Know Less and Understand More[1]

Where is the wisdom we have lost in knowledge?
Where is the knowledge we have lost in information?
T. S. Eliot 1888-1965.

Preface- A Winter of Discontent?

At past J. Newell Stannard Lecture Series some speakers have informally offered broad assessments of the progress that the science of radiological protection has made over the past fifty years and concluded it to be disappointing.

To many these views may seem surprising and indeed there appear to be arguments to the contrary. About five years ago the author wrote: "*What deeply troubles me is that as a profession we have snatched defeat from the jaws of victory. After a wonderfully successful 30 years in which radiation exposures have, in general, steadily declined we are left with a situation in which airline personnel are among those workers experiencing the highest estimated radiation exposures-and that due to natural radiation to boot. When I began my career in 1948 such an outcome would have been regarded as a triumph!*" (Thomas 2000). Why, when there is a successful history of improving radiological protection, do several scientists express this winter of discontent? What is the nature of this unease?

In his notes to a lecture entitled "Internal emitters –are we in the know?' at the Twelfth Stannard Lecture Series Bill Bair commented our "knowledge is inadequate to resolve current and future health issues" Bair (2004) - this after nearly 50 years of experience. In his lecture notes Bair's list of "unknowns" and "knowns" in radiological protection is helpful and revealing.

At the eleventh meeting in 2003 Bob Thomas bemoaned the very conservative choice of the Dose Rate Effectiveness Factor (DREF) when extrapolating from high to low dose rates in estimating risk from external photon exposure. In his opinion more suitable data were available for low dose, low dose, rate human exposures (Thomas, R. G. 2003, NAS 1980).

In 2005 the author pleaded that the concepts and quantities of radiological protection quantities, and models derived from these concepts, should be defined with greater rigor than at the present time. (Thomas, R. H. 2005).

Neither has this "discontent" been limited to "Stannard Lecturers" nor is it new. Others have been critical for some time and on many fronts. Seven years ago no less a scientist than Harald Rossi commented "*During the past two decades the* <u>*concepts of radiation protection*</u> *and the applicable physical quantities have drifted into what may be regarded as chaos*" (Rossi 1999) [The underline is the author's]. More recently, the BEIR 7(Phase 2) report of the (US) National Academy of Sciences has drawn fire from some quarters - particularly on the issue of risk assessment at low doses and dose rates. Tubania and Aurengo (2005) have compared its conclusions with those of the equivalent French report: "(In contrast with the conclusions of)----- *the French Academies' report, the BEIR 7 report, ----, concludes that the linear no-threshold relationship (LNT) should be used for assessing the carcinogenic risks of low or very low doses* (whereas the French report determines the opposite). *Since both reports rely to a large extent on the same data, the causes of this disagreement need to be investigated*." In a letter to the President of the National Academy of Sciences a senior official of the US Department of Energy expressed disappointment that BEIR 7 did not discuss *"---- new and exciting biological research* (that) *has been published demonstrating that cells in tissues respond very differently to radiation than isolated cells in culture and that cellular responses to low doses of radiation are very different from responses to high doses of radiation ----- Biological mechanisms are now known to exist----to repair the damaged cells, and to suppress tumorigenisis"* (Orbach 2005). Some have even dismissed BEIR 7 as "bad science". Rockwell (2006) asserts "*Only one of BEIR VII's* more than *700 pages directly discusses the subject of the report; 'How does a living organism respond to low-dose radiation?'"*

There can be no doubt that the last fifty years has accumulated much information. Is the "Winter of Discontent" then a debate about differentiating between information, knowledge and wisdom?

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[1] A corruption of "*Women are wiser than men because they know less and understand more*" from "The Crock of Gold" (1912), chapter 2. James Stephens [1882-1950].

Radiological Protection – the first 50 years

At the outset it is important to recognize that in the fifty years following the discovery of X-rays in 1895 were productive. A practical system of radiological protection was established using the empirical models established by toxicology. With this approach protection standards for external exposure to photons fell about 50-fold between 1920 and 1950. By 1936 the maximum permissible level for radiation workers recommended by NCRP was 0.3R per day (for references see Thomas 1970). A year earlier in Berkeley, Lawrence and his colleagues had established control of neutron exposures using an RBE of 10 for neutrons (Heilbron and Seidel, 1989). About the same time internal exposures were limited to a body burden equivalent to 0.1 μC_i radium, largely due to the work of Robley Evans and his colleagues (Stannard 1988).

