Department of Veterans Affairs

Office of Inspector General

COMBINED ASSESSMENT PROGRAM REVIEW

RICHARD L. ROUDEBUSH VA MEDICAL CENTER INDIANAPOLIS, INDIANA

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VA Office of Inspector General

Combined Assessment Program Reviews

Combined Assessment Program (CAP) reviews are part of the Office of Inspector General's (OIG's) effort to ensure that high quality health care and benefits services are provided to our Nation's veterans. CAP reviews combine the knowledge and skills of the OIG's Offices of Healthcare Inspections, Audit, and Investigations to provide collaborative assessments of VA medical facilities and regional offices on a cyclical basis. CAP review teams perform independent and objective evaluations of key facility programs, activities, and controls:

- We evaluate how well the facility is accomplishing its mission of providing quality care and improving access to care, with high patient satisfaction.
- We also review selected financial and administrative activities to ensure that management controls are effective.
- Finally, we conduct fraud and integrity awareness briefings to improve employee awareness of fraudulent activities that can occur in VA programs.

In addition to this typical coverage, a CAP review may examine issues or allegations that have been referred to the OIG by facility employees, patients, members of Congress, or others.

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Combined Assessment Program Review
Richard L. Roudebush VA Medical Center Indianapolis, Indiana

Executive Summary

Introduction — The Office of Inspector General (OIG) conducted a Combined Assessment Program (CAP) review of the Richard L. Roudebush VA Medical Center (VAMC) Indianapolis, Indiana from January 24 to 28, 2000. The purpose of the review was to evaluate selected operations, focusing on quality of care and management controls.

VAMC Indianapolis is a tertiary care facility, providing a full range of medical, surgical, and psychiatric services. As of December 31, 1999, the medical center had 139 acute care and 21 nursing home care beds. The medical center operates outpatient facilities at Indianapolis and Terre Haute, Indiana, and is part of Veterans Integrated Service Network (VISN) 11. The major healthcare affiliation is with Indiana University. For Fiscal Year (FY) 1999, VAMC Indianapolis had a budget of over $253 million, served 36,597 unique veteran patients, and facility staff provided 344,817 outpatient visits.

Patient Care and Quality Management — We concluded that the patient care activities were generally operating satisfactorily. Overall, quality management (QM) controls were effective and comprehensive. The following areas required management attention:

- Administrative oversight and review of clinical operations
- Training and education of clinical staff
- Development of special programs
- Development and implementation of Performance Improvement Plans
- Medical care treatment environment
- Equipment
- Infection Control
- Patient and employee safety
- Medical record documentation
- Patient and employee survey results

Financial and Administrative Management — We concluded that the administrative activities reviewed were generally operating satisfactorily, and management controls were generally effective. Management controls should be strengthened in the following areas:

- Informed consent for human research
- Informed consent for surgery
- Accountability and security over controlled substances
- Government purchase cards
- Timekeeping for part-time physicians
- Equipment accountability
- Supply, Processing, and Distribution
- Information technology security

Fraud Prevention — We provided fraud and integrity awareness briefings to 163 employees of the facility. These briefings provided information on recognition of frauds, referrals to the Office of Investigations, and information needed to make referrals. In addition, two investigations were opened as a result of this CAP review.

Medical Center Director Comments — The Medical Center Director provided acceptable comments and details of implementation actions for all recommendations in this report. Therefore, we consider all issues resolved and all recommendations implemented, although we may follow up on implementation actions. The Director also provided acceptable comments to all suggestions.

(Original signed by:)

RICHARD J. GRIFFIN
Inspector General

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Introduction

Richard L. Roudebush VA Medical Center

VAMC Indianapolis is a tertiary care facility, providing a full range of medical, surgical, and psychiatric services. As of December 31, 1999, the medical center had 139 medical care beds, consisting of 64 medicine, 31 surgery, 12 psychiatry, 8 rehabilitation medicine, 21 intermediate medicine, and 3 neurology beds. The medical center also operated a 21-bed nursing home care unit (NHCU). In addition to outpatient facilities at Indianapolis, the medical center had a community-based outpatient clinics (CBOC) in Terre Haute and Bloomington, IN. The medical center is part of VISN 11. The major affiliation is with the Indiana University Schools of Medicine, Dentistry, Nursing, and Allied Health. Major clinical research focuses on alcoholism, cancer, heart disease, pulmonary disease, and rheumatic disease.

Key budget and workload data for the period FY 1997 through December 31, 1999, is shown below:

Key Budget and Workload Data

Fiscal Year	Medical Care Beds	Unique Patients	Outpatient Visits	FTEE[1]	Medical Care Budget
1997	156	31,196	284,271	1559	$229,555,943
1998	137	35,144	308,589	1513	$233,805,235
1999	139	36,597	344,817	1540	$253,398,524
2000	139[2]	22,355[2]	84,158[2]	1509[2]	$65,391,277[2]

1. Cumulative full-time equivalent employees (FTEE)
2. As of December 31, 1999

In FY 1999, medical center clinicians treated 6,223 inpatients, an 11 percent increase over FY 1998. The FY 1999 average daily inpatient census was 103. The NHCU had 83 discharges for FY 1999, a 28 percent increase over FY 1998. During FY 1999, outpatient visits also saw an 11 percent increase over FY 1998. The in-house dialysis section completed 733 acute procedures and 7,504 chronic procedures for FY 1999.

Objectives and Scope of the Combined Assessment Program Review

The purpose of the CAP review was to evaluate selected clinical, financial, and administrative operations and to provide fraud and integrity awareness briefings to medical center employees.

Patient Care and QM. We reviewed numerous quality assurance documents and 59 patient medical records. We also inspected the physical environment of inpatient and outpatient treatment facilities. Using structured survey instruments, we interviewed and analyzed responses from 23 clinicians/managers, 9 senior managers, and 119 patients. We also distributed questionnaires to 289 medical center employees, of which 160 (55 percent) were returned. We summarized the results of the 160 questionnaires and shared them with management. Also, we reviewed the following patient care and QM areas:

Ambulatory Care Service
Chaplain Service
Dental Service
Dialysis Unit
Education Service
Infection Control
Medical and Surgical Intensive Care
Medicine Service
Neurology Service
Nuclear Medicine Imaging Service
Nursing Home Care Unit
Nutrition and Food Service
Pathology and Laboratory Medicine Service
Physical Medicine and Rehabilitation Service
Former Prisoner of War Program
Prosthetics Service
Psychiatry Service
Radiation Therapy
Radiology Service
Recreation Therapy
Speech Pathology
Surgery Service

Financial and Administrative Management. We also reviewed the following medical center administrative activities and management controls to determine if they were operating effectively:

Automated Data Processing Acquisitions
Agent Cashier Activities
Compensation and Pension Examinations
Contract with Beverly Corporation
Contract with the State of Indiana
Decision Support System
Equipment Accountability
Government Purchase Cards
Hazardous Materials Handling
Information Technology Security
Informed Consent – Human Research
Informed Consent – Surgical Procedures
Medical Care Collection Fund Billing Processes
Mobile Angiography Justification
Pharmacy Accountability/Security
Scarce Medical Specialist Contracts
Supply, Processing, and Distribution
Timekeeping for Part-Time Physicians
Transcription Services
Warehouse Inventory Controls

Fraud and Integrity Awareness Briefings. We conducted five fraud and integrity awareness briefings attended by 163 employees. The briefings included a lecture, a short film presentation, and question and answer opportunities. Each session lasted approximately 60 minutes and provided a history of the OIG, discussions of how fraud occurs, criminal case examples, and information to assist in preventing and reporting fraud. We also opened two investigations as a result of this CAP review. In addition, we received 36 inquiries from patients and employees. The details of our follow-up on these inquiries are contained in Appendix II.

Scope of the CAP Review. The review generally covered medical center operations for FY 1999 through the first quarter of FY 2000. In performing the review, we inspected work areas; interviewed medical center managers, employees, and patients; and reviewed pertinent administrative, financial, and clinical records. This review was conducted in accordance with Standard Operating Procedures for Combined Assessment Program Reviews issued by the VA OIG.

Results and Recommendations

Patient Care and Quality Management

Patient Care and Quality Management Were Generally Effective

We concluded that patient care activities were generally operating satisfactorily and overall QM controls were effective.

The Executive Management Team (EMT) Demonstrated a Comprehensive Commitment to Veterans and Employees. VAMC management expressed a strong desire for the medical center to be an employer of choice in the Indianapolis area. The EMT met daily in an effort to keep communication channels open. The EMT also met regularly with veterans service organization (VSO) representatives. Senior managers stated that the meetings resulted in an increased level of understanding between VAMC Indianapolis and the VSOs. Communication and cooperation between the EMT and VISN 11 managers appeared evident through jointly developed goals and objectives.

The Primary Care Model Had Been Successfully Implemented in Ambulatory Care Clinics. Attempts to improve efficiency in the Ambulatory Care Clinics were evident through the operations of the Patient Response Center (PRC). PRC nurses answered patients' calls concerning health matters. Approximately 400 calls were received daily, with an average wait time of only 1.5 minutes from the time the call was received until a nurse came on the line. As a result of the PRC, physician response time had improved, as most calls were returned by a physician or by another clinician relaying the physician's input within 24 hours. VSO representatives told us that veterans and their families were pleased with the Primary Care Model and the way that the Ambulatory Care Clinics had functioned since the model was implemented.

Inpatient and Outpatient Rehabilitation Units Supported the Continuous Rehabilitation Process. The rehabilitation assessment and treatment planning processes were well defined and had interdisciplinary involvement. Functional Independence Measures (FIM) were being utilized, and all employees were certified in FIM. Referrals for rehabilitation care were made efficiently and effectively. Medical center staff were able to verbalize performance improvement (PI) efforts and use of FIM in evaluating a patient's functional improvement. Outpatient clinics providing rehabilitation activities had decreased waiting times from 21 to 14 days. Staff informed us that they had a productive relationship with Prosthetics Service staff that strengthened their ability to manage high cost prosthetic items (e.g., scooters and electric wheelchairs).

Pathology and Laboratory Medicine Service Had Extensive Quality Controls and PI Activities. The Anatomic Pathology Section monitored the verification of all surgical

pathology with malignant diagnoses by: (a) a second pathologist's review prior to finalization of a report; and (b) correlation of final diagnoses with frozen section diagnoses, with discrepancies subjected to peer review. External peer reviews were also conducted through the Armed Forces Institute of Pathology's Systematic External Review programs for surgical pathology and autopsies.

The Clinical Pathology Section monitored turnaround times for "stat" (urgent) requests, verification of critical value results, and appropriateness of tests requested. Monitors for the Blood Bank were reviewed quarterly and included availability of blood prior to surgery; distribution, handling, and dispensing of blood and blood products; review of all suspected transfusion reactions; blood usage review; and completion and return of Blood Request Forms (SF 518). The use of a pneumatic tube system for specimen delivery from the Medical Intensive Care Unit (MICU), the Surgical Intensive Care Unit (SICU), and the Operating Room had reduced turnaround times for laboratory requests from these areas. This system eliminated the need for nursing employees to manually deliver specimens to the laboratory and reduced the transit time for blood gases.

The Ancillary Testing Program[1] Was Effective. The Ancillary Testing Coordinator (ATC) checked the accuracy of all equipment prior to initial use, after repairs, and annually. The ATC conducted orientation and training and ensured that nursing employees were tested for competency before they were allowed to perform ancillary testing. Also, the ATC conducted monthly reviews of quality control tests performed by nursing employees, notifying the nursing manager of improper quality control results for follow-up. The ATC reviewed results of PI monitors established for each test, and in collaboration with nursing employees, took corrective actions when thresholds were exceeded.

SICU and MICU Functioned Effectively. Both the SICU and MICU protocols for restraint use had clear criteria for restraint application and discontinuation. Nurses had been educated about administration of conscious sedation including appropriate patient monitoring and recovery. MICU nurses had begun to provide inpatient chemotherapy, and nursing managers were monitoring this new service which should result in cost savings to the facility. This service had previously been provided on a fee basis by Indiana University Medical Center.

Suggestions for Improving Patient Care and QM

Opportunities to improve the delivery and quality of patient care were noted in the following areas. (The Medical Center Director's comments to our suggestions are included in Appendix III.)

