

FOREWORD

This review has been prepared from a study undertaken by the author following the award of a World Health Organization Fellowship for a three month period in 1979. The study was undertaken in Canada and the U.S.A. to determine methods used in those countries to overcome problems in the control of radiation, to prescribe standards for such purposes and to ensure that compliance with the standards is achieved.

In both Canada and the U.S.A., several authorities exercise control over the manufacture, import, distribution and use of radiation sources, the relevant authority depending on the particular control requirement and on the type of source. Nevertheless, within each country there is a degree of collaboration between the authorities in the overall control of radiation and a desire to achieve a uniform approach to control measures. This review outlines the relevant Acts and Regulations and the action taken by various authorities in the implementation of legislation. It also outlines the efforts undertaken to reduce even further the existing levels of exposure of individuals and of the general public. It is noted, that in both countries, the federal governments play very important roles in assisting the Provinces and States in programs undertaken to reduce these radiation exposures.

Following this study, it has been possible to suggest a number of options that could be applied in the Australian scene for the control of radiation. It is recognized that some options could take some time to implement and take effect. However, other options, or parts of them, could be implemented without too much delay and this could result in a substantial reduction in the exposure of individuals and of the public in the immediate future.

The author gratefully acknowledges the World Health Organization in awarding the Fellowship and the assistance so readily given by all persons with whom he held discussions in Canada and the U.S.A. This review is issued as an attachment to the author's report to the World Health Organization following completion of the study. It is being issued to relevant authorities and interested parties for consideration of the most appropriate measures that could be taken to ensure effective and uniform control of radiation in Australia.

INTRODUCTION

It has been recognised for many decades that hazards arise in the exposure of persons to ionizing radiation, and more recently to non-ionizing radiation, and action needs to be taken to minimize such exposures to safeguard the public health. Accordingly radiation sources* are subject to regulatory control in most countries. In countries, such as Australia, there may be a number of governments with regulatory authority in these matters. The extent of the hazard to the population will depend largely on the activities of the governments legislating to provide adequate control and on the administration of associated regulations.

There is a need in those countries with a number of autonomous governments, for the governments to make a uniform approach to the control of radiation so that one part of the population is at no greater risk from exposure than other parts of the population. In Australia, regulations covering the control of radioactive substances and irradiating apparatuses have been in existence for about 20 years. However, the approach to the administration of the various regulations varies considerably by the different governments and consequently uniform control is not always obtained throughout the country. An outline of methods used to achieve control of radiation in Australia is given in Annexe I.

In order to determine methods used to overcome problems in achieving adequate control over radiation, a study was undertaken in Canada and the USA of the following:

- how federal/State (Provincial)** co-operation in other countries of similar constitution to Australia achieves effective control of radiation sources,
- procedures followed for investigating the hazards arising in the use of radiation sources, including surveys undertaken to assess their public health implications, and
- the preparation of codes of practice, performance standards and procedures for testing sources for compliance with prescribed standards.

* throughout this review, the term "radiation sources" includes radioactive substances and devices that emit ionizing radiation. In some uses, the term also includes devices that emit non-ionizing radiation, but it is not considered important to distinguish these uses each time the term appears.

** throughout this review, "Province" is used when referring specifically to the Canadian scene and "State" used for the USA scene. Where the review refers to both countries the word "State" includes Provinces in Canada and States and Territories of the U.S.A.

Canada and USA were chosen as suitable countries to undertake the study as they both have federal and State governments and the relationships between the governments in each of these countries are similar to those between the various governments in Australia. Canada in particular has a similar number of Provinces as Australia has States, a population about 50% greater and a population distribution not unlike that of Australia.

Two months (20 August - 19 October 1979) were spent at the Radiation Protection Bureau (RPB) of the Department of National Health and Welfare, Ottawa, Canada and one month (22 October - 16 November 1979) at the Bureau of Radiological Health (BRH) of the Department of Health, Education and Welfare, Rockville, Maryland, USA.

During the two month period in Canada, several visits were paid to the Atomic Energy Control Board and its Laboratory, one day was spent at the National Research Council, Ottawa and one day was spent at the Ontario Ministry of Health, Toronto. Whilst in the USA visits were paid to the Nuclear Regulatory Commission and the Environmental Protection Agency, Washington and to the National Bureau of Standards, Gaithersburg, Maryland. Visits to all these places were considered necessary to cover as many aspects of radiation control as possible. At the Bureau of Radiological Health, brief discussions were also held with officers of various State regulatory authorities who were attending a meeting at the Bureau.

CONTROL OF RADIATION SOURCES IN CANADA AND USA

Before studying how federal/State co-operation is achieved, it was necessary to study the various Acts and Regulations covering radiation control in both countries. These Acts and Regulations are similar in a number of respects, but the approach to control differs somewhat. Controls in each country have their merits but they must be considered in relation to the extent to which control is necessary. Naturally, much greater facilities for control are needed for the larger population of USA - on the other hand, the larger population renders available a much greater expertise for the purpose.

In both countries there are several authorities responsible for the control of radiation sources. Briefly, control is effected as follows:

- . the manufacture, import and distribution of radioactive substances used for medical purposes are controlled under Food and Drug Acts by the federal Health Departments,
- . the possession, use, storage and disposal of most radioactive substances are controlled under Atomic Energy Acts and Regulations or by State Authorities,

- . the manufacture, import and distribution of radiation emitting devices are controlled under special Acts and Regulations through federal Health Departments, and
- . the possession and use of most radiation emitting devices are controlled by State authorities.

For most radiation sources likely to create public health hazards, design and performance standards are prepared and these standards promulgated as regulations under the relevant Acts. Radiation sources must comply with prescribed standards and rigorous compliance testing programs are necessary to ensure this is the case. The preparation of standards in Canada and USA follow similar lines, but they have different approaches to compliance testing procedures aimed at ensuring that the prescribed standards are met.

Both countries rely on collaboration between the federal and State radiation control authorities, even though regulations differ between the States of each country. However, there is a growing desire for a uniform approach to radiation control throughout each country and for the exposure of the general public to be reduced and kept as low as reasonably achievable. For this purpose, radiation control programs have been instituted in each country so that the contribution to the population dose from individual radiation sources can be assessed and steps taken to reduce that contribution. It has been found that such programs need to be undertaken on a national level, with considerable federal input and with State collaboration. The federal funding of such programs has been the only way by which substantial reduction of the public health hazard from radiation sources has been achieved.

Reference has been made to the control of the manufacture, import and distribution of radiation sources under federal Acts and Regulations. The need for federal legislation grew out of the problems facing the States in carrying out comprehensive radiation control programs and in ensuring that at least new devices coming into use met acceptable standards. It was recognised by the States that only the federal governments had any power to institute such standards. Greater detail of the various federal Acts and Regulations in Canada and the USA is given in Annexe II.

PREPARATION OF STANDARDS

The preparation of acceptable standards for regulatory purposes for controlling radiation emissions from devices is a very important, but time consuming effort. The standards must be not only such that radiation emissions

are reduced to acceptable levels, but also such that the design and performance of equipment is technically and economically feasible. In Canada and USA, the preparation of standards follows similar lines of action. Before a standard is prepared, however, assessments are made to determine the likely hazard arising from a particular type of device and its use and prevalence throughout the community. The assessment may arise as a result of surveys undertaken, reports of accidents, information in the literature or questions arising from users or the general public.

After the preparation of necessary background information for a standard, a draft standard is published in the official government gazette and comments invited from the general public and from professional associations, industry, labour organizations, etc. who would have a direct interest in the standard and who would be able to contribute to ensuring that the standard is acceptable to all parties. Such an interchange between the agency preparing the standard and others may take many months before a final suitable standard is available. This final standard would then be published in the government gazette as a regulation under the enabling Act. A date from which the regulation would be effective is also published and all devices manufactured and imported after that date must comply with the regulation.

As a result of comment from the general public and interested parties, it sometimes appears that it would be preferable to prepare a code of practice or recommendation rather than a regulation. Codes of practice and recommendations do not have the force of law, as does a regulation. Nevertheless, States can use codes of practice and recommendations as guides in implementing their regulations.

Devices that are subject to regulations must be tested in due course for compliance with the regulations. For this purpose, compliance testing procedures are prepared, but not necessarily included in the regulations. Such procedures can be issued as guidelines for manufacturers and for inspectors. This is necessary, so that in the event of there being a choice of compliance testing procedures, different choices of parameters do not result in conflicts in the interpretation of compliance. The procedures followed in Canada and USA for preparation of standards are given in Annexe III.

IMPLEMENTATION OF REGULATIONS

The various Acts in both countries provide for regulations to control radiation sources, but implementation of the regulations varies according to the type of radiation source involved. These are discussed briefly here, with more detail given in Annexe IV.

