REPORT TO THE CONGRESS

Problems Of The Atomic Energy Commission Associated With The Regulation Of Users Of Radioactive Materials For Industrial, Commercial, Medical, And Related Purposes B-164105

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

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To the President of the Senate and the
Speaker of the House of Representatives

This is our report on problems of the Atomic Energy Commission associated with the regulation of users of radioactive materials for industrial, commercial, medical, and related purposes

Our review was made pursuant to the Budget and Accounting Act, 1921 (31 U S C 53), and the Accounting and Auditing Act of 1950 (31 U S C 67)

Copies of this report are being sent to the Director, Office of Management and Budget, and to the Chairman, Atomic Energy Commission

Comptroller General
of the United States

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ABBREVIATIONS

AEC	Atomic Energy Commission
DOC	Division of Compliance
GAO	General Accounting Office

CHAPTER 1

INTRODUCTION

Under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011), the Atomic Energy Commission (AEC) is required to insure, through a system of regulation, that the possession, use, and disposal of radioactive materials[1] and the construction and operation of reactors and other nuclear facilities are conducted in a manner consistent with the health and safety of the public.

As of June 30, 1971, there were about 12,600 organizations or persons licensed to use radioactive materials (materials licensees). Materials licensees are those licensees involved in (1) the manufacturing and processing of fuel for nuclear reactors and (2) any industrial, commercial, medical, or educational operation in which radioactive materials are used. Materials licensees do not include those licensees which construct and operate nuclear reactors.

Organizations or persons licensed to use radioactive materials can have one or more licenses, depending on the nature of their activities. The 12,600 materials licensees mentioned above have about 16,300 materials licenses. Regulatory responsibility for about 8,200 of these licenses rests with AEC. The remaining 8,100 licenses have been issued by, and are subject to regulation by, States which have entered into regulatory agreements with AEC pursuant to section 274 of the Atomic Energy Act of 1954.

Under section 274 of the act, AEC may, by formal agreement, relinquish to an individual State certain of its

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[1]The term "radioactive materials," as used in this report, refers to source material (uranium and thorium), byproduct material (radioisotopes produced in nuclear reactors), and special nuclear material (plutonium and enriched uranium). Other materials which emit radiation that either are naturally occurring, such as radium, or that are produced other than by reactors, such as by accelerators, are not regulated by AEC. X-ray machines are not regulated by AEC but are subject to State regulation.

regulatory authority over radioactive materials when the State's program is compatible with AEC's program for regulating these materials and is adequate to protect the public health and safety. As of January 1972 there were 23 States (agreement States) which had been granted such authority. (See p. 7.)

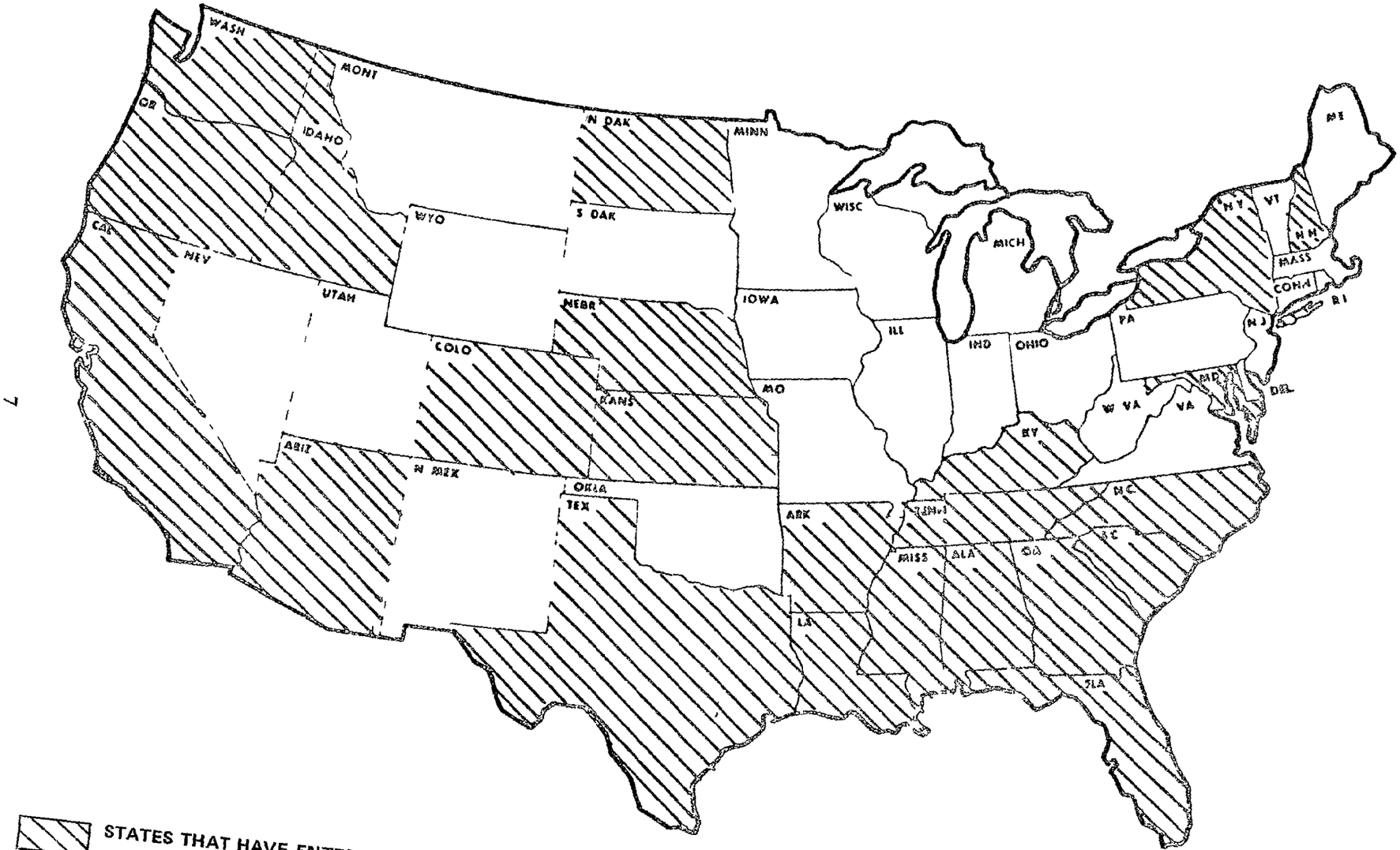
AEC may not transfer regulatory responsibility to States for materials licensees which possess quantities of special nuclear material above certain specified limits or which obtain, distribute, or dispose of licensed materials in certain ways. For example, a State cannot authorize a licensee to export or import radioactive materials to or from foreign countries.

Also AEC maintains regulatory responsibility for Federal installations, such as Veterans Administration hospitals and Department of Defense installations, located in agreement States. Further, licensees located in agreement States are required to obtain AEC licenses if they operate for more than 180 days a year in nonagreement States.

Our review was concerned with the efficiency and effectiveness of AEC's inspection and enforcement programs for materials licensees. Our review did not include the regulatory practices or procedures of agreement States.

Within the regulatory organization of AEC, the responsibility for regulating licensees was placed in the Division of Compliance (DOC) at the time of our review. On April 25, 1972, major changes were made in AEC's regulatory organization. The functions of DOC were transferred to the newly established Directorate of Regulatory Operations. Therefore the activities discussed in this report, which were formerly the responsibility of DOC, are presently the responsibility of the Directorate of Regulatory Operations.

AEC conducts onsite inspections and investigations to determine the extent of licensees' compliance with health and safety standards contained in title 10 of the Code of Federal Regulations and with specific license conditions which set forth operating requirements a licensee must follow.



STATES THAT HAVE ENTERED INTO REGULATORY AGREEMENTS WITH AEC

AEC has established five regional compliance offices which inspect and investigate materials licensees in selected geographical areas. (See chart on page 10.) The following table shows, as of June 30, 1971, the materials licenses in each region and the number of professional inspectors and investigators available in each regional office.

	Licenses	Inspectors	Investigators
Region I	3,080	11	1
Region II	766	4	-
Region III	3,185	7	1
Region IV	769	3	1
Region V	408	3	-
	8,208	28[a]	3

[a]Includes six persons who also have supervisory responsibilities.

INSPECTION FREQUENCY

AEC has established a materials priority system which defines the frequency of routine inspections of the different types of licensed operations. Inspection frequencies have been developed on the basic premise that the frequency of inspection and the utilization of available manpower should be related as nearly as possible to the potential hazards associated with each licensed operation. The priority system includes five different classifications.

The current inspection frequencies for routine inspections for each priority and examples of the types of operations under each priority follow.

--Priority I licensees are large fuel facilities and major processors. Each priority I licensee is to be initially inspected within 1 month after receiving a license and reinspected two to three times a year.

--Priority II licensees are waste disposal firms, field radiographers, and refineries. Each priority II licensee is to be initially inspected within 6 months after receiving a license and reinspected once every 1-1/2 to 2 years.

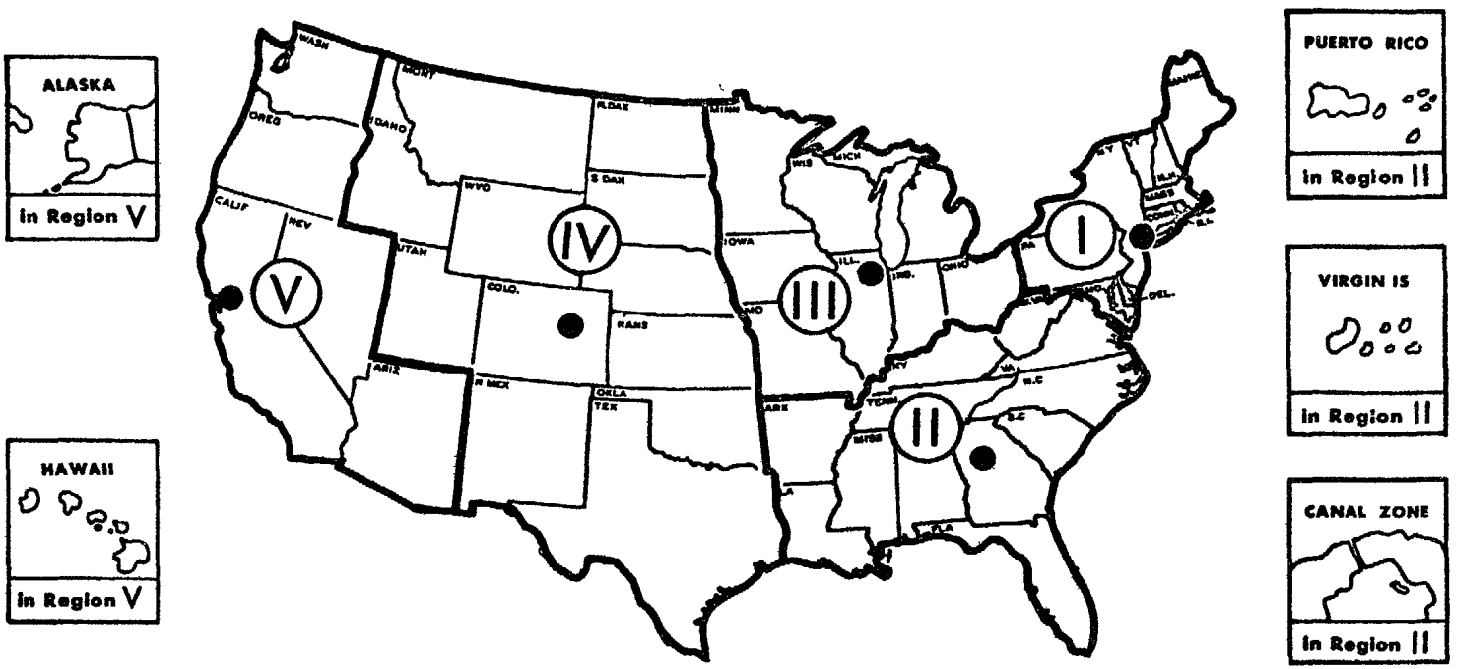
--Priority III licensees are industrial users which conduct activities such as exploration, oil well logging, and certain manufacturing and processing operations Each priority III licensee is to be inspected within 6 months after receiving a license. They are required to be reinspected only if manpower is available.

--Priority IV licensees are academic and medical users and are to be initially inspected within 12 months after receiving a license. They are not required to be reinspected.

--Priority V licensees are limited medical or industrial users and are not required to be inspected.

Regional compliance office officials told us that inspections which are not required under the priority system,

REGIONAL COMPLIANCE OFFICES



including inspections of priority IV and V licensees, may be conducted for various reasons. (See p. 65.)

The following table shows the number of materials licenses, by priority, within each regional compliance office as of June 1971

Regional compliance office	License priorities I	II	III	IV	V	Total
I	33	183	575	1,152	1,137	3,080
II	7	63	100	285	311	766
III	14	140	364	1,421	1,246	3,185
IV	-	111	131	233	294	769
V	6	63	87	105	147	408
Total	60	560	1,257	3,196	3,135	8,208

The basic premise behind AEC's regulations is that all unnecessary exposure to radiation should be avoided because of the possible biological effect.

As a primary step in controlling nuclear radiation, AEC has established exposure limits for all persons who are directly employed in nuclear activities or who handle sources of radiation in their employment.

Workers in the nuclear industry are not permitted to have more than a limited amount of exposure each year, which, according to AEC, is an amount deliberately set lower than the amount which might be expected to cause detectable physical impairment even though the exposure continues for a long time. Where the public is concerned, AEC requires that no activities expose anyone to more than one-tenth of the level set for radiation workers.

AEC's regulations require licensees to notify AEC immediately of certain types of incidents involving radioactive

materials and within 24 hours of certain less significant types of incidents. The licensees are also required to submit a report, in writing, within 30 days of such incidents.

An example of an incident requiring immediate notification to AEC is one that involves the whole-body exposure of an individual to radiation levels five times greater than the annual exposure level permitted by AEC's regulations or the release of radioactive material to the environment in a concentration which, if averaged over a 24-hour period, exceeds 5,000 times the regulatory limit. An example of an incident requiring notification within 24 hours is one which involves the whole-body exposure of an individual to radiation levels which exceed the maximum exposure allowed for 1 year or a release of radioactive material to the environment in a concentration which, if averaged over a 24-hour period, exceeds 500 times the regulatory limit.

Licensees are required to report in writing all (1) exposures of individuals to radiation or concentrations of radioactive material above AEC's regulatory limits or specific license conditions and (2) incidents involving levels of radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times the regulatory limit or specific license conditions. These reports are to be submitted within 30 days after the exposures or incidents occur.

AEC investigates accidents or incidents involving radioactive materials at AEC-licensed facilities. These investigations are made to ascertain the cause, determine whether there is any threat to the public health and safety, and insure that prompt, adequate action is being taken by the licensee.

