United States General Accounting Office

GAO

Report to the Honorable Edward F. Feighan, House of Representatives

October 1988

NUCLEAR REGULATION

Stricter Controls Needed for Radioactive Byproduct Material Licenses

GAO/RCED-89-15

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-221188

October 12, 1988

The Honorable Edward F. Feighan
House of Representatives

Dear Representative Feighan:

On November 13, 1987, you asked us to assess the Nuclear Regulatory Commission's licensing, inspection, and enforcement program for the use of radioactive materials. This report presents the results of our review.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies of this report to appropriate congressional committees; the Chairman of the Commission; and the Director, Office of Management and Budget. We will also make copies available to others upon request.

This work was performed under the direction of Keith O. Fultz, Senior Associate Director. Other major contributors are listed in appendix III.

Sincerely yours,

J. Dexter Peach

J. Dexter Peach
Assistant Comptroller General

- NRC does not have assurance that applicants and licensees can pay to clean up facilities contaminated by a spill or release of radioactive material. Cleanup costs from a single accident can total over $1 million.
- NRC can take up to a year, and sometimes longer, to renew licenses, possibly allowing licensees to operate in an unsafe manner.
- NRC does not have specific criteria directing the use of financial penalties against licensees who repeatedly violate training, radiation monitoring, and record-keeping regulations.
- NRC has been slow to establish a certification program for industrial radiographers, a group of licensees who use x-ray-type devices to locate cracks and defects in pipe welds and structures. This group has a long-time poor compliance record.

Principal Findings

Better License Reviews Needed

NRC usually does not inspect an applicant's facility before granting a license, nor does it verify the information submitted. As a result, NRC headquarters staff say they have denied only three applications since 1985, although some applicants withdrew them before they were denied. A number of past reports and one GAO case study point out the potential adverse affects of dishonest applicants' claims. One licensee, who lied on his application, cost NRC years of escalated enforcement activity.

In 1988, an NRC internal group recommended that NRC develop detailed license denial criteria and institute prelicensing visits for some applicants, such as large radiopharmaceutical firms. Although NRC has improved license reviewers' training, it has not developed detailed denial criteria or a prelicensing inspection policy. (See ch. 2.)

Financial Assurance Delayed

NRC licensees must clean up (decommission) their facilities when they are retired and pay for cleanup costs following an accident. NRC has had to find other sources if the licensees could not pay. In one GAO case, a licensee was able to pay about $1 million to clean up accidental contamination, but in another case, NRC had to obtain about $385,000 from the Environmental Protection Agency when a licensee could not pay to clean up a contaminated facility.

case, NRC found that a small radiographer company repeatedly violated safety, record-keeping, and other requirements for over 10 years, but NRC did not impose financial penalties. GAO believes that repeat or numerous minor violations warrant financial penalties that may motivate the licensee to improve controls. (See ch. 2.)

NRC Slow to Focus on Industrial Radiographers

Sixteen years ago, GAO found that NRC needed to strengthen training and safety standards for industrial radiographers. Subsequent reports also found that NRC provides little incentive for individual radiographers to adhere to proper safety procedures and recommended that NRC establish a program to certify individual radiographers and penalize those that do not comply with NRC's regulations. NRC and a national radiographer organization are discussing the feasibility of implementing a national certification program. NRC staff could not estimate when the program would be in place. (See ch. 2.)

Recommendations

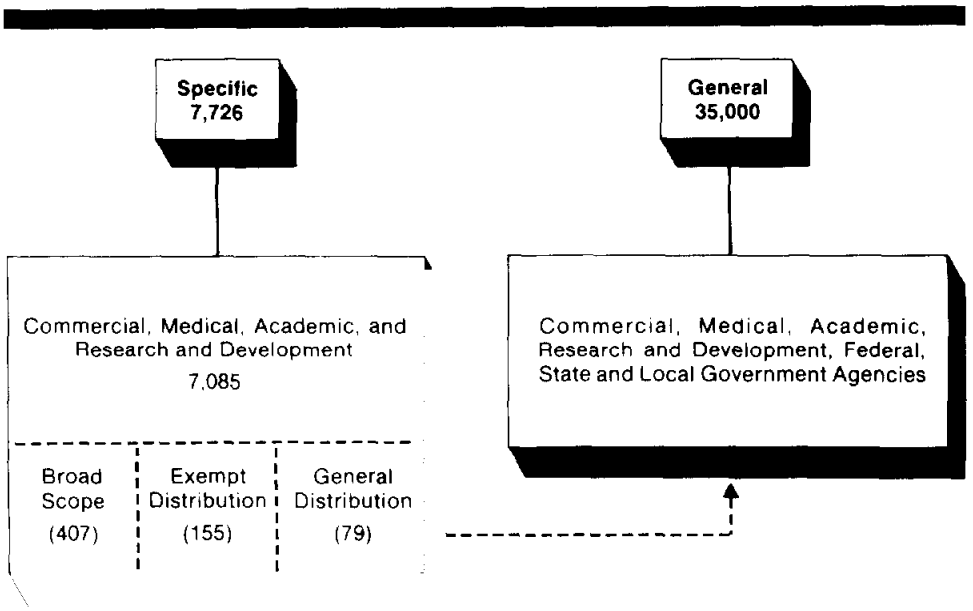
To enhance NRC's ongoing efforts to improve the materials licensing program, GAO recommends that the Chairman, NRC,

- develop detailed license denial criteria and define the circumstances that require a prelicense inspection or information verification procedures;
- finalize regulations that would provide at least a minimum level of financial assurance that licensees can pay for the cleanup of accidental spills and releases;
- require that broad scope or, at a minimum, medical treatment licensees begin license renewal actions 1 year in advance and that NRC conduct inspections before extending the licenses; and
- review NRC's policies for imposing civil penalties on licensees who repeatedly violate administrative requirements in order to determine whether further guidance on appropriate enforcement actions is needed.

Agency Comments

GAO discussed the facts presented in this report with NRC staff. Generally, the staff agreed with the facts but offered some clarifications that were incorporated where appropriate. As requested, GAO did not ask NRC to review and comment officially on this report.

Figure 1.1: Number and Types of Nuclear Byproduct Material Licenses as of June 1988



Note: General distribution licensees manufacture and/or distribute radioactive byproduct material devices and products to general licensees.

Source: NRC's Licensing Management System.

the license. NRC issues specific licenses for 5 years; renewal requests must be made 30 days in advance of the expiration date.

As can be seen from figure 1.1, NRC issues most of the specific licenses to industrial/commercial, medical, and academic institutions. However, if an applicant wants to use a wide variety of radioactive material at numerous locations, NRC may issue a specific license of broad scope. These licensees are usually large universities or companies and include 114 medical facilities. They usually are involved in many of the same activities as more restricted licensees, but on a far larger scale. Broad-scope licensees must establish a comprehensive radiological protection program, including a radiation safety committee and a radiation safety officer. The University of Michigan and Case Western Reserve University are examples of institutions with broad scope licenses.

NRC also issues an exempt distribution license to companies that manufacture and/or distribute devices containing very low levels of radioactive material. Some examples of exempt distribution devices include

NRC's Inspection and Enforcement Program

NRC inspects specific licensees to ensure compliance with its regulations, rules, and guidelines according to a priority system. Licensees fall into seven priority groups. Priority 1 licensees require the most frequent inspections because of the nature of their operations and the kinds of materials they handle. Priority 1 licenses include medical product distributors and industrial radiographers. Priority 7 licensees handle materials that create little potential hazard to health and safety and require the least frequent inspection. A small independent laboratory with a gas chromatograph would be a priority 7 licensee.

NRC's procedures require it to inspect specific licenses in priorities 1 through 5 at intervals in years corresponding to their priority number: priority 1, each year; priority 2, every 2 years; etc. The procedures also require NRC to inspect priority 6 and 7 licensees within 1 year of their receiving a license; thereafter, NRC inspects these licensees if complaints, allegations, or incidents arise or if they are located near higher priority licensees. Generally, NRC inspects general licensees only in instances related to allegations or complaints of unsafe practices or in connection with an inspection involving a specific licensee. Table 1.2 shows the number and priorities of inspections performed by NRC from October 1986 through September 1987.

Table 1.2: Inspections Performed by NRC's Regional Offices During Fiscal Year 1987

Priority	Region I	Region II	Region III	Region IV	Region V	Total
1	97	42	91	37	31	**298**
2	52	19	33	11	8	**123**
3	459	153	280	100	58	**1,050**
4	108	71	163	22	12	**376**
5	55	22	63	4	3	**147**
6	34	6	41	0	0	**81**
7	158	64	271	8	4	**505**
Total	**963**	**377**	**942**	**182**	**116**	**2,580**

Source: NRC's Licensing Management System.

NRC generally does not announce its inspections. To determine a licensee's compliance with regulations, NRC inspectors directly observe work activities, interview the licensee's employees, and, in appropriate cases, independently measure radiation and air concentration of radioactive material. If NRC finds that a licensee violates its regulations, NRC can use three types of enforcement actions: (1) notices of violation, (2) civil penalties, and (3) orders to cease and desist operations.

NRC's Region III manages about 36 percent of the specific licenses, we selected this region for a detailed review of its licensing, inspection, and enforcement activities.

