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FOREWORD

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The so called 'medico-legal procedures' were introduced in the European legislation with the adoption in 1997 of Council Directive 97/43/Euratom *on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure* (Medical Exposure Directive, MED). According to MED, the exposure due to medico-legal procedures, defined as "those procedures performed for insurance or legal purposes without a medical indication", is a sub-category of medical exposure; therefore radiation protection in this area is arranged under the common legal framework for protection of patients and individuals participating in health screening, occupational health surveillance or biomedical research programmes.

The difficulties in implementing MED's legal requirements were recognized soon after the Directive was adopted. Therefore, in 2002 the European Commission organized an International Symposium with the objective to discuss the various practices involving medico-legal procedures and to look at ways of addressing the associated radiation protection issues. The proceedings of this meeting, including the main discussion points and conclusions, were published by the Commission in 2003 as "Radiation Protection 130, Medico-legal exposures, exposures with ionising radiation without medical indication".

The 2002 symposium identified a number of issues in different areas; most importantly, it recognized that the MED framework failed to address all existing cases of deliberately exposing humans to ionising radiation without medical indications. It was also concluded that the MED protection philosophy, primarily intended for medical patients, can not always be successfully applied to practices driven by legal, security and other non-medical considerations. All this has lead to the conclusion that the issues in this area could not be resolved by guidance or other 'soft tools' while the legal framework remained unchanged.

In 2005, with support of the Group of Experts established under Article 31 of the Euratom treaty, the Commission launched a major revision of the Euratom radiation protection legislation including, among others, the European Basic Safety Standards (EU BSS) and the Medical Exposure Directives. This opportunity was used to propose also changes in the protection framework for the deliberate exposure of people without medical indication or motivation, now more appropriately named 'non-medical imaging exposures' (NMIE). The draft proposal was worked out by the Commission staff together with experts from the Article 31 group. The authors of the proposal were also familiar with the ongoing revision process of the International Basic Safety Standards.

The imaging technology utilizing ionising radiation has advanced rapidly, allowing more people to be scanned faster and cheaper, not only for medical reasons but also for security, immigration control and law enforcement purposes. The societal concerns in those areas were also growing. This changing environment could lead to a situation where the wide-spread use of ionising radiation on humans for non-medical reasons would be more easily accepted.

Therefore the Commission decided to call another international meeting in 2009 to review the development of the situation in the non-medical imaging area and to discuss with stakeholders the newly developed draft EU BSS provisions on those practices. The meeting

brought together a wide range of experts from very different disciplines, ranging from ethics and philosophy, through sport and forensic medicine, to security and law-enforcement. International organizations, most notably the International Atomic Energy Agency, made major contributions to the meeting. This allowed on the one hand to review the developments and to discuss the legal and regulatory framework within which the NMIE procedures should be implemented, on the other hand to provide discussion material and conclusions which can serve as a basis for future guidance in the area.

These proceedings of the meeting are published at a time when the revised EU BSS is still in draft (http://ec.europa.eu/energy/nuclear/radiation_protection/radiation_protection_en.htm). It has been approved by the Euratom Article 31 group but has not yet become an official Commission proposal. The draft responds to some of the conclusions in the document. The Commission will continue to monitor the developments in the area of non-medical imaging exposure and if appropriate take further initiatives.

Augustin Janssens
Head of Radiation Protection Unit

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Session 1 - Scene Setting

1 EUROPEAN COMMISSION'S EXPECTATIONS FROM THE INTERNATIONAL SYMPOSIUM ON NON-MEDICAL IMAGING EXPOSURES

Augustin Janssens

Radiation Protection Unit, Directorate-General for Energy, European Commission

Radiation Protection is protection against exposure to ionizing radiation. Protection includes the means to reduce exposures, by shielding or distance for instance, but also, and in the first place, avoid the exposure to occur. The principle of justification means that all unnecessary exposures should be avoided. The subject matter of this Symposium is however concerned with the deliberate exposure of individuals for imaging purposes. This is meant, in general, to be justified for medical applications, even though the Conference on Justification, 2 – 4 September in Brussels, has clearly demonstrated that there is a need for better implementation of this principle. I expect that our Symposium will clarify whether, and when, other uses of X-ray imaging are justified.

The justification of non-medical imaging exposures will be looked at in the context of a technological revolution in digital imaging, which has led to an amazing quality of the pictures. This technology ranges from the backscatter technique at very low doses to computerized tomography (CT) at rather high doses.

The Basic Safety Standards Directive prohibits frivolous uses of ionizing radiation, such as the deliberate addition of radioactive substances to toys or personal ornaments. This made me think of so-called "X-ray spectacles", with no other purpose than voyeurism. Such glasses featured in cartoons when I was a child, and aroused my curiosity and fantasy. Just yesterday I did a Google-search and to my surprise they still are on sale, under brand names such as "X-reflect" glasses or video cameras. Fortunately, it turns out that despite references to X-rays, these devises use visible light. If X-rays would actually have been used, this would certainly qualify as a frivolous application that would be forbidden.

Excuse me for this discursion, more seriously now: justification implies that the exposure is to the benefit of the individual, or at least, to the clear benefit of society.

The assessment of societal benefit, of what is "good" for society, implies ethical or moralistic considerations. The radiation protection philosophy of course already includes, at least implicitly, ethical or value judgements. When we discuss non-medical exposures in the context of law enforcement or security, the ethics or moral values underlying such applications are beyond the radiation protection remit. It is a matter of political values or preferences, on which people tend to have different or opposing views, which in our European societies are resolved by democratic ruling. This may not be the case in the whole world however, and even in a democracy the scientist, engineer or regulator has a responsibility for the applications he introduces or allows to exist.

I am worried not only about the justification of such practices, but also about the fact that these may escape regulatory control. Also in medical applications the role of the regulator is limited, and we rely above all on requirements for education and training in radiation protection and on professional guidance.

I am worried that such education and training, or even awareness, may not exist for instance for security screening. In addition, many people would view the police or intelligence services to be above the law. Indeed, in the areas under their responsibility there are limitations on the rights of the individual, for instance with regard to privacy. Law enforcement implies a balancing of risks. In the case of X-ray imaging, this implies balancing the adverse health effects of exposure to ionizing radiation against other risks.

I fear that, without proper oversight from a radiation protection point of view, X-ray imaging may become commonplace. Users may be found to ignore radiation protection requirements, or the risk to the exposed individual, there may be a proliferation of such equipment, and hence a person may become subject to multiple exposures in a year. These may not only be low doses, high doses from CT-type of devices or transmission scanning, such as used already now to screen trucks and trains for illegal immigration, may become commonplace as well.

The topic of this Symposium is therefore very important. It affects the foundations of the radiation protection philosophy, and it represents a difficult regulatory challenge to fit these exposures into the three categories: occupational, medical and public exposures. There will be no 4^{th} category for security exposure or a 5^{th} category e.g. for the comforters and carers in medical exposure. With the revision of the Basic Safety Standards, we now regard non-medical exposures clearly as public exposure. The old term "medico-legal" should be avoided.

So it is public exposure, but the dose limit can be exceeded in exceptional cases. It is difficult to define a reference group of the population. Since it is not possible to control the number of exposures we must rely on dose constraints rather than dose limits.

We operate at the boundary of the scope of radiation protection. The basic rule is that justification overrules exemption. No practice that is not justified shall be exempted from regulatory control. But does this apply to very low dose applications? Should we balance the risks of backscatter imaging against techniques using electromagnetic radiation or ultrasound?

This Symposium is at the right time. It will provide input to the revision of our Euratom Basic Safety Standards as well as to the international standards. The final drafts of these should be completed by the end of this year, but will go through a possibly long endorsement process. G. Simeonov will present the ongoing work for the Euratom Standards, R. Czarwinski for the international standards.

We have been discussing this topic internationally even before we started reviewing the Basic Safety Standards, for instance in the framework of the International Agency Committee on Radiation Safety (IACRS). We are now getting close to some consensus, or rather a compromise. ILO and PAHO for instance have outspoken views respectively on X-ray imaging for theft detection and for security screening.

I appreciate that this Symposium takes place in Dublin, and is a follow-up to the first Dublin Conference in 2002. I am grateful to G. O'Reilly for the efforts that she put in organising this event, and I am very pleased that C. Zuur is here to explain the long intellectual journey that we have made since this first conference.

That first conference highlighted the need for a more precise definition of "medico-legal" exposures, and broadened the scope beyond the exposures for insurance of legal purposes. It was also underlined that there was a need for guidance in the different areas. This is why this second conference addresses not only security and crime prevention, but also sports and occupational medicine, age-determination of adolescents, immigration health checks etc., where the borderline with medical exposure is rather thin.

The proceedings of the Symposium will be in the European Commission Radiation Protection series. I hope this will be another milestone in the development of our thinking and a reference for the development of national policies.

2 NON-MEDICAL IMAGING EXPOSURES – REVIEW OF PREVIOUS WORK

Ciska Zuur

Formerly Ministry of Housing, Spatial Planning and Environment, the Netherlands

Geraldine O'Reilly

Department of Medical Physics and Bioengineering, St.James's Hospital, Dublin, Ireland

2.1 Introduction

The Medical Exposure Directive (MED)[1], 97/43/Euratom, defines medico-legal procedures as 'procedures performed for insurance or legal purposes without a medical indication'. When the Directive was first drafted, it was envisaged that medico-legal procedures would comprise x rays for insurance purposes and those required as a result of legal proceedings. Whereas, in fact, the definition of medico-legal procedures is such that the scope is almost certainly wider than this.

The European Commission is currently in the process of revising the European Basic Safety Standards[2]. As part of this exercise a number of European Directives dealing with radiation safety and protection will be recast into a single Directive. This will include the Medical Exposure Directive. The revision will provide an opportunity to address issues that have arisen since the introduction of the MED in 1997. One of the issues to be addressed is that of medico legal Exposures which have been redefined and will in future be known as non-medical imaging exposures.

2.2 What are Medico Legal Exposures?

Medico-legal exposures are defined as 'procedures performed for insurance or legal purposes without a medical indication'. This can lead to a degree of ambiguity when discussing medico-legal exposures and exposures which have a medical indication. Often the latter are referred to simply as medical exposures – a term that is clearly imprecise within the context of the Directive as medico-legal exposures are in fact a sub-set of medical exposures.

Medico-legal exposures are difficult to define and it is not always easy to decide which exposures are real 'medico-legal' and which are not. Often certain exposures could be interpreted as being occupational or medically indicated. The definition contained within the Directive is not sufficient to solve this problem. Some examples may help to illustrate some of the difficulties that arise.

2.3 Examples of Medico Legal Exposures

2.3.1 Age Determination

An x-ray of the wrist of an individual who presents with symptoms of a recently fractured wrist has a clear medical indication, is supported by existing referral criteria and would be the norm in clinical practice. This is clearly a justifiable exposure.

However, an x-ray of the wrist for the purpose of age determination is almost certainly a medico-legal examination. Other radiological techniques, used for age determination, based on the evaluation of bone maturity include x-rays of the elbow, iliac crest, AP view of the hand and wrist or CT of the clavicle.[3] The accuracy is of the order of 6 months to 1 year, resulting in a possible error in evaluation of age by as much as two years.

Other methods of age determination include a simple height measurement which is a rather imprecise first approach. Dental radiography can also be used. However it has been reported that the use of dental radiography can lead to errors of between 9 months and 3 years, particularly when used for individuals between the ages of 16 and 21.

Age assessment is sometimes required, for example, to determine if an individual should be assigned to a juvenile or an adult court. In this instance it is clear that the result of the assessment could have very material and significant consequences for the exposed individual. This would suggest that the technique should be robust and accurate, whereas in fact there are unresolved issues surrounding the validity and accuracy of the technique, particularly in relation to the selection of appropriate reference groups for comparison. So although most of the techniques outlined above are considered to be relatively low dose techniques, the justification is complex as instead of the normal risk benefit ratio, the individual exposed may be disadvantaged by the consequences of the exposure.

If the age determination is required in the case of someone seeking asylum, some Member States will grant asylum to those under 16 years, so the age assessment can be critical where age is unknown or in doubt.

Another application in which age assessment is required is that of placement of a child in care. It is important for a child's psychological development and well being that they are treated in a way that is appropriate to their age. For this, accurate age assessment is required.

So, it is clear from consideration of the examples above that radiological examinations used for age determination are not medically indicated exposures and should not be classified as medical exposures. They fall into the category of non-medical imaging exposures. Although there may be compelling reasons for determination of age, serious concerns remain about the accuracy of the methods that are currently in use. With this level of doubt surrounding their accuracy, extreme caution is required in their use and they are likely only to be suitable for a limited range of applications and across a limited age range.

2.3.2 Sports Medicine

Imaging in sports medicine can be for acute or chronic overuse injuries or for screening purposes. Imaging for acute sports injuries is, on the whole, medically justified. With chronic overuse injuries, the need for imaging may either be for diagnosis or prognosis. While the former is clearly a medical exposure, the latter may have financial implications and the

motivation to perform such imaging may not be for medical care. Such imaging falls into a grey area which may involve non-medical exposures.

Imaging is also used to aid selection for competition, to support decisions on training and nutrition and as a preventative tool. Imaging is also used for screening purposes in certain contact sports as a precautionary tool to rule out certain conditions which if present would lead to heightened risk for the individual involved.

Imaging for screening purposes is also used where x-rays are requested without any specific clinical indication, for example, to assess an individuals potential before a transfer or appointment, as part of professional or contractual obligations or, with young persons, to assess their potential future growth. Each of these examples should be treated as a separate type of practice requiring explicit justification.

2.3.3 Non Accidental Injury (NAI)

In the setting of possible child abuse, x-ray, may be used to diagnose acute injuries that may need treatment but also older injuries no longer requiring treatment. The x-rays can be used to support the diagnosis of abuse. For those injuries that are acute, the initial x-ray can be considered to be medical and justifiable. For older injuries, the classification is less clear and open to interpretation. For those x-rays that are required for legal proceedings or as part of an investigation, then they are most probably medico-legal exposures but could be considered to be justifiable. And finally, x-rays of asymptomatic siblings are likely to be medico legal but again could be considered to be justifiable. It is clear that in this particular example of NAI, the classification is not straightforward and there are a number of issues that should be considered as part of the justification process.

2.3.4 Growth Prognosis

There are numerous other examples for which the classification is unclear. X-rays can be used in the prognosis of growth for individuals such as dancers where height may be an issue. In this situation it is not clear what classification should apply to these exposure types or whether the use in this situation is justifiable.

2.3.5 Criminal Activities

Other uses include the use of x-rays to combat criminal activities through the detection of weapons or drugs. X-ray equipment based on the use of backscatter techniques can be used in the surveillance of passengers prior to air travel. Given that there is certainly no medical indication for the scan, these exposures must be classified as non-medical. The justification will be influenced by how the scanners are intended to be used. If they are only to be used on those who are suspected of attempting to smuggle weapons on board, then the case for justification might be strengthened. If the scanners are to be used on all passengers then a number of considerations will arise. These will include those relating to dose, privacy issues and general ethical considerations. It is clear that whatever the intended use, the justification process will be challenging and will demand input from a number of parties. Similar considerations will apply in relation to the use of scanners in prisons.

X-ray examination is also used when there is a suspicion that drugs have been concealed within the body. While the norm for this type of exposure would be a general x-ray, some countries use computed tomography[4], resulting in a potential dose of the order of

milliSieverts. Because this is carried out as if it was a medical exposure, a dose limit is not applied, whereas if this were considered to be a public exposure, then a dose limit of 1 mSv would apply. It has been argued on occasion that the detection of drugs within the body is potentially advantageous to the individual exposed as the consequences of the packages rupturing within the body are severe. However, it is questionable whether this argument is a valid one as the primary motivation for the exposure is unlikely to be related to the health of the individual being exposed. In this case, a number of issues arise but it is clear that the justification of both the practice and individual exposures must take into account a broad range of technical and societal considerations. It is not clear that the current framework within which medico-legal exposures such as this take place, is appropriate for such complex issues.

2.3.6 Cargo Search

Scanning techniques are also used for the detection of attempted clandestine entry via deep concealment in vehicles. Whereas there is clear agreement that the use of scanning to detect trafficking of illegal goods or substances is an industrial exposure and is covered by the Basic Safety Standards (BSS), there is not universal agreement on its use to detect clandestine entry. Some would consider this to be covered by the MED under the category of medico-legal exposures and others would feel that the MED does not apply and only the BSS is relevant here[5]. This remains as an issue to be resolved. Therefore the classification is unclear and clarification on this issue would be an important first step in considering the justification of these exposures. It has been observed that the detection of individuals hidden in containers may in fact save their lives and that this should be considered as part of the justification. This would have to be considered in the context of the motivation for the exposure which is unlikely to be linked to the safety of persons who might be hidden.

2.4 Conclusions from Earlier Work

The various examples cited above demonstrate the complexity of both the classification of exposure types and the justification process. Previous work has identified a range of exposures that might be termed medico-legal and initiated a debate on whether or not they were in fact medico-legal. It was concluded that although it was possible in many instances to classify or categorise the exposure, the justification remained difficult. It was recognised that the justification process had to take account of a broad range of considerations with a wide array of social and economic issues that are integral to this matter. In fact it can be seen that the key issue in medico-legal exposures is justification. There may be cases where there is a strong public health, legal or security/safety reason which may dictate that the exposure should go ahead even without consent. This must be decided by a legally entitled authority. Where the decision to proceed resides with individuals, then very clear guidance on selection criteria is required.

Some of the key issues that emerged from previous work can be summarised as follows:

2.4.1 Prescriber

All individual exposures should be justified by both prescriber and practitioner. What can happen in practice is that a medical doctor can be asked for advice from a judge, an employer, an insurance company or others. Depending on the nature of the request, it may be that in order to properly respond, an x-ray is required. However, the net result of this

interaction can be that the judge or the individual requesting the information in effect becomes the prescriber. So legally, the doctor is still the prescriber but in practice, it may be another individual or entity. This is an undesirable situation and one that should be avoided.

2.4.2 Multidisciplinary Issues

In considering the justification of non-medical exposures it is clear that input will be required from sources that extend beyond the established radiation protection and radiological community. Balancing the advantages and disadvantages of such exposures is complex, because not only can these be difficult to quantify and hence compare, but often the advantage may be to society whereas the disadvantage is usually to an individual. This adds an additional layer of complexity to the problem and one, which requires input from a number of sources beyond the established radiation protection community. Those that might be included in the justification process will vary depending on the practice under consideration but might include public health experts, law enforcement agencies, immigration authorities, customs, Occupational Health, the judiciary etc. Communication between a diverse range of professions and disciplines is essential to develop understanding and improve practice.

2.4.3 Referral Criteria

The proliferation of imaging equipment has meant that access to specialist imaging techniques is not necessarily restricted to medical use. Ease of access can in certain circumstances remove one of the obstacles that often focuses attention on justification. For this and other reasons, the establishment of selection or referral criteria for all practices involving non-medical exposures is of critical importance. The fact that the risk/benefit ratio is severely altered in non-medical exposure means that existing selection criteria can not be automatically used. The choice of imaging modality should be suited to the diagnostic question. This also suggests that specific criteria are required as the level of image quality or detail required even when imaging similar anatomy may be quite different in medical and non-medical examinations. Such criteria do not yet exist but must be developed as an essential tool required to support the justification process.

2.4.4 Common Views and Values

One of the issues that emerges in relation to non-medical exposures is that there can be very differing views on the justification of certain practices and individual exposures among the various stakeholders or groups concerned. The following two practices illustrate some of the conflicting views and opinions that can arise.

The first of these is the use of chest radiography to screen for tuberculosis (TB). The practice of screening for TB for immigrants might be viewed as being ‘politically incorrect’ by some. On the other hand, there is also a view that it is reasonable to take steps to protect vulnerable individuals in society by employing measures to ensure that the spread of TB is avoided or at least curtailed.

Another example where diverging opinions can occur is the use of radiography in pre-employment screening. X-rays may be required as a pre-requisite to employment in order to rule out any underlying conditions that might compromise the ability of the employee to fully discharge the duties expected of them. In this context the motivation is primarily to protect the employer from future liability, financial or otherwise. While, there is a general social concern about the compromise of health for commercial gain, reflecting a wider public

distrust of corporate entities[6], it may also be the case that other employees would resent extended periods of absence as a result of chronic illness that render an individual unsuitable for a particular type of work, especially if this could have been identified prior to commencement of employment.

2.4.5 X-Ray for All?

The use of security scanners at airports and other locations is likely to result in large numbers of individuals being scanned and hence exposed. Yet the vast majority of these individuals will pose no threat to either security or the control of goods/substances across borders. The question arises as to whether it is reasonable to subject many individuals to both the inconvenience of a scan and the associated radiation dose, however small, in order to deal with the possible actions of a minority.

2.4.6 Preventative Medicine

Imaging in sport can be used to diagnose a possible injury at an early stage or to determine the progression of the injury or subsequent recovery. Preventative medicine is not a term that was defined in the Medical Exposure Directive and hence we have no framework within which these practices can easily fit. Imaging is also used as a prognostic tool, both in sport and other areas such as dancing, where it can be used to predict growth. It could be argued that this use is justified in terms of the individual benefit as it avoids disappointment at a later stage. However, the problem remains that our current system of protection and regulation is not well suited to deal with exposures of this type.

2.4.7 Collective Dose

The numbers of individuals travelling through airports on a daily basis means that there is a potential for very significant numbers to be affected by the introduction of security scanners on a wide scale basis. Scanners based on x-ray technology will result in a collective dose for the travelling population. Although the individual doses are likely to be small[7], the cumulative dose should be considered in the justification of the use of this technology for this practice. However, it must be remembered that the use of collective dose for risk assessment should be used with great caution where the numbers exposed are large and the associated doses small.

2.4.8 Overuse of X-ray

The technological developments that have taken place over the last two decades have resulted in the availability of a vast array of imaging techniques that can be applied to a wide range of situations. While this has undoubtedly brought with it many advantages, it can at times lead to the neglect of other simpler less complex methods of obtaining a diagnosis or assessing a situation. It is important to ensure that clinical assessment using conventional methods and essential skills is still an integral part of diagnosis.

2.5 Final Conclusions

Previous work has confirmed that the key issue in medico-legal exposures is justification[8]. Justification is the balancing of the advantages against the disadvantages, but both are difficult to quantify and are therefore often difficult to compare. Justification must take account of all of the relevant social and economic issues and requires engagement with all of the relevant stakeholders. Establishing a mechanism to facilitate this and ensure that the required expertise, experience and knowledge is drawn into the process is challenging but is an essential pre-requisite for an effective justification process. The justification of new and existing practices requires an appropriate legal framework that can accommodate the inherent complexities of the process. The recast of the BSS provides an ideal opportunity to review and amend existing legal provisions.

