

GENERAL ACCOUNTING OFFICE
REPORT TO THE CHAIRMAN,
NUCLEAR REGULATORY COMMISSION

REPORTING UNSCHEDULED EVENTS
AT COMMERCIAL NUCLEAR
FACILITIES: OPPORTUNITIES
TO IMPROVE NUCLEAR REGULATORY
COMMISSION OVERSIGHT

D I G E S T

The Nuclear Regulatory Commission regulates the construction and operation of nuclear powerplants and other facilities and the possession, use, and disposal of nuclear materials to protect the public from radiation hazards. To oversee these activities, the Commission relies on information obtained in reports from licensees. The Commission uses these reports to (1) identify safety-related incidents and problems, (2) assist it in making safety-related decisions, and (3) disseminate information to the public on the nuclear industry's operating experiences.

Examples of safety-related incidents or events that licensees must report are over-exposures of workers or the public to radiation and failures of instruments used to monitor various safety-related activities. GAO reviewed the Commission's program for collecting and evaluating licensees' reports of incidents or unplanned events.

GAO found that the Commission needs to improve its licensee report assessment procedures to better assure that it is identifying and acting on all safety-related problems. For example, the Commission's review of reported events following its discovery of a safety-related problem at two operating nuclear powerplants revealed that the problem had been widespread for sometime. Better assessment procedures may have enabled the Commission to identify this problem earlier. (See pages 3 to 8.)

GAO also found that the Commission should extend its licensee report requirements to types of events not now covered. The Commission should:

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- Require utilities operating older nuclear powerplants to monitor and report on the performance of safety-related systems and components in a manner consistent with requirements for utilities operating newer powerplants. This would give the Commission more complete information on unplanned events at operating nuclear powerplants. (See pages 13 to 15.)
- Require licensees using hazardous types and quantities of nuclear materials in conjunction with equipment such as radiography devices to report equipment failures which could cause or contribute to safety-related incidents. The most significant occupational overexposures occur in these types of nuclear programs, but the Commission now receives equipment failure information only when safety-related incidents actually occur. (See pages 15 to 16.)
- Require medical licensees to report to the Commission misadministrations of radiation or radioactive materials to patients. The Commission needs to be informed of these incidents so it can determine their causes and, if appropriate, alert other medical licensees of the hazards associated with certain operating practices and modify its medical licenses or regulations. (See pages 16 to 18.)

This report also addresses the President's request in his 1977 energy message that the Commission make mandatory a nuclear industry voluntary system for reporting minor mishaps and component failures at nuclear powerplants. The primary objective of this system is to develop a data base for industry so it can increase the reliability and performance of future plants through improved designs and operating practices. Many utilities have not made meaningful efforts to participate in the system. The Commission attributes this to uncertainty over the future of nuclear power. At this time, the Commission is not convinced of the need to mandate full industry participation because it does not believe any major nuclear powerplant

design improvements would result. The Commission intends to study the issue further while increasing its financial support to the system. (See pages 8 to 10.)

At this time, GAO believes it unlikely that the Commission can justify mandatory industry participation in the reporting system when factors such as additional industry costs, limited expected safety benefits, and duplication with the Commission's event report system are considered. GAO does, however, believe a full examination of the issue is warranted. An alternative approach to continued Commission staff study, which GAO favors, would be to decide the issue in the near future using rulemaking procedures. This format would best insure that the Commission obtains and considers the views of the nuclear industry and the public in reaching its decision. At a minimum, the Commission should address

- the objectives, benefits, and costs of a mandatory reliability report system;
- responsibility for funding and operating a mandatory reliability report system; and
- the reliability report system's interface with the Commission's present reporting requirements.

GAO RECOMMENDATIONS

To provide the Commission with reasonable assurance that it promptly identifies all safety-related problems from licensee event and/or incident reports, the Chairman, Nuclear Regulatory Commission, should:

- define the scope and frequency of required analyses, and documentation and disposition procedures, for staff use in assessing licensee event reports; and
- establish a system for controlling and evaluating incident reports with clearly defined objectives, responsibilities, requirements for analyses, and administrative procedures. (See pages 3 to 12.)

In addition, the Chairman, Nuclear Regulatory Commission, should extend its event and incident reporting requirements to require

- uniform surveillance and reporting requirements on safety systems and components common to all nuclear powerplants,
- nuclear materials licensees using equipment containing hazardous radioactive materials to report equipment design deficiencies and malfunctions, and
- medical licensees to report all misadministrations of patient radiation treatments and radioactive drugs. (See pages 13 to 20.)

GAO also believes that the Chairman, Nuclear Regulatory Commission, should use rulemaking procedures to decide the issue of mandating full nuclear industry participation in the industry's voluntary reliability report system. (See pages 8 to 11.)