To gain a better understanding of NRC's materials licensing process, we reviewed the Atomic Energy Act; NRC regulations contained in 10 C.F.R. parts 19 through 21, 30 through 35, 39, 40, 70, and 71; and policy and guidance directives. We also obtained statistical data on the number of licenses by various categories and NRC's inspections conducted in fiscal year 1987, the latest year for which data were available. We did not verify this information. However, we noticed some discrepancies and discussed these with NRC staff. Using the information provided, we conducted a limited assessment of NRC's internal controls related to licensing, inspection, and enforcement activities. In addition, at NRC headquarters we met with the Director of the Office of Nuclear Material Safety and Safeguards; the Chief, Medical, Academic, and Commercial Safety Branch; and the Deputy Director, Division of Industrial and Medical Nuclear Safety within that office. We also met with NRC managers, license reviewers, and inspectors within the Division of Radiation Safety and Safeguards at NRC Region III, Chicago, Illinois.

We also developed six case studies to illustrate how NRC exercises its responsibilities throughout the materials licensing, inspection, and enforcement process. (The case studies are described in detail in app. I.) We selected five of the cases because they illustrate NRC's management of the program, demonstrate a wide spectrum of NRC's licensing and regulatory responsibilities, and illustrate the potential effect of identified NRC program weaknesses. The case studies included licensed materials used for research and development, well logging, academic studies, industrial processing, chemical analyses, and radiography. The cases also included a broad scope and a general distribution license. We selected the sixth case randomly from radiography licenses because this group historically has experienced many materials handling problems. We obtained information for the case studies from file documents as well as through interviews with NRC staff having first-hand knowledge of the cases. Finally, we analyzed the six case studies to determine whether any common or pervasive weaknesses exist within the materials licensing process.

To determine the evolution of NRC's licensing, inspection, enforcement, and administrative programs over the years, we obtained 17 past reviews and studies that were initiated and conducted by NRC or other organizations. For example, we reviewed NRC's December 1986 Materials

Continuing Problems Within NRC's Materials Licensing Program

Although NRC documents show that most reported materials contamination or exposure events are directly caused by individual licensees' carelessness or irresponsibility, NRC materials program weaknesses probably contributed to some of these events. Past reports and the case studies that we developed show continuing and sometimes chronic problems affecting NRC's materials licensing, inspection, and enforcement activities. These problems include

- inadequate assurance that licensees can pay for the cleanup of accidental releases,
- too much reliance on applicant- and licensee-provided information,
- license and inspection backlogs,
- the need to improve radiographer training and develop a certification program, and
- inadequate material transfer records.

Our case studies also identified weaknesses in licensee reporting and a need for consistent escalated enforcement actions against those that violate minor administrative regulations. According to NRC materials program managers, they have tried to address these problems, but no final action has been taken in most cases.

Past Reports and Case Studies Identify Materials Program Weaknesses

Since 1972, at least 17 reports have identified problems with NRC's licensing, inspection, and enforcement activities. We issued several of these reports; others were issued by congressional committees and internal NRC study groups and task forces. In particular, over the past 2 years, NRC's materials licensing program has been critically examined and analyzed by its Materials Safety Regulation Review Study Group, composed of expert consultants, and its Strategic Planning Group, made up of senior NRC materials managers.

The reports and our follow-up work on NRC actions showed that NRC has improved its operations in some areas and has addressed some of the past problems. For example, in 1976, NRC began publishing a series of formal requirements for license applications, and in 1983, NRC headquarters began allowing regional offices to review license applications. In addition, in 1987, NRC initiated comprehensive team inspections of certain broad scope licensees, issued proposed regulations to improve controls over radiation therapy practices, and finalized new regulations for well loggers, who use sealed source devices to locate oil and other natural resources. Finally, as discussed in detail below, new NRC regulations

that it can meet decommissioning costs. The type and amount of funding required depend on the type and amount of radioactive material the applicant proposes to possess or use.

Past studies also pointed out that NRC needs financial assurance that licensees can pay to clean up accidental spills or releases of radioactive material. Most recently, an NRC strategic planning committee recommended in 1988 that the agency aggressively pursue actions to finalize regulations proposed in 1985 to provide such assurance. However, NRC suspended efforts to develop these regulations in 1988 because of various difficulties, such as the lack of available insurance.

Two of our case studies illustrate the need for financial assurance. In one case, J.C. Haynes, a jeweler in Licking County, Ohio, received a materials license in 1970 to use americium-241, a highly toxic, potentially carcinogenic substance, in sealed sources to change the color of diamonds. In 1971, NRC amended the license to permit Haynes to use larger amounts of americium in unsealed sources. In the late 1970s, NRC found that Haynes, because of careless handling procedures, had contaminated his facilities.

However, NRC did not revoke the license or require Haynes to decontaminate the building because a waste disposal site was not available and Haynes could not pay the cleanup costs. NRC staff told us they could not terminate the license until the site was decontaminated. Therefore, NRC amended the license to allow Haynes to possess only the americium that contaminated his facility. The amended license did not allow him to use americium. In 1985, NRC discovered that Haynes possessed unauthorized amounts of americium and was continuing to irradiate diamonds in violation of the amended license. As a result, in 1985, NRC terminated the license and obtained $385,000 from the Environmental Protection Agency's Superfund to pay for the cleanup of Haynes' facilities.

Another case also illustrates the need for financial assurance to clean up accidents. On September 13, 1983, three employees of Shelwell Services, Inc., a well-logging company[3] operating in Ohio and Illinois, accidentally punctured a sealed source containing cesium-137 (a highly toxic material). The employees, who were conducting an unauthorized procedure, attempted to remove the sealed source from a well-logging tool by using a drill. The company did not immediately report the incident to NRC but

[3]Well loggers lower devices containing sealed radioactive material to the bottom of oil and gas wells to determine the types of rocks and fluids in a geological formation.

2,100 requested license actions. Instead, information submitted by the applicant is usually verified during the inspection required within the first year after NRC issues a license or during inspections conducted after NRC amends or renews a license. As a result, NRC license reviewers deny very few new materials license applications. NRC headquarters staff told us that they have formally denied only three license applications since 1985, but probably several times that number were withdrawn by applicants when it became clear they could not meet NRC requirements.

A number of reports have pointed out NRC's vulnerability to applicants' and licensees' claims. As a result, NRC issued a policy and guidance directive in 1984 stating that certain applicants, such as large radiopharmaceutical firms, should be considered for prelicensing visits. However, in 1988, an NRC strategic planning study group stated that NRC should further define situations in which reviewers must do a prelicensing site visit. The study group also pointed out that NRC does not have adequate license denial guidance and recommended that NRC train reviewers to recognize when a denial is appropriate and how to formally deny a license.

The J.C. Haynes case that we developed illustrates NRC's need for more stringent prelicensing verification and denial criteria. After Haynes received a license, an inspector discovered that Haynes lied about his training and experience on his application. Despite this finding, Haynes was not only allowed to keep the license, but it was amended to permit him to use larger quantities of americium in any form. Later, after Haynes told NRC in 1975 that he had shipped all but a small quantity of the americium to a commercial waste site, NRC amended his license to allow only possession of a minimal amount of americium. NRC staff told us that they were unable to verify whether Haynes actually shipped the material because waste site operators normally do not inspect shipments sent to them for disposal. NRC regulations do not require it to verify such shipments. In 1985, as a result of an anonymous allegation, NRC discovered that Haynes illegally possessed americium, which he was using to irradiate diamonds.

NRC staff recognize the need to improve materials license review procedures and have taken a number of interconnected steps. For example, they improved the training for license reviewers beginning in 1987, emphasizing the general requirements a potential licensee must meet. In the staff's view, these requirements establish adequate license denial criteria. NRC staff also told us that they recently targeted certain licensees, such as fuel fabrication facilities and large radiopharmaceutical

NRC issued 3M a broad scope license in 1964 to manufacture static eliminators and a general distribution license in 1965 to market one particular model. Static eliminators—used to control static buildup in food, beverage, cosmetic, and other processes—contain polonium-210, a highly toxic but short-lived radioactive material, enclosed in tiny spheres. As part of the licenses, NRC required 3M to report any problems with the devices.

In 1972, when 3M's license was about to expire, the company filed for a renewal within NRC's 30-day required time period. According to available records, the company was allowed to market its devices, although NRC did not start to process the renewal until 1974. During that time, the Department of Energy's Oak Ridge National Laboratory and others reported potential problems, such as possible radioactive leakage from the devices, and NRC began to receive reports from purchasers that 3M's devices might not be as safe as the company claimed. However, NRC permitted 3M to continue marketing the device for 5 more years, while asking the company to submit safety data and reviewing its application. In 1979, NRC renewed 3M's license to distribute the devices.

In January 1988, Ashland Chemical Company reported to NRC that it detected radioactive contamination at its Pennsylvania and Texas plants. After Ashland Chemical officials attributed the contamination to 3M's static eliminators, NRC ordered 3M to suspend distribution of the devices and began a review of 3M's records. NRC found that 3M had not reported all previous failures of the devices. Subsequently, NRC, 3M, and various state officials found additional defective devices. On February 18, 1988, NRC ordered all general licensees to stop using almost all 3M static eliminators and to return them to 3M within 90 days. NRC also ordered 3M to show cause why its license should not be revoked. As of July 1988, NRC was continuing to investigate the incident and considering the specific actions it would take against 3M.

