

NUREG/CR-3601
PNL-4813
BHARC-400/83/016

Management and Organizational Assessments

A Review of Selected Organizations

Prepared by M. V. Nadel, C. M. Kerwin/BHARC

Battelle Human Affairs Research Centers

Pacific Northwest Laboratory

Prepared for
**U.S. Nuclear Regulatory
Commission**

NOTICE

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, or any of their employees, makes any warranty, expressed or implied, or assumes any legal liability of responsibility for any third party's use, or the results of such use, of any information, apparatus, product or process disclosed in this report, or represents that its use by such third party would not infringe privately owned rights.

Availability of Reference Materials Cited in NRC Publications

Most documents cited in NRC publications will be available from one of the following sources:

1. The NRC Public Document Room, 1717 H Street, N.W.
Washington, DC 20555
2. The NRC/GPO Sales Program, U.S. Nuclear Regulatory Commission,
Washington, DC 20555
3. The National Technical Information Service, Springfield, VA 22161

Although the listing that follows represents the majority of documents cited in NRC publications, it is not intended to be exhaustive.

Referenced documents available for inspection and copying for a fee from the NRC Public Document Room include NRC correspondence and internal NRC memoranda; NRC Office of Inspection and Enforcement bulletins, circulars, information notices, inspection and investigation notices; Licensee Event Reports; vendor reports and correspondence; Commission papers; and applicant and licensee documents and correspondence.

The following documents in the NUREG series are available for purchase from the NRC/GPO Sales Program: formal NRC staff and contractor reports, NRC-sponsored conference proceedings, and NRC booklets and brochures. Also available are Regulatory Guides, NRC regulations in the *Code of Federal Regulations*, and *Nuclear Regulatory Commission Issuances*.

Documents available from the National Technical Information Service include NUREG series reports and technical reports prepared by other federal agencies and reports prepared by the Atomic Energy Commission, forerunner agency to the Nuclear Regulatory Commission.

Documents available from public and special technical libraries include all open literature items, such as books, journal and periodical articles, and transactions. *Federal Register* notices, federal and state legislation, and congressional reports can usually be obtained from these libraries.

Documents such as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings are available for purchase from the organization sponsoring the publication cited.

Single copies of NRC draft reports are available free upon written request to the Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at the NRC Library, 7920 Norfolk Avenue, Bethesda, Maryland, and are available there for reference use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

Management and Organizational Assessments

A Review of Selected Organizations

Manuscript Completed: November 1983
Date Published: February 1984

Prepared by
M. V. Nadel, C. M. Kerwin, Battelle Human Affairs Research Centers

Battelle Human Affairs Research Centers
2030 M Street, NW
Washington, DC 20036

Pacific Northwest Laboratory
Richland, WA 99352

Prepared for
Division of Human Factors Safety
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
NRC FIN B2360



EXECUTIVE SUMMARY

The management appraisal activities of five organizations were reviewed. While these organizations have far different responsibilities than the NRC, each is concerned with the capability of management, conducts reviews of management and organization, and utilizes procedures basically similar to the responsibilities of the NRC.

In each case, agencies were selected that, like the NRC, focus on management based on the assumption that good management will lead to sound practices in the regulated activity. The study focuses on the process and content of the management and organization evaluations conducted by the agencies. It does not assess the validity, reliability, or effectiveness of those evaluations.

STATE PUBLIC UTILITY COMMISSION MANAGEMENT AUDITS

In the last ten years, an increasing number of state public utility commissions have utilized management audits as part of the overall process by which utility commissions attempt to assure the reasonableness of rates. A 1979 survey found that 22 state utility commissions utilized management audits.

The purpose of the audits is to provide comprehensive information to the commission about the effectiveness and efficiency of the operation of a particular utility. A management audit is useful because it focuses on such issues as efficiency of operations and planning--factors that affect whether particular expenditures would have been lower with better management.

Most management audits are comprehensive. A recent study identified twelve major areas that were assessed at least 75 percent in management audits of utilities. They are:

- Executive management
- System planning and design
- Interchange and pooling of power
- Construction
- Fuels management
- Power generation operations
- Power delivery and division operations
- Financial management
- Rate structure and research
- Human resource management
- Corporate support services
- Productivity practices

MANAGEMENT APPRAISAL BY THE COMPTROLLER OF THE CURRENCY

The Comptroller of the Currency, a regulatory agency in the Department of the Treasury, conducts extensive appraisals of the management of banks whose operations fall within its statutory jurisdiction. It is responsible for assuring the solvency and operational soundness of nationally chartered banks. Its management appraisals are conducted on a regular basis and are part of larger bank examinations in which the overall performance of financial

institutions is reviewed. The purposes of such an examination are to ensure solvency, to verify compliance with governing regulations, and ultimately to guarantee the security of depositors' funds.

The management appraisal is a major data collection exercise which draws on available written documents and interviews to obtain a comprehensive profile of management in a given bank. This profile consists of a large number of items that we grouped in the following categories:

- Leadership
- Management policies and reports
- Management structure and process
- Management responsibilities

REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS

Health Maintenance Organizations (HMOs) are combinations of health care professionals who, as a unit, offer comprehensive medical services to those enrolled as members or clients of the organizations. The Office of Health Maintenance Organizations (OHMO) in the Department of Health and Human Services (DHHS) evaluates and, when necessary, regulates the management of HMOs in order to prevent their economic collapse. They carry out these functions in the context of a larger management-oriented program. The purpose of these evaluations is to assure the economic viability of HMOs which have been the beneficiaries of federal financial assistance.

OHMO uses a set of protocols that present the criteria for management and organization. OHMO stresses, however, that the protocols should not be used as a "rigid checklist" or "cookbook," but it outlines in considerable detail those elements of HMO management deemed critical to success. The protocol presents these elements in "modular" form, as separate analytical exercises which site visit teams must complete for a comprehensive management appraisal.

Of particular interest for NRC purposes, are the more detailed elements of the general management appraisal. According to the protocol, the HMO should have a management and organizational arrangement that includes:

- Logical organization of management personnel characterized by clearly defined lines of authority and reporting relationships.
- Clear delegation responsibilities.
- Stability of management personnel.
- Good working relationships between the Board of Directors, CEO, and other key managers.
- Organizational performance indicators.
- A management reporting system which provides the CEO with adequate information to manage current operations and forecast future needs.

- A policy definition process and regular update procedures.
- Routine mechanisms for communicating objectives and policy changes.
- A management recruiting process which uses qualification-oriented position descriptions.
- A long range planning process.

NON-CLINICAL LABORATORY REGULATION

Another part of the Department of Health and Human Services, the Food and Drug Administration (FDA), exerts similar regulatory influences over laboratories which conduct non-clinical testing as part of the substance clearance process.

The stated purpose of the portion of the review dealing with organization and personnel is to determine the adequacy and capability of personnel and the management structure.

In the categories of organization and personnel and quality assurance, the FDA has set forth a number of areas in which management issues are probed. There is no a priori set of criteria. Rather, reviewers are provided with a set of subjects to include in their written report. For example, under "Organization and Personnel," reviewers are directed to "Describe how study organizational structures relate to the facility organization structure." Altogether, twelve subjects are listed under organization and personnel and quality assurance. Under these headings, the following areas of management and organization are stressed:

- Organizational structure
- Individual qualifications
- Lines of authority between headquarters and off-headquarters facilities
- Training
- Individual level workload
- Quality assurance recordkeeping

MANAGEMENT REVIEWS BY THE GENERAL ACCOUNTING OFFICE

The U.S. General Accounting Office (GAO) recently has adopted an institutional focus on the management process of federal agencies. This approach differs from previous GAO work in that it does not focus on auditing a particular program, but rather focuses on the management of entire agencies. The purpose of GAO reviews (generally called "audits") is not only to assure that government agencies and recipients of federal funds are using appropriated funds in accord with law and sound accounting practices, but also to assess the efficiency and effectiveness of government programs. Previously, specific management problems such as the lack of planning have been identified as leading to programmatic deficiencies. Now, however, GAO has decided to take a more proactive approach in the belief that systemic management deficiencies should be addressed in and of themselves, because they will inevitably lead to programmatic problems.

One GAO division utilizes the following criteria in its reviews:

- Clear statement of mission
- Goals and objectives
- Planning processes and priority setting
- Implementation
- Administrative support services
- Communication
- Management information systems
- Internal audit and evaluation

INSURANCE UNDERWRITING REVIEWS

As part of its decision on whether to write workers compensation and other casualty insurance and under what conditions, insurance companies assess the management and organization of firms applying for insurance. We reviewed the procedures and criterion of a large multi-line insurer that writes a substantial amount of workers compensation and other commercial insurance.

In determining whether to insure a firm, the purpose of the underwriters' evaluation of the management is to assess two essential elements. First, how competent is the management to run the business soundly so that it will be a profitable organization of continuing viability? Second, how effective is management in controlling hazards?

There is no established checklist or standard set of criteria for evaluating management in a variety of situations. There are, however, a number of elements that are considered in making an overall assessment.

The initial element that is reviewed is the financial strength of the prospective insured. Experience is a major consideration, both in and out of itself as well as a factor in assessing the company on other criteria. The underwriters stress the importance of the experience of key company personnel. They prefer a management team whose members had successful and extensive experience.

In terms of organizational factors, the primary areas of review are reporting and authority relationships. In particular, the underwriters are concerned with the organizational placement of the risk manager. They regard the optimum organizational form as one in which the risk manager of a company reports directly to the president.

The attitude of management is an overriding characteristic that is given a great deal of emphasis. While seemingly subjective, the assessment of attitude is based on tangible evidence rather than professions of safety-consciousness. The adherence to policies and procedures is a key indicator as is the response taken to accident reports and safety evaluations. This kind of responsiveness to safety concerns is actively probed as insurance auditors have access to corporate files.