Radioactive Substances in Canada

Radioactive substances and devices containing radioactive substances are controlled by the Atomic Energy Control Board (AECB) through the Atomic Energy Act (1946, amended 1954). The Provinces have no authority over radioactive substances whatsoever. Regulations introduced under the Act cover the designation of workers, maximum permissible doses received by workers and dose limits for members of the public exposed to radioactive substances, monitoring requirements, instruction and qualification of radiation workers, disposal and discharge of radioactive wastes and the security and export of radioactive substances and of devices containing such substances. Inspections are carried out by AECB inspectors or by Provincial inspectors who report direct to AECB and not back to the Provinces. The Provincial inspectors are seconded to the AECB for this purpose and the latter pays all costs associated with the inspections and trains the inspectors.

AECB sets out guidelines for licensing requirements and for the safe use of radioactive substances. The guidelines set down specific requirements for radioactive substances, compliance with which must be obtained before licences are granted. Users of radiopharmaceuticals are also subject to approval by an Advisory Committee on Clinical Uses of Radionuclides.

Radioactive Substances in USA

The licensing and regulatory functions in USA are the responsibility of the Nuclear Regulatory Commission (NRC) under the Atomic Energy Act, 1954 with 1959 Amendments and the Energy Reorganisation Act 1974. The Act only allows the NRC to regulate by-product, source and special nuclear radioactive material. Regulations cover safety requirements, protection standards for workers and members of the public exposed to these substances, disposal and discharge of radioactive substances and maximum permissible concentrations of contaminants in air and water. The 1959 Amendments allowed States to enter into agreements with the NRC -

the so-called "Agreement States" - to license and have responsibility for control of these substances. Such States also carry out inspections provided their regulatory programs are compatible with NRC's requirements. The NRC funds such States in its regulatory programs and trains the inspectors.

The licensing and control of other radioactive materials - naturally occurring and accelerator produced radioactive materials (NARM) is left to the States. Most States have some regulations covering these materials, but a few make no or very little attempt to license or register these materials. Where regulations are available, the same type of control is exercised over NARM as over the other type radioactive materials. The States carry out any inspections of NARM. Performance standards have been prepared for these materials, but they may not always be included in regulations.

Radiation Emitting Devices in Canada

Control of radiation emitting devices is effected by the Radiation Protection Bureau (RPB) of the Environmental Health Directorate of the Department of National Health and Welfare through the Radiation Emitting Devices Act (1969) at the manufacture, import and distribution stage. The Act provides for the prescribing by regulation of classes of radiation emitting devices and of standards regulating the design, construction and functioning of those classes of devices.

Inspection of devices to determine compliance with prescribed standards is often made in conjunction with manufacturers prior to marketing or in the field. Manufacturers are not legally required to advise RPB of new or modified devices coming on to the market so that an extensive field inspection system is necessary. Inspections are carried out by RPB, but not by Provincial officers, although the Provinces are informed of the inspections out of courtesy.

Regulations exist in all Provinces in Canada for the control of X-ray equipment, but not always of non-ionizing radiation equipment. Regulations generally cover registration of equipment, installation and use of equipment, requirements for persons using equipment, maximum permissible doses received by workers and members of the public. Provincial inspectors carry out inspections to determine compliance with the Provincial regulations, but in some Provinces the inspections are carried out by RPB on behalf of the Provinces. RPB has the authority

to inspect radiation emitting devices in all federal departments and undertakings. Such places are required to inform RPB of equipment and to comply with prescribed requirements on radiation protection. Radiation workers are required to use the Personnel Monitoring Service of RPB.

Radiation Emitting Devices in USA

The Radiation Control for Health and Safety Act (1968) is administered by the Department of Health, Education and Welfare through its Bureau of Radiological Health (BRH) of the Food and Drug Administration (FDA). It provides for the prescribing by regulation of performance standards for radiation emitting electronic products and of products that emit radiation of which electronic products are components. The Act applies at the manufacture, import and distribution stage of such products. It also provides for studies to be undertaken in relation to such radiation emissions and to means by which they might be reduced.

Under this Act, manufacturers must certify that their products comply with prescribed standards and, before marketing, must submit to BRH their quality control programs and test procedures to show how compliance will be achieved during their manufacture. The quality control programs and test procedures are inspected periodically by FDA inspectors or by State inspectors who are paid a fee for such inspections. Failure by a manufacturer to meet the prescribed standards for equipment or to have a satisfactory quality control program can result in the Department of Health, Education and Welfare disapproving the program. The manufacturer cannot market his goods until this is rectified. In-house tests to show compliance may be carried out by BRH, but most testing is at manufacturer's premises or in the field.

Electronic products that do not comply with standards are to be modified or withdrawn from the market. The action to be taken will depend on the degree and type of non-compliance.

In addition to ensuring compliance with the regulations of Radiation Control for Health and Safety Act, regulations for the safe use of radiation emitting devices exist in all States. About one half of the States have some legislation that also covers non-ionizing radiation sources. The regulation in the States cover licensing and registration, inspection, exposure to workers and members of the public, monitoring, exemptions, etc. and in some cases they include some basic standards for equipment. Inspections for compliance with the State regulations are carried out by State inspectors, but the programs for this purpose vary considerably between the States.

SUPPLEMENTARY RADIATION CONTROL PROGRAMS

Canada

Apart from programs undertaken to ensure compliance with the relevant regulations, programs at present exist on a Provincial basis, rather than a federal basis for reduction of radiation exposure. For example, in one Province one program undertaken in conjunction with inspectorial activities requires that X-ray equipment in use delivers radiation within specified dose ranges. The dose ranges take into account the functioning of X-ray equipment as well as the image receptor system and processing conditions. In the event that these dose ranges are not met, owners of equipment are required to undertake corrective action.

Records of radiation exposure of patients are also being maintained and these are scrutinized on a periodical basis to determine trends. As part of this program, participants in the program have instituted quality control for processing of radiographic films and this is also studied in association with the records of radiation exposure. This program forms a peer review of facilities and procedures and is organized by a committee comprising representatives of the Ministry of Health, radiologists, radiographers, hospital administrators, hospital physicists, manufacturers and referring physicians.

As part of a program to determine the exposure of patients on the national level, RPB plans to make use of the American NEXT (Nationwide Evaluation of X-ray Trends) program. Use of this program will make it possible to obtain a better surveillance of radiation exposure throughout the country, to determine how and where radiation exposures can be reduced, to pin-point areas of types of equipment and procedures where more intensive research and study are necessary and to highlight the need for modifying or strengthening any of the prescribed standards.

USA

Most radiation control programs in the USA are initiated at the federal level by BRH, but carried out by or in collaboration with the States. Reference has been made above to NEXT programs and BRH was highly involved in initiating these so that a national surveillance of radiation exposure could be obtained. The States collaborated in this, but the program has been refined to such an extent that BRH involvement is now minimal and the States use this program as they consider necessary. The intention of these programs is to evaluate the X-ray output and the dose delivered to standard "patients"

for various radiographic examinations and to investigate techniques and procedures used in X-ray departments and practices if the output and doses are found to be outside specified ranges. These ranges take into account the different type image receptors likely to be used. Measurements in the various X-ray departments and practices are often made in conjunction with inspections by the States for either compliance with the State regulations or for compliance with prescribed standards under the Radiation Control for Health and Safety Act. Unfortunately, the co-operation by the States is not as good as had been hoped or as good as when the programs were first put into operation. Nevertheless, the States do have the power to delicense or deregister X-ray equipment if it is found to be unsatisfactory as a result of these programs. At present, because of BRH's efforts in simplifying the procedures and calculations involved in the NEXT programs, State inspectors are able to assess the performance of X-ray equipments on the spot.

Other programs, such as DENT (Dental Exposure Normalization Technique) and BENT (Breast Exposure Normalization Techniques) are undertaken by BRH, with assistance from the States. All these programs aim to optimize the facilities in X-ray departments and practices so that suitable diagnostic quality images are obtained with the minimum radiation exposure. Radiotherapy departments are also involved in "therapy" surveys and co-operation of hospital physicists is obtained through the Medical Devices Amendments requiring the safe use of devices.

As a further step in obtaining non-regulatory control over the use of radiation, BRH, through the States, is encouraging X-ray departments and practices to set up their own quality assurance programs. After developing its own expertise in this matter, BRH prepared manuals for use in the departments and practices. State inspectors assist departments and practices in the implementation of such programs.

Efforts to reduce radiation exposure to patients are being undertaken by educational programs to:

- . educate radiologists and radiographers in the need for reduction of exposure and in methods of achieving this,
- . by recommending syllabi for training radiographers (diagnostic and therapy) so that a uniform standard is achieved throughout USA and for teaching undergraduate medical students, and
- . for the education of the public through group discussions and lectures by FDA personnel on a variety of health topics, including radiation.

