Mobile PET: What are the Issues?

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Report prepared by:
Dr Wendy Tindale, Honorary Secretary of BNMS
Introduction

This document is an edited transcript of a workshop which took place during the Spring 2003 meeting of the British Nuclear Medicine Society (29th April – 1st May 2003). The workshop was chaired by Dr Derek Pearson and comprised invited presentations from Mr Paul Hinton, Dr Chris Englefield (representing the Environment Agency) and Mr Steve Ebdon-Jackson (representing the Department of Health), followed by a question and answer session. The workshop was taped with the agreement of the speakers, with the intention of providing documented practical advice and guidance to those considering using a mobile clinical PET facility on a hospital site. We hope that this edited transcript meets this aim and provides appropriate guidance at a time when clinical PET is developing rapidly throughout the UK.

Every effort has been made to ensure that the proceedings of the meeting are adequately reflected in this document. Thanks are due to the chairperson, speakers and the members of the audience who contributed to making this a memorable and valuable workshop.

Session 1: Mobile PET Scanning: A User Perspective

Mr Paul Hinton, Royal Surrey County Hospital, Guildford, UK

It is fair to say that everybody working in Nuclear Medicine in the UK now appreciates that PET is clinically useful. A number of reports [1,2] have been published recently that confirm this to the wider medical community.

There are currently two mobile PET facilities in this country, both of which have the GE Advance NXi PET scanner installed. However, before you can scan a patient on one of these mobile PET scanners, you have to undertake a large amount of paperwork. Nuclear Medicine appears to be one of the most heavily regulated area of medicine, with some of the relevant legislation being: The Radioactive Substances Act 1993 [3], The Medicines Act 1968 [4] The Medicines (Administration of Radioactive Substances) Regulations 1978 [5], The Ionising Radiations Regulations [6] and The Ionising Radiation (Medical Exposure) Regulations [7]. These are regulated by various agencies, specifically the Environment Agency, the Medicines Control Agency (now the Medicines and Healthcare Products Regulatory Agency), the Health and Safety Executive and the Department of Health.
The Radioactive Substances Act 1993 requires premises to be registered and authorised for the keeping and disposal of radioactive substances. Even if these exist for a Nuclear Medicine department on a particular site, these will almost certainly not include PET radiopharmaceuticals and therefore a submission to the Environment Agency is likely to be necessary. This will need to include an open source registration for fluorine-18 and an authorisation to dispose of the fluorine-18 waste. The PET service providers will already have the appropriate (mobile) closed source registration. This is required because radioactive rod sources are used to perform the attenuation correction for the PET imaging and to cover a constancy check source for the radionuclide calibrator.

The Medicines (Administration of Radioactive Substances) Regulations 1978 require a site-specific ARSAC certificate. Again, even if there is an existing Nuclear Medicine department on-site, it is unlikely that the local ARSAC holder will already have the appropriate certificate to cover PET imaging. Demonstration of relevant training and experience will be necessary before this can be granted. If needed, the companies will provide a suitably trained clinician, in which case an honorary contract would need to be arranged for this person. As already stated, the ARSAC certificate needs to be site-specific and just completing the section C of the application form, with possibly four different signatures, can be an organisational problem.

If PET scanning is planned at a site with no existing Nuclear Medicine facilities then the Health and Safety Executive will have to be notified of intended use of radioactive materials. This will then require relevant risk assessments, systems of work and local rules to be produced (to try to reduce staff and public doses). If necessary, the companies can provide templates for this documentation. A Radiation Protection Adviser (RPA) must be appointed and they should be appropriately qualified with specific unsealed radioactive materials experience. The private companies will have available the services of a Radiation Protection Adviser, but a local Radiation Protection Adviser should still be appointed. Suitably trained Radiation Protection Supervisors (RPS) must also be appointed.
With regard to the Ionising Radiation (Medical Exposure) Regulations 2000, Employer’s Procedures will need to be in place and these must be approved by the local hospital management where the PET scanning is to be performed. The duty holders (referrers, practitioners and operators) will all need to be identified and arrangements put in place to maintain the list of these.