In addition, following a 1986 incident in Oklahoma, the House Subcommittee on Environment, Energy, and Natural Resources concluded that NRC takes too long to renew licenses and that the delays may allow licensees to operate unsafely for years. In response to the committee's concerns, NRC has asked special nuclear material (enriched uranium and plutonium) licensees to start the license renewal process 1 year in advance of the license expiration date. Once NRC receives the request, NRC staff told us they will inspect the facility before renewing the license. However, the committee did not recommend, and NRC is not pursuing, similar actions for byproduct materials licensees.

to occur and that some licensees may never be inspected after the required first-year inspection. Between 1976 and 1986, five reports addressed inspection staffing shortages. For example, in 1986, NRC's Materials Safety Regulation Review Study Group reported that staffing for inspections might be too low to ensure quality performance. The group found that inspection frequency is not based on a studied assessment of need, but instead on the application of available resources in the best possible manner. Currently, because of limited resources, NRC does not inspect licensees in priorities 6 and 7 after the first year, unless NRC learns of a problem with the licensee or an inspector is in the vicinity conducting a higher priority inspection.

Our Aztec Laboratories case shows the type of problem that can occur when NRC routinely defers inspections of low priority licensees. NRC issued Aztec Laboratories, Kansas City, Missouri, a license in 1977 to operate gas chromatographs to analyze pollutants in water. At that time, NRC did not inspect licensees within 1 year of their receiving the license. Further, because Aztec holds a priority 7 license, NRC did not inspect the laboratory during the first 10 years of the license. In March 1987, an NRC inspector, who was in the vicinity of Aztec performing two higher priority inspections, visited the licensee. The inspector found that Aztec had failed to notify NRC of a 1984 fire that destroyed the facility and damaged a gas chromatograph containing nickel-63 (a moderately toxic substance). The inspector ultimately identified seven safety violations, including Aztec's leaving the contaminated chromatograph at the site without proper safety precautions and moving its operations without notifying NRC and/or amending the license. NRC imposed a $500 fine on the licensee; Aztec spent more than $2,000 decontaminating the building.

NRC staff told us that they have requested additional inspection resources and initiated several actions to improve the quality of inspections. They expect to obtain additional staff over the next 2 years to help eliminate backlogs. NRC staff also told us that in an effort to improve the quality of inspections, they have expanded their scope into new technical areas, such as fire and chemical hazard protection. They have also emphasized team inspections for licensees, such as radiopharmaceutical firms, where previously they had not been used.

would give radiographers an incentive to follow established safety procedures.

Some states have also begun to consider the merits of a radiographer certification program. In 1986, the state of Texas, while working with NRC under a $56,000 contract to improve its training and testing requirements for radiographers, independently developed a statewide certification program. The program requires individual radiographers to complete training and pass a test before they can be certified. Under this program, the state can then revoke an individual's certification if he or she violates established procedures. According to NRC staff, the program was enacted into state law and became effective in early 1987. According to NRC staff, the state of Louisiana is considering a similar program.

NRC staff also told us that the American Society for Nondestructive Testing, Inc., a professional organization that includes radiographers, is considering a national certification program similar to the Texas program. The society met with NRC in June 1988 to discuss the implementation of a nationwide program. NRC staff told us that they are considering supporting this national certification program, since the program now has the backing of a large professional organization. They also said that they will determine whether any regulatory changes are needed and then make a recommendation to the commission if warranted. They could not estimate when a national program might be implemented.

NRC Relies on Suppliers for Material Transfer Records

NRC does not track byproduct materials purchases but relies primarily on suppliers and licensees to account for the transactions. NRC requires suppliers to check customers' licenses to verify that they are authorized to receive byproduct material. Licensees are responsible for ordering materials only in amounts authorized by the license. Suppliers must retain records for 5 years after a purchase. Licensees must keep records as long as they hold the material, plus 2 years following the transfer.

NRC is not required to, and does not, independently monitor licensees' radioactive material inventories. Therefore, when radiation safety questions arise, NRC depends on records maintained by the suppliers and licensees. However, as illustrated by the J.C. Haynes case, these records are not always available. In that case, NRC, in trying to determine how much americium Haynes had originally purchased, contacted the supplier—the Department of Energy's Oak Ridge Operations Office. Oak Ridge, however, could not locate complete records for Haynes' early

most serious accidents, such as those resulting in significant individual exposure or property damage. Other incidents, such as one causing minor disruptions of licensee operations, must be reported within 24 hours. For example, NRC's regulations require licensees to report within 24 hours any event that results in property damage in excess of $2,000; those that result in property damage in excess of $200,000 must be reported immediately.

Although the regulations seem to provide specific guidance, NRC has recognized for years that its reporting regulations are subject to various interpretations. For example, in 1978, NRC's Acting Director, Division of Fuel Facilities and Material Safety Inspection, requested guidance on incident reporting. In response, NRC's Office of General Counsel concluded that the regulations regarding reporting requirements were ambiguous and needed to be clarified.

Four of our cases raise questions about the adequacy and clarity of NRC's reporting requirements and illustrate the adverse effects that reporting delays can have on NRC and licensee actions to minimize worker or public exposures. Confusion over NRC reporting requirements appears to have been a contributing factor in two of these cases. The four cases are discussed below.

J.C. Haynes

After his arrest in 1985 on charges of illegal possession of radioactive materials and lying to NRC, Haynes told NRC that he transferred americium waste to Wright-Patterson Air Force Base, Ohio, at least once in the 1970s. In September 1986, Air Force personnel unknowingly opened a drum containing the waste, accidentally spilling the americium and contaminating the building in which it was stored. According to NRC documents, Air Force personnel initially believed that they did not have to report this release. Further, NRC staff could not initially agree among themselves whether the Air Force should have reported the spill to NRC. Later, NRC determined that a violation had occurred, and on June 17, 1988, it issued a notice of violation and proposed a $102,500 civil penalty against the Air Force. Ultimately, the Air Force spent about $1 million to clean up the contamination and dismantle the building in which the waste was stored.

In addition, a Senate Committee on Governmental Affairs report on this incident concluded that the disagreement within NRC apparently disrupted potential criminal enforcement actions against individuals who proposed covering up the incident. The Senate Committee also concluded

its emergency response center at headquarters rather than to the regional offices, thereby eliminating delays in initiating corrective actions. In February 1988, NRC also issued new regulations that require licensees to report within 2 working days any event they consider to have significant implications for public health and safety not otherwise covered by existing reporting requirements. In May 1988, NRC also issued an information notice to its licensees emphasizing the need to promptly report all significant incidents involving radioactive material. It is too early to tell whether these efforts will improve licensee reporting.

NRC's Director, Office of Nuclear Materials Safety and Safeguards, told us that licensee reporting is not a serious problem. He said that the four cases cited above do not illustrate incident reporting problems because once the licensees reported the incidents, NRC took the appropriate regulatory actions. However, the Director did acknowledge that NRC continues to work on clarifying its regulations to better explain the type of events that licensees should report to the headquarters emergency response center. According to the Director, confusion still exists concerning the regulatory requirement that events resulting in property damage in excess of $2,000 must be reported to NRC within 24 hours. Using the J.C. Haynes case, he pointed out that although the Air Force's building was contaminated, it was not "damaged." The director believes that the regulatory revisions being developed will eliminate such confusion.

NRC Lacks Specific Enforcement Criteria for Repeat Violations

Although NRC's enforcement policy allows it to impose civil (financial) penalties on licensees who repeatedly violate minor NRC requirements, NRC has not developed specific criteria to determine when escalated enforcement actions should be taken against such violators. According to NRC's Director, Office of Nuclear Materials Safety and Safeguards, NRC looks for the root causes of repeat minor violations, such as inadequate management attention to the program or the same violation in each inspection, before it levies a civil penalty. The Director also pointed out that the decision to escalate enforcement actions is often a judgment call and specific criteria do not exist to determine when escalated enforcement actions should be taken for minor violations.

Two of our case studies show that NRC's decision to impose civil penalties for repeated violations is made on a case-by-case basis. In one case, NRC imposed a large civil penalty on a licensee after finding repeated

Conclusions and Recommendations

NRC oversees the safe use of hundreds of kinds of radioactive materials by thousands of individuals, businesses, universities, and medical institutions. Although the mishandling of some of these materials would have a limited impact on public health and safety or the environment, others are very toxic and can be lethal. Fortunately, given the number of licensees in the United States, actual releases or overexposures to radioactive materials have been infrequent with minor health and safety consequences, although cleanup costs in some cases have totaled over $1 million.

Given the universe of radioactive materials used in this country, NRC will probably always be somewhat vulnerable to careless, irresponsible, or unscrupulous applicants or licensees. Licensee carelessness or other irresponsible actions have caused most radiation releases or exposures. Nevertheless, past studies and the cases we developed show that a number of weaknesses continue in NRC's materials program and that NRC has been slow to act to correct these weaknesses.

Some of these weaknesses may have contributed to individual licensee problems in the past and, unless corrected, may cause future problems. For example, NRC relies heavily on the licensees to carry out established rules and regulations and report incidents or events. In doing so, NRC places too much reliance on applicants and licensees, to the extent that it has not

- developed detailed license denial criteria for its license reviewers,
- finalized criteria for determining facilities that must be inspected before receiving a license, and
- verified information provided by those applying for or renewing a license.