CONCLUSION

It is quite clear that the NRC should continue its emphasis on administration and organization. Other agencies with quite different responsibilities have independently reached the judgment that management is not only the key to performance of functions that complies with regulations, but also that management and organizational factors themselves can and should be subject to monitoring and detailed evaluation.

In comparing the areas of emphasis of the organizations reviewed in this report with the actual areas of emphasis in NRC management reviews, based on an earlier Battelle analysis, some contrasts can be noted. First, other organizations devote much more attention in their reviews to the use of strategic planning by the organization under review. Second, other organizations appear to stress the importance of performance indicators for individuals and operations units more than was evidenced in NRC reviews. Third, there was considerable emphasis on management information systems to provide information on current operations and future needs. While the NRC probes the ability of plant management to receive useful and timely information about functional areas, this aspect of management competence capability does not appear to be stressed to the same extent by the NRC as by other organizations.

With regard to the process used in conducting reviews, a major difference between the other organizations and the NRC is in the training of staff. The other organizations reviewing private firms relied on staff that was specifically trained or had an educational background emphasizing management issues. To some extent, the insurance company was an exception since it uses loss control staff (safety engineers, etc.), but it also provides back-up by individuals with in-depth experience in the industry in question. In that sense, the insurance underwriters are similar to the NRC although the staff experience still is more managerial and financial in orientation.

In conclusion, to the extent that the NRC finds it desirable to rely on the experience of other organizations, our findings suggest that more attention be paid to planning, performance indicators, and management information systems and that there should be more training available for staff on management and organization review.



TABLE OF CONTENTS

	Page
1. INTRODUCTION	1
1.1 Purpose	1
1.2 Scope and Methodology	1
2. SUMMARY	2
3. STATE PUBLIC UTILITY COMMISSION MANAGEMENT AUDITS	2
3.1 Purpose	2
3.2 Areas of Emphasis	6
3.3 Process	7
4. MANAGEMENT APPRAISAL BY THE COMPTROLLER OF THE CURRENCY	8
4.1 Purpose	8
4.2 Areas of Emphasis	9
4.3 Process	11
5. REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS	12
5.1 Purpose	12
5.2 Areas of Emphasis	13
5.3 Process	15
6. NON-CLINICAL LABORATORY REGULATION	16
6.1 Purpose	16
6.2 Areas of Emphasis	17
6.3 Process	18
7. MANAGEMENT REVIEWS BY THE GENERAL ACCOUNTING OFFICE	20
7.1 Purpose	20
7.2 Areas of Emphasis	21
7.3 Process	23

8. INSURANCE UNDERWRITING REVIEWS	
8.1 Purpose	24
8.2 Areas of Emphasis	24
8.3 Process	27
9. IMPLICATIONS FOR THE NUCLEAR REGULATORY COMMISSION	28

1. INTRODUCTION

1.1 Purpose

This report is part of a larger project designed to assist the NRC in its responsibilities for assessing the management and organization of utilities applying for an operating license for a nuclear power plant. This report reviews the processes and criteria used by other organizations that conduct management and organization audits and evaluations. It was undertaken in order to provide data and a basis for future analysis by taking a comparative perspective. When considering changes in criteria and procedures as the NRC is doing, a standard benchmark is the performance of other organizations that are similarly situated. It was our goal to directly inform the NRC about the activities of other organizations so that a reconsideration of NRC activities could benefit from the perspective of organizations with a longer, broader, and different experience than the NRC has in the management and organization area. Data collected for this report has provided useful information in designing organization and administration guidelines and assessment procedures for consideration by the NRC.

1.2 Scope and Methodology

Although most federal regulatory agencies do not evaluate the management of regulated firms as does the NRC, a few government agencies and several private organizations do perform such evaluations. Three agencies with regulatory responsibilities were chosen for review. Each is concerned with the capability of management, conduct reviews of management and organization, and utilize procedures basically similar to the responsibilities of the NRC. These agencies are the Comptroller of the Currency and two subunits of the Department of Health and Human Services, the Office of Health Maintenance Organizations, and the Food and Drug Administration. The private organizations whose management these public agencies regulate are, respectively, banks, health maintenance organizations, and nonclinical laboratories. Additionally, we examined the management assessment activities of the General Accounting Office and the insurance underwriting department of a large commercial property casualty insurance company.

These organizations were selected for examination on the basis of our previous research, a literature review, and professional judgment. In each case, agencies were selected that, like the NRC, focus on management based on the assumption that good management will lead to sound practices in the regulated activity. The statements made in this report are based on interviews and examination of guidelines and other documents of the reviewing organizations. The study focuses on the process and content of the management and organization evaluations conducted by the agencies. It does not assess the validity, reliability, or effectiveness of those evaluations.

2. SUMMARY

Other agencies and firms that are responsible for evaluating external organizations regard management and organization as the key factor affecting organizational performance and compliance with relevant standards. These organizations generally take a "top-down" approach in which they focus attention on top management. They devote substantial resources to management evaluation and most, but not all, emphasize the training of their own staff who conduct the management evaluations.

The purpose of the appraisal, the areas of emphasis, and the process that is used, including methodology and staffing, is described for each of the five organizational programs reviewed.

The content of the evaluations can be best understood in the context of the purpose and process. However, in order to provide a concise examination of the elements of management and organization used by other reviewing bodies, Table I presents those elements that are utilized by at least two of the five organizations. Within each of the areas of emphasis in Table I, there are a number of specific criteria or elements that the reviewing organizations use. In attempting to further refine these areas of emphasis, however, it has become clear that there is no concensus on a specific list of "best practices" that are useful as criteria. In fact, what emerges is that the reviewing organizations are generally not rigidly prescriptive in their management approach--even though, like the NRC, they may be highly prescriptive in technical regulations. Nonetheless, breaking down the areas of emphasis into finer categories does yield some implicitly prescriptive guidelines for management. It should be stressed that most of these elements are only implicitly prescriptive. That is, we assume that the fact that an appraisal that includes a determination of whether there are written job descriptions means that there should be written job descriptions--that the element is not neutral. These guidelines are presented in Table II. These guidelines are also being incorporated into Battelle's work on preparing the forthcoming organization and administrative guidelines for utilities, possible revisions of the Standard Review Plan, and staff workbook, all currently in progress. The summary tables are followed by the full text of this report.

3. STATE PUBLIC UTILITY COMMISSION MANAGEMENT AUDITS

3.1 Purpose

In the last ten years, an increasing number of state public utility commissions have undertaken to perform management audits of electric and gas utilities. The impetus for this trend has apparently been substantial rate increases tied to rising fuel prices, the greatly increased cost of capital, and reduced demand. Political pressure by consumers on state regulatory bodies resulted in a number of new initiatives such as variable rate pricing, life line rates, and, of primary importance in the present context, greater vigilance during the rate review process. Consequently, state regulatory bodies have utilized management audits as part of the overall process by which

TABLE I

AREAS OF EMPHASIS IN MANAGEMENT AND ORGANIZATION REVIEWS

Areas of Emphasis *	State Public Utility Commission	Comptroller of the Currency	Office of Health Maintenance Organization	Food & Drug Administration	General Accounting Office	Crum & Forster
1. Budgeting			X		X	
2. Individual Qualifications		X	X	X		X
3. Board of Directors Supervision		X	X			
4. Disaster/Emergency Plans		X				
5. Organizational Structure	X	X		X		X
6. Adequate Compensation Plan	X	X				X
7. Mechanisms to Assure Reg. Compliance		X		X		X
8. Existence of Strategic Planning Process	X	X	X		X	
9. Recruitment & Staffing	X	X	X	X	X	
10. Clear lines of authority & reporting relationships			X	X	X	X
11. Performance Indicators for Organizational Performance			X	X	X	
12. Performance Indicators for Individual Performance			X			
13. Management Information System to provide information on current operations and future needs		X	X		X	
14. A policy definition process with written policies and procedures		X	X		X	X
15. Training	X	X	X	X		
16. Individual Workload/Span of Control			X	X		
17. Communications among Management		X	X		X	

* Used by two or more organizations.

TABLE II
MANAGEMENT ASSESSMENT ELEMENTS WITH AREAS OF EMPHASIS*

Existence of Strategic Planning Process

- Specification of Mission, Goals, and Objectives (Comptroller of the Currency, GAO).
- Progress Monitoring Capabilities (Comptroller of the Currency)
- Analysis of Costs and Benefits of Options Designed to Implement Strategic Plan (Comptroller of the Currency)

Recruitment and Staffing

- Primary Source of Recruits (Comptroller of the Currency)
- Staff Experience (OHMO, FDA, Comptroller of the Currency)
- Lag between Vacancies and Recruits (GAO)

Clear Lines of Authority and Reporting Relationships

- Degree of Formal Organization and Presence of Formal Job Descriptions (FDA)
- Relationship of Goals and Objectives to Accountability (GAO).