COMMISSION STAFF VIEWS

The Commission's staff agreed that it should improve its controls over and reviews of licensee event and incident reports. The staff also agreed on the need to promptly resolve the issue of mandating industry participation in its voluntary reporting system. The staff suggested advance notice of proposed rulemaking as an appropriate method for resolving this issue. The staff did not agree that the Commission should require uniform surveillance and reporting on all operating nuclear powerplants, or require medical licensees to report all misadministrations.

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ABBREVIATIONS

AEC	Atomic Energy Commission
FDA	Food and Drug Administration
GAO	General Accounting Office
NRC	Nuclear Regulatory Commission

CHAPTER 1

INTRODUCTION

The Nuclear Regulatory Commission (NRC) regulates the possession, use, and disposal of nuclear materials to protect the public from radiation hazards. There are presently about 8,800 NRC-issued licenses. ^{1/} Included in this figure are operating licenses for 69 nuclear powerplants and construction permits for 89 more. Thirty-three licenses are for nuclear fuel cycle facilities, 73 are for research and test reactors, and the remaining licenses are for various research, industrial, medical, and educational applications of nuclear materials.

To oversee such a large and diverse number of activities, NRC relies to a great extent on information from licensees to assist it in making safety-related decisions concerning all aspects of the possession, use, and disposal of nuclear materials. Information supplied by licensees often becomes the basis for regulations and standards by which licensees are regulated. Because it needs this information, NRC has established general licensee reporting requirements in its regulations and sets more specific requirements in individual licenses.

NRC's regulations require all licensees to report radioactive material releases and radiation exposures to individuals in excess of regulatory limits; and to report the loss or theft of nuclear materials. The regulations also contain many other reporting requirements directed at specific types of licensees.

NRC uses these reports to assess licensees' day-to-day operations. In this way, NRC tries to identify and investigate incidents and problems, assure corrective actions, develop information on generic problems, and disseminate information to the public concerning the nuclear industry's operating experiences. In addition, the Energy Reorganization Act of 1974 (42 U.S.C. 5848) requires NRC to investigate unplanned or unanticipated incidents and report significant safety-related

^{1/}Also, 25 States have signed agreements with NRC to regulate about 11,000 additional nuclear materials licenses.

events--abnormal occurrences 1--to the Congress and the public on a quarterly basis. These reports must also state the causes and the corrective actions taken to prevent recurrence.

SCOPE OF REVIEW

We reviewed NRC's program for collecting and evaluating licensees' reports of unscheduled events or incidents. These events are unplanned and usually are related to safety. Examples include overexposures of workers or the public to radiation, failures of systems that may permit overexposures or excessive releases of radiation, or failures of critical instruments used to monitor important systems. We did not review NRC's periodic or routine reports such as annual or quarterly occupational exposure reports, routine effluent monitoring reports, and notifications of nuclear material transfer. Our report addresses

- the efficiency and effectiveness of the entire incident report system,
- whether or not the system is broad enough in coverage, and
- the President's request that NRC make mandatory a nuclear industry voluntary system for reporting minor mishaps and component failures at nuclear powerplants.

The report also contains our conclusions, observations, and recommendations on these matters.

1/NRC has established specific criteria for determining which unscheduled safety-related events should be classified and reported as abnormal occurrences.

CHAPTER 2

LICENSEE REPORTS SHOULD BE

USED MORE EFFECTIVELY

NRC requires licensees to report incidents and unplanned events associated with the construction and operation of nuclear powerplants and the use of nuclear materials. NRC has identified safety-related problems by assessing these reports. More effective use of these reports, however, is hampered by a lack of clearly defined assessment objectives and methods, responsibilities, and procedural controls. As a result NRC does not know if it is promptly finding and identifying all potential safety-related problems. Furthermore, its report review procedures are fragmented. Finally, it cannot be certain it has received and appropriately reviewed all reports.

NRC also encourages utilities operating nuclear powerplants to participate in a nuclear industry system for voluntarily reporting minor mishaps and component failures at these plants in order to develop a reliable data base for NRC and industry to use in improving powerplant designs and operating practices. The President has asked NRC to mandate full nuclear industry participation in this reliability report system; but NRC has not yet decided if the benefits from a mandatory industry participation program outweigh the additional industry reporting burden--especially in view of the present duplication between the voluntary reliability report system and NRC's licensee event report system. We suggest that NRC consider resolving this question by means of rule-making procedures.

NRC NEEDS TO BETTER MANAGE REPORTS OF EVENTS AT OPERATING NUCLEAR POWERPLANTS

NRC has established an extensive reporting system--called a licensee event report system--to gather information on the operating experience at nuclear powerplants. During 1977 utilities submitted about 3,000 reports to NRC describing incidents and unplanned events at powerplants. Depending on their safety significance, utilities are required to report the events immediately, within 24 hours, or within 30 days of their occurrence.

Immediate or 24-hour reports are required for important events such as excessive releases of radiation, overexposures to individuals, or attempted sabotage. Utilities must report

these events by telephone or other means of rapid communication to the nearest of NRC's five regional inspection and enforcement offices. Based on these notifications, NRC regional offices take action on a case-by-case basis in accordance with established response procedures. Detailed written follow-up reports must also be submitted within 14 days. The 30-day reports submitted to NRC regional offices usually involve equipment failures during tests, utility failures to perform required surveillances, or inadequate procedures.

