LOW DOSE RADIATION: THE MILLION WORKER STUDY – FINDINGS, IMPLICATIONS, CHALLENGES, AND YOU

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Abstract

Radiation protection consists of the concepts, requirements, technologies and operations with regards to protection of people (and environment) against the harmful effects of ionizing radiation. Ionizing radiation and radioactive substances are either naturally found in the environment, or may be permanent features. Beginning in the early twentieth century, the use of man-made radiation has now become widespread. More than any time in our previous history, this progressive increase in the use of nuclear energy and other applications of its by-products among nation states has brought radiation protection concerns ever more closely to the individual in society, as well as policy makers. Nuclear power production and the nuclear techniques used in industry, agriculture, medicine and many fields of research, are benefiting more people, and providing employment to millions of people in these related occupations. This growth is also creating greater concern among society regarding the health effects of ionizing radiation. This concern raises one main question for the various stake holders: Are current radiation protection standards, as now constituted, too lenient or too stringent?

The National Council on Radiation Protection and Measurements (NCRP) is coordinating an expansive epidemiologic effort entitled the *One Million U.S. Radiation Workers and Veterans Study* [Million Worker Study (MWS)]. This encompassing overview of the radiation risks from exposure to various cohorts gradually over time and not within seconds, as was the case for Japanese atomic bomb survivors, provides significant scientifically validated information that may provide a baseline reference for more precise and applicable radiation protection standards. This paper seeks to sift through the MWS findings, determine the implications to radiation protection standards, explore the challenges toward public acceptance of changes to radiation standards as a result of the MWS, and finally the effect on the various stakeholders.

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Introduction

Radiation has always, and will continue to be, part of humankind's experience while on the planet earth. Similar to death and taxes, radiation is one of the constant variables humankind must accept as part of the natural progression and order of human life. Radioactivity is everywhere, either naturally occurring within our own bodies (which contain radioactive elements), or is received through exposure from man-made sources used in medicine (e.g., X-rays and other sources of radiation used in medically diagnostic procedures) to the "fallout from nuclear explosives testing, and small quantities of radioactive materials released to the environment from coal and nuclear power plants" [1].

The international community has for almost 100 years recognized that large doses of ionizing radiation can damage human tissues, with individual dose limits for radiation workers averaged over a 5 year time span limited to a level of 100 mSv, while levels of exposure for members of the general public are limited to levels of ≥1 mSv per year [1]. These dose limits are established in line with the ALARA (As Low As Reasonably Achievable) principle, that the most cautious approach is the assumption that no threshold dose level exists below which there would be no effect. In other words, if receiving a dose no matter how small has no direct benefit to you the person, then it is better to avoid receiving the dose if possible [2].

Civilian nuclear power program must especially be constantly on guard and proactive in keeping any man-made radioactive materials limited and controlled in order to adequately protect humankind in general and industry workers specifically, as it strives to meet this ALARA principle. A hurdle for those persons entrusted with promulgating radiation protection standards is that causality between negative health effects to radiation doses below 100 mSv has been nearly impossible to determine. The radiation protection standards, as now constituted, "are based upon expert assumptions validated for higher doses, which are extended to cover the range of low dose exposures" [3].

Many epidemiologic studies have sought to understand the health effects of ionizing radiation exposure using multiple sources and variables associated with exposure to low levels of ionizing radiation. Mostly, each has drawn a similar conclusion "that human epidemiologic data on cancer induction observed at acute doses of 100 mGy and above are more reliable than those observed at <100 mGy, the low dose region" [4]. The National Council on Radiation Protection and Measurements (NCRP) led an epidemiologic study[3] (NCRP Commentary No. 27) published in early 2018 with the purpose to understand and seek out scientifically validated and detailed data on whether low dose levels of radiation received gradually over time can be linked to an increase in health risks, such as cancer. This paper seeks to sift through relevant findings associated with NCRP Commentary No. 27 as these relate to the Million Worker Study (MWS) to determine if the scientific data warrants changes in current radiation protection standards and the effect on the various stakeholders.

Radiation Protection – Basic Knowledge

Nuclear energy's role in helping to reduce carbon emissions as nation states seek to fulfill international commitments regarding climate change is certainly having a net positive outcome throughout Asia as a number of nation states in this part of the globe are expanding, or planning to expand, their civilian nuclear power programs (e.g. China, India, and United Arab Emirates). At the same time, many western industrialized nation states are scaling back or ending their nuclear power programs (e.g., Germany). One must wait and see what the consequence on these programs for positive or negative will be once small modular reactor technology is approved for use by the national regulatory bodies. However, one thing is

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[3] A copy of NCRP Commentary No. 27 is available for purchase at: https://ncrponline.org/shop/commentaries/commentary-no-27-implications-of-recent-epidemiologic-studies-for-the-linear-nonthreshold-model-and-radiation-protection-2018/, viewed August 30, 2018.

clear; the future role nuclear power will continue to play in many of the power generating programs of nation states in their social and economic development around the globe will be essential.

