AECL-6194

ATOMIC ENERGY OF CANADA LIMITED

L'ÉNERGIE ATOMIQUE DU CANADA LIMITÉE

A REGISTRY FOR THE STUDY OF THE HEALTH OF RADIATION WORKERS EMPLOYED BY ATOMIC ENERGY OF CANADA LIMITED

UN REGISTRE POUR L'ETUDE DE LA SANTE DES TRAVAILLEURS SOUS RAYONNEMENT EMPLOYES PAR L'ENERGIE ATOMIQUE DU CANADA LIMITEE

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RESUME

Ce rapport comporte un examen des facteurs à considérer dans l'élaboration d'une étude sur la santé des travailleurs sous rayonnement ainsi qu'une proposition pour l'établissement de cette étude en fonction des employés de l'Energie Atomique du Canada Limitée (EACL).

Lors de cette derniére décennie, l'intérêt du public a porté sur différents aspects de l'industrie nucléaire. Des questions ont surtout été soulevées sur la possibilité d'effects nocifs qui, avec le temps, pourraient résultés d'une exposition professionnelle à un rayonnement ionisant. Pour répondre à ces questions d'une façon satisfaisante et pour apaiser les inquiétudes que pourraient éprouver les employés et les membres du grand public, il faut que nous ayions des données sur l'état de santé professionnel de notre personnel et comparions ces données avec celles sur l'état de santé professionnel d'un groupe-témoin approprié. En établissant un registre des travailleurs sous rayonnement de l'EACL, on pourrait accumuler des données convenant pour la surveillance à long terme de leur santé et l'établissement de rapports provisoires périodiques sur la mortalité et la morbidité.

Le nombre de personnes et de rads-hommes disponibles pour l'etude ne sera pas grand sous l'angle de l'épidémiologie mais les renseignements que l'on obtiendra sur ce groupe de travailleurs sous rayonnement constituera un ensemble important de connaissances bien documentées. Conjointement à des études similaires entreprises dans d'autres pays, cet ensemble viendra s'ajouter à la base sur laquelle se font les évaluations du dommage à long terme par le rayonnement ionisant.

Cette proposition ne représente pas un programme duquel aucun écart n'est possible; c'est plutôt une évaluation d'un probléme d'une certaine urgence.

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ABSTRACT

This report contains a discussion of the factors to be considered in formulating a study of the health of radiation workers, and a proposal for the establishment of such a study in relation to the employees of Atomic Energy of Canada Limited (AECL).

During the past decade, public concern has been directed at various aspects of the nuclear industry. In particular, questions have been raised about the possibility of harmful effects which, in the long term, may follow occupational exposure to ionising radiation. To answer such questions adequately, and to allay concerns which may be felt by employees and by members of the general public, we need to have data on the health experience of our staff and to compare these data with the experience of suitable controls. By setting up a registry of AECL radiation workers, data could be accumulated suitable for the long-term follow-up of their health, and for preparing periodic interim reports on mortality and morbidity.

The number of people and of man-rads available to the study will not be large in epidemiological terms, but the information on this group of radiation workers is a significant body of well-documented knowledge. In conjunction with similar studies undertaken in other countries, it would add to the basis on which estimates of the long-term detriment of ionising radiation are made.

This proposal is not meant as a program from which no departure is possible; it is rather an assessment of a problem of some urgency.

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1. INTRODUCTION

The development of nuclear power programs in many countries has led to increased interest in the long-term biological effects of low doses of ionising radiation, delivered at low dose-rates over a prolonged period of time. Information is available on long- and short-term effects in humans and experimental animals after relatively high-dose, high-dose-rate exposures. There is little information on long-term effects on human populations following exposure to radiation delivered in low doses and at low dose-rates. The identification of such effects, if they exist, is relevant to the preparation of risk estimates for nuclear power programs, and for other scientific or industrial activities which may entail population exposure.

