

MAINE STATE LEGISLATURE

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CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INCORPORATED

PROGRAM REVIEW

REPORT

State: MAINE

Date(s) of Review: September 13 - 16, 1982

REPORT

At the request of Mr. Wallace Hinckley, Manager of the Maine Radiological Health Program, the Conference of Radiation Control Program Directors, Inc. coordinated a comprehensive review of the activities performed by the Maine Program. This review was conducted from September 13 to 16, 1982. The objective of this external, independent review was to provide Mr. Hinckley with recommendations on areas in which improvements could be made which would provide better radiological health and safety protection for the citizens of Maine.

The review was performed by a team of persons with extensive training and experience in radiation protection. There were six team members, each member addressing specific program areas. The team members and the agencies they represented were: (See Attachment #1 for addresses and phone numbers.)

<u>Members</u>	<u>Representing</u>
Eugene Fisher	Conference of Radiation Control
Charles M. Hardin	Conference of Radiation Control
Richard E. Gross	U.S. FDA, ORH
Warren W. Church	U.S. FDA, EDRO, Region I
Byron S. Keene	U.S. EPA, Region I
E. C. Ashley	U.S. NRC

Two documents were used as the basis for evaluation of the Maine Program. These documents were, "Criteria for Adequate Radiation Control Programs (X-Ray)," and the draft document, "Criteria for Adequate Radiation Control Program (Radioactive Materials)."

In addition to Mr. Hinckley, the following persons were interviewed during the review: William Nersesian, M.D., Director of the Bureau of Health, Donald Hoxie, Director of the Division of Health Engineering, John Cameron, Radiation Specialist, Russell Martin, Nuclear Engineering Specialist, Chester Small, Radiation Chemist, Cheryl Baker, Radiation Chemist, Joe Blinick, Medical Physicist, Terry Zipper, Medical Physicist, Haven Whiteside, Legislative Assistant, and Harvey DeVane, Commissioner, Department of Business Regulations.

In addition to the above persons interviewed, a summary of the team findings was conducted with the Honorable Judy Kany, Legislator, John Bailey, Legislative Assistant, Marjorie W. Harris, Executive Director, Maine Dental Association, Grant Heggie, Maine Hospital Association, and Pamela Sirois, Maine Association of Certified Radiological Technologists.

The various areas reviewed, with recommendations, are provided below. For additional comments on the areas reviewed, see individual reports of Mr. Gross, Mr. Church, Mr. Keene, and Mr. Ashley.

A. LEGISLATIVE AUTHORITY:

It is essential that clear legislative authority be enacted that provides for the establishment of a comprehensive radiological health program. Existing legislation which relates to radiation is:

1. Title 10, Chapter 3, Sections 103, 104, 105, 151, 152, 153, 201, 202, and 203; Chapter 4, Section 253, Subchapter III-B, Sections 171 thru 176;
2. Title 25, Chapter 5, Sections 50 and 51;
3. Title 35, Chapters 225 and 269;
4. Title 37A, Chapter 3 and Chapter 5, Sections 50 and 51; and
5. Title 38.

Although the above legislation provides certain needed enabling authority, and provides for certain type fees, there appears to be several areas in which legislation could be improved.

Recommendation #1

It is recommended that the state of Maine consider the provisions contained in the "Suggested State Radiation Control Act" recently adopted by the Council of State Governments as a comprehensive radiation act for the state of Maine.

Areas which should specifically be considered are:

1. Enabling authority for the control of nonionizing sources of radiation.
2. Enabling authority for the credentialing of radiation allied health operators.
3. Legislative authority to charge fees which will directly support radiation control activities, such as radiation source registration and inspection.
4. Legislative authority to levy civil penalties.
5. Clarification in the existing Title 10, Chapter 3, Subchapter II 1791, Section 103, item 11. This law states, "The department shall further promulgate rules requiring periodic certification and calibration of this

equipment by competent technicians." During discussions on this statute, it was unclear as to what criteria should be used to determine what constitutes a competent technician. Also, it was unclear as to what criteria should be applied to certify the referenced equipment.

6. Clarification of the role of the Radiation Control Program in the Department of Human Services as related to the management of low-level radioactive waste.

7. Consideration should also be given to codification of all authority of the Department of Human Services for radiation protection into Title 22.

B. REGULATIONS:

Once legislative authority has been enacted, the designated agency should adopt comprehensive regulations for the control of radiation sources. The most serious deficiency noted during the review of the Maine Radiation Program was the non-existence of any regulations pertaining to the control of x-ray sources and radioactive sources not regulated by the U.S. Nuclear Regulatory Commission (NRC). Although radiation protection rules and regulations were promulgated in 1964, these 1964 regulations were preempted on January 1, 1980, since they were not refiled as required by law. Therefore, since January, 1980, no health and safety regulations have existed.

Recommendation #2

Immediate action should be considered to adopt comprehensive regulations for the control of radiation sources not regulated by the NRC. Authority already exists in Title 10, Chapter 3, Subchapter II, Section 103, to promulgate such regulations.

Consideration should be given to adopting regulations which conform with the "Suggested State Regulations for Control of Radiation," prepared by the Conference, U.S. FDA, U.S. NRC, and U.S. EPA.

It is further recommended that such regulations be reviewed at least every two years for any necessary updated revisions.

C. ADMINISTRATIVE:

The area of administration will be subdivided into specific administrative items.