This regimen well-served the need of the medical profession in its needs to protect both patients and hospital staff. During the Second World War the Manhattan Project was conducted with an exemplary degree of radiation safety, using those protection standards that had been developed a decade or more earlier.

By the mid-1950s it was possible to understand what we did not know. To be able set radiological protection on a firm scientific basis answers were necessary to many fundamental questions including:

Is radiation exposure potentially harmful at low doses?
Is there a dose threshold?
Is there hormesis?
What is the dose-rate dependence?
What is the LET dependence?
What information about risk may be obtained from epidemiological studies?
How can experimental studies on cells or animals be extrapolated to Humans?

Despite much new information these questions remain to a large extent unanswered today.

Radiological Protection – 1955-2005

In 1956 the ICRP made a significant change in protection standards based on theoretical grounds. The limit to the annual dose equivalent for radiation workers was reduced by a factor of 3, from 15 to 5 rem per year. The theoretical basis for this reduction was based on predicted genetic effects. It is now generally accepted that those predicted effects have not been seen in humans. Since then the emphasis on protecting individuals from any harmful effects resulting from radiation exposure has been largely devoted to estimates of the risks of radio-carcinogenesis.

Over the past fifty years the priorities of the radiological protection profession have properly been focused upon the immediately contemporary specific societal needs. These were largely the control of external exposure to photons, particularly from the medical uses of x-rays. Even today the exposure to low-LET radiations contributes by far the largest part (~80%) of the collective occupational exposure of radiation workers. Similarly, the larger part of man-made radiation exposure to members of the general population results from diagnostic radiology.

Although the number of personnel exposed to the so-called “internal emitters” and to high-LET radiations was about equal, over the last fifty years the greater attention has been devoted to internal emitters. This is consonant with Bair’s opinion that internal emitters presented the greater risk (Bair 2004). The initial concern for internal emitters, spurred by the radium dial painters, later became directed towards the protection of workers from products of the nuclear fuel-cycle such as, for example, plutonium and fission products (Stannard 1988).

This period was marked by the evolution and introduction of many “modified-absorbed dose quantities”. Starting with absorbed dose itself in 1953 the list includes such “quantities” as RBE Dose (1948, 1956); Dose Equivalent (1964); Maximum Dose Equivalent (1957); Dose Equivalent Index (1980); Effective Dose Equivalent (1977,1980); Ambient Dose Equivalent (1985); Equivalent Dose (1990) and Effective Dose (1990). These changes made difficulties for dosimetrists and others because they involve not only changes in nomenclature but also result in small but bothersome numerical differences in the interpretation of measurements. While these changes may be explained, or excused, by the steady evolution of these concepts they nevertheless seem to have occurred too frequently – reflecting perhaps some uncertainty within ICRP, coupled with a rush to premature publication of “work in progress”.

On a more positive note, with the aid of computer programs, metabolic models and anthropomorphic phantom models information has been abundantly available. Many details have been worked out and are now available to dosimetrists, greatly facilitating their task of demonstrating compliance with the dose limits set by advisory bodies such as ICRP and NCRP. The second fifty years of radiological protection might thus be aptly called “the age of information”.

Hypotheses, Theories and Laws

“Theories are nets cast to catch what we call ‘the world’: to rationalize, to explain and to master it. We endeavour to make the mesh ever finer and finer.” (Popper 1959)

Popper’s insight into the progression of the physical sciences and now, increasingly, the biological sciences, suggests the development towards maturity has three stages of increasing certainty, from Hypothesis through Theory to Law.

These terms are often confused in scientific writing and, sometimes, even by leaders of the profession. The precise use of words, important in all successful communication, is crucial to Science. Indeed some misgivings have even been expressed at the highest level within ICRP itself as to the transparency of its own publications Lindell (1998); Beninson *et al*. (2000); Clarke, (2003). The ICRP on its part could do a great deal to improve clarity if it were to avoid frequent changes in its own nomenclature.

If we are not to confuse the general public – and perhaps even ourselves - it is essential that the profession itself uses the terms “hypothesis”, “theory” and “scientific law”, the underlying concepts of the development of science, and the system of radiological protection in a consistently correct manner.

A hypothesis is an unproved proposition or theory. Popper holds that a necessary condition for a scientific hypothesis is that it may tested by observation.

