

NCRP SC 4-4 Committee Meeting

**NCRP Office
7910 Woodmont Avenue, Suite 400
Bethesda, MD 20814-3095**

October 30-31, 2008

AGENDA

Thursday, October 30, 2008

- 8:30 – 8:45 Greetings from President Tenforde
- 8:45 – 9:00 Self-introduction of the members of the committee
- 9:00 – 9:20 President Tenforde will present the activities and discussions of the NCRP staff in preparing for the application for funding the committee's activities and the actual funding of SC 4-4. The time-line for the committee's activities, the frequency of meetings, and the length and completion date of the committee's activities and estimated date of the final report. Any additional instructions from the staff.
- 9:20 – 9:40 Material distributed at this meeting and material that is available to committee members and staff. (PDF of publications and a list of radiation developmental and reproductive publications.
- 9:40 – 10:00 Discussion of Handbook 54 (1977), which was primarily concerned with ionizing radiation risks for the developing fetus.
- 10:00 – 10:15 **Break**
- 10:15 – 12:00 Radiation effects to be included or excluded in the final report
- a.) Ionizing radiation exposures to the fetus during embryonic development from conception to delivery (term). This will include exposures from diagnostic imaging studies utilizing x-ray equipment, CT scanning equipment and nuclear medical procedures and the therapeutic use of ionizing radiation equipment and radionuclides.
 - b.) Preconception exposures to ionizing radiation from external radiation sources and radionuclides.

- c.) Should we include new sections dealing with:
1. ultrasound, sonography, diagnostic and therapeutic
 2. MRI
 3. other sources of electromagnetic radiation exposures

Noon -1:00 **Lunch**

1:00 – 3:00 Continuation of discussion of scope and contents of report

3:00 – 3:15 **Break**

3:15 – 3:30 Should the report include an appendix containing a guide for calculating fetal exposures, especially from exposures to ionizing radiation (external beam radiation and radionuclides)?

3:30 – 4:30 Should the report include a section of typical questions from professionals and patients and the answers to the questions?

4:30 – 5:00 Further discussion.

5:00 **Adjourn**

Friday, October 31, 2008

8:30 – 8:45 Selection of the date and location of the next meeting.

8:45 – 10:00 Refine scope and contents of report.

10:00 – 10:15 **Break**

10:15 – 11:00 Writing assignments, consultants to the committee, literature requirements

11:00 – 12:00 Summary of schedule for report development.

12:00 **Adjourn**

12:00 – 1:00 Lunch at NCRP

NCRP SC 4-4
Meeting 1 Notes
October 30, 2008

0835 Introduction by Tom Tenforde
Self introductions

0925 Tom also introduced Bob Gorson, Roger Harms and Susan Wiltshire

0932 Tom reviewed the conflict of interest policy and policy on dissemination of committee materials.

0955 Tom gave a background of NCRP and on the CDC funding of the project.

1015 Schedule and milestones:

- Assuming finish in three years.
- Funds for up to five meetings, but hopefully less.
- Capability for web conferencing (WebEx) of about 4-6 hour meetings:
 - Put Word or PowerPoint info onto PC and others can edit and see.
- Encourage committees to refine scope at first meeting.
- Encourage committees to decide in detail on content – down to the third level of detail.
- Then decide on writing assignments – one given primary responsibility to develop draft.
- Try to begin drafting and identify references and additional consultants after first meeting.
- Goal: Have initial full draft by spring of 2010.
- Go to program committee area four for review and subject matter experts to give candid feedback.
- After revision of draft, hope to go to Council in fall of 2010.
- Council feedback and revisions in 2011 and publishing.
- Technical consultant to pull together committee work into fairly consolidated form in conjunction with chairman.
- Final editorial review at NCRP, then publisher, who do not need much time.
- Final publication – mid end 2011.