Once the legislative issues are resolved, on a practical level, you will physically need somewhere to park the trucks. These are around 40 tonnes and so a suitable hard standing with electricity, phone and water supply is required, with reasonable patient access.

A decision needs to be taken locally as to whether to administer the FDG or other radiopharmaceuticals on the hospital site or on the truck. Even if there is a local Nuclear Medicine department, the facilities available for injection and resting of the patient are probably not appropriate for the high-energy photons. This is particularly critical near gamma cameras. Whatever is decided, a dedicated toilet must be made available on-site as neither of the trucks have an on-board toilet (and have been designed that way for the UK). If the patients are to be injected and rested on the trucks they will then have to be taken into the hospital to go to the toilet before being scanned, with all the radiation protection problems that this may involve.

Imaging procedures and protocols should be considered and some discussion should take place about whether to accept the private company’s procedures or to establish local protocols. This will depend on the availability and involvement of the practitioner.

Also required locally will be waste storage facilities. I am not clear how this issue will be resolved, but any solid waste that is generated from procedures on the truck should probably be transferred to the local site from the truck for safe decay storage. Again, there will need to be protocols and procedures in place covering waste disposal and record keeping.

In conclusion, mobile PET is going to be a very important stepping stone for the introduction of routine clinical PET imaging in the UK. It is not a trivial undertaking for a hospital that has an existing Nuclear Medicine department
and is going to be even more difficult for a hospital without Nuclear Medicine, but is probably achievable, with the appropriate co-operation.

Dr Chris Englefield, National Manager: Radioactive Substances Regulation (Non-nuclear)

I am grateful for the opportunity to explain the Environment Agency’s position on mobile PET scanning.

When we were first approached to look into this problem it appeared to be extremely straightforward and didn’t really look as if it was going to take a lot of effort from our perspective. In fact it has transpired to be one of the most complex non-nuclear regulatory issues that we have encountered for quite a time, from the point of view of our legislation, and it has been quite a challenge to address issues of flexibility and proportionality.

What I am going to try and do is explain our approach to the regulation of mobile PET scanning and give a very brief insight into what we see to be the future.

Our policy objectives were based on the fact that it was quite clear from the representations that were made to us that use of mobile PET scanners should be supported because of their clinical benefits. It also became clear subsequently that the environmental impact from this practice is low and that therefore we would aim to regulate with a ‘light touch’. However, we cannot lose sight of the fact that a ‘light touch’ doesn’t mean ‘no touch’ - we would want to take an enforceable risk-based approach.

You will be well aware, of course, that the normal position if you want to use radioactive substances for the purposes of your undertaking on a premises, is that you would apply for registration under the Radioactive Substances Act 1993 with your environment agency (which is Environment Agency in England and Wales, SEPA in Scotland and IPRI in Northern Ireland). There is also a need for authorisation to permit the accumulation and disposal of radioactive wastes. So our normal regulatory approach, which is still available, would be to register the operator of the mobile PET scanner to hold closed sources for
calibration purposes with a section 10 mobile certificate, and to register each hospital to be visited to hold the Fluorine-18 under a section 7 open source certificate – assuming, of course, that those permissions are not already in place. In addition, our normal practice would be to authorise each hospital to be visited to accumulate the solid waste arising and dispose of those wastes after decay, and also to dispose of aqueous wastes to drain under Section 13 of the Act.

As a result of representations made to the Environment Agency we have looked at ways of offering additional flexibility beyond the measures that I have just described, for the purposes of meeting the requirements of the Radioactive Substances Act.

We would be content if an operator of the mobile PET scanning facility chose to take up the option to obtain the traditional Section 10 mobile registration for the calibration sources, as I described before, and to obtain a Section 10 environmental studies registration for the open sources, allowing operation at a number of pre-identified hospital sites. Before such permission is issued, we require the applicant to assess the environmental impact of the study to be undertaken. As long as this is satisfactory, and the practice continues within the defined parameters, then no further assessment is required.