A theory rests at a higher level of understanding than does a hypothesis and is a formulation, which has been verified to some degree, of underlying principles that relate several observed natural phenomena.

Finally, a law is a generalization that describes recurring facts or events in nature that has been observed to occur with unvarying uniformity under the same conditions. (Oxford [1971,1987]; Webster [1964]).

With no underlying theory or law yet available, radiological protection must create models on which to construct administrative systems of regulation. So that the importance of models not be overrated an essential caveat to be borne in mind is that models are used at many stages in the development of science but the mere existence of a model in itself gives no implication of the degree of confidence in which it may be held.

Professional Societies could play a major role in enhancing the credibility of our profession if serious attempts were made to provide information to educated lay-people. Documents might be prepared, avoiding professional jargon, which summarize major policies, underlying principles and describing how judgments are made that safeguard the general public and workers. Credibility would be enhanced if these documents also described what new knowledge is needed to confirm the validity of our judgments. There is no shame in admitting that we do not yet understand everything.

The limitations of models, statistical & epidemiological analysis

Models

In the absence of a sound theoretical basis for radiological protection the development of models to facilitate the practical and administrative implementation of protection programs is essential. Basic uncertainties in fundamental theory should, place constraints on the design of these Models. Unfortunately these constraints are not always recognized in practice

Models should be developed that are simple and internally consistent. The KISS[2] principle should be kept in mind. A false sense of reality is created if models are unjustifiably complex..

Models must be consistent with the laws of physics, mathematical logic and with the recommendations of advisory bodies. It follows that a corresponding responsibility is placed on Advisory Bodies[3] to make recommendations that are similarly constrained.

Models, once created, should be changed only infrequently. Changes should only made either if serious errors are to be corrected, or if there has been significant improvement in our basic understanding. Frequent tinkering with, or fine-tuning of, the models used in routine radiological protection has a counter-productive impact on administrative and legal systems.

Designers and users of models should also keep the aphorism “GIGO”[4] firmly in mind. Naturally, calculations made with models incorporate the uncertainties intrinsic to those models. There is sometimes a naive belief that complicated models or technologies can work magic. Charles Babbage[5], inventor of the first calculating machine recalled "*On two occasions I have*

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[2] The KISS Principle is a popular maxim often invoked when discussing a design process as a reminder to avoid the unnecessary complexity that can arise during the design process. The traditional expansion of this acronym is "Keep it Simple, Stupid".(Wikipedia)

[3] The term “Advisory Bodies” includes organizations whose purpose is to offer advice in all aspects of radiological protection, including international organizations such as ICRP and ICRU and national organizations such as, for example in the USA, NCRP.

[4] An abbreviation for the aphorism “Garbage in, Garbage out”. The origin is unclear but appears to have originated within the computer industry in the 1970s and means that if invalid data are entered into a computer system the resultant output will also be invalid. First applied to computer software the phrase is now applied to all decision-making systems

[5] Charles Babbage (1791-1871), inventor of the “Difference Engine”.

been asked, 'Pray, Mr. Babbage, if you put into the machine wrong figures, will the right answers come out?' Babbage did not reveal to us his answer to such questions.

Knowledge will be found in making judgments not from the detailed information obtained from models but through the prism of a comprehensive understanding of the fundamental basis for the model being used.

Some of these points may be illustrated by reference to the linear-no-threshold *model* (LNT) that is itself the cornerstone of many other detriment or risk models used by ICRP. LNT is often assumed for the dose effect relationship and has been variously described as hypothesis or theory or even law [Benison, 1996; Cohen 1999; Rossi 1999; for references see also Thomas 2000]. It nevertheless does not qualify for the status of a scientific hypothesis because it does not meet Popper's requirement testing against falsification. Indeed it is doubtful if there is any general expectation that, at low doses and low dose rates, scientific investigation will eventually show that all radiation-induced malignancies will be shown to exhibit identical dose-effect relationships in humans.

Given this status of LNT it is at best not helpful to overstate its utility. While arguably helpful in some facets of radiological protection practice it is, for example, unhelpful and misleading to either compare LNT favorably with Newton's Laws of Motion or to assert that '*it is at present the best tool to predict the risk probability of radiation at low doses*' – a thought that the recent BEIR VII Report seems to endorse (Beninson 1996, NAS 2005). If administrators and the general public alike are not to be misled it is imperative that, in any discussion of LNT by advisory bodies, it is clearly stated that the reliability of LNT as a predictor of risk is severely circumscribed by its intrinsic assumptions (see Thomas 2004a,b). Unless such a caveat is clearly stated the misuse of LNT may be encouraged, for example in the prediction of "extra deaths" that might result from small doses to individuals within large populations.

