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D/SG(Med Pol)/350/6/7

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RESPONSES TO THE MOD INVITATION TO PROFESSIONAL AND OFFICIAL BODIES TO COMMENT ON THE TECHNICAL ISSUES OF A VOLUNTARY SCREENING PROGRAMME FOLLOWING HEALTH CONCERNS IN RESPECT OF DEPLETED URANIUM

1. On 13th February, MOD issued a Consultation Document¹ "*An invitation to professional and official bodies to comment on the technical issues of a voluntary screening programme*". The Consultation Document was based on the work of an Expert Advisory Group (EAG).
2. MOD is most grateful for the responses received. Without exception, the responses were constructive, helpful and supportive. We will be addressing most of the technical issues raised during the development of any screening programme. Some respondents also raised more general issues that will be addressed in the next Consultative Document that MOD will publish containing its proposals for screening.
3. The EAG was tasked by MOD to provide a summary of the responses to be published concurrently with MOD's 2nd Consultative Document. The summary is attached for information. It should be noted that any opinions and recommendations expressed are those of the EAG and represent internal advice to MOD. MOD policy will only be determined following the ending of the second consultation exercise.

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Brigadier
for Surgeon General

Encl.

1. Summary of Responses to the Consultation Document *An invitation to professional and official bodies to comment on the technical issues of a voluntary screening programme*.

¹ D/SG(Med Pol)/350/6/7 dated 13 Feb 01 available on MOD Wen site at <http://www.mod.uk/index.php3?page=1819>

Ministry of Defence

Introduction of a Voluntary Screening Programme Following Health Concerns in Respect of Depleted Uranium



A summary of responses received by MOD resulting from the MOD Consultation Document “*An invitation to professional and official bodies to comment on technical issues*”.

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MOD EXPERT ADVISORY GROUP ON SCREENING FOR DU: A REVIEW OF THE RESPONSES TO THE INITIAL CONSULTATIVE DOCUMENT

INTRODUCTION

1.1 In January 2001 the MOD formed an in-house Expert Advisory Group (EAG) to develop a consultative document entitled 'Introduction of a Voluntary Screening Programme following health concerns in respect of Depleted Uranium'. The document was published on the MOD web-site on 13 February 2001 and professional and official bodies were invited to comment.

1.2 The EAG was reconstituted on 9 March 2001 to assess the response to the consultative document and identify options for the development of the proposed occupational and population screening programmes.

1.3 The MOD has received 36 written responses and a list of respondents is at [Annex A](#). All of the responses have proved to be thought provoking and extremely useful. Some of the responses are detailed and highly technical, particularly in regard to the type of analytical tests that may be appropriate. In view of the time constraints placed on the EAG it has not yet been possible to evaluate all of the information received in great detail. However, the EAG has been able to collate the replies and extract the important issues raised by each respondent. This has been achieved by collating the information under 2 major section headings. Under the first heading (General Response to Specific Questions), a brief synopsis of the replies to the questions posed in the MOD Consultation Document is given. Where deemed appropriate the EAG provides an opinion/overview of the comments received. Under the second heading (Major Issues), the EAG focuses on topics raised by respondents either in response to questions or elsewhere, that may have a major impact on the development of the screening programmes.

GENERAL RESPONSE TO SPECIFIC QUESTIONS

CHOICE OF SCREENING TESTS

2.1 Question 1: To what extent should MOD rely on current ICRP recommendations and advice?

The majority of respondents who answered this question appear to support the concepts of the ICRP with the proviso that, whenever possible, biokinetics models should use input parameters derived from specific studies of DU munitions residues rather than ICRP default values. Any alteration to the ICRP models should be approved by a qualified body (NRPB or IAEA) and the alterations clearly documented. Nevertheless, there are several other responders who do not embrace the ICRP principles and support alternative scientific and biological parameters/models of risk. Furthermore, the issue of chemical toxicological effects needs to be considered. . Although it is clearly preferable to achieve a consensus of opinion, this may not be

possible and different groups may interpret the results of the programmes in different ways.

