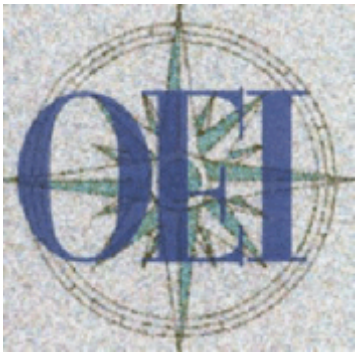


Office of Evaluation and Inspections Procedures Manual May 2002

Office of Inspector General

http://www.oig.hhs.gov/

The mission of the Office of Inspector General (OIG) mandated by Public Law 95-452, as amended by Public Law 100-504, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Procedures Committee

The Procedures Committee comprises representatives from OEI Headquarters and the Regions. It is Chaired by Jesse Flowers, Regional Inspector General for Evaluation and Inspections, Atlanta Regional Office. Other members of the Committee are:

Madeline Carpinelli, *Program Analyst, Chicago Regional Office*
Linda Hall, *Program Analyst, Headquarters Program Evaluation Division*
Rodney T. Holliman, *Program Analyst, Atlanta Regional Office*
Barbara J. Hyman, *Program Analyst, Headquarters Policy and Oversight Division*

Perry A. Seaton, *Program Analyst, Kansas City Regional Office*

Please submit suggested changes, additions, and deletions to this manual to the Committee Chair or any member.

INTRODUCTION

BACKGROUND

Program inspections are one of the tools used by the Office of Inspector General (OIG)[1] to effect positive change within the Department of Health and Human Services (HHS). Within the OIG, program inspections are performed by the Office of Evaluation and Inspections (OEI). OEI staff initiate most inspections, but policy-makers within HHS, Congress, and other entities may request an inspection when desired. Principal requesters of OEI inspections include the HHS Secretary, Deputy Secretary, Assistant Secretaries, and agency heads, and Congress.

OEI conducts national inspections on HHS program policies and operations. Typically, OEI provides inspection findings and recommendations in a written report targeted to specific issues and needs of decision makers. The inspections disclose program inefficiencies and ineffectiveness, and program vulnerabilities that may lead to fraud, waste, and abuse of Federal resources. Through its inspections, the OIG provides decision-makers with timely and valid data and analysis on current policy and operational issues.

Program inspections combine the best features of various disciplines, including traditional program evaluation, survey research, operational auditing, program monitoring, compliance reviews, investigations, and management analysis.

INSPECTOR GENERAL AUTHORITY

The Inspector General's authority to conduct evaluations derives from the Inspector General Act (5 U.S.C. App.) at sections 2, 4 and 6 of the Act, which authorize the HHS Inspector General to conduct inquiries and make recommendations relating to the economy, efficiency and effectiveness of programs administered or funded by HHS. Additional authority is found in Title II of the Health Insurance Portability and Accountability Act (42 U.S.C. 1320a-7c(a)), which directs the Attorney General and the HHS Inspector General (on behalf of the Secretary), to establish a health care fraud and abuse control program that includes, in part, "conduct[ing] investigations, audits, evaluations and inspections relating to the delivery of and payment for health care." Appendix B of this manual provides the abbreviated text of Section 6(a)(1) of the Inspector General Act.

[1] Appendix A lists frequently used acronyms.

PURPOSE OF PROCEDURES MANUAL

The *Procedures Manual* provides guidance to OEI staff for conducting program inspections. It provides basic guidance[2] rather than rigid rules, and by no means replaces the professional judgment of OEI staff. The written procedural guidance is adequate for most inspections, but some inspections require unique approaches. In such instances, regional and headquarter staffs jointly determine appropriate procedures. Flexibility is important for quality program inspections.

[2] Other helpful publications include: *Quality Standards for Inspections*; *Implementation of the Conflict Resolution Process*, April 1990; and OEIs *Technical Assistance Guides*. The guides provide information on *Focusing the Inspection*, *Targeting the Information Needed*, *Specific Sources of Information*, *Gathering Information*, *Analyzing the Information Gathered*, *Specific Steps for Writing an Inspection Report*, *Presenting an Effective Inspection Briefing*; and *Using Graphics Effectively*.

OEI QUALITY ASSURANCE PROCESS

OEI's quality assurance procedures are a collaborative, team effort by staff who conduct program inspections and staff who assist, guide, and review written and oral inspection plans and products. Any OEI member involved with a particular inspection is responsible for helping assure quality of work done and products released.

Specific responsibility for conducting and ensuring quality program inspections rests with Regional Inspectors General (RIGs). OEI RIGs assign a Team Leader and other team members to each inspection. This team is responsible for doing quality inspection field work-- including design, data collection, data analysis, and written and oral reports. RIGs must certify for draft and final reports that the inspection was done in accordance with OEI's procedures and PCIE quality standards (see I-12, and I-19).

OEI's Program Evaluation Division (PED) Directors assign Program Specialists who serve as facilitators, coordinators, liaisons, and technical advisors for each inspection team. The assigned Program Specialist reviews and comments on designs, data collection instruments, working drafts, drafts, final reports, and other related inspection products to ensure quality.

REVIEW TEAMS

OEI establishes a Review Team process to help assure the quality of inspection results and reports. The Review Team may include all or a select number of individuals, identified below.

- Inspection Team Leader, Project Leader, and other key members of a regional team
- Program Specialist
- Technical Support Staff representative
- PED, Public Health and Human Services Staff Director
- PED, Medicare and Medicaid Staff Director
- Regional Inspector General (RIG) and/or Deputy Regional Inspector General (DRIG)
- Director of Regional Operations (DRO)
- Deputy Inspector General (DIG)
- Others as needed

The composition of the Review Team for a specific product depends largely on the type of product, sensitivity of issues, and customers. The Review Team brings a vast range of knowledge to bear on each inspection product. Review Team members apply institutional knowledge on program policies and agency operating practices and problems, as well as knowledge of current and proposed policy and operations.

Regional inspection teams and program specialists will convene an OEI Review Team meeting to decide if products such as designs, data collection instruments, and reports are ready to be used either internally or externally. Review Team members consider content, structure, presentation, target dates, and potential customers for all OEI work products before they are released.

Review Team members strive to reach a consensus on inspection products. However, when this does not occur, the decision-making authority rests with the DIG.

Regional inspection teams are responsible for making all agreed upon Review Team changes as soon as possible -- usually within 1 to 3 days. Thereafter, inspection products are resubmitted for review until the Review Team or Deputy Inspector General decides it is ready for release.

Several Review Team meetings may be required before a product is approved for release. To decrease time required for the Review Team process, regional inspection team members are strongly encouraged to consult with Program Specialists on the content and presentation of a product before submitting it for review by the Review Team.

REPORT VALIDATION

Regional inspection teams validate all key facts used in inspection products to help ensure accuracy, reliability, and compliance with PCIE quality standards. The inspection Team Leader must assure that all facts, findings, conclusions, and recommendations reported by OEI are supported in work paper files. The accuracy of reports directly impacts OEI's credibility and potential impact of its work.

Regional inspection teams complete the validation process before a draft report is released for agency review. For final reports, the team will also validate any substantive changes resulting from reviews by HHS agency staffs. (See pages 28 and 32).

AGENCY REVIEWS

To help assure quality and impact of its inspection results, OEI obtains comments and other input from applicable agency staffs on inspection plans, results, and selected products. Inspection teams obtain such input in a variety of ways, including entrance, exit, and other conferences; and comments on inspection designs, data collection instruments, working draft, draft and final reports. Inspection teams use such meetings and reviews to help identify client needs, identify relevant data for accomplishing

inspection purposes, verify accuracy and reliability of data collected, and verify soundness of findings and recommendations.

WORK PLANNING

OEI work planning must be done in context of the broader OIG work plan. Staff at all levels participate in OEI's work planning effort, both individually and as members of planning groups.

OIG-WIDE WORK PLANNING

The OIG has oversight responsibility for all HHS program policies, operations and funding. To accomplish its oversight mission, the OIG uses program evaluations, audits, investigations, and other means as needed. The OIG recommends improvements to the HHS Secretary, individual HHS agency heads, and the Congress. Each OIG component produces individual work plans that are consolidated into an OIG-wide work plan. This process requires coordination of planned work activities among the different OIG components.

Key Elements of OIG-Wide Work Planning

Collectively, the work planning processes of OIG components must include consideration of factors such as those listed below. Consideration of these factors helps OIG components identify and target significant issues that warrant OIG attention.

- The results of previous oversight activities by the OIG, General Accounting Office (GAO), and others.
- The priorities and goals of the Administration, the Department, the Inspector General, and Congress for HHS program policies, operations, and funding.
- The effect of HHS program policies and operations on beneficiaries, providers, and others.
- The potential reauthorization or termination of particular HHS programs.
- The fiscal responsibility and practice within a program or agency.
- The size and focus of an agency or program budget.

- The vulnerability to fraud or abuse within a program or agency based on indicated weaknesses in program controls and other management information.

- The potential for improvement in program efficiency and effectiveness.

- The extent to which OIG attention is mandated for a particular agency or program, (new, substantially changed, or particularly sensitive programs).

- The public perception on how well a program meets intended objectives.

Issue Areas

Specifically defined issue areas provide a focus for OIG work planning over a 12-36 month period. Issue, or strategic, areas are broad policy, operational, or service areas that have the greatest potential influence on HHS program impact and costs. An issue area may span several categorical programs.

Work Plan Proposals

Work plan proposals are primarily driven by established issue areas. Proposals should always be timely and focused on potential improvement to HHS program policies and operations. In addition, OIG component staff may develop a work plan proposal independently of an established issue area. Such proposals are typically narrowly focused on specific needs that warrant attention.

Steps and Time Line

The key steps and time line for developing an OIG-wide work plan are summarized below.

- **September - October:** Identify strategic issue areas.

- **February - March:** Prepare work plan proposals.

- **April:** Review proposals. An OIG work planning committee review and approves proposals.

- **May:** Submit approved draft proposals to Office of Audit Services.

  Coordinate draft work plan with other OIG components to avoid potential duplication.

- **June - July:** Send a draft work plan to HHS agencies for review.

- **July:** Revise a draft work plan to incorporate HHS agency comments where needed.

- **September:** Publish the OIG fiscal year work plan.

OEI WORK PLANNING

In the Fall of each year, OEI's Medicare and Medicaid Staff Director and Public Health and Human Services Staff Director solicit work plan proposals by sending a memorandum to regional offices. That memorandum outlines established issue areas and time lines for work plan proposals.

Content of Work Plan Proposals

Work plan proposals should provide sufficient information for a Work Planning Committee to understand and judge the potential merits of each proposal. Proposals should also contain sufficient detail to allow regional staffs to acquire a general understanding of proposed work and its potential impact before they accept an assignment (see Appendix C for examples). Proposals should be limited to no more than two pages.

While the format of proposals may vary, all should include the following information.

1. **Title:** Succinctly capture the essence of a proposed inspection. Because of its visibility, a concise, clear title is important.

2. **Purpose:** State what a proposed inspection is expected to accomplish. Usually, a brief, thoughtful action statement works well.

3. **Background:** Include a concise statement on the following topics in work plan proposals. In some instances, information may be known, but it is still helpful to include it so that each proposal will stand alone for review by the Committee.

The Program: Briefly describe the HHS program that is the subject of a work plan proposal. Include key provisions of law, implementing regulations, funding, and other information to help the committee judge the potential merits of a proposal.

***The Problem*:** Describe known and suspected problems and concerns that justify a proposed inspection. A well-defined problem shows precisely why an inspection is needed. In some instances, the need may be descriptive. If so, state why. An entire inspection proposal should be logically linked to the problem statement.

***Audience*:** Identify requesters and/or other potential users of a proposed inspection. For example, if an agency official requested the proposed inspection, say so. If the inspection is proposed to produce information for consideration of a task force or other decision-makers, identify them and their need.

***Potential Impact*:** Describe the potential impact of a proposed inspection. For example, how would a proposed inspection lead to positive impact on identified problems such as a need to improve beneficiary access to services or a need to prevent costly waste and abuse in program operations.

Appendix D-8 through D-10 provides a checklist on developing impact-oriented work plan proposals. Also, OEI's impact documentation system provides guidance that will help classify potential impact of OEI inspections.

4. **Issues:** Identify major issues that a proposed inspection would likely address. Each proposal should have a logical linkage between the issues, the problem, and the purpose. The issues serve to focus inspection work leading to logical, compelling analysis and recommendations for resolving identified problems.

5. **Methods:** Suggest a methodology that will accomplish the purpose, fully answer each issue question, and identify potential causes of identified problems. Briefly, identify data and information needs and sources, and types of analysis needed.

   Discuss any limitations or constraints that could affect the proposed inspection. For example, requestor's schedule, windows of opportunity, difficult data gathering, and analysis.

Review and Approval of Proposed OEI Inspections

Individual OEI staff members and members of planning groups submit work plan proposals to the appropriate PED Staff Director. The PED Staff Director will review each proposal, provide feedback to the authors, and advise the Work Planning Committee of important considerations.

The Work Planning Committee typically includes the DIG, DRO, and PED Staff Directors. The Committee reviews each proposal forwarded by the PED Staff Directors and accepts or rejects proposals for inclusion in the OEI Work Plan.

Generally, OEI criteria for approving work plan proposals include, but are not limited to

- timeliness needs and available resources,
- relevance to strategic issues,
- clients,
- methodology and expected results, including potential savings,
- prior work on the subject area, and
- agency and program coverage.

The PED Staff Directors will return proposals not selected to the originators along with an explanation on why the proposal was declined. Appendix D-8 through D-10 furnishes a review check list for drafting impact focused inspections.

For approved work plan proposals that are included in the work plan, the Committee will establish a priority list. The Committee will then provide the approved work plan to Regional Offices, along with a listing of inspections that have the highest priority for each PED Staff Director.

OEI's Work Planning Committee will review the Work Plan semi-annually. At this time, the Committee will decide whether or not approved inspections that have not been started still have merit and should remain in the plan.

PROGRAM INSPECTION

ASSIGNMENT OF INSPECTIONS

When a region is ready for an inspection assignment, typically the RIG/DRIG will submit an e-mail request to the DRO. The DRO will consult with RIGs and the appropriate PED Staff Director and then advise the Region on its assignment.

The DRO expects inspection teams to start inspections as soon as possible after receiving the assignment. The start dates should rarely be delayed beyond 30 days. If the inspection team has not started an assigned inspection after 30 days, the RIG will decide whether to return the proposed inspection to the work plan or request a late start date from the DRO.

The regional staff will obtain an inspection control number for each assignment from the Program Specialist that is assigned to the inspection team. Inspection control numbers are managed by a Secretary for OEI's Policy and Oversight Division (POD). Each OEI inspection requires a separate and distinct control number.

PRE-INSPECTION

Pre-inspection is an important first step for a program inspection. The objective is to allow assigned inspection teams to design and scope the inspection work to fully respond to the purpose of an inspection. In some instances, the purpose of an inspection may be refined and crystalized during pre-inspection. Specifically, pre-inspection allows inspection teams to properly scope and determine key inspection issues, identify data needs (including types, sources, and availability), determine data collection and analysis methods. During pre-inspection, the inspection team should clearly formulate analytic questions that the inspection will address.

Typically, pre-inspection includes functions such as

- coordinating with the PED Staff Directors, Program Specialist, Technical Support Staff (TSS), and the person(s) who submitted the proposal,

- reviewing existing data, including possible site visits,

- conducting discussions with program officials, providers, provider groups and organizations, and special interest organizations about proposed inspection issues, and

- conducting literature searches (including OIG and GAO reports).

The RIG and the appropriate PED Staff Director, in collaboration with the DRO is responsible for advising whether an inspection is worth continuing at the conclusion of pre-inspection. Based on the potential results of an inspection, the RIG should recommend either continuing, revising, or canceling the inspection.

Pre-inspection generally includes, but is not limited to, the following tasks. Some of the tasks noted below may also be done as part of the OEI work planning process.

- The RIG assigns a Team Leader and inspection team members to the inspection. If needed, the RIG will also request staff support from other regions. Support staff from other regions may be involved in any phase of an inspection -- pre-inspection, data collection and analysis, report writing, or briefing.

- After notification by a RIG or DRIG on when an inspection will start, the appropriate PED Staff Director will assign a Program Specialist and inform the region.

- The Team Leader sets up a work paper file (see section entitled "Work Papers" and Appendix L).

- The Program Specialist should determine if organizations such as other OIG components and the GAO have conducted, or are planning work that is related or relevant to the inspection. The Program Specialist should share the results of this determination with the inspection team as early as possible.

- The Team Leader and Program Specialist should identify other related studies within or outside the Department. In addition, they should identify relevant pending or recently enacted regulations or legislation.

- The Program Specialist sends a start notice of the proposed program inspection (see Appendix E) to the appropriate agency. Generally, regional staff will not contact agency or State program officials prior to release of a start notice. In circumstances where prior contact is necessary, the Team Leader should coordinate with the Program Specialist. The date of the start notice is the start date of the inspection. While OEI may informally send this notice via e-mail, the official notice must always be sent via hard copy, using OIG memorandum paper.

- As appropriate, the Team Leader and/or the Program Specialist discuss the overall scope of the study with OEI's Technical Support Staff (TSS). Appendix F summarizes procedures for requesting information or assistance from TSS.

- After discussions between the Program Specialist and the Team Leader, the RIG determines a due date for the program inspection design.

- The Team Leader and the Program Specialist develop a list of contacts such as STAFFDIV and OPDIV officials who may have critical information about the issues.

- The Team Leader, Project Leader, and/or Program Specialist arrange and attend meetings with other appropriate officials. These meetings help to define the inspection, identify critical issues, and determine the current state of the program. Sometimes, meetings take place after pre-inspection is completed and suffice as both an Entrance and Design Conference.

- The Team Leader reports any possible "material weakness" to the RIG/DRIG for further development. This may occur at any stage of the inspection. (See Appendix G for the definition of "material weakness" and a detailed explanation of the procedure).

- The Team Leader collaborates with the Program Specialist and recommends to the RIG whether to continue with the program inspection and, if so, which central questions the inspection will address. If the RIG believes that they should curtail further inspection activity, he or she consults with the DRO. If we drop or cancel the inspection, PED notifies the Operating Division's (OPDIV's) Audit Liaison staff and makes appropriate adjustments to the OEI tracking system, work plan documents, etc.

- The Team Leader, in collaboration with the RIG, will establish reasonable target dates for completion of each phase of the inspection (see page 15).

- The Program Specialist and the Team Leader will jointly contact OCIG for information and advice when an inspection involves legal issues, or if they need subpoenas to collect data or information.

DESIGN

The next step is to design the full program inspection. The design clearly defines the issues and describes how to conduct the program inspection. OEI's *Technical Assistance Guide 1, Focusing the Inspection*, will help specify the inspection issue areas and *Technical Assistance Guide 2, Targeting the Information Needed*, will help in deciding the appropriate inspection process. A design includes the following sections.

Purpose: State what the inspection intends to accomplish. It should be a brief action statement clearly showing why we are performing the inspection.

Background: Provide relevant contextual information and a framework for viewing the major issues addressed in the inspection. It should close with a clear

statement of why the inspection is important. This section should include information about the following, as they apply to the inspection

- the HHS program being studied and how it operates,
- the funding and number of individuals affected,
- the impetus for the inspection,
- special departmental interests, such as Secretarial initiatives,
- relevant stakeholders and any particular interests of theirs,
- relevant legislative or regulatory history,
- explanation of any unfamiliar terminology, and
- OIG work (including OI and OAS) in this area.

Scope: Discuss parameters of an inspection by identifying the areas to be covered. This section should refer to the specific focus of the inspection and any limits that affect areas of inquiry that the inspection will not pursue.

Issues and Analytic Questions: List the major issues the inspection will attempt to address. The issues form the core of the inspection design. They flow from and are more specific than the purpose. They form the basis for developing the analytic questions to be answered and the analysis plan. Together with the analytic questions they form an outline of inquiry.

List analytic questions under each issue. These questions are more specific than the issues and will drive data collection. The inspection will need to answer the analytic questions in order to address the issues and purpose. After each analytic question, indicate the comparisons to be made in order to answer the question (See *Analysis Workshop Manual*, page 14 for examples of analytic questions).

Data Collection: Clearly identify and explain the source of data (or vectors) that are planned to answer each analytic question. Assure that planned data collection will lead to findings and conclusions that are relevant to the stated purpose and issues. This section should also discuss the types of data to be collected from each source (quantitative and/or qualitative, continuous and/or categorical). This section should provide the specific information listed below as it applies to the

inspection

- data to be collected,
- sources of data,
- types of data,
- method of data collection,
- identify respondents,
- sampling methods, including population size and sample size if known,
- methods to ensure reliability of record and interview data, whether computerized or manual,
- cost avoidance and/or cost recovery techniques, if applicable,
- name(s) of software program(s) to be used in data collection and analysis, and
- contractor assistance.

If we anticipate cost avoidance or cost recovery, we should mention and consider this point when developing the methodology.

Analysis Plan: This section specifies plans for analysis of data collected for each analytic question and the comparisons that will be made. For quantitative data, it identifies how we plan to summarize the data, graph the data, and apply statistical tests. For qualitative data, the analysis plan identifies how we intend to reduce the data, display the data, and interpret the displays.

Products: Identify the plan for presenting inspection results. Program inspection products typically take the form of inspection reports. If we plan multiple reports, note that point in this section.

Audience: Identify groups that will receive copies of the final report. We are not looking for specific individuals, but rather primary audiences that would benefit from knowing the study results. (The Team Leader should maintain a list of potential clients for this inspection product).

The following sections on Budget and Staffing, Schedule, and Inspection Impact are placed on separate pages. These sections are not disseminated outside of OEI.

Budget and Staffing: Includes estimates of the inspection cost and identifies OEI staff conducting the inspection. Include costs incurred during pre-inspection work and an estimate of all expected costs for the inspection, such as

- field work,
- briefings,
- printing,
- postage, or
- contractor work, including medical review.

Schedule: List key milestones from pre-inspection through final report issuance. Examples include

- complete pre-inspection,
- design approved,
- Entrance Conference,
- complete field work,
- complete data analysis,
- submit working draft to Headquarters,
- Exit Conference,
- submit draft report for IG signature, and
- submit final report for IG signature.

Inspection Impact: In conjunction with the design, attach a three-column potential impact statement (see Appendix D for language and formatting examples). The potential impact will be discussed at the time of the design Review Team meeting.

If there is no design, the potential impact statement should be written once the region is assigned an inspection number and the inspection is in progress.

Actual impact can occur at any stage of the inspection. When it does, an actual impact statement takes precedence over potential or anticipated impact statements.

Submitting Design

Regional inspection teams are responsible for preparing inspection designs consistent with a scheduled date. When design calls for sampling, the Team Leader works with the regional statistical resource and OEI's TSS to develop an appropriate sampling plan. After approval by RIG, the Team Leader submits the design to the Review Team, and the Secretary to the DIG by e-mail, and copies the appropriate Program Specialist. Use the "OEI Review Team" group list in the Outlook e-mail system. The Review Team's e-mail list consists of the

- Deputy Inspector General,
- Director, Regional Operations,
- PED, Public Health and Human Services Staff Director,
- PED, Medicare and Medicaid Staff Director,
- Director, Technical Support Staff,
- Special Assistant to the Director, Regional Operations.

The Region will also need to manually add the following

- Regional Inspector General (RIG) and Deputy Regional Inspector General (DRIG),
- Inspection Team, including Team Leader,
- Regional Statistical Resource.

The design package e-mail distribution should be carbon copied to

- Appropriate Program Specialist,
- TSS analyst,
- Secretary to the DIG,
- POD, Team Leader for Report Processing.

The Program Specialist is responsible for scheduling a Review Team meeting to discuss designs. The Specialist is also responsible for summarizing the results of Review Team meetings, and disseminating the summary to all participates. If changes are needed, the Inspection Team will revise the design and resubmit it to the Review Team. The Program Specialist, in collaboration with the DRO, will determine if a follow-up Review Team meeting is needed.

ENTRANCE CONFERENCE

The RIG sends approved design to the Review Team. For Medicare and Medicaid inspections, the Program Specialist will provide a copy of the design to the agency 2 weeks before the Entrance Conference. For discretionary inspections, the Specialist provides an outline or briefing package to the agency 2 weeks before the Entrance Conference.

The Program Specialist consults with the Project Leader and arranges for the Entrance Conference with agency staff. Most agencies have a liaison with the OIG (generally called "Audit Liaison"). The Entrance Conference provides an important opportunity for soliciting and incorporating agency interests and concerns. The Program Specialist will furnish a copy of the draft design or appropriate documents to the agency prior to the Entrance Conference.

The purpose of the Entrance Conference is to solicit agency feedback on the inspection design. Specifically, the meeting is intended to identify any omissions or potential weaknesses in the inspection

issues and methods.

The Team Leader should be prepared to present the inspection design and respond to any questions. Preparation for the meeting could include visual aids such as slides, charts, etc.; draft data collection instruments (DCIs); and knowledge of data systems and files needed to complete the inspection work. The Team Leader should coordinate presentation equipment needs with the Program Specialist.

Where appropriate, the Team Leader will revise the inspection design based on agency feedback. The Team is also responsible for summarizing the Entrance Conference comments and conveying that summary to the inspection team.

DATA COLLECTION

Program inspections require inspection teams to collect various types of data relevant to each issue identified in the design for analysis. Some inspections may require document reviews, data reviews, and telephone or mail surveys. Such data collection efforts may be done through site visits or desk reviews of documentation of data files. For example, data collection techniques include

- conducting on-site discussions/observations,
- inspecting original documents,
- collecting data from computer systems or written records,
- matching files against each other,
- reviewing guidance and procedures,
- conducting telephone surveys,
- conducting e-mail/mail/fax survey questionnaires, and
- conducting focus groups.

The Team Leader coordinates data collection and delegates tasks to inspection team members as needed to collect all relevant information to fully respond to each design issue. The Team Leader may also ask the Program Specialist to participate in field work for data collection.

Inspection teams should make all responsible efforts to collect needed data. In some instances, this may require several follow-up visits, phone calls, or mail outs. To illustrate, if a survey response is inadequate, the team may need to conduct two or three follow-up surveys. The final follow-up survey should be sent via certified mail.

When individuals or agencies fail to release records or documents that are accessible to the Inspector General (IG) by statute, the Team Leader notifies the RIG. The RIG consults with the DRO, and OCIG to determine appropriate action. In some instances an administrative subpoena may be the appropriate action.

The Team Leader communicates periodically with the Program Specialist to keep him or her appraised of inspection status and any factors that may require deviation from the approved design. Any changes to inspection target dates should be communicated to the DRO and Program Specialist as soon as they are recognized.

Data Collection Instruments

Program inspections often require collecting data systematically from experts, program administrators, beneficiaries, Federal, State and local officials, and others. OEI staff typically use a data collection instrument (DCI) to assure systematic data collection.

DCI's vary and are unique to each program inspection. An effective DCI should be focused and concise, yet thorough, logically organized, and tailored to inspections needs and to different respondent groups. The Team Leader is responsible for designing, pretesting, and revising DCIs as needed.

In compliance with the Paperwork Reduction Act, Team Leaders are also responsible for obtaining certification approval for all DCIs [Data Collection Burden Certification (see Appendix M)].

DCI Training

Once the Team Leader has finalized the DCIs, team members must be adequately prepared to carry out their responsibilities. The Team Leader develops a training program and conducts training for both the lead and support regions. All team members involved in the inspection should participate in the training. Sometimes, the Team Leader may condense training to a series of individual staff meetings or conference calls. The training may include

- an introduction of team members,
- the purpose of the program inspection,
- relevant program background,
- specific inspection issues,
- the program inspection design,
- the roles and responsibilities of team members,
- a description of the settings and respondents,
- practice with data collection instruments,
- a review of analysis and reporting plans, and
- logistics of site scheduling and respondent access.

The Program Specialist provides information and resources as necessary and sometimes attends the

training.

Data Collection Sensitivities

Concern and sensitivity by agency staff and others to OEI's data collection efforts can cause delays in the completions of our inspections. Therefore, the inspection team must make every

effort to recognize any sensitivities before implementing data collection plans. To this end, we subject our samples, cover letters and other correspondence to sensitivity reviews.

- ***Review of Samples by OI*:** All samples of health care providers will be submitted to TSS, who will obtain clearance from OI. This process is performed to assure that sample members are not under an investigation.

  TSS will send each sample to an OI contractor. The contractor will notify TSS of the number of matches (sample members under investigation) and the provider names of any matches.

  If the number of matches is small, TSS will simply exclude them from the sample and send the revised sample to the region. If the number of matches creates some concern in TSS, then on a case by case basis the inspection team will decide whether to send the list on for OI to review the matches and provide advice and guidance on how to proceed.

- ***Review of Cover Letters/Preliminary Notices*:** The Team Leader should submit all letters and preliminary notices to healthcare providers or provider groups to the Review Team for a sensitivity review. These documents should be submitted to the Special Assistant to the DRO. After their review, the Review Team will return the documents to the Team Leader with any suggested changes.

- ***Data Collection Instruments and Associated Introductory Letters*:** All data collection instruments and associated notices used in inspections will be submitted to the Review Team once pre-testing is completed and the documents are finalized. These include written survey instruments and other standardized DCIs. These documents should be submitted to the Special Assistant to the DRO. After their review, the Review Team will return the documents to the Team Leader with any suggested changes.

The above sensitivity reviews do not include testing of the DCIs validity. Such testing should be conducted by the regional inspection team.

Data Requests

OEI uses both primary and secondary data as part of our inspections. Information we obtain

directly is primary data. Information collected by others is secondary data. It is important to consult with TSS during the design phase of an inspection regardless of the data type we plan to use. For secondary data, TSS verifies that the data needed will not duplicate previous OEI requests. In addition, if OEI does not have access to needed data files, the Director, TSS will assist in obtaining the data.

All OEI requests for Medicare & Medicaid Services (CMS) data must be submitted by the Director, TSS, because of a need to limit the number of people making requests to CMS staff. The Director, TSS has been assigned to make such requests for OEI.

DATA ANALYSIS

One of the most important steps in any program inspection is analyzing the information collected to produce accurate and reliable inspection findings and recommendations (see *Technical Assistance Guide 5, Analyzing the Information Gathered* for additional advice).

The Team Leader and TSS should determine the appropriate methods of data analysis. *The Evaluator's Statistical Handbook Analytical Tools Using SAS®* (available from TSS), contains additional analytical guidance and describes various statistical methods and analysis using SAS® computer software. There is also a series of frequently ask questions (FAQs) on the OEI Intranet web site that can be used to explain common statistical and programming procedures.

The Team Leader works with the Regional Statistical Resource, and when necessary, will contact OEI's national TSS staff. Both the regional and national TSS staff will assist the Team Leader in establishing the degree of reliance that can be placed on an entity's computer-based data systems. Since this determination affects the sampling plan, it should be discussed in the methodology section of the inspection design.

The lead region conducts the analysis by, for example, systematically reviewing the information recorded during site visits, using computer software to analyze quantitative information from mail questionnaires, record reviews, and/or examining files. They can manually review and/or code qualitative information by type of response for computer software analysis.

If, after completing data analysis, it appears that the inspection has detected suspected criminal/civil fraud activity, the Project Leader should consult with the RIG/DRIG for referral to OI.

The region may also formally request assistance from TSS (see Appendix F) to analyze and project data, findings, cost savings, and validate appropriateness of proposed analytical methods.

Reliability of Computer-based Data

To maintain credibility, OEI must take reasonable steps to assess the reliability of pre-existing computerized data used as the basis for inspection findings and recommendations. Many inspections either begin with a computerized sample selection or are based entirely on analyzing data extracted from computerized records not under OEI's direct control. Project staff should not assume that such computer extracts or sample selections are complete or that they accurately reflect the universe of people or transactions being studied.

For OEI purposes, data reliability means the degree to which data extracted from computer records for a program inspection completely and accurately reflect the individuals or transactions being studied. This is a relative concept, one that recognizes that data with errors may still be usable, if the errors are not of a magnitude that would cause a reasonable person to doubt findings or conclusions that are based on the data.

To provide reasonable assurance of computerized data reliability or to notify readers that reliability was not determined

- Identify prior reviews by OIG, GAO, or by system managers attesting to the computer system and data reliability,

- Review the data dictionary, if it exists, for the database to assure a full understanding of the relevant data elements' structure, content, how the elements are derived, and their interrelationships before requesting data extractions,

- Discuss data extraction criteria with TSS to ensure that the criteria for the extraction will produce the data needed,

- Obtain frequency counts of critical data elements to determine if the data selection criteria are providing the information anticipated and ask the TSS to review the data,

- Conduct data accuracy tests to ensure that required data elements have been provided and

are in the expected format [e.g., Health Insurance Claim Numbers are nine digits with one or two alpha/numeric suffixes; names are character (alphabetical) fields; dates of birth are in the MMDDYYYY format],

- Obtain detailed printouts for a sub-sample of records included in the data extract to confirm that the extraction produced the types of records sought and the required information from those records,

- Obtain source documents (e.g., claim folders) for a sample of extracted records to determine the validity of the data contained in the automated records. If the data reliability is questionable, include a statement in the Methodology section of draft and final reports describing the extent of reliability testing performed and our confidence in the data used. If serious data errors exist, consider a separate finding of this fact in the inspection report or a separate report describing the situation.

The methodology section of a report should always show the reliability of data used. If reliability was not determined then the methodology should show that. Finally, if an inspection team used questionable data in a report (not recommended) that should be described in the methodology.

REPORTING

OEI normally communicates inspection results through written reports. However, as needed, OEI will provide oral reports and briefings.

REPORT TYPES

OEI typically uses three types of written reports. They are referred to as "Standard Report," "Inspector General Memorandum," and "Deputy Inspector General Memorandum." Each report, regardless of type, will have a unique inspection number.

OEI's objective is to use the report type that provides the best service to our clients, and therefore, achieves the strongest positive impact on HHS program operations. Decisions to use a particular type of report are based largely on client needs, report message, timing, and other considerations such as pending legislative hearings, or regulatory decisions that would affect program policy, operations, and beneficiaries.

Based on such considerations, OEI occasionally uses other types of written reports. For example, given the nature of OEI's message, its client needs, and the urgency of this need, OEI sometimes decides that a "vulnerability alert," "white paper," or "term paper report" is the best way to communicate its inspection message. In other instances, OEI may issue a report signed by a RIG.

Similarly, OEI may decide that an oral report or briefing is the most effective way to communicate inspection findings. In many instances, written reports are supplemented by oral reports and briefings to enhance understanding and use of written reports to positively impact HHS program operations.

Report Type Decided By Review Team

The decision on which report type to use will typically be made during OEI's Review Team process (see page 3). This process includes the DIG and all other staff involved in planning, designing, conducting and overseeing an inspection.

Each Report Type Has Equal Value

Regardless of which report type is used, OEI views each report as equal in importance. Each report type is chosen because the Review Team believes it will have the greatest positive impact on HHS program operations and beneficiaries. Therefore, a memorandum report, for example, has the same value as OEI's Standard Report.

REPORT WRITING

Regional inspection teams are responsible for writing OEI reports. In drafting a report, the Inspection Team Leader may request a story conference. A story conference is designed to engage both inspection team and Review Team members in designing the report message. Usually, the inspection team will furnish an outline or a rough draft to guide discussion on the potential report message, including development of findings and recommendations.

Guidance on report writing is available in *OEI's Report Instructions and Formatting Guide* (April 2000), *and Technical Assistance Guide 6, Specific Steps for Writing an Inspection Report*.

Standard Reports: Form and Content

The standard OEI report has a blue cover. It usually consists of 10 to 15 pages. In releasing OEI standard reports, the Inspector General signs a transmittal memorandum addressed to the appropriate agency head.

OEI standard report products (working draft, draft, or final) should contain the following elements.

Cover & Inside Page: Use the approved standard report cover and inside page. Electronic copies of these documents have been distributed to each Regional Office. The cover page uses a watermark to designate working draft or draft on the cover as appropriate. The cover page of working drafts and drafts also contains a standard note restricting use of the products. Appendix H provides examples of report covers.

Title Page: The title page is identical to the report cover.

Executive Summary: The Executive Summary highlights the report. It should be easy to read and understand. It should almost always be limited to two pages or less. Normally, findings begin on the first page of the Executive Summary.

Table of Contents: A listing of each section of the report and the corresponding page numbers.

Introduction:

Purpose:	A brief action statement that clearly shows why we did an inspection.
Background:	A brief summary of programs and subjects being evaluated. More specifically, it should briefly describe program policy and operations, funding, affected parties, relevant problems, HHS, congressional, or public concerns that justified the inspection, and other information to establish a foundation for readers to understand and use report findings and recommendations.
Methodology:	A brief description of inspection methods used. It should specify data collection types, sources and methods used; sampling criteria and methods; limitations in the inspection methods; and analysis conducted. It should also specify the steps taken to test for data reliability and the degree of confidence in the data and our analysis. Also include time periods of an inspection. A detailed explanation of the methodology used can be included as an appendix. Finally, it should include a statement that we conducted our inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency (see Appendix N). Any deviation from the standards should be noted. Usually this statement is presented at the end of the methodology section.
Findings:	A balanced, objective presentation on inspection results. In certain instances an inspection team and the Review Team may jointly choose another title for this section (e.g., Observations).
Recommendations:	Proposed actions based on findings or observations of an inspection. In certain instances the inspection team and Review Team may jointly choose another title for this section (e.g., Options or Conclusions).
Agency Comments:	Final reports should summarize the agency or other reviewer's comments on the draft report. Following the summary should be a brief OIG response.

Endnotes/Footnotes: Regions may use either endnotes or footnotes to provide clarification and source information.

Appendices: Include essential information that is too voluminous or technical to include in the body of the report. For example, statistical methodologies, flow charts describing operational processes, and summary tables of key data analysis. In final reports, also include a scanned copy of Agency Comments (do not include the technical comments)..

Acknowledgments: The acknowledgments page contains information showing appropriate regional office, RIG, DRIG, regional and headquarters staff who worked on the Inspection (see Appendix H-6)

Memorandum Reports: Form and Content

Generally, OEI uses two types of Memorandum reports.

IG Memorandum Reports: These reports are signed by the IG. Such reports typically reveal significant problems, weaknesses, or vulnerabilities in agency or program policy and operations. IG memorandum reports will be released under OEI's traditional blue cover. These are placed on the OIG Internet site.

DIG Memorandum Reports: These reports are signed by the DIG for Evaluation and Inspections. Such reports are typically narrower in inspection scope and program implication than the IG Memorandum. They may also be more informational or descriptive in nature. These reports will not be processed with a blue cover. They are placed on the OIG Internet site on a case-by-case basis.

The OEI Review Team process may result in a decision to issue other types of memorandum reports. This decision will be made on a case-by-case basis. Such reports could be signed by the IG, DIG, or a RIG. The format and content of other memorandum reports will be decided by the Review Team.

Memorandum reports usually contain an introduction that serves as an executive summary, and report sections on background, findings and recommendations.

They should be prepared using the Times New Roman TT font, 12 pitch size. The Team Leader should include a watermark on each page of a working draft memorandum report showing that it is a "Working Draft." Likewise, draft memorandum reports should also contain a "Draft" watermark on each page. The watermark should be shaded at 10 percent so that it does not impede readability of photocopies.

OEI typically subjects working drafts, drafts, and final memorandum reports to the same quality reviews as done for standard reports. All reports will be shared with agency staff through exit conferences or other means, and will typically be issued as a formal draft report. On a case-by-case basis, the Review Team may decide to issue the report directly to final.

REPORT PROCESSING

Report processing rules generally apply to all report types. OEI staff should follow similar procedures in processing all reports for release to our clients. The notable difference is in the submission of draft and final reports for IG signature. Exceptions to the rule may occur, but they should be specifically discussed and noted during the Review Team process.

Working Drafts

Submitting Working Drafts to Review Team

After the RIG has approved a working draft, the Team Leader will request a Review Team meeting through the appropriate Program Specialist. The Program Specialist is responsible for scheduling the meeting and notifying all participants. Upon concurrence by the RIG, the Team Leader submits the working draft via e-mail to each member of the Review Team. (See Review Team list on pages 15 - 16).

In addition to the working draft, the Team Leader includes a potential impact statement (Appendix D). As the working draft is revised, the potential impact statement should be revised as needed and resubmitted. Also, OEI's Impact Documentation System should be updated as potential or actual impact of inspections are documented.

OEI typically conducts Review Team meetings by tele-conference.

Incorporating Review Team Suggestions

While comments by Review Team members are advisory to the region, the RIG and the inspection team should seriously consider all comments and make revisions where applicable. Generally, the Review Team will reach a consensus before authorizing a report for release outside of OEI. The DIG will settle any unresolved issues.

Exit Conference

After working draft reports are ready for release by the Review Team, the applicable Program Specialist will furnish a copy to affected HHS agency staff and schedule an exit conference. The agency staff is asked to review the working draft in preparation for an exit conference. OEI staff will use exit conferences to advise agency staff on what we did and found. Equally important, exit conferences are another way for OEI inspection teams to help assure quality and accuracy of inspection reports.

Draft Reports

Draft reports are revised versions of working drafts. Any comments furnished by agency staff during an exit conference will be seriously considered by the inspection team and incorporated into draft reports where appropriate.

Typically, OEI draft reports contain the same basic elements as those outlined previously. The major difference is that the cover page and title page are specific to a draft report. Appendix H furnishes examples.

Submitting Draft Reports to Review Team

After incorporating exit conference comments where needed, the inspection Team Leader, with concurrence by the RIG, will e-mail a revised draft to the Review Team for review and critique of changes. Use the same OEI Review Team e-mail list shown above on pages 15 - 16.

The draft report should be accompanied by a

- transmittal memorandum from the RIG to the DIG (Appendix I-12),
- updated potential impact statement (Appendix D),
- draft morning mail report, and
- draft transmittal memorandum from the IG to the appropriate agency(ies).

The transmittal memorandum should be conversational in tone and language. For example,

- Would you please send us your comments within 45 days.
- If you have any questions about this report, please do not hesitate to call me or [NAME] Deputy Inspector General for Evaluation and Inspections, or have your staff call [NAME OF APPROPRIATE PED STAFF DIRECTOR] at [(xxx) xxx-xxxx].

Further, the opening sentence should clearly explain why we did an inspection. For example, was the inspection requested by someone, or was it part of an OEI initiated body of work. Some suggested wording follows

- This inspection was requested by (identify requestor) for (identify the reason),
- This report follows up on vulnerabilities (specify) identified in a prior report,
- This report is one of a series of inspections on (specify subject), and
- This report is a companion to an earlier report on (generic subject). It was performed to (specify reason).

Review Team Meeting

The Team Leader will ask the Program Specialist to schedule a Review Team meeting to review the draft message presentation. At this time, the Inspection Team and Review Team are concerned with a number of considerations such as the development of findings and recommendations, tone, timing, and message sensitivity. As appropriate, the regional inspection team will revise the draft report, morning report, impact documentation, and IG transmittal memorandum to incorporate Review Team suggested changes.

When the Review Team is in agreement that a draft report is ready for release outside of OEI, the Program Specialist will notify POD (Barbara Hyman) and the regional inspection team via e-mail that the draft is ready for IG signature, pending report validation.

Regional Report Validation

As part of its quality assurance process, regional inspection teams should validate the accuracy and reliability of each report. Report Validation is a process that is used to help ensure that the facts, findings and recommendations contained in OEI reports are accurate, reliable, and supportable by inspection work papers and analysis.

Report validation will be conducted prior to submitting the draft report for IG signature. For objectivity, validation should be performed by OEI regional staff that are not a part of the inspection team. To facilitate this process, the draft report should be cross indexed to applicable work papers (see principle number 4 on page 48 and Appendix L-6).

Any major changes to the draft report, resulting from the validation process, should be coordinated with the Review Team before submitting it for IG signature.

Submitting Draft Reports for IG Signature

In printing the draft report, the regional inspection Team Leader will date the cover and title pages for the current month if it will arrive in OEI headquarters prior to the 15th day of the month. If not, the report cover and title page should be dated for the next month.

Standard Report: After the RIG has approved all revisions, the inspection Team Leader will prepare the following draft report package.

1. 25 unstapled copies of the draft (appropriate blue front cover, no blue back cover),
2. 10 stapled copies of the draft (appropriate blue front cover, blue back cover),
    - For Medicare-related drafts, express mail all 10 stapled copies to the PED Staff Director in Baltimore.
3. 2 camera-ready copies of the draft report,
4. 1 copy of the morning report - on white bond paper (Appendix I-11),
5. 1 copy of the IG memo to agency(ies) - on white bond paper (Appendix I-5 thru I-9),
6. 1 copy of a letter to outside agency(ies) (if requesting agency comments) - on white bond paper,
7. A diskette or CD containing the morning report, memo to agency(ies), and letters to outside agencies (label the diskette or CD with report name and number),
8. 5 folders each containing a stapled copy of the draft report (appropriate blue front cover, blue back cover), morning report and transmittal memoranda/letters (on white bond paper). Label the folders for the DIG, DRO, appropriate PED Staff Director, Director of TSS, and Program Specialist.

Team Leaders will express mail the draft report package to POD (Barbara Hyman) –with the exception of item #2 if the report is Medicare related.

Memorandum Reports: With RIG concurrence, regional inspection Team Leaders will e-mail the following draft report package to POD (Barbara Hyman). In addition to POD, regional inspection teams will e-mail the draft report package to the Review Team.

- Cover (if IG signed)
- Inside Cover (if IG signed)
- Report (If the report contains a lengthy attachment, send POD 25 copies of it and the attachment in express mail)
- Morning Report

Fax a copy of the draft to Barbara Hyman for use in comparing pagination.

Team Leaders should always include a watermark showing "Draft" on every page of a draft memorandum report that is ready for IG signature or distribution to agency and other reviewers outside of OEI.

Do not send an external distribution list for draft reports.

Headquarters Processing of Draft Reports

The DIG or PED Staff Director requests POD to prepare the draft report package for IG signature. Prior to forwarding a report package to OIG/Executive Secretariat (OIG/ES), the Program Specialist should notify POD to obtain clearance from other applicable OIG components, and to ascertain consistency of the message with any products or work results they have released or are planning to release. The Program Specialist and POD can obtain informal clearance to facilitate the official clearance process. Thereafter, POD can obtain official clearance by getting the other component(s) DIG's signature(s) on a yellow file copy.

The POD prepares the package in final form and forwards it to the OIG/ES for clearance and IG signature.

After the IG signs the draft, POD notifies the region and requests any additional copies needed to complete headquarter's distribution. POD also sends the region two copies of the signed IG memorandum and a copy of the morning report. For CMS related studies, the OIG/ES will fax copies of signed memoranda directly to the Baltimore staff.

Releasing Draft Reports for Agency Comments

After the IG signs the transmittal memorandum, OIG/ES sends the morning report to the Deputy Secretary (when appropriate), and draft inspection report(s) and transmittal(s) to the agency(ies). In addition, POD distributes the draft report using the Internal Distribution List (see Appendix J).

The Program Specialist will maintain contact with the agencies to promote a timely response to the draft. OEI allows 45 calendar days from the date of the IG transmittal memorandum for agencies to review and comment on a draft report. The Program Specialist should notify and keep regional inspection teams appraised of comment due dates and any extensions.

OEI does not routinely grant extensions to the 45-day time allowed for agencies to comment on a draft report. Normally, if they have not furnished comments within the allowed 45 days, OEI's DRO will decide whether or not the draft report will be issued without benefit of official comments. However, in instances where an extension seems applicable, DRO may authorize an additional 15 calendar days.

The Program Specialist will assure that OEI's Management Information System reflects the original comment due date and any extensions.

Agency Comments

Agencies normally furnish comments on OEI draft reports to the IG via a memorandum. When this memorandum is received by the OIG/ES, it is provided to the DIG for Evaluation and Inspections. The administrative staff within the DIG's central office will distribute the comments to the Review Team. The inspection team will consider agency comments and make needed revisions when preparing the final report.

In instances where the normal procedure is not followed, the Program Specialist will obtain a copy of agency comments and route them appropriately.

Final Reports

The final report is a revised version of the draft report. It addresses agency written comments and any additional revisions by the inspection team and Review Team.

Incorporating Agencies Comments

Regional inspection teams will seriously consider all critiques and comments received from agency staff and other reviewers of its drafts. This process helps assure the accuracy, reliability, and credibility of OEI products. Based on comments received, regional inspection teams will make needed revisions.

Inspection teams will include a response to agency comments in the final report. OEI inspection teams should include the full text of the agency written comments, excluding the technical comments, as an appendix to the report. Exceptions to inclusion of the full text of comments may be made on a case-by-case basis. Agency comments are typically scanned using either JPEG or GIF format.

Submitting Final Report to Review Team

After regional inspection teams have incorporated and responded to agency comments, the RIG will submit the final report, via e-mail, to the Review Team. Use the OEI Review Team e-mail list on pages 15-16.

Each final report should have a transmittal memorandum from the applicable RIG to the DIG. In that memorandum, the RIG should certify that the inspection was done in accordance with OEI procedures and PCIE quality standards, and that it is ready for the Inspector General's signature and release (see Appendix I-19 for an example).

Each final report should also be accompanied by a morning report and a transmittal memorandum from the Inspector General to the appropriate agency. The final report package should also include an Anticipated Impact Statement (see Appendix D-5).

As shown above for draft reports, the transmittal memorandum should be conversational in tone and language, and the first sentence should clearly show why we did the inspection.
Appendix I-15 and I-16 provide examples for wording IG's transmittal memorandum.

Review Team Meeting

A Review Team meeting is frequently not needed at this point. However, if a meeting is needed or desired, the Team Leader will ask the Program Specialist to schedule a Review Team meeting

to review all changes to the report, transmittal memorandum, and morning report. Its main focus is on responding to agencies' comments and general polishing of the final report.

Incorporating Review Team Comments

As appropriate, regional inspection teams will revise the final report, morning report, and IG transmittal memorandum to incorporate Review Team suggested changes. When the Inspection Team and Review Team are in agreement that a final report, morning report and IG transmittal memorandum are ready for release outside of OEI, the Program Specialist will notify POD (Barbara Hyman) and the Regional Inspection Team via e-mail that the final report is ready for IG signature, pending report validation.

Final Report Validation

Regional Team Leaders will validate any substantive changes to the report following release of the draft. Such changes could have been initiated by various sources such as the Inspection Team, Review Team, agencies, or other reviewers. The Team Leader should consult with the RIG or others as appropriate on what changes are substantive and need validation. The validation should always be done before the final report is processed for IG signature.

Submitting Final Reports for IG Signature

When the inspection team and Review Team decides a final report is ready, the applicable Program Specialist will advise regional inspection teams to begin processing the final report for signature by the IG or other appropriate IG official.

The Program Specialist will advise the regional inspection Team Leader to submit 25 copies for headquarters distribution and use.

In printing the final report, the regional inspection Team Leader will date the cover and title pages for the current month if it will arrive in OEI headquarters prior to the 15th day of the month. If not, the report cover and title page should be dated for the next month.

> **Standard Reports:** With concurrence by the RIG, Team Leaders will express mail the following report package to OEI's POD (Barbara Hyman).

1. 25 unstapled copies of the final (appropriate blue front cover, no blue back cover),
2. 10 stapled copies of the final (appropriate blue front cover, blue back cover),
    - For Medicare-related finals, express mail all 10 stapled copies to the PED Staff Director in Baltimore.
3. 2 camera-ready copies of the final report,
4. 1 copy of the morning report - on white bond paper (Appendix I-17),
5. 1 copy of the IG memo to agency(ies) - on white bond paper (Appendix I-15),
6. 1 copy of a letter to outside agency(ies) (if requesting agency comments) - on white bond paper,
7. 1 copy of a completed external distribution list (Appendix I-18)
8. A diskette or CD containing the morning report, memo to agency(ies), and letters to outside agencies (label the diskette or CD with report name and number),
9. 5 folders each containing a stapled copy of the final report (appropriate blue front cover, blue back cover), morning report and transmittal memoranda/letters (on white bond paper). Label the folders for the DIG, DRO, appropriate PED Staff Director, Director of TSS, and Program Specialist.

The inspection Team Leader will express mail the draft report package to POD (Barbara Hyman)–with the exception of item #2 if the report is Medicare related.

Memorandum Reports: With RIG concurrence, regional inspection Team Leaders will e-mail the following report package to POD (Barbara Hyman) for Memorandum reports signed by the IG.

- Cover (if IG signed)
- Inside Cover (if IG signed)
- Transmittal Memo to OPDIV (See Appendix I-15)
- Report (*If the report contains a lengthy attachment, send POD 25 copies of it and the attachment in express mail.*)
- Morning Report (Appendix I-17)
- An external distribution list (Appendix I-18)

Fax a copy of the report to Barbara Hyman for use in comparing pagination. Also, e-mail the entire memorandum report package to the Review Team.

Headquarters Processing of Final Reports

Prior to submitting a report package to OIG/ES, the Program Specialist should notify POD to obtain final clearance from other applicable OIG components, and to ascertain consistency of the message with any products or work results they have released or are planning to release. The Program Specialist and POD may have already obtained clearance during processing of the draft.

The POD prepares the package in final form and forwards it to the OIG/ES for clearance and IG signature.

Releasing the Final Report

The OIG/ES sends the morning report to the Secretary. Thereafter the IG signs the transmittal memorandum for a standard report or the memorandum report. POD will then release the report to applicable HHS agencies and others according to OEI's internal and external distribution list (see Appendix J and I-18).

POD informs the region that the IG has signed the final report and sends the region two copies of the signed IG transmittal memoranda and a copy of the morning report. POD may request regional inspection teams to provide any additional copies needed to complete headquarter's distribution.

The region makes widespread distribution of reports to interested parties and sends at least three copies to each regional office (six copies for regions 7 and 9).

Agency Comments

The OIG requests agencies to furnish written comments on implementation of final report recommendations to the IG within 60 calendar days of the date on the transmittal memorandum. The Program Specialist will monitor the comment period and contact agency staffs, as appropriate, to promote a timely response.

The OEI will not routinely grant requests for extending the 60-day comment period. Should an agency need an extension, the Program Specialist will advise the RIG, then forward the request to the DRO. The DRO may grant an extension up to 15 calendar days upon receiving a written request. If the DRO grants an extension, the Program Specialist will prepare a memorandum for the record noting the date comments are due. The Program Specialist will give a copy of the memorandum to the RIG and appropriate PED Director. The Specialist will assure that OEI's Management Information System reflects the original comment due date and any extensions. As appropriate the Review Team will discuss the agency comments and decide on the appropriate action. In situations where an agency is non-responsive, OEI will decide whether or not to implement OEI's conflict resolution processes (see page 37).

ORAL REPORTS or BRIEFINGS

In some instances, oral reports and briefings may be the most effective way to communicate inspection

findings and recommendations. Typically, such reports can be given much earlier in the inspection process than a written report. This often enables more timely use of our findings and recommendations internally by OIG members, and externally by our clients. *Technical Assistance Guide 7, Presenting an Effective Inspection Briefing*, provides guidance for preparing oral presentations.

In addition, oral briefings may be given to supplement our written reports. Such briefings facilitate understanding and use of our inspection results. Briefings are most often used as part of OEI's exit conference process with HHS agencies. However, they are also used in many other settings. To illustrate, we frequently provide oral briefings for outside groups such as State and local officials, associations, and congressional staff, when appropriate.

Internal OEI Oral Reports and Briefings

Regional staffs should always consult with the RIG, who will consult with the DRO and DIG as needed, to decide who within OEI is the appropriate person to provide an oral report or briefing. The decision will involve consideration of many factors, including subject sensitivity, audience, and understanding of issues and related implications.

- Generally, regional inspection Team Leaders and members will prepare briefing papers and any other needed visual aids such as charts, slides, and handouts. In planning oral presentations, we should always allow ample time for questions and discussion. In most instances oral presentations will be tailored to a particular audience.

- The Program Specialist will schedule internal presentations and those to our HHS clients.

- The Program Specialist will also prepare a memorandum for IG signature for briefings to the Department Secretary, Deputy Secretary, and other Departmental officials. That memorandum will confirm the briefing and summarize issues to be addressed.

- The RIG, DRO, and DIG will determine attendance for oral presentations on a case-by-case basis.

Presentations to External Groups

OEI staff should never discuss our work with outside groups before consulting with and obtaining approval and guidance from the OIG Office of External Affairs (OEA). This is particularly important when contacted by the news media, congressional staff, and attorneys of organizations interested in our evaluations.

When an OEI employee is asked to speak in an official capacity at conferences, meetings or other

events sponsored by an external party, specific approval must be obtained as outlined in the steps below. For these purposes, an external party is defined as individuals, organizations, and entities outside HHS. The employee must complete the "OIG Clearance Form for External Speeches" (see Appendix K-2). The immediate supervisor, the DIG for OEI and the DIG for the Office of Management and Policy (OMP) must approve the request. The request to speak before not-for-profit organizations that are not included on the OIG list will be approved on a case-by-case basis.

Requests to speak at for-profit organizations will be carefully considered. Many of them stand to gain financially and may possibly benefit directly from the employee's participation in the event. The OIG has determined that generally the appearance of conflict of interest and preferential treatment outweigh the benefits of allowing an OIG employee to speak at the event. Generally, these speaking requests will be denied unless the employee can demonstrate that the benefits outweigh the risks.

Organizations That Pay Travel Costs

Generally, OEI will pay the costs for the employee to attend and speak at events, even if the organization has offered to pay those costs. If OEI cannot pay these costs because of resource constraints, the employee must get formal, signed approval from their immediate supervisor and the DIG using the "OIG Clearance Form for External Speeches." This is true regardless of the type of organization making the request. This approach should be rarely, if ever used.

Requests that require the approval of the DIG should be faxed to the Special Assistant to the DIG. They will coordinate the approval process and keep the employee and supervisor informed of the status of the request.

FOLLOW UP TO RECOMMENDATIONS

The Program Specialist is responsible for follow-up on implementation of report recommendations. The Program Specialist prepares summaries for the Red Book (unimplemented monetary recommendations) within 2 weeks after the release of draft reports. They also prepare summaries for the Orange Book (unimplemented non-monetary recommendations) within 2 weeks from the date we receive the agency response. Both are submitted to POD (Barbara Hyman).

The agency has 60 days to respond to a final report. Their response is their "management decision" or commitment to act on agreed upon recommendations. Possible options include, but are not limited to, (1) the agency agrees to implement, or (2) the agency disagrees and does not implement.

If the agency agrees to implement our recommendations, OIG may do one of the following:

- Accept the agency agreement and proposed actions and indicate that we will follow up until final action occurs.

- State that we do not believe that agency plans adequately address the issue. We could take one of the following actions: take it to conflict resolution, handle it in a less formal but structured way but continue to track it, or decide not to pursue other than through the Orange or Red Books.

If the agency disagrees and will not implement the recommendations, OIG may do one of the following:

- Accept the agency position--and the recommendation is closed. Neither the OIG nor the agency will track or pursue the issue. We will not include the information in the Red or Orange Books.

- Accept the agency position but indicate that we intend to include the information in the Red or Orange Books.

- Not accept the agency position and pursue through conflict resolution.

The Team Leader and the Program Specialist will monitor agency disposition of OEI recommendations until they are closed and removed from the Red and Orange books. The Program Specialist, in consultation with the region, will recommend when to close OEI inspection recommendations.

Any impact resulting from the report recommendations should be immediately updated in the impact documentation system (IDS) by the Team Leader or Program Specialist (Appendix D-6).

CONFLICT RESOLUTION

Conflict resolution is a process for resolving disagreement between agency staffs and OEI on implementation of recommendations contained in an OEI report.

BACKGROUND

The 1988 IG Amendments to Public Law (P.L.) 100-504 established new reporting requirements for both the OIG and agency management. The IG Amendments require agency management to make final decisions on OIG recommendations within 6 months of issuance of final reports and to implement recommendations accepted by agency management within 1 year of issuance of the final report.

The intent of the IG Amendments is to encourage OIG and agency management to reach final resolution on areas of disagreement and to establish accountability for action and reporting by both the OIG and agency management. We must work closely with Assistant Secretary for Budget, Technology and Finance (ASBTF) and the agencies on individual OIG reports, as well as our semiannual reports, so that we can comply with the requirements of the IG Act.

The Department has developed a formal conflict resolution process to ensure compliance with the IG Amendments and to resolve OIG and management disagreements on specific OIG recommendations. The formal process begins with the agency's official nonconcurrence with an OIG recommendation. However, OIG and agency attention to the process must begin much earlier than this official nonconcurrence.

OEI RESPONSIBILITIES

The regions and Program Specialist share the responsibility for ensuring that agencies accept our findings and implement our recommendations. As a result, we need to develop recommendations that (1) help correct the problem identified, (2) are reasonable and cost-effective, and (3) are specific enough for the OIG and the agency to understand the implementation process and to know when it has occurred.

The Program Specialist has responsibility for advising the Project Leader on how the agencies might react to the recommendations and for suggesting ways to state recommendations that will enhance the likelihood of agency acceptance and action.

While we may proceed in one of two ways, informally or formally, our efforts should focus on resolving conflicts before using the formal process. Once the formal process begins, it becomes resource intensive for everyone. A third party will impose a decision and we risk losing control of the process.

Further information regarding the conflict resolution process may be found in the OEI publication, *Implementation of the Conflict Resolution Process*, April 1990.

INFORMAL CONFLICT RESOLUTION PROCESS

The Exit Conference has traditionally been, and will continue to be, the point at which we initially discuss our potential recommendations and get the agencies reaction. Another important opportunity to resolve disagreements with the agency occurs when we release the draft report.

When the agency responds to our draft and final reports, the Program Specialist and Project Leader should carefully consider any recommendations with which the agency does not concur. They should confer with each other, the RIG, and the appropriate PED Staff Director. Informal discussion can occur at this point between OEI and agency management officials to decide if their response is acceptable and if the planned actions are responsive. If no resolution occurs, the PED Staff Director and RIG should confer with the DIG, and the DRO to identify and submit recommendations for formal conflict resolution. If we decide not to elevate it to conflict resolution, we will need to decide what action we will take, if any.

FORMAL CONFLICT RESOLUTION PROCESS

When issues cannot be resolved through the informal process, the formal conflict resolution should be initiated. The formal conflict resolution process consists of four steps:

1. In response to our final report transmittal memorandum, the agency states that it does not concur with our recommendation(s).

2. If the OIG does not agree with the agency's nonconcurrence within 60 days after we issue the final report, agency and OIG representatives of comparable rank must meet to discuss the recommendation. If we reach agreement, resolution occurs.

3. If we do not reach agreement within 90 days after the date of the final report, the OIG

formally appeals to the Department Audit Follow-up Official and the ASBTF. We give a copy of the appeal to the agency. Both the OIG and the agency furnish their positions in writing to ASBTF within 30 days using the following format:

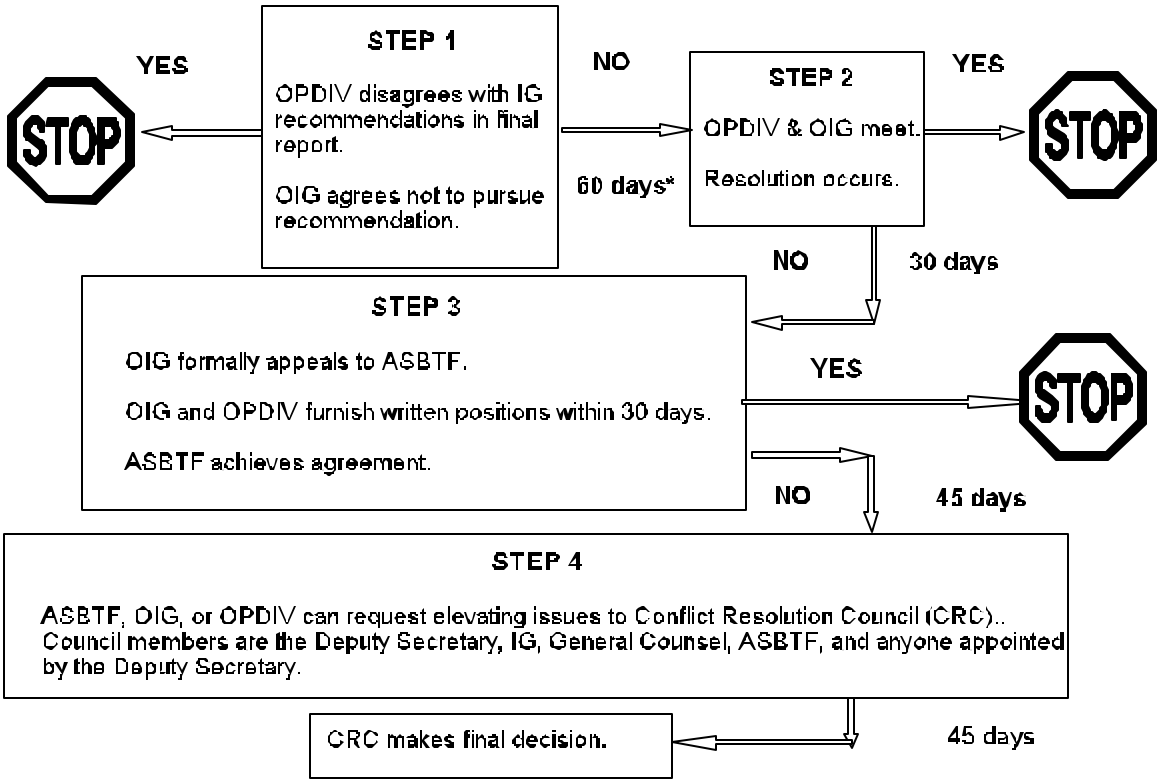
- Title, IG number, and the date of issuance of the final report.
- List of IG findings and recommendations accepted.
- List of IG findings and recommendations not accepted.
- Statement of the issue and supporting arguments (in bullet form).
- Impact analysis including financial data quantifying the cost or savings to the Federal, State, and local Government, program or service providers, and program beneficiaries.
- Assessing the benefits to be achieved and identifying who benefits.
- Assessing any adverse consequences from the recommendations and identifying who would be adversely affected. and
- Describing the results of previous reviews or decisions on this issue (budget, policy, or legislative reviews, etc.).

If ASBTF obtains agreement or makes a decision that satisfies both sides, resolution occurs.

4. If we do not reach agreement with ASBTF intervention within 135 days after the date of the final report, the Inspector General, the ASBTF, and the agency head may raise the issues to the Conflict Resolution Council (CRC). The Council advises the Deputy Secretary, who makes the final decision *within 180 days* after the date of the final report.

The following chart helps to clarify the steps

Formal Conflict Resolution Process (Graphic)



* Time is counted from the release of the final report. Total days for the process 180.

DISCLOSURE AND DISTRIBUTION OF INFORMATION AND REPORTS

DISCLOSURE

Final reports are normally released to the public upon request. All unclassified reports are available on the Internet at http://oig.hhs.gov/. After OEI issues a final report, relevant work papers may be requested and obtained under the Freedom of Information Act (FOIA). We cannot release classified work papers and those containing information on identifiable individuals due to federally mandated privacy protections (see page 45).

We also protect and control draft reports. We do not release them publicly. Because they are still under development and will likely change, they are only available to agencies within the Department, and to selected outside organizations for comment.

DISTRIBUTION

For external distribution, we will tailor dissemination of final reports in accordance with agreements reached during the Review Team meeting. Distribution will be documented on OEI's External Distribution List that the Team Leader sends to Headquarters with the final report package (see Appendix I-18).

We should delay distribution of final reports for 7 working days to outside organizations to allow for department-wide review.

Both OEI headquarters and regions will distribute final reports. We should widely distribute finals for maximum impact. Further, we should target organizations and individuals that have particular interest in the report.

For internal distribution, draft and final reports should be disseminated in accordance with OEI's Internal Distribution List (see Appendix J).

External Affairs Policy

OEI staff should refer all inquires by the press, congressional staffers, and representatives of special interest organizations (usually attorneys) to the OIG's Special Counsel for External Affairs. Requesters for copies of released OEI final reports, however, may be referred to the OIG web site http://oig.hhs.gov/ as indicated on the inside report cover and on the acknowledgment page.

In some instances, OEA may designate regional or other OEI staff members to respond to inquiries from external sources. When OEI members respond to inquiries from outside entities, they should always make a record of events leading up to their selection to respond, the information provided, and the subjects discussed. Copies of the record should be furnished to the RIG, DRO, DIG, appropriate PED Staff Director, and Special Counsel for External Affairs as soon as possible after responding to the inquiry.

Regardless of who responds, OEIs objective is to furnish a consistent OIG message. Therefore, when OEI analysts are asked to respond to outside inquires for information, they should always coordinate with the RIG and other OEI staff in the accountability chain, including the OEA.

Contacts by News Media

The OIG's OEA will usually respond to media inquires. Accordingly, OEI staff who receive media contacts directly should always refer them via e-mail and telephone to the OIG Special Counsel for External Affairs. The e-mail should show the requestor's name and organization, the date of request, the inspection title and number, and any known details on the nature and subject of interest.

In instances where OEA asks OEI headquarters or regional members to respond to media inquires, the OEI staff should keep appropriate records as noted above. In other instances, OEA may request OEI headquarters or regional members to assist them in responding to media requests.

In instances where the news media request a final report that has already been released, OEI staff should first refer the requestor to OIG's web site. If the requestor cannot obtain a copy from this source, OEI staff may furnish a copy. In such instances, OEI staff should keep a record and notify the RIG, OEA Director, the DIG, and the DRO by e-mail.

Congressional Interaction

The OIG's OEA will usually respond to inquiries from members of Congress and their staffs. OEI's procedure for disposition of such inquiries is generally the same as that described above for media inquiries.

Contacts by Special Interest Organizations

The OIG's OEA will usually respond to inquiries from members of special interest organizations. OEI's procedure for disposition of such inquiries is generally the same as that described above for media inquiries.

SAFEGUARDING CONFIDENTIAL INFORMATION

PRIVACY ACT PROTECTION

The Privacy Act governs most personal data collected and used by the HHS agencies. This gives individuals some control over the records a Federal agency collects about them, and over the use of the records. The Privacy Act provides criminal penalties for any Federal employee who makes unauthorized disclosure of Privacy Act protected information.

Under the Inspector General Act of 1978, 5 USC App., an agency may disclose personal data contained in a system of records (as defined by the Privacy Act, 5 USC 552a) to the OIG. The records are available to the OIG without the consent of the individual for whom the records are maintained. However, OIG staff are entitled to such records only in an official capacity.

OEI USE OF PERSONAL AND SENSITIVE INFORMATION

To prevent improper use, all OIG staff are required to safeguard any personal and sensitive data they obtain and use. Much of the data OEI staff obtains and uses come from systems of records covered by the Privacy Act, and as such it must be protected from unauthorized use.

During inspections, for example, OEI staffs typically obtain and use data containing beneficiary names and Social Security numbers. Such data is protected under the Privacy Act, and must be protected consistently with applicable laws and regulations.

In general, sensitive data should not be left open to the view of others that may not have a need to examine it. We should always protect such data from scrutiny, theft, tampering, damage, or loss. The listing below provides minimum guidelines for safeguarding personal and sensitive information.

- Include in inspection designs a reminder that work papers must be safeguarded against unauthorized disclosure if they contain sensitive or Privacy Act information, such as payroll records, personnel records, benefit payment histories, etc.

- Label all electronic and hard copy working papers that contain sensitive information. Labeling will reduce the probability of accidental abuse of the data.

- Store both electronic and hard copy working papers containing sensitive data in a secure manner when not in use. Do not make unnecessary copies of the work papers or information and data contained therein. Protect sensitive data stored on local hard drives with password protection that covers access to local hard drives.

- Protect sensitive data stored on network hard drives in such a manner that limits access rights to a specific individual or group of individuals who have need to know. For example, access may be precluded for Regional Technical Officer (RTO) staff who have no need to know.

- Understand and sign the *Office of Evaluation and Inspections memorandum On the Use of Data with Individual Identifiers (Attachment D)* and only share sensitive data with other OIG employees who have a need to know and have signed the agreement.

Finally, for inspections that require use of contractors for functions such as medical review or management advice and assistance, the contractors must also protect classified and Privacy Act information and data. When using a contractor, Team Leaders should always use OEI's standard contract language which spells out contractor responsibilities and steps for protecting sensitive and Privacy Act information and data.

FREEDOM OF INFORMATION ACT

The Freedom of Information Act (FOIA) affords any person access to Federal agency records, except for those protected under one or more of nine exemptions (see 5 U.S.C. Section 552). Also, the FOIA provides access to records of certain non-Federal entities that act as agents of the Federal government. For example, records of Medicare intermediaries and carriers and State disability determination agencies may be available under the FOIA.

Request for OEI Information Under the FOIA

Requests under the FOIA may come in many forms, from individuals or organizations. All requests are equally valid and need not cite the FOIA or the Privacy Act (PA) by name.

OI is responsible for processing all OIG FOIA requests and providing a liaison to the Department's FOIA/PA Division.

OEI staff should forward all requests for nonpublic information to the FOIA liaison (currently Diane Diggs). Written FOIA request may be sent to:

Freedom of Information Liaison or, fax to Department's FOIA/PA

Office of Inspector General
Room 5246, Wilbur J. Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Division - (202) 690-8320
(Please mark on the fax that the
FOIA request is for OIG documents.)

Available Information Under FOIA

Any request for Federal agency records that are not in the public domain is considered a legitimate FOIA request. Generally, this means OEI work papers containing information, data, and records that are not protected by the Privacy Act or other requirements for protecting information may be obtained by individuals and entities outside the OIG under the FOIA. However, information will only be released after coordination and discussion with the DIG and the FOIA Coordinator, OI. Any refusal to provide requested FOIA information must be thoroughly coordinated and justified with appropriate liaison staff and managers who have OIG responsibility for FOIA matters.

Requests for information in the public domain such as OEI reports are not considered FOIA requests. Simply refer the requester to the OIG website or send a copy of the document. Do not notify the FOIA liaison of requests of this type.

Information Not Available Under FOIA

The OIG may not release information that is exempted by Section 552 of 5 U.S.C. (see Appendix O). Further, the OIG's policy prohibits release of any information from an ongoing inspection, investigation, or audit. Therefore, OEI typically will not release supporting work papers, records, data, and information prior to issuing a final report.

Responding to FOIA Requests

Upon receiving a written FOIA request, Team Leaders should notify the requester in writing that the request was received and forwarded to the FOIA Officer. A sample letter may be found in the OIG Administrative Manual (Chapter 9-40). A copy of the OIG Administrative Manual is available in each regional office through the Administrative Officer.

The FOIA Liaison sends all written requests to the Department's FOIA/PA Division. The Department logs it in, assigns the request a case number, and affixes a tracking sheet.

The FOIA Liaison then forwards the requests for inspection records to the FOIA coordinator for OEI (FOIA/OEI). Any questions regarding OEI's response should be directed to the FOIA/OEI who coordinates OEI's response.

Tracking Responses to FOIA Requests

The FOIA/OEI will furnish a tracking sheet to Team Leaders or Program Analysts who respond to FOIA. The tracking sheet should contain a response due date in the upper right-hand corner. This is the date that the documents are due in the Department's FOIA office.

For FOIA requests involving a large number of work papers, the Team Leader should provide the FOIA/OEI with a rough estimate (by box or inch count) prior to filling the request.

The Department's FOIA/PA Division may assess a fee for processing FOIA requests. Therefore, all analysts who help respond to a FOIA request should include the time spent and the hourly rates of pay. Enter the time spent in 30 minute increments, with a minimum of 30 minutes. This information should be included on the tracking form, next to the lines marked "review/edit/sanitize" and "search records."

Withholding Information

The Department's FOIA/PA Division has final authority on what information to release or deny in responding to a FOIA request. However, the FOIA/OEI will coordinate and negotiate with the Department's FOIA Liaison to withhold information that OEI regions and headquarters believe should be denied under one or more of the FOIA exemptions.

To this end, Team Leaders should send two copies of requested FOIA documents to the FOIA/OEI. One should be a clean copy, and the other should contain notes identifying any information that the region thinks should be exempted from disclosure. On the annotated copy, the Team Leader should bracket or highlight all sections the Region believes should be withheld. Also, the Team Leader should submit a memorandum to the FOIA/OEI that describes the information and justifies why it should be withheld from the FOIA requester.

The Department's FOIA/PA Division does not normally furnish OEI staff with a copy of the final response to a FOIA request. However, the OIG FOIA Liaison and the Department's FOIA/PA Division will contact applicable OEI staff on any disagreements over what information is released. Team Leaders may also contact the FOIA/OEI with any questions regarding requested documents.

Additional Information on FOIA Request

Chapter 9-40 of the OIG Administrative Manual contains complete policies and procedures for responding to FOIA requests. A copy of a FOIA request may be viewed on the Department's web site.

Additional requirements and procedures for FOIA request may be found in:

- 5 U.S.C. § 552
- 45 C.F.R. Part 5
- 42 C.F.R. 401

WORK PAPERS

Work papers are written and electronically stored (computer) records, data, and other information obtained or created during an inspection. The procedures below provide guidance rather than rigid rules for obtaining, using, and retaining work papers for OEI inspections. The procedures apply to all OEI inspection-related activity, regardless of the type of records or report. In all instances, OEI staff should exercise professional judgment and common sense when organizing, using, and storing work papers.

PURPOSE OF WORK PAPERS

Work papers are key to the integrity of OEI inspections. They contain supporting evidence for findings and recommendations presented in final inspection reports. They also establish a linkage between data collection and analysis done during pre-inspection and field work and the inspection reports. In summary, work papers furnish

- a systematic record of the work performed in conducting an inspection,
- a record of evidence obtained (data, information, and analysis) to support inspection findings and recommendations,
- a record documenting that we performed inspection work in a responsible, objective manner (we certify in inspection reports that our work meets the standards specified by the PCIE standards), and
- a record of useful information for planning future inspections.

WORK PAPER PRINCIPLES

The following six principles provide fundamental guidance for inspection teams in organizing and maintaining work papers. Following the list is a discussion of each principle. The principles are not intended to answer every question that comes up regarding work papers. Instead, they provide guidance and flexibility for Team Leaders to exercise professional judgement about how best to maintain work papers.

Principle 1
Work papers should allow someone not associated with an inspection to determine work done, identify supporting evidence for findings, and determine basis for recommendations.

Principle 2
Work papers should be organized in a logical system that is clearly identifiable by a table of contents.

Principle 3
Work papers can be stored electronically or in paper form, or any combination that makes sense for a particular inspection, as long as they are accessible and well labeled.

Principle 4
Work papers must include documentation that inspection teams verified data presented in draft reports by checking it against supporting evidence in the work papers.

Principle 5
Work papers should adhere to general standards for completeness, accuracy, and clarity; legibility and neatness; relevance; and retention.

Principle 6
Work papers should be reviewed and approved by the regional manager at the close of an inspection to certify that they comply with principles 1-5.

Principle 1: ***Work papers should allow someone not associated with an inspection to determine work done, identify supporting evidence for findings, and determine the basis for recommendations.***

This represents the most basic principle for determining what work papers to collect and keep as a record. Could someone from another office easily discern how the project developed from proposal or request to pre-inspection and design all the way to data collection and analysis? Is the logic of the inspection process documented and apparent? Would it be clear where the evidence for particular findings came from? Are the formulas used in data analysis available for scrutiny? Can anyone tell what the sources of data are? Could someone figure out when the inspection started and was completed? Has the inspection had any impact? These questions, among others, are the kinds of questions the Team Leaders should ask as they determine what should constitute the official work paper file for an inspection.

Principal 2: ***Work papers should be organized in a logical system that is clearly identifiable***

by a table of contents.

The Team Leader in consultation with the DRIG/RIG establishes a work paper filing system at the beginning of an inspection. Such a system can be the filing system described in Appendix L. However, other filing systems can be used, as long as it meets the work paper purposes and principles.

Principal 3: ***Work papers can be stored electronically or in paper form, or any combination that makes sense for a particular inspection, as long as they are accessible and well labeled.***

Inspections vary widely in the amount and types of work papers generated. In some cases, it may be unreasonable to maintain paper copies of every key document. Team Leaders must use their professional judgment in determining the manner in which the work papers will be maintained. In most cases, the work papers will be a combination of electronic and paper records. In the case of electronic records, diskettes or CDs should be clearly labeled with the inspection number and included in the work paper files. The paper files should contain a corresponding table of contents for each diskette or CD, with files names, descriptions, and programs.

Principal 4: ***Work papers must include documentation that inspection teams verified data presented in draft reports by checking it against supporting evidence in the work papers.***

The primary goal of the verification is to ensure that statements of fact and findings are supported by the evidence collected in the inspection. This step helps ensure the integrity and credibility of OEI's work. We accomplish this through a cross-indexed copy of the draft report. Cross-indexing generally involves a system of notes in the report margins or endnotes tying each statement of fact to the appropriate evidence in the work papers, thereby verifying the facts. Long and complex numbering systems are generally unnecessary.

Principal 5: ***Work papers should adhere to general standards for completeness, accuracy, and clarity; legibility and neatness; relevance; and retention.***

Complete and Accurate– Work papers should be complete and accurate to support findings and recommendations and to document activities performed during the conduct of an inspection. They should include any work by support regions or TSS. Where a contractor was used, work papers should include materials specified as deliverables in the contract.

Clear and Understandable– Work papers should be clear and understandable as to their purpose, the nature and scope of work done, and the resulting findings and recommendations. Conciseness is important, however, do not sacrifice clarity and completeness for the sake of brevity.

Neat and Legible– Work papers should be neat and legible. Handwritten work papers are acceptable.

Relevant – Work papers should be restricted to data, documents, information, and analysis that are materially important, relevant**,** and useful, as determined by the Project Leader/Team Leader/DRIG/RIG.

Retained– Supporting work papers should be maintained in the regional office for at least 3 years after issuing a final report. This allows for easy access for follow-up and responding to Freedom of Information Act requests. After the 3-year period is completed, the Team Leader and regional managers should determine if the work papers need to be retained or stored at the Federal Records Center for longer periods. In some cases, work papers can be helpful for other related inspections, work planning, or follow-up studies.

Principle 6: ***Work papers should be reviewed and approved by the regional manager at the close of an inspection to certify that they comply with principles 1 - 5.***

At the close of an inspection, the RIG must review and sign-off on the work papers. The RIG's signature certifies that the work papers are in order and adhere to the principles discussed in this manual.

APPENDICES

APPENDIX A - List of Acronyms

AoA	Administration on Aging
ACF	Administration for Children and Families
AHRQ	Agency for Health Care Research and Quality
ASAM	Assistant Secretary for Administration and Management
ASH	Assistant Secretary for Health
ASL	Assistant Secretary for Legislation
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASPA	Assistant Secretary for Public Affairs
ASPE	Assistant Secretary for Planning and Evaluation
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Center for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CRC	Conflict Resolution Council
DCI	Data Collection Instrument
DIG	Deputy Inspector General
DRIG	Deputy Regional Inspector General
DRO	Director, Regional Operations
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FMFIA	Federal Managers' Financial Integrity Act
GAO	General Accounting Office
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
IDS	Impact Documentation System
IG	Inspector General
IHS	Indian Health Service
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OEA	Office of Inspector General External Affairs
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General
OIG/ES	Office of Inspector General Executive Secretariat
OMB	Office of Management and Budget
OMP	Office of Management and Policy
OPDIV	Operating Division
OPHS	Office of Public Health and Science
OS	Office of the Secretary
PA	Privacy Act
PCIE	President's Council on Integrity and Efficiency
PED	Program Evaluation Division
POD	Policy and Oversight Division
PSC	Program Support Center
RIG	Regional Inspector General

RTO	Regional Technical Officer
SA	Special Assistant to the Deputy Inspector General
SAMHSA	Substance Abuse and Mental Health Services Administration
STAFFDIV	Staff Division
TSS	Technical Support Staff
U.S.C.	United States Code

APPENDIX B - Inspector General Act of 1978[3]

5 USC App. INSPECTOR GENERAL ACT as of June 19, 1998

Pub. L. 95-452, Oct. 12, 1978, 92 Stat. 1101, as amended by Pub. L. 96-88, title V, Sec. 508(n), Oct. 17, 1979, 93 Stat. 694; Pub. L. 97-113, title VII, Sec. 705, Dec. 29, 1981, 95 Stat. 1544; Pub. L. 97-252, title XI, Sec. 1117(a)-(c), Sept. 8, 1982, 96 Stat. 750-752; Pub. L. 99-93, title I, Sec. 150(a), Aug. 16, 1985, 99 Stat. 427; Pub. L. 99-399, title IV, Sec. 412(a), Aug. 27, 1986, 100 Stat. 867; Pub. L. 100-504, title I, Secs. 102(a)-(d), (f), (g), 104(a), 105-107, 109, 110, Oct. 18, 1988, 102 Stat. 2515-2529; Pub. L. 100-527, Sec. 13(h), Oct. 25, 1988, 102 Stat. 2643; Pub. L. 101-73, title V, Sec. 501(b)(1), title VII, Sec. 702 (c), Aug. 9, 1989, 103 Stat. 393, 415; Pub. L. 103-82, title II, Sec. 202(g)(1)-(5), Sept. 21, 1993, 107 Stat. 889, 890; Pub. L. 103-204, Sec. 23(a)(3), (4), Dec. 17, 1993, 107 Stat. 2407, 2408

Sec. 1. Short title

This Act may be cited as the "Inspector General Act of 1978."

Short Title of 1988 Amendment

Pub. L. 100-504, title I, Sec. 101, Oct. 18, 1988, 102 Stat. 2515, provided that: "This title [enacting sections 8B-8F of Pub. L. 95-452, set out in this Appendix, amending sections 2, 4-6, 8, 9, and 11 of Pub. L. 95-452, set out in this Appendix, sections 5315 and 5316 of this title, sections 405 and 1105 of Title 31, Money and Finance, and section 410 of Title 39, Postal Service, repealing sections 3521-3527 and 7138 of Title 42, The Public Health and Welfare, and section 231v of Title 45, Railroads, and enacting provisions set out as notes under sections 1, 5, 8D, 8E, and 9 of Pub. L. 95-452, set out in this Appendix] may be cited as the 'Inspector General Act Amendments of 1988'."

Sec. 6. Authority of Inspector General; information and assistance from Federal agencies; unreasonable refusal; office space and equipment

(a) In addition to the authority otherwise provided by this Act, each Inspector General, in carrying

[3] This Appendix contains an abbreviated text version of The Inspector General Act of 1978, (Amendment citations have been deleted, as well as those sections which do not pertain to the Inspector General authority for access to records). If the deleted sections, and/or the amendment citations are needed, the correct citation for electronic searches is "**5A USC Inspector General Act of 1978**".

out the provisions of this Act, is authorized--

(1) to have access to all records, reports, audits, reviews, documents, papers, recommendations, or other material available to the applicable establishment which relate to programs and operations with respect to which that Inspector General has responsibilities under this Act;

(2) to make such investigations and reports relating to the administration of the programs and operations of the applicable establishment as are, in the judgment of the Inspector General, necessary or desirable;

(3) to request such information or assistance as may be necessary for carrying out the duties and responsibilities provided by this Act from any Federal, State, or local governmental agency or unit thereof;

(4) to require by subpoena the production of all information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary in the performance of the functions assigned by this Act, which subpoena, in the case of contumacy or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, that procedures other than subpoenas shall be used by the Inspector General to obtain documents and information from Federal agencies;

(5) to administer to or take from any person an oath, affirmation, or affidavit, whenever necessary in the performance of the functions assigned by this Act, which oath, affirmation, or affidavit when administered or taken by or before an employee of an Office of Inspector General designated by the Inspector General shall have the same force and effect as if administered or taken by or before an officer having a seal;

(6) to have direct and prompt access to the head of the establishment involved when necessary for any purpose pertaining to the performance of functions and responsibilities under this Act;

(7) to select, appoint, and employ such officers and employees as may be necessary for carrying out the functions, powers, and duties of the Office subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates;

(8) to obtain services as authorized by section 3109 of title 5, United States Code, at daily rates not to exceed the equivalent rate prescribed for grade GS-18 of the General Schedule by section 5332 of title 5, United States Code; and

(9) to the extent and in such amounts as may be provided in advance by appropriations Acts, to enter into contracts and other arrangements for audits, studies, analyses, and other services with public agencies and with private persons, and to make such payments as may be necessary to carry out the provisions of this Act.

(b)

(1) Upon request of an Inspector General for information or assistance under subsection (a)(3), the head of any Federal agency involved shall, insofar as is practicable and not in contravention of any existing statutory restriction or regulation of the Federal agency from which the information is requested, furnish to such Inspector General, or to an authorized designee, such information or assistance.

(2) Whenever information or assistance requested under subsection (a)(1) or (a)(3) is, in the judgment of an Inspector General, unreasonably refused or not provided, the Inspector General shall report the circumstances to the head of the establishment involved without delay.

(c)) Each head of an establishment shall provide the Office within such establishment with appropriate and adequate office space at central and field office locations of such establishment, together with such equipment, office supplies, and communications facilities and services as may be necessary for the operation of such offices, and shall provide necessary maintenance services for such offices and the equipment and facilities located therein.

(d) For purposes of the provisions of title 5, United States Code, governing the Senior Executive Service, any reference in such provisions to the "appointing authority" for a member of the Senior Executive Service or for a Senior Executive Service position shall, if such member or position is or would be within the Office of an Inspector General, be deemed to be a reference to such Inspector General.

APPENDIX C - Work Plan Proposals

Example #1: CMS Education Strategy and Beneficiary Understanding of Medicare

Example #2: Medical Necessity in Medicaid: DME

Work Plan Proposal - Example 1

CMS Education Strategy and Beneficiary Understanding of Medicare

Purpose

To evaluate CMS's 2001 education strategy and the impact on beneficiary understanding of Medicare options.

Background

The Centers for Medicare & Medicaid Services (CMS) emphasizes beneficiary education as one of its top priorities. In response to the expanded choices for beneficiaries under Medicare+Choice, CMS implemented its "National Medicare Education Program" (NMEP). Some of the NMEP elements designed to inform beneficiaries about their Medicare options include a "Medicare and You" handbook, "Medicare Compare" database, and customer service telephone lines. The "Medicare Compare" database, found at www.medicare.gov, provides beneficiaries with comparative information about managed care plans in areas of quality, satisfaction, and plan benefit information. The goal of the NMEP strategy has always been to provide consistent information to the beneficiaries, so they might make informed decisions about the type of plan to enroll in, whether it be traditional Medicare, managed care, or supplemental, such as Medigap.

Recognizing the need to improve beneficiary awareness and understanding, CMS announced updated education strategies during the Fall of 2001, which includes: increased capacity of Medicare's Toll-Free Lines (expansion to 24 hours a day, seven days a week) effective
October 1, 2001; multi-media advertising campaign; improved "Medicare & You" educational efforts; and improving comparative information on Medicare Compare, including information on State-based Medigap options and costs.

Issues

- What significant parts of the recent strategy have actually been implemented? What significant changes were made to the NMEP?
- What source of awareness is most memorable to beneficiaries?
- What source of information is most helpful to beneficiaries?

- How well do beneficiaries understand their Medicare+Choice options?

Methodology

- Interview representatives from CMS to clarify the key improvements and changes to the NMEP.
- From universe of HMOs (which exclude demos, costs and HCPPs), obtain representative sample of Medicare beneficiaries from GHP.
- Survey beneficiaries to ask about issues above, including: CMS source used most; how helpful the sources are; what they selected (traditional, type of managed care, Medigap) and their perceived understanding.

Audience

Congress, CMS, beneficiaries

Impact

- Identify strengths and weaknesses in the education campaign
- Improved beneficiary understanding of Medicare options

Work Plan Proposal - Example 2

Medical Necessity in Medicaid: **DME**

Purpose:

To identify Medicaid expenditures for DME that are either medically unnecessary or unsupported.

Background:

Medicaid is a jointly funded, Federal-State program that provides medical assistance to certain groups of low-income people and others with special health care needs. In FY 2000, the State share of funding for Medicaid was approximately 43 percent with the remaining 57 percent provided by the Federal Government.

Medical Necessity

Several key or basic Federal requirements must be met in order for a service to be covered by Medicaid. These are: 1) the service must be primarily medical or remedial in nature; 2) the service must fit into a service category (as defined by 42 CFR440.1-440.225); and 3) the service must be provided by a qualified provider (42CFR 431.51(c))(2)). Regulations at 42CFR 440.230 also require that each covered medical service be sufficient in amount, duration and scope. States may also establish limits on the services they cover.

Medical necessity has not been specifically defined from the Federal point of view. In fact, it is never mentioned in Medicaid statutes and is only generally mentioned in the regulations (42CFR 440.230(d)). Basically, States are given flexibility and the authority to define medical necessity and determine when services do not meet their definition. Many States make use of practice guidelines when determining medical appropriateness and necessity. The Federal government, or CMS, is not involved in making these determinations. However, it is CMS's role to oversee the intent of the Federal guidelines and to ensure that federal outlays are being directed towards medically appropriate services in the Medicaid program.

HCFA-64 Financial Reporting

On a quarterly basis, States submit Form HCFA-64 in accordance with 42 CFR 430.30(c)), which reports actual disposition of Medicaid grant funds for the quarter being reported. It also reports any adjustments, overpayments, or underpayments that should be made for prior periods. The

HCFA-64 is used to reconcile against the monetary advance requested and received through the Form HCFA-37, which is filed previously.

According to the HCFA-64, the types of services with significant fee-for-service expenditures include: inpatient hospital; physician services; mental health; home health; and outpatient hospital. Aside from the HCFA-64, transportation, lab tests, and DME are potential areas of vulnerability. **This inspection would focus on DME.**

Issues:

- What is the incidence of Medicaid billing for inappropriate services – medically unnecessary or unsupported - for DME?
- If inappropriate services are being billed, what is the impact on the Federal outlay of matching funds - for DME?
- Have inappropriate billings for DME identified and adjusted on the HCFA-64 form?

Methodology

This type of study cannot be efficiently carried out for all 50 States. Therefore, it is important to select a sample of States on which to focus the review.

Identifying Several States and Services on Which to Focus

The HCFA-64 database displays the level of expenditure for each service category and State. This can be used to select States with various levels of expenditures. Additionally, States with high managed care penetration should not be included because of the lack of fee-for-service claims data.

Conducting Medical Record Review

It is critical that OIG work closely with States when conducting this inspection, due to the complexities in Medicaid claims and accounting systems. For the selected States, a sample of claims can be requested from the States for DME. Each State's medical necessity criteria, as well as their medical record review processes are somewhat unique. Therefore, contractors (PROs, EQROs, etc.) selected to conduct medical record review for an inspection must be familiar with the selected States' rules. (Each State has a SURS unit that can be helpful with this).

After the results of the review are complete, the States should confirm whether or not any of the errors from the review had already been found previously and adjusted through the HCFA-64. If the errors have been adjusted, they would not be legitimate errors.

For instances of inappropriate billing that has not been or will not be adjusted on the HCFA-64, estimate State and Federal expenditures associated with errors.

Audience

Congress, CMS, State Medicaid Agencies

Impact

- Reduced inappropriate billing in Medicaid
- Reduced FFP for Medicaid services

APPENDIX D - Impact Focused Inspections

Measuring Qualitative OIG Impact

CONSUMER PROTECTION

Increase Consumer Safety
Improve Quality Care
Increase Consumer Access

IMPROVE PROGRAM OPERATIONS

Improve Efficiency, Effectiveness
Reduce Fraud and Abuse Vulnerability
Increase Coordination
Improve Controls
Increase Compliance
Improve Reporting

SAVE TAXPAYERS MONEY

Capture Recoveries
Document Savings

ENFORCE LAWS

Convict Criminals
Exclude Bad Providers
Settle Civil Judgments

PROVIDE GUIDANCE

Issue Advisory Opinions
Propose Safe Harbors
Establish Corporate Integrity Plans

Measuring Qualitative OIG Impact
Definition of Terms

Types of Impact:

A. Consumer Protection: Impact which benefits the consumers of the Department's services in one of the following ways:

1. ***Increase Consumer Safety*:** Following OIG recommendations, ACF took actions to ensure a healthier and safer child care environment.
2. ***Improve Quality Care*:** As a result of OIG work, PHS has undertaken efforts to examine mis-medication among the elderly.
3. ***Increase Consumer Access*:** In response to an OIG report, HRSA's Bone Marrow Donor registry improved contracting to recruit and retain more minority donors.

***B. Improve Program Operations*:** Impact which results in improved program operations in one of the following ways:

1. ***Improve Efficiency, Effectiveness*:** OCSE is using OIG reports on paternity establishment to design technical assistance documents and model forms to facilitate replication of best practices in paternity establishment by child support agencies.
2. ***Reduce Fraud and Abuse Vulnerability*:** Following OIG recommendations HCFA implemented a new policy to facilitate the Medicare beneficiary complaint process.
3. ***Increase Coordination*:** In response to OIG recommendations, AoA and the USDA have engaged in cooperative efforts to increase meal service delivery to the elderly without increasing Federal or State expenditures.
4. ***Improve Controls*:** In response to an OIG report, Texas issued guidance to child placing agencies on meeting licensing standards for foster care homes and has increased monitoring of the homes used by child placing agencies.
5. ***Increase Compliance*:** Through the development of performance measures, recommended by OIG, AoA will be able to meet the congressional mandate to report on project outcomes and to compare individual projects.
6. ***Improve Reporting*:** Based on OIG findings, HRSA undertook efforts to improve hospital reporting of adverse actions taken against doctors.

POTENTIAL IMPACT STATEMENT (Example) [Completed by the region and submitted with the design, working draft, and draft to the Review Team]		
ISSUE	**POTENTIAL ACTION**	**POTENTIAL IMPLICATIONS**
Head Start/Child Care Collaboration	As a result of work in this issue area, OIG will assist the Department in their efforts to facilitate collaboration between the Head Start and Child Care programs to provide wrap-around services.	***Increase Coordination Improve Efficiency and Effectiveness:*** Through increased Head Start/Child Care collaboration, HHS will be able to serve the child care needs of families more efficiently. Increase Consumer Access: Through increase availability of wrap-around services, families will be better able to access quality child care services during their working hours.

ANTICIPATED IMPACT STATEMENT (Example) [Completed by the region when a final report is issued]		
REPORT AND IMPACT	**ANTICIPATED ACTION**	**ANTICIPATED IMPLICATIONS**
Grantees & Providers Delinquent in Child Support Department will take action to ensure that child support obligors receiving Department funds are current in their child support payments.	***Practice Change*** As a result of our report that identified HHS grantees and providers who owed some $21.5 million in back child support, the Department will implement a plan to ensure that no individual receiving HHS funds is in arrears in their child support.	***Increase Consumer Access*** ***Increase Compliance*** As a result of the Department's efforts to ensure that individuals receiving HHS funds are current in their child support payments, the children of these obligors will receive the support they are due through the IV-D system.
State Child Care Certificate System: An Early Assessment of Vulnerabilities and Barriers Department will provide parents with more information to choose quality child care providers.	***Practice Change*** As a result of our report describing a lack of information available to consumers choosing child care providers, the Administration for Children and Families will develop a guide to assist parents to select quality child care providers and a brochure for states on improving consumer education to parents.	***Increase Consumer Access*** Parents will have more information available to them to make informed choices in selecting quality child care providers for their children.
National Marrow Donor Registry: Progress in Minority Recruitment HRSA Bone Marrow Donor Registry will improve contracting to recruit and retain more minority donors.	***Policy Change*** In response to our recommendations, HRSA will require donor centers and recruitment groups to meet performance indicators in recruiting and retaining donors from racial and ethnic minority groups. It will also phase out inefficient cost reimbursement contracts and tie payment to donor center performance.	***Increase Consumer Access*** ***Improve Controls*** ***Improve Efficiency and Effectiveness*** More minorities will be able to receive bone marrow treatments for conditions such as certain leukemia and other cancers.

ACTUAL IMPACT STATEMENT (Example) [Completed by the region when actions are implemented after the final report is issued]		
REPORT AND IMPACT	**ACTION TAKEN**	**IMPLICATIONS**
Grantees & Providers Delinquent in Child Support Department takes action to ensure that child support obligors receiving Department funds are current in their child support payments.	***Practice Change*** As a result of our report that identified HHS grantees and providers who owed some $21.5 million in back child support, the Department has established agency action plans to ensure that no individual receiving HHS funds is in arrears in their child support. **Source:**	***Increase Consumer Access Increase Compliance*** As a result of the Department's efforts to ensure that individuals receiving HHS funds are current in their child support payments, the children of these obligors will receive the support they are due through the IV-D system.
State Child Care Certificate System: An Early Assessment of Vulnerabilities and Barriers Department provides parents with more information to choose quality child care providers.	***Practice Change*** As a result of our report describing a lack of information available to consumers choosing child care providers, the Administration for Children and Families developed a guide to assist parents to select quality child care providers and a brochure for states on improving consumer education to parents. **Source:**	***Increase Consumer Access*** Parents will have more information available to them to make informed choices in selecting quality child care providers for their children.

National Marrow Donor Registry: Progress in Minority Recruitment HRSA Bone Marrow Donor Registry improves contracting to recruit and retain more minority donors.	***Policy Change*** Based in significant part on our recommendations, HRSA's new contract to operate the registry requires that donor centers and recruitment groups meet performance indicators in recruiting and retaining donors from racial and ethnic minority groups. It is phasing out inefficient cost reimbursement contracts and will tie payment to donor center performance. **Source:**	***Increase Consumer Access*** ***Improve Controls*** ***Improve Efficiency and Effectiveness*** More minorities will be able to receive bone marrow treatments for conditions such as certain leukemia and other cancers.

Checklist for Developing Impact Oriented Work Plan Proposals

I. Environmental Items: What's Happening and Who Cares?

OIG Mission

- G Do we have legal authority to review the issue?
  - F HHS dollars involved?
  - F Oversight/management issue?
- G Consistent with the OIG mission?
- G Consistent with the OEI mission?

Audience

- G HHS primary and secondary audience(s)?
- G Audience(s) interested in the study idea?
- G Did the idea originate from an HHS program official?
  - F Formal or informal request?

Timeliness

- G Best time to conduct an inspection on this issue?
- G Upcoming programmatic changes on the horizon?
- G Related legislative activity?
- G Does the issue address OEI, OIG, HHS or congressional priorities?
- G Is the issue "ripe?"

Relationship to Other Work: Duplicative or Complementary?

- G Prior OEI reports?
- G Prior or ongoing work planning proposals?
- G Related work?
  - F Office of Audit Services
  - F OIG investigative activities
  - F Office of Counsel to the Inspector General/compliance activities

- **F** GAO
- **F** ASPE grants
- **F** Operating division research/grants
- **F** Private research organizations
- **F** Industry

G How does the issue expand on or duplicate work by these groups?

II. Focusing the Proposal: What is the question to be answered? How are we going to get our data?

The Problem

- What is the specific question?
- Is it solvable?

Program Background

- Magnitude or significance of the program or issue?
  - Level of program expenditures?
  - Extent of the program's impact on the public?
  - Extent to which the beneficiaries are impacted?
  - Importance to the mission of HHS?
  - Program integrity or material weakness?
  - Vulnerability to fraud and abuse?
  - Emerging issue?
  - Persistent operational or management problem?
- Program structure?
- If a request, do you have additional background?
- Relevant statutes, regulations and policy guidance?
- Agency that administers the program?
- How is the program administered?
  - Direct Federal?
  - Federal/State?
  - Grants?
- Program funding structure?

Methods

- Sufficiently narrow scope with a manageable number of objectives?
- An effective methodology to answer the study questions?
- Reasonably accessible data to answer the study questions?
- Significant methodological constraints, limitations or concerns about data reliability in answering the study questions?
- Is the data "credible?"
- Are the methods designed to produce a timely OEI product?

III. Expected Impact: What is the potential outcome of the report?

Types

- Program recommendations?
  - Monetary?
  - Programmatic?
- Impact on beneficiaries?
- Brings new data to the attention of decision makers?
- Describes the scope or extent of a problem?
- Will audience use information from this inspection?
- Likelihood that agency/HHS/Congress will take action to solve the identified problems?

APPENDIX E - Start Notice - Example

[USE OIG MEMORANDUM PAPER]

Date: [DATE]

From: [NAME]

Subject: Planned [Month] Start of New Inspection: [Title of Inspection], [OEI Control Number]

To: Audit Liaison, [Name]

Assignment: To examine effective State and county initiatives to meet the maintenance of effort requirement of the Job Opportunities and Basic Skills Training (JOBS) program.

OIG-OEI Headquarters' and/or Region: Region [Number] will lead the project with the assistance from [whomever is assisting].

Background and General Description of Work: The JOBS program prohibits using JOBS funds to supplant non-Federal funds for existing services and activities. JOBS [rest of paragraph deleted].

This study will examine how States are identifying and utilizing existing services and activities.

Where Work Will Be Done: Work will be done in a sample of States and counties.

Program Specialist: [Name]

cc:
DIG - OAS
DIG - OI
OEA
Region [Number]

APPENDIX F - Technical Support Staff

Requests for Technical Support Staff (TSS) assistance should be via electronic mail. Send requests for data assistance to the TSS Director and requests for statistical assistance to the TSS Statistician, with a copy to the Program Specialist and the appropriate PED Director.

This requirement for written request does not prevent informal discussion between TSS and inspection team members. Team Leaders and members should consult with TSS members as needed. However, once the Team Leader decides what service or information is required, he or she must send a written request to TSS and the appropriate Program Specialist.

Team Leaders should request TSS assistance as soon as possible in the inspection process to alleviate potential delays. The date of receipt of the written request will constitute the start date for the work undertaken by the TSS members.

While no specific format is required for requesting TSS assistance, the Team Leader should include the following, if possible.

- inspection number,
- title of inspection,
- Team Leader,
- Project Leader,
- Program Specialist,
- approximate due date for the request, and
- description of the work requested (be as specific as possible).

This process will help TSS manage its workload and provide a record for both TSS and the inspection work paper files.

APPENDIX G - Material Weakness

DEFINITION OF MATERIAL WEAKNESS

A material weakness is a specific instance of noncompliance with the Federal Managers' Financial Integrity Act (FMFIA) of sufficient importance to be reported to the President and the Congress. Such weaknesses would significantly impair the fulfillment of an agency component's mission; deprive the public of needed services; violate statutory or regulatory requirements; significantly weaken safeguards against waste, loss, unauthorized use or "misappropriation of funds, property, or other assets; or result in a conflict of interest."

Many factors must be considered in deciding if a weakness should be classified as material. From the departmental standpoint, the key factors that must be evaluated are listed below. Generally any positive response to any question should alert the appropriate Internal Controls Officer that OEI should classify the weakness as a "material weakness" for purposes of reporting in the Secretary's Annual FMFIA Report to the President and the Congress unless his/her professional judgment can support a different decision.

1. Does the weakness significantly impair the fulfillment of an OPDIV/STAFFDIV agency mission?

2. Does the weakness deprive the public of needed services?

3. Does the weakness violate statutory or regulatory requirement?

4. Does the weakness significantly affect the safeguards against waste, loss, unauthorized use of funds, property, or other resources?

5. Does the weakness result in a conflict of interest?

6. Is the weakness of high political sensitivity such that it could result in embarrassment to the Department

7. Is the weakness a crosscutting weakness that indicates major systemic problems?

8. Is the real or potential dollar loss associated with the weakness of significant magnitude to affect judgment in decision-making?

9. Is the weakness so important that it otherwise warrants reporting to the President and the Congress?

PROCEDURE TO FOLLOW

When an issue is identified as a potential material weakness, the following steps should be taken.

1. The regional office and Program Specialist responsible for the inspection will prepare a short, self-contained draft memo that outlines the material weakness and the reasons for this designation based on OMB criteria. The memo goes to the appropriate PED Staff Director.

2. The PED Staff Director will discuss the material weakness with the Office of Audit Services prior to briefing the DIG to ensure the appropriateness of the material designation.

3. The PED Staff Director will submit the draft memo to the DIG for review. The DIG will decide whether the finding should be identified as material weakness. On occasion, the PED Staff Director will meet with the DIG to discuss the determination. It is the Program Specialist and PED Staff Director's joint responsibility to brief and defend the decision.

4. After the DIG and OAS agree that the finding is a material weakness, the memo is prepared in final. The memo is then sent to the DIG, and OAS for signature. Then the memo is forwarded to the head of the program being reviewed and the Management Oversight Council with copies to the OPDIV's Internal Control Officer. Most often, this memo should precede the draft report.

5. The OPDIV is invited to discuss the memo with OEI.

6. Then, if OEI staff continues to believe that a material weakness exists when the draft report is prepared, do the following:

    - Clearly indicate at the beginning of the report that the finding is material and state our reasons.

    - Specifically state that OEI should report the finding to the President and the Congress and that a corrective action plan should be developed. The OPDIV's response to our draft report should include their concurrence or nonconcurrence, not only with the finding, but also with the materiality of the finding.

- Include a detailed corrective action plan with specific steps the OPDIV will take to correct the weakness and anticipated dates for implementing the changes.

The cover memo transmitting the report should also request a direct and specific response to the materiality of the finding. The language in our report ***must*** leave no doubt that OEI has identified what we believe is a material weakness. Suggested language could be as follows:

> We believe that [finding] is not in compliance with the FMFIA, Public Law 97-255, and should be reported as a material weakness through the Secretary to the President and the Congress in accordance with the Office of Management and Budget Circular A-123. We recommend that the Operating Division report this material weakness to the Secretary and start developing and implementing a corrective action plan.

Both the OPDIV's Internal Control Officer and the Management Oversight Council should always receive a copy of every report in which OEI has identified a material weakness.

7. The OPDIV must respond to our draft report regarding their concurrence or nonconcurrence with the materiality of the weakness. If they concur, they should also describe their intended corrective actions, a schedule for corrective action, and an explanation of how their actions will correct the problem. OEI staff should incorporate their response into the Findings section of our final report.

QUARTERLY FOLLOW-UP

The PED Staff Directors will send the headquarters OAS a consolidated list of all material weaknesses identified on OEI reports once each quarter. The list will include those weaknesses that have not been corrected and a detailed status report on the specific steps that have been taken to correct the problem. Each PED Staff Director is responsible for follow-up and providing the necessary information to OEI senior management, including the region, on these items as with other recommendations made in our reports.

APPENDIX H - Report Covers and Acknowledgments

NOTE: Titles should be entered with Initial Caps
Title Page is the Same as the Cover
Print 2 copies of Cover Page

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Working DRAFT

[Type Report Title in Initial Caps]

JANET REHNQUIST
Inspector General

MONTH YEAR
OEI-00-00-00000

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

[Type Report Title in Initial Caps]

JANET REHNQUIST - INSPECTOR GENERAL

NOTICE - THIS DRAFT RESTRICTED TO OFFICIAL USE

This document is a draft report of the Office of Inspector General and is subject to revision; therefore, recipients of this draft should not disclose its contents for purposes other than for official review and comment under any circumstances. This draft and all copies thereof remain the property of, and must be returned on demand to, the Office of Inspector General.

MONTH YEAR **OEI-00-00-00000**

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

[Type Report Title in Initial Caps]

JANET REHNQUIST
Inspector General

MONTH YEAR
OEI-00-00-00000

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

JANET REHNQUIST - INSPECTOR GENERAL

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JANET REHNQUIST
Inspector General

MONTH YEAR
OEI-00-00-00000

DECEMBER 2001 **OEI-07-00-00580**

OFFICE OF INSPECTOR GENERAL

http://www.oig.hhs.gov/

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended by Public Law 100-504, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG

sanctions to the health care community, and issues fraud alerts and other industry guidance.

ACKNOWLEDGMENTS

This report was prepared under the direction of (Name), Regional Inspector General for Evaluation and Inspections in the (City) Regional Office and (Name), Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

(Name), *Team Leader*
(Name), *Project Leader*
(Name), *Program Analyst*
(Name), *Program Specialist*
(Name), *Director,*
Public Health and Human Services Branch

Technical Assistance

(Name), *Program Analyst, (City)*
(Name), *Mathematical Statistician (City)*

[DELETE THE FOLLOWING IF A DRAFT REPORT]

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Public Affairs office at (202) 619-1343.

Reports are also available on the World Wide Web at our home page address:

http://www.oig.hhs.gov/

APPENDIX I - Guidance for and Samples of Transmittal Memoranda, Related Documents, and Checklist

WORKING DRAFT REPORT– (E-Mail)

DRAFT REPORT PACKAGE TO REVIEW TEAM – (E-Mail)

DRAFT REPORT PACKAGE FOR IG APPROVAL– (Express Mail)

Note: Refer to the check list on page I-13 for other items that should be included in the Draft report package.

FINAL REPORT PACKAGE TO REVIEW TEAM – (E-Mail)

FINAL REPORT PACKAGE FOR IG APPROVAL– (Express Mail)

Note: Refer to the check list on page I-20 for other items that should be included in the Final report package.

Referring Memorandum
Working Draft Report to the Review Team

[USE OIG OR REGIONAL OFFICE MEMORANDUM]

[DATE]

[NAME]
Regional Inspector General for
  Evaluation and Inspections

OIG Working Draft Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME]
Deputy Inspector General for
  Evaluation and Inspections

Attached is the working draft inspection report on. . . .

If you or your staff have any questions or comments, please call me or [PROJECT LEADER] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachment

cc:
[NAME], Director, Regional Operations
[NAME], Appropriate PED Staff Director
[NAME], Program Specialist
[NAME], Director, Technical Support Staff
[NAME], Secretary to the DIG
[NAME], Special Assistant to the DIG
[NAME], Program Analyst, POD (cover memo only)

NOTE: Regions may transmit working drafts to Review Teams by e-mail. In such instances, the e-mail message will serve as the referring memorandum.

Referring Memorandum
Draft Report to the Review Team

[USE OIG OR REGIONAL OFFICE MEMORANDUM]

[DATE]

[NAME]
Regional Inspector General for
Evaluation and Inspections

OIG Draft Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME]
Deputy Inspector General for
Evaluation and Inspections

Attached is the draft inspection report on . . . , the appropriate transmittal memoranda and the morning report.

If you or your staff have any questions or comments, please call me or [PROJECT LEADER] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachments

cc:
[NAME], Director, Regional Operations
[NAME], Appropriate PED Staff Director
[NAME], Program Specialist
[NAME], Director, Technical Support Staff
[NAME], Secretary to the DIG
[NAME], Special Assistant to the DIG
[NAME], Program Analyst, POD (cover memo only)

NOTE: Regions may transmit working drafts to Review Teams by e-mail. In such instances, the e-mail message will serve as the referring memorandum.

Transmittal to OPDIV/STAFFDIV
Draft Report For IG Approval

[USE WHITE BOND PAPER]

[INSPECTOR GENERAL'S NAME]
Inspector General

OIG Draft Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

This report follows up our prior work on validating the accuracy of physicians' credentials. This is an on-going concern, since credentialing information is used as part of the Centers for Medicare & Medicaid Services Unique Physician Identification Number (UPIN) data file.

Our inspection revealed that. . . .

We recommend that. . . .

Would you please send us your comments on the draft report within 45 days. If you have any questions about this report, please do not hesitate to call me or [NAME], Deputy Inspector General for Evaluation and Inspections, or have your staff contact [APPROPRIATE PED STAFF DIRECTOR] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachment

cc:
[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

Transmittal to OPDIV/STAFFDIV
Draft Report For IG Approval

[USE WHITE BOND PAPER]

[INSPECTOR GENERAL'S NAME]
Inspector General

OIG Draft Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

This report follows up our prior work on validating the accuracy of physicians' credentials. This is an on-going concern, since credentialing information is used as part of the Centers for Medicare & Medicaid Services Unique Physician Identification Number (UPIN) data file.

Our inspection revealed that. . . .

We recommend that. . . .

Would you please send us your comments on the draft report within 45 days. If you have any questions about this report, please do not hesitate to call me or [NAME], Deputy Inspector General for Evaluation and Inspections, or have your staff contact [APPROPRIATE PED STAFF DIRECTOR] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachment

Transmittal to One OPDIV/STAFFDIV for Comment with an Information Copy to Multiple OPDIVs/STAFFDIVs– Draft Report For IG Approval

[USE WHITE BOND PAPER]

[INSPECTOR GENERAL'S NAME]
Inspector General

OIG Draft Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

This report follows up our prior work on validating the accuracy of physicians' credentials. This is an on-going concern, since credentialing information is used as part of the Centers for Medicare & Medicaid Services Unique Physician Identification Number (UPIN) data file.

Our inspection revealed that. . . .

We recommend that. . . .

Would you please send us your comments on the draft report within 45 days. If you have any questions about this report, please call me or [NAME], Deputy Inspector General for Evaluation and Inspections, or have your staff contact [APPROPRIATE PED STAFF DIRECTOR] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachment

cc:
[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

Transmittal to Multiple OPDIVs/STAFFDIVs for Comment with an Information Copy to Multiple OPDIVs/STAFFDIVs– Draft Report For IG Approval

[USE WHITE BOND PAPER]

[INSPECTOR GENERAL'S NAME]
[TITLE]

OIG Draft Report: ["TITLE"], [OEI INSPECTION NUMBER]

See Attached Addressees List

This report follows up our prior work on validating the accuracy of physicians' credentials. This is an on-going concern, since credentialing information is used as part of the Centers for Medicare & Medicaid Services Unique Physician Identification Number (UPIN) data file.

Our inspection revealed that. . . .

We recommend that. . . .

We would appreciate receiving your comments on the draft report within 45 days of the date of this memorandum. If you have any questions about this report, please do not hesitate to call me or [NAME], Deputy Inspector General for Evaluation and Inspections, or have your staff contact [APPROPRIATE PED STAFF DIRECTOR] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachment

Second Page of Transmittal to Multiple OPDIVs/STAFFDIVs

[USE WHITE BOND PAPER]

Addressees:

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

cc:
[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

Note: If the transmittal memo is not lengthy, it may fit on one page. If so, change the TO line to "See Addressees Below" instead of "See Attached Addresses List" and list the Addressees and cc's two lines below the word "Attachment."

EXAMPLE

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Memorandum

Date: March 25, 2002

From: Janet Rehnquist
Inspector General

Subject: OIG Draft Report: "Workplace Violence: Perceptions and Experiences of Local Public Assistance and Child Support Enforcement Staff and Managers," OEI-06-98-00044

To: Wade F. Horn, Ph.D.
Assistant Secretary for
Children and Families

This report follows up our prior report on workplace violence in local public assistance and child support enforcement offices. The issue emerged as a concern during our inspection of State efforts to gain Temporary Assistance for Needy Families client cooperation with child support enforcement.

We found that a majority of public assistance and child support local office administrators we surveyed have had reason to fear for the safety of workers in their offices. While actual reported violence is rare, some incidents have occurred. Staff report incidents of threatened violence including verbal abuse, bomb threats, and death threats, as well as actual violence including fighting, altercations, carrying of guns and knives, and one murder. Staff report that enforcement of public assistance program rules, and many child support enforcement actions, may trigger violent reactions, especially from clients and noncustodial parents with violent histories or mental, emotional, or substance abuse problems. While most local offices appear to utilize security measures, some staff express concern that their offices do not have sufficient precautions in place. The Administration for Children and Families may wish to share this information with its State partners.

We would appreciate receiving your comments within 45 days. If you have any questions, please do not hesitate to call me or Joseph E. Vengrin, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Elise Stein at (202) 619-2686.

Attachment

cc: Bobby P. Jindal
Assistant Secretary for
Planning and Evaluation

Morning Report
Draft Report For IG Approval

[USE WHITE BOND PAPER]

Morning Mail: ___Yes ___No (Check one - determined by Review Team)

Title: (Report Title - Initial Caps)

References: OEI-(number) **Contact:** [APPROPRIATE PED STAFF DIRECTOR]
(AREA CODE) [TELEPHONE NUMBER]

The OIG plans to issue a draft report on the role of clinical trial web sites in fostering informed consent and the role of institutional review boards in overseeing the information on these web sites. Clinical trial web sites are emerging as an important recruitment strategy and show promise as a means of fostering informed consent. However, these web sites do not take full advantage of their potential to foster informed consent. Some web sites provide inaccurate information about the clinical trial process, exclude key information in trial listings, and fail to disclose policies that address the use of personal information that is collected by the web site.

The OIG recommends that FDA and OHRP jointly provide further guidance to institutional review boards and encourage clinical trial web sites to undergo periodic review by independent bodies.

The Review Team will determine if the report is of interest to the Deputy Secretary. In such cases, we must state why in the morning report. The OIG/ES provides a 48-hour advance notice of the anticipated release of the report to OS/ES and the Deputy Secretary. The morning report would begin with

"The OIG plans to issue a draft report on [subject matter] . . . ."

At the end of the morning report, include the following statement,

"This report is significant because it . . . "

If we also believe the report is of interest to the Secretary, add the following statement at the end of the morning report,

"The OIG recommends it be sent to the Secretary."

Adding the statement means the Secretary will receive the advance notice of the release of the report, it does not mean he will receive the report.

[Note: The body of the morning report generally should not exceed more than 8 - 10 lines. To achieve this standard, the findings and recommendations may have to be summarized].

Referring Memorandum
Draft Report for IG Approval

[USE OIG OR REGIONAL OFFICE MEMORANDUM]

[DATE]

[NAME]
Regional Inspector General for
Evaluation and Inspections

OIG Draft Report: ["OEI INSPECTION TITLE,"] [REPORT NUMBER]

[NAME]
Deputy Inspector General for
Evaluation and Inspections

Attached is the subject draft inspection report, the appropriate transmittal memorandum, and the morning report.

The inspection was conducted in accordance with OEI procedures and the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency. I have reviewed the report and supporting documents and certify that it is ready for the Inspector General's signature and release.

[NAME OF PROGRAM SPECIALIST] notified us that this report is ready for the Inspector General's approval. We forwarded 25 copies of the report and appropriate hard copy and [diskette or CD] files to the Policy and Oversight Division.

If you have any questions or comments, please contact me or [NAME OF TEAM LEADER] at [(AREA CODE)] [PHONE NUMBER].

Attachments

cc:
[NAME], Director, Regional Operations
[NAME], PED Staff Director
[NAME], Program Specialist
[NAME], Director, TSS
[NAME], Program Analyst, POD (cover memo only)

[NAME], Team Leader, Region [NUMBER]

Checklist For Submitting Draft Reports to Headquarters

Draft Report

For IG Approval

REPORT TITLE#: _____

_____

_____

CHECK (√) EACH ITEM WHEN COMPLETED

____ 25 copies of report(s) to Washington (unstapled, no blue back cover)
____ 10 copies of report(s) (stapled, with blue back cover) to

____ Washington (Discretionary Studies)

or

____ Baltimore (Health Care Studies)

____ 2 camera-ready copies of report(s)
____ A 3-1/2" diskette or CD containing:

- ____ Memo to OPDIV(s)
- ____ Letter to outside agency(ies) (If requesting agency comments)
- ____ Morning report

____ A hard copy of documents on the diskette or CD

____ A copy of transmittals, report(s), and a morning report to:

- ____ Joseph Vengrin, DIG
- ____ Debra Robinson, Director, Regional Operations
- ____ Elise Stein, PED Staff Director (Discretionary Studies)

or

- ____ Stuart Wright, PED Staff Director (Health Care Studies)
- ____ Program Specialist
- ____ Brian Ritchie, Director, TSS

SUBMITTED BY: _____ DATE SUBMITTED: _____

Referring Memorandum
Final Report to the Review Team

[USE OIG OR REGIONAL OFFICE MEMORANDUM]

[DATE]

[NAME]
Regional Inspector General for
Evaluation and Inspections

OIG Final Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME]
Deputy Inspector General for
Evaluation and Inspections

Attached is the subject final inspection report on . . . , the appropriate transmittal memoranda, and the morning report.

If you or your staff have any questions or comments, please call me or [PROJECT LEADER] at [(AREA CODE)] [TELEPHONE NUMBER].

Attachments

cc:

[NAME], Director, Regional Operations
[NAME], Appropriate PED Staff Director
[NAME], Program Specialist
[NAME], Director, Technical Support Staff
[NAME], Secretary to the DIG
[NAME], Special Assistant to the DIG
[NAME], Program Analyst, POD (cover memo only)

Transmittal to OPDIV/STAFFDIV
Final Report for IG Approval

[USE WHITE BOND PAPER]

[INSPECTOR GENERAL'S NAME]
[TITLE]

OIG Final Report: ["TITLE"], [OEI INSPECTION NUMBER]

[NAME OF OPDIV/STAFFDIV HEAD]
[TITLE]

This inspection is one of a series we have conducted to assess Medicare beneficiaries' understanding of their benefits and experiences in dealing with the Medicare program.

Our inspection revealed that . . .

We recommended that . . .

Would you please send us your action plan within 60 days. If you have any questions, please do not hesitate to call me or [NAME], Deputy Inspector General for Evaluation and Inspections, or have your staff contact [APPROPRIATE PED STAFF DIRECTOR] at [(AREA CODE)] [(TELEPHONE NUMBER)].

Attachment

[Note: If no recommendations are made in the report and the report is being issued directly in final, the last paragraph should be replaced with the following:]

This report is being issued directly in final since it contains no recommendations. You are not required to comment on the report. However, if you have any questions or comments, please do not hesitate to call me or [NAME], Deputy Inspector General for Evaluation and Inspections, or have your staff contact [APPROPRIATE PED STAFF DIRECTOR] at [(AREA CODE)] [TELEPHONE NUMBER].

EXAMPLE

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Memorandum

Date: January 25, 2002

From: Janet Rehnquist
Inspector General

Subject: OIG Final Report: "Medicare Administrative Appeals, The Potential Impact of BIPA," OEI-04-01-00290

To: See Addressees Below

This study was performed to ascertain the impact of amendments made by the Benefits Improvement and Protection Act of 2000 (BIPA) to the Medicare appeals system. It is a companion report to an earlier report on the administrative appeals process.

The amendments, which go into effect on October 1, 2002, will negatively affect the already backlogged and overwhelmed appeals process. Short time frames called for by BIPA could result in appeal cases being prematurely accelerated to higher, more expensive levels of appeal. This could reduce the quality of decisions and adversely affect financing and administration of the Medicare program.

This report should be considered in light of our earlier report which details fundamental weaknesses in the Medicare appeals process, many of which will be exacerbated by the implementation of the BIPA amendments. We offer recommendations to restructure and improve the administration of the system, including establishment of an administrative appeals process that is dedicated to Medicare. We also suggest adjustments to the mandated time frames. The Department generally agreed with our recommendations.

Would you please send us your action plan within 60 days. If you have any questions about this report, please do not hesitate to call me or Joseph Vengrin, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Stuart Wright at (410) 786-3144.

Attachment

Addressees:

Thomas Scully Cecilia Sparks Ford

Administrator
Centers for Medicare & Medicaid Services

Chair
Departmental Appeals Board

Morning Report
Final Report for IG Approval

[USE WHITE BOND PAPER]

Morning Mail: ___Yes ___No (Check one - determined by Review Team)

Title: (Report Title, Initial Caps)

References: OEI-(number) **Contact:** [APPROPRIATE PED STAFF DIRECTOR]
[(AREA CODE)] [TELEPHONE NUMBER]

The OIG issued a final report on the impact of amendments made by the Benefits Improvement and Protection Act of 2000 (BIPA) to the Medicare appeals system. The amendments, which are to go into effect on October 1, 2002, will negatively affect the already backlogged and overwhelmed appeals process. Short time frames called for by BIPA could result in appeal cases being prematurely accelerated to higher, more expensive levels of appeal. This could reduce the quality of decisions, with adverse effects on the financing and administration of the Medicare program. The OIG offered recommendations to restructure and improve the administration of the system, including the establishment of an administrative appeals process that is dedicated to Medicare and adjustments to the mandated time frames. The Department generally agreed with our recommendations.

The Review Team will determine if the report is of interest to the Deputy Secretary. In such cases, we must state why in the morning report. The OIG/ES provides a 48-hour advance notice of the anticipated release of the report to OS/ES and the Deputy Secretary. The morning report would begin with

"The OIG plans to issue a final report on [subject matter] . . . ."

At the end of the morning report, include the following statement,

"This report is significant because it . . . "

If we also believe the report is of interest to the Secretary, add the following statement at the end of the morning report,

"The OIG recommends it be sent to the Secretary."

Adding the statement means the Secretary will receive the advance notice of the release of the report, it does not mean he will receive the report.

[Note: The body of the morning report generally should not exceed more than 8 - 10 lines. To achieve this standard, the findings and recommendations may have to be summarized.]

EXTERNAL DISTRIBUTION LIST

ASSOCIATION/ADVOCACY GROUPS
Checklist

____ The attached report will not be distributed to any associations/advocacy groups.
____ The attached report will be distributed to the following after signature:

Report Title/Number:_____

____ American Association for Home Care
____ American Association of Homes and Services for the Aging
____ American Association of Retired Persons (AARP)
____ American Clinical Laboratory Association (ACLA)*
____ American Health Care Association
____ American Hospital Association (AHA)*
____ American Medical Association (AMA)*
____ American Medical Directors Association*
____ American Public Health Association (APHA)
____ American Public Human Services Association (APHSA)
____ Association of American Medical Colleges*
____ Association of American Universities
____ Children's Defense Fund
____ Council of State Governments
____ Council on Government Relations (COGR)
____ Health Industry Distributors Association (HIDA)*
____ Health Industry Manufacturers Association (HIMA)
____ Health Insurance Association of America (HIAA)
____ Hospice Association of America
____ National Association of Attorneys General (MFCU reps)*
____ National Association of College and University Business Officers (NACUBO)
____ National Association of Home Care*
____ National Conference of State Legislatures
____ National Foster Parent Association
____ National Governors Association
____ National Head Start Association
____ National Health Care Anti-Fraud Association
____ National Health Care Association
____ National Hospice and Palliative Care Organization
____ National Medical Association*
____ Pharmaceutical Manufacturers Association (PMA)*
____ Public Citizen Health Research Group

____ Other: _____

Component:_____

By:_____
(initial of DIG or Acting)

* Organizations which have met or are scheduled to meet with the IG. Rev. 3/16/01

Referring Memorandum
Final Report to the Review Team

[USE OIG OR REGIONAL OFFICE MEMORANDUM]

[DATE]

[NAME]
Regional Inspector General for
Evaluation and Inspections

OIG Final Report: ["OEI INSPECTION TITLE,"] [REPORT NUMBER]

[NAME]
Deputy Inspector General for
Evaluation and Inspections

Attached is the subject final inspection report, the appropriate transmittal memorandum, and the morning report.

The inspection was conducted in accordance with OEI procedures and the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency. I have reviewed the report and supporting documents and certify that it is ready for the Inspector General's signature and release.

[NAME OF PROGRAM SPECIALIST] notified us that this report is ready for the Inspector General's approval. We forwarded 25 copies of the report and appropriate hard copy and (diskette or CD) files to the Policy and Oversight Division.

If you have any questions or comments, please contact me or [(NAME OF TEAM LEADER)] at [(AREA CODE)] [PHONE NUMBER].

Attachments

cc:
[NAME], Director, Regional Operations
[NAME], PED Staff Director
[NAME], Program Specialist
[NAME], Director, TSS
[NAME], Program Analyst, POD (cover memo only)

[NAME], Team Leader, Region [NUMBER]

Checklist For Submitting Final Reports to Headquarters

Final Report	For IG Approval

REPORT TITLE#: _____

CHECK (√) EACH ITEM WHEN COMPLETED

____ 25 copies of report(s) to Washington (unstapled, no blue back cover)
____ 10 copies of report(s) (stapled, with blue back cover) to:

- ____ Washington (Discretionary Studies)

or

- ____ Baltimore (Health Care Studies)

____ 2 camera-ready copies of report(s)
____ A 3-1/2" diskette or CD containing:

- ____ Memo to OPDIV(s)
- ____ Letter to outside agency(ies) (If requesting agency comments)
- ____ Morning report

____ A hard copy of documents on the diskette or CD
____ An External Distribution List
____ A copy of transmittals, report(s), and a morning report to:

- ____ Joseph Vengrin, DIG
- ____ Debra Robinson, Director, Regional Operations
- ____ Elise Stein, PED Staff Director (Discretionary Studies)

or

____ Stuart Wright, PED Staff Director (Health Care Studies)

____ Program Specialist

____ Brian Ritchie, Director, TSS

SUBMITTED BY: _____ DATE SUBMITTED: _____

APPENDIX J - Internal Distribution List

Draft Inspection Distribution List Final

Report Title/Number: _____

DATE	ADDRESSES	MEMO (# copies)	REPORT (# copies)	MORNING REPORT (# copies)	CAMERA READY COPY	√
	OPDIV/STAFFDIV: OUTSIDE AGENCY:	1 ORIGINAL FOR EACH ADDRESSEE	1 ORIGINAL FOR EACH ADDRESSEE			
	OIG/ES	1	5 (Draft) 9 (Final)	1		
	OEI DISTRIBUTION (DRAFTS AND FINALS)					
	Robinson	1	1	1		
	PED FILES (Franklin)	2	5		1	
	Holmes		1			
	Hyman	1	1	1		
	Rawdon		1	1		
	Region	2		1		
	PED [ ] Wash. or [ ] Balt.	2	1		1	
	OAS		2			
	OI		1			
	OCIG		1			
	ASPE (Rm. 447D HHH)		2			
	ASL (Rm 416G HHH)		2			
	OEI DISTRIBUTION (FINALS ONLY)					
	OMP/OEA (Judy Holtz)	1	10			

	OMP/OEI (K. Brandt & P. Radway)		2			
	ASPE/PIC (Rm. 438F HHH)		1			
	ASPA (Rm 647D HHH)		2			
	Dept. of Justice (Shelly Slade) *		1			

* Address: DOJ/Health Care Fraud Coordinator, Commercial Litigation Branch
601 D Street, NW, Rm 9030; Washington, D.C. 20530

Revised 03/30/98

APPENDIX K - Speeches to External Groups

Major National or Widely-Recognized Groups Routinely Addressed by the OIG

___ American Association for Home Care
___ American Association of Homes and Services for the Aging
___ American Association of Retired Persons (AARP)
___ American Clinical Laboratory Association (ACLA)*
___ American Health Care Association
___ American Hospital Association (AHA)*
___ American Medical Association (AMA)*
___ American Medical Directors Association*
___ American Public Health Association (APHA)
___ American Public Human Services Association (APHSA)
___ Association of American Medical Colleges*
___ Association of American Universities
___ Children's Defense Fund
___ Council of State Governments
___ Council on Government Relations (COGR)
___ Health Industry Distributors Association (HIDA)*
___ Health Industry Manufacturers Association (HIMA)
___ Health Insurance Association of America (HIAA)
___ Hospice Association of America
___ National Association of Attorneys General (MFCU reps)*
___ National Association of College and University Business Officers (NACUBO)
___ National Association of Home Care*
___ National Conference of State Legislatures
___ National Foster Parent Association
___ National Governors Association
___ National Head Start Association
___ National Health Care Anti-Fraud Association
___ National Health Care Association
___ National Hospice and Palliative Care Organization
___ National Medical Association*
___ Pharmaceutical Manufacturers Association (PMA)*
___ Public Citizen Health Research Group
___ Other:_____

* Organizations which have met or are scheduled to meet with the IG. Rev. 3/16/01

OIG CLEARANCE FORM FOR EXTERNAL SPEECHES

TO: Deputy Inspector General for Management and Policy
SUBJECT: Request for Approval to Present an External Speech

NAME OF ORGANIZATION TO BE ADDRESSED:

STATUS OF ORGANIZATION:

[ ] Not-for-Profit Organization
[ ] For-Profit Organization

DESCRIBE NATURE OF SPEECH:

DATE, TIME AND LOCATION OF SPEECH:

ESTIMATED SIZE AND COMPOSITION OF AUDIENCE:

ADDITIONAL INFORMATION (e.g., outside reimbursement) (OPTIONAL):

SIGN-OFFS:

REQUESTING EMPLOYEE _____

- OIG Component _____
- Telephone Number _____

DIRECT SUPERVISOR _____

DEPUTY INSPECTOR GENERAL _____

APPENDIX L - Sample Work Paper File System

OEI work papers should contain all supporting evidence on which inspection reports are based. Well-organized work papers logically links related evidence, and allow inspection teams to establish a linkage from report facts, findings, conclusions, and recommendations to the supporting evidence in the work papers. The ability of inspection teams to support and defend report messages is critical to OEI's integrity, and the use of OEI reports to improve HHS policy and operations.

Team Leaders should establish work paper file system at the beginning of an inspection. OEIs procedures allow considerable flexibility in the system used as long as it meets the six Principles discussed earlier in the Procedures Manual (see page 48). Team Leaders may test the system they choose in a variety of ways. One test is to determine if a person, who is unfamiliar with the inspection, can readily trace all facts, used to support findings and recommendations in the report, back to the supporting evidence in the work papers.

Generally, the work paper system should be tailored to a specific inspection, considering such factors as work paper standards, scope of work, methods, participants, types of work papers generated, analysis done, etc. One sample work paper system that Team Leaders may use as a model is described below.

TYPES OF WORK PAPERS

OEI work papers take a wide variety of forms. The following list illustrates some of the various forms of work papers used by OEI.

- Hand written or typed records of discussion with agency staffs, experts, and others on inspection issues, questions, and background.
- Electronic data files or extracts from such files.
- Photo copies of agency records, documents, and correspondence.
- Analysis by Program Analysts.
- Mail, telephone, or in person survey responses and any related summaries of such responses.
- Analytical work sheets, schedules, and summaries prepared on computer diskette or CD.
- Photographs and other records to document observations on program operations.
- Other.

Electronic or Automated Work Papers

Electronic or automated work papers may require special attention for protection, use, and retention. Generally, Team Leader should include copies of electronic data files (on a diskette or CD) in the Primary File. Label each diskette or CD with the inspection name and inspection number, and attach a short, narrative description of its contents. A printout of the diskette or CD directory may also be included in the work paper files. Place a "write protecting" tab on the diskette to prevent unintentional destruction. File the diskette or CD, description, and the directory of the files it contains in thee Table of Contents and Schedule Section (e.g., category
P-1-C).

Likewise, the Team Leader should retain a copy of databases and specific queries for any automated database management systems used to support and develop report findings in the inspection report. Without this information, the logic of the query and the resulting observations may be difficult, or impossible, to recreate at a future date. Typically such supporting work papers are filed in the Data Collection and Analysis section (e.g., file category P-4-F).

Summary Work Papers

OEI does not require the Team Leader to systematically summarize the data collected and analyzed for each inspection issue. However, summaries are a useful tool in many instances such as helping to describe the result of analysis, particularly when large data bases are sources of evidence, and when complicated statistical procedures are used.

Summaries may take a variety of forms, including narrative presentations, tabulations, schedules, charts or grafts, and calculations. However, they should always simplify the message that we want to communicate to our report advances. Further, to aid the validation process, summaries should identify sources of information, and should be cross-indexed to the supporting evidence in the work papers. All summary documents become part of the work paper file.

GENERAL WORK PAPER STANDARD

In collecting, generating, and organizing work papers, the Team Leader should apply the following general standards. Application of the standards enhances use of work papers, which in turn will help ensure creditable support for OEA reports.

- Work papers should be complete and accurate to support findings and recommendations and to document activities performed during an inspection.

- Work papers should be clear and understandable, reflecting the purpose of specific work papers, and the nature and scope of work done. Conciseness is important, however, do not sacrifice clarity and completeness for the sake of brevity.

- Work papers should be titled and prepared in a neat and legible manner. Handwritten work papers are acceptable.

- Work papers should be relevant to the purpose and issues included in the inspection.

RETENTION PERIOD

- Retain the Primary File in the regional office for at least 3 years after the release of the final report, when we can send it to the Federal Records Center.

- Send the Secondary File to the Federal Records Center 6 months after the release of the final report.

- The Primary and Secondary files may be destroyed after 5 years. However, the RIG may extend the retention period depending on specific circumstances associated with an inspection.

Team Leaders should collect, organize, and retain all work papers generated by support regions. Generally, the Project Leader in a support region should send all work papers to the Team Leader when inspection work has been completed. The Team Leader should organize, use, and retain such work papers in the same manner as those collected by the lead region.

ORGANIZATION OF WORK PAPER FILES

Organize work papers into two broad categories – Primary File(s) and Secondary File(s). Depending on the particular inspection, Team Leaders may conclude that all file categories are not needed or desired. The Team Leader determines the appropriate work paper filing system and coordinates the decision with Regional supervisors.

Primary File

The Primary File contains essential supporting documentation for the inspection report. It should be complete and logically organized so that (1) links related material in the work papers, and (2) links report facts, findings, conclusions, and recommendations to appropriate supporting evidence (documentation, interviews, observations, and analysis) contained in the work papers.

The primary file is organized into the following six subdivisions.

(1) Table of Contents,
(2) Pre inspection research,
(3) Inspection Design,
(4) Data collection and Analysis,

(5) Report, and
(6) Follow-up and Inspection Impact.

Table of Contents and Schedule (File P-1)

P-1-A The completed Work Paper File Checklist is designed to aid in the review of work papers, and validation of the report.

P-1-B The Table of Contents is a topical index for all work papers regardless of type. It should be include the contents of both the Primary and Secondary file(s).

P-1-C All Electronic data files

Research and Pre-inspection (File P-2)

P-2-A The work plan proposal and any information supporting the proposed inspection, such as request letters from the Secretary or Congress.

P-2-B Relevant background information, such as laws, regulations, related studies, funding, and program vulnerabilities and operational problems.

P-2-C Selected correspondence.

Inspection Design (File P-3)

P-3-A Inspection design, transmittal memorandum, records on discussions such as Entrance Conference, Review Team meetings, and meetings with agency staffs. Briefing material for such meetings may be filed in the Report section (P-5-A).

P-3-B Copies of data collection instrument(s), related transmittal letters, sensitivity approval documents, and respondent burden determinations. Also, include a description of the statistical methodology and sampling plan used.

Data and Analysis Section (File P-4)

P-4-A Listing of data sources (e.g., sites visited, databases used, officials interviewed) and descriptions of data analysis procedures, including those for accessing data from mainframe computer systems. Also, summaries (hardcopy and/or electronic) of all data analysis included in the report (e.g., cross tabulations, synthesis).

Report (File P-5)

P-5-A Records on Review Team Meetings, meetings with agency staffs, experts, and others, including the Exit Conference, including briefing material used.

P-5-B A copy of the released draft report and related transmittal memoranda, morning report, and other documents.

P-5-C A copy of all comments on draft reports from any organization outside the regional office. A copy of the internal and external report distribution lists for draft report (see Appendices J and I-18).

P-5-D Validated copy of the draft and final report showing cross-indexing to supporting evidence in the work papers for all facts and findings contained in the report(s). Also, the validator's review notes along with the Team Leader's action on the Validator's notes should be included.

P-5-E A copy of the final report and related transmittal memoranda and morning report, etc. Also a copy of the internal and external distribution lists for final report (see Appendices J and I-18).

P-5-F Briefing and presentation materials used for meetings such as those with the Review Team (refer to P-5-A), Exit Conference (refer to P-4-A), and other briefings.

Follow-up and Inspection Impact (File P-6)

P-6-A Records and other evidence showing responses by decision makers to our findings and recommendations, and our action on such responses, including changes to reports, follow-up inspections, spin-off products, etc.

P-6-B A record on Freedom of Information Act requests and OEI's response.

P-6-C A record of requests for data and information from other sources such as Congress, media, special interest groups, and others. The record should include OEI's response to such request.

P-6-D Records and other evidence showing action by decision makers to implement and use our findings and recommendations, including changes to legislation, regulation, program operations. Such evidence may be obtained from various sources, including managers, Program Specialist, news media, congressional record, and agency staffs. Improvements resulting from our inspections and reports should be documented in OEI's Impact Documentation System (IDS). File a copy of the IDS in this section.

Secondary File

The Secondary File usually contains bulky work papers that do not contain critical supporting evidence for facts, findings, conclusions, and recommendations presented in the report. The files frequently contain general and background information that supports the Primary Files. For example, completed data collection instruments could be included here to support summaries maintained in Primary Files. The Team Leader should purge the work paper files of any documents that are not relevant to the inspection or follow-up plans.

At the discretion of the Team Leader the secondary file may or may not contain all six work paper file sections discussed for primary files. However, typically OEI Team Leaders establish a secondary file for the following work paper sections.

- Research and Pre-inspection,
- Design, and
- Data Collection and Analysis.

The Team Leader should clearly label each work paper section that is used in the secondary file, including inspection title and number. Further, the Team Leader should prepare a table of contents for the Secondary Files, and include a copy of it in the Primary File.

General Reference File

In addition to the primary and secondary work paper files, a regional office may choose to maintain a general reference file. This file could contain key documents relevant to an inspection such as documents of key decisions that affect the scope, methods, and results of the inspection. The file could also contain documents that are deemed useful for planning future inspections and drafting work plan proposals. If documents from this file are used to support a report message, the documents should either be removed or photocopied and included in the primary file. Some examples of documents that are normally included in a general reference file are

- legislative history of programs,
- descriptions of organizations and personnel,
- statistics on appropriations and expenditures,
- studies, and other information on issues of interest to OEI, and
- Examples for techniques and process that may be useful for future inspections.

CROSS-INDEXING

Each work paper Primary File must contain a cross-indexed copy of the draft report, significant changes in the final report. The Primary file should also contain the Validators notes, and action taken by Team Leaders to resolve the Validator's questions and concerns. Cross-indexing is a process to

establish and document a necessary linkage between facts used in a report and the supporting evidence for those facts in the work papers.

Cross-indexing is a valuable tool for validating the facts used in OEI reports. It is also critical when reported facts and conclusions are challenged or questioned by reviewers and users of OEI reports. The cross-indexed report and related work papers allow applicable Program Analyst to quickly and readily find supporting evidence needed to rebut any challenges to our report message. This ability helps maintain OEI's credibility, and it instills confidence in our users.

OEI regions and Team Leaders have considerable flexibility in designing a cross-indexing scheme. Accordingly, OEI regions have adopted indexing systems that are unique to their region. Some regions use a system of numbers and/or letters to identify each work paper. The numbers and/or letters are usually placed at the top of each work paper. Where applicable, those numbers and letters are annotated in the margin of the inspection report to precisely link specific facts to the supporting evidence in the work papers. Other regions have opted to use a system of endnotes for this purpose.

The important consideration is not the type of indexing system used, but rather will it facilitate locating supporting evidence in the work papers for facts contained in OEI reports. Also, the system should be simple enough to allow a person who has no familiarity with an inspection and related work papers to trace reported facts back to the evidence and sources we relied on.

OEI's work papers are the historical records of inspection work done. In instances where the Program Analyst who did an inspection has retired or is no longer with OEI, the work paper system and the related indexing system must be sufficient for an independent person to use in responding to any challenges or questions about the inspection.

RIG Certification of Work Papers

Inspection Name: _____

Inspection Number: OEI-_____

Team Leader:_____

RIG or Designee:_____ Date:_____

Signature by the RIG or designee indicates that work papers are in order and adhere to the six principles.

FORMAT FOR PRIMARY FILE

TABLE OF CONTENTS

Inspection Title: _____

Inspection Number: _____

Work Paper Section	Box No.	File No.	Index No.	Box Location
P-1--TABLE OF CONTENTS	**P-1**	**P-1**		
	P-1	*P-1-A*		
	P-1	*P-1-B*		
	P-1	*P-1-C*		
P-2-RESEARCH AND PRE-INSPECTION	**P-1**	**P-2**		
	P-1	*P-2-A*		
	P-1	*P-2-B*		
	P-1	*P-2-C*		
P-3--INSPECTION DESIGN	**P-1**	**P-3**		
	P-1	*P-3-A*		
	P-1	*P-3-B*		
P-4--DATA AND ANALYSIS	**P-1**	**P-4**		
	P-1	*P-4-A*		
	P-1	*P-4-B*		
	P-1	*P-4-C*		
P-5--REPORT	**P-1**	**P-5**		
	P-1	*P-5-A*		
	P-1	*P-5-B*		
	P-1	*P-5-C*		
	P-1	*P-5-D*		
	P-1	*P-5-E*		
	P-1	*P-5-F*		
	P-1	*P-5-G*		

Work Paper Section	Box No.	File No.	Index No.	Box Location
P-6--FOLLOW UP	**P-1**	**P-6**		
	P-1	*P-6-A*		
	P-1	*P-6-B*		
	P-1	*P-6-C*		
	P-1	*P-6-D*		

FORMAT FOR SECONDARY FILE
TABLE OF CONTENTS

Title: _____

Number: _____

Work Paper Section	Box No.	File No.	Index No.	Box Location

Work Paper Section	Box No.	File No.	Index No.	Box Location

OEI Inspection Schedule

Inspection Name: _____

Inspection Number: _____

MILESTONE	ORIGINAL PLANNED DATE	ACTUAL DATE
1. Inspection Assigned		
2. Start Notice		
3. Pre-inspection Begins		
4. Design Conference		
5. Design to Review Team		
6. Design Approved		
7. Entrance Conference		
8. Complete Data Collection		
9. Complete Data Analysis		
10. Working Draft to Review Team		
11. Working Draft Approved		
12. Exit Conference		
13. Report Validation		
14. Draft Report Sent for Signature		
15. Draft Report Signed		
16. Final Report Sent for Signature		

17. Final Report Signed		

I have reviewed this Inspection Schedule and everything is in order.

Signed:_____ **Title:**_____ **Date:**_____

(Signature of RIG or Designee)

APPENDIX M - Data Collection Burden Certification

These procedures are intended to keep the reporting burden of respondents to a minimum while allowing needed independence and objectivity to OEI analysts in collecting and analyzing data on HHS program operations.

To assure that these important objectives are met, each inspection will be executed consistently with an approved written design. The approved design document will provide a detailed description of data needs, sources, types, collection methods, sampling, and analytical methods. Regional offices will not start the inspection phase of a study before the design and any corresponding data collection instruments are approved.

Generally, when an inspection design calls for data collection from 10 or more members of the public, the data collection instruments and resulting burden on respondents must be approved.

RESPONSIBILITIES

Inspection Team

OEI inspection teams (analyst, Project Leader, and Team Leaders) have responsibility for designing inspections and any needed data collection instruments. In doing so, they must obtain input, advice, and approval from OEI Review Team members as appropriate.

The inspection team prepares a written design for the inspection. The approved design document will provide a detailed description of data needs, sources, types, collection methods, sampling, and analytical methods. A data collection certification will be prepared for every inspection (see Attachment A).

Also, when an inspection requires a survey of 10 or more respondents, inspection teams will prepare a certification for each data collection instrument as outlined in Attachment B. In such cases, inspection teams will obtain the needed OIG certifications to document that public reporting burdens are limited.

Regional Inspectors General

The Regional Inspectors General are responsible for reviewing and approving all inspection designs and data collection instruments. The RIGs will certify that designed inspection work and the reporting burden for survey respondents are appropriate.

Further, the RIG will ensure that the completed certification documents (Attachments A, B and C) are completed and filed by the Team Leader in the official work paper file of each inspection. The RIGs cannot delegate their overall responsibility but in their absence, may delegate certification responsibilities to their Deputy Regional Inspector General.

Director of Regional Operations

The Director of Regional Operations will ensure that Regional Inspectors General and their staffs design and execute inspections which embrace the policy and procedural guidance in this memorandum.

Director, Technical Support Staff

When appropriate, the Director will assign a Technical Support member(s) to assist and advise regional inspection teams on sampling and analytical methods. Further, the TSS members will on the sampling method, size, precision, and confidence level of approved survey designs.

For each inspection design that calls for 500 or more respondents, the TSS senior Statistician will independently review data collection methods and the burden on respondents. The Statistician will then recommend modifications or approval (see Attachment C).

Director, Policy and Oversight Division

During its periodic reviews of inspection work papers, the Policy and Oversight Division will assure that survey certifications were completed, properly approved by Regional and Headquarters officials, and included in the work paper files.

The Director will also conduct an annual analysis of OEI inspection designs to assess the extent that the requirements of this procedure are met to minimize unnecessary and burdensome data collection and advise, if appropriate, on additional measures.

Deputy Inspector General for Evaluation and Inspections

The Deputy Inspector General for Evaluation and Inspections is responsible for ensuring that each inspection is appropriately designed and executed. For inspection designs calling for surveys of 500 or more respondents, the Deputy will review and certify (Attachment C) that data collection methods are appropriate, and not unnecessarily burdensome for respondents, given the particular inspection objectives and circumstances.

CERTIFICATION

The inspection team will provide a data collection certification for each inspection conducted by OEI. The certification is to be signed by the Regional Inspector General (Attachment A).

The inspection team will obtain written certification for each data collection instrument designed to survey 10 or more respondents.

The certification form, which will be signed by the Regional Inspector General, will document that the data collection instrument is appropriate for the purposes of the study, and it minimizes collection of unnecessary and burdensome data. Attachment B contains a sample Certification Form.

For each data collection instrument involving 500 or more potential respondents, three additional reviews are required. First, TSS must provide a separate written certification that the sample size, planned confidence level, precision, and expected values are mutually consistent. In addition, the Director of the Program Evaluation Division will review the data collection methods and recommend modifications or approval of the data collection. Finally, the Deputy Inspector General for Evaluation and Inspections must certify the data collection method (see Attachment C).

IMPLEMENTATION

The principles and procedures described in this memorandum are effective immediately.

Inspection methodologies calling for surveys of 10 or more respondents will be certified using the certification form in Attachment B.

Surveys of 500 or more potential respondents will also require a certification by appropriate Headquarters officials using the Certification Form in Attachment C.

The Procedures Committee will include this memorandum in the Procedures Manual and will evaluate them after one year of operation, and will recommend any changes deemed appropriate.

Attachment A

Data Collection Certification

Name of Inspection:

Number of Inspection:

No Data is being collected from the public ❑

Data is being collected from 9 or fewer respondents ❑

Give a brief description of the data used in the study and the source.

Data is being collected from 10 or more respondents ❑

If this block is checked, the data collection instrument certification form must also be completed.

(Signature of Regional Inspector General)

original is filed in work paper files
copy is sent to Program Specialist

Original is filed in work paper files **Copy is sent to Program Specialist**

Attachment B

Data Collection Instrument
CERTIFICATION

Title and Number of Inspection:

Number and Type of Respondents from whom Response Will be Solicited:
Federal ❑ **Non-Federal** ❑

Estimated Responses
Percent: **Number:**

Overall Sampling Approach (Select One)
Universe: **Purposive Sample:** **Representative Sample:**

Description of Universe:

For Purposive Samples, Describe Selection Method:

For Representative Samples,
Description of Sampling Method:

Confidence Level:
Precision at Typical Expected Values (give examples):

Estimated Burden Hours Per Response:
Estimated Total Burden Hours:

If the sample size is 499 or less the certification is complete. Otherwise, complete Attachment C and send all forms along with the design to Headquarters for further action.

REGIONAL INSPECTOR GENERAL: I certify that this survey and data collection instrument is appropriate for the purpose of this study. The survey and data collection instrument was designed to minimize collection of unnecessary data, and the reporting burden on respondents. The reporting burden is commensurate with the value of the information to be received.

(Signature of Regional Inspector General)

Attachment C

CERTIFICATION OF SURVEY METHODOLOGY
FOR OEI INSPECTION

To be completed in all cases with a sample size of 500 or more.

Title and number of inspection:

TECHNICAL SUPPORT STAFF: I certify that the sample size, planned confidence level, precision, and expected values are mutually consistent.

_____

(Signature of TSS Senior Statistician)

ASSOCIATE DIRECTOR OF THE PROGRAM EVALUATION DIVISION: I certify that this survey and data collection instrument is appropriate for the purpose of this study. The survey and data collection instrument was designed to minimize collection of unnecessary data, and the reporting burden on respondents. The reporting burden is commensurate with the value of the information to be received.

_____

(Signature of Associate Director, PED)

DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTION: I certify that the survey and data collection instrument is appropriate for the purpose of this study. The survey and data collection instrument was designed to minimize collection of unnecessary data, and the report burden on respondents. The reporting burden is commensurate with the value of the information to be received.

(Signature of DIG for OEI)

APPENDIX N - President's Council on Integrity and Efficiency Quality Standards for Inspections March 1993

Qualifications Individuals assigned to perform inspection work must collectively possess adequate professional proficiency for the task required.

Independence Individuals performing inspection work must be free from impairments that hinder objectivity. Inspectors must consistently maintain an independent, objective attitude and appearance, and shall be subject to supervisory guidance and review to preclude actual or perceived impairments or bias in conducting inspection work and presenting results.

Due Professional Care Due professional care will be used in conducting inspection work and in preparing reports of other products.

Quality Control To ensure quality and to expedite the progress of an inspection, proper supervision will be exercised from the start of an inspection to completion of the final inspection report.

Planning To ensure adequate planning, inspection work will be coordinated, researched, and designed to achieve the objectives of the inspection.

Data Collection and Analysis Information and data obtained about the organization, program, activity, or function being inspected should be consistent with inspection objectives and sufficient enough to provide a reasonable basis for reaching conclusions.

Evidence Evidence supporting inspection conclusions should be competent and relevant and lead a prudent person to the same conclusion as that of the inspectors.

Supporting Documentation All relevant information generated, obtained, and used in supporting inspections findings, conclusions, and recommendations should be retained.

Timeliness Inspectors should seek to deliver significant information to appropriate management officials in a timely manner.

Fraud and Other Illegal Acts

If during or in connection with an inspection, inspectors become aware of illegal acts, or indications of such acts, they should promptly present such information to their supervisors for review and possible referral to the appropriate investigative office.

Reporting

All inspection reports shall present factual data accurately, fairly, and objectively, and present findings and conclusions in a persuasive manner.

Follow-up

Appropriate follow-up will be performed to assure that any recommendations made to agency officials are adequately considered and appropriately addressed.

APPENDIX O - Exceptions to The Freedom of Information Act

5 U.S.C. § 552

As Amended

§
552. Public information; agency rules, opinions, orders, records, and proceedings

(b) This section does not apply to matters that are--

(1)

(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and
(B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute

(A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or
(B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information

(A) could reasonably be expected to interfere with enforcement proceedings,
(B) would deprive a person of a right to a fair trial or an impartial adjudication,
(C) could reasonably be expected to constitute an unwarranted invasion of personal

privacy,

(D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source,

(E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection. The amount of information deleted shall be indicated on the released portion of the record, unless including that indication would harm an interest protected by the exemption in this subsection under which the deletion is made. If technically feasible, the amount of the information deleted shall be indicated at the place in the record where such deletion is made.