September 13, 2004

MEMORANDUM TO: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: Janice Dunn Lee, Director ***/RA/***
Office of International Programs

SUBJECT: VISIT OF DR. ROGER CLARKE, CHAIRMAN, INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, SEPTEMBER 14-15, 2004

Dr. Roger Clarke, Chairman, International Commission on Radiological Protection (ICRP), and former Director of the UK National Radiological Protection Board, will meet with the Commissioners and staff on Tuesday and Wednesday, September 14-15, 2004. He will be accompanied by Lars-Erik Holm, Director General of the Swedish Radiation Protection Authority and Vice Chairman of the Main Commission of the ICRP. Dr. Clarke requested meetings with the Commissioners to brief them on the most recent draft 2005 ICRP recommendations. The Internet link to the 81-page set of recommendations was provided to the Commissioners by a D-Note dated June 25, 2004. A summary of the key points of the recommendations was prepared by ICRP, and is provided in Attachment 4. NRC staff will be developing comments on the draft recommendations and providing the proposed comments, along with our recommendation on approval of the draft, to the Commission for its consideration by the end of October 2004.

In addition to meeting with the Commissioners, Dr. Clarke and Dr. Holm will visit EPA, and participate in a meeting of the Interagency Steering Committee on Radiation Standards (ISCORS) in the U.S., hosted by the NRC staff.

Attached are the meeting schedule, biographical information, background information and suggested talking points for use during the visit.

By copy of this memorandum, the SECY, OGC, EDO, OPA, RES, NRR, NSIR, OSTP, and NMSS are being advised of Dr. Clarke's visit. .

Attachments:
1. Meeting Schedule
2. Biographical Information
3. Background Information and Suggested Talking Points
4. Summary of Key Points

cc: SECY EDO OPA RES NMSS OGC NRR NSIR OSTP

CONTACT: Howard Faulkner, OIP
415-2762

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DR. ROGER CLARKE VISIT
CHAIRMAN
INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

MEETING SCHEDULE:

Tuesday, September 14, 2004

1:30 pm	Meeting with C. Paperiello, RES, and J. Strosnider, NMSS (T 8D43)
2:30 pm	Meeting with Commissioner Merrifield (O 18F1)
3:15 pm	Meeting with Commissioner McGaffigan (O 18G1)

Wednesday, September 15, 2004

9:00 am	Meeting with Interagency Steering Committee on Radiation Standards (TWFN -ACRS Meeting Room)
1:00 pm	Public Workshop (TWFN-ACRS Meeting Room)

Accompanying Persons:

Dr. Lars-Erik Holm, Vice Chairman, ICRP
Howard Faulkner, OIP

Proposed Topic for Discussion:

Draft 2005 ICRP recommendations.

ATTACHMENT 1

Professor Roger Clarke BSc, MSc, PhD, DUniv, FRCR, FSRP

Professor Roger Clarke is currently Chairman of the International Commission on Radiological Protection (ICRP). From 1987 until 2003 he was the Director of the UK National Radiological Protection Board, the focal point for radiation protection research and advice to the UK government, industry and the public. He was the UK representative to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and a member of the Group of Experts who advises the European Commission on protection standards and research. In the UK, Prof Clarke has been a member of the Secretary of State for the Environment's Radioactive Waste Management Advisory Committee, the Health and Safety Commission's Ionizing Radiation Advisory Committee, and the Medical Research Council's Committee on the Effects of Radiation.

He was a Visiting Professor at the Centre for Analysis and Research into the Environment at Imperial College of Science, Technology and Medicine, University of London, from 1992 to 2002, and is currently Visiting Professor in Radiation and Environmental Protection at the University of Surrey. He has been elected as an Honorary Fellow of the Royal College of Radiologists and an Honorary Fellow of the Society for Radiological Protection.

