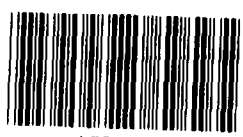
BY THE U.S. GENERAL ACCOUNTING OFFICE

# Report To The Committee On Veterans' Affairs United States Senate

# VA Has Not Fully Implemented Its Health Care Quality Assurance Systems

One of the Veterans Administration's (VA's) primary goals is to provide quality medical care to veterans in its medical centers. It has established a formal quality assurance program with two focuses: (1) Each medical center reviews the quality of care it provides, and (2) VA's Medical Inspector reviews the medical centers' quality assurance programs. GAO found that the medical centers had not implemented the quality assurance programs required by VA's regulations and the Medical Inspector was not evaluating the effectiveness of the centers' programs.

The Medical Inspector and VA medical centers are also responsible for investigating allegations of poor quality care. VA's Inspector General oversees the Medical Inspector's investigation activity and conducts audits that occasionally involve quality of care issues.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WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

B-219035

The Honorable Frank H. Murkowski
Chairman, Committee on Veterans'
Affairs
United States Senate

The Honorable Alan Cranston
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate

In response to the December 21, 1983, request from the previous Chairman and the September 6, 1984, request he made jointly with the Ranking Minority Member, we have reviewed the Veterans Administration's (VA's) systems and procedures for assuring the provision of quality health care. This report discusses (1) the extent to which the VA medical centers we visited had implemented quality assurance programs and (2) the roles of and processes used by other VA organizations in assuring quality of care. We did not evaluate the effectiveness of VA's programs and therefore do not comment on the quality of health care provided.

Copies of this report are being sent to the Administrator of Veterans Affairs; the Director, Office of Management and Budget; and other interested parties.

Richard L. Fogel
Director

GENERAL ACCOUNTING OFFICE
REPORT TO THE SENATE COMMITTEE
ON VETERANS' AFFAIRS

# VA HAS NOT FULLY IMPLEMENTED ITS HEALTH CARE QUALITY ASSURANCE SYSTEMS

## D I G E S T

The Senate Committee on Veterans' Affairs asked GAO to provide information on processes and procedures that the Veterans Administration (VA) uses to assure that it provides quality health care. GAO was specifically requested to determine (1) whether VA's medical centers have required quality assurance mechanisms and procedures, (2) the role of other VA organizational units in assuring quality of care, and (3) the answers to a number of questions related to quality assurance. GAO was not asked to evaluate the quality of care provided. (See apps. I and II.)

GAO visited 13 medical centers--selected to represent a cross-section of VA's 160 centers--to determine if quality assurance programs had been implemented as required by VA regulations. At VA's central office, GAO interviewed officials and reviewed relevant documents.

## VA'S QUALITY ASSURANCE PROGRAM

VA's quality assurance program was designed to systematically evaluate the (1) appropriateness of patient care and services provided, (2) effective utilization of resources, (3) safety of patients, and (4) conduct and performance of VA employees and others providing patient care.

VA's formal quality assurance program has two primary focuses. First, each medical center is required to review the quality of care provided to its patients. Second, VA's central office is required to evaluate the quality of care in each medical facility and the effectiveness of each facility's internal review. In addition to its formal program, VA uses day-to-day supervision of staff and oversight of activities to help assure that its patients receive quality medical care.

The Chief Medical Director is responsible for implementing, maintaining, and enforcing quality assurance requirements. He relies on medical center directors, regional directors, and Department of Medicine and Surgery officials responsible for quality assurance policies, evaluations, and investigations to meet VA's objective of providing high-quality health care.

On March 3, 1985, in an effort to place greater emphasis on quality assurance, the Chief Medical Director established an Office of Quality Assurance within the Department of Medicine and Surgery. Among other things, this organizational change placed the quality assurance evaluation activities, previously performed by the Medical Inspector, in the new office reporting directly to the Chief Medical Director. The Medical Inspector retained his investigative functions and reports to the Deputy Chief Medical Director. (See p. 2.)

The Inspector General, responsible to the VA Administrator, also contributes to VA's quality assurance activities through facility evaluations, program reviews, and general oversight of the Medical Inspector's activities.

## MEDICAL CENTERS HAVE NOT FULLY IMPLEMENTED QUALITY ASSURANCE PROGRAMS AS REQUIRED

VA's regulations require medical center directors to develop and implement written plans that establish program responsibility, define policy and program operations, and include the following five mandatory program functions: (1) continuous monitoring of 15 separate clinical elements, (2) patient injury control, (3) utilization review, (4) problem-focused health care studies, and (5) review of the credentials of health care professionals. (See pp. 5 to 9.)

All 13 medical centers GAO reviewed had quality assurance plans and operated quality assurance programs. The programs included efforts to (1) establish policies regarding the provision of quality health care, (2) hire quality health care providers, and (3) identify and resolve health care problems through day-to-day oversight and specific reviews of care and services provided.

However, the individual medical center programs were limited in scope. The 13 centers did not perform, or only partially carried out, the five required functions. For example, none of the 13 continuously monitored all of the 15 required clinical elements. As a result, the centers did not systematically (1) determine whether health care and services provided were appropriate to patient needs, (2) determine patterns and trends of health care provided, and (3) resolve systemic quality of care problems. (See pp. 9 to 15.)

Officials of these medical centers responsible for quality assurance acknowledged that their programs did not fully incorporate all of VA's requirements. With some exceptions, the officials did not view such noncompliance as a problem. Although the VA regulations were mandatory, center officials interpreted them as allowing (1) flexibility in the nature and content of quality assurance programs and (2) the exclusion of quality assurance functions, elements, or task analyses that they perceived as unnecessary. For example, 4 of the 13 centers reviewed a sample of certain types of cases, whereas VA regulations require them to review all cases. (See pp. 16 and 17.)

Because GAO did not analyze the effectiveness of the medical centers' quality assurance activities, it could not conclude that medical centers' failure to comply with VA's requirements resulted in poor quality care. Nor would full compliance necessarily assure high quality care.

GAO believes that when quality assurance activities are not performed, neither VA's central office nor the medical centers can be sure that patients receive optimum care. Further, the widespread noncompliance GAO found with required quality assurance processes, varied interpretations of the regulations, and disagreement on the need for required processes raise several questions about VA's existing program:

1. Are all the specific quality assurance requirements needed?

2. If the requirements are needed, should VA's central office enforce compliance?

3. Should the central office provide better guidance to assure consistent interpretation and implementation of the requirements?

4. Should the central office develop and require medical centers to use national standards in measuring quality of health care provided?

5. Do medical centers' quality assurance processes affect the quality of care provided?

## VA'S EVALUATION OF MEDICAL CENTERS' QUALITY ASSURANCE PROGRAMS

Until March 3, 1985, VA's Medical Inspector was responsible for overseeing medical centers' quality assurance programs and reported directly to the Chief Medical Director. The Medical Inspector reviewed the quality of care and the quality assurance programs at medical centers through VA's Systematic External Review Program. This program will continue in the future under the newly established Office of Quality Assurance.

Reviews performed under this program involve week-long evaluations of medical facility services and programs by teams of health care and administrative personnel from other medical centers. The teams use a standard methodology and prepare reports on their findings. (See pp. 19 to 21.)

The reviews are supposed to serve two purposes--to ascertain the quality of health care or support being provided and to assess the effectiveness of each medical center's internal quality assurance program. GAO found, however, that (1) the reviews have not evaluated the effectiveness of centers' quality assurance programs; (2) though VA planned to conduct 60 reviews annually, it has not achieved this goal since fiscal year 1977, averaging about 44 reviews annually since then; and (3) some reviewers and center officials believe the time frame for conducting reviews is too short. (See pp. 21 to 25.)

GAO also found that the Medical Inspector had conducted limited trend and other data analyses and had not developed standards for use in the quality assurance program. (See p. 26.)

## MEDICAL INSPECTOR INVESTIGATIONS

The Medical Inspector also has been and will continue to be responsible for investigating allegations, complaints, or incidents of poor quality care. Medical facility officials are required to report to the Medical Inspector certain types of incidents, such as suicides or suicide attempts. They are also required to investigate certain of those incidents, such as those resulting in permanent disability and transfusion accidents, and report the results to the Medical Inspector.

The Medical Inspector opens investigations when (1) incidents should have been investigated at medical centers but were not; (2) in his opinion and that of other central office reviewers, center investigations are found to be inadequate; or (3) allegations of poor quality care appear to have merit. In fiscal year 1984, the Medical Inspector opened 199 investigations. These investigations may have consisted of having personnel at the medical center provide additional information concerning incidents, requiring the centers to conduct investigations, or making site visits to the centers. (See ch. 4.)

## THE INSPECTOR GENERAL'S QUALITY ASSURANCE ACTIVITIES

VA's Inspector General receives allegations of fraud, waste, and mismanagement from his telephone "hotline" and other sources, reviews each, and investigates those he determines to have merit. He refers allegations of poor quality care to the Medical Inspector.

The Inspector General also oversees the Medical Inspector's investigation activities. The Inspector General has assigned a member of his staff to review the adequacy and timeliness of the Medical Inspector's investigations and those conducted by medical centers. In November 1982 the Inspector General recommended a more formal

relationship between him and the Medical Inspector. In December 1984 the Inspector General and the Chief Medical Director signed an agreement to implement that recommendation.

The Inspector General also conducts routine audits to determine whether VA medical centers are operating efficiently, economically, and in accordance with applicable laws and regulations. In fiscal year 1984, these routine audits began addressing certain aspects of the medical centers' quality assurance programs, such as tracking the centers' implementation of recommendations to improve the quality of care. In addition to facility audits, the Inspector General conducts reviews that cover quality assurance matters, such as assessing malpractice claims against VA. (See ch. 5.)

## AGENCY COMMENTS

VA was given the opportunity to comment on a draft of this report but did not respond within the 30 days provided by law.

# Contents

ILLUSTRATIONS



ABBREVIATIONS

| | |
|---|---|
| GAO | General Accounting Office |
| JCAH | Joint Commission on Accreditation of Hospitals |
| MIEO | Medical Inspector and Evaluation Office |
| SCEM | Standards, Criteria, Evaluative Algorithms and Measuring Instrument |
| SERP | Systematic External Review Program |
| SIR | Systematic Internal Review |
| VA | Veterans Administration |

# CHAPTER 1

## INTRODUCTION

The Veterans Administration (VA) operates one of the largest health care delivery systems in the United States. In fiscal year 1984, VA's system included 172 hospitals, 226 outpatient clinics, 105 nursing home care units, and 16 domiciliaries. These facilities are managed by VA's Department of Medicine and Surgery under the Chief Medical Director.

VA's goal is to provide high-quality health care to all eligible veterans on a timely basis. Before 1970, VA had no comprehensive program to evaluate the quality of care it provided. While VA held itself accountable to the Joint Commission on Accreditation of Hospitals (JCAH) standards[1] and had programs to inspect hospitals and review specific quality of care problems, attempts at evaluation were fragmented. In 1974, VA established a more systematic, comprehensive program for assuring that high-quality health care was provided.

According to VA's quality assurance guidelines, the quality assurance program was designed to objectively and systematically review VA's total health care activities, focusing on patterns of care rather than individual cases or clinicians. The program was expected to lead to better patient care by providing recommendations to health care providers and managers for improving such activities as (1) staff performance and productivity and (2) quality and timeliness of service.

The quality assurance program was further defined in 1982 as a process to systematically evaluate the (1) appropriateness of patient care and service provided, (2) effective utilization of resources, (3) safety of patients, and (4) conduct and performance of VA employees and others providing patient care.

VA's formal quality assurance program has two primary focuses: each medical center[2] reviews the quality of care provided to its patients (VA calls this a systematic internal

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[1]JCAH is an organization that periodically inspects hospitals and other health care facilities at their request and accredits them if they meet specific JCAH standards.

[2]Most of VA's health care facilities are organized into 160 medical centers. A medical center may consist of one or more hospitals, one or more outpatient clinics, a nursing home, and a domiciliary. Only eight outpatient clinics and one domiciliary are independent of any medical center.

review--SIR), and VA's central office reviews the quality of care provided by each medical center and determines the effectiveness of the center's quality assurance program (VA calls this its systematic external review program--SERP). In addition to this formal program, each medical center uses day-to-day supervision of staff and oversight of activities to ensure that its patients receive quality care.

ROLES AND RESPONSIBILITIES

The Chief Medical Director is responsible for implementing, maintaining, and enforcing VA's quality assurance requirements. He relies on medical center directors, six regional directors, VA's Medical Inspector, and a newly created Office of Quality Assurance to meet VA's objective of providing high-quality health care to veterans. The Office of the Inspector General also reviews quality assurance activities.

Medical facility directors are responsible for the quality assurance program within their facilities. However, the authority for coordinating and conducting day-to-day supervision of the quality assurance activities is generally delegated to members of their staffs.

Regional directors exercise direct line supervision of medical facility directors within their region. They are also responsible for assuring that facility directors take appropriate action on recommendations contained in SERP, JCAH, and Inspector General reports.

Until early March 1985, VA's Medical Inspector headed the Medical Inspector and Evaluation Office (MIEO), which developed policies and procedures and provided guidance and oversight for medical facility quality assurance programs. MIEO also conducted VA's SERP reviews and investigated reported quality of care incidents to evaluate and improve the quality of patient care and the effectiveness of medical center quality assurance programs.

On March 3, 1985, the Chief Medical Director, in an effort to place additional emphasis on quality assurance, established the Office of Quality Assurance in the Department of Medicine and Surgery. The new office is responsible directly to the Chief Medical Director for the former MIEO's quality assurance evaluation functions, including SERP reviews. In addition, the new office will be responsible for developing and operating a new area of VA quality assurance emphasis--the Medical District

Initiated Peer Review Organization Program.[3] The Chief Medical Director has stated that VA's new quality assurance office will provide a more prospective means of identifying and dealing with potential quality of care problems before incidents occur.

VA's quality of care investigative functions are to remain with the Medical Inspector, who will report to the Deputy Chief Medical Director. VA's Office of Inspector General performs audits and investigations of VA programs and operations and recommends policies that (1) promote economy, efficiency, and effectiveness and (2) prevent and detect fraud, waste, and abuse. These functions include audits of medical quality assurance programs and oversight of Medical Inspector quality assurance investigations.

## OBJECTIVES, SCOPE, AND METHODOLOGY

In a December 21, 1983, letter, the Chairman of the Senate Committee on Veterans' Affairs asked us to review MIEO's general operation and effectiveness. In a September 6, 1984, letter, the Committee's Chairman and Ranking Minority Member requested us to expand our work to include determining (1) whether VA's medical centers have in place and operating the required quality assurance mechanisms and procedures and (2) the role of other VA organizational units regarding quality of care. (See apps. I and II.)

To determine if VA medical centers were complying with quality assurance regulations, we selected 13 centers for review. The ones we selected were geographically dispersed and varied in size and in services offered. We selected some facilities with psychiatric units, nursing home care units, and medical school affiliations. We also included several medical centers that had SERP reviews conducted in fiscal year 1982 or later and others that had not been evaluated for several years. (App. III lists these medical centers.) While we believe these facilities represent a good cross-section of the 160 VA medical centers, our findings regarding the 13 centers we reviewed cannot be projected to the entire system.