Therefore, in order to ensure a high level of public and political support for these civilian nuclear power programs, it is vital that nuclear safety is their first commitment. To this end, the International Atomic Energy Agency (IAEA) reaffirms that "each country engaged in nuclear energy activities is itself [primarily] responsible for ensuring the nuclear and radiation safety, physical security and environmental compatibility of its nuclear facilities and activities" [5]. This clear delineation of responsibly as the sole burden of the nation state is set out in Article 15 of the Convention on Nuclear Safety:

> "Each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits" [6].

Radiation in and of itself is not a feature that was created solely as a by-product of discoveries associated with the progression of atomic energy. All life on earth is, and has been, subjected to natural sources of radiation from the first moments the planet was formed. Scientific discoveries from the end of the 19th century through to today have progressed from Wilhelm Conrad Roentgen's discovery of X-rays, or what he called 'Roentgen rays,' to the use of radioactive isotopes in medicine, the radioactive features of current civilian nuclear power programs, as well as the more nefarious radiological aspects of military uses as weapons of war. All of these experiences have provided humankind with a wealth of knowledge and information on dealing with radiation as such technologies are employed, leading to permissible levels of exposure being established. What is new is that "[a]tomic energy [has] introduced radiation problems far beyond anything man had previously dealt with" [7].

A central challenge in determining permissible levels of radiation exposure for the nuclear worker or the civilian population is hampered by the fact that each individual will receive different levels of exposure in their natural environment, as background radiation is found in each locality with radiation levels varying from place to place [8]. This inability to exactly statistically validate each individual level of exposure creates exceptional burdens for radiation protection measures, increasing these associated costs for nuclear reactor sites, which produce all types of ionizing radiation, as well as for other uses of radioactive isotopes in medical, industrial and agricultural applications [9].

Levels of Radiation Exposure

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) regularly prepares reports for the United Nations General Assembly on radiation exposure and the effects of ionizing radiation. UNSCEAR uses various dose bands to bring order to what is a complex system of radiation quantities into a coherent structure, which allows for consistency by radiation protection experts in the recording of individual doses that may then be statistically compared among those individuals working in the radiation industry and who are occupationally exposed. This scientific information may then be used to determine the health effects of radiation exposure on humans, and provides a path to discover any causal links between an associated level of radiation exposure and any negative health risks. Currently, UNSCEAR considers exposure to dose levels[4] below 100 mGy but greater than 10 mGy as a 'low dose' exposure, with any levels below 10 mGy as a 'very low dose' exposure [10].

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[4] Dose bands used by UNSCEAR: High dose = More than ~1 Gy; Moderate dose = ~100 mGy to ~1 Gy; Low dose = ~10 mGy to ~100 mGy; Very low dose = > 10 mGy.

The International Commission on Radiological Protection (ICRP), which is a non-governmental organization, outlines for the international community a common framework for radiological protection standards, legislation, guidelines, etc., to assist states and organizations to prevent cancer and other diseases associated with an increased exposure to ionizing radiation. It functions under three guiding principles of radiation protection, two of which are source related principles and one individual related, which are found in Table I, ICRP Radiation Protection Principles.

Table I: ICRP Radiation Protection Principles [11]

Source Related Principles	
Justification	*A decision altering the radiation exposure situation should be more beneficial than harmful. Whenever there is the introduction of a new radiation source, one should consider its cumulative positive net effect and negative detriment to the individual or society. The ability and methods of reducing existing exposure, or by reducing the risk of potential exposure, should be weighed and taken into consideration and such methods applied.*
Optimization	*Any situation causing the likelihood of incurring an exposure, should be kept as low a reasonably possible taking into account factors including the number of people exposed, the magnitude of their individual doses, and other economic and societal factors.*
Individual Related Principle	
Application of Dose Limits	*Considering any pre-planned exposure situation, the total dose to any individual from regulated sources (other than medical exposure of patients) should not exceed the appropriate limits recommended by ICRP.*

Due to the increased likelihood of risk for cancer at doses higher than 100 mSv, the ICRP uses this value as its reference point in which exposure during a single point in time or during the year's period is justified only under extreme circumstances (e.g., in exceptional situations such as the saving of life or the prevention of a serious disaster). The current recommendation by the ICRP for occupational exposure in planned exposure situations is as an effective dose of 20 mSv per year, averaged over defined 5 year periods (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year. The recommended allowable public exposure in planned exposure situations continues to be an effective dose of 1 mSv in a year. [11]. A cursory review of four nation states and EURATOM show that these ICRP recommendations are typically followed in the national regulations, as shown in Table II, Smörgåsbord – Country Specific Radiation Protection Regulations.

