Canada's Nuclear Regulator

Setting Radiation Requirements on the Basis of Sound Science: The Role of Epidemiology

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FORWARD

Epidemiology is the study of the distribution and determinants of diseases in human populations. It serves as the foundation for public health and preventive medicine and is based on observations, rather than on experiments.

The purpose of this document is to describe the role of epidemiological research in setting radiation protection requirements, part of the mandate of the Canadian Nuclear Safety Commission (CNSC). The CNSC regulates the use of nuclear energy and materials to protect workers, the public and the environment.

This document presents the main types of epidemiology studies, key studies which form the basis of our understanding of radiation risk (i.e., Atomic bomb survivors, radiotherapy patients, people exposed during the Chernobyl accident, nuclear energy workers and uranium miners) and regulatory requirements for radiation protection.

It summarizes CNSC's assessment of the health effects of the past and present radium and uranium refining and processing industries in Port Hope, CNSC's assessment of the health effects of tritium, and CNSC's assessments of radon risk among uranium miners. It also discusses studies of people living near nuclear facilities both in Canada and around the world.

The document discusses the role of national and international expert committees like the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the National Academy of Science's Biological Effects of Ionizing Radiation (BEIR) Committee that review and summarize current radiation research. It also discusses the work of the International Commission on Radiological Protection (ICRP) that makes radiation protection recommendations for workers and the public.

The CNSC uses epidemiology and a wealth of other radiation science to protect the health of Canadians. The CNSC bases its risk assessments for populations exposed to low dose levels of ionizing radiation on the linear no-threshold (LNT) model. This model assumes a direct and proportional relationship exists between radiation dose and cancer (i.e., an individual's likelihood of cancer increases in proportion to his/her radiation dose). However, at doses below 100 millisieverts (mSv), it is not possible to distinguish cancer due to radiation from that of the natural variation of the disease among the general population.

Although recent radiobiological findings indicate that cellular repair processes could happen at low doses, these findings are not understood well enough to trigger changes to the current regulations. The LNT model is still supported by data from both epidemiology and radiobiology and provides a conservative, precautionary assessment of radiation risk at low doses.

The CNSC sets radiation protection requirements on the basis of sound science. In so doing, the CNSC effectively limits radiation exposures as a result of the nuclear industry to protect the health of Canadians.

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1.0 INTRODUCTION

The Canadian Nuclear Safety Commission (CNSC) regulates the use of nuclear energy and materials to protect workers, the public and the environment.

In order to manage radiation risks and to set regulatory limits that will protect workers and the public from ionizing radiation, CNSC has first to assess the risks that are present.

The assessment of radiation risks involves many steps and requires the input of several disciplines such as physics, radiobiology, genetics, and epidemiology. The combination of these different disciplines will contribute to the estimation of the risk.

The main discipline involved in the assessment of human health risks from radiation exposure is epidemiology. Several epidemiological studies of populations exposed to radiation have been conducted to assess these risks and they are considered the best source of evidence on which the current models used in radiation protection have been based.

The CNSC has produced this document to help explain how epidemiology is used in radiation risk assessment. It describes the different types of epidemiological studies used to assess health risks from radiation, and highlights key studies that have laid the foundation for international radiation protection models. It also describes how world experts work together to share and review scientific studies on radiation health effects that are further used to set the radiation protection recommendations adopted by regulatory agencies internationally. Finally, this document discusses how CNSC uses epidemiology to protect nuclear workers and the Canadian public.

2.0 SOURCES OF IONIZING RADIATION IN EVERYDAY LIFE

According to the International Agency for Research on Cancer, ionizing radiation is perhaps one of the most studied causes of cancer. Multidisciplinary research (such as radiobiology, genetics, molecular biology, physics, chemistry, and biochemistry) is continuously being conducted all over the world to improve the understanding of the sources and the effects of radiation exposure. Scientists regularly publish their most recent findings in peer-reviewed journals, or in other types of publication (e.g., governmental publications and books) to ensure that these findings will provide a better understanding of ionizing radiation sources and effects. All of these publications create a bank of knowledge that is further reviewed and synthesized by scientific experts who come to a consensus on the current understanding of the available scientific information.

Exposure to radiation occurs from several sources (see Figure 1 and Table 1) such as:

a. natural background radiation (from the sun, earth and the food we eat)

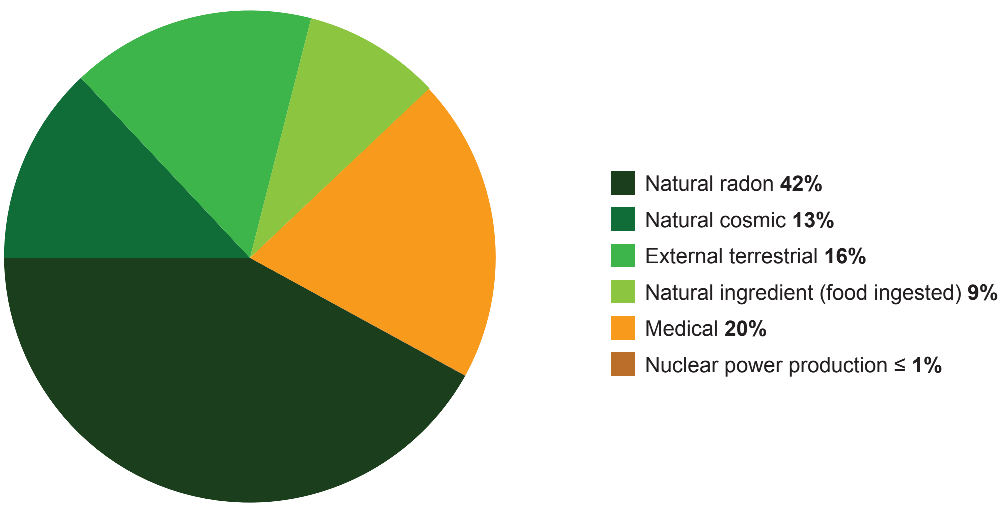
b. medical screening, diagnostic and therapeutic procedures (e.g., CT scan and radiotherapy)

c. nuclear weapons testing fallout

d. nuclear electricity generation

e. occupations that entail increased exposure to man-made or naturally occurring sources.

Figure 1. Source of Radiation to Which an Individual is Exposed in Everyday Life
Total Dose: 3.0 mSv/year (1)



According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 2008), the total annual dose from all sources, averaged over the population of the world, is 3.0 mSv in total. Over 80% of this dose comes from natural sources with about half from radon and radon decay products (RDPs). Medical exposure of patients represents 20% of the total dose, whereas all other artificial sources – fallout, consumer products, occupational exposure, and nuclear power production – represent less than 1% of the total value.