1. *Ancillary testing refers to tests done at the care site, not in the laboratory.*

Administrative Oversight and Review

The Food Preparation and Storage Section Needed a Properly Trained Supervisor. The Chief, Fiscal Service was the acting Chief of the Food Preparation and Storage Section, but did not have a background in food handling and storage. The food storage and preparation areas were unsanitary, and the floors were dirty. Floors in the storage coolers had food spill stains, and a mousetrap was found under a table in the food preparation area. The food preparation tables had dirt accumulated on the table legs. The ice machine drains were dirty and one drain had standing water, creating a potential infection control issue.

The temperatures of food storage coolers and refrigerators were monitored. However, Nutrition and Food Service policies did not define the acceptable temperature ranges, and the temperature record forms did not alert the staff to appropriate temperature ranges. Additionally, the forms did not allow for documentation of actions taken in case the temperatures were out of the acceptable ranges.

Undated food items were found in storage areas. Medical center policy requires employees to remove all food from the refrigeration units within 24 hours after opening if not used. Employees' food was found in the food preparation area and in coolers. Employee food and patient food should be kept separate to allow for quality control.

Cleaning chemicals were located adjacent to the food preparation area, creating the possibility of food contamination. The food preparation and storage area had a Canteen Service refrigeration unit that did not have a temperature log. Directly beside this unit was an oven that was not being used by either Canteen or Nutrition and Food Services. This equipment was dirty, and employees told us that it had not been cleaned in some time.

Facility managers should continue an active search for a properly trained manager for the Food Preparation and Storage Section. If a new manager cannot be hired quickly, facility managers should consider a temporary detail of a qualified individual from another facility. In addition, managers should implement and monitor quality control measures for this area. Environmental rounds should be increased for the food storage and preparation areas, including review of outdated food items, cleanliness of the area, and infection control.

In the NHCU, refrigerators were not appropriately utilized and maintained. There was no temperature log for recording the temperatures of the patient nutrition refrigerator, and there were numerous items found in the nutrition refrigerator that were not nutritional supplements. These included a package of cheese, sausage, and other breakfast items. Nutritional supplements that were in the refrigerator did not have patients' names and some items were outdated. The quality control process for review of temperatures and

management of nutritional supplements should be standardized throughout the facility. Nutrition and Food Service is responsible for delivering nutritional supplements on a daily basis and would be the most appropriate medical center activity to be given responsibility for these quality control issues.

In view of the serious deficiencies in food preparation and storage, we strongly urge the Medical Center Director to hire a qualified manager for the Food and Nutrition Service as soon as possible.

Facility Management Needed To Encourage Anonymous Reporting of Medication Errors. Medical center management believed that reporting of medication errors should be educational for the clinicians involved. Clinicians indicated that there had been a gradual change in management's attitude toward medication errors; however, several clinicians indicated that some managers continued to believe that employees involved in medication errors should be punished. To address these errors comprehensively and accurately, medical center management should develop anonymous procedures for reporting them.

One particular category of medication errors was worthy of note. We found that 12 percent of reported variances during the previous 2 fiscal years involved heparin administration. Clinicians involved included physicians, nurses, and pharmacists. Clinical managers should provide heparin administration training for all clinicians.

All Employees and Volunteers Need Training to Effectively and Safely Deal With Violence. The medical center had a comprehensive workplace violence policy. However, the policy did not have a provision for a multidisciplinary committee or team to monitor violent incidents in the medical center. Management should consider establishing a facility-level team to focus on awareness and prevention of violence in the workplace.

We reviewed the Uniform Offense Reports for assaults between January 1, 1999, and January 20, 2000. During this time period, there were 96 incidents of disorderly conduct, 1 aggravated assault, and 2 simple assaults. Additionally, there were three incidents involving contraband drugs, nine incidents involving contraband and alcohol, and weapons were confiscated by medical center security officers on three occasions.

At the time of our review the Chief, Security Service had been providing "Prevention of Violence in the Workplace" training for 3 years during new employee orientation and also provided training at the service line level when requested. Education Service also offered workplace violence prevention training, focused on employees assigned to inpatient units. However, 22 percent of medical center employees indicated that they had not received violence prevention and management training. Because of the number of

incidents of violence that have occurred, all employees should have training regarding workplace violence.

Management Should Include Directions for Disposal of Transdermal Narcotic Patches in Medical Center Policy. The facility's narcotics policy comprehensively addressed disposal of unused narcotics, but management had not developed a consistent protocol for the disposal of used transdermal narcotic patches, such as fentanyl. Management should provide employees and patients with training on proper disposal of transdermal narcotic patches.

Management Should Reevaluate Processes for Inspecting Contract Nursing Homes. The Community Nursing Home (CNH) program had a defined process for inspecting and reinspecting local CNHs. However, the process for multi-state contract facilities did not follow the same inspection/reinspection process. In general, all inspections and CNH patient visits were conducted only during the administrative workweek, and management did not require CNHs to provide performance data pertaining to patient satisfaction, processes of care, or treatment outcomes. Management should consider standardizing the process for all CNH inspections. Employees should schedule patient visitations outside the normal administrative tours of duty, to include weekends and evening hours. Also, the CNH contracts should include a requirement for the provision of performance data on a quarterly basis.

Management Should Review Procedures for Witnessing Informed Consents for Interventional Radiology. Interventional Radiology employees told us that nurses who monitor patients during procedures often also sign as witnesses for informed consents. Since nurses are considered members of the treatment team, this practice is contrary to Veterans Health Administration (VHA) policy on informed consent. Management should review the informed consent policy and make appropriate changes in this practice.

Managers Should Implement Glucose Meters Capable of Reading Bar Codes. We reviewed PI monitors for glucose meters, including the Accucheck™ PI monitors for July through November 1999. We found that the threshold for acceptable errors in reporting glucose levels had been exceeded on Wards 5 East and 5 South during 4 out of the 5 months. The ATC explained that Accucheck™ errors occurred when nursing employees manually entered Social Security numbers in the system and transposed one or more numbers. Errors due to these manual entries apparently had not adversely affected patient outcomes because correct results were being properly documented in patient medical records. The ATC recommended the use of glucose meters that can read bar codes, thus eliminating manual entry of Social Security numbers.

Training and Education

Training Was Needed To Enable Supervisors To Assist Impaired Employees. Supervisory training to identify and manage employees who were involved in substance abuse was inconsistent. Some supervisors told us that they had been provided recent training, some indicated that they had received training 4 to 5 years previously, and some reported never receiving training. Management should ensure that supervisors are provided training for identifying and managing employees impaired by substance abuse.

Pharmacy Technician Training Was Not Documented. Documentation of pharmacy technician training regarding the preparation of highly specialized pharmaceuticals, such as intravenous (IV) admixtures, total parenteral nutrition (TPN), and chemotherapy was not maintained. The pharmacy inpatient supervisor reported that technicians received verbal instructions, followed by observation of their techniques. The inpatient supervisor indicated that continuous observation of technicians by a pharmacist was not possible.

Although verbal instructions and observation provide an educational foundation, management should ensure that employee training and skill competencies are properly documented. In addition, Pharmacy Service's procedure manual included written instructions for the preparation of IV admixtures, TPN, and chemotherapy, but the manual did not contain instructions for intrathecal antibiotic preparation.

Nursing Competencies Needed To Be Developed in the NHCU. The NHCU provided basic skilled nursing care, respite care, complex medical care, rehabilitation care, and comfort end-of-life care. Nursing managers told us that the scope of care, in addition to skilled nursing functions, included care for patients with central lines, IV antibiotic therapy, blood administration, medication management, pain management, restorative mobility; bowel and bladder training; and aspiration prevention. Although the unit had published admitting criteria, nursing staff routinely performed duties outside the scope of their competencies. Employees informed us that competency reviews were not conducted for blood administration, central line management, and mobility assistance training. In addition, nursing staff without appropriate competency checks were performing high-risk treatments. Management should revise the admitting and discharge criteria to more properly reflect the scope of care and services provided in the NHCU. Management also need to establish employee competencies addressing the needs of the patient population.

NHCU Managers Needed To Develop Interdisciplinary Treatment Plans and Processes. The NHCU interdisciplinary (implying integrated activities) treatment plans were actually multidisciplinary (implying separate activities) in nature, as evidenced by the use of different forms by nursing staff and the other members of the treatment team. For example, one patient's care plan had "self-care deficit" identified by three different disciplines, but none of the separate plans suggested a coordinated approach of the

separate planned interventions. The treatment plan goals were not measurable and in many instances were not individualized for each patient. Recreation Therapy treatment plans had the same intervention listed for each patient. The treatment plans had different sections for nursing and for the remainder of the team, further suggesting that the treatment team process was not interdisciplinary. Management should develop an interdisciplinary approach to treatment planning and to the treatment process itself.

Program Development

Management Needed To Increase Awareness of the Employee Assistance Program (EAP). A clinical psychologist was assigned to the EAP and had developed a brochure about the EAP that had been distributed to employees. The psychologist indicated that the medical center did not have a PI initiative to deal with the EAP, and none was planned for the future. Overall, employees seemed uncertain of the services offered through the EAP. We suggest that management increase awareness of the EAP through presentations at employee meetings and more frequent articles in the facility newsletter.

The Former Prisoner of War (POW) Coordinator Position Needed To Be More Fully Utilized. The position of Former POW Coordinator is a collateral duty. The coordinator plans special activities to recognize former POWs and assists with the entry of former POWs into medical center treatment. The coordinator estimated that he spent less than 10 percent of his time dealing with issues related to the needs of former POWs and that his access to the physician responsible for compensation and pension (C&P) examinations of former POWs was limited. Also, the coordinator received complaints from former POWs that they had difficulty understanding the physician due to a language barrier. Management should ensure that the Former POW Coordinator becomes more active in the coordination of services for POWs, such as C&P examinations.

Recreation Therapy Programs Warranted Evaluation. Some Recreation Therapy programs may not have been needed. For example, the need for the Ceramics Clinic, operated from the hours of 8 a.m. to noon, Monday through Friday is questionable based on workload. The clinic area accommodates no more than four patients, and when wheelchair users are in attendance the working area is further reduced. Recreation Therapy employees stated that approximately five outpatients and five NHCU patients utilized the clinic. The clinic was operated for "diversional" purposes and there were no treatment goals/interventions relating to patients' involvement in the clinic. Continued operation of the Ceramics Clinic is questionable from the standpoint of achieving the most productive use of therapists' time, and management should evaluate the need for continued operation of the clinic. Recreation Therapy coverage needs to be addressed with a plan formulated for the provision of comprehensive and constant coverage.

Evening, weekend, and holiday coverage in Recreation Therapy is limited, with only three full-time employees assigned. Volunteer groups, who were supervised by nursing

employees, provided evening activities on patient units. Recreation Therapy I was not provided on Sunday for any patient units.

An additional area of concern is that Recreation Therapy assessments were not completed in the time frame delineated by facility policy. Recreation Therapy was organizationally aligned under Physical Medicine and Rehabilitation Service (PM&RS). PM&RS policy stated that leisure assessments were to be completed by the recreation therapist within 48 hours of receipt of a request for consultation. Medical record reviews and interviews with Recreation Therapy employees showed that this was not being accomplished. Management and PM&RS employees need to review facility policy regarding completion of leisure assessments and consider altering the timeframes for completion. PI indicators should be developed to review the timeliness of leisure assessment completion.

Performance Improvement

There Was No Facility PI Plan, and the Plan for the Provision of Patient Care Services Was Inadequate.

The facility had not had a documented PI Plan for about 3 years at the time of our review. The lack of an assessment of the prior year's performance initiatives and the effect these initiatives had on the organization impeded the organization's ability to improve operations. Risk management (RM) and QM documents demonstrated that while QM employees collected and analyzed data, management did not consistently share this information with employees. The facility's Plan for the Provision of Patient Care Services did not delineate:

- Services provided at the facility
- Staffing models and variance reports
- Hours of operation
- Services obtained through contracts or other agreements

QM employees were aware of the need to strengthen this document but had not done so. Management should consider developing a facility-wide strategic plan. This plan would provide guidance to the Quality Manager in the completion of the PI Plan and the Plan for the Provision of Patient Care Services.

QM/RM Data Was Not Utilized for Clinicians' Proficiency Reports and Credentialing and Privileging Actions. QM employees could not demonstrate the process whereby information gained through the QM and RM programs was used in practitioners' annual proficiency reports and/or clinicians' credentialing and privileging actions. The only instance when QM/RM data was clearly utilized for these processes occurred when Quality Assurance staff obtained information in relation to a tort claim that required reporting to the National Practitioners Data Bank. The Director should

establish policy for consideration of information gained through QM and RM programs in practitioners' annual proficiency reports and clinician reprivileging actions.