Table II: Smörgåsbord – Country Radiation Protection Regulations

Nation States		
Brazil [12]	Basic Radiation Protection Directives - CNEN-NN-3.01 – March 2014	Annual occupational dose limits for workers at Angra 1 & 2 is limited to 20 mSv for Effective Dose and Equivalent Dose for the lens of the eyes averaged over 5 consecutive years and a maximum of 50 mSv in any single year.
Canada [13]	Radiation Protection Regulations (SOR/2000-203)	Considers 50 mSv in a one-year dosimetry period and 100 mSv over a five-year dosimetry period for a nuclear energy worker and 1 mSv per calendar

		year for a person who is not a nuclear energy worker.
Sweden [14]	Swedish Radiation Safety Authority Regulatory Code: SSMFS 2008:51 and SSMFS 2008:26, also SSMFS 2008:23	The occupational dose limit is a maximum of 50 millisievert (mSv) in an individual year, or 20 mSv on average per year over a period of five years (currently being revised to be in line with EURATOM directive 2013/59). The effective dose limit for members of the public is 1 mSv per year.
United Arab Emirates [15]	FANR-REG-04	The limit for the Effective Dose to a Worker who is Occupationally Exposed during the normal operation of a nuclear facility is an average of 20 millisieverts (mSv) per year averaged over a period of five years (100 mSv in 5 years), and 50 mSv in any one year. The limit for the annual Effective Dose to a member of the public (this includes persons working in the nuclear facility other than those categorized under the Worker definition) is 1 mSv.
International Organization		
EUROPEAN ATOMIC ENERGY COMMUNITY (EURATOM) [16]	2013/59/Euratom Basic Safety Standards Directives	"The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv may be authorised by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv" (Article 9, para. 2.). The effective dose for public exposure is at 1 mSv in a year.

Linear No-Threshold Model

The ALARA philosophy for ionizing radiation is rooted in the linear no-threshold (LNT) theory and forms the basic mechanism for determining radiation protection practices and regulatory decision-making. The theory is predicated on the concept that there is no safe dose of radiation and therefore "any dose of radiation, no matter how small, might cause cancer" [17]. It is precisely this lack of certainty and precision in such radiation dose models, with widely varied parameters and uncertainties that ferments the extreme conservatism in radiation protection measures applied throughout the nuclear industry. These models use reference parameters, subject to uncertainty; while other parameters are fixed by convention. Furthermore, regulatory compliance is achieved by creating point estimates of effective dose applied to a 'Reference Person' that assumes that such estimates interact with no uncertainties or variables in real life application, especially where low dose estimates and its consequences are concerned.

For these reasons, the LNT remains highly divisive among radiological scientists/experts and legal academics, as there are those whom view the theory as a sacred cow of 'settled science,' while others see open matters of interpretation ripe for the picking [18]. There are those whom argue that the LNT is "based on simplistic mechanistic modelling," while many others would affirm that LNT, as a theory, is the most plausible [19]. Therefore, epidemiological studies on low dose radiation and its effects, such as Commentary No. 27, create an enormous amount of interest and discussion.

Commentary No. 27 – Overview & Findings

Commentary No. 27 provides a review of various recent epidemiologic data from studies with low doses or low dose rates. Using the Life Span Study (LSS) of atomic bomb survivors as its benchmark, it seeks to determine whether the reviewed epidemiologic studies with low doses provides similar validated scientific data to support the LNT model of carcinogenic risk or to determine that evidentiary supporting conclusions may be obtained to provide a basis for rebutting the underlying premise argued by some that the LNT model is inappropriate for the purposes of radiation protection in low dose situations. The obstacle that the authors of Commentary No. 27 incurred is that dose rate exposures of individuals working in the dawn of the nuclear industrial complex development were higher than current, but are associated with the utmost levels of uncertainties. As can be readily understood, this is in part due to that technologies for recording of dose exposure rates were far less advanced in these earlier years, and dose record-keeping practices were not as stringent and advanced as current methods. As the authors of Commentary No. 27 readily find: "more in-depth analysis of early exposures is necessary to identify any deficiencies in recorded doses," especially as any validated study must be able to "depend upon reliable dose estimates, among other things" [4].

While most of the large and high-quality low-dose studies do show a positive risk coefficient, which may lend a minimal level of credence to a causal effect of an uptick of cancer rate at low doses, this neither proves nor disproves the applicability of the LNT model for radiation protection according to the study's authors. Similarly, it cannot be ascertained that the risk of cancer at low doses is of any great significance and it is nearly impossible to determine at this time whether such rates of cancers may be distinguishable from background exposure risk, leading the authors to conclude:

> "Because of the small imputed risks paired with high background cancer rates, plus uncertainties in the doses and risk estimates, the epidemiologic data cannot justify using the LNT model to estimate numbers of excess cancers by applying the estimated collective dose to large, general populations who received very small individual doses" [4].