NRC license reviewers deny very few license applications. In response to past reports, NRC staff have improved the training of individual license reviewers, but they continue to believe that NRC's general requirements establish clear licensee denial criteria. However, we agree with recent reports that suggest that the license review process would be improved if reviewers could refer to specific denial criteria when reviewing applications. Such criteria, perhaps in the form of a detailed checklist, would more clearly enable license reviewers to determine the applications that are acceptable and those that should be denied. NRC has yet to provide such a tool to its reviewers.

NRC should review its policies for imposing civil penalties against licensees who repeatedly violate NRC record-keeping and administrative requirements.

NRC has initiated actions to address some identified licensing and/or inspection and enforcement weaknesses, but in most cases final action has been slow. For example, NRC has been working for several years to clear up reporting ambiguities but has not yet finalized its rules. Further, for 16 years, NRC has been aware of the need to strengthen training and certification requirements for radiographers but has only recently taken action to do so.

In another example, NRC, in response to repeated recommendations in many reports, issued proposed regulations in 1978 that would require licensees to secure a bond to cover decommissioning costs before they obtain a materials license. The regulations took effect in July 1988. However, NRC has yet to promulgate regulations providing financial assurance for the cleanup of accidental releases, even though it drafted such regulations in 1985. NRC recently discontinued its efforts to develop these regulations because of difficulties in defining accident parameters and the potential shortage of insurance in some areas. If NRC cannot establish a comprehensive program, it should set a limited amount of needed assurance that would be appropriate for most cases. Even a limited amount would reduce the government's financial risk. By setting a limited assurance requirement, NRC may also reduce the problem of insurance availability.

Recommendations to the Chairman, NRC

To enhance NRC's efforts to improve the materials licensing program, we recommend that the Chairman, NRC,

- develop detailed license denial criteria and define the circumstances that require a prelicense inspection or information verification procedures;
- finalize regulations that require a minimum level of financial assurance that licensees can pay for the cleanup of accidental spills and releases;
- require that broad scope or, at a minimum, medical treatment licensees begin license renewal actions 1 year in advance and that NRC conduct inspections before extending the licenses; and
- review NRC policies for imposing civil penalties on licensees who repeatedly violate administrative requirements in order to determine whether further guidance on appropriate enforcement actions is needed.

1986, Air Force personnel unknowingly opened a drum containing the waste and accidentally spilled the americium. During the ensuing decontamination activities, Air Force personnel accidentally reopened the drum, and one official inhaled a small quantity of the radioactive material. The official is undergoing tests to determine the extent of his exposure. The Air Force tore down the storage building, decontaminated the area at a cost of about $1 million, and recovered 3.5 curies of americium waste.

According to NRC documents, Air Force personnel initially believed they did not have to report the spill. Also, NRC staff could not initially agree among themselves whether the Air Force should have reported the incident. However, the Senate Committee on Governmental Affairs concluded that the disagreement within NRC disrupted potential criminal enforcement actions against individuals who proposed covering up the incident. Later, NRC determined that a reporting violation had occurred and, on June 17, 1988, issued a notice of violation and proposed a $102,500 civil penalty against the Air Force.

Case II: Shelwell Services, Inc.

In 1964, NRC issued a specific license to Shelwell Services, Inc., a well logger operating in Ohio and Illinois. On September 13, 1983, three Shelwell employees accidentally punctured a cesium-137 (a highly toxic substance) sealed source capsule as they attempted to remove it from a well-logging tool. Shelwell did not immediately report the incident to NRC but waited until late the next day. In the interim, company employees contaminated their homes and some local businesses, including two restaurants and a bar. NRC staff were on-site within a few hours of being notified and began to retrieve the company's radioactive sources.

NRC subsequently concluded that

- at least two of the three employees present at the time of the incident received radiation exposures of 0.2 to 1.0 millirems per hour,[2] which is in excess of NRC's quarterly limit;
- two other individuals involved in cleanup activities were also slightly exposed;
- 16 homes had been contaminated in excess of the NRC limit of 100 microrems per hour (except for the employees, the individuals residing in the homes were not exposed); and

[2]A rem is the basic unit of measurement for radiation received.

the 1986 inspection, NRC again discovered coffee cups and food in the laboratories and expressed concern over the lack of management attention to radiation safety, such as the nonperformance of tests to determine the presence of radioactive material. NRC told Case Western that these actions could result in civil penalties if future inspections showed that corrective action had not been taken.

In November 1987, a consultant hired by Case Western to perform radiation surveys as required by NRC regulations found tritium and carbon-14 contamination in a laboratory. Two technicians, concerned that they may have ingested some radioactive material while they ate and drank in the laboratory, contacted the Cleveland news media on November 7, 1987, which, in turn, notified NRC. The technicians later told NRC that children were allowed into the laboratory for Halloween "trick or treating" and were given wrapped candy that was stored there. Subsequently, NRC ordered tests for the two workers and offered free tests for the children. Three or four children were subsequently tested; none of the tests showed any exposures.

As a result of the incident, NRC conducted a special inspection of the university and identified 21 violations, including failure to train workers as required by the license, storage and consumption of food and beverages in restricted areas, and failure to perform periodic radiation surveys. NRC concluded that Case Western did not effectively manage its broad scope program and suspended the license on November 25, 1987. Later, NRC imposed a $10,000 civil penalty.

On December 8, 1987, NRC rescinded the suspension after the university implemented extensive changes to its safety program. For example, Case Western agreed to correct its training deficiencies, perform surveys, and post required information and warning signs. At about the same time, Case Western submitted a license renewal request to NRC, but NRC did not approve it. NRC expects to receive a revised renewal application incorporating the programmatic changes that the university implemented as a result of the incident.

Case IV: Minnesota Mining and Manufacturing (3M)

In January 1988, following a report that a number of facilities were contaminated, NRC ordered 3M, a distributor of generally licensed devices headquartered in St. Paul, Minnesota, to suspend the distribution of four static eliminators. These devices control the buildup of static electricity during manufacturing processes and contain polonium-210 within tiny spheres. Polonium-210 is a highly toxic material but has a half-life of

During the subsequent weeks, NRC, 3M, and state officials found additional defective devices, and on February 18, 1988, NRC ordered all general licensees to stop using most 3M static eliminators and to return the devices to 3M within 90 days. NRC also ordered 3M to show cause why its license to distribute these devices should not be revoked.

As of July 1988, NRC had not found any evidence to indicate that the devices had contaminated any consumer products. Further, NRC staff concluded that if the devices had contaminated consumer products, they probably would not pose significant public health hazards because polonium has a short half-life and the material is encapsulated in spheres, which makes it unlikely that the polonium would be absorbed into the body. NRC staff also believe that employees probably had not been exposed to significant amounts of radiation from the faulty devices. As of July 1988, NRC was continuing to investigate the incident and considering the specific actions it would take against 3M.

Case V: Aztec Laboratories

NRC issued a license to Aztec Laboratories, Missouri, in 1977 to operate gas chromatographs used to analyze pollutants in water. Throughout its licensing history, Aztec has been limited to using devices containing not more than 0.015 curies of nickel-63, a moderately toxic material. Since gas chromatograph licenses fall within the lowest inspection priority, NRC did not inspect Aztec during the first 10 years of the license.

In March 1987, however, an NRC inspector, who was in the vicinity performing two higher priority inspections, visited Aztec's address, shown on the license. The inspector found that Aztec had moved its operations without notifying NRC and/or amending the license. Because of this and six other safety violations, including failure to (1) notify NRC of a 1984 fire that damaged a gas chromatograph and (2) properly safeguard the contaminated chromatograph, NRC imposed a $500 civil penalty against Aztec.

In response to NRC's findings, Aztec's owner told NRC staff that he did not believe he had to report the incident. Under NRC's regulations, licensees must report incidents involving $2,000 or more in damages. Since the owner had paid less than $2,000 for the device, he did not report the incident. Ultimately, Aztec paid more than $2,000 to decontaminate the site and dispose of the damaged chromatograph.

In 1987, NRC transferred authority for this license to Illinois when it became an agreement state.

Results of the General License Study and Corrective Measures Taken or Planned by the Staff (NRC, July 9, 1987).

Study Group I Report (NRC, Feb. 1, 1988).

Commission Paper on Accountability of Radioactive Material Used by Material Licensees (EDO-3405) (NRC, Feb. 4, 1988).

A Summary and Analysis of Key Events Relating to the Americium Leaks at Wright-Patterson Air Force Base During Autumn 1986 (Senate Committee on Governmental Affairs, Mar. 1988).

Requests for copies of GAO reports should be sent to:

U.S. General Accounting Office
Post Office Box 6015
Gaithersburg, Maryland 20877

Telephone 202-275-6241

The first five copies of each report are free. Additional copies are $2.00 each.

There is a 25% discount on orders for 100 or more copies mailed to a single address.

Orders must be prepaid by cash or by check or money order made out to the Superintendent of Documents.

Reports Related to NRC's Materials Licensing Program

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

Management of the Licensing of Users of Radioactive Materials Should Be Improved (GAO/RED-76-62, Feb. 11, 1976).

Review of Materials Inspection Program (NRC/Office of Inspector and Auditor, Dec. 21, 1976).