1025 Questions?

- Lunch here – yes. Dinner: Positano on Fairmont St. at 1830.
- Travel reimbursement form: Use Oak Ridge form. Allowance \$10 breakfast, \$10 lunch, \$30 dinner.
- Web communication sites have been established for every committee for access via ID and password, with Technical Consultant being the manager of the web site.

Break

1055 Bob Brent:

- Performed literature search and prepared DVD for the committee and have also printed out a list of his publications.
- Also bibliography of all the relevant publications in case committee wants them.

Tom:

- Web site manager should create directory structure.
- 10 Mbyte limit on email attachments.
- No limit on web site.
- Instructions on format and labelling of reports. Everyone should follow instructions on template that will be put on the web site.
- If possible, please provide fresh figures and tables.
- NCRP does all of the handling of copyrights. Please be overly thorough in giving citations.

Bob Brent:

- Referenced and discussed some key papers for consideration.
- Discussed Handbook 54:
 - Only covers irradiation during fetal development.
 - Pretty much only x-ray irradiation.
 - No section on counseling – what to tell patients.
 - Nothing on preconception.
 - What about other types of examinations – ultrasound etc.
- Don and Bob Brent discussion on some public communication/legal issues.

Tom:

- Have entered into some of the legal and ethical issues on previous reports.
- Bob Brent:
 - Discussion of some past legal interactions.
 - Should we have a section on ultrasound, MRI etc.?
 - Andrew: How does this fit with existing documents?
 - Bob: NCRP 54 in each radiology dept.
 - Linda: Can we clarify the title?
 - Tom: Commentary 9 goes beyond x-rays. Women are very concerned wrt cell phone use and fetal effects. MRI and ultrasound now becoming so common is use that consideration should be given to including them. We have some background info from Report 140.

1145 Bob Gorson on phone, Tom reviewed current place on agenda.

- Don: Addressing non-ionizing radiation is off original report. If just summary then not helpful. MRI etc. should be separate reports themselves. To properly answer these questions would require a different and much larger committee.
- Bob: Only wants to make the report helpful to physicians. Can we at least include something about getting similar info using methods other than ionizing radiation.
- John: Argue for greater inclusivity of the agent. This committee's specialty relates to the fetus. This report could be the place to turn for all impacts on the embryo/fetus.
- Tom: Mammography can be an example of how to include other modalities used for diagnostics. Report is on ionizing radiation exposures only, but could mention other imaging methods.
- Tom: Target audience? Probably diagnostic radiologists.
- Andrew: Suggest three ways that the report can be structured; Diagnostic radiology to choose optimum modality...diagnostic optimization methodology.

Second, ionizing radiation itself...what are the different sources and their impact. Third, discussing the principles of risk management using ionizing radiation as the model, but not covering the other modes.

- Tom: This is consistent with the original scope statement. Do need to include therapeutic procedures as well.
- Bob: There are often combined exposures: x-ray, MRI and ultrasound. Must include the therapy issues – pregnant needing therapy...and having therapy and becomes pregnant. Almost every case is different and must take into account the real world situations.
- Don: These issues are hot subjects in radiology departments. Great anxiety and uncertainty about what needs to be done. Would have to commit the same amount of effort to the other diagnostic modalities. This would be a huge undertaking.
- Bob: Let's discuss and think about this over lunch.
- Tom: Don't want to give the impression that the document is covering all modes of radiation, both ionizing and non-ionizing. Only include recognition up front about other exposures. Intent of report is to provide a framework for evaluation the ionizing radiation risk to the fetus and threshold levels of risk for deterministic or longer term effects. Limit to ionizing radiation at outset. Can reference good literature on non-ionizing risks.
- Bob: For ionizing radiation we have enough data to answer most of the questions, but cannot do this for most of the other non-ionizing radiations. Some of the consultations are very complicated and gave example to illustrate this.
- Tom: In introduction, when narrow focus to ionizing radiation, need to mention multimodalities of diagnosis and potential increased risk from these.
- Andrew: It seems you are suggesting all three, rather than one of the suggested structures.
- John: Justifiable in keeping a high level view.