1. Organization:

As related to public health and safety, it appears that four agencies have some responsibility as required by law. These are:

- a. Department of Human Services - Title 10, Chapter 3, Title 25, Chapter 5; and Title 35, Chapter 225.
- b. Public Utilities Commission - Title 10, Chapter 4.
- c. Bureau of Civil Emergency Preparedness - Title 37A, Subpart 9.
- d. Department of Environmental Protection - Title 10, Subchapter III-B.

Additionally, should legislation be passed for the credentialing of radiation allied health operators, it is the understanding of the review team that the Business Regulations Department would have responsibility for implementing its provisions.

Recommendation #3

The authority and responsibilities of each state agency that has some involvement in radiation protection should be clearly defined and understood by each respective agency. Consideration should be given to the development of Memoranda of Understanding between agencies if such would more clearly define responsibilities.

2. Budget:

The funding for the radiation control activities in the Department of Human Services have primarily come from federal contracts, or in the case of environmental monitoring activities, from fees collected from nuclear power facilities. It is the team's understanding that little, if any, general funds have been used to support the radiation control activities. Due to the uncertainty of continued federal funding, and the non-flexibility of the existing fee structure, which also do not consider inflation, it is very difficult to establish any long-range plans in radiological health.

Many of the federal funds provided by contract were intended as "seed money" to assist the state with start-up costs.

To develop the comprehensive radiation control program recommended in this report, additional funding would be required. Such funding would either have to come from general funds, or from a newly established fee system, or a combination of the two.

Recommendation #4

Appropriate supervisory personnel should critically review the present funding mechanism for the radiation control activities in the Department of Health Services. Such review should include a comparison of expenditures by other states with a similar number of radiation sources and similar population. Consideration should be given to a fee system or the use of general funds which would allow budget support for a complete comprehensive radiation control program.

3. Advisory Committees:

Many states have effectively utilized an advisory committee, consultants, or other outside resources to provide guidance and assistance. Advisory committees consisting of professionals with a variety of expertise can be especially helpful for unique and technically complex problems.

Recommendation #5

Consideration should be given to the establishment of a technical advisory committee to provide assistance when needed. Should a formal committee not be appropriate, consideration should be given to utilizing other outside resources where appropriate.

4. Personnel:

- a. Staff Size - Based on the best estimates of x-ray registrations through the voluntary registration program, there are approximately 1200 medical/dental tubes, and about 80 nonmedical tubes. Using the criteria document previously referenced, this workload of tubes would require a staff of 2.5 full-time equivalent technical persons, plus clerical and management personnel, estimated at an additional 0.5 full-time equivalent person, or a total of 3 full-time equivalent persons in the x-ray program.

Based on an estimated 26 radioactive sources used in Maine, which are not regulated by the NRC, and using the referenced criteria document as a guide, this workload of radioactive sources would require a staff of 0.5 full-time equivalent technical persons.

For environmental monitoring activities, it is recommended that at least 2.0 full-time equivalent technical persons would be required for the needed radiological environmental monitoring in the state of Maine.

Based on the described "other" radiological activities being performed by the radiation control staff, primarily in the area of radiological emergency planning and exercises associated with nuclear power facilities, an additional 1.0 full-time equivalent technical person should be available.

Finally, the administrative and clerical staff necessary to support the above comprehensive program is 1.5 full-time equivalent persons.

Therefore, the total recommended staff for a comprehensive program, based on the number of ionizing sources in the state, is 8.0 full-time equivalent persons. The total existing full-time equivalent personnel for radiation safety activities is only 4.45, leaving a needed balance of 3.6 additional staff persons.

Additionally, should the state consider future agreements with the NRC for state licensing of existing NRC regulated material, and for state licensing of a low-level radioactive waste (LLW) site, an additional 1.0 full-time equivalent would be required for NRC related materials licensing. For regulating a low-level radioactive waste site, an additional 1.0 full-time equivalent would be required for LLW licensing activities. Also, for LLW regulation, consideration must be given to additional supporting laboratory personnel.

Recommendation #6

Efforts should be made to increase the radiological health staff, in a step-wise fashion, to meet the above identified full-time equivalency, with an objective to reach a fully staffed program on a long-term basis.

- b. Staff Classification - One of the major problems in many state governments is "holding" qualified persons. One identified reason in many states is an inadequate career development ladder for advancement. This situation appears to exist with the Maine Radiation Control Program.

Recommendation #7

A review should be made of the existing classification structure for radiological health positions. If this review shows that there is not adequate opportunity for career advancement, a new series may be appropriate. One example would be a health physics series.

- c. Staff Training - Proper radiation control involves very complex and technical measurements, analysis, and decision making. Such

can only be performed if the staff is properly trained in all aspects of radiation protection.

Recommendation #8

A review should be made of the existing training program for the technical radiological staff, and where found deficient, efforts should be made to upgrade such training. Special efforts should be made to have professional staff supported and encouraged to obtain outside formal training when such is available.

5. Program Planning:

Many radiation problems can be corrected quickly, whereas others require substantially more time. Therefore, both short-term and long-range plans should be in place. Such plans should have set objectives and goals which allow a set schedule of events, and provide a "yardstick" from which to measure accomplishments. In establishing the objectives and goals, careful attention must be paid to proper priorities in addressing areas where radiation exposure is greatest. For example, nationwide assessments of population exposure to ionizing radiation from man-made sources has shown that medical and dental exams contribute the major part.