Prof. Clark has published more than 180 papers and reports in the scientific literature and in conference proceedings. In recent years he has been the recipient of the G. William Morgan award from the Health Physics Society of the USA, the Ellison-Cliffe medal from the UK Royal Society of Medicine, the Hanns-Langendorff medal from the German Radiology Society, and the Lindell award from the Swedish Risk Academy. He has been made an honorary Vice-President of the UK Institution of Nuclear Engineers, and has recently been awarded an honorary doctorate, DUniv, by the University of Surrey.

Lars-Erik Holm

Date of birth: April 30, 1951

Academic degrees:
* M.D. at Karolinska Institute, Stockholm, 1977.
* Ph.D. in Oncology at Karolinska Institute, Stockholm, 1980.

Present appointments
* Director General of the Swedish Radiation Protection Authority.
* Vice Chairman of the Main Commission of the International Commission on Radiological Protection, ICRP.
* Swedish Representative of the United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR.
* Member of the Commission on Safety Standards of the International Atomic Energy Agency, IAEA
* Member of the Board of the Swedish Nuclear Power Inspectorate.

Previous appointments
* Secretary of the Swedish Society of Radiotherapy, 1981-85.
* President of the Nordic Society of Radiotherapy, 1983-86.
* Associate Professor (lecturer) of Oncology, Karolinska Institute, Stockholm, 1982-92.
* Head of the Department of Cancer Prevention, Karolinska Hospital, Stockholm, 1987-92.
* Director of the National Institute of Public Health, 1992-95.
* Member of Committee 1 of ICRP, 1985-89 and 1993-96.
* Representative of the Swedish delegation to UNSCEAR since 1996. Vice Chairman of the Committee, 1997-98, and Chairman, 1999-2000.
* Deputy Member of the Board of the Nordic School of Public Health, 1994-95.
* Member of the Board of the Institute for Environmental Medicine, Karolinska Institute, 1995-96.

Publications
* About 300 reviewed papers in scientific journals, mostly in epidemiology and particularly radiation epidemiology.

Background

ICRP

The International Commission on Radiological Protection (ICRP) was established for the purpose of identifying appropriate radiation protection measures that it recommends be adopted by its member states. It is composed of a Main Commission and four standing Committees: Radiation Effects, Doses from Radiation Exposure, Protection in Medicine, and Application of ICRP Recommendations. Its members serve as individual experts, not as national or organizational representatives.

In making its recommendations, the ICRP considers the fundamental principles and qualitative measures upon which appropriate radiation protection measures can be established, while leaving to the various national protection bodies the responsibility of formulating specific advice, codes of practice, or regulations that are best suited to the needs of their individual countries. ICRP has no authority for imposing its proposals on member states, but legislation in most countries adheres closely to ICRP recommendations.

The activities of the ICRP are financed mainly by voluntary contributions from national and international bodies with an interest in radiological protection.

The ICRP elects its own members under rules that are subject to approval of the International Society of Radiology. Three to five members must be replaced every fourth year. Committees typically consist of 15-20 members. Biologists and medical doctors dominate the current membership; physicists are also well represented.

Both ICRP Task Groups (performing defined tasks) and Working Parties (developing ideas) prepare reports. A Task Group usually contains specialists from outside the ICRP membership, so that the ICRP functions as an independent international network of specialists in various fields of radiological protection. About one hundred eminent scientists are actively involved in the work of the ICRP.

Background and Context of ICRP Visit

The ICRP is developing an updated set of recommendations, evolved from, and elaborating on the recommendations published in 1990 as ICRP Publication 60. ICRP's current objective is to prepare a simplified and more coherent set of recommendations. The recommendations will continue to be based on the need to justify exposures which are introduced, the need to protect an individual from exposures from the source of radiation, and the goal of optimizing protection in order to provide additional protection. The recommendations are considered "evolutionary" in nature. Protection of the individual will be emphasized, and optimization achieved by placing constraints on the individual doses for a variety of exposure situations.