Cleaning Up the Remains of Nuclear Facilities—A Multibillion Dollar Problem (GAO/EMD-77-46, June 16, 1977).

NRC Actions Taken on OIA Report, "Review of Materials Inspection Program" (NRC/Office of Inspector and Auditor, Dec. 1978).

Cleaning Up Nuclear Facilities—An Aggressive and Unified Federal Program Is Needed (GAO/EMD-82-40, May 25, 1982).

OIA Survey Audit Report on NRC's Materials Licensing Program (NRC/Office of Inspector and Auditor, Nov. 4, 1982).

Ruptured Cesium-137 Well-Logging Source at Shelwell Services, Inc., Hebron, Ohio (NRC/NUREG-1028, Apr. 1984).

Report to the Commission: Review of the Office of Inspection and Enforcement's Materials Inspection Program (NRC/Office of Inspector and Auditor, Feb. 8, 1985).

Report to the Commission: Review of NRC Regionalization (NRC/Office of Inspector and Auditor, Apr. 30, 1985).

Inspection Report of Unauthorized Possession and Use of Unsealed Americium-241 and Subsequent Confiscation (NRC/NUREG-1153, Nov. 1985).

NRC Staff Analysis of the Recommendations of the Materials Safety Regulation Review Study Group (NRC, July 29, 1987).

NRC's Regulation of Fuel Cycle Facilities: A Paper Tiger (Eighth Report By the Committee on Government Operations, June 18, 1987).

Case VI: J.T. Cullen Company, Inc.

In February 1972, J.T. Cullen Company, Inc., Illinois, applied to NRC for an industrial radiography license. On three separate occasions, NRC requested additional information from the company on the training program it would provide to the individual radiographers in its employ. NRC issued Cullen a license in June 1972 to use cobalt-60 and iridium-192 sources (both highly toxic substances) at temporary job sites throughout the country.

Between 1972 and 1986, NRC inspected the company and the activities of its employees 13 times. As a result of these inspections and during subsequent license renewals, NRC repeatedly criticized the company's training, inventory control, and radiation monitoring practices. NRC found, for example, that

- in 1972, 1979, and 1985, Cullen did not require its employees to wear the required film badges to determine the amount of radiation exposure they received or have film badges analyzed as required;
- in 1975 and 1986, Cullen did not conduct required quarterly inventory checks of the devices within its possession;
- in 1978, Cullen did not submit sufficient information for NRC to approve its training program; and
- in 1981, 1982, 1983, and 1984, Cullen did not conduct job site inspections or maintain inventory and instrument calibration records as required.

In each instance, NRC issued a notice of violation to Cullen; Cullen provided NRC a written response stating the corrective actions the company planned to take. NRC staff verified during the next inspection that Cullen took the action required. Although Cullen had a long-standing history of repeated safety violations, NRC staff told us that they did not escalate the enforcement by proposing a civil penalty because the violations did not pose a direct public health and safety risk.

However, as a result of a May 1985 anonymous allegation criticizing the company's training program, NRC conducted a special inspection of the company. In the notice of violation issued following the inspection, NRC expressed concerns about the company's oversight of the individual radiographers in its employ and its failure to issue radiation monitoring badges to all employees. To assist Cullen in taking corrective actions, NRC provided him with a set of tasks to improve all aspects of the company's program. In responding to the notice, Cullen criticized NRC's regulations, stating that NRC makes it very difficult for small businesses to operate economically within the law.

only 138 days. Further, its radiation does not penetrate the skin. 3M distributes thousands of static eliminators annually to photography, food and beverage processing, electronics, and other industries.

NRC issued 3M a broad scope license in 1964 to manufacture static eliminators and a general distribution license in 1965 to market one particular model. By 1986, NRC had authorized 3M to distribute 14 models. In the 1965 distribution license, NRC included a condition that the devices be leak-tested at 12-month intervals instead of the then-required 6-month intervals. Three years later, NRC allowed 3M to extend the test period to 13-month intervals.

During the 1970s, Oak Ridge National Laboratory and others reported discovering problems, such as possible leaking static eliminators, that appeared to conflict with 3M's assurance about its devices' integrity. In a 1976 memorandum, a member of NRC's licensing staff questioned whether 3M should be allowed to distribute the devices. In the memorandum, the staff member recommended that 3M's license prohibit the use of static eliminators in food processing and require leak tests at 7-month intervals. From late 1974 through 1978, NRC asked 3M to respond to several safety-related questions concerning the devices. 3M provided voluminous, detailed responses to the questions, including arguments that a short-term leak test interval would be uneconomical.

In 1979, NRC renewed 3M's distribution license but required the company to submit annual reports detailing who received the devices, the number of units returned and an evaluation of the reason for the return, and significant incidents that occurred with the devices. However, NRC continued to allow 3M to conduct leak tests at 13-month intervals. Between 1967 and 1983, NRC inspected 3M six times but identified few, if any, safety violations.

However, on January 25, 1988, Ashland Chemical Company reported to NRC that it detected radioactive contamination at plants located in Pennsylvania and Texas and attributed the source of the contamination to 3M's static eliminators. As a result of this report, NRC ordered 3M to suspend distribution of four models and immediately began a review of 3M's records. NRC found numerous cases of failed devices and, on February 5, 1988, ordered the recall of all static eliminators used by the food, beverage, pharmaceutical, and cosmetics industries.

- six businesses, including two restaurants, had been contaminated with low levels of radiation, but no one who worked in or frequented these businesses was exposed.

NRC formally suspended Shelwell's license on September 20, 1983, a week after the incident. Shelwell decontaminated the homes and businesses at a cost of about $1 million and submitted an on-site decontamination plan to NRC along with a justification as to why its license should not be revoked. On November 7, 1983, NRC rescinded the license suspension, although Shelwell did not complete the on-site decontamination activities until February 1984. When NRC rescinded the license suspension, it told Shelwell that the company needed to, among other things, improve its worker training program and develop a procedure for the handling of sealed sources containing radioactive material. NRC renewed the license in December 1985 with additional worker training and source handling requirements.

In response to this case and other well-logging accidents, NRC amended its well-logging regulations in 1987 (10 C.F.R. part 39). One section of the new regulations states that a licensee may not drill, cut, or chisel into a source holder unless NRC provides prior approval for such action.

Case III: Case Western Reserve University

In 1958, Case Western Reserve University, Ohio, received a broad scope materials license. The license authorizes Case Western to possess a number of different radioactive materials, such as tritium and carbon-14, for research and development purposes. Case Western also holds three specific licenses to use plutonium-239, cobalt-60, and uranium-235 for research and training purposes. As of December 1987, about 200 university researchers used the radioactive material in 333 Case Western laboratories; about 700 other individuals were authorized to enter the laboratories for research and academic purposes.

Between 1958 and 1979, NRC inspected Case Western on 10 different occasions. The inspections usually covered all licenses held by the university at the time of the inspection, and revealed few, if any, items of noncompliance. For example, in 1975, NRC found laboratory technicians eating in close proximity to radioactive materials and sent a letter requiring Case Western to specify the corrective action taken.

On the basis of NRC's inspection priorities, the university should have been inspected every 2 years. However, because of an administrative error, NRC did not inspect the licensee between 1979 and 1986. During

NRC Materials Licenses Case Studies

Case I: J.C. Haynes

In 1970, J.C. Haynes, a jeweler in Licking County, Ohio, applied for a specific license to use radioactive material to change the color of diamonds. NRC issued a license that allowed him to use 0.9 curies[1] of americium-241—a highly toxic, potentially hazardous carcinogen—in sealed sources. Shortly after Haynes received the license, inspectors found that his application contained erroneous statements. Despite the inspectors' findings, NRC amended the license in 1971 to permit Haynes to use larger amounts of americium—up to 25 curies—in unsealed sources.

In addition, following a 1975 inspection, NRC cited Haynes for 10 regulatory violations. The inspector concluded that Haynes did not adequately understand the possible radiological problems associated with a spill or airborne release of americium and did not have the training needed to evaluate air sampling data under emergency conditions. As a result, the inspector recommended that NRC license Haynes to use americium only in sealed sources. NRC did not take any action until 1980, when another inspection disclosed that Haynes had contaminated his facility and NRC learned that a bank was considering foreclosure on the building.

In response, NRC issued an order prohibiting Haynes from conducting further activities under the license and limiting him to possessing only the americium that contaminated his facility. However, NRC did not revoke the license or require Haynes to decontaminate the building because no commercial facility was available to accept the waste and Haynes could not pay the decontamination costs. Therefore, NRC amended Haynes' license in 1982 to allow him to maintain his facility. The license did not allow him to use any americium. Then, in 1985, NRC received an allegation that Haynes possessed americium and continued to irradiate diamonds, contrary to the license.

As a result, NRC notified Federal Bureau of Investigation officials, who arrested Haynes and confiscated over 20 curies of americium. In 1986, Haynes was convicted of illegal possession of radioactive material and lying to the NRC, placed on 5 years of probation, and fined $129,580. By this time, NRC had cleaned up his facilities; the Environmental Protection Agency provided the $385,000 needed through the Superfund Trust.

After his arrest, Haynes told NRC that he had transferred an unknown but probably small amount of americium waste to Wright-Patterson Air Force Base, Ohio, on at least one occasion in the 1970s. In September

[1]The curie is the basic unit of measurement for radioactivity.