Recommendation #9

Consideration should be given to the development of both short-term and long-range plans in radiological health protection. These plans should have quantifiable indices so that accomplishments can be measured.

D. PROGRAM ACTIVITIES:

1. Low-Level Waste Management (LLW):

As stated under Legislative Authority, the role of the radiation control program in the management of low-level waste should be clarified. Specifically, considerations should be given as to the appropriate agency which would license a site in Maine, should that be the desire of the state. Options would include either the NRC or a state agency. Should it be a state agency, discussions should begin as to which agencies would be the licensing agency.

In connection with this issue, is the consideration of an agreement with the NRC. Should the state decide that the licensing entity should be a state agency, then an agreement with NRC will be necessary. This can be either partial for LLW only, or full agreement for all radioactive sources allowed for state control under the Atomic Energy Act.

Recommendation #10

Since the radioactive waste issue is at a stage of regional compact negotiation, consideration should be given as to identifying the role of the radiation control program for health and safety matters. Of particular importance, is the initial planning for potential state licensing of a site, should such become necessary.

2. Radioactive Materials:

As discussed in Mr. Ashley's report, at the time of the review, there were 95 radioactive material licenses in the state of Maine, issued by the NRC. In addition, there were an estimated 26 radioactive sources being used not under NRC jurisdiction. Since only voluntary registration is occurring, the actual number of non-NRC regulated sources could be higher. Mandatory registration or licensing should be considered to accurately account for the non-NRC regulated sources.

Since the improper use of non-NRC regulated radioactive sources, especially for radium, represent a significant potential for radiation exposure, consideration should be given for the establishment of a total radioactive materials program. This program should include a set schedule of inspections to assure that proper health and safety procedures are being followed.

Experience has shown that once a state properly "gears" up to control and regulate non-NRC regulated radioactive sources, then the program has a strong base to consider the control and regulation of NRC regulated materials. However, should the state consider such action, an agreement between the state of Maine and the NRC would be required.

Recommendation #11

Immediate consideration should be given to the establishment of a comprehensive regulatory program for the control of radioactive materials not regulated by the NRC. During consideration of such a program, the state should weigh the benefits of becoming a full "Agreement State," and if such evaluation appears beneficial, steps should be taken to begin such negotiations.

For additional specific recommendations in the area of radioactive materials, please refer to Mr. Ashley's report (Attachment #5).

3. X-Rays:

Since medical and dental x-rays have been shown to be the greatest source of man-made radiation exposure, consideration should be given to placing this area in top priority. A comprehensive program should be in place which requires registration of all x-ray sources, and a set schedule of inspections should be conducted to assure that proper health and safety procedures are being followed. Consideration should also be given to the implementation of a quality assurance program for x-ray facilities, although such a program would be of a lesser priority than registration and inspections.

Consideration may also be given in the use of qualified outside consultants to assist in the inspection of x-ray equipment. For more detailed recommendations in the x-ray and nonionizing area, please refer to Mr. Gross' report, (Attachment #2) and Mr. Church's letter (Attachment #3).

Recommendation #12

A comprehensive radiation control program should be established for x-ray sources used in the state of Maine. The program should include required registration, a set schedule for inspections, and a strong enforcement program.

4. Environmental Surveillance:

It appears that the Maine environmental surveillance program for ionizing radiation is optimum, and should be continued at its present level of effort. For more detailed discussion, please refer to Mr. Keene's letter (Attachment #4).

Recommendation #13

Since the Maine environmental surveillance program is considered to be at an optimum level, no significant recommendations can be made. Reporting could be improved with the issuance of an annual report on the environmental surveillance activities and findings.

REFERENCES

1. Criteria for Adequate Radiation Control Programs - (X-Ray), A Report of Task Force 2A, Conference of Radiation Control Program Directors, Incorporated, April 1981.
2. Criteria for Adequate Radiation Control Program - Radioactive Materials, A Report of Task Force 2B, Conference of Radiation Control Program Directors, Incorporated, Draft.
3. Report of State and Local Radiological Health Programs - Fiscal Year 1979, U.S. Department of Health and Human Services, October 1980.

Addresses and Phone Numbers

of

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Memorandum

Date October 20, 1982

From Chief (HFX-77), Federal/State Programs Branch, DTMA

Subject Trip Report

To Director (HFX-70)
Division of Training and Medical Applications

RECEIVED OCT 25 1982

DATES OF TRAVEL: September 13-16, 1982

DESTINATION: Augusta, Maine

PURPOSE: To participate with the Conference of Radiation Control Program Directors, officials of EPA and NRC, and the RRHR, Region I in a review of the radiation control program in Maine. To provide recommendations for improved radiological health actions in controlling exposure from x rays.

Members of the Review Team were:

Chuck Hardin, Executive Secretary, CRCPD, Team Leader
Gene Fisher, New Jersey
Byron Keene, EPA, Region I
James Ashley, NRC, Bethesda, Maryland
Warren Church, RRHR, Region I, FDA

ACCOMPLISHMENTS:

The attached report outlines the findings and recommendations that resulted from my review of the Maine program. This time we had a verbal exit report that was attended by people from the legislature, the user community and the executive branch of government. While this was unusual, it did not seem to hurt the delivery. Chuck Hardin did an excellent job in coordinating the recommendations of the various team members and presented them to a varied audience without losing their interest. He was able to handle this new situation without any problems—a very balanced report, nicely done.