Further, a Committee has been set up in consultation with the various medical colleges for determining and recommending referral criteria for the selection of patients undergoing specific diagnostic examination - pelvimetry, chest, skull and urocytography.

Control in teaching hospitals is also effected through a voluntary organization - the Joint Commission on Accreditation of Hospitals. The Commission inspects X-ray departments every year or two and checks on the quality control programs used in the departments. Failure to meet standards may mean decreditation and this will curtail or stop the teaching program of the department and may also mean restriction in funds for purchasing new or extra equipment.

FEDERAL/STATE INTERACTIONS

In both Canada and USA, the State officers responsible for radiation control programs meet at least once each year and discuss matters of mutual interest and concern in these programs, the interpretation of regulations and the updating of regulations. Federal agencies involved in radiation control programs also meet with the State officials so that all concerned can come to common agreement to solutions to the problems arising. In Canada, the Committee is the Federal-Provincial Sub-Committee on Radiation Surveillance and is supported by the Federal government and in USA the meeting is the Conference of Radiation Control Program Directors and this is sponsored by BRH, NRC and Environmental Protection Agency (EPA).

As indicated earlier, recognition of the need for uniform control of radiation emitting devices arose in both countries from the States and it was the meeting of the State officials that afforded the opportunity to present this need to the federal governments. In the USA, problems beyond the capabilities of an individual State are addressed through task forces and workshops of the Conference. At the present time, the Conference is updating the model Regulations for Control of Radiation so that the implementation of these in all States would result in a uniform approach to control of radiation throughout the USA. It was through the Conferences that BRH has been able to implement programs such as NEXT, as several States desired an approach through which effective control of radiation would be obtained. BRH developed, in collaboration with the States, methodology for such programs and this has been continually improved over its years of use.

Fortunately, the federal governments of both countries have had the basic philosophy of assisting the States in regulatory controls relating to the health of the people. In regard to radiation hazards, this assistance has been in advisory and surveillance facilities as well as in financial assistance. It has also resulted in the enactment of Federal Acts and Regulations covering radiation emitting devices. In USA, financial assistance is given directly to the States so that federal compliance testing and federal radiation control programs can be undertaken, whereas in Canada, the federal government pays all costs for those Provincial inspections it undertakes. It also carries out compliance testing under the RED Act and will be carrying out NEXT programs.

For programs such as NEXT, no payment is made to States in USA for their involvement in those. However, for such programs, BRH has made available to the States, free of charge, a quantity of equipment for the purposes of carrying out these programs. The equipment is also used by the States for their own programs. In addition, BRH as part of this collaborative effort, calibrates, free of charge, dosimeters and other instruments used by the States in their programs. In addition, measurements involved with NEXT programs are often carried out at the time of compliance inspections by the States (for which a fee is paid) so that travelling costs associated with the programs are basically covered in the inspection fee.

The States do not carry out inspections in Federal departments and agencies in the USA, each department or agency being expected to carry out its own radiation control program. BRH trains staff of these departments and agencies specifically for this purpose.

The Radiation Control for Health and Safety Act required the Secretary, DHEW, to undertake a study of the then "State and Federal Control of health hazards from electronic product radiation and other types of ionizing radiation". In his report of 1 January 1970 to Congress, the Secretary reported that the States had sufficient regulatory authority to control the possession and use of electronic product and other sources of ionizing radiation, but not of non-ionizing radiation. Gaps exist in the regulatory authority of some States because of exemptions from control given to certain professions and radiation facilities.

The Secretary reported that some compliance testing is carried out, but this varies throughout the country with State programs for this purpose ranging from deficient and inadequate to comprehensive and satisfactory. Many radiation facilities and sources have not been brought into compliance with acceptable standards and nor are adequate registration records kept in a number of cases. Additional manpower is required by the States to enable satisfactory programs to be put into operation, but Agreement States are in a much better position than non-Agreement States. Funds are also necessary to provide effective control of hazards from electronic product radiation at the user level.

Subsequent to the report to Congress by the Secretary, the federal government has made significant contributions to the control of radiation and there has been increased collaboration between federal agencies and the States. By States becoming Agreement States with the NRC and entering into agreements with BRH for regulatory purposes, they have greater funding available for their radiation control programs and this has given them much more rigorous control over radiation sources and has resulted in the lowering of radiation hazards to the general public.

OPTIONS FOR EFFECTING BETTER CONTROL OF RADIATION IN AUSTRALIA

The study was undertaken to determine methods used to overcome problems in achieving adequate control over radiation in countries with similarly constituted governments as those in Australia. From this, it should be possible to determine appropriate methods that might be used in Australia.

Australian States and the Northern Territory already have a sound basis, through their health Acts and Regulations, for the control of the possession and use of radioactive substances and of devices that emit ionising radiation. Some States have or are developing regulations covering sources that emit non-ionizing radiation. With the exception of control over uranium mining activities, it is fortunate that control is exercised through only one authority in each State and the Northern Territory and not through a number of authorities as in Canada and the USA. However, there is no authority exercising control over and setting legal standards for radiation sources manufactured in and imported into Australia. Because of this, the States and the Northern Territory have very little basis for refusing to license radiation sources and this situation needs remedying.

There exists in Australia a Laboratory which has a number of functions similar to those of RPB and BRH, but without any regulatory authority. This is the Australian Radiation Laboratory (ARL) of the Commonwealth Department of Health. In 1976, its functions were revised so that it now has a national role in the surveillance of radiation exposure to the public. This Laboratory is in a unique position to take action so that some of the deficiencies in the Australian scene can be overcome.

In order that some of the problems existing in Australia are overcome, rigorous and consistent radiation control programs need to be introduced on a national level. Before such programs can be instituted, ARL should undertake:

- . surveys and assessments to determine those radiation sources that present potential hazards to the public, and
- . the preparation of standards, codes of practice and compliance test procedures for those types of radiation sources.

These activities should be undertaken, regardless of any options adopted for control of radiation sources as they are basic ingredients to subsequent action. Surveys may be carried out in local areas for sampling purposes or on national level on the basis of NEXT, DENT and BENT type programs. It is recognized that collaboration with State Health Authorities may be necessary in this regard, but such collaboration should be left at a level so that State activities are not disrupted significantly.

It is not proposed to outline in this review mechanisms for preparation of standards, codes of practice and compliance test procedures. The actual mechanism to be adopted will depend on decisions taken with respect to future legislation dealing with radiation control. However, the general pattern used in Canada and the USA should be followed, i.e. the development of standards should be a collaborative effort involving input from interested parties. Where standards are in existence, either in Australia or overseas and they are considered suitable for Australian conditions, then ARL could recommend the use of these, rather than developing new standards from the beginning.

The following options for obtaining satisfactory radiation safety throughout the country warrant consideration -

Option 1. Recommend through the National Health and Medical Research Committee (NHMRC) that the States adopt, as part of their licensing procedures, the standards, codes of practice and compliance testing procedures prepared or recommended by ARL. (This would be the simplest method available, but because of the differing attitudes of State Health Authorities to the implementation of NHMRC recommendations in the past, there would be no guarantee that such an option would improve the present situation, at least not for a very long time.)

Following the above action, the Commonwealth should fund and institute radiation control programs to confirm compliance of radiation sources with standards. Inspections in such programs could be undertaken by either Commonwealth officers on behalf of the States or by State officers. The Commonwealth would need to have access to the results of inspection, so that the need for future legislation could be considered in the light of such inspections. Such programs would not infringe on State rights, but the States would be expected to use their licensing powers to have radiation sources modified and brought into line with standards or to have sources delicensed if they are of a very hazardous nature.

Option 2. Recommend through the NHMRC that the States incorporate the standards prepared or recommended by ARL into their regulations, rather than adopt them for their use as part of their licensing programs. For this, it may well be necessary for the Acts in the States to be modified to allow for regulation to be made on the design and performance of radiation sources (so that non-ionizing radiation sources would be included). All States would need to regulate a particular standard at approximately the same time. It would also be necessary that the States carry out comprehensive radiation protection programs to ensure that the regulations are being met and to require corrective action to be taken when necessary. ARL would prepare compliance testing procedures for use with these standards.

Option 3. The Commonwealth to pass an Act, allowing for regulations to control the manufacture, import and distribution of radiation sources. As in Canada, this could be by virtue of the power of the Commonwealth Government over interstate and foreign trade and commerce, if other powers are not available. Alternatively, the States could request the Commonwealth to legislate for such control. Any such Act would need to be considered carefully. It would need

to overcome some of the deficiencies in the Canadian Radiation Emitting Devices Act but not need to be as extensive as the US Radiation Control for Health and Safety Act. In general, it would appear that, because most types of radiation sources are imported into Australia, inspection of sources rather than of quality control programs would be preferable, with manufacturers and importers being required to submit sources for compliance testing before distribution or before finalization of purchase.