2.2 Question 2: Does whole body monitoring have a part to play in screening?

The general consensus of these responses seems to be that whole body monitoring is an inappropriate method for the routine screening of personnel potentially exposed to DU. However, some parties believe that it might have a role to play in follow up screening where high levels of U are detected in urine. The relatively insensitive nature of the method means that only recent, large exposures would be detected and the ability of the technique to determine isotope ratios is questionable. A small number of responders highlighted the importance of developing a technique for the accurate determination of U lung burden but this is essentially a long-term research issue.

2.3 Question 3: Does analysis of bone using K x-ray fluorescence, or analysis of hair, blood, faeces or tooth enamel have any part to play in any screening programme to be established in 2001?

It is clear that analysis of urine is the preferred method for the estimation of an individual's exposure to DU rather than analysis of hair, blood or faeces, each of which have their own practical difficulties. The work being carried out in Ontario by Professor Chettle on the analysis of bone using K x-ray fluorescence was the subject of some comment. A member of the EAG has discussed the technique, which is non-invasive, with this research scientist. Following further development work it may have some utility although it still may not have the flexibility of urine testing since it would require a subject to attend a specialist centre rather than have his urine sent there. Several respondents also suggested a role for electron paramagnetic resonance of tooth enamel. However this technique is still developing and has the major problem that it is much more invasive than urine sampling.

2.4 Question 4: For exposures occurring some time in the past, the EAG conclude that DU must be sought directly (rather than first testing for total uranium). They further conclude that Thermal Ionisation Mass Spectrometry (TIMS) is the only test capable of detecting exposures more than 2 years previously, and then only if the exposure was significantly high. By implication they conclude that TIMS is the only suitable test for population screening. However, the EAG states that a technique for use on biological samples has yet to be validated and there are no laboratories accredited to undertake such work. Are these conclusions valid and if so what are the implications for a screening programme?

Question 5: For relatively high concentrations of DU in the urine (e.g. from a recent occupational exposure or from retained foreign bodies containing DU) the EAG states that High Resolution Inductively Coupled Plasma Mass Spectrometry is a validated test. However, its validity depends on the excretion in urine of DU being 1½ times the natural background uranium concentration. It would thus seem a valid test only for recent or current exposures. Is this a valid conclusion?

Question 6: The EAG state that Inductively Coupled Mass Spectrometry is a validated test for total urinary uranium, but the normal values in the population are not accurately known, nor is it known whether the values in those deploying on operations conform to the normal population values. The test does not differentiate between natural uranium and DU. Is it correct to conclude that it is not appropriate for screening personnel for past exposure (except perhaps for those with retained foreign bodies that might include DU), but it could quickly be developed as a measure of current exposure?

OCCUPATIONAL SCREENING

Question 7: MOD believes a coherent policy that includes biological monitoring should be developed for measuring and controlling exposure on future battlefields. Is it reasonable to rely on Inductively Coupled Mass Spectrometry for total urinary uranium, backed up in the case of a positive result by High Resolution Inductively Coupled Plasma Mass Spectrometry? What value for total urinary uranium should constitute a positive?

a. Due to some differences of opinion over definitions in the original consultative document and amongst analytical laboratories, the replies received from respondents on questions 4 to 7 overlaps to some degree. As a result replies to these questions were grouped together to try to clarify the responses and to identify areas of agreement that could act as a pointer to the next stages of the programme. Good technical responses concerning uranium analysis were received from a number of respondents.

b. Although not all laboratories have experience of urine uranium analysis what is clear from these papers is that there is more than one valid approach to measuring uranium in urine.

c. An overview of the technical responses shows that the following techniques are available. The following paragraphs describe the techniques and also state some of the obvious advantages and disadvantages of each.

1) TIMS. Thermal ionisation mass spectrometry. This technique has been widely used especially in geochemical laboratories to give precise measurements of isotopic ratios and is accepted as the method likely to give the best quality uranium isotope ratio data. Unfortunately this technique requires considerable sample preparation and long analysis times (1-3 hours per sample). This means that sample throughput may be low and the costs

correspondingly high. The consensus on the technique appears to be that whilst it is a “gold standard” method it may be inappropriate for large numbers of samples.