The people from the legislature seemed genuinely interested in providing the legislative corrections necessary to really implement the recommendations of the review team. Assuming that this can be done the next major hurdle will be the establishment of a program to utilize consultants in the x-ray inspection program.

It is anticipated that the work I will be doing with Indiana and Illinois in developing their programs using private consultants will be helpful in working out details for Maine. Maine has not been able to put any significant resources into

their consultant program. Their request for a State assignee to develop the program is not likely to be filled. The RRHR and I will continue to work toward the development of a draft that can be sent out for comments.

Richard E. Gross

Attachment

cc: Mr. Hardin
Mr. Church (HFR-19)
Mr. Manny (HFX-70)
Mr. Jans (HFX-77)
Dr. King (HFX-77)
Ms. Miller (HFX-77)

Summary Report: Findings and Recommendations
X-Ray Control Program
Maine Occupational and Radiological Health Program

Importance of X-ray Sources to Population Exposure:

Nationwide assessments of the population exposure to ionizing radiation from manmade sources has shown that x-ray exposures from medical and dental exams contributed the major part of the average annual genetically significant dose to the population as well as of the per capita annual mean bone marrow dose. Specifically, in 1964 diagnostic x rays were estimated to be responsible for 85 percent of the exposure to the population, occupational exposure less than ten percent and manmade radiation sources in the environment less than two percent of the total exposure. Later studies in the U.S. (1970) and worldwide have not changed those estimates markedly. Perhaps more importantly, not only is diagnostic x ray by far the single largest source of exposure to manmade radiation, it is also the area in which the largest dose reduction can be made without having adverse effects on the important benefits these sources provide.

While exposure from medical and dental use of x-radiation is the largest source and easiest to reduce, the State of Maine has placed increased emphasis on the smallest of those sources, radiation exposure from manmade sources in the environment. In FY 1979 45 percent of the resources were allocated to environmental surveillance and 40 percent to x-ray surveillance. By FY 1981 the allocation to x ray fell to 15 percent. The expenditures for FY 1983 are expected to remain at 15 percent or less. This is occurring even though the number of medical and dental machines has increased from about 1240 units in 1979 to an estimated 1310 by 1981 (about 2.7 percent per year).

One reason for this decline has been the 1979 revocation of the Maine radiation revocation laws which had been originally promulgated in 1964. Another impact of this preemption (by the "Sunset Law") has been the lack of authority to register new sources of radiation. Without this authority the program can only estimate the number of units and their location. Currently, the State of Maine has no laws which relate to the safe and effective use of x rays in the healing arts.

Recommendation 1

Maine should take the necessary steps to correct the current legislative and regulatory voids that currently exist with respect to the use of radiation in the healing arts. Two resources are available to provide assistance in this important area: (1) The suggested model law which was endorsed this past summer (1982) by the Council of State Government, and (2) the Suggested State Regulations for the Control of Radiation which can provide for a comprehensive set of regulations that may need only minimal modification to be appropriate for Maine.

Budget:

The financial resources available to the radiation control program are presently provided only by outside sources. The program was initiated through federal funds which were intended as "seed money" to assist the State with start-up costs. Unfortunately the State budgeting process has not provided funds to maintain the program. Since the financial resources that are provided support only certain aspects of the program, the program

priorities are set by outside forces, not by public health need. Clearly, of the areas of potential exposure reduction, x ray use in the healing arts has the most potential for reducing exposure to the people of Maine, without reducing its benefits, yet no money is available from Maine for this program.

Should this situation continue only those healing arts users who are especially concerned about their patient exposures and those facilities that are required to have radiation surveys for private accreditation will have their equipment and technique evaluated. In addition there will be a lack of uniformity in those inspections since there is no "standard" or "recognized" evaluation protocol.

Recommendation 2

Maine should establish a source of funding that enables the State to provide the financial resources necessary to operate the radiation control program consistent with public health goals—not availability of outside funds.

Program Priorities:

Currently program priorities are determined by financial constraints placed upon the program. The only areas to which significant time is devoted are those which have funding. In the past the radiation control program was basically federally funded. As these funds have declined over the past several years so has the radiation control program except in those areas where private funds could be tapped. In 1979 some money was obtained from the nuclear power industry to assist in the environmental monitoring and emergency response planning tasks but still no money has been provided to control the largest sources and most easily correctible sources of unnecessary exposure to the people of Maine.

Recommendation 3

Immediate attention should be given to correcting the current methods of setting priorities. Resources should be allocated, to some large extent, based on the potential for the successful reduction of unnecessary radiation exposure. It must also be realized that the expenditure of resources to monitor radiation exposures or potential exposures is an important step in setting those priorities, but these activities do not in themselves result in the identification and control of unnecessary exposures. One important change in priorities must be to raise the priority placed on the reduction of exposure to people from x rays used in the healing arts.

Inspections

It seems that the only inspection work currently conducted in the healing arts use of x ray is under contract with the Food and Drug Administration for inspections of a limited number of x-ray installations less than one year old. This contract calls for inspections of x-ray equipment performance alone. These inspections do not evaluate how the x-ray equipment is set up with respect to the other required ancillary equipment such as film, screen, grid, processing, etc. These inspections are also limited to inspection of the equipment which is most likely to perform well by reason of its being newly installed. Problems that might arise from wear and tear of the equipment with use

will not be identified. For that, the people of Maine must rely on the user or facility personnel to detect and correct these problems before they adversely affect patient exposures.