Inspections could be carried out by Commonwealth officers or by State officers with Commonwealth funding for this purpose. The Commonwealth would require access to reports of inspections so that subsequent action in the event of non-compliance can be determined. Any action would be at cost to the manufacturer, importer or distributor.

There may well be other options available, or combinations of the above. Nevertheless, early consideration of the various options needs to be undertaken so that action can be implemented as quickly as possible in order to reduce the radiation hazard to the population. Whatever course of action is implemented, there should result in a marked improvement in standards generally and in obtaining effective control over radiation sources. The Commonwealth would almost certainly need to contribute to radiation protection programs initiated for the purpose of obtaining better control of radiation. Such programs may be carried out by the States, in collaboration with the Commonwealth. Such assistance would greatly encourage the States in the implementation of any of the options.

ANNEXE I

CONTROL OF RADIATION IN AUSTRALIA

Australia consists of a federation of six States, each with its own government, the Northern Territory which was governed by the Commonwealth Government of Australia until June 1978, when it was granted independent government by the Commonwealth and the Australian Capital Territory which is governed by the Commonwealth Government. The State* governments have responsibility for matters in their own States and the Commonwealth Government has responsibility for matters at the national level (and for the A.C.T.) but does not infringe on the State's rights.

In relation to matters of public health, the Commonwealth Government has limited authority and can merely provide advice to the States. One source of such advice is the National Health and Medical Research Council (NH & MRC). This was constituted in 1936, under the auspices of the Commonwealth Department of Health. Its functions include:

- . enquiring into, advising and making recommendations to the Commonwealth and the States on matters of public health legislation and administration and on any other matters relating to health, medical and dental care and medical research, and
- . advising and making recommendations to the Commonwealth on the expenditure of money on medical research and in connection with projects of medical research generally.

Council is chaired by the Commonwealth Director General of Health and comprises the Directors-General of Health (or equivalent) of the States, representatives of the various medical and dental associations and colleges, other associated experts and two lay persons. Matters approved or adopted by Council thus have the acceptance of the State Health departments and they, in turn may incorporate such matters in their legislation, thereby affording a mechanism for a uniform approach to health legislation in Australia. The matters approved or adopted by Council do not in themselves have any legal standing.

Council operates through the establishment of a number of committees to advise it in specific areas of interest. In 1951, the Committee on Industrial Hygiene prepared a Model "Act to Make Provision with respect to Dangers arising from Radioactive Substances and Certain Apparatus Producing Radiation" (referred to as the Model Radioactive Substances Act). This was modified in 1953 and again in 1959.

* The term "State" hereinafter in this Annexe includes the Northern Territory, unless it is obviously excluded in the context of a particular paragraph.

In 1957 the Committee prepared "Draft Regulations Under the Radioactive Substances Act". These Model Acts and Regulations were accepted by Council, and the States and Commonwealth were encouraged to incorporate them into legislation to cover their respective areas of responsibility. By the end of 1963, all six States had regulations either under a Radioactive Substances Act or under existing Health Acts. The regulations were mainly based on the model regulations, but were modified in various respects. Some States are at present updating their Acts and regulations and these will include non-ionizing radiation sources. When the Northern Territory was granted independent government in 1978, it passed a Radiation (Safety Control) Ordinance the same year. An ordinance for the Australian Capital Territory has been in preparation for a number of years.

State regulations basically cover licences, exemptions, maximum permissible doses, monitoring, storage of radioactive substances, control of radioactive contamination, transport of radioactive substances, disposal of radioactive wastes and medical examinations. They do not include design or performance standards for radiation sources and there is therefore no regulatory basis for refusing licences on those grounds. This gap in the regulatory system has been partly overcome by Council, through its Radiation Health Committee, issuing codes of practice and recommendations on the safe use of various radiation sources. These codes and recommendations are user orientated, but some include some design and performance criteria for radiation sources. Council recommends that the various State authorities adopt these codes and recommendations as part of their radiation control programs and that they be distributed widely to the users of the sources. Although the codes and recommendations are prepared by sub-committees of the Radiation Health Committee (the members of which are mainly from State Health Departments) and are approved by Council, they are not used as extensively as they might be. For example, the Committee has prepared model standards for television receivers and Council has recommended that the States incorporate these in their legislation. So far, most States have not acted on this recommendation.

The Radiation Health Committee meets once or twice each year and discusses problems of mutual concern in the regulatory control of radiation sources. It prepares codes of practice through sub-committees or small working groups of persons who are expert in the relevant field. However, little comment is sought outside the Committee during these preparations. The need for codes becomes apparent from the discussions relevant to regulatory control. In addition, the Committee addresses itself to such matters as formulating radiation protection standards for use in Australia, medical requirements for radiation workers, licensing of consumer products, etc.

Apart from test procedures for microwave ovens and television receivers, there has been little attempt to persuade the States to agree on standardised procedures for testing radiation sources. This is mainly due to the fact that there are few suitable standards recommended for use in Australia (apart from those in codes of practice) against which compliance can be checked.

In addition to the Radiation Health Committee preparing codes of practice, the Standards Association of Australia (SAA) develops standards for equipment and these are often based on standards of the International Electrotechnical Commission and of the International Standards Organisation. Many of the SAA standards relating to radiation sources, when produced in final form, do not, on their own, have any legally enforceable basis. Nevertheless, they form a useful base on which to judge equipment. These standards are prepared by working committees of 10 to 20 persons representing all interests and are issued for public comment before final acceptance.

The approach to control of radiation sources in the States varies considerably, with the result that effective uniformity of control is not always obtained. This is often due to inadequate staff and facilities provided by the States and this, in turn, could be caused by the lack of legal requirements for the application of acceptable standards and, in some cases, due to the complete absence of standards. Consequently, licences are issued by State Health authorities for radiation sources unless there are exceptional grounds for refusing them.

Apart from those radioactive substances produced at the Australian Atomic Energy Commission Research Establishment, most radiation sources are imported into Australia. Radioactive substances are imported under the Customs (prohibited imports) regulations. Clearance for imports are given provided that it is shown that the materials will be used safely and that a licence has been issued by the relevant State Health Authority. No such clearance is required for radiation emitting devices (unless they contain radioactive substances) but licences are required from the State Health Authorities to possess and use such devices. The Commonwealth Government has no other power over the importation of radiation sources into Australia.

There are no legally enforceable regulations covering radiation sources within Commonwealth departments and agencies. However, the Commonwealth government requires that Commonwealth departments and agencies abide by the relevant State regulations. They may seek the State's assistance or advice, but the States do not have any inspectorial rights in them. This means that those Commonwealth departments and agencies functioning in more than one State may have different requirements relating to radiation protection.

The Commonwealth Department of Health has a function by virtue of the Order in Council setting up the Department of, inter alia, inspiring and co-ordinating public health measures. In particular, the Australian Radiation Laboratory of the Department, in a review of its functions in 1976, now has the functions, through research and development, of providing surveillance and advisory services on health hazards from the various radiation sources, of preparing radiation protection standards and codes of practice for the safe and effective use of radiation sources, of maintaining national standards of radiation dose and of radioactivity and of conducting quality assurance programs on radioactive materials used in diagnosis and treatment. The Laboratory is therefore in a good position to undertake the background work necessary for the development of standards and codes of practice. However, neither it nor the Commonwealth Department of Health has any authority to prescribe and enforce any standards. Nor is there certainty at present that the States would act on any standards prepared by the Laboratory.

ANNEXE II

ACTS AND REGULATIONS FOR CONTROL OF RADIATION IN CANADA AND USA

The control of radiation in Canada and the USA is exercised through several Acts and Regulations under varying authorities, the relevant authority for a particular control depending on the radiation source of concern. In both countries the Federal Governments' jurisdiction is bound to some extent by constitutional limitations. In Canada, for example, the Federal Government's authority to regulate hazardous substances (e.g. medical devices, radiation emitting devices, hazardous products and environmental contaminants) is derived from its jurisdiction over criminal law (section 91(27)) interprovincial trade and commerce (section 91(21)) and its residual authority to legislate for the "peace, order and good government of Canada" through the British-North American Act. Parliament's jurisdiction over occupational health is restricted to federal works, undertakings and business under section 92(10).

A. Federal Acts in Canada

The Department of National Health and Welfare Acts

This is the enabling Act to set up the Department of National Health and Welfare. It does little more than confer a general authority on the Department for investigation, research and information collection and dissemination in relation to public health. However, it does give the Department (through its Minister) the function of "promotion and conservation of the health of civil servants and other Government employees" and provides for co-operation with provincial authorities with a view to the co-ordination of efforts made or proposed for preserving and improving public health of the people of Canada". The Act provides for the setting up of a Dominion Council of Health comprising the Deputy Minister (Chairman) the chief executive officer of each provincial department or board of health and up to 5 other persons appointed by the Governor in Council. The Dominion Council is charged with such duties and powers as the Governor in Council may prescribe. (The Council is now defunct). Nothing in the Act or in any regulations made authorizes the Minister or Department to exercise any jurisdiction or control over any provincial or municipal board of health or other health authority operating under the laws of any province.