2) ICPMS. Inductively coupled plasma mass spectrometry. There are two basic forms of ICPMS as follows.

i. Low resolution ICPMS (ICPMS). These instruments tend to be quadrupole based and are typically somewhat less sensitive than other types of ICPMS although continuing instrument development makes the distinction harder to make. These instruments are suitable for measuring total uranium concentration and can also be used to determine isotope ratios but at low precision. Many responders consider this to be the best instrument for high throughput screening for total uranium in urine.

ii. High resolution ICPMS (HRICPMS). These are typically magnetic sector instruments. They are typically more sensitive than low-resolution instruments and can produce isotope data that is better than some of the low resolution instruments but still falls short of both TIMS and MCICPMS, which is mentioned below. A number of responders consider that HRICPMS is a valid alternative to ICPMS for screening urine for total uranium but not the best choice for ratio data. At least one responder sees no obvious advantage in the use of HRICPMS over low-resolution instruments.

3) Multiple collector ICPMS (MCICPMS). These instruments are a relatively new development of ICPMS technology. They are designed to produce high precision isotope ratio data that is claimed to approach and in some case equal the data available from TIMS. Many respondents consider this to be the technique of choice for isotope analysis.

d. What is most obvious from the replies is that there is a difference of opinion within analytical laboratories on what are the best methods for both screening and isotope ratio determination. TIMS appears to be problematic, as although the method is capable of producing high quality isotope ratio data the sample preparation is onerous. Both low and high resolution ICPMS appear to be accepted for screening urine samples for total uranium but not for isotope ratio work on untreated samples although these techniques may be usable if the uranium is separated first. MCICPMS is quoted by a number of responders as being the best technique for isotope ratio measurement and would appear to be the method of choice subject to suitable method development. Many of these methods can be adapted by the addition of sample introduction systems that may cloud the choice of technique further.

e. The availability of a particular technique is also a consideration. TIMS, MCICPMS and HRICPMS are only available in a limited number of laboratories and may not be available due to pressures of existing work. This is an important point, as samples need to be analysed quickly. Uranium concentrations may not be stable if

samples are processed a long time after collection. Low resolution ICPMS is widely available and is able to produce uranium concentration data quickly.

f. It is also obvious that those responders with experience of uranium isotope analysis do not necessarily have experience of handling urine samples. Similarly some organisations that may be expected to have experience in this area have not responded and may not have been aware of the consultation process. It is also clear there is a need for participating laboratories to demonstrate their ability to analyse uranium in real urine samples before the programmes commence.

g. Following the initial consultation process the way forward for assessment of past exposure would appear to be to obtain concentration and isotope ratio data from urine samples using MCICPMS backed up by the use of TIMS if necessary.

h. The clearest consensus at the moment is that retrospective intakes are best measured by MCICPMS using changes in isotope ratio. For the biological monitoring of ongoing exposure the clearest consensus is that total uranium should be measured using a low resolution ICPMS and that any samples with concentrations above a pre-determined limit should re-analysed by MCICPMS to give more precise uranium isotope ratio data and thus an indication of exposure to DU.

i. Two respondents raised concerns over the presence of non-uranic radioactive materials in DU munitions and suggested there was a need to analyse for some of these specific radionuclides. The opposing view is that there is no need for such an analysis as there is an increasing amount of information on the composition of the DU used in munitions from analyses of DU metal. A further consideration is the extent to which the additional analyses would complicate and delay the setting up of the proposed programmes.

2.5 Question 8: The EAG raise a number of issues that question the utility of the measurement of total urinary uranium for those currently in the Balkans, or recently returned from it. Nevertheless, should there be a programme of voluntary anonymous testing undertaken of an appropriate cohort of Balkans personnel both as part of research to ascertaining the normal values and to confirm that significant exposures are not occurring?

The responses overall were quite strongly supportive of this proposal. However concerns were expressed that the voluntary nature of testing would leave the results susceptible to bias and that any cohort of servicemen would not give a 'normal' background level of uranium excretion since all servicemen may possibly have had prior exposure to DU during their service careers.