The requirement placed on the radiation control program to utilize private consultants to alleviate these problems has not resulted in any benefits to date. Perhaps the largest impediment is financial although it certainly is not the only impediment. The above mentioned funding restrictions placed on the radiation control program result in no resources to even work out an acceptable approach to using consultants. Secondly, only one State in the U.S. has had very extensive experience with this approach and there is significant dissatisfaction within the executive branch of that State with the results. One other State which has recently begun a similar approach seems to be having more success but they have been in operation only a short period of time. It is incumbent upon the Maine Radiation Control Program to critically analyze these two existing programs and develop a program for Maine that will meet the needs of Maine and avoid the problems of other programs. Some of the critical questions that must be resolved include:

- What are the criteria that will be used to determine who is qualified to perform inspections acceptable to the State?
- How can conflicts-of-interest problems be avoided?
- What requirements need there be for upgrading the inspections for new technology and new equipment?
- Since the State cannot delegate its authority to private individuals for the enforcement of the Maine regulations, how can the information obtained by the State from private consultants be used in enforcement actions conducted by the State?
- Will this approach be considered legal if a situation should arise that would require resolution in the courts?

Recommendation 4

The use of competent technicians (private consultants) as a supplement to the radiation control program must be carefully developed to assure that the public health interests are met. Development must include specific regulations or policies that clearly outline how the program will be implemented. It must not reduce the States' authority in detecting and correcting radiological health problems.

Registration:

Since there are no regulations currently in force as a result of the action of the Sunset Laws, there are no requirements for registration of radiation devices with the State. By taking advantage of federal policies which require that the State radiation control agency be given a copy of the assemblers certification and the voluntary submission of registration data by former registrants, Maine has been able to keep the pre-existing registration system reasonably up-to-date for diagnostic x-ray machines used in the healing arts. There has not been, however, a concerted effort to determine if there might be some types of users who have not been made aware of the need to register equipment.

One of the plans for the future is the utilization of their word processor system to manage the registration program. This should not only reduce the clerical requirements for managing the registration program but it permits more flexible use of the information as well. One important area for consideration is that of having the ability to sort by type of equipment. With this ability when model-specific concerns are identified the State could determine whether or not there is equipment which might be included and if so, locate that equipment exactly. This rapid response could be significant in reducing the exposure problems.

Recommendation 5

New authority must be obtained for registration (Recommendation 1) and the registration program must be improved. The registration system should be expanded and automated to allow for a rapid and flexible response to data summaries.

A concerted effort should be made in the State to assure itself that all potential radiation users have been notified of the requirement (when re-enacted) to register their sources. Some areas to look at include industrial health clinics, State-owned institutions—especially educational (sports medicine), and other nontraditional health delivery centers.

Staffing:

This topic is of special concern. A quick review of the literature will demonstrate that the exposure problems in recent years are related more to the ways in which the x-ray equipment is selected and used in conducting examinations than to the equipment design and malfunction issues. This means that if public health benefits are to be realized in radiation control, the control programs must also be prepared to deal with the problems associated with the use of the equipment during diagnostic x-ray examinations.

Recommended staffing levels for these programs can be estimated using the guidance contained in the report "Criteria for Adequate Radiation Control Programs (X Ray)" (available from the Conference of Radiation Control Program Directors). This guidance is based upon the number of radiation sources and the situations in which they are used in a given State. In other words, the magnitude of the problems to be dealt with is used to determine the appropriate staffing level.

Assuming that the number of x-ray sources in Maine is fairly close to those currently in the voluntary registration program, there are approximately 1200 medical-dental tubes (some estimates are as high as 1300 tubes) and about 80 nonmedical tubes. For this workload the typical x-ray program should be staffed at 2.5 full-time equivalents plus clerical and management personnel. This of course assumes that the State would conduct all aspects of a total x-ray control program, that dental tubes would be screened every five years in a program like the DENT program, that medical facilities are inspected (without the help of a screening program) every year for hospitals and clinics and every two years for other medical facilities. This staffing level also assumes that the personnel are adequately qualified to handle the technical aspects of the use problems associated with medical and dental x ray and that because the staff are sufficiently qualified (i.e., specific training and experience), large amounts of time for staff training are not necessary.

The new requirement for the State to utilize private consultant reports obtained by the registrant to demonstrate degree of compliance with good practices requires revising the standard guidance to determine new estimates of the proper staffing levels. The difficulty here is that no programs have operated in this fashion long enough to provide a basis for such revisions. Additionally, since the Maine x-ray program has not been recently funded, there are no firm plans that detail exactly how this new program will be managed. However, by making some assumptions about how long certain actions would take and the amount of work required of the State to manage this new program it appears that the staffing requirements would be reduced but only slightly, from 2.5 to about 1.9 FTE. (See Appendix A for method of determination.)

Assuming that nonionizing sources of radiation will be included in new legislative powers, some consideration should be given to uses of lasers and high-powered RF sources such as those that might be found in the wood and paper industry. Many States have found a need to have at least some surveillance activities in these areas to assure that these sources are not causing immediate hazards.