The information presently available on the long-term effects of high-dose, high-dose-rate irradiation provides the basis for current concepts of long-term biological effects. From such information is derived the working hypothesis that a linear relationship between dose and effect represents an upper limit of hazard for an exposed person. This hypothesis, involving as it does extrapolation from high to low doses, is generally held to be conservative. It excludes the possibility that a threshold may exist for the induction of cancer by radiation.

The linear hypothesis has been widely discussed, and the current view is that it may be pessimistic to calculate the biological costs of nuclear power programs in terms of such an hypothesis. However, it has also been suggested that the linear hypothesis may not be conservative and that the biological effects of radiation, particular the late effects, may be enhanced at low doses and low dose-rates.

It is in the context of these two viewpoints that epidemiological studies of radiation workers are considered, and it is proposed that the epidemiological study of populations occupationally-exposed to ionising radiation would provide useful information on the prevalence of late effects of low-level exposure.

2. EPIDEMIOLOGICAL AND THEORETICAL ASPECTS

In 1970, Duncan and Howell[1] published the results of their study of the health of radiation workers in the United Kingdom Atomic Energy Authority (UKAEA). They found no evidence of work-related illness, but the study did not extend to ex-employees. While it provides much useful information, this paper has been questioned on the grounds that it is a painstaking demonstration of the so-called "well worker" effect. Mancuso, Stewart and Kneale (MSK), at a Health Physics symposium in 1976[2], presented a preliminary paper dealing with their study of Hanford radiation workers. In this paper and its developments[3,4], the authors concluded that the effects of prolonged low-dose, low-dose-rate exposure were greater than had been believed.

The arguments against such a conclusion have been convincingly marshalled by Anderson[5], who bases his criticism on several factors. These include the use by MSK of cumulative mean radiation doses in which a high dose to one individual can distort the mean of a series of doses, the use of proportional mortality, the selection of a single year (1960) as the control point for an unexposed population and the fact that a change in the international classification of deseases (ICD) was not reflected in the treatment of data by MSK. Nonetheless, Anderson points out that the Hanford data do indicate that among those radiation workers there has been increased incidence of deaths from myeloma, carcinoma of

the pancreas and possibly lung cancer. There is also a deficit of leukaemia deaths. In these observations, he is supported by Marks from Hanford[6]. It is possible that there is not a causal relationship between these disease patterns and radiation exposure, and that exposures to other occupational and non-occupational carcinogens should be considered as possible confounding factors. The rising incidence of pancreatic carcinoma in Europe has been commented upon[7], and it is possible that, for this disease, the Hanford figures are a reflection of a general trend.

Dolphin, in 1976, published a report[8] on the incidence of cancers of the haematopoietic and lymphatic systems among employees of the British Nuclear Fuels Limited (BNFL) plant at Windscale. This first report has subsequently undergone revision and in particular, the confidence limits on the incidence of leukaemia (ICD 204-207), myeloma (203) and lymphosarcoma (200) have been reviewed, with the result that the excess incidence of myeloma is now considered to be significant. It is interesting that this rare disease figures in reports from two similar but widely separated plants, Hanford and Windscale. In his report Dolphin referred to the need to follow up ex-employees, and pointed out that the National Registry for Radiation Workers would meet this need in the United Kingdom.

A preliminary communication by Narajian and Colton[9] describes their study of mortality in shipyard workers, some of whom were exposed to radiation during the maintenance of nuclear submarines. The group was divided into nuclear and non-nuclear workers. In the former category, the death rate for leukaemia was 5.62 times higher than expected and, for all other malignant neoplasms, 1.61 times higher than expected (6 and 46 deaths, respectively). The authors and others[10] have pointed out the limitations attendant on these observations, but suggest that more-detailed studies of the health of radiation workers should be undertaken.

A report of a survey of the health of employees at the Lucas Heights Research Establishment of the Australian Atomic Energy Commission (AAEC)[11] describes the prevalence of disease among those employees. The study was done because of concern at the incidence of sarcoidosis at this site, 4 known cases have occurred among some 1200 employees over a 19-year period. This first report of a continuing study brings to light no other unusual disease-occupation relationships.