2.6 Question 9: To what extent should occupational screening be targeted and, once normal population values are known, is there a need for a baseline, pre-deployment, measured as suggested by the EAG?

This question was only partially answered by most respondents. However, the overall impression gathered from the data seemed to support the targeting of occupational

screening on the basis of risk assessments for actual exposure. Even once normal population values are known, most respondents thought that baseline measurements would still be required in order to interpret the results after possible exposure. One respondent suggested that baseline samples could be frozen for use only if required to interpret results of a post exposure specimen. This is a technique that would need to be validated before use however.

2.7 Question 10: In the context of occupational screening, should screening be voluntary or should it be treated on the same basis as occupational lead or radiation exposure?

There were mixed views on whether the occupational screening programme should be voluntary or compulsory. However the most comprehensive responses all agreed that the decision should be based on the degree of risk of harm and that voluntary testing using informed consent is most appropriate when the risk is low. The Health and Safety Laboratory added that compulsory screening is only appropriate if an exposure-disease model can exactly identify a safe level of exposure and they did not consider this to be the case with DU.

POPULATION SCREENING²

2.8 Question 11: Is it accepted that population screening could only be introduced after the further work recommended by the EAG?

There are obviously mixed feelings over whether the implementation of a screening programme should proceed before further work has been conducted to validate the analytical and quality control procedures required to obtain reliable data. Several parties express concern over the additional delays likely to be incurred in setting up a screening programme, while others feel that if the programme is to be a success every attempt should be made to validate the procedures involved. The psychological stress that could result from participants having to be given revised intake estimates if measurement and quality control arrangements were progressing in parallel also needs to be considered. There was also considerable support for the implementation of a pilot study to achieve these aims.

2.9 Question 12: Is it accepted that screening based on a specific disease is inappropriate?

Most contributors seem to be in agreement that there is a lack of evidence to link DU exposure with a specific disease or pathological process. One correspondent has highlighted the possible association between low level radiation and haemopoietic effects such as changes in monocyte population, B-lymphocyte dysfunction, and free radical activity leading to the rupture of cell membranes.

² The EAG recommends that population screening is renamed as “retrospective exposure assessment.” See Paragraph 3.2

2.10 Question 13: Would the more limited testing, outlined in paragraph 19, be appropriate?

Limited testing, as an alternative to screening, is not seen to be acceptable to the Gulf Veterans and their support groups - primarily because it fails to address individuals' primary concern (i.e. do I have DU inside my body?). However, it is generally accepted that some forms of limited testing as parts of a wider research programme may help to define some aspects of a suitable population-screening programme.

MANAGEMENT OF POSITIVE RESULTS

2.11 Question 14: Is it correct to conclude that no action can be taken in the event of a positive result during population screening, other than providing reassurance?

a. Many respondents agreed that no further action other than the provision of reassurance could be taken in the case of positive results. However other respondents argued that increased levels of medical surveillance including a range of biomedical tests would be appropriate as this might result in earlier detection of disease and a better chance of successful treatment. The provision of advice on lifestyle changes that could reduce overall cancer risks, such as the importance of stopping smoking was mentioned. There was also a suggestion that some treatments would be appropriate to reduce the risk of cancer (ie. the use of antioxidants to offset the effect of free radicals includes extensive and intensive therapy with anti-oxidants. Vitamins C and E, selenium, copper, iron, glutathione and pycnogenols and related compounds were all suggested).

b. Most respondents stressed that the appropriateness of surveillance or treatment required are entirely dependent on the dose of a substance absorbed and therefore the excess risk of ill health effects such as cancers. This is due to the need to balance the chance of benefit against the risk of harm from false positive medical surveillance test results and the side effects of treatment. The EAG supports these concepts. It also agrees that some forms of medical surveillance and medical treatment are appropriate in some specific situations for individuals who have been exposed to high intakes of DU. However, exposures to DU in UK troops and civilians deployed to the Gulf and Balkans have been assessed as low and the vast majority of troops who served in these areas have not expressed concern over possible DU exposures. An appropriate screening test should assist in the actual quantification of exposure and therefore risk but when exposures are low, the risk/benefit balance will not indicate that further action is appropriate. However the EAG recognises the need to assess every individual's need separately and accepts that in cases of confirmed exposure the final decision must be based on an agreement between a treating physician and the individual concerned.