The PI Process Was Not Specific. The PI process was defined for organization-wide activities that were tracked and trended by the PI oversight body. However, that oversight body only dealt with requirements of external oversight bodies. QM employees could not describe the process for oversight of PI activities that did not require the attention of the oversight body, i.e., PI activities that were peculiar to specific services. In addition, the medical center did not have a list of all of the facility's PI activities. Management should identify a separate reporting mechanism and process for PI activities that falls outside the scope of the facility's PI oversight body, or include such activities under that existing body. QM employees also need to initiate a procedure that will facilitate tracking of all facility-wide PI initiatives with outcome measures.

Ward 6 West and NHCU PI Initiatives Were Not Well Defined. QM and nursing employees informed us that PI processes had been inconsistent during the previous year on Ward 6 West and on the NHCU. The performance measures in place covered only the required "ORYX" Measures for Long Term Care,[2] which included geriatric depression screening, influenza vaccinations, and pneumonia vaccinations. The overall PI program had not identified issues from past reviews as areas in need of improvement, and performance indicators that track and trend processes and outcomes of improvement efforts were not available. Employees were aware of these indicators, but could not show us any documentation of tracking and trending of the indicators. Employees were unable to describe any evidence of PI efforts on the nursing units, which indicated a lack of dissemination of PI data to employees. Management should better define PI initiatives, improve tracking of PI indicators, and strengthen dissemination of PI data.

Management Did Not Thoroughly Evaluate Serious Patient Incidents. Staff on Ward 8 East reported three serious patient safety incidents in FY 1999. One of these incidents was a sentinel event, and management did a root cause analysis. Another event should have been considered a sentinel event, because it resulted in a major injury, but management did not classify it as such. In addition, facility reviews of these incidents did not explore all possible contributing or causative factors, such as staffing, tour of duty, and education or training needs that would identify possible process deficits. It should be noted that the reviews did result in appropriate changes in the physical environment and the establishment of regular environmental rounds. However, two of the three reviews did not comply with the directions in the Patient Safety Handbook on how to conduct focused reviews or root cause analyses. Management should establish a clinical review team to do an aggregate analysis of the three prior incidents to identify common themes and process deficits. Finally, a facilitator not directly involved in the incidents should lead the clinical review team.

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2. *A minimum standard of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).*

Pharmacists Did Not Check Complex Mixtures Prepared by Pharmacy Technicians. GS-6 pharmacy technicians prepared IV admixtures, TPN, chemotherapy, and intrathecal antibiotics after a pharmacist entered the order information into the computer system. Once the technicians prepared these mixtures, a pharmacist did not examine them for accuracy. The facility position description for GS-6 pharmacy technicians states, "Depending on protocols, complexity and nature of the preparation, manufacturing steps are completed without the need for certification by another person." In contrast, VHA policy states, "All orders and preparation will be checked by a pharmacist prior to dispensing and administering of the product."

As healthcare moves towards a systems approach to medication variances, the practice of a second check by a pharmacist appears to be a valid systems intervention. Facility and pharmacy managers should consider implementing a pharmacist second check for IV admixtures, TPN, chemotherapy agents, and intrathecal antibiotics.

Treatment Environment

The Inpatient Pharmacy Sterile Products Room Did Not Meet JCAHO or Occupational Safety and Health Administration (OSHA) Requirements. The inpatient pharmacy sterile products room should be a separate room that is used solely for the purpose of mixing and preparing sterile products. Although there was an area within Pharmacy Service where this function was performed, other pharmacy tasks (such as storage, IV mixtures, and dispensing) were also performed at the same location. The inpatient pharmacy supervisor told us that the inadequacies of the existing sterile products room were well known to the EMT and that a potential move for the inpatient pharmacy had been considered. The supervisor indicated that relocation would be the only realistic way to comply with JCAHO and OSHA requirements for the sterile products room. Pharmacy Service and Environmental Management Service (EMS) need to comply with JCAHO and OSHA requirements for the sterile products room.

The CHAMPUS/TriCare[3] Clinic Needed Housekeeping Services. The CHAMPUS/TriCare Clinic was very dirty. The clinic's floor and rug were dirty, as were the examination room sinks and floor. Management, EMS, and CHAMPUS/TriCare employees should identify and initiate procedures for improving the cleanliness of the clinic.

The NHCU Patient Care Environment Was Not Acceptable. NHCU employees were maintaining the environment in the best manner possible given stringent space limitations. However, patient rooms were cluttered and we identified risks that could

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3. *CHAMPUS/TriCare is the Civilian Health and Medical Program of the Uniformed Services. The program is for retired members of the uniformed services, and spouses and children of active duty, retired, and deceased members.*

result in patient falls, fires, and infections. Examples of these risks included oxygen tubing running across the floor creating a tripping hazard, a surge protector taped to a patient's bedside table, and clutter in the patient rooms making it difficult to clean the areas. The patient shower on Ward 6 West was dirty and presented other safety issues. Wet towels were on the floor. A chair placed in a small adjacent area prevented the door from opening completely, which could impede employees from assisting a patient in an emergency. Another patient bathroom had a bar of soap on the floor of the shower room, which created a safety hazard and demonstrated a lack of compliance with infection control policies. Management should address the above deficiencies and follow up to assess compliance during routine facility environmental inspections.

Privacy Curtains Were Needed in Nuclear Medicine Imaging Service. The imaging room did not have privacy curtains. There were five pieces of imaging equipment in a large room and patients could see each other while undergoing imaging procedures. Employees told us that the privacy curtains were taken down during construction and were not reinstalled. Patient privacy needs to be improved.

Ambulatory Care Did Not Have Adequate Examination Rooms. The medical center had more than an 11 percent increase in ambulatory care visits from FY 1998 to FY 1999. Ambulatory Care examination room space was a significant concern, since there were not enough examination rooms to allow two rooms per provider. To promote efficiency, each provider should have two examination rooms. While a provider is working in one room, another patient can be prepared in the second room, allowing the provider to continue working from one room to the other without interruption. Management and Ambulatory Care personnel should explore methods of increasing the number of examination rooms.

Equipment

The Facility Lacked Feminine Hygiene Product Dispensers. None of the public women's restrooms had feminine hygiene product dispensers. The Veterans Canteen Service had been approached to install and maintain these dispensers in the restrooms. However, little progress had been made toward this goal. Management should ensure that sanitary napkins and tampons are readily available throughout the facility.

Infection Control

The Urinary Bladder Catheter Management Protocol Warranted Review. The urinary bladder catheter management protocol states, "bag and drainage tubing are changed each Sunday and bag is labeled with the current date and initials of caregiver." The policy of changing the bag and drainage tubing did not meet current infection control practices, which dictate that a closed system, such as a urinary catheter, should not be opened. Employees were unable to give a rationale for the weekly changing of bags and

drainage tubing. Infection Control and Urology Service employees should review this protocol and make appropriate clinical practice changes.

Screening for Tuberculosis (TB) Was Not Consistently Provided. Patients in the NHCU and on Ward 6 West were not consistently screened for TB at admission. In addition, TB screening was not a routine part of patient assessments on Ward 8 East. Employees indicated that TB skin tests are given only when Ward 8 East patients are discharged to nursing homes. Management should conduct a facility-wide review for the establishment of a consistent TB screening protocol, and incorporate this protocol in the facility PI Plan.

Orders for Influenza and Pneumonia Vaccinations Were Inconsistent. There were also inconsistencies in the ordering of influenza and pneumonia vaccinations for the NHCU and Ward 6 West patients. Management should develop a proactive approach to assure that all patients are offered influenza and pneumonia vaccinations at the time of admission to the NHCU and Ward 6 West. This approach should also be incorporated into the facility PI Plan.

NHCU and Ward Clean Supply Areas and Isolation Carts Presented Security and Sterility Concerns. Employees were storing dirty items in the clean supply rooms on Ward 6 West and the NHCU, creating the potential for contamination of sterile supplies. These rooms had boxes stored on the floor and on shelves, preventing appropriate clearance for the fire sprinkler system. Storage carts for isolation supplies were stored in the hallway covered by sheets, and they contained unsecured chemicals. We also found an environmental management cart unattended, with chemicals readily accessible. There was laundry detergent in the patient laundry area. The isolation supplies, chemicals, and detergent were readily accessible to patients and visitors, creating the potential for cross-contamination and exposure to hazardous chemicals. During facility inspections, facility and NHCU management should place increased emphasis on supply rooms, isolation carts, and security of chemicals on the NHCU and Ward 6 West. Management should also provide refresher training to NHCU and Ward 6 West employees about storage of clean and dirty supplies.

Safety

Security and Storage of Medications Was Inadequate in the NHCU and on Ward 6 West. Nurses stored medications in a cart at the nurse's station and in a medication refrigerator. However, there was no locking mechanism for the refrigerator, and the refrigerator temperature log was not consistently completed by the employees. The absence of documentation indicated a lack of ongoing quality control monitoring. Management should review medication security and storage in the NHCU and on Ward 6 West, and should consider construction of a lockable medication room which would better control access to medication.

Reutilization of Soft Wrist Restraints Should Be Discontinued. Soft wrist restraints utilized in intensive care units were routinely sent to the laundry when soiled and returned to the units for re-use. Soft wrist restraints are designed for one-time use only. Clinicians should dispose of soft wrist restraints after each use.

The Appropriateness of Fire Sprinkler Heads on Patient Wards Needed To Be Assessed. Sprinkler heads throughout Ward 8 East were not recessed into the ceiling, and employees were unsure if they were of the "breakaway" type or how much weight they could support. This is of particular concern in bathroom and shower areas where patients who are at elevated risk for suicide may be unsupervised. If the sprinkler heads are determined not to be of the breakaway type, a change to breakaway sprinkler heads is indicated.

Medical Record Documentation

We reviewed 25 randomly selected patient medical records and found that medical record documentation supported the need for patient admissions. The treating clinicians appropriately prescribed medications, ordered follow-up appointments, and provided needed patient education. However, the following areas required management attention.

Multiple Record Systems Impeded Rapid Access to Pertinent Patient Information. Patient information was maintained in an automated patient medical record called the Computerized Patient Record System (CPRS) and in a paper record system. Although the MICU and the SICU had fully computerized medical records, the system in use on these two units was different from and not totally compatible with CPRS. In the NHCU and Ward 6 West there was even less ease of access to patient medical information because these units relied on three different medical record systems; CPRS records, traditional paper medical records, and a separate record for the documentation of patient care plans. Patient medical information should be consolidated into a single record to facilitate access by clinicians. Management should use the CPRS exclusively for this purpose.

Medical Record Documentation in the NHCU Needed To Be Improved. We reviewed nine NHCU medical records. Five records were for current patients and four were for former patients. Although physician assessments and nutritional assessments were present in all nine records, other documentation was lacking as shown in the following table.

Lack of Documentation in NHCU Medical Records

Documentation Rate	Discipline or Activity
88% (100% in current records)	Nursing assessments
66%	Psychosocial assessments (Social Work)
85%	Functional assessments
0%	Recreation Therapy assessments
44%	Spiritual assessments
44%	Oral assessments (Nursing)
50%	Interim Care plans (Nursing)
50%	Interdisciplinary Team Care plans
50%	Problem prioritization by Interdisciplinary Care Team
0%	Measurable goals by Interdisciplinary Care Team
77%	Interventions identified for problem areas

While documentation by some disciplines and of some activities appeared adequate, documentation by others needed improvement. An in-depth review of NHCU records may be warranted. In addition, the Medical Center Director should ensure the accessibility and adequacy of medical record documentation by implementing only CPRS throughout the medical center, and by evaluating the need for better documentation by all disciplines for NHCU patients.

Survey Results

We surveyed 119 patients, 23 clinicians, and 12 managers about a variety of healthcare-related issues. Highlights from these surveys are presented in the following paragraphs. We provided complete survey results to service managers.

In response to the statement, "If eligible, I would recommend medical care at this facility to a family member or friend," 89 percent of patients, 81 percent of clinicians, and 80 percent of managers indicated "Yes, all or most of the time." Responses to the statement, "If a patient could go to any hospital, they would prefer to return to this facility," showed 85 percent of patients, 80 percent of managers, and 74 percent of clinicians indicating "Yes, all or most of the time."

