

Considering the problem of protection against radiation hazards from a legal viewpoint, a lawyer outlines the functions of various Federal and State agencies in this field. He sees the problem as a mutual one of the agencies concerned.

Public Control of Radiation Emitters

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SHORTLY after the discovery of X-ray and the isolation of radium at the turn of the century, radiation was found to be a useful research tool and to offer promises of high utility in the fields of medicine and industry. The potentially harmful properties of X-rays and naturally occurring radioactive materials, such as radium and thorium, were also recognized at an early date. Pierre Curie, H. Becquerel, E. Grubbe, and other scientists reported cases of dermatitis, epilation, and other types of damage from X-rays and injuries traceable to radiation from radium prior to 1900.

Nevertheless, as X-rays were used in World War I for industrial radiographic purposes, only minimal precautions were observed in many instances. The equipment itself did not possess the safety features found on modern

X-ray units. During the early 1920's occurred the radium poisoning cases in which a number of girls engaged in painting watch dials apparently ingested pernicious quantities of radium. Reportedly, at least 20 of a total of 800 employees died during subsequent years with symptoms strongly suggestive of radium necrosis or radium-induced tumors. During this same period radium was found to be a useful external and interstitial source of radiation in therapy. Radium was also injected into patients for a variety of ailments ranging from arthritis to gout, and radium water was advertised and sold as a tonic and a rejuvenator.

As early as 1913, the National Bureau of Standards undertook the standardization of radium for medical uses, and in 1929 it sponsored the formation of the Advisory Committee on X-ray and Radium Protection. This committee, the name of which was later changed to the National Committee on Radiation Protection, has prepared a number of handbooks dealing with means of protection against the harmful effects of radiation. They cover such subjects as the safe handling of radioisotopes, control and removal of radioactive contamination in laboratories, maximum permissible concentrations in air and water, and disposal of

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radioactive wastes. The committee is comprised of representatives from such organizations as the Atomic Energy Commission, the Public Health Service, the National Bureau of Standards, the American Medical Association, the Radiological Society of North America, the American Radium Society, and the National Electrical Manufacturers Association. Its recommendations are accepted as reliable and authoritative, and they are the basis for many of the present radiological safety procedures.

With the development of the atomic energy program after 1942, the need for increased attention to the hazards of radiation became apparent. Today, not only substantial amounts of naturally occurring radioisotopes, such as radium and polonium, and approximately 125,000 X-ray units (1), but also relatively large quantities of reactor-produced radioisotopes, made available through this program, are in use in medicine, industry, and research. From August 1946, when distribution was begun, through May 1954, the Atomic Energy Commission distributed reactor-produced radioisotopes to over 2,000 medical institutions, physicians, colleges, universities, industrial firms, Federal and State laboratories, foundations, and institutes (2). (The actual number of persons currently using radioisotopes is considerably greater than this figure, inasmuch as an institutional program usually includes several persons qualified to handle radioisotopes.) Users of these materials are found in every State, but the greatest number, in order of decreasing representation, are in New York, California, Pennsylvania, Illinois, Ohio, Massachusetts, Texas, New Jersey, Michigan, and Maryland.

The problem of protection against the hazards associated with radioactive materials, both those occurring naturally and those produced artificially, and radiation-generating devices can best be met through the cooperation of the several Federal and State agencies concerned with the protection of the health of the public. The following presentation outlines the functions of each of these agencies in assuring that radiation emitters are handled in a safe manner and indicates how they are inter-related.

AEC's Authority and Functions

In the Atomic Energy Act of 1946, the Atomic Energy Commission was authorized to distribute, in accordance with certain general provisions, the byproduct materials (radioisotopes) resulting from operation of nuclear reactors and to establish radiological health safety standards governing the possession and use of these materials. The commission's authority in this regard was expressed with greater precision and clarity in the Atomic Energy Act of 1954. Section 81 of the act provides as follows:

No person may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, own, possess, import, or export any byproduct material, except to the extent authorized by this section or by section 82. The Commission is authorized to issue general or specific licenses to applicants seeking to use byproduct material for research or development purposes, for medical therapy, industrial uses, agricultural uses, or such other useful applications as may be developed. The Commission may distribute, sell, loan, or lease such byproduct material as it owns to licensees with or without charge . . . Licensees of the Commission may distribute byproduct material only to applicants therefor who are licensed by the Commission to receive such byproduct material. The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission. The Commission is authorized to establish classes of byproduct material and to exempt certain classes or quantities of material or kinds of uses or users from the requirements for a license set forth in this section when it makes a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Section 161 (b) authorizes the commission to :

Establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property.