NRC staff has participated actively in opportunities to discuss and comment on early material developed by the ICRP. The ICRP has been receptive to changes in its proposals. NRC staff have submitted comments approved by the Commission directly to ICRP, and participated in the development of comments through the NEA Committee on Radiation Protection and Public Health. The staff has also participated in both national and international forums and workshops

held during the early development of the draft recommendations, using the Commission approved positions as a basis for discussion. Furthermore, Dr. Donald A. Cool, NMSS, has been able to utilize NRC positions directly in discussion of the ICRP as a result of his membership on ICRP Committee 4 on Practical Application of the Commission Recommendations.

The updated set of recommendations was placed on the ICRP web site on June 23, 2004. Comments will be accepted through the end of December 2004. ICRP has indicated a tentative schedule for approval of the recommendations in 2005. The final set of recommendations is expected to be published in late 2005. The NRC staff is developing comments on the draft recommendations, and providing the proposed comments along with our recommendation regarding approval of the draft for Commission consideration by the end of October 2004.

ICRP is conducting an outreach program for stakeholders to solicit comments and answer questions concerning the proposed recommendations. In addition to the drop-in visits with NRC and EPA next week, an Interagency Steering Committee on Radiation Standards (ISCORS) special meeting will be held on the morning of Wednesday, September 15, and a public workshop, sponsored by ISCORS and hosted by the NRC, will be held during the afternoon of September 15. These meetings provide a valuable opportunity to discuss the draft recommendations, and engage directly in a dialogue which will facilitate the NRC's development of its comments. It is also expected that the public workshop will provide the NRC staff with insights into the issues of concern within industry and for members of the public.

Contents of Draft Recommendations

The current draft of the recommendations is based upon quantitative standards for protection of individuals, complemented by the requirement to optimize the level of protection achieved. The quantitative standards consist of constraints applied to a single source, and limits which apply to the sum of all relevant exposures to an individual. Occupational and public exposure limits are expressed in the same way that they are in ICRP Publication 60 (occupational two rem per year average, max of five in anyone year; public 100 mrem per year). Four "maximum constraint" values are identified, including 10 rem for acute emergency situations, two rem per year for a single source in informed (occupational) setting, 100 mrem per year public (30 mrem in case of multiple dominant sources), and one mrem per year minimum value of any constraint. The draft recommendations also address optimization, protection of non-human species, radiation risk coefficients, biological aspects such as tissue weighting factors, and exclusion of sources from the system of protection.

Attachment 4 provides a summary of the key points in the draft recommendations prepared by ICRP.

Commission Direction on ICRP Activities

In SRM-SECY-01-0148, the Commission approved the staff's proposal to work with and monitor the efforts of other Federal agencies to ensure a coherent approach to U.S. radiation protection standards and dosimetric models, and directed the staff to work with the EPA through ISCORS on possible revisions to the Presidential Guidance in this area. The Commission also directed the staff to continue to monitor the work of the ICRP as it develops its revision to ICRP Publication 60.

More recently, in its response to SECY-04-0030 and SECY-04-0055, the Commission directed the staff to evaluate scientific information and radiation protection recommendations. The Commission also expressed deep misgivings about the ICRP recommendations to enhance optimization, and specifically the need to go forward with the development of a separate standard for protection of non-human species. The Commission directed the staff not to expend resources on research activities aimed at protection of the environment.

Once the ICRP has published its final recommendations in 2005, the staff will suggest possible options for action to the Commission, including a consideration of whether revisions to 10 CFR Part 20 should be initiated.

Talking Points

The Commissioners may wish to:

- Welcome Dr. Clarke and acknowledge his long and distinguished career in the radiation protection field. Also, congratulate Dr. Holm on being elected the next ICRP Chairman, starting in 2005.

- Note the continuing involvement of former NRC Commissioner Greta Dicus on the ICRP Main Committee.

- Indicate that tomorrow Dr. Clarke will have the benefit of hearing both U.S. government interagency views and industry/public views relating to the draft recommendations.

- Share their views on the ICRP recommendations and the potential impact on U.S. licensees.