ENFORCEMENT ACTIONS

An enforcement action is taken by AEC whenever an inspection or investigation discloses that a licensee is operating in violation of AEC regulations or specific license conditions.

A licensee may be cited (notified, in writing, of a violation) if any segment of its operations is found to be in noncompliance with specific license provisions or published AEC regulations. In addition, AEC notifies licensees of safety deficiencies which should be corrected but which do not involve items of noncompliance (safety items).

The form of citation or enforcement action taken by AEC varies, depending on the nature of the violations. AEC has developed an enforcement program which classifies enforcement actions into two broad categories--informal and formal. Informal enforcement action is that action taken by the appropriate regional compliance office and is limited to notifying the licensee of certain types of violations or safety items, whereas formal enforcement action is that action taken by AEC Headquarters.

Informal enforcement action consists of:

1. AEC Form 591, Inspection Findings and Licensee Acknowledgment, which is a listing of 16 different minor or readily correctable violations relating to posting, labeling, or recordkeeping. (See app. III). If a licensee is in violation of one of the provisions contained on this form, the appropriate block is checked and the licensee is required to sign the form indicating acknowledgment of the violation checked and the licensee's intention to correct the deficiency within 30 days. This form is also used when no items of noncompliance are found during the inspection.

2. Letters, which are signed by the directors of the appropriate regional compliance offices. These letters replaced AEC form 592 in June 1971. This form was used when items of noncompliance other than posting, labeling, or recordkeeping were

disclosed and when the inspection did not reveal (1) an immediate threat to the public health and safety, (2) any failure to take promised corrective action regarding noncompliance observed during the previous inspection, and (3) any other situations for which referral to AEC Headquarters was required under DOC procedures. The licensee was requested to notify the regional compliance office, in writing, of the corrective action it was taking or planning to take, unless the corrective action had been taken prior to completion of the inspection.

Formal enforcement actions taken by AEC Headquarters in cases where informal regional enforcement actions are not considered sufficient are.

1. A notice of alleged violation which requires the licensee to submit a written explanation or statement of reply to AEC Headquarters, within 20 days, indicating (1) the corrective steps which have been taken and the results achieved, (2) the corrective steps which will be taken to avoid further violations, and (3) the date when full compliance will be achieved.

   Occasionally AEC Headquarters will issue enforcement letters to licensees that are not categorized as notices of alleged violation. These "safety letters" relate to safety items which do not involve violations of specific regulations or license conditions.

2. An order which is issued to a licensee for instituting a proceeding to modify, suspend, or revoke a license or for such other action as may be proper. Examples of some types of orders which AEC has issued are discussed on page 42. An order may be issued for violation of, or failure to observe any terms and provisions of, the Atomic Energy Act of 1954, as amended, or of any rule, regulation, or order of AEC. An order must be preceded by a notice of alleged violation, unless AEC determines that this requirement should be waived because the public health, safety, or

interest so requires or because the violation is willful.

A licensee may respond to an order by filing a written answer under oath or affirmation. The answer is to specifically admit or deny each allegation or charge made in the order. In addition, the licensee may demand a hearing, in which case AEC designates the time and place of the hearing. A hearing examiner presides over the hearing and makes a decision on the order.

In addition, AEC, in September 1971, completed requirements permitting it to impose civil penalties. (See p. 43.) The Atomic Energy Act of 1954 also provides for the imposition of criminal penalties in those cases in which the licensee has willfully violated AEC regulations or license conditions. Criminal cases must be referred to the Department of Justice for prosecution.

From January 1, 1968, through December 23, 1971, AEC performed 5,616 inspections of materials licensees, of which 3,684, or about 66 percent, disclosed no noncompliance or safety items. Of the 1,932 enforcement actions, 1,724, or about 90 percent, were informal enforcement actions taken by the regional compliance offices. The following tabulation shows the 208 formal actions taken by AEC Headquarters.

Notices of alleged violation	173
Letters (safety letters) not involving violations of specific regulations or license conditions	32
Orders	3
Total	208

CHAPTER 2

NEED FOR AEC TO IMPROVE ITS ENFORCEMENT ACTIONS FOR PROBLEM LICENSEES

We reviewed 10 cases for which AEC records showed that prompt corrective actions were not obtained after inspections had disclosed (1) a history of noncompliance with AEC regulations, (2) questionable operating practices, or (3) the existence of potentially hazardous operating practices. In eight of these cases, persons had been exposed to levels of radiation in excess of the limits specified in AEC regulations. We believe that these cases illustrate the need for stronger and more prompt action by AEC to achieve improved radiation protection practices.

The Director of Regulation has not provided DOC with written criteria describing the circumstances under which actions stronger than the issuance of notices of alleged violation should be taken. The Director, DOC, said that AEC's enforcement practices had evolved on a case-by-case basis, over a period of several years, as a result of precedents and management guidance. He stated that these practices were to suspend a licensee's operations only when circumstances or conditions indicated that there was an immediate threat to the public health and safety or when a significant incident occurred. According to the Director, DOC, the suspension, which was not used as a punitive measure, was obtained either by AEC's issuing an order or a letter or by the licensee's voluntarily suspending its operations.

In our opinion there is a need for AEC to strengthen its enforcement program by (1) developing and applying criteria for enforcement actions sufficiently severe to provide licensees with incentives to comply with AEC's regulations and (2) communicating the criteria to all licensees. When we brought our findings to AEC's attention, AEC advised us that it had initiated action to develop criteria for civil penalties. Later AEC told us that it was developing criteria also for the suspension and revocation of licenses.

PROBLEM LICENSEES

About 66 percent of AEC's inspections revealed no items of noncompliance. AEC believes that, in those cases in which items of noncompliance were found, licensees generally took appropriate and prompt corrective action. However, AEC has had chronic problems with certain licensees.

In May 1971 AEC Headquarters requested the five regional compliance offices to review their materials license files and identify licensees which had chronic problems with one or more of the following items:

--Frequent external or internal exposures exceeding or approaching regulatory limits.

--Effluent releases exceeding or approaching regulatory limits.

--Inadequate evaluations of exposures or effluent releases.

--Inadequate management control (as evidenced by number of deficiencies or recurring similar deficiencies).

--Other practices which demonstrated continuing problems.

Between May and July 1971, the five regional compliance offices identified 19 active materials licensees which had experienced or were experiencing such problems. We reviewed AEC's records for six of these licensees in detail. In addition, we selected for review one licensee and three former licensees which, according to AEC records, had experienced chronic problems relating to one or more of the above items.

Our review of these 10 cases showed that, for the most part, the strongest action taken by DOC to obtain corrective action by the licensees had been the issuance of notices of alleged violation, including those cases in which AEC inspectors had stated that there were potential hazards to the health and safety of the licensees' employees or the general public Furthermore, top regulatory management did not

promptly exercise its authority when it did take stronger action.

In the 10 cases AEC took four actions which were stronger than the issuance of notices of alleged violation The circumstances surrounding these actions were:

--After excessive radiation levels were found for the third time in or near an occupied apartment building adjacent to a licensee's facility, the licensee was told to suspend certain of its operations.

--After a radiation incident occurred that resulted in widespread radioactive contamination, a licensee was told to suspend operations and to not resume them without AEC's concurrence. An order was subsequently issued denying the licensee's application for renewal of the license.

--After five inspections and investigations conducted between August and October 1967 showed that a licensee's operating practices (1) in some instances constituted chronic hazards to its employees and (2) resulted in exposing employees to excessive quantities of airborne concentrations of radioactive material because of inadequate health physics procedures, AEC concluded that "it appears that radiological safety conditions" at this licensee's plant were "inadequate to protect the health and safety" of its employees. In December 1967 AEC told the licensee to suspend certain of its operations.

--After an inspection disclosed that a licensee apparently was knowingly and willfully processing special nuclear material in two areas of its plant without license authorization, AEC ordered it to cease and desist from such operations.

Following is a discussion of three of the cases included in our review. A brief discussion of the seven other cases we reviewed in detail is included as appendix II. (See p. 78.)

Licensee A

This priority I licensee used radioactive materials for research and development purposes and processed radioactive materials for redistribution to authorized recipients. Our review of the inspection file for this licensee showed that since 1960 it had been in noncompliance with AEC regulations on numerous occasions. Through August 1971 AEC had conducted 23 inspections, 18 of which resulted in the licensee's being cited for one or more items of noncompliance, some of which were similar items. Examples of the types and similar nature of the items of noncompliance were.

--Radiation levels exceeding regulatory limits in unrestricted areas[1] in and around the plant, including, on four occasions, areas in or near an occupied apartment building adjacent to the licensee's plant (nine inspections).

--Failure to conduct adequate surveys to evaluate radiation safety for employees or the public (13 inspections).

--Overexposure of employees to radiation (nine inspections).

Between 1960 and 1969 AEC did not take any formal enforcement action stronger than the issuance of notices of alleged violation. Top regulatory management officials did, however, have several discussions with the licensee's top management. As a result of a discussion on December 19, 1969, the licensee suspended certain of its operations. The licensee was subsequently found in noncompliance on several occasions, and in March 1971 AEC met with the licensee's top management and advised the licensee that AEC was considering not renewing its license. Two inspections conducted subsequent to the March 1971 meeting showed that the licensee had made substantial improvements in its radiation safety program.

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[1]An unrestricted area is any area to which access is not controlled by the licensee for purposes of protecting individuals from exposure to radiation and radioactive materials.

A chronological account of the licensee's inspection history and AEC's enforcement actions is shown below.

1960 to March 1969

AEC conducted 10 inspections of the licensee's facility during this period, eight of which disclosed two or more items of noncompliance with AEC regulations.

The history of noncompliance of this licensee was mentioned by the regional compliance office when it transmitted the results of a September to October 1968 inspection to AEC Headquarters The transmittal letter stated.

> "*** the number and quality of the surveys that have been conducted since April 1968 when the former health physicist left the licensee's employ, has deteriorated significantly.***"
>
> * * * * *
>
> "In consideration of the quantity of material being processed, the marginal adequacy of the handling facilities, and the past history of noncompliance it is our belief that the licensee's failure to assign a replacement health physicist, who could at least spend as much time with health physics as his predecessor, indicated a lack of responsibility that is prejudicial to health and safety. We identify this failure as a basic cause of noncompliance, which if allowed to continue will result in a progressive degradation of the licensee's radiation safety program despite whatever action he takes to correct the specific items of noncompliance listed in this report."

As a result of this inspection, the Director, DOC, issued a notice of alleged violation to the licensee citing it for seven items of noncompliance, including:

--Failure to report to AEC overexposures of employees to radiation or to notify the employees, in writing, of such overexposures.

--Inadequate surveys to determine compliance with allowable airborne concentrations of radioactive material.

--Failure to supply appropriate personnel-monitoring equipment to employees so that their exposure to a certain type of radiation while handling radioactive material could be monitored.

The licensee, responding in December 1968, advised AEC of a number of corrective measures which had been or would be taken in the near future to correct the problems. With respect to the three items of noncompliance mentioned above, the licensee stated:

--"The exposed individuals have been furnished the required written notification of their overexposure ***."

--"A conscientious program of air-monitoring for the determination of airborne concentration *** is operating on a continual basis to insure compliance ***."

--"Personnel monitoring equipment has been issued to each and every individual handling radioactivity along with written instructions in the use of equipment and proper retrieval of data."

April 1969 to January 1970

During an April 1969 inspection, the AEC inspector found unshielded radioactive sources on the licensee's loading dock and in a waste container in the licensee's laboratory; he reported that the licensee's general radiation survey program was inadequate and that its procedures and equipment used for monitoring airborne radioactivity provided no assurance of reliability or efficiency.

The licensee was again cited for overexposure of employees (including the failure to report one overexposure to AEC and the failure to inform several employees, in writing, of such overexposures), failure to conduct adequate radiation surveys, and excessive radiation levels in unrestricted areas. Excessive radiation levels were found in six unrestricted areas, including the roof of the licensee's building,

the first floor of the licensee's building (which was occupied by another business firm), and an occupied apartment building adjacent to the licensee's facility. The AEC inspector measured radiation levels up to 45 milliroentgens[1] an hour in one of the apartments.

Removal of the unshielded radioactive source from the waste container in the licensee's laboratory reduced radiation levels in the apartment building to about 1 to 3 milliroentgens an hour. A reinspection a few days later revealed that the licensee had further reduced radiation levels in the apartment building to within regulatory limits of 2 milliroentgens an hour.

DOC officials discussed the results of this inspection with the licensee and sent it a notice of alleged violation which stated:

> "*** We believe the recurrent nature of the violations, as well as the increasing number of deficiencies disclosed during inspections conducted in 1968 and 1969 are indicative of inadequate management control over the safety aspects of the company's licensed operation."

In this notice AEC stated, for the first time, its intent to modify, revoke, or suspend the license if adequate corrective actions were not taken.

The licensee agreed with the inspection findings, stating that in certain instances there had been a management disregard for, and an inadequate development and maintenance of, health physics procedures. The licensee outlined the corrective actions taken, expressed the belief that it was then in compliance, and gave assurance that it would continue efforts to maintain a safe and effective radiation control program.

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[1] A radioactivity level of 45 milliroentgens an hour is approximately 22 times greater than the level permitted by AEC's regulations--section 20.105 of title 10 of the Code of Federal Regulations.

In May 1969 AEC conducted another inspection and found that the licensee had made considerable progress in reducing radiation levels in unrestricted areas and had initiated corrective actions for other deficiencies found in April 1969; however, the inspection disclosed new violations as well as violations for which the licensee had previously been cited

DOC expressed some concern regarding the licensee in a June 1969 internal summary report which stated that.

> "***the shortcomings in health physics and management controls raise questions as to the company's ability to continue to operate a safe program."

An inspection conducted from November 12 through 14, 1969, revealed that the licensee's health physics program had deteriorated. Serious deficiencies--deficiencies previously brought to the licensee's attention--were again noted. Some of the noncompliance items found were:

--Radiation levels in excess of regulatory limits in two unrestricted areas, including the alleyway between the licensee's facility and the apartment building.

--Failure to conduct adequate surveys

--Major defects in the bioassay program.[1]

--Failure to make evaluations of possibly significant uptakes[2] of radioactive material by employees.

--Failure to report several overexposures to AEC or to employees, in writing.

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[1]A bioassay is an analysis of urine and feces samples to determine levels of radioactivity in the body.

[2]Uptake is the inhalation or absorption of radioactive materials into the body through the mouth, nose, or skin.

The regional compliance office promptly informed DOC headquarters of the nature and seriousness of the inspection findings. Prior to receiving the written inspection report from the regional compliance office, the Director, DOC, called the licensee's president in to AEC Headquarters for a meeting on November 25, 1969, to discuss the licensee's inspection history, the seriousness of the November 1969 inspection findings, and the need for immediate corrective action by the licensee. During this meeting the licensee's president stated that immediate corrective action would be taken.