Distribution Regulations

The Federal regulations governing distribution of AEC-controlled radioisotopes are published in the Federal Register and appear also in the Code of Federal Regulations, 1953 supplement, title 10, chapter 1, part 30. These regulations set forth the application procedure for obtaining the radioisotopes and limit procurement, possession, and use of the materials, except exempted quantities, to persons holding a valid authorization (license) from the commission.

Exempt from the requirements concerning procurement, possession, and use of radioisotopes are 1 microcurie or less of beta and/or gamma emitters with half lives greater than 30 days and 10 microcuries or less of beta and/or gamma emitters with half lives no greater than 30 days. These quantities, however, may not be combined or otherwise altered or treated so as to increase the rate of radiation exposure above the original radiation intensity, nor may they be used for medical purposes except upon authorization of the commission. In addition, the commission may exempt specific items, upon application for exemption, from any or all of the regulatory requirements.

All persons desiring to procure radioisotopes, other than the exempted quantities, produced in or distributed by or through AEC facilities, produced in any nuclear reactor within the United States, or produced in foreign nuclear reactors for shipment into the United States must file an application for radioisotope procurement, form AEC-313, with the AEC's Isotopes Division, Oak Ridge, Tenn. The technical staff of the Isotopes Division reviews the application to determine if the applicant is equipped to use the requested radioisotope as outlined in the proposed use in a manner that will not endanger health and safety. This review entails an analysis of the applicant's experience and training, facilities, equipment, and radiological safety procedures. Applications involving novel or relatively abstruse medical uses are referred to the AEC's medical advisers for evaluation and recommendation.

If a review of the application indicates that the applicant has the facilities and qualifications necessary to use the requested material in

a safe manner, an authorization for radioisotope procurement is issued to the applicant authorizing him to procure, possess, and use the specific type and quantity of radioisotope for which he has applied. If an applicant does not possess sufficient experience in the use of radioactive materials, he is requested to obtain such experience or associate himself with a person possessing the requisite experience and training. If facilities, equipment, or safety procedures are inadequate, the deficiency must be corrected before an authorization is issued.

Each person possessing or using radioisotopes must keep permanent records showing the receipt, use, storage, delivery, and disposal of radioisotopes, and the safety procedures to protect health. These records must be made available to the commission upon request. Such persons must also permit the commission at all reasonable times to make inspections of facilities where radioisotopes are stored or used.

If the commission at any time finds that a person is not equipped to observe or has failed to observe health safety standards established by the commission, or has used the radioisotopes in a manner other than as stated in his application, or has used the radioisotope in violation of law or any regulation of the commission, the commission may withhold or recall radioisotopes from such person.

Visitation Program

In accordance with the regulation concerning inspections, the Isotopes Division of AEC maintains a staff of technical specialists who visit institutions possessing radioactive materials. They note and evaluate such items as availability of handling equipment; adequacy of laboratory facilities, shielding, ventilation, and storage; radioisotope handling procedures; monitoring instruments and procedures; posting of caution signs; and labeling and waste disposal procedures. They advise on means of improving radiological safety procedures when improvement is indicated.

More than 500 institutions and individual radioisotope users are visited annually by AEC representatives. The visitation program is constantly expanding to meet the problems created by increasing use of radioisotopes. Selection

of institutions to be inspected is usually dependent on amounts and types of radioisotopes which the user has received. As a rule, those institutions which possess large quantities of long-lived radioisotopes, such as strontium-90 and cobalt-60, are visited more frequently than users having only limited amounts of short half-life or low-energy emitters.

These visits to radioisotope users are not only instrumental in improving radiological safety procedures, but they also provide information of value in reviewing future applications from the user. The visits also keep the AEC Isotopes Division informed on specific problems facing radioisotope users in their day-to-day operations.

Cooperation With States

A copy of each authorization issued to users within a certain State is forwarded to the State health agency or other State office charged with the responsibility of protecting the health of the State populace. When time and travel schedules permit, AEC representatives routinely invite State personnel to accompany them on visits to radioisotope users. In addition, State personnel make independent visits and followup inspections to assure that recommendations are being followed and that undesirable conditions have been corrected. Information resulting from such visits by State representatives is frequently forwarded to the Isotopes Division, particularly when the inspection is a followup to a joint AEC-State visit.