At the 13 medical centers, which we visited between October 1984 and February 1985, we applied the criteria set forth in the

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[3]This program, currently undergoing testing in two VA regions, is designed to focus VA attention more directly on clinical outcomes and practitioner patterns of care. VA is also assessing the feasibility of phasing in a complete risk analysis function, including occupational safety and health, consumer affairs, medical-legal, and civil rights activities.

regulations published in the Federal Register on October 12, 1982 (38 CFR, §17.500 - 17.540, see app. IV) to determine if the facilities had implemented quality assurance programs as required.

In accordance with the Committee's request and later discussions with the Committee staff, we determined the extent that VA and its medical centers had implemented quality assurance requirements set forth in VA's regulations. We did not evaluate the thoroughness, quality, or effectiveness of SIRs or SERPs that were performed. Therefore, we cannot conclude that performing the required monitoring and reviews in compliance with the regulations assures high quality medical care. Nor can we conclude that noncompliance with the regulations results in poor quality care. Given the focus and scope of our work, our observations in this report are directed to the degree to which medical centers had the required quality assurance monitoring procedures and reviews in place. As agreed with the Committee's staff, our work was designed to provide a basis for possible future evaluations concerning the need for and effectiveness of individual quality assurance activities.

At the VA central office, we interviewed Office of Inspector General officials responsible for oversight of MIEO and others who conducted cyclical audits at the medical centers. We also reviewed relevant Office of Inspector General documents, such as audit guidelines and reports. Within MIEO we interviewed officials involved in all aspects of investigations and evaluations and reviewed such documents as guidelines, reports, staffing levels, and budget requests. We interviewed regional directors and their staffs and other VA officials concerning their involvement in quality assurance matters.

VA was given the opportunity to comment on a draft of this report but did not respond within the 30 days provided. Our review was conducted in accordance with generally accepted government auditing standards.

## CHAPTER 2

## MEDICAL CENTERS WERE NOT FULLY COMPLYING WITH VA'S QUALITY ASSURANCE REGULATIONS

VA has established a systematic program for providing high-quality medical care. However, VA has experienced problems in implementing the program. None of the 13 centers we reviewed had fully implemented all of VA's quality assurance requirements.

### MEDICAL CENTERS' INTERNAL QUALITY ASSURANCE PROGRAMS

VA's regulations require medical center directors to develop and implement written quality assurance plans that establish responsibility, define policy and program operations, and include five mandatory program functions: (1) continuous monitoring, (2) patient injury control, (3) utilization reviews, (4) problem-focused health care evaluations, and (5) credentialing and delineation of clinical privileges. Medical centers can include additional quality assurance program functions as deemed appropriate.

#### Continuous monitoring

The regulations define continuous monitoring as a systematic review and evaluation of 15 clinical elements that are key indicators of the quality of medical care provided. However, the monitoring process is different from day-to-day management in that explicit quality of care criteria are used to collect patient care information over specified time periods. VA health care providers are supposed to then use the information collected to (1) determine patterns or trends of health care provided, (2) compare quality of care provided with accepted national, areawide, or local standards or norms, and (3) propose corrective action to maintain or improve quality of care. The 15 clinical elements and the purpose of monitoring them are as follows:

1. Medical records review determines whether records (1) are readily available, complete, and secure and (2) provide appropriate documentation to determine the patient's needs, services provided, outcome of treatment, and identity of health care provider(s) responsible for care and treatment of each patient.

2. Surgical case tissue review determines appropriateness of and need for all patient surgery.

3. Blood services review determines whether blood and blood products are safely stored, ordered, cross-matched, delivered, and administered in a timely, therapeutic, and reliable manner.

4. Therapeutic agents and pharmacy review determines whether health care providers appropriately prescribed and administered medications, drugs, or other chemicals in a manner, dose, route, and time schedule appropriate to patients' needs; prescribed medications are effective; and allergic reactions to medications are assessed.

5. Laboratory review determines whether laboratory tests are appropriate to meet patient care needs, laboratory quality control is satisfactory, and laboratory results are communicated to requesting clinicians within established time standards.

6. Radiology and nuclear medicine review determines whether all radiology and nuclear medicine diagnostic and therapeutic procedures are necessary, appropriate, and timely and minimize patient exposure to radiation.

7. Psychiatric program review determines whether each program is meeting its treatment goals and is providing high-quality care.

8. Restraint and seclusion analyses determines whether patients exhibiting disturbed behavior are protected from inappropriate, excessive, or harmful restraint or seclusion.

9. Commitment usage analyses determines whether patients who are under legal commitment continue to require such commitment and that commitment is clinically justified.

10. Infection control review determines the trend and extent of hospital-related infections, proposes corrective actions, when appropriate, and should ensure that exposure to such infection is minimized.

11. Autopsy review determines whether autopsy services are appropriately provided and that findings are reviewed at least quarterly by the medical staff to determine thoroughness of patient care, cause of death, appropriateness of major clinical diagnoses, existence of any unsuspected conditions, effectiveness of therapeutic measures, and accuracy of the medical record.

12. Review of rejected applications identifies possible errors so that rejected patients may be reevaluated and appropriate diagnostic treatment measures instituted.

13. Surgical complications and anesthesiology review determines whether high-quality care is provided to surgical patients and assesses allergic reaction to anesthesia.

14. Morbidity and mortality review determines whether the mortality and/or morbidity rates meet accepted professional standards and expectations and evaluates all deaths that are unexpected or occur within 24 hours of admission to determine whether certain procedures or practices are contributing to deaths.

15. Patient incident review provides a statistical or descriptive summary of reported incidents of poor quality care and indicates trends, such as the types and frequency of incidents, hospital location where incidents occurred, age and type of patient, and severity of incident.

While the regulations are explicit on what should be monitored, they give medical center directors considerable flexibility in carrying out monitoring. For example, each center director is required to monitor and evaluate the clinical elements on a regular and recurring basis, but except where a specific frequency is prescribed, they can choose a daily, monthly, quarterly, or semiannual basis. Also, center directors can use sampling procedures for reviewing and evaluating records and documents for most cases. However, for some clinical elements, such as surgery and radiology and nuclear medicine, all cases must be reviewed. Further, center directors can choose to monitor the clinical elements through the use of a committee, service, program, or individual, or the directors may combine the monitoring with other quality assurance functions as appropriate.

Patient injury control

The patient injury control program requires monitoring, reporting, analyzing, reviewing, and investigating any unusual, unexpected, or unfavorable incident that a patient may experience during medical management. These incidents would not be considered a natural consequence of a patient's disease process or illness. Examples of such incidents are suicides, suicide attempts, self-inflicted wounds, homicides, falls, assaults, patient abuse or neglect, unexpected deaths, and deaths within 24 hours of admission.

VA requires immediate reporting to physicians in charge of areas where such incidents occur. The supervising physician should review the incident, prepare a statement of findings, and submit a report to the medical center director. VA requires the center director to report certain incidents, such as suicides, attempted suicides, and transfusion accidents, to the regional director, who in turn reports to the Medical Inspector.

The center director or other authorized designee may choose to initiate a quality assurance investigation of incidents involving assault upon, injury to, or unusual deaths of patients. VA describes specific types of incidents that must be investigated. The focus of an investigation is to identify health care delivery problems and analyze such problems and propose corrective action.

Utilization reviews

Utilization reviews include clinical and administrative screening and studies to assure that VA medical center resources are appropriately used. For example, the medical centers may periodically review generic or disease-specific problems and patient needs to assess the (1) appropriateness of admissions and rejections, (2) length and continuance of stay, (3) appropriate and effective use of services, special medical programs, and other resources, and (4) timeliness of admission and outpatient processing. Utilization reviews will frequently concentrate on problems identified during the continuous monitoring process.

Problem-focused health care evaluations

Problem-focused health care evaluation is an approach to understanding and managing complex problems of major consequence to patient care processes and outcomes. Such evaluations could involve studies (1) of the control of diabetics at the time of discharge from a hospital or (2) to determine if communicable diseases were being reported to the public health department by the hospital. The approach focuses on problem assessment, corrective action planning, implementation, and follow-up. Problem-focused health care evaluations usually involve a multiple services approach, but each clinical or administrative service is responsible for carrying out the studies to the extent necessary within its area of responsibility. The need for such a study may surface through utilization review, continuous monitoring, patient injury control, or other sources.

## Credentialing and delineation of clinical privileges

Credentialing and delineation of clinical privileges is a systematic process for reviewing the qualifications of all applicants for appointment to medical facilities and requests for clinical privileges to assure that (1) applicants possess the professional capability required of their disciplines and (2) their skills are commensurate with the needs of the particular diagnostic and therapeutic procedures for which they are responsible. The regulations require centers to review, at least annually, each provider's clinical privileges and recommend reappointment, reduction, or expansion of clinical privileges as appropriate.

In addition to the center-wide SIR program, each service chief at a VA medical facility is responsible for planning and implementing systematic internal reviews for his/her particular service. These self-evaluation internal review activities and functions must be integrated with and support the center-wide SIR program.

## MEDICAL CENTERS' QUALITY ASSURANCE PROGRAMS DID NOT MEET VA REQUIREMENTS

All 13 medical centers we reviewed had quality assurance plans and operated quality assurance programs, but none fully met the requirements of VA's regulations. The centers' programs included efforts to (1) promulgate policies aimed at assuring provision of quality health care, (2) hire quality health care providers, and (3) identify and resolve health care problems through day-to-day oversight and specific reviews of care and services provided. Neither VA's central office nor its medical centers have developed standards for use in the continuous monitoring processes. The approaches used identified and resolved some health care problems. However, the individual medical center programs were often limited in scope and only partially complied with VA's quality assurance program requirements.

The medical centers we reviewed either did not perform or only partially carried out the five required functions--particularly the requirement for continuously monitoring the 15 clinical elements. Some medical centers did not include VA's requirements in their quality assurance plans. Others included the requirements, but either did not perform or only partially performed the required monitoring or review tasks. As a result, the centers did not always (1) determine whether health care and services provided were appropriate to patient needs, (2) determine patterns and trends of health care provided, and (3) resolve systemic quality of care problems.

The noncompliance resulted in part from (1) misinterpretation of VA's specific mandatory requirements or (2) disagreement on the need for required monitoring, reviewing, and analyses.

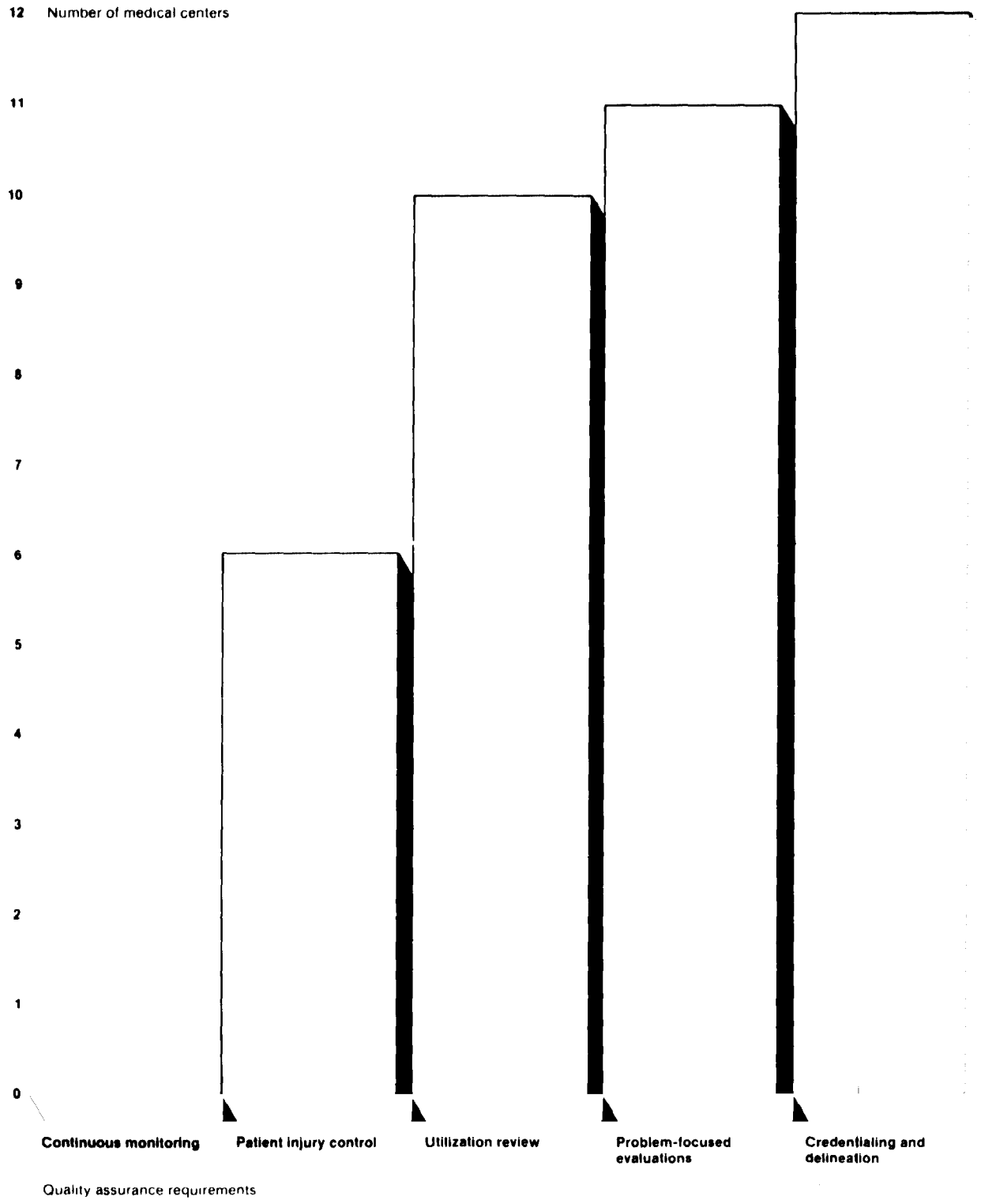
Level of compliance

None of the 13 medical centers we reviewed fully complied with VA's mandatory quality assurance requirements. Three centers fully met requirements for four of the five functions and partially complied with the fifth. Another center fully complied with two and partially met requirements for the other three. Chart 1 shows how many of the 13 medical centers that we reviewed fully complied with each of the five mandatory functions.