NRC regional offices forward report copies to an NRC headquarters distribution office set up in February 1978 to account for all licensee event reports and route them to appropriate staff offices. Before this, NRC had no assurance that it was receiving and properly distributing all reports. It is still too early to determine if this office will be able to account for all reports. The distribution office sends report copies to the headquarters Office of Inspection and Enforcement, Division of Operating Reactors (in NRC's Office of Nuclear Reactor Regulation), and Office of Management and Program Analysis.

At NRC regional offices, inspectors are required to assess each licensee event report for (1) the appropriateness of licensee corrective action and the need for a follow-up inspection effort; (2) the event's generic importance to other components, systems, or activities within the powerplant or at other powerplants in the region; and (3) possible reporting to the Congress as an abnormal occurrence. Staffs of the three NRC headquarters offices assess each report for its safety importance at the powerplant, its applicability to all other powerplants, and its potential for reporting as an abnormal occurrence. An important part of this assessment is the identification of potential safety-related problems needing further evaluation and perhaps action in the form of new regulatory requirements.

NRC has clearly defined staff and Commission responsibilities, administrative procedures, and assessment criteria for identifying events at operating nuclear powerplants and other licensed activities which must be reported to the Congress as an abnormal occurrence. It has not, however, clearly defined these assessment elements for identifying potential safety-related problems from licensee event reports. Rather, it has left to each of the three headquarters offices and five regional offices the discretion of deciding on the scope and frequency of analyses necessary to identify new safety problems as early as possible. The offices have further delegated this decisionmaking to individual staff members. Furthermore, neither NRC as a whole nor its respective staff offices has established decision documentation and disposition procedures.

Thus, only when a new safety problem is identified can NRC be assured that the report or series of reports has received an adequate assessment.

In the past, NRC has identified certain safety-related problems at operating nuclear powerplants using the fragmented approach described above. NRC officials said these problems were usually discovered through the cooperative efforts of utilities, powerplant component manufacturers, and the NRC staff. Most of these problems, they said, were originally described in licensee event reports. By querying NRC's computerized file of event reports, NRC staff members were then able to determine that these problems were widespread and significant enough to warrant additional investigation. We believe a more systematic assessment process in which analytical and procedural requirements are clearly defined would give NRC better assurance that it is promptly identifying all safety-related problems.

For example, one problem now under NRC review deals with shock absorbers attached to piping in nuclear powerplants to prevent vibrations from cracking the pipes. These shock absorbers are filled with fluid and must retain this fluid to remain effective. In 1973 an NRC inspection of two operating powerplants revealed a high incidence of inoperable shock absorbers. The regional inspection office pointed out the problem to NRC headquarters officials. These officials then reviewed NRC's file of licensee reports and found that the problem had been widespread for some time. Its initial investigation revealed problems related to inadequate materials. Further investigation revealed still other problems including design, manufacture, and installation deficiencies.

This example highlights the need for NRC to clearly define the scope and frequency of analysis required to promptly identify potential safety-related problems. Had such requirements been in effect, NRC may have detected the shock absorber problems earlier. We are not alone in our concern that NRC is not making full and effective use of its licensee event report system. Recently, members of the Advisory Committee on Reactor Safeguards ¹/ expressed concern that the NRC staff is not adequately using data collected from reports because the staff has not, in the Committee members' opinions, set up a systematic methodology for using this data. Members of the NRC staff have also recognized shortcomings in the system.

¹/An independent committee of up to 15 members established by the Congress. It is required to review each nuclear powerplant application and make other reviews as requested.

For example, in an evaluation of licensee reporting requirements, the technical advisor to NRC's Executive Director for Operations concluded that NRC should be obtaining, analyzing, and feeding back nuclear powerplant operating data into the licensing process much better than it is now doing.

NRC NEEDS TO SYSTEMATICALLY
ACCOUNT FOR AND EVALUATE
NUCLEAR MATERIAL LICENSEE
INCIDENT REPORTS

Significant nuclear-related incidents, such as overexposures to workers or members of the public, occur more often at nuclear material licensee facilities than at operating nuclear powerplants. In part, this is due to the comparatively large number--over 8,000--of nuclear material licensees. NRC requires these licensees to report radiation exposures or radioactive material releases in excess of limits established in its regulations; and the loss or theft of nuclear materials. These licensees report about 300 incidents annually. Officials of several NRC offices said they use these reports as follows:

- regional inspection offices use them in determining the causes of incidents and evaluating licensees' corrective actions;
- the Office of Inspection and Enforcement uses them in evaluating NRC's inspection and enforcement program and to identify potential abnormal occurrences;
- the Office of Nuclear Material Safety and Safeguards uses them in determining if specific license conditions or general licensing policies and standards need improvement, and to identify safety problems that could be common to other licensees; and
- the Office of Management and Program Analysis uses them to prepare NRC reports and to identify potential abnormal occurrences.