Since State health agencies are kept currently informed of the type and quantity of radioisotopes allocated to persons within their jurisdiction, it is possible for them to concentrate on those users possessing substantial amounts of radioactive materials. It is believed that the increasing cooperation between the State and Federal Governments in discharging their respective obligations is highly effective in maintaining high standards of radiological health safety in the radioisotope-distribution program.

AEC Safety Standards

Recognizing that radiological safety standards could be more easily adapted to the chang-

ing concepts of radiological safety if they were established by regulation or administrative order rather than by statute, Congress delegated to the AEC the authority to establish safety standards relative to the handling of AEC-controlled radioisotopes. Under this authority, the AEC may publish health safety standards having general application and also may issue specific instructions applicable to a situation not covered adequately by the general regulations.

AEC is in the process of developing standards governing the manufacture, testing, and labeling of sealed sources containing radioactive materials and radiological health safety standards of general application. In addition, the director of the Isotopes Division is authorized to establish for individual users safety standards and instructions governing the possession and use of AEC-distributed radioisotopes. He is also empowered to issue an order requiring immediate correction of any unsatisfactory conditions or procedures involving the use of such radioisotopes.

In furthering radiological health safety, the AEC Isotopes Division relies heavily on education. Through correspondence with radioisotope users, speeches, on-the-job visits, and the quarterly publication *Isotopics* and other publications, the division attempts to keep users currently informed of accepted safe practices. As a result of these efforts, not only have unsafe practices been corrected, but in many instances unduly restrictive safety programs have been reorganized so that greater emphasis is placed on their most important features. Such reorganization frequently has resulted in an improved radiological safety program at less expense to the company.

In only a few instances has the AEC found it necessary to issue formalized safety instructions in order to effect correction of unsatisfactory conditions. The majority of the users voluntarily attempt to keep radiation exposure at the lowest rate possible and well within the limits recommended by the National Committee on Radiation Protection. Some industrial users, however, have expressed a desire for definitive radiological health safety regulations having the force of law. These requests, for the most part, are based on the desire to know the

rules within which they must operate and a wish to avoid the mistakes and growing pains which attended the early use of radium and X-ray.

It is unlikely that any enterprise involving potentially hazardous materials can continue to operate successfully without specific safety rules. Experience of such agencies as the Food and Drug Administration and the Federal Trade Commission indicates that an agency cannot expect 100 percent unqualified voluntary compliance with accepted minimum safety standards and procedures. Therefore, for the proper administration of the AEC isotopes program, regulations and laws appear to be essential. It is to be noted, however, that a unanimity of opinion does not exist on this point, some persons believing that laws and regulations are not necessary and, in general, are objectionable. A portion of this group acknowledges the necessity for some degree of legal control but wishes to avoid unrealistic or ill-advised legislation.

Carefully drawn health safety regulations, aside from their regulatory aspects, could prove of inestimable value from an information point of view. It is true that a wealth of information exists today in the form of recommendations and standards set forth in the various handbooks of the National Bureau of Standards and in numerous publications of the Atomic Energy Commission, the Public Health Service, and other sources, but this information is not in the form of regulations or laws and therefore does not provide a binding norm. The recommendations prescribe safe handling procedures that may be possibly desirable, definitely desirable, or necessary. Consequently, the average individual may experience difficulty in ascertaining what is required of him in his own particular operation. Regulations consistent with current technical knowledge of radiation hazards and subject to modification as more knowledge is obtained could set forth in concise fashion the basic essential requirements.

Other Federal Agencies

Radioactive materials shipped in interstate commerce must be packed and labeled in accordance with regulations of the Interstate Commerce Commission. These regulations are

applicable to radioisotopes produced in nuclear reactors or cyclotrons and those occurring naturally. Civil air regulations also affect the transportation of radioisotopes. Radioisotopes intended for drug use fall within regulations issued under the Federal Food, Drug, and Cosmetic Act. A shipment in interstate commerce must be labeled in accordance with the regulations of the Food and Drug Administration. An ad hoc committee comprised of representatives of the Atomic Energy Commission and the Food and Drug Administration studies and advises on problems of mutual interest.