In a paper unrelated to occupational exposure, Boice and Stone[12] have described their study of 1764 women repeatedly fluorographed during the course of collapse therapy for pulmonary tuberculosis. The authors conclude that multiple-radiation doses may carry the same breast-cancer risk as a single exposure of the same total dose, and point out the apparently-increased sensitivity of the pubertal and prepubertal breast to radiation. The significance of age at exposure to radiation was also mentioned in the MSK study[3].

During recent years, papers have been published dealing with the methodology of studies of the health of radiation workers. Reissland and his colleagues[13] drew attention to the large amount of data necessary before it can be concluded with confidence that an excess incidence of a relatively uncommon disease, such as leukaemia, does or does not exist. In a subsequent paper, Reissland[14] described the conceptual basis of the National Radiation Registry in the United Kingdom, and concluded that, provided such a registry is maintained over several decades, it will contribute usefully to the placing of upper limits to risk coefficients. Newcombe[15] considered the methods by which dose records may be integrated with relevant death registrations. He emphasized the need for adequate identification of a registry, and noted that considerable economy could be effected in the operation of a registry if use were made of data which is already being collected for other purposes.

A major purpose of epidemiological studies is to determine the incidence of disease in a population and to relate this to factors which may have a bearing on observed variations in disease patterns. It has been noted that one of the factors of interest in a study of radiation workers is the relationship of dose and dose-rate to the incidence of cancer. The theoretical aspects of this factor have been reviewed by Mole[16] and Brown[17], who suggested that an enhanced radiation effect at low dose-rates could not be excluded on the basis of information then available. The experimental studies reported by Petkau[18], moreover, demonstrated such an enhanced effect in an isolated system, the model cell membrane. Petkau emphasized that his observations applied only to this particular system, and in his continuing studies identified mechanisms which, in the intact animal, protect against radiation[19]. Lafuma[20] has recently reported findings which lend some support to the concept of an inverse dose-effect relationship.

This survey of reports related to the question of the health of radiation workers indicates that no firm conclusion on the late biological effects of low-dose radiation is yet possible, and that many years may elapse before such a conclusion can be reached. The answer to this question bears not only on the health of radiation workers, but also on the preparation of risk estimates for a general population exposed to low doses of radiation as a result of the use of the nuclear fuel cycle. The most important criticism of present risk estimates is that they depend upon extrapolations from high-dose, high-dose-rate exposure to the low-dose, low-dose-rate regime. There is no conclusive evidence of the validity or otherwise of such extrapolations. It is not unreasonable to suggest that the inconsistencies in the linear dose-effect hypothesis, such as the Hanford and Windscale observations, may be due to factors other than radiation. At the present time, however, such a suggestion falls short of refutation.

Atomic Radiation Workers are a well-monitored, well-documented population who, during their occupation, are exposed to a physical agent of known carcinogenic properties. It is important to know how their health experience compares with that of the general population. This type of information is a normal component of good occupational health practice; in the context of the nuclear industry, it is an essential data source from which may be answered questions relating to the health of radiation workers.

The fact that such information would be derived from a population exposed in the main to low-dose, low-dose-rate radiation suggests that it would be useful in the formulation of risk estimates for the general public. Should this prove to be the case, then much would have been done to meet the criticism of present risk estimates which has been referred to above. These considerations, together with the relative accessibility of data on occupationally-exposed populations, underly the proposal which follows.

3. PROPOSAL FOR A STUDY OF THE HEALTH OF AECL RADIATION WORKERS

It is proposed that AECL should establish a registry to study the health of its employees in relation to their radiation exposure.

The registry should be designed so that other agencies and utilities would subsequently be able to join it or, alternatively, that data from the AECL registry could be integrated with a national registry for the study of the health of radiation workers, should such a registry come into being.

3.1 OBJECTIVES

The registry would have one major purpose which may be expressed as follows:

> "To determine by follow-up study whether there is evidence of any differences in the causes of and ages at death of workers exposed at different levels of radiation".

