UNITED STATES GENERAL ACCOUNTING OFFICE

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STATEMENT OF

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GENERAL ACCOUNTING OFFICE

BEFORE THE
SENATE SUBCOMMITTEE ON ENERGY, NUCLEAR PROLIFERATION,
AND FEDERAL SERVICES
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
ON

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S. 1938--TO ENSURE ADEQUATE PROTECTION OF WORKERS, THE GENERAL PUBLIC, AND THE ENVIRONMENT FROM HARMFUL RADIATION EXPOSURE, TO ESTABLISH MECHANISMS FOR EFFECTIVE COORDINATION AMONG THE VARIOUS FEDERAL AGENCIES INVOLVED IN RADIATION PROTECTION ACTIVITIES, TO DEVELOP A COORDINATED RADIATION RESEARCH PROGRAM, AND FOR OTHER PURPOSES.

Mr. Chairman and Members of the Subcommittee:

We are pleased to appear here to discuss our report, "Radiation Control Programs Provide Limited Protection," which was issued today. This report, which resulted from a request by the Committee Chairman, deals primarily with State and Federal programs to protect the public from radiation. We would also like to discuss a review we have underway which addresses the direction of ionizing radiation research effort. On the basis of our work, we strongly support the intent of Senate bill 1938, which would seek to ensure adequate protection of workers, the general public, and the environment from harmful radiation exposure.

RADIATION PROTECTION

With the number of radiation-emitting sources continually increasing, assurance against unnecessary exposure becomes an increasingly difficult task and one of growing concern. The activities and responsibilities for such assurance are scattered among several Federal agencies. Also, nearly all States regulate radiation to some degree.

Our report discusses the radiation control programs of the Nuclear Regulatory Commission, Occupational Safety and Health Administration, Food and Drug Administration, and eight States--California, Colorado, Massachusetts, Missouri, North Carolina, Texas, Vermont, and Virginia. These States were selected to provide a representative view of State

radiation control activities. They include States with varying size programs, including some of the largest and smallest programs, and States which operate inspection and enforcement programs under the authority of the Nuclear Regulatory Commission and the Occupational Safety and Health Administration.

Despite widespread recognition of the hazards of radiation, there is no comprehensive program to protect the public from radiation hazards. Federal programs did not cover many sources of radiation and often provided limited protection in the areas they did cover. Some State programs were broader in scope, but they often lacked depth. Officials in every State we visited believed they needed more staff and other resources to fulfill their responsibilities.

NUCLEAR REGULATORY COMMISSION

The Nuclear Regulatory Commission regulates certain users of radioactive material in the States and territories through a program of standards, licensing, inspections, and enforcement. Under the law, NRC may delegate certain authority to the States and has done so through agreements with 25 States. Together, the Nuclear Regulatory Commission and the States are responsible for regulating about 17,000 users of nuclear materials. In fiscal year 1978, NRC inspectors made 2,411 inspections, and in about 40 percent of these inspections violations were cited. For calendar year 1978 the agreement

States made 4,070 inspections and identified violations in about half of the inspections.

Although NRC considered the regulatory programs in its agreement States to be compatible with its program and adequate to protect the public, its annual evaluations disclosed many problems in the State programs, including lengthy delays in promulgating regulations, inspection backlogs, and deficiencies in awarding licenses and conducting inspections. Lack of sufficient staff appeared to be a major contributor to these problems. NRC often made recommendations to correct the problems it identified. However, the problems often recurred. NRC appeared to have little authority over the States' activities. It doesn't provide money to the States. Its only sanction, termination of the agreement, is rather extreme.

NRC does not have jurisdiction over many sources of radiation, including naturally occurring and accelerator-produced radioactive materials which are common sources of exposure to the public.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The Department of Labor's Occupational Safety and Health Administration and 24 States operating OSHA-approved plans are responsible for assuring that employers comply with OSHA radiation standards except for radiation sources regulated by

NRC or NRC-agreement States. Radiation hazards were not a high priority for OSHA or the OSHA-plan States. OSHA did not know how many inspections covered potential radiation hazards. However, according to OSHA data for fiscal year 1978, only five businesses were cited for radiation violations or sampled for radiation hazards.

FOOD AND DRUG ADMINISTRATION

The Department of Health, Education, and Welfare's Food and Drug Administration has several programs that deal with radiation hazards, including enforcement authority over radiation from electronic products. A major aspect of its enforcement program involves field testing of newly installed X-ray systems. In addition to its own field tests, FDA contracted with 22 States for field tests in fiscal year 1978. That year over 11,700 X-ray systems were installed and 3,152 field-tests were done by FDA and the States. These tests identified 32 violations which warranted ceasing operations and 1,119 other major violations of FDA's standards.

