Oct. 98		Aug. 98
3. OTT will improve its information systems, so it can accurately document the status of each patent application.	Oct. 98	June, 2001	
4. OTT will develop an integrated management information system that will effectively track and report on CRADAs, inventions, patent prosecution status and costs, licensing, and receipt of royalty payments for domestic and foreign filed cases.	Oct. 98	June 2001	March 98
5. OTT will update the Technology Transfer Policy Manual, Chapter 206, and establish clear internal procedures on the processing and content of infringement log items.	March 98		
6. Information from the infringement log will be migrated to the new data system where it will be maintained in the future.	Oct. 98	June 2001	
7. OTT will review how the new process for announcing the availability of technologies is working after it has been in effect for one year. Part I: Conduct an analysis Part II: Complete an Evaluation	June 98 Nov. 98		Oct. 98 Oct. 98
8. OTT will make further adjustments, as necessary, to reduce the amount of time between the filing of a patent application and publication of the abstract in the Federal Register.	Nov. 98		Aug.98 and ongoing
9. OTT will provide assistance and guidance, as necessary, in preparing technology training, and will provide oversight to ensure the training provided by the ICDs is conducted properly.	Oct.98 and ongoing		
Note: Items 1, 3, 4, and 6 are tied to the completion of the new OTT data system.			