NRC has not, however, established a system for controlling licensee reports to insure that each office receives and assesses all reports nor has it defined evaluation procedures and responsibilities of each office.

NRC does not account for incident reports

NRC's regulations generally direct nuclear material licensees to report incidents to the nearest NRC regional office. NRC has not, however, set up procedures to insure

that regional offices forward incident reports to appropriate headquarters offices. As a result, the NRC headquarters inspection, licensing, and program analysis offices are not receiving all incident reports submitted by licensees to NRC regional offices.

The NRC headquarters offices rely heavily on regional inspection offices' telephone calls, daily activity reports, and license inspection reports as sources of information on licensee incidents. But these have proved to be unreliable sources to identify incident reports. For example, neither the NRC headquarters inspection, licensing, nor program analysis offices has a complete list of 23 overexposure incident reports submitted to one regional office in 1977. In fact, the Office of Management and Program Analysis, which annually publishes a report on overexposure statistics, was aware of only 8 of the 23 overexposures.

NRC has not defined assessment procedures and responsibilities

NRC has not established procedures for its offices to follow in assessing nuclear material licensee incident reports which would define review objectives and scope, office responsibilities, or coordination required among offices. As a result, there is some confusion among the various headquarters and regional offices over the scope of assessments each office performs. For example:

- NRC headquarters officials said they rely on regional office inspectors to identify from incident reports weaknesses in licensees' nuclear programs that might be common to other licensees. Regional office inspectors, however, said NRC headquarters should be responsible for this type of evaluation because it receives reports from all five regional offices.
- Two of the three regional offices we visited do not attempt to identify weaknesses in licensees' nuclear programs that might apply to other licensees. On the other hand, the third office accords this its highest priority.
- Officials of NRC's headquarters inspection office and its licensing office each said the other office is responsible for maintaining a complete file of incident reports. As a result, neither office maintains a complete file.
- NRC's licensing office has not assigned staff review and disposition responsibility for identifying safety

problems that might apply to other licensees. Officials of this office could not provide us examples of any such safety problems identified from incident reports, nor could they provide any documentation to show the reviews were performed.

NRC's failure to define objectives, procedures, and responsibilities has resulted in incomplete incident assessments. For instance, incident reports submitted to two regional offices are not reviewed by either regional or headquarters staff for the purpose of identifying safety problems which might apply to other licensees.

MANDATORY INDUSTRY RELIABILITY
SYSTEM PARTICIPATION MAY NOT BE
NECESSARY

In his April 1977 energy message, the President requested NRC to make mandatory the present nuclear industry system for voluntarily reporting minor mishaps and component failures at operating nuclear powerplants. It was expected that mandatory participation would enable industry and NRC to develop a more reliable data base of safety-related system and component failures than attainable with voluntary participation. The reliability system was designed to produce system and component failure statistics from nuclear powerplant operating experience useful to NRC and those who design, construct, and operate these plants by

- improving systems reliability and increasing the time powerplants are on line,
- improving system designs and surveillance and test schedules,
- identifying failure trends and wear-out patterns,
- reducing powerplant licensing times, and
- improving maintenance and spare parts management and component purchasing evaluations.

There are at least two important differences between the industry's reliability report system and NRC's licensee event report system. First, NRC requires reports of many other types of safety-related events besides system or component failures. Second, NRC's report system is primarily oriented towards operating safety--NRC needs to be notified of events so it can investigate their public safety implications--and secondarily towards improving the reliability of powerplant systems and components.

Reliability system operation and funding

The Edison Electric Institute developed the reliability system in the early 1970s at the suggestion of the American National Standards Institute. In 1973 a contractor was selected to operate the system and the American National Standards Institute established a subcommittee to oversee the system's operation. NRC was, and continues to be, represented on this subcommittee and in 1978 provided \$150,000 of the system contractor's \$370,000 operating budget. The remainder of the budget is provided by the Edison Electric Institute, the American Public Power Association, and the Tennessee Valley Authority.

Full system participation by a utility operating a nuclear powerplant requires a one-time initial effort to develop engineering data on all safety-related components and systems. In a typical nuclear powerplant there are dozens of safety-related systems and as many as 6,000 components. Two to three man-years of effort at an estimated cost of \$200,000 to \$250,000 is necessary to develop the one-time engineering data. The annual cost of reporting component and system failures is estimated at \$50,000 per powerplant. Except for six of the oldest operating plants, all utilities operating nuclear powerplants are eligible to participate in the reliability system. The six oldest plants were considered atypical and thus not included. Utilities operating 55 of 58 presently eligible plants are participating in the reliability system. Two utilities have declined to participate, and another has not reported any system and component engineering data. Many utilities, however, have limited their participation. While some utilities have completed their engineering data, others have not put forth meaningful efforts. Overall, NRC estimated that utilities have submitted engineering data on about 65 percent of their plants' safety-related systems and components. Furthermore, in reviewing the utilities' failure reports, NRC found many examples of poor and incomplete reporting. For example, when it compared component failure-related licensee event reports to utilities' reliability system failure reports, NRC found that utilities reported only about 20 percent of the failures that they should have reported in the reliability system.