Quality of care questions indicated that 100 percent of managers, 95 percent of clinicians, and 91 percent of patients rated care at VAMC Indianapolis as "good to excellent." Questions pertaining to satisfaction with treatment resulted in 100 percent of managers, 91 percent of patients, and 90 percent of clinicians responding "good to excellent."

When asked if prescription medications were available within 60 minutes, 88 percent of patients, 80 percent of managers, and 59 percent of clinicians responded "Yes, all or most

of the time." Likewise, 89 percent of patients, 86 percent of managers, and 64 percent of clinicians stated that, "Outpatient prescriptions are given before discharge, when applicable."

While most of these perceptions tended to be positive, some employee perceptions showed a need for management attention:

- Thirty-eight percent of the employees responded that they "agreed or strongly agreed" with the statement, "I cannot be totally efficient because of inadequate resources." Furthermore, 60 percent of the employees "disagreed or strongly disagreed" that recognition and awards adequately reflected performance. Additionally, 53 percent of employees "agreed or strongly agreed" that, "Incompetence is encouraged and rewarded at VAMC Indianapolis." In response to the statement, "Who you know is what counts, not what you do," 46 percent of employees "agreed or strongly agreed."

- The statement, "There is sufficient staff in my area to provide care to all patients who need it," resulted in 35 percent of employees "disagreeing or strongly disagreeing." Interestingly, this conflicts with patients' responses to, "When I come for an appointment, there seems to be enough staff to meet my medical needs and answer my questions." Eighty-five percent of the patients who responded to this question said that, "Adequate staffing was the case all or most of the time." Additionally, 87 percent of patients indicated "Yes, all or most of the time" in response to the statement, "Staff is available to talk to you when you need to talk."

- Thirty-three percent of the surveyed employees indicated that, "The person completing my evaluation is not qualified to do so," while 74 percent of employees indicated they felt they had no input into other team members' evaluations.

Overall, patient, manager, and clinician perceptions of VAMC Indianapolis were positive. However, as identified through our surveys, it appears that the facility is not meeting employees' expectations in terms of their perceptions of staffing adequacy, appropriateness of rewards, supervisory qualifications, or the performance appraisal process.

The Medical Center Director should evaluate our survey results to determine whether more intensive employee-management communication is needed to resolve what may be misconceptions on the part of some employees.

Financial and Administrative Management

Management Controls Were Generally Effective

We concluded that the administrative activities we reviewed were generally operating satisfactorily and management controls were generally effective.

- Agent Cashier funds were accounted for and unannounced audits were performed as required.
- C&P examinations performed by medical center staff for the Veterans Benefits Administration were timely and complete.
- A contract for the construction and operation of a veterans nursing home on medical center property complied with Federal and VA procurement policies.
- An enhanced use lease for the non-VA use of the medical center's Cold Spring Road property was in accordance with applicable regulations.
- Management fully supported implementation and use of the Decision Support System (DSS), anticipated workload increases, and formulated a plan to increase DSS staffing.
- A contract to acquire mobile angiography was appropriate.
- Medical center management had instituted a 100 percent review of Medical Care Collection Fund (MCCF) billings, and MCCF billings were appropriate.
- Terms and payments for a scarce medical specialist contract to obtain surgical services for the medical center were appropriate.
- A contract to obtain transcription services for the medical center was cost-effective, and medical center staff reported that transcription services obtained under the contract were timely and of acceptable quality.
- Warehouse inventories were maintained at acceptable levels, and the Generic Inventory Package (GIP), an automated inventory control system, was fully implemented.
- Hazardous materials were inventoried and stored appropriately, a Hazardous Materials and Waste Management Plan had been established, and employees had been trained in the use and handling of hazardous materials.
- Automated data processing equipment was acquired in accordance with the requirements of VA's Procurement of Computer and Software contract.

Recommendations for Improving Management Controls

Informed Patient Consent for Research Was Not Consistently Documented. Staff responsible for monitoring medical center research programs could not assure that informed consents were obtained from participating patients. This occurred because Research Service staff had not identified all patients who were receiving care under the auspices of research protocols and because they had not reviewed cases that had been identified for compliance with Department policies.

VA policy requires that informed consents be obtained from all research subjects or, in the case of those adjudged incompetent, from a legally authorized representative. To further ensure that patients are fully informed of the risks of and alternatives to treatment under research protocols, VHA policy also identifies several specific elements that must be included in informed consents. VHA policy also contains specific requirements for documenting informed consents.

Research Service administrative staff informed us that a significant number of VA patients could be participating in some or all of the 110 or more approved research projects involving human subjects conducted at either the medical center or its affiliate. However, these staff could not tell us which projects involved human research or VA patients. Some projects might have involved only Indiana University School of Medicine patients. Systematic reviews were not conducted to ensure that informed consents were obtained prior to enrolling patients in research projects.

Research Service administrative staff depended on research investigators to obtain and document informed consents from the patients involved in their projects. In some instances investigators provided copies of consent forms and other administrative information, but there was no policy requiring this and research administrative staff did not have complete documentation.

VHA policy requires that the original consent form be maintained in the patient's medical record. We reviewed the medical records of 10 patients whom research staff were able to identify as participants in research projects.

- In four cases, the original consent forms were in the patients' medical records.
- In four cases, only copies of the consent forms were in the medical records.
- In two cases, neither originals nor copies of the consent forms were in the medical records. For one of these two cases, we located a copy of the consent form in Research Service records. In the other, Research Service records contained only an incomplete copy. In neither case were we able to locate an original of the consent form.

VHA policy allows an Institutional Review Board (IRB) to approve the use of consent forms that are different from VA's standard consent form. However, the policy also states that any variant approved by the IRB must include, at a minimum, 12 specific components of informed consent.

None of the 10 consent forms we reviewed were VA forms; all were Indiana University School of Medicine forms. Consent forms for 2 of the 10 VA patients, both using the same variety of form, did not meet VA requirements. Both failed to specify the lengths of time the patients would be involved in their respective research.

VHA policy requires that research records pertaining to VA patients be maintained in conditions of confidentiality. Because research administrative staff did not know which projects involved VA patients, medical center management cannot ensure that the confidentiality of research records is maintained. Research Service staff could help ensure that this requirement is met if they knew which projects involved human subjects and where, and under what conditions, the investigators' records were maintained.

Recommendation No. 1:

The Medical Center Director should improve controls over human subject research projects involving VA patients by:

a. Maintaining appropriate administrative records of VA research projects and identifying the VA patients involved.

b. Ensuring compliance with all informed consent requirements for human subject research.

Medical Center Director Comments

Concur and completed.

a. The Research Service office maintains a human study file that contains lists of patients involved in each study, copies of IRB approvals, and updated, approved informed consents. Since the CAP assessment, the Research Service has begun maintaining a computerized list of patients in studies.

b. During the CAP assessment, informed consents were not in the charts in 2 of the 8 (sic) patient records reviewed. Those consents have since been placed in the chart. Educational efforts are underway to make certain that investigators know the required elements for informed consent. Investigators are advised to place the consent in the charts, rather than send them un-filed to medical records.

Office of Inspector General Comments

The Director's comments and implementation actions are acceptable. We consider this recommendation implemented, although we may follow up on implementation actions.

Informed Consent for Surgery from a Potentially Incompetent Patient Needed Review. We reviewed a sample of 24 surgical procedures selected from the November 1999 surgical log. Medical center staff obtained and documented informed consents appropriately for 23 of these cases. However, we identified a variety of problems associated with the case of a long-term care patient who was transferred to VAMC Indianapolis from the VA facility at Marion, IN on October 22, 1999. During the 2 years preceding the transfer, the patient was hospitalized at VA facilities in both Marion and Fort Wayne, IN, and at other contracted facilities. During the course of care at VAMC Indianapolis the patient underwent several invasive procedures, including multiple colonoscopies leading to a sigmoid colectomy with a colostomy. The patient was later transferred back to Marion on November 10, 1999.

Problems we noted in connection with this patient's treatment included:

- A disagreement among clinical staff about the patient's ability to provide informed consent.
- Incomplete documentation of consents obtained by telephone from a next of kin.
- Conflicting information about which procedures were performed when and under the authority of which consents.

Medical record documentation revealed an apparent disagreement among clinicians about whether the patient was competent to provide informed consent. On October 29, 1999, two VAMC Indianapolis staff psychiatrists performed separate psychiatric evaluations of the patient. The purpose was apparently to determine competency, although neither psychiatrist's medical record entry clearly defined that purpose. Both psychiatrists indicated that the patient was incompetent, one even recommending that a legal guardian be appointed. However, on same day a third physician noted in the record that the patient was competent, and thus obtained a consent from the patient for an endoscopy that was performed later that day. This difference in medical opinion about the competency and legal status of the patient brings into question the validity of the consent that was obtained by the third physician.

A telephone consent obtained from the patient's next of kin to initially transfer him to VAMC Indianapolis from the VAMC Marion, IN was not adequately documented. The form used to document this consent did not include the name and relationship to the patient of the party providing consent.

Because of incomplete telephone consent documentation, we could not be certain that there was proper consent for the patient's last surgical procedure before his transfer back to Marion. Medical records show that a sigmoid colectomy with a colostomy was performed on either November 5 or 6, 1999.[4] Medical center administrative staff executed two separate reports of telephone consent, both dated November 4, presumably for the colectomy. However, because we could not locate a transcribed copy of either conversation, we could not determine with certainty that they pertained to the procedure that was performed on November 5 or 6. VHA policy requires that a transcribed report of each telephonic consent be included in the medical record and that the consent be specific as to the date of the proposed procedure.

VAMC Indianapolis staff contacted staff at VA facilities in both Marion and Fort Wayne to determine if medical records there could resolve the problems detailed above. Staff at neither facility could locate documentation pertaining to invasive procedures performed at VAMC Indianapolis on this patient.

While this was the only case among the 24 reviewed that indicated a problem with obtaining informed consent for surgery, the multiple lapses in documentation of consent may indicate systemic problems in obtaining informed consents for procedures on severely debilitated or incompetent patients.

Recommendation No. 2:

The Medical Center Director should order an in-depth review of the case cited to determine if a review and a revision of overall surgery consent policy is needed.

Medical Center Director Comments

Concur and in progress. Surgery Service has requested all medical record volumes of the case cited and will complete a comprehensive review. The results of the review will determine the need for further action regarding the surgery consent policy.

Office of Inspector General Comments

The Director's comments and implementation actions are acceptable. We consider this recommendation implemented, although we may follow up on implementation actions.

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[4] *The surgical log and the operative report showed that the procedure was performed on November 5. The discharge summary showed that it was performed on November 6. While it ultimately proved irrelevant for the purpose of this review, the discrepancy in the medical records should be of concern to medical center management.*

Accountability and Security Over Controlled Substances Needed Improvement. We identified several conditions related to accountability and security over controlled substances which indicate that overall controls needed to be improved, as follows:

- Monthly inspections of Schedule II, III, IV, and V controlled substances took too long to complete.
- Monthly inspections identified deficiencies involving failure by ward staff to document the administration and destruction of controlled substances and validation of shift change inventory levels.
- Destruction of expired drugs was not conducted when required.
- Expired controlled substances were kept for an extended period at one location.
- A spoiled consignment of a controlled substance was retained too long without being returned to the vendor and was inappropriately removed from, or never entered into, inventory records.
- An accountability document was removed from one area where controlled substances were stored and dispensed, and another accountability document in another area did not include three controlled drugs.
- An accountability document in one area could not be reconciled.
- An inventory balance discrepancy in another area needed to be resolved.

Reviews of unannounced controlled substances inspection records for January through December 1999, revealed that all inspections required by VHA policy were performed. However, inspections took too long to complete. For example, the narcotics inspection for December was carried out over a 15-day period, from December 16 to 30. Such an extended period of time between initiation and conclusion, gives too much advance warning to those locations inspected last, making their inspections, in effect, "announced." In addition, an inspection conducted over an extended period makes accounting for controlled substances more difficult in that they may have been moved from one location to another in the interim. It also makes it easier to improperly move controlled substances from an inspected area to an uninspected area for the purpose of hiding a shortage. Ideally, controlled substances inspections should occur at all locations on the same day, or as close to the same day as possible.