2.6 References

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3 CONCLUSIONS FROM THE PREVIOUS SURVEY ON MEDICO-LEGAL EXPOSURES

Wolfram Leitz

Swedish Radiation Safety Authority

3.1 Introduction

As one of the inputs to the previous symposium on medico-legal exposures (1) in 2002 a questionnaire was prepared with the aim of gaining information on these practices. This survey sought to ascertain if certain types of exposures are performed at all, if yes with what frequency, doses involved, legal framework etc. The outcome of this questionnaire was presented and discussed during the workshop and conclusions were drawn on what further actions would be needed. This presentation gives a short overview on the achievements at the workshop in 2002 and the conclusions drawn on what activities should be performed. Then it is discussed which of these activities were performed, which not and whether they are valid still today.

3.2 Questionnaire 2002

The questionnaire was designed by the members of the working party MED of the group of experts according to Article 31 of the EURATOM treaty. Eleven categories of exposures were defined, e.g. search of concealed drugs or weapons on the body of suspects, drugs inside the body, verification of child abuse, routine x-ray examinations for immigrants, emigrants or as condition for insurance policies. Questions asked for each of this exposure types were among others - is this examination performed? If yes, with what frequency? What are the typical doses? What is the legal frame work? Who is entitled to order such an exposure? What about voluntariness?

The questionnaire was sent out to 15 countries where 13 responded. Some of the results were:

- Some procedures were performed in all countries (drug search, civil litigation and child abuse).
- Search for weapons in only one country.
- The remaining categories in 2 to 10 countries.
- Little information was given on the frequency of such exposures.
- Little information was given on the radiation doses involved for the different practices.
- Theoretically medico-legal exposures are mostly voluntary but in practice frequently not.
- Legal provisions for most of the procedures exist.
- Most of the exposures are performed in a hospital by medical personnel.

An analysis of the responses revealed some weaknesses in the design and response of the questionnaire:

Terms were misinterpreted, questions were ambiguous, some topics were complex and had not just a single answer, there are difficulties on how to treat cases in grey zones and as mentioned above difficulties to obtain information about medico-legal exposures. One reason for the latter was obviously that not just one but many bodies are involved in the various types of medico-legal exposures which were not always identified as such or were not contacted by the radiation protection authority which was normally the recipient of the questionnaire.

3.3 Conclusions of 2002 Symposium

It was found that despite the weaknesses of the questionnaire, a fairly good view on the situation in Europe on medico-legal exposures was obtained. These findings can form a basis for future actions within this area. It was concluded that further actions were needed for increasing the knowledge about the practices with medico-legal exposures in the member states and then to find ways to ensure that they are performed following radiation protection principles. Strategies on how to proceed were also given. More precisely the following conclusions were drawn.

- A network between radiation protection authorities and other bodies involved in the actual medico-legal procedure should be established, including also the professions involved.
- A refined questionnaire should be designed where especially questions regarding legal issues and processes need to be defined more conclusively. Measures should also be taken to ensure that the questionnaire is forwarded also to other stakeholders involved, not only to the radiation protection authorities.
- Guidelines should be established for especially those procedures which envisage difficult ethical aspects such as security checks with very low doses or exposures in connection with child abuse.
- A new follow-up symposium should be organized within the near future.

3.4 Achievements since the 2002 Symposium

Very few of the suggestions at the 2002 symposium were achieved. The present symposium did finally take place, but a long time later than foreseen. To the author's knowledge no networks or targeted cooperation with other stakeholders have been established. Hence, European guidelines on the practices presented here were not developed. During the spring of 2009 the IAEA designed a new questionnaire and distributed it to some hundred countries. The preliminary results were presented at the present symposium. It is too early to conclude to what extent this questionnaire has solved the problems envisaged in the 2002 survey.

In the following chapter recent activities in fundamental radiation protection standards are discussed in the light of medico-legal exposures. The issue is discussed whether it would have been beneficial if the plans suggested in 2002 had been realized.

3.5 Recent Basic Radiation Protection Standards

International Commission on Radiological Protection (ICRP): In 2007 the ICRP issued its new basic recommendations. Medico-legal exposures are mentioned in just one paragraph (5.7.2 (210)): Radiological examinations for occupational, health insurance, or legal purposes undertaken without reference to clinical indications should be deemed to be unjustified, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations.

This requirement is somewhat too restrictive; benefits in connection with radiation exposures are not totally limited to health issues and progress in crime investigations. Some other types of exposures such as e.g. radiological examinations for age assessments or health checks for sportsmen are not addressed at all. It would have been valuable if there had been more guidance in this fundamental radiation protection policy document on how to deal with these types of exposures.

International Atomic Energy Agency (IAEA): IAEA is revising its Basic Safety Standards (BSS) on radiation protection. The revision has reached an advanced stage. Various types of medico-legal exposures are addressed in the draft explicitly. It is stated that exposures for occupational, legal or health insurance purposes are normally not justified. Exposures for theft detection are deemed to be not justified. Exposures for detection of concealed objects are normally deemed to be not justified. These requirements are quite restrictive and are implying generally that no medico-legal exposures should be justified.

European Commission (EC): Also the EC is currently revising the Basic Safety Standards of the EURATOM. The present draft is addressing Medico-legal exposures somewhat differently compared to the IAEA BSS. Medico-legal exposures are redefined as “non-medical imaging exposures”. These exposures require special attention to justification. If they are justified, informed consent is required from the person who is subject to this exposure. These exposures are normally considered to be exposures of the public and the dose limits for the public apply. However, in exceptional circumstances the dose limit may be exceeded.

Common for all the three new basic radiation protection documents is that the importance of justification for medico-legal exposures is emphasized. The requirements for the different types of exposures differ, between a more or less categorical “not justified” to a weaker “special attention to justification is needed”. The common impression of all three documents is that there is a lack of input from other stakeholders in the field of medico-legal exposures, and this might have consequences.

3.6 Future Work

Very much the same actions as required at the 2002 Symposium are still important to accomplish. Those involved in the various practices need rather detailed and concrete guidance on how to proceed, when and under which circumstances medico-legal exposures may be performed. It is crucial that the stakeholders are closely involved in the process of issuing guidance in order to make sure that their legitimate needs are duly taken into account. Networks between stakeholders and the radiation protection community can contribute to a mutual understanding of their corresponding problems. The outcome of this cooperation could very well result in recommendations for some of the practices that are not completely in line with all the recommendations and requirements in the three basic radiation protection standards mentioned. Maybe in the justification process a wider range of beneficial factors will be taken into account, there might be too much focus today on medical benefits.

The initiative to create the networks mentioned should naturally come from the radiation protection community. Many of the factors to be considered in the judgment of the various practices are not related directly to monetary costs and somatic consequences. Therefore not only the directly involved stakeholders such as police and customs should be taken on board, but also expertise in other disciplines such as representatives in ethics, societal sciences and philosophers. Thus solutions can be achieved that are well balanced between the sometimes opposite opinions among the various interested parties.

3.7 Conclusions

It has been shown that the decisions for actions at the symposium in 2002 were well-founded and needed. Unfortunately there might be negative consequences of having neglected these recommendations until now. Requirements laid down in the new basic safety standards may prevent the “best solution” for e.g. guidance or legal requirements for some of the medico-legal practices. It is therefore important to start establishing networks very soon. For some of the practices, e.g. child abuse, search for weapons or drugs and immigration/emigration related exposures, there is an urgent need to develop guidance following a comprehensive evaluation where all aspects are duly taken into account. The reputation of radiation protection would suffer if the radiation protection community once more neglects to perform the necessary actions.

3.8 References

1. Radiation Protection 130. Medico-legal exposures, exposures with ionising radiation without medical indication. Proc.Int.Symp. Dublin, 4-6 September 2002.

Session 2 - Update from International Organisations

4 ICRP POSITIONS, EXPERIENCES AND INITIATIVES

Donald A. Cool, Ph.D.

ICRP Committee 4

4.1 Overview

This presentation will review some of the activities of the International Commission on Radiological Protection.

It will also include a brief overview of some of the things that have been happening in the United States.

The views and material in this paper do not represent the formal views or positions of the U.S. Nuclear Regulatory Commission but are those of the author as a member of Committee 4 of the International Commission on Radiological Protection.

4.2 ICRP Publication 103

As with previous versions of the ICRP recommendations, the most recent recommendations in ICRP Publication 103 state the fundamental principles of justification, optimization, and limitation for exposures. Publication 103 moves to consolidate and organize the Commission's recommendations, and move to a "situation" based approach, recognizing "planned", "emergency", and "existing" exposure situations.

With respect to justification of exposures, ICRP Publication 103 provides several situations in which an exposure should normally be deemed to be unjustified unless there are exceptional circumstances. One of those circumstances is a radiological examination of an individual taken without reference to clinical indications.

The relevant part of the text in ICRP 103 is as follows:

'The Commission considers that certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances. These include the following: Radiological examination for occupational health insurance, or legal purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations. This almost always means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified'.

4.3 Initial Work

ICRP Committee 3 on Medical Exposures, and ICRP Committee 4 on Application of the Commission's Recommendations, have engaged in a dialogue over the last few years on the question of exposures of individuals.

In fact, there have been two aspects under discussion. The first was situations in which an exposure was taking place without a specific referral from a physician. These still constitute a medical exposure, and Committee 3 has been examining what may be said about the justification of such exams that do not have specific clinical indications, or which are part of an approved screening process.

The second case, and the subject of this symposium, is the set of situations in which an exam is made for some other purpose, be it legal information, security screening, etc. As these discussions have progressed, one of the key questions faced within Committee 4 has been the role for ICRP, and whether there is a specific useful place for some type of statement or publication on the part of the Commission.

4.4 Dublin Meeting Review

ICRP Committee 4 last met here in Dublin, almost exactly one year ago, in another room within this beautiful venue. During that meeting, we again reviewed the topic, and specifically some of the things that are going on within the International Atomic Energy Agency, within the Inter-Agency Committee on Radiation Safety (IACRS), and within the United States. It is clear that considerable work has been done within the radiation protection community on the subject.

The work of the IAEA will be presented during this symposium and so further discussion of what is happening, particularly with respect to the International Basic Safety Standards will be left to that time. Some of the activities in the United States will be reviewed in this paper.

Committee 4 concluded that it was not appropriate for a formal task group to be moved forward at that time and that the Committee would maintain a review of the ongoing developments. A Task Group is formed by ICRP when there is a clear topic that will lead to a formal publication in the Annals of the ICRP published by Elsevier.

As a member of Committee 4 as we begin a new 4 year term of the Main Commission and Committees, I am therefore grateful for this opportunity to hear from you about some of the things going on. The discussions in this meeting will serve as one source of information for a discussion that will take place within the ICRP in Oporto, Portugal, in November.

Committee 4, in taking the decision to maintain a review of the situation, noted several things in particular. First, it observed that justification decisions are matters for national authorities, or duly authorized agents of those authorities, and that the components of a justification decision generally go far beyond the radiological protection considerations. While the radiation protection information must be a significant contributor in the analysis, there are always other factors that also must be weighed in determining the net benefit of any particular exposure that is being proposed.

Because of this fact, ICRP has, and continues to maintain that it is generally not appropriate for the ICRP to be making a specific recommendation on what types of activities are, or are not justified. The ICRP has made observations on the general findings that have taken place, and has noted, as seen earlier, that there are some circumstances that would seem to be not justified unless there are exceptional circumstances.

In fact, it is a question before us here, and for each national authority, on what the exceptional circumstances may be that would result in a decision to perform some type of radiological examination.

Committee 4 also took a clear position that these types of exposures, if justified, should be considered as planned exposure situations, and the appropriate optimization of protection and necessary radiation control programs should be applied. Although obvious, this is, in fact, something which needs to be carefully considered, because in many instances the organizations that may be doing the screening are not the typical authorized user, and may have little expertise in the conduct of an acceptable program.

Application of the system of protection for planned exposure situations would include the selection and use of constraints in the optimization of protection for the activity or facility. Here again, there may be information that is important to the selection of the constraint values, and the optimization of protection for workers who may be operating the equipment, and a member of the public that may be receiving an exposure.

Committee 4 of the ICRP welcomes information on the status of various proposals, and any advice on whether there are particular recommendations or statements that ICRP could properly and usefully make within its mandate and scope competence.

4.5 US Activities

Recent activities within the United States will now be reviewed. These will include a report published last year by the U.S. Interagency Steering Committee on Radiation Standards, known as ISCORS, some of the work being done in the area of consensus standards, and a couple of the questions faced by the Nuclear Regulatory Commission (NRC).

4.6 ISCORS GSSHUIR

Control of radiation and radioactive materials is widely distributed across a variety of agencies and organizations within the United States. In particular, machine produced radiations, including x-rays and accelerators, are under the control of the States. Control of radioactive materials, including now accelerator produced radioactive materials, is under the jurisdiction of the NRC, and the State programs that have entered into a formal agreement with the NRC.

The Interagency Steering Committee on Radiation Standards (ISCORS) is an organization of the major U.S. Federal Agencies with some responsibilities for radiation protection in the United States. The agencies include the Nuclear Regulatory Commission, the Environmental Protection Agency, the Department of Energy, the Department of Health and Human Services, the Department of Transportation, the Department of Defence, and the Department of Labour (Occupational Safety and Health Administration). We also have representatives from selected State radiation control programs as invited observers to share with us their expertise.

The “Guidance for Security Screening of Humans Utilizing Ionizing Radiation” (GSSHUIR) was developed by ISCORS in response to requests from agencies such as the Transportation and Security Administration for information on how to make decisions about use of radiation in security screening.

The report was published in July, 2008, and provides advice. It is not a mandatory document, and does not change the obligations or responsibilities of any of the Federal Agencies. The report provides advice on both the process and factors that should be considered in making a justification decision, and advice on the implementation of an appropriate radiation protection program if a decision is made to use such systems. It is a

relatively high level treatment of the subject, providing a good starting point for setting up decision-making discussions.

The guidance acknowledges that decisions involve many factors in addition to radiation protection and provides examples of the information that may be important to consider. The guidance also suggests that the agency obtain legal advice, and take into account the current threat assessment, physical security, and a variety of cultural and social issues in making the decision of when security screening using radiation is justified.

The guidance makes use of the categorization of systems as “general use” and “limited use” as found in Commentary 16 of the National Council on Radiation Protection and Measurements (NCRP), and consensus standard ANSI 43.17.

The steps in the process start with defining the need for security screening, including the threats, the populations, and the consequences of a failure of screening to protect against the threat. The second step is to evaluate the options for screening that are available, both radiological and non radiological. It is then necessary to evaluate privacy concerns. Interestingly, this has been the issue of primary importance in press interest in such systems. With this information, the radiation risks and net benefit can be assessed to determine if radiation screening provides a positive benefit and is the most appropriate for the circumstances. Finally, it is important to evaluate the ability of the organization to safely and effectively carry out the screening, including the necessary radiation protection program implementation.

The second part of the report provides advice on maintaining an adequate radiation safety program commensurate with risks posed to employees who operate the security screen systems, employees who may happen to work nearby, the screened individuals, and members of the public.

The report also provides summaries of the information that is available from the different federal agencies, and where additional resources can be found.

4.7 ANSI Standards

As mentioned previously, there have been statements prepared by the National Council on Radiation Protection and Measurements, and there continues to be work within the consensus standard area related to security screening. This includes a revision of N43.17 on Radiation safety of personnel security screening systems, as well as work to develop standards on Safe Operating Practices for systems using fast neutrons, and on Radiation Safety for X and Gamma cargo security screening systems.

The relevant ANSI standards are:

- N43.14 Safe Operating Practices for Active Interrogation Systems for Security Screening Using Fast Neutrons (The standard is under development.)
- N43.16 Radiation Safety for X-Gamma Cargo Security Screening Systems (The standard is under development.)
- N43.17 Radiation Safety of Personnel Security Screening Systems ("People Scanners") (HPS Web site as ANSI/HPS N43.17-2002. The standard is under revision.).

4.8 Summary of Provisions of ANS Standard N43.17

N43.17 has the following requirements:

In terms of the exposed individual the subject dose is 0.1 μSv (10 mrem) effective dose per scan with an additional limit of 250 μSv (25 mrem) per year. There is a requirement to consider benefit vs. risk and negligible individual dose (< 10 μSv) and the subject must be informed of the x-ray exposure and associated risk.

In terms of the scanner, radiation leakage should not exceed 2.5 μSv (0.25 mrem/h) @30 cm from surface. There should be bystander protection with an Inspection zone – 20 μSv (2 mrem/h). There should be safety interlocks and the equipment should be appropriately labelled.

There is also a requirement for operator training. Manufacturer and user facility records must be kept. The annexes of the standard detail approaches in terms of risks and rationale along with protocols for measurement and estimation of effective dose.

4.9 NRC Jurisdiction

As outlined earlier, the jurisdiction of the NRC extends to what is referred to as “Source”, “By product”, and “Special Nuclear Material”. With the Energy Policy Act of 2005, the definition of by product material was expanded to include materials made radioactive in an accelerator. However, the NRC has not been given authority over machine produced radiations, including the accelerators, or various types of x ray machines. States have authority over machine produced radiation. NRC has authority over ‘By product’ materials but the provisions of 10 CFR Part 20 exclude radiation exposure due to background, diagnostic/therapeutic medical exposure to patients and voluntary exposure from medical research.

Thus, the role of the NRC in the discussions on security screening with x-rays has been more limited to consultation on radiation protection, rather than active licensing or inspection.

4.10 Current Issues

The NRC is aware of an increasing interest in the use of x-ray systems in a variety of situations, including prisons, military applications, and customs and border protection. As noted earlier, there is continuing interest by the Transportation and Security Administration, which is part of the Department of Homeland Security.

While the individual screening systems have generally been x-ray systems, much of the cargo scanning is done with devices using radioactive materials in sealed sources. Thus these sources and systems are under the licensing jurisdiction of the NRC. More recently, there have been increasing interest and questions about authorization of human scanning with devices using sealed sources. At least some of these are a result of application of cargo screening in situations where the driver may be present.

For example, the NRC has had requests to amend the sealed source device registrations sheets to include the provision for human screening. This has raised serious questions within the NRC and is currently the subject of a policy discussion within the agency.

Our regulations include dose limits for occupational and public exposure, and requirements for licensees to implement radiation protection programs, and take steps to maintain doses

"As Low as Reasonably Achievable". Medical exposure of patients is not directly regulated by the NRC. Instead, our regulatory role is to ensure that the treatment and dose intended by a physician for a patient is accurately delivered.

4.11 Conclusion

This paper has provided a quick synopsis of the activities of the ICRP, and some of the things going on within the United States. It is hoped that there will be a productive discussion throughout this symposium.

5 HUMAN IMAGING FOR PURPOSES OTHER THAN MEDICAL DIAGNOSIS OR TREATMENT – DEVELOPING A CONSISTENT AND COMPREHENSIVE APPROACH TO RADIATION PROTECTION

Renate Czarwinski and John Le Heron

Radiation Safety and Monitoring Section, Division of Radiation, Transport and Waste Safety, International Atomic Energy Agency, Vienna

5.1 Introduction

The deliberate exposure of humans to ionizing radiation is usually in the context of medical exposures of patients, intended either for diagnosis or treatment. In these cases, the benefits to the patient from the radiation exposure are expected to more than outweigh any radiation detriment that may ensue.

However, there are situations in which persons might be deliberately exposed, typically in order to produce an image, but not on the basis of medical indications. The perceived need might arise for many reasons, including security, law enforcement, theft detection, legal proceedings, insurance concerns, and immigration requirements. However, unlike medical exposures, the benefit for the irradiated person in these cases may not be so evident, and indeed there are significant ethical issues[1,2]. Recent events in global and national security, together with the development of sophisticated security imaging technologies, have heightened interest in such activities with the potential for further increases in the use of these non-medical human imaging techniques. A companion paper in these proceedings[3] presents data on current practices and regulatory activities in the area of human imaging for purposes other than medical diagnosis or treatment, showing wide variations in the approach to implementing radiation protection. This lack of consistency, together with the increasing interest in such activities, emphasizes the need to have current and appropriate international safety standards setting out the radiation protection requirements for these applications.

The revision of the current International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS)[4] has provided the opportunity to develop an up-to-date consistent and comprehensive approach to ensuring appropriate radiation protection for all situations of human imaging for purposes other than medical diagnosis or treatment.

The phrase “human imaging for purposes other than medical diagnosis or treatment” is the terminology that is being used in the revision of the BSS to refer to these imaging procedures, but in recognition of its wordiness, the shorter phrases “non-medical human imaging” and “human imaging for non-medical purposes” are used as equivalent alternatives in this paper.

It is important to first discuss the historical context of the current BSS with respect to non-medical human imaging, high-lighting the lack of stability in how these exposures were viewed. This is followed by a discussion of the shortcomings of the current BSS in non-

medical human imaging, and finally the approach being taken with the draft revised BSS is presented and discussed.

5.2 The Road to the Current BSS

Radiation protection recommendations and requirements for the use of ionizing radiation in many of these situations have been made by the International Commission on Radiological Protection (ICRP), the World Health Organization (WHO), the International Atomic Energy Agency (IAEA) and the European Commission (EC) over the last 40 years, but often in response to particular issues as they arose, giving an uneven approach. This section will briefly discuss those pronouncements made in the period up to the development of the current BSS.

5.2.1 The ICRP

ICRP Publication 15[5], in 1969, strongly disapproved of human imaging for non-medical purposes, citing the two examples of anti-crime fluoroscopy and customs examinations (see Table 1). From this default position, the recommendation then allowed for exceptional circumstances under which these activities could be carried out – namely, permission by the competent authority, that the examinations were considered essential, and that they would be carried out under the supervision of a radiologist. There was no elaboration on how or on what grounds the competent authority might grant permission; and it was not clear who would decide whether the examinations were essential. International events at the time, namely a spate of aircraft hijackings, led the ICRP in 1971[6] to state that they believed security-screening of airline passengers could be justified, but again there was no elaboration with respect to responsibilities and processes.

The general Recommendations of the ICRP in 1977, in Publication 26[7], did not supersede some of the previous committee publications, including the above mentioned Publication 15. Publication 26 also considered additional situations with respect to non-medical human imaging (see Table 1). Examinations for occupational, medico-legal or insurance purposes were included as part of medical exposure. In a specific recommendation, the ICRP noted that examinations carried out to assess the fitness of an individual for work, to provide information for medico-legal purposes, or for insurance purposes, carried advantages for other parties and that this needed to be considered in the justification of such examinations. No recommendations were made on how the justification process might actually take place.

Perhaps surprisingly, the 1990 Recommendations of the ICRP[8] did not contain any recommendations with respect to human imaging for non-medical purposes. But now, the scope of medical exposures no longer included examinations for occupational, medico-legal or insurance purposes.

The pertinent ICRP recommendations in the period leading up to the publication of the BSS, as discussed above, are presented in Table 1.

Table 1: ICRP recommendations relevant to human imaging for purposes other than medical diagnosis or treatment in the period leading up to the publication of the BSS[4].