We would also be content to issue the PET operator with authorisation under Section 13 of the Act to dispose of the wastes arising (unused materials, sharps etc) by transfer to each hospital which is visited. That particular arrangement allows for the option of the operator being the only authorised entity, so there would not be a requirement for the hospital in those circumstances to hold an authorisation solely for the purposes of mobile PET scanning.

We have tested these ideas on a variety of interested parties, including a number of RPA’s around the country, and we have specifically consulted the following regulators: HSE, SEPA, IPRI [Northern Ireland], DoH, and DfT (Radioactive Materials Transport Division). As far as I am aware, from the point of view of what we are proposing for regulation under the Radioactive Substances Act, there are no outstanding issues.
What this means in terms of implementation is an issue more for the operators of the equipment than for hospitals - at least those which do not have existing permissions under the Radioactive Substances Act. Application would be made by the operator using the forms RSA2 (Mobile Closed Sources), RSA2 (Environmental Studies) and RSA3. We have drafted bespoke template certificates (S10M, S10E (mobPET) and S13 (mobPET)) to enable a consistent and straightforward approach to the delivery of the regulatory instruments to the applicants in these cases. What we do require is that in the application the PET operator declares all the hospitals that are likely to be visited so they can be listed on the certificate. We have arrangements in place which would allow additional hospitals to be added to that list, at fairly short notice. As long as the requirements of application for registration for the environmental studies certificate are met, it should be a straightforward process to add further hospitals to the list.

The information I have provided has been promulgated within the Environment Agency and there is support available to our inspectors in the field. We would hope, therefore, that should operators choose to take up this approach, it should run smoothly. As far as the future is concerned, if this alternative approach is taken up, from our perspective it relies on good co-operation between the mobile PET operator and the hospitals visited. Perhaps that is especially the case where the hospital may not have any existing permissions under RSA93, because they do not have an existing Nuclear Medicine department. It relies also on the maintenance of best practice where, if you like, the regulatory arrangements are reduced compared to what would be in place traditionally. This is appropriate because of the low level of environmental risk. Environment Agency will be especially interested in ensuring standards of good practice are being maintained.

It is worth mentioning here that use of our 'alternative approach' for Mobile PETs does not impact on a hospital's use of the Hospitals Exemption Order. The Exemption Order [8] states that exemption from registration does not apply where a registration under section 7 is in force in respect of the premises, and that exemption from authorisation does not apply where an authorisation under section
13(1) is in force in respect of the premises. The certificates issued to the mobile PET operator specify the hospitals where the mobile PET may be used and could, therefore, be construed as permissions in force in respect of those hospital premises. However, the registration is issued under section 10, and the authorisation under section 13(2), so the Exemption Order can still be used. If the hospital wanted to hold their own registration/authorisation for the mobile PET work, they would, of course, then have to be registered/authorised for all radioactive work.

As a regulator I have to reserve the right to say that if we find this does not work we would have to find another way of addressing this problem. We have tried to come up with an alternative to the traditional approach which would allow greater flexibility in terms of reducing the costs to hospitals being visited, reducing the administrative burdens on the hospitals being visited, and which would allow the operators of the equipment additional flexibility, beyond that which would be in place, for example, if they had to wait four months for every application that they made for a new hospital which they wanted to add to their list. This demonstrates that the Agency is basing its regulatory position on environmental risk.

Mr Steve Ebdon-Jackson, Radiation Protection (Medical), Public Health Directorate, Department of Health

The talks you have had so far demonstrate a couple of important points. First of all, that the Regulations should not in any way stop mobile PET services as long as we are all being sensible and reasonable, and secondly, that whatever the systems that come into place happen to be, in the end we must have something that complies with the Regulatory requirement.