The Radiation Emitting Devices Act (RED Act) (1969-70)

This Act is administered by the Environmental Health Directorate of the Department of National Health and Welfare through its Radiation Protection

Bureau (RPB) and allows for prescribing by regulation of classes of radiation emitting devices and of standards regulating the design, construction and functioning of any prescribed class of device and of any of its components "for the purpose of protecting persons against personal injury, impairment of health or death from radiation". It prohibits the sale or lease by manufacturers and distributors and the import of prescribed devices that do not comply with the regulations. Authority is given for inspection and seizure of devices. The RED Act came into being through a demonstrated need that there should be some control over such devices. The Act excludes those devices designed for the production of atomic energy within the meaning of the Atomic Energy Control Act.

The Food and Drugs Act*

This Act is administered by the Department of National Health and Welfare covers the manufacture, sale, labelling, advertising, packaging, inspection, seizure and analysis of foods, drugs, cosmetics and medical devices. Medical devices were included when the Act was extended in 1954. It provides for the making of regulations of such items and allows for exemptions from requirements where appropriate. The term "drugs" includes radiopharmaceuticals but in practice in vivo radiopharmaceuticals are classed as drugs and in vitro as medical devices. "Medical devices" includes sealed radioactive sources, teletherapy equipment, medical and dental X-ray equipment, microwave diathermy units, surgical lasers etc., although the Act is not generally used for such devices. The Regulations give power over the importation of goods into Canada and prevent the sale of goods until safety of the goods is shown. The Act allows for the investigation of the efficiency of those radiation emitting devices used in medical procedures.

The Atomic Energy Control Act (1946 amended 1954)

This Act sets up the Atomic Energy Control Board (AECB) and was originally introduced for security and defence purposes. It gives power to make regulations for developing, controlling, supervising and licensing the production, application and use of atomic energy and to designate prescribed substances. "Atomic energy" is defined as meaning all energy of whatever type derived from or created by the transmutation of atoms. "Prescribed substances" means uranium, thorium, plutonium, neptunium, deuterium and their respective derivatives and compounds and any other substances that the Board may, by regulation, designate as being capable of releasing atomic energy, or as being requisite for the

* Full title - An Act Respecting Foods, Drugs, Cosmetics and Therapeutic Devices

production, use or application of atomic energy. Under regulations (1962, revised 1974) made pursuant to the Act all radioactive substances have been declared "prescribed substances" and licences are required for the import, export, production, mining, prospecting, refining, use, sale and possession of these and for use, sale and possession of devices containing radioactive substances.

The Canada Labour Code (Part IV). (1966-67, amended 1977-78)

This Code is administered by the Department of Labour and deals with the safety and health of employees in federal works, undertakings and businesses; other than that of employees in departments under the Financial Administration Act. "Federal works, undertakings or business" is defined as any that are within the legislative authority of the Parliament of Canada and includes interprovincial communications - shipping, railways, communications, aircraft, banks, etc. as well as any work or undertaking declared by the Parliament of Canada to be for the general advantage of Canada or for the advantage of two or more of the Provinces. The Code applies to, and in respect of, employment by a corporation established to perform any function or duty on behalf of the Government of Canada. It provides for making regulations covering use and operation of machinery, provision of protective facilities, health and physical requirements of persons, adoption and implementation of safety codes, etc. and for the setting up of safety and health committees in a particular work, undertaking or business.

Under this Code, the Canada Dangerous Substances Regulations (1972) (Regulations Respecting the Use, Handling, Transportation and Storage of Dangerous Substances and Radiation Emitting Devices in Federal Works, Undertakings and Businesses) set down limits for airborne contaminants (by reference to American Conference of Governmental Industrial Hygienists), requirements for use of personal protective equipment, ventilation, housekeeping, emergency equipment, restriction of areas, design of work places, medical examinations and requires that all radiation emitting devices to which employees are exposed be registered with the RPB and be designed, constructed, installed, maintained and used in accordance with a standard acceptable to RPB.

The regulations do not specifically refer to radioactive substances, or devices containing radioactive substances, as dangerous substances, but states that if any inconsistency occurs between the regulations and those made under the Atomic Energy Control Act, the regulations made under that Act shall prevail. The Code recognizes that radiation safety levels may be set by either federal or provincial authorities.

The Financial Administration Act

This Act is administered through The Treasury Board. Section 7 of the Act authorizes a number of health and safety policies, standards and guides for application throughout the Public Service of Canada and through this Section a Public Service Safety Program has been established.

This program is embodied in a document on Policies, Standards and Guides. Reference is made in the document to Canada Labour Code (Part IV), to procedures to be followed for various requirements, to safety standards for dangerous substances, etc. The latter are similar to Canada Labour Code (Part IV) and RPB is specifically referred to in regard to radiation emitting devices. Precedence is given to the Atomic Energy Control Act, where appropriate. Departments are reminded and encouraged to use the services of RPB in periodic bulletins that are circulated by Treasury Board.

Environmental Contaminants Act (1975)

This Act empowers the Minister of the Environment or the Minister of National Health and Welfare to collect data and conduct investigations when the concentration of a substance in the environment is likely to constitute a danger to human health. The investigations relate, inter alia, to accumulation of that substance in tissues, thereby possibly causing biological change and to methods of controlling the presence of the substance in the environment. Recommendations may be made to control the hazard arising from the substances and these would cover the manufacture, process or import of the substance. The recommendations would be implemented through other Acts and Regulations either federal or provincial, when possible to do so. If no alternative legislation is available, the substances may be prescribed and regulations made limiting the maximum amount of that substance that can be released to the environment in the course of manufacturing or processing. For radioactive contaminants, investigations etc. could be carried out by the Department of National Health and Welfare, but implementation would be through the Atomic Energy Control Act and Regulations.

Hazardous Products Act (1968-69)

This Act prohibits or restricts the advertising, sale and import of specified hazardous products and provides for the inspection, seizure and regulating of such products. Radioactive substances are not included in the schedule, but provision is made for the Schedule of Products to be amended by the Governor in Council, on the recommendation of the Minister of Consumer and Corporate Affairs or the Minister of National Health and Welfare when necessary,

to include products not listed elsewhere. The Schedule of Products does not cover any products already covered in the Food and Drugs Act, the Atomic Energy Control Act and the RED Act.

B. Provincial Acts and Regulations in Canada

At the Provincial level, a number of Provinces have their own Acts and Regulations and these relate to X-ray safety. Some Provinces still do not have Acts specifically related to X-ray safety, but may use general health legislation. In these cases, regulations are made under the Health or Labour Acts of the Provinces, but may be administered by different departments. For example, in Ontario, the Ministry of Health is responsible for medical X-ray safety whilst the Ministry of Labour is responsible for other X-ray safety. Other divisions of responsibility occur in other Provinces. The regulations preclude any devices that contain radioactive substances or devices capable of inducing radioactivity in irradiated matter. They regulate for persons using X-ray equipment, registration of equipment, doses received by workers and members of the public, installation and use of equipment, etc.

Control of radioactive substances or devices containing such substances in the Provinces is obtained through the Atomic Energy Control Act. However, the Provinces have regulations covering occupational health and there is some overlap between these regulations and the AECB regulations. The Provinces do not appear to have comprehensive regulations covering all types of radiation emitting devices.

C. Federal Acts in USA

The Radiation Control for Health and Safety Act of 1968

This Act is an amendment to the Public Health Service Act and provides for the protection of the public health from radiation emissions from electronic products. It requires the establishment of an electronic product radiation control program that includes the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organisations of research and investigation into the effects and control of such radiation emissions. It is administered by the Food and Drug Administration (FDA) of the Department of Health, Education and Welfare (DHEW) through the Bureau of Radiological Health (BRH) and effects control over the manufacture, import and distribution of such products.

As part of the electronic product radiation control program, the Secretary of DHEW is required to:

- . develop and administer performance standards for electronic products in order to control electronic product radiation emissions,
- . plan, conduct, co-ordinate and support research, development, training and operational activities to minimize the emissions of, and the exposure of people to, unnecessary electronic product radiation,
- . liaise with Federal and State departments and agencies, professional organisations, industry and labour organisations on present and future potential electronic product radiation,
- . study and evaluate emissions of and conditions of exposure to, electronic product radiation and techniques for minimizing exposure to electronic product radiation.

In order to carry out the above, the Secretary is authorised to:

- . collect and publicize the results of research and studies relating to the nature and extent of the hazards and control of electronic product radiation,
- . make recommendations relating to such hazards and control as he considers appropriate,
- . make grants to, and enter into contracts with, public and private agencies, institutions, organisations and individuals, and
- . accept from State and local authorities, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of the Act. He may commission any officer or employee of such authorities as an officer of DHEW for the purpose of carrying out examinations, investigations and inspections.