Our review of the most recent monthly narcotics inspections identified instances in which controlled substances were dispensed or destroyed ("wasted") by nursing staff without adequate documentation. The December 1999 inspection report identified 44 occasions where controlled substances were dispensed or wasted but, those actions were not documented and/or witnessed, as required. Of the 44 instances, 12 occurred on one ward. The report also noted a number of instances in which ward inventory levels were not verified at the time of shift changes. There was no indication in the inspection report that

corrective action was either recommended or taken. The deficiencies identified should have been corrected, especially since they could have facilitated the undetected theft of drugs.

Expired drugs were not destroyed as frequently as necessary. VHA policy requires that outdated or otherwise unusable controlled drugs be destroyed at least quarterly. Reviews of drug destruction records revealed that only two destructions occurred in 1999. At the time of our review, no destruction had taken place in the prior 6 months, and there were 65 containers of drugs awaiting disposal in the pharmacy. The presence of large quantities of expired drugs increases the possibility of pilferage. Drug destruction should occur at least every 3 months and more often if the quantity of expired drugs on hand warrants.

During our review in January 2000, we also observed a large quantity of expired controlled substances on hand in a Research Service area. Some of these drugs had been expired for as long as 20 months (April 1998). These drugs should have been noted by both Research Service staff and narcotics inspectors and should have been turned in for destruction.

We noted one example of a shipment of a controlled substance that was improperly accounted for and inadequately safeguarded. Pharmacy staff had marked a container of 100 codeine ampules for return to the vendor because it showed evidence of damage upon arrival.[5] At the time of our review, the container had been stored under a table in the main pharmacy area for 14 days, without either being returned or placed into inventory. No accountability record had been established, and the drugs could have been easily diverted without detection.

An important control document for controlled substances maintained in a pulmonary clinical area (a bronchoscopy laboratory) was missing. We asked medical center narcotics inspectors to perform a routine monthly narcotics inspection, which we observed. During the inspection, we were unable to locate the Controlled Substance Administration Record for stocks of morphine, midazolam, Valium©, and medperidine. This document records receipts, issues, and wastings of drugs and is essential in controlling them. The document must remain with the drugs until the stock is completely depleted or the document is full and replaced with another. Because the document was missing, all accountability for these particular drugs was lost.

Subsequent to our review, we located the document among records in the medical center security office. We believe that the document was probably inadvertently removed during the previous monthly inspection. In the interim, clinical staff responsible for maintaining and dispensing this drug had kept dispensing records on scratch paper.

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[5] *There evidently had been some sort of spillage on the container either prior to its shipment or while it was in transit.*

Using this scratch record and the newly located control document, we were able to verify the drug stock level. Nevertheless, even the temporary loss of this record created a serious accountability problem. Should a similar situation occur in the future, clinical staff should immediately alert pharmacy staff so that a replacement control record can be created using pharmacy issue records.

In a related example, we observed that the CSAR for drugs maintained in a Research Service area did not contain entries for three of four kinds of controlled drugs; Nembutal©, pentothol, and metofane. All accountability for these drugs was lost. These drugs should be removed from Research Service stock until an accountability trail can be reconstructed.

Finally, we could not establish the correct inventory level for pentobarbital, a controlled substance maintained in a Research Service area. Our physical count of the drug found only one unit on hand. However, the CSAR for that drug showed that there should have been at least 10 units on hand. This lack of accountability was compounded by conflicting inventory balance entries on the control record, i.e., one entry showed 10 units on hand, whereas a subsequent "balance forward" entry showed 20 units on hand. Thus, either 9 or 19 units were missing, depending on which inventory level was correct. This discrepancy should be resolved.

These discrepancies indicate a need for a general review and strengthening of medical center-wide controls over controlled substances.

Recommendation No. 3:

The Medical Center Director should strengthen controls over controlled substances by:

a. Ensuring that monthly controlled substances inspections occur at all locations within as short a time frame as possible.

b. Taking appropriate remedial action when narcotics inspections reveal instances of ward staff failing to properly document the dispensing or wasting of controlled substances and the drug inventory balances at a shift change.

c. Destroying outdated drugs at least once every 3 months.

d. Establishing or enforcing controls for removing and disposing of outdated drugs from dispensing locations.

e. Returning spoiled controlled substances to vendors immediately upon discovery, or recording them in inventory records to assure control over the drugs pending disposition, or both.

f. Maintaining a CSAR for all controlled substances kept at dispensing locations.

g. Reconstructing a CSAR for nembutol, pentothol, and metofane issued to a Research Service dispensing location and removing those drugs from that area pending reconstruction of the control record.

h. Resolving an inventory balance discrepancy for pentobarbital maintained at a Research Service dispensing location.

Medical Center Director Comments

Concur and completed.

a. All of these recommendations have been reviewed extensively with nursing staff and supervisors on each ward/area and controls that were already in place have been strengthened. Meetings with appropriate services were conducted and policies reviewed and reinforced. Areas of concern where quality improvement could be enhanced have been completed. Since the CAP assessment, all of the items noted have been monitored and any discrepancies found have been reviewed and corrected.

b. During the most recent inspections the charge nurse for each dispensing location reviews and takes appropriate action to ensure discrepancies are corrected immediately.

c. Narcotic destruction will be done every 3 months, regardless of the quantity of product requiring destruction.

d. Controls that were already in place have been strengthened for outdated drugs.

e. Timely return of spoiled containers continues to be done.

f. The strengthening of the inspection process will ensure that CSARs are kept at dispensing locations. Staff have been educated in the proper record keeping.

g. The Research Service, in conjunction with the Narcotics Control Officer, have reviewed and corrected problems with the CSARs. Instructions have been given to the key control personnel to document and maintain training records on the use of the CSARs for those who withdraw narcotics.

h. The inventory balance discrepancy has been resolved.

Office of Inspector General Comments

The Director's comments and implementation actions are acceptable. We consider this recommendation implemented, although we may follow up on implementation actions.

Controls Over Government Purchase Cards Required Strengthening. VA medical centers are required to use commercially issued Government purchase cards for most small purchases of goods and services, usually of $2,500 or less per transaction. VHA has established controls to ensure that items purchased were actually received, charges were for official purposes, and bills were correctly paid. Cardholders must reconcile payment charges reported by the purchase card contractor with the purchase amounts recorded in the Integrated Funds Distribution, Control Point Activity, Accounting, and Procurement (IFCAP) system within 5 days of a message confirming VA payment. Approving officials are to certify the reconciled purchase transactions within 14 days of receipt from the cardholder. Program coordinators are to conduct periodic audits of purchase card transactions, and the Chief, Fiscal Service is required to review monthly quality reviews conducted by the program coordinators.

We reviewed a judgment sample chosen from 10,791 purchase card transactions occurring between June and November 1999 and identified several that were for goods or services not normally associated with allowable Government purchase card acquisitions. We also identified two purchases that had been split into smaller increments, presumably to avoid the $2,500 limitation for single purchases.

- A purchase card was used for a rental car. This may have violated VHA policy that prohibits use of a purchase card for rental of motor vehicles except under very specific circumstances.
- A purchase card was used to buy a laptop computer costing $2,177. Acquisition of computer equipment with a purchase card is not allowed by VAMC policy.
- A single purchase card was used for three transactions on the same day to acquire 10 laser printers costing a total of $5,070. The purchase was split into three separate transactions of $1,996, $1,996, and $1,078. In addition to violating VAMC policy on the use of a purchase card for computer-related items, splitting the purchase avoided the $2,500 limitation on single purchase card transactions and avoided any higher-level review that a purchase of this size normally would have required.
- A purchase card was used for 2 transactions on the same day to acquire 20 pacemaker transmitters. Each transaction totaled $1,450. This violated VA policy by circumventing the $2,500 limitation on purchase card transactions.

According to the Government purchase card program coordinator, no audits of purchase card transactions have been conducted for at least 3 years. VA policy requires that the coordinator conduct periodic audits to ensure that cardholders and approving officials comply with Government purchase card policies and procedures. Regular audits of purchase card transactions should have identified these or other questionable purchases. VA policy also requires that Fiscal Service staff conduct monthly quality reviews of selected purchase card transactions to ensure that they comply with VA requirements.

Our review showed that, while these quality checks were being conducted as required, the Chief, Fiscal Service was not signing the reviews to attest to their accuracy.

Recommendation No. 4:

The Medical Center Director should take action with regard to the Government purchase cards to ensure that:

a. A program of regular audits is established.

b. When such audits identify questionable transactions, each case is researched to determine if VA purchase card policies were violated.

c. If a determination is made that a purchase violated policy, appropriate remedial action is taken, including disciplinary action against the cardholder, if warranted.

d. Particular attention is paid to purchases of computer equipment and split purchases of any type.

e. The Chief, Fiscal Service signs monthly quality reviews.

Medical Center Director Comments

Partially concur and completed.

a. Since the inception of the purchase card program, there has been a "program of regular audits," in addition to the monthly Financial Service Center (FSC) quality reviews, in place at this medical center. These audits are conducted by the staff in the Accounting section and were presented to the auditor during the CAP assessment. The audits were performed on a quarterly basis, using a sample of one randomly selected transaction per cardholder per quarter. It is recognized that the guidance provided in VA Handbook 1730.1, dated June 14, 2000 is significantly improved over previous versions. In an effort to strengthen our purchase card audit program, joint Fiscal and Logistics audit will be performed on a monthly basis as required in addition to the FSC's monthly reviews. During the month of October 2000 the VISN CLO conducted site reviews at all VISN facilities using a detailed audit guide. Each month every purchase card transaction conducted by this medical center is reviewed using the Citibank Merchant Activity Report and the IFCAP Purchase Card Statistic report. These two reports provide sufficient data to determine if cardholders are purchasing from appropriate sources and if purchases are being split to defeat the purchase card limits. In addition one control point is selected per month for a focused review by Acquisition and Materiel Management Service (A&MMS) and Fiscal Service.

b. Audits completed since the new Handbook was released revealed that most purchase cardholders are compliant with agency and medical center credit card policies. While no

critical discrepancies have been identified by the audits, each questionable item that has been identified has been presented to the approving official and the cardholder. Serious irregularities are brought to the attention of the Chief Accountant, Chief Financial Officer, and the Purchase Card Program Coordinator. If policies are violated, the cardholder and approving official are notified of the discrepancy and advised of the proper use of the purchase card. In addition, all credit card holders and approving officials now sign a specific list of responsibilities. Documentation is available to confirm that the medical center has identified situations in which items have been returned to the vendor due to violations of purchase card requirements. The medical center will continue to thoroughly research each questionable transaction identified during the routine audits or by other control mechanisms to determine if purchase card policies have been violated.

c. If it is determined that a card holder or an approving official is repeatedly violating or ignoring department or medical center policy, then appropriate remedial action will be taken. Through our on going audits it was determined that a purchase card had been stolen and misused. Our investigation uncovered photographic evidence of the thief, which resulted in his prosecution, sentencing, and restitution to the VA. A verbal counseling was provided to the cardholder by his supervisor for failure to secure the card.

d. During our monthly audits two reports are used to determine the sources used to procure from and to determine if orders are being split to defeat the $2,500 purchase card limit (Citibank Merchant Analysis report and the IFCAP Purchase Card Statistics Report). Also, since the issue of the new VHA Handbook all cardholders are now required to enter each purchase card transaction into IFCAP using the Detailed menu option. This provides detailed information that assists us during our audits to determine the appropriateness of the items being procured.

e. The Chief, Fiscal Service had delegated authority to review and sign monthly quality reviews to the Chief, Accounting Section. The Chief, Accounting Section signed all quality review reports inspected by the CAP assessment reviewers.

Office of Inspector General Comments

The Director's comments and implementation actions are generally acceptable.

However, we should note two points. First, at the time of our review in January 2000, two separate audits of purchase card transactions were required: one by the program coordinator and one by Fiscal Service. When VHA purchase card criteria were updated in June 2000, the one audit by the program coordinator was removed as a requirement. Thus, while the medical center was not in compliance at the time of our review, the issue is moot as audit requirements now call for only the one audit, by Fiscal Service. Secondly, delegation of authority to sign monthly quality assurance reviews from the

Chief, Fiscal Service to the Chief, Accounting Section may be technically permissible. However, we believe that, in the spirit of VHA purchase card directives (as upheld in the June 2000 update), the importance and high degree of vulnerability in the purchase card program call for the Chief Financial Officer of the medical center to personally sign quality assurance reviews.

We consider this recommendation implemented, although we may follow up on implementation actions.

Suggestions for Management Attention

Other opportunities to improve management controls were noted in the following areas. The Medical Center Director's comments to our suggestions are included in Appendix III.