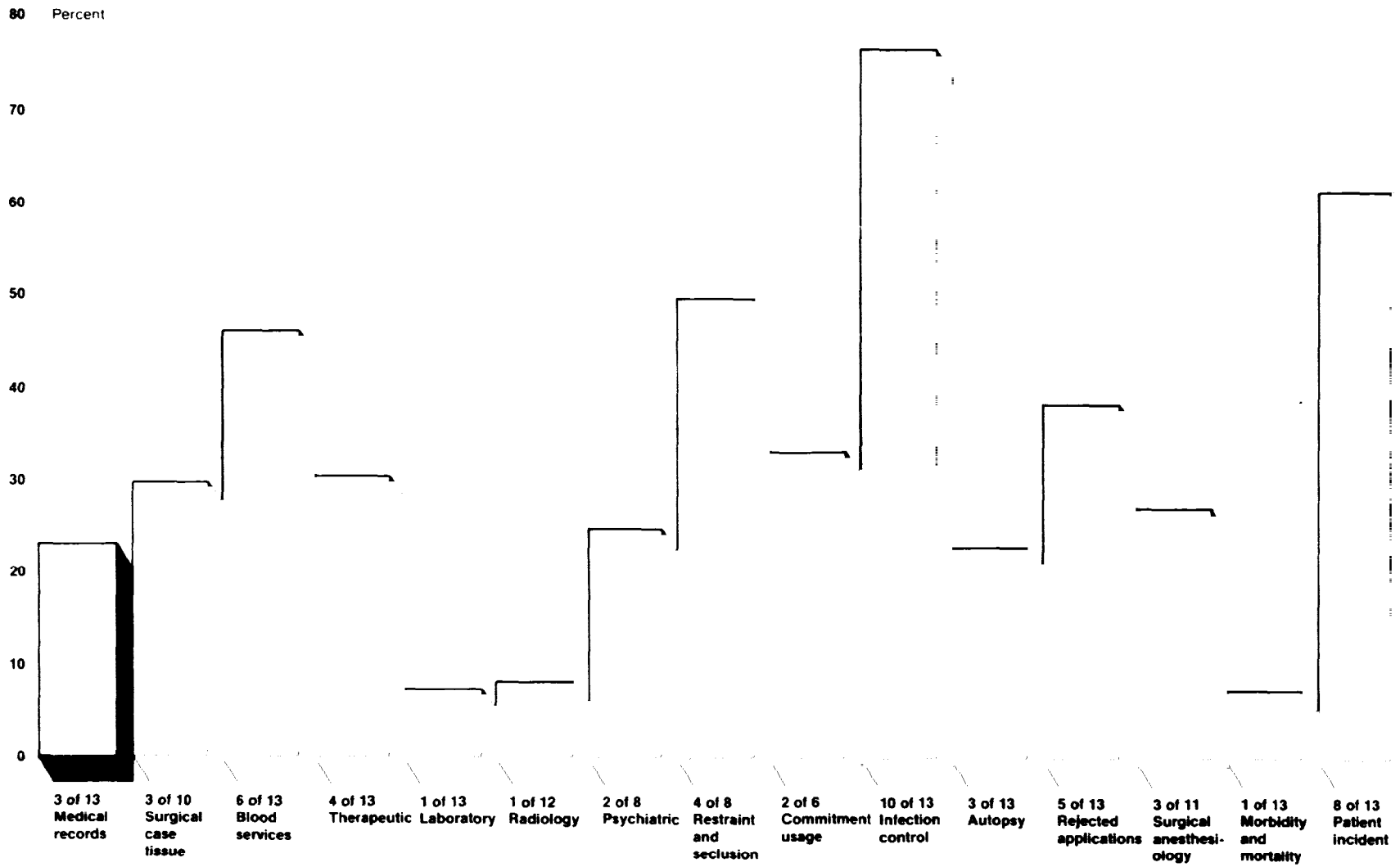
No medical center fully complied with VA's quality assurance requirements for performing continuous monitoring of 15 clinical elements. However, all 13 centers were monitoring some of the elements. Chart 2 shows the percentage of the centers we reviewed that complied with each of the 15 clinical elements. The chart shows the significant range in the extent that centers met monitoring requirements for specific clinical elements. For example, 10 centers met continuous monitoring requirements for the infection control clinical element, but only 1 met requirements for monitoring laboratory services. All 15 clinical elements were not applicable to each center. For example, some centers did not perform surgery or operate psychiatric programs. In such cases, we eliminated those elements in computing the percentage of compliance.

If a medical center's quality assurance program included (1) all five mandatory functions, including the 15 elements of the continuous monitoring function, and (2) reviews or monitoring activities addressing the required task for each function or element, we assumed full compliance with VA requirements. We did not question the thoroughness, quality, or effectiveness of reviews performed. If, on the other hand, required functions and elements were excluded from a center's quality assurance program, or were included but not performed, we judged the medical center to be in noncompliance. If a center included required functions and elements in its program and performed certain task analyses to improve quality of care, but did not perform VA's specific task analyses, we considered the medical center to be in partial compliance. This was the typical condition observed at the 13 medical centers reviewed. To illustrate, five medical centers monitored laboratory reviews and tested laboratory equipment and quality controls, but did not perform task analyses to determine whether laboratory tests were appropriate to patient needs or were timely. In such cases, we concluded that the medical centers were partially complying with VA's requirements.

## Chart 1
## Number of VA Medical Centers That Fully Complied With VA's Quality Assurance Requirements



## Chart 2
## Number and Percent of VA Medical Centers That Fully Complied With Continuous Monitoring Clinical Elements



Medical centers were not in full compliance usually because they did not

--include all required quality assurance functions or elements in their plans,

--determine the appropriateness of health care or services provided,

--establish patterns and trends of health care to evaluate opportunities for improvement, or

--track identified quality of care problems to ensure that they were resolved.

Incomplete quality assurance plans

All the medical centers we reviewed had quality assurance plans; however, their plans did not always include functions and elements required by VA's regulation for determining the quality of care provided.

--Three of the 13 centers we reviewed did not include at least two of the five required functions in their plans. Two of the three centers excluded utilization reviews, whereas the other excluded problem-focused evaluations.

--Six centers failed to incorporate 1 or more of the 15 required continuous monitoring elements into their plans. One center excluded 10 of the 15 required elements from its plan. At another center the continuous monitoring function was not incorporated into the quality assurance plan. The most often neglected continuous monitoring elements were reviews of laboratory service, radiology and nuclear medicine service, autopsies, rejected applications, and morbidity and mortality.

--Seven medical centers' plans did not always establish responsibility for specific quality assurance functions or elements. For example, one center's plan did not assign responsibility for two elements--surgical complication and anesthesiology reviews and morbidity and mortality reviews. In six other centers, quality assurance monitoring and reviews were fragmented among several committees or groups. For example, one center had five different groups or committees performing autopsy reviews.

These fragmented reviews often met VA's minimal requirements; however, the review results were not coordinated and integrated facility-wide as required by the regulations.

## Medical centers were not determining the appropriateness of health care provided

All medical centers we visited were performing various functions designed to assure that quality health care was provided. However, as shown in the following examples, they often did not perform the systematic monitoring and analyses required by the regulations to determine whether the care and services provided were appropriate to patient needs:

--At one medical center the surgical case tissue quality assurance committee selected 97 surgical cases for review during 1984. The committee discussed the cases at weekly teaching conferences, but did not always examine whether the surgery provided was needed or appropriate. The quality assurance coordinator told us that the committee was not designed to identify or resolve problems, but rather to meet the center's educational needs.

--At another medical center, two committees performed therapeutic agents and pharmacy reviews. However, neither committee was conducting analyses to determine whether medication, drugs, or other chemicals were administered appropriately. Such analyses were not done even though the center had reported 22 medication errors in 1984.

--Seven of the 13 medical centers were not complying with VA's regulations to determine whether patient records were readily available or secure. While exceptions were noted, medical records quality assurance committees usually checked records to determine whether they contained the diagnoses, history, and identity of health care provider. However, the committees rarely tested to determine whether patient records were readily available and secure. This was not done at one center even though the center's medical information section had previously reported that records were frequently removed and not promptly returned. Also, the surgical case tissue quality assurance committee at this center reported in July 1984 that 8 of 19 patient records selected for review were unavailable.

## Medical centers were not identifying patterns and trends

According to VA's regulations, the continuous monitoring function is supposed to provide patient care information that health care professionals can use to identify patterns and

trends over time. Ten of the medical centers we reviewed did not determine patterns and trends for 1 or more of the 15 continuous monitoring clinical elements. For example:

--The committee chairman at one center told us that a frequent turnover in medical interns and residents caused a corresponding turnover in types of problems; thus, trending was unwarranted. However, our review of the committee's minutes showed repeated occurrences of the same deficiencies. For example, records were not properly documented with medical diagnosis. Also, an August 1984 report prepared by the center showed that the incomplete medical record rate had exceeded JCAH criteria by 254 percent.

## Medical centers were not systematically following up on identified quality of care problems

Medical center directors are fully responsible for quality assurance programs within their facilities. However, according to VA's regulations, resolutions of problems should be initiated at the lowest possible organizational level. We found that centers frequently initiated corrective action for health care problems identified. However, certain quality of care problems were not always recorded and tracked to assure resolution. For example, the blood service review committee at one center reported 14 cases in which patients had adverse reactions from blood transfusions. The center's clinical executive board received those reports, but did not take corrective action, and the quality assurance coordinator told us that frequently quality of care problems are not presented to the board because of its inaction.

## Reasons for medical centers' noncompliance with VA's regulations

Medical center officials responsible for quality assurance frequently agreed with our assessments that their programs did not fully incorporate all VA required functions, elements, or task analyses requirements. With some exceptions, the officials did not view such noncompliance as a problem. Notwithstanding the mandatory wording of VA regulations, some center officials interpreted them as allowing (1) flexibility in the nature and content of quality assurance programs and (2) the exclusion of quality assurance functions, elements, or task analyses that they perceived as unnecessary. Medical center officials generally said their programs met the intent of VA's regulations for assuring quality health care.

### Inconsistent interpretation of quality assurance requirements

Medical center officials relied on various activities--such as day-to-day management and supervision, external reviews, and teaching conferences--for meeting required quality assurance monitoring and reviews. Center officials generally interpreted VA's regulations to allow flexibility for such substitutions. They stated that their programs met the intent of VA's regulations for assuring quality health care. For example, officials at four centers told us that daily management activities were adequate for meeting VA's regulations for radiology and nuclear medicine reviews.

Medical centers made similar substitutions for other continuous monitoring elements, including medical records, autopsies, therapeutic agents and pharmacy, laboratory test, psychiatric services, morbidity and mortality, and rejected applications. For example, two centers relied on problem-focused reviews for continuous monitoring of laboratory tests, five centers relied on teaching conferences for continuous monitoring of autopsies or mortality rates, two centers relied on reviews by the College of American Pathologists for continuous monitoring of laboratories, and several centers relied on internal evaluations by individual services for monitoring of certain clinical elements.

Such activities contribute to quality health care by identifying and resolving problems. However, the results of some of the activities were not analyzed and tracked to systematically identify quality problems and assure corrective action.

### Disagreement with required quality assurance activities

Although VA's quality assurance regulations are mandatory, some medical center officials excluded certain monitoring elements or task analyses from their programs. In such cases, these officials disagreed with VA's regulations on either the need for the required review and analyses or the required level of review.

Four medical center officials told us that medical centers are more concerned with meeting JCAH's quality assurance standards than VA's. For example, one center whose quality assurance program did not include the continuous monitoring required by VA's regulations added that function to its program in October 1984 because JCAH began emphasizing continuous monitoring. Even with its revised program, however, the center's continuous monitoring activities did not comply with VA's regulations. The

quality assurance coordinator noted that (1) compliance with JCAH standards provides a level of assurance to the public that the center meets national quality of care standards and (2) failure to meet JCAH standards results in either nonaccreditation or a contingency accreditation. Two coordinators said there is no penalty for noncompliance with VA's requirements.

Officials at several medical centers disagreed with the level of monitoring or review required by VA's quality assurance regulations. Officials at four centers said that reviewing all cases of certain clinical elements, such as surgical, or radiology and nuclear medicine, as required by VA's regulations was impractical. One quality assurance coordinator said such comprehensive monitoring would restrict the centers' ability to perform surgery. Likewise, the coordinator at another center said that reviewing about 15 to 20 percent of 24,000 radiology procedures performed in 1984 should be adequate. This center reviewed about 2 percent of its radiology procedures although VA's regulations require that all be reviewed.

## GAO OBSERVATIONS

The 13 medical centers we reviewed did not perform all required quality assurance reviews and analyses. Center officials generally stated that their programs, while not always complying with VA's specific requirements, did comply with the spirit of the regulations. Given the scope of their day-to-day management and external review activities, some center officials disagreed with the need for specific reviews and analyses required by VA's regulations.

We did not analyze the thoroughness or effectiveness of medical centers' quality assurance activities. Accordingly, we do not know whether a low level of compliance with the regulations results in poor quality service or whether a high level of compliance would assure high quality. However, where quality assurance activities are not performed, neither VA's central office nor the centers can be sure that patients receive optimal care. Further, the widespread noncompliance with required quality assurance processes, various interpretations of the regulations, and disagreement on the need for required quality assurance processes raise the following questions about VA's current program:

1. Are all the specific quality assurance requirements needed?

2. If the requirements are needed, should VA's central office enforce compliance?

3. Should the central office provide better guidance to assure consistent interpretation and implementation of the requirements?

4. Should the central office develop and require medical centers to use national standards in measuring quality of health care provided?

5. Do medical centers' quality assurance processes affect the quality of care provided?

# CHAPTER 3

# VA'S MEDICAL INSPECTOR HAS NOT ADEQUATELY EVALUATED MEDICAL CENTERS' QUALITY ASSURANCE PROGRAMS

Before early March 1985, MIEO had two basic functions--to evaluate the medical centers' quality assurance programs and to investigate allegations or incidents of poor quality care. A March 3, 1985, organizational change within the Department of Medicine and Surgery abolished MIEO. The evaluation function, including SERP reviews, remained unchanged and became the responsibility of a newly created Office of Quality Assurance. The investigative function also was unchanged and remained the responsibility of the Medical Inspector. This chapter discusses our review of the evaluation activities; chapter 4 discusses VA's investigation activity.

We found that the limited number and scope of MIEO quality assurance evaluation activities diminished VA's ability to achieve the intended purpose of SERP reviews.

## THE SERP PROCESS

MIEO reviewed the quality of care and the quality assurance program of every medical center through the SERP. Federal regulations state that SERP reviews will periodically ascertain the quality of care or support being provided to veterans and assess the effectiveness of each center's internal quality assurance program. A SERP review at a center involves a week-long evaluation of medical care and related services by a team of health care and administrative personnel from other centers. The team uses a standard methodology and prepares a report on its findings.

SERPs differ from the SIRs discussed in chapter 2 in that SERPS periodically assess the provision of care, while SIRs continuously monitor it. Thus, the SERP activities do not duplicate those of SIR.

### The SERP team

SERP reviews are conducted by a multidisciplinary team of health care and administrative personnel from medical centers other than the one being reviewed. The team was led by a designated team leader from MIEO. MIEO required team members to (1) be highly competent in a field germane to the review, (2) have

recent experience in a service or organization viewed as effectively providing quality health care, and (3) be able to comprehend and review services outside of, but related to, their area of specialty. To assure familiarity with day-to-day operations, physician, dentist, and nurse team members are required to be service or section chiefs or be senior staff members.

MIEO selected SERP team members from those nominated by the medical centers based on (1) geographic proximity to the center being reviewed to minimize travel costs, (2) activity level of the member's facility in comparison to that of the center being reviewed, (3) evaluations of the member's performance in previous SERP reviews, if applicable, and (4) a limitation of one review per team member per year.

Team leaders evaluated the performance of the team members. According to MIEO officials, most team members were dedicated and performed well. Of the 723 team members who served on SERP reviews in fiscal years 1982, 1983, and 1984, team leaders identified about 100 who were ineffective reviewers.

The SERP review

SERP team member preparation begins before the actual review. Team members receive statistical data about the medical center--such as number of inpatients, hospital occupancy rates, and staffing levels--and instructions on how to conduct their review. The team leader also briefs the team members on conducting a SERP review when they arrive at the facility being reviewed.