FDA also has voluntary programs, two of which deal with dental X-rays and breast X-rays. Since the programs began, 38 States have participated in the dental program and 45 States have participated in the breast program. These programs seek to reduce X-ray exposure by identifying X-ray machines with either excessively high or unusually low X-ray exposures. Low exposures could result in additional X-rays to get an

acceptable picture. Of 35,224 dental units surveyed by FDA and the States, exposures from 12,680 appeared excessively high. Nearly 1,500 of the 3,253 mammographic units surveyed had either excessively high or unusually low exposures.

STATE PROGRAMS

The State programs we reviewed varied widely in scope and depth. All eight States had inspection programs for X-ray machines. However, only California and Vermont had certification programs to assure that X-ray operators were qualified.

All the NRC-agreement States had licensing and inspection programs for naturally occurring and accelerator-produced radioactive materials. Of the nonagreement States, only Virginia licensed such materials; however, it made no inspections during fiscal year 1978. Massachusetts registered and inspected these materials. Missouri and Vermont registered some materials, but had no inspection program. Missouri planned to make inspections this fiscal year.

Only two States' radiation control programs covered some sources of nonionizing radiation. Texas registered and/or inspected lasers, audiometers, and microwave ovens. Massachusetts registered and inspected lasers. The other six States did not regulate sources of nonionizing radiation. Nonionizing radiation is covered under Federal or State OSHA programs but inspections are infrequent.

Some State officials said they believed that many radiation sources are not licensed or registered. A State official said several thousand X-ray machines in Texas may not be registered. Also, some officials said that naturally occurring and accelerator-produced radioactive materials may be shipped into their States without their knowledge from manufacturers in States that do not regulate them.

Inspection frequency goals varied widely among the States. For example, the number of years between inspections of X-ray machines in physicians' offices ranged from 2 to 10 years. With long intervals between inspections, the potential is great for radiation hazards to go undetected and cause unnecessary exposure to many people.

In every State except North Carolina, material inspection frequencies were not met. None of the six States that had inspection priorities for X-ray machines during our review was meeting its inspection frequency goals. Many Federal and State officials said more people were needed to provide adequate inspection coverage.

CORRECTION OF VIOLATIONS

When inspections were made, violations of standards were sometimes not cited. When violations were identified, but not immediately corrected, the States, NRC, and FDA relied upon responses from users or assemblers that hazards had or would be corrected. In some instances, such responses were not received and no action was taken to obtain a response.

Followups to verify correction were rare. The inspectors did not normally verify correction until the next scheduled inspection, which could be years later. In the few instances we identified where followups were made, violations usually had not been corrected.

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In summary, many sources of radiation were not regulated, the coverage of many regulated sources was limited, and there was little assurance that identified hazards were corrected. We believe the actions called for in S. 1938 are needed to better protect the public from the hazards of radiation.

Our report recommended that evaluations of the adequacy of Federal and State radiation programs and the coordination among Federal and State regulatory agencies be given high priority. Such actions could be accomplished through the
4 Federal Council on Radiation Protection which would be P.3453
created under S. 1938.

RESEARCH

We also believe that there is a need for continued research into the biological effects of radiation--especially low-level radiation. Without knowing its effects, it is impossible to determine how much should be done to protect people from unnecessary exposure or overexposure to low levels of radiation. S. 1938 provides for identifying and setting priorities for research needs, evaluating research

proposals, and coordinating research activities relating to ionizing radiation.

THE CANCER RISKS OF LOW-LEVEL IONIZING RADIATION EXPOSURE

We are currently doing a study of the cancer risks of low-level ionizing radiation exposure in which we deal with some of the concerns addressed by provisions of Title II of S. 1938. We undertook this study because of long-continuing and unresolved concerns about the health effects of low-level ionizing radiation.

The first known forms of ionizing radiation (X-rays and the radiation from radium) were discovered and put into use in the early 1890's. Concern about the carcinogenic effects began in 1902, when cancer was first attributed to overexposure to X-rays.

Since that time, many experiences have confirmed that ionizing radiation can increase the incidence of cancer. Groups of people who have been exposed to radiation occupationally or medically or from atomic explosions have been studied, and this effect has been observed.

In spite of over 70 years of study, millions of dollars of research, and tens of thousands of scientific papers on the subject, many questions remain unanswered about the action of radiation on people. Scientists are still trying to understand exactly how ionizing radiation causes cancer, and to determine how many cancers are caused by a given amount of

radiation. With the increasing use of materials and processes that produce ionizing radiation, it has become increasingly important to answer those questions.