Timekeeping for Part-Time Physicians Needed Improvement. Official duty hours recorded for some part-time physicians did not correspond to their actual hours of work. This occurred because supervisors and timekeepers regarded established official tours of duty as mere formalities.

We reviewed timekeeping controls for part-time VA physicians. We interviewed four timekeepers in Medical and Surgical Services and staff in Fiscal and Human Resources Management Services to identify the controls in place that ensure the presence of physicians during their duty hours. VA policy requires that timekeepers have personal knowledge of staff whereabouts during scheduled tours and that supervisors certify staff's attendance during the hours for which they are to be paid. We also confirmed that five randomly selected physicians with less than full-time VA appointments were present during official duty hours.

Fiscal and Human Resources Management Service staff maintained formalized and documented tours of duty as reflected on timecards, but these tours did not necessarily reflect the hours actually worked by physicians. Rather, the tours actually worked by physicians were a function of clinic schedules, the needs of their service chiefs, and the needs of the physicians themselves. In addition, we were told that historical records were not maintained of the hours worked. Rather, temporary or disposable rosters were maintained via such media as erasable boards located in common areas.

This situation meets neither the spirit nor the letter of time and attendance regulations. Certification of timecards known to be in error by supervisors is technically a false certification that is potentially sanctionable.[6]

We believe a solution exists that would permit clinical supervisors a large measure of flexibility in scheduling physician tours that conforms to VA policy. Use of a "core hour" concept, which we have seen at other medical centers, assigns a certain percentage of a physician's total biweekly time to a fixed tour of duty, which becomes the physician's "core hours." The remaining percentage of their time is flexible and can be adjusted as needed with supervisory approval. We suggest that the Medical Center Director explore adoption of the "core hour" concept for part-time physicians or, otherwise, enforce official scheduled tours.

Periodic Inventories of Equipment Needed To Be Conducted. Medical center staff had not inventoried some equipment in nearly 3 years. VHA policy requires that nonexpendable equipment be inventoried at least every 2 years. We found that equipment valued at over $11.5 million dollars had not been inventoried since mid-1997.

We examined the medical center's 164 Consolidated Memorandums of Receipt (CMRs) for evidence that they had been reviewed in compliance with VHA policy. Those CMRs included equipment valued at $65 million. We found that equipment valued at $11.3 million and appearing on eight Surgical Service CMRs had not been inventoried since June 1997. Also, equipment valued at $240,000 and appearing on six Research Service CMRs had not been inventoried since March and October of 1997.

A&MMS staff informed us that the surgical equipment could not be reviewed because surgical areas are too busy to permit access to the equipment. They also informed us that the whereabouts of equipment on the Research Service CMRs could not be verified because it was located at the Indiana University School of Medicine and that VA employees did not have access to it. We suggest that the Medical Center Director ensure that the eight Surgical Service and the six Research Service CMRs are inventoried as required.

Inventory Controls in Supply, Processing, and Distribution (SPD) Were Inadequate. Inventory controls over medical supplies maintained in the SPD unit needed improvement. GIP records showed that as of January 19, 2000, medical supplies on hand in SPD were valued at $715,078.

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[6] *Medical center management asked us to make a special note of their assurance to us that physicians at this medical center very often worked more hours than they were paid for and, as a result, the best interests of VA and its patients were served.*

With the assistance of SPD staff, we inventoried 10 randomly selected items of SPD stock valued at $47,335. The inventory showed that GIP records did not accurately reflect stock on hand for 8 of the 10 items tested. In six cases, actual stock levels were less than reported and represented unaccounted for supplies. In two cases, more items were on hand than reported in the GIP system, representing supplies that were essentially uncontrolled.

Loss of control over such items could negatively impact Surgical Service operations. For example, the SPD records referenced above showed 35 custom surgical packs for cardio-aortic bypass grafts "on hand." In fact, only 12 packs were in stock.

SPD staff subsequently conducted a wall-to-wall inventory of SPD stock, reporting an 87 percent accuracy rate. We suggest that the Medical Center Director ensure that GIP records are brought up to date, using SPD staff's wall-to-wall inventory to establish base line inventory levels.

Some Aspects of Information Technology Security Needed To Be Improved. Security over the medical center's information resources management program should be addressed. We reviewed selected aspects of the medical center's information security program to determine compliance with VA and Office of Management and Budget policy.

The medical center's Information Security Officer (ISO) is an employee of the Information Resources Management (IRM) Service. VHA policy prohibits this practice because the function is compromised if the ISO is an employee of IRM. We suggest that the Medical Center Director appoint an ISO who is not an employee of IRM Service.

The medical center did not have a formal, approved, entity-wide security plan, as required by VHA policy. IRM staff informed us that a plan was in development. Development of a security plan should be accelerated insofar as practicable.

The medical center's emergency contingency plan does not include an inventory of automated data processing (ADP) equipment, nor does it identify an alternate ADP processing facility. To better ensure that information stored on the medical center's automated systems is adequately safeguarded, the contingency plan should identify the inventory of ADP equipment and an alternate processing site.

Fraud and Integrity Awareness Briefings

During the week of January 24 through January 28, 2000, we conducted five fraud and integrity awareness briefings at the medical center. The presentations were well received by 163 employees from all services. The briefings included a lecture, a short film presentation, and question and answer opportunities. Each session lasted approximately 60 minutes.

The presentations provided a history of the OIG, discussions of how fraud occurs, criminal case examples, and information to assist in preventing and reporting fraud. Specific case examples were used to demonstrate how administrative safeguards can be circumvented.

Requirements for Reporting Suspected Wrongdoing. The attendees of the fraud and integrity awareness briefings were strongly encouraged to report all types of fraud immediately to their direct supervisors or to the OIG Hotline Center in Washington, D.C. Attendees were made aware of VA Manual MP-1, Part 1, Chapter 16 that outlines the responsibility of VA employees in reporting such allegations. The OIG is heavily dependent upon VA employees to report suspected instances of fraud, waste, and abuse and, for this reason, all contacts with the OIG to report such instances are handled confidentially.

Importance of Timeliness. It is important to report allegations promptly to the OIG. Many investigations rely heavily on witness testimony. The greater the time interval between the occurrence and an interview, the greater the likelihood that witnesses will not recall the event in significant detail. Over time, documentation can be misplaced or destroyed. Also, most Federal criminal statutes have a 5-year period of limitations.

Referrals to the Office of Investigations Administrative Investigations Division. The Administrative Investigations Division investigates allegations of serious misconduct on the part of VA officials that are not criminal in nature. An example would be misuse of a Government vehicle by a senior VA official.

Referrals to the Office of Investigations Criminal Investigations Division. Upon receiving an allegation of criminal activity, the Office of Investigations will assess the allegation and make a determination as to whether an official investigation will be initiated. Not all referrals are accepted. If the Office of Investigations decides to initiate an investigation, the matter is assigned to a case agent. If the investigation substantiates criminal activity, the matter is then referred to the Department of Justice (DOJ), usually the local U.S. Attorney's Office. DOJ then determines whether it will accept the matter for prosecution. Not all cases referred to DOJ by the OIG are accepted. If DOJ accepts the case, either an "indictment" or a "criminal information" follows. These two processes are used to formally charge an individual with a crime. Following the issuance

of an indictment or information, an accused individual either pleads guilty or goes to trial. If a guilty plea is entered or a person has been found guilty after trial, the final step in the criminal referral process is sentencing.

If the investigation only substantiates administrative wrongdoing, the matter is referred to VA management, usually the medical center or regional office director, for action. Management, with the assistance of Human Resources and Regional Counsel staff, will determine what administrative action, if any, to take.

Areas of Interest for the Office of Investigations Criminal Investigations Division. The Office of Investigations, Criminal Investigations Division, is responsible for conducting investigations of suspected criminal activity. The range and types of investigations conducted by this office are very broad. VA is the second largest Federal department and does a large volume of purchasing. Different types of procurement fraud include bid rigging, defective pricing, double or overbilling, false claims, and violations of the Sherman Anti-Trust Act. Another area of interest is bribery of VA employees; which sometimes ties into procurement activities. Bribery of VA officials can also extend into the benefits area. Other benefits-related frauds include fiduciary fraud, C&P fraud, loan origination fraud, and equity skimming. Healthcare-related crimes include homicide, theft and diversion of pharmaceuticals, illegal receipt of medical services, improper fee basis billings, and conflicts of interest. Still other areas of interest include workers' compensation fraud, travel voucher fraud, and false statements by staff or beneficiaries.

Videotape Presentation. The videotape presentation covered the same basic information as presented above, but depicted real life scenarios. Attendees were provided with points of contact for the VA OIG and encouraged to call and discuss any concerns regarding bringing particular matters to the attention of the OIG.

Summary of Inquiries Received

As part of the CAP process, we encourage patients and staff to come to us with any information dealing with fraud, waste, abuse, or poor quality of medical care. During the week of our visit, we received inquiries on 36 issues from 23 individuals. Fourteen of the 23 individuals were anonymous, which limited our ability to follow up on the information provided and to draw any conclusions about the validity of their complaints. The following list summarizes the inquiries received into five general categories:

- 13 inquiries were personnel-related
- 9 inquiries alleged mismanagement
- 5 inquiries contained allegations of fraud or other criminal activity
- 5 inquiries addressed quality of care issues
- 4 inquiries were of a miscellaneous nature

Office of Investigations staff are continuing to follow up on two of the issues that appeared to contain allegations of fraud or other criminal activity. We have closed all of the remaining inquiries because: they were unfounded; medical center management appropriately addressed the issues; there was insufficient information for us to pursue the issues further; or the issues fell outside the OIG's jurisdiction. In the latter case, we referred the individuals to other appropriate offices, such as the General Counsel or the Office of Resolution Management.

In our opinion, there was no particular pattern to these inquiries that would cause us to recommend any particular action to medical center management or for us to pursue the issues further.

Medical Center Director Comments

Department of Veterans Affairs

Memorandum

Date: January 29, 2001

From: Medical Center Director, Indianapolis

Subj: Response to Draft CAP Report

To: Director, Chicago Audit Operations Division, VA Office of Inspector General

1. Thank you for forwarding the draft response for our review. The report has been shared with a limited number of key staff to seek input regarding the recommendations put forth.

2. Enclosed is our response regarding the recommendations.

[ROBERT H. SABIN]

VA FORM
2105
SEP 1984

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

Facility managers should continue an active search for an appropriate manager for the Food Preparation and Storage Section.

Medical Center Director comments: Concur and completed. A highly qualified Supervisory Dietitian has been hired to manage the food production and clinical dietetics sections of Nutrition and Food Service. We also have a certified HACCP-trained supervisor working in the service. We continue to pay close attention to the strict cleanliness and sanitation requirements for this area. Reviews within the service as well as routine Environment of Care Rounds have identified only minor discrepancies, which have been corrected in a timely manner. JCAHO reviews in 1997 and 2000 identified no concerns in this area. We concur with your comments on temperature control documentation, and have instituted appropriate measures.

It should be noted that at all times a Registered Dietitian was responsible for ensuring compliance with food preparation and delivery standards as well as all nutritional standards. During the period of vacancy in the Supervisory Dietitian position, the Chief of Fiscal and Business Operations took a more direct role in the managerial aspects of the program to ensure proper supervision of the staff and management of the program, but did not manage clinical aspects of the program.

Facility managers should encourage anonymous reporting of medication "variances" (errors).

Medical Center Director comments: Concur and completed. In February 2000, an 8-hour inservice focusing on sentinel events and root cause analysis was offered. The target audience was the nursing unit managers, staff nurses, and other ancillary staff. As part of this inservice, the Quality Manager presented the VA's new safety program and the importance of reporting medication variances: those, which actually occur, and those, which are close calls. The VA patient safety program emphasizing anonymous reporting was implemented here May 2000.

We suggest that clinical managers provide heparin administration training for all clinicians.

Medical Center Director comments: Concur and in progress. Any variances in medication administration are reviewed daily by nursing management and risk management. Data is tracked and reviewed by the appropriate service along with review at Pharmacy and Therapeutics Committee. The Clinical Practice Council will review the procedure for administration of Heparin and a best practice model will be initiated. A clinical Fact of the Week will also be presented.

All employees, including volunteers, should have training regarding workplace violence.