The registry's secondary purposes would be:

1. to assemble incoming data for periodic review, by means of which the incidences of diseases in AECL employees can be compared with the experience of similar age and sex groups in Canadian provinces,

2. to assemble information on the health experience of AECL staff in such a way that it can be compared with information derived from similar studies elsewhere in the world.

These objectives would be met by identifying a cohort of AECL workers and assembling information on their health experience until an adequate quantity of data is available for analysis. The precise form of this analysis is not at present identified, but it is important to ensure that provision is made to meet anticipated requirements. This phase constitutes the prospective cohort study and it would be the source for the periodic reviews referred to above.

It is also important to recognise that data are already available on the health of past employees of AECL. It is improbable that this information can be completely recalled, and the task of gathering it will be not be easy; nonetheless, a retrospective record search

should be undertaken to determine what in fact has happened to those who have been employed by AECL.

3.2 GENERAL OUTLINE OF PROCEDURE

There are four groups of radiation workers in Canada:

1. Atomic Radiation Workers employed by AECL,
2. Atomic Radiation Workers employed by utilities - Ontario Hydro, Hydro-Quebec and New Brunswick Hydro,
3. Atomic Radiation Workers employed by hospitals, universities and by industry,
4. Workers in mines and related industries who are occupationally exposed to radiation.

The present proposal is limited to Group 1, although the possibility is not excluded that an AECL radiation health registry could later be joined by Groups 2 and 3. It would, however, be necessary to ensure that the dosimetric and record-keeping practices of the three groups were consistent. Provisions are being made or have been made by provincial governments for the follow-up of workers in Group 4.

A registry designed for the study of the health of radiation workers employed by AECL would consist of two main components: (1) data collection and (2) data analysis.

The first component is divided into three parts:

1. the identification of an entrant to the registry,
2. the recording of the annual dose received by each entrant,
3. the identification of cause of death for each entrant.

The second component will be discussed in Section 5.

3.3 IDENTIFICATION OF AN ENTRANT IN THE REGISTRY

The following information would be required:

Social Insurance Number

Marital Status

Family name and full given names
(name change(s) where known)

Year, month and day of birth

Sex

Maiden name of mother

Place of birth (of entrant)

Province of residence

(Film Badge Number may be included, but is not necessarily unique to an entrant)

3.4 RECORDING OF DOSE FOR EACH ENTRANT

In the first instance, use could be made of dose records maintained by AECL. When the National Dose Register is fully operational, it may be preferable and possible to use this source of data, provided that the two sets are compatible. The following dose information should be recorded for each entrant, and should include any dose received during previous employment:

1. Body-penetrating external radiation dose:
   (a) Life time to start of study
   (b) Annual
   (c) Total

2. Skin dose:
   (a) Life time to start of study
   (b) Annual
   (c) Total

3. Neutron dose (if applicable):
   (a) Life time to start of study
   (b) Annual
   (c) Total

4. Internal contamination:
   (a) Tritium
   (b) Plutonium
   (c) Other
   (d) Known body burden? YES
   NO
   (d) Dose commitment:
      (a) Life time to commencement of study
      (b) Annual
      (c) Total

5. Involvement in accident or incident? YES
   NO

6. Overexposure? YES How much?
   When?
   NO

Here it must be emphasized that if the conclusions eventually made from the study of the information provided by the registry are to be valid, the dosimetric information must be complete insofar as occupation is concerned. Failure at this point would mean that a given cause of death could be associated with a spuriously-low recording for total occupa-

tional exposure to radiation. It will therefore be necessary to ensure that exposure incurred before and after employment with AECL is included in the dose record. This would entail liaison with the National Dose Registry when it is established.

