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Our Reference:

D/GVIU/7/1/8/2

Date:

18<sup>th</sup> February 2002

*These minutes are published in draft form and are subject to confirmation at the next Board.*

**MINUTES OF THE THIRD DEPLETED URANIUM SCREENING PROGRAMME OVERSIGHT BOARD ON 28<sup>th</sup> JANUARY 2002**

<b>Present:</b>			
Board:	Professor David Coggon Mr Ron Brown Dr Chris Busby Dr Peter van Calsteren Mr Ivor Connolly Mr Ray Bristow Miss Frances Fry Miss Beverley Green Dr David Lewis Dr Gordon Paterson Professor Brian Spratt GVIU Representative	DRPS LLRC OU NGV&FA NGV&FA NRPB RBL INM BRC RS GVIU	Chair          Secretary
Observers:	Surg Cdr Stuart Allison Mr Alan Duncan Mr Neville Higham Mrs Brigid Rodgers Mr Mark Newman Mrs Janie Walker	SGD HJA HSE GVIU GVIU GVIU	
<b>Apologies:</b>	Surg. Cdre Nick Baldock Professor Nick Day Prof Ian Gilmore Dr Muir Gray Dr Len Levy Prof Malcolm Hooper Dr Hilary Walker	INM IPH RBL NSC MRC IEH GVA DH	

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<b>Item</b>	<b>Discussion and Decisions</b>	<b>Actions (Action date)</b>
1.	<p><b><u>Introduction</u></b></p> <p>a) New attenders were welcomed and introduced.</p> <p>b) The Chairman re-iterated the point that discussions and comments made at the OB meetings are only to be communicated to persons external to the Board through the published minutes. Individual members should be free to speak more generally about issues relating to DU, but should make it clear that they are acting as an individual and not representing the OB. The Chairman also re-iterated that any individual who was not content with any aspect of the OB would be welcome to discuss the matter with him.</p> <p>c) The Chairman stated that the main aims of this meeting were to:</p> <ul style="list-style-type: none"><li>• Provide an update on the pilot exercise to establish if a suitable urine test is available for retrospective assessment of exposure to DU</li><li>• Select the pilot study laboratories</li><li>• Clarify a number of issues regarding the pilot exercise protocol</li></ul>	
2.	<p><b><u>Minutes of last meeting</u></b></p> <p>a) These were accepted as a true record of the meeting.</p>	
3.	<p><b><u>Matters arising from last meeting</u></b></p> <p>a) A full list of actions arising from previous meetings and their current status is attached at Annex A to these minutes.</p> <p>b) The ‘Definitions of Terms’ attached to the draft protocol were accepted by the OB.</p> <p>c) The Secretary gave an update on progress with the DUOB website. He stated that web pages had been produced for this site and he was currently awaiting the registration of the domain name before the site could be launched. The address of the site will be <a href="http://www.duob.org">www.duob.org</a>.</p> <p>d) The draft Terms Of Reference for the OB have been accepted by US of S, Dr Moonie.</p> <p>e) The Chairman stated that he had been in contact with the MRC to keep them informed of DUOB activities. He had also talked with Professor Simon Wessley of Kings College regarding the possibility of using the established Kings College cohorts in future research incorporating DU exposure assessment.</p> <p>f) Brigid Rodgers stated that the MOD was prepared to fund a number of regional centres for urine collections (Action 2.17) but the details had yet to be discussed.</p> <p>g) There was some discussion regarding George Etherington’s paper on the practicability of taking autopsy samples for DU testing. There was general agreement that this was not easy to achieve, particularly because of the need to obtain consent from the next-of-kin soon after death. This would be</p>	