Medical Center Director comments: Concur and in progress. An annual mandatory computer based training module for employees has been developed to ensure all employees receive training. Since the CAP assessment, over 1242 individuals have completed this module representing over 77% of all personnel employed at the medical. Additionally, there is a session in New Employee Orientation regarding workplace violence. The volunteer handbook covers the following areas:

- *Dealing with an angry person*
- *Dealing with a nervous or anxious person*
- *Dealing with a depressed person*
- *Dealing with disturbed behavior*
- *Communicating with the hard-of-hearing*
- *Ways to improve communication with the elderly*
- *People Principles*
- *Harassment*
- *Volunteer rules of conduct and ethics agreement*
- *Patient abuse*

The volunteer signs a statement, that the above was given to them during their orientation. We will continue efforts to reach 100% of staff and volunteers with training. Violence in the workplace will be added to the volunteer check sheet for greater emphasis. Violence assessment and prevention is undertaken by the Environment of Care Committee.

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

Managers should include directions for disposal of transdermal narcotic patches in the medical center's narcotics policy.

Medical Center Director comments: Partially concur and completed. Pharmacy Service provides with each order for Fentanyl Patches, written instructions on how to properly destroy these patches. Staff have been instructed to follow pharmaceutical company inserts regarding disposal. Disposal is to be by flushing.

Managers should re-evaluate the process for inspecting contract nursing homes.

Medical Center Director comments: Partially concur. The process for contract nursing home inspections has been standardized. Contract Nursing Home Committee has been reestablished with membership from extended care, fiscal, pharmacy and A&MMS to discuss any issues. Inspections occur, unannounced, by established team members and established inspection criteria are utilized. Data from the Indiana State Department of Health and the OSCAR (HCFA) database are also utilized during the inspection process. A subcommittee plans and carries out all inspections. Written inspection reports are completed. Vendors' responses to any cited deficiencies are considered by the inspection team members and written acceptance or rejection of their plan is completed. Community Health Nurse role has been reestablished and serves on the inspection team for both routine and 'special cause' inspections. Consideration will be given to flexible scheduling options, compensatory time off and overtime as mechanisms to provide for visits during non-administrative hours. Contractual requirements for provision of performance data on a quarterly basis will be discussed and planned for in the Contract Nursing Home Committee meeting.

Managers should review the procedure for witnessing informed consents in Interventional Radiology.

Medical Center Director comments: Concur and completed. No procedures are performed on patients without a signed and witnessed informed consent. Issue not cited in recent JCAHO survey. Random audits are done for invasive procedure documentation that includes informed consent form process. It is Radiology policy that all patients should have the consent executed either on the ward (for inpatients) or on the Outpatient Care Unit prior to arriving in Interventional Radiology. Accordingly, nurses who monitor procedures are neither required nor permitted to witness informed consents except in extreme circumstances.

Managers should consider implementing glucose meters capable of reading bar codes.

Medical Center Director comments: Under advisement. During the routine replacement of equipment for this function, this feature will be considered for implementation. Pathology and Laboratory Service has previously looked at these devices and believe that the ones currently available are sub-optimal. Within a few months, new and improved meters will be available for purchase, and Indianapolis will re-evaluate for implementation.

Managers should ensure that supervisors attend training for identifying and managing impaired employees.

Medical Center Director comments: Concur and completed. Supervisors participate in a "Effective Supervision" Seminar. This workshop includes a section on identifying and supervising impaired employees. Medical Center Memorandum 05-05 was revised this year and states that it is the Service Chiefs and Supervisors who are responsible for "initiating reasonable suspicion testing; referring employees to the Employee Assistance Program and initiating appropriate disciplinary/adverse action upon finding of illegal drug use…". Common practice at this medical center is for the identifying supervisor to call HRMS. HRMS then refers the supervisor to Employee Health for action and follow up.

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

Managers should ensure that employee training and skill competencies are properly documented (related to pharmacy technician training for complex intravenous (IV) admixtures, total parenteral nutrition, and chemotherapy).

Medical Center Director comments: Concur and completed. A competency checklist has been prepared and is being used by the Inpatient Pharmacy Supervisor to document competency by Technicians and RPh's preparing IV solutions.

NHCU nursing employee competencies needed to be developed.

Medical Center Director comments: Concur and completed. All medical center staff members have competencies identified as evidenced by recent JCAHO review

The NHCU needed to develop interdisciplinary treatment plans and processes.

Medical Center Director comments: Concur and completed. In preparation for transition to the Beverly Enterprises Enhanced Use Lease Nursing Home, the medical center has evaluated the demand for in-house NHCU services. Due to the need to transition as well as the availability of quality contract nursing homes in the community, the medical center has placed all the patients from the NHCU and 6 West into clinically appropriate settings. For the three patients that remain at the West Tenth Street facility, interdisciplinary treatment plans are present. Should the NHCU or 6 West be staffed or admit patients, the appropriate care planning will be in place.

Managers should increase awareness of the Employee Assistance Program (EAP).

Medical Center Director comments: Concur and partially completed. The EAP and other special emphasis programs have been restructured with the appointment of a new manager. An article was recently published in the employee newsletter discussing the EAP. Medical center memorandum (05-27) was created solely to define and inform about the EAP. A web page on various resolution programs has been developed and is available via the Indianapolis Medical Center home page. Other mechanisms such as elevator posters and inservices will continue to be utilized to increase awareness.

Managers should increase the activities of the "Former Prisoner of War" (POW) Coordinator.

Medical Center Director comments: Concur and in progress. Discussions are being pursued with Coordinator and Psychiatry Service to evaluate the role and activities.

Overall Recreation Therapy programs/activities warrant evaluation.

Medical Center Director comments: Concur and completed. Evaluation of ceramics clinic resulted in operational changes. A therapist no longer staffs the clinic. It operates as a "drop in" area for outpatients only and is staffed by a volunteer. However, therapists working specifically with patients for gross and fine motor tasks and cognitive tasks as a therapeutic intervention may use the ceramics clinic. A therapist provides treatment of all appropriate patients on a regular basis as outlined by PMRS policy. Adequacy of treatment is ensured by Recreation Therapist competencies that have been developed and are administered to all staff annually. Recreation Therapy has met repeatedly with consulting services to remedy the issue of timeliness of completion of assessments. Reporting and calculation processes have changed for determining timeliness of leisure assessments, and the completion of assessments is corresponding with policies.

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

The Plan for the Provision of Patient Care Services was inadequate, and there was no facility Performance Improvement (PI) Plan. Managers should consider developing a facility-wide strategic plan.

Medical Center Director comments: Partially concur and completed. A facility PI plan was in place during the CAP assessment and was presented to CAP reviewers. As part of the regular review cycle, it was subsequently revised in October 2000. Both the Plan for Provision of Patient Care Services as well as the Performance Improvement plan were reviewed in November 2000 by JCAHO and found acceptable. The facility-wide strategic plan was finalized in August 2000.

The Director should establish policy for consideration of information gained through QM/RM programs in clinicians' proficiency reports and credentialing and privileging.

Medical Center Director comments: Partially concur and completed. The Chief of Staff and Credentialing Coordinator have been working with Services over the last several months to improve the collection and reporting of QM/RM and other data at the time of renewal of Physician's and Advance Practice Nurse's clinical privileges. On our recent JCAHO survey every credentials file pulled by the surveyor had QM/RM data included for each provider. A provider's proficiency report may not be protected from discovery (as are QM/RM data). Physician supervisors and Service Chiefs have knowledge of QM/RM data at the time they complete a provider's proficiency report and use these data in a general way in determining clinical competence. However, the specific data is not stated in the proficiency report due to confidentiality. Furthermore, stating this data in the proficiency would be redundant to the C&P process.

There was a lack of definition in the Performance Improvement process.

Medical Center Director comments: Partially concur and completed. The tracking of facility-wide PI initiatives is the responsibility of each facility-wide PI team with the support from the quality management coordinators. The Improving Organizational Performance Committee on a no less than quarterly basis reviews each initiative. This review includes the analysis of aggregated data related to the initiative. The status and resource needs for these initiatives are reported to the newly established Leadership Council on a routine basis. The reporting mechanism for PI activities outside the scope of the PI oversight body is now defined. The process was outlined as part of the revision to the PI Plan.

The manager of Ward 8 East should establish a clinical review team to do an aggregate analysis of the three prior incidents.

Medical Center Director comments: Concur and completed. The aggregate analysis of the three prior incidents is complete resulting in further process changes. A multidisciplinary team now reviews each episode of seclusion/restraint resulting from patient behavior that is dangerous to self or others. The team reviews the process from identification of the initial behavior, attempts to use appropriate alternative interventions, care of the patient during seclusion/restraint use, and a post-episode review/discussion with the patient. "Lessons learned" are identified and shared with staff through discussion in unit staff meetings. Throughout 2000 training was provided in the root cause analysis process & this continues this fiscal year.

Facility and Pharmacy managers should consider implementing a pharmacist second check for IV admixtures, TPN, chemotherapy agents and intrathecal antibiotics.

Medical Center Director comments: Concur and completed. Pharmacy Service policy has been updated to require a second check of all chemotherapeutic and intrathecal medications. This second pharmacist check is done regardless of whether the solution was prepared by a Tech or RPh.

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

The Inpatient Pharmacy sterile product room did not meet JCAHO or Occupational Safety and Health Administration (OSHA) requirements.

Medical Center Director comments: Concur and in progress. Construction plans are being developed to update the Inpatient Pharmacy space with implementation subject to availability of resources. In the interim, Plexiglas has been installed to provide additional protection.

Top managers, EMS, and CHAMPUS/TriCare employees should identify and initiate procedures for improving the cleanliness of the clinic.

Medical Center Director comments: Concur and completed. EMS has altered tours to provide more convenient coverage. Additionally, they have increased inspections/reviews of areas and met with staff to ensure satisfaction. The staff have expressed satisfaction with the cleanliness of the clinic.

The overall NHCU environment was not conducive to providing effective care.

Medical Center Director comments: Concur and in progress. It is agreed that the NHCU environment was not ideal. The Enhanced Use Lease project with Beverly Enterprises for the construction of a 94-bed NHCU adjacent to the medical center will provide veterans with appropriate long term care space when medically indicated. Groundbreaking is anticipated in Spring 2001 with construction lasting 12 - 18 months.

Privacy curtains were needed in Imaging Service.

Medical Center Director comments: Concur and completed. Privacy curtains were installed in our Nuclear Medicine Imaging Service in September, 2000 and are used to cordon off imaging stations when a patient is being examined. Curtain usage meets patient privacy standards and was reviewed during the recent JCAHO survey.

Ambulatory Care Service had an inadequate number of examination rooms.

Medical Center Director comments: Concur and in progress. Plans have been developed and funding allocated as part of the NRM process to make significant improvements in Ambulatory Care space. The new Ambulatory Care Project, Project No. 583-01-02, identifies 5,000 GSF tol be renovated to meet the needs of the growing patient clientele in a better manner. In addition, a specialized and designated Women's Clinic area will require the renovation of approximately 2,500 GSF. This project is scheduled to commence spring 2001.

The facility lacked adequate feminine hygiene product dispensers.

Medical Center Director comments: Concur. The issue will be discussed with the new Chief, Canteen Service for implementation.

Additional diaper changing stations are needed throughout the rest of the facility.

Medical Center Director comments: Do not concur. For safety of everyone, medical center policy discourages children below the age of 14 to be above the 2nd floor. The placement of diaper changing stations on the first floor was purposeful in order to encourage veterans and others to keep small children on that floor. Placing stations throughout the facility would be contrary to that policy.

The urinary bladder catheter management protocol warranted review.

Medical Center Director comments: Concur and completed. The policy and practice has been changed to improve infection control.

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

There was inconsistent screening for tuberculosis (TB) and ordering influenza and pneumonia vaccinations. (6 West, NHCU and 8 East)

Medical Center Director comments: Under advisement. The issue will be discussed with the Chief, Psychiatry Service for 8 East patients. Patients are screened for TB based on risk factors. Vaccinations will continue to be offered to patients based on risk.

NHCU and Ward 6 West clean supply areas and isolation carts presented security and sterility concerns

Medical Center Director comments: Concur and completed. Due to operational changes, there are no further security or sterility issues.

Security and storage of medications was inadequate in the NHCU and on Ward 6 West

Medical Center Director comments: Concur and completed. No medications are being stored on NHCU or 6 West.

The practice of reusing soft wrist restraints should be discontinued.