The Agencies that are key in this are: The Environment Agency, The Health and Safety Executive and the Department of Health. We have already heard from the Environment Agency and it is good to see the flexible approach being shown. From the HSE’s point of view, clearly IRR99 [6] is relevant and notification of specified work may be required – but for detailed advice you should contact HSE.
So what is the DoH position? The Department of Health is obviously interested in the MARS Regulations [5] and IR(ME)R [7]. Of course there is some interaction between these Regulations and that might give us problems in terms of concept and practicalities.

In simple terms, for the MARS regulations we are talking about the ARSAC certificate - and there we are looking, in part A, for training and experience around PET use, we are looking for a purpose - whether it is diagnostic or research - and clearly we are interested in the staff facilities and equipment involved. With mobile PET the latter might be somewhat different to normal. In part C of the ARSAC application form the supply of radiopharmaceuticals needs also to be registered and, again, that might be different to normal (it might be different for each hospital even using the same PET service supplier as time goes on).

Under IR(ME)R we are looking at key responsibilities of duty holders. We look at the employer, who is responsible for written procedures and protocols, and the entitlement of duty holders and their scope of work. We also look at issues around practitioners and operators, and one of the things I want to major on here is that under the Ionising Radiation Regulations and under IR(ME)R we have minor differences in terms of who is defined as the employer. It is important to demonstrate in your own mind who is the employer (under RSA93 [3], under IRR99, under MARS and under IR(ME)R) - because if you can’t work out who the employer is, you will never work out where the responsibilities rest and therefore you will never work out who is supposed to do what. If we look at IRR99 the definition of the radiation employer is: **an employer who in the course of a trade, business or other undertaking carries out work with ionising radiation.**

Under IR(ME)R the definition of an employer is

*Any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee) or engages others to carry out, medical exposures or practical aspects, at a given radiological installation*
The definition of employer under IR(ME)R concerns the person who engages others to carry out, as well as themself, medical exposures or practical aspects at a given radiological installation and here you can see straight away why there are some issues around mobile PET - how do you decide what the installation is, as well as who the employer is. The term ‘employer’ under IR(ME)R is not the same as that used in conventional employment law. Thus if the staff on the mobile are employed by a company you contract to, under IR(ME)R that company may not be the employer. The Trust is the employer of operators and practitioners involved in undertaking medical exposures on the Trust site - so even though the external supplier of the service may employ people under employment law, they may not be the employer under IR(ME)R.

Under MARS, the ARSAC certificate is individual and site-specific and under IR(ME)R the Trust entitles individuals to act as its practitioners and operators, bearing in mind that the Trust is the employer. The Trust provides the written procedures and protocols under IR(ME)R, under which practitioners and operators work.

The IR(ME)R duty holders can be identified as follows:

- Person justifying procedure is the practitioner
- Person authorising procedure is an operator
- Persons preparing, injecting and scanning are operators
- Person interpreting the image is an operator

So what are the implications for mobile PET services under IR(ME)R? The Trust is the employer of operators and practitioners provided by the third party acting on the Trust site. The third party is the employer under the employment law - don’t get them mixed up. This is stated in IR(ME)R guidance which is available on the web.

I think each Trust that takes a mobile PET service will require some sort of ‘patch’ in its written procedures which will include entitlement of staff as operators and practitioners (who may be employed by a third party) and the scope of their entitlement (which will need to be specified - are they allowed to be operators in terms of image interpretation, for instance, or is it just the scanning, is it the injections? etc). The written protocols for the PET procedures will have to be provided by the Trust because the Trust is the employer. What
this means is that the Trust has to ensure that they are in place (that is what the Regulations state) - it does not necessarily mean that the Trust has to write them – you can see there is a difference between the Trust ensuring that procedures are there and adopting them as its own and writing them explicitly. So, it is important to have a very well specified contact between the Trust and the service provider to make this work. You need to decide and be clear about:

- who will be the practitioner? – is this someone on the site or is it somebody remote (be aware that the practitioner will have to understand PET and all the implications of PET, including overall justification of the procedure not just the image interpretation).
- who will be the person who authorises? – this is particularly relevant if the practitioner is off-site. Will the person who authorises the individual exposure be employed by the Trust under IR(ME)R or under employment law?
- Who will be the operator who interprets the image? - is it someone on your own site i.e. somebody on your own staff (where you are the employer under IR(ME)R as well as under employment law) or is it someone remote who indeed will be under your jurisdiction under IR(ME)R even if they are employed by somebody else?
- Will these duty holders change with time? The contract needs to be considered to be a flexible and evolving contract because over time you may wish, for instance, for the person who interprets the image, who will be an operator throughout under IR(ME)R, to change from someone who is not your employee under employment law to someone who is.

In summary, if you get the terminology sorted out in your mind in the beginning and make sure that you have got it established for each of the sets of legislation and accept that it may have to be different in each case, then it really is relatively simple.

Finally a piece of advice: If I were an employer under IR(ME)R I would be looking for a supplier who could provide a ready made ‘patch’ that tells me exactly what I have to do, so I just have to add that into my written procedures covering entitlement and written protocols. I would want it to fit the service that
I want to provide, in conjunction with them, and I would want to ensure that that contract could evolve in time with agreement from both parties.

**Q (Peter Julyan, Christie Hospital)**

A question for Paul Hinton. What is your impression of the impact that a mobile service has on the hospital department? Although we expected minimal impact, it was quite substantial in terms of the department sending letters, answering queries and the general day to day things you do in order to scan patients.

**A (Paul Hinton)**

It was a bit of a nightmare. After the scanners were commissioned at Guildford, there was pressure from various quarters to put some patients through. A lot of time was then spent running around, trying to arrange ARSAC cover, faxing requests for authorisation and producing all the other paperwork required. It was very labour intensive – but we were at the very bottom of learning curve. As everyone gets more experienced with mobile PET the process of getting patients through the system will get a lot slicker and obviously the set-up only needs to be done once.

**Comment from Steve Ebdon-Jackson:**

I think this demonstrates that PET is not a service you just add on to your services as an extra. PET, however it is conducted, whether mobile for few session or with a permanent installation, is a real commitment in every sense of the word, both in terms of staff and systems that you need in place. If you know that is the case and get things planned in advance, it is fine. The problem comes when people add it on as just another modality. A full PET system requires people reporting and running the system. We are not going to have our current radiologist doing half an hour of PET - we need to do it properly. The same applies to mobile PET: plan it thoroughly, get the systems in place, even if it is only one session a week. The clued-up people know what this means and experience will travel quickly - so don’t feel bad about contacting someone who has already done it and seeing what it really meant. Get prepared and it is relatively straightforward.
Comment from Ralph Clauss, Royal Surrey County Hospital:

A few points on the running of the service: if the preparation is done it runs smoothly. We had experience with six patients with the mobile trucks. A week before, we allocated times and put in place a system of getting patients from the injection area to the truck. The planning was essential - if it had not been done properly it would have been chaos.

Comment from Andrew Shaw, Operations Director for Alliance Medical for mobile PET

I am concerned about nightmare scenario that has been discussed in relation to providing mobile PET. It is not an easy concept, but we have provided two mobile services visiting sites on a regular basis - one site on two occasions scanned seven patients in a day. There are logistical issues - but they can be solved – and you can provide a mobile service where you do a reasonable number of patients in a day and obtain excellent image quality. As long as you have people who can help you get through the process and the issues you have to deal with, then that's the important aspect. It can be done and is being done already.

Q. (Nick Archer, Glan Clwyd Hospital, North Wales)

Can you clarify who would be acceptable to undertake the process of justification?