Performance Indicators for Organizational Performance

- Assessment of Structural Components (Relationship of Facilities, Staff, Organizational Structure to Goals and Objectives) (OHMO)
- Process Assessment: Appropriateness and Adequacy of Services/Tasks to Goals and Objectives (OHMO)
- Outcome Assessment: Degree to which achieved Goals and Objectives Succeed in Achieving Mission (OHMO)

MIS to Provide Info on Current Operations and Future Needs

- Types of Information Received by Senior Management (Comptroller of the Currency)
- MIS System Starts with Assessment of Organizational Needs and Objectives (GAO)
- Timeliness of Information Received (GAO, Comptroller of the Currency)
- Degree of Compatibility of Info Flows between various Management Levels (GAO)

Policy Definition Process with Written Policies and Procedures

- Comprehensiveness (GAO)
- Achievability (GAO)
- Priority Setting (GAO)
- Accountability (GAO)
- Specific Mission, Goals, and Objectives (GAO)

Training

- Type of Training Available (Ongoing, in-house, etc.) (Comptroller of the Currency)
- Degree of Participation (Comptroller of the Currency)
- Variety of Learning Opportunities (Comptroller of the Currency)
- Level of Targeted Employees (Comptroller of the Currency)

Communications Among Management

- Productivity of Meetings (Comptroller of the Currency)
- Level of Discussion of Policy Changes with Supervisors (Comptroller of the Currency)

Budgeting

- Controllability (GAO)
- Degree of Oversight by Senior Management (GAO)

Individual Qualifications

- Leadership Capability (Comptroller of the Currency, OHMO)
- Experience (FDA, OHMO)

Organizational Structure

- Presence of Formal Organization (Chart) (Comptroller of the Currency, FDA)
- Presence of Written Job Descriptions (Comptroller of the Currency, FDA)
- Qualifications of Management Personnel (FDA)
- Method and Frequency of Meetings (Comptroller of the Currency)

Adequate Compensation Plan

- Type of Salary Scale Utilized (Comptroller of the Currency)
- Degree to which Competition is Considered when Setting Salaries (Comptroller of the Currency)
- Presence and Type of Executive Bonuses (Comptroller of the Currency)
- Types and Competitiveness of Benefit Programs (Comptroller of the Currency)

Mechanisms to Assure Regulatory Compliance

- Presence and Type of Audits (OHMO)

* Includes only those areas for which there are more detailed criteria.

utility commissions attempt to assure the reasonableness of rates. A 1979 survey found that 22 state utility commissions utilized management audits.¹

The purpose of the audits is to provide comprehensive information to the commission about the effectiveness and efficiency of operation of a particular utility. Unlike many other PUC activities, which are more narrowly focused, the management audit addresses management as an overriding issue and reviews the operation of the utility as a whole. It has often been suggested that utilities have little incentive to hold down capital or operating costs because those costs are simply passed on to consumers in cost-plus rate setting. Normal rate review simply establishes that certain costs were in fact incurred. A management audit is useful because it focuses on such issues as efficiency of operations and planning--factors that affect whether particular expenditures should have been lower with better management.

3.2 Areas of Emphasis

Most management audits are comprehensive. This designation does not mean that everything is reviewed, but it does imply that many functional areas are reviewed. In some cases, an audit has multiple stages. That is, a comprehensive audit identifies major problem areas that are then examined in more detail in a second stage focused study. In contrast, some audits are focused from the outset and only a few selected areas are examined.

One hybrid approach that is sometimes used is the reconnaissance audit. Like the comprehensive audit, many functional areas are examined, but not in significant depth. However, the reconnaissance audit is used to reveal those aspects of a company's operations that should be probed in a further study.

Drawing on an examination of 39 management audits (of which 28 were reviewed by Price Waterhouse), and by the National Regulatory Research Institute (NRRI), a recent study identified twelve major areas that were assessed at least 75 percent in management audits of utilities.² They are:

- Executive management
- System planning and design
- Interchange and pooling of power
- Construction
- Fuels management
- Power generation operations
- Power delivery and division operations
- Financial management
- Rate structure and research
- Human resource management
- Corporate support services
- Productivity practices

¹ National Regulatory Research Institute, Commission Ordered Management Audits, 1979.

² Ibid.

Within each area, a number of elements are listed and apparently, there is considerable consensus on the specific areas of emphasis. The NRRI survey, however, does not reveal the particular criteria or measurement tools that were used. Of particular interest in the context of the NRC's interest are executive management, human resource management, and corporate support services. The commonly used elements (more than 40 percent of the audits) within each of these areas are as follows:

Executive Management

Organizational structure
Long-range (strategic) planning
Relationships with affiliated companies

Human Resource Management

Salary administration
Benefits
Staffing
Labor relations
Training
Safety

Corporate Support Services

Inventory
Management
Transportation management
Purchasing
Land management
Facilities management
Electronic data processing
Legal

3.3 Process

There is no typical audit procedure characterizing audits in the approximately two dozen states that utilize management audits. This section then will describe the various types of procedures used in order to enumerate the possibilities.

The audit itself is only one step in the audit process which starts with the commission deciding to have an audit and selecting the consultant to perform the audit. Once the audit is completed, there must be acceptance of the final management audit report, implementation of recommendations, and a procedure for the commission to monitor implementation.

In most states, the undertaking of a management audit is not a routine or automatic task and so some initiating action must be taken to sponsor an audit. Almost always, the audits are instigated by commissioners or their staffs. They have generally been conducted by private consulting firms

because the commissions often lack the specialized expertise or available staff to conduct the audits. The auditing firm usually is chosen by the PUC (as opposed to the utility). The audits are substantial undertakings and reportedly range in cost from \$25,000 to \$1,670,000, although most cost less than \$300,000.

Although conducted by consultants, PUCs are heavily involved in setting the parameters of the audits. The audits are usually let out on competitive bid with the request for proposal specifying the objectives of the audit. The most frequent objectives have been the examination of the overall efficiency of a utility and the identification of unspecified problem areas where efficiency could be improved. Commissions also select the auditor and monitor the progress of the audit.

The audits result in written reports which are almost always made available to the public. Those commissions that have performed audits generally reported that they are satisfied or very satisfied with the results of the audit process, and could point to specific improvement in most instances. Nonetheless, it is instructive to note some of the shortcomings that have been cited in the NRRI survey of state utility commissions. Among those states that do not use management audits, the most common reasons for not using them were (1) lack of resources, and (2) doubt that any savings or improvements resulting from management audits were worth the cost. Among those states that used management audits, the use of consultants to perform the audits was central to most complaints. Most complaints centered on the difference between the promise and the performance by contractors. The second most common complaint was that the recommendations were overly general or were watered down. Significantly, many staff members expressed the belief that some audit consultants "pulled their punches" so as not to offend utilities from whom they might solicit future business. Finally, there were also a number of complaints about the lack of agreed upon criteria used in the audit.

In conclusion, it should be emphasized that these utility audits focused primarily on issues of financial performance and efficiency rather than the kinds of safety concerns that are the subject of NRC management reviews.

4. MANAGEMENT APPRAISAL BY THE COMPTROLLER OF THE CURRENCY

4.1 Purpose

The Comptroller of the Currency, a regulatory agency in the Department of the Treasury, conducts extensive appraisals of the management of banks whose operations fall within its statutory jurisdiction. It is responsible for assuring the solvency and operational soundness of nationally chartered banks. Its management appraisals are conducted on a regular basis and are part of larger bank examinations in which the overall performance of financial institutions is reviewed. The purposes of such an examination are to ensure solvency, to verify compliance with governing regulations, and ultimately to guarantee the security of depositors' funds. Management appraisal is an important part of bank examination, and those interviewed at the Comptroller of the Currency were unanimous in their agreement that when solvency problems are discovered they are usually attributable to management failure.

4.2 Areas of Emphasis

The preamble in Section 502.1 in the Handbook for National Bank Examiners³ published by the Comptroller of the Currency states that the "first priority in evaluating the condition of the bank is to make an accurate appraisal of the competency of the management team." The official policy states further that management is to be evaluated on the basis of future performance as well as its past record and current activities. There is an established policy which sets the priorities of the Comptroller of the Currency in its management reviews. The management appraisal is a major data collection exercise which draws on available written documents and interviews to obtain a comprehensive profile of management in a given bank. This profile consists of a large number of items that we grouped in the following categories:

- Leadership--Examiners review a comprehensive listing of bank directors, complete with biographical and financial background data, and of top management officials. Membership in the latter category is determined by federal regulation.
- Management Policies and Reports--Examiners are to determine whether the bank's board of directors is meeting their management responsibilities. This involves an inventory of all bank operations covered by policies written and published by the board, review of reports to the board by bank officials on compliance with board policies, and an evaluation of omissions or deficiencies in policies or reports from management officials which should be corrected. In the latter activity examiners are guided by a list of the kinds of reports one might expect to be routinely prepared by management for review by directors. Of particular importance is that policies and reports are disseminated to all levels of management whose responsibilities are affected by them.
- Management Structure and Process--Examiners are to determine the respective roles and powers of the board of directors and stockholders, their method and frequency of meetings, the content of their deliberations, and the means of communicating the decisions of these groups to management officials. Especially important is that a regularized mechanism exists by which the board assigns responsibility to management to correct deficiencies identified by examiners in previous evaluations or by the board itself in its own reviews.
- Management Responsibilities--There are a number of general responsibilities associated with sound management that examiners are concerned with. These include mechanisms to assure full compliance with all regulations governing bank operations, contingency plans for bank operations in the event of disaster, procedures to fill key

³ "Comptroller's Handbook for National Bank Examiners," U.S. Comptroller of the Currency, August 1980.

management vacancies, personnel and compensation systems that assure current and future management of high quality, and record systems which adequately support each of these measures.

It is also important to note that, for those banks with unblemished records and a currently strong solvency position, the presumption in the appraisal is that management is sound. While this may be the result of the evaluation, the management appraisal is still carried out as fully in banks with outstanding histories as in those whose position is less well established.

A recent major area of emphasis in the management review is the planning process of banks. The Comptroller considers planning not just a desirable management tool, but rather a necessity due to the increasingly competitive banking environment. Therefore, a planning process is now mandatory. However, a formal written plan is not required for all banks in the belief that such a requirement may be inappropriate for smaller institutions.