1230 Adjourn for 45 minute lunch.

1315 Bob: Agreed that we are going to do ionizing radiation, diagnostic and therapeutic.

- Tom: Worthwhile to talk about need for optimization to maximize benefit and minimize risk. Leave it up to the physician to balance ionizing with the other alternatives.
- John: Do most documents have a 'future actions' section?
- Tom: Trying to encourage most committees to begin with an Executive Summary and finish with a Conclusions and Recommendations Chapter.
- Bob: Discussion of use of animal data and application to humans and five biological principles. Many teratogenic epi studies incorrectly focus on single symptoms rather than a syndrome. Biological plausibility is one of the key principles...and one of the problems with MRIs causing birth defects.
- Don/Bob: Discussion regarding whether or not a woman needing a MRI and is pregnant will have one.
- Bob: Discussed the other principles of teratology and deterministic vs stochastic effects. Some of the epidemiology starts off with the wrong premise.

- Martha: To what extent do you see this document as an updating of some of the ICRP material?
- Bob: Yes, write it and see what it looks like at the end.
- Martha: Should refer to good reviews of cell phones for example...not cover in detail ourselves.
- Tom: Not aware of any human study with regard to children and fetal studies.
- Martha: Concerned about going out of ionizing radiation in a big way, but understand concerns with dealing with the public.
- Tom: Lack of credible human data and quality of lab data suggests staying away from too much detail with regard to thresholds and levels of risks.
- Bob: Willing to do what the majority want...not dominate as the Chair.
- Tom: Discussion of EMF and power lines.
- John: Summary – Focus of report on ionizing, but that inclusion in intro and conclusion of the other modalities.
- **Bob: Summarize: Decided on: Report should cover all aspects of ionizing radiation. Feels strongly that preconception effects should also be included because we have all that data. Helpful to put in there – what the risks are.**
- John: By the time this comes out we should have results from three nations study with dose response curves.
- Bob: Is this agreed? Yes.
- Bob Gorson: Should think about having an appendix with case studies, taken from real life examples of irradiated pregnant women.
- Bob B: Never tell a patient what to do, but just answer the questions and tell them what the risks are as well as the spontaneous risks are. They make the decisions.
- Tom: ICRP 90 does not treat preconception exposure, so you will be well advised to address it.
- Andrew: What about post-delivery? Do we have to look at mother's milk issue – where do we stop.
- Bob: Get very few questions about breast-feeding. Easy to take care of because of short half life of diagnostic radionuclide.
- Linda: Commentary 9 includes material about breast-feeding. There is quite a lot out there with regard to this subject.
- Andrew: Would not argue for including. Just asking. Incidentally, BEIR VII includes something on preconception.
- Bob: Have we resolved about how to handle the other modalities? i.e. get Andrew to write then discuss. Summarized situation of different committee members.
- Andrew: Should only include diagnostic imaging.
- Linda: Is it just medical exposure to ionizing radiation? Cuts out occupational and a list of other things.
- Tom: Should include all ionizing radiation exposure. Need guiding evaluation criteria, whatever the setting. Including an accident or deliberate malicious use of radiation. This would be very valuable to a wide range of users.