A.(Steve Ebdon-Jackson)

The person who justifies is the person who is entitled to be the practitioner for this purpose by the employer, and they need to demonstrate that person is adequately trained. This could be someone from the Trust who is employed by the Trust, or it could be someone external if you wish. This person would need an ARSAC certificate for the site where the PET scanning is being undertaken. The ‘patch’ would be that the employer would say ‘This person, whom I don’t formally employ, becomes entitled to act as a practitioner on my behalf’. It really depends on your local knowledge of PET, and whether you can demonstrate that, or whether you want to use someone external. The Regulations are flexible enough to use either system, but what is important is that whoever is your practitioner needs to be able to demonstrate that they are adequately trained.
Can I again reassure you, we have seen prompt response from the Environment Agency and I think we’re also winning the mobile PET situation from the ARSAC and IR(ME)R point of view. When people have ‘phoned the Department of Health we have been able to respond promptly - but don’t leave it till the day before please. Let us know a little bit in advance and we can talk some of these problems through with you. The Regulations do not block as long as you accept what they require and make the appropriate arrangements.

Q. (Derek Pearson, Nottingham City Hospital)
The IR(ME)R employment issues are presumably the same whether there is a managed service in a building on your site or if there is a mobile van coming in.

A. (Steve Ebdon-Jackson)
Effectively I think we expect once managed sites are fixed static services that the decision about who is going to be the practitioner - whether external or someone you employ yourself - will go away. This is because once you have made the commitment to a static service you are likely to be in a position where you will negotiate with your own radiologist to become trained and take on the role of practitioner (and operator for reporting). If this does not happen immediately I expect it will happen with time. I think the issues are slightly different in the two situations - clearly the commitment to get someone trained in PET if you are only going to have one session a week on a mobile service is less than one would expect with a static service. So the arrangement for the legal situation allows the transition - it allows for either methodology for the service provision and it allows flexibility – it is up to you to specify. You may need to have a contract which changes and you may have to be willing to change your procedures as time goes on to reflect who is doing what and what their experience is.

Q. (Marge Rose, Christie Hospital)
Can I just be clear about this - when you say site-specific you mean an ARSAC certificate holder who is going to do the justification for a mobile unit. They would have to get site-specific licence for each site – it’s not the mobile?
A. (Steve Ebdon-Jackson)

It would be linked to the hospital. If we look as case law from other things that are nothing to do with ionising radiation, there are issues about what constitutes a premise. We have looked at this in the past with things like breast screening programmes and caravans and fuel tankers and so on - all go into this general pot about what constitutes a premise. Interestingly enough, neither the MARS Regulations nor the IR(ME)R Regulations use the term ‘premise’ so whether any of this case law is applicable is difficult to say, but the easiest thing to say is that we will grant you an ARSAC certificate for someone associated with the hospital at which this undertaking is happening. In fact, it doesn’t have to be a hospital - it needs to be an installation where there are appropriate facilities and appropriate staff. Because the certificate is site-specific we would expect, for instance, that if you have an external practitioner to your hospital that you would have some sort of honorary contract between that hospital and the person who is going to be the practitioner (otherwise they cannot really be entitled to be a practitioner by the Trust as an employer). No money needs to change hands, unless you want it to. This type of arrangement is very common in certain parts of the country, less so in other areas. The precedent is there for people to have ARSAC certificates on a number of sites where there is no legal employment law connection between the site and that individual (apart from an honorary contract of some description). Basically it comes back to whose patients are these - are they patients of the Trust? If so, under civil action the Trust is going to be liable for anything that happens associated with that patient. The Trust, sensibly, will want to embrace the individual who is making clinical decisions about those patients within its remit in terms of its civil liability. I would like to suggest that any doctor or operator who is going to offer those services will also want to be very clear in their own mind that they are linked back to the Trust, should civil action ever be necessary, and be very clear who is taking responsibility and liability for these patients. But it all can be done very early – it is not a problem as long as you think about it and plan it in advance.

Q (Peter Julyan, Christie Hospital)

In terms of the specific part of the ARSAC application form (Part C): is the person signing to indicate they can vouch that the scanner is calibrated, and if that is signed by the local Medical Physics staff, how does this operate?
A (Steve Ebdon-Jackson)

I think before you can answer the question you have to define what the service is and who is providing the various elements of the service and from then on it falls out fairly clearly. It is no different for PET than for any other mobile service that may already have come to your site, except there is a Nuclear Medicine issue you might argue that does not apply for mobile angiography or mobile CT. But many of you will have gone through this already with a mobile CT scanner - defining who is responsible for the issues around the provision of a CT scanner that is properly calibrated.