NRC believes some utilities are not fully participating in the reliability system because the expected benefits are essentially long term and will be realized on future--rather than presently operating--nuclear powerplants; and these utilities do not presently plan to build additional nuclear plants. Also, there has not been any effort to date to develop

reliability system information with short-term usefulness in maintenance or spare parts management. Finally, the reliability system includes only safety-related systems and components. There are many systems and components important to powerplant operations which are not safety-related.

A major consideration on the issue of mandatory industry participation in the reliability system is its interface with NRC's licensee event report system. Presently, about 60 percent of the information utilities report on component failures in the reliability system is also reported to NRC. On the other hand, because the two systems' objectives are different, each report system requires some information on component failures not required by the other. Furthermore, NRC requires licensees to report many types of events besides system or component failures--about 50 percent of the event reports NRC receives relate to system or component failures.

NRC staff, industry, and other
opinions on mandatory participation

There is presently no consensus within NRC to mandate full industry participation in the reliability report system. In 1977 an NRC study group recommended mandatory participation, but also concluded it would probably not result in any major nuclear powerplant design improvements. An Advisory Committee on Reactor Safeguards subcommittee was not convinced of the need for mandatory participation in view of (1) the costs, (2) duplication with the NRC licensee event report system, and (3) lack of systematic NRC staff analyses of licensee event reports.

The nuclear industry opposes NRC mandating industry participation on the basis that the needs for and uses of component reliability data go far beyond legitimate regulatory needs. They point out that the reliability system was not designed to be a regulatory tool, and that by mandating industry participation NRC would essentially be taking over the system for regulatory purposes.

In August 1978 the principal NRC official addressing this issue told us that the NRC staff is preparing a paper for presentation to the NRC Commissioners which will recommend that industry participation not be made mandatory at this time; that NRC study the issue further; and, in the meantime, that NRC increase its financial support to the reliability report system in order to promote increased voluntary participation and use of the system.

CONCLUSIONS

An important part of NRC's overall assessment of events reported by utilities operating nuclear powerplants is the identification of potential safety-related problems needing further evaluation and perhaps action in the form of new regulatory requirements. NRC has identified some safety-related problems from licensee event reports. Its present assessment system, however, is fragmented and inefficient with as many as four offices reviewing an event report or series of reports. Moreover, NRC does not have assurance that it is promptly finding all identifiable safety-related problems because it has not clearly defined the scope and frequency of required analyses. Instead, these matters are left to the discretion of individual reviewers. Finally, NRC has not established review and decision documentation and disposition procedures.

Likewise, NRC cannot account for nuclear material licensee incident reports to insure that they are all adequately assessed. It has not defined assessment (1) objectives and required analyses; (2) responsibilities; and (3) procedures to insure that all reports are properly received, routed, and evaluated. Thus, as is the case for its assessments of licensee event reports, NRC cannot be assured that it is promptly identifying all safety problems from incident reports.

With respect to the industry's voluntary reliability report system, NRC is not convinced of the need for mandating full industry participation. It therefore intends to continue studying the issue while increasing its financial support to the system. At this time, we believe it unlikely that NRC can justify mandatory industry participation when factors such as additional industry costs, limited expected safety benefits, and duplication with NRC's event report systems are considered. We do, however, believe a full examination of the issue is warranted. An alternative to continued in-house study, and one we favor, would be to decide the issue in the near future using rulemaking procedures. In a rulemaking proceeding, NRC sets out a proposed course of action, and a timetable for implementing it, and invites public comment. NRC then must consider comments received in deciding on a final course of action. Rulemaking in this case would provide the nuclear industry and the public, as well as the NRC staff, the opportunity to get their views on record; and would better insure that all of these views are properly considered by NRC in deciding the issue. We believe this is particularly important since the reliability system was developed, operated, and primarily funded by industry for industry's--rather than NRC's--benefit. A rulemaking proceeding should, at a minimum, address

- the objectives of a mandatory reliability report system;
- the costs of mandatory industry participation and the expected benefits;
- the beneficiaries, and how they will benefit from mandatory industry participation;
- responsibility for funding and operating a mandatory reliability report system; and
- the reliability report system's interface with NRC's existing event report system and how the two systems could be operated or merged to minimize duplication.

RECOMMENDATIONS

To provide NRC with reasonable assurance that it promptly identifies all safety-related problems from licensee event and/or incident reports, the Chairman, NRC, should

- define the scope and frequency of required analyses, and documentation and disposition procedures, for staff use in assessing licensee event reports; and
- establish a system for controlling and evaluating incident reports with clearly defined objectives, responsibilities, requirements for analyses, and administrative procedures.