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	<p>difficult unless the procedure had previously been agreed by the prospective donor. A possible way of achieving the required consent might be to provide veterans who wished to participate with a card or information sheet that could be given to his/her doctors, rather like the card that was used by organ donors.</p> <p>h) Annex A and D of the Royal Society report Part 1 had been distributed with the calling notice for this meeting. It was noted that these Annexes are very technical and that they are summarised in the main body of the RS report. The Chairman asked about the levels of DU that might be excreted in urine following an acute exposure many years earlier. Brian Spratt responded that an inhaled dose of 25mg DU as insoluble oxides should be detectable after 10 years. Ron Brown stated that he had already seen some results of DU testing in urine and that at the Society for Radiological Protection seminar two weeks ago Neil Stradling of the NRPB had made a presentation on excretion profiles. GVIU undertook to make the slides of this presentation available.</p> <p><b><u>Action 3.1 GVIU to distribute NRPB Presentation</u></b></p> <p>i) There was also some discussion of the results of testing that had been carried out by Durakovic and colleagues. GVIU undertook to seek permission to distribute the slides from a Durakovic presentation to the Royal Society in November 2001 which contained these results.</p> <p><b><u>Action 3.2 GVIU to seek permission and distribute Durakovic presentation to RS</u></b></p> <p>j) Brian Spratt stated that part 2 of the Royal Society report is in press and will be released on 11<sup>th</sup> March 2002. The Chairman asked if an advance copy of the section relating to urine excretion could be made available to some members of the OB. Brian Spratt said he would look into this.</p> <p><b><u>Action 3.3 Brian Spratt to investigate if advance copies of urine excretion section of RS report can be made available to members of the OB</u></b></p> <p><b><u>Action 3.4 GVIU to distribute part 2 of RS report when available</u></b></p> <p>k) The Chairman briefly described his meeting with Under Secretary of State, Dr. Lewis Moonie, on 16 January 2002. He had explained the approach being taken by the OB in setting up the testing programme and stressed that the Board is aware of veterans' concerns over the timescale. Dr Moonie was content with the way things are proceeding.</p>	Secretary (15/2/02)  Secretary (15/2/02)  Spratt (15/2/02)  Secretary (when available)
4.	<p><b><u>OB Additional Members</u></b></p> <p>a) Dr Len Levy from the MRC Institute for Environment and Health has been appointed to the Board to fill the toxicologist role.</p> <p>b) The Secretary gave an update on the additional names that have been put forward for the Radiation Medicine role on the board. Following discussions about the nominations it was agreed that only one candidate had the required clinical experience. GVIU undertook to contact the proposed nomination to see if they were interested in joining the Board.</p> <p><b><u>Action 3.5 GVIU to contact proposed specialist in radiation medicine</u></b></p>	Secretary (15/1/02)

5.	<p><b><u>Programme Plan</u></b></p> <p><b><u>Update on pilot study laboratories</u></b></p> <p>a) Seven expressions of interest in carrying out the pilot exercise had been received and evaluated by a subset of the OB. Copies of these were handed out at the meeting along with a summary document. The Chairman stressed that these documents were Commercial-in-Confidence and should not be removed from the meeting room and, in particular, not circulated to non-members.</p> <p>b) The Chairman stated that the aim of this discussion was to select from the expressions of interest up to 6 laboratories that were judged most suitable to carry out the pilot exercise. Ron Brown questioned the reason for this. The Chairman replied that constraints were imposed by the amount of spiked urine that the NEQAS laboratory could provide and by MOD funding.</p> <p>Post meeting note: At the first DUOB meeting discussions indicated that 3 or 4 laboratories would be chosen for the pilot exercise. MOD funding had therefore been sought for this number.</p> <p>c) Peter van Calsteren led a discussion on the merits of the 7 expressions of interest. He had evaluated them on the basis of the relevant experience of the laboratories, accreditation, publications in journals and the equipment to be used. This led to a prolonged discussion which is not documented in these minutes due to the Commercial-in-Confidence nature of the expressions of interest.</p> <p>d) One expression of interest was considered technically much weaker than the others, although it did propose a novel method that might be worth investigating. After some further discussion, it was agreed to issue an Invitation To Tender (ITT) to all 7 laboratories. If all 7 labs provided bids at acceptable prices then, all other things being equal, the bid that had been identified as the weakest technically would be eliminated.</p> <p>e) Gordon Paterson expressed a concern that some of the laboratories did not have the accreditation that would be expected by, say, the NHS. David Lewis pointed out such accreditation would only cover the basic functions of the laboratory and would not necessarily reflect their ability to do specific tests for DU exposure. The Chairman said that this was not such an important issue for the pilot exercise and that the necessary QA procedures etc. would be built into the contract for the main testing programme.</p> <p>f) There was some discussion regarding the size of the urine samples that would be required. Ray Bristow said that when he went to the US for testing by Dr Durakovic he gave a 72 hour sample which removed some of the problems of daily variation. The Chairman pointed out that there was a balance to be struck between accuracy and practicalities, and large volumes of urine were difficult to obtain, store and transport. Ray Bristow stated that anything less than 24 hour samples would not be acceptable to members of the NGV&amp;FA. The Chairman pointed out that one of the aims of the pilot exercise was to establish what size of sample would be required for an accurate test and that each lab would receive large samples (probably 1 litre) and smaller samples (probably 100 ml) for this purpose. It was generally agreed that it would be wise to wait for the results of the pilot exercise.</p>	
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g) Brian Spratt asked if the Canadian laboratory involved in the Durakovic testing had been contacted about the pilot exercise. The Secretary confirmed that they had been contacted but had not responded with an expression of interest.

