State Regulation of Radioactive Materials

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WITH minor exceptions, the genesis of interest by States in controlling radioactive materials stemmed from the enactment of Public Law 86–373 by Congress in 1959. This added section 274 to the Atomic Energy Act, providing for transfer from the U.S. Atomic Energy Commission to States of regulatory responsibility and authority over byproduct and source materials and special nuclear material in quantities less than a critical mass. The enactment provided for an historic step: the voluntary relinquishment of authority by the Federal Government to States.

This enabling legislation was followed in 1960 by AEC's issuance of criteria which govern the transfer to States. For a State to qualify, its Governor must make a formal request and must certify that his State has a program which is compatible with that of AEC and is adequate to protect health and safety. In turn, the AEC must make a finding that the statements regarding compatibility and adequacy are correct. This law and these criteria have provided the basis for development by States of radioactive material control programs.

By the end of 1963, six States had entered into formal agreement with the AEC for transfer of regulatory authority. For convenience of notation, they are called "Agreement States," and include Arkansas, California, Kentucky, Mississippi, New York, and Texas. A number of other States were in various stages of negotiation or planning.

Some States have not reacted favorably to Public Law 86–373. Objections have been on at least the following grounds: (*a*) the States already have an inherent right to control radioactive materials, and to enter into an agreement with AEC constitutes an unwarranted admission to the contrary; (*b*) AEC retains jurisdiction over the really important matters, such as nuclear reactors and high-level waste disposal; and (*c*) the Federal Government wishes to have the States take an expensive program off its hands without providing any money for it.

These have not proved to be convincing arguments to most States. It appears quite clear that the Federal Government has occupied the field with respect to regulation of radioactive materials covered by the Atomic Energy Act, except as relinquished to States pursuant to section 274. There are good reasons for retention of Federal control over those matters which section 274 denotes as not being transferable to States. Export, import, and ocean waste disposal have international implications and are thus constitutionally reserved to the Federal Government. Evaluation and control of nuclear reactors and critical quantities of fissionable materials require highly specialized competence which individual States cannot be expected to possess for some time. The same may be said of disposal of high-level radioactive wastes, although in our view, the argument here is less convincing. The third objection really concerns separation of powers between Federal and State governments, which is beyond the scope of this paper.

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From the positive rather than the negative viewpoint, one may ask why a State should wish to assume this responsibility. Here is a program already being conducted by someone else. There is a constant struggle to stretch State tax dollars to cover State government services not otherwise provided. Is a State justified in taking on this program in such circumstances?

The principal philosophical answer to these questions is that health and safety matters generally are, by tradition, handled at the State level of government. There is no good reason why regulation of radioactive materials for purposes of health and safety should be an exception.

As a practical matter, it is our firm conviction that a State should seek an agreement with AEC only as part of a comprehensive radiation control program covering all other sources of ionizing radiation as well. Until recently in all States, and presently in most, the AEC regulates in great detail only a very narrow segment of the total radiation problem, with no one regulating the remainder. From a public health standpoint this is indefensible. It leads to ridiculous situations such as use of radium and cobalt 60 interchangeably in a hospital. The cobalt is regulated, the potentially more hazardous radium is not. More importantly, the overwhelmingly predominant public health problem is not dealt with at all. It is generally accepted that medical and dental X-rays contribute about 95 percent of population exposure to manmade radiation. It has also been amply demonstrated that significant reductions can be made in exposure to X-ray without in any way decreasing the benefits.

Since, of course, the biological effects of ionizing radiation are the same whatever the radiation source, if any such sources are regulated all types should be. Also all should be regulated under a common set of ground rules and preferably in a single comprehensive program for each State.

To sum up this aspect, then, in our view, the most important practical advantage to a State in entering into an agreement with AEC is that it provides a vehicle for obtaining a comprehensive radiation control program.

How does a State begin a radioactive material control program? In general, enabling legislation is required although this is apparently unnecessary in at least two States. Such enabling legislation has been adopted in 21 States in addition to the 6 Agreement States. In most cases, such legislation has included provision for a comprehensive radiation control program. At least the framework of virtually all of this legislation is a model act prepared under the sponsorship of the Council of State Governments.

Such legislation is seldom easily obtained. It has been opposed in various States by one or more groups representing the medical profession, the dental profession, industrial groups, organized labor, and State fiscal officers. The pattern has varied with each State and no further generalizations are possible.