Non-occupational radiation exposures should also be considered. It is likely that these will, in the main, be incurred as the result of diagnostic or therapeutic radiological procedures. There is at present no way in which an accurate history of this type of radiation exposure can be obtained. It may well be that the exposure of the group to be studied does not differ significantly from that of the general population, but it would be necessary to test this assumption. This could be done by addressing an initial and subsequent annual questionnaire to each participant in the study. Such questionnaires would also relate to other aspects of the follow-up of participants. Their handling and evaluation would be a time-consuming though necessary task, but one which has, however, been undertaken for other studies of similar size, such as the RCAF Cardiology study.

By this stage, an entrant in the study has been identified, and information is available on that entrant's life-time occupational exposure and on the history of the exposure. In connection with the latter point, it is important to know when the exposure was acquired so that the significance of age at exposure can be determined. The questionnaire could also be used to gather information on other occupational factors which may have a significant bearing on the cause of death. Such factors include exposure to industrial dusts, asbestos, and other chemical carcinogens. As in the case of enquiries about medical radiation exposure, the information will constitute something less than total recall, since some people are unaware of, or forget, their exposure to such things as chemical carcinogens. However, such information is important and must be recovered to the extent possible.

3.5 IDENTIFICATION OF CAUSE OF DEATH

In Canada, provincial registrars are the custodians of death statistics. Before any study could be established, it would be necessary to determine whether the provincial registrars and their counterparts in the territories would be prepared to release such information for the purpose of the study. The question has been discussed with staff of Statistics Canada, and mechanisms exist whereby the AECL registry might be approved as a suitable recipient for this type of information, similar provisions having been made for a study of the causes of death of uranium miners in the Province of Ontario.

Given that mortality data can be obtained, a final record could be generated when an entrant to the study dies. This would consist of the name and other identifying characteristics of the entrant, the radiation dose incurred during occupation and the cause of death. To this record would be added any available information on other factors such as medical radiation and exposure to chemical carcinogens. Whenever possible, the cause of death, as recorded in provincial statistics, should be supported by reference to the medical record and autopsy report, if any, of the dead person. This would be necessary because the cause of death, particularly in accident cases, might be unrelated to the concurrent existence of a condition which would be relevant to the purpose of the Registry.

It is also necessary at this point to consider changes which may occur in cancer as a disease entity during the next two or three decades. During recent years there has been a small but significant change in the prognosis for breast cancer, Hodgkin's Disease and the acute leukaemias. It is not beyond all possibility that people developing these and other cancers during the period of the study may survive to die of other diseases. The incidence of these cancers as opposed to

their mortality would also be of considerable interest to the Registry. It would be necessary to attempt to arrange a notification system with provincial cancer agencies, similar to that which has been proposed for mortality statistics.

A further source for the corroboration of mortality statistics would be the Public Service Superannuation Fund (PSSF) and, in the case of data for hourly-rate employees who died prior to May, 1975, its predecessor, the Sun Life Assurance Company. These sources would provide no corroboration for employees who left the service of AECL with less than ten years service and opted to receive a refund of their pension contributions. Similarly, Statistics Canada and the Provincial Registries could provide no information on those who had, at some time after leaving AECL, taken up residence in another country and died there. Death data on some, probably the majority, of this group could however be obtained from PSSF. There would remain a small group of employees with short service, who die outside of Canada, for whom it will not be possible to collect full mortality data.

4. DOSIMETRY DATA IN AECL

4.1 DOSIMETRIC TECHNIQUES

It may be useful to summarize the development of dosimetric techniques used in AECL.

During the early period of operations (post 1945), dosimeter film in a standard dental X-ray package with a 15-mil cadmium filter was used to record radiation exposures. A densitometer was used to read the films. In 1959, the filtration was increased to 40-mil cadmium for some

special badges worn by employees who were potentially exposed to higher levels of radiation during the course of their work. The films in use during this time had a tendency to overestimate gamma-exposures, sometimes indicating an exposure a factor of two higher than that shown on the quartz fibre self-reading dosimeter worn by many employees. This circumstance understandably caused operational problems, and was in part responsible for the introduction of a more sophisticated film badge holder in 1963. After this time, the difficulties caused by the overestimation of gamma dose diminished sharply, and the system continued in use until the early 1970's, the only change being the introduction of Kodak Monitoring Film II in 1968. A major change took place during 1972-73 with the adoption of the lithium fluoride, thermoluminescent dosimeter (TDL) which continues in use to the present time. This type of dosimeter has many advantages, including that of improved sensitivity, and it is possible to record a dose as low as 1 mrem received during a film-badge period (two weeks). There is therefore increasing confidence in the accuracy of dosimetric methods used during the period of AECL operations, but it must be recognised that estimates of gamma-exposure obtained prior to 1963 may be erroneously high.