Annual radiation doses of workers are limited in most countries to 50 mSv/year or less. Only a small fraction of the work force exceeds 20 mSv/year. The dose limit for the public is set at 1 mSv/year. It is unlikely that any member of the public would receive more than a fraction of this dose in a year from artificial sources of radiation. However, doses to patients in some diagnostic procedures may be around 10 mSv. The annual dose of radiation emitted by certain consumer products, such as smoke detectors and luminous watches, is at the most 1 µSv or 1/1000th of one mSv.

Table 1. Average Annual Dose to the World Population From All Sources of Radiation (1)

Source	Dose (mSv)/year
Natural	
Cosmic	0.39
Gamma Rays	0.48
Internal	0.29
Radon	1.26
Artificial	
Medical	0.60
Atmospheric Nuclear Testing	0.005
Chernobyl	0.002
Nuclear Power	0.0002
Total (rounded)	3.0

Health risks to radiation-exposed populations are assessed using different types of epidemiological studies. These studies serve as the basis for implementation of mitigating measures to reduce the assessed risks.

3.0 OVERVIEW

3.1 What is Epidemiology?

Epidemiology is the study of factors affecting the distribution and determinants of diseases in human populations. It serves as the foundation for public health and preventive medicine. Epidemiology is based on observations, rather than on experiments, which can lead to the introduction of varying degrees of bias. A well designed epidemiological study will try to minimize these potential biases.

There are three main types of epidemiological studies: cohort studies, case-control studies and descriptive ecological studies. The first two types are analytical while the third one is descriptive. In order to be able to assess the risks associated with exposure (e.g., cancer) to a certain factor (e.g., ionizing radiation) particular attention has to be given to the soundness of the study design and to its statistical power. Advantages and disadvantages for each type of study are listed in Table 2.

Table 2. Advantages and Disadvantages of Each Type of Study

Study Type	Advantages	Disadvantages
Cohort (LSS - Uranium miners)	Effective in studying rare diseases	Logistically difficult, expensive and time-consuming
	Exposure precedes the health outcome	Requires a large number of subjects
	Ability to evaluate multiple health outcomes for a given exposure	Long follow-up period required
	Less vulnerable to bias; the most reliable type of study	Potential loss of cohort members (for various reasons) after several years
Case-Control (Parental exposure – residential radon)	Detailed histories of exposure and other information can be collected relatively quickly and easily	Vulnerability to selection and recall biases
	Useful for rare health outcomes	Difficulty with the collection of accurate and complete information
	Number of subjects can be small and results can be obtained quickly	Difficulty with selection of appropriate control group and matching on variables
	Relatively inexpensive	Less reliable than cohort studies
	Ability to identify more than one risk factor	
Descriptive Ecological (Leukaemia in children – People living close to nuclear power plants)	Relatively simple, easy and inexpensive to conduct	Precision of the statistics may be limited due to the small numbers of observed and expected cases or deaths
	Although not exposure specific, can evaluate a wide range of exposures	Results are averaged over a group, not on an individual level
	Often rely on pre-existing data	"Individual" exposures are not known
		Does not consider multiple risk factors (i.e., smoking, diet, exercise, etc.)
		Impossibility to draw conclusions on causal factor associated with a disease
		Potential errors in the assignment of place of residence
		Difficulty in interpreting results; less reliable than case-control studies

3.2 The Three Main Types of Epidemiological Studies

3.2.1 Cohort Studies

Cohort studies are analytical studies. They start with a defined group of individuals (the cohort) who are free of disease, but who vary in exposure to a risk factor within a defined period of time. Individuals within the cohort are classified according to their exposure. Exposed individuals are assumed to represent all persons exposed to the risk factor in a given population. Unexposed individuals are assumed to represent all unexposed persons in the same population. Cohort studies are "prospective" which means that they start at the moment of exposure and follow the individuals in time to determine if they develop a disease. More than one disease can be studied at a time.

Cohort studies can assess if there is a relationship between a risk factor to which individuals have been exposed and the development of a disease, e.g., it can assess if there is a relationship between ionizing radiation exposure and cancer.

Cohort studies measure the relative risk (RR). The RR is the ratio of the risk of an event (e.g., death or cancer incidence) in the exposed group (i.e., workers with radiation exposure) over the risk in the non-exposed group (i.e., workers with no radiation exposure). A RR that has a value close to 1 indicates that the risk of the event is the same in the two groups. A RR less than 1 indicates that the risk of the event is lower in the exposed group. A RR greater than 1 indicates that the risk of the event is greater in the exposed group.

Cohort studies are the strongest type of epidemiological study. The Life Span Study (LSS) of the atomic bomb survivors and the studies of uranium miners exposed to radon decay products are examples of cohort studies.

3.2.2 Case-Control Studies

Case-control studies, unlike cohort studies, tend to focus on a single disease. Individuals recently diagnosed with a disease (the cases) are compared with individuals who do not have the disease (the controls). The control individuals are matched with the cases for different factors (such as age, sex and the opportunity of having been exposed to the studied risk factor) and are representative of the general population.

Case-control studies are retrospective since they look back in time to determine the risk factors related to the incidence of the disease. The methods used to collect the data are similar for the cases and the controls. The main purpose of this type of study is to establish if a risk factor has a causal relationship with a disease. In case-control studies, risk is expressed as "odds ratios".

Case-control studies are the second strongest type of epidemiological study. The studies that assessed the relationship between childhood leukaemia and parental pre-conception exposure, and the studies that assessed of the relationship between lung cancer and residential radon exposure are examples of case-control studies.

3.2.3 Descriptive Ecological Studies

Descriptive ecological studies compare the occurrence of a specific disease within a population at a certain time in a given geographical area to the "expected" occurrence of the disease in a stable reference population (such as the general population of Canada). Results from ecological studies are for a whole population or groups of people; they do not give information on individuals. For this reason, they cannot serve to draw conclusions on a causal relationship between an individual's exposure to a risk factor and a disease outcome; thus, these studies are only used to generate hypotheses.

In ecological studies, Standardized Mortality Ratios (SMR) and Standardized Incidence Ratios (SIR) are commonly used for comparison. They represent the ratio of the observed number of deaths (for SMR) or cases (for SIR) to the number of deaths or cases expected based on what occurs in the larger and stable reference population. A ratio of 1 indicates that the observed number of deaths or cases for the study population is the same as the expected number in the reference population.