h) The Chairman pointed out that he was indirectly linked professionally (although not financially) to an organisations involved in one of the expressions of interest, and asked if the OB had any objections to his participation in the selection process. No objections were raised.

### **Update on laboratory to supply spiked samples**

i) At the last meeting, the National External Quality Assurance Schemes (NEQAS) laboratory at the University Of Surrey was identified as the preferred supplier of the spiked samples. The Chairman had visited this laboratory along with David Lewis, Peter van Calsteren and the Secretary on 18<sup>th</sup> December 2001. It was agreed that NEQAS would be suitable for carrying out the task with supervision by an appropriate Board member. Peter van Calsteren agreed to supervise the NEQAS work.

j) The Secretary gave an update on the status of the NEQAS contract. The quote for the work had been received and approved. The contract was expected to be placed in the next two days.

Post meeting note: NEQAS contract placed on 30/1/02.

k) Ivor Connolly asked if NEQAS could produce the samples to fit in with the DU pilot study timescales. The Chairman confirmed that this was the case.

l) The Chairman asked for the Board's thanks to David Lewis and Peter van Calsteren to be minuted for their efforts in this area.

### **Pilot Study Protocol**

m) There was extensive discussion regarding the spiking regime, particularly with regard to the size of the samples and the uranium isotope ratios and concentrations in the urine. The Chairman stated that members of the OB should not discuss this outside the meeting in case the credibility of the pilot exercise was compromised. It was agreed that the spiking regime should be finalised between David Lewis, Peter van Calsteren, Malcolm Hooper and NEQAS.

n) Ray Bristow expressed concern that the standards used to spike the samples would not be representative of the DU contained in weapons. David Lewis confirmed that the standards used would be 'pure' DU standards and that to create, and gain accreditation for, standards that exactly represented the DU used in weapons would add excessive time and cost to the programme without increasing its scientific rigour. Peter van Calsteren stated that other elements, such as Plutonium, would not affect the analyses, which would look at the  $^{235}\text{U}/^{238}\text{U}$  ratio.

o) There was some discussion regarding the supply of aqueous samples to the pilot study laboratories. It was generally agreed that these would be useful should there be a problem with the analyses of urine samples, to establish whether the problem lay with the testing of urine specifically, or whether it was a problem with the method more generally.