2.12 Question 15: Assuming population screening is technically feasible, is it acceptable to risk identifying positives, for whom there is no treatment, in order to give reassurance to those who will test negative?

a. The responses to this question essentially highlighted two valid ethical views. The first view, based on the inability of a DU population-screening programme to fulfil some of the NSC criteria (since there is no appropriate medical intervention to prevent ill health), is that this action is ethically unacceptable. The second view is that veterans have a 'right to know' and that this is equally important.

b. As the proposed population screening programme is to be voluntary, and fully informed consent is to be obtained, these issues are matters upon which the individual's concerned can make their own choice. The view of the EAG therefore is that this is not a major obstacle to the development of a voluntary screening programme.

HEALTH SCREENING

2.13 Question 16: Does a Veterans Assessment Centre have a part to play in addition to, or in place of, a population screening programme?

There was good support for the view that a Veterans Assessment Centre would complement a population-screening programme. Several respondents expressed the view that the Veterans Assessment Centre would need to be independent from MOD for the advice to be considered trustworthy. However an alternative view is that some veterans might feel military Medical Officers could better appreciate the nature of their past experiences and concerns.

2.14 Question 17: Should referral be only via an individual's GP or consultant or should an individual be able to self refer?

a. A number of respondents expressed the view that the facility for self-referral would be desirable and this was the preferred option expressed by veteran's representatives.

b. However, the EAG considers that before an informed decision can be made on this issue, the views of a number of important medical bodies such as the Royal College of Physicians and the Royal College of General Practitioners should be sought. The opinions of organisations with previous experience of dealing with similar health concerns should also be sought

OTHER ISSUES AND QUESTIONS

2.18 Question 18: Are there any comments on the EAG's paragraphs on other core technical issues?

It is clear that responses to this question overlap with those to other questions and that the comments above should be considered together with, at least, the answers to question 19. Several papers make very useful technical suggestions that should be considered further. A number of papers emphasise the need for the screening sub programmes to be run by a specialist scientific group independent of the MOD although it is felt that such a group would have to include representatives from MOD. The initial major task of this group would be to make decision on appropriate

analytical methodology especially for *retrospective exposure assessment*³ where a number of methods have been offered as suitable.

It is also clear that there is a degree of controversy over the merits of 24 hour as opposed to “spot” urine collections and the usefulness of relating measured uranium levels to creatinine excretion. This is an area where further work and a consensus view are needed.

2.19 Question 19: Are there any comments on the EAG’s discussion on important analytical issues?

a. In general the technical approach taken by MOD in the consultative document is accepted subject to comments on the suitability of some points on method performance. It is clear that accreditation is not seen as an issue by some responders, particularly research institutions, but independently organised laboratory inter-comparisons, strict quality control and careful sample handling is. Of course, accreditation by HSE is mandatory for any laboratory providing information for statutory dose assessments.

b. As a separate issue there is a belief that all aspects of the project should be independent of MOD. This is an issue that is, quite reasonably, given the clearest expression by Veteran’s representatives with regard to the assessment of historic DU exposures. This viewpoint is fully understood and it is obvious that external organisations will need to be involved. However MOD must maintain a clear role in this project as both the employer and as the customer for the work undertaken. . Biological monitoring of current exposure is fundamentally different as it forms just one component of statutory health and safety systems that include risk assessment, the provision of safe working instructions and personal and environmental monitoring. The conclusion is that these functions are best retained within MOD’s existing and comprehensive health and safety system.

2.20 Question 20: Are any of the proposals received by MOD and listed at Annex B (of the original Consultation Document) of practical relevance to the introduction of occupational and population screening.

This question asked respondents to comment on some submissions received by the MOD prior to the issue of the initial consultative document. Few comments were offered. Most felt that the better option was to review all the responses received during the consultation period.

2.21 Question 21: Are there any issues that are not exposed in this consultative document, and is there a completely different approach that could be taken by MOD?