The confidence interval evaluates whether the difference in rates between the study population and the reference population are real or are due to chance. If the confidence interval does not include 1 (1 means no difference in risk), the ratio (SMR, SIR) for the study population is considered significantly statistically different from that for the reference population. If the confidence interval includes 1 the study population is considered no different from the reference population. When a SMR/SIR is based on few observed cases or deaths, the confidence interval can be very wide. In these situations, cautious interpretation of findings is necessary since a few cases/deaths can result in large variations in the SMR or SIR. The difference between a statistically significant and a non-significant finding can be based on just one or two cases or deaths.

Descriptive ecological studies are the weakest form of epidemiological studies. This is why they can only be used to generate hypotheses regarding risk factors within the population and disease. Most studies of people living in the vicinity of nuclear power plants (NPPs) are descriptive ecological studies.

3.3 Causation

3.3.1 What is Causation? Does Factor A Cause Disorder B?

A causal relationship can very rarely be established based on a single study. Evidence from many sources of information (i.e., other epidemiological studies, health physics, radiation biology, laboratory experiments or animal studies) has to be taken into account. In order to establish causation, it has to be proven that a specific factor causes a disease. In 1965, Sir Bradford-Hill (2) established a set of nine criteria to establish the causal link between a specific factor and a disease. These criteria are:

1. Temporal Sequence: Exposure always precedes the outcome. This is the only absolutely essential criterion.
2. Strength: The stronger the association, the more likely it is that the relation of “A” to “B” is causal.
3. Biological Gradient (Dose-Response): An increasing amount of exposure increases the risk. If a dose-response relationship is present, it is strong evidence for a causal relationship.
4. Consistency: The association is consistent when results are replicated in studies in different settings using different methods.
5. Biological Plausibility: The association agrees with existing biological and medical knowledge.
6. Consideration of Alternate Explanations: It is always necessary to consider multiple hypotheses before making conclusions about the causal relationship.
7. Experiment: similar effects are observed in carefully controlled experiments or in other biological models.
8. Specificity: a single supposed cause produces the specific effect. When specificity of an association is found, it provides additional support for a causal relationship.
9. Coherence: The association should be compatible with existing theory and knowledge.

These criteria are used to scientifically determine valid causal connections between potential disease agents and the many diseases that afflict humankind. These criteria are used to evaluate, for example, whether ionizing radiation exposure causes cancer.

3.3.2 What is Correlation?

Correlation is a statistical measurement of the relationship between two variables (e.g., radiation exposure and cancer incidence). Possible correlations range from -1 to +1. A zero correlation indicates that there is no linear relationship between two variables. A correlation of -1 indicates a perfect negative linear correlation, meaning that one variable goes up, and the other goes down. A correlation of +1 indicates a perfect positive linear correlation, meaning that both variables move in the same direction together.

“Correlation does not imply causation” is a phrase used in science and statistics to explain that correlation between two variables does not automatically imply that one causes the other.

3.3.3 Errors that have an Impact on the Accuracy of Risk Estimates in Epidemiology

The validity of a study is dependent on the degree of systematic error. A systematic error is an error that is constant in a series of repetitions of the same experiment or observation. The two important systematic errors that can affect the validity of a study in epidemiology are the presence of bias and confounding factors. A well designed study will attempt to minimize these errors.

A. Bias: A bias is an error in the design of a study that can influence the results or conclusions of the study. It could mask the true association between the exposure and the disease. For example, the manner the subjects are selected for a study (which is called selection bias) can have an influence in the estimate of association between a risk factor and a disease.

B. Confounding Factor: A confounding factor is associated with both disease and exposure. For example, when studying the relationship between occupational RDP exposure and lung cancer, the true effect of radon exposure can be masked by a third factor which is a confounding factor (e.g., age and sex). Age and sex are both associated with lung cancer and occupational RDP exposure. These factors must therefore be controlled for in a study of the relationship between occupational RDP exposure and lung cancer.

4.0 STUDIES ON WHICH EPIDEMIOLOGICAL EVIDENCE OF RADIATION HEALTH EFFECTS IS BASED

The epidemiological evidence of radiation-related health effects comes from several main research populations. These include the atomic bomb survivors, people involved in the Chernobyl disaster, patients treated with radio-therapy for non-cancer diseases, miners exposed to radon decay products and nuclear energy workers.

This section provides a brief overview of these study populations and summarizes what has been learned about the health effects of exposure to radiation from these populations.

4.1 Atomic Bomb Survivors Life Span Study

The Life Span Study (LSS) on the life-long follow-up of the Japanese atomic bomb survivors was developed after the 1945 bombing of Hiroshima and Nagasaki. It is the largest, most comprehensive and most detailed cohort study ever performed, with more than 60 years of follow-up after radiation exposure. The results of this study are the most important source of scientific information on the health effects of ionizing radiation exposure (primarily high doses and high dose rates) on which today's radiation protection regulations are largely based.

The LSS is comprised of over 120,000 people, and includes both sexes and all age groups. Since the dose rate decreased over the distance from the blast, the whole body dose range was large and permitted an assessment of the risk of different types of cancer. Mortality data from 1950 to 1997 has been assessed in detail and reported in international scientific publications.

To date the LSS results are:

- The main radiation effect observed in the LSS is cancer (both solid cancers and leukaemia).
- The excess risk of cancer increases as the radiation dose increases.
- Clinical studies of some of the LSS survivors have also demonstrated that radiation dose is clearly associated with the incidence of thyroid disease, benign tumour of the uterus, hypertension, chronic liver disease and cirrhosis.
- Studies of survivors' offspring conceived after the bombings have shown no excess of congenital abnormalities (birth defects), mortality, or cancer incidence when followed up through to the late 1990s.
- In contrast, radiation exposure of a foetus (during pregnancy) has been related to an increased incidence of cancer in adulthood, small head size and mental retardation in infants.

The LSS data has been used for the construction of models describing how radiation-induced cancer risk varies according to dose, as well as with factors such as age at exposure, time since exposure and sex. The incidence of solid cancers and leukaemia from the atomic bomb survivors' studies gives some of the best evidence of the linear no-threshold dose response hypothesis (or the LNT hypothesis) down to doses of about 100 mSv.

The LSS has also been used to investigate the incidence of non-cancer health effects. Radiation exposure can increase the risk of diseases, particularly cardiovascular diseases, such as heart disease and stroke, in people exposed to high doses (greater than 1,000 to 2,000 mSv). According to UNSCEAR 2008 (1), there is no evidence that there is an increased risk of non-cancer diseases at doses lower than 500 mSv.

4.2 The Chernobyl Accident

The accident at the Chernobyl nuclear power plant in 1986 is the most severe accident in the history of the nuclear power industry. Large areas of Belarus, Ukraine and the Russian federation were contaminated with radionuclides released from the accident.