The Food, Drug and Cosmetic Act, with Medical Device Amendments (1976)

The Medical Device Amendments to the Act are to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes. The Act and the Amendments provide for the classification of goods into those requiring general controls, those requiring performance standards and those requiring premarket approval. The classification is based on:

- (i) the goods purporting or not purporting to be used in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,
- (ii) the goods presenting or not presenting a potential unreasonable risk of illness or injury, and
- (iii) insufficient information to establish a performance standard.

Radiopharmaceuticals when used in vivo are regarded as drugs but when in vitro as medical devices. Instruments used in nuclear medicine, such as gamma cameras, are covered by the Medical Device Amendments. The Amendments are sufficiently broad to include all electronic products used in the healing arts even if they do not of themselves emit radiation. The Amendments cover the safety and effectiveness of devices whereas the Radiation Control for Health and Safety Act covers safety only. Goods such as radiopharmaceuticals are administered by FDA through the Bureau of Drugs, Oncology and Pharmaceuticals with medical devices through the Bureau of Medical Devices and BRH.

The Atomic Energy Act, 1954 and the Energy Reorganisation Act, 1974

The Atomic Energy Act of 1954 establish the Atomic Energy Commission (AEC) and gave it regulatory functions over specified radioactive materials, as well as a development and promotional role for radioactive materials. The radioactive materials specified are source materials (uranium and thorium for production of nuclear power), by-product radioactive material (i.e. that produced in nuclear reactors) and special nuclear material in quantities not sufficient to form a critical mass. The Act did not give regulatory functions over other radioactive material, i.e. naturally occurring and accelerator produced radioactive materials (NARM).

In 1959 the Atomic Energy Act was amended to allow States to enter into agreements with the Atomic Energy Commission for purposes of regulating and controlling the specified radioactive materials in their own States. States entering into agreement with the Commission are referred to as "Agreement States". The Amendments also established the Federal Radiation Council to advise the President on radiation matters directly or indirectly affecting the health of the people and to provide guidance in the formulation of radiation standards for all Federal agencies and in the establishment and execution of programs of co-operation with States.

The Energy Reorganisation Act of 1974 established the Nuclear Regulatory Commission (NRC) as an independent agency. This Commission was given the regulatory functions of the previous Atomic Energy Commission whilst the development functions of that Commission were assigned to the Energy Research and Development Administration. The role of the Federal Radiation Council was assigned to the Environmental Protection Agency (EPA).

The Public Health Service Act

This Act provides, inter alia, for co-operation of Federal authorities with State and local authorities on matters relating to the preservation and improvement of the public health. It enables the various authorities to co-operate in inspectorial, education and surveillance activities in all matters of public health, including radiation. BRH, NRC and EPA all have roles under this Act, particularly in the promotion of uniform approaches to regulatory problems throughout USA and in regard to consumer products containing radioactive materials.

The Clean Air Act and The Safe Drinking Water Act

These Acts cover the levels of different contaminants in air and water and through them, EPA sets standards for radioactive contaminants in air and water for workers and for members of the public.

The National Environment Policy Act

This Act requires that all agencies of the Federal Government prepare detailed environmental statements or proposals for legislation and other major federal actions that will significantly affect the quality of the human environment. The principal objective of the Act is to build into the energy decision-making process an appropriate and careful consideration of environmental aspects of proposed actions. As part of achieving this object, NRC requires that an environmental report be submitted by any person seeking exemption from licensing for the use of radioactive material in consumer products. BRH prepares such reports in the preparation or amendment of performance standards.

Consumer - Patient Radiation Health and Safety Act (1979)

This is a new Act that covers the training and licensing of radiological technologists, the provision of accreditation standards in radiology education and the establishment by EPA, in consultation with DHEW, of federal radiation protection guidelines. It is understood that this Act was before Congress but had not been proclaimed at the time of the study.

D. State Acts and Regulations in USA

The control of radiation sources varies considerably between the States and depends on the particular type of source under consideration. All States have enabling Acts for radiation protection regulations, many of which have been effective since the early 1960's. Regulations exist in most States under the Acts and these are substantially similar to "Suggested State Regulations for the Control of Radiation", prepared in 1962. These regulations cover general provisions (definitions, exemptions, violations, etc), licensing and registration (general and specific licences), records, inspections and tests, transportation, permissible doses and connections, monitoring, labelling, instructions, waste disposal and notifications. They also cover basic standards for equipment and installations.

The incorporation of such standards enables the consistent and uniform application of regulations throughout the country. The Regulations in the States are generally administered by the Health departments and at present are being updated. It is hoped that all States will adopt the updated regulations in due course.

For by-product, source and special nuclear materials, control is effected by the States in the Agreement States and by NRC in the other States. About one half of the States are Agreement States. The regulations controlling these materials are virtually the same throughout the USA, as NRC (previously AEC) would not agree to States having control of these materials unless the State regulations and enforcement programs were compatible with NRC requirements. For NARM, about 30 States licence these materials, 16 register them and the remainder (7) have very little, if any, control over them.

Approximately one half of the States have regulations covering non-ionising radiation sources.

ANNEXE III

PREPARATION OF STANDARDS FOR REGULATORY PURPOSES IN CANADA AND USA

Procedures Followed in Canada

Before a class of device is prescribed, assessments of the potential hazards from that class are made. These assessments may be based on reports in scientific literature, measurements made in surveys carried out in either selected areas or generally throughout the country, reports made during inspection visits by staff of the Radiation Protection Bureau (RPB) or by the provinces or on complaints or questions arising from users. Surveys would be undertaken by a professional officer and an inspector making measurements on a number of devices for a short period of time, determining the causes of the hazards and how they can be eliminated or reduced and planning the pattern and information required for an extended survey to be undertaken by an inspector. From such surveys, basic data can be obtained for the draft preparation of a standard. If the assessments show that a hazard is small and only arises from a very small number of users or equipments, action to correct the situation is taken on an individual basis, rather than resorting to regulation. Such action is usually by persuasion but the Provinces could require modifications to be made under their regulations if they considered it necessary.

If it appears that there is likely to be a radiation hazard with devices, safety codes may be prepared and issued, irrespective of there being a need for a standard or not. These safety codes may be issued well before a standard appears as a regulation or at the same time as the regulation.

Once it has been determined that a standard for a class of device is necessary, a preliminary draft of the standard is prepared at RPB and this is issued to the Provinces for early comment. It is then issued for comment to selected persons or associations likely to have some expertise and interest in the devices under consideration, (e.g. manufacturers throughout the world who are likely to produce such devices for use in Canada, hospital physicists, medical associations, radiologist associations, X-ray technologist associations). The US Bureau of Radiological Health (BRH) is also invited to comment, in accordance with a Memorandum of Understanding between that Bureau and RPB.

On the basis of comments received, a revised draft is prepared and distributed as above. Following receipt of new comments, face-to-face discussions may be held with manufacturers and professional associations. On the basis of these comments and discussions, a new draft is prepared. This is then forwarded to the Department of Justice for publication in Canada Gazette Part I.

The draft standard appearing in Canada Gazette Part I is distributed as before by RPB by means of an Information Letter. Although this is not necessary legally, it helps ensure that the distribution of this draft standard has as wide a circulation as possible.

Comments received after the above gazettal are taken into account in the preparation of the final form of the standard by RPB and the Compliance Services of the Department of National Health and Welfare. Meetings may also be held with those making comments. The final form of the standard is reviewed by an expert committee, mainly comprising federal government departmental officers and it is then forwarded in its regulatory form to the Department of Justice for promulgation and publication in Canada Gazette Part II. This will include a date from which the regulation will be effective.

The time involved before final promulgation of a regulation varies, but may be two to three years. A period of two or three months is necessary for each stage of seeking comments on a draft, this period depending on the standard and on the distribution. Further time is necessary for redrafting and for consultation with relevant persons.

Procedures Followed in USA

Different and individual performance standards may be prescribed for different electronic products so as to recognise their different operating characteristics and uses. Any performance standard may be revoked or amended by regulation. Federal standards prevail over any other standards, unless the latter are more restrictive.

Before undertaking any action to prepare or amend standards, the need for standards must be ascertained. This is shown by:

- . field inspectors, in undertaking compliance testing,
- . reports on injuries arising from electronic products (these reports are required in the FDA regulations), and
- . petitions from any person suggesting regulations. These suggestions are put to a committee for consideration.

Action involves a literature search and the development of a rationale for initiating the project. An alert will then be published in the Federal Register on the potential problem and advice sought from all persons interested in problems arising with the equipment involved and on methods that might be considered appropriate for standards (regulatory) purposes. This period may involve six months for comment as it is of a preliminary nature.