Publication	Recommendation
ICRP 15, 1969[5]	(285) The irradiation of persons for non-medical purposes, such as "anti-crime" fluoroscopy and in customs examinations, is generally deprecated. If, in exceptional circumstances that are permitted by the competent authority, such examinations are decided to be essential, they shall be carried out under the supervision of a qualified medical radiologist.
ICRP London statement, 1971[6]	The Commission has been asked for its views on an international proposal to use radiography as part of a system for security-screening of airline passengers. This envisages that a small proportion of passengers might be examined radiographically, using specially developed techniques that would restrict the exposure to 1 mR or less in any part of the body, to be used only when other methods have indicated the presence of unexplained objects on the passenger. Such passengers would be given the choice between x ray examination and a body search. The Commission has already recommended that the irradiation of persons for non-medical purposes, such as anti-crime and customs examinations, is generally to be deprecated. However, in view of the grave risks involved in the seizure of aircraft, the Commission believes that the proposal, if performed under the conditions already specified, could be justified in the light of the benefits that might be expected.
ICRP 26, 1977[7]	(196) The objectives of the medical procedures are: examinations or treatments directly associated with illness; systematic examinations undertaken for mass screening purposes or for periodic health checks; examinations forming part of the medical surveillance of workers or carried out for medico-legal or insurance purposes; examinations or treatment forming part of a medical research program. *Examinations for occupational, medico-legal or insurance purposes* (202) Examinations carried out to assess the fitness of an individual for work, to provide information for medico-legal purposes, or to assess the health of a subscriber to, or beneficiary of, an insurance may carry some direct or indirect advantages for the individual examined, but they also carry advantages for the employer, third parties and the insurer. All these aspects should be considered in assessing the justification of such examinations.
ICRP 60, 1991[8]	(No recommendations were made; and the scope of medical exposure did not include exposures for medico-legal purposes.)

5.2.2 WHO

The WHO, in 1977, in its Technical Report Series 611 on the Use of ionizing radiation and radionuclides on human beings for medical research, training and nonmedical purposes[9] considered many nonmedical situations, including medico-legal, occupational, immigration, irradiations as a routine administrative procedure, weapon detection and the detection of smugglers. The overall general recommendation from this publication was that irradiation for purposes unrelated to health should be done only when no satisfactory alternative methods exist. This is stronger than the ICRP statement of 1971 where it was envisaged that a passenger, for example, would be given the choice between an exposure and a body search – i.e. a satisfactory alternative was part of the proposal.

5.3 The Current BSS and its Shortcomings

The BSS[4] was developed in the period immediately following the publication of the 1990 ICRP Recommendations (Publication 60)[8], culminating in its publication in 1996. Germane to this paper are two requirements of the BSS, both appearing in Appendix II on medical exposures in a subsection on justification of medical exposures. Table 2 reproduces those requirements.

Table 2: The BSS[4] requirements relevant to human imaging for purposes other than medical diagnosis or treatment.

Paragraph in Appendix II	Requirement
II.6	Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.
II.9	Radiological examinations for theft detection purposes are deemed to be not justified; should they nonetheless be conducted, they shall not be considered medical exposure but shall be subject to the requirements for occupational and public exposure of the Standards.

Paragraph II.6 addresses occupational, health insurance, or legal purposes undertaken without reference to clinical indications, taking the default stance that these are not justified but then giving two caveats.

The first caveat is “unless the examination is expected to provide useful information on the health of the individual examined”, which would suggest that the intended exposure was really a medical exposure.

The second caveat is a more general condition for exception where the specific type of examination is justified by those requesting it in consultation with relevant professional bodies. It is difficult to interpret exactly what was envisaged with this second caveat. Is the requester also the justifier? Are the relevant professional bodies, medical bodies or some other bodies – legal, insurance, etc.?

It is also not clear what radiation protection is to be afforded persons who are to be subjected to exposures arising from justified exceptions to II.6. The placement of II.6 in the medical exposure section would imply that such persons would be offered the protection that would be given if they were a patient undergoing medical exposure. However, there is doubt for two reasons. First, the definition of medical exposure does not include these exposures and, second, the relevant requirements in the medical exposure section are written from the perspective of protecting a patient undergoing a radiological examination.

The second requirement in the BSS, paragraph II.9, specifically addresses radiological examinations for theft detection and clearly states that these are deemed to be not justified. Unlike paragraph II.6, there are no exceptions. Recognizing that some countries indeed do allow such exposures and without wishing to condone such practices, the requirement then carries on to say that if, however, these exposures do occur, then they must be subject to the requirements for occupational and public exposure. No elaboration is provided on how the requirements for occupational and public exposure might be applied and which requirements to whom, or who has responsibilities.

Finally, the current BSS[4] does not address the area of human imaging for the purposes of security screening.

5.4 The Road to the Revised BSS

The decision to revise the current BSS, made in late 2006, has given the opportunity to introduce a consistent and comprehensive approach to radiation protection in the area of human imaging for purposes other than medical diagnosis or treatment. Further, since the publication of the current BSS in 1996, focus on security screening has increased dramatically and inspection imaging technology has evolved considerably, making its use seemingly more viable.

Again, a brief look at what has happened with respect to international recommendations and requirements since the current BSS was published is useful.

5.4.1 European Commission (EC)

The EC, in its Medical Exposures Directive EU 97/43/Euratom[10], defines the exposure of individuals as part of the so-called medico-legal procedures as medical exposure, where medico-legal procedures are defined as procedures performed for insurance or legal purposes without a medical indication. This was the first time that medico-legal exposures had been brought into an EU directive.

The specific requirements given in EU Directive 97/43 for medico-legal exposures appear to give a good radiation protection framework for these types of exposures, covering the radiation protection principles of justification and optimization, and assigning responsibilities. However, implementation has been difficult, with quite different approaches being adopted in the various EU member states. An international symposium was organised by the EC in 2002 to discuss the issues and difficulties associated with the implementation of the Directive's provisions[2]. Many presentations at this symposium highlighted the problems being encountered. The re-cast of the EU BSS is reconsidering the medico-legal exposures issue.

5.4.2 ICRP

Since the publication of the BSS in 1996, several relevant ICRP publications have been issued, as discussed below, and presented in Table 3.

ICRP Publication 73[11] is a publication that was dedicated to radiological protection and safety in medicine. The scope of medical exposure was expanded (with respect to Publication 60) to include exposures for medico-legal purposes. A specific recommendation stated that special consideration was needed with diagnostic investigations where benefit to the patient was not the primary objective, with insurance purposes being specifically mentioned, as were medico-legal purposes. The implication was that special consideration meant that justification needed special consideration, but there were no recommendations on how the justification process might actually take place.

The recently issued recommendations of the ICRP in Publication 103[12] indicate a return to taking a philosophical stance on whether certain exposures are justified or not. In a subsection entitled "Unjustified exposures", a default position of being not justified is taken with certain exposures unless there are exceptional circumstances. Such unjustified exposures include radiological examinations for occupational, health insurance, or legal purposes undertaken without reference to clinical indications. Two exceptions are given, namely, unless the examination is expected to provide useful information on the health of the

individual examined or unless the examination is expected to provide useful information in support of important criminal investigations. By way of explanation, the recommendation adds that a clinical evaluation of the acquired images would almost always be expected.

Table 3: ICRP recommendations relevant to human imaging for purposes other than medical diagnosis or treatment in the period after the publication of the BSS [4].

ICRP 73, 1996[11]	(37) Medical exposure is essentially limited to (a) the exposure of individuals for diagnostic and therapeutic purposes, including screening and medico-legal purposes (for convenience, all these individuals are called patients herein) and (b) exposures…in the support and comfort of patients…. (47) The justification of diagnostic investigations for which the benefit to the patient is not the primary objective needs special consideration. In the use of radiography for insurance purposes, the primary benefit usually accrues to the insurer, but there may be some economic benefit for the individual examined. Examinations ordered by physicians as a defence against medico-legal malpractice claims may have only marginal advantages for the individual patient.
ICRP 103, 2007 [12]	**5.7.2. Unjustified exposures**: (210) The Commission considers that certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances. These include the following: Radiological examination for occupational, health insurance, or legal purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations. This almost always means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified.

5.5 Revision of the BSS

The above overview of retrospective considerations of past ICRP recommendations, IAEA requirements and EC requirements highlight the need for the radiation protection framework for human imaging for non-medical purposes to be re-examined and developed further, especially with respect to justification and responsibilities.

In developing an appropriate set of requirements for the revised BSS[13], the following questions, *inter alia*, needed to be considered:

- Are some activities simply not justified?
- When should there be caveats to a default position of an activity being not justified?
- Where do the sovereign rights of individual Member States fit into an international standard?
- Who should be responsible for the justification of a proposed practice?
- How can appropriate requirements for the optimization of protection be invoked for the irradiated person in all the different situations?
- Is there a place for dose constraints?
- What dose limits, if any, should apply?
- Does the irradiated person need to be informed?
- Should non-ionizing alternatives be made available?

The draft requirements for the revised BSS have been developed on the basis of dividing the various uses of radiation for non-medical human imaging into two categories, referred to as

simply “Category 1” and “Category 2” in this paper. While the purposes within each category differ, especially for Category 1, there are common attributes within each category – where the imaging is performed, what sort of radiation equipment is used, who operates that equipment and what happens to the images. The synergies within each category simplify the development of a consistent radiation protection framework for the disparate purposes of radiation use.

To elaborate further, Category 1 is non-medical human imaging that:

- Takes place in a medical radiation facility;
- Uses medical radiological equipment;
- Is performed by radiology personnel;
- Produces images reported by a radiologist or other doctor;

For the purposes of:

- Obtaining legal evidence;
- Insurance;
- Employment;
- Immigration;
- Age determination;
- Assessing physiological suitability or status;
- Detection of drugs within a person.

On the other hand, Category 2 is non-medical human imaging that:

- Takes place in a non-medical facility (often in a public place);
- Uses specialized inspection imaging equipment;
- Is performed by non-radiology personnel;
- Produces images viewed by a non-medical person;

For the purposes of:

- Detection of concealed weapons on:
    - Airline passengers; persons crossing a national border; visitors to prisons, court houses, public buildings, etc.; prisoners within a prison;
- Theft detection;
- Screening cargo containers and vehicles.

The listing of the various purposes above does not in any way pre-empt the need for justification or imply that such a justification is likely – it is merely a listing of possible non-medical human imaging uses.

The radiation protection framework for human imaging for purposes other than medical diagnosis or treatment must follow the ICRP system of radiological protection, underpinned by the 3 principles of radiation protection – justification, optimization and limitation.

In line with the recommendations on “Unjustified exposures” in ICRP in Publication 103[12], the draft revised BSS takes a stance with respect to human imaging for purposes other than medical diagnosis or treatment. Two different stances are taken, namely:

- A default position of simply being deemed to be not justified is applied to human imaging using radiation performed for theft detection purposes.
- A default position of being normally deemed to be not justified is applied to human imaging using radiation performed for:
    - Occupational, legal or health insurance purposes, and undertaken without reference to clinical indication;

- The detection of concealed objects for security or anti-smuggling purposes.

The latter default position recognizes that there might be exceptional circumstances where the justification of such imaging might be considered, and in this case there are specific requirements that then apply to ensure an appropriate framework for radiation protection in these instances.

The crucial stage in these exceptional circumstances is the process around the consideration of the justification for the contemplated radiation use. The draft requirements place this responsibility with government, and the justification process has to consider, *inter alia*:

- Appropriateness of the radiation equipment for the proposed use;
- The use of alternative techniques that do not utilize ionizing radiation;
- The benefits and detriments of implementing the procedure;
- The benefits and detriments of not implementing the procedure;
- Evaluation of various radiation technologies available, including the effectiveness and limitations of the procedures;
- Availability of sufficient resources to safely conduct the imaging procedure during the intended period of use;
- The impact of any legal or ethical issues which may be raised by the use of the technology.

If, after this process, a particular practice of human imaging for purposes other than medical diagnosis or treatment is judged as being justified, then such a practice has to be subject to regulatory control, with the radiation protection regulatory body, in cooperation with other relevant authorities, agencies and professional bodies as appropriate, establishing the requirements for this regulatory control.

The starting point for the optimization of radiation protection for the irradiated person is for:

- Category 1 procedures:
  - As if they were undergoing a medical exposure
- Category 2 procedures:
  - As a member of the public.

For Category 1 procedures, this is further reinforced by the use of dose constraints. Appropriate dose constraints are required to be established for such non-medical human imaging procedures. In other words, the appropriate optimization requirements for medical exposures are applied, with the exception that these dose constraints are to be used instead of diagnostic reference levels. Such a dose constraint may be lower than the diagnostic reference level for the “equivalent” diagnostic procedure – for example, the dose from a CT abdomen performed to detect swallowed drugs should be significantly lower than a medically-indicated CT abdomen looking for anatomical detail.

For Category 2 procedures, clearly the requirements for public exposure in planned exposure situations must be met for the imaged person, including the dose limits. Further, the optimization of protection and safety needs to be subject to any dose constraints set by the regulatory body in consultation with other relevant authorities and professional bodies. The draft also includes a requirement that the person about to be irradiated must be informed about the possibility of choosing an alternative technique that does not use ionizing radiation, where such an option is available. A final requirement invokes conformance with relevant standards of the International Electrotechnical Commission (IEC), the International Organization for Standardization (ISO) or equivalent national standards for the imaging equipment.

5.6 The Way Forward

This paper has discussed the background to the development of the draft requirements in the revised BSS for human imaging for purposes other than medical diagnosis or treatment. The draft revised BSS has yet to pass through several review processes before it can be formally adopted by the cosponsoring organizations and published. Changes to the requirements may occur, but the intent is to ensure that there is a consistent and comprehensive approach to radiation protection in the non-medical imaging area, based on the three radiation protection principles of the ICRP.

It is also clear that guidance on the implementation of the requirements will need to be developed.

5.7 Conclusions

Radiation protection recommendations and requirements for different non-medical human imaging situations have been made over the last 40 years. These have often addressed topical issues of the day and have tended to be anecdotal rather than part of a coherent approach to radiation protection for all aspects of this area of human exposure. Specifics on implementation, including responsibilities and processes for justification, were typically missing. The requirements in the current BSS with respect to human imaging for purposes other than medical diagnosis or treatment are inadequate for the world situation today.

The revision of the BSS has provided the opportunity to develop an up-to-date consistent and comprehensive approach to ensuring appropriate radiation protection for all situations of non-medical human imaging.

The draft requirements for the revised BSS have been developed on the basis of dividing the various uses of radiation for non-medical human imaging into two categories, namely those that take place in a medical radiation facility, using medical radiological equipment, performed by radiology personnel, with the images reported by a radiologist or other doctor; and those that take place in a non-medical facility (often in a public place), using specialized inspection imaging equipment, performed by non-medical personnel, with the image viewed by a non-medical person.

The draft requirements are based on the three radiation protection principles of the ICRP. Government is assigned responsibility for the crucial justification process. Justified activities are subject to regulatory control, including requirements for optimization of protection and safety, with dose constraints, and, where appropriate, dose limitation. For Category 1 procedures, the imaged person is afforded the same protection as if they were a patient undergoing a medical exposure. Additionally, purpose-specific dose constraints replace diagnostic reference levels. For Category 2 procedures, the imaged person is afforded protection as a member of the public, again with purpose-specific dose constraints.

5.8 Acknowledgement

The authors would like to acknowledge the input from the experts representing the cosponsoring and potential cosponsoring organizations in drafting the text for the section of the revised BSS on human imaging for purposes other than medical diagnosis or treatment.

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6 NON-MEDICAL IMAGING EXPOSURE IN THE DRAFT EURATOM RADIATION PROTECTION DIRECTIVE

Georgi Simeonov

Radiation Protection Unit, Directorate-General for Energy, European Commission

6.1 Introduction

The European Union's legal framework for protection of human health against the adverse effects of ionizing radiation consists of the EURATOM Treaty[1] and the legislative documents established under its relative provisions. Council Directive 96/29/EURATOM (BSS)[2] establishes the basic standards for radiation protection in the Union; it is supplemented by several other Directives covering different aspects of protection and categories of exposure, medical exposure being dealt with in Council Directive 97/43/EURATOM (MED)[3]. The European Commission is currently in a process of revising and bringing together the BSS and the similar radiation protection Directives in one single piece of legislation – the 'recast BSS'.

6.2 Medico-Legal Exposure in Medical Exposure Directive

The MED defines 'medical exposure' as the exposures incurred by:

- patients (being medically diagnosed or treated),
- individuals participating in health screening, occupational health surveillance or (bio)medical research,
- individuals being subject to medico-legal procedures,

The Directive's definition of 'medico-legal procedures' is: "procedures performed for insurance or legal purposes without a medical indication".

That grouping is made in order to ensure that individuals undergoing medico-legal procedures enjoy the same level of protection as patients by making them subject to the same legal requirements, including those for justification, optimization, training of the staff, quality assurance, etc.

The MED also contains several provisions specific to the medico-legal procedures. Those include the requirements that special attention shall be given to the justification and optimization of these practices and that procedures have to be established for their implementation. Nevertheless, the Directive leaves considerable freedom to the national authorities to decide on how they are going to arrange for the appropriate justification and regulation of medico-legal procedures.

6.3 Issues in the Current Euratom Legal Framework

The existing legal framework provided by MED causes several conceptual concerns that need to be discussed, and as much as practicable, resolved:

- Provided that in most cases there is no direct benefit to the exposed individual, why a dose constraint is not imposed (as it is for the exposure of volunteers in research)?
- Provided that there is no relation to the health of the exposed person, why allow for exclusion from the general radiation protection principle of dose limitation?

There are also more practical issues, such as:

- Does the current definition miss important cases of deliberate exposures of humans similar to medical exposure (athletes, child abuse, pre-employment, security screening, etc.)?
- How to apply certain requirements for medical exposure to the medico-legal procedures - e.g. those on the role of the prescribing medical professional, on the clinical responsibility, etc.?

As a result, the general question arises: "Is the medical exposure legal framework at all suitable for medico-legal procedures"?

6.4 The Way Forward

An attempt to resolve the situation has been made in the current draft of the recast BSS where a new definition of the exposures in question has been proposed and the corresponding legal requirements have been defined. It is well recognized that the proposed solutions are not ideal and may in some cases cause other concerns. It is therefore very important for the Commission to get feedback on them during the following two days. The Commission's proposal is explained below.

In the current draft of the revised BSS the former "medico-legal procedures" have been replaced by "non-medical imaging exposure" (NMIE) defined as "any exposure of humans for imaging purposes where the primary motivation for making the exposure is not related to the health of the individual being exposed". The new category of NMIE is taken out of the definition of medical exposure and it has been established that they "should normally be considered to be public exposures".

The draft BSS requires that special attention is given to the justification of practices involving NMIE, taking into account that they should normally be considered as public exposures. It is stipulated that the informed consent of the exposed individuals shall be received prior to executing the NMIE procedure. However exceptional circumstances are allowed, where the law enforcement bodies may proceed without consent but only in accordance with national law.

In the case where a particular NMIE is deemed justified (by the regulatory body) it shall be subject to authorization and the requirements for the practices, including criteria for individual implementation, have to be established by the competent authority in cooperation with other relevant agencies and professional bodies.

In justified cases of NMIE, the practice should be subject to the dose limits for the members of the public. However, the public dose limit may be exceeded for an individual in exceptional circumstances, where the expected advantages for the population as a whole are sufficient

to compensate for the disadvantages; in those cases the criteria for individual implementation of the exposure are particularly relevant.

Dose constraints shall be set for the justified NMIE practices. The constraints shall be defined in such a way as to ensure compliance with the dose limit for the sum of doses to the same individual from all regulated sources. The relevant optimization requirements as for medical exposure shall also apply.

Finally, the Directive calls for the availability of alternative techniques which do not involve ionizing radiation where the exposure is routinely carried out for security purposes.

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7 HUMAN IMAGING FOR PURPOSES OTHER THAN MEDICAL DIAGNOSIS OR TREATMENT – PRACTICAL EXPERIENCES AND ISSUES IN THE IMPLEMENTATION OF RADIATION PROTECTION IN MEMBER STATES

John Le Heron and Renate Czarwinski

Radiation Safety and Monitoring Section, Division of Radiation, Transport and Waste Safety, International Atomic Energy Agency, Vienna

7.1 Introduction

There are situations in which persons might be deliberately exposed, typically in order to produce an image, but not on the basis of medical indications. The perceived need might arise for many reasons, including security, law enforcement, theft detection, legal proceedings, insurance concerns, and immigration requirements. The revision of the current International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS)[1] has provided the opportunity to more adequately address current worldwide needs for a consistent and comprehensive approach to radiation protection in these areas of human imaging for purposes other than medical diagnosis or treatment, as described in the companion paper in these proceedings[2].

In the process of developing draft requirements, it became apparent that there was a lack of information about how such uses of radiation were currently being regulated in Member States. Anecdotally, there was evidence that several different types of bodies or organizations might be involved in the regulation in different countries, and that coordination or cooperation within a country might be lacking. A questionnaire was developed to gather information on these activities, addressed to the national or state regulatory body for radiation protection, to help identify issues that needed to be addressed by the draft radiation protection requirements for these applications.

The phrase “human imaging for purposes other than medical diagnosis or treatment” is the terminology that is being used in the revision of the BSS to refer to these imaging procedures, but in recognition of its wordiness, the shorter phrases “non-medical human imaging” and “human imaging for non-medical purposes” are used as equivalent alternatives in this paper.

This paper presents the questionnaire and the results from the responses to the questionnaire, and discusses the implications for the revision of the BSS.

7.2 The Questionnaire

The questionnaire was addressed to the radiation protection regulatory body. It was recognized that there may be other bodies in a given country or jurisdiction that also have regulatory responsibilities in the area of human imaging for purposes other than medical

diagnosis or treatment. However, part of the strategy was an attempt to identify the extent to which the radiation protection regulatory body had regulatory control over non-medical human imaging in a given country.

The survey needed to consider a wide range of non-medical human imaging applications that utilize ionizing radiation. To help simplify filling in the questionnaire, it was divided into five parts, as follows:

- Part A, covering those procedures typically performed in a medical facility,
- using medical X ray equipment operated by medical personnel (called "category 1" in the companion paper[2]) – specifically: obtaining legal evidence; insurance purposes; employment purposes; immigration purposes; age determination; assessment of physiological suitability or status; and detection of drugs within a person.
- Part B, covering security screening – specifically: the detection of concealed objects on: airline passengers, persons crossing a national border, visitors to a prison, visitors to a court house, visitors to a public building, other specified persons.
- Part C, covering theft detection – specifically: screening of workers to detect theft; and screening of other specified persons to detect theft.
- Part D, covering screening of cargo containers and vehicles that might house persons.
    - Part E, covering any other use, including for works of art.

All exposures mentioned in Parts B to E fall into what is called "category 2" in the companion paper[2] – namely, typically performed using imaging equipment specifically designed for the purpose, operated by non-medical personnel, in a non-medical facility.

Part A was the most complicated, with a wide range of disparate purposes linked by their typically being performed in a medical environment and hence, at least partially, within an established radiation protection infrastructure. Because the boundaries between an exposure being performed for medical purposes and those being performed on some other non-medical basis can often be blurred, some guidance was given for each of the purposes being specifically looked at – see Appendix A.

Part B was specifically addressing the increasing necessity of security screening in all its guises in current times, and the likely role of devices utilizing ionizing radiation. Concealed objects were intended to include firearms, knives, explosives, etc.