The next step is development of administrative regulations to implement the enabling legislation. Although existing AEC regulations provide a basis for developing State regulations, it is not possible to translate these directly. Minutiae become very important. This is particularly true when the same regulations cover all types of radiation sources. Two examples of many cases in point are: Should leak-test criteria for sealed radioactive sources as established by AEC apply to radium, where leaking radon gas may also be a problem? Should industrial radiography requirements be the same for X-ray and isotope sources? There are no simple answers to such questions.

We found that an advisory committee representative of various radiation users was invaluable in the preparation of the California Radiation Control Regulations. Not only was the background and experience of the members invaluable, but they also assisted in selling the regulations, which they helped to prepare, to the groups that they represented. The importance of this latter point cannot be overemphasized. A regulatory program which is not generally acceptable to the regulated is doomed to failure.

New York was the first and still is the only Agreement State to develop regulations which are substantially different in format and content from those of the AEC. Certain basic elements such as exposure standards and concentrations of effluents are the same but, beyond

these, there are marked differences. We in California are proposing, based on experience, extensive changes in our regulations in an attempt to simplify, streamline, and enhance understanding. As more States join this program, we all face a real challenge to maintain a reasonable degree of nationwide uniformity while permitting enough diversity to satisfy local differences.

Obviously, a law and regulations do not of themselves make a control program. A competent professional staff and detailed plans for conducting the program are essential ingredients. Usually, accumulation of staff and program planning will proceed concurrently with development of regulations. The law, the regulations, the program plans, the composition of existing and proposed staff, all must be included in a submission to AEC with an application for Agreement State status. Before this formal step, however, there will, in practice, have been a series of informal meetings and exchanges of correspondence with AEC staff during which any real problems will have been ironed out. Thus, although the formal submission is given a full-dress review by AEC, at that stage approval should be essentially a formality.

As to administrative relationships within States for control of radioactive material, in four of the six current Agreement States, responsibility rests solely with the State health department and certainly this will be the case with most States. However, in several of the more industrialized States, the labor department or equivalent has considerable responsibility for employee health and safety and, further, there are frequently one or more autonomous or strong local health departments. Perhaps the approaches taken by New York and California, representative of this category of Agreement States, will be instructive.

New York has, in effect, three separate radiation control programs. The State labor department maintains statewide control over essentially industrial radiation uses. The New York City Health Department controls essentially nonindustrial uses in the city and the State health department does the same outside of New York City. Each agency has different, although compatible, regulations. Each issues separate licenses for radioactive materials and conducts its control program independently of the other two. There is an interagency committee on licensing to resolve any jurisdictional disputes.

In California the State health department is the focal point for the program. Its regulations pertain throughout the State. It issues all radioactive material licenses. On the other hand, the State division of industrial safety (labor department), under the terms of a formal agreement, participates in evaluating license applications and conducts inspection and enforcement activities with respect to industrial uses. There is also provision for participation in the program by local health departments. A local health department may participate only if it meets certain well-defined, high standards in terms of competency of personnel and the like. Participating local health departments carry out the same activities as mentioned for the division of industrial safety for both industrial and nonindustrial uses within their respective jurisdictions.

Having played a major role in establishing the California program, I am not unnaturally somewhat biased in its favor. It has the advantage of a single, integrated program while at the same time recognizing the legitimate interests and making use of the experience and talents in other agencies than the State health department.

Now, an AEC-State agreement must go into effect on a specific day. Shortly before that day there will have been a transfer of file material from AEC. One aspect of this bears stressing for the benefit of States contemplating an agreement. The normal new program for any agency generally starts small and grows with the problem. In this case, however, a State must assume responsibility immediately for a sizable ongoing program. I daresay that no matter how much planning has been done, the impact of this will come as somewhat of a shock.

Perhaps the key element in a radioactive material control program is the requirement for approval of an application before one can possess or use radioactive materials. When an application is evaluated, among the items carefully scrutinized are types, quantities, and physical and chemical forms of radionuclides; train-

ing and experience of personnel; equipment and facilities; instrumentation; routine and emergency radiation safety procedures; uses; method of radioactive waste disposal; and special considerations, such as for human use. Since applications vary from microcurie to megacurie amounts and since potential hazards vary widely even for a given amount of material, depending on form and use, it is obvious that the absolute and relative importance of these various factors will be quite different for individual cases. Within the general framework of regulations and policy, good health physics principles should govern the evaluation of each license application.

After a license is issued, routine periodic inspections of licensees are essential. Frequency of inspection should be based on an evaluation of potential radiation safety hazards. In addition, actual or suspected incidents must be investigated, whether a lost source, overexposure of personnel, a major contaminating event, or any of a number of other situations.