A strategy document is then prepared giving a description of the problem, an analysis of the effort involved and a recommendation is made on the need for a regulation. Before proceeding any further with a regulation, approval of the FDA Commissioner is necessary.

A notice of intent is then initiated through the Federal Register and the public is invited to comment on requirements and to submit technical comments, etc. The comments received are analysed and a draft standard prepared by BRH, taking into account their experience with the particular type of equipment. Before publishing the draft proposed standard in the Federal Register, it must be reviewed by the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC). This Committee consists of 15 persons, 5 government officials (e.g. 1 from NBS, 2 from State Health departments, 1 from US Army Health Services and one other, but not one involved in this preparation of standards), 5 persons from industry and 5 from the public, one of whom represents organised labour. The Committee cannot require changes to be made to the draft proposal. However, it may propose electronic radiation safety standards to the Secretary.

The process of publishing draft proposed standards in the Federal Register and obtaining comments may occur several times before a final standard is obtained. For large proposals, drafts may also be sent to interested parties before appearing in the Federal Register. All comments received are listed in the Federal Register, together with their acceptance or reason for objection. Each publication requires 60 days before closing date for comments. The final proposal is published as a regulation, without referral back to TEPRSSC and becomes effective not less than one year nor more than two years after publication unless there is good reason to go outside this period.

The same procedure for an amendment to a regulation occurs as for a new regulation although the overall time may be somewhat reduced. Manufacturers may request variances from the regulations, due to technological changes and such variances can be incorporated into the regulations after following the above procedures.

Quite often, it appears after receiving comments on a proposal that recommendations rather than regulations would be preferable. Recommendations are also published in the Federal Register, but will be considered in advance by appropriate bodies (e.g. American College of Radiologists). They may also be issued through BRH as an independent pamphlet. Such recommendations often form the basis for an educational program for public, for professional association, for employee groups and for other appropriate persons.

For new type equipment, such as CT scanners, it is virtually impossible to write a performance standard and it is proposed to write a quality control program for such equipments into a standard. This will require, amongst other things, the dose values in a standard phantom to be quoted in the literature, although the values are not regulated. Thus, each manufacturer will need to aim to give as low a radiation dose as possible to specific body sites. This, together with a greater awareness of people using equipment will help to reduce the doses delivered to patients.

ANNEXE IV

PRACTICAL IMPLEMENTATION OF REGULATIONS IN CANADA AND USA

Control of Radioactive Substances and Devices Containing Radioactive Substances in Canada

The Atomic Energy Control Board (AECB) has the responsibility for ensuring control over radioactive substances in Canada. All persons possessing or using such substances must obtain licences from AECB. Applicants for licences for radioactive substances must give, inter alia, descriptions of:

- . premises where radioactive substances are to be located,
- . equipment in connection with use of the substances,
- . measures for security of the substances and to prevent exposure of individuals above prescribed levels,
- . disposal proposals and
- . qualifications and experience of persons using the substances.

A licence may be issued for one, two or five year periods, depending on the particular use of the substances covered by the licence.

Radiopharmaceuticals are only issued to persons whose qualifications are acceptable to an Advisory Committee on Clinical Uses of Radionuclides. The AECB does not issue licences for radiopharmaceuticals to persons who have not been approved by the Committee.

The Board aims to reduce the exposure of radiation workers as low as possible by setting lower exposure limits than those recommended by the International Commission on Radiological Protection. These limits are based on values routinely achieved in similar type institutions undertaking the same type of activities. It also sets values for discharge of radioactive substances. Licences are issued on demonstration that these lower limits will be or will be expected to be achieved and achievement of these is a consideration of licence. For organisations such as mining companies, universities, nuclear power stations, etc. the Board expects them to develop their own internal programs for radiation protection and for radiation monitoring, but requires to be informed of these programs and of the rationale behind the development of them. It does not expect to receive great detail on these programs. Because these organisations have considerable expertise, the AECB expects them to determine discharge levels, based on annual limits of intake. rather than to apply the general values that are set for smaller users. In general, users are required to use the RPB Personal Monitoring Service (except Ontario Hydro which operates

its own). Reports of the Service are forwarded to users and the Provinces, with the AECB being informed of high doses by the Provinces. Inspectors (Provincial or AECB) will inspect these cases and report to AECB. RPB will give advice and assist when necessary in these cases. For consumer devices containing radioactive substances licences are only issued for the manufacture and prime distribution of these. However, such devices must meet certain requirements, although at the present time these requirements have not been formalized. For example, requirements for smoke detectors are based on 1977 NEA standard and reliance is placed on Oak Ridge Laboratory reports on testing of such detectors; for tritium gas digital watches (up to 200 mCi) the module containing the elemental tritium should have no more than 2% tritiated water and the watches must be tamperproof, exit signs utilizing tritium gas would only be approved in specific locations and not in general public places (e.g. allowed to prevent defacing historical buildings where electrical connections could be difficult, aeroplanes, etc). Other type devices would not be approved unless they are shown to have a positive benefit over devices not containing radioactive substances.

Radioactive substances used for medical purposes are subject to the requirements of the Regulations under the Food and Drugs Act as well as subject to AECB control. The Department of National Health and Welfare, through the RPB is responsible for the regulatory control of manufacturing and distribution premises of radiopharmaceuticals, periodic plant inspection and a quality assessment program of licensed products. Regional dispensing pharmacies within a hospital are considered as distributors and are also subject to inspection.

The quality control program consists of obtaining periodic samples of the "popular" kits and generators and taking steps to remedy situations when tests show that products are not up to standard. Hospitals are encouraged to do their own radiochemical purity tests. Standards used are those in recognised pharmacopeia, where available, otherwise manufacturers are allowed to establish their own standards, provided they are realistic and acceptable to RPB. New products must conform with the regulations relating to new drugs.

Control of Radioactive Substances in USA

For regulatory purposes, radioactive substances are divided into two groups:

- Group (a) . by-product radioactive materials, i.e. material yielded in, or made radioactive by exposure to radiation incident to the process of producing or utilizing special nuclear material,
- . source material, i.e. uranium or thorium or any combination thereof,
 - . special nuclear material in quantities not sufficient to form a critical mass, i.e. uranium enriched in U-235, uranium-233 and plutonium not in excess of specified masses.

Group (a) is referred to as by-product, source and special nuclear materials.

- Group (b) . naturally occurring and accelerator - produced radioactive material, except source material.

Group (b) is referred to as NARM.

Group (a) - By-Product, Source and Special Nuclear Materials

The NRC has the prime responsibility for the regulation and control of these materials and licences are issued for the possession, use, storage, etc. of them. In issuing licences NRC will often set levels to be achieved at only a small fraction of the prescribed levels when it is shown that these lower levels can be easily attained in certain type organisations. Licences to possess or use radioactive materials are renewable every five years. When applying for licence renewals, organisations must submit reports to show clearly their efforts in achieving the limits set and to explain why any set limits or goals have not been or cannot be achieved. NRC also issues guidelines to assist users of materials in safe working procedures and in requirements to meet compliance with regulations.

Radiopharmaceuticals, both in vivo and in vitro, whilst subject to licensing and control by the NRC or Agreement States, must be approved in terms of intended use and activities by the FDA under the Food and Drug Act. FDA carries out inspections of manufacturing premises using standards in recognised pharmacopeia for the purpose. Where no such standards exist, the manufacturers may set their own standards provided they are acceptable to FDA.

As part of the control of radiopharmaceuticals, FDA investigates radiopharmaceuticals with respect to their efficiency for their intended purposes and to the optimization of doses received in various procedures. Nuclear medicine equipments, such as gamma cameras, dose calibrators, etc, are also investigated to ensure that optimum results are obtained in the various procedures. FDA is also concerned with the training of nuclear medicine technologists. It also receives reports from time to time of malfunctioning of different types of equipment and of any incidents arising in the case of radiopharmaceuticals (this is required under the Food and Drug Act) so that they can be investigated and steps taken to reduce the possibility of such occurring in the future.

Radioactive materials in consumer products may be exempted from regulatory control, provided it can be shown that there will be an insignificant effect on public health and safety. To this end, a manufacturer must prepare and submit to NRC an environmental report on the particular product for which exemption is sought giving a concise description of the product, its specific design features, intended use, operation, distribution and disposal together with alternative proposals (both radioactive and non-radioactive) to achieve the same intent as the product and adverse and beneficial environmental and socioeconomic effects of the production, use and disposal of the product.

Group (b) - NARM

The control of NARM varies between the States. NRC has no responsibility for these materials, but it produces guidelines for the safe use of these materials and the States may use these, if they so desire. Some States have regulations to control NARM, through either licensing or registration of the materials, but a few States have very little, if any, regulations covering them.