Some useful suggestions were made in answers to this question that have been incorporated into the consensus replies to the questions above. No completely new

³ Called “Population-screening” in the original document. See Paragraph 3.2.

approach was suggested.

MAJOR ISSUES

Terminology

3.1 It is important to have an agreed terminology in order to provide clarity and accuracy to any debate on issues. Several high profile respondents including the Royal Society made comment that the terms used to define the different types of screening caused confusion. For population screening the terms ‘health risk assessment’, ‘retrospective exposure assessment’ and ‘testing programme’ were proposed as alternatives. There was a strong suggestion that the term ‘screening’ should be reserved for programmes that fulfil most of the NSC criteria (ie able to offer treatment to people testing positive to improve their health). For occupational screening respondents who commentated, including the HSE, the preferred the term biological monitoring.

3.2 Since the different types of screening fulfil different purposes, and since the issues involved are complex, it is essential that the terms used are defined so that educated debate can continue without confusion. Furthermore, the definitions must correspond to the definitions of the terms used elsewhere in the fields of health, safety, legislation and clinical medicine. Since its inception the EAG has been aware of the importance of these matters although the use of some terms is enforced by the group’s terms of reference. The correct choice and use of terminology is essential for swift progress and therefore the EAG recommends that:

- a. the emerging population screening programme is renamed (or at least defined clearly) as a programme of ‘*retrospective exposure assessment*’.
- b. that the emerging occupational screening programme is renamed ‘*biological monitoring*’.
- c. that any system of medical consultation and/or medical investigation to assess illness and disease in an individual who believes himself/herself to be ill, tailored to the needs of that individual, is defined as ‘*medical assessment*’.

Separate programmes, separate issues.

3.3 Within the overall screening programme being developed the separate population screening and occupational screening sub programmes each have different aims and the methods to achieve the aims for each programme will be different. The Responses to the consultation document as well as examples of work conducted within the MOD show how easily needing to deal with a challenge in two similar but different contexts can confuse issues. Whilst recognising that technical advances for one sub programme may also be relevant to the other, and that today’s service men will be tomorrow’s veterans, the EAG foresees the need to separate the development of the two sub programmes. This is necessary to avoid confusion in the complexities of achieving the different aims of the programmes. Different medical specialists

(occupational physicians vs public health physicians/GP's/clinicians) have more expertise appropriate for each sub programme and the external authorities appropriate to comment on each sub programme are different. Therefore, it is sensible to address each separately.

Transparency and public trust

3.4 The responses from representatives of Veterans organisations make it quite clear that they have many reservations about MOD involvement in the development of the population-screening programme. The potential impact of these views is also stressed by a number of institutions. Their responses therefore call for the development to be taken forward by an independent project team and secondary scientific committees (similarly independent).

Risk communication

3.5 The EAG is grateful for the very comprehensive response from organisations with experience of related issues, such as the controversy elsewhere in the civilian community over organophosphates pesticides. Past experience has shown that care has to be taken to avoid mixed messages around the aim of any screening and its interpretation in terms of health risk. The MOD is presently attempting to answer the veteran's question 'How much DU is in my body' and this can only be done by isotopic analysis. At the same time the internationally accepted scientific view is that any absorbed DU will only represent a fraction of the natural uranium body burden and that there is no inherent difference in toxicity hazard between DU and natural uranium. Consequently, the DU will be contributing only a fraction of the total risk. Therefore, it is essential to ensure that isotope analysis to measure DU exposure does not lead to a public perception that DU is a specific cause of ill health irrespective of the dose received. Experience suggests that avoiding this pitfall is not easy and expert risk perception/communication advice is required.

Technical issues

3.6 There was also almost universal agreement that further work was needed to establish the capabilities and limitations of the various laboratories that might carry out uranium in urine analyses. A key requirement was to address the problems of dealing with such a complex matrix such as urine and the need to standardise procedures. Laboratory inter-comparisons are also required. This is a technical task for analysts specialising in low level uranium and uranium isotope measurements by mass spectrometry techniques. A further important task will be to investigate the relative merits of Thermal Ionisation Mass Spectrometry and Multi Collector Inductively Coupled Plasma Mass Spectrometry for the investigation of historic exposures. There are also particular difficulties associated with collecting samples for low level uranium analysis. Care must be taken to avoid the sample being contaminated with natural uranium that is present throughout the world.