ICRP 2005 DRAFT Recommendations

Summary of Key Points

Features

* Recommending dose constraints that quantify the most fundamental levels of protection for workers and the public from single sources in all situations.
* Maintaining the Publication 60 limits for the combined dose from all regulated sources that represent the most that will be accepted in normal situations by regulatory authorities
* Complementing the constraints and limits with the requirement for optimization of protection from a source
* Recognizing where the responsibility for justifying the introduction of a new practice lie.
* Updating the weighting factors in the dosimetric quantity Effective Dose.
* Emphasizing that patient dose should be commensurate with the clinical benefit expected from a given justified diagnostic or therapeutic procedure.
* Including a policy for radiological protection of non-human species.

Scope

* Applies to situations in which either the source of exposure or pathways leading to the doses can be controlled by some reasonable means.

Justification

* Usually falls to government or government agencies.
* Radiological protection is recognized as only one input that could influence the justification decision.
* Practices should be periodically reexamined to ensure that they are still justified.

Quantities

* Stochastic effects refer to cancer induction, represented with quantity *effective dose*.
* Tissue Reactions (formerly deterministic effects) refers to acute effects, and late effects such as cataracts. Threshold applies. Quantity is the *absorbed dose*.
* *Radiation Weighted Dose* is a product of absorbed dose and radiation weighting factor.

  W_R for Photons and Electrons is 1

  W_R for Protons is 2

  W_R for Alpha particles, fission fragments, heavy nuclei is 20

  W_R for Neutrons is a continuous curve, peak at 20 at about 1 MEV. Curve results in lower W_R for low energy neutrons

* *Effective Dose* is the product of the radiation-weighted dose and the tissue weighting factors.

Tissues	W_T	$^*W_T$
Bone Marrow, Breast, Colon, Lung, Stomach	0.12	0.60
Bladder, Oesophagus, Gonads, Liver, Thyroid	0.05	0.25
Bone Surface, Brain, Kidneys, Salivary glands, Skin	0.01	0.05
Remainder Tissues (applied to average dose to 14 tissues)	0.10	0.10

* Annual effective dose recorded for a worker is to be assessed as the sum of the effective dose from external exposure in that year and the committed effective dose from intakes of radionuclides in that year.

* ALI and DAC no longer given, but noted as still useful in a variety of practical situations.

* "...the Commission judges that the weight of evidence on fundamental cellular processes supports the view that in the low dose range up to a few tens of mSv, it is scientifically reasonable to assume that in general and for practical purposes cancer risk will rise in direct proportion to absorbed dose in organs ant tissues. "

Stochastic Effects Coefficients

Exposed Population	Lethality adjusted cancer risk	Lethality adjusted heritable effects	**Detriment**	Detriment (Pub. 60)
Whole Population	6.2	0.2	6.5	7.3
Adult Workers	4.8	0.1	4.9	5.6

Classes of Exposure

* Occupational
* Medical
* Public

Exposure Situations

* Normal exposure

  Everyday situations usually referred to as practices
* Accidents and Emergencies
* Unexpected situations requiring urgent action. Could be from a sudden event of from slow deterioration, leading to the point of urgent action
* Controllable existing exposure

  Situation exists, control only be action to modify pathways of exposure. Could result from natural or artificial radionuclides, previous practices, or result of emergencies.

Constraints

* Maximum Constraints specified as required basis of protection.

Maximum Constraint (mSv)	**Situation to which it applies**
100	In emergency situations, for workers, other than for saving life or preventing serious injury or preventing catastrophic circumstances, and for public evacuation and relocation, and for high levels of controllable existing exposures. There is neither individual nor societal benefit from levels of individual exposure above this constraint
20	For situations where there are direct or indirect benefit for exposed individuals, who receive information and training, and monitoring or assessment. It applies into occupational exposure, for countermeasures such as sheltering, iodine prophylaxis in accidents, and for controllable existing exposures such as radon, and for comforters and cares to patients undergoing therapy with radionuclides.
1	For situations having societal benefit, but without individual direct benefit, and there is no information, no training, and no individual assessment for the exposed individuals in normal situations.
0.01	Minimum value of any constraint

* Values selected using natural background as a benchmark for judgement about relative importance and the need for action.