The seriousness of the conditions at this licensee's facility was expressed by the regional compliance office in transmitting the results of its November 1969 inspection to AEC Headquarters The transmittal letter, dated December 12, 1969, contained the following observations.

> "It is felt there is serious cause for concern about the use of licensed materials by *** [the licensee]. There is a continual history of noncompliance with AEC requirements and safety standards ever since the company started operations in 1961. These have been discussed with the licensee and corrective actions have been promised and taken, but it is overwhelmingly evident that these corrective actions have not been adequate. The same or similar deficiencies have been found again and again. The 1969 inspections have disclosed major shortcomings in nearly every area of licensee operations that has been given a close examination. After the April and May 1969 inspections and ensuing discussions so clearly highlighted the problem of excessive radiation levels in unrestricted areas, it was still found in November that continuous radiation levels in unrestricted areas were substantially in excess of the allowable limit and that the licensee was knowingly continuing operations for months without correcting this situation.
>
> "The failure to properly control stray radiation levels into unrestricted areas is particularly of concern because it is not an academic matter but has led to actual exposure of families in an adjacent apartment house. The extent of exposure to these

men, women and children is not known, but it appears likely that the situation found in April 1969 resulted in doses received at that time alone being as much as ten times the recommended annual limit *** for persons in the general public and possibly much more Furthermore, the levels still found in November 1969 were such as to expose these same people at a rate on the order of ***[twice the recommended annual limit]***.

"Similarly, there is reason for concern for the health and safety of licensee employees. There are many overexposures that have apparently occurred so far in 1969 on a continual basis. In addition, bioassay results suggest even more exposures that were not evaluated, at least one of which may have been substantial ***

"It is recommended that effective action be taken to ensure that the licensee does not continue to possess and use any licensed materials that are not possessed and used in compliance with AEC requirements and safety standards."

Early in December 1969 the licensee reported to AEC that radiation levels in unrestricted areas had been reduced to within regulatory limits. In mid-December AEC conducted another inspection to verify the licensee's progress. AEC again found excessive radiation levels in four unrestricted areas in and around the licensee's plant, including the adjacent apartment building and the other business firm located in the same building as the licensee. AEC inspectors also found that two more licensee employees had been overexposed to radiation and that the licensee was not conducting adequate surveys to evaluate the radiation levels in and around its plant.

After this inspection DOC drafted an order to suspend the licensee's operations. The draft order stated that:

"The activities of the licensee *** demonstrate that radiation safety conditions at the company's plant *** constitute a hazard to the health and safety of the public."

The suspension order was not sent to the licensee. Instead, the Director of Regulation told the licensee, by telephone, on December 19, 1969, to suspend immediately certain operations which were considered to constitute an immediate hazard.

An inspection made on December 22, 1969, to verify the discontinuance of certain operations, revealed that excessive radiation levels still existed in the alleyway between the licensee's facility and the apartment building and that the licensee had not discontinued all the operations it was told to suspend. The Director of Regulation met with the licensee on December 22, and the licensee agreed to suspend its operations, except those which were specifically approved by AEC. AEC confirmed the suspension in a telegram to the licensee dated December 24, 1969.

On January 14, 1970, the licensee requested authorization from AEC to exclude certain additional types of radioactive materials from the suspension. An inspection on January 15 and 16, however, revealed that the licensee had performed further processing of certain types of materials which were covered by the suspension and that the licensee again had radiation levels in unrestricted areas which were, according to AEC, slightly in excess of regulatory limits. Therefore, by telegram dated January 19, 1970, AEC informed the licensee that its January 14 request was not approved and further clarified the terms of the suspension. During this period the licensee also was seeking license authorization to move its operations to a new and better equipped facility, completion of which was anticipated early in February 1970

To place the items of noncompliance on the record, the Director, DOC, prepared a notice of alleged violation which listed 21 items of noncompliance found in the November and December 1969 and January 1970 inspections. When he submitted this notice to the Director of Regulation on March 25, 1970, he stated:

> "I want this history on the record so it can be used, if it is needed, should more than routine enforcement action again be required in the future."

On May 14, 1970, the Director of Regulation advised DOC that he would prefer not to send the notice to the licensee in view of the length of time which had passed since the inspection dates mentioned in the notice

February 1970 to June 1971

The licensee moved to another facility in February 1970 and agreed to decontaminate its old facility by April 1970. Inspections conducted at the old facility between March 1970 and June 1971, however, disclosed such deficiencies as excessive radiation levels in unrestricted areas, fixed and loose contamination inside and outside the plant, failure to secure the plant against unauthorized entry, and failure to perform surveys to adequately control and evaluate the release of radioactivity and contamination.

During that period the licensee repeatedly told AEC that corrective action would be taken to eliminate the problems at the old facility. Following one inspection at the old facility in December 1970, the AEC inspector advised AEC Headquarters that the licensee's "indifferent attitude toward his defined problems continues to be a source of amazement."

In March 1970 AEC made an initial inspection of the licensee's new facility before it was fully operational. Although the inspection did not reveal any violations, the inspector did discuss with the licensee several areas in which, he believed, operational improvements could be made.

In an inspection conducted from April 29 to May 1, 1970, AEC found that the licensee's radiological safety program was not adequate for properly evaluating or controlling the hazards associated with using radioactive materials. Some of the violations were in those areas discussed during the previous inspection Other violations included some which were similar to those found in previous inspections at the licensee's old facility. These included:

--Failure to conduct adequate radiation and contamination surveys

--Failure to evaluate airborne effluents released to unrestricted areas

--Exposure of an employee to radiation in excess of regulatory limits

In transmitting the results of the inspection to AEC Headquarters, the regional compliance office stated that the licensee's radiation survey program had not been adequate for properly evaluating a significant skin contamination and thyroid uptake which an employee had experienced prior to the inspection. The report further stated that, at the request of the inspector, the employee's car had been surveyed and that slight contamination had been detected on and removed from the steering wheel.

As a result of this inspection, the Director, DOC, on May 20, 1970, transmitted to the Director of Regulation a draft of an order to suspend the licensee's operations until AEC was provided with more positive assurance that the licensee's management would be adequate to protect the public health and safety. The draft order stated:

> "It is hereby found that the activities of the licensee *** demonstrate that *** [the licensee] is not qualified to use byproduct material and that there exists a potential hazard to the health and safety of the public, including the licensee's employees ***. Therefore, the public health, interest, and safety require that this proceeding be instituted without prior notice to the licensee ***."

On June 18, 1970, the Director, DOC, was advised by the Office of the Director of Regulation that, because too much time had elapsed since the inspection in April and May, which was the basis for the order, and because the public record did not include the basis for the December 1969 suspension of operations by the licensee, an alternative course of action should be taken

Accordingly, on June 19, 1970, DOC sent a notice of alleged violation to the licensee, setting forth seven items of noncompliance, and stated that these items indicated

serious deficiencies in the licensee's program for the protection of employees and the public In reply to the enforcement letter, the licensee stated that it

--Disagreed with AEC's statement that the noncompliance items were serious.

--Attributed some of the deficiencies to its radiation safety officer

--Outlined corrective actions taken as a result of the inspection, including the replacement of the radiation safety officer

Although an August 1970 inspection showed marked improvement over the inspection in April and May, a January 1971 inspection disclosed numerous items of noncompliance. The AEC inspector stated that:

> "**the deterioriation of their health and safety program, and the recurring items of noncompliance, provides a potential atmosphere for the development of a serious incident. It further reflects management's disregard for health and safety, and compliance with the AEC regulations.
>
> "In view of the licensee's long history of failure to comply with the regulations, it is recommended that strong enforcement action be taken. The action should be such that it will place mandatory requirements on management to accept and implement their responsibility for health and safety, consistent with regulatory requirements."

In a memorandum dated February 12, 1971, to the Director of Regulation, the Director, DOC, stated.

> "You will recall the difficulty *** [the licensee had at its old facility] After their move in early 1970, we made an inspection in April and found several items of noncompliance You will recall that following that inspection we drafted a suspension order but issued a notice instead the following June. The next inspection in August indicated they had taken corrective actions

and things looked pretty good. We have now made another inspection in late January 1971 and we again find several violations, most of which related to inadequate evaluations of possible exposure of employees and releases to the environment At the exit interview *** [the president of the licensee company] appeared rather indifferent and did not make any commitments with respect to corrective action. They have not had an RSO [radiation safety officer] on their staff for several months. The old facility *** has not been decontaminated to levels where it can be released--this was to have been done by April 1970.

"We have exhausted the usual remedies we employ in these cases to get the licensee to operate in compliance. We have made repeated inspections; we have issued formal Part 2 Notices of Violation; we met with management in our *** [regional compliance] office; I have met with management in my office; and you have met with management during the December 1969-January 1970 suspension and so forth

"I feel the only remedy left *** is to deny the application for renewal and if *** [the licensee] wants a hearing (and I am certain they will) let the Hearing Examiner decide as to whether they should be allowed to continue to have a license. The order will be drafted so that it will not require suspension during the course of the hearing should one be requested. The type of violations involved do not, in our opinion, constitute an immediate threat. They are repeat, recurring type violations which pose a potential threat to the health and safety of employees. The problem is the inadequate management control of the radiation safety program for materials they are licensed to possess and use "

On March 10, 1971, the Director, DOC, submitted a draft order to the Director of Regulation denying renewal of the licensee's license Although the order was never issued to the licensee, the licensee was told by the Director of Regulation during a March 30, 1971, meeting that AEC could not make a finding that there was reasonable assurance that operations would be conducted with due regard for radiation safety and in compliance with regulatory requirements. The licensee explained that major changes had been made in the plant management and that a new radiation safety officer had been hired. (The licensee had been without a full-time radiation safety officer between June 1970 and March 1971.)

As a result of this meeting, the Director of Regulation neither denied nor approved the licensee's renewal application but rather told the licensee that frequent, unannounced inspections would be conducted during the ensuing few months and that the results of those inspections would, in part, serve as the basis for determining whether the application for renewal would be approved by AEC The matters discussed during the March 30, 1971, meeting were confirmed by AEC in a letter to the president of the licensee company on April 13, 1971. Inspections conducted in April and June 1971 showed that the licensee had assumed control over its radiation safety program and that it was making considerable improvements therein

AEC's regulations regarding renewal applications state that, if a licensee files a renewal application at least 30 days prior to the expiration date of its existing license, the existing license shall not expire until the application for renewal has been acted on by AEC.

In commenting on the above inspection history, the licensee informed us in April 1972

--that it had begun taking positive and effective steps to permanently remedy the causes of the recurring incidents of noncompliance identified by AEC;

--that it had hired, on a temporary basis, a full-time certified health physicist to make a thorough evaluation of the status of the company's radiation safety program and to implement at once whatever

procedures were necessary to bring the facility "well into the zone of compliance with AEC regulation;" and

--that it regarded as serious any overexposure of personnel, however slight, and that it had no intention of disregarding any weaknesses in the company's health physics program disclosed by periodic AEC inspections.

As of June 1, 1972, AEC had not acted on the licensee's application for license renewal.

Licensee B

AEC first issued licenses to this licensee in 1959. Inspections conducted during the period October 1959 to January 1962 disclosed numerous items of noncompliance, including the failure to conduct adequate radiation surveys, levels of radiation in excess of regulatory limits, and radioactive contamination in unrestricted areas in and around the licensee's plant. For example, radiation levels in excess of regulatory limits were found in a business firm adjacent to the licensee's facility and radioactive contamination was found on public sidewalks around the licensee's plant.

The findings in the last two inspections--conducted in October 1961 and January 1962--were significant enough for the inspector to conclude that the findings constituted a hazard to the health and safety of employees and of the general public. As a result of these inspections, AEC modified the licenses to include stronger controls over the spread of radioactive contamination and the excessive radiation levels. Soon thereafter responsibility for these licenses was transferred, under an agreement with AEC (see p. 5), to the State in which the licensee was located and the licensee did not again operate under an AEC license until 1967.

In 1967 the licensee obtained an AEC license to receive, store, and process up to 288 grams of plutonium 238. An AEC license was required because the amount of plutonium requested exceeded the amount allowed under a State license.

Following the commencement of operations, AEC inspected this priority II licensee on May 24, June 5, July 11, and December 14 and 15, 1967. Each of these inspections disclosed various items of noncompliance with AEC regulations and the conditions of the license. Enforcement actions were taken by the regional compliance office and by AEC Headquarters. In response to these enforcement actions, the licensee represented that the items of noncompliance had been corrected. Subsequent inspections, however, disclosed additional items of noncompliance of the same types. The licensee's operations were suspended in January 1968, and AEC denied the license renewal after a radiation incident which resulted in the internal deposition of plutonium in two employees and contamination of the licensee's facilities.

Following is a chronological account of the results of AEC inspections, enforcement actions, and the radiation incident.

The inspection of May 24, 1967, disclosed three items of noncompliance: (1) the licensee had only one of the two survey-monitoring instruments required under its license, (2) air-sampling surveys were inadequate for establishing compliance with AEC regulations on exposure of employees to concentrations of airborne plutonium, and (3) the licensee had not posted appropriate notices to employees. The evaluation report prepared by the regional compliance office stated:

> "It is the inspectors' opinions that the licensee's operations have not resulted in a threat to the health and safety of the licensee's employees or the general public. The inspectors believe, however, that the licensee's activities should be closely reviewed to insure that concern for production does not outweigh concern for health and safety."

Item 3 was corrected during the inspection. Items 1 and 2 were cited in an informal notice (AEC form 592) issued to the licensee. The licensee's response to the enforcement action stated that appropriate corrective action had been taken.

The inspection of June 5, 1967, also disclosed three items of noncompliance: (1) inadequate air-sampling surveys (uncorrected from last inspection), (2) excessive levels of radiation in unrestricted areas, including a building adjacent to the licensee's facility, and (3) incomplete and improperly maintained records of air-sampling surveys. The regional compliance office expressed concern to AEC Headquarters over the licensee's apparent lack of concern with the hazards associated with this program. The regional compliance office also pointed out that the licensee's records were not adequate for demonstrating that it was operating safely.

The licensee was cited for the three items of noncompliance in a notice of alleged violation dated June 19, 1967.

The notice pointed out the uncorrected item of noncompliance and the fact that the licensee had previously indicated that appropriate corrective action had been taken. The licensee's reply to the notice again represented that full compliance had been achieved.

Two additional items of noncompliance were disclosed in the July 11, 1967, inspection: (1) bioassay samples had not been submitted when available information had indicated that internal deposition of radioactive material might have occurred, nor had the bioassay analyses received been adequately evaluated to estimate possible doses resulting from ingestion of plutonium and (2) one employee had been overexposed. The inspector's evaluation stated that, although the licensee's records were still difficult to analyze for compliance, there had been a great improvement in the records and that it appeared that no immediate health and safety problems existed.