Q (Peter Julyan, Christie Hospital)

Do you think it may be appropriate for the third party to sign that part of the ARSAC application form?

A (Steve Ebdon-Jackson)

It could well be, if that is the way you formulate the contract, but bear in mind what people are signing for on the ARSAC form. It is likely that in the next revision of the ARSAC Notes for Guidance there will be clearer guidance about what the responsibilities of those individual signatories are. Things such as where the isotopes are delivered to (are they delivered to the mobile itself or delivered to the hospital), which you will need to sort out with the Environment Agency, will dictate that different people will sign on the ARSAC form for various sections of it. Similarly for the RPA - what are they signing for? There are sections under the HSE legislation about co-operation between RPAs. You really need to define initially how your system is going to work and then largely these things will fall out. If you have any concerns, 'phone us up. That goes for the Environment Agency as well as ourselves because we will solve this problem for your specific site. It is evolving and I think as long as I am confident that the right things are being put together and links are being made then if we don't get it the same for two sites because things have evolved I am not too concerned. The important thing is that safety has been ensured for all those parties that have a right to the safety being ensured. It might change, but if you have any doubts, 'phone us up and talk it through and after a while it will become more natural and maybe we can produce not exactly definitive guidance but a clearer set of guidelines. I must emphasise that many of these problems have
been sorted out, certainly around IR(ME)R and certainly around provision of services and contracts with mobile CT or mobile MR, in terms of who provides what and who is responsible.

Q. (Derek Pearson, Nottingham City Hospital – Chairperson)

Would either of the other two speakers like to make any final comments?

A. (Paul Hinton)

I would like to make a final point about justification. Hopefully some referral guidelines for PET images will be coming out soon from Guy’s and St Thomas’ Hospital. The ARSAC certificate holder can delegate the authorisation process to the local centre based on the referral guidelines.

A. (Chris Englefield)

We see this, as I have already said, as a low risk practice from the point of view of the environment, but that does not mean we withdraw all our Regulatory involvement. We have a duty to enforce the Radioactive Substances Act. So, if something does go wrong - even if it is low risk and the impact may be low - in the worst case scenario we need to be clear who we are going to take enforcement action against. I don’t suppose for one moment, with a professional organisation with the expertise that this Society represents, that that is going to be a frequent occurrence by any means. But if you want to understand where the Inspector is coming from, he has to get that clear. Once he’s got that clear, everything else should be straightforward. Like any regulator, we need to understand “who is in charge”, so this will be a key issue for us in considering applications for mobile PET. I hope this helps.

References

3. Radioactive Substances Act 1993
   London, HMSO
4. Medicines Act 1968
   London, HMSO

5. Medicines (Administration of Radioactive Substances) Regulations 1978
   (SI 1978 No1006) London, HMSO

6. Ionising Radiations Regulations1999 (SI 1999 No 3232)
   London, HMSO


9. NHS Estates Health Building Note. Facilities for Diagnostic Imaging and Interventional Radiology Section 14. Mobile vehicle scanning units to include CT/MRI and PET.


List of acronyms

ARSAC Administration of Radioactive Substances Advisory Committee
DfT Department for Transport
DoH Department of Health
FDG Fluorodeoxyglucose
HSE Health and Safety Executive
IPRI Industrial Pollution and Radiochemical Inspectorate
IR(ME)R Ionising Radiation (Medical Exposure) Regulations 2000
IRR99 Ionising Radiations Regulations 1999
MARS Medicines (Administration of Radioactive Substances) Regulations 1978
PET Positron Emission Tomography
RPA Radiation Protection Adviser
RPS Radiation Protection Supervisor
RSA93 Radioactive Substances Act 1993
SEPA Scottish Environment Protection Agency