- The highest radiation doses were received by emergency workers and on-site personnel, in total about 1,000 people, during the first days of the accident.

- The majority of the residents (over 5 million people) of the contaminated areas were exposed to relatively low whole-body doses of radiation, not much higher than doses due to natural background radiation.

Now, over 20 years later, international agencies have reviewed the health, environmental and socio-economic consequences of the accident (3, 4, 5). The conclusions from this review are:

- A hundred and thirty-four emergency workers were diagnosed with acute radiation syndrome within the first few days. Twenty-eight of these workers died within the year and three additional workers died shortly thereafther.
- Approximately 4,000 thyroid cancer cases were diagnosed in children and adolescents who were exposed at the time of the accident. Doses of radioactive iodine to the thyroid, received in the first few months after the accident, were particularly high for children who drank milk containing high levels of radioactive iodine. More cases can be expected during the next decades among those children who were exposed at the time of the accident. According to UNSCEAR 2008 (1), there were 15 reported deaths up until 2005.
- Apart from the increase in thyroid cancer incidence among those exposed at a young age, there is no clearly demonstrated increase in the incidence of solid cancers or leukaemia due to radiation in the most affected populations. There is also no scientific evidence of an increase in rates of other diseases.
- Nonetheless, a significant psychological and social impact was observed as a result of the accident.

In contrast with the Chernobyl accident, the event that happened at the Three Mile Island nuclear power plant in Pennsylvania, United States, in 1979, is an example of an accident that successfully avoided releases of radioactivity in the environment and exposures to the public. The Kemeny Commission, established to shed light on the accident, concluded the following: "*There will either be no case of cancer or the number of cases will be so small that it will never be possible to detect them. The same conclusion applies to the other possible health effects.*" (6)

4.3 Patients Treated with Radiotherapy for Non-Cancer Diseases

Up to the 1960s, many patients were treated with radiotherapy for non-cancer diseases, such as painful degenerative joint disorders, tennis elbow, and autoimmune diseases. Some of these treatments were associated with a statistically significant increased risk of leukaemia and solid cancers. In 1957, Court-Brown and Doll (7) analysed the mortality of 14,554 patients treated with radiation and found a ten-fold increase in mortality from leukaemia in these patients. This conclusion has been confirmed by a follow-up study (8). The findings from this study are consistent with the LSS findings, together they remain the most important source of information about radiation-induced leukaemia.

4.4 Miners Exposed to Radon Decay Products

At the end of the 19th century, lung cancer in miners was linked to the exposure to radon, but it was only recognized in the 1950s that the cause of lung cancer was the radioactive decay products (RDP) of radon.

In 1994, an important combined study (9) of eleven large miner cohorts, including four from Canada (Beaverlodge and Port Radium uranium miners, Ontario uranium miners, and Newfoundland fluorspar miners) assessed the relationship between RDP exposure and lung cancer. The study also included cohorts of miners from the USA, Sweden, Australia, the Czech Republic, France, Germany and China. The study revealed that:

- There was an excess risk of lung cancer mortality attributed to RDP exposure.
- The risk of lung cancer increased linearly with increasing RDP exposure.
- Several modifying factors affected this risk. The risk of lung cancer mortality per unit of RDP exposure decreased with increasing time since exposure, with increasing attained age and with increasing exposure rate.
- Tobacco had an important impact on the relationship between RDP and lung cancer risk.
- Lung cancer was the only established health effect of RDP.

These findings form the basis of today's radiation protection programs for uranium miners. Based on this study, the model for assessing RDP risks was adopted by the Biological Effects on Ionizing Radiations VI (BEIR VI) Committee (10).

Recent updates of the French, German, Czech Republic, Colorado Plateau, and Canadian (Newfoundland Fluorspar miners and the Beaverlodge and Port Radium uranium miners) miners' studies (11-20) have increased the statistical power and precision of risk estimates and largely support the BEIR VI risk model (10).

4.5 Effects of Radiation on Nuclear Energy Workers – IARC 15-Country Study

In 2005, the International Agency for Research on Cancer (IARC) released a study (21) on cancer mortality among nuclear energy workers. The IARC Study included cohorts of workers from 15 countries with a mortality follow-up from 1957 to 1994. The results from this study were:

- There was a statistically significant increased risk of mortality from all cancers (excluding leukaemia) per radiation dose in nuclear workers, based on all 15 countries.
- The workers from Canada had the highest risks of solid cancer mortality (an excess risk of 6.5 per radiation dose (Sv)). Their risk estimate was the highest of all of the cohorts and was statistically significantly higher than the combined risk estimate for all 15 countries studies.
- The exclusion of the Canadian workers rendered the risk estimates statistically non-significant for the remaining 14 countries, which was consistent with previous international studies of nuclear energy workers and with the atomic bomb survivors' studies.

An earlier study of Canadian workers (22) that used the same source of data (the National Dose Registry) as the 15-country study, found a sizeable but statistically non-significant increase in risk of solid cancer mortality per radiation dose for Canadian workers. This apparent discrepancy in the results between the Canadian study and the 15-country study for the Canadian workers attracted attention and questions from regulatory agencies and industry.

In order to understand the Canadian workers' cancer risk estimate in the IARC 15-country study, the CNSC initiated a preliminary comparison of the two studies in 2005. It was discovered that workers who were missing information on their socioeconomic status had been excluded from the solid cancer analysis in the international study. This was the case for about 50% the Ontario Hydro workers' cohort that represented 50% of the Canadian nuclear workers, thus Ontario Hydro workers were excluded from the Canadian cohort in the 15-country study. However, SES information was also missing for 40% of Atomic Energy of Canada Limited (AECL) workers; nonetheless, they were not excluded. It was also discovered that workers from AECL, who now dominated the Canadian cohort in the 15-country study, were missing important historical dose data.

Canadian investigators reviewed the reasons for the missing dose data. Consequently, the CNSC initiated an in-depth reanalysis of the Canadian nuclear workers' study using the Ontario Hydro worker data and corrected AECL worker data. The purpose of this reanalysis was to determine if the corrections could explain and resolve the initial high solid cancer mortality risk estimates. This reanalysis suggests that there is no reason to conclude that Canadian workers are at higher risk than any other workers carrying out similar work. The final results of this independent reanalysis of the Canadian nuclear workers' cohorts will be available soon in a report from the CNSC.

4.6 Summary

The above-mentioned studies have contributed to the current scientific understanding of the health effects from radiation exposure. Based on this understanding, national and international experts have agreed on principles and practices that best protect workers and the public from the health effects of ionizing radiation exposure.