At present, radioactive materials that are exempt from the packing and labeling requirements specified in the ICC regulations may be admitted to the United States mails if packed and labeled in accordance with specifications set forth in the Postal Regulations. In 1936, after receiving complaints that photographic films were being fogged by being placed in proximity to packages containing radium or other radioactive materials, postal authorities issued an order which read, in part, ". . . any radioactive materials, including radium, thorium, or other radioactive substance, or any materials containing radioactive substance, such as powders containing radium or thorium, liquids containing radium emanation, radium salts, or radioactive minerals is prohibited transmission in the mails . . ." This order, of course, failed to take into account that radium and thorium in minute quantities are present in all materials. It was later revoked in favor of a more realistic rule.

Obligated by law to protect and to improve the health of the Nation's populace, the Public Health Service has been actively engaged in radiological health activities for a number of years. It has cooperated with the Atomic Energy Commission and its contractors in studies of such problems as the decontamination of radioactively contaminated waters; the treatment of radioactive wastes and methods of waste disposal for the predicted nuclear power reactor program; and evaluation of the varying degrees of hazards associated with the many radioactive elements formed as a result of nuclear reactions. The Service has also conducted nationwide surveys to determine the dangers associated with many varieties of radi-

ation emitters, such as particle accelerators, X-ray units, and fluoroscopic devices, and has made the information available to persons concerned with radiation problems. At present, the agency is encouraging the development of State radiological health programs.

As part of the Public Health Service's liaison and educational activities, the Robert A. Taft Sanitary Engineering Center in Cincinnati, Ohio, offers the opportunity for State and local health personnel to acquire basic knowledge regarding radiological health and safety problems. The center offers courses in basic theory of radiation, radiation detection instrumentation, the biological effects of radiation, and methods of protection against radiation.

States' Duties and Functions

The several States as sovereign powers have the authority, and duty, to protect the health of their citizenry. This authority is based upon the police powers inherent in all sovereigns and covers such items as handling and sale of drugs, preparation and sale of foods, regulation of sanitary conditions of buildings and industry, purity of water supplies, disposal of sewage and garbage, and protection of the health of employees. Statutes and regulations based upon the police power and designed to protect the health of the public are common today, and in most instances they have been held valid by the various courts. It is a cardinal principle of law, however, that exercise of the police power must be reasonable. Further, it must not violate provisions of the Federal Constitution or the State constitution.

Almost all States have statutes which could affect the use, transportation, storage, and disposal of radioactive materials. It is common, for example, to find statutes prohibiting the pollution of streams. Usually such legislation authorizes the State health department or a special board, such as a stream pollution board, to carry out the purpose and intent of the statute involved, to promulgate regulations, and to modify or amend them, as may be necessary.

A number of the State agencies have made remarkable progress during the past 2 years in developing programs and in acquiring competent personnel to further radiological health

within their respective jurisdictions. Some agencies, however, have failed to exercise their authority, and in some instances funds have not been made available to them.

Proposed Action

During the past year, a number of States have prepared preliminary drafts of standards and regulations applicable to the use of radioactive materials and radiation-generating devices. Generally, these proposed drafts have included provisions whereby special boards or State health groups would prepare rules and have authority to amend them as necessary. These drafts would indicate that the States do not contemplate including specific detailed tolerance and contamination values in statutes. This approach, of course, is desirable inasmuch as statutes often are difficult to amend, usually requiring action by the State legislatures, whereas codes or regulations established by administrative agencies can be readily amended by action of the agency. Control by administrative regulations has two advantages: If a situation not previously contemplated should develop, a rule may be established and put into effect with a minimum of delay; if an unreasonable or unduly stringent rule should be published, this rule may be relaxed with a minimum of delay.

Care should be exercised to assure that such regulations are realistic and that they place the emphasis on those conditions or practices which present a real problem as opposed to a theoretical one. A preliminary draft of one proposed State regulation defines a radiation hazard in such a manner that, if the definition were interpreted literally, a radiation hazard would exist if one wore a luminous dial watch or worked with infinitesimal quantities of radioactive materials. Inasmuch as all persons are exposed to radiation from naturally occurring radioisotopes in the soil and from cosmic radiation, it could be concluded from this definition that all human beings on this planet are subject to radiation hazards at all times.

The maximum permissible concentration of radioactivity in air, in another proposal, would be $1 \times 10^{-7} \mu\text{c./ml.}$ for beta-gamma emitters. This value is unduly stringent for some radioisotopes and much too liberal for others. The

National Committee on Radiation Protection, for example, would permit 2×10^{-5} $\mu\text{c./ml.}$ for tritium (hydrogen-3) and 2×10^{-10} $\mu\text{c./ml.}$ for strontium-90 and yttrium-90 for radiation workers. The proposed regulation would permit an air contamination of strontium-90 that is 500 times the amount recommended as a maximum permissible level by the committee. With the exception of radium and perhaps polonium-210, strontium-90 is possibly the most dangerous radioactive material in general use today.