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	<p>p) David Lewis mentioned that NEQAS had contacted him to see if his laboratory would carry out checks on the spiking agents prior to the actual spiking of the samples and asked the members of the OB if they had any problem with this as he was a MOD employee. Ivor Connolly expressed the view that some veterans might be concerned about the MOD using this to introduce delays into the programme. David Lewis clarified his position as a board member and stressed his desire to ensure that veterans are tested correctly. The proposed testing would not be expected to introduce any delays. It was agreed that David Lewis's laboratory should make the checks required by NEQAS.</p> <p>q) Gordon Paterson asked if the final details of the spiking regime could be circulated to OB members as soon as they were finalised. He also expressed the view that some urine samples should be held in reserve in case unforeseen problems arose.</p> <p><b><u>Chain of Custody for Urine Samples in the main testing programme</u></b></p> <p>r) The Secretary introduced his Chain of Custody paper which had been distributed prior to the meeting.</p> <p>s) Ron Brown asked if tamper-evident containers were available for 24 hour urine samples. David Lewis stated that he did not believe this would be a problem.</p> <p>t) Chris Busby asked what was known about the absorption of uranium onto storage containers etc. Peter van Calsteren stated that this problem was well recognised, and that appropriate plastic containers are available.</p> <p>u) There was some discussion regarding the logistics of taking large samples if they turned out to be necessary. The Chairman stated that he envisaged the donors being given a large container and collecting the sample at home rather than staying at a hospital for 24 hours. Gordon Paterson noted that there are now sophisticated ways of carrying samples to a collection point i.e. by the use of specially-designed holdalls. He also pointed out that there are contractors who have experience in the bulk distribution/collection of sample containers.</p> <p>v) Ivor Connolly expressed concern over the splitting of samples if this were required. It was agreed that there was little point in veterans taking their own sample away with them as the testing could always be repeated if results were doubted. In this respect, the situation was different from a test, say, of blood alcohol concentration, where the timing of sample collection was critical.</p> <p>w) Chris Busby expressed concern that analyses might under-estimate the level of DU excreted because DU particles excreted by the kidney were not completely dissolved. Peter van Calsteren pointed out that the samples would be acidified in nitric acid and did not see this as a problem.</p> <p>x) Ron Brown asked if the Chain of Custody paper needed expanding. The Chairman stated that the paper was a good starting point and would be refined in the future once the results of the pilot exercise had been examined.</p>	
6.	<p><b><u>Timescales</u></b></p> <p>a) The Secretary gave an update on the pilot exercise timescales. He stated that the ITTs would be issued to the 7 laboratories by mid-February, once the Statement of Requirement had been finalised. Following this, ECC regulations require that the laboratories should have 40 days to reply. This</p>	

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	<p>means that the bids will come back in at the end of March. Ivor Connolly expressed concern that the ITTs were being issued 2 weeks later than had previously been envisaged. The Secretary stated that he believed the programme was still on track because a month had been allowed for the assessment of the bids and two months for the actual pilot studies to take place, both of which were probably over-generous.</p> <p>b) The Secretary asked for clarification of the purpose of the Protocol as compared to the Statement Of Requirement. The general agreement was that the protocol details how the entire pilot exercise is to be carried out and is effectively an agreement between the OB and NEQAS. The SOR will be the instructions to the pilot study laboratories stating what they actually have to do and will, effectively, be one part of the protocol. It was agreed that the contracted laboratories should be given a chance to comment on the protocol before it is finalised, particularly with regard to the arrangements for handling, storing and transporting samples. If necessary, a meeting could be arranged for this purpose.</p> <p>c) The Chairman confirmed that it was still the intention that the pilot exercise would take place in May. In parallel with this, thought would have to be given to the advertisement and design of the contract for the main testing programme. The Secretary agreed to produce a paper on the requirements for this contract.</p> <p><b><u>Action 3.6 GVIU to produce paper on requirements for main testing programme contract</u></b></p>	<p>Secretary (15/3/02)</p>
<p>7.</p>	<p><b><u>DU Background &amp; Scientific Issues</u></b></p> <p>a) Chris Busby questioned the interpretation of a recent study by the Italian Commission of Experts into tumour cases among military personnel who had served in the Balkans and, in particular, the response from US of S to Caroline Lucas MEP on the subject. Ray Bristow voiced the opinion that if a map of where DU was fired in Kosovo was examined it would be apparent that a large number of DU attacks occurred in the Italian sector. The Chairman said he was interested in this and would like to receive further information, but that it was not mainstream OB business.</p> <p>b) Gordon Paterson enquired about the process of setting up epidemiological studies. The Chairman suggested that any assessment of research should be carried out by the MRC, and that it should not be the function of the OB to set up the research programme, although it should have input to the assessment of proposals.</p> <p>Post meeting note: GVIU have now written to the MRC for assistance in establishing epidemiological studies to explore possible health effects of DU, if and when a reliable method of retrospective exposure assessment becomes available.</p> <p>c) Ray Bristow expressed concern that the results of the studies might be kept secret from veterans. The Chairman stated that the results would not be secret from the veterans. As with any medical investigation, any veteran who was tested as part of an epidemiological study would be told of the result if he or she wished to know it. In addition, the results of the epidemiological study would be published in the open scientific literature.</p>	