5.0 EPIDEMIOLOGICAL STUDIES OF PEOPLE LIVING NEAR NUCLEAR POWER PLANTS OR URANIUM PROCESSING FACILITIES

A tremendous amount of work has been conducted in Canada and internationally to assess the radiation risk of people living near nuclear facilities. Most of these studies have been descriptive ecological studies which compare disease rates among populations living near nuclear facilities to disease rates within the general population. Case-control and cohort studies have also been conducted. This section will discuss some of these studies in more detail.

It is known that disease clusters (such as childhood leukaemia) do exist near some nuclear facilities, as well as elsewhere, where no nuclear facilities are located. There are, for example, 264 reported leukaemia clusters in England, Wales and Scotland (23) and most of them are not in the vicinity of a nuclear facility. Three main hypotheses have been put forward to explain why clusters have occurred around nuclear facilities. These include parental pre-conception radiation exposures, environmental exposures from nuclear facilities, and the Kinlen (24) hypothesis. This latest hypothesis suggests that leukaemia could be explained by the existence of an infectious agent that is present as a result of population mixing when people migrate to communities near nuclear facilities. To date, none of these three hypotheses have been proven.

5.1 Offspring of Ontario Hydro Workers

5.1.1 Childhood Leukaemia

In Canada, a case-control study (25, 26), based on childhood leukaemia cases from the Ontario Cancer Registry diagnosed between 1950 and 1988 assessed the relationship between childhood leukaemia and the father's ionizing radiation exposure before conception.

This study showed:

- No statistically significant association between childhood leukaemia and the father's occupational exposure to ionizing radiation.
- No evidence of an elevated leukaemia risk in relation to any exposure period (lifetime, six months or three month prior to conception) or exposure type (total external whole-body dose of gamma radiation, tritium dose, or radon exposure).
- That the results were the same when taking into account the father's whole-body external radiation or tritium exposure.

5.1.2 Birth Defects

A case-control study (27) was conducted to evaluate the risk of having a child with a birth defect (also referred to as a congenital anomaly) as a result of parents (fathers or mothers) pre-conception occupational radiation exposures.

The study showed:

- No statistically significant increased risk of having a child with birth defects when the parents were exposed to radiation before the conception of a child.

These Canadian studies are consistent with other studies of nuclear workers, and provide no evidence of a causal link between workers' pre-conception exposure and cancer or birth defects in their children. These findings are consistent with higher-dose studies of atomic bomb survivors and cancer patients who subsequently became pregnant (28).

5.2 Communities Near Nuclear Facilities in Ontario

Several descriptive ecological studies (29, 30, and 31) examined mortality and the incidence of childhood leukaemia among children aged 0-14 years living in the vicinity of Ontario nuclear facilities. Analyses were performed separately for each of the nuclear facilities.

The results of these studies were:

- No evidence was found of any excess leukaemia incidence or mortality close to the AECL Facilities in Chalk River or the nuclear power demonstration station in Rolphton.
- The occurrence of leukaemia in the vicinity of the Bruce and Pickering nuclear generating stations (NGS) was greater than expected. Similar findings were found prior to the opening of the Pickering facility. Based on the small number of cases and deaths, and the wide confidence intervals, there was no statistical evidence that the leukaemia was due to anything but the natural variation in the occurrence of the disease.
- The findings for leukaemia cases and deaths were similar.

The rarity of childhood leukaemia and the small number of observed and expected cases and deaths lead to the limited statistical power of the study.

Another descriptive ecological study (32) compared rates of birth defects, stillbirths, and deaths within the first year of life among the offspring of residents living within 25 km of the Pickering NGS in Ontario (1971-1988) with those of the general Ontario population.

The results were:

- Mortality rates of stillbirth, neonatal mortality and infant mortality were statistically significantly lower than the Ontario average.
- Rates of birth defects were generally lower than provincial rates.

The Durham Region Health Department (DRHD) conducted a descriptive ecological study in 2007 to examine the rates of cancer incidence and mortality, birth defects and stillbirths from 1981 to 2004 in the areas of Pickering and Darlington Nuclear Generating Stations (NGSs) (33). The Durham Region is unique due to the presence of a large population (285,000) living within 10 kilometres of two NGSs.

The results of this study were:

- This study is consistent with the original analysis conducted from 1979 to 1993 (34) and with two Snapshot reports for the region on cancer (35) and healthy newborns (36).
- In general, the rates of cancer incidence and mortality were similar to the Ontario averages; the prevalence of birth defects was statistically significantly lower, and rates of Down syndrome were similar to those in the rest of Ontario.
- Given the extremely low levels of radiation exposures, which included tritium, it is unlikely that any radiation related effects would be observed.

5.3 Health Studies in the Port Hope Community

Several epidemiological studies have been conducted in Port Hope in the last 30 years, covering the time period from the 1950s to the present day.

In 2009, the CNSC published a report: *Understanding Health Studies and Risk Assessments Conducted in the Port Hope Community from the 1950s to the Present* (37). This report used a weight of evidence approach to assess the health effects within the community looking at toxicological and radiological properties of the contaminants within the town. Over thirty environmental studies, thirteen epidemiological studies conducted in Port Hope, and over forty international studies were reviewed in the report.

Based on the radiological and non-radiological contaminants present in the community, the plausible health effects considered were: lung cancer (due to radon exposure), bone cancer (due to radium exposure above a threshold dose of 10 Sv) and kidney disease (due to uranium toxicity).

The descriptive studies reviewed in the CNSC report compared the overall health status of Port Hope residents with that of residents in other similar communities, and with the general Ontario or Canadian population. The rates of mortality, cancer incidence, and birth defects were assessed.

The main conclusions from this review were:

- Overall, mortality from all cancers in Port Hope was statistically similar to the general Ontario population.
- Childhood cancer mortality and birth defects were statistically similar to the general population of Ontario.
- Overall cancer incidence in Port Hope was statistically similar to the general Ontario population and similar communities.
- No statistically significant excess of kidney disease mortality or statistically significant excess of bone cancer incidence or mortality in residents was demonstrated during the period when the radium and uranium refining and processing industries were in operation in Port Hope.
- A statistically significant excess of lung cancer incidence was found in Port Hope women between 1986 and 1996, but no excess risk was found in men or women in other time periods.

A case-control study conducted in Port Hope assessed the relationship between lung cancer (38, 39) and residential radon in Port Hope.

The study concluded:

- There is no conclusive link between residential radon and lung cancer rates, even among people living in homes with levels of radon identified as "high" in the study.

Finally, approximately 3,000 radium and uranium processing workers from Port Hope (20, 40) were assessed to determine the relationship between occupational radiation exposure (RDP and gamma radiation dose) and mortality and cancer incidence. Workers were followed for 50 years for mortality and for 30 years for cancer incidence.