We also recommend that the Chairman, NRC, resolve the issue of NRC mandating full nuclear industry participation in the reliability report system by using rulemaking procedures.

NRC STAFF VIEWS

NRC's staff agreed that it should improve its controls over and reviews of licensee event and incident reports. The NRC staff also agreed on the need to promptly resolve the issue of mandating industry participation in its voluntary reporting system. The staff suggested advance notice of proposed rulemaking as an appropriate method for resolving the issue.

CHAPTER 3

NRC SHOULD EXTEND CERTAIN REPORTING REQUIREMENTS TO LICENSEES NOT NOW INCLUDED

NRC's event-oriented reporting requirements are not sufficiently broad and should be extended to cover additional licensees and types of events. Specifically, NRC should require

- all utilities operating nuclear powerplants to report the same unscheduled events,
- nuclear materials licensees to report equipment failures which could cause or contribute to safety-related incidents, and
- medical licensees to report misadministrations 1/ of radiation or radioactive materials to patients.

NEED FOR UNIFORMITY IN NUCLEAR POWERPLANT REPORTING

NRC's nuclear powerplant reporting requirements are much more comprehensive than for other types of licenses. In 1977 utilities operating 64 powerplants reported about 3,000 events. These included such things as small errors in instrumentation gauges, valve malfunctions, utility failures to make periodic surveillances, and inoperative emergency equipment.

The requirements for nuclear powerplant reporting are established in NRC's licensing process. At that time a utility submits detailed information on the nuclear powerplant, including proposed operating limits for the plant's systems, NRC reviews the proposed operating limits and, if acceptable, approves them for licensing purposes. This part of the license is referred to as the "technical specifications" and becomes the requirements by which the utility must operate the plant. The technical specifications also describe what deviations from these operating limits must be reported to NRC. Utilities

1/Error in administering a radioactive drug or radiation treatment to a patient, including (1) the wrong drug or radiation treatment source, (2) the wrong patient, or (3) a dose or method of administration other than prescribed.

also must report any overexposures of individuals to radiation and excessive releases of radiation.

Under its present reporting system, NRC does not require all licensees to report the same events. This is attributable to two developments. First, NRC's technical specification requirements have historically become more stringent. Thus, utilities operating newer plants are required to perform more surveillances, make more tests, and consequently may report more deviations on the same components and systems than utilities operating older plants. For example, NRC officials told us that surveillance requirements for reactor cooling water pumps at a new plant are much more stringent than those of an older plant with the same type of pumps. Therefore, these officials said, a utility operating a newer plant is required to report certain pump failures which a utility operating an older plant is not required to report.

Second, new plants which use more sophisticated equipment and have more systems than older plants consequently have more surveillance requirements. This in turn results in increased deviations and reporting. For example, an NRC comparison of a nuclear powerplant licensed to operate in 1970 and another licensed in 1977 showed that the utility operating the older plant was required to make 13,633 annual surveillances compared to 169,216 annual surveillances for the utility operating the newer plant. Each time a surveillance is made and an excessive deviation noted, the utility must report the deviation to NRC. The effects of both the more stringent licensing review and the additional surveillance requirements at new plants as opposed to old plants are further demonstrated by comparing the number of reports submitted to NRC by all utilities operating nuclear powerplants during 1977. Utilities submitted an average of 29 reports on plants licensed before 1970, 42 reports for plants licensed between 1970 and 1975, and 99 reports for plants licensed in 1976. Two utilities operating plants licensed before 1964 did not submit any reports.

NRC is presently standardizing technical specifications for future plants and some plants under construction. However, NRC officials said this would not affect nuclear powerplants now operating because NRC will not require utilities operating these plants to change their technical specifications.

NRC's stated purpose of the licensee event report system is to identify and correct safety problems at existing and future plants. If reporting requirements for all plants are not the same for essentially the same systems and components, NRC may not be receiving complete information on the nature and frequency of unscheduled events at operating nuclear powerplants.

We find it paradoxical that NRC imposes its most stringent surveillance and reporting requirements on utilities operating newer powerplants. These newer plants incorporate the latest technological improvements and NRC safety requirements and presumably are safer to operate than older generation plants. It seems, therefore, that the more stringent requirements for newer powerplants should logically also fall on the older powerplants.

NRC DOES NOT REQUIRE MATERIALS
LICENSEES TO REPORT EQUIPMENT
FAILURES

NRC does not require licensees which use equipment containing hazardous materials to report equipment design deficiencies or malfunctions. Licensees use hazardous nuclear materials in industrial radiography 1/, medical teletherapy 2/, nuclear fuel processing, and irradiation 3/ activities. They are required to report safety-related incidents--such as overexposures but are not required to report near incidents resulting from malfunctioning equipment. For these licensees, NRC learns of equipment design deficiencies or malfunctions only when licensees report safety-related incidents.