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8.	<p><b><u>A.O.B.</u></b></p> <p>a) The Chairman asked David Lewis if he would write a short paper on evaluating the relative performance of laboratories [This will come out of the protocol work] and explaining some of the statistical jargon for a lay reader.</p> <p><b><u>Action 3.7. David Lewis to produce paper on how laboratories can be judged against each other.</u></b></p> <p>b) There was further discussion regarding the work of Dr Durakovic. Ray Bristow stated that Dr Durakovic should be invited to speak to the OB. Brian Spratt pointed out the lack of controls in the Durakovic work. The Secretary stated that MOD were very keen to talk to Dr Durakovic and that GVIU had just written to Dr Durakovic inviting him to come over to discuss his work. The Chairman stated that it would probably be better if we had some results of our own before we invited Durakovic to talk to the OB. The Chairman asked if the McDiarmid et al paper ‘Surveillance of Depleted Uranium Exposed Gulf War Veterans: Health Effects Observed in an Enlarged “Friendly Fire” Cohort’ could be circulated to the board.</p> <p><b><u>Action 3.8. GVIU to circulate the McDiarmid paper</u></b></p> <p>c) There was some discussion about whether other tests, particularly blood tests for lymphoma, myeloma etc, should be carried out at the same time as the urine testing. The Chairman stated that this was not appropriate and that it was necessary to first look at the primary indicator of DU exposure i.e. the urine test for uranium isotopes. A possible future study that could then be carried out would be to relate the exposure to DU to early biological effects.</p> <p>d) Gordon Paterson expressed the view that, whatever test was carried out, it was very important that the method of presenting the results to veterans was correct.</p>	<p>Lewis (15/3/02)</p> <p>Secretary (15/2/02)</p>
9.	<p><b><u>Date of next meeting</u></b></p> <p>a) The date of the next meeting is currently set for 28<sup>th</sup> March 2002 at 09:45 and it will be held at the Royal British Legion HQ on Pall Mall. A decision as to whether this date needs to change will be made nearer the time, particularly as it very close to the expected return date for the pilot exercise tenders.</p>	

Distribution:

All members

All observers

Devolved Health Administrations

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### **ANNEX A - DUOB Action List**

<b><u>Action</u></b>	<b><u>Date placed</u></b>	<b><u>Action Date</u></b>	<b><u>Detail</u></b>	<b><u>Owner</u></b>	<b><u>Comments</u></b>
1.1	27/9/01	16/11/01	'Definitions of Terms' appendix to be drafted and circulated for comment	Lewis/ Calsteren	<b>COMPLETE</b> – Definitions attached to draft protocol distributed at 2 <sup>nd</sup> meeting
1.2	27/9/01	16/11/01	Nominations for toxicologist and radiation medicine experts to be sent to GVIU	All OB Members	<b>COMPLETE</b> – See actions 2.2, 2,3
1.3	27/9/01	26/10/01	CVs and declarations of interest to be sent to GVIU	All OB Members	Still awaiting Hooper (short), Levy and Gilmore
1.4	27/9/01	12/10/01	Secretary to establish if payments can be made for Board members to attend meeting	Secretary	<b>COMPLETE</b> – Payments will be considered on an individual basis. Written justification must be forwarded by Board member to GVIU for consideration.
1.5	27/9/01	12/10/01	Secretary to create a claim form for expenses	Secretary	<b>COMPLETE</b> - Form distributed on 23/10/01
1.6	27/9/01	26/10/01	Secretary to distribute a copy of the press release to board members	Secretary	<b>COMPLETE</b> – Press release distributed on 23/10/01
1.7	27/9/01	Ongoing	Board members to write to GVIU with suggestions for further background reading	All OB Members	Ongoing
1.8	27/9/01	26/10/01	GVIU to obtain permission and distribute responses to the 2 <sup>nd</sup> consultation paper to Board Members	Secretary	<b>COMPLETE</b> – distributed by email on 13/11/01
1.9	27/9/01	26/10/01	GVIU to distribute list of email addresses	Secretary	<b>COMPLETE</b> – Distributed on 23/10/01
1.10	27/9/01	26/10/01	Board members to suggest suitable laboratories to GVIU	ALL OB Members	<b>COMPLETE</b> – 30/11/01
1.11	27/9/01	26/10/01	Secretary to arrange for invitation to express an interest in the 'pilot study' to be advertised in the relevant journals	Secretary	<b>COMPLETE</b> - Advert in MOD Contracts Bulletin on 21/11 and OJEC on 13/11/01
1.12	27/9/01	16/11/01	Produce and circulate draft protocol prior to next meeting	Lewis/ Calsteren	<b>COMPLETE</b> – 30/11/01
2.1	30/11/01	4/1/02	GVIU to send TOR to Minister for comment	Secretary	<b>COMPLETE</b> - Sent on 11/1/02. Minister has approved the TOR.
2.2	30/11/01	8/1/02	CVs for toxicologist to be sent to GVIU. GVIU to forward to Minister	Secretary	<b>COMPLETE</b> – Sent on 15/1/02
2.3	30/11/01	8/1/02	Suggestions for radiation medicine experts to be sent to GVIU	All	<b>COMPLETE</b>
2.4	30/11/01	8/1/02	GVIU to consult Royal College of Radiologists	Secretary	<b>COMPLETE</b> – RCR recommendation received on 24/1/02
2.5	30/11/01	12/12/01	GVIU to notify members of expressions of interest	Secretary	<b>COMPLETE</b> – emailed on 13/12/01
2.6	30/11/01	7/12/01	Draw up Statement Of Requirement for the sample preparation	Van Calsteren	<b>COMPLETE</b> – 1 <sup>st</sup> draft discussed at meeting with NEQAS on 18/12/01. Will be revised in discussion between LEWIS, van Calsteren and NEQAS
2.7	30/11/01	10/12/01	David Lewis to contact the preferred supplier of spiked samples (and other suppliers if required) to assess interest and costs	Lewis	<b>COMPLETE</b>
2.8	30/11/01	13/12/01	Arrange meeting with supplier of spiked samples	Lewis	<b>COMPLETE</b> – see 2.9 below