SERP reviews are conducted in 1 week (5 workdays). The evaluation is done using an evaluation methodology called Standards, Criteria, Evaluative Algorithms and Measuring Instruments (SCEMs). MIEO had established SCEMs for 32 medical facility services and programs. The SCEMs describe the tasks a team member should perform and the criteria against which performance of a service should be measured.

SCEMs have been developed by VA central office and medical center personnel and tested in the field. For example, both the Acting Director for Mental Health and Behavioral Sciences and the Assistant Chief Medical Director for Geriatrics and Extended Care said that they worked with MIEO in developing a SCEM for their respective services--psychiatry and psychology and nursing home care. Each team member generally completes a SCEM for two to four assigned services, meets daily with the team leader, participates in both entrance and exit conferences with medical center management, and drafts his/her review findings. Team members are required to complete their report drafts by the end of the fourth workday.

The SERP team assigns an adjective rating to each service it reviewed. This rating is based on a comparison of findings with criteria established by MIEO. The resulting rating can be excellent, very good, good, acceptable, or unacceptable.

The SERP team leader briefs medical center management on a daily basis throughout the week of the review, and after completing its review, the SERP team briefs the medical center's management team on its findings. Team members discuss any problems found, as well as proposed recommendations for the services they reviewed. In addition, the SERP team leader briefs regional and central office staff on the team's findings and prepares a summary for the Chief Medical Director. Shortly after the review, a group of central office officials (including the Deputy Chief Medical Director and the Medical Inspector) decide when the center should be reviewed again.

## The SERP report

The team leader prepares the final SERP report. According to an MIEO official, it takes 30 to 45 days from the completion of the review to prepare and send a final report to the medical center. During that time the team leader may revise or rewrite report segments without consulting with the appropriate team member, revise the report based on MIEO officials' comments, or change the adjective rating given to service within the facility reviewed. Team members we interviewed at 12 centers generally did not see a copy of the team leader's report; therefore, they were not aware of any changes to the segments they may have drafted. To test the degree to which changes were being made, we examined the adjective ratings in 21 reports of fiscal year 1983 SERP reviews and found that 11 percent had been changed, some upward and others downward. Of 300 adjective ratings given by team members, 34 were later changed. Of the 34 changes, 23 were to a higher and 11 to a lower rating.

Medical centers must prepare an implementation plan detailing how they will address each SERP team recommendation. Central office officials also review the SERP team report and comment on the center's plan. Once MIEO determined that all issues had been satisfactorily addressed, it officially ended the review. VA's regional directors are responsible for assuring that centers actually implement the SERP team's recommendations.

## PROBLEMS WITH THE SERP PROCESS

From our discussions with MIEO, other central office, and medical center officials and our analysis of the SERP process and MIEO documents, we found that (1) SERP reviews have not evaluated the overall effectiveness of the centers' internal

quality assurance programs, (2) MIEO had not conducted the number of SERP reviews it had planned to, and (3) some SERP team members and center officials believe that the time frame for conducting reviews is too short.

## SERP reviews have not included evaluations of the effectiveness of medical centers' quality assurance programs

According to VA's regulations, SERP reviews should address the effectiveness of each medical center's quality assurance program. Yet SERP teams did not assess program effectiveness, and no methodology existed for doing so.

We selected six reports on SERP reviews conducted after October 1982 to determine whether the teams were assessing the effectiveness of the medical centers' five quality assurance functions, including the 15 continuous monitoring elements described in chapter 2. We found that two reports made no mention of these functions, one referred to utilization review, one referred only to problem-focused studies, one referred to two of the continuous monitoring elements, and one briefly mentioned utilization review and one continuous monitoring element.

MIEO officials told us that SERP reviews address components of the centers' quality assurance programs but do not directly address program effectiveness. As a result, SERP teams

--do not assess every continuous monitoring function,

--do not review patient incident reports to determine if they were properly investigated or the necessary corrective action was taken, and

--do not assess how the credentials reviews were conducted or the basis for the delineation of privileges.

MIEO officials said that SERP teams did not have enough time to evaluate the effectiveness of a center's quality assurance program. One official told us that it would require 6 or 8 weeks to thoroughly review the effectiveness due to the amount of detail involved.

At the time of our review, SERP teams did not have a methodology or evaluation criteria to use to assess the effectiveness of medical centers' quality assurance functions. However, in October 1984, team leaders began using draft evaluation criteria to review medical centers' quality assurance programs. The criteria address whether a medical facility has a written systematic internal review policy but include only four of the

five functions and 14 of the 15 continuous monitoring elements.[1] The criteria, however, require examinations of only utilization reviews and five of the continuous monitoring elements.

VA had not conducted the number of SERP reviews it had planned to

To ensure that SERP reviews were conducted periodically, as required by VA's regulations, VA planned to review about 60 medical centers annually. However, it has not achieved this goal since fiscal year 1977.

VA's SERP program began in January 1975. At that time, VA planned to review each medical center every 3 years, covering about 60 annually. The listing below shows the number of SERP visits made each year since fiscal year 1975.

| Fiscal year | No. of SERP visits |
|---|---|
| 1975 | 23 |
| 1976 | 69 |
| 1977 | 72 |
| 1978 | 54 |
| 1979 | 48 |
| 1980 | 53 |
| 1981 | 47 |
| 1982 | 30 |
| 1983 | 37 |
| 1984 | 41 |

In January 1982, the Department of Medicine and Surgery began assigning a time frame within which each medical center reviewed should undergo its next SERP review. In this way, MIEO scheduled those centers at which long-standing or serious problems were found for review sooner than centers with relatively minor problems. Since then, centers have received a review status of 1 to 4 years.

MIEO officials told us that about 70 SERP reviews should be conducted annually to cover all centers within the 4-year cycle and to ensure that those with shorter review cycles are covered. Our review of MIEO records indicated that as of March 15, 1985, 44 centers had not been reviewed since December 1981. Twenty of

[1]The criteria do not address the problem-focused health care evaluation function or the patient incident review element of VA's quality assurance program.

those have not been reviewed since 1980. Twenty-one of the 44 are scheduled to be reviewed through the end of fiscal year 1985. In addition, reviews based on the variable cycle were not being accomplished as scheduled. For instance, in fiscal year 1982, 16 medical facilities were given a 2-year review status. However, 12 of those had not been reviewed again within 2 years.

Information we obtained for fiscal years 1983, 1984, and part of 1985 showed that MIEO had not received the travel funds it requested to conduct the recommended 70 SERP reviews each year. The following chart compares the budget requests to conduct the recommended 70 reviews with the funds expended and reviews conducted.

| Fiscal year | Budget request | Planned SERP reviews | Funds received | Funds spent | SERP reviews conducted |
|---|---|---|---|---|---|
| 1983 | $629,000 | 70 | $281,000 | $272,000 | 37 |
| 1984 | 709,400 | 70 | 313,032 | 264,625 | 41 |
| 1985[a] | 504,000 | 70 | 310,855 | 159,379 | 29 |

[a]Through March 1985.

Even if all requested funding was allocated, MIEO would be unable to conduct the 70 reviews. According to MIEO officials, their budget requests were based on seven team leaders conducting 10 reviews each. However, as of March 1985 only six of the seven team leader positions were filled. Of these, five were fully trained team leaders and one was a trainee. According to a MIEO official, the remaining team leader slot was not filled because, over the past few years, requested travel funds were not made available for SERP reviews.

## Officials believe the time frame for conducting SERP reviews is too short

SERP reviews are conducted in 1 week, and the time actually spent assessing the quality of patient care is less than 5 days. During the week of the review, a team of 6 to 12 members participates in an opening conference with center management; review all medical care and related services within the medical center; attend daily meetings with the team leader; attend a close-out conference on the last day; and complete draft report segments for each service reviewed.

Each SERP team member is usually assigned two to four medical services to review, including his/her specialty. Team members review documents and records, interview the chief of each service and selected staff, and observe the functions of

the service. The information obtained is used to complete a SCEM checklist for each service.

SERP team members have about 3 to 3-1/2 days to review their assigned services. Team members generally spent more time reviewing the service with which they were most familiar and less time reviewing other assigned services. We asked 33 former SERP team members if they had enough time to conduct a review of the services assigned to them. Nineteen of them said that either the time was inadequate or they had to work long hours to complete their SERP responsibilities. The other 14 said they had sufficient time to complete their work.

## OTHER MIEO ACTIVITIES

In addition to conducting SERPs, MIEO was responsible for (1) providing guidance to medical facilities on establishing quality assurance programs and (2) performing analyses of data generated from all sources, including the quality assurance programs. Guidance had been provided and some data analysis performed, but more could be done in both areas.

### VA recognized the need for improved guidance

At the time of our review, VA had provided guidance to medical centers on developing and operating a quality assurance program. MIEO's guidance was fragmented in that it was contained in a manual, numerous circulars, newsletters, and a workshop for quality assurance coordinators. A MIEO official said that in view of the number of inquiries received from medical center quality assurance officials, a critical need exists for uniform VA-wide criteria to follow in implementing their programs.

Recognizing a need to improve its guidance, MIEO convened a study group to consolidate and revise the quality assurance manual. The official responsible for the group said a draft was completed and forwarded to the Medical Inspector for review in September 1983. As of March 1985 the revised quality assurance manual had not been issued. The Medical Inspector stated that the results of a quality assurance pilot project should be incorporated and terminology used throughout the revised manual was out of date and in need of revision.

MIEO was also preparing a program guide, which, according to a MIEO official, will provide practical information on (1) setting up a quality assurance program, (2) meeting JCAH requirements, (3) conducting utilization reviews, and (4) meeting SERP criteria. As of March 1985 the program guide had not been finalized.

## More data analysis could be performed

MIEO was responsible for analyzing quality of care information. It conducted some trend and other analyses based on the medical center deficiencies and problems cited in SERP, JCAH, and Inspector General reports. For instance, MIEO's analysis of JCAH reviews conducted in 1983 showed that JCAH's quality assurance standard was most frequently cited for deficiencies, including deficiencies in reviewing surgical cases, integrating quality assurance activities, and documenting quarterly blood utilization reviews. Deficiencies of the quality assurance standard were also the third most frequently cited as remaining uncorrected from a previous JCAH review.

MIEO did not compile quality assurance data, such as surgical complications or mortality rates, for analysis purposes. In addition, other than the criteria in the SCEMs, no standards or norms were developed for use in data analysis. A MIEO official said staffing constraints have limited the ability to perform these types of analyses.

An MIEO official said that before June 1984, MIEO had not collected or analyzed malpractice information. Beginning in June 1984, information on the types of claims settled was collected. Also, the Medical Inspector plans to collect more detailed information, including the involved physician's name and a complete summary of the case.

## IMPLEMENTATION OF SERP RECOMMENDATIONS

Federal regulations require that VA medical centers take corrective action on all unresolved issues or recommendations resulting from the quality assurance program. Recommendations made as a result of SERP reviews and Medical Inspector investigations discussed in chapter 4 are sent to the directors of medical centers and to the regional directors. The VA Organization Manual states that a regional director is responsible for (1) exercising direct-line supervision of directors of field facilities in the region and (2) following up on approved recommendations contained in both internal and external reports.

At four medical centers we visited that had SERP reports for reviews conducted in fiscal years 1982, 1983, and 1984, we checked to see if the centers had a follow-up system to determine if SERP recommendations had been implemented. From our review of documentation and discussions with center officials, it appears that the centers have tracked implementation of the recommendations. Because of the large number of recommendations--77 at one center--and time constraints, we did not fully verify implementation. We asked regional officials how they

followed up to assure implementation of the recommendations. We were told that (1) no specific guidance has been published to aid the regional directors in exercising their monitoring responsibilities and (2) they had no systematic means of following up on recommendations. However, they said they do take actions to see that recommendations have been implemented. According to the regional directors' staffs, they review current SERP reports and facility implementation plans before annual site visits and selectively choose which recommendations to follow up. They said that since follow-up on SERP recommendations is only one of many items on their site visit agenda, they generally spot-check the recommendations to see if they were implemented.

## GAO OBSERVATIONS

SERP reviews conducted by MIEO served two purposes: (1) to ascertain the quality of health care or support being provided to veterans and (2) to assess the effectiveness of each medical center's internal quality assurance program. Through application of the SCEMS, the SERP teams assessed the quality of care being provided at centers, but their reviews were limited by the time allotted for SERP team members to conduct their reviews. VA has not, over the past few years, conducted the number of SERP reviews it planned to.

SERP reviews have not determined the effectiveness of medical centers' internal quality assurance programs and therefore did not meet their second purpose. Meeting that purpose would require a methodology for determining effectiveness and considerably more time and resources for conducting SERP reviews. It would also require reviewing the 5 quality assurance functions, including the 15 elements, in addition to examining facilities' services.

MIEO was responsible for analyzing quality assurance data and had conducted some trend and other analyses using deficiencies found during external reviews. More could be done, however, to analyze quality assurance data, compare it to standards, and identify trends. This could lead to increased targeting of investigations and reviews of potential quality assurance problems.

As discussed on pages 2 and 19, VA has recently placed the responsibility for central office quality assurance activities in a newly established Office of Quality Assurance. VA expects that the new office will emphasize the importance of operating a proactive program to identify and deal with potential quality assurance problems before incidents occur. This discussion of problems we identified with VA's SERP evaluations, conducted by the former MIEO, should be of use to the new director as the Office of Quality Assurance initiates its evaluation activities.

# CHAPTER 4

# QUALITY ASSURANCE INVESTIGATIONS CONDUCTED BY MEDICAL CENTERS AND THE MEDICAL INSPECTOR

One of the Medical Inspector's principal responsibilities is to investigate incidents that may have adversely affected the quality of care provided to VA's patients. The Medical Inspector learns of these incidents from many sources, but most are reported by the medical centers through a formal system. We found, however, that centers were not reporting these incidents as timely as required. In addition, VA has an incentive program to encourage employees to report incidents of fraud and waste in general, but has no such program for reporting incidents of poor quality care. We found, however, that centers were adequately safeguarding information about employees who did report such incidents.

## THE MEDICAL INSPECTOR INVESTIGATION PROCESS

Medical Inspector investigations may result from incidents, allegations, and complaints from a variety of sources. During fiscal year 1984 the Medical Inspector opened 199 investigations. The sources of these investigations are indicated on the following chart.

Source of Investigations Opened by VA's Medical Inspector in Fiscal Year 1984

| Source | Number |
|---|---|
| Medical centers | 117 |
| Office of Inspector General | 53 |
| Patients, relatives, friends, and anonymous sources | 12 |
| Congress | 6 |
| VA (other than medical centers and the Inspector General's office) | 9 |
| White House | 1 |
| SERP visit | 1 |
| Total | 199 |

In fiscal year 1984, 1,224 incidents were reported to the Medical Inspector by medical centers. These represented only a

fraction of the 80,273 incidents reported at centers and later reported to VA's central office in a semiannual statistical report. VA's internal regulations require centers to collect data on many categories of incidents, ranging from falls or medication errors to unexpected deaths and suicides. For example, the 1,224 incidents reported to the Medical Inspector can be categorized as follows:

| Category of incident | Number of incident reports |
|---|---|
| Abuse of patients | 233 |
| Unexpected deaths | 133 |
| Suicides and suicide attempts | 440 |
| Poor quality care (medication errors, transfusion errors, etc.) | 167 |
| Other (suicide gestures, falls, fires, patient injury other than falls, assault by patients, etc.) | 251 |
| Total | 1,224 |

Likewise the 80,273 incidents reported at the medical centers have been categorized as follows:

| Category of incident | Number of incident reports |
|---|---|
| Suicide gestures | 615 |
| Suicides and suicide attempts | 573 |
| Abuse of patients | 658 |
| Falls | 40,030 |
| Transfusion errors | 114 |
| Medication errors | 10,530 |
| Patient injury (other than falls) | 11,498 |
| Unexpected deaths | 693 |
| Fires | 161 |
| Other | 15,401 |
| Total | 80,273 |

Centers are also required to investigate certain incidents, such as those resulting in permanent disability and transfusion accidents, and forward copies of the investigative reports through the appropriate regional director to the Medical Inspector. This process is part of each center's internal quality assurance program (patient injury control) described in chapter 2.