The study concluded:

- Port Hope workers are as healthy as the general male population of Canada.
- No statistically significant relationship was found between Port Hope worker's radiation exposures and any cause of death or cancer incidence. This was largely due to the relatively low occupational radiation exposures of these workers.

Findings concerning Port Hope residents and workers are consistent with findings from over 40 epidemiological studies conducted elsewhere in the world analyzing the health status of workers and the public exposed to the radium and uranium refining and processing industry.

5.4 Communities Near Gentilly-2 in Québec

In 2003, the "Régie régionale de la santé et des services sociaux de la Mauricie et du Centre-du-Québec" published the results of a study (41) on the cancer incidence and mortality in the vicinity of Hydro-Québec's Gentilly-2 nuclear power plant between 1994 and 1996. The study compared the rates of cancer incidence and mortality in the vicinity of Gentilly-2 with the general population of Québec. The study looked at the incidence of the ten most common cancers, as well as thyroid cancer and leukaemia in the overall population and the ten most common cancers in children (aged 0 to 19 years old).

The study concluded:

- There was no excess risk of cancer in the Gentilly-2 area compared to the general Québec population.
- The cancer rates among boys were similar to the general Québec population.
- Women had lower rates of cancer compared to the general Québec population, especially for lung and breast cancer.

The study was based on few cases and this means it should be interpreted with caution. This is especially true for the youngest group (aged 0-19 years old) for whom the rareness of childhood cancers resulted in variations in disease rates in the different geographical areas of the province of Québec.

5.5 Summary

In summary, Canadian studies provide no evidence of statistically significant excess rates of cancer, childhood cancers, birth defects, stillbirths or infant mortality related to the operation of Canadian nuclear facilities.

5.6 Communities Near German Nuclear Facilities

5.6.1 Studies Conducted Around Nuclear Power Plants

In 1992, a case-control study (42) looked at the incidence of childhood cancer within the 15 km radius of 20 West Germany nuclear installations that had started to operate between 1960 and 1988.

This study found:

- No increased risks of all cancers including leukaemia in children less than 15 years of age within the 15 km zone of the nuclear plants.
- Statistically significant increased risks of leukaemia in children less than five years of age living less than five km from the installations, especially those living in the neighbourhood of installations that started to operate before 1970.

However, this increase could not be explained by radiation exposure. In addition, an even more pronounced increase in childhood leukaemia was observed in regions where no nuclear power plants (NPPs) were operating.

This study was further updated to include the period from 1991 to 1995 (43). It was not able to reproduce the original results and only found a tendency towards an increased risk of acute leukaemia in children younger than five years of age within the five km radius of an installation. This finding was strongly influenced by the cluster near the Krümmel NPP.

Another study (44) was initiated in 1999 to compare cases of childhood leukaemia in the vicinity of Krümmel NPP and in the vicinity of the Savannah River Site (SRS) in South Carolina, USA. It was thought that the German cluster was related to tritium discharges.

This study found:

- The amount of tritium released by the SRS facility exceeded several times the amount of tritium released by the Krümmel NPP.
- No cluster of childhood leukaemia was found at the SRS.
- The excess of childhood leukaemia near the Krümmel NPP cannot be explained by tritium discharges.

A further study in the region of Hamburg, which is located 30 km from Krümmel (45), looked at the childhood leukaemia incidence for the period of 1990 to 2005.

This study found:

- Elevated rates of childhood leukaemia had persisted in this community for more than 15 years (since the first study conducted in 1992).

The cluster observed near Krümmel is the largest childhood leukaemia cluster reported to date worldwide.

5.6.2 Case-Control Study on Leukaemia in German Children (KiKK)

As a response to concerns resulting from the above mentioned studies, the German Federal Office for Radiation Protection (BfS) initiated in 2003 a case-control study of children less than five years of age. This study, named the KiKK study, was based on the German Childhood Cancer Registry (GCCR) and looked at all childhood cancer cases diagnosed between 1980 and 2003 compared to control children without cancer. The KiKK study (46) used distance from a NPP as a substitute for radiation exposure to evaluate the risk of childhood cancer and focused on cases within the 5 km zone of the 16 NPPs in Germany.

The main finding was:

- An increased risk of leukaemia in children less than five years of age with decreasing distance from a NPP.

A follow-up to the KiKK study (47) was conducted. The study focused only on the childhood leukaemia cases registered between 1980 and 2003.

The study concluded that:

- The risk of leukaemia in children less than five years of age increased the closer their home was to a NPP. The results were consistent for all 16 nuclear power sites.

A further follow-up to the KiKK study (48) collected information on other risk factors of childhood leukaemia to help explain the earlier findings.

The study concluded that:

- The observed trends in childhood leukaemia decreased over time.
- There was no clear causal explanation for the childhood leukaemia.

No estimates of radiation exposures from the plants were available, therefore distance (between home and reactor) was used as a substitute for radiation exposure. Nonetheless, the relationship between childhood leukaemia and distance from the NPPs cannot be explained by the radiation exposure from these plants. Environmental exposures during routine operations were extremely low, especially compared to natural and other ionizing radiation sources, and the findings were not consistent with the current understanding of radiation effects observed in radiation biology and epidemiology. In light of this, the observed positive distance trend remains unexplained and no statements on the causes of the increased cancer rates can be made, according to the BfS and GCCR.

5.6.3 The German Radiological Protection Commission

The KiKK Study raised considerable public concern and scientific debate. The German Radiological Protection Commission reviewed the findings of the KiKK study using an interdisciplinary working group of international experts. The working group task was to review the data and make a final evaluation of the study's overall design, conduct, results and interpretation (47, 49).

The main conclusions of the working group are summarized as follows:

- There are several weaknesses in the methods used to estimate radiation exposure and to identify other potential influencing factors.
- The evidence of increased childhood cancer risks was limited to a 5 km zone around the NPPs.
- The study examined distance from the NPP and not radiation exposure; distance is not a suitable substitute for radiation exposure.
- The natural radiation present within the study area was greater by several orders of magnitude than the radiation emissions from the NPPs.
- The actual radiation emissions from the NPPs cannot explain the KiKK results.
- The KiKK study was not able to survey other risk factors, thus cannot be used to help explain the causal reasons for the relationship between distance and leukaemia.
- Finally, studies conducted in other countries were not able to produce similar findings.

In conclusion, the German Radiological Protection Commission working group found no evidence of a causal relationship between radiation and childhood leukaemia among children less than 5 years of age within 5 kilometres of the German NPPs.