The reaction to the BEIR VII Report has fanned the embers of a long-standing controversy over LNT. Despite the information gleaned over the past twenty-five years current literature suggests that, because of the present limitations of epidemiology and animal-to- man extrapolations, the agonies of the BEIR III committee in the late seventies, so well described by Walker (2000), in formulating a model for the low dose relationship, continues to this day.

Limitations on space and time limits constrain discussions in what follows to statistical and epidemiological information only. For information on animal-to- man extrapolations the reader is referred to the recently issued NCRP Report 150 (NCRP 2005).

The need for statistical and epidemiological analyses

Statistical and epidemiological analyses of data are necessary if all the intrinsic information available from observed data is to be to efficiently extracted. Both kinds of analysis are fraught with traps for the unwary and are often viewed with suspicion. D'Israeli is said to have complained "*There are three kinds of lies: lies, damned lies and statistics*"[6]. As Andrew Lang understood this is a criticism not of the raw data but rather its interpreters[7].

Analysis of data by statistical techniques by experts skilled in these methods can bring enlightenment but alas in the hands of novices often brings error and unreasonable conclusions. If errors are to be avoided amateurs should resist any temptation to dust off their textbooks on "Elementary Statistics" but instead seek expert advice.

Common deductive flaws (naiveté) using Statistical Analysis

"He uses statistics as a drunken man uses lamp posts-for support rather than illumination". Andrew Lang (attributed)[7].

Small sample size. A not uncommon difficulty in biological and epidemiological studies is that of small sample size. Small sample size requires special statistical techniques if reasonable assessments of data are to be made (see, for example, Appendix G in Robley Evans' "*The Atomic Nucleus*"). Errors may be made in error estimation unless appropriate techniques are applied. In Least Squares calculations and hypothesis testing a rough rule of thumb suggests at least ten data points per parameter are required (Draper and Smith, [1966]; Snedecor and Cochran [1980]). This requirement is often ignored in practice

Correlation. Good correlation does not necessarily imply or validate causation. There is an apocryphal story that Sir Ronald Fisher, one of the great pioneers of statistical methods, used to reinforce this point with his students by having them determine the correlation coefficient for the population of storks in some German towns with the human population (they were tightly correlated because people in that part of Europe believed storks to be lucky and built platforms to enable storks to nest among the warmth of their chimneys).

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[6] Benjamin D'Israeli 1804-1881. Novelist and prime Minister of England168, 1874-1880. Attributed by Mark Twain in "*Autobiography*" (1924).

[7] Andrew Lang, 1844-1912. Scottish man of letters. Now most famous for his translations of the *Iliad* and *Odyssey*.

Error estimation: failure to identify random and systematic errors can make error estimation difficult or impossible.

Method of least squares: The Method of Least Squares developed by Gauss (1823) is sometimes ignobly used to give "respectability" to poor data. Of course it cannot do this. Its proper purpose is to determine the best estimate of the set of values for the parameters of an assumed relationship between two (or more) variables that is imposed by a set of experimental data. The application of the method tacitly assumes that the experimental data are randomly distributed and untainted with systematic error. If this condition is not met the "best estimates" or their computed accuracy may be in error.

A personal experience of the author's of such an error was in the measurement of the half-life of ^{60}Co [see Lockett and Thomas (1953, 1954), Littler and Thomas (1952)]. After observations of the radioactive decay of ^{60}Co over 8 months a value of 4.95±0.04 years was obtained using the method of least squares. This value was considerably lower than the then generally accepted value of 5.3 years. The estimated error of ±0.04 encouraged publication. The publication was premature – the estimated error was incorrect by about an order of magnitude because of systematic errors.

"*It is apparent that the error of ±0.04 quoted on our earlier value of 4.95 years was not realistic. On examination of the* (earlier) *measurements we find that they do not form a Gaussian distribution. This is probably due to incomplete correction by our radiation standard for pressure and temperature variations in the electroscopes* (ionization chambers). *However, with the present results, the observations do form a reasonably good normal set and we are justified in applying the method of least squares to compute the half life and its accuracy*". The value obtained after observations over more than 3 years, which were normally distributed, was 5.20±0.03 years.