- Andrew: Summarized further his three structures as modified by modification and the complexity of what has been discussed.
- Martha: All topics will not all be treated equally. Some are very brief.
- Bob G: Can you tell me who is present at the meeting? Bob B and Andrew summarized those involved in the meeting.
- Martha: Summarized some of the epi studies regarding preconception exposure, genetic and teratogenic effects.
- Don: Pregnant or potentially pregnant women. Exposed to radiation. Next question: Include any radiation source or just medical. If medical MRI etc. then further down the list.
- Bob B: Rather than just medical it's man-made radiation. Four times when the questions asked, before, during and after.
- Don: Is it any radiation exposure or just medical?
- Martha: Nice to focus in medical or diagnostic – but most of data is from atomic bomb survivors. If only deal with medical it is too limiting.
- Brian: Feels strongly that it should include all ionizing radiation exposure from whatever the source because it is fetal dose and the risk therefrom which is important...not the source of the radiation.
- Bob: Questions come from a lot of women from a variety of exposures not just medical. Agrees with Brian and can write an intro that lays this out.
- ACTION: Bob B rewrite introduction
- Shiao: Suggest new title “Ionizing Radiation Exposure...”
- Tom: CDC hat on for a moment. Their purview is quite large. They would want it as broad as possible i.e. whatever the source of radiation.
- Linda: Proposed a title including the gonads and nursing child.
- Further discussion of the title. Reproductive risk of ionizing radiation.
- Tom: No that's confusing.
- **Agreed working 'final' title: “Reproductive and developmental effects of ionizing radiation to the human gonads, embryo, and fetus”.**
- Bob B: Agreed also to include an Appendix on consultations. Would like to print and provide table of types of consultations.
- John: Should be in the body, not an appendix.
- **Bob: Decided: Three sections, cases, preconception and ionizing radiation section.**

Break

1540 Bob: Can figures be updated? Anyone have a form similar to that on p.8?

- Linda: We have a committee coming up with one.
- Don: No national standard for this type of form. Different policy for those coming through the ER vs the clinic.
- Bob: Form is hard to develop because of the variety of situations. Fractionation has a large effect and questionnaires do not take this into consideration.
- Don: ACR has a form that may be helpful, but cannot be released yet.
- Bob: Prose that goes with the form is as important of the form itself. Next table is an important one but unsure whether it has been updated.

- Bob: Mike Stabin's report has a lot of useful data.
- **ACTION: Brian email Malcolm Crick wrt availability of UNSCEAR data for Table 1.**
- Tom: NCRP population dose report is available and can be looked at.
- Bob: Task Group Cttee 3 has a useful table too.
- Andrew: Doses are likely low.
- Bob/Don: Discussion of CT screening worldwide. Anyone can do a scan, but whether you can get paid for it is the question.
- **Bob: *The HPs Roger, Linda and Andrew will put together the tables of doses for the report?***
- Bob: Question regarding Appendix A. Is it out of date, do we need something else?
- Andrew/Linda: Methodology is well laid out.
- Bob: Needs to be simple to understand and in a form that is most useful to physicians and patients.
- Linda: Discussion of badging and compliance problems.
- Tom: Complexities associated with determining fetal dose, size, direction.
- Bob: Lot of consultations from dental staff.
- Tom: Challenge is to get ranges of exposures for all significant sources and occupations. (Can also include exposures from food and water – which can be higher than some occupational ones.) Look at thresholds for the different effects and compare with the exposure ranges.
- John: How about adding a column on the table of reasonably achievable, under best practices?
- Don: But this might be regarded as a guideline for imaging and that's not our task here and would be controversial.
- Bob: Include discussion of 'precautionary principle'.
- Tom: No! It's been soundly rejected by numerous groups.
- Bob: All ten members are authors of the document – as on the committee. Does Tom want to write any part of the report?
- Tom: Always writes the preface. Has been a back up author – wrote intro on NASA report. Tom and David Schauer are the first line of review...so like to keep a little separate from original drafting. So is engaged at various stages as will Brian.
- Tom: Got a little off track on developing the framework of the report.
- John: Drafted an outline on the projected computer with input from Tom and Andrew.
- Brian: Print for review overnight and discussion tomorrow.