There are two types of guidance. The first consists of a series of questions which outline the strategic planning process for affected banks. They are intended as a basic framework for managing the strategic planning process:

What do we want to be?	(statement of mission)
Where are we now?	(evaluation of firm and its operating environment)
Where do we want to go?	(goals and objectives, informed by projections about the operating environment)
How will we get there?	(cost/benefit analysis of options)
Who is going to do what is needed?	(preparation of human resources, operating and capital budgets)
How are we doing?	(analysis of results, revision of plans)

This accessible, simplified outline of strategic planning is meant to apply to all banks and introduce managers to the concept of strategic planning. A second form of guidance follows. It is more detailed, and meant as a guide for both bank management and examiners. It provides specific information on what bank strategic plans are to contain. For example, the revised section states that the answer to "Where are we now?" should include evaluation of the following internal factors:

- Overall financial condition of the bank
- Overall risk position
- Management ability and personnel resources
- Adequacy of management information systems and effectiveness of bank policies

- Adequacy of physical facilities
- Existing product lines, customer base and marketing
- Organizational structure
- Legal and regulatory requirements affecting internal structure of bank

In addition to these internal factors, banks also should include the following kinds of information about the external environment:

- Economic conditions on the local, national, and/or global levels, as appropriate
- Characteristics of the marketplace
- The technological environment
- Sociological trends
- Legal and regulatory activities

Staff of the Comptroller of the Currency recognize that planning requirements of such stringency create a sensitive situation with the banks since they may feel that the agency is attempting to "run the show" or "second guess" management. They countered this potential criticism by developing planning requirements which, in their view, "emphasize a process, not outcomes." Nevertheless, the details of the process have very clear implications for the content of strategic plans. If nothing else, they tend to produce a uniform approach to planning nationwide, assuring that all banks manage their futures according to the same methodology.

4.3 Process

Bank examinations, of which management appraisals are a part, are conducted on a regular schedule, which is generally known to the banks. Since these examinations constitute comprehensive evaluations of bank conditions each time they are conducted, the Comptroller of the Currency has determined that advance knowledge gives little advantage to those banks wishing to mislead examiners. The frequency of management appraisals depends on the size of the bank being examined. Banks with less than \$300 million in assets, which constitute nearly 90 percent of the industry, are examined once every three years if they maintain a good track record. In contrast, banks with assets in excess of \$1 billion are examined every year, and these examinations include a full management appraisal. The schedule also depends on a bank's current condition, and the historical record of the bank's examinations.

There is no special communication between the Comptroller and examined banks on expectations regarding management appraisals. When general procedural regulations which govern the management appraisal phase of bank examinations are changed or new regulations are added, the Comptroller consults widely with industry officials and management consultants as to the type of information that will be collected. Once this is determined there is no "continuing dialogue" between the Comptroller and the banks. The guidelines for bank examinations are published in the Handbook, copies of which are available to banks. The Comptroller does not, however, issue additional guidance to banks on how to prepare for management appraisals; they are expected to read the Handbook, which is updated every six months, and plan accordingly. Management appraisal really begins with an "examination planning and control" session at

which available documentation is reviewed and the staff involved brief themselves on the general situation in the bank. These documents include profiles of top bank leadership, internal organization and control systems, and the various reports issued by the banks to the Comptroller of the Currency. Previous audits of various financial aspects of operations are used as sources of questions regarding management. When all information available off-site is reviewed, the staff involved in the examination develop a general plan to guide them in their work.

The actual management appraisal is conducted by one or more members of a team of bank examiners. Depending on the size of a bank, the team may be as few as four examiners or as many as several dozen, with as few as one or as many as fifteen assigned to the management appraisal. The crew chief for management appraisal is a critical element in the on-site coordination of the evaluation effort and is the primary source of advice on sources of data, including who to interview. Each bank presents a different set of conditions and different management arrangements. Some banks, particularly the larger ones, will have extensive written documentation on management policies, internal management structures and procedures, employment and personnel matters, and related concerns. Other, smaller banks may have less written documentation and more of the alive information may have to be collected through interviews or other means. In all banks, face-to-face contact with the board of directors, bank officers, managerial personnel, employees, and, at times, persons outside the bank are needed to determine if written and unwritten policies are actually being carried out.

The educational background and training of examiners emphasizes management appraisal. Entry level bank examiners generally are new college graduates with course work in business administration, accounting, banking, finance and related areas to be selected. Prior to their appointment as commissioned bank examiners, candidates receive training on the basic elements and process of a bank examination, including management appraisal. As bank examiners move up the ranks and approach a stage at which they might be named crew or team chief, they have access to specialized training on types of problems which arise in appraisals.

Overall, the management appraisal is an essential adjunct to the more technical audits of accounts and investments, and it serves as a form of management consulting as well. Personnel in the Comptroller of the Currency offices in Washington stressed to us that exposure of management deficiencies in some banks allows regulators to advise other institutions on how to avoid the same problems in their own institutions. To this extent, the appraisal conducted by the Comptroller of the Currency helps to advance the science of bank management, as well as to regulate current banking operations.

5. REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS

5.1 Purpose

Health Maintenance Organizations (HMOs) are combinations of health care professionals who, as a unit, offer comprehensive medical services to those enrolled as members or clients, of the organizations. Instead of fees for

each service, health maintenance organizations provide members most care needed for an annual fixed fee.

The primary devices for promoting the HMO concept have been federal financial assistance of various sorts and requirements that employers include HMOs as options in sponsored medical plans for their employees. As experience with the program developed in the 1970s, failures of health maintenance organizations were not uncommon. When an HMO failed there were several implications. The financial commitment which the federal government had made

to the organization was either lost or put in jeopardy. Also, there was the real possibility that care for those enrolled as members of the HMO would be interrupted. Experience showed, as it has with financial institutions, that solvency problems could be traced most often to poor managements. Unlike banks which at least had a long institutional history and had standard, if not always effective, management practices, health maintenance organizations were new entities with no operational history. The conceptual development of the idea outdistanced by quite a long way actual experience with the wide variety of conditions that might affect the way of delivery in health care. As a result, the Office of Health Maintenance Organizations in DHHS undertook to evaluate and, when necessary, regulate the management of HMOs in order to prevent their economic collapse. They carry out these functions in the context of a larger management-oriented program. The purpose of these evaluations is to assure the economic viability of HMOs.

5.2 Areas of Emphasis

OHMO uses a set of protocols that present the criteria for management and organization. OHMO stresses, however, that the protocols should not be used as "a rigid checklist" or "cookbook" but it outlines in considerable detail those elements of HMO managements deemed critical to success. The protocol presents these elements in "modular" form, as separate analytical exercises which site visit teams must complete for a comprehensive management appraisal. The following is a summary of general protocol items, with explanations of what these entail:

- General Management--determination of organizational objectives and operating standards in areas such as leadership, internal communications, policy documents, personnel, and planning.
- Budgeting--determination of methods of preparation, participation and management of the process, revenue estimation, expense estimation, performance analysis.
- Service Delivery Management--determine method of organization of services provided, staffing levels, staff qualifications, utilization review and forecasting, referral procedures, service contracts, and enrollee eligibility.
- Marketing Management--determination of the status of the enrollment program, enrollment projections for the next fiscal year, profiles of marketing activities, organization and operations of the marketing

group, method of handling consumer complaints, and involvement of board in marketing decisions.

- Financial Management--determination of organizational capacity for financial management, methods of forecasting and covering cash needs, methods of preparing financial reports, accounting system performance, fee-for-service billing procedures, claims processing, membership management, cash flow management, breakeven analysis methods.
- Board of Directors Management--determine legal and organizational element of board operations, review of information available to board regarding HMO operations, review minutes of board meetings, determine degree of board chairman involvement in HMO operations.

Of particular interest for NRC purposes, are the more detailed elements of the general management appraisal. According to the protocol, the HMO should have a management and organizational arrangement that includes:

- Logical organization of management personnel characterized by clearly defined lines of authority and reporting relationships; a reasonable span of control for the CEO; and a management team which is accountable to the CEO.
- Clear delegation of major management responsibilities to specific individuals.
- Adequate stability among management personnel to provide continuity of direction in HMO operations.
- Working relationships between the Board of Directors, CEO and other key managers that permit major issues to be discussed and resolved in a timely manner.
- Performance indicators which are used by the CEO to assess the organization's performance against plan and to evaluate the performance of key managers.
- A management reporting system which provides the CEO with adequate information to manage current operations and forecast future needs. These reports should provide comparative information on current performance against plan.
- A policy definition process which includes approval by the Board and regular update procedures.
- Routine mechanisms for communicating objectives and policy changes among the CEO and key managers to ensure a common understanding of the HMO's goals and objectives.

- A management recruiting process which uses position descriptions that define, at a minimum, required education, experience and skill levels, and describe the functions and responsibilities of the position.
- A long range plan to provide the capacity required to serve the HMO's projected enrollment.
- Actions by the CEO and the Board which demonstrate an awareness of the need to address long range planning issues as they affect the future of HMO. Documentation might include a formal planning document, projects underway to address specific issues, or minutes of Board meetings to discuss planning issues.

5.3 Process

The Department of Health and Human Services through its Office of Health Maintenance Organizations, operates a national reporting system to monitor the financial well-being of all HMOs supported by federal funds. The frequency of reports depends on the current financial status of the HMO (red or black), but financial statements are usually filed on a quarterly basis and audits are conducted once a year. The contents of these reports and audits are reviewed against a number of indicators, which comprise a range of acceptable performance. When an HMO is found to be "out of range," a mandatory management assessment is conducted. The assessment, an audit as it is also called, is frequently conducted by private accounting or management consulting firms according to an elaborate protocol developed by the Office of Compliance in OHMO.⁴

When the data pertinent to these elements of the management audit are collected, the evaluation team analyzes them and reports to OHMO. The Office of Health Maintenance Organization also reviews the data and analysis and decides on the action to be taken. The HMO may be given a clean bill of health, and if so, it is given a period of time to bring its operations back in range. Alternatively, OHMO may conclude that the HMO must file a corrective action plan which details the steps the organization will take to bring its financial performance back in range. The content of the corrective action plan is negotiated directly with the HMO, but is based on the findings of the management assessment. If the HMO cannot or will not produce an acceptable corrective action plan, a regulatory action is filed in which the Office of Compliance develops unilaterally and outlines conditions of continued federal support. Again, these are based on management audits, but may include harsher conditions, such as firing top management, than would have been produced in a corrective action plan. An extreme outcome, possible in regulatory action situations of this sort, is full receivership of the HMO by a group designated by OHMO to bring the organization back to financial health.