Part C was specific to theft detection. The current BSS [1] contains a requirement that specifically states that such exposures are deemed to be unjustified. Historically, this stance has been driven primarily by concerns for workers (such as in a diamond mine) being subject to exposure for the benefit of the employer. Concerns clearly would extend to the use of detection methods utilizing ionizing radiation on, for example, shoppers leaving a supermarket.

Part D was on cargo screening in the first instance, but was really concerned about whether this included specifically looking for concealed persons and thence the irradiation protection.

The questions for each purpose within each part (A to D) were similar, asking in the first instance whether such imaging procedures were occurring in their jurisdiction. If the answer was "yes", then there were a series of questions on that purpose, including:

- What is the legal basis that allows exposures for this purpose?
- Was the question of "justification" formally considered in establishing the legal basis?
- Who can request such exposures and who can authorize them?
- Who is responsible for radiation protection of the person being imaged?

- What particular requirements does the regulatory body impose for the radiation protection of the irradiated person?
- Does the regulatory body's inspection programme specifically address radiation protection issues associated with human imaging for this purpose?
- Does the regulatory body consider that there is adequate regulatory control of radiation protection for these procedures?

Contact with the national regulatory bodies was made by email in late June 2009.Some Member States have a federal system of government, where each "state" within the country has jurisdiction over the use of X rays. In these cases, each "state" regulatory body was contacted. Questionnaires were sent to 178 regulatory bodies in 124 countries. The initial email included an invitation to participate in the survey, plus the questionnaire itself as an attachment. Follow up emails were sent in early August 2009 to those regulatory bodies that had not responded at that time.

It is acknowledged that there are some issues over sensitivity of information versus the need for radiation protection knowledge – a balance being needed. Individual countries and regulatory bodies are therefore not identified. Instead, the anonymized results are used to identify any gaps in the draft revised BSS requirements (see the companion IAEA paper), as well as providing the basis for a reality check on the practical implications of the proposed approach.

7.3 Results

Responses to the questionnaire were returned to the IAEA by email. Responses to the survey were received from 74 regulatory bodies and 48 countries, in each case approximately 40% of the number contacted. Many responding regulatory bodies answered only parts of the questionnaire.

Results for each part of the questionnaire will be presented in turn. In many cases the number of regulatory bodies responding was low, and hence caution is needed in interpreting the results.

7.4 Part A Results

As stated above, Part A covered non-medical human imaging for the purposes of: obtaining legal evidence, insurance, employment, immigration, age determination, assessment of physiological suitability or status, and detection of drugs within a person. It should be noted that the number of regulatory bodies that gave answers for age determination and for physiological assessment purposes was low.

In response to questions about the prevalence of these uses of non-medical human imaging:

- Approximately 50% of responding regulatory bodies reported that human imaging was being performed for drug detection and for employment purposes.
- A little less than half (about 40%) reported "yes" for obtaining legal evidence, for insurance purposes and for immigration purposes.
- Only a few (about 20%) reported "yes" for age determination and for physiological

status or suitability determination.
- A not insignificant proportion of regulatory bodies (10 to 30 %, depending on the purpose) did not know if such procedures were taking place.

Detailed results of the stated prevalence for each purpose covered in Part A is given in Table B1 in Appendix B.

The responding regulatory bodies stated that almost all exposures for the "category 1" purposes were taking place in a medical facility – namely:

- 100% for insurance purposes, immigration purposes, age determination, and physiological assessment;
- 94% for employment purposes;
- 92% for obtaining legal evidence; and
- 80% for drug detection within the body.

In most countries, a law or regulation was the legal basis that allowed such exposures to take place, and justification had been formally considered in establishing the legal basis in the majority of countries. Details are given in Table B2 in Appendix B. Because of the nature of the questionnaire, no information was available on the quality of the law or regulation, or on how the justification process had been performed.

Overall about 70% of responding regulatory bodies stated that the person or authority that can request a procedure for a given purpose is established by the legal basis. Details are given in Table B3 in Appendix B. In response to who can request a procedure, the survey produced no real surprises. For example:

- The police, justice department or ministry and courts of law or judges comprised approximately 90% of those permitted to request exposures for obtaining legal evidence, and 80% with respect to exposures for detecting drugs within the body.
- Insurance companies represented about 60% of permitted requesters for insurance purposes.
- Employers and the labour department or ministry represented about 70% of permitted requesters for employment purposes.
- Immigration authorities represented about 50% of permitted requesters for immigration purposes.

In addition to these "agents", medical practitioners were also named as being allowed to request an exposure for these non-medical purposes.

The majority of responding regulatory bodies stated that the person or authority that can authorize the performance of a particular procedure for a given purpose is established by the legal basis. Details are given in Table B3 in Appendix B.

In response to who can authorize a procedure, most responses for the various non-medical purposes stated that medical doctors had this responsibility, with radiologists in particular. The one exception was the detection of drugs within the body, where the responses were fairly evenly divided between the doctors and the authorities (police, courts, justice).

Responsibility for radiation protection of the person being imaged is mostly with the radiologist (65 to 83% of responses, depending on the purpose) or, in some cases, other medical practitioners. Responsibility for the radiation protection of the particular procedure was assigned by law or regulation, primarily, and/or by licence or authorization condition.

In response to questions on regulatory activities:

- Approximately 90% of responding regulatory bodies stated that they impose

requirements that would afford the person being imaged the same level of radiation protection as if the person were a patient undergoing a medical exposure.
- For almost all non-medical purposes, less than half of the regulatory bodies were performing inspections which specifically addressed radiation protection issues associated with human imaging.
- The level of satisfaction of responding regulatory bodies with the appropriateness and adequacy of their regulatory control of radiation protection for these non-medical imaging procedures was not very high –namely between 30 and 70%, depending on the purpose.

These results are detailed in Table B4 in Appendix B.

7.5 Part B Results

In general, the prevalence of the use of radiation for human imaging for the detection of concealed weapons, as reported, was very low – less than 15% for airline passengers, and less than 10% for all other situations, with no regulatory body reporting the screening of visitors to court houses or public buildings . A reasonable proportion of regulatory bodies stated that they did not know if such activities were taking place in their jurisdiction. Detailed results of the stated prevalence for each purpose covered in Part B are given in Table B5 in Appendix B.

For the few regulatory bodies reporting the use of radiation for personal security screening:

- the majority reported that a law or regulation was the legal basis that allowed these procedures to be performed;
- about one half stated that justification had been formally considered in establishing the legal basis;
- few reported placing conditions on the doses which are allowed to be received by persons being screened;
- few reported that a person to be screened can choose an alternative form of procedure that does not involve being exposed to ionizing radiation;
- less than half of responding regulatory bodies reported being satisfied with the appropriateness and adequacy of their regulatory control of radiation protection for these non-medical imaging procedures.

7.6 Part C Results

Only one regulatory body reported the use of human imaging for theft detection purposes, 53 said such exposures where not taking place in their jurisdiction, and 6 stated that they did not know.

The response from the one regulatory body indicated that it was taking place at the entrance/exit to a factory/warehouse, that there had been no formal justification, that there were no conditions on who could be screened or the doses associated with the screening, and no provision for an alternative procedure to being screened with ionizing radiation. The operator was required to have received radiation protection training.

7.7 Part D Results

Nearly 80% (48 from 63) of regulatory bodies reported that cargo containers and/or vehicles are screened with ionizing radiation in their jurisdiction, indicating a high level of prevalence of this technology throughout the world. However, a much smaller percentage (10%, 5 from the 48) stated that one of the specific purposes of screening was to detect concealed persons, with a further 17% (8 from the 48) stating that they did not know. Even allowing for these latter responses, the focus for the screening was clearly to detect unwanted or undeclared objects.

Of the five regulatory bodies that reported the use of radiation for the detection of concealed humans:

- All stated that this was occurring as part of national border control;
- 3 out of 5 stated that law or regulation was the legal basis;
- 4 out of 5 stated that potential human exposure was part of the justification considerations in establishing the legal basis;
- 4 out of 5 stated that the person performing the actual screening was required to have had formal radiation protection training;
- Only 1 out of the 5 stated that there were conditions on the doses which are allowed to be received by concealed persons;
- 3 out of 5 stated that their regulatory inspections to these facilities included radiation protection issues for potential exposures of concealed persons; and
- 3 out of 5 stated that they considered there was appropriate and adequate regulatory control, with respect to radiation protection, for human exposure that occurs as a result of container and vehicle screening.

7.8 Part E Results

No responding regulatory body reported any other situations where there was human imaging occurring for purposes other than medical diagnosis or treatment.

7.9 Discussion – Implications for the Revision of the BSS

The survey has confirmed that human imaging for purposes other than medical diagnosis or treatment is being performed for many different purposes in many countries and states, emphasizing the need for the revised BSS to adequately address the particular radiation protection issues associated with such uses.

A significant number of responding regulatory bodies indicated that they did not know whether particular purposes were occurring in their jurisdictions or not. This underlines an important point necessary for adequate regulatory control – namely the need for active cooperation and coordination between the various regulatory authorities that have responsibilities in the use of ionizing radiation for a particular purpose.

Effective implementation of the radiation protection principle of justification needs strengthening in the area of non-medical human imaging – not just lip service. Stronger emphasis on justification needs to be reflected in the revision of the BSS.

The results indicated that regulatory control of doses received by persons being imaged for non-medical purposes, through the implementation of the optimization principle, was not particularly well established. For the "category 1" exposures of Part A, reliance is placed on the exposures being part of the radiation protection infrastructure for medical exposures. This may seem adequate in the first instance, but closer examination would suggest that there is one area where this may not be so. Namely, diagnostic reference levels (DRLs) are a very powerful tool in the optimization of radiation protection for imaging medical exposures. But the values of DRLs are determined on the basis of clinical needs – sufficient image quality to show the required anatomy, for example. A non-medical imaging procedure being performed for drug detection, for example, may involve the abdomen being imaged by a CT scanner. However the DRL for a CT abdomen is not appropriate – the drug detection imaging needs are less demanding, and should be able to be acquired at a dose significantly less than the medical CT procedure. Requirements in the revised BSS need to strengthen the optimization of radiation protection for the imaged person through the use of dose constraints.

Similarly, for the "category 2" exposures the imaged person needs to be protected as a member of the public, allowing the application of the public dose limits and dose constraints.

The survey has identified some other areas that need attention. For example, the responses to Part A indicated that most of the regulatory bodies considered that the radiologist or other medical practitioner had the responsibility for authorizing given procedures, even though the purpose of the exposure was not medical. Many regulatory bodies also indicated that the medical practitioner had a role in requesting such exposures. Are these requesting and authorizing roles appropriate? What specific expertise do these doctors have in these non-medical issues?

It is perhaps understandable why the medical practitioners appear to have these roles. Clearly, the exposures are taking place in a medical facility. Historically, the radiologist has been given a supervisory role – ICRP Publication 15[3] strongly disapproved of human imaging for non-medical purposes, but from this default position, the recommendation then allowed for exceptional circumstances under which they could be carried out – namely, permission by the competent authority, that the examinations were considered essential, and that they would be carried out under the supervision of a radiologist. Since that time, many of the "category 1" exposures have been in and out, several times, of the ICRP definition of medical exposures[4,7]. The current European Directive EU97/43/Euratom[8] includes medico legal exposures as part of medical exposure, although this is currently under review.

The real problem is the interface between three distinct stages of the non-medical human imaging procedure – namely, the "initiation or request", the "approval or authorization", and the subsequent "execution or performance" of the imaging procedure. The first two stages should be occurring in a non-medical environment, but the last almost always occurs in the medical environment. Guidance is clearly needed on how this separation of roles and the necessary interfaces can be achieved in practice. Such guidance would need to be in the supporting documentation to the revised BSS.

For personal security screening, the survey indicated that there was limited availability of alternative procedures to be offered to persons needing to be screened. Consideration needs to be given to whether regulatory bodies should require, through conditions of a licence or similar, the provision of an alternative procedure not requiring exposure to ionizing radiation. The alternative may be more time consuming and more invasive, but the person is being offered a choice.

The survey results for Part C would suggest that countries have an aversion to the application of human imaging for theft detection purposes. Historically, the context for such

use was in diamond mines, and this was the context in which the current BSS takes the stance that screening for theft detection is deemed to be not justified. The draft revised BSS[9] retains the default position of their being deemed not justified.

The use of radiation to screen cargo containers and vehicles is widespread, but little regulatory attention appears to be given to the potential doses to concealed persons .Such exposures should be subject to dose constraints, and satisfy the public dose limits

Several websites present art works involving or incorporating radiographic images of humans. Most of these websites indicate that such images were either acquired from images of skeletons or were computer generated in some way. The survey, in Part E, elicited no responses to indicate that any radiation protection regulatory body, at least, was aware of practices in their countries or states that involved non-medical human imaging for the purposes of art.

As a final comment, responses to the qualitative question on whether there was appropriate and adequate regulatory control for non-medical human imaging exposures indicated that there was a general sense that the regulatory control was not as good as it should or needs to be. This would support the need for consistent radiation protection requirements and guidance on their implementation.

7.10 Conclusions

The survey has confirmed that non-medical human imaging is being performed for many different purposes in many countries and states. The means by which Member States regulate the use of radiation for these purposes differ. A not insignificant number of radiation protection regulatory bodies did not know whether given non-medical human imaging activities were or were not taking place in their jurisdictions, indicating that better coordination and cooperation between authorities is needed. There was a lack of formal justification of some uses of radiation for non-medical human imaging, and there were in general limited requirements for optimization of radiation protection for the exposed person. Issues of responsibility for requesting, approving and performing exposures in “category 1” were identified. Clearly, the revised BSS must provide a consistent approach that adequately addresses the radiation protection issues associated with non-medical human imaging.

The consistent approach needs to be based on a strengthened emphasis on justification, purpose specific optimization utilizing dose constraints, and public dose limitation where applicable.

Requirements in the revised BSS will need to be implemented and the survey indicates that specific guidance in the area of human imaging for purposes other than medical diagnosis or treatment needs to be developed to facilitate implementation.

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Appendix A. Guidance notes for Part A of the Questionnaire

1. **Obtaining legal evidence** – The images are being obtained to establish the presence or absence of diseases or injuries to be used in court proceedings with a view to justice. Examples would include a child abuse victim (but not the images used for diagnosis or treatment), and siblings of a victim.
2. **Insurance purposes** – The images are being obtained for the insurance company for their purpose sand interests. The images will be reported by a radiologist or specialist, but for the purpose of providing information to the insurance company. It is not the intent in making the images to use them in the medical management of the individual being imaged. Exposures could occur before the insurance contract begins; during its currency; or when a claim is made on the basis of the insurance contract. Examples would include assessing the significance of pre-existing disorders; assessing the degree of permanent injury; assessing any later deterioration of a disorder; and exclusion of other causes of the disease. Images obtained on the basis of medical indications for diagnosis or treatment, but subsequently used for insurance purposes, are excluded.
3. **Employment purposes** – Either, pre employment: The employer may seek to be satisfied that the prospective employee is in good general health, and hence not a potential liability, or the employer may seek to be satisfied that the prospective employee has the particular health or physical profile necessary for the particular tasks involved or for the particular environment, and hence not a danger to themselves, their fellow workers, or others who might depend on them (such as a pilot). Or, occupational health surveillance with screening exposures based on frequency or other criterion, but not on medical indications specific to a given worker. Note: Exposures arising from specific symptoms/medical condition of a given worker are medical exposures and are not part of this survey.
4. **Immigration purposes** – An exposure made in one country because of a requirement, not based on individual medical indications, given by another country, where positive identification of disease results in refused entry or emigration.
5. **Age determination** – Includes X ray examinations performed to: check the age of older children seeking adoption who have no or poor quality documentary information as to their age; assess the age of asylum seekers or illegal immigrants; assess the age of young offenders, who have no or poor quality documentary information as to their age, in order to decide whether or not adult laws are applicable.
6. **Assessing physiological suitability or status** – Exposures for the assessment of likely suitability for a sport or activity (e.g. projected height for basketball, growth prediction of young dancers or gymnasts); exposures performed to establish the health status of an athlete with respect to a transfer – a commercial transaction. Note, these exposures do not include the use of imaging in sports medicine – exposures based on clinical indications, where the result (either positive or negative) will influence patient management.
7. **Detection of drugs within a person** – The images are obtained to determine whether a person has swallowed drugs or other contraband for the purposes of avoiding detection.

Appendix B. Detailed Results from the Questionnaire

Table B1. Responses for Part A to the question:

Is human imaging for these purposes occurring within your jurisdiction?

Purpose	Number and percentage of regulatory bodies who responded:			
	Yes	No	Don't know	Total
Legal evidence	26 (42)*	22 (35)	14 (23)	62 (100)
Insurance	25 (42)	24 (41)	10 (17)	59 (100)
Employment	34 (54)	22 (35)	7 (11)	63 (100)
Immigration	16 (38)	16 (38)	10 (24)	42 (100)
Age determination	9 (22)	24 (59)	8 (19)	41 (100)
Physiological suitability assessment	7 (17)	22 (52)	13 (31)	42 (100)
Detection of drugs within a person	25 (57)	14 (32)	5 (11)	44 (100)

*Values in parentheses are percentages of the corresponding total.

Table B2. Responses for Part A to the question:

1. *Is the legal basis that allows these procedures to be performed a law or regulation?*

2 *Was "justification" of the use of radiation formally considered in establishing the legal basis?*

Purpose	Number and percentage of regulatory bodies who responded "yes":	
	1. Law or regulation?	2. Justification considered?
Legal evidence	23 out of 26 (88)*	16 out of 24 (67)*
Insurance	14 out of 21 (67)	12 out of 20 (60)
Employment	29 out of 34 (85)	17 out of 28 (61)
Immigration	13 out of 16 (81)	8 out of 14 (57)
Age determination	7 out of 8 (88)	6 out of 7 (86)
Physiological suitability assessment	6 out of 7 (86)	5 out of 6 (83)
Detection of drugs within a person	20 out of 25 (80)	16 out of 21 (76)

*Values in parentheses are percentages of the corresponding total.

Table B3. Responses for Part A of the question:

1. *Does the legal basis specify who can request a procedure for the given purpose?*

2. *Does the legal basis specify who can authorize a particular procedure for the given purpose?*

Purpose	Percentage of regulatory bodies who stated that the legal basis established who could:	
	1. Request a given procedure	2. Authorize a given procedure
Legal evidence	68	73
Insurance	48	50
Employment	81	63
Immigration	77	64
Age determination	86	75
Physiological suitability assessment	67	83
Detection of drugs within a person	71	70

Table B4. Responses for Part A to the question:

1. *Does the relevant regulatory body impose requirements that would afford the same radiation protection to the imaged person as if they were undergoing a medical exposure?*

2. *Does the relevant regulatory body's inspection programme specifically address radiation protection issues associated with human imaging for these purposes?*

3. *Do you consider that there is appropriate and adequate regulatory control of radiation protection for these procedures in your country/state?*

Purpose	Number of regulatory bodies who responded "yes":		
	1. RP same as for a patient?	2. Specific inspections?	3.Satisfied with regulatory control?
Legal evidence	25 out of 27 (93)*	12 out of 27 (44)*	19 out of 28 (68)*
Insurance	21 out of 23 (91)	10 out of 24 (42)	12 out of 23 (52)
Employment	30 out of 31 (97)	14 out of 32 (44)	20 out of 31 (65)
Immigration	16 out of 17 (94)	8 out of 18 (44)	10 out of 17 (59)
Age determination	9 out of 10 (90)	3 out of 10 (30)	3 out of 10 (30)
Physiological suitability assessment	7 out of 8 (88)	4 out of 8 (50)	3 out of 8 (38)
Detection of drugs within a person	22 out of 24 (92)	10 out of 24 (42)	14 out of 23 (61)

Table B5. Responses for Part B to the question:

Are imaging procedures (screening) for these purposes being performed in your country or state?

Human imaging (with ionizing radiation) for the detection of concealed objects on:	Number of regulatory bodies who responded:			
	Yes	No	Don't know	Total
Airline passengers	9 (14)*	49 (78)	5 (8)	63 (100)
Persons crossing a national border	4 (7)	43 (75)	10 (18)	57 (100)
Visitors to prisons	3 (5)	45 (76)	11 (19)	59 (100)
Prisoners within a prison	2 (3)	39 (67)	17 (29)	58 (100)
Visitors to court houses or public buildings	0 (0)	52 (90)	6 (10)	58 (100)
Other persons	0 (0)	37 (74)	13 (26)	50 (100)

8 NON – MEDICAL IMAGING (MEDICO-LEGAL) EXPOSURES – THE UK EXPERIENCE

Steve Ebdon-Jackson

Health Protection Agency, United Kingdom

8.1 Introduction

The EC Directive 96/29/Euratom (the Basic Safety Standards Directive (BSS)) provides for Europe a high level framework for the health protection of individuals against the hazards of ionising radiation. Article 6 of this Directive lays down requirements for the justification of types or classes of practice. These include exposures as part of an individual's medical diagnosis or treatment.

The importance of medical exposures as a contribution towards the total radiation dose received by individuals has been recognised by an additional Directive – 97/43/Euratom (the Medical Exposure Directive (MED)). This specifies that medical exposures include a range of exposures in addition to those as part of medical diagnosis or treatment, including those as part of medico-legal procedures. Article 2 of the MED defines medico-legal procedures as those that are performed for insurance or legal purposes, where there is no medical indication. While this definition is welcome, it has not provided absolute clarity and many Member States have stretched this definition to include a range of exposures that are neither diagnostic nor research but require the principles and processes of individual justification and optimisation to be applied and dose limits to be excluded.

This lack of clarity and consistency across Member States has been recognised by the European Commission's Article 31 Group of Experts and it is expected that the revised Basic Safety Standard Directive will drop this category of medical exposure, introducing the more comprehensive term "non-medical imaging". This approach makes a clearer separation between those exposures that are normally associated with an individual's healthcare and those conducted for other reasons. Nevertheless, consideration of existing approaches to exposures as part of medico-legal procedures can provide an approach for the future and highlight the important criteria that should be applied to ensure adequate protection of the individual.

8.2 Current UK Approach

In the UK requirements for these exposures are implemented primarily under the Justification of Practices Involving Ionising Radiation Regulations 2004 (JOPIIR) and the Ionising Radiation (Medical Exposures) Regulations 2000 (IR(ME)R. The facilities provided by both sets of regulations are used in combination to provide the level of safety and the requirements for exposures of individuals as part of medico-legal procedures.

The JOPIIR identify a range of types of practice that existed when the BSS was adopted and include both the purpose and the type or class of practice. The intention is to include all practices from all sectors. As an example, in the non-medical sector the enrichment of

uranium through the use of centrifuge processes is identified as a specific type or class of practice.

For medical diagnosis, the JOPIIR identifies that the use of radiography, fluoroscopy, CT and in-vivo and in-vitro nuclear medicine apply as existing practices, whereas for health screening, only radiography and in-vitro nuclear medicine apply. Specifically, for medico-legal exposures, radiography, fluoroscopy, interventional radiography, CT and in-vivo nuclear medicine can be used. Neither these regulations nor guidance provide a comprehensive list of medico-legal procedures. All new procedures which might be considered as medico-legal are considered on a case-by-case basis. When assessing new procedures for inclusion within this category, it is considered that it is sufficient for an exposure to be part of a process that is itself specified within a legal process. It is not necessary for the medical exposure to be expressly included or referred to within a legal instrument, regulation or legislation.