The Medical Inspector told us that he, and occasionally a central office official with special expertise, review incident reports for which there have been no investigations to determine if one should have been conducted. The Medical Inspector, the Inspector General, and appropriate central office officials, such as the Director of Nuclear Medicine or the Director of Medical Service, review medical center investigation reports to determine if the investigations were adequate. When the Medical Inspector or other reviewers are not satisfied with what the center did, the Medical Inspector will conduct an independent investigation by either requesting more information, requesting a medical center investigation, or arranging for a personal site visit or a visit by a personally selected team. During fiscal year 1984 the Medical Inspector or an appointed team conducted 17 investigations through site visits.

Investigation reports

Medical centers send their investigation reports through their regional director to the Medical Inspector. The Medical Inspector then sends copies to the Inspector General and central office staff responsible for services covered in the report. Centers also send incident reports that have not resulted in investigations, such as those relating to certain falls and attempted suicides that do not result in the death of a patient, to the Medical Inspector.

Reports of the Medical Inspector's site visit investigations are sent to the Inspector General and through the regional director to the medical centers. Rather than distributing copies of site visit reports to other central office officials (including the Chief Medical Director), the Medical Inspector told us he prefers to brief them on the investigation results and recommendations because site visit reports are usually confidential and sensitive and he believes they should not be widely disseminated.

Some investigation reports had not been referred to the Inspector General for review

The Inspector General is supposed to review all investigation reports for adequacy; however, in fiscal year 1984, 154 of the 724 investigation reports received by the Medical Inspector were not forwarded to the Inspector General. An official in the Medical Inspector's office said all investigation reports probably were not sent to the Inspector General for the following reasons:

--The Medical Inspector accepts reports dealing with psychological factors surrounding suicides in lieu of suicide investigation reports. These reports are sent to VA's Mental Health and Behavioral Sciences Service and not to the Inspector General.

--Investigations of complications or deaths resulting from cardiac catheterizations are not reviewed by the Medical Inspector but are sent to the Chief of Cardiovascular Diseases in the Department of Medicine and Surgery. The Medical Inspector follows this process because cardiac catheterization procedures are highly specialized and anyone outside of the field of cardiology would likely lack the expertise to adequately review the investigation reports.

--A secretary within the Medical Inspector's office retired in June 1984 and was not replaced until October 1984. This resulted in some investigation reports not being forwarded to the Inspector General by the end of fiscal year 1984 as they should have been.

--One medical center investigates numerous incidents involving patient on patient assaults. The reports were not sent to the Inspector General for review because many of the incidents were not serious.

On April 25, 1985, a meeting between an official of the Medical Inspector's office and an Inspector General official resulted in an agreement that in the future all investigation reports received by the Medical Inspector will be referred to the Inspector General regardless of their nature.

Some incidents are not reported in a timely manner

VA requires center officials to "immediately" report certain types of incidents, such as assaults or allergic reactions to anesthesia or drugs, to the appropriate regional director, who will forward the information to the Medical Inspector. Other incidents must be reported but not immediately. Although VA has not defined "immediately," a MIEO official told us that centers were expected to inform MIEO by the next morning or by Monday morning if an incident occurs on a Friday or Saturday.

To determine how well this reporting requirement was being met, we selected 22 incidents that should have been reported immediately from those that the Medical Inspector had received from 16 medical centers during fiscal year 1984. Upon receipt, MIEO staff did not record the date on which three incidents occurred. Of the other 19, 2 were reported by the next working

day, 2 were reported within a week, and 4 were not reported for over 1 month.

## MEDICAL INSPECTOR INVESTIGATION RESOURCES

The Medical Inspector's investigative staff includes a health science officer with some health-related experience, a staff assistant, and two program assistants, none of whom have a medical background. Travel funds requested, received, and spent for fiscal year 1984 and 1985 as of March are reflected in the following chart.

| Fiscal year | Budget request | Funds received | Funds spent |
|---|---|---|---|
| 1984 | $45,000 | $42,411 | $31,946 |
| 1985 | 60,000 | 60,000 | 6,639[a] |

[a]As of March 1985.

The Medical Inspector told us that since he had access to professional and other staff within VA, he did not need additional staff within his office to conduct investigations. In addition, an official of the Medical Inspector's office said the Medical Inspector has had adequate travel funds to conduct investigations.

## INCENTIVES AND SAFEGUARDS

VA employees may report incidents of perceived poor quality care to their medical center, directly to the Medical Inspector, or through the Inspector General's telephone "hotline." Although VA has a cash award program to encourage employees to report fraud and waste, it has no such program for those who report quality of care problems.

The Inspector General Act of 1978 (Public Law 95-452, as amended) precludes the Inspector General from disclosing the identity of any employee making a complaint or allegation, unless the Inspector General determines that this disclosure is unavoidable during the course of the investigation, and specifies that reprisals not be taken against employees unless they deliberately disclose false information. VA regulations require investigation reports to be confidential but do not consider incident reports to be confidential. During our work at 13 medical centers, we noted that incident and investigation reports were both secured.

# CHAPTER 5

# THE INSPECTOR GENERAL'S ROLE IN QUALITY ASSURANCE

The Committee's request included several questions about the relationship between VA's Inspector General and the Medical Inspector. This chapter briefly describes the Inspector General's organization and responsibilities and then answers the Committee's questions.

## OFFICE OF INSPECTOR GENERAL ORGANIZATION AND RESPONSIBILITIES

The Office of Inspector General was established pursuant to the Inspector General Act of 1978, and the Inspector General reports directly to the Administrator. The Office conducts regular audits of every VA medical facility, including the medical centers, and special investigations as required. Both functions are directed by Assistant Inspectors General.

The Office receives allegations of fraud, waste, and mismanagement from its telephone "hotline" and other sources. It reviews each allegation and investigates those with merit. It refers allegations of poor quality care to the Medical Inspector. The Office reported that during fiscal year 1984 it had received 3,944 allegations, of which 137 were handled within the office, 500 were referred to other VA offices, and further action was not considered necessary on the remaining 3,307. Of the 500 referred, about 60 were referred to the Medical Inspector.

The Office also conducts routine audits to determine whether each medical center has been using its resources efficiently and economically and operating in accordance with applicable laws and regulations. VA's Assistant Inspector General for Audits said that beginning in fiscal year 1984, these routine audits have been addressing certain aspects of centers' quality assurance programs, such as tracking implementation of recommendations to improve quality of care. In addition to facility audits, the Inspector General conducts special program reviews which may cover quality assurance matters. As of March 8, 1985, the Inspector General was conducting three such audits:

--A review of VA physicians' credentials.

--An assessment of malpractice claims against VA, including resulting disciplinary actions.

--A review of central office and medical center use of standards in monitoring the quality of care provided in VA facilities.

## RELATIONSHIP OF THE INSPECTOR GENERAL TO THE MEDICAL INSPECTOR

The Committee asked how the Office of Inspector General exercised oversight responsibilities over the Office of Medical Inspector. The Committee also asked about specific Inspector General policies, procedures, and mechanisms to monitor and evaluate the quality of the Medical Inspector's investigations.

The Office of Inspector General does not assess the quality of care actually provided to VA patients and therefore has not applied any standards of performance, such as mortality or morbidity rates. It has assigned an investigator to review all complaints involving quality of care issues that it receives from its telephone "hotline" and other sources to determine which ones need to be investigated. Those determined to need further attention are referred to the Medical Inspector. In addition, that investigator reviews the Medical Inspector's investigation of those complaints, as well as reports of investigations conducted by medical centers and submitted to the Medical Inspector, to determine whether the investigations, in the reviewer's judgment, were adequate and actions were timely. During fiscal year 1984, the investigator reviewed 570 reports of investigations conducted by medical centers. The investigator also reviewed 217 reports of Medical Inspector investigations.

The Committee asked whether the resources that the Inspector General allocated to monitor the Medical Inspector's efforts were sufficient to effectively carry out this activity. The Inspector General has assigned the director of its special investigative operations and one full-time investigator to monitor the Medical Inspector's efforts. The Office does not maintain data on the costs associated with this oversight activity. Officials of both the Office of Inspector General and MIEO told us that resources had been sufficient to effectively carry out the investigator's responsibilities.

The Committee asked whether the recommendations in the Inspector General's November 29, 1982, report on its oversight of the Medical Inspector's activities had been effectively implemented. These recommendations included, among other matters, a more formal relationship and improved communications between the Inspector General and the Medical Inspector, better tracking of Medical Inspector cases, and more Office of Inspector General resources for its oversight activities.

We found that the recommendations had been implemented. The relationship between the Inspector General and Medical Inspector was formalized by a December 1984 agreement between the Inspector General and the Chief Medical Director (see app. V). The Inspector General established better communication and coordination through daily telephone calls to the Medical Inspector's office, two or three informal consultations a week, and a formal meeting with the Medical Inspector once a month. The Inspector General also organized a system for tracking Medical Inspector investigations and documenting other monitoring activities. An investigator now works full time on this responsibility, as compared to part time before the Inspector General's report.

Finally, the Committee asked which, if any, of the quality assurance efforts performed by the Medical Inspector's SERP reviews would more appropriately fall within the Office of the Inspector General's mission. The SERP and Inspector General reviews at individual medical centers serve different purposes. SERP reviews are conducted mainly by health care professionals and involve professional judgment regarding the quality of care being provided to the patients. Inspector General reviews, on the other hand, are conducted by auditors and seek to determine whether centers are operating efficiently and economically. In addition to the different review objectives and reviewers' qualifications, the levels of reporting for each differs. SERP reports are issued to the Chief Medical Director, and Inspector General reports to the Administrator.

APPENDIX I



**United States Senate**

**COMMITTEE ON VETERANS' AFFAIRS**

**WASHINGTON, D.C. 20510**

December 21, 1983

Honorable Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
Washington, D.C. 20548

Dear Mr. Bowsher:

I am writing as Chairman of the Senate Committee on Veterans' Affairs to request that the General Accounting Office review the Office of Medical Inspector and Evaluation which was established July 30, 1981, by the Administrator of Veterans' Affairs to monitor and report on the quality of care within the Department of Medicine and Surgery. The Office of Medical Inspector and Evaluation conducts regularly-occurring system-wide inspections (such as the Systematic External Review Program called SERP) and one-time investigations in response to specific incidents or requests. The GAO review would be intended to provide the Committee with information concerning the management processes and procedures of these inspections and investigations.

I would like GAO to review the general operation and effectiveness of the Office of Medical Inspector and the specific procedures and mechanisms for reporting the findings of inspections and investigations. I am most interested in how a request for investigation is processed, how the scope of the investigation is defined and how the review action is implemented? To what review processes are the findings subject and how are they disseminated to all levels of VA management? I am also interested in the mix of investigatory actions performed by this Office and the relation between the Medical Inspector and VAMC Directors, the Chief Medical Director, and the VA Inspector General. Any other areas you may review which would aid in understanding the operation of the Office of Medical Inspector would be appreciated.

It is my view that the GAO review would provide a useful resource to oversight activities of this Committee during the 2nd Session of the 98th Congress with respect to the Office of Medical Inspector. Any questions or needs for further coordination of this request may be directed to Victor Raymond of my staff at 224-9126.

With warm regards,

Sincerely,

Alan K. Simpson
Chairman

CC: Harry Walters
Donald Custis, M.D.

APPENDIX II



United States Senate

COMMITTEE ON VETERANS' AFFAIRS

WASHINGTON, D.C. 20510

September 6, 1984

Honorable Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Charles:

We are writing, as the Chairman and Ranking Member of the Senate Veterans' Affairs Committee, in follow-up to Chairman Simpson's December 21, 1983, letter to you concerning the Veterans' Administration Office of Medical Inspector and Evaluation, subsequent meetings between GAO staff and Committee staff on this subject, and the Committee's June 6, 1984, oversight hearing on this same subject. The efforts by your staff to conduct the review of the Office of the Medical Inspector and to provide information to the Committee prior to the June 6 hearing have been very helpful and are greatly appreciated. We are writing to request that your efforts in response to Chairman Simpson's initial request be continued and expanded. In addition to the issues outlined in the Chairman's December 21, 1983, letter, we ask that the following issues, among others, also be addressed:

1. The relationship between the Inspector General and the Medical Inspector. Specifically, please address the following issues and questions, among others:

- How does the Inspector General meet the various statutory missions of the Office of Inspector General and exercise his oversight responsibilities with respect to the Office of Medical Inspector, including the responsibility to keep "the head of the [VA] and the Congress fully and currently informed about problems and deficiencies" in quality assurance activities?

- What specific policies, procedures and mechanisms has the Inspector General set up to monitor and evaluate the quality of the Medical Inspector's investigations and to what extent have these policies, procedures and mechanisms been implemented?

- What standards of performance, such as surgical mortality rates, surgical complication rates, morbidity rates, incident reporting data, malpractice claims data, and others does the Inspector General review to monitor periodically the quality of care by VA physicians?

- How many full- and part-time FTEE and what amount of funding does the Inspector General allocate to monitoring the Medical Inspector's efforts and are these personnel and fiscal resources sufficient to carry out effectively this activity?

- How effectively has the Inspector General implemented the recommendations made in the November 29, 1982, report pursuant to his own internal review of his oversight of the activities of the Medical Inspector?

- Which, if any, of the quality assurance efforts performed by the Medical Inspector's Systematic External Review Process (SERP) would more appropriately fall within the mission of the Inspector General?

2. The implementation of the Systematic Internal Review (SIR) program at VA medical centers. Specifically, please address the following issues and questions, among others:

- To what extent have VA medical facilities implemented quality assurance programs as required by regulations published in the Federal Register, October 12, 1982 (38 CFR, § 17.500-17.540) and certifying bodies such as the Joint Commission on Accreditation of Hospitals?

- Which, if any, of the Systematic External Review Process quality assurance activities would more appropriately fall within the mission of the Systematic Internal Review program?

- What quality assurance activities does the VA have in place and operating which are directed specifically to monitor the quality of nursing home care?

- What quality assurance activities does the VA have in place and operating which are directed specifically to monitoring the quality of psychiatric care?

- What policies, procedures and mechanisms do the VA medical centers have in place and operating to monitor and evaluate the credentialing of VA physicians?

- What standards, such as those based on surgical mortality rates, surgical complication rates, morbidity rates, incident reporting data, and malpractice claims data, are applied by the VA medical centers, to monitor the quality of care provided by VA physicians? How and how often are data developed through

such monitoring efforts reviewed and analyzed by the Medical Inspector or by the Inspector General as possible indicators of problems in quality of care? What data base is compiled and retained to enable the Systematic Internal Review program and the Medical Inspector to undertake such reviews and analyses?