Industrial radiography illustrates how equipment design deficiencies or malfunctions have contributed to safety-related incidents. From 1971 to 1977, 46 of the 87 significant overexposures reported to NRC--53 percent--occurred in industrial radiography, including 16 of the 18 worst overexposures. An NRC study attributed 40 percent of all radiography overexposures, from 1971 to 1975, in whole or part, to malfunctioning equipment.

NRC found that radiography device manufacturers had made design improvements only after overexposure incidents revealed equipment design and/or manufacturing defects. One manufacturer's radiography device had a poorly designed lock which permitted the radioactive source to slip to an unshielded

1/The use of sealed sources of radioactive materials in industrial applications to examine the structure of materials by nondestructive methods.

2/The use of radioactive devices external to the body to treat diseases.

3/The industrial use of radioactive materials to sterilize products such as pharmaceuticals.

position. The lock was redesigned only after a safety-related incident. Because NRC does not require reports unless safety-related incidents occur, it does not know how often radiography equipment has malfunctioned nor does it know if previous over-exposures could have been avoided if it had required routine reporting of equipment malfunctions.

Some NRC officials believe overexposure incidents in radiography could have been avoided if employees had followed approved operating procedures which would have enabled them to detect higher than expected radiation levels before being overexposed. In the past, NRC has emphasized instruction and training for radiographers, but these efforts have not been successful to date as overexposure incidents continue to occur--frequently involving equipment malfunctions.

Other NRC officials believe radiography equipment malfunction is a problem needing NRC's attention. One regional office has asked radiography and medical teletherapy licensees to voluntarily report malfunctions or design problems that could cause incidents. The region believes these reports have enabled it to identify equipment problems. For example, a recurring problem was found in a teletherapy device used at a university. Upon finding that this device was being used in three other locations, the region alerted each licensee of the potential hazards.

NRC DOES NOT REQUIRE MEDICAL LICENSEES TO REPORT MISADMINIS- TRATIONS

About 2,800 of NRC's 8,000 materials licenses are for the use of nuclear materials in the practice of medicine. Another 4,000 medical licenses are regulated by agreement States. NRC estimates the annual level of nuclear materials administrations in the United States has surpassed 30 million. NRC does not require medical licensees to report misadministrations, nor do NRC inspectors determine, during routine inspections, whether misadministrations have occurred.

Misadministrations at hospitals and other medical facilities have and continue to occur. NRC officials told us that licensees voluntarily reported from as few as none to as high as 12 misadministrations to each of the 5 NRC regional offices in the last year. From March 1975 through January 1976, about 400 patients at an NRC-licensed hospital received excessive radiation from medical teletherapy--a contributing factor in the deaths of several patients. But NRC did not become aware of the misadministrations until April 1976. Following its investigation, NRC required all of its medical teletherapy licensees

to test their equipment and report the test results. It is also preparing changes to its medical teletherapy regulations.

Between November 14, and December 13, 1977, a patient at another hospital received twice the prescribed dose of radiation. NRC became aware of the misadministration by chance on December 15, 1977, during a routine inspection when the hospital staff--mistakenly believing NRC was investigating the incident--told NRC's inspectors.

In 1972 GAO was aware of the problems in this area and recommended 1/ that the then Atomic Energy Commission (AEC), require medical licensees to report misadministrations so it could determine the causes and assess whether the licensees had taken adequate corrective actions. This information could then be analyzed and, if appropriate, AEC could (1) alert other medical licensees of the hazards associated with certain operating practices and (2) modify medical licenses or its regulations.

AEC, and now NRC, have been considering requiring licensees to report misadministrations since our 1972 report. The requirement has not been imposed, however, because of (1) controversies over whether or not NRC should also require licensees to tell patients of misadministrations and (2) confusion between NRC and the Food and Drug Administration (FDA) over their responsibilities in regulating the administration of radioactive drugs and radiation treatments to patients.

In July 1978 NRC published another proposed misadministration rule for public comment. The proposed rule would require licensees to

- keep records for 5 years of all misadministrations, and make them available for NRC inspections;
- report all misadministrations related to the treatment of patient diseases or disorders; and
- report diagnostic-related misadministrations which could cause a detectable adverse effect on the patient.

1/"Problems of the Atomic Energy Commission Associated with the Regulation of Users of Radioactive Materials for Industrial, Commercial, Medical and Related Purposes." (B-164105, August 18, 1972)

Licensees would be required to report to NRC, patients' physicians, and the patients, or their relatives or guardians. In reports to NRC, the proposed rule specifically states that licensees should not name patients, physicians, or other health personnel, but should describe the events, effects on patients, actions taken to prevent recurrence, and whether the patient, relative, or guardian was informed.

As occurred with the rule AEC proposed in 1973, medical community comments on NRC's proposed rule generally oppose mandatory misadministration reporting, and particularly the proposed patient notification part. Some commenters also stated that the requirement to report diagnostic misadministrations which could cause a detectable adverse effect on the patient was not stated with enough specificity to be uniformly and clearly interpreted and followed. The underlying reason of the opposition to reporting misadministrations to NRC, and particularly to the patient, is fear of malpractice suits. Another major reason is that the requirement would constitute an unwarranted NRC intrusion into medical practice.