The quality of the personnel required for the above activities places a special burden on a small State. For an equivalent level of protection for the public, the larger States will be able to operate programs with expertise available from several different members of the staff. Maine cannot afford the situation of having several people to draw upon and must, as a result, place special emphasis on obtaining staff that are broadly qualified. The program must also provide for keeping as well as attracting people. A high turnover in staff will prevent the program from making progress because of the time required for training and orienting new staff. The current budget problems and the need for developing the "consultant programs" make it very difficult to put together a logical/rational approach to staffing the x-ray control program.

Recommendation 6

The current staffing level devoted to x-ray control must be increased from the current estimated .77 FTE to at least 1.9 FTE plus appropriate clerical and administrative support in order for the program to begin to operate at an adequate level and to develop an effective x-ray control program utilizing private consultant reports. In adding this new staff, special attention should be paid to the qualifications and the training of the added staff in medical x-ray control issues.

Organization:

Currently the radiation control efforts are all combined within the same program. This is usually looked upon as a benefit in that personnel can be cross-trained and the highly technical demands of radiation control programs can provide sufficient challenge to those technically trained personnel so that they are likely to remain with the program.

There is, however, potential for splitting of radiation control responsibilities if legislation is passed for the credentialing of healing arts operators of radiation producing machines. It is our understanding that should the legislation be passed it is likely that the Business Regulations Department would have responsibility for implementing its provisions. Should this come to pass there will need to be close coordination between those responsible for the credentialing program and those responsible for the radiation control program. Inasmuch as the credentialing program is promoted on the basis of

efficient use of radiation on humans, the data collected by the radiation control program should be used to help direct the development of the credentialing program.

Recommendation 7

The various agencies in government must work together smoothly to effectively handle radiation control issues. In order to clarify how this cooperation should occur and to assure continuity as personnel change, memoranda of understanding or similar vehicles should be developed and used to assure that actions taken by the various agencies are mutually supportive.

Appendix A

Staffing Determination

Note: This does not include administrative and clerical support!

<u>Activity</u>	<u>"Typical" Staffing</u>	<u>"Consultants" Staffing</u>
Inspection, Followup and Registration		
1. Dental, Medical and Industrial inspections (0.8 FTE/1000 tubes)	0.96	? (Industrial)
2. Followup on noncompliances & registration (0.2 FTE/1000 tubes)	0.24	0.24
3. Followup on consultants (10%)	0	0.096
4. Management of consultants program (approvals, communications, etc.)	0	0.2
Education and Quality Assurance (0.5 FTE/1000)	0.6	0.6
Staff Training (New Technology, turnover) (0.1 FTE/1000)	0.12	0.12
Special Projects (0.2 FTE/1000)	0.28	0.28
Miscellaneous (0.3 FTE/1000)	0.36	0.36
TOTAL - 2.1 FTE/1000 tubes	2.56	1.9



October 19, 1982

Office Of
The Regional Director
585 Commercial Street
Boston, Massachusetts 02109

RECEIVED OCT 22 1982

Mr. Charles Hardin
Executive Secretary
Conference of Radiation
Control Directors
65 Fountain Place
Frankfort, Kentucky 40601

Dear Mr. Hardin:

Attached is my report on our recent evaluation of Maine's Radiation Control Program. I have limited my report to x-ray and non-ionizing aspects of Maine's program since these were the areas which I reviewed. I have also included a comparison of the salary schedules for several positions in other New England radiation control programs. When we were in Maine, Wallace Hinckley mentioned that such a comparison would be helpful to his program.

It was a pleasure working with you and the rest of the evaluation team. If you have any questions concerning my report, please feel free to contact me.

Sincerely,

Warren W. Church

Warren W. Church
Regional Radiological Health
Representative
Region I

1981 Annual Salary Ranges For
 Selective Categories in
 New England Radiation Control Programs

<u>State</u>	<u>Rad. Health Director</u>	<u>Specialist</u>	<u>Principal Chemist</u>
CT	\$28K-\$35K	19.6K-23.9K	21.2K-25.9K
MA	21.8K-27K	15.4K-26K	15.8K-19.4K
ME	19.9K-26.1K	17.4-22.7K	16.8K-23K
NH	16.3K-20K	15K-18.3K	14.4K-17.6K
RI	23.2K-31.5K	17.7K-29.1K	19.2K-21.5K
VT	Not Available	Not Available	14K-15K

REVIEW OF MAINE'S RADIATION CONTROL PROGRAM

INDUSTRIAL AND MEDICAL X-RAY PROGRAM

Current Program

Maine's Medical X-Ray Program is currently limited to carrying out its FDA compliance testing contract which calls for the evaluation of 40 newly installed x-ray units per year. Other than a voluntary registration program there are no other medical x-ray activities. Important areas not being addressed include: 1. Industrial x-ray equipment; 2. Dental x-ray equipment; 3. Medical x-ray installations over one year old; 4. X-ray user control; 5. X-ray personnel protection; 6. X-ray protection in the environs of x-ray facilities; and 7. X-ray user qualifications and training. In short, at the present time Maine has no coordinated program or activities to insure that unnecessary radiation exposure from medical and industrial x-ray sources is kept at a minimum.

There exists enabling legislation providing for the spectrum of activities necessary for a well-rounded program; however, recent addition, Title 10, Section 103.11, has added some ambiguity to these laws. This Section charges the Health Department with the responsibility promulgating "rules requiring periodic certification and calibration of this equipment by Certified Technicians". The law does not specify the types of calibration nor does it define "Certified Technicians".