3. The roles of Department of Medicine and Surgery Regional Directors in the quality assurance activities. Specifically, please address the following issues and questions among others:

- What are the roles of the Regional Directors in the quality assurance process?
- What specific guidance has been provided to them to clarify their roles and aid them in implementing their responsibilities in this regard?
- Have they been carrying out effectively their roles and ensuring that VA medical centers implement recommendations resulting from Medical Inspector investigations or SERP reviews?
- What policies, procedures, and mechanisms do the Regional Directors have in place to ensure that quality of care deficiencies found by a SERP review are corrected [rather than left to be discovered again]?

4. Protection of Department of Medicine and Surgery employees who report poor quality of care incidents. Specifically, please address the following issues and questions, among others:

- What policies and procedures does the VA have for providing incentives to Department of Medicine and Surgery personnel to report poor quality of care or related incidents and for protecting their confidentiality when such reports are made?
- What safeguards are applied and operational to protect "whistleblowers" from possible retaliation by other VA personnel?

5. Resources allocated to the Medical Inspector. Specifically, please address the following issues and questions, among others:

- Does the Medical Inspector receive sufficient resources, including personnel ceilings and position levels and travel funds, to carry out effectively the investigatory function of the office?

APPENDIX II



- Has the Medical Inspector sought and been denied greater staff and financial resources for that purpose and, if so, at what level was this request denied and for what reasons?

- Are sufficient staff and financial resources available to the Medical Inspector to carry out the other (SERP evaluations, data collection and analysis of trends in quality assurance problems, use of standards to measure physician performance, general oversight and guidance to SIR and Regional Offices) quality assurance functions of the office?

In order for GAO's review to be of maximum benefit to the Committee, please submit a report, no later than March 1, 1985, on your findings based upon the aforementioned issues and questions, as well as those developed as a result of Chairman Simpson's December 21, 1983, request.

In addition, either as part of the March 1, 1985, report or as soon thereafter as is feasible in light of resources available to GAO to carry out this review, we would appreciate your views on the following point:

- How does the division of responsibility for investigating medical issues within the VA compare with the approach adopted in the Department of Defense? (For initial reference, please see DOD's June 6 oversight hearing testimony).

Finally, for your information and use, we are enclosing copies of the questions we submitted to the VA in connection with the Committee's June 6 hearing and the agency's responses.

Thank you for your continuing cooperation and assistance. If additional information is needed regarding this request, please have GAO staff contact either Cynthia Alpert (224-9126) or Bill Brew (224-2074) on the Committee staff.

Sincerely,

Alan K. Simpson
Chairman

Alan Cranston
Ranking Minority Member

CC: Honorable Harry N. Walters
Honorable Frank Sato
Dr. John A. Gronvall

Enclosures

## INFORMATION ON MEDICAL CENTERS SELECTED FOR REVIEW

| Medical center | Hospital beds | | | | Other beds | | Affiliated | SERP review in fiscal years 1982 or 1983 |
|---|---|---|---|---|---|---|---|---|
| | Medical | Surgical | Psychiatry | Total | Domiciliary | Nursing home | | |
| Augusta, Ga. | 435 | 150 | 431 | 1,016 | 0 | 40 | Yes | Yes |
| Butler, Pa. | 320 | 0 | 0 | 320 | 0 | 104 | No | No |
| Dublin, Ga. | 278 | 36 | 0 | 314 | 344 | 86 | No | No |
| Erie, Pa. | 96 | 39 | 0 | 135 | 0 | 40 | No | Yes |
| Hines, Ill. | 683 | 273 | 240 | 1,196 | 0 | 111 | Yes | Yes |
| Lake City, Fla. | 251 | 75 | 0 | 326 | 0 | 40 | No | No |
| Lakeside, Ill. | 266 | 146 | 40 | 452 | 0 | 0 | Yes | No |
| Long Beach, Ca. | 737 | 228 | 143 | 1,108 | 0 | 180 | Yes | No |
| Phoenix, Ariz. | 210 | 124 | 136 | 470 | 0 | 120 | Yes | Yes |
| Pittsburgh, Pa. | 428 | 183 | 30 | 641 | 0 | 228 | Yes | No |
| Prescott, Ariz. | 138 | 49 | 30 | 217 | 214 | 0 | No | No |
| Tomah, Wis. | 333 | 0 | 465 | 798 | 0 | 100 | No | No |
| Tuscaloosa, Ala. | 146 | 0 | 358 | 504 | 0 | 120 | Yes | No |



APPENDIX III

APPENDIX IV

# code of federal regulations

## Pensions, Bonuses, and Veterans' Relief

# 38

PARTS 0 to 17

**Revised as of July 1, 1984**

CONTAINING
A CODIFICATION OF DOCUMENTS
OF GENERAL APPLICABILITY
AND FUTURE EFFECT

AS OF JULY 1, 1984

*With Ancillaries*

Published by
the Office of the Federal Register
National Archives and Records Service
General Services Administration

as a Special Edition of
the Federal Register

APPENDIX IV

## HEALTH SERVICES REVIEW ORGANIZATION (HSRO)

AUTHORITY: 38 U.S.C. 3305.

SOURCE: Sections 17.500-17.540 appear at 47 FR 47010, Oct. 22, 1982, unless otherwise noted.

### § 17.500 General.

(a) Health Services Review Organization (HSRO), the Veterans Administration's Medical Quality Assurance Program, is a systematic effort by the Veterans Administration to ensure an optimal level of quality patient care. The HSRO program is an ongoing, efficient, flexible, integrated health care monitoring and improvement system. HSRO shall review the following aspects of medical quality in VA Medical Facilities:

(1) The appropriateness of patient care and services provided,

(2) The effective utilization of resources,

(3) The safety of patients, and

(4) The conduct or performance of VA employees and others engaged in the provision or support of patient care.

(b) HSRO is a two faceted program:

(1) Health Services Review Organization—Systematic Internal Review (HSRO-SIR) is an integrated quality assurance process that is internal to each VA Medical Facility.

(2) Health Services Review Organization—Systematic External Review Program (HSRO-SERP) is a system-wide VA peer review mechanism external to each VA Medical Facility that evaluates the quality of care in each VA Medical Facility and the effectiveness of its HSRO-SIR program.

(c) Corrective action on all unresolved issues or recommendations identified by an HSRO-SIR or HSRO-SERP review will be taken by the VA Medical Facility. Such action will be initiated and implemented at the lowest possible organizational level.

(d) The term "VA Medical Facility or Facilities" used throughout these regulations includes VA Medical Centers, Independent Outpatient Clinics and Independent Domiciliaries. (38 U.S.C. 3305)

### § 17.501 Departmental responsibility.

(a) The Chief Medical Director is responsible for the implementation, maintenance, and enforcement of these HSRO regulations, and will ensure that each VA Medical Facility maintains an effective and efficient HSRO-SIR program.

(b) The Director, Medical Inspector and Evaluation Office (Medical Inspector) will provide guidance, oversight, and recommendations to the Chief Medical Director concerning the status, efficiency and the need to improve the HSRO program. (38 U.S.C. 3305)

### § 17.502 [Reserved]

### § 17.503 Individual facility responsibility.

(a) Each VA Medical Facility Director is fully responsible for the HSRO-SIR program within the facility. The authority for coordinating, training, providing technical support, and conducting day-to-day supervision of HSRO-SIR activities is delegated to the HSRO Coordinator. Supervision of the HSRO Coordinator may be by either the Medical Facility Director or Chief of Staff as determined by the Medical Facility Director.

(b) The Chief of Staff and Assistant Medical Facility Director are responsible for assuring that services under their supervision adequately support and participate in the HSRO-SIR program.

(c) Each Service Chief at a VA Medical Facility is responsible for planning

APPENDIX IV

and implementing HSRO-SIR for his/her service and ensuring that HSRO-SIR activities or functions of his/her service are integrated with and supportive of the VA Medical Facility HSRO-SIR program and meet the intent of the HSRO-SIR plan of the VA Medical Facility.

(d) The VA Medical Facility Director will authorize an existing committee or subcommittee to integrate and coordinate HSRO activities. This committee or subcommittee will be composed of VA Medical Facility employees. (38 U.S.C. 3305)

**§ 17.504 Conduct and evaluations.**

(a) Any VA employee participating in HSRO-SIR or HSRO-SERP evaluation activities will exercise prudent and diligent care and act in good faith while gathering and analyzing factual information prior to making any judgment which may reflect adversely on a VA employee or VA Medical Facility.

(b) Only those employees in supervisory, executive, or HSRO capacities who have sufficient job related needs to study or otherwise utilize the data should have access to patient or provider identification information or to the confidential coding system. Access to HSRO records is governed by § 17.527. (38 U.S.C. 3305)

**§ 17.505 HSRO-SIR plan.**

Each VA Medical Facility will develop a written HSRO-SIR plan which establishes responsibilities, defines policy and describes the procedures and mechanisms necessary to maintain an effective HSRO-SIR program. The plan will be reviewed annually as part of the Medical Facility's evaluation of its HSRO-SIR program, and updated according to need. Each VA Medical Facility HSRO-SIR plan will identify and address itself to the following subjects:

(a) *Philosophy and objectives of the HSRO program* (as described in § 17.500).

(b) *Policy statement.*

(c) *Responsibilities for:*

(1) Program organization and operation.

(2) Annual evaluation of the HSRO-SIR program.

(3) Development and revision of the HSRO-SIR plan.

(4) Staff education regarding HSRO-SIR.

(5) Integrating/coordinating information collection and analysis with planning, evaluation and monitoring activities.

(6) Eliminating duplication and nonproductive review activities.

(d) *HSRO-SIR functions and elements (as described in § 17.506).*

(e) *HSRO-SERP and other external reviews.*

The plan will be combined with other facility policies and procedures for assuring the quality of patient care to constitute the facility's comprehensive HSRO-SIR program. (38 U.S.C. 3305)

**§ 17.506 Mandatory HSRO-SIR functions and elements.**

The HSRO-SIR plan includes mandatory functions. Each function may contain various elements. Additional HSRO-SIR elements not identified in these HSRO regulations may be included within a function in the HSRO-SIR plan as the VA Medical Facility Director deems appropriate. However, such additional elements will not be considered a part of the HSRO-SIR program for purposes of 38 U.S.C. 3305 and these HSRO regulations and therefore, shall not be considered confidential HSRO records or documents. The five mandatory functions and the elements within these functions are:

(a) *Continuous monitoring.* (1) Medical records review.

(2) Surgical case (tissue) review.

(3) Blood services review.

(4) Therapeutic agents and pharmacy review.

(5) Laboratory review.

(6) Radiology and nuclear medicine review.

(7) Psychiatric program review.

(8) Commitment usage analysis.

(9) Restraint and seclusion usage analysis.

(10) Infection control review.

(11) Surgical and anesthetic complications review.

(12) Autopsy review.

(13) Mortality and morbidity review.

(14) Review of rejected applications.

(15) Patient incident review.

APPENDIX IV

(b) *Patient injury control.* (1) Reporting.

(2) Quality assurance investigations.

(c) *Utilization review.*

(d) *Problem focused health care evaluation studies.* This includes special audits of specific problem areas performed at the direction of the VA Medical Facility Director or Central Office.

(e) *Credentialing and delineation of clinical privileges.* (38 U.S.C. 3305)

**§ 17.507 Description of continuous monitoring.**

(a) The continuous monitoring function is a process by which VA Medical Facility personnel review and objectively assess those clinical activities which are key indicators of the quality of medical care being provided. These clinical activities must be monitored and evaluated on a regular and recurring basis, which may involve reviews on a daily, monthly, quarterly or semiannual basis or as prescribed by VA policy.

(1) All HSRO monitoring techniques, reviews, studies or surveys shall use an appropriate sampling procedure. This methodology does not require 100 percent review of all records and documents being evaluated.

(2) The continuous monitoring process can be differentiated from day-to-day facility operational management. Unlike day-to-day management, this monitoring process is based upon the use of explicit quality of care criteria to collect patient care information over a specified period of time. This information is used by health care professionals to determine patterns or trends, assess the quality of care in conjunction with accepted national, areawide or local professional standards or norms and propose action necessary to maintain or improve the quality of care provided.

(3) Elements of continuous monitoring may be performed by a committee or may be the responsibility of a service, program, or individual, and may be combined with other HSRO-SIR functions as considered appropriate by the VA Medical Facility Director.

(4) The following is a description of the elements which constitute the continuous monitoring function of the HSRO-SIR program:

(i) *Medical records review.* The monitoring of facility medical records requires at least quarterly reviews to ensure that records are readily available, complete, secure, and provide appropriate documentation so that health care providers can determine the patient's needs, the services provided and the outcome of each episode of care. The monitoring should also ensure that the provider(s) responsible for the care and treatment of each patient is (are) clearly identified.

(ii) *Surgical case (tissue) review.* This review includes regular assessment of all surgical cases, regardless of whether a specimen is or is not removed, to assure the appropriateness of and the need for the surgery (surgical indications). This review also includes an evaluation of all cases in which there is a discrepancy between the preoperative, postoperative, and pathologic diagnoses.

(iii) *Blood services review.* This review includes regular and frequent monitoring to ensure that all aspects of blood services are handled in a safe, appropriate and therapeutic manner. Thus, the monitoring will determine whether blood and blood products are safely stored, ordered, cross-matched, delivered and administered in a timely and reliable manner. This review monitors the utilization of blood and blood products and analyzes transfusion reactions and errors.

(iv) *Therapeutic agents and pharmacy review.* Included in a therapeutic agents and pharmacy review is a requirement for an assessment to determine that appropriate medications, drugs, or other chemicals were used or administered properly in a manner, dose, route and time schedule appropriate to the patient's care requirements. This also includes a review of clinicians' prescribing practices and the administration of chemical agents by nurses and other health care providers. It also provides for the assessment of the effectiveness of the prescribed medications and allergic reactions to them.

(v) *Laboratory review.* This review includes the assessment of a wide variety of laboratory service tests and pro-

cedures to ensure that such tests are appropriate in relation to individual patient care needs. The monitoring also determines if the quality control is satisfactory and if the results are being communicated or transmitted to the requesting clinician within established timeliness standards.

(vi) *Radiology and nuclear medicine review.* This review includes the surveillance of all Radiology and Nuclear Medicine diagnostic and therapeutic procedures to ensure that they are necessary and appropriate. This review also includes an evaluation of the timeliness of responses to requests for these procedures and an assessment of the quality of the professional service provided so that patient exposure to radiation is minimized.

(vii) *Psychiatric program review.* This process evaluates inpatient and outpatient psychiatric programs on a recurring basis to ensure that each program is meeting its treatment goals and is providing high quality patient care.

(viii) *Restraint and seclusion usage analysis.* This process provides a regular review to ensure that patients are protected from inappropriate, excessive or harmful restraint or seclusion.

(ix) *Commitment usage analysis.* This review provides monitoring on a regular basis to ensure that patients who are under legal commitment continue to require such commitment and that commitment is clinically justified.

(x) *Infection control.* Infection control includes a recurring review by facility personnel to determine the trend and extent of nosocomial infections and to propose corrective actions to control such nosocomial infections. This review should ensure that patient exposure to nosocomial infection is minimized.