Further, NRC has not adequately defined the circumstances that require a prelicense inspection or verification procedures. Currently, NRC staff only inspect a very small number of applicants or otherwise verify the information submitted. Although NRC has started to preinspect some applicants, it needs to develop a screening process to better identify cases that need preinspection and verification. In the J.C. Haynes case, a prelicense inspection and/or verification of applicant information, plus adherence to specific license denial criteria, might have saved NRC years of escalated enforcement activity and the taxpayers over $1.3 million, including $1 million to clean up the Wright-Patterson Air Force facility.

We recognize that NRC also continually faces the problem of allocating limited inspection and license review staff. License renewal and inspection backlogs are common, and some low priority licensees may never be inspected after an initial review. In addition, NRC must constantly react to day-to-day problems that cause it to change priorities and further delay needed inspections or licensing actions.

To address some of these problems, NRC has requested one type of licensee to begin working on the renewal application 1 year—rather than 30 days—before the license expires. NRC does not plan to request byproduct licensees to take this action. Although we do not believe that NRC should institute such a requirement for all byproduct licensees, NRC could do so for the 407 broad scope licensees or, at a minimum, the 114 broad scope medical treatment facilities that directly affect public health and safety.

In addition, NRC has not developed specific criteria to determine when escalated enforcement actions should be taken for repeat or continued record-keeping or other administrative violations. Two of the cases we developed indicate that the decision to impose civil penalties for repeated violations is made on a "case-by-case" basis. We believe, however, that these violations may be indicative of licensee carelessness, which could lead to more serious problems. NRC should consider adopting a more conservative enforcement stance that assumes that repeat, minor regulatory violations may reflect inadequate licensee attention to proper handling of radioactive materials. In addition, civil penalties, even though they may be relatively small, could motivate smaller companies to pay more attention to their radioactive materials handling activities. More rigorous enforcement is especially important for licensees involved in dangerous activities, such as radiography. Therefore,

violations. In another case, NRC found repeated problems but never imposed a civil penalty.

After a 1987 contamination incident, NRC found widespread, repeat violations at Case Western Reserve University. NRC had warned the university during a previous inspection that it would escalate enforcement actions if repeat, minor violations continued. Citing a breakdown of the licensee's management controls and continued poor performance in adhering to NRC regulations after the incident and later inspection, NRC imposed a $10,000 civil penalty, rather than the typical $4,000 for similar types of violations.

However, in the case of J.T. Cullen, Inc., a radiography company located in Illinois, NRC inspections (13 in all) identified many violations between 1972 and 1986, and NRC repeatedly criticized the company's training, inventory controls, and radiation monitoring practices. NRC issued nine notices of violations, after which the company said it took the corrective actions required, such as conducting quarterly inventory checks and job site inspections. During a 1985 inspection, undertaken as a result of an anonymous allegation criticizing the company's training program, NRC expressed concerns about Cullen's oversight of the individual radiographers in his employ and his failure to issue radiation monitoring badges to all employees. To assist Cullen in taking corrective actions, NRC provided him with a set of tasks to improve all aspects of the company's program.

Although Cullen had a long-standing history of repeat, minor violations and NRC was concerned about his attention to ensuring safe operations, NRC did not escalate its enforcement action by imposing civil penalties against the company. Further, NRC headquarters staff do not believe that they should have escalated the enforcement action against Cullen. They pointed out that the violations were not found during each inspection but rather on an "on-again, off-again" basis. They concluded, therefore, that the violations did not represent a significant lapse in regulatory compliance on the part of Cullen. We noted, however, that in 1981, 1982, 1983, and 1984, NRC found that Cullen did not conduct job site inspections or maintain inventory and instrument calibration records as required. This situation, contrasted with Case Western, provides evidence of the need for NRC to review its policies on imposing civil penalties on licensees who repeatedly violate administrative requirements.

that NRC's differing interpretations of accident reporting requirements raise serious questions about the effectiveness of NRC's materials licensing and inspection program.

Shelwell Services, Inc.

As discussed earlier, three Shelwell employees conducting an unauthorized procedure accidentally punctured a sealed source containing cesium, which resulted in considerable contamination. By delaying its report of the incident until just within NRC's 24-hour notification requirement and not taking proper precautions, the company's employees spread the contamination over a much greater area including private homes and public businesses. According to NRC staff, if Shelwell had reported the event immediately and taken proper precautions, it could have avoided most of the $1 million it incurred to clean up the contamination.

Case Western Reserve University

On November 8, 1987, the Cleveland news media informed NRC that a laboratory at Case Western Reserve University was contaminated with tritium (low toxicity) and carbon-14 (moderate toxicity). After receiving the allegation, NRC conducted a special inspection and found numerous safety violations, including the storage and consumption of food in restricted areas. NRC imposed a $10,000 civil penalty.

NRC also found that the university was aware of the contamination at least 3 days before NRC received the allegation. However, in the enforcement notice NRC did not cite Case Western for not reporting the event within 24 hours because, according to NRC staff, no requirement existed for Case Western to do so.

Aztec Laboratories

As discussed earlier, Aztec Laboratories' owner failed to report a fire that destroyed the facility and damaged a device containing radioactive material. Three years later, when NRC discovered the incident, the licensee argued that the reporting requirements did not clearly apply to this situation. The owner argued that NRC regulations call for reports on incidents involving damage over $2,000 and, since he paid less than that for the device, the rule would not apply. NRC disagreed, stating that total damage to the facility was over $2,000 and thus the incident should have been reported.

NRC has recently tried to improve licensee reporting. In September 1987, NRC amended its regulations to require licensees to report all events to

shipments. As a result of NRC's inquiry, Oak Ridge amended its policy to better preserve records on sales of materials with long hazardous lives.

For national security reasons, NRC imposes strict material accountability and reporting controls on enriched uranium, plutonium, and other types of material. According to NRC's Director, Office of Nuclear Materials Safety and Safeguards, it costs the government about $4 million annually to track about 20,000 transactions dealing with these materials. In a 1988 study, NRC considered the need for similar controls on byproduct material and concluded that tracking all byproduct material purchases would be very costly, even if it were feasible to do so. NRC estimates that about 2 million such transfers occur each year and that the benefits to be derived from a materials accountability system would be questionable. However, the study concluded that an accountability system might be practical for large byproduct material shipments but did not define what constitutes a large shipment. NRC is considering the feasibility of such an accountability system.

NRC also requires quarterly reports from the distributors of generally licensed devices to ensure that it knows who has them. NRC needs this information to contact the licensees when inspections are scheduled and when problems arise that require a product recall. However, NRC does not consolidate this information. Thus, when a problem arises, such as in the 3M case, NRC must rely on the distributor to tell it who received the devices. According to NRC's 1988 study, it is also considering an automated system to track generally licensed devices.

Other Problems Identified by the Case Studies

Our case studies showed two other areas that need improvement. First, four of our case studies showed that licensees do not always promptly report problems or events to NRC and/or clearly understand their reporting responsibilities. NRC is continuing to try to clarify its reporting requirements. Secondly, two of our case studies led us to believe that NRC needs to review its policy on escalated enforcement actions against licensees that repeatedly violate nonmaterials handling regulations, such as record-keeping and training requirements.

Licensee Incident Reporting Problems

NRC requires licensees to report events, incidents, or accidents involving radiation exposures, excess release of radioactive material, loss of facility operations for more than 1 day, property damage in excess of $2,000, and loss or theft of significant quantities of radioactive material. The regulations state that the licensees must immediately report the

NRC Slow to Improve Radiography Training and Require Certification

NRC has long characterized industrial radiographers as a problem group of licensees. These licensees use radioactive material, permanently sealed in an x-ray-type device, to examine pipes, welds, steel structures, and other high-stress parts to determine whether cracks or other defects exist. Although NRC issues a specific license to a company or individual, the company or individual may employ—and the license may cover—a number of radiographers. Historically, radiographers, who held only about 4 percent of all licenses as of June 1988, account for a large percent of all reported exposure events—about 60 percent of the exposures reported in 1986. The J.T. Cullen case discussed later in this chapter provides an example of the types of problems NRC has experienced with certain licensees in this group.

NRC approves radiography licensees' training programs after reviewing a training course outline and the written examination to be administered after the course. The licensee conducts the training, administers and grades the examination, and establishes other criteria for the course. Although NRC approves the test that the licensee gives, it does not control the conditions under which the examination is given or how it is graded. Further, when NRC finds violations of radiography safety requirements, it imposes sanctions against the licensee but not the individual radiographer.

As early as 1972, we pointed out that NRC needed to strengthen its training requirements and other standards for radiographers.[4] In 1979, NRC amended its regulations to improve radiographer training requirements. However, since that time, at least two more reports, including one by the 1986 Materials Safety Regulation Review Study Group, again expressed concern about the adequacy of NRC regulations for radiographer training and compliance. The group concluded that deficient training may contribute to radiographer overexposure incidents. The group also found that NRC provides little incentive for individual radiographers to adhere to proper safety procedures.

To address these weaknesses, the 1986 study group recommended that NRC certify each individual radiographer after ensuring that he or she has received appropriate training on the use and handling of the devices. NRC had previously considered a radiographer certification program but decided in 1985 that such a program would have limited benefits. The 1986 study concluded, however, that individual certification

[4]Problems of The Atomic Energy Commission Associated With the Regulation of Users of Radioactive Materials for Industrial, Commercial, Medical, and Related Purposes (GAO/B-164105, Aug. 18, 1972).