The two items of noncompliance were cited in an AEC form 592 issued on August 1, 1967. The licensee's first and second replies were not prompt and were also considered inadequate. The matter was referred to AEC Headquarters for enforcement action on September 21, 1967. The regional compliance office's transmittal memorandum stated, in part, that:

> "Somehow, this licensee must be impressed with the importance of radiation safety and compliance with AEC requirements. It is our opinion that the licensee has little respect for the AEC, and his actions approach willful disregard of our requests."

DOC issued a notice of alleged violation, dated November 14, 1967, informing the licensee that its responses were inadequate. The notice also informed the licensee that another inspection would be conducted in the near future and that the results of that inspection would determine what further enforcement action, such as issuance of an order for suspension, revocation, or modification of the license, might be taken.

The next inspection, December 14 to 15, 1967, disclosed that the licensee had still not made any attempt to evaluate the results of the bioassay analyses made prior to the last inspection, nor had he evaluated bioassay results received after the last inspection. The inspection also revealed two additional items of noncompliance--possession of too much plutonium and failure to clean glove boxes after each use.

Due to the still uncorrected item of noncompliance, the inspection report was submitted to AEC Headquarters for further action on December 29, 1967. The regional office stated that (1) it found the operation to be considerably improved since the last inspection even though the item of noncompliance had not been corrected, (2) the program still left much to be desired, and (3) it believed that, with the possible exception of the lack of evaluation of bioassay results, there was no serious safety problem at the facility. The regional office concluded that pressure should be kept on the licensee but that there was no justification for drastic action, such as suspension or revocation of the license.

On January 18, 1968, a radiation incident occurred at the licensee's facility. AEC's investigation report of the incident stated that:

--The active portion of a 35-curie plutonium-beryllium neutron source had been cut into when two of the licensee's employees had attempted to remove its outer encapsulation.

--The operation had been performed under inadequate health and safety procedures, in an area having no provision for containing contamination.

--The direct cause of the incident had been the failure of the licensee's employees to comply with the conditions of the license (for example, the plutonium was being used in a location not authorized by the license) and to follow the licensee's own procedures.

--The incident had been brought about by lack of adequate supervision.

According to AEC's investigation report.

--The incident had resulted in extensive contamination to the operating part of the facility, as well as in spotty contamination throughout the office area of the facility; the rooftop of the building; and the public sidewalks in the vicinity of the building.

--The severity of the incident had been increased by management's inadequate evaluation of the hazards during and immediately following the incident.

--Contamination had been picked up on shoes, cars, and clothing of three employees and had been tracked to their homes.

--The final laboratory results of tests on one of the employees who had cut into the capsule showed that he had ingested 10 to 14 times the maximum allowable lung burden of plutonium.

AEC records show that the licensee did not immediately notify the regional office of the incident, contrary to AEC's regulations, and that the regional office became aware of the incident only after an anonymous phone call 4 days after the incident occurred.

Immediately after the incident the licensee agreed with AEC to suspend operations and to not resume them without AEC concurrence. This suspension was confirmed in a telegram to the licensee from AEC on January 24, 1967. Operations were never resumed because, in June 1968, AEC denied the licensee's request to renew its license. The licensee did not appeal AEC's decision.

On March 9, 1972, we sent an excerpt from our draft report to the licensee's parent company in an attempt to obtain its comments on the foregoing information. Since that date we have made several additional attempts to obtain its comments, but, as of July 19, 1972, we had not received them.

Licensee C

This priority II licensee has three active licenses which authorize the use of byproduct materials for laboratory research and instrument calibration. The problems which existed with this licensee were not as significant as those that existed with licensees A and B in that in only one inspection was any violation of AEC regulations identified. This case related to the adequacy of the licensee's radiation safety staff, about which AEC was concerned for 6 years

The adequacy of the licensee's centralized control over the radiation safety program and the number of radiation safety staff had been a continuing concern of the regional compliance office since 1965. Although the regional compliance office had considered the licensee's radiation safety program to be marginal and had discussed this matter with the licensee, the inspections had disclosed no immediate health and safety problems When the June 1970 inspection identified two violations of AEC regulations, however, the case was referred to AEC Headquarters with a recommendation that the enforcement letter also discuss the adequacy of the licensee's radiation safety staffing This was done in a formal enforcement letter in July 1970 Reinspections in March and July 1971 confirmed that the licensee had taken appropriate corrective action regarding the two violations but that it still had not obtained additional radiation safety staff

On August 26, 1971, the licensee advised AEC that an additional health safety staff member had been hired and would report in October 1971 AEC informed the licensee in September 1971 that an inspection to ascertain the effectiveness of the added staff member would be made in the near future. An April 1972 inspection revealed no noncompliance or safety items

Following is a chronological history of the AEC actions to require the licensee to obtain sufficient radiation safety staff

Between December 1965 and April 1968, the regional compliance office conducted four inspections of the licensee's operations and on three occasions expressed concern regarding

the licensee's radiation safety staff No items of noncompliance were found during these inspections In addition, the inspectors expressed the opinion that no health and safety problems existed.

An inspection of the licensee's program in March 1969 revealed no items of noncompliance The inspector's evaluation, however, again expressed concern regarding the apparent limitations on the number of radiation safety personnel. The evaluation concluded that the licensee's program did not present a threat to the health and safety of the licensee's employees or of the general public The conclusion was based on the licensee's statement that it would assign one employee to devote his activities mainly to radiological safety matters

The next inspection, conducted in June 1970, showed that the licensee had not hired additional radiation safety personnel and that the workload of the radiation safety officer had increased to a point where he no longer had sufficient time to devote to needed safety functions, such as audits, surveys, and observations of work areas In addition, the inspector's evaluation report stated that the licensee apparently did not have time to follow up on potential radiation safety problems and that the licensee's safety organization was such that the matter should be more forcefully brought to management's attention by AEC Headquarters The inspection also disclosed two items of noncompliance--failure to follow procedures on personnel monitoring and failure to adequately instruct personnel

The adequacy of the radiation safety program was discussed in a notice of alleged violation issued by DOC to the licensee on July 17, 1970, which also cited the licensee for the two items of noncompliance The licensee's reply stated that corrective action had been taken on the two items of noncompliance and that certain organizational changes had been made that would relieve the radiation safety officer of many of his administrative duties The licensee pointed out, however, that, because of recent restraints on personnel levels, it did not expect rapid improvement in its radiation safety program

The next inspection, conducted in March 1971, disclosed that, although the licensee had not hired any additional radiation safety staff members, it had made significant improvements in its radiation safety program by increasing training for users of radioactive materials and by reducing some of the excessive responsibilities of the radiation safety officer The inspector concluded, however, that more improvement was needed in the area of health physics staffing, to provide better administrative controls over the use of radioactive materials

The inspector noted that the licensee had been trying to recruit an additional health physicist for the preceding few months but that these attempts had been unsuccessful because of restraints on hiring. AEC advised us that, since no violations were disclosed during the March inspection and since corrective action regarding the staffing was being attempted, no enforcement action was taken at that time Instead, it was decided to conduct a reinspection within 3 to 6 months.

During the March 1971 inspection, the licensee advised the AEC inspector of an event which, in our opinion, demonstrated the potential hazards of an inadequate radiation safety program The event, which took place in one of the licensee's laboratories, involved ingestion of radioactive material by a high school student who was participating in the licensee's cooperative program with local high schools whereby students assisted in experiments for which they received school credit The student ingested radioactive material when mouth-pipetting a radioactive solution The licensee's internal procedures prohibited mouth-pipetting, but the student had not been told about the procedures The amount ingested, according to the inspection report, was just below the maximum body burden for minors

The licensee's review of this event concluded that (1) insufficient instructions had been given to this particular student, (2) gloves and protective clothing had not been employed in this situation as required, and (3) the minor had been exposed to a hazardous amount of radioactivity because of his incorrect pipetting techniques As a result of its investigation, the licensee had taken action to prevent a reoccurrence

A reinspection conducted in July 1971 disclosed that the licensee had still not hired additional staff The inspector found that (1) the licensee delayed 3 to 4 weeks in beginning cleanup of radioactive contamination, (2) the radiation safety officer did not have time to visit facilities using radioactive materials on a routine basis and actually spent only one-third to one-half of his time on radiation safety duties, and (3) the radiation safety officer was not familiar with personnel using radioactive materials and with the locations and nature of such use, except in a general way

In transmitting the results of the inspection to AEC Headquarters for enforcement action, the regional compliance office pointed out that, although the inspection did not disclose any threat to health or safety because of the limited scope of the licensee's activities, a hazardous situation would very likely develop if the licensee were to utilize the more hazardous or larger quantities of materials that were authorized in its license For this reason the regional compliance office suggested that, if the licensee did not take corrective action, consideration be given to modifying the license to prohibit the use of the more hazardous and larger quantities of materials.

The licensee's radiation safety staffing problem was again discussed in a safety letter issued by DOC on September 16, 1971 The letter acknowledged the licensee's letter, dated August 26, 1971, which stated that an additional health safety staff member had been hired and would report for work in October 1971 The safety letter further stated that an inspection would be conducted in the near future to ascertain the effectiveness of the proposed increase in the safety staff and that the inspection findings would be considered in determining further actions An April 1972 inspection revealed no noncompliance or safety items

In commenting on an excerpt from our draft report, the licensee told us that the above information was accurate according to its records

PROBLEMS IN ACHIEVING LICENSEE COMPLIANCE

In our opinion the following factors contributed to the difficulties encountered by AEC in achieving full compliance with its regulations by some licensees

--There was a lack of specific criteria as to when enforcement actions stronger than the issuance of notices of alleged violation should have been taken.

--Regulatory top management did not take sufficiently strong and prompt enforcement actions in some cases involving serious or chronic violations.

--Until September 1971 AEC had no effective enforcement option less severe than suspending or revoking a license or requesting the imposition of criminal penalties to bring licensees into compliance with AEC's rules and regulations.

Enforcement criteria

As of December 1971 DOC had not established written policies, standards, or procedures for determining under what conditions enforcement actions stronger than notices of alleged violation should be issued. Between January 1, 1968, and December 23, 1971, AEC Headquarters issued 173 notices of alleged violation and three orders. In 1968 AEC issued two orders--one (an order denying a license renewal application) to a licensee that had experienced a significant radiation incident and one (a cease and desist order) to a licensee that was conducting part of its operation involving radioactive materials in an area of its plant where such activities were not authorized. The third order involved the imposition of a civil penalty in November 1971.

In 1964 AEC's Division of Inspection reviewed the compliance program and issued a report stating that the personnel involved in the enforcement program did not have any written standards or guidance defining and describing the types of enforcement actions which should be used under various circumstances. The report pointed out that written standards and procedures appeared necessary to insure that formal enforcement action was handled on a consistent basis.

DOC officials told us in November 1971 that they recognized the need for written standards and guidance but stated that the urgency of other business and staffing limitations had precluded the assignment of staff for this purpose.

The Director of Regulation also had not provided any written criteria describing those circumstances under which enforcement actions stronger than the issuance of notices of alleged violation should be taken. The Director, DOC, told us that AEC's enforcement practices, which had evolved on a case-by-case basis as a result of precedents and management guidance, were to suspend licensee operations (either by issuance of an order or letter or by written confirmation of a voluntary suspension) when circumstances or conditions indicated that there was an immediate threat to the public health and safety or when a significant incident occurred. In addition, he stated that suspension was not used as a punitive measure.

Apparently this policy resulted in regulatory management's not taking strong enforcement action in such cases as when licensee A continued to experience chronic problems over extended periods.

Civil penalties

In 1967 AEC recognized the need for intermediate action--civil penalties--between the rather severe order and the less severe notice of alleged violation. In January 1969 AEC submitted a proposal to the Congress for legislation authorizing civil penalties; the proposed legislation had already been approved by the Office of Management and Budget and by the Department of Justice.

In hearings before the Joint Committee on Atomic Energy on the proposed authorization, AEC stated that civil penalties would materially assist it in carrying out its program to protect the public health and safety. AEC pointed out that civil penalties, along with existing enforcement actions, would provide a full range of remedial powers and thereby would enable it to act flexibly and effectively against any safety violations.

Legislation authorizing AEC to impose civil penalties, not to exceed $5,000 for each violation and $25,000 for all violations, was enacted in December 1969. In September 1971 AEC completed the administrative and publication procedures necessary to impose civil penalties.

According to criteria published in the Federal Register, AEC intends to impose civil penalties when the violation is a threat, but not an immediate threat, to the public health and safety. Violations that may warrant the imposition of civil penalties include

--repeated violations of license requirements,

--willful violation of the provisions of AEC regulations or conditions of the license, and

--failure to take prompt corrective action on matters which may affect public health and safety and which have previously been brought to the attention of the licensee.

Before AEC can issue an order imposing a civil penalty, it must serve a written notice of violation to the licensee informing it of AEC's intention to impose the civil penalty. The licensee may either pay the penalty proposed by AEC in the notice of violation or it may protest its imposition, in writing. The licensee may either deny the violations, in whole or in part, or may show extenuating circumstances, error in the notice of violation, or other reasons why the penalty should not be imposed and may request remission or mitigation of the penalty. If the licensee fails to file a written protest or to pay the penalty prior to the date specified in the notice of violation, AEC may issue an order imposing the civil penalty. If AEC issues an order imposing a civil penalty, the licensee may request a hearing.

We inquired into the reasons for the delay in completing administrative and publication procedures required before civil penalties could be imposed. We were told that the time involved in obtaining the concurrences and approvals and the time needed to analyze and evaluate the strong comments from the public in response to the Notice of

Proposed Rule Making, which was published in December 1970, had contributed to the delay.

The AEC regulations for imposing civil penalties have been in effect since September 1971. As of December 1971 AEC had not developed any specific policies, standards, or procedures with respect to the imposition of such penalties.

In November 1971 we met with the Director, DOC, and discussed our findings. He stated that·

--In his opinion more effective enforcement measures were needed with respect to chronic violators to insure more strict compliance with AEC requirements.

--DOC was developing criteria for application of the civil penalty rule (which became effective on September 23, 1971). In the meantime the rule was being applied on an ad hoc basis for chronic violation cases as reinspections of them were made.

On December 7, 1971, the Director, DOC, sent a memorandum to all regional compliance directors in which he stated that

> "*** it is imperative that we take prompt action to make our enforcement program more effective. To get started I want to flush up, on a prompt and timely basis, all cases which may warrant the imposition of our Civil Penalty and suspension sanctions even though we have not developed criteria and procedures."

RECOMMENDATION

We recommend that AEC, to improve the effectiveness of its enforcement program, develop and apply criteria for the circumstances under which licenses will be suspended or revoked and under which civil penalties will be assessed. The criteria should provide for enforcement actions sufficiently severe to provide licensees with incentives to comply with AEC's regulations.