Invalid comparisons: the comparison of observed morbidity or mortality incidence rate data with estimated "expected" incidence is prone to error. The difficulties that may arise will be discussed later using the incidence of childhood leukæmia as an example (Barton et. *al*. 1985).

Some limitations of epidemiological analysis

When, as is the case with radiation exposure, the risk of cancer exposure is small and the latent period may be many years or even decades, there are limitations on the information available in epidemiological studies. For example, when considering mortality statistics a considerable fraction of all deaths (~ 30%) will be due to cancer. When attempting to differentiate between deaths due to radiation-induced cancer and cancer deaths due to “other causes” there are rarely, if ever, specific laboratory tests that can identify the cause of a malignancy and one is faced with identifying a small number of cancers caused by radiation superimposed on a very large background of “others”. An ideal study would compare two populations of people, exposed or not exposed to ionizing radiation but identical in all other respects, followed until death to determine it there were any differences in cancer mortality between the two groups. Suffice it to say that, with many confounding variables, ideal studies are never possible.

With the relatively small number of radiation induced cancers any study must follow the health of large number of people over a long time. A rough estimate of the number of person years (PY) necessary may be obtained from a simple expression due to Pochin (1988) and Patterson and Thomas (1972)

$$PY \geq 4M.(KD)^{-2} \qquad (1)$$

where:

P = number of people exposed
Y = years of exposure (y)
M = annual risk of death from cancer (y^{-1})
D = annual excess dose rate ($Sv.y^{-1}$)
K = estimated risk of radiation-induced cancer $(Sv)^{-1}$

With $M = 3.5 \times 10^{-3}\ y^{-1}$ and $K = 5 \times 10^{-2}\ Sv^{-1}$ equation (1) gives:

$$PY \geq 5.6 \times D^{-2} \qquad (2)$$

For example a study of population exposed to 10^{-3} Sv y^{-1} and lasting 40 years would require about 140,000 persons, with a matching population of unexposed people.

It is worth noting that under the hypothesis and assumptions of such a study (40 years of exposure @ 10^{-3} Sv y^{-1}), if it were continued until death there would be ~ 42,000 and 42,280 cancer deaths in the unexposed and exposed populations respectively. The difference between the two groups could be detected but the information would not be sufficient data are available to explore all the factors of interest such as differences in radiation sensitivity with age, sex, dose rate and tumor type in detail. which explains the need for the adoption of general assumptions (models), such as LNT, to provide a basis for reasoned judgments in the determination of protection limits.

It is important to note, however, that if, as some have asserted, the risk M had been underestimated by at least an order of magnitude the number of people in the study is reduced by a factor of 100 making rebuttal feasible with much smaller population. In the example above if the risk of cancer were 50% per Sv the deaths due to cancer would be ~ 42,000 and 44,801 cancer deaths in the unexposed and exposed populations respectively. There is clearly sufficient evidence to rebut the suggestion.

Very large studies are expensive and in the case of cancer protracted. Decades are required and funding is difficult. Many studies reported in the scientific literature have therefore selectively followed either populations exposed to very large doses of radiation (*e.g.* the radiation dial painters; nuclear weapons attack survivors), or exposure to sensitive organs (*e.g.* radio-iodine and the thyroid), or incidents in which rare malignancies appear at higher than expected rates (e.g. childhood leukæmia).

Childhood Leukæmia as an example of pitfalls in epidemiological analysis

Of all the malignancies perhaps childhood leukæmia is the most troubling. The thought of innocent children suffering properly heightens public consciousness and the medical profession and public health personnel have devoted great attention to studying and developing cures for this disease. What follows is a brief summary of events in the United Kingdom in the eighties and nineties following a reported cluster of childhood leukæmia near one of England's nuclear facilities.

"Clusters". One of the curiosities of childhood leukæmia is that it oftentimes appears, approximately at the same time, in small geographically localized groups (Wood 1960). An informative and helpful guide to clusters is given by Taylor and Wilkie (1988).

As early as 1937 Kellet observed: "----*there is a tendency to find tiny foci living in close proximity*". When these "clusters" occur in, say, twos, threes or fours standard statistical tests may show them to be unlikely due to chance. (It should also be kept in mind that, at the 5% significance testing level, on the average 1 case in 20 may be found "significant" by chance alone, even if the events are random). Because the cause or causes of the disease are uncertain the occurrence of clusters is often generate great concern. Wood (1961) has made a detailed study of clustering in the County of Cornwall in the UK.