The situation at Case Western Reserve University, Ohio, another of our case studies, also demonstrates the types of license renewal problems NRC has experienced. In 1958, Case Western received a broad scope license that authorized the university to possess a number of different radioactive materials, such as tritium and carbon-14, for research and development purposes. As of December 1987, about 200 researchers used radioactive materials in 333 laboratories, and about 700 other individuals were authorized to enter the premises for academic purposes. Between 1958 and 1979, NRC inspected the university every 2 years as required. Because of an administrative error, however, NRC conducted no inspections between 1979 and 1986. When it did, NRC identified 21 safety violations, such as eating and drinking in contaminated areas, and expressed concern about the lack of management attention to radiation safety. If NRC required broad scope licensees, such as Case Western, to submit renewal applications in time for NRC to conduct an inspection before extending the license, problems like these might be resolved earlier.

Inspection Backlogs

NRC also constantly faces the question of how best to use its limited inspection staff. As of fiscal year 1987, NRC had 36 full-time inspection positions to monitor more than 7,700 materials licensees. NRC's inspection schedule and the frequency of inspections are based on a priority system. However, unexpected requirements and/or significant events can impose other priorities, increase the demand for inspection resources, and delay "routine" high priority inspections. For example, in 1987, after several people were exposed to cesium from a scavenged teletherapy machine in Brazil, NRC directed its inspectors to focus immediate attention on teletherapy machines in the United States. Region III staff also increased inspections of licensees possessing machines that they believed might present similar hazards.

NRC Region III also temporarily reordered its inspection priorities in 1988 while responding to the 3M case. The top four priorities became: (1) responding to incidents, (2) conducting field surveys of 3M's general licensees, (3) completing inspection and enforcement actions for 3M, and (4) conducting overdue inspections for priority 1 and 2 licensees (e.g., radiographers and broad scope medical institutions). As a result, the region will probably have a backlog of overdue inspections at the end of fiscal year 1988.

Past reports have cited deferred inspections as evidence of understaffing. In addition, our review work at NRC shows that backlogs continue

manufacturers, for comprehensive license renewal "team" inspections, which include Environmental Protection Agency and Occupational Safety and Health Administration officials. Regional inspection staff have also been directed to follow up quickly on new licensees that are not inspected before they obtain their licenses to ensure they "get off to a good start."

However, we believe that more needs to be done to try to ensure that only responsible applicants receive licenses. We concur with a recent report that suggested that detailed license denial criteria be developed as a checklist for reviewers to apply against license applications. Such a tool would simplify the reviewer's job and make it easier for him or her to determine when to deny a license. We also believe that NRC needs to develop a screening process for identifying applicants that must be inspected before they receive a license.

License Renewal Problems and Inspection Backlogs

License renewal problems and inspection backlogs have occurred for years within NRC's materials licensing program. Many of the studies we reviewed concluded that these problems and backlogs occur because NRC does not have sufficient licensing and/or inspection staff. Although we did not assess the staffing issue, our work shows that problems still occur and result in untimely license renewals and inspections. The case studies also show that renewal problems and backlogs can prolong unsafe circumstances.

License Renewal Problems

In fiscal year 1987, NRC had about 25 full-time positions to review about 700 new and 1,000 renewal applications. NRC's five regional offices take an average of 43 to 70 days to process new license applications. Because NRC gives higher priority to new license applications and amendments, a licensing backlog has its greatest potential impact on renewals. NRC allows licensees to continue operations if they file renewal applications 30 days prior to the license expiration date. Although NRC's 1987 goal was to process renewals within 120 days, the average time to do so in NRC's Region III was 327 days, and in other regional offices the time ranged from 56 to 370 days.

Our Minnesota Mining and Manufacturing Company (3M) case illustrates how license renewal problems can allow possible unacceptable practices to continue. In this case, NRC did not begin to review 3M's license renewal application for about 2 years; final approval took another 5 years. Later, many of 3M's products had to be recalled because of a defect.

waited until late the next day. In the interim, the employees contaminated their homes and six local businesses, including two restaurants. According to NRC's Director, Office of Nuclear Materials Safety and Safeguards, NRC staff were on site within a few hours of being notified and began to retrieve the company's radioactive sources. A week later, NRC formally suspended Shelwell's license and required the company to decontaminate the homes and businesses and submit an on-site decontamination plan. Shelwell's decontamination costs totaled about $1 million. Unlike Haynes, Shelwell was able to pay for the required cleanup. However, if Shelwell had not been able to pay, NRC would have had to find another source of funds. NRC later allowed Shelwell to renew its license but placed additional restrictions on it.

In 1985, NRC issued a proposed rule requiring materials licensees to ensure that funds would be available to clean up accidental spills or releases of radioactive material. In 1988, NRC suspended this effort. NRC staff explained that developing this type of regulation is "not easy" because of the many variables involved in a potential accident and the resulting difficulty in determining the appropriate amount of insurance that the various licensees should have. According to NRC's Director, Office of Nuclear Materials Safety and Safeguards, the availability of insurance may be limited in some areas. Therefore, a regulation could jeopardize the continued business operations of some licensees, something that NRC does not want to see happen.

We recognize that difficulties arise in defining the appropriate level of financial responsibility for all possible accidental releases of radioactive material. However, we believe that NRC needs some assurance that the government will not have to pay cleanup costs when such instances occur. Therefore, we suggest that if NRC cannot develop a comprehensive program, it should set a minimum amount of needed assurance that would cover most foreseeable cases. This step may also encourage insurers to provide coverage. Even a limited level of financial assurance would reduce the government's risk of paying for future accidents.

NRC Performs Few Prelicense Inspections and Does Not Verify Applicant Claims

NRC staff say that the primary responsibility for safe operations and protection of the public and workers rests with the licensees. Therefore, NRC largely relies on information submitted by applicants or licensees to issue new licenses, amendments, and renewals. NRC usually does not verify applicants' claims of training and experience or inspect applicants' facilities before issuing licenses. In fiscal year 1987, for example, NRC's Region III staff performed only 27 prelicense site visits for more than

requiring financial assurance for decommissioning[1] costs took effect in July 1988.

However, our case studies, review of recent reports, and follow-up discussions with NRC staff identified several continuing problems that have not been completely addressed by NRC. For example, several recent reports (1) suggested measures to provide financial assurance for accidental releases, (2) highlighted NRC's vulnerability to irresponsible or careless licensees, and (3) recommended prelicense inspections and license denial criteria. Other continuing program weaknesses include

- periodic inspection and license renewal backlogs,
- the need for additional regulations and a certification program for individual radiographers, and
- the possible need for a materials accountability system for large transfers of byproduct material.

In addition, our case studies showed two other program weaknesses. NRC needs to (1) improve licensee reporting and (2) review its policies on escalated enforcement actions for repeated record-keeping and administrative violations. All of these weaknesses or problems increase the public's risk of exposure and/or potential government costs.

NRC Slow to Require Financial Assurance for Decommissioning and Accidental Releases

NRC has long recognized the need for regulations providing assurance that licensees will have funds available to pay decommissioning costs. Prior to terminating a license, the holder must clean up the radioactivity to a level that will allow the site to be used safely for other purposes. As early as 1977, we recommended that NRC obtain financial assurance before it approves a license.[2] Later, other studies identified similar concerns.

In 1978, NRC proposed a rule to require licensees to provide financial assurance that funds would be available to cover decommissioning costs. NRC finalized the rule in May 1988; the regulations took effect on July 27, 1988. According to NRC, higher priority work, such as the Three Mile Island cleanup, delayed NRC's taking action sooner on the regulations. The new regulations require a prospective material licensee to establish a trust, obtain a bond, or provide some other type of financial assurance

[1]Cleanup or removal of radioactive contamination.

[2]Cleaning Up the Remains of Nuclear Facilities—A Multibillion Dollar Problem (GAO/EMD-82-46, June 16, 1977).

Safety Regulation Review Study Group report and its 22 recommendations. Appendix II lists the reviews and studies we considered. As part of our analysis, we also compared the weaknesses identified in the six case studies with those discussed in the 17 studies, reports, and reviews. We then determined the steps that NRC has taken to resolve the weaknesses by contacting responsible NRC regional and headquarters staff.

We discussed the facts presented in the report with NRC's Office of Nuclear Material Safety and Safeguards staff. Generally, they agreed with the facts but offered some clarifications that were incorporated where appropriate. At their suggestion, we included a description of (1) the benefits obtained from the use of radioactive materials and (2) NRC's strategy of publicizing enforcement actions in hopes of deterring similar problems in the future. As requested, we did not ask NRC to review and comment officially on this report. We conducted our work between January 1988 and July 1988 in accordance with generally accepted government auditing standards.

NRC issues notices of violations for all instances of noncompliance with NRC requirements; the notices require a written response within 20 days. NRC may also issue civil penalties in the case of significant or repeated noncompliance or when a notice of violation has not been effective. Orders to cease and desist operations or orders to suspend, modify, or revoke licenses may be issued in more serious cases. According to NRC's Director, Nuclear Materials Safety and Safeguards, NRC also publicizes the violations that occur. The Director believes that this action is an effective tool in deterring similar incidents.