A complicating factor is the fire which occurred at Chalk River Nuclear Laboratories (CRNL) during 1956. In this fire, many dose records were lost although, by a fortunate chance, records for some employees, who had received relatively high exposures during the NRX accident and subsequent clean-up, were stored in another building and escaped destruction.

4.2 STORAGE OF DATA

The methods and locations of storage have varied over the years. It is planned that in 1979 an AECL data storage system will become operational at CRNL. This will provide in machine-readable form:

1. individual identification characteristics,
2. total exposure during employment with AECL,
3. annual increments of exposure after 1978,
4. exposure due to tritium.

Records of exposures due to internally-deposited radionuclides are kept separately at CRNL (Medical Division).

4.3 USE OF RECORDS

There have been no recorded exposures of employees to neutrons. Records of exposures prior to 1978 will not permit machine-reading of annual increments, but in individual cases of particular interest, these increments can be determined by hand. The post-1978 records will provide machine-readabale information on annual increments, but will not provide specific information on "over-exposures" unless an administrative limit has been exceeded. Again, in a case of particular interest, this information can be obtained by reference to Radiation and Industrial Safety (RIS) Branch records.

From the viewpoint of an epidemiological study, the information available on the exposure of workers to radiation, while less than perfect, is a great deal more satisfactory than that available to the investigators of toxicological effects. This information falls into three time categories:

Pre-1963 - here there has been some accidental loss of data because of the CRNL fire, and it is also recognized that the data available may, in fact, overestimate γ-exposures.

Post-1963 - the data are more accurate indicators of exposure and are, as far as is known, intact.

From introduction of TLD to present time - the data are accurate and intact, with improved retrievability after 1978.

Given these considerations, some approach can be made to the type of epidemiological study to be carried out. If this is a prospective cohort analysis of those radiation workers employed by AECL on, say, January 01, 1980, the task of assigning dose to individuals is not difficult. Some of those employed on that date will have been working for AECL since the early days of operations at CRNL, but they will be few in number. A larger number of employees will have occupational histories dating back prior to 1963 and, together, these two groups will contribute some dosimetric anomalies to the study. If, however, it can be assumed that the inaccuracy of any individual dose record prior to 1963 is unlikely to exceed a cumulative total of ± 5.0 rem, the overall impact on the study is likely to be small.

If, on the other hand, a retrospective study of all known exposed employees is undertaken, it will be necessary to assign doses to past as well as present employees. This task will be very time consuming. The type of dosimetric information available, therefore, favours a prospective cohort analysis.

It can be argued that a retrospective study would provide information more quickly than a cohort study which will last a number of years before useful information is obtained, and this factor merits careful consideration.

To summarize: the dosimetric data available for AECL employees is an adequate basis for the type of epidemiological study presently being discussed.

5. ANALYSIS OF DATA

The study which is proposed has two components:

the first and major component is the analysis of the experience of a cohort of workers employed on and after the starting date of the registry,

the second component is the retrospective study of the experience of the exposed population, including those who have left the employment of AECL before the start of the registry. This latter study would, in fact, be a record search which, although incomplete, would be useful for the identification of questions which should be asked of the prospective cohort analysis.

The purpose of the registry at its outset is not to commit the investigators to one form of analysis which may be inappropriate at some time in the future, but rather to provide an adequate data bank upon which appropriate analyses can be based as the study progresses.