⁴ (PHS)80-5011, "Protocol for Management Assessment of Health Maintenance Organizations," U.S. Department of Health and Human Services, Public Health Service, undated.

In addition to the management appraisal, which is conducted as a regulatory activity, the Office of Health Maintenance Organizations also conducts educational and self-help programs for HMOs. The education program includes a large scale series of two-day seminars in various aspects of HMO management, and a program for training individuals specifically and extensively as managers of HMO operations. Rather than supplementing the medical skills of HMO officers with organizational tools, this approach seeks to establish a cadre of persons with a common foundation of education and "hands-on" experience in and exclusive interest in management.

The self-help aspect of the OHMO program consists of the development and distribution of a number of handbooks and manuals which provide guidance on management to those working in HMO. Two of these, Guide to Development of Health Maintenance Organizations⁵ and HMO Governing Board Handbook,⁶ are quite detailed in their advice to their respective audiences. The former includes a full chapter to the development of the organization and to ongoing management. The HMO Governing Board Handbook has a similar general purpose but its guidance is directed to HMO boards of directors.

To supplement the training and developmental programs, OHMO organized groups of "consultants" to assist health maintenance organizations in need. These consultant groups consist of managers of successful HMOs who agreed to provide this service. Participation in a consultant or client organization was entirely voluntary. If an HMO contacted OHMO for assistance, it would act as a clearinghouse to assemble a consultant team from a master list of managers, often matching specific skills to specific problems. When they did work with the HMO, they would conduct a site visit for a comprehensive review of the organization. Problems would be identified and analyzed, and recommendations for change would be made in a formal report to the board and senior management of the client HMO.

6. NON-CLINICAL LABORATORY REGULATION

6.1 Purpose

Another part of the Department of Health and Human Services, the Food and Drug Administration, exerts similar regulatory influences over laboratories which conduct nonclinical testing as part of the substance clearance process. The purpose of this regulation is different than that governing HMOs. Here the concern is not with the financial stability of the lab; instead it is the quality and reliability of the results of tests reported by the laboratory to the FDA. Under authority established under several Acts, including the Food, Drug and Cosmetic Act, the Public Health Service Act, the Radiation Control for Health and Safety Act and the Medical Device Amendments of 1976, industries of various types must submit evidence of the safety and

⁵ "Guide to Development of Health Maintenance Organizations," U.S. Department of Health and Human Services, Public Health Service, March 1982.

⁶ "HMO Governing Board Handbook," U.S. Department of Health and Human Services, Public Health Service, April 1981.

effectiveness of human and animal drugs. Since testing is, in effect, delegated to the very persons interested in marketing a given product, the FDA is very concerned that the procedures used employ "scientifically sound protocols and detailed attention to quality control." At the same time, the means used to guarantee the reliability of a given manufacturer's study results should not be so burdensome as to establish what is, in effect, a parallel testing program within the FDA.

The stated purpose of the portion of the review dealing with organization and personnel is "To determine whether the facility has an adequate number of qualified personnel to perform the types and number of nonclinical studies which it has been or is performing and to determine whether the organizational structure is appropriate to ensure that studies are conducted in compliance with GLP regulations."

6.2 Areas of Emphasis

The examination of nonclinical laboratories involves the collection of information on nine interrelated items:

- Organization and personnel
- Quality assurance
- Facilities
- Equipment
- Testing activities and operations
- Animal care
- Test and control articles
- Study protocol
- Record keeping

Obviously, not all these questions involve management, but in the areas of organization and personnel and quality assurance, the FDA has set forth a number of areas in which management issues are probed. There is no a priori set of criteria. Rather, reviewers are provided with a set of subjects to include in their written report. For example, under "Organization and Personnel," reviewers are directed to "Describe how study organizational structures relate to the facility organization structure." Altogether, twelve subjects are listed under organization and personnel and quality assurance. Under these headings, the following areas of management and organization appear to be stressed:

- Organizational structure
- Individual qualifications
- Lines of authority between headquarters and off-headquarters facilities
- Training
- Individual level workload
- Quality assurance record keeping

The quality assurance unit in the laboratory is the focal point of the management study since FDA considers this group as the primary mechanism, beyond personnel involved in a study, to assure reliability of results. The

examiners are concerned with standard operating procedures used by these units, particularly if they maintain master schedules and full research protocols for individual studies and if they audit regularly. It is considered important to determine who the unit reports to and how records regarding its work is maintained. While the quality assurance unit is deemed vital to management of a well-run laboratory, FDA personnel will not attempt to review the actual internal reports that the quality assurance units prepare about studies for involved laboratory personnel. In order to guarantee that quality assurance units will issue accurate and meaningful reports internally, the FDA has determined that their content must remain confidential and requires only that records show if and when an audit was done.

Facilities and equipment are also stressed and have obvious management implications, since their continued adequacy for the studies which are conducted is vital to the reliability of work which is produced. The study team examines these elements in the course of a careful review of the adherence of laboratory staff to established research protocols. Equipment, facilities, test animals and test articles, and the protocol itself are examined and the study team establishes if and how supervisory personnel were familiar with the research procedure, the methods to ensure personnel were informed of their specific study responsibilities, and the methods used by the Study Director to assure all elements of the protocol were implemented. They are also concerned with the capacity of the study group to respond to unforeseen events that might threaten the study. Finally, the study group is concerned with the "reliability, integrity, and utility" of record keeping. This includes not only archival materials that chart the progress and interim results of a study, but actual specimens as well. In addition to these data, FDA personnel should be concerned with methods of access, indexing and means of storage.

In this instance, profitability is not an appropriate test of the performance of management; on the contrary, it is quite possible that a given laboratory could become quite profitable by producing low quality research. Hence, the examination which is conducted seeks to determine the degree to which management promotes high quality results.

6.3 Process

The approach adopted by the FDA is a procedure which is superficially similar to that of the Comptroller of the Currency and the Office of Health Maintenance Organization; teams of evaluators go to the field to examine all phases of a laboratory's operations, including its internal management.

Inspections begin with a decision by the FDA regarding the laboratory to be visited. The laboratory is informed in writing of the intent to inspect by the Commission, and a specific study may be selected as the object of the site visit. The critical variable in selecting a specific study is whether it allows FDA personnel to establish whether the laboratory is in full compliance with GLP regulations. The process of selecting the actual examples of laboratory work which will be examined requires the team to obtain a master list of all FDA nonclinical laboratory studies conducted since GLP regulations and all those currently underway. Many laboratory examinations will consist

of data and procedure audits of completed studies, as well as evaluations of studies in progress. When the preliminary planning work with involved personnel and affected laboratory is completed, the team goes on site to collect the essential data.

Inspections of nonclinical laboratories occurs at least once every two years under a regulatory program known as Good Laboratory Practices (GLP). Current guidelines require that field inspectors chosen for assignment to non-clinical laboratories must be experienced in reviews of non-clinical laboratories. A team leader is assigned, with general responsibilities not unlike the group leader in Comptroller of the Currency appraisals. He is assisted by headquarters (Washington) staff who serve in a scientific advisory capacity. There are occasions when an inspection may be done jointly with other agencies of the government concerned with environmental, workplace safety, and health or other aspects of a given laboratory's operations. FDA inspections may impact on these other agency programs without joint activities being involved, so interagency cooperation guidelines have been developed. In all such instances, the team leader for the GLP program acts as team leader and FDA concerns assume a top priority. It is the team leader's responsibility to assure all members are familiar with precautions regarding the type of clothing to be worn, the type of equipment which may be used, and the state of their physical health at the time of inspection.

Those conducting inspections are generally trained in the hard sciences, and a Bachelor of Science degree is considered minimum qualification. Once selected for the position, however, those handling inspections receive extensive training in both the drug manufacturing process and the elements of good laboratory practice. While formal education is expected to assure a background in the development and use of scientific data, it is the training programs sponsored by FDA which are the primary means by which inspection criteria are communicated. New inspectors observe more experienced colleagues conduct on-site inspections before they are given their own assignments.

6.3.1 Reporting. When these elements of a site examination are finished, the team leader is required to report on findings. The method of reporting depends on whether the inspection is classified as a "surveillance" or a "directed" inspection. The former are "periodic, routine" actions undertaken to determine a laboratory's compliance with GLP. The latter is undertaken when a surveillance inspection reveals questions regarding the performance of the laboratory or when information from other sources reveals potential problems in operations. Surveillance inspections treat the elements described above in an overall assessment of compliance; a direct inspection is more narrowly concerned with the validity of results of a specific study. Both may entail a facility inspection and both report deviations from the GLP regulations. On site personnel are expected to report findings and to refrain, when possible, from interpretation of them. Interpretation is left to the Washington Office, which routinely consults with the program office in FDA with special expertise in the substantive area of the lab's work. So, there is considerable review and discussion of whether a lab's performance is acceptable.