(xi) *Autopsy review.* This monitor includes assuring that autopsy services are appropriately provided and that autopsy findings are a component of the VA Medical Facility's review of medical practice. Findings of all autopsies are to be reviewed at least once each quarter by the medical staff to determine the thoroughness of patient care, ascertain the cause of death, confirm or clarify major clinical diagnoses, identify unsuspected conditions, assess the effects of therapeutic measures, and validate the medical record. This review process also includes monitoring of postmortem examinations conducted on VA patients by local coroners on referral from a VA Medical Facility.

(xii) *Review of rejected applications.* A review of the previous day's rejected applications for care and admission will be conducted each morning, consistent with VA policy. The review will serve to identify possible errors in judgment in order that the patient may be reevaluated and appropriate diagnostic or treatment measures instituted.

(xiii) *Surgical complications and anesthesiology review.* This review provides for the study of surgical/anesthetic complications to ensure high quality of care for surgical patients. It also provides for the assessment of allergic reaction to anesthesia.

(xiv) *Mortality and morbidity review.* This review requires the routine collection and analysis of data to determine that the mortality and/or morbidity rates meet accepted professional standards and expectations. This includes an evaluation of all unexpected deaths and deaths within 24 hours of admission and the review of data to determine whether certain procedures or practices are contributing to deaths.

(xv) *Patient incident review.* This review provides a regular statistical and/or descriptive summary of incidents reported under the Patient Injury Control program. This summary may include such data and information as the types and frequency of incidents, hospital location where incidents occurred, age and type of patient and severity of incident. This review will analyze trends and may indicate deficiencies that require further study, policy changes, enforcement, investigation, etc. (38 U.S.C. 3305)

**§ 17.508 Patient injury control.**

(a) The Patient Injury Control program will include the monitoring, reporting, analysis, review and investigation of any unusual, unexpected or unfavorable incident which a patient may experience during the course of

his/her medical management. Such incidents include those which would not be considered a natural consequence of the patient's disease process or illness, as well as those incidents which would carry a recognized risk of medical intervention. The incident may be an illness or injury resulting from either omission(s) or commission(s) by a health care provider(s) or the direct result of medical intervention during the course of either inpatient or outpatient care. The following types of cases are examples of incidents for the purposes of the Patient Injury Control program, HSRO-SIR and these HSRO regulations:

(1) *Suicides, suicide attempts and self-inflicted wounds.*

(2) *Homicides.*

(3) *Falls.*

(4) *Assaults and patient abuse/neglect.*

(5) *Allergic or idiosyncratic reaction to anesthesia, blood or medications.*

(6) *Unexpected deaths, including those under anesthesia and during the performance of a procedure, and deaths within 24 hours of admission.*

(7) *Transfusion, medication, diagnostic and therapeutic errors.*

(8) *Surgical complications.*

(9) *Other incidents which result or may result in injury, harm, disability, disfigurement or death to a patient.*

(b) *Reporting.* Incidents of patient injury, as defined in paragraph (a) of this section, will be reported on VA Form 10-2633, "Report of Special Incident Involving a Beneficiary" or other appropriate document. VA Form 10-2633 or other documents describing incidents of patient injury used in lieu thereof will not be considered confidential and privileged documents under 38 U.S.C. 3305 and these HSRO regulations.

(c) *Quality assurance investigation.* (1) An investigation for quality assurance purposes in the Patient Injury Control program, or any other quality assurance program described in these HSRO regulations, is an inquiry into any incident involving a patient, examples of which are described in paragraph (a) of this section. The focus of a quality assurance investigation is to identify problems in the delivery of health care, to analyze and review such problems and to propose corrective action.

(2) If it is determined by the Medical Facility Director, the Chief Medical Director, the Medical Inspector, or other authorized designee, that such an incident necessitates an investigation for quality assurance purposes, any reports, minutes, records or other documents contained in the investigation will be considered confidential and privileged for the purposes of 38 U.S.C. 3305 and these HSRO regulations provided the following step is taken:

The decision to conduct a quality assurance investigation must be documented in writing and signed by the authorizing official. In the first paragraph of the document, the following statement will be included to indicate that a quality assurance investigation is being initiated:

In accordance with the provisions of 38 CFR § 17.508(c)(2), I hereby direct that a quality assurance investigation be conducted regarding (describe incident). All documents, memoranda, reports and other records generated by and included in this investigation will be strictly confidential and will only be disclosable as permitted by 38 U.S.C. 3305.

(3) A Board of Investigation for quality assurance purposes may be convened in all the following:

(i) Unexpected death of a patient.

(ii) Transfusion error.

(iii) Medication errors that result in death of a patient, generate a new medical problem or significantly aggravate the patient's existing condition.

(iv) Homicide.

(v) Alleged patient abuse by staff, another patient(s), visitors and others.

(vi) Rape involving a patient.

(vii) Serious injury and/or death by fire.

(viii) Any incidents which result or may result in injury, harm, disability, disfigurement or death of a patient.

(ix) All other incidents involving patients which the authorizing official believes should be investigated by a Board.

(4) All VA Medical Facility copies of quality assurance investigation records and documents will be placed in a secure file established for the purpose in the Office of the Medical Facility

APPENDIX IV

Director, in accordance with the provisions of § 17.527(g). The following procedures will be observed to ensure the confidentiality of the quality assurance investigation for purposes of 38 U.S.C. 3305:

(i) Quality assurance investigation records and documents will not be filed in a manner by which they can be retrieved by an individual identifier such as a name or other identifying particular assigned to an individual, nor will they be placed in other records systems, e.g., patient medical record or employee personnel file.

(ii) Quality assurance investigation records and documents will not be made part of investigations conducted for any purposes other than quality assurance as defined in paragraph (c)(1) of this section. (See paragraph (c)(5) of this section.)

(5) Prior to, concurrently, or upon completion of a quality assurance investigation, the Chief Medical Director, Medical Facility Director, Medical Inspector or other authorized official may initiate a separate, independent investigation for nonquality assurance purposes, e.g., administrative, personnel, and criminal or tort liability investigation. Any reports, documents, memoranda or other records generated by these types of nonquality assurance investigations are not covered by the confidentiality provisions of 38 U.S.C. 3305 and these HSRO regulations. VA employees with an official need to know may have access to quality assurance investigation records and documents for nonquality assurance purposes, in order to ascertain sufficient background information to conduct a separate and independent nonquality assurance investigation, e.g., personnel action, or to enable the Agency to assess its position in a tort liability case (See § 17.527). Quality assurance investigation records and documents cannot be used by Agency employees as evidence, or relied upon in a manner which could require them to be treated as evidence so that they would be subject to mandatory disclosure in an administrative, statutory or judicial process. (38 U.S.C. 3305)

**§ 17.509 Utilization review.**

(a) The utilization review function includes a number of clinical and administrative screening, techniques, studies, and reviews to assure that resources within the VA Medical Facility are appropriately utilized. Utilization review may be performed by committee(s), clinical staff and/or administrative support staff.

(b) Utilization review studies topics with generic, problem or disease specific or patient-need specific concerns to determine whether health care utilization is effective. Frequently, utilization review studies will concentrate on problems identified by the continuous monitoring process. Utilization review will periodically assess:

(1) Appropriateness of admission(s) and rejection(s),

(2) Length of stay and continuance of stay,

(3) Appropriateness/effectiveness of utilization of services, special medical programs and other resources,

(4) Timeliness of admission and outpatient processing. (38 U.S.C. 3305)

**§ 17.510 Problem focused health care evaluation.**

(a) Problem focused health care evaluation is an approach taken to understand and manage complex problems of major consequence to patient care processes and outcomes. This approach focuses on problem assessment, corrective action planning, implementation and follow-up. Each clinical and/or administrative service will be responsible for carrying out problem focused health care evaluation studies, to the extent necessary, within their respective areas of responsibility.

(b) Problem focused health care evaluation studies usually involve a multidisciplinary approach. The necessity for conducting a problem focused health care evaluation study may be identified from problems detected through utilization review, continuous monitoring, patient injury control, or other sources.

(c) A VA Medical Facility Director may request a special audit or study of a certain program or process of care to be performed by either VA and/or non-VA reviewers external to the Fa-

cility. These special audits or studies will be considered as problem focused health care evaluations. (38 U.S.C. 3305)

§§ 17.511–17.514 [Reserved]

§ 17.515 Credentialing and delineation of clinical privileges.

(a) Credentialing is the systematic process of reviewing the qualifications of all applicants for appointment and requests for clinical privileges to ensure that the applicants possess the professional capability required of their respective disciplines and that their skills are commensurate with the needs of the particular diagnostic and therapeutic procedures for which they are responsible. Credentialing requires documentation of the general and special or specific clinical privileges to be granted to the provider.

(b) Delineation of clinical privileges ensures that physicians, dentists, nurses, and other health care professionals perform only those diagnostic or therapeutic procedures in which they are considered to be competent, as judged by their professional peers. Each VA Medical Facility Credentialing Committee or other appropriate credentialing review process will review, at least annually, each provider's clinical privileges and will recommend reappointment, reduction or expansion of clinical privileges as appropriate.

(c) All records and documents collected during the HSRO-SIR process which are provider specific will be available to the Credentialing Committee or other appropriate credentialing review entity. (38 U.S.C. 3305)

§ 17.516 HSRO-SERP.

(a) HSRO-SERP is an ongoing review program concerned exclusively with the quality of patient care provided at each VA Medical Facility and the effectiveness of its HSRO-SIR program. HSRO-SERP evaluates each VA Medical Facility service as well as the Facility as a whole. The SERP review includes a periodic assessment conducted at each VA Medical Facility by a multidisciplinary peer review team of VA health care professionals. Team members are selected from other VA Medical Facilities for their expertise in their respective disciplines and their evaluation skills.

(b) HSRO-SERP also includes reviews and analyses of HSRO-SIR and HSRO)-SERP documents by VA Central Office.

(c) The HSRO-SERP program is intended to complement other evaluations, reviews and surveys of VA Medical Facilities that utilize standards and criteria which may be unrelated to the quality of patient care. Such activities are conducted by a variety of agencies and organizations including the VA Department of Medicine and Surgery, accrediting bodies such as the Joint Commission on Accreditation of Hospitals, Federal regulatory agencies, e.g., Nuclear Regulatory Commission, and veterans organizations. (38 U.S.C. 3305)

§ 17.517 HSRO records and documents.

(a) Section 3305, title 38, United States Code was enacted to protect the integrity of the VA's medical quality assurance program (HSRO) by making confidential and privileged certain records and documents generated by the HSRO program. Disclosure of HSRO records and documents made confidential and privileged by 38 U.S.C. 3305 and these HSRO regulations may only be made in accordance with the provisions of 38 U.S.C. 3305 and these HSRO regulations.

(b) Disclosure of those HSRO records and documents not made confidential and privileged by 38 U.S.C. 3305 and these HSRO regulations will be governed by provisions of the Freedom of Information Act, the Privacy Act and/or, if applicable, any other VA confidentiality statutes. HSRO records and documents protected by 38 U.S.C. 3305 and these HSRO regulations are not within the scope of the Privacy Act and therefore, shall not be filed in a manner so that they may be retrieved by reference to an individual identifier. (38 U.S.C. 3305)

§ 17.518 HSRO-SIR records and documents.

(a) For purposes of 38 U.S.C. 3305, HSRO-SIR records and documents which are considered confidential and

privileged are those which pertain to mandatory HSRO-SIR functions or elements as identified in § 17.506. Such records and documents are confidential and privileged even if individual identifiers are deleted.

(b) Records and documents which are aggregations of statistical data from quality assurance studies and reviews, and which do not identify, even by implication, VA employees or others involved in the quality assurance process are not privileged or confidential.

(c) Continuous monitoring and utilization review functions generate committee or study team minutes, reports and memoranda that contain the deliberations of health care evaluators. Such minutes, records and documents are confidential and privileged in their entirety. Individual continuous monitoring and utilization review documents comparing one or more patient's treatment with objective criteria or norms would be such a confidential document. Other memoranda and study documents or records prepared for review by HSRO-SIR committees are confidential and privileged only if they reveal the identity, even by implication, of VA employees or others involved in the quality assurance process or the results or outcomes of HSRO-SIR reviews or studies. Summary documents or records which only identify study topics, the period of time covered by the study, criteria, norms, interpretive comments and major overall findings, but which do not identify health care providers, even by implication, are not considered confidential and privileged documents or records under 38 U.S.C. 3305 and these HSRO regulations.

(d) Patient Injury Control records and documents include incident reporting forms (VA Form 10-2633), screening records, patient incident analyses and quality assurance investigations. However, only those records and any documents generated in conformance with § 17.508(c)(2) are confidential and privileged under 38 U.S.C. 3305 and these HSRO regulations.

(e) Problem focused health care evaluation studies generate committee or study team minutes, reports or audits and memoranda that contain the deliberations of health care evaluators. Such records and documents are confidential and privileged in their entirety. Study documents revealing actual results or outcomes of individual patient care and treatment, as compared with objective criteria or norms or which may identify, even by implication, VA employees or others involved in a quality assurance process or reveal the results or outcomes of HSRO-SIR reviews are confidential and privileged.

(f) The credentialing and delineation of privileges process generates numerous records and documents, most of which are maintained in personnel files or similar files which are subject to the provisions of the Privacy Act, 5 U.S.C. 552a. Those documents which are maintained in personnel or similar files are not made confidential and privileged by 38 U.S.C. 3305. Section 3305, title 38, United States Code makes confidential and privileged the minutes and other memoranda that reflect the deliberations of the Credentialing Committee or other appropriate entity when it reviews a health care professional's performance for the purposes of establishing or reconsidering clinical privileges. Such documents must not be filed in a manner by which they can be retrieved by reference to an individual identifier. (38 U.S.C. 3305)

**§ 17.519 HSRO-SERP records and documents.**

(a) Only those records and documents generated by HSRO-SERP in accordance with § 17.516 are confidential and privileged.

(b) HSRO-SERP records and documents made confidential and privileged as provided by 38 U.S.C. 3305 include the following:

(1) Standards, Criteria, Evaluative Algorithms, and Measuring Instruments (SCEM) worksheets prepared by individual SERP surveyors and team leaders.

(2) Working notes, dictation and reports prepared by individual SERP surveyors and team leaders.

(3) SERP reports and statistical reports based on SCEM data, both in draft and final form.

(4) Information provided SERP teams by VA Medical Facilities prior to an on-site assessment.

(5) Responses by VA Medical Facility Directors and VACO staff to findings or recommendations identified in a SERP report.

(6) Memos covering items of a confidential nature which are related to but not necessarily contained in the SERP report.

(7) Special audits of a VA Medical Facility service or health care program, conducted by VA or non-VA reviewers (or a combination) external to the VA Medical Facility, at the request of Central Office. This includes audits or studies of one or more VA Medical Facilities where the study or audit concerns the same service or program in each Facility. (38 U.S.C. 3305)

**§ 17.520 Improper disclosure.**

(a) Improper disclosure is the release of confidential and privileged HSRO records or documents (or information contained therein), as defined in §§ 17.517, 17.518 and 17.519, to any person who is not authorized access to the records or documents.

(b) "Disclosure" means the communication, transmission, or conveyance in any way of any confidential and privileged HSRO records or documents to any individual or organization in any written or oral form. (38 U.S.C. 3305)

**§ 17.521 Disclosure methods.**

(a) Disclosure of confidential and privileged HSRO records and documents outside the VA will always be by copies, abstracts, summaries, or similar records or documents prepared by the Veterans Administration and released to the requestor. The original confidential and privileged HSRO records and documents will not be removed from the VA Medical Facility by any person, VA employee or otherwise, except in accordance with § 17.527 (h) and (i).