The Million Worker Study

The Million Person (worker) Study of Low Dose Radiation Health Effects (MWS) is currently being conducted in the United States of America. The purpose of the MWS is to determine if a causal link can be sufficiently established for risk of organ-specific cancers from radiation doses received at low dose rates over an expanded length of time. The MWS seeks to study a number of sub-population groups or cohorts including: (1) 115,000 atomic veterans who participated in above-ground nuclear weapons testing; (2) 360,000 workers during the Manhattan Project years; (3) 250,000 early radiologists and medical workers; (4) 150,000 Nuclear Power Plant workers (NPP); and, (5) 130,000 industrial radiographers. It is believed that once the MWS is finalized, that the information gleaned from the study will increase our understanding of "worker radiation-related cancer risks and reduce the uncertainties in risk estimation after exposures at low dose rates" [4]. A summary of several MWS cohort and results is provided in Table III: MWS Cohort Summary and Findings.

Table III: MWS Cohort Summary and Findings [4]

Cohort	Population Group	Cancer Rates	Summary	Conclusion
Rocketdyne workers	7,634	651 deaths from all cancer except leukemia	Analyses revealed no significant dose-response trends for any cancer.	Strong conclusions could not be drawn because of small numbers and relatively low career doses.
Mound workers	7,270	968 cancer deaths, including 31 leukemia cases	External radiation dose-response analyses showed no significant association with death from any of the outcomes chosen a priori.	No conclusions can yet be drawn.
Mallinckrodt workers	2,514 (white males)	Using a standardized mortality rate[5]: 0.94 for all causes, 0.97 for all cancer, and 0.89 for all heart disease.	Evidence inconclusive.	No conclusions can yet be drawn.
NPP workers	150,000	Through 2011: 30,993 deaths from all causes, including 68 from CLL[6] and 320 from leukemia other than CLL	A linear relationship between dose and leukemia could not be rejected.	Currently, the study only weakly supports the LNT model for radiation protection.
Industrial radiography workers	127,910	Includes nearly 200 leukemia cases	The dose-response curve is consistent with both a linear and an LQ[7] Model.	Preliminary leukemia analyses for NPP workers and industrial radiographers are consistent with a positive dose response <100 mGy and with the LNT model
Atomic Veterans	114,270	Mortality follow-up conducted with status for nearly 97	No significant trends with dose were found.	No conclusions yet drawn.

[5] Standardized Mortality Rate (SMR): The ratio of the mortality rate from a disease in the population being studied to the comparable rate in a standard population.
[6] Chronic Lymphocytic Leukemia
[7] linear-quadratic

		% of the veterans was determined.		

Implications for You and Me

Should scientific studies eventually demonstrate that constant exposure to low dose radiation level poses less of a health threat than was originally and currently assumed, then this would have a profound effect on the nuclear industrial complex as radiation protection standards would be relaxed allowing for nuclear power plants, hospitals, and other business using low-level radioactive materials to save large amounts of money. Companies and governments would not be required to spend billions to clean up industrial locations that have been only slightly contaminated. Such a scientifically validated reasoning could potentially change "negative public attitudes and opinions about all things nuclear" [20]. However, given that society has been conditioned to believe that radiation in any amount is dangerous, it must be believed that this change would move with glacial speed, and would take a generation or two at a minimum to overcome.

Conclusion

Commentary No. 27 does little at this time to resolve the divisions in opinion of those engaged in the LNT debate, nor does it provide conclusive evidence that confirms or rejects conclusions that exposure to small doses of radiation bring about serious health risks. Therefore, currently such individual studies as outlined within Commentary No. 27 may only make a minor contribution to our full understanding of low dose radiation and supposed health risks to the worker and society. Additionally, no conclusions can yet be drawn regarding an evaluation of the LNT model for radiation protection purposes and standards. Consequently, most, if not all, national and international scientific committees will continue to work under the assumption that the only pragmatic or prudent mechanism for the evaluation of radiation protection purposes is the LNT model.

Going forward, it is required that academics and professional scientific organizations remain fully engaged in conducting vital research and holding scientific conferences/debates to discuss low-dose radiation and whether changes may be desirable/warranted to applicable technical standards and procedures, and/or regulatory guidance in this area. The greatest unknown variable is of course public acceptance to any changes in radiation protections standards, as society has been conditioned for the last half century, at least, that any amount of radiation presents a negative risk associated with the radiation industrial complex. It will prove to be a nearly insurmountable task to communicate effectively any differences between 'big' and 'little' in relation to dose exposure levels given the current political climates in many of nation states with civilian nuclear power programs following both Chernobyl in 1986, and Fukushima in Japan in 2011.

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