In summary, the reason for the increased childhood leukaemia rate around German NPPs is unclear. However, the increased rates could not be explained by the actual radiation emissions from the German NPPs. Since childhood leukaemia is thought to be caused by several factors, other factors may have been responsible for the observed results. More extensive, interdisciplinary research on the causes and mechanisms of the development of childhood leukaemia is required to fully understand the disease.

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5.6.4 Reviews of Studies of Childhood Leukaemia Around Nuclear Facilities

Numerous literature reviews of epidemiological studies of childhood leukaemia around nuclear facilities have been conducted over the years. Laurier *et al*. conducted several comprehensive literature reviews of studies of childhood leukaemia in the vicinity of nuclear sites. The most recent review (50) included 198 local nuclear sites in 10 countries and 25 multiple site studies in 8 countries concluded that:

- Out of all the studies, there were only three confirmed clusters: one in Sellafield (West Cumbria) near the reprocessing plants, one in Dounreay (Scotland) and one in the village of Elbmarsch near the Krümmel NPP (Germany). These three clusters have persisted over time.
- The clusters cannot be explained by environmental radiation exposures near the nuclear facilities.
- None of the multi-site studies indicated an increased risk globally.

Laurier *et al* concluded that the Kinlen hypothesis is the most convincing hypothesis for disease clusters; however, this infectious agent has yet to be found. Many additional risk factors associated with childhood leukaemia (e.g., genetic pre-disposition, nutrition, gestation and other environmental factors) should be considered. Only large-scale national or international analytical studies would be able to characterize the origins of such clusters and clarify the main risk factors for childhood leukaemia. Finally, their review emphasized that the KiKK studies were not supported by studies in other countries, and that to date nothing can explain the excess risk observed.

5.7 Committee on Medical Aspects of Radiation in the Environment Reports

5.7.1 Childhood Leukaemia Around Nuclear Power Plants

In 1983, the UK Government set up the Black Advisory Group to look at the presence of an unexpected excess of childhood leukaemia cases in Seascale, a village located 3 km from the Sellafield nuclear fuel processing plant. The Black Advisory Group found no explanation for such an excess. In 1985, The UK Department of Health and the Health and Safety Executive (HSE) established the Committee on Medical Aspects of Radiation in the Environment (COMARE) to monitor these kinds of findings. COMARE produced three separate reports on the incidence of childhood leukaemia around NPPs in 1996 (51), 2005 (52) and 2006 (53), using the National Registry of Childhood Tumours.

COMARE's conclusions were:

- Leukaemia and many other types of childhood cancers did not occur evenly within the population of Great Britain and these differed more than would be expected from simple random or chance variations.
- There was no evidence of excess childhood cancer around NPPs, although some clusters existed and persisted over time near other nuclear installations (e.g., the Sellafield reprocessing plant).
- Since disease clustering was found in many locations with and without NPPs, other factors in the environment needed to be considered.

Based on the Bradford-Hill criteria, COMARE concluded there was no evidence that increased childhood leukaemia rates were due to the radiation discharges from the facilities.

5.7.2 Effects of Radiation on Offspring of Nuclear Workers

In 1990, Gardner *et al*. conducted a case-control study (54) on leukaemia and lymphoma among young people living near the nuclear fuel processing plant in Sellafield, UK. They concluded that the increased incidence of leukaemia and Non-Hodgkin Lymphoma (NHL) among the children was associated with parental occupational radiation exposure prior to child conception.

COMARE also extensively reviewed epidemiological studies, laboratory and genetic research related to possible biological mechanisms for childhood leukaemia in their 1996 (51) and 2002 (55) reports.

COMARE concluded that:

- There was no evidence of a causal relationship between the workers' radiation exposure and cancer or birth defects in their children.
- These findings were consistent with high dose studies of the atomic bomb survivors and radiotherapy patients who become pregnant.

5.8 Summary

In summary, the many epidemiological studies of populations living in the vicinity of nuclear facilities have provided no substantive evidence that any adverse health outcomes are related to environmental radiation exposures from these facilities. The current levels of environmental or occupational radiation exposures in Canada are low. There is no evidence of increased birth defects, cancer incidence or mortality in populations due to these radiation exposures.

Three leukaemia clusters have been identified in the vicinity of the three nuclear facilities located in England, Germany and Scotland. It would be necessary to conduct large-scale national and international analytical studies to be able to characterize the origins of these clusters and to clarify the main risk factors for childhood leukaemia.

6.0 INTERNATIONAL GROUPS OF EXPERTS IN RADIATION PROTECTION

6.1 United Nations Scientific Committee on the Effects of Atomic Radiation

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was established in 1955. The mandate of the Committee was to undertake broad reviews of the sources of ionizing radiation and its effects on health and the environment. UNSCEAR has since become the world authority on global levels and effects of ionizing radiation.

UNSCEAR reviews all new information on radiation levels and effects and synthesizes it into a coherent picture for use by policy makers and other stakeholders. These reviews are the scientific foundation used by the International Commission on Radiological Protection (ICRP) in developing its recommendations on radiation protection, and by other agencies such as the International Atomic Energy Agency (IAEA), in formulating the international Basic Safety Standards (BSS) for protection against ionizing radiation.

UNSCEAR is composed of delegations from 21 countries. Each delegation contributes to the work of the Committee by providing specific expert knowledge on a broad range of issues in the field of radiation sources and effects, and competent assessment of draft scientific documents. The CNSC has two members on the Canadian delegation to UNSCEAR.

6.2 The Biological Effects on Ionizing Radiation Committee

The United States (U.S.) National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR Committee) reports directly to the U.S. government on the health effects of low-level ionizing radiation. The Committee reviews the latest findings on ionizing radiation and presents its conclusions in reports. The most recent report from this Committee is the BEIR VII Report: *Health risks from exposure to low levels of ionizing radiations* (2005) (56).

The BEIR VII Committee was given the mandate to develop "risk models" for estimating the relationship between exposure to low dose levels of ionizing radiation and its harmful health effects. After a thorough review of the most recent literature available, the BEIR VII Committee concluded that:

- The linear no-threshold model (LNT) provides the most reasonable and a very conservative description of the relation between low-dose exposure to ionizing radiation and the incidence of solid cancers. It assumes there is a direct relationship between radiation exposure and cancer rates.
- There is a dose-response relationship at doses in the order of 100 mSv or more delivered at high dose rates.