Time Scales

3.7 There was support for the view that it could take some time to set up a high

quality population-screening programme but that the time spent to produce a good programme would not be wasted. However there were also views that Veterans could lose confidence in the population-screening programme if it is not pursued with vigour. Direct involvement of the veterans or their representatives in the population-screening programme should help to reduce these concerns.

Royal Society Report on DU

3.8 The MOD is committed to take account of the impending Royal Society report on DU and it is grateful for the response to the consultation document from the Royal Society's Working Group on DU. The views of this working group have been incorporated into this synopsis.

Role of the NRPB

3.9 In its reply the NRPB makes reference to the fact that the organisation was set up by act of Parliament to provide a national authoritative point of advice on radiological protection matters. Furthermore the NRPB has considerable experience in areas related to the consultation document. Specifically, the NRPB has extensive experience with experimental work on the behaviour of various industrial uranium compounds, and have used this to advise on occupational monitoring programmes. The NRPB is prepared to assist MOD with the proposed programmes. This offer of assistance is strongly supported by the EAG.

Inclusion of other MOD employees and non-MOD civilians in the proposed screening programmes

3.10 Responses from representatives of voluntary organisations that have served in the Balkans and the Gulf express the wish to be included in the screening programmes. Since the duty of care rests with an individual employer there needs to be further consideration of this request.

3.11 There has also been representation that MOD employees involved in the test firing of DU rounds or working with DU in other industrial settings should be considered eligible for the screening programmes. The risk assessments for these employees are different and they are already subject to full peacetime health and safety and environmental monitoring systems, including biological monitoring. Therefore there is no reason at present to extend the screening been considered by MOD to this specific group.

NHS interface

3.12 Concerns have been raised that if NHS General Practitioners were to be involved in the screening programmes then they would require appropriate training and ongoing support. Furthermore, the BMA might not view screening as part of the General Medical Services that NHS General Practitioners are contracted to provide.

Epidemiological and statistical issues

3.13 The EAG recognises a need for epidemiological studies and for statistical analyses at various points in the development and running of the screening sub programmes. Epidemiological studies are required to confirm or refute the current view that service in the Balkans, and exposure to DU in the concentrations encountered in the Gulf and Balkans, does not cause ill health. The studies will also need to include data on personnel who have not previously served in the Gulf, Bosnia or Kosovo depending on the type of control group required, and the control group should also have urinary analysis for uranium isotopes. The data will need to include some form of medical assessment in order to establish the relationship, if any, between exposure to DU and ill health.

3.14 In respect of urinary analysis for uranium isotope levels, the EAG acknowledges that this is a complex procedure requiring careful interpretation and that quantitative criteria will need to be pre-defined as to what constitutes evidence of an individual's urine sample indicating DU exposure. It is also recognised that data on self-selected groups may give a biased picture. The design and conduct of the investigations does need to be performed using good scientific and statistical principles. However it must also be recognised that some individuals may not wish to participate in this testing. Pilot studies are likely to be required and studies will require protocols that should be peer reviewed and subject to ethical approval.

Contentious statements in the original consultative document

3.15 The risk of ill health effects (para 4.6). One respondent took the EAG to task over the concept that 'there is no proven mechanism linking DU exposure to increased mortality or specific health effects' and states that alpha emitting materials of this type are clearly associated with cancer causation. The EAG is further challenged in regard to the statement in the consultative document that 'at cumulative dose levels lower than 200 milliSievert there is limited/suggested evidence of no association between exposure to uranium and lung cancer'. There was an opinion that the linear no threshold model should always be applied. The EAG acknowledges and accepts these comments, but notes that, in the context in which the statements are made in the first consultative document, the essential point is whether reasonably foreseeable DU exposures are likely to give rise to observable medical effects within a population.