The IR(ME)R implement the MED and address individual medical exposures. They include within regulations 2 and 3 the definition and inclusion of medico-legal exposures within the scope of the Regulations. The Regulations broadly implement the MED and emphasise the requirements for justification and optimisation. In addition, the IR(ME)R specify duty holders and their responsibilities, including those of the referrer and the practitioner. The referrer is required to provide clinical data which provides the basis for the justification of the exposure. The justification itself is undertaken by the practitioner. The regulations clearly define that the referrer and the practitioner must be healthcare professionals.

The application of these two sets of Regulations can be illustrated by considering two types of exposure:

1. x-ray exposure of suspected drug smugglers
2. x-ray exposure of suspected drug swallowers

The identification of drug smugglers at national borders is included within JOPIIR and the use of x-ray exposures is identified as an existing type of practice using radiography. Although this practice is not identified in regulations or legislation intended to address this illegal activity, there are legal processes in place to detect and detain suspected drug smugglers and as such it is deemed that x-ray exposures of drug smugglers can be considered as a medico-legal exposure, and therefore subject to the requirements of IR(ME)R.

In contrast, the identification of drug dealers who swallow drugs to avoid detection when apprehended (drug swallowers) are not included within JOPIIR as the practice was not identified in 2000. It is considered therefore as a new type of practice. In 2005, the Drugs Act 2005 provided for the x-ray examination of such drug swallowers and therefore there is little doubt that these exposures can be classed as part of a medico-legal procedure. Again, the full force of IR(ME)R applies.

The practical implications for both of these types of exposures are the same. In each case, the referrer and the practitioner must be healthcare professionals. Therefore neither customs officials nor police officers alone are allowed to request or justify these exposures. In each case, all exposures must be undertaken with the full involvement of a medically qualified individual and other healthcare professionals.

8.3 Discussion

The x-ray procedures utilised for these examinations include abdominal radiography and CT and a reasonable degree of contrast resolution is required if the examination is to provide

reliable information. In each case, the radiation doses involved are in the range of 0.5 – 1.5mSv. These doses levels in themselves do not have implications within the context of medical exposures, where dose limits do not apply.

The intention to remove exposures as part of medico-legal procedures from the category of medical exposures has strong conceptual merit. It emphasises that these exposures are not part of the individual's own diagnosis or treatment. Nevertheless, in doing so, practical issues may emerge such as the application to these exposures of dose limits for members of the public and removal of the need for individual justification. The practical implications of doing so may also remove the intended merit and benefit to society of these exposures – for instance will imposition of the public dose limit mean that such procedures can be used on only one or two occasions per individual in any year?

8.4 Conclusion

The concept of exposures as part of medico-legal procedures has been addressed within the UK legislation and regulation intended to implement European Directives. It has proved to be effective within the regulatory framework and provides the intended protection for individuals and society as a whole. Repositioning of medico-legal exposures with non-medical imaging has clear philosophical advantages but may introduce operational difficulties and reduce or remove some of the safeguards currently in place.

9 NON-MEDICAL IMAGING EXPOSURES: HEARSAY AND RESEARCH

Hermann Vogel

Hamburg, Germany

9.1 Introduction

Since the last meeting, non-medical imaging exposures have remained a topic. Own research has concerned the exposure dose due to the search of persons. In national and international meetings, the results have been presented to the public and have been published in national and international journals. In co-operation with the European Congress of Radiology and the Deutsches Röntgen-Museum, exhibitions have been created, which have treated the search of persons, the search for persons and related exposures. Today, six exhibitions exist in 7 languages; they have been shown more than 60 times all over the world. These publications and the exhibitions induced discussions about the radiation risk, about the probability of terror attacks and the possibility of their prevention, about the perception of the available technology by the public, and about the way politicians choose aspects for their statements which have a chance to be reported by the media and noticed by the public.

In the following, some of these topics shall be treated.

9.2 Material and Methods

Own research concerned the

- exposure dose connected to the search of persons
- analysis of the possibilities of the technology for the search of persons, luggage and shipped goods, including containers, autos, trucks and railway cars
- probability of future designs of terrorist attacks
- proof of previous torture by diagnostic imaging.

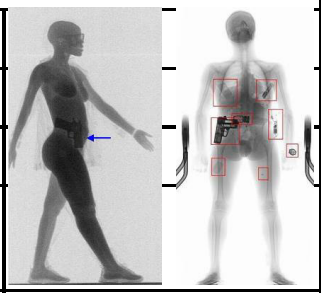
9.3 Search of Persons

In our working group, *measurements* have been performed by Hupe and Ankerhold[1,2] from the PTB (Physikalische Technische Bundesanstalt in Braunschweig). The possibilities of technology have been analysed by Haller[3], who evaluated the imaging material of the manufacturers and of the internet; his work intended to make predictions about future terrorist attacks and the possibilities and the limitations of different technology designs.

The exposure dose in Backscatter Imaging is less than in Transmission Imaging (Table 3.1). A transatlantic flight results in a higher exposure dose than any of these exposures for control – the equipment used has to be adjusted to low values. Individuals obtain such a dose by radiation from natural sources in seconds to hours. The choice of the holiday site

can make a larger difference to radiation exposure than the exposure of the flight and the security control.

Tab. 1: Exposure Dose, Hp(10), during Flight, Controls, and Holidays modified after 1 and 2

	Hp(10) in µSv	
Backscatter Imaging	***0.1***	
Transmission Imaging	***6***	
Frankfurt - New York 7 hours	35	
Germany, external exposure natural sources	2100 µSv/year	40µSv/week
Chest X-Ray	10-100	
CT	8000-15000	

The *analysis of image material* from the manufacturers and those who employed the equipment indicated possible future developments of terrorist attacks[3]: Body-packers and body-stuffers transported up to 2.5 kg drugs in their bodies. Such an amount of Semtex or C4 could easily destroy the outer wall of an airplane. The larger parcel in the rectum and/or the vagina could be accessible even in the plane; other components like the ignition device a clock and a cell phone could be transported into the airplane separately; a suicidal attack or the placement of a concealed explosive device which could be ignited via the cell phone seemed realistic. It seemed all the more thinkable when one takes in consideration that large items have been introduced and hidden in the rectum and the vagina for other reasons (figures 3.1 - 3.3).

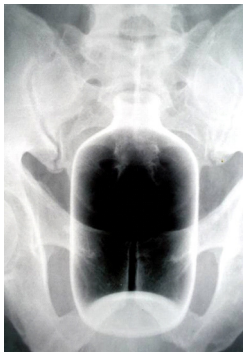


Fig. 3.1: Cell phone in the rectum. In prison, the drug dealer continued his business[4]

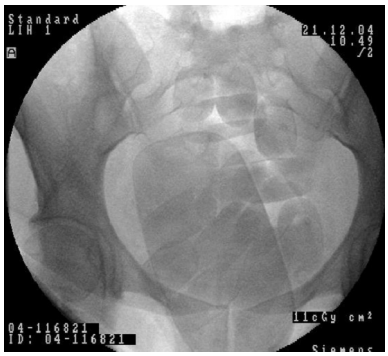


Fig. 3.2: Body-stuffer. Large Cocaïn parcel in the vagina

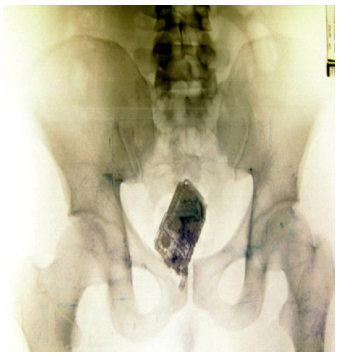


Fig. 3.3: Bottle in the rectum, self stimulation

Recently these analyses have been verified by new events: A key Saudi Prince has been injured in a terror attack. “United States private sector intelligence group Stratfor said the terrorist adopted the novel tactic of concealing an improvised explosive device (IED) in his anal cavity. This is a technique more often used by drug mules.” This attack has been connected to airline security: ”A terrorist bombing in Saudi Arabia has raised fresh concerns about airline security after the bomber detonated an explosive device concealed in his anal cavity.”[6, 7]

W*hole-body scanners have been in the media* quite recently: In February 2009, nuns protested against a parade float of the carnival of Mainz. The media had published pictures from the float, which showed the figure of a nun who had been scanned at an airport; the figure wore underwear and was practically naked[8]. In April 2009, the media reported about the initiative of the EU to test whole body-scanners at airports. Instead of whole body scanner they referred to “Nacktscanner”; the reports were connected to interviews of politicians. These stated that such equipment would not be admitted, because of the compromise to human dignity. This was a reference to Art. 1GG (Grundgesetz, German Constitution) stating “Die Würde des Menschen ist unantastbar” (The dignity of the human being is untouchable)[9].

9.4 Age Determination and Search for Persons

In France, recent legislation classified sex with minors a legal offence. The consequence has been that a male who has sex with a minor prostitute will be punished. The young women – often from poor countries – have an interest to avoid punishment of their clients because this would hurt their business. Their age would be determined with a radiograph of the hand. In the discussion with the police and the medico legal radiologists, they insist that they are older than 18.

In Germany, young criminals claim to be younger than 18 because they want to be judged according to the law for minors; this law envisages less severe punishments for minors compared with those for adults. These two observations demonstrate that general rules are more difficult to draft than one would expect at first sight.

In Kassel, Germany, inmates of the prison repeatedly escaped by hiding in the laundry packing. The administration applied for X-ray equipment for control. The request was dismissed with the argument that X-ray exposure to humans for other than medical reasons had to be regulated by law; the equipment should serve the detection of evaders which meant that exposure of humans was considered possible at least. There was no law to justify such an exposure, therefore the request could not be granted.

9.5 Art

At the ECR 2006, Benedetta Bonichi, an Italian artist, had an exhibition, which showed radiographs. Among others, there could be seen a whole body radiograph of the artist herself with the title “Pin up”; another radiograph showed the artist together with a partner and had the title “Kiss”, and a third “Banchetto di nozze” displaying several persons (fig. 5.1), which bore a resemblance to the last supper of Leonardo da Vinci. The radiographs had been produced in cooperation with the Università Sapienza di Roma.

5.1: Benedetta Bonichi – Banchetto di nozze10

9.6 Torture

In a project, my group and I examined in Chile persons who claimed to have been tortured under Pinochet and asylum seekers in Vienna[11]. We wanted to know whether previous torture could be proven or made probable with diagnostic imaging. Rapidly it became apparent that the possibilities of diagnostic imaging would be limited to exceptional cases like broken bones and introduced foreign bodies (fig. 6.1 and 6.2). Previous beating could be visualized for up to two years with scintigraphy (fig. 6.3)[11,12]

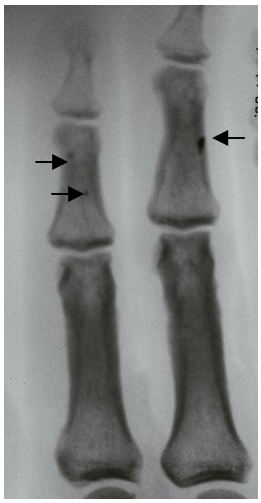


Fig. 6.1: Nail torture. A wire had been introduced under the fingernails, when retracted some splinters have remained.

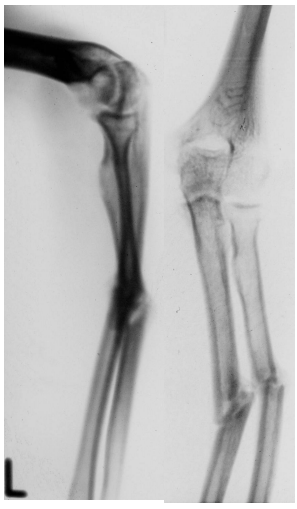


Fig. 6.2: Parrying fracture. The person tried to protect his head when bee beaten.

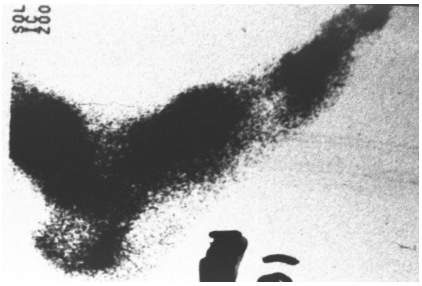


Fig. 6.3: Falaka. Increased uptake in scintigraphy. 6 months after the beating of the feet.

9.7 Murder

In 2007, the *murder of Litwinenko* with Polonium 210 (^{210}Po) in London attracted the interest of authorities and the public[13,14]. One central question was who transported the ^{210}Po to the meeting in the Pine Bar in the Millennium Hotel in London. It was known that at least three persons had been present, including the victim. The authorities followed the hypothesis that on the way to the meeting the person transporting the ^{210}Po could have left traces of the substance. Finding traces of ^{210}Po would help to identify the presumable killer. One of the three had travelled to London via Hamburg; he had stayed in the apartment of his ex-wife and for a night in the apartment of his former mother in law. In these places, the authorities of Hamburg looked for ^{210}Po (fig. 7.1 and 7.2). They brought the woman and the children to my hospital for collecting excrement. In the woman and in one of the two children traces of ^{210}Po could be found. This was exceedingly demanding because the presence of ^{210}Po has to be proven with alpha dosimetry – which is performed only by a few specialized institutions; in our case it has been performed in Heidelberg. To detect ^{210}Po by its gamma emission is practically impossible.

Fig. 7.1: Looking for ^{110}Po in the car and the apartment, where one of the suspects had been during his stop over in Hamburg

Fig. 7.2: Asklepios Klinik St. Georg Hamburg. The suspect's ex-wife and children had to stay in the hospital for collecting their excretions in search of traces of ^{110}Po

The suspect denied having transported the ^{210}Po; he insisted that the ^{210}Po had contaminated his ex-wife, the apartment and his children on other occasions. However, while in Hamburg the person had visited the immigration office to prolong his residence authorisation; there, he had signed the request for extension. The analysis of this form resulted in the detection of traces of ^{210}Po.

9.8 Secret Services

We reviewed our material about the use of radiating material by the Stasi (Staatsicherheit, special unit of the Ministry of Security (MfS) of the former German Democratic Republic). We wanted to know whether there were guidelines for the agents who used radioactive substances. It became evident that the MfS took the existing radiation protection laws of the GDR into consideration, and interpreted them according to their actions by assigning limiting exposure values[15,16]: for proving and uncovering punishable and anti-state actions, the following annual limiting exposure values have been valid for explorative action:

(a) for all male and female persons up to 35 years, who are not professionally exposed:
Group I: Gonads and the haematopoietic organs up to 80mSv.
Group II: Eye lens, GI-tract, liver, spleen, kidneys, lungs, muscles, fat tissue and others with exception of the organs of group I,III, and IV up to 120mSv.
Group III: Bone, thyroid, skin up to 120mSv.

Group IV: Hands, lower arms, feet up to 400mSv.

(b) For women up to 35 years of age as a rule, the half of the indicated values ought not to be exceeded.

(c) For children it has to be guaranteed that heir exposure must remain below 1/10 of the values indicated under (a).

(d) For women, who are pregnant or nursing, it has to be guaranteed that the exposure remains under 5 mSv. Furthermore, one has to pay attention, that persons, who are exposed during their actions with radiating substances and who have been exposed up to the limiting exposure values, will be in contact with these substances no more than 3times in 10 years maximum[15] .

In table 7.1 the exposure values for agent (pursuer) and target person are indicated, which had to be observed.

Table 7.1 Exposure dose considered acceptable by the MfS for the agent (pursuer) and for the person being pursued (target person)[14, 15]

Distance from the body	Permissible dose per time	Site of transport	
3 cm	< 1 mSv/week	Trouser pocket	Agent MfS
3 cm	< 3 mSv/ week	Coat pocket	Agent MfS
30 cm	< 1 mSv/ week	Brief case	Agent MfS
3 cm	< 1 mSv/ week	Trouser pocket	Target person
3 cm	< 80 mSv/action	Coat pocket	Target person
30 cm	< 80 mSv/action	Brief case	Target person

Examples how the Stasi employed radioactive substances have been published by our group[14, 17].

9.9 Discussion

Airport security is an important topic in the search of persons with X-rays. The discussion is highly emotional and not always to the point[18]. Ionizing radiation may lose its importance as the main argument against these controls, when terahertz radiation is employed on a larger scale.

The analysis of the available technology can provide an insight into the design of future terrorist attacks. Already today, suicide bombers could attack airplanes with incorporated IED (improvised explosive devices); these IED could be concealed in their gastrointestinal tract, in the vagina or somewhere else, placed by surgery. Whole body scanning seems the only option to prevent such attacks. The IED could be ignited by the terrorist him/herself for example by calling the incorporated cell phone.

In Germany, laws limit the exposure of humans by ionizing radiation. The exposure for medical reasons is regulated in the Röntgenverordnung, the exposure for age determination could be justified and demanded by a judge using the code of criminal procedure (Strafprozessordnung). Many radiologists may know this; however, many of them behave in a way, which replaces the medical indication or the request of the judge to produce a radiograph by the consent of the person. The judges do not see a problem to obtain the information about the age of a person. If a radiologist refuses to produce the radiograph and the expertise, the judge would send the person to another institute or radiologist. The judge is not interested in the reasons for the refusal to perform.

The medical ethics is not conclusive concerning the age determination. It seems possible to argue that the wish of the person to be examined should be the guideline; however, following

the wish of a person may result in acting against the person's interests. It is to question, whether the radiologist is obliged to evaluate what the person's best interests would be. The situation in France compared to the situation in Germany shows differences.

The dilemma of medical ethics is evident where torture is concerned. Being recognised as a torture victim is an understandable wish and sometimes even a vital necessity, for example if a request for asylum is at stake. An evaluation, which is purely scientific, of the X-ray findings seems difficult when the basics of medical ethics are taken into account.

Often objections against the fact that people claim to have been tortured exist; political correctness forces to leave them unexpressed and hidden. Our group encountered such objections, when we asked for permission to look at radiographs with the viewing boxes in a hospital, which was near to the centre in Chile, where the torture victims were taken care of. Our request was turned down. No explanation was given.

9.10 Conclusion

In whole body scanning, the exposure dose seems low compared to the exposure due to natural sources. Backscatter imaging is possible with minimal exposure, transmission imaging means a higher exposure, which seems to be minor compared to the additional exposure during a flight. Exposure for non-medical reasons can be approached by ethics and it can be regulated by law.

9.11 References

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10 DRUG SMUGGLING BY "BODY PACKERS"

Mr. Tony Magnusson

Director of Operations, Western Sweden
Swedish Customs, Law Enforcement

10.1 Introduction

This paper will consider the topic of 'Body packers' and examine related issues. It will look at the standard procedure used for these individuals. Experiences in other Nordic countries will be reviewed. The use of CT will be considered and it will be contrasted to alternative imaging or other methods.

10.2 Background

First of all I would like to explain what a body packer is and then I will briefly describe the procedure when we try to detect them. Besides how we manage that in Sweden, I will also tell you about the experiences from some other countries. Although I am just a simple law enforcement officer and not a scientist, I will also try to explain why CT is used and a little about the alternatives. At the end I will also present some points and issues that I have identified during my studies when preparing this presentation.

I will talk about "body packers", but what is that? I use that expression as a technical term for people who use their own body for concealment of illicit drugs. Other names that are rather commonly used (at least amongst customs officers) are "swallowers", "stuffers" (insertion of packets in rectum or vagina), "internal carriers" or just "couriers" or "mules".

10.3 Body Packing

Cocaine and heroine are the most commonly body packed drugs, but we sometimes also find other drugs such as cannabis, amphetamine, ecstasy and recently we made a seizure of raw opium. It can also happen that a body packer has both cocaine and heroine at the same time.

Usually the small packets consist of 8–10 grams of drugs, but we have seen examples of packets as small as 5 grams and as much as 20–25 grams. One body packer normally swallows 5–100 packages, which in most cases means that they have about 500–1000 grams of illicit drugs in their body. Again, we have seen examples of both less and more and the worst case I have heard of was a man that had 2.2 kilos.

The drugs used to be packed in some kind of latex sheath and condoms are also very often used. When the inner cover is tied at the open end, it is packed into other layers of latex and finally it is often sealed with a hard wax coating. In some cases they use various kinds of wrapping in order to alter the density in an attempt to limit the risk of detection.

Nowadays the packets are wrapped in a very professional way and probably by using an automated process. However, there are examples of not so well packed drugs and that may lead to a disaster. Each packet contains more than enough drugs to be lethal if it breaks when it is still in the body.

10.4 What Drives a Body Packer?

It's of interest to consider why people become body packers? Internal concealment (i.e. inside the human body) is one of the most common modus operandi used for smuggling of illicit drugs. The method is mainly used by couriers that use flights for transportation, but also in connection with other means of transport. As the security checks at airports have become more and more stringent the last years, internal concealment is the modus operandi with the lowest risk (from a smugglers point of view) and so called body packers are a big challenge to customs officers all over the world.

Money or other material compensation is of course one of the most common reasons as to why people are smuggling drugs. Another reason can be that a person is promised a safe and paid passage to another country. We also know of examples when someone in a person's family has been taken as hostage in order to force him to perform a body pack smuggling.

In some cases the smugglings are just individual initiatives, but smuggling by body packers is also a very well organized business. An investigation we had recently, showed that various couriers that we revealed in Sweden and Norway in a short time period were all sent out from the same apartment in an European country. They came from all over the world and then they were directed to that apartment, where they got prepared drugs to swallow and when they were ready, they got tickets and information where to go.

A body packer could actually be anyone nowadays, both men and women at various ages and unfortunately there are also a few examples of young teenagers and even pregnant women. Sometimes we can see that the body packers predominantly originate from certain countries or regions, but that varies from time to time.

10.5 Experience in a European Airport 2009

This is a true example from a big European airport last summer. It shows that the business is well organised. In two days, within a week, customs detected six body packers. They were of various nationalities, but all came from the same country in Central America. The amount of drugs varies and one body packer had as much as up to 2.2 kilos!

Date	Substance	Weight (kg)	No. of Packets	Gender	Age
28.06.2009	Cocaine	1.0	70	Male	38
	Cocaine	0.4	30 + 1 large packet	Male	22
	Cocaine	2.2	173	Male	42
5.07.2009	Cocaine	1.0	79	Male	27
	Cocaine	1.3	105	Male	38
	Cocaine	1.0	69	Male	46
	Cocaine				

10.6 The Procedure – Customs

Selection of travellers for inspection is based on observations by the customs officer (using his experience and intuition), information from our intelligence service or a tip. If the primary inspection of the traveller's luggage does not give any result, but we still have reason to believe that the person is hiding illicit drugs, a customs officer has far-reaching authorities to go further. A customs officer may conduct what we call a *body search* or a *superficial body examination* and also ask for a urine sample. If those checks do not give any result either or if the urine sample indicates the presence of drugs in the body, the only remaining power is what we call an *extensive body examination*.