AEC concurred in our recommendation and stated that

"The development of such criteria has already been initiated. As the draft report states, however, the enforcement actions available range from written notices of specific violations or safety problems to license suspension or revocation, with civil penalties falling somewhere in between. Judgment must be exercised in determining the specific types of enforcement to be taken in a given case. Many factors must be considered in making such judgments. We believe that the criteria being developed will provide guidance for making such judgments and for determining the amounts of civil penalties, they should result in a reasonable degree of uniformity in the enforcement process, and they should provide licensees with a greater incentive to comply with AEC's regulations."

CHAPTER 3

PROBLEMS IN THE USE AND DISTRIBUTION OF RADIOACTIVE MATERIAL IN THE PRACTICE OF MEDICINE

Approximately 2,800, or about 34 percent, of AEC's 8,200 materials licenses relate to the use of radioactive material in the practice of medicine. AEC informed us that the annual level of administrations of radioactive material in the United States had reached about 8 million. Under AEC's interpretation of current regulations, medical licensees are not required to report the accidental overexposures of patients to radiation during intentional exposures for medical diagnoses or therapy when such overexposures are attributed exclusively to the actions of physicians or to those acting under their orders. Also AEC inspectors are not required to determine, during routine inspections, whether such accidental overexposures have occurred.

Therefore there are no statistics on the extent to which medical patients have been overexposed to radiation through wrong doses or overdoses (commonly referred to by AEC as misadministrations). From February 1961 through April 1972, however, 20 misadministrations[1] had been brought to AEC's attention.

In our opinion the opportunity exists for AEC to improve its regulations relating to the use and distribution of radioactive materials in the practice of medicine. We recognize, however, that misadministrations of radioactive materials involve human errors and that, even with improved regulations, the possibility of such errors will not be eliminated.

TRAINING AND SUPERVISION OF PERSONNEL ASSISTING PHYSICIANS

To obtain a license to use radioactive material for diagnosis or therapeutic treatment of patients, a medical

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[1]These 20 misadministrations resulted from 12 different occurrences--two occurrences resulted in multiple misadministrations.

institution must furnish AEC with evidence that the physicians named as users in the license application have had substantial experience in the proposed use, handling, and administration of these materials.

Most of AEC's licenses authorizing the use of radiopharmaceuticals in hospitals and clinics for the treatment of patients provide for the use of the material "by, or under the supervision of," the medical doctors identified in the licenses. Other AEC licenses which authorize the use of radioactive material in the diagnoses or treatment of patients by private practitioners provide for the use of such material by specifically named physicians. In the former instances, the provision that radioactive materials may be used under the supervision of the physicians named on the licenses is to allow the physicians to train other physicians to practice nuclear medicine.

Nuclear medicine technicians are employed in hospitals and clinics and by physicians in private practice. They handle the radiopharmaceuticals used for the diagnoses or treatment of patients. AEC considers that the authorized physician users are responsible for insuring that technicians assisting them are adequately trained to perform their assigned tasks. Therefore AEC's licenses authorizing the use of radioactive material in the treatment of patients do not provide minimum qualification standards for technicians who will handle radioactive material under the supervision of the physician named in the license.

AEC has not specifically defined in its medical licenses the activities that may be delegated by physicians to technicians and those that may not. Further AEC has not specifically required physicians to determine whether technicians have been properly trained to perform their assigned duties or to maintain records showing the bases for such determinations.

One AEC investigator, in transmitting his investigation report of the administration of a significant overdose of a radioactive material to a patient in August 1968 (see discussion concerning licensee K on p. 50), commented on the practices followed in hospitals which had licenses authorizing the use of radioactive materials and on the need for AEC to

have assurance that technicians are qualified. He stated, in part, that:

> "It must also be realized that authorized users as a practical matter do not and probably cannot exercise any real personal supervision over many of the activities being carried on in a radioisotope laboratory with an active program. ***
>
> "Operations within the institution's laboratory, therefore, are in many cases carried on under the supervision of a technician on whom the physician(s) comes to place a high degree of reliance. *** As long as the technician was present in the laboratory, this was a workable arrangement. While we agree this is a practical and reasonable mode of operation, we feel it should be realized by the Commission that this is the normal condition. This being true, it appears the Commission has a responsibility for obtaining assurance from the hospital or clinic that these individuals are competent and that operating procedures are promulgated for them to observe ***."

The same investigator, after completing an investigation of alleged unsafe radiation practices at another hospital in April 1969, which the investigator found to be largely unsubstantiated, stated that:

> "The hazard at *** [the hospital], in our opinion, as in several other medical programs, lies not so much in the potential for the overexposure of the hospital personnel but in the possible misadministration of isotopes to patients due to a lack of supervision and control of the technicians."

The investigator concluded his evaluation by reiterating his belief that AEC should obtain assurance that technicians are qualified.

Following are two licensee case summaries, one of which related to a misadministration of radioactive material which involved the actions of a technician. The other case involved the conduct of a medical diagnostic program by a person who was not a physician.

Licensee K

This priority IV medical licensee received a by-product materials license in 1963 that authorized the use of such materials by, or under the supervision of, certain named physicians. AEC made its initial inspection of this licensee in March 1967. The inspection report did not contain any specific comments by the inspectors relating to (1) the adequacy of the supervision provided or (2) the training or qualifications of the persons working with the radioactive materials. The report concluded that the licensee had an adequate health physics program.

In August 1968 the licensee reported to AEC that a patient had been inadvertently administered 200 millicuries, instead of the intended 200 microcuries, of radioactive material for diagnostic purposes. This dosage was 1,000 times greater than intended In investigating the incident the regional compliance office concluded that the physician named in the institution's license had not properly supervised personnel and had permitted inadequately trained personnel to work with radioactive materials in the treatment of the patient.

The investigation revealed that a practical nurse, in the absence of the chief technician, had ordered the radioactive material from the supplier and that a student X-ray technician, who was unable to verify the quantity of material received because she could not convert from millicuries to microcuries, had prepared the material for administration to the patient. Subsequently the physician--a radiologist--assisted by a student aide, prepared to administer the dose; however, upon noting that the syringe seemed larger than usual, he requested that the student aide verify the dosage. The student aide was informed by the student X-ray technician that the entire dose was to be administered; the student aide so informed the physician, and the patient was injected.

The specific comments made by the investigator in transmitting his investigation report to AEC Headquarters on September 4, 1968, are summarized below.

--Several events, in themselves not extraordinary but only departures from the norm, combined to cause the incident.

--The primary responsibility for the administration of the overdose was with the doctor performing the injection.

--The most immediate cause of the incident was the student X-ray technician's "almost impervious ignorance concerning the amounts of material involved." She lacked an understanding of the relationship between millicurie and microcurie.

--The ultimate responsibility rested with the hospital, because the hospital had not developed procedures adequate for insuring that the nuclear laboratory would be staffed with personnel competent to perform or supervise the work in the absence of the chief technician. The hospital allowed circumstances to arise wherein an inadequately trained or experienced person could perform duties without supervision, which resulted in an error having grave, and perhaps fatal, consequences.

The investigator concluded, because of the experience gained in the case, that.

> "*** consideration should be given to one aspect of licensing medical institutions. Hospitals and clinics are not required to include in their license applications information relating to the technical training and qualification of personnel working with isotopes in their laboratories other than the physicians. We realized each license stipulates that byproduct material shall be used by or under the supervision of named doctors. Over the years, however, the phrase 'under the supervision of,' has received the broadest possible interpretation. A medical licensee is rarely, if ever, cited for noncompliance with that license condition <u>even under such circumstances as are described in this case</u>." (Underscoring supplied.)

Subsequent to the incident the patient was transferred to another hospital where she died in October 1968. AEC hired a medical consultant to review the medical facts of

the case. After an autopsy had been performed, the consultant, in his November 12, 1968, report to AEC, stated that the death had been classified as being due to radiation following the inadvertent administration of an overdose

In its report to AEC on the incident, the licensee pointed out a number of extensive procedural changes which had been made to prevent the recurrence of such an incident. The licensee, however, was not cited for any items of noncompliance as a result of the incident.

AEC reinspected the licensee in April 1972 and found six items of noncompliance. Enforcement action was pending at the time of our review. AEC subsequently told us that no enforcement action had been taken as a result of the investigation because there had been no specific violations of AEC requirements and that further, the licensee had taken corrective action to minimize recurrence.

In commenting on an excerpt from our draft report, the licensee told us that it had no objection to our discussing this case in our report.

Licensee L

This priority IV medical licensee received a byproduct materials license in 1957 which authorized the use of such materials by, or under the supervision of, certain named physicians. Also the license authorized a person who was not a medical doctor to use the material for experimental purposes, but not on human beings. AEC initially inspected the licensee in 1963 and reinspected it in July 1966. The inspectors, however, did not contact the physicians named in the license during their inspections.

In October 1970 AEC was informed that this licensee's nuclear medicine program was not being supervised by a physician. Therefore the AEC regional office reinspected the licensee in January 1971. The inspection report stated that diagnostic doses of radioactive materials had been administered to patients without medical supervision, that the results of diagnostic tests had been interpreted by a person who was not a physician, and that numerous items of noncompliance with AEC regulations had been found regarding the hospital's control over its radioactive materials program.

The inspector, in transmitting the results of the January 1971 inspection to AEC Headquarters, stated that.

> "Administratively, the most significant item concerned the routine human use of byproduct material (diagnostic radiopharmaceuticals) by *** [a nonmedical doctor] and little or no involvement of the authorized M.D.'s in the diagnostic byproduct material program."

In April 1971 AEC issued a notice of alleged violation citing the licensee for 13 items of noncompliance and requested comments concerning the corrective steps taken or planned. In responding to this notice, the licensee disagreed with the finding of the AEC inspector concerning the supervision of the hospital's diagnostic radioactive materials program. The licensee stated that until January 1971 the diagnostic program had been carried out under the supervision of one of the physicians named in the license.

AEC did not consider the hospital's reply to be completely adequate and requested notification of additional corrective measures planned or taken with respect to some of the noncompliance items. As part of its second reply in June 1971, the licensee advised AEC that an authorized physician who worked at the hospital on a part-time basis was temporarily supervising the diagnostic uses of materials and that it was still in the process of looking for a full-time, qualified physician to take over active direction of the radioisotopes department. AEC acknowledged this reply on July 6, 1971, and advised the licensee that the corrective actions reported would be examined during the next inspection.

When a followup inspection was made in September 1971, AEC determined that a medical doctor had assumed control and was properly supervising the radioisotope laboratory and confirmed that the licensee had taken the other corrective actions it had reported to AEC earlier.

In commenting on an excerpt from our draft report, the licensee reiterated its disagreement with AEC's inspection finding that radiopharmaceuticals were being used without proper supervision.

SUPPLIERS OF RADIOACTIVE MATERIALS

Title 10, part 30, of the Code of Federal Regulations states that, except for certain exemptions, no person shall manufacture, produce, transfer, receive, acquire, own, possess, use, import, or export byproduct material, except as authorized in a specific or general license issued pursuant to the regulations.

AEC has placed no specific requirements on licensed suppliers of radioactive materials as to the means by which they are to ascertain that recipients are authorized to receive the types and quantities of radioactive materials they order. The manner in which the supplier assures itself that a transfer is made only to a licensed recipient is left to the supplier. Some suppliers require the proposed recipients to furnish their AEC license numbers (sometimes during telephone conversations when the orders are placed) without checking to ascertain whether the radioactive materials being

ordered are, in fact, authorized under the recipients' licenses.

DOC officials told us that AEC did not routinely cite a supplier of radioactive materials for making an unauthorized transfer unless the circumstances established that the unauthorized transfer was made without any attempt by the supplier to determine the recipient's authorization. They said that instead, the recipient of the materials generally is cited for the unauthorized possession.

Inspections performed between July 1, 1968, and June 30, 1971, showed that the three regional compliance offices where we performed our review had issued 140 citations to all types of AEC licensees for possessing unauthorized types and amounts of radioactive materials or for possessing radioactive materials without licenses for the materials. Also there were 24 citations for unauthorized transfers of radioactive materials.

Medical licensees receive radioactive materials from licensed pharmaceutical companies. One pharmaceutical company, after being cited by AEC for shipping certain radioactive materials to two hospitals which were not authorized to possess the materials (which AEC discovered during inspections at the hospitals), stated that:

> "We think the two cases cited are excellent examples of the plight the radio-pharmaceutical manufacturer has always been in. *** (the supplier) has been as diligent as it could be in trying to get license information. The cost in manpower exerted has been more than we care to estimate, and the results are by no means gratifying.
>
> "The Commission has no mechanisms by which the manufacturer can get the desired information. Ideally, the Commission would send a copy of each license, renewal or amendment to all radiopharmaceutical manufacturers at the time action is taken; or a complete summary of actions taken arranged in usable form so that every order could be compared with the license record, with assurance that the record is fully up-to-date.

"Lacking data of this kind, *** (the supplier) has continually requested users to send copies of licenses or at least data on materials authorized and on expiration dates. Our diligence has been rewarded with a fair amount of resentment, ranging from reluctance to give us the information to flat refusal. You can imagine the problems created. It has often been pointed out to us that we have no legal basis for asking for a copy of a license. The implication is made that it is the Commission that should keep us informed."

Following are examples of misadministrations of radioactive materials that occurred under medical licenses. These cases involved types or quantities of material which the licensees were not authorized to possess.

Licensee M

In January 1966 this priority IV medical licensee received 150 millicuries of radioactive material and subsequently injected a patient with 120 millicuries, instead of the intended dose of 120 microcuries, of the material.

This incident was not reported to AEC by the licensee. AEC did not become aware of the incident until August 1968 when it was investigating licensee K. (See p. 50.)

AEC's investigation of the incident, which began in August 1968, revealed that, at the time the order for the material had been placed with the pharmaceutical supplier, the licensee was authorized to possess only 3 millicuries of the material, or one-fiftieth of the quantity he received. The investigation report also stated that the assistant distribution manager of the supplier had provided the following information concerning the supplier's procedures:

> "*** a customer would telephone in his order for isotopes. Inquiry would be made by the sales clerk whether the individual was licensed by the AEC and a note was made of the license number which is incorporated in all invoices. ***[assistant distribution manager] did not know whether any effort was made by the sales people to determine whether the material ordered was authorized under the license or whether the activity ordered was within the license's limits. ***he was not aware of any requirement by *** [the supplier] that the order be confirmed in writing."

The investigator's report to AEC Headquarters in December 1968 stated that the patient who received the misadministration died in October 1966, or about 9 months after receiving the overdose. The report pointed out that a doctor who had treated the patient after the overdose believed the patient had fully recovered from it. Because of the time which had elapsed since the incident had occurred and because of the corrective measures taken by the licensee, AEC did not cite the licensee for possessing too much radioactive material.