3.16 Population Screening (para 6.13). There was a concern that the statement 'The need for appointment and attendance would act as a natural filter to select the most concerned' suggested that MOD desires to restrict up-take of the offer to screen. In fact this was a simple statement of past experience and especially of experience gained after the Chernobyl accident. However there is a desire to restrict screening to the most concerned in as much as the risk/benefit balance of the screening process is much more likely to be harmful to individuals with less concern. There is no intention to limit the overall numbers of voluntary participants in a valid programme.

CONCLUSIONS

4.1 There has been an extensive response to the consultative document from a wide range of organisations and independents with an interest in this subject. In

particular the information from technical institutions, National authoritative bodies and Veterans representatives has been most informative and has enabled the EAG to gain a better understanding of the important scientific, ethical and legal issues pertaining to the development of a voluntary screening programme. The concerns of the Veterans are now better understood.

4.2 The majority of responders appear to support the general intent of the consultative document. The comments received are generally aimed at supporting, modifying and improving the intended screening programmes. In short, the consultative document has stood up well to detailed scientific scrutiny and there does not appear to be any major changes required in terms of the concepts of the population and occupational screening programmes. It is the details within the programmes that must now be developed.

4.3 Most of the 'general issues' dealing with ethics, involvement of the Veterans, terminology, time-scales etc. seem to have been well aired and there does not appear to be any major barriers preventing further development of the programmes.

4.4 The scientific issues relating to the type of analytical test to be used and the interpretation of the resulting data are still unclear. Further detailed work is required to achieve a consensus on a suitable analytical package.

4.5 Further development of the retrospective exposure assessment programme, must be undertaken by an independent scientific group. The membership must be carefully selected to ensure that all stakeholders are represented and the group has the required breadth and depth of expertise to address both the technical and ethical issues.

4.6 The issues raised in the section 'Major Issues' should all be addressed as the sub programmes are developed.

LIST OF RESPONSES AS AT 17.00 on 30 MAR 2001

No.	Organisation	Department
1	Richard Mould	
2	Lionel Gay	
3	British Geological Survey	National Environmental Research Council
4	British Red Cross	Chief Medical Advisor
5	Office of Science & Technology	Chief Scientific Advisor
6	Committee on Medical Aspects of Radiation in the Environment (COMARE)	
7	Department of Health	
8	Defence Evaluation & Research Agency (DERA)	CHSEA
9	Faculty of Occupational Medicine of the Royal College of Physicians	
10	Faculty of Public Health Medicine of the Royal College of Physicians	Public Health Environmental Group..
11	Harwell Scientifics	
12	Health & Safety Laboratory Sheffield	Biomedical Sciences Group
13	Hodge Jones Allen, Solicitors	On behalf of some Gulf Veterans
14	Hodge Jones Allen	With Report from Prof. Medical Statistics London School of Hygiene and Tropical Medicine
15	Health & Safety Executive (HSE)	Chief Medical Officer
16	Institute of Naval Medicine	
17	Low Level Radiation Campaign	

18	Low Level Radioactive Measurements SCK-CEN, Belgium	Head of Department
19	Nat Inst Sc & Tech (USA)	Ionising Radiation Division
20	New Cross Hospital Wolverhampton	Radiation Protection Adviser West Midlands)
21	National Radiation Protection BoardB	
22	Open University,	Department of Earth Sciences
23	Royal British Legion	Gulf Veterans' Branch
24	Royal College of General Practitioners	
25	Royal Holloway University of London	Dept of Geology
26	Royal Society	Working Group on Depleted Uranium
27	Scottish Executive	Chief Medical Officer
28	Society of Occupational Medicine	
29	Southampton Oceanography Centre	Geosciences Advisory Unit,
30	Sure Screen Diagnostics	
31	University of Manchester	Department of Medical Genetics
32	University of Middlesex	School of Health, Biological & Environmental Sciences.
33	University of Newcastle	Dept of Environmental and Occupation Medicine
34	University of Sheffield	Centre for Analytical Sciences
35	University of Sunderland	Chief Scientific Adviser to Gulf Veterans' Association
36	US veterans programme	
37	Welsh Assembly	Public Health Division