Events and Incidents Reporting

Materials licensees are required to report events involving suspected leaking sources; lost, abandoned, or stolen material; potential radiation exposures; and/or any other activity suspected of having an impact on health and safety. NRC's latest report on nonreactor events states that in calendar year 1986, materials licensees submitted 202 incident reports. NRC categorized these reports into 317 entries in 10 areas, such as exposures; lost, abandoned, or stolen material; leaking sources; and releases of material.

The reports, along with NRC inspection findings, identified 13 cases in which 16 individuals were exposed to radiation in excess of NRC limits. NRC characterized each of these as a minor overexposure. Licensees also reported 68 cases of lost, abandoned, or stolen material that resulted in one known exposure in excess of established NRC limits; 21 cases of leaking sources resulting in no known exposures; and 22 cases of material releases with no known exposures. Medical, transportation, and other events account for many of the remaining cases. According to NRC's 1986 report on these events, the number and types of events reported in 1986 did not differ substantially from those of previous years.

Objectives, Scope, and Methodology

On November 13, 1987, following an Ohio incident involving the accidental release of a highly toxic, radioactive substance that cost over $1 million to clean up, Representative Edward F. Feighan asked us to review NRC's byproduct materials licensing program. At subsequent meetings with Representative Feighan's staff, we agreed to identify (1) NRC's licensing responsibilities; (2) case studies that illustrate NRC's program for different types of licenses; (3) licensing, inspection, enforcement, and administrative weaknesses revealed by the case studies and other reviews; and (4) NRC's actions to correct the weaknesses. We limited our work to the approximately 7,700 specific byproduct licenses administered by NRC headquarters and its five regional offices. Since

watches, balances, compasses, and smoke detectors. The persons or commercial entities that purchase these items are exempt from licensing requirements.

Lastly, NRC issues specific licenses for general distribution to the manufacturers and/or distributors of radioactive material in certain devices or products. These devices or products usually contain radioactive material in a capsule, generally called a sealed source, designed to prevent leakage or escape of the material. They also have built-in safety features that allow them to be used by persons with little radiation training or experience. The bulk of these licenses are for relatively low-hazard devices, such as tritium exit signs used in office buildings and aircraft.

When a specific licensee sells or leases a general distribution item, the recipient is called a general licensee. NRC estimates that 300,000 such devices are used by about 35,000 general licensees throughout the country. On a quarterly basis, specific licensees provide NRC the names of the general licensees, the type and model of devices, and the quantity and type of material contained in the devices. The general licensees do not actually obtain an NRC license but must comply with applicable NRC reporting and disposal regulations and policies. The specific licensee usually installs, services, and conducts periodic tests of the devices. When no longer needed, the general licensee usually transfers the device to a specific licensee for disposal.

NRC's five regional offices administer about 98 percent of the specific licenses. NRC headquarters administers the rest. In addition, NRC has formal agreements with 29 states to regulate about 15,000 additional licenses under programs comparable to NRC's. Table 1.1 shows the number of licenses administered by NRC headquarters and the five regional offices.

Table 1.1: Byproduct Material Licenses Administered by NRC as of June 1988

NRC Office	Location	Licenses
Headquarters	Washington, DC	158
Region I	Philadelphia	2,746
Region II	Atlanta	956
Region III	Chicago	2,768
Region IV	Dallas	816
Region V	San Francisco	282
Total		**7,726**

Introduction

Throughout the United States, thousands of individuals, companies, and organizations routinely use over 120 kinds of radioactive materials for research and development, medical diagnosis and treatment, and industrial and academic activities. The public derives many benefits from these materials. For example, nuclear medicine is credited with saving over 200 lives each week, and devices containing radioactive material are used to test the structural safety of aircraft and bridges.

Most radioactive materials are produced by research reactors or the Department of Energy's production reactors; others are imported from Canada. These radioactive materials are commonly called byproduct materials. Some of these materials emit relatively low levels of radiation, posing little or no threat to public health and safety; others can result in a significant radiation dose if not properly handled.

NRC's Materials Licensing Program

Under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, the Nuclear Regulatory Commission (NRC) is responsible for ensuring that radioactive materials are handled safely and do not endanger the users and/or public. NRC's Office of Nuclear Material Safety and Safeguards issues licenses to qualified individuals, businesses, and other institutions to handle specific radioactive materials according to its regulations.[1] The regulations, as well as a number of internal policies, specify the actions NRC must take prior to and after issuing a license. They also specify the testing, reporting, inspecting, and record-keeping requirements for the licensee.

NRC issues two types of materials licenses—specific and general. NRC issues specific licenses to industrial/commercial, medical, and academic institutions. Depending on the size of the institution and its activities, the specific license may also fall into one of three categories: (1) broad scope, (2) exempt distribution, and (3) general distribution. Figure 1.1 depicts the types and number of NRC materials licenses as of June 1988.

A specific license authorizes the individual or organization to possess and use certain types and quantities of materials for a specified purpose. To receive a specific license, the individual or organization must submit an application to NRC that outlines how and where the radioactive material will be used, the training and other qualifications of the individuals involved in the activity, and the radiation safety program to be established. Specific licensees pay NRC a fee to review and administer

[1] NRC's regulations are set forth in 10 C.F.R. parts 19 through 21, 30 through 35, 39, 40, 70, and 71.

Abbreviations

GAO	General Accounting Office
NRC	Nuclear Regulatory Commission
3M	Minnesota Manufacturing and Mining Company

Since 1977, NRC has recognized the need for regulations to shift the financial risk from the government to the licensees for decommissioning and accident cleanup. New decommissioning regulations took effect in July 1988. In 1985, NRC initiated efforts to ensure that licensees will have funds to clean up accidental spills or releases of radioactive material. However, because of various difficulties, such as the lack of available insurance, NRC suspended these efforts.

License and Inspection Backlogs

NRC constantly faces the question of how best to use its limited license review and inspection staff. In fiscal year 1987, NRC had 25 full-time license reviewers and 36 inspectors. As a result, NRC historically has license renewal backlogs. For example, in 1987, NRC's goal was to process license renewals within 120 days; the time to do so averaged between 56 and 370 days in NRC's five regions. In one GAO case, NRC took about 7 years to renew a license.

NRC also experiences inspection backlogs. NRC inspects licensees in the first year; thereafter, they are conducted according to a priority system based on the kinds and amounts of materials handled by the licensees. However, unexpected events, such as the need to recall unsafe devices, cause NRC to change inspection priorities and delay needed inspections or licensing actions. As a result, some licensees may never be reinspected after the first year. In one case, NRC did not inspect a licensee for 10 years. When it did so in 1987, NRC found that a fire had destroyed the facility 3 years earlier and the licensee had abandoned a damaged piece of equipment containing radioactive material.

To address some of these problems, NRC has requested additional staff and has asked one type of licensee to begin the renewal process 1 year before the license expires. Although GAO does not believe that NRC should require all licensees to begin renewals that far in advance, NRC could consider doing so for large, broad scope licensees, such as universities or medical facilities, that use many radioactive materials at numerous locations. (See ch. 2.)

Enforcement Criteria Needed

NRC has not developed specific criteria to determine when escalated enforcement actions should be taken against licensees who repeatedly violate minor regulatory requirements. Two GAO cases show that NRC imposes financial penalties against these licensees on a case-by-case basis. For example, in 1987, NRC found widespread, repeat minor violations at a large university and imposed a $10,000 penalty. In another

Executive Summary

Purpose

Throughout this country, thousands of businesses, hospitals, laboratories, and universities routinely use over 120 radioactive substances for research and development, medical diagnosis and treatment, and industrial activities. Some of these materials emit relatively low levels of radiation, posing little or no threat to public health and safety; others pose a significant concern if mishandled.

Representative Edward Feighan asked GAO to assess the Nuclear Regulatory Commission's (NRC) licensing, inspection, and enforcement program for the use of radioactive materials. This report draws on 17 past studies, including recent internal NRC reviews, and presents information on six case studies that GAO developed. (See ch. 1.)

Background

The Atomic Energy Act of 1954 and the Energy Reorganization Act of 1974 require NRC to ensure the safe handling and disposal of radioactive materials. To carry out its responsibilities, NRC issues licenses and conducts inspections to ensure that licensees use the materials safely and do not endanger the users and/or public. As of June 1988, NRC had issued about 7,700 licenses for specific purposes, such as industrial activities. Also, about 35,000 businesses and other organizations use about 300,000 devices, such as aircraft exit signs, that contain radioactive material sealed inside them. These entities, while not licensed directly by NRC, must comply with NRC regulations.

Because of the number and range of activities conducted, NRC largely relies on the licensees to follow the regulations established with little monitoring by NRC. However, almost all serious events, such as exposures to and releases of radioactive material, result from careless or irresponsible licensee actions. Over the past 16 years, GAO, NRC internal reviews, and others have identified a number of chronic weaknesses in NRC's materials program. (See ch. 1.)

Results in Brief

In response to past studies, NRC has taken some actions to improve its regulation of nuclear materials activities. However, recent reports and six case studies developed by GAO show that many problems identified years ago still exist. GAO found the following:

- NRC usually does not verify license application information; visit the facility before granting a license; or have specific, detailed criteria for its license reviewers to determine when a denial is warranted. As a result, NRC is overly vulnerable to dishonest or careless applicants.