In commenting on an excerpt from our draft report, the licensee advised us

--that, at his own expense, he had admitted the patient to the hospital and that he had told the hospital about the misadministration;

--that he had not reported the misadministration to AEC because he had been told that an AEC medical consultant had seen the patient in the hospital and that he therefore assumed that AEC was fully aware of the incident;[1]

--that he could not explain why the misadministration had occurred in spite of the procedures he had established to insure that proper doses were ordered and administered;

--that, at the time of the investigation, he consulted with AEC about further protective measures for avoiding the recurrence of such an error.

In transmitting his report of this incident to AEC Headquarters, the AEC investigator recommended that the supplier's policies and procedures for processing orders for radioactive materials be reviewed. No action was taken in response to this recommendation, however, until December 1969.

During 1969 AEC became aware of five additional unauthorized shipments of radioactive materials by this same supplier. Four of these shipments were brought to AEC's attention by officials of States which had assumed regulatory responsibilities for materials licensees within the States and in which medical licensees had received unauthorized types or

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[1]AEC advised us that, although a doctor employed by one of its laboratories had been contacted by the hospital, the doctor was not an AEC medical consultant and had not seen the patient.

quantities of radioactive materials. One State official, in advising AEC of three such unauthorized shipments, stated that:

> "We were under the impression that each radiopharmaceutical supplier had a check system for assuring himself of the licensed status of any customer."

The State official asked AEC to clarify the procedure it required a pharmaceutical supplier to follow for assuring that a potential recipient is authorized to receive the type and quantity of materials ordered.

We were told that AEC had advised the State official that it did require suppliers to ascertain that recipients were authorized to receive the amounts and types of radioactive materials ordered. Although AEC told the State official that suppliers were not required to follow any specific procedures to make these determinations, examples of acceptable methods were provided.

During a routine reinspection of the supplier conducted in December 1969 and January 1970, AEC inspectors discussed these unauthorized shipments with the supplier's sales manager. The sales manager stated that he planned to discuss the problem of unauthorized shipments during a training program for the supplier's staff in January 1970; however, AEC's inspection report did not indicate that the inspection had included tests or checks of the supplier's procedures.

Licensee N

In September 1970 a technician employed by this priority IV medical licensee erroneously ordered a radioactive material from a supplier in a chemical form which the licensee was not authorized to possess. Subsequently a patient was intravenously injected with the material. The licensee reported the incident to AEC immediately upon discovery of the misadministration, which was 2 days after the injection when the licensee was making a routine recheck of labels. AEC records indicate that the patient had not suffered adverse effects as a result of the misadministration.

AEC inspected the licensee in November 1970. The inspection confirmed the cause of the incident as being an error by the isotope technician and the physician who prescribed and injected the material. AEC's inspection report stated that the physician who had administered the wrong material had always been afraid an error like this might happen, and, for this reason, had not requested authorization to possess a number of different radioactive materials.

AEC sent the licensee a form 592 citing the licensee for the possession and use of a radioactive material not authorized under its license and determined that the licensee had taken appropriate corrective actions to prevent the recurrence of such an incident. AEC's compliance files did not indicate that the inspector had discussed the unauthorized transfer of the material with the supplier. AEC advised us that it had taken no enforcement action against the supplier for the shipment since the error primarily had been the hospital's in ordering the wrong chemical form of the material. The hospital was authorized to possess and use the material in another chemical form.

In commenting on our draft report, the licensee told us that it believed that the supplier of the unauthorized material had a copy of its license on file. We contacted an official of the supplier who told us that a copy of this license was on file at the time the unauthorized shipment was made. He further advised us that he could not recall what measures had been taken to determine whether the licensee was authorized to receive the material.

CONCLUSIONS

In view of the circumstances surrounding these cases, we believe that AEC should strengthen its regulatory requirements to provide increased control over the handling of radioactive materials by medical licensees and pharmaceutical suppliers. We recognize, however, that the cases discussed in this chapter involve human errors and that, even if maximum training and supervision had been given to technicians handling radioactive materials and if there had been specific requirements for suppliers to verify that customers were authorized recipients, such errors could still have happened.

Specifically we believe that AEC should, in its medical licenses or regulations, define the activities that may be delegated by physicians to technicians and those that may not. In addition, AEC should require that physicians determine whether technicians have been properly trained to perform their assigned duties and keep records showing the bases for such determinations. In our opinion such provisions would do two things. they would place increased requirements on medical licensees to insure that only qualified persons work with radioactive materials and they would provide inspectors with some criteria for evaluating the adequacy of the medical licensees' compliance with the requirements.

With respect to the misshipments of radioactive materials by pharmaceutical firms, AEC should establish a specific requirement that suppliers verify that transferees are authorized to receive the quantity or type of material being shipped and should provide guidance on acceptable methods of verification.

Further AEC should require medical licensees to report all known misadministrations of radioactive materials so that AEC can determine the causes and whether adequate corrective actions were taken by the licensees. This information could then be assembled and, if appropriate, disseminated to all medical licensees so that they would be aware of the hazards associated with certain operating practices and could take steps to improve their controls over the handling of radioactive materials, if necessary. In

addition, AEC could evaluate this information and, if appropriate, could incorporate additional requirements in its medical licenses or regulations.

RECOMMENDATIONS

We recommend that AEC, to strengthen its controls over the shipment and use of radioactive materials:

--Define in its medical licenses or regulations the activities that may be delegated by physicians and those that may not.

--Require that physicians determine whether technicians have been properly trained to perform their duties and keep records showing the bases for such determinations.

--Establish a specific requirement that suppliers verify that transferees are authorized to receive the quantity or type of material being shipped and provide guidance as to acceptable methods of verification.

--Require medical licensees to report to AEC all known misadministrations of radioactive materials to patients so that AEC can determine the causes and whether adequate corrective actions were taken by the licensee.

AEC made the following comments with respect to our recommendations.

--Work was underway to define in its medical licenses or regulations the activities that could be conducted by technicians.

--Licensees were responsible, under existing regulatory requirements, for insuring that all activities authorized by a license were conducted in accordance with regulations and license conditions. AEC planned to incorporate into medical licenses or the regulations a specific requirement that user physicians identified on the license determine whether technicians have

been properly trained to perform their duties and keep records showing the bases for such determinations. In addition, AEC was preparing a "Manual of Good Radiopharmaceutical Practice" as an aid for technicians working in nuclear medicine laboratories.

--AEC regulations prohibited shipment of radioactive materials to persons who were not licensed or otherwise authorized to receive them. AEC planned (1) to amend its regulations to state specifically that licensees, including suppliers, must verify that persons to whom they ship radioactive materials are authorized to receive them and (2) to provide guidance on acceptable types of verification.

With respect to our recommendation that AEC require medical licensees to report to it all known misadministrations of radioactive materials to patients, AEC stated that this recommendation was under study and would be reviewed by its Advisory Committee on the Medical Uses of Isotopes. AEC explained that it was necessary to study accepted medical ethics of the physician-patient relationship and the possible consequences of a Government agency's interjecting itself into this relationship.

CHAPTER 4

NEED FOR INCREASED INSPECTION COVERAGE OF MATERIALS LICENSES

During the past few years, AEC has reduced the required number of inspections for materials licenses to the point where periodic reinspections are required for about 620, or less than 10 percent, of the 8,200 licenses for which it has regulatory responsibility. DOC officials advised us that the reduction in inspection frequency was intended to be temporary and was made because of staff shortages and higher priority work. AEC believes that the types of inspections eliminated should be made and intends to make as many as possible within available-manpower limitations.

Our review of the documentation prepared by inspectors at the three regional offices included in our review showed that:

--DOC had not provided its inspectors with specific guidance on the extent to which inspection results which did not relate to planned enforcement actions should be documented. About 63 percent of the inspections performed during fiscal year 1971 revealed no items of noncompliance.

--Inspectors spent a substantial part of their time documenting the results of inspections, including those inspections revealing no items of noncompliance.

--There were inconsistencies in the manner in which the various regional compliance offices documented inspection results.

We believe that AEC should explore the feasibility of developing streamlined documentation techniques which might reduce the time spent documenting inspection results and thus increase the time available for performing additional inspections.

INSPECTION COVERAGE

As previously discussed (see p. 9), AEC's inspection practices have been developed on the basic premise that the frequency of inspection and the utilization of available manpower should be related as nearly as possible to the potential hazards associated with each licensed operation. Priority I licenses encompass the greatest potential hazards, priority V licenses the lowest.

Prior to August 1969, AEC required periodic reinspections of priority III and IV licensees and annual inspections of at least 5 percent of priority V licenses. In a memorandum to the regional offices in August 1969, the Director, DOC, established revised inspection requirements which were to be temporary.

These revised inspection requirements eliminated all inspections of priority V licensees and required reinspections of priority IV licensees only when the initial inspection, a licensee report, or other information indicated the presence of a potential or actual health or safety problem.

However, regional compliance office officials told us that, to cover as many licensees as practicable, priority IV and V licensees had been reinspected for other reasons, such as (1) while the inspector was at the licensee's facility inspecting a priority I or II license, he also inspected the priority IV or V license or (2) the inspector was in the same geographical area on an inspection of a priority I or II license and easily made both inspections on the same assignment.

AEC officials told us that the changes in inspection requirements in August 1969 were made because of staff shortages and were based, in part, on a study prepared in January 1969 regarding the basis for the materials license priority system. They stated that the reactor inspection workload had increased significantly. Because of the greater potential risks associated with reactor operations and because of a numerically insufficient reactor inspection staff, materials inspectors had been transferred to, and new inspectors had been assigned to, the reactor inspection staff.

In September 1971, AEC recognized that, due to continued staff shortages, it could no longer meet the requirements established in August 1969 and it eliminated the requirement for periodic reinspections of priority III licenses. The instruction stated that reinspections of priority III licenses were to be performed on a manpower-availability basis and only after other required inspections had been performed.

About 35 percent of DOC's reinspections of priority III and IV materials licenses revealed items of noncompliance. For example, during fiscal year 1971 the three regional compliance offices where we performed our review conducted 337 reinspections of priority III and IV licenses, excluding assist inspections for other regions. In 119, or 35 percent, of the 337 inspections, the licensees were cited for 235 violations of AEC regulations or license conditions. Informal enforcement action was taken on about 91 percent of these inspections. About 75 percent of the 235 violations fell into the following 10 categories.

Violation of specific license conditions	59
Failure to perform appropriate radiation surveys	25
Lack of, or inadequate records of, surveys and disposals of radioactive materials	22
Insufficient or improper posting of caution signs and labels	17
Unauthorized use of radioactive materials	12
Lack of, or inadequate records of, receipts and transfers of radioactive materials	11
Possession of unauthorized forms and amounts of radioactive materials	8
Lack of, or insufficient posting of, notices to employees	7
Unauthorized places of use	7
Unauthorized users	4
Total	172

We visited officials of two States which had assumed the regulatory responsibility for certain materials licenses, to obtain their views on the need to periodically inspect all licensees. Officials of one State told us that they believed that licensees should be inspected periodically

because (1) licensees' programs tended to deteriorate administratively if inspections were not performed, (2) licensees were reminded by means of inspections that there is a regulatory program which they must follow, and (3) licensees were informed during inspections of potentially hazardous operating practices. Both States inspected licensees which were equivalent to those classified by AEC as priority V licensees. The results of 98 State inspections of equivalent priority V licensees from March 1968 to August 1971 revealed a significant number of noncompliance items.

Limited staff resources have also had an impact on the DOC regional compliance offices' abilities to perform initial inspections promptly. AEC generally does not conduct prelicensing inspections except for complex facilities. Initial inspections provide the first opportunity for AEC inspectors both to confirm that the licensees' programs, facilities, and equipment are as described in their license applications and to orient the licensees' personnel concerning the regulatory program.

In the three regional offices where we performed our review, 264 materials licenses were issued during fiscal year 1970 that were required to be initially inspected according to DOC's requirements. (See p. 9.) As of August 1971, however, only 185 of these inspections had been performed, of which about 50 percent were overdue at the time they were performed. Approximately 34 percent of the initial inspections resulted in the identification of one or more items of noncompliance. The types of noncompliance items found were similar to those found during reinspections of priority III and IV licensees as shown on page 66.

UTILIZATION OF MATERIALS INSPECTORS

During fiscal year 1971 the three DOC regional offices included in our review performed a total of 798 inspections, excluding assist inspections for other regional offices. DOC inspectors had spent 1,690 man-days, or about 55 percent of the total 3,000 man-days of available inspection time,[1] documenting the results of their inspections.

AEC's records show that most of the documentation time had been spent preparing field notes. The purposes of the field notes were to (1) provide a basis for enforcement actions and (2) enable supervisory personnel to assess the adequacy of the inspection.

Instructions provided to the regional compliance offices relating to the content of field notes, which were issued by AEC Headquarters in April 1971, state that

> "There is no limitation on the type of information that may be included in field notes. ***
>
> "There is no prescribed format for field notes ***."

Generally the field notes contained discussions of the licensee's organization, facilities, equipment, surveys performed, leak-testing procedures, waste disposal practices, and many other subjects having a bearing on the adequacy of the licensee's radiation protection practices.

DOC had not provided its inspectors with specific guidance on the extent to which inspection results which did not relate to planned enforcement actions should be documented. About 63 percent of the inspections performed during fiscal year 1971 revealed no items of noncompliance.

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[1] "Available inspection time" is defined as the total time spent preparing for the inspection, performing the inspection, and documenting the results of the inspection.

For a brief time in 1968, DOC did instruct its inspectors to limit documentation for inspections of priority III and IV licenses to substantive matters. This instruction came when AEC recognized that its inspection backlog had risen to an unacceptable level: there were 1,111 overdue inspections.

To reduce the backlog to an acceptable level, AEC instituted a crash program, for about a 3-month period, which called for a number of changes in inspection practices. One of these changes was the development of a special, limited-inspection report format (an optional format for field notes) to be used when inspecting priority III and IV licensees. The instructions accompanying the report format stated that reports which were to result in enforcement actions must contain sufficient detail to support the particular citation and that nonaction case reports (clear inspections) should be brief and be limited to substantive information.

AEC's study of the results of the crash program showed that about 50 percent of the inspection backlog had been eliminated and that DOC inspectors had increased their productivity. The study stated that two of the significant factors accounting for the increase in productivity were that the inspectors had spent more time conducting inspections and less time documenting inspection results. Comments received from the five regional office directors showed that four out of five DOC regional directors believed that the greatest time savings during the crash program had resulted from reduced documentation.

In transmitting the results of its study of the crash program to the regional compliance offices in October 1968, AEC Headquarters stated that the reporting ground rules used during the crash program should continue to be used through December 1968 for priority III through V licensee inspections. AEC further told the regional compliance offices that it planned to determine what actions could be taken for improving the reporting requirements for materials licensee inspections and to revise its instructions accordingly by December 31, 1968.