A good records system is crucial. Standard operating procedures are important but should be flexible enough to adapt to unanticipated situations.

Of perhaps greater importance than the preceding relatively straightforward informational material are some of the philosophical aspects of a radiation control program. By introducing these thoughts, we must appear somewhat critical of the AEC. It should be kept in mind that the health and safety record of radioactive material use under AEC control has been outstandingly good. As new agencies enter this field, however, it is desirable to critically examine AEC practices and procedures with a view toward improving them wherever possible. It is within this spirit that the following remarks are made.

In California we are doing two things differently, and we believe they are improvements. First, more attention is given to evaluation of original license applications, particularly by conducting more pre-licensing inspections and by closer involvement of compliance inspectors in application evaluations. In a surprising number of cases a visit to a site has revealed conditions markedly different from those described in the written application. We believe strongly that extreme care at this stage will serve to reduce significantly subsequent health and safety problems.

The other difference is more substantial and concerns the fundamental approach to radiation safety. It is only a slight oversimplification to say that the AEC is principally concerned with enforcing a law while we are principally concerned with assuring radiation safety and consider the law as a necessary evil. This, of course, is not to imply that the AEC is not concerned with radiation safety, only that its approach is overly legalistic.

The AEC compliance inspectors are essentially factfinders. They make inspections, accumulate facts, and transmit these to another group in Washington who decides what action to take with regard to any items of noncompliance. In contrast we regard our field personnel essentially as consultants whose main role is to evaluate a licensee's radiation safety program and to assist him in making any necessary or desirable improvements based on good health physics practices. We aim to solve most problems at the time of inspection or in followup. We have available and certainly will use legal mechanisms whenever necessary. We will, however, consider it a measure of our failure if this has to be invoked more than occasionally. On the basis of admittedly limited experience, we believe that our approach is working and that it is in the best interests of both regulated and regulator.

We made a major misjudgment in estimating the effort required to replace AEC licenses with State licenses. We had expected this to be a rather routine, not very time-consuming process. For a variety of complex and subtle reasons this did not prove to be the case. In effect, we have had to treat each licensee's application as completely new. After 14 months the task of replacing AEC licenses with State licenses was still only two-thirds complete, and the total job will take about a year longer than originally estimated.

Even though we had done considerable planning, relatively routine matters, such as forms, procedures, and record systems, have proved continually troublesome and overly demanding of professional staff time.

We failed to realize how much time would be

required to investigate actual or suspected incidents, to track down citizen complaints, to discuss general problems with licensees, and the like.

Earlier we mentioned the necessity for acceptance of the program by licensees. Generally, our licensees appear to be more pleased to be regulated by the State than by the AEC, although they have to pay substantial license fees not required by AEC, because of our more helpful approach and our closer geographic proximity which makes personal or telephone contact more feasible than with Washington.

In becoming and being an Agreement State, our relationships with AEC have been amicable and generally harmonious, but occasionally frustrating. The frustrations arise primarily from situations in which an actual or potential conflict arises between AEC and State jurisdiction. Fortunately, this occurs in only a small percentage of cases. One such example is that of reactor operators who also do research and development and other work, requiring both AEC and State licenses. Frequently, the activities authorized by the two licenses are not separable. Another example is the case of private companies who conduct contract work with radioactive material in Federal facilities.

Section 274 of the Atomic Energy Act and the regulation CFR 150 adopted pursuant thereto were intended to provide a clear separation of jurisdiction between AEC and Agreement States. Experience has shown that a perfect fit is impossible in some cases. The main frustration is that a strict legalistic interpretation of the law and regulation precludes any decision in some cases and leads to technically ridiculous solutions in others. We must have laws and regulations. We would only plead that they be written so that interpretation will allow administratively and technically reasonable solutions to problems.

Organizations for Radiation Protection

A recently published bibliography, prepared by the Committee on Ionizing Radiation of the American Conference of Governmental Industrial Hygienists, represents a compilation of selected national and international organizations whose activities relate to radiation protection. Groups currently active in this field, as well as those which have issued reports in the past, are described. Details, such as circumstances and date of founding, composition, main functions, accomplishments, publications, and address, are given.

The compilation is primarily for industrial hygienists. However, the foreword states that "if the document also provides individual agencies with a more complete picture of what is being done, perhaps this will lead to a consolidation of effort and reduction of duplication."

Copies may be obtained from: Secretary-Treasurer, American Conference of Governmental Industrial Hygienists, 1014 Broadway, Cincinnati, Ohio, at $2.00 a copy (checks to be made payable to the conference).