At the request of Agreement States a task force has been established at NRC to look at the question of whether and to what extent NRC or other appropriate Federal Agency should seek legislative authority to regulate such materials. BRH and EPA have also been involved in efforts to control NARM. They have also drafted guidelines that will be useful to the States in implementing their programs. EPA has investigated consumer products such as fertilizers, concrete, wallboard, natural gas and building land that contain naturally occurring radioactive materials. It has studied the environmental levels and public health input of these products and is developing and promulgating Federal radiation protection guidelines for such products.

In the uranium mining and milling area, the control of mining is the responsibility of the States, whereas the control of milling is the responsibility of the NRC.

Control of Radiation Emitting Devices in Canada

RPB has the responsibility for preparing standards for various classes of devices and for ensuring compliance of new items of equipment with the regulations. However, the RED Act does not require manufacturers, distributors and importers to notify RPB (or Dept. of National Health and Welfare) of new items of equipment or new models coming on to the market or being imported for any one organisation or person. RPB therefore depends for information on equipment in or likely to come into Canada from the following sources:

- . advice from BRH of tests carried out on models of various devices - particularly when non-compliance occurs.
- . advice on devices found by RPB inspectors in the field.
- . advice on devices found by Provincial inspectors in the field.
- . scientific literature, trade brochures, etc.

- . manufacturers' willingness to advise RPB of new devices and models - this is easier for medical devices than for other devices due to the restricted market outlet of the former.
- . for medical devices, the Bureau of Medical Devices will periodically advise RPB of new devices and models as manufacturers are required under the Food and Drug Act to advise the Department of National Health and Welfare of new devices (and new models of a device).

When RPB becomes aware of a new device or model, it requests the manufacturer to make available, either at the Bureau or other mutually convenient place, one or more samples of the device for compliance test purposes or, as for television receivers, it will seek detailed information on the device before carrying out tests. Manufacturers are not legally required to do this, but are usually co-operative. If manufacturers do not supply a sample for test, then tests for compliance must be made in the field, with provincial co-operation when necessary. For consumer products, these "field" tests would be made at retailing outlets. In the event of BRH advising non-compliance, RPB will seek information from manufacturers on the distribution of the devices in Canada, on modifications they propose for models sold or to be sold in Canada and on the timetable for such modifications.

Devices in the field as well as those on the premises of manufacturers, distributors and importers can be seized and held for inspection. RPB will also ask Customs to hold shipment of any devices coming into Canada so that compliance can be checked.

If a device is found not to comply with regulations, the manufacturers or distributors are required to modify at their cost all devices sold (after the regulation date) or yet to be sold. RPB may suggest corrective action that could be taken and will then check for compliance. Subsequent field inspections will show if devices previously sold have been modified. Penalties for non-compliance in Canada are heavy and it has been found in practice that, if a device does not meet the prescribed standards and a manufacturer is not co-operative in modifying the device, it is more fruitful to issue a Press Statement by the Department/or Minister than to force a prosecution. This is more damaging to the manufacturer, particularly in relation to consumer products, and saves the extra involvement associated with a prosecution.

Devices in use prior to the date proclaimed in Canada Gazette Part II and that do not comply with the regulations cannot be acted on through the RED Act. However, action can be taken through the Food and Drugs Act to have medical devices modified so that they are "safe" and conform to the regulations as closely as the devices permit. If the owner of a device is not willing to have gross deficiencies modified, the device could be seized under the Food and Drugs Act (if the device is a medical device) or the provinces could require modifications to be made to it (if the device is of a type requiring registration with the province).

It is a requirement of the Act that all prescribed devices conform with the regulations. In the case of a number of classes of devices (e.g. extra-oral dental equipments, low energy electron microscopes), it is possible to test a small sample in the Bureau and for others to be inspected in the field. For other types of devices (e.g. television receivers, microwave ovens, etc) extensive field testing is not possible as these devices are not registerable devices with the Provinces. It is therefore necessary for a number of samples of each model of such devices to be tested and statistical sampling applied to determine compliance of each model. In practice, the radiation levels for such devices are usually well below the standards and they cause no great concern. If the measured levels approach the levels set in the standards, manufacturers would be requested to make modifications to ensure that the levels are reduced.

If several devices of a particular model have been tested and found to comply, but subsequently a component of one of those devices malfunctions, thereby increasing a radiation hazard, the manufacturers would be advised of this so that future models of the device can be modified. They would also be requested to modify existing models.

Under Provincial Acts and Regulations, control is obtained over the installation and use of equipment. In addition Acts and Regulations specify the qualifications of persons who may prescribe irradiation for and carry out irradiations of human patients and the qualifications of the persons who may undertake industrial radiography. Provision is made in some instances for others to carry out the irradiations, but these persons must be subject to specified supervision. In remote areas, radiography of patients is carried out by nurses, etc. who have been specifically trained in this and who may only carry out simple examinations, e.g. chests and extremities. This training is carried out by the Medical Services Branch of the Department of National Health and Welfare with assistance from RPB.

Control of Radiation Emitting Devices in USA

Electronic products, or devices containing electronic products as components, that emit radiation are subject to the Radiation Control for Health and Safety Act in regard to their manufacture, distribution, importation and assembly. Such products include X-ray equipment, laser, microwave equipment, ultraviolet and infra-red sources as well as sonic equipment. The definition of the products in the Act is sufficiently broad that equipments such as cobalt-60 teletherapy units are included.

As defined in the Act, "manufacturer" means any person involved in manufacturing, assembly or importing electronic products. Thus, any person installing an X-ray equipment made up of components supplied by several manufacturers would be regarded as a manufacturer. Manufacturers, as distinct from assemblers, must provide instructions for the assembly of all their components and of all compatible components of other manufacturers so that assemblers can assemble equipment and ensure that prescribed standards are met. Assemblers are required to certify that the manufacturers' instructions have been followed and that compliance with standards is obtained. The instructions for assembling components must be submitted to the BRH for evaluation.

The Secretary of DHEW is to receive, and evaluate on a continuing basis, test programs carried out by manufacturers to assure the adequacy of safeguards against electronic product radiation and to assure that electronic products comply with prescribed standards. In order to assist manufacturers BRH issues guidelines on suitable test programs. If the Secretary determines that an electronic product does not comply with the prescribed standards and that a defect exists he is to notify the manufacturer of the facts and can require modification of products so that they are brought into compliance. In the event that a manufacturer discovers that a product has a defect relating to its safe radiation use or fails to comply with prescribed standards, he must notify the Secretary and, where necessary, the purchaser of the product. (It is to be noted that requirements on manufacturers apply to US manufacturers as well as to overseas manufacturers who market their products, either directly or through agents in the USA).

Manufacturers are required to maintain records (including test records) and make reports to and provide such information as is required by the Secretary so as to enable him to ensure that the prescribed standards are being met. Dealers and distributors of products are required to advise manufacturers of the names of purchasers of products.

In addition to submitting test programs and results of tests to BRH, control is also effected by an inspection network. The USA is divided into 10 regional areas and inspections are carried out in manufacturer's premises of their test programs by FDA inspectors or by State inspectors who are paid a fee per inspection, irrespective of the type of inspection involved. FDA and State inspectors are trained in the various test procedures and compliance tests necessary to ensure that compliance is obtained with the prescribed standards. Inspections are also made at purchaser's premises. It should be noted that not all States have agreed to provide inspectors for this purpose and in those States not so agreeing, FDA inspectors are used to a greater extent than in the agreeing States.

Reports of inspections are made to regional offices and any action considered necessary can be initiated by the regional offices for equipment to be recalled or modified - the action necessary depending on the degree and type of non-compliance. BRH is informed in due course of any such non-compliance and will, if necessary take steps to disapprove the quality assurance program of the manufacturer.

In addition to the above inspections, equipment may also be tested in BRH Laboratories. Such tests may be on prototype equipment or on consumer products. It is obviously not practicable to carry out tests on all types of equipment. Nevertheless, even if BRH tests show that the samples tested comply with prescribed standards, the manufacturers must still carry out their quality control programs and submit results to BRH regularly. Such programs include calibration and testing of their measuring equipments. The manufacturer's programs will vary considerably from one product to another, for example, with television receivers, manufacturers may construct a model with each component at the maximum tolerance allowed and provided this is well within prescribed radiation limits, spot checking of production models suffices. On the other hand, it is common to test each microwave oven as it is produced with daily performance checks on the equipment used for testing the ovens.

Microwave ovens, for example, are often checked in homes by FDA inspectors - mainly on a request basis resulting from educational programs aimed at the public. Retailers advise manufacturers of names and addresses of purchasers of ovens. By contacting purchasers, inspectors can make measurements and determine if any deterioration has occurred in the ovens through use.

In addition to testing electronic products for compliance with prescribed standards, inspections are also carried out by the States to ensure that there are no radiation hazards from the installation and use of the products. Licensing or registration of the products is effected through State legislation and this can be withdrawn if inspections show that the products are not installed or used safely.