Regional compliance office officials told us that written instructions had not been provided by AEC Headquarters after October 1968, and that, as a result, the current documentation techniques employed by the regional offices had evolved.

Our review of the documentation techniques employed by these regional compliance offices showed that there were inconsistencies in the manner in which the various regional offices documented inspection results. For example.

Region I generally used the special limited-inspection report format developed during the crash program, or some variation thereof, for inspections of priority I through V materials licensees when inspections disclosed no items of noncompliance or when the inspections resulted in regional enforcement action.

Region III used what the regional office referred to as the long form report format for all inspections of priority I and II materials licensees even if such inspections did not reveal any noncompliance items or resulted only in regional enforcement action; however, the special limited-inspection report format was generally used for inspections of materials licensees in priority III through V.

Region V developed a form called Inspectors Guide to record notes during the inspection of all materials licensees except radiography licensees. After returning to the regional office, the inspectors prepared formal field notes. (The region had developed a different format for recording notes during inspections of radiography licensees.)

CONCLUSIONS

We believe that AEC should explore the feasibility of developing streamlined documentation techniques, including formats for field notes, which might reduce the time spent documenting inspection results and thus increase the time available for performing additional inspections. We recognize, however, that careful balancing and judgment is required to determine the extent of documentation of inspection

results. There should be sufficient documentation to enable AEC management to assess the adequacy of inspections and to support the items of noncompliance.

RECOMMENDATION

We recommend that AEC explore the feasibility of developing streamlined documentation techniques, including formats for field notes, which might reduce the time spent documenting inspection results and thus increase the time available for performing additional inspections.

AEC concurred in our recommendation and stated that it was reexamining its documentation techniques to eliminate any unnecessary documentation.

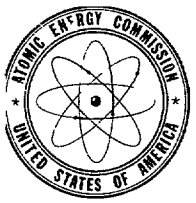
CHAPTER 5

SCOPE OF REVIEW

We conducted our review at AEC's DOC headquarters office in Bethesda, Md., and at three AEC regional compliance offices located in Newark, N.J., Glen Ellyn, Ill., and Berkeley, Calif.

We reviewed pertinent legislation, regulations, policies, procedures, and practices relative to AEC's inspection and enforcement activities. We examined AEC inspection reports and correspondence concerning the violations of AEC regulations and reviewed AEC's files for selected licensees in detail.

As part of our review, we obtained (1) the views of various AEC officials knowledgeable of and responsible for conducting inspections and taking enforcement actions, (2) information from officials of two States which had entered into agreements with AEC whereby they assumed regulatory responsibilities for certain materials licensees, and (3) comments from licensees whose activities are discussed in this report.



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON D C 20545

MAY 23 1972

Honorable Elmer B. Staats
Comptroller General of the United States
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Staats

This is to acknowledge receipt of the draft report to the Congress of the United States on "Problems Associated with the Regulation of Users of Radioactive Materials," by the General Accounting Office (GAO). In accordance with your staff's request, we are setting forth our comments concerning the recommendations contained in the draft report for improving the effectiveness of AEC's regulatory program in certain areas with respect to materials licensees.

We are in general agreement with the recommendations set forth in the draft report. Our comments concerning each recommendation are contained in the enclosure to this letter. As described therein, one of the recommendations will require further study.

The primary objective of AEC's regulatory program is to provide reasonable assurance that licensees use radioactive materials subject to AEC jurisdiction in a safe manner and in compliance with AEC regulatory requirements developed to achieve that objective. It has been our experience that most licensees use licensed radioactive materials substantially in compliance with AEC's requirements. About two-thirds of AEC's inspections disclose no violations, and in most of the cases where noncompliance is identified, appropriate corrective action is taken by licensees in response to written notices. There have been a few licensees, however, whose inspection histories have shown that written notices of violation have not been entirely effective in causing them to achieve and maintain a continuing program of full compliance with all regulatory requirements.

When noncompliance is found (in the absence of an immediate threat to the health or safety of the public or employees which, of course, would result in suspension action) we have attempted to obtain corrective action rather than revoke a licensee's authority to use radioactive materials, which in many cases could deprive the public of an essential service. We agree, however, that certain licensees must be provided greater incentive to comply with regulatory requirements than in the past. We intend to accomplish this through a more rigorous enforcement

program utilizing all available enforcement sanctions to the extent necessary to achieve this objective We believe that the recently acquired authority to impose civil monetary penalties, which we have already begun to implement, will provide a necessary incentive.

The draft report makes several references to situations involving radiation levels or personnel radiation exposures which were in excess of the regulatory limits. Regulatory limits for occupational radiation exposures have been deliberately set at levels which are much lower than levels which are likely to cause observable biological damage. Where individual members of the public are concerned, the regulatory limits are only one-tenth of the level set for radiation workers.

For these reasons, exposures in excess of regulatory limits discussed in the draft report should not be viewed as necessarily affecting the health of the exposed individual. We shall, however, increase our efforts to require that radiation exposures be kept as far below the limits as practicable.

With regard to the use of radioisotopes in medicine, there are now an estimated eight million administrations of radiopharmaceuticals performed annually for medical diagnosis or therapy. There have been 12 known cases of misadministrations of radiopharmaceuticals, involving 20 individuals, during the eleven-year period discussed in the draft report. While there have been no studies to our knowledge that would establish the precise number of actual misadministrations, we believe because of close contacts with the medical community, that the number of misadministrations has not been substantial. We are aware of studies that have been made of misadministrations of non-radiological drugs and our experience with radiopharmaceuticals, by comparison, appears to be extremely favorable. We agree, however, that certain actions as recommended in the draft report could be taken which might reduce the probability of misadministrations even further. Misadministration cases such as those discussed in the draft report are attributable in large part to human error and it should be recognized that no reasonable amount of regulation can preclude such errors.

I wish to express our appreciation for the opportunity to review this document and to submit the foregoing comments.

Sincerely,

L. Manning Muntzing
Director of Regulation

Enclosure
Recommendations and Comments

ENCLOSURE

RECOMMENDATION

Develop and apply criteria describing the circumstances under which licenses will be suspended or revoked and civil penalties will be assessed. The criteria should provide for enforcement actions sufficiently severe to provide licensees with an incentive to comply with AEC's regulations.

COMMENT

The development of such criteria has already been initiated. As the draft report states, however, the enforcement actions available range from written notices of specific violations or safety problems to license suspension or revocation, with civil penalties falling somewhere in between. Judgment must be exercised in determining the specific types of enforcement to be taken in a given case. Many factors must be considered in making such judgments. We believe that the criteria being developed will provide guidance for making such judgments and for determining the amounts of civil penalties, they should result in a reasonable degree of uniformity in the enforcement process, and they should provide licensees with a greater incentive to comply with AEC's regulations.

RECOMMENDATION

Define in its medical licenses or regulations the activities that may be delegated by physicians and the activities that may not.

COMMENT

Work is under way to define in medical licenses or regulations the activities that may be conducted by technicians.

RECOMMENDATION

Require that physicians determine that technicians have been properly trained to perform their duties and maintain records showing the basis for their determinations.

COMMENT

While the licensee is responsible under existing regulatory requirements for assuring that all activities authorized by the license are conducted in accordance with regulations and license

conditions, we plan to incorporate into nuclear medicine licenses or the regulations a specific requirement that user physicians identified on the license determine that technicians have been properly trained to perform their duties and that the licensee maintain records showing the basis for such determinations. In addition, we are preparing a "Manual of Good Radiopharmaceutical Practice," as an aid for technicians working in nuclear medicine laboratories.

RECOMMENDATION

Establish a specific requirement that suppliers must verify that a transferee is authorized to receive the quantity or type of material being shipped and provide guidance as to acceptable methods of verification.

COMMENT

As the report points out, AEC regulations currently contain provisions which prohibit shipment of radioactive material to persons who are not licensed or otherwise authorized to receive it. We plan to amend the regulations to state specifically that all licensees, including suppliers, must verify that persons to whom they ship radioactive material are authorized to receive it. We will also provide guidance as to acceptable types of verification.

RECOMMENDATION

Require medical licensees to report to AEC all known misadministrations of radioactive materials to patients so that AEC can investigate the occurrence and determine the cause and whether adequate corrective action was taken.

COMMENT

This recommendation is under study. It is necessary to study accepted medical ethics of the physician-patient relationship and the possible consequences of a government agency interjecting itself into this relationship. This matter will be reviewed with our Advisory Committee on the Medical Uses of Isotopes.

RECOMMENDATION

Explore the feasibility of developing streamlined documentation techniques, including formats for field notes, which might permit the time spent documenting inspection results to be reduced, thus increasing the time available for performing additional inspections.

COMMENT

As is recognized in the draft report, documentation of inspection findings is necessary to enable AEC management to assess the adequacy of inspections and to support the items of noncompliance, and the extent of such documentation is a matter which requires careful balancing. In the interest of increasing the number of inspections performed, we are currently re-examining our documentation techniques with the objective of eliminating any unnecessary documentation.

BRIEF SUMMARY OF COMPLIANCE PROBLEMS ENCOUNTERED WITH CERTAIN LICENSEES

Licensee D (priority I)

Of the 39 inspections and seven investigations of this licensee between April 1966 and December 1971, 23 revealed no noncompliance or safety items. AEC cited the licensee for 60 noncompliance items and identified 16 safety items as a result of the remaining 23 inspections and investigations. The licensee, however, disagreed with AEC on 19 noncompliance items and five safety items.

According to AEC, this licensee has had significant problems regarding (1) employee exposures from external radiation, (2) radiation contamination, (3) effluent releases, and (4) management controls over radiation safety. Between April 1966 and December 1971, for example, AEC cited the licensee for

--failure to conduct adequate radiation surveys (eight occasions),

--failure to adequately instruct employees regarding appropriate safety procedures (three occasions), and

--radiation levels in excess of regulatory limits in an unrestricted area (three occasions).

In February 1972 DOC compiled a history of the licensee's compliance and radiological safety problems which included the following tabulation of employee exposures to radiation in excess of regulatory limits.

Year	Employee exposures
1967	29
1968	5
1969	25
1970	21
1971	18
	98

In commenting on an excerpt from our draft report, the licensee told us that it had been taking steps to improve its employee exposure controls since 1967; it believed that the reduction in the number of employees exposed to radiation in excess of regulatory limits between 1967 and 1971 demonstrated that its radiological safety program had improved.

The data tabulated by DOC, however, showed that the number of employees who received exposures in excess of the level which AEC considered desirable under routine operating conditions but which did not constitute violations of AEC regulations went from 66 in 1968 to 117 in 1970; the average whole-body exposure of licensee employees more than doubled during that period. AEC expressed the belief that this data demonstrated that the licensee's radiological safety controls had not been effective in controlling employee exposures and that the upward trend in average whole-body exposures should be reversed.

The licensee told us that it recognized the desirability of minimizing the exposure of employees to radiation and that it had begun taking additional measures to improve its radiological safety controls. It further told us that planning and preparation for these improvements began as early as 1967 but that such improvements had not yet been completed because of their complexity and magnitude.

Licensee E (priority I)

This licensee holds five AEC licenses for byproduct materials. We examined the compliance history of one of the licensee's priority I licenses. Between March 1967 and December 1971, AEC made nine inspections and two investigations of the operations conducted under this license. AEC cited the licensee for 26 items of noncompliance and five safety items as a result of these nine inspections; AEC found no violations during the two investigations.

Of the nine inspections involving noncompliance items, seven resulted in 12 citations for the licensee's failure to conduct adequate radiation surveys. In addition, AEC expressed concern over inadequacies in the licensee's bioassay program--a safety item--as a result of three inspections.

In commenting on an excerpt from our draft report, the licensee told us that, in its opinion, the majority of the violations and safety items identified had resulted from either (1) differences in technical judgment where standard operating procedures did not exist and where it disagreed with AEC or (2) clerical errors which resulted in violations of the letter of the rule but not of the intent of the rule. The licensee further believed that management control over radiation safety should not be evaluated merely on the number of deficiencies without considering the relative degree of hazards involved.

In April 1972, after we had received the above comments from the licensee, AEC sent the licensee a notice of alleged violation citing it for 10 items of noncompliance found during December 1971 and January 1972 inspections of operations conducted under three of its licenses. DOC also notified the licensee of one safety item: activities were conducted without a person to direct the health physics aspects of the program for about 6 months during 1971. In this regard, DOC stated that:

> "We consider this a substantial deficiency in management's recognition of its responsibility for the health and safety of its employees and the public."

DOC also issued a Notice of Proposed Imposition of Civil Penalty to the licensee as a result of the continued pattern of noncompliance items associated with the operations conducted under three of its licenses. DOC made the following statements.

> --"*** during the past 3 years we have made 11 inspections of your activities *** these inspections disclosed 30 violations of AEC requirements and in 6 instances similar violations were disclosed during two or more inspections."
>
> --"*** [these] inspections *** have revealed a pattern of decline in the company's radiation safety program in both scope and effectiveness."

--"It is necessary that appropriate management action be taken promptly to assure the maintenance of a strong radiation safety program for your licensed activities to protect your employees and the public."

In responding to AEC's April 1972 notice of alleged violation, the licensee

--denied AEC's allegation that activities had been conducted without a person to direct the health physics aspects of the program for about 6 months during 1971,

--disagreed with one item of noncompliance cited by AEC in the notice of alleged violation and explained a technical problem associated with another noncompliance item and the corrective actions taken, and

--described the corrective actions taken for the eight remaining items of noncompliance cited by AEC.

With respect to AEC's Notice of Proposed Imposition of Civil Penalty, the licensee stated that the penalty should not be implemented because

--the 30 violations cited by AEC had not constituted a threat to public health or safety and had not been willful;

--of the 30 violations, 10 related to differences in technical judgment with respect to an analytical procedure and 13 related to its failure to organize its recordkeeping; and

--continuous improvements had been made in the size and quality of the licensee's radiation safety program.

As of May 15, 1972, AEC was evaluating the licensee's comments and had not decided what action to take with respect to the proposed imposition of the civil penalty.

Licensee F (priority II)

This licensee, which conducted radiography operations, obtained its license from AEC in February 1968; it sold the assets of its radiographic division to another company in November 1970. (Although the licensee told AEC of its intention to sell the assets of its radiographic division to another company, AEC apparently did not learn of the actual sale until January 1971.) Between February 1968 and November 1970, AEC conducted four inspections and cited the licensee for 32 items of noncompliance, of which eight were similar in nature and were found on two or more inspections. Some of the items of noncompliance for which the licensee was cited included:

--Failure to report overexposures to AEC (four inspections).

--Exposure of employees to radiation levels in excess of regulatory limits in restricted areas (three inspections).

--Failure to require a radiographer to wear appropriate radiation-monitoring equipment during radiographic operations (two inspections).