CONCLUSIONS

NRC should extend its event and incident reporting requirements to types of events not now included. Specifically, NRC should require

- all utilities operating nuclear powerplants to report the same kinds of unscheduled events;
- nuclear materials licensees using equipment containing hazardous radioactive materials to report equipment design deficiencies and malfunctions; and
- medical licensees to report all misadministrations of patient radiation treatments and radioactive drugs.

In recent years, NRC has imposed more and more surveillance requirements on utilities operating newer nuclear powerplants. This results in increased frequency of event reporting. NRC attributes much of this additional surveillance and reporting to sophisticated plant systems and components in newer plants but not in older plants. Some of it, however, is due to general NRC increases in surveillance requirements at newer plants for all plant safety systems and components--including systems and components common to old and new plants. NRC has not, however, also imposed the increased surveillance requirements on utilities operating older plants. Thus, for identical or similar systems in older and newer plants, utilities operating the older plants are required to make fewer surveillances

--and thus report fewer events--than utilities operating newer plants.

Therefore, NRC's information on the performance of safety systems and components common to both old and new plants is incomplete. To enable it to fully evaluate the frequency and significance of events which may occur in safety systems and components common to old and new nuclear powerplants, NRC should impose uniform surveillance and reporting requirements on similar systems and components at all nuclear powerplants.

Many NRC nuclear materials licensees use hazardous radioactive materials in equipment which must be carefully designed, manufactured, and operated in order to prevent overexposures to licensee employees or members of the public. NRC does not, however, license the design or manufacture of this equipment. Instead, it reviews and approves the applicant's plans for safely using the hazardous material for the stated purpose, including a description of the equipment and its safety features.

Although overexposure incidents occur most often with licensees who use equipment containing hazardous radioactive materials, and the causes of these incidents are often attributable in whole or in part to equipment malfunctions or design deficiencies, NRC does not require these licensees to report malfunctions or design deficiencies similar to the way it requires utilities to report events at operating nuclear powerplants. Licensees are only required to report incidents--such as overexposures--to NRC. In these reports, licensees may identify equipment problems as causes or contributing causes of incidents, or NRC inspectors may reach these conclusions after investigating incidents. We believe NRC should require these licensees to report equipment design deficiencies and/or malfunctions when they are identified or occur, rather than only when reportable incidents occur. Such a requirement would enable NRC to promptly identify and act on equipment problems which could contribute to safety incidents.

We continue to believe that NRC should require medical licensees to report misadministrations of radiation and radioactive drugs. This would enable NRC to (1) determine the causes and whether licensees took adequate corrective actions and (2) if appropriate, disseminate information on misadministrations to other medical licensees to enhance their awareness of the hazards associated with certain operating practices and improve their controls over the handling of radioactive materials. NRC, and AEC before it, has been considering this requirement for over 5 years. The requirement has not been imposed, however,

because of controversy over the proposed patient notification requirement and confusion about NRC's and FDA's respective responsibilities.

Medical community comments generally opposed NRC's proposed misadministration reporting rule, particularly the patient notification part, out of fear of malpractice suits and NRC intrusion into medical practice. In our view, requiring medical licensees to report misadministrations to NRC is not an intrusion into medical practice. This is clearly consistent with NRC regulatory responsibilities and a necessary part of an effective nuclear medicine regulatory program. Without this kind of feedback on incidents affecting public health and safety, NRC cannot be sure it is adequately regulating the possession and use of nuclear materials in medical practice.

Also, as we concluded in our 1972 report, NRC should require medical licensees to report all misadministrations--whether hazardous to the patient's health or not--because they could potentially indicate weaknesses in licensee operating or management control procedures.

NRC should not permit the issue of patient notification to delay requiring medical licensees to report all misadministrations to NRC and patients' physicians. Therefore, in view of the continuing and intensive medical community opposition to the patient notification issue, NRC should delete it from the proposed rule and decide on it at a later date; and immediately require medical licensees to begin reporting all misadministrations to NRC and to patients' physicians.

RECOMMENDATIONS

We recommend that the Chairman, NRC, extend its event and incident reporting requirements to require

- uniform surveillance and reporting requirements on safety systems and components common to all nuclear powerplants,
- nuclear materials licensees using equipment containing hazardous radioactive materials to report equipment design deficiencies and malfunctions, and
- medical licensees to report all misadministrations of patient radiation treatments and radioactive drugs.

NRC STAFF VIEWS

The NRC staff said that at this time it does not believe it would be justified in requiring uniform surveillance and reporting requirements on both older and newer nuclear powerplants. The NRC staff also disagreed that medical licensees should be required to report all misadministrations to NRC. The NRC staff view is that requiring licensees to record all misadministrations and only report to NRC those which could cause a detectable adverse effect on patients would be sufficient.