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2.9	30/11/01	20/12/01	Subgroup to visit supplier	Coggon/ Lewis/ van C/ GVIU	<b>COMPLETE</b> – lab visited on 18/12/01
2.10	30/11/01	28/1/02	Nick Day to review protocol and proposed statistical methods	Day	Ongoing – awaiting redraft of protocol following discussions with NEQAS
2.11	30/11/01	21/12/01	David Lewis to redraft protocol for pilot study of analytical methods	Lewis	Ongoing- awaiting NEQAS contract
2.12	30/11/01	21/12/01	David Lewis to draft the SOR for the urine testing in the pilot study, to be distributed to the OB by 21/12/01	Lewis	<b>COMPLETE</b> – ITT sent to NEQAS on 14/1/02
2.13	30/11/01	10/1/02	OB to comment on the SOR for urine testing by 12.00, 10 Jan 02	All	<b>COMPLETE</b>
2.14	30/11/01	28/1/02	Chairman to appraise MRC of the planned timetable for the development of the testing method	Chair	<b>COMPLETE</b> – Chairman talked to Catherine Moody of MRC
2.15	30/11/01	21/1/02	Chairman to produce paper for next meeting summarising the different types of epidemiological study that might be relevant	Chair	<b>COMPLETE</b> – Paper circulated on 11/1/02
2.16	30/11/01	21/1/02	GVIU to produce a paper on the options for a chain of custody of urine samples	Secretary	<b>COMPLETE</b> – Paper circulated on 25/1/02
2.17	30/11/01	28/1/02	GVIU to identify the position of MOD funding of regional centres	Secretary	<b>COMPLETE</b> – MOD will fund regional centres but the details of this need to be decided
2.18	30/11/01	28/1/02	NRPB to obtain advice on the feasibility of testing for DU in tissue samples obtained at autopsy	NRPB	<b>COMPLETE</b> – paper distributed on 18/1/02
2.19	30/11/01	14/1/01	GVIU to circulate Annexes A and D (on the current ICRP models and Organ Doses from intakes) from the Royal Society report	Secretary	<b>COMPLETE</b> – Circulated on 11/1/02
2.20	30/11/01	21/1/02	GVIU to provide Contracts Branch with the draft protocol in time for ITT issue on 31 Jan 02	Secretary	Ongoing – awaiting NEQAS contract
2.21	30/11/01	21/1/02	David Lewis/ van Calsteren to prepare a paper on laboratory methods	Lewis/ van Calsteren	Not possible within this timescale – due to DL and PvC commitments will be re-considered in the future
2.22	30/11/01	7/12/01	GVIU to arrange a meeting between Chairman and US of S	Secretary	<b>COMPLETE</b> – Chairman met with US of S on 16/1/02

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