Seascale[8]. The observation of 4 deaths (less than 1 expected) from childhood leukæmia during the period 1963-1980 in the area around Seascale led to intense activity studying the Seascale cluster and searches for similar clusters near other nuclear installations in the United Kingdom.

In an attempt to determine if the Seascale cluster might have been caused by radiation exposure resulting from discharges from the Sellafield Works the National Radiological Board of the United Kingdom carried out a thorough dose assessment to members of the general public in Seascale. Besides estimating radiation exposure due to BNFL discharges from the Sellafield Works the contributions to exposure from natural background, medical practices and nuclear weapons fall-out were also evaluated (Linsley, G. S. *et al*. 1984). From these studies it was possible to estimate that an upper limit to the number of radiation induced leukæmias in the Sellafield population over the time studied was ~ 0.1. The number of cases attributable to Sellafield operations would no higher than ~ 0.01. Less than 1 case would be "expected" in the population studied over the period. but 4 cases were diagnosed. No knowledgeable person believes that the dose estimates are incorrect by a factor of ~400. The Sellafield episode remains unexplained, except as a statistical quirk, as is winning the Lottery - as rare as it is inevitable. It still haunts the papers on childhood leukæmia by British researchers to this day. The Sellafield cluster stimulated many searches throughout the United Kingdom for similar events particularly near other nuclear facilities.

West Berkshire. One such study stimulated by the Sellafield episode was by Barton *et al*. and entitled "*Childhood Leukaemia in West Berkshire*". It was published in the medical journal Lancet on 30 November 1985. This Letter to the Editor reported that for the period 1972–1984 there were 45 children diagnosed with acute leukæmia whereas 33.3 cases were expected ($p<0.06$) in the Health District in which the authors worked. This district contained two nuclear facilities.

In a professional manner the authors express caution in interpreting their data because "*we were already suspicious that there was an excess of children* (with leukæmia) *and this was the reason for the analysis*". The authors were also aware that there was to be a television program discussing childhood cancers in their district and wished their work to be published before the

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[8] The first British plutonium production nuclear reactors were constructed in the late forties and early fifties at Windscale in Cumbria, NE England, a site closebye the Irish Sea. Subsequently the area has been referred to as Sellafield and also as Seascale a nearby village and railway station.

program was broadcast. In a sense the authors honestly impeached their own paper (expectations, nuclear installations, forthcoming TV exposé).

There was an immediate flurry of papers in response to Barton *et el*., most of them offering helpful comment. In the 25 January 1986 issue of Lancet Cartwright pointed out the geographical variation in childhood leukæmia rates in England - a twofold difference between southern and northern England (from 4 to 8 per 10^5 people per year). Such variations must be taken into account when estimating the "expected rates”. In the same issue of Lancet, Barclay also drew attention to a gradient in leukæmia incidence rates from lower values in urban areas to higher rates in rural areas in the Wessex[9] region of England. Barclay also suggested that the Cancer Registry in Wessex was incomplete by between 8% to 32% (presumably dependent on the locations of the recording offices). To further confound the interpretation is the actual the statistical distribution of leukæmia clusters. Many of the statistical significance tests applied assume Poissonian statistics. Papers by Cartwright and Miller (1985) and Swansbury (1985) debate whether the distribution is in fact Poissonian in character. If the distribution is not as assumed the significance of significance testing is obscure. Despite the number of diagnosed cases, the uncertainties in the estimation of the expected cases in the population suggests that the authors were correct in expressing caution in the interpretation of their observations.

Scrutiny of the Health of Radiation Workers

Concurrently with the childhood leukæmia studies the obvious strategy of monitoring the health and radiation dose of those most exposed - radiation workers - was underway. Fatalities due to malignant disease in radiation workers both in the UK and USA have been closely followed.

Table 1 shows results from a pooled group 23,000 male workers of radiation workers from five UKAEA sites. The mean accumulated dose equivalent was $3.2.10^{-2}$ Sv per worker and the group was followed for 16 years. Standardized mortality rations for all cancer and for six specific cancers were compared.

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[9] Wessex is a region in SW England comprised of the counties of Berkshire, Devon, Dorset, Gloucestershire Hampshire, Herefordshire, Oxfordshire, Somerset and. Wiltshire.