Limits

* Occupational: 20 mSv per year, averaged over five years, with maximum of 50 mSv in any single year
* Public: 1 mSv in a year. Special circumstances of higher value, provided average over five years does not exceed 1 mSv.
* Organ Limits: Occupational 150 mSv for Lens of the eye, 500 mSv for Skin averaged over 1 cm^2, and 500 mSv for hands and feet.

Protection of the Fetus

*
* ICRP policy that protection at work for women who may be pregnant should provide a level of protection for any conceptus broadly comparable to that provided for members of the general public.
* Occupational Exposure for pregnant woman should make it unlikely that the additional radiation-weighted dose to the fetus will exceed about 1 mSv during the remainder of the pregnancy

Radon

* Maximum constraints of 600 Bq m^{-3} for domestic dwellings and 1500 Bq m^{-3} for workplaces.
* Apply optimization below maximum constraints to establish levels below which no

account is taken, and the dose is not added to occupational exposure.

Optimization of Protection

* Quantitative criteria complimented by requirement to optimize dose
* "...Forward-looking iterative process aimed at preventing exposures before they occur. "
* "...continuous, taking into account both technical and socioeconomic developments and requires both qualitative and quantitative judgements. "
* ALARA
* Safety Culture: "...Have I done all that I reasonably can to reduce the doses?"
* "...For the control of emissions to the environment, the 'best available technology not entailing excessive costs' principle may be used with due consideration to social and economic factors. "
* Involvement of stakeholders
* Expectation to reduce the number of exposed individuals. "The integral of low individual exposures over large populations, large geographic areas, and over large periods of time is generally not a useful tool for decision aiding because this may aggregate information excessively."
* Dose matrix reflecting the characteristics of the exposed individuals and the time and space distributions of exposures.
* Best Available Technology (BAT) equated with optimization for effluent controls.

Exclusion of Sources

* Artificial radionuclides exclusion based on 0.01 mSv, and fact that no international activity concentrations are below 0.1 Bq g^{-1} for beta/gamma and 0.01 Bq g^{-1} for alpha.
* "...The Commission has concluded that these values provide a practical definition of what is to be considered as radioactive..."
* Natural radionuclides exclusion based on value toward the higher end of generally observed range. 1 Bq g^{-1} for U-238 and Th-232 head of chain. 10 Bq g^{-1} for K-40.
* Exemption is a regulatory construct, useful to further specify sources that are part of the system of protection, but that does not warrant further protection consideration.

Medical Exposure

* Exposure of informed and consenting individuals helping to support and comfort patients is a part of medical exposure. A few mSv per episode is likely to be reasonable.

Potential Exposures

* Risk constraints, taking account of both the probability of incurring a dose and the detriment if the dose is received.
* Probability of attributable death, defined as product of probability of incurring the dose and the lifetime conditional probability of attributable death. For example, see Pub. 81 on geologic disposal of solid radioactive waste.
* Generic risk constraint for occupational potential exposure of 2 10^{-4}. For the public, risk constraint of 5 10^{-6}.
* Approach also recommended for "hot particles" in the environment.

Protection of the Environment

* "...The Commission recognizes that there is a need to explore further the nature of the 'risks' that may apply to other species, how such risks may be quantified, and thus how it can be positively demonstrated that they are, indeed, '...not put at risk'. "
* Developing a small set of reference animals and plants, plus their relevant databases.
* Objectives of a common approach:

"Safeguard human health by preventing the occurrence of deterministic effects; limiting stochastic effects in individuals and optimizing the protection of populations; and to

safeguard the environment by reducing the frequency of effects likely to cause early mortality, or reduced reproductive success, in animals and plants to a level where they would have a negligible impact on conservation of species, maintenance of bio diversity, or the health and status of natural habitats or communities. "

* Derived Consideration levels - logarithmic bands of dose rates relative to normal natural background dose rates.