10.7 Extensive Body Examination

According to The Swedish Code of Judicial Procedure, an *extensive body examination* may be performed if a person is reasonably suspected of a punishable offence for which imprisonment may be imposed. The decision to perform such an examination must be made by a public prosecutor and it must be carried out at a hospital and by a medical doctor. It is up to the customs officer to convince the prosecutor that a person is a reasonably suspected body packer. It happens that we fail to do that sometimes and one reason may be that we lately had some suspected body packers that have not had any internally concealed drugs. We know that criminal organizations sometimes send out so called dummies that fit in to the profile of a body packer, but do not carry any drugs.

The examination can be made by vaginal/rectal palpation, rectoscopy, normal X-ray (plain film), CT or in some cases ultrasound scanning or sometimes a mix of the various methods. Which method is used, may vary between different countries and even between various hospitals within the same country. However, it seems that CT is becoming more and more common as the primary method.

10.8 What if suspicious packets are identified?

If drugs are detected inside the body, the body packer is nowadays always taken to a care unit at the hospital for observation. If no complications set in, the normal procedure is to let nature take its course and just wait for the body packer to "produce" the drugs. In those cases it is always customs that is responsible for guarding the body packer.

At some hospitals they refuse to take a body packer to a care unit as long as his/her general medical condition is good. In those cases the body packer is taken in to custody.

10.9 Example from Norway

This is an example of a body packer that was detained in Bergen in Norway at the end of 2007. The man, a 46 years old Turkish citizen reside in Germany, travelled from Casablanca in Morocco via Amsterdam in Holland to his final destination in Bergen, Norway. The customs officers became suspicious and the man was taken for body examination, which detected unknown packets. The man admitted that he had swallowed 150 packets with 10 grams of cannabis (hashish) in each packet. Al1 in all 1.5 kilos!

Figure 1 1500g cannabis (150 x 10g capsules), Bergen, Norway 2007

10.10 Questionnaire

In order to see how the procedure with detection of body packers works in other places, a short questionnaire was sent to the Central Customs Administrations in the Nordic countries and I got answers from Denmark, Iceland, Norway and my Swedish colleagues.

The questions asked were as follows:

- Who decides if a person is to undergo a scan?
- Where are the examinations carried out?
- Does the customs officer and/or the prosecutor take in to consideration that a young woman may be pregnant?
- Is CT or plain radiography used?
- Do you have any statistics or can you make an estimation of the number of scans per year and the hit rate?

10.11 Results of the Questionnaire

10.11.1 Who decides if a person is to undergo a scan?

The procedure is about the same as in Sweden, which I described previously. Due to differences in the judicial systems, Customs in some countries must involve the police when they suspect or detect a serious crime.

10.11.2 Where are the examinations carried out?

In all countries the body examination (incl. X-ray) is carried out at a hospital.

10.11.3 Pregnant women?

The question was: Does the customs officer and/or the prosecutor take in to consideration that a young woman may be pregnant?

- No, that is something for the physician to take care of
- If a pregnancy test is positive some hospitals uses ultrasound to examine the body of a pregnant woman
- One radiologist in Sweden said that he would use CT also for examination of a pregnant woman

10.11.4 Is CT or plain radiography used?

In both Sweden and Norway, CT is the primary tool. (One hospital first uses rectoscopy and then plain radiography.). In Iceland, plain radiography is almost always used as the primary tool. (There are a few exceptions). In Denmark, first plain radiography is used and if the result of that examination is uncertain, CT is used.

10.11.5 Statistics

The statistics are a mixture of figures from 2007 and 2008. In some cases there were no exact statistics available, but in those cases estimations were made and I consider the presented statistics to be pretty reliable.

Country	How many per year?	Male /Female?	Confirmed to have drugs?
Sweden	≈ 55	80 % M / 20 % F	≈ 50 %
Iceland	42	30 M / 12 F	50 %
Denmark	16	14 M / 2 F	56 %
Norway	≈ 60	No information	≈ 50 %
TOTAL	≈ 173	About 20-25 % are female	≈ 50 %

In total for the four countries about 150 – 200 persons a year had to undergo a CT-scan or plain radiography. About 20 – 25 % of them are women. The “hit rate” is about 50 % even if it varies from time to time. For example at Arlanda Airport in Stockholm (SE) the hit rate was only 14 % in 2007.

10.12 Why CT?

When I took my first suspect body packer to a hospital over 20 years ago, the routine was to first make an examination by palpation and thereafter rectoscopy. After that a plain abdominal radiography was performed. As I said before, CT is nowadays the first choice at the hospitals in Stockholm and Gothenburg and that is also the primary method used in Norway.

I asked a Swedish radiologist about the reason for that and the answers I got was:

- Higher resolution,
- Better sensitivity,
- Faster,
- CT is widespread today,
- Technological development has led to lower doses for CT,
- It is better to make one CT-scan instead of many scans with plain radiography,
- Possibility to determine type of foreign bodies.

10.13 Example

An article in a Swedish medical journal[1] tells about studies made with both model trials (a plastic drum filled with water and drug packets) and with two suspected smugglers. The conclusion was that CT is a more reliable tool and it revealed a lot more packets than plain radiography. The author meant that the results are not only important from a judicial point of view, but also from a medical viewpoint. Especially it is important to use CT if a final scan is necessary after the body packer is said to be “empty”. Otherwise there is a very big risk for intoxication if a remaining (not detected) packet should burst or start to leak.

In this example you can see, in figure 2 (a), an image from a plain abdominal radiography, which doesn’t show any clear signs of drug packets.

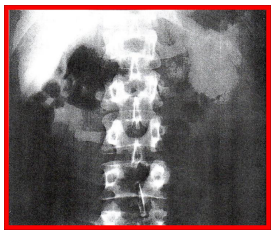

Figure 2 (a)

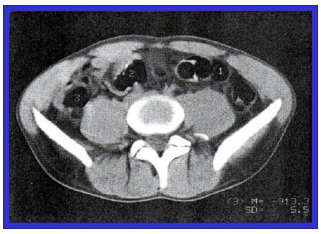

Figure 2 (b)

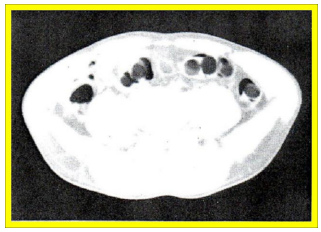

Figure 2(c)

In figure 2 (b), you can see a CT-image, in which some suspected packets or perhaps gas bubbles are visible. A measurement of the CT number (attenuation coefficient) shows that number 1 and 2 in this image has a value of about 250 Hounsfield units (HU) which indicates drugs (cocaine or amphetamine) and number 3 in this image has a value of 913 HU, which indicates a gas bubble.

In figure 2(b), you can see another CT-image with a different window setting and that image reveals additional packets.

10.14 New England Journal of Medicine

Another article, in the New England Journal of Medicine[2] also proves that plain abdominal radiography is not sufficiently sensitive. In that article there also is a table with a comparison between various radiographic approaches (figure 3):

Table 1. Radiographic Approaches to the Identification of Body Packing.

Study	Indications	Sensitivity	Comments
Plain abdominal radiography	Screening test	85–90%	Sensitivity for finding small numbers of packets may be lower May miss substantial numbers of packets[14,24]
Ultrasonography	Screening test	Not established	Has the potential to be very useful Large studies needed
Computed tomography	Used if equivocal results obtained on initial screening test Used to document that gastrointestinal tract is clear	Not established	Large studies lacking One false negative study reported[25]
Contrast-enhanced abdominal radiography	Used if equivocal results obtained on initial screening test Used to document that gastrointestinal tract is clear	96%	Reported sensitivity based on one study[20]

N ENGL J MED 349;26 WWW.NEJM.ORG DECEMBER 25, 2003 2521

Figure 3

"The comparative value of CT and barium-enhanced radiography has not yet been determined. Since barium may interfere with the subsequent performance of CT, CT may be the preferred initial choice." In the previously mentioned article in Läkartidningen (≈ Swedish Medical Journal) it is also said that CT is faster and easier than contrast examination.

10.15 Disadvantages of using CT

When I have studied the articles I mentioned and spoken to radiologists in Sweden, I have identified a few disadvantages of using CT instead of plain radiography:

- Higher dose to the suspect,
- Higher costs,
- It requires co-operation from the suspect to avoid movement artefacts.

10.16 Points at Issue

The conclusion is that CT is more and more used for examination of suspect body packers. As a representative of a law enforcement agency, I think CT is a very good method for the purpose of detecting internal concealment of drugs. However, I am not a scientist and I am aware that there are differing opinions amongst various physicians and radiologists. During my "studies" I have identified some points of issue:

- Is it right to expose people with X-rays without medical indication?
- What dose is reasonable in such case?
- How do we handle possibly pregnant women?
- Who will be responsible if someone claims that the CT-scan of a suspected body packer is the reason for some kind of future illness?
- What if an X-ray image of a suspected body packer (for instance a paperless African citizen) indicates the occurrence of a tumour?

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11 CARGO SCANNING – THE EUROPEAN EXPERIENCE

Michael O Dochartaigh

Investigations Coordination Unit, Revenue, Ireland

11.1 Background

In recent years there has been a major increase in the worldwide movement of containerised traffic. This has resulted in an increased opportunity for cross border trafficking of illicit drugs, explosives and other contraband. Faced with the challenge of intensifying inspection rates of containers and trucks, while ensuring minimum disruption and expense to legitimate trade, Customs and other enforcement agencies have increasingly turned to X-ray and gamma scanners to screen import and export consignments.

11.2 Brief History of Container Scanning in EU

The earliest scanning systems were large fixed installations; the first maritime container scanners being deployed at Calais and Folkestone in 1993 for use at the Eurotunnel. Between 1994 and 1999 similar high-energy systems were installed in Le Havre, Hamburg, Rotterdam and Vaalima.

In 2001 HMRC introduced a fleet of mobile scanning systems into the UK primarily to tackle the ever-increasing problem of tobacco smuggling.

The first “relocatable” system was commissioned in Antwerp in 2004.

At the present time, container scanners of varying formats are deployed throughout the EU at major ports and border crossings.

11.3 Types of Scanners

Fixed Systems, as the term implies, are permanently constructed structures usually using linear accelerators having an energy source in the order of 8-9 MeV. They are relatively expensive and are usually deployed in large seaports having a large throughput of containerised traffic. Traditionally they have tended to provide the best performance especially in terms of cargo penetration and scanning throughput.

Mobile Scanners, which are generally built on conventional truck chasses, have the advantages of lower cost and greater flexibility. They can be readily moved from one scanning location to another according to risk and traffic requirements. Until recently they have had an energy range of between 300keV and 4 MeV, but 6MeV energy systems are now available. The disadvantages associated with mobile scanners include higher maintenance levels, reduced system availability owing to travelling times, and a relatively large footprint in port areas to provide for significant safety exclusion areas.

Relocatable systems incorporate many of the advantages of the fixed systems including good reliability, high quality imaging and the capability to use dual-view format. They are available with energies of up to 6MeV and are significantly less expensive than fixed scanners. While they can be relocated from one scanning site to another, a significant amount of permanent infrastructure is required for each site, and the time taken – 6 to 8 weeks – means that they are relocated infrequently. While scanning systems are available in both X-ray and gamma formats, the majority of scanners now operating in the EU use X-ray energy sources.

11.4 End User Requirements

The primary end users of cargo scanners are Customs administrations and other Law Enforcement Agencies such as Immigration and Police services. However, the end user community can be taken to include other groups such as Port authorities, Shipping Companies, Importers/Exporters, Truck Drivers and other members of the public upon whom cargo scanning impacts. As such, the requirements of these various groups must be taken into account in the operation of detection technology applications.

In terms of detection priorities, the following are the most common:

- Illicit drugs
- Arms and explosives
- Cigarettes and alcohol
- Radioactive materials
- Nuclear materials
- Counterfeit goods
- CITES (flora, fauna and endangered species) and other prohibited goods
- Other contraband

The order of priority may alter according to region and associated risk, but container cargo scanning has proved to be an effective detection tool in all of these areas.

11.5 Radiological Safety

The use of ionising radiation for cargo scanning purposes can be justified on the grounds that any radiological risk is trivial and is far outweighed by the societal benefits that they can bring. Cargo scanning must, however, be subject to a well- regulated radiological safety regime and must comply with the terms of the licence issued by the regulatory body. Important factors include the appointment of a Radiological Protection Advisor (RPA) and Radiological Protection Officer (RPO), appropriate training of all operators, formulation of radiation safety procedures, establishment and preservation of safety zones and ongoing dose monitoring.

The size and nature of safety exclusion zones depends on the value of the energy source and the extent of any shielding measures put in place, whether or not integrated into the scanning system. In the case of mobile scanners, a typical zone may measure up to 1,500m². Such zones are preserved by infrared sensors which act to shut down the system's operation should a beam be broken and/or physical barriers such as traffic cones/tape etc.

An important consideration in radiation safety is the prevention, as far as possible, of inadvertent exposure to stowaways. The possibility of a stowaway being present in a target container is influenced by such factors as source and destination countries, shipping routes,

and the nature of container cargoes. Precautions to limit inadvertent scanning include the broadcasting of warnings in several languages and the use of sirens to signal the commencement of scanning. Where scanning of persons is unavoidable, the radiation dose involved is relatively trivial, normally not exceeding 10μSv for a single scan.

11.6 Image Interpretation

Modern container scanners provide good quality image-based information relating to shape, density, size and positioning of cargo, and are best suited to the detection of risk goods or threat objects of known shape, size and density e.g. firearms, alcohol and cigarettes.

Image interpretation forms a critical part of the scanning process and requires operators to have a good awareness of the nature of maritime cargoes, the characteristics of risk goods and knowledge of the design/construction of containers and vehicles.

Irregularly shaped consignments of risk goods such as illicit drugs and explosives are especially difficult to detect. Specialist training in image interpretation can greatly improve performance, although it is fair to say that image interpretation training for container scanner operators has not been developed to the extent that training for baggage screeners performing security scanning at airports has.

11.7 Concealment Techniques

The classic contraband concealment involves placing a “cover load” of expendable goods close to the container doors. This serves to hide the smuggled goods from any partial or cursory examination. Container scanners have had significant success in detecting concealments of smuggled goods in such circumstances.

Smugglers have reacted accordingly by using shielding techniques in an effort to defeat the screening process. These can take the form of straightforward shielding using dense materials such as lead, steel, marble etc, or by concealing the smuggled goods within cargoes having similar shape, form or density to the contraband.

In such cases the experience and expertise of the operators is of paramount importance in detecting any anomaly which may lead to detection.

11.8 Multi-Application Approach

While there is an increasing desire to move towards 100% screening of cargo, it is not currently a viable proposition on a global scale. Accordingly, Customs and other law enforcement authorities must utilise all available tools to detect smuggled consignments.

These include the use of risk analysis and profiling techniques to select targets for further screening. Container scanning and radioactive/nuclear substance detection systems can eliminate many low-risk containers in a speedy and non-intrusive procedure. Where “suspicious” cargoes are selected for physical examination, sniffer dogs, trace detection units and other applications can offer additional help.

The use of container scanners having integrated radioactive/nuclear detection capability provides an extra dimension to cargo screening.

11.9 New and Emerging Applications

The majority of the scanning systems currently in operation use single X-ray radiography, varying in energy between 450kV and 9 MeV. However recent years have seen the introduction of a number of new applications.

These include **Dual View** systems which use a second linac source directed at a different angle. This technique can enhance detection capability by providing additional information to the image interpreter.

Security requirements have resulted in the need to scan an increasing number of containers in shorter periods of time. **Drive Through** scanning, which allows target containers to be driven through a scanner portal without stopping, has been developed to address this need. Early drive through systems suffered from inferior quality imaging, and reduced cargo penetration on account of radiological safety concerns. More recent systems have sought to address both of these issues.

Until recently, **Material Discrimination** capability was not available in X-ray systems having an energy source > 450 kV. The recent introduction of so-called **Dual Energy** applications in high-energy scanners has made it possible to distinguish organic, inorganic and heavy metal materials from each other.

Nonetheless, specific identification of component materials encountered in containerised cargo, using X / gamma–ray scanners, is still not possible. **Neutron scanning** is seen as a potential solution, using fast neutrons to identify the chemical elements of threat materials.

11.10 European Riposte against Illicit TR@ffiCking (ERITR@C)

ERITR@C is an EU-funded project – JLS/2007/ISEC/550 – which aims to find an industrial application for the neutron scanning techniques developed in the earlier EURopean Illicit TRAfficking Countermeasures Kit (EURITRACK) project.

A tagged neutron inspection system (TNIS) portal has been established in the port of Rijeka, Croatia. The system works in tandem with a conventional X-ray scanner whereby a “suspicious” area is identified in the X-ray image and is then referred to the neutron portal for additional screening. The suspect voxel is irradiated by 14 MeV tagged neutrons. Gamma rays are used to characterise carbon, oxygen and nitrogen which are the major elements of threat materials such as drugs and explosives. By measuring relevant elemental ratios such as O: C and N: C, it is possible to distinguish between illicit and legitimate cargoes.

12 THE USE OF X-RAY FOR SECURITY CONTROL – CZECH EXPERIENCE

Karla Petrová, Ivanka Zachariášová

State Office for Nuclear Safety, Prague, Czech Republic

12.1 Introduction

X-ray scanners for security checks have been the subject of discussions for many years but no common internationally recognized opinion and procedure has been implemented so far.

The approach to this complicated issue depends very strongly on the evaluation of the conditions and circumstances in each particular country. There was a European initiative on this field in 2002 when there was a workshop on medico-legal exposures organized in Dublin, however there were no unequivocal and consensual conclusions reached.

The latest official documents addressing this problem are the draft IAEA IBSS and also the latest version of the draft EU BSS Directive. The security control of persons using X-rays is defined as non-medical exposure and the exposure is classified as public exposure. This use of sources of ionizing radiation is understood in IAEA IBSS as not justified unless the assessment of the current threat of terrorism in the particular country shows an elevated risk. This formulation is however still under discussion as well as the appropriateness of the publication of the final judgment in IBSS (exposure is generally justified or unjustified). The EU BSS leaves the justification of such exposures for each member state and for justified procedures requires some conditions for their performance in the same way as is required for medical exposures.

12.2 The Current Situation in the Czech Republic

Recently there were five companies in the Czech Republic distributing sources which have got the type approval for X-ray machines – whole body scanners (using backscatter) – for personal security control. The Czech Regulator in radiation protection - the State Office for Nuclear Safety (SONS) categorised these devices for non-medical human imaging as sources needing authorisation. All types of such devices are thus under regulation and control - regardless the very low doses involved – a feature that is often incorrectly used as a main argument for their widespread use. Based on this fact, one of the conditions of its type approval requires that potential user of such a device is informed that a licence from SONS is required. The applicant for the licence has to prepare all necessary documentation including the justification of the use of the source.

In 2009, SONS received the first request from one airport in the country for the approval of the use of X-ray machine for security control of persons. SONS organized a discussion at a national level inviting the representatives of other ministries and offices which had an involvement in this problem – the Ministry of Health, the Ministry of Interior, the Ministry of Transport – the Civil Aviation Department, the Office for personal data protection, the Civil Aviation Authority. Based on this discussion and further analyses, the response of SONS was for the moment negative. Such use of ionizing radiation is understood as unjustified

under current circumstances and from the point of view of radiation protection. Moreover their use at the airport is influenced also by the fact that current EU legislation doesn't currently allow the use of such security control at the airports – there was only a sort of pilot project testing the use of these devices at selected European airports – however at the end of 2008 there was a discussion initiated by some European representatives which focused mainly on the ethical aspects of the use of such devices. One of the important arguments influencing the decision was that alternative techniques which enable a surface body control of persons and which can identify "suspicious" objects on the body exist.

What should also be pointed out here is the observation that the main driver in the discussion with the regulator and the source of pressure was a distributor of device. Unfortunately there was not a clear and strong signal from the side of the potential user – airport - that the device is urgently needed for the current security improvement. We understand this fact as a serious omission in the process of justification for such new sources of public exposures.

According to current international recommendations, adverse health effects of ionizing radiation in terms of increased probability of cancer initiation can't be ruled out even at small doses. Therefore, also this radiation shall be subject to established radiation protection rules and regulations. Basic principles of radiation protection require that any exposure be justified by clear benefits for society or an individual (e.g. medical exposures). Justification of the use of ionizing radiation sources lies also in demonstrating the non-existence of alternative techniques which could achieve comparable results.

Passengers passing through X-ray scanners are exposed to ionizing radiation. Effective doses range from 0.1 to 10 microSv - a dose naturally very low but which can't be taken for negligible in case of repeated exposures which will be probable while introducing this kind of check due to the growth of terrorist threats worldwide.

Very often the comparison with doses from other types of exposures is used to justify this kind of exposure, however, this could sometimes be a very misleading approach. We have to remember that also within the principle of exemption we require for exempted practices or activities to be justified. It means that when we compare the dose from a scanner to the dose received during the flight or to the dose obtained during a simple X-ray examination of the lung it tells us nothing if we are not comparing these exposures in all relevant aspects. It means not only for doses but also for justification. Another good example are discharges from Nuclear Power Plants (NPPs) – in fact they are also only few milisieverts per year and yet they are not regarded as negligible – they are measured and regulated very strictly.

Another aspect of this problem is the potential size of the irradiated group of people of all ages and both sexes. This includes exposure of women of reproductive age, potentially pregnant and children – in this context there are a lot of unsolved questions. Again these questions are not connected principally with doses and risk however in the case of pregnant women we can imagine the fear, stress, misunderstandings – who will explain the level of risk to them – the security guy? But if we exclude these groups we are in the situation that only men over 18 could be checked without a problem – this of course sounds very strange and illogical.

What is also a very important fact is that this is the first situation when people are deliberately irradiated without medical indication. This breach could mean that a precedent is set which could lead to the further introduction of such control into the practice (stadiums, shopping centres, railway stations, factories, important buildings, etc.).

12.3 Conclusions

The State Office for Nuclear Safety (SÚJB) is recently of the view that other methods not employing ionizing radiation but at the same time providing comparable information for improving safety of air transport exist for security checks of passengers. Therefore, at this point in time, the SÚJB considers the use of X-ray scanners at airports which represent a source of public exposure as **unjustified** from a radiation protection point of view.

It is clear that the evaluation of societal benefits of an introduction of such security measures including the assessment of effectiveness of alternatives techniques is not a responsibility and matter of radiation protection only. This is closely connected to the overall evaluation of risks and threats in society and the establishment of priorities and strategies to ensure the highest level of safety in society. Here is the role of other governmental bodies to prepare and present to the government their evaluation and proposals on this field. If the threat at the whole societal level is evaluated as very urgent and real so that all measures adopted for its reduction are for a given situation justified, then of course this one aspect and view –the view of radiation protection –is only one of all others assessed by the society (government) and the final decision depends on the result of these complex analyses.