1730 Adjourn

Working Title:
Reproductive and Developmental Effects of [Ionizing] Radiation to the [?] Human
Gonads, Embryo, and Fetus

I. Introduction Brent

Principles of Risk Management
Justification
Optimization
Limitation (non-medical)
Protection, Public Health, and Clinical Consultation

II. Radiation Exposures

Types
Ionizing—External
Ionizing—Internal
Non-ionizing
Sources
Medical
Occupational
Environmental

III. Reproductive Stage and Radiation Risk (Adverse Reproductive Outcomes)

Outcomes
Mutation
Miscarriage
Stillbirth
Birth defect
Genetic disease
Life Stage
Adult (gametogenesis): biology, outcomes, risks
Pregnancy (teratogenesis): biology, outcomes (syndromes), risks
Postnatal (Nursing)

IV. Assessment of Risk

Dose estimation
(continuous vs. threshold; population vs. strata)
Background
Genetic variation
“Spontaneous” mutation and miscarriage
Foundations of risk evaluation
Optimization Procedures
Diagnostic Imaging
Radiotherapy
Environmental/Occupational

Accidental or deliberate

- V. Management of Risk (in view of benefits)
 - a. Communicating benefits and risks
 - Professional
 - Public
 - b. Illustrative clinical consultations
- VI. Conclusions and Recommendations

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- 0835 Bob: Review – SI units plus traditional units in parenthesis, in tables have columns for each unit.
- Tom: Agree. SI as primary but with column of conventional units next to it.
 - Bob: Await Bob and Roger before talking about schedule. Refine content and scope.
 - Andrew: Need better idea of the scope of the document.
 - Tom: Communication has two components – prospective and retrospective. Would like decision from committee with regard to additional consultants on non-ionizing radiation.
 - Bob: Need to have updated views on risks from experts.
 - Tom: Can invite to next meeting and share their views.
 - Bob: Questions: Item I...Andrew write
 - Andrew: Edit the content outline.
 - Tom: Limitation not applicable to medical.
 - Don: Image gently principles are applicable.
 - Discussion of justification, optimization.
 - Bob: Can you express ALARA in a way that implies that a higher dose has a higher risk?
 - Don: Philosophy is that what is good for the pregnant person is good for the non-pregnant. i.e. don't have special protocols for pregnant patients...or treat the pregnant person differently. Good imaging is good imaging.
 - Bob: How do we put it in words that do not promote anxiety?
 - Don: Objective is to clarify what the doses are from all sources.
 - Tom: Replace 'limitation' with 'dose control consistent with achieving medical objectives'.
 - Discussion with regard to digital imaging cf. film and excess dose.
 - Don: Are we going to discuss how pregnancy is established? Do we ask or require a test?
 - Bob: It is found out in multiple ways and we don't have control over it. Will write it up when writing the exposure risk part. Tests are good, but won't work less than 6-7 days.
 - Tom: Testing should be discussed in the document in terms of reliability of detection of pregnancy.
 - Andrew: Editing of content outline with discussion of authors for each section.
- 0930 Roger Harms joined the meeting via telecom.
- Bob/Tom: Review of non-ionizing issue and options with Roger.
 - John: Perhaps use the clinical consultations section to weave in the non-ionizing.
 - Tom: Broaden section to clinical consultation and decision making.
 - Bob: Still feels that the scope needs to be broadened to include non-ionizing radiation because of ignorance (medico/legal paranoia) of many physicians...and gave examples of laser and ultrasound.
 - John: Field of expertise of committee is pregnancy and embryo and fetus.

- Bob: Back to refining the outline and assigning writing tasks.
- 0950 Bob Gorson joined the meeting.
- ***Discussion of dates for the next meeting: Decided on 12-13 March.***
 - ***Tom: Need drafts in hand minimum of 3 weeks before. i.e. Feb 20 deadline.***
 - Tom: Encourage routine WebEx or conference calls.
 - ***ACTION: Tom to invite non-ionizing experts to next meeting.***
 - Bob G: Can help with review and editing of the document if no specific assignments. Be glad to review any early drafts that are sent around. His role will be reactive.

1130 Printed outline and adjourn.