(b) Disclosure of written confidential and privileged HSRO records and documents to authorized individuals under either § 17.527 or 17.534 shall bear the following statement: "These documents or records (or information contained herein) are deemed confidential and privileged under provisions of 38 U.S.C. 3305 and §§ 17.500-17.540, which provide for fines up to $20,000 for violations. This material shall not be transmitted to anyone without proper consent or other authorization as provided for by law or regulation." (38 U.S.C. 3305)

**§ 17.522 Non-Veterans Administration requests.**

Requests for confidential and privileged HSRO records and documents from organizations or individuals outside the VA must be in writing and signed and must specify the nature and content of the information requested, to whom the information should be transmitted or disclosed, and the purpose for which the information requested will be used. In addition, the requestor will specify the beginning and final dates of the period for which disclosure or access is requested. (38 U.S.C. 3305)

**§ 17.523 Director's authority.**

The VA Medical Facility Director alone is authorized to make disclosure of any confidential and privileged records or documents to other agencies, organizations, or individuals where these HSRO regulations expressly provide for disclosure. (38 U.S.C 3305)

**§ 17.524 Appeal of Director's decision.**

When a request for records or documents subject to these HSRO regulations is denied by the VA Medical Facility Director, he or she will notify the requestor of the right to appeal this decision to the Administrator of Veterans Affairs within 60 days. The Administrator's decision is the agency's final decision. (38 U.S.C 3305)

**§ 17.525 Facility responsibilities.**

(a) Each VA Medical Facility will have written policies regulating access, disclosure, transmittal and destruction of confidential and privileged HSRO records and documents consistent with these HSRO regulations and VA policy.

(b) Each VA Medical Facility Director will designate an appropriate official as the HSRO Confidentiality Offi-

cer and the responsible VA official for ensuring confidentiality of HSRO records and documents.

(c) VA Medical Facility Directors, Service Chiefs, and supervisors shall ensure that all persons under their supervision are aware of their responsibilities to maintain confidentiality of HSRO records and documents and of the existence of penalities for any violation of 38 U.S.C. 3305 and these HSRO implementing regulations.

(d) All VA employees, students, trainees, residents, volunteers, and contract personnel will comply with the requirements of these HSRO regulations and will treat the findings, views, and actions of colleagues relating to HSRO in a confidential manner.

(e) Employees, upon voluntary or involuntary termination of VA employment for any reason, will not disclose any HSRO records or documents which are designated as confidential and privileged to any source. (38 U.S.C. 3305)

**§ 17.526 [Reserved]**

**§ 17.527 Access to HSRO data within the agency.**

(a) Access to HSRO data within the agency pursuant to this section is restricted to VA employees (including consultants and contractors of the VA) subject to the requirements of § 17.504.

(b) No individual shall be permitted physical access to privileged and confidential HSRO records and documents identified in §§ 17.518 and 17.519 unless such individual has received adequate training and has been informed of the penalties for unauthorized disclosure. Any misuse of confidential and privileged HSRO records or documents shall be reported through the HSRO Confidentiality Officer to the VA Medical Facility Director.

(c) Access to confidential and privileged HSRO records and documents shall generally be limited for quality assurance purposes only, and only to those persons who have a need for such information and who are authorized by the VA Medical Facility Director or these HSRO regulations.

(d) A list should be maintained of those VA Medical Facility employees or others who are authorized access to confidential and privileged HSRO records or documents. Each authorized individual will sign a statement that he/she is aware of the requirements for confidentiality and will not divulge any information in any way to any source or person except in accordance with these HSRO regulations.

(e) Any VA employee or other individual, not on this List of Authorization, who is granted disclosure of or access to confidential and privileged HSRO records or documents, must sign a statement that he/she is aware of the regulations and penalties relevant to improper disclosure of confidential and privileged HSRO records and documents and agrees to hold the records or documents confidential. These signed statements will be maintained in a file along with a copy of individual requests for confidential and privileged HSRO records and documents and a notation of those records or documents which have been released or disclosed.

(f) In cases of oral disclosure, the person disclosing the confidential and privileged information shall inform the recipient that such information is confidential under the provisions of 38 U.S.C. 3305.

(g) Confidential and privileged HSRO-SIR records and documents shall be maintained in secure filing cabinets and locked when not under personal supervision. A security system for storing and processing data will be developed and will include procedures to identify individuals who have had access to those data and at what time such access occurred. Each VA Medical Facility will provide for the periodic review of confidential and privileged HSRO records and documents to determine whether security is adequate and which if any records and documents shall be retained. In general, confidential and privileged HSRO records and documents will be maintained for a minimum of 3 years and may be held longer if needed for HSRO research studies or related activities.

(h) HSRO-SERP records and documents as defined in § 17.519(a), will be

APPENDIX IV

available to VA Central Office management officials working in HSRO functions, service and staff office Directors and Associate Chief Medical Directors.

(i) Any HSRO record or document, whether confidential and privileged or not, may be provided to the General Counsel or his/her designee, a District Counsel or his/her designee or to a Department of Justice (DOJ) attorney who is investigating a claim or potential claim against the VA or who is preparing for litigation involving the VA. If necessary, such a record or document may be removed from the VA Medical Facility to the site where the General Counsel (designee), District Counsel (designee) or the DOJ attorney is conducting an investigation or preparing for litigation.

(j) Nothing in these HSRO regulations shall be construed as banning disclosure to the Office of the Inspector General pursuant to the Inspector General Act of 1978, Public Law 95-452. (38 U.S.C. 305)

**§§ 17.528–17.533 [Reserved]**

**§ 17.534 Authorized disclosure: Non-Veterans Administration requests.**

(a) Disclosure shall be made to approved Federal agencies upon their written request to permit the VA's participation in health care programs, evaluation research, planning, or related activities with the requesting agencies. Any Federal agency may apply to the Chief Medical Director for approval. Upon approval, the requesting agency will enter into an agreement with the VA to ensure that such agency and its staff will ensure the confidentiality of any HSRO records or documents shared with such agency or organization.

(b) The Chief Medical Director may approve such a written request if it meets any of the following criteria:

(1) Participation by the VA in such activity will benefit patient care.

(2) Participation by the VA in such activity will enhance health care research.

(3) Participation by the VA in such activity will enhance evaluation research.

(4) Participation by the VA in such activity will enhance health care planning or program development activities.

(c) Qualified persons or organizations engaged in the provision of health care delivery, including academic institutions, shall, upon written request and approval by the Chief Medical Director have access to confidential and privileged HSRO records and documents where needed for such research provided that no records or documents are removed from the VA Medical Facility which prepared them. Such request, together with the research plan and/or protocol, shall first be submitted to, and approved by, an appropriate VA Medical Facility Research and Development Committee and then by the Director of the VA Medical Facility. The VA Medical Facility staff together with the qualified person(s) conducting the research shall be responsible for the preservation of the anonymity of the patients, clients and providers and shall not disseminate any records or documents which identify such individuals. This applies to the handling of data or information as well as reporting or publication of findings.

(d) Confidential and privileged HSRO records or documents shall be disclosed to a civil or criminal law enforcement governmental agency or instrumentality charged under applicable law with the protection of public health or safety if a written request for such records or documents is received from an official of such an organization. The request must state the purpose authorized by law for which the records will be used. This includes disclosure to State licensing and disciplinary agencies or boards of credentialing or delineation of clinical privileges records pertaining to a specific individual provider.

(e) Federal and private agencies or organizations charged with protecting the public health and welfare by various monitoring and quality control activities or those agencies responsible for licensure of individual health care facilities or programs or similar organizations shall be provided confidential and privileged HSRO records and documents so long as the records or

APPENDIX IV

documents requested are to assist the requesting agency or organization to carry out its licensing or monitoring mandate or mission. The VA Medical Facility Director will determine the extent of information disclosable and the circumstances under which release is appropriate.

(f) In general, HSRO-SERP and Joint Commission on Accreditation of Hospitals (JCAH) survey teams and similar national accreditation agencies or boards, are entitled to full disclosure of any and all privileged and confidential HSRO-SIR records or documents with the following qualifications:

(1) Evaluation agencies which are charged with facility-wide monitoring, i.e., all aspects of patient care, may have access to all confidential HSRO-SIR records and documents.

(2) Evaluation agencies charged with more narrowly focused monitoring (e.g., College of American Pathologists, American Association of Blood Banks, Nuclear Regulatory Commission, etc.) may have access only to such confidential HSRO-SIR records and documents as are relevant to their respective focus.

(g) Confidential and privileged HSRO records and documents shall be released to health care personnel upon request to the extent necessary to meet a medical emergency affecting the health or safety of any individual.

(h) Confidential and privileged HSRO records and documents shall be released to Congressional Committees or subcommittees if such records or documents pertain to any matter within the jurisdiction of such committee or subcommittee.

(i) Confidential and privileged HSRO records and documents shall be released to the General Accounting Office if such records or documents pertain to any matter within its jurisdiction.

(j) For any disclosure made under paragraphs (a) through (g) of this section, the name of and other identifying information regarding any individual VA patient, employee or any other individual associated with the VA for purposes of the HSRO program shall be deleted from any confidential and privileged HSRO record or document before any disclosure under these HSRO regulation is made, if disclosure of such name and identifying information would constitute a clearly unwarranted invasion of personal privacy. (38 U.S.C. 3305)

**§ 17.535 Redisclosure.**

No person or entity to whom an HSRO record or document has been disclosed under §§ 17.527 or 17.534 shall make further disclosure of such record or document except for a purpose provided for in these HSRO regulations. (38 U.S.C. 3305)

**§§ 17.536–17.539 [Reserved]**

**§ 17.540 Penalties for violations.**

Any person who knows that a document or record is a confidential and privileged HSRO document or record described herein and willfully discloses such confidential and privileged HSRO record or document, except as authorized by these HSRO regulations, shall be fined not more than $5,000 in the case of a first offense and not more than $20,000 in the case of each subsequent offense. (38 U.S.C. 3305)

APPENDIX V

STATEMENT OF RESPONSIBILITIES AND RELATIONSHIPS

BETWEEN

THE OFFICE OF MEDICAL INSPECTOR

AND

THE OFFICE OF INSPECTOR GENERAL

This memorandum constitutes an agreement between the Chief Medical Director and the Inspector General, Veterans Administration.

A. Purpose

The purpose of this agreement is to establish a clear statement of Inspector General oversight responsibilities and relationships between the Office of Inspector General (OIG) and the Office of Medical Inspector to assure that duties, policies and procedures are mutually understood and followed.

B. Applicable Authority

The Office of Medical Inspector was established in September 1980 to carry out quality of medical care investigations. The Office was established within the Department of Medicine and Surgery as an alternative to placing this function within the OIG. The Medical Inspector is responsible to the Chief Medical Director for monitoring, investigating, and reporting on quality of care issues within the Department of Medicine and Surgery.

The Inspector General Act of 1978, Public Law 95-452, created the Office of Inspector General to conduct and supervise audits and investigations relating to the programs and operations of the Veterans Administration. In order to carry out the provisions of the Act the Inspector General is authorized to have access to all records, reports, audits, reviews, documents, papers, recommendations, or other material which relate to Agency programs and operations.

C. Policy

This memorandum acknowledges the role of the Medical Inspector to monitor quality of care and conduct appropriate investigations, and the statutory mandate imposed upon the Inspector General to conduct and supervise investigations relating to the programs and operations of the Veterans Administration, and to keep the Administrator and the Congress fully informed concerning problems and deficiencies relating to such programs and operations.

APPENDIX V

This memorandum also recognizes Congressional concerns regarding the establishment and placement of the Medical Inspector's Office in the Department of Medicine and Surgery, the independence and objectivity of the Medical Inspector, and the necessity for Inspector General oversight.

Nothing in this memorandum abrogates the jurisdiction of the Department of Medicine and Surgery over issues relating to quality of care and competency of medical professionals, e.g., matters involving peer reviews are not affected by this Memorandum of Understanding.

D. Responsibilities of the Medical Inspector

1. The Medical Inspector will insure that the Office of Inspector General is provided with sufficient information to adequately document all Medical Inspector inquiries and investigations to include:

   a. Documents that indicate the initiation of a case;

   b. The Medical Inspector's updating of the status of the case should it continue beyond a forty-five (45) day period;

   c. The Medical Inspector's closing report and recommendations which will include responses or summaries of responses from the field stations or other elements within the Department of Medicine and Surgery to substantiate the conclusions and recommendations;

   d. In those cases in which above mentioned report did not finalize the case, the final closing statement will include actions taken as a result of the Medical Inspector's recommendations; and,

   e. Additional information, as appropriate, when requested by the Office of Inspector General to enhance their understanding of the conclusions and action recommended and/or taken.

2. Upon request of the OIG the Medical Inspector will make investigative files available for review at the Medical Inspector's office.

APPENDIX V

3. The Medical Inspector will maintain a file of complaints received that do not result in investigative action. Upon request of the OIG this file will be made available for review at the Medical Inspector's office.

4. The Medical Inspector is not expected to regularly provide voluminous material such as entire medical records. However, such records will be made available to the OIG upon request.

5. The Medical Inspector will promptly report to the Inspector General any suspected violations of the US Criminal Code.

6. The Medical Inspector will also insure that the Office of Inspector General is provided with copies of all station investigative reports received by the Medical Inspector and will provide any information regarding the reports that may be raised by the review of the OIG.

E. Responsibilities of the Inspector General

1. The Inspector General will perform oversite review of the Medical Inspectors' investigations for adequacy of investigation, and timeliness of actions. The OIG recognizes that the final decision on implementation of recommendations rests with the Department of Medicine and Surgery.

2. The Inspector General will provide the Medical Inspector with suggestions designed to improve the quality of Field Station investigations, as needs are identified.

3. The Inspector General will provide technical investigative assistance to the Medical Inspector when appropriate.

4. The Inspector General will make recommedations to the Chief Medical Director regarding system wide trends or problems observed as a result of the oversight activities.

5. The Inspector General will maintain close and continuous liaison with the Office of Medical Inspector. Representatives of the OIG and the Medical Inspector will routinely discuss on-going reviews and investigations. Regularly scheduled meetings will be held at least monthly and will be documented.

6. The Inspector General will provide relevant investigative training to Department of Medicine and Surgery Field Stations as resources allow.

7. The Inspector General will promptly report matters relating to quality of care issues to the Medical Inspector.

F. COLLATERAL ENDEAVORS BY THE MEDICAL INSPECTOR AND THE INSPECTOR GENERAL

The Medical Inspector and the Inspector General may agree to enter into collateral investigative endeavors in appropriate circumstances. The specific details of each endeavor, including resources to be committed, the delegation of responsibility, liabilities, etc., will be mutually determined prior to the commencement of these endeavors. All collateral investigations will be conducted under the supervision of the Inspector General.

G. REVISIONS TO THIS MEMORANDUM

At any time that either party to this memorandum believes that modifications are needed to improve the working relationship, both parties agree to consider changes proposed by the other.

APPENDIX V

H. AGREEMENT APPROVAL

This agreement becomes effective when approved and signed by both parties.

APPROVED:

John W. Ritzlin

Chief Medical Director
Veterans Administration

Date: 12/12/84

APPROVED:

Frank S Sato

Inspector General
Veterans Administration

Date: 12/12/84

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