Session 4 - Ethical, Legal & Social Issues

13 BALANCING PUBLIC AND INDIVIDUAL INTERESTS: A PHILOSOPHICAL ANALYSIS

Prof. Santiago Sia

Professor and Dean of Philosophy, Milltown Institute, Dublin

13.1 Introduction

The specific context in which the topic assigned to me arises is the use of non-medical exposures in specified situations. [1] The particular issue is the extent that one can justifiably resort to such exposures in circumstances which are not determined by or necessitated on medical grounds.[1] Following from the reflections at the 2002 International Symposium on Medico-legal Exposures[2] the question that requires attention here is thus, given our present awareness of a tension between the individual and public interest, how one can strike a balance in a way that one does justice to both.

Since my own background is philosophy, and more specifically, ethics, my contribution to the present discussion will take the shape of a philosophical analysis. By this I mean focusing on the relevant issues by firstly providing a wider philosophical context to the topic and then offering some relatively specific guidelines. The hope is that with these, those who do have to make the judgement as to the use of non-medical exposures in the various situations, will be enabled to make an ethical judgment.[3] There is some advantage in engaging in a philosophical analysis when one is looking at specific situations, even if at times it does complicate matters, in that a different way of viewing the perceived tensions in these situations can result, if not in a resolution, at least in a clearer perception of the important issues. At times, it may even change one's understanding of the tension itself. It is a claim that of course remains to be seen.

13.2 Contextualising the Discussion

There is a wider context that we need to become aware of at the outset; namely, that the question of the relationship between the individual and society, of which our topic today is a part, is an ever-recurring problem. Should a human being be considered primarily as an individual, responsible for oneself alone and therefore above society; or should society be given the preference thereby making the individual, not necessarily a fragment of society, but subservient to it? To deal with the question, some tend to emphasise society or the social aspect of the human self, his or her obligations to the rest of the group or the fact that the human self is formed physically, mentally and psychologically within society. These would seem to uphold the priority of society over the individual members. Others, in contrast, would be inclined to underline the dignity of the individual being and would therefore claim that no society has the right to suppress any individual member or to treat him or her as if they were merely jigsaw pieces whose value lies in fitting into the whole pattern of society. The challenge to those who would not go along with either standpoint is to look for a balance.

[1] The phrase has been correctly acknowledged to be rather ambiguous because of the diversity of circumstance and situations.

That is our present task here—a task that is daunting not only because situations are different

and distinct, as borne out in the papers from the previous symposia, and may therefore require some fine tuning to whatever is considered as acceptable but also because making a judgment that is ethically justified is itself a highly complex one.

Philosophers have debated this topic in various contexts—with varying success. It may be helpful for our purposes to take such debate into account in our considerations not only because there is a realisation that the philosophical basis of radiological practice needs to be examined[4] but also because the debate itself has been influential in our daily thinking. Two names immediately come to mind: Immanuel Kant who championed the dignity of the human individual and John Stuart Mill who strongly supported a utilitarian interpretation of the social good.

13.3 Philosophical Bases

For Kant, each and every human individual is an "end to itself". This means that every human being has intrinsic worth, and is not a means to an end and should not be treated merely as such. The nature of each one of us deserves to be respected, and it confers an obligation on others to honour that. It is therefore not conferred but acknowledged. It is for this reason that a human individual is not just described as "human" but more significantly a "person". This evaluative term is the basis for the fundamental rights of the individual which all others have a duty to respect and the foundation for the acceptance of the status of individual interests. It is for this reason that, as Kant would put it, every human individual has dignity and not just value. Unlike the worth of, say, a work of art or a material possession, it is invariable and cannot be taken away without doing an injustice to that human individual. In our times, one can contrast the worth of a human being, which unlike stocks, shares and pension funds, does not fall! A human person has dignity, irrespective of background, achievements or interests. For Kant (and for the vast majority of philosophers) the human individual is therefore itself the source of one's law, by which he meant that such an individual is truly free or autonomous and has inalienable rights. This dignity is what marks the human individual off from every other creature.

But the affirmation of human dignity is complicated by the fact that such affirmation takes place within a social context. In other words, since every human individual is autonomous and since every such individual needs to exercise its autonomy in human society, a conflict of rights does take place. There is a fundamental need to recognise and acknowledge that other human individuals, who together form a society, are themselves centres of autonomy whose dignity and rights must also be respected. It is for this reason that Kant's view has been modified by others: the suggestion has been made that while one cannot and should not compromise human dignity, one must not regard human autonomy or human rights in absolute terms.[2] Even Kant qualifies his own statement by using the phrase "treating the person *merely* as a means". That means that one may treat human being as means so long as their personhood, i.e. as "ends-in-themselves" do not degrade them. There has been talk therefore of prioritising human rights. But this is much more than just putting rights on a sliding scale, an impossible task in itself, but rather of putting the onus on those who wish to override the fundamental status and rights of the human individual to provide reasons which can legitimately and justifiably be accepted. In other words, the autonomy of the human individual remains intact until there are good and solid reasons to affirm otherwise.

[2] An important qualification needs to be introduced here: the claim that human rights are not absolute does not mean that they are not fundamental.

To a large extent, this is where utilitarianism, particularly as developed by the philosopher JS Mill, can be helpful, particularly when we are focusing on society's interests, in that it does supply us with a way towards reconciling competing claims. The need to reckon with the consequences of our actions and to evaluate them in terms of the kind of impact and the number of affected parties—despite the ambiguity of both the criterion itself and the difficulty of its implementation—gives a more tangible and manageable way out. However, it should be added that among others, this philosophical ethical theory is criticised for sacrificing the individual good—and not always in a laudable way—by pushing forward what some may claim to be the common good. The common good is after all not simply the majority view. Moreover, it can be accused—at least, in certain versions of utilitarianism—of prejudging both the kind and extent of the consequences while ignoring the basic rights.

Despite its seemingly theoretical air about it, this philosophical discussion—intended to provide the wider context—has practical implications, not least for our present topic. Accepting the need for a balance between individual and social interests is in fact an implicit recognition of the dignity of every individual as subject, rather than an object. In other words, the individual is not a thing but rather a unique individual. For this reason, each human individual and his or her interests do require serious attention.

But we do need to qualify all this—again implicit in the acceptance of the need for a balance between individual and social interests. Just as there are difficulties with the Kantian emphasis on the autonomy of the subject, we must also be aware that the grouping of human individuals *as a whole* gives that grouping, known as society, a set of justified expectations. "Society" is not just an aggregate of individuals, but an important entity that is distinct from its individual members. This means that social interests must also be taken into serious account. Along the same lines, the concept of "common good", prevalent in ethics as well as in social and political philosophy, is not to be confused with the majority view. The common good is what is good for all members of society and does not or should not disadvantage the minority or specific subgroups. It is important that social or public interests, as least in ethics, be acknowledged as a distinct category for only then can one have a legitimate referent for the concept of public or social interests to be distinguished from those of the majority or dominant group.

Earlier, I had referred to the notion of autonomy as indeed highlighting the dignity of the human individual. At the same time I stated that it has to be understood in context. For our purposes here, we ought to note that what is really more crucial is not the autonomous nature of the human individual as such but *the exercise* of that autonomy. The distinction between the two is conceptual of course, hence abstract, but its reality is concrete and therefore has practical implications. That is to say, while we must indeed respect the autonomy of each human individual because of its dignity, we must also be alerted to the factual situation regarding its exercise. It is worth repeating that this is because the exercise of autonomy is always social: it is always over another. And that other—whether another individual, especially if it is also autonomous, and society as such—has rights which must also be respected. And that is what leads not just to a conflict of rights between individuals but also to the tension between public and individual interests.

13.4 A Different Philosophical Perspective

Reconciling competing claims or maintaining a balance between different interests is acknowledging the existence of a tension. Indeed, in the majority of cases, including the situations we are discussing regarding non-medical exposures, we accept this not just to be true but even more so, to be problematic. The expectation therefore is for some kind of a set of guidelines which will enable us to deal with the matter and any issues which may arise. But philosophical thinking, rather than just taking for granted the accepted starting point,

sometimes challenges the traditional or dominant way of looking at reality and at specific situations. In other words, it looks at the underlying assumptions and questions those. The resulting conclusion, as would be expected, can be quite different. Admittedly, this can be irritating—remember what Socrates did and note what happened to him! On the hand, at times a different way of looking at things does change the outcome—a lesson we have learned even in ordinary life.

The wider philosophical context that we have just analysed has been criticised by some contemporary philosophers like the Jewish philosopher, Martin Buber and the British philosopher, Alfred North Whitehead, as a development that, while close to our commonsense view, rests on a foundation that needs a more critical investigation. To accept that we are not just individuals but distinct individuals and that society is a separate entity can lead not just to the tension that we have been focusing on but also—and more regrettably so—to extolling individualism on the one hand and societism on the other hand.[3] What both of these philosophers propose—and argue for—is taking seriously the relationship itself and giving it primacy.[5] This is quite different from simply maintaining that a relationship is what separate individuals "enter into", by which we mean that these individuals retain their individuality but "bonds" with another. For these two thinkers, relationship *is* what constitutes the partners. More importantly, as Buber would express it, the I (or she or he) becomes so *because* of the relationship. Each of us is constituted by the kind of relationships which dominate our lives and shape our realities. While this philosophical perspective may be somewhat unfamiliar and would seem to be contrary to our ordinary perception of our reality as individuals truly different from everyone else, it is actually closer to our contemporary experience of the interconnectedness of reality and of the world we live in today. More significantly, if one were to delve deeper into reality—as we do in various fields—and not just assume what is regarded as factual because our senses tell us so, then the reality is actually different. A good illustration is when we disregard the commonsense view and ordinary language usage which regard the sun as "setting or rising". Reality, as contemporary physics in fact shows us, is in essence relatedness itself.[4] Buber takes seriously our existential situation while Whitehead is very much informed by contemporary science. Both of these philosophers, highlighting this relatedness of and in reality, show the implications for our understanding of the human situation.

What relevance has this perspective to the present topic? It is not possible to develop this philosophical perspective here,[6] but it should be stated that one of the advantages of this view on reality is that it shows that "balancing" or "reconciling" public and individual interests is a rather misplaced issue. Separating rather than just simply distinguishing individual from public interests, because it is assumed that an individual *is* separable from society and vice-versa, means that what is good for one party may not be so for the other. It leads to thinking that there can be disparity or inequity of bargaining power—the phrase used in the previous symposium—between the two parties. In Buber's and Whitehead's philosophical perspective, since there is no separation, merely conceptual distinction, whatever takes place—good or bad, an advantage or a risk—affects both parties always. The issue therefore is not whose interests are served—the individual or society—but rather whether the activity, the practice or the situation *is itself* good or advantageous, bad or risky. Every happening to and by any member affects the whole as well as itself, and any development in the whole has repercussions for every member. It seems that this way of thinking—so long one takes into account the central concept of relatedness even if it removes us from the factual circumstances that we find ourselves in—will have implications for practice, including the various situations dealing with non-medical radiation.

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[3] I am using this word to indicate that society is pitted against the individual but not necessarily in any sociological or political sense.

[4] The word I have used is "relatedness" because "relativity" (which is also used) is sometimes associated with "subjectivism"—which is denied by this perspective.

13.5 Some Practical Considerations

A philosophical analysis, such as the one which I have just undertaken, is not intended by its nature to lead to determinate guidelines that will regulate conduct. Nonetheless, it should provide some pointers that will hopefully assist with our deliberations if it is to be an effective conceptual tool. Let me therefore suggest the following practical considerations in the context of the present topic.

- It is useful to be reminded that a value judgment complicates matters since it involves taking a number of relevant factors into account. Hence, since it is a human act, there is a certain amount of subjectivity—which should not, however, be equated with subjectivism. Rather, this means that there is always the possibility of error, a consideration that is integral to any value judgment. At the same time, however, a value judgment should be as informed as is reasonably possible. This is where a constant review which results in guidelines or codes of conduct can facilitate the decision-making process.
- The concept of the 'dignity of a human individual', irrespective of interpretation or elaboration, means that no activity, practice or situation should be so degrading that a human being loses his or her special status. If it does then it cannot be justified—even if some other acceptable outcome, such as a benefit for others, can be achieved or foreseen. As Kant shows us, this is a fundamental consideration. The question of course is whether the activity, practice or situation—and here the issue of individual and public interests is a good example—is truly degrading. The concreteness and the specificity of each situation and its consequences (as Mill and utilitarians remind us) do matter. However, it will have to be assessed with that fundamental consideration as the benchmark. This means that a value judgment is called for, and takes us a step removed from the fundamental consideration.
- The issue of "interests", whether individual or public, needs to be contextualised. These interests, if they are expressive of the individual or society rather than integral to them, do need to be prioritised since some—compared to others—may be more instrumental in respecting or furthering the individual's dignity or society's general well-being. But if indeed they truly contribute to society's general being, then, as Buber and Whitehead show us, they actually further the interests of the individual even if these do not always manifest themselves as such. Hence, these should be constantly questioned and reviewed. If they harm individuals—and not merely inconvenience them—then they also contribute to the deterioration of society's well-being.
- While it must be acknowledged that our deliberations will have to evaluate the extent that certain practices, like non-medical exposures on specific individuals or groups (this is where the evidence provided by scientific or medical studies is crucial), we should also note that these cannot be isolated from the general impact on society as such. It is false to continue to think, as Buber and Whitehead remind us, that individual and public interests are really poles apart. The relevant consideration here is not just the benefits/risks to the affected party or parties but also the general well-being of the whole of society. Most of that impact can be measured or is immediately evident but others are not. Some may be positive in the short term but actually detrimental in the long run. This calls for vigilance and caution therefore.
- Public interest and the common good have been closely and rightly associated. Thus, we sometimes hear of sacrificing individual interests or needs for the same of the greater interests or needs of the group, of the community or of society. But we need to be aware that the 'common good' is not always the same as the view

of the majority or what is deemed to be beneficial to the majority. The 'common good'—admittedly a difficult criterion to define and measure—is more properly understood as the general well-being of the whole (including its individual members).

- Finally, the issue of "informed consent" (or lack of it) in non-medical situations is important and makes these situations distinct from medical ones. However, informed consent can be actual or implied. By belonging to a society, one can assume that one supplies consent to its practices. The real issue therefore is whether those situations or activities can be ethically justified or not in the first place.

13.6 Concluding Remarks

The issue of balancing individual and public interests has both concrete and theoretical aspects. Those who have to make the decision, based on certain relevant evidence and relying on a value judgement, are faced with the concrete demands of the situation. A philosophical analysis, such as what this paper offers, attempts to provide a conceptual tool in the hope that it can aid with the decision-making. It is focused on the theoretical aspect of the issue and is not, therefore, a substitute for individual and group constant review of the specifics. On the other hand, the underlying assumptions in any decision-making and value judgements do need to be investigated. In this respect, one hopes that philosophical thinking has a positive contribute to make.

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Session 5 - Justification Issues

14 JUSTIFICATION, DOSE LIMITS AND DILEMMAS

Jim Malone

Trinity College and St James's Hospital, Dublin, Ireland
IAEA, Vienna

14.1 Introduction

Non-medical exposures give rise to a number of conceptual and practical problems, many of which were identified in the predecessor to this seminar.[1] This was groundbreaking; it was the first time the Pandora's box involved had been subjected to a steady gaze and much that had not been previously noticed emerged. This paper attempts to build on the earlier work in seeking to more clearly identify the defining differences between medical and non-medical exposures. In doing so, it also takes account of developments in the understanding and practice of medical justification.[2,3,4,6]

It has also become clear that the freedom from dose limits enjoyed by medical exposures is unlikely to be shared by those exposures that are clearly and frankly non-medical. Hence there is a need to explore the extent to which dose limits or dose constraints may place obstacles in the path of non-medical activities. This area requires considerable further exploration so that unintended obstacles to proposed activities in the non-medical area can be anticipated and dealt with. Part of this will involve raising awareness of the potential impact of dose constraints, in particular. But it will also be necessary to clarify the defining characteristics of both medical and non-medical exposures so that the borderline cases can be dealt with in a manner that is transparent and publicly accountable. This may require that solutions ***outside the box*** be considered to avoid underpricing risk and ignoring the impact of proposed solutions on closely allied fields.

14.2 Medical and Non-medical Exposures

Medical exposures are now the dominant source of the human dose from man made radiation. They are generally felt to confer benefit on the exposed persons, and are conducted under the supervision of medical practitioners with specific authorisation to do so. A group of borderline situations exist where it is doubtful if all the requirements for *bona fide* medical exposures exist. These include: lifestyle radiology, self presentation, unapproved screening programmes, unintended or inadvertent exposures in medical settings, and some others. This meeting deals with a further category, non-medical exposures.[1] From the papers in these proceedings, it is clear that the types of exposure that may be considered as "non-medical" include those undertaken for reasons such as: security, smuggling, crime prevention, emigration and immigration controls, child protection, some exposures arising from litigation and others.

How do these exposures and medical exposures differ? To answer this question, it is helpful to consider some of the defining features of medical exposures. Medical exposures are generally considered ***justified*** when it can be confidently asserted that the benefit of the procedure to the patient will outweigh the associated risks.[3,4,7,8,9] It is also generally implicitly assumed that the exposures are conducted within the framework and practices of medicine.

The judgment is made for the individual patient, following a 3 step process detailed by ICRP which, in most countries, is the subject to formal regulation.[7-9] Rare exceptions to the individual justification process arise in the case of formally established screening programmes, e.g. in mammography.

Within medicine justification is not as effective as it might be.[3,4] However its necessity is not disputed. In addition, the fact that there is an aspiration and expectation that it be part of normal practice inevitably underpins the exemption of medical exposures from dose limits .[8,9] With non-medical exposures, the justification issue is quite different and in the absence of direct benefit to the subject exposed must be approached *de novo*. Further, in the absence of direct benefit to the subject, the main consideration for exemption of an examination from dose limits is no longer present.

Table 1. Medical and Non-medical Exposures

Characteristics and Concerns with Medical and Non-medical Exposures	
Medical	**Non-medical**
• Justified Medically (3 levels)	• How and Who Justifies
• Authorised Personnel	• Are Personnel authorised?
• Benefit to Individual irradiated	• Benefit not to individual irradiated
• Consent is Given	• Consent not necessary
• Confidentiality required and assured	• Confidentiality may be breeched in many ways
• Governance, special features	• Governance, disseminated + with many other influences

From a broader perspective, the differences between medical and non-medical exposures is summarised in Table 1. Apart from justification the two are differentiated by issues associated with the level of consent required to undertake the procedure; the confidentiality required and the framework to ensure it is respected; and finally the governance framework within which the exposure takes place. These proceedings concentrate mainly on the justification and its implications. However, the other issues are also important in framing a good practice that will prove transparent, socially acceptable and accountable.

We will briefly look at the consent, confidentiality and governance issues before returning to the justification question and its implications. With *bona fide* medical exposures, consent is always required. Ultimately this is based on the dignity of the person and is non negotiable..[3,4,11] How it is determined that the patient consents will be influenced by circumstances, but depending on the level of risk involved, it may be implicit or explicit in practice. [2-6]

Table 2. Five levels of structure and responsibility for and activity. Risk declines as one goes form Level 1 to Level 5.*

Level	Risk	Type of Structure or Support, Guidelines, Policies	Responsibility and Implementation
1. No Structure	+++++	Activity highly distributed. No guidelines	Dependent on (limited?) peer pressures to identify issues
2. Individual Institutions	++++	Guidelines adopted locally	Either ad hoc or standing committee
3. Agency or Professional Body	+++	Policy/guidelines from professions or other agency	Regional or national agency, and/or professional body
4. Local with National Oversight	++	Policy/guidelines agreed nationally.	National Body oversight but local implementation
5. National	+	National legislation/charter	National Office or Standing Committees

*Adapted from a Table for risk management and governance in research, presented by Maura Hiney ((HEALTH Research Board, Dublin) at The Royal Irish Academy Research Integrity Workshop, 2009.

However, it is always required for medical exposures, and thereby only allows for actions that are undertaken in the best interest of the individual patient. Art. VI.2(d) of the draft of the recast Directives, available at the time of the workshop, envisaged situations in which non-medical exposures would proceed without consent.

The governance framework for medicine has an exceptionally high threshold for confidentiality. What happens to information about a patient is protected and, outside of the necessary exchanges for clinical management is entirely up to the patient. Thus, within the EU, use of patient information without consent is now heavily constrained. Even anonymised information may require specific consent, when it is to be used for purposes, such as research outside the clinical management of the patient.[12] This is a major change in both practice and ethical sensibility from that which prevailed in medicine a generation ago.[13]

With regard to governance the framework in medicine is different, for example, to that prevailing in migration assessment centres, or customs investigation units. One of the great problems in ensuring good practice with non-medical exposures is the diversity of the governance arrangements for them. The activities involved are highly distributed and there is little uniformity in governance. They are undertaken and output from them is used at a distance from the governance arrangements for both medicine and radiation protection. Table 2 provides a useful classification of governance structures and the risk of things going wrong. There is always some risk, but it is greatest in highly distributed activities with few guidelines. Risk is, or should be, least in formally regulated activities that are concentrated in centres of expertise.

To ensure good justification of non-medical exposures, considered answers or protocols dealing with the following questions should be available:

- What is the justification process followed in practice on a day to day basis?

- What are the grounds for justification of the exposures in question?
- Is the justification individual or collective?
- Is there a statutory basis for it?
- Which professionals are responsible? For example is it:

    - Radiologists. (*They may not be trained in public health, security, child-care issues etc*).
    - Judges? (*They may not be trained in medical issues and radiological risk benefit analysis*).
    - Customs Officers? (*They may not be trained in medical issues and radiological risk benefit analysis*).
    - Social Workers? (*They may not be trained in medical issues and radiological risk benefit analysis*).

It may be worth trying to identify parallels with the 3 level justification system of ICRP (see Table 8).[8,9] This might be helpful in developing a system that can be adapted to the needs of this area. It is essential that this be undertaken if it is proposed to conduct non-medical exposures in medical facilities.[14] Not doing so could ultimately place the medical exposure dose limit exemption at risk, or at least attract new attention to it. Localised weak non-medical justification will, where it persists in medical facilities, inevitably add to the accountability and transparency issues arising from an already significant level of unjustified medical exposures.[3,4]

14.3 Possibilities for Dose Limitation

The system of dose limitation in the member states follows the Commission Directives. The most important aspects of statutory dose limits are set out in Tables 3 and 4. As already mentioned, *bona fide* medical exposures are not subject to legal dose limitation, as in contrast with almost every other situation the person being irradiated is the main beneficiary. In these circumstances it is easy to justify the irradiation of the individual, provided the risk from the radiation exposure does not outweigh the benefit.

Table 3. Dose Limitation for Medical and Non-medical Exposures

Medical	**No Dose Limit**	**DRLs**
Non-medical	**Public Dose Limit**	**Dose Constraints**

Table 4. Dose Limits prescribed by Law in Member States

Type of Limit	**Occupational (mSv)**	**Public (mSv)**
Effective Dose in 1 yr	20	1
Equivalent dose in 1 yr Lens of the eye	150	15
Skin	600	50
Hands and Feet	500	

Dose Limits for occupationally exposed workers and members of the public. Some freedom with regard to averaging over longer periods is also recommended [ICRP 103]*.