To provide this information for each entrant, it will be necessary to prepare an individual record as follows:

IDENTIFYING CHARACTERISTICS (as noted in 3(d))	
ENTRANT NUMBER	000015*
ETHNIC GROUP	-
YEAR OF DEATH	81
PROVINCE OF RESIDENCE AT DEATH	-
CAUSE OF DEATH	203.0**

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* Name can be included with record or coded separately

** International Classification of Diseases, 1975 Revision

ASSOCIATED CONDITION(S)	413**	
LIFETIME DOSE	32 rads	External***
		Internal
CANCER OTHER THAN CAUSE OF DEATH	-	
AGE AT FIRST ENTRY TO RADIATION WORK	34	
AGE AT LEAVING RADIATION WORK	65	
SMOKING HISTORY	-	
EXPOSURE TO CHEMICAL CARCINOGENS	-	
MEDICAL RADIATION EXPOSURE	-	
DATE OF ENTRY TO REGISTRY (Y,M,D)	-	

This record will provide three essential pieces of information:

1. Identity
2. Accumulated lifetime radiation dose
3. Cause of death

When an entrant dies, the entry will be assigned to an appropriate dose category and the entries in each category scanned annually. This annual scanning provides an opportunity to check that the system is functioning, to follow up medical records of those who have died in the previous year, to cross-check data sources and to provide information on which the periodic reports of the registry would be based.

The preparation of such periodic reports would be an important function of the registry. While they would not provide definitive answers to the question asked of the study (see Section 3.1), they could provide valuable information on the health experience of AECL employees

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** International Classification of Diseases, 1975 Revision

*** History of year-by-year exposure recorded separately where appropriate

in comparison with that of control groups in the general public. It is appropriate to demonstrate that measures have been taken to determine the precise impact of radiation work on the health of AECL employees. This type of interim information could be of great value if at any time a public statement should be required, or if concern should arise in a particular group of employees.

While the value of short-term reports should not be underestimated, it must be appreciated that the long-term answer, which is the main purpose of the study, will take at least twenty years to complete.

As suggested above, the precise form of the final evaluation of the study should not be decided at the outset. The intent is to gather sufficient information in a readily-retrievable form so that, a generation hence, those reponsible for the evaluation will have some flexibility in selecting the form of their analysis.

6. CONTROLS

The proposed structure of the study, entailing as it does the assignment of an entrant to an appropriate dose group, provides a degree of internal control. For example, the most important difference between entrants in the highest dose group and those in the lowest dose group may well be the level of radiation to which they have been exposed. However, it will be necessary to test this assumption before it is admitted, and to determine whether or not exposure to medical radiation and to chemical carcinogens differs significantly between the groups. No less important than the need to recognise such confounding factors is the need to ensure that the dose groups are comparable in terms of age

and sex distribution. It is probable that more highly-exposed groups will consist of older male employees, while the groups with lower levels of exposure will contain a higher population of females who were young at the time of their exposure. The differing disease-incidences in these groups will necessitate careful age and sex standardization of the groups before evaluation of their disease experience is carried out.

While the presence of such internal controls is useful, external controls will be necessary for the evaluation of the data gathered by the registry. The selection of appropriate control groups is a matter of importance. It has been suggested that the employees of public utilities who are not occupationally exposed to radiation would constitute an appropriate control group whose health experience during and after employment can be readily assessed. The fact that the majority of such people live and work in urban areas, whereas the majority of AECL radiation workers reside in rural areas, is a complicating factor, since the incidence of some neoplastic disease is known to be higher in urban than in rural areas. A similar consideration would apply to the selection of Federal Government civil servants as the control group. An alternative and usual approach, would be to use the general population statistics of a Canadian province or provinces as a source of control data. This option is valid, but it would be difficult to obtain continuing information on exposure to medical radiation and chemical carcinogens from such a population. For the present purpose, no recommendation is made on the selection of the control group; it is simply necessary to be alerted to the bias which can be inherent in such selections as those considered above.