These points are noted, not in a sense of adverse criticism, but to point up the fact that regulations should be drawn with care and with a thorough realization that they must be practicable and reasonable. This is not easy, admittedly, when dealing with a relatively new and complex subject. The National Committee on Radiation Protection is currently engaged in a study of the desirability of State legislation, problems associated therewith, and possible solutions.

Bases for Sound Programs

The basic tenet of a radiological health program should be that radiation can be used safely if proper precautionary measures are followed. Hospitals, laboratories, industrial firms, universities, and other institutions should be encouraged to employ persons trained in accepted measures of protecting against radiological hazards. They should be encouraged to continue the practice of employing and delegating responsibility to a radiological safety officer.

The State program should be based on actual needs rather than remote theoretical possibility. In all probability, at this time a greater number of people are exposed to excessive radiation from shoe-fitting machines, inspectoscopes, fluoroscopes, X-ray units, and similar devices than from radioactive materials. In any event a program could be initiated on a rather modest scale and could include monitoring of X-ray operations to determine the amount of exposure to which operating personnel and other individuals are exposed. As experience is obtained, the program could be extended.

As previously mentioned, AEC is presently working on radiation safety standards applicable to AEC-controlled radioisotopes. It is possible that State groups might find it de-

sirable to refrain from enacting a stringent set of regulations until these have been published. Their use as guides by the States should help in achieving a greater degree of practicability and uniformity.

Summary

In the final analysis the control of potential radiation hazards is a problem which can best be solved in all of its various facets by cooperation among the various Federal agencies and State groups charged with public health responsibilities.

The Atomic Energy Commission licenses users of reactor-produced radioisotopes and other radioisotopes subject to its jurisdiction before such users are permitted to receive the materials. This application must include information as to the laboratory facilities available, monitoring and survey instruments on hand or immediately available, the training and experience of the individual who will be responsible for use of the material, the amounts and types of materials which will be in use during a particular operation, storage containers, radiological safety procedures, and other information useful in evaluating the safety problems which may be encountered.

The Atomic Energy Commission is authorized to establish regulations, having the force of law, violation of which may subject the offender to fine or imprisonment. In addition, since the commission controls the supply of reactor-produced radioisotopes, an effective deterrent to violation of established safety rules and procedures is the fact that the commission may withhold further shipments of the materials or recall those already distributed.

Other Federal agencies control the transportation of radioactive materials in interstate commerce and such applications of radioactive materials as the inclusion of them in food or drugs. The Public Health Service is engaged in studies of radiation problems and is encouraging the development of State radiation health programs.

State health personnel make joint inspections with AEC representatives and conduct independent inspections of users of AEC-controlled radioisotopes. They also visit X-ray installa-

tions and users of naturally occurring radioisotopes. Although some State agencies have failed to exercise to the fullest extent the powers invested in them, others have made remarkable progress in recent years in acquiring competent personnel and developing effective inspection and educational programs in the field of radiological health safety.

Despite the increasing availability and use of radioactive materials, the radiological health picture in the United States is good. It is believed that continued cooperation among all agencies involved, whether Federal, State, or local, is the best insurance that this picture will continue to be good. The abuses and misuses associated with the early use of radium and the overexposures to operating personnel

from X-ray units, fluoroscopes, and other radiation-generating devices can be avoided. Caution, even extreme conservativeness, has been the keynote in the development of atomic energy. Fortunately, this has been one field in which the public health controls have kept pace, and they can continue to do so, with the increasing scope and growth of the industry.

REFERENCES

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Dial C for Cancer

The health education problem of providing information on cancer to the public without arousing anxieties and fears about being thought foolish or of embarrassing examinations or mutilating operations has been given an entirely new approach according to the *British Medical Journal*, October 2, 1954 (pp. 802, 807).

The Hull City Council in England put into operation "a remarkable scheme," according to the journal, in the hope that it will prove effective as a means of breaking down these fears. The scheme makes it possible for those who are too nervous or too uninformed to consult their own doctors simply to dial a number on their telephones for advice. A recording was made from a script prepared by medical authorities. Text of the record is now played when anyone in Hull dials the appropriate number. According to newspaper accounts, hundreds dialed the number during the first week. Results have not yet been determined.