The uncertainties about the cancer risks of radiation, especially at low levels, have been difficult to resolve for many reasons. Consider the following factors:

--everyone is exposed to some ionizing radiation;

--it is impossible to avoid cosmic rays and other naturally occurring sources of radiation that permeate the environment;

--people of different ages, sexes, or lifestyles respond to radiation differently;

--a cancer produced by radiation cannot be distinguished from one that did not have radiation as a cause;

--most data on people involve groups exposed to very high levels of radiation, and their experiences have an uncertain relationship to what happens at lower exposure levels; and

--scientists cannot yet characterize what cancer fundamentally is, much less describe precisely what role radiation plays.

Considering all this uncertainty, it is not surprising that scientific and political issues have become intertwined in the public debate on radiation protection regulation.

The scientific questions are: How does radiation cause cancer? How many cancers are caused by a given amount of radiation? Who is likely to get cancer if exposed to radiation, and when? The political questions are: If the risks from radiation are known, how much risk is acceptable? If the

precise risks are not known, how much uncertainty is society willing to tolerate? Who gets paid when radiation produces cancer, and who pays?

GAO undertook this study to consider the scientific questions about the health effects of low-level ionizing radiation apart from the political ones. Our goals were to determine:

--what definite conclusions, if any, about low-level effects can be drawn from current scientific knowledge; and

--what conclusions can be drawn about the best direction for current and future research.

At least 80,000 articles have been published on the health effects of ionizing radiation. About 40,000 were funded by the Federal Government through various agencies. We reviewed many of those articles, particularly those considered to be important and influential. We then arranged a series of meetings with many people having expertise or specific interest in the subject of low-level ionizing radiation. These people represented a broad spectrum of viewpoints on the subject. Some maintained that current radiation protection standards were not strict enough. We met with others who had strong opinions on the current Federal research efforts in this area.

We also analyzed the data on some groups of people exposed to radiation, reviewed the current status of the major lines of research, and evaluated the directions and emphasis

of the research programs funded by Federal agencies. Throughout the study, we have made extensive use of consultants and experts in fields ranging from pathology to statistics.

We are just finishing analyzing much of the data prior to formulating conclusions and recommendations and obtaining agency comments on a draft report. Based on our tentative conclusions to date, however, I can offer several comments pertinent to provisions of S. 1938.

We agree with the provisions of S. 1938 that call for coordinating Federal research efforts in this area. The Federal Conference on Research Into Biological Effects of Ionizing Radiation can be an effective means of achieving that coordination. Research projects are now approved by individual agencies according to the needs of their own missions. It is important that research priorities be set so that promising ideas are funded, duplication of effort is avoided, and the limited Federal research dollars are spent effectively.

I am sure that you are aware that the Administration has proposed creating an Interagency Radiation Research Committee (also chaired by the Director, National Institutes of Health) that would perform many of the same duties as the Federal Conference proposed in S. 1938. The Administration plans to create this Interagency Committee by Executive Order.

We also fully agree with the bill's provisions that would require that any proposed epidemiological studies be carefully reviewed to assure that they are of sufficient scientific merit. Our tentative findings suggest that due to many limitations, epidemiological studies cannot provide reliable scientific data on the relationship between cancer and low-level ionizing radiation exposure. In order to determine the precise risks of low levels of ionizing radiation exposure, an epidemiological study would initially require:

--accurate dosimetry for each individual in the study population;

--a lifetime followup on each individual;

--complete health and occupational records;

--suitable comparison populations; and

--a knowledge of other influences (e.g., environment, smoking habits, genetic heritage) each individual had been subject to.

It is difficult, if not impossible, to satisfy all these criteria.

There are valid social and legal reasons for doing epidemiological studies, but these studies cannot be expected to precisely define how many cancers are caused by a given amount of radiation.

Animal studies have similar limitations, and also yield results that are difficult to apply to human beings.

Experiments with laboratory-grown cells, on the other hand, are relatively inexpensive, and are more easily monitored

and measured. The cell is the fundamental building block of life.

Researchers are attempting to determine whether laboratory results are the equivalent of the radiation effects that occur in body tissue. If this can be established, cell studies are likely to provide important insights into the process of radiation-induced cancer. We therefore believe fundamental cell research is the most promising area for eventually defining the relationship between cancer and low-level ionizing radiation exposure.

NONIONIZING RADIATION

In its deliberations on S. 1938, we believe the Subcommittee should consider applying the bill's provisions to nonionizing radiation. Everyone is exposed continuously to nonionizing radiation, and the number of sources of nonionizing radiation is increasing. While the effects of low levels of nonionizing radiation are uncertain and controversial, there is growing concern over these effects. We believe further study is warranted.

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Mr. Chairman, this completes my statement. We would be happy to respond to any questions you or members of the Subcommittee may have.