There are no rules and regulations specifying requirements and standards for the use of x-ray equipment. The latest rules and regulations having been allowed to expire in 1981. The Department is empowered to utilize temporary regulations in order to abate serious conditions due to an emergency.

Other than dedicated funds for the federal x-ray contract, the Department has no available funds from which to carry out an x-ray control program.

Personnel

In terms of personnel, the State is not adequately equipped to handle a well-rounded x-ray protection program. One person has extensive training and experience to perform a variety of x-ray inspections. Other staff members have had only a limited x-ray training and experience in x-ray protection.

Equipment

At the present time, Maine's x-ray equipment is essentially limited to two MDH survey meters and a federal compliance testing kit, all of which are on loan from the FDA.

Recommendations

It is my understanding that the Maine Department of Health is currently under mandates from the State Legislature to implement an x-ray inspection system in which private consultants would periodically provide medical and dental x-ray survey data to the State. Since this is not completely clear in the current law, it should be clarified in future legislation, i.e., current legislation makes reference to "calibration by competent technicians"; it does not address other aspects of x-ray protection nor does it define what is meant by a "competent technician".

In order to implement an x-ray consultant x-ray inspection program, it is suggested that the following action items be carried out:

1. Clarify enabling legislation as mentioned above.
2. Institute rules and regulations governing the mechanics of the Program including:
 - a) consultant credentials
 - b) inspection components and frequency
 - c) auditing program
 - d) inspection fee schedule
3. Establish rules and regulations to cover requirements for x-ray users. It is further recommended that the Suggested State Regulations for Control of Radiation (SSRCRs) be adopted.
4. Establish stable source of funding to cover oversight and auditing of the Program. Funding will also be needed to cover State follow-up inspections and any necessary regulatory action.
5. In addition to a regulatory inspection program, the State should implement non-regulatory x-ray protection activities in order to effectively carry out its goals of minimizing unnecessary radiation exposure. Specifically, a quality assurance program should be instituted which would promote quality assurance activities in individual x-ray facilities.
6. It is estimated that a total of two State man years would be required to both oversee the consultant program and to carry out the other non-regulatory aspects of the radiation control program.
7. A radiation control program should also be established for non-medical users of x-rays including the establishment of rules and regulations. Again, adoption of appropriate sections of the SSRCRs is recommended. An additional .5 man year would be required for this effort.

Because of the many problems involved with implementation of a consultant program, it is suggested that Maine consider reinstituting an x-ray protection program based on State inspections rather than consultants. It is estimated (from Task Force Quality Assurance Report) that a total x-ray protection program including inspections and quality assurance activities could be carried out with 3 State man years/year. This would only be 0.5 man years more than if the consultant program were implemented.

Such a program could be made even more efficient by utilizing surveys done by private consultants for hospitals. For example, in inspecting hospital x-ray facilities, the State Inspector need not inspect all x-ray units. Instead, he would review the consultant's reports and check to make sure follow-up actions have been taken on defective items. He might perform physical inspections on one or two random units and on items not covered by the consultant.

If the x-ray inspectors are also cross-trained in radioactive materials, as is recommended in a small State program such as Maine's, then the inspector could also carry out any needed R/M inspections and activities while in the facility.

NON-IONIZING RADIATION CONTROL PROGRAM

Present Activities

The State of Maine is not currently conducting any non-ionizing activities. They have no applicable enabling legislation nor is there any applicable rules and regulations on the books.

Recommendations

1. Enabling legislation should be established to cover the wide range of non-ionizing hazards from RF radiation to UV light.
2. Non-ionizing regulations are not recommended at this time; however, a survey should be taken to determine if any non-ionizing radiation hazards exist in Maine that should be regulated. The use of RF sealers or dryers by the paper industry would be an example.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION I

J. F. KENNEDY FEDERAL BUILDING, BOSTON, MASSACHUSETTS 02203

September 27, 1982

Mr. Charles M. Hardin
Executive Secretary
Conference of Radiation
Control Program Directors, Inc
65 Fountain Place
Frankfort, Kentucky 40601

RECEIVED OCT 28 1982

Dear Chuck:

In response to a formal request from Mr. Wallace Hinckley, manager, Maine Radiological Health Program dated June 29, 1982, the Conference of Radiation Control Program Directors, Inc, agreed to perform a formal review of Maine's Program, and to provide Maine a report on its findings and recommendations. At your request, I served as a member of the team (other members besides yourself were; Gene Fisher, N.J. Dept. of Environmental Protection; Richard Gross, Bureau of Radiological Health, FDA; James Ashley, Office of State Programs, NRC; and Warren Church, Region I Radiological Health Representative, FDA) which conducted the review of September 13-16, 1982.

At your request, I particularly reviewed Maine's efforts in the area of environmental radiation surveillance, and my comments are directed to this part of the program.

According to figures supplied by Mr. Hoxie and Mr. Hinckley, Maine is presently committing 2.1 FTE's to the environmental radiation program. This includes approximately 1.3 FTE from the Radiological Health Program and 0.8 FTE from the Public Health Laboratory. Major activities include collecting and analyzing environmental samples in the vicinity of Eastport (PT. LePreau Nuclear Power Station, New Brunswick), Wiscasset (Maine Yankee Nuclear Power Station) and York County (Seabrook Nuclear Power Station and Portsmouth Naval Shipyard), as well as operating a network of TLD gamma monitoring stations in each location. Other activities include a limited amount of work in the area of high radon levels in well-water supplies.