Table 1

Standardized Mortality Ratios for Malignant Disease

Malignancy	**SMR**
All Cancer	75 (p<1%)
Lung	69 (p<1%)
Stomach	79
Bladder	79
Leukæmia	110
Multiple Myeloma	60
Prostate	115

The “Healthy Worker Effect” is evident in this table. The small numbers in the study make specific statements difficult for any thing other than death by all cancers and cancer of the lung. No information is available about smoking habits.

The result of a study about 10 years later than that for Table 1 was published in 1999 by Muirhead, C. R. *et al.* This was a study of nearly 125,000 British radiation workers. The “healthy worker effect” is still evident. In some respects the results are similar to those for the Japanese atomic bomb survivors at low doses. As the studies continue risk estimates are trending lower and it is not surprising that the confidence limits are tightening. The abstract of the paper is interesting and given in full:

“**Abstract**. *The National Registry for Radiation Workers is the largest epidemiological study of UK radiation workers. Following the first analysis published in 1992, a second analysis has been conducted using an enlarged cohort of 124,743 workers, updated dosimetry and personal data for some workers, and a longer follow-up.*

Overall levels of mortality were found to be less than those expected from national rates; the standardised mortality ratio for all causes was 82, increasing to 89 after adjusting for social class. This “healthy worker effect” was particularly strong for lung cancer and for some smoking-related non-malignant diseases.

Analysis of potential radiation effects involved testing for any trend in mortality risk with external dose, after adjusting for likely confounding factors. For leukæmia, excluding chronic lymphatic leukæmia, the central estimate of excess relative risk per Sv was similar to that estimated for the Japanese atomic bomb survivors at low doses (without the incorporation of a dose-rate correction factor); the corresponding 90% confidence limits for this trend were tighter *than in the first analysis, ranging from just under four times the risk estimated at low doses from the Japanese atomic bomb survivors to about zero.*

For the grouping of all malignancies other than leukæmia, the central estimate of the trend in risk with dose was closer to zero than in the first analysis; also, the 90% confidence limits were tighter than before and included zero.

Since results for lung cancer and non-malignant smoking-related diseases suggested the possibility of confounding by smoking, an examination was made, as in the first analysis, of all malignancies other than leukæmia and lung cancer. In this instance the central estimate of the excess relative risk per Sv was similar to that from the A-bomb data (without the incorporation of a dose-rate correction factor), with a 90% confidence interval ranging from about four times the A-bomb value to less than zero. For multiple myeloma there was an indication of an increasing trend in risk with external dose (p = 0.06), although the evidence for this trend disappeared after omitting workers monitored for exposure to internal emitters.

The second National Registry for Radiation Workers analysis provides stronger inferences than the first on occupational radiation exposure and cancer mortality; the 90% confidence intervals for the risk per unit dose are tighter than before, and now exclude values which are greater than four times those seen among the Japanese A-bomb survivors, although they are also generally consistent with an observation of no raised risk. Furthermore, there is evidence, of borderline statistical significance, of an increasing risk for leukæmia excluding chronic lymphatic leukæmia, and, as with solid cancers, the data are consistent with the A-bomb findings."

Studies of Leukæmia and other cancer near Nuclear Sites

Baron (1984) has reported studies of trends in cancer mortality in populations living in small areas around fourteen nuclear and five non-nuclear facilities in England and Wales. Cancer mortality trends were examined for the small areas around fourteen nuclear and five non-nuclear facilities in England and Wales. Using data, standardized mortality ratios for these areas were computed for selected causes of death including cancer of the female breast, lung and uterus. Changes in the standardized mortality ratios were then sought by comparing the standardized mortality ratios for the five years before the facility opened with the period 10 (in some cases 15) years after start-up, and by computing the weighted regression of the SMRs on calendar year. These analyses indicate no overall pattern of increasing cancer SMRs around nuclear facilities.

In a similar study Forman *et al*. (1987) reported that "*There has been no general increase in cancer mortality near nuclear installations in England and Wales during the period 1959-1980. Leukæmia in young people may be an exception, though reasons remain unclear*."