The FDA regulatory authority in the operation of laboratories is considerable. While FDA can compel inspections at only certain types of

nonclinical laboratories (i.e., those performing tests on new drugs, new animal drugs, and medical device products), failure to permit inspections causes serious and immediate consequences. It is an FDA policy "not to accept studies submitted to the agency in support of any research or marketing permit if those studies were performed and conducted by a facility that has refused" They add that partial refusals are tantamount to complete refusals and treated accordingly. The FDA can avail itself of strong sanctions, including sealing of records, when there is reason to suspect fraud or some other type of criminal action. In general, the results of inspections lead to three types of possible action by FDA. "No action indicated (NAI)" means the inspection has revealed substantial compliance with GLP regulations and that deviations which do exist are very minor. Recommendations may be made for improvements in laboratory practices, and a response may be requested, but there is no time limit as to when it is to be received. "Voluntary action indicated" is a conclusion that substantial management problems exist, but they are not sufficient to require formal regulatory action by FDA. Instead, the laboratory will be required to submit a response, in a specified period of time, stating how it will correct the identified deficiencies. An adequate response may put the laboratory in the "NAI" category, but FDA might also determine that a reinspection is required. This device is not unlike the "corrective action plan" used by the Office of Compliance in OHMO, and it is clear to the laboratories who receive it that more stringent actions will be taken if the voluntary actions are unsatisfactory.

The final option, "Official Action Indicated," is a formal regulatory action representing a decision by FDA that the laboratory is not able or willing to correct perceived problems and must be required to undertake actions specified by the agency. Failure to meet these requirements on a specified timetable will lead to serious sanctions, such as refusal of studies, complete disqualification of the laboratory, injunction, or prosecution. Such action is potentially more severe than actions taken against HMOs and indicates the degree of regulatory authority the FDA enjoys. Its evaluation of management is as penetrating as any conducted by the other agencies discussed here, and its approach to evaluating management is fixed and consistent. In this regard, like the Comptroller of the Currency and OHMO, the FDA is a powerful face in private management and the impact of its work can be observed in the substantial uniformity of nonclinical laboratory operations in firms under its jurisdiction.

7. MANAGEMENT REVIEWS BY THE GENERAL ACCOUNTING OFFICE

7.1 Purpose

The U.S. General Accounting Office (GAO) recently has adopted an institutional focus on the management process of federal agencies. This approach differs from previous GAO work in that it does not focus on auditing a particular program, but rather focuses on the management of entire agencies. The purpose of GAO reviews (generally called "audits") is not only to assure that government agencies and recipients of federal funds are using appropriated funds in accord with law and sound accounting practices, but also to assess the efficiency and effectiveness of government programs. Previously, specific

management problems such as the lack of planning have been identified as leading to programmatic deficiencies. Now, however, the new head of GAO, Comptroller General Charles Bowsher, has decided to take a more proactive approach in the belief that systemic management deficiencies should be addressed in and of themselves, because they will inevitably lead to programmatic problems. There have been two major initiatives in support of that orientation: a special management studies group in its General Government Division (GGD) which did a review of management at the Federal Emergency Management Agency and a large task force that conducted a management review of the Department of Housing and Urban Development.

7.2 Areas of Emphasis

GAO staff in the GGD management studies group say that they have no "hard and fast" criteria for judging management systems, and they cite as one problem the fact that within the substantial literature on public management as well as among managers, there are mutually conflicting views on what constitutes good management. Unique agencies environments may preclude general criteria for good management. When it undertook its management review process, GAO lacked a set of criteria against which to assess agency management. They interviewed experts in a number of accounting and management consulting firms but did not find any single management review protocol that could be readily adapted to its needs. Nonetheless, they did refine and condense the material they reviewed. Nonetheless, the GGD group established criteria based on a mission accomplishment model--the concept that organizations are established to fulfill certain purposes and that systems processes, and resources should be in place and working to achieve an organization's basic mission. With this as the orientation, the management review proceeds with the following criteria:

Clear Statement of Mission--GAO first looks for a clear statement of the rationale for the agency's existence and what purposes it serves. This may be in enabling legislation or, if not, the agency should develop a mission statement. There should also be a mission statement for subordinate units which should be consistent with the agency's total mission. GAO also tries to find out whether a mission statement actually served as the basis for forming specific goals and objectives and establishing priorities.

Goals and Objectives--GAO then seeks to determine whether managers break down the mission statement into specified goals for subordinate units and ultimately into more detailed objectives to be accomplished in specified time periods. GAO looks for several attributes that it believes enhances the usefulness of statement of goals and objectives.

- **Comprehensiveness.** Are there goals and objectives for all major agency and unit missions? Are priorities assigned to provide a manageable agency? Were any major activities omitted?
- **Achievability.** Are the objectives achievable given the available resource levels?
- **Performance measures.** Are specific results or outputs defined? Such definitions can be used as performance measures in assessing progress

in achieving the goals and objectives. GAO expressed a preference for measures related to outputs rather than process, but indicated that the latter were better than nothing at all.

- **Accountability.** Is there a clear designation of who is responsible for achieving each goal and objective?

Planning Processes and Priority Setting--GAO assesses whether plans (tied to the budget process) were developed to carry out the agency's goals and objectives, and whether there is leadership from top management. With regard to the plans themselves, GAO asks whether agency plans defined the resources that would be needed, established priorities in case needed resources were unavailable, and integrated the required inputs when more than one operating subunit was involved.

Implementation--Other than noting that implementation mechanisms should be appropriate for established goals and objectives and that they function as efficiently and economically as possible, GAO so far has little to say about implementation because this is the normal subject of other GAO reviews. Thus, GAO's pilot study did not focus on implementation.

Administrative Support Services--GAO tries to determine whether the missions of such support services as accounting, budgeting, personnel, and procurement are consistent with the overall mission of an agency while also complying with applicable statutes, regulations, and standards.

Communication--Clear communication channels are needed to help ensure coordinated action among operating units within an organization and between the organization and its external environment. These communications channels include both formal systems such as operations manuals and less formal means such as scheduled and unscheduled meetings between managers and their staffs, peers, and superiors. Communication links also include printed material such as in-house newsletters, agency reports to the Congress, and monitoring systems for periodic feedback to management on agency performance. GAO also includes electronic communications links in this category.

Management Information Systems--Management Information Systems (MIS) are communications systems that aid management in making, implementing, and controlling decisions. They provide a way for assessing individual and organizational performance measured against predetermined criteria. GAO's position is that the MIS should take a "top down" approach--it starts from an appraisal of management needs and organizational objectives. GAO tries to find out whether FEMA managers have reliable and timely information available on what is happening currently in an organization, what changes need to be made to accomplish goals and objectives, and how the goals and objectives themselves need to be adjusted in light of actual operating experience.

Internal Audit and Evaluation--This has long been a major element in GAO reviews and continues its prominence in the management assessments also. GAO looks at whether agency managers are assessing the extent to which agency programs are meeting the agency's goals and objectives and doing so in

compliance with existing law. In particular, GAO pushes for strong internal audit organizations which assist management by providing information, analyses, and recommendations.

GAO also looks at whether there is internal program evaluation--a process of appraising the extent to which agency programs achieve their objectives, meet performance expectations of external groups, and are producing other significant effects (either positive or negative) to assist management decisions.

Unlike the approach used by GGD, the task force reviewing the Department of Housing and Urban Development did not develop or use pre-existing criteria. Rather it was characterized as a "results-oriented" approach that looked for the link between management and program effectiveness. That is, the task force looked at existing management structures in order to see whether those structures were achieving the results desired by the agency itself. The basic orientation was efficiency of resource use by the agencies and the GAO reviewers examined the following management problems and issues:

- Organizational structure
- Managing/Directing
- Planning/Policy Development
- Budgeting
- Personnel/Manpower Planning
- Procurement
- Financial Management
- Auditing and Inspections
- Monitoring
- Management Information Systems
- ADP
- Program Evaluation
- Interagency and Intergovernmental Relations
- Environment
- Legislative
- Communications

As the review proceeded, two major areas of emphasis emerged. The first was planning which included operational planning, strategic planning, policy development, and program planning. The second was the budget development process which was regarded as being (or which should be linked) to the planning process. Budget development includes controllability, program evaluation, and resource management issues such as work standards.

7.3 Process

GAO's process of management reviews differs little from other GAO audits. That is, the work is done by regular GAO staff rather than contractors and is aimed at informing the agency and/or Congress where improvements are needed in the agency's operations.

The initial GAO effort was to establish a special group in its General Government Division to develop a methodology and conduct pilot studies

assessing the management of federal agencies in order to spearhead the development of management auditing in the agency. This group has grown to about twelve staff members as of January 1983, and is composed entirely of existing GAO staff. Several of the staff members have had supplementary government training courses, but none has an extensive background in management, management consulting, or management auditing. The group also undertook a pilot study of the management of the Federal Emergency Management Agency in which the criteria were applied.

The GAO review of the Department of Housing and Urban Development was undertaken by a task force composed of five teams which had a total of about 25 auditors working full time at any given time. The staff were all regular GAO employees with a variety of audit backgrounds, but none had received specific management review training. GAO also employed two high-level, part-time consultants to review work products and plans. The task force, composed of staff from several divisions, is an unusual approach for GAO, since nearly all GAO reports are the responsibility and work of a single division. The reason for a task force in this instance was the need for a multiplicity of skills and also as a reflection of the priority placed on an overall management review. This is therefore a one-time enterprise and no decision has been reached on whether the task force management review approach will be used again. It appears, however, that management reviews will be conducted by a separate unit within each GAO division.

As with most GAO efforts, these management reviews result in reports to the agencies involved or to the Congress. These reports are first presented in draft form to the affected agencies for comment, and then after addressing any comments, are issued in final form. GAO has no authority to compel changes, but agencies are required to report to the governmental affairs committees in each House of Congress what their response has been to GAO recommendations.

8. INSURANCE UNDERWRITING REVIEWS

8.1 Purpose

As part of its decision on whether to write workers compensation and other casualty insurance and under what conditions, insurance companies assess the management and organization of firms applying for insurance. We reviewed the procedures and criterion of a large multi-line insurer that writes a substantial amount of workers compensation and other commercial insurance.

In determining whether to insure a firm, the purpose of the underwriters' evaluation of the management is to assess two essential elements. First, how competent is the management to run the business soundly so that it will be a profitable organization of continuing viability? Second, how effective is management in controlling hazards?