Medical Center Director comments: Concur and completed. Staff have been instructed not to re-use soft wrist restraints.

A definitive determination regarding the status of fire sprinkler heads was needed.

Medical Center Director comments: No action needed. The 8 East wing is currently being utilized to house veteran psychiatric care patients. As a result, this area requires special, specific safeguards, including sprinkler heads that are specifically designed to prohibit an individual from hanging him or herself. Engineering Service has verified that the sprinkler heads within 8 East are in fact quick response institutional type heads. These quick response institutional type sprinkler heads are specifically designed for use in correctional and mental facilities, and in any other type of institution where attempts by an occupant at self injury might involve the use of a fire sprinkler. The fire sprinkler heads are safe and appropriate for this area.

Multiple record systems impeded rapid access to pertinent patient information. Managers should use the CPRS exclusively for this purpose.

Medical Center Director comments: Partially concur and in progress/under advisement. The Chief of Staff is leading efforts to fully implement additional components of CPRS. All inpatient and outpatient provider progress/clinic notes will be entered into the computer. Billing data will be entered directly into the computer. An accurate, comprehensive problem list will be built. Procedure reports will be placed into the computer for those tests currently reporting results on paper only. Entry of Nursing notes, vital signs, and other nursing documentation into CPRS will be pursued. Some limited provider order entry in the outpatient clinics will be phased in. In addition, an evaluation is being conducted regarding the use of EMTEK at our facility. If the decision is made to retain EMTEK, then a mechanism to import into CPRS key EMTEK data/information will be pursued, thus integrating the two systems.

Improvement was needed in documenting treatment in the NHCU by all disciplines. Medical Center Director should ensure the accessibility and adequacy of medical record documentation by implementing only CPRS throughout the medical center, and by evaluating the need for better documentation by all disciplines for NHCU patients.

Medical Center Director comments: In preparation to transition to the Beverly Enterprises Enhanced Use Lease Nursing Home, the medical center has evaluated the demand for in-house NHCU services. Due to the need to

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

transition as well as the availability of quality contract nursing homes in the community, the medical center has placed all the patients from the NHCU and 6 West into clinically appropriate settings. For the three patients that remain at the West Tenth Street facility, interdisciplinary treatment plans are present. Should the NHCU or 6 West be staffed or admit patients, the appropriate documentation will be in place. As mentioned, CPRS implementation will be expanded in this next year.

The Medical Center Director should evaluate our survey results to determine whether more intensive employee-management communication is needed to resolve what may be misconceptions on the part of some employees.

Medical Center Director comments: Concur and in progress. Senior management retreat chartered a work group to evaluate employee morale. The interdisciplinary group has made recommendations to Executive Management, which are under advisement for implementation. A separate work group evaluated medical center staffing from a zero-based approach. Likewise, a report has been generated and is under advisement for implementation of recommendations. Annual performance appraisal training will take place in March of this year to encourage timeliness and expansion of details for appraisals of employees. Supervisor qualifications are nationally regulated and although they cannot necessarily account for the supervisory abilities of a candidate, we do have Title 5 probationary periods to ensure new supervisors have the necessary competencies. We will continue to strive for the maximum effective communication with employees through a variety of mediums: town hall meetings, service-level meetings, newsletters, e-mails, the medical center web site, and any other available and effective mechanism.

Timekeeping for VA physicians with part-time appointments could be better documented.

Medical Center Director comments: Concur and under advisement. The issue will be referred to the Executive Committee of the Medical Staff. Adoption of "core hours" will be considered. This would be subject to negotiations with the local AFGE professional unit.

The Medical Center Director should ensure that the eight surgical and six research CMRs are inventoried as required.

Medical Center Director comments: Concur and completed. Supply Technicians from A&MMS worked with affected services and jointly conducted the inventories. Eleven of the inventories were completed in February 2000 and the rest were completed by April 2000. A spreadsheet is currently in place tracking all Medical Center Inventories and due dates. All inventories are current as of this date.

Supply Processing and Distribution inventory controls should be improved. Medical Center Director ensure that automated records are brought up to date, using SPD staff's wall-to-wall inventory to establish base line inventory levels.

Medical Center Director comments: Concur and in progress. Inventory counts and inventory management is extremely important. SPD implemented the following actions to improve inventory controls. Weekly wall-to-wall inventory is done on night shift when supply activity in and out of the department low. A QM monitor was developed picking 20 random inventory items that are counted after the inventory was completed. The count has improved to 98% correct. There was a 2% error rate that was associated with human error when inputting the count. Staff identified errors in the GIP report. Assistance is being sought from GIP specialists to analyze problems in the GIP package for accurate reporting of the status of inventory.

Some aspects of automated information security need to be improved.

Medical Center Director comments: Partially concur and in progress. In November 2000, the VISN created and filled a VISN Information Security Officer position to work with the ISO's at each site in the network to develop a comprehensive security plan. The plan is currently in process. Presently, this group is assessing each site and creating a plan to address the new external access requirements that have been establish for VHA. Additionally, each site is ensuring that all employees are receiving the new Information security training. The Medical Center Director is

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

currently reviewing the position description for the Information Security Officer. In November 2000, an updated Information Security Policy (IMS-31) was crafted, submitted and approved. By February 2001, an ADP inventory will be attached to the contingency plan. An assessment of the alternate processing site recommendation will be done by April 2001 and submitted to the executive team.

Formal Recommendations

Recommendation No. 1:
The Medical Center Director should improve controls over human subject research projects involving VA patients by:
a. Maintaining appropriate administrative records of VA research projects and identifying the VA patients involved.
b. Ensuring compliance with all informed consent requirements for human subject research.

Medical Center Director comments: Concur and completed.
a. The Research Service office maintains a human study file that contains lists of patients involved in each study, copies of IRB approvals, and updated, approved informed consents. Since the CAP assessment, the Research Service has begun maintaining a computerized list of patients in studies.
b. During the CAP assessment, informed consents were not in the charts in 2 of the 8 patient records reviewed. Those consents have since been placed in the chart. Educational efforts are underway to make certain that investigators know the required elements for informed consent. Investigators are advised to place the consent in the charts, rather than send them un-filed to medical records.

Recommendation No. 2:
The Medical Center Director should order an in-depth review of the case cited to determine if a review and a revision of overall surgery consent policy is needed**.**

Medical Center Director comments: Concur and in progress
Surgery Service has requested all medical record volumes of the case cited and will complete a comprehensive review. The results of the review will determine the need for further action regarding the surgery consent policy.

Recommendation No. 3:
The Medical Center Director should strengthen controls over narcotics by:
a. Ensuring that monthly narcotics inspections occur at all locations within as short a time frame as possible.
b. Taking appropriate remedial action when narcotics inspections reveal instances of ward staff failing to properly document the dispensing or wasting of controlled substances, and the drugs' inventory balances, at a shift change.
c. Destroying outdated drugs at least once every 3 months.
d. Establishing or enforcing controls for removing and disposing of outdated drugs from dispensing locations.
e. Returning spoiled controlled substances to vendors immediately upon discovery, or recording them in inventory records to assure control over the drugs pending disposition, or both.
f. Maintaining a Controlled Substance Administration Record for all controlled substances kept at dispensing locations.
g. Reconstructing a Controlled Substance Administration Record for nembutol, pentothol, and metofane issued to a Research Service dispensing location and removing those drugs from that area pending reconstruction of the control record.
h. Resolving an inventory balance discrepancy for pentobarbital maintained at a Research Service dispensing location.

Medical Center Director comments: Concur and completed
a. All of these recommendations have been reviewed extensively with nursing staff and supervisors on each ward/area and controls that *were already in place have been strengthened. Meetings with appropriate services were conducted and policies reviewed and reinforced. Areas of concern where quality improvement could be enhanced have been completed. Since the CAP assessment, all of the items noted have been monitored and any discrepancies found have been reviewed and corrected.*

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

b. During the most recent inspections the charge nurse for each dispensing location reviews and takes appropriate action to ensure discrepancies are corrected immediately.

c. Narcotic destruction will be done every 3 months, regardless of the quantity of product requiring destruction.

d. Controls that were already in place have been strengthened for outdated drugs

e. Timely return of spoiled containers continues to be done.

f. The strengthening of the inspection process will ensure that CSAR are kept at dispensing locations. Staff have been educated in the proper record keeping.

g. The Research Service, in conjunction with the Narcotics Control Officer, have reviewed and corrected problems with the Controlled Substance Administration Record. Instructions have been given to the key control personnel to document and maintain training records on the use of the CSAR for those who withdraw narcotics.

h. The inventory balance discrepancy has been resolved.

Recommendation No. 4:

The Medical Center Director should take action with regard to the Government Purchase Cards to ensure that:

a. A program of regular audits is established.

b. When such audits identify questionable transactions, as those cited in this report, each case is researched to determine if VA purchase card policies were violated.

c. If a determination is made that a purchase violated policy, appropriate remedial action is taken, including disciplinary action against the cardholder, if warranted.

d. Particular attention is paid to purchases of computer equipment and split purchases of any type.

e. The Chief of Fiscal Service signs monthly quality reviews.

Medical Center Director comments: Partially concur and completed. Item one listed in the results of the purchase card review indicates that there were 370 cash advance fees charged to one card. These fees are related to the processing of convenience checks. The VA contract with Citibank provides for the payment of an $0.83 processing fee per convenience check. Citibank refers to this fee as a cash advance fee. The convenience checks are an approved part of the purchase card program and these charges are an accepted part of the convenience check process. If this information had been presented to the VAMC prior to the writing of this report, this item clearly could have been resolved.

a. Since the inception of the purchase card program, there has been a "program of regular audits", in addition to the monthly Financial Service Center quality reviews, in place at this medical center. These audits are conducted by the staff in the Accounting section and were presented to the auditor during the CAP assessment. The audits were performed on a quarterly basis, using a sample of one randomly selected transaction per cardholder per quarter. It is recognized that the guidance provided in VA Handbook 1730.1, dated June 14, 2000 is significantly improved over previous versions. In an effort to strengthen our purchase card audit program, joint Fiscal and Logistics audit will be performed on a monthly basics as required in addition to the Financial Service Center's (FSC's) monthly reviews. During the month of October 2000 the VISN CLO conducted site reviews at all VISN facilities using a detailed audit guide. Each month every purchase card transaction conducted by this medical center is reviewed using the Citibank Merchant Activity Report and the IFCAP Purchase Card Statistic report. These two reports provide sufficient data to determine if cardholders are purchasing from appropriate sources and if purchases are being split to defeat the purchase card limits. In addition one control point is selected per month for a focused review by A&MMS and Fiscal services.

b. Audits completed since the new Handbook was released revealed that most purchase cardholders are compliant with agency and medical center credit card policies. While no critical discrepancies have been identified by the audits, each questionable item that has been identified has been presented to the approving official and the cardholder. Serious irregularities are brought to the attention of the Chief Accountant, Chief Financial Officer and the Purchase Card Program Coordinator. If policies are violated, the cardholder and approving official are notified of the discrepancy and advised of the proper use of the purchase card. In addition, all credit card holders and approving officials now sign a specific list of responsibilities. Documentation is available to confirm that the medical center has identified situations in which items have been returned to the vendor due to violations of purchase card requirements.

Medical Center Director Comments (Continued)

Combined Assessment Program
Indianapolis VA Medical Center Comments

The medical center will continue to thoroughly research each questionable transaction identified during the routine audits or by other control mechanisms to determine if purchase card policies have been violated

c. If it is determined that a card holder or an approving official is repeatedly violating or ignoring Department or Medical Center policy then appropriate remedial action will be taken. Through our on going audits it was determined that a purchase card had been stolen and misused. Our investigation uncovered photographic evidence of the thief, which resulted in his prosecution, sentencing, and restitution to the VA. A verbal counseling was provided to the cardholder by his supervisor for failure to secure the card.

d. During our monthly audits two reports are used to determine the sources used to procure from and to determine if orders are being split to defeat the $2500 purchase card limit (Citibank Merchant Analysis report and the IFCAP Purchase Card Statistics Report). Also, since the issue of the new VHA Handbook all cardholders are now required to enter each purchase card transaction into IFCAP using the Detailed menu option. This provides detailed information that assists us during our audits to determine the appropriateness of the item/s being procured.

e. The Chief, Fiscal Service had delegated authority to review and sign monthly quality reviews to the Chief, Accounting Section. The Chief, Accounting Section signed all quality review reports inspected by the CAP assessment reviewers.

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