7. DISCUSSION

This proposal concerns a study of the health experience of a group of radiation workers; this would identify the causes of their deaths and determine whether there is a relationship between cause of death and occupational exposure to ionising radiation. In addition, the morbidity due to neoplastic disease in the population would be determined. The information would be of value for risk estimation, in that it would relate to relatively low-level exposure. It would also provide, in the form of interim periodic reports, a base from which questions from the general public and from employees themselves can be answered. Comparison of the results of this study with those of similar studies which are being undertaken elsewhere would provide a significant addition to current knowledge of low-level radiation effects.

It is important to consider the degree of confidence that can be attached to the study, that is to say: if indeed radiation exposure at occupational levels is associated with an increased incidence of a particular disease, how confident can one be that the study has sufficient sensitivity to detect such and effect? Cutler and his colleagues[21] have discussed this problem. They suggest that, for a disease with an incidence of ten cases in a population of 100 000, such as leukemia (ICD 204), 180 000 person-years of observation will carry a 0.97 probability of concluding that the incidence rate in the studied population exceeds that of the general population when in fact it is twice as high. If the incidence in the population is three times as high, the probability is greater than 0.995. If, in this particular instance, only 26 cases are observed, the probability of incorrectly concluding that an excess incidence exists, when in fact it does not, is less than 0.05*. The

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* Table I, Reference (21)

study of radiation workers employed by AECL may be expected to contribute in excess of 200 000 person-years of observation over a thiry-year period. It is necessary here to assume that all of the people in the study population will receive some occupational exposure to radiation, although in many cases this will not exceed the exposure of the general population. The assumption that the study-population is in fact exposed is warranted if the current concept is accepted that there is no threshold for the induction of neoplasia by radiation.

Reissland and his colleagues[13] have suggested that, if a large population (100 000) is studied, the first conclusion could no be expected for at least 20 years. If total exposures are less than 100 per million person-rads, the time required to prove a positive effect of radiation on the incidence of cancer becomes very long, with little possibility of making statistically-valid intermediate statements. These observations are undoubtedly correct insofar as they relate to the definition of precisely quantifiable positive effects. An important objective of epidemiological studies is to determine whether or not such effects exist. Equally important is the gathering of comprehensive information on the health of radiation workers. In recognition of this fact, it has recently been decided that periodic reports will be published by the National Registry for Radiation Workers in the United Kingdom. The decision, which is a departure from the philosophy set out in the paper[13] referred to above, is, nevertheless, supported by Reissland.

The question of sensitivity has been discussed at length with epidemiologists in Canada, and it has been concluded that the data available to the registry would provide for adequate sensitivity in terms of the specific question asked of the study.

The gathering of data on the major points (i.e., radiation dose and cause of death) is not likely to prove complicated but subsid-

iary points, such as smoking history, exposure to medical radiation, exposure to chemical carcinogens and continuing health status, would be less simple to determine. It would be necessary to send an annual questionaire to each participant in the study to obtain information on these points. Sending out such questionnaires and compiling the information returned would be a major part of the work load of the registry. The questionaires would be sent to all entrants whether or not they were currently employed and, because of the need to ensure a high return of information, it would be necessary to explain the purpose of the study to each entrant. This might be done by a series of information meetings at each site before the study begins, and thereafter by the preparation of a written information sheet which would be given to each entrant.

Here it is important to re-emphasize the fact that the study would concern itself with the subsequent health experience of each entrant, whether or not that person continues in the service of AECL. An individual record would only be closed when the entrant dies. It must also be stressed that the incidence of all causes of death would have to be recorded. The incidence of neoplastic disease as a cause of death and as an associated condition will be of particular interest, but the study should not be limited to the consideration of neoplasia alone.

8. CONCLUSION

This report has been written as an examination of the many factors which go into the study of the health of a group of workers occupationally exposed to ionising radiation. The form which the study might take is suggested, and it is recommended that a small group be established by Atomic Energy of Canada Limited to implement the proposal as a study of the health of employees at all sites of the Company.

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