8.2 Areas of Emphasis

There is no established checklist or standard set of criteria for evaluating management in a variety of situations. There are, however, a considerable

number of elements that are considered in making an overall assessment. In interviews with senior officials of the insurance company, the two elements that received the greatest amount of emphasis were financial strength and experience.

The initial element that is reviewed is the financial strength of the prospective insured. The underwriters review the standard financial indicators that are commonly used such as return on capital and debt to equity ratio as well as profitability and cash flow. One of the more subjective judgments that is made is the reputation of the prospective insured in its industry.

Experience is a major consideration, both in and of itself as well as a factor in assessing the company on other criteria. The underwriters stress the importance of the experience of key company personnel. They prefer a management team whose members had successful and extensive experience. If a company is new, the insurers look for managers who have had experience in similar kinds of companies. Similarly, the technical background of managers is also weighed. Experience is regarded as a key determinant in deciding whether a company will be viable as a business entity.

There are three reasons for the insurers' emphasis on the financial prospects of the insured. First, is the issue of moral hazard. A company that is in poor financial condition might yield to the temptation to purposely incur a total loss through arson or other fraudulent means. Second, should a company go bankrupt, it may still incur liability claims for workers compensation (effects of past injuries) or product liability. Indeed, it is feared that such potential liabilities would increase with a firm in poor financial health. Finally, the insurers regard good organization and efficient operations as themselves a good proxy for safe operations.

In terms of organizational factors, the primary areas of review are reporting and authority relationships. In particular, the underwriters are concerned with the organizational placement of the risk manager. They regard the optimum organizational form as one in which the risk manager of a company reports directly to the president. The next best arrangement is direct reporting to the financial vice president in the belief that the latter's control of finances would give greatest weight to the risk management function.

Table III reproduces part of a memorandum to the underwriting staff on characteristics of management and of the work force that are regarded as favorable or unfavorable in terms of likelihood for loss in workers compensation claims.

This list is meant to be used as an aggregate evaluation. It is noted that acceptable risks will not necessarily meet every item, but "in the majority, most acceptable risks will meet most of the favorable items."

Another specific characteristic that is appraised is the existence, quality, and adherence to formal policies and procedures on safety and loss control. The underwriters also review the evaluations that management itself conducts. There are several criteria for assessing these evaluations. First,

evaluations should be a regular part of a management self-assessment system and conducted periodically. Second, they should be carried out by qualified staff. Third, they should be documented against pre-established criteria. Fourth, the results should be conveyed to top management.

TABLE III

<u>FAVORABLE</u>	<u>UNFAVORABLE</u>
<u>Employer/Management Characteristics</u>	
Long tenure in business	New enterprise
Expertise/experience	New activity/experimental
Financial strength	Shoestring operation
Good new hire screening	Lax employee procurement
Written/enforced safety program	No objective safety program
Thorough accident investigation/review	No investigation
Adequate, on-going supervision	Little or no supervision
Successful, growing slowly but steadily	Rapid, sudden expansion
Business Increasing	Decreasing business
Cooperative, positive safety attitude	Uncooperative, lip-service
Good employee relations	Adversary employee relations-- suits, strikes
<u>Employee Work Force Characteristics</u>	
Adequate wage base for industry	Below prevailing wage base
Low turnover	High turnover
Properly trained	No training

The attitude of management is an overriding characteristic that is given a great deal of emphasis. While seemingly subjective, the assessment of attitude is based on tangible evidence rather than professions of safety-consciousness. The adherence to policies and procedures is a key indicator as is the response taken to accident reports and safety evaluations. This kind of responsiveness to safety concerns is actively probed as insurance auditors have access to corporate files. For example, insurers would check on whether certain licensed employees had thorough background checks prior to their being hired rather than just filled in later. Finally, an indicator of management seriousness about loss control is whether safety and loss control is tied into the company's performance appraisal and compensation system. Safety for oneself may be its own reward, but the insurers believe that safety for others is enhanced by financial incentives.

8.3 Process

The initial steps in the underwriting review are accomplished by the insurance agent who sells the policy. The agency supplies much of the specific financial information about a firm. Assuming a favorable response, the insurer then sends one or two loss control specialists to the company to interview top management as well as to visit production areas. In the case of a firm with multiple worksites such as a contractor, the loss control specialists visit the various sites. It is considered imperative to inspect

plants and other types of worksites because the underwriters believe that safety consciousness and management attitude are effectively revealed by the appearance of work sites and the handling of routine hazards.

These reviews are not a one-time event. The insurance company's loss control specialists regularly inspect and review the insured company, and the frequency of review depends on individual circumstances such as size of company and degree of hazard. The underwriting loss control staff typically have formal training in loss control. They generally have physical science degrees and/or are graduates of safety programs in college. The insurance company has a broad range of safety experts available. In addition to the loss control representatives, they have experts in such subjects as industrial hygiene and fleet safety. While the insurer does not utilize experts in management or management auditing per se, it does have staff with loss control experience in particular industries.

The methodology of underwriting evaluations is not empirical or quantitative. It is judgmental, with a great number of individual factors that go into that judgment. In coming to judgments on whether companies meet certain criteria, the underwriters often utilize a comparative perspective. In the case of financial indicators, the position of a company is assessed in relation to industry averages. Frequently, a firm that is known to be extremely well managed is used as a benchmark against which to evaluate other prospective insureds.

Although the process is seemingly subjective, there is a continuous empirical base to validate or invalidate the subjective judgments. No one expects zero

accidents, but the insurance company expects an acceptable frequency of moderate claims. Although there is no precisely quantified correlation between any one of the elements reviewed and acceptable results, experience has convinced the insurance company that in the aggregate the factors they look for are associated with reasonable claim frequency and severity. Like the NRC, the worst outcome from the insurer's standpoint is a catastrophe leading to huge claims. Insurers, however, can use a large number of lesser accidents to validate whether their management assessments are correct.

9. IMPLICATIONS FOR THE NUCLEAR REGULATORY COMMISSION

The areas of emphasis in the criteria used by other organizations are summarized in Table I on page 3 of this report. Because current NRC criteria and procedures are still changing, it is not useful to make a point by point comparison between the criteria of other agencies and those of the NRC. However, several general observations can be made about the implications of the findings of this report for the NRC's assessment of administration and organization.

It is quite clear that the NRC should continue its emphasis on administration and organization. Other agencies with quite different responsibilities have independently reached the judgment that management is not only the key to performance of functions that complies with regulations, but also that management and organizational factors themselves can and should be subject to monitoring and detailed evaluation.

In comparing the areas of emphasis of the organizations reviewed in this report with the actual areas of emphasis in NRC management reviews, based on an earlier Battelle analysis, some contrasts can be noted.⁷ First, other organizations devote much more attention in their reviews to the use of strategic planning by the organization under review. Admittedly planning is different and may be of different importance for any firm in a market environment such as a bank or for a government agency with multiple programs, some of which are optional. Nonetheless, other competent reviewing organizations still regard planning as a hallmark of management competence per se. Secondly, other organizations appear to stress the importance of performance indicators for individuals and operations units more than was evidenced in NRC reviews. Again, this is viewed as a key element of management's ability to control and, equally important, improve an operation. Third, there was considerable emphasis on management information systems to provide information on current operations and future needs. While the NRC probes the ability of plant management to receive useful and timely information about functional areas, this aspect of management competence capability does not appear to be stressed to the same extent by the NRC as by other organizations.

With regard to the process used in conducting reviews, a major difference between the other organizations and the NRC is in the training of staff. The other organizations reviewing private firms relied on staff that was specifically trained or had an educational background emphasizing management issues. To some extent, the insurance company was an exception since it uses loss control staff (safety engineers, etc.), but it also provides back-up by

individuals with in-depth experience in the industry in question. In that sense, the insurance underwriters are similar to the NRC although the staff experience still is more managerial and financial in orientation.

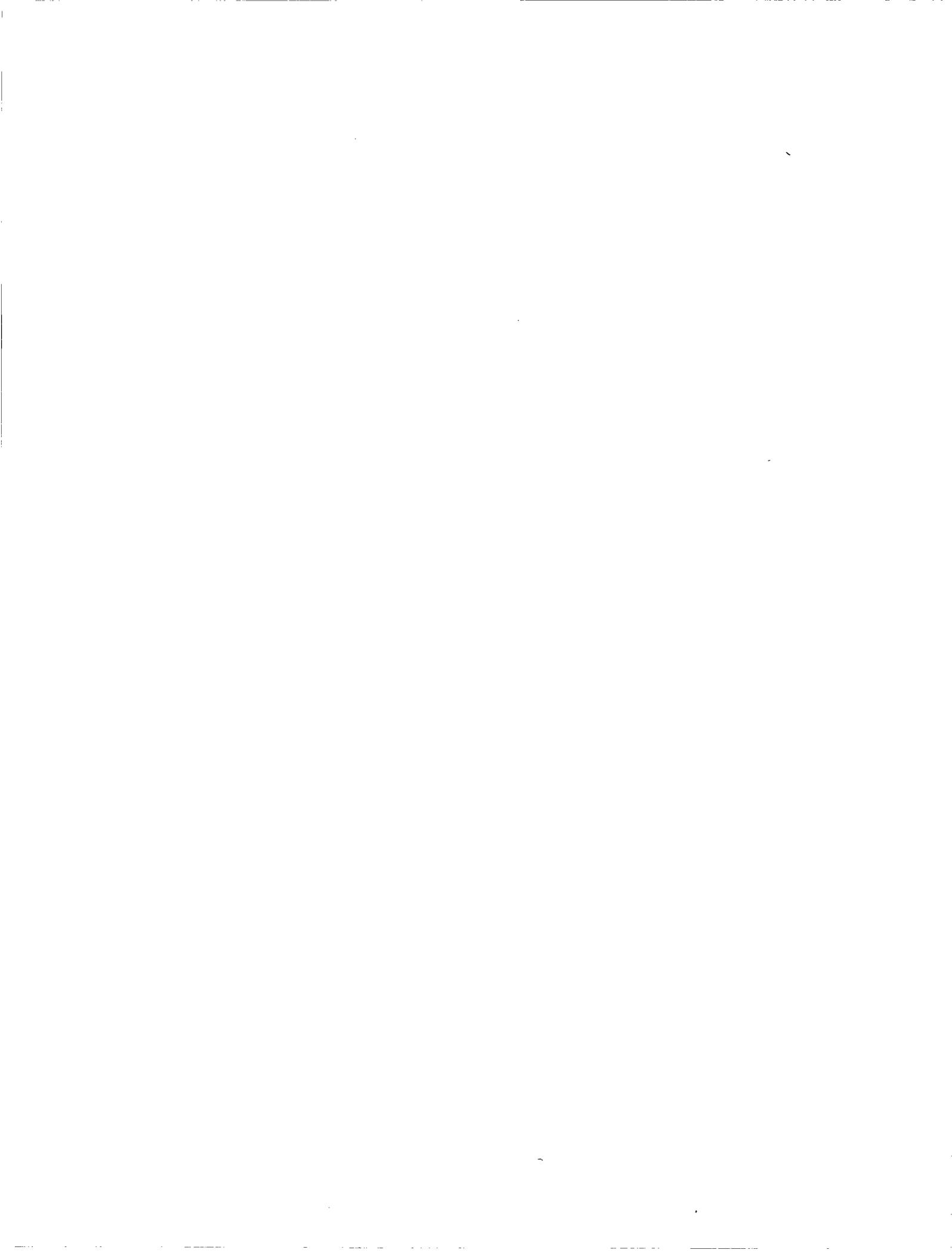
In conclusion, to the extent that the NRC finds it desirable to rely on the experience of other organizations, our findings suggest that more attention be paid to planning, performance indicators, and management information systems and that there should be more training available for staff on management and organization review.