Funding for the environmental surveillance activities around Maine Yankee is presently provided by a special levy on Maine Yankee and by a contract with the NRC. Funds for this year's activities at Eastport and in southern Maine were apparently "found" by the Governor's office, and should be requested from and approved by the legislature as a regularly funded item in the next fiscal year's budget (i.e. these activities are necessary, but the power reactors are in New Brunswick and New Hampshire, and the Navy Yard is a federal entity. Therefore, it does not appear that Maine can require payment into a dedicated fund, as it has for Maine Yankee).

The Public Health Laboratory is a long-time subscriber to and participant in EPA's Environmental Radioactivity Laboratory Intercomparisons Studies Program provided by the Quality Assurance Division of EPA's Environmental Monitoring Systems Laboratory in Las Vegas. The Maine Laboratory has consistently maintained a high level of performance, and has demonstrated an ability to promptly detect, identify and correct adverse trends in analytical procedures.

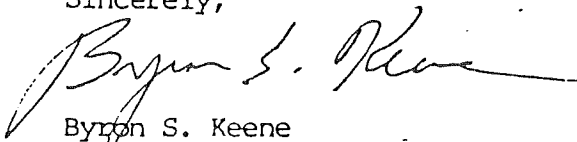
In my opinion, the present size and effort of the environmental ionizing radiation surveillance program in Maine is optimum. No attempt was made to explore any needs in the non-ionizing (i.e. radio-frequency) field, since there is no consensus at either the federal or state level as to what constitute needed or desirable activities in this area.

I recommend that Maine's environmental radiation surveillance program be continued at it's present level of effort. As noted, the funding medianism for this program needs to be clarified by legislative recognition in the annual budget. I understand that you and Gene Fisher will be addressing the overall funding problems in your portion of the report and recommendations, and I ask that you include this matter as one of your concerns.

I also recommend that the Radiological Health Program issue an annual report on its environmental surveillance activities and findings. Apparently a report to the NRC is required under the terms of the NRC contract. However, this appears to cover only the activities in the area of Maine Yankee. An annual report which also included the Eastport and York County activities, and radon-in-water activities, and which was brought to the attention of the proper members of the legislature prior to budget hearings might help in assuring adequate funding for the program.

For your information, while I was back in Maine on the weekend after our review, I noticed an item in the Portland Press Herald for Saturday, September 18th which said that Judy Kany (our legislative friend) was going to take steps to see that the Maine Department of Health had an adequate radiation program and regulations in place. It stated she was "shocked" (sound familiar?) to learn that the former regulations had lapsed. It sounds like she meant it when she told us she'd follow through on the matter.

Sincerely,



Byron S. Keene
Regional Radiation Representative

cc: Wallace Hinckley

Report of the Review of the Radioactive Materials Aspects of
the Maine Radiation Control Program (RCP)

E. C. Ashley
September 13-15, 1982

At the request of Wallace Hinckley, Director, Maine radiation control program, the Conference of Radiation Control Program Directors, Inc. conducted a review of Maine's non-agreement State radiation control program. The review was performed by a team of representatives from the Conference, State of New Jersey, USFDA, USEPA and USNRC.

The subjects of legislation, regulations and funding were covered by other members of the review team and, therefore will not be discussed here in any detail. This review covered the radioactive material aspects of the Maine radiation control program.

NRC Regulated Activities

At the time of this review there were 95 NRC radioactive material licenses issued to persons in the State. Copies of licenses and amendments are received from NRC and placed in folders and filed alphabetically by licensee name. A spot check of these files showed the documents to be placed loose in the folders and not in any particular order. Some of the folders also contain NRC enforcement correspondence. The RCP screens all enforcement correspondence as received from NRC. Some are filed while others are discarded. It was recommended that all documents in the folders be organized chronologically, by license, and bound in the folder.

The reviewer provided a 9/8/82 computer printout of all NRC radioactive material licenses in Maine to Mr. Hinckley. It was recommended that Mr. Hinckley request a computer printout approximately annually as an aid in keeping current his information on NRC materials licenses in Maine.

The RCP has not accompanied the NRC during routine inspections of NRC licenses in Maine for several years according to Mr. Hinckley. It was recommended that Mr. Hinckley call NRC Region I and request that the State be notified of all planned routine inspections of material licenses in Maine so that an RCP representative may accompany the NRC inspectors. This would be an aid in training RCP personnel for NARM* inspections. The Maine RCP does not now have a compliance program for NARM. The RCP has, on occasion, conducted investigations into lost or leaking sources at the request of NRC Region I.

* Naturally occurring and accelerator produced radioactive material.

NARM Regulation

The RCP has a voluntary registration program for X-Ray and NARM. The main purpose of the registry is X-Ray but registrants do include NARM on the submitted form. Mr. Hinckley estimated there are about 26 NARM users at the present time. The reviewer received the impression that the RCP considers radium separately from other NARM sources. Of the estimated 26 NARM users, 20 are radium.

Until the time the RCP has a separate registry or licensing system for NARM, it was recommended that X-Ray registrant folders that also contain information on NARM be highlighted for easy identification.

Mr. Hinckley indicated that proper funding would allow him to organize and staff the RCP such that one person could be assigned part time to licensing/registering and compliance functions for NARM.