BEIR VII also reported that at low doses (less than 100 mSv), there is no clear scientific evidence of any adverse health effects. Likewise, the presence of other risk factors (e.g., age, sex, genetics, and other behavioural and environmental risk factors) can make it difficult to separate the effects due only to radiation from the effects from other risk factors. Nonetheless, the Linear No-Threshold model (LNT) is a risk model used internationally by most health agencies and nuclear regulators to set dose limits for workers and members of the public. Because the LNT assumes all radiation exposures carry some risk, in addition to dose limits, licensees are required to keep radiation exposures as low as reasonably achievable (ALARA). This is a core principle of the CNSC's approach to radiation protection. Thus, the LNT model plays a key role in how the Canadian Nuclear Safety Commission (CNSC) approaches radiation protection.

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6.3 The International Commission on Radiological Protection

The International Commission on Radiological Protection (ICRP) is an advisory body providing recommendations and guidance on radiation protection. The ICRP publishes its recommendations and advice in the fields of medicine and physics in the shape of a scientific journal, entitled the *Annals of the ICRP*.

In preparing its recommendations, the ICRP considers the fundamental principles and the scientific results upon which appropriate radiation protection measures can be established, while leaving to the various national protection bodies the responsibility of formulating the specific advice, codes of practice, or regulations that are best suited to the needs of their individual countries. While the ICRP has no formal power to impose its recommendations, legal authorities in most countries adhere closely to the ICRP recommendations.

As the leading group in radiation protection, the ICRP has formulated a practical working system of radiation protection that is scientifically based on straightforward assumptions. CNSC adheres to the ICRP system. The most recent recommendations from the ICRP (2007) are set out in ICRP 103 (57).

6.4 The International Atomic Energy Agency

The International Atomic Energy Agency (IAEA) is the world's centre of cooperation in the nuclear field. The Agency works with its 151 Member States and multiple partners worldwide to promote safe, secure and peaceful nuclear technologies.

The IAEA helps countries to implement nuclear safety and to prepare for and respond to emergencies. Their mandate is to protect people and the environment from harmful radiation exposure. The IAEA's work has set a framework to which Canada adheres. This framework includes advisory international standards, codes and guides; binding international conventions; international peer reviews to evaluate national operations, capabilities and infrastructures; and an international system of emergency preparedness and response.

The IAEA safety standards provide a system of fundamental safety principles, safety requirements and safety guides for ensuring safety. They reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation.

The IAEA Statute makes the safety standards binding on the IAEA in relation to its own operations. Any State entering into an agreement with the IAEA concerning any form of Agency assistance is required to comply with the requirements of the standards that pertain to the activities covered by the agreement.

The principal IAEA safety guide is the Basic Safety Standards (BSS) which are currently undergoing revision. The BSS is based upon the latest recommendations of the International Commission of Radiological Protection (ICRP) and applies to three categories of exposure: occupational exposure, public exposure and medical exposure. The BSS is written in legal terminology such that states can take sections of the BSS verbatim and include it in their radiation protection regulations. Canada has contributed to the drafting of the BSS although our radiation protection regulations were developed directly from the ICRP recommendations and so do not directly mirror the BSS text.

7.0 DISCUSSION AND CONCLUSIONS

7.1 How Does the CNSC Use Epidemiology To Protect Nuclear Workers and the Canadian Public?

The CNSC's mandate is to regulate the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment.

To meet this objective, the CNSC sets regulatory limits on radiation exposures for workers and the public on the basis of ICRP's recommendation. These limits are outlined in the Canadian *Radiation Protection Regulations* (58). The CNSC also produces guidance documents to help licensees implement a radiation protection program and other measures (e.g., action levels) that keep the amount of exposure to ionizing radiation as low as reasonably achievable (ALARA).

The purpose of these regulatory limits and guidance documents is to prevent health effects and to establish an acceptable level of safety for workers and members of the public. The primary concern is the minimization of radiogenic cancers. Setting adequate protective exposure limits and providing appropriate guidance requires an assessment of risks.

The health effects of radiation have been extensively studied. Epidemiological studies based on good quality radiation exposure data are the best source of evidence for assessing human health risks from radiation exposure. Cohort studies are the strongest type of epidemiological study and provide the strongest evidence of the relationship between radiation exposure and health effects. However, even cohort studies have a limited ability to assess health risks at low exposures. This is the reason why at low doses, very large populations, high quality individual exposure information, and the control of biases and confounding factors are essential. Thus, at low doses, it becomes absolutely necessary to understand the mechanisms of the onset of cancer through the study of radiation biology.

The CNSC staff keeps its knowledge up to date through the coordination of national epidemiology studies of radiation workers (e.g., Eldorado uranium workers, Ontario miners, AECL reanalysis), the review of recent multi-disciplinary research (such as genetics, molecular biology, health physics and epidemiology in peer-reviewed scientific publications), participation in multi-disciplinary international committees of experts (e.g. UNSCEAR, IAEA), and the review of the documents produced by BEIR, the ICRP and other authorities involved in radiation risk assessment. In this process, the CNSC bases its decisions on objective scientific information from reports by scientific advisory bodies including UNSCEAR, the ICRP, and the BEIR Committee, with additional input from its own independent review of the literature, and the results of CNSC funded research.

The shape of the dose response curve for cancer at low doses is a matter of considerable scientific debate. Hypotheses range from beneficial effects of small radiation doses (hormesis) to a threshold response, or to a no-threshold supra-linear response (implying that small doses are more hazardous than previously assumed).

The CNSC bases its risk assessments for populations exposed to low level of ionizing radiation on the linear no-threshold (LNT) hypothesis, which assumes that the risk of cancer due to a low dose is proportional to dose, with no threshold. The use of LNT for radiation protection purposes has been repeatedly endorsed by authoritative scientific advisory bodies, including UNSCEAR, the ICRP and the BEIR Committees, and remains the best model on which to base radiation protection regulations. However, it should be noted that BEIR VII also recognizes that the use of this model might over estimate (for example, the overestimation of the predictions on the excess risks of cancer following the Chernobyl accident) the risk at low doses making it conservative and suitable to protect the health of workers and the public.

Although recent radiobiological findings indicate that cellular repair processes could happen at low doses, these findings are not understood well enough to trigger changes in the current regulations. LNT is still supported by data from both epidemiology and radiobiology and provides a conservative, precautionary assessment of risk at doses below 100 mSv. At doses below 100 mSv, it is not possible to distinguish disease attributed to radiation from that of the natural variation in disease among the general population.

The *Radiation Protection Regulations* exposure limits for the Canadian public are set at 1 mSv/year, and at 50 mSv annually, or at a maximum of 100 mSv for five years, for workers. These limits, in addition to the ALARA principle, are included in the Radiation Protection Program required by the CNSC for each licensee. Any radiation exposure to Canadian nuclear workers or the public, as a result of the nuclear industry, are thus limited to exposure levels well below the regulatory limits. This ensures that Canadians are safely protected from ionizing radiation health effects.

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