The dose limitation schemes that presently apply, in theory at least, to non-medical exposures appear to be those for the general public in the European Directives. It is clear that the provisions for patients are not appropriate for the reason already cited. It is equally clear that the provisions for occupational exposure are not appropriate. This leaves the provisions for the members of the public (Table 4).

The system of dose limits for members of the public is supplemented in the Directives by the idea of Dose Constraints.[8,15] A dose constraint is defined as follows:

> *"a restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimization is involved"*

A useful comment on applying dose constraints is available from a joint NEA EC report[16] :

> *"value[s] of individual dose used to limit the range of options considered in the process of optimization; for public exposure, the dose constraint is in addition an upper bound on the annual doses that members of the public should receive from the planned operation of any regulated (authorised) practice; -----"*

Table 5. Some Dose Constraints for Members of Public*

Country	Value	Comments
Sweden	0.1 mSv/y	RT shielding, external beam, Site Limit (Nuclear)
Netherlands	1.0 mSv/y	Outside room shielding (Occupancy issues)
	10 micro Sv/y	Site Border
Belgium	0.02 mSv/week	Shielding. Outside room.
	0.5 mSv/y	Patients with sources
Ireland	0.3 mSv/y	General
Germany	0.3 mSv/y	Site Limit (Nuclear)
UK	0.3 mSv/y	Site Limit (Nuclear); DR Room Design
Finland	0.1 mSv/y	Site Limit (Nuclear)
US: public "limit" of 0.25 mSv/y to single non-medical sources		

*Based on values from [15] and [17].

More work needs to be undertaken on the establishment of dose constraints for many purposes. For example the dose constraints used for the design of facilities in which medical exposures are undertaken are now an important factor.[18] To date the values used in member states are not always those that might be expected based on the public dose limits and the approach generally adopted for calculating dose constraints from dose limits.

For non-medical exposures, the dose constraint for members of the public might reasonably be taken as those identified in an unpublished paper of the Article 31 Committee.[15] These are presented for consideration in Table 5. In so far as a trend can be identified, it suggests that 0.25 to 0.3 mSv per year is a likely value for the dose constraint for exposure to a single source on a single occasion. The values are based on the assumption that the individual may be exposed to other sources on other occasions.

Table 6. Dose Constraints recommended by ISCORS in the USA

Security General	D < 0.00005 mSv/scan (ISCORS)
Security Limited Use	0.0001 < D < 0.01 mSv/scan (ISCORS)
Quasi Medical	US: 0.25 mSv. EC: 0.3 mSv for single source.

The doses within which non-medical exposures should be achieved for various categories, as stated by ISCORS in the US are summarised in Table 6.[17] The first two categories, ***Security General*** and ***Security Limited Use,*** are unlikely to give rise to difficulties with the EC dose limits and/or dose constraints in practice. On the other hand, quasi medical procedures are quite likely to exceed the EC dose constraints, the EC public dose limits, and the American recommendations given the doses commonly encountered with medical examinations as summarized in Table 7, based on an EC study of medical doses in 10 countries.[19] Clearly, particularly with CT, medical doses are well above the limits, constraints and recommendations.

In the medical area, where there are no dose limits, an alternative to dose constraints is employed. This is the Diagnostic Reference Level (DRL). These are widely used to guide the optimization processes in medicine. Similar approaches might be pursued with non-medical exposures and would allow many, but not all, non-medical exposures be pursued without coming into conflict with the dose limitation system. As the gap between the high and low dose countries in Table 7 illustrates, optimization processes could do much to bring some non-medical exposures within the dose constraints and/or limits, but will not be further discussed here.[19]

From the above, it is evident that potential problems arise from the system of dose limitation or dose constraints. The potential areas of difficulty might include the following, depending on the definitions of medical and non-medical that eventually emerge:

- Some high dose investigations, eg. for drug searches or litigation
- Non accidental child injury investigations (NAI), e.g. a full skeletal survey
- High or Medium Resolution X-ray or CT of Abdomen and/or Thorax
- Variation in dose and practice between and within Countries
- Variations in same projection for different tasks.

Table 7. Doses from Medical Examinations in 10 European Countries

Exam Type	Higher Exposure Group (DE, CH) Mean per Exam (mSv)	Average (All) Mean per Exam (mSv)	Lower Exposure Group (NL, UK) Mean per Exam (mSv)
Chest/Thorax	0.25	0.10	0.03
Cervical Spine	0.70	0.27	0.04
Thoracic Spine	2.00	1.00	0.40
Lumbar Spine	2.80	1.90	0.50
Mammography	0.40	0.33	0.25
Abdomen	1.80	1.50	0.50
Pelvis and Hip	1.35	0.90	0.45

Exam Type	Higher Exposure Group (DE, CH) Mean per Exam (mSv)	Average (All) Mean per Exam (mSv)	Lower Exposure Group (NL, UK) Mean per Exam (mSv)
Ba Meal	15.00	7.70	2.60
Ba Enema	12.50	8.60	6.40
Ba Follow	24.50	10.00	4.40
IVU	3.50	4.00	2.60
CT Head	2.40	2.00	1.60
CT Neck	2.80	2.50	2.40
CT Chest	8.20	8.00	6.60
CT Spine	6.00	5.30	3.60
CT Abdomen	13.50	12.00	10.20
CT Pelvis	8.80	8.70	8.70
CT Trunk	24.40	14.00	10.40
All CT	7.05	6.10	5.35

Derived from EC Publication 154 [19].

14.4 Possibilities and Conclusions

It is evident that most general and limited security applications will not encounter dose constraint/limit upper bounds. However, some child protection, and other radiographic/CT applications will encounter bounds, particularly where repeats are necessary. The extent of these problems can be greatly reduced by identifying, optimising and validating low dose protocols, within dose constraints, for non-medical applications. Adjusting the dose to the task involved and optimizing can significantly reduce the amount of radiation needed in many cases.[19] In practice, this will only be successfully delivered with a new well developed education and training programmes for operational staff outside hospitals (and within hospitals where they choose to be involved in non-medical work), that are tailored to the specific purposes of the examinations involved.

Notwithstanding this, some non-medical human exposures may pose regulatory problems. Various approaches to these may be adopted. For example it is possible to take new initiatives within the existing framework without interfering with it in any way. This would allow some of the difficulties be adequately dealt with. For example, the problems that arise from dose constraints in the area of sports medicine injuries and non accidental injuries of children could be dealt with by creating new approved screening programmes with defined criteria for admission that allow the problems involved be addressed. This would require minimal interference with the legislation, but would require significant professional and administrative initiatives. It leaves other problems untouched, e.g. identification of drug swallowers. Other problems in the areas of self referral/presentation may be susceptible to this approach.

On the other hand a view that attracted support during discussion in the Symposium favoured redefining the meaning of “medical benefit” to include health and well being, so that it includes “benefit” in the sense that siblings in NAI cases, athletes, or others might benefit from having their situation examined. This has the advantage of removing the problem in the areas to which it applies by simply redefining it. However doing so is not neutral and without implications elsewhere. One of the most incisive thinkers on how social harm arises, Naom Chomski, attributes much of it to the capacity of groups to “ignore externalities” in decision making.[20] In this case changing the meaning of medical benefit will have an impact everywhere the word medical is used. The enterprise of medicine, on a world wide scale is

very large consuming 10 – 20% of national resources in developed countries.[21] Its scale vastly outstrips the radiation regulatory and nuclear industries (including power generation, military and peaceful uses).[21] Changing the meaning of medical in this way, to simplify a radiation regulatory problem, is probably not a good way of solving the problem. It will almost inevitably, at the very least, result in significant training and compliance problems within medicine.

With low dose techniques a more structured and formal approach to justification based on the ICRP three level system might be considered [Table 8]. If adopted, it would have advantages in the areas of transparency and public accountability. To be successful it would require that much attention be given to establishing sound protocols and training of front line staff.

Table 8. Three Levels of Justification

	Level 1 Generic	**Level 2 Specific Technique or Concern**	**Level 3 Individual Justification**
Security General	Yes	–	–
Security Limited Use	Yes	Yes	?
Quasi Medical	Yes	Yes	Yes

Table 8 shows the three levels of justification used by ICRP across the top. They are the generic, the specific technique, and its application to an individual patient. With quasi medical procedures all three levels should apply and those involved should have the range of experience and expertise required to make a good decision. These techniques might include NAI, sports cases, and drug searches/ drug swallowers. The inputs to generic justification of these techniques need to be much improved. The criteria for their use for specific purposes need to be developed in much the same way that referral guidelines are available for diagnostic radiology.[22] Application of these guidelines to a specific case will almost definitely involve the medical or radiological practitioner under whose care the examination takes place, but may also need to involve other professionals.

General or limited use security investigations may be applied to all individuals in a certain class; for example, all passengers at an airport travelling to certain destinations. The question of generic justification of such techniques needs attention over and above that given to them to date. Likewise, the examination protocols, and the guidelines that determine when they may be used need much more attention. The doses involved must be subject to ongoing monitoring and the extent of the exposure of frequent travellers will need to be determined.

Thus, it is clear that generic, socially acceptable justification will have to be highly nuanced, and have regard to social, ethical and legal issues. Current practice will be at risk of becoming publicly unacceptable pending the arrival of well tested peer reviewed protocols for the area. US justifications may not transfer to Europe. In addition, when assessing medical/non-medical classification: there is a need to be aware of consent and confidentiality, as well as benefit to the patient. The level of consideration given to these concerns to date is probably not adequate to ensure a sound framework for the conduct of

non-medical exposures. With respect to governance arrangements it is essential to identify and recommend less risky, less distributed more joined up systems.

It is not reasonable to assume that medical practitioners or support professionals will be familiar with all the social issues and concerns involved in dealing with criminal investigation, migration policies, deprivation of individuals of their liberty etc. Therefore in the case of non-medical exposures they can not be relied on to provide operational justification, particularly as purely medical justification is the weakest element in medical radiation protection.[3,4] What medical professionals can be relied on to do is to conduct the procedure properly if it is already justified.

Last, and by no means least, there is the question of ensuring whatever solutions are adopted will not ultimately damage the capacity of medicine to function. If for example the idea of medical exposure is stretched beyond the meaning that normally applies in the general understanding of the professions, this may have anticipated consequences (mentioned above) and unanticipated consequences once hard cases begin to emerge. Recent work on justification has demonstrated that the radiation protection system has not successfully transferred well in practice to medicine. In view of this and in view of the scale of the medical enterprise, it may be well not to nuance the definition of medical exposures in a way that is seriously counter intuitive, as it may place a further obstacle in the way of establishing good justification practice.

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15 BODY SCANNERS / OVERVIEW OF TECHNOLOGY & ASSOCIATED DOSES

Kari Nurmela

FINAVIA, Finland

15.1 Introduction

Body Scanner (or Body-worn Threat Detection System, Whole Body Imager...) is a system that is capable of detecting concealed prohibited items worn on a person's body and indicates detection by means of an alarm. A human operator can be an integral part of the system.

There are different kinds of scanners for different kinds of uses. Some are designed to detect items concealed beneath clothing and some items concealed in cavities of the human body. Some are to detect big bulk IEDs, some small liquid containers, metal objects etc.

Body Scanners based on X-ray back scatter have been available for over twenty years but have not been used in the field of aviation security until recently. Body scanners based on other, non-ionising technologies like mmW, are currently available and have been in (test) use for some years. At this moment Body Scanners have been accepted in test use as a secondary screening method in some countries.

15.2 Current Technologies in Use or under Development

There are several manufacturer and R&D organisations working on the subject. At least the following technologies are in use or under development.

15.2.1 Ionising

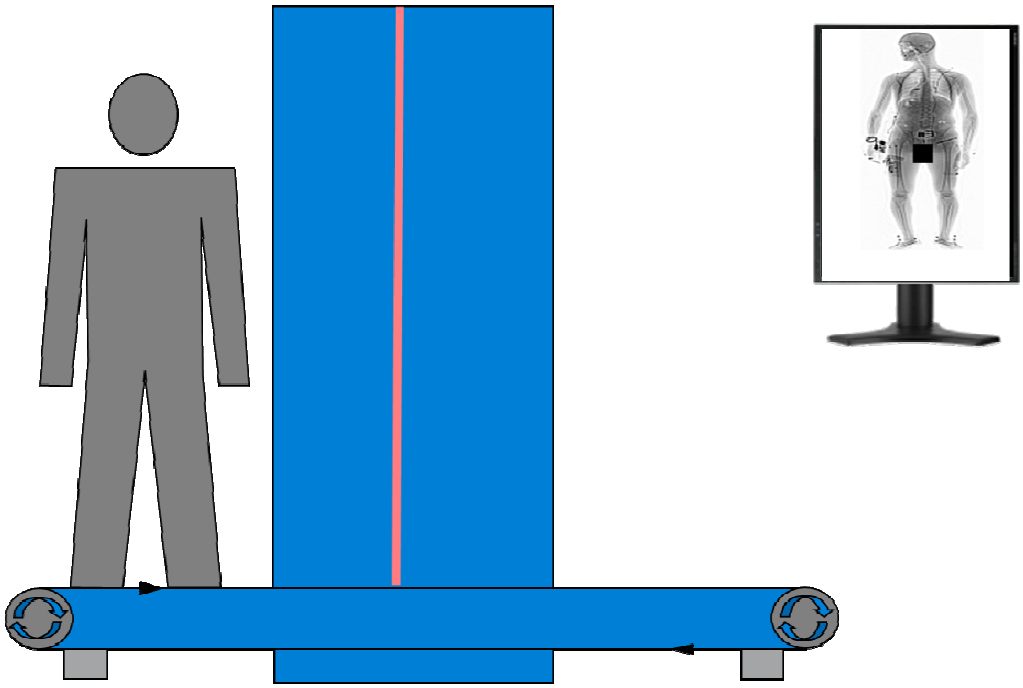
- X-ray back scatter, still images
- X-ray transmission, still images

15.2.2 Non-Ionising

- Active mmW, range of still images, 3D reconstruction, real time imaging (30GHz - 300GHz)
- Passive mmW imaging
- THz imaging (300GHz – 10THz)
- THz spectroscopy
- Thermal imaging
- Multi-band imaging

15.2.3 Transmission X-ray

The person stands on a conveyor or a platform which transports him/her across a fan shaped X-ray beam. Penetrated X-rays are measured slide after slide and an image is created. There can be one or more beams.



Transmission X-ray: Smiths Detection B-SCAN operating principle

15.2.4 Back Scatter X-ray

In back scatter systems, the person stands with their hands up in front of the machine and it scans them from left to right and from head to heel using a pencil beam. Scattered X-rays are measured and an image is created. At least two scans are needed to cover the whole body. There is a machine currently on the market which can scan both sides of the person simultaneously.

Normal system parts of the Body Scanner include the following: Scanner itself, Remote Monitor which is located so that the operator evaluating the image has no contact with the person being scanned, Assisting Security Screener Workstation which shows the status of the person screened and indicates the possible location(s) of threat and possible threat classification(s). Normally there is also direct voice communication between the Image evaluation and Screening positions.

15.2.5 mmW

There are several different types of equipment. For example some are used to scan persons entering a building and are capable of detecting big objects. In Aviation Security small metallic and non-metallic objects are looked for.

In simple terms, the operating principles can be described as follows:

Passive systems measure using “mmW-camera” cosmic radiation reflecting from the target. Normally equipment is used outdoors because buildings attenuate cosmic radiation strongly.

Active systems use mmW-transmitter(s) to illuminate the target and “mmW-camera” to measure mmWs reflected from the target.

15.2.6 Radiation Doses

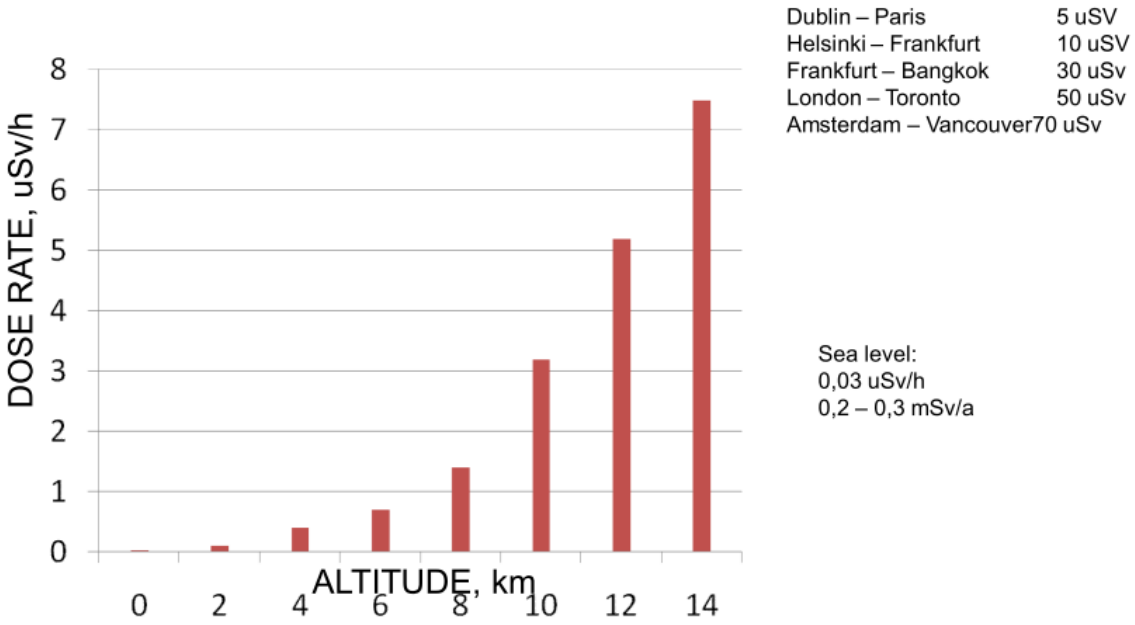
Radiation Doses for Body Scanners employing ionizing radiation are relatively low compared to medical or background doses, especially for scanners using back scatter as imaging technology.

15.2.7 Background

As we know background doses vary and depend on time, location, altitude etc.

For example at 12 km altitude the background dose rate is 3μSv/h on the equator and 5-9μSv/h near the poles. At 9km the readings are 1μSv/h and 2-4μSv/h respectively.

At the sea level 0.03-0.2μSv/h is quite a normal range.



Cosmic Radiation, Latitude 60°N and some example doses to passengers on different routes.

15.2.8 Transmission X-ray

Doses on transmission systems vary and on some systems they can be adjusted or different operating values can be selected (kV/mA).

Typical values vary from 0.1μSv to 6μSv. So assuming a dose rate of 2μSv/h (~10km) for the flight and 3μSv per inspection, this means that one inspection equals 1.5 hours flight.

Transmission X-ray equipment is not used in aviation security to screen masses in EU.

15.2.9 Back Scatter X-ray

There are small variations depending on the source but the following effective doses can be used:

	50kVp system	**125kVp system**
Passenger Dose	0.03μSv per scan	0.03μSv per scan
Operator Dose	indistinguishable from background	
Bystander Dose	indistinguishable from background (outside primary beam)	

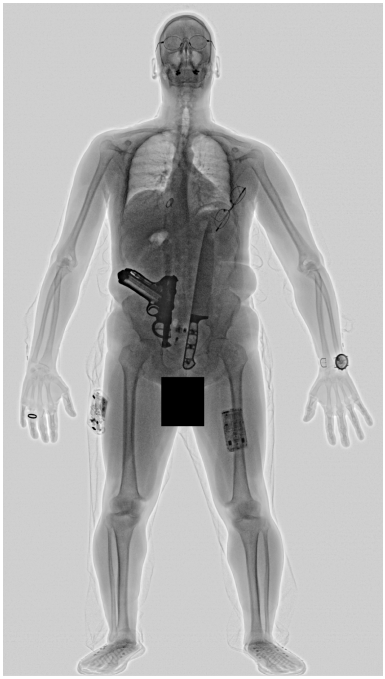
Normal screening means that 2-4 images are needed to cover the whole body but four scans does not mean that the total dose per inspection is 0.12μSv.

So assuming a dose rate of 2μSv/h (~10km) for the flight and 0.1μSv per inspection means that one inspection equals 3 minutes flight or one scan (0.03μSv) equals 1 minute flying time.

15.2.10 Images

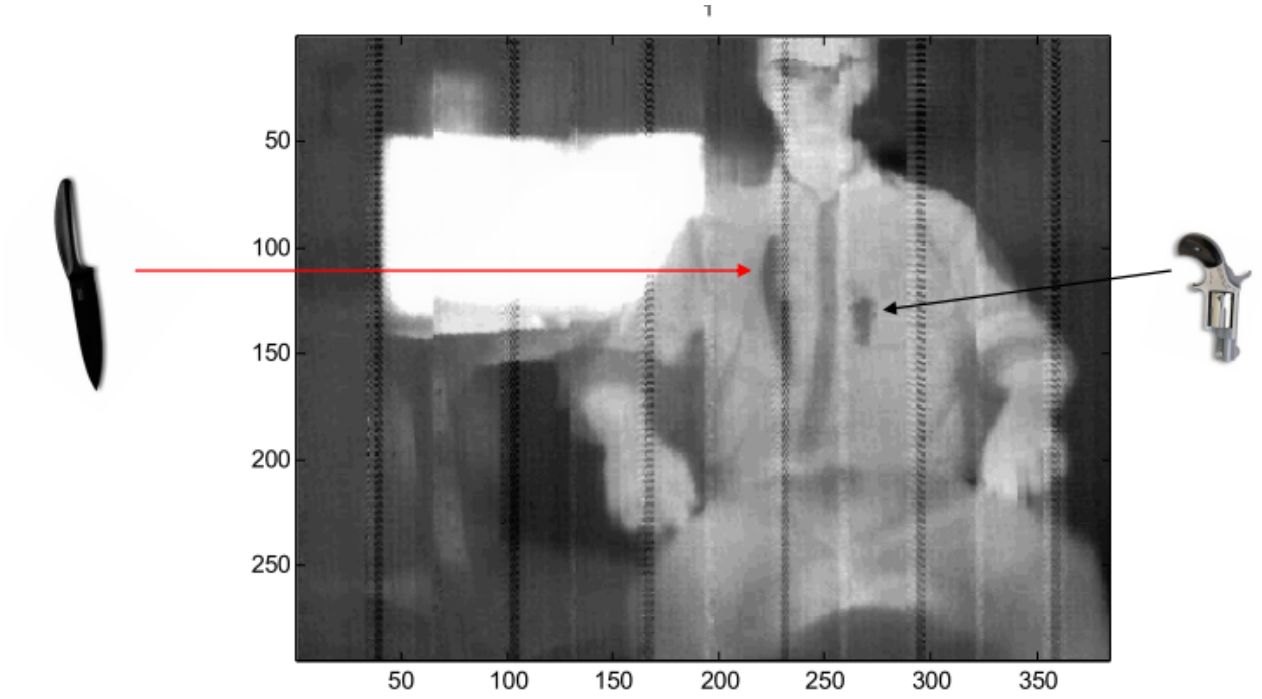
Below are some example images.

15.2.10.1 Transmission X-ray



Transmission images produced using Smiths Detection B-SCAN.
Source: Smiths Detection

15.2.10.