--Lack of proper training for employees who performed radiographic operations (one inspection).

In December 1970 AEC sent a notice of alleged violation to the licensee citing it for 16 items of noncompliance. The notice pointed out that a licensee employee, with the approval of the radiation safety officer, had certified that he had calibrated radiation survey instruments when, in fact, he had not calibrated them. The employee advised AEC that, although he had prepared and signed the calibration certificate, he never actually had calibrated the instruments. The radiation safety officer told AEC that this practice had been followed in about 11 instances.

AEC's notice of alleged violation concluded that:

"The number and recurrence of the items of noncompliance disclosed during inspections

> conducted in 1970 appear to be indicative of the absence of effective management controls to assure compliance with established safety procedures. We believe the recurrent nature of the violations, as well as the increasing number of deficiencies, indicates inadequate indoctrination of personnel in sound safety practices and inadequate management control of the safety aspects of the company's licensed operations."

In a memorandum prepared by an AEC inspector subsequent to the issuance of the above notice, the inspector stated that the notice of alleged violation described a program that was "regressing from an unsatisfactory to an intolerable condition."

On January 5, 1971, 1 week after the issuance of the notice of alleged violation, a radiation incident occurred in which two employees were overexposed to radiation. AEC's investigation of the incident revealed that the licensee had sold the assets of its radiography division to another company in November 1970 and that the company which had purchased these assets was performing radiography operations without an AEC license. Although AEC was notified in November and December 1970 that the sale of these assets was contemplated, it apparently was not notified of the actual sale until its investigation of the January 1971 incident.

AEC's investigation revealed two additional items of noncompliance similar to certain items identified by AEC during its previous inspections of the licensee. These were the failure to insure that employees were wearing proper radiation-monitoring devices and the failure of the supervisor, who was inadequately trained, to take necessary precautions.

The items of noncompliance found during the investigation of the incident and the December 1970 notice of alleged violation were discussed with the president of the new company in a meeting at AEC Headquarters on January 14, 1971. The president described the corrective actions being taken to strengthen the company's radiation safety program. A

temporary license was issued to the new company on January 18, 1971, and a regular license was issued on June 30, 1971.

In February 1971 the new licensee told AEC that it not only was continuing to implement the remedial actions already initiated by the predecessor organization to correct the deficiencies identified by AEC during 1970, but that it also had made additional improvements to the predecessor's radiological safety practices.

In commenting on an excerpt from our draft report, the new licensee stated that

--it did not accept any responsibility for the noncompliance items associated with the predecessor licensee's operation;

--the January 5, 1971, radiation incident had not been handled to its satisfaction and had been the apparent result of ineffective training and improper utilization of personnel-monitoring equipment; and

--it had made an immediate evaluation of the predecessor's radiological safety practices after assuming control of the operation, had found that an entirely new system of radiation controls, employee training, and monitoring was necessary, and had implemented such a system.

AEC conducted inspections of the new licensee's operations from January to February and in November 1971. The inspection from January to February 1971 revealed one item of noncompliance, which the licensee corrected. Four items of noncompliance were identified during the November 1971 inspection. The new licensee corrected three of the items during the inspection and agreed to take corrective action for the fourth item.

Licensee G (priority I)

This licensee operates two separate facilities under two priority I licenses. The two principal problems at these licensed facilities were:

--Exposure of employees to airborne concentrations of radioactive material in excess of regulatory limits.

--The licensee's apparent reluctance to take prompt corrective action on matters brought to its attention as the result of AEC inspections and investigations.

Facility A

Only two of the 18 inspections conducted at facility A between July 1966 and November 1971 disclosed no items of noncompliance. The remaining 16 inspections resulted in the licensee's being cited for 71 items of noncompliance. During that period AEC cited the licensee for 12 violations of a similar nature on two or more inspections, including

--failure to maintain an adequate monitoring system in an area where special nuclear materials were handled, used, or stored (four inspections),

--failure to conduct required periodic health and safety inspections (three inspections);

--radiation levels in excess of regulatory limits in unrestricted areas (three inspections).

Also during that period the licensee reported to AEC that there had been 135 exposures, or potential exposures, of employees to radioactive material (mostly airborne concentrations) in excess of regulatory limits.

Facility B

Three of the 15 inspections conducted at facility B between July 1966 and December 1971 disclosed no items of noncompliance. The remaining 12 inspections resulted in the licensee's being cited for 37 items of noncompliance. AEC identified six violations of a similar nature on two or more inspections, including

--failure to conduct adequate radiation surveys (six inspections) and

--exposure of employees to radiation in excess of regulatory limits (four inspections).

During that period the licensee reported to AEC that at facility B there had been 212 exposures, or potential exposures, of employees to radioactive material (mostly airborne concentrations) in excess of regulatory limits.

In November 1971, the licensee corporation was sold to another firm. In commenting on an excerpt from our draft report, the new firm told us that, since it had assumed control over operations, it had acquainted its entire staff with AEC's requirements to insure that regulations and license conditions would be followed. The new firm also pointed out that its timely initiation of corrective action with respect to the three noncompliance items found by AEC at facility A in November 1971 and the one noncompliance item found by AEC in its December 1971 inspection at facility B demonstrated the firm's interest in complying with AEC's requirements.

Licensee H (priority II)

This licensee received its radiography license in August 1967. Shortly thereafter it reported an overexposure incident to AEC. AEC investigated the incident in October 1967 and cited the licensee for six items of noncompliance. Between the date of the incident and April 1971, AEC conducted four inspections. As a result of three of these inspections, AEC cited the licensee for 12 additional items of noncompliance.

In May 1971 the regional compliance office advised AEC Headquarters that

> "Inspections conducted during 1970 and 1971 revealed inadequate management control of program. This appears to result from inadequate management. Licensee President who is owner, RSO [Radiation Safety Officer] and a radiographer does not have adequate knowledge of safety procedures and AEC regulations to qualify others as radiographers which he is permitted under the license to do. April 1971 inspection revealed wrong tests being administered and tests not graded prior to permitting individuals to act as radiographers. Report in preparation for Headquarters action. Frequent reinspections are planned."

In commenting on an excerpt from our draft report, the licensee told us that several noncompliance items for which it had been cited related to the failure of technicians to properly prepare reports. It further stated that it had informed its technicians numerous times of the need to properly prepare these reports and that it had even fined them for not doing so but that this deficiency had continued as a result of their carelessness.

In addition, the licensee stated that (1) it believed that the radiation safety officer did have adequate knowledge of safety procedures and AEC regulations, (2) it currently had a fair management program in regard to AEC rules and regulations, and (3) it had taken corrective action to resolve the problems which had formerly existed.

A December 1971 inspection showed that the licensee had corrected the four items of noncompliance found during the April 1971 inspection and disclosed one violation which related to recordkeeping and which the licensee agreed to correct.

Licensee I (priority I)

Between September 1968 and April 1970, AEC conducted six inspections of the licensee's facility. As a result of four of these inspections, the licensee was cited for 12 noncompliance items, 10 of which were in the following areas.

--Failure to conduct adequate surveys to determine employee exposures to airborne concentrations of radioactive materials or to determine the extent of contamination in restricted areas (two inspections).

--Failure to adequately evaluate releases of airborne concentrations or liquid effluents to unrestricted areas (three inspections).

--Improper storage of certain nuclear materials (two inspections).

During that period AEC also notified the licensee of seven safety items relating to a number of weaknesses in the radiation safety program, including contamination control and employee exposures in certain restricted and unrestricted areas, problems in the storage of certain nuclear materials, and problems in monitoring liquid effluents released to unrestricted areas. For example, the May 1969 inspection showed that the licensee's employees, when leaving restricted areas in the facility, had retained considerable quantities of contamination on their shoes and clothing and had not used monitors to survey themselves.

Between September 1968 and April 1970, the licensee reported to AEC the exposure of 24 employees, and the potential exposure of 11 employees, to airborne concentrations of radioactive materials in excess of AEC regulatory limits. The licensee's reports stated that the overexposures generally had been caused by

--problems with existing processing equipment and

--leakage of radioactive material or excessive airborne concentrations in production areas, both of which were to be corrected by improved administrative controls

In commenting on an excerpt from our draft report, the licensee stated

--that license requirements for safety from nuclear hazards were measured against the standard of providing the highest safety factors practically attainable;

--that this standard provided a safety system with reinforcing and duplicating safety mechanisms designed to give early warning of potential trouble before a hazardous condition could be created by concurring failures of several parts of the system;

--that some instances of noncompliance were to be expected and that such occurrences alone did not support a conclusion that employees or the public had been endangered;

--that its facility had been subjected to the most rigorous nuclear safety requirements by AEC and that AEC enforcement actions for items of noncompliance had been at least as severe as the situations warranted.

The four inspections performed since October 1970 showed that appropriate corrective actions had been taken by the licensee and disclosed no items of noncompliance or safety items. These inspections showed that the licensee had considerably improved its radiation safety program

Licensee J (priority II)

Between April 1966 and April 1968, AEC conducted three inspections and three investigations of the licensee and cited it for 26 items of noncompliance. These included

--the failure to conduct adequate radiation surveys or to maintain records of radiation surveys (five occasions) and

--inadequate personnel monitoring controls (three occasions).

During an April 1966 inspection, AEC found that the licensee's operating practices had created a significant potential hazard to the health and safety of the licensee's employees and of construction workers on the construction site where the radiographers were working. Therefore the regional compliance office requested the licensee to voluntarily suspend operations until the deficiencies could be corrected; the licensee agreed to do so.

In transmitting the results of the inspections to AEC Headquarters for enforcement action, the regional compliance office attributed the violations to the

> "*** willful disregard on the part of the radiographer for the requirements of the regulations and safe operating procedures and *** management's failure to maintain sufficiently close supervision of field radiographic operations."

As a result of the inspection and investigation conducted in April and May 1966, DOC issued a notice of alleged violation to the licensee citing it for eight items of noncompliance. This notice of alleged violation was apparently ineffective, however, because the inspections and investigations conducted between October 1966 and March 1967 revealed a total of 15 violations, four of which were similar in nature and were found on two or more inspections. The regional compliance office concluded that the violations found on three investigations during 1966 and 1967 appeared to have resulted from management's lack of control over field operations, and DOC again issued notices of alleged violation.

Inspections conducted since April 1968 showed improvements in the licensee's program. The AEC license, however, was terminated at the licensee's request in April 1971.

In commenting on an excerpt from our draft report, the licensee stated that

--the serious problems in its radiation safety program in 1966 and 1967 had been caused by the carelessness and recklessness of one radiographer whose employment was terminated after a retraining attempt had failed;

--the two violations found in the April 1969 and March 1970 inspections, in its opinion, had been technical violations which were not potentially injurious or harmful;

--the adequacy of a radiation safety program and the enforcement actions taken should not have been determined on the basis of the number of noncompliance items alone without distinguishing items involving hazards or actual health and safety problems from those which related solely to technical violations attributable to the wording of a company's license;

--AEC should assist license applicants in the wording of their license applications, to avoid technical violations caused by unnecessarily restrictive language;

--controls over radiographers would be strengthened if individual radiographic technicians were licensed by AEC rather than by the licensees.

APPENDIX 1II

FORM AEC 591
(6/71)

UNITED STATES ATOMIC ENERGY COMMISSION
DIVISION OF COMPLIANCE

INSPECTION FINDINGS AND LICENSEE ACKNOWLEDGMENT

1 LICENSEE	2 REGIONAL OFFICE

3 DOCKET NUMBER(S)	4 LICENSE NUMBER(S)	5 DATE OF INSPECTION

6 INSPECTION FINDINGS

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Commission s rules and regulations and the conditions of your license The inspection consisted of selective examinations of procedures and representative records interviews with personnel and observations by the inspector The findings as a result of this inspection are as follows

☐ No items of noncompliance or unsafe conditions were found

The following items of noncompliance related to records signs and labels were found

☐ A Rooms or areas were not properly posted to indicate the presence of a RADIATION AREA 10 CFR 20 203(b) or 34 42

☐ B Rooms or areas were not properly posted to indicate the presence of a HIGH RADIATION AREA 10 CFR 20 203(c) (1) or 34 42

☐ C Rooms or areas were not properly posted to indicate the presence of an AIRBORNE RADIOACTIVITY AREA 10 CFR 20 203(d)

☐ D Rooms or areas were not properly posted to indicate the presence of RADIOACTIVE MATERIAL 10 CFR 20 203(e)

☐ E Containers were not properly labeled to indicate the presence of RADIOACTIVE MATERIAL 10 CFR 20 203(f) (1) or (f) (2)

☐ F A current copy of 10 CFR 20 a copy of the license or a copy of the operating procedures was not properly posted or made available 10 CFR 20 206(b)

☐ G Form AEC 3 was not properly posted 10 CFR 20 206(c)

☐ H Records of the radiation exposure of individuals were not properly maintained 10 CFR 20 401(a) or 34 33(b)

☐ I Records of surveys or disposals were not properly maintained 10 CFR 20 401(b) or 34 43(d)

☐ J Records of receipt, transfer disposal export or inventory of licensed material were not properly maintained 10 CFR 30 51, 40 61 or 70 51

☐ K Records of leak tests were not maintained as prescribed in your license or 10 CFR 34 25(c)

☐ L Records of inventories were not maintained 10 CFR 34 26

☐ M Utilization logs were not maintained 10 CFR 34 27

☐ N Records of radiation survey instrument calibration were not maintained 10 CFR 34 24

☐ O Records of teletherapy electrical interlock tests were not maintained as prescribed in your license

☐ P Other _____

_____
(AEC Compliance Inspector)

7 The AEC Compliance Inspector has explained and I understand the items of noncompliance listed above The items of noncompliance will be corrected within the next 30 days

_____ _____
(Date) *(Licensee Representative – Title or Position)*

ORIGINAL TO LICENSEE

PRINCIPAL MANAGEMENT OFFICIALS OF THE ATOMIC ENERGY COMMISSION RESPONSIBLE FOR ADMINISTRATION OF ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
CHAIRMAN:		
James R. Schlesinger	Aug. 1971	Present
Glenn T. Seaborg	Mar. 1961	Aug. 1971
DIRECTOR OF REGULATION:		
L. Manning Muntzing	Oct. 1971	Present
Harold L. Price	Sept. 1961	Oct. 1971
DIRECTOR, DIVISION OF COMPLIANCE:		
Lawrence D. Low	June 1961	Apr. 1972
DIRECTOR OF REGULATORY OPERATIONS (note a):		
Frank E. Kruesi	July 1972	Present
Lawrence D. Low (acting)	Apr. 1972	June 1972

[a]A major change in AEC's regulatory organization was made on April 25, 1972. The functions of DOC were transferred to the newly created Directorate of Regulatory Operations.

Copies of this report are available from the U S General Accounting Office Room 6417 441 G Street N W , Washington D C , 20548

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