In a more recent study Bithell *et al*. (1994) focused on childhood leukæmias and non-Hodgkin's lymphomas at distances up to 25 km from nuclear installations in England and Wales. Populations living near to 23 nuclear sites were selected. Six populations living in areas that had been initially selected as being suitable for the operation of nuclear electricity-generating stations but at which no nuclear station had been constructed were selected as controls. In none of the 25 km circles around the installations was the incidence ratio significantly greater than 1.0 and the authors conclude: "*There is no evidence of a general increase of childhood leukæmia or non-Hodgkin's lymphoma around nuclear installations*".

Conclusions

The apparent "discontent" discussed at the beginning of this lecture is a hopeful sign. Debate is always healthy and beneficial. The problems that now have to solve are difficult and their resolution will take time but they will be solved. Patience and diligence is all that is required. There will ultimately be a general theory of radiocarcinogenesis that explains all we health physicists need to place radiological protection on a firm scientific basis.

The current debate may be understood in terms of two opinions within the radiological protection profession having differing emphases, pragmatism and philosophy. Pragmatism, of course, is even today largely the basis of medical science as practiced in the doctor's office. It is perhaps not surprising then, considering ICRP's close association with the medical profession, that much of the ICRP's approach to radiological protection has been pragmatic in character. The pragmatists look back at the history of radiological profession that shows an ever-increasing degree of protection of worker and public alike. Where judgments have had to be made in the absence of any comprehensive theory or hard data those judgments have typically erred on the side of safety. Finally, in the absence of demonstrated deleterious health effects in humans that may be attributed to radiation exposures at or below modern protection standards the status quo seems acceptable. Nevertheless this not a time to rest on our oars. The future will bring with it a changing regime of exposure patterns with increasing potential for exposure to high-LET radiations.

The philosophers look forward and ponder the question whether the supporting structure of current practice is adequate to meet the challenges of the future. Low-LET radiations have been dealt with in an ambiguous manner *“in line with the Commission’s generous and appropriate recommendations on accuracy”* (Lindell 2001). These generous recommendations have produced muddle and been costly. The current practice of radiological protection is quasi-scientific in character: it is not yet predictive but merely reflective of experience. Epidemiological studies are helpful but not yet (and probably never will be) completely adequate to reassure those who wish for more certain proof of “safety” than the inability to observe deleterious health effects. They are however, useful in rebutting assertions that radiation risks have been underestimated by more than an order of magnitude. Estimates of radiation risks from non-human experimental systems are difficult (NCRP 2005). It will be some time before a general theory of radiocarcinogenesis is developed.

While philosophers agree with pragmatists that pragmatism has served well in the past it is feared that it will be insufficient to meet the challenges of the future. Fresh challenges are ahead.

The world is moving towards an energy crisis that will need resolution. If greenhouse gas emissions are to be reduced and the peoples of the Third World are to achieve a reasonable standard of living it seems inevitable that the World will resort to an alternative to fossil fuels for its sources of energy. Many now believe that some form of safe nuclear energy offers one of the better options. If the nations of the world opt for nuclear energy - whether it be "conventional " nuclear reactors, breeder reactors or fusion devices then accelerators or accelerator-like devices will also be involved (for references see Thomas 2002, 2003). This development will certainly lead to larger numbers of people being exposed high-LET radiations, particularly to neutrons with energies spanning a wide range. The resources now offered by the ICRP for sensible radiation protection against neutron exposure are poorly framed and must be improved. (ICRP [2003]; Kellerer [1990]; Thomas 2004a,b,c] . To this end it would seem sensible for the appropriate advisory organizations such as NCRP, ICRP and ICRU to cooperate in reviewing the needs of radiological protection for next 25 years and to develop an action plan. In such a plan priority should be given to anticipating technological developments, particularly in the field of energy-production, which will almost certainly lead to larger numbers of people having a potential for exposure to high-LET radiations. If the radiological protection profession is not to stand in the way of progress it should be prepared for the future.

Acknowledgments

It is a great honor to be invited by the Sierra Nevada and Northern California Chapters of the Health Physics Society to speak this the fourteenth in the Newell Stannard Lecture Series, the first since his death on 19 September 19, 2005. Newell was a great scientist and human being, modest and truly a gentleman. I shall remember most of all his kindness and sweet reason in discussion.

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This ideas expressed here are not new, being drawn several previous papers and lectures drawn together into a single theme. The reason that many self-references are cited is because many contain useful bibliographies.

Finally, I should like to thank Marcia Hartman yet again for her advice and important help in preparing the final versions of the slides and text.

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