⁷ Mark V. Nadel, et al., "Analysis of Processes Used in Evaluating Utility Management and Organization for an NRC Operating License," Battelle Human Affairs Research Centers, 1982.

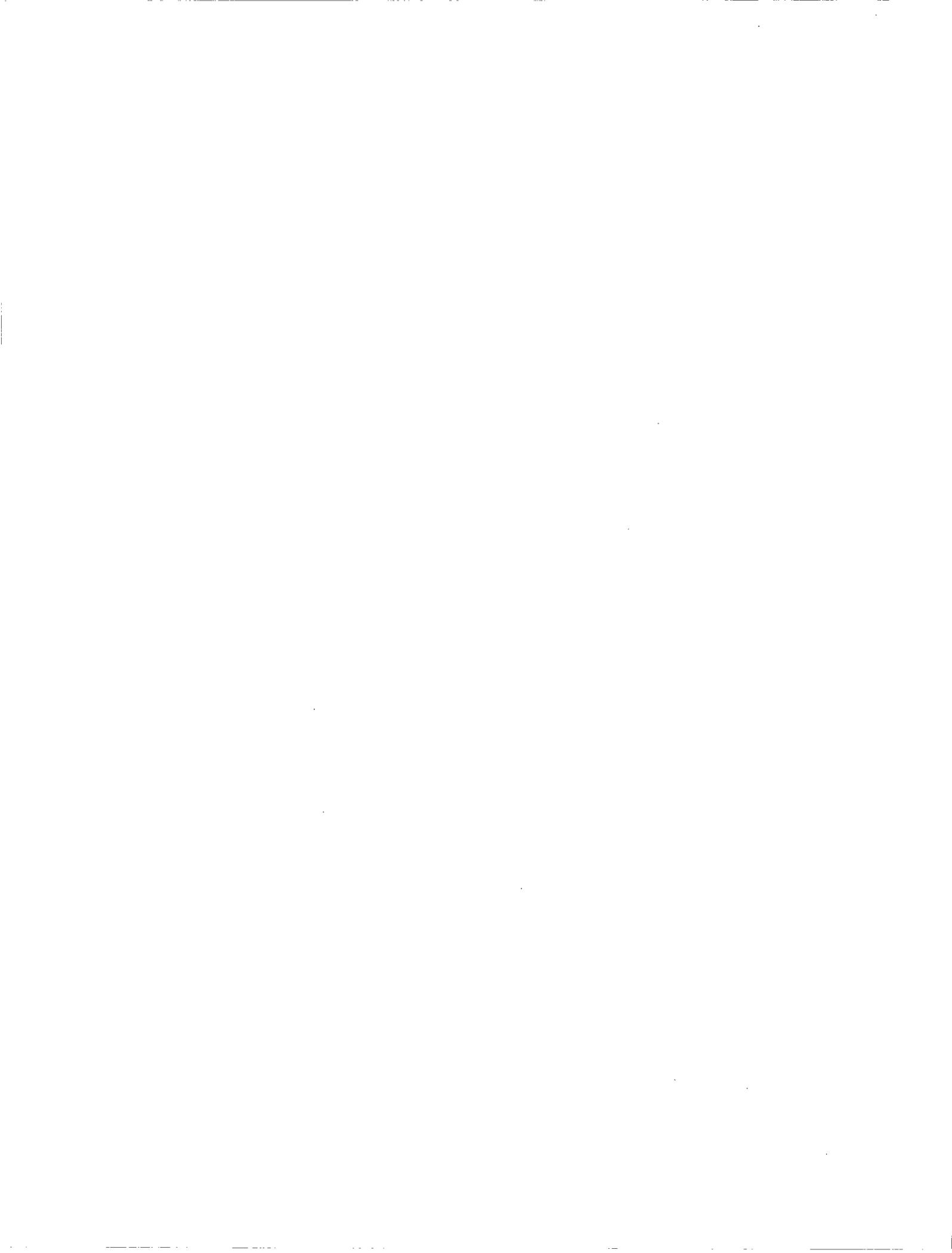


DISTRIBUTION

<u>No. of Copies</u>		<u>No. of Copies</u>	
10	Dr. Mark V. Nadel U.S. General Accounting Office 441 G Street, N.W., Room 6150 Washington, D.C. 20548		<u>ONSITE</u>
		29	Battelle <u>Human Affairs Research Centers</u>
10	Dr. Cornelius M. Kerwin 5301 Westbard Circle Bethesda, Maryland 20014 U.S. Nuclear Regulatory Commission Division of Technical Information and Document Control 7920 Norfolk Avenue Bethesda, MD 20014		R. J. Cole A. A. Marcus S. D. McLaughlin J. Olson R. N. Osborn R. Shinkiar P. E. Sommers S. M. Nealey J. A. Thurber (20) C. R. Schuller
20	P. Clare Goodman U.S. Nuclear Regulatory Commission Washington, DC 20555	9	<u>Pacific Northwest Laboratory</u> R. D. Widrig (2) Publishing Coordination (2) Technical Information (5)



NRC FORM 335 <small>(11-81)</small>		U.S. NUCLEAR REGULATORY COMMISSION BIBLIOGRAPHIC DATA SHEET		1. REPORT NUMBER (Assigned by DDC) NUREG/CR-3601 PNL-4813 BHARC-400/83/016	
4. TITLE AND SUBTITLE (Add Volume No., if appropriate) Management and Organizational Assessments: A Review of Selected Organizations				2. (Leave blank)	
7. AUTHOR(S) M.V. Nadel, C.M. Kerwin/BHARC				3. RECIPIENT'S ACCESSION NO.	
9. PERFORMING ORGANIZATION NAME AND MAILING ADDRESS (Include Zip Code) Battelle Human Affairs Research Centers 2030 M Street, NW Washington, DC 20036 Pacific Northwest Laboratory Richland, WA 99352				5. DATE REPORT COMPLETED MONTH YEAR July 1983	
12. SPONSORING ORGANIZATION NAME AND MAILING ADDRESS (Include Zip Code) Division of Human Factors Safety Office of Nuclear Reactor Regulation U.S. Nuclear Regulatory Commission Washington, DC 20555				6. (Leave blank)	
13. TYPE OF REPORT				10. PROJECT/TASK/WORK UNIT NO.	
15. SUPPLEMENTARY NOTES				11. FIN NO. B2360	
16. ABSTRACT (200 words or less) <p>This report reviews the processes and criteria used by organizations other than the NRC in conducting management and organization audits and evaluations. As part of a larger project assisting the NRC in establishing improved procedures and guidelines for assessing the management and organization of applicants for nuclear power plant operating licenses, this report provides a comparative perspective on organizational assessment. The organizations whose management audits are reviewed are state public utility commissions, the Comptroller of the Currency, the Department of Health and Human Services' Office of Health Maintenance Organizations, the Food and Drug Administration, the General Accounting Office, and a large commercial insurance company. This report examines the purposes, areas of emphases, and processes used in these reviews. These organizations conclude that management is the key performance of organizational functions.</p>				8. (Leave blank)	
17. KEY WORDS AND DOCUMENT ANALYSIS Management, organization, management audit				14. (Leave blank)	
17a. DESCRIPTORS				13. PERIOD COVERED (Inclusive dates)	
17b. IDENTIFIERS: OPEN-ENDED TERMS				14. (Leave blank)	
18. AVAILABILITY STATEMENT Unlimited		19. SECURITY CLASS (This report) Unclassified		21. NO. OF PAGES	
20. SECURITY CLASS (This page) Unclassified		22. PRICE \$			



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

FOURTH CLASS MAIL
POSTAGE & FEES PAID
USNRC
WASH. D C
PERMIT No. G-67

NUREG/CR-3601

MANAGEMENT AND ORGANIZATIONAL ASSESSMENTS:
A REVIEW OF SELECTED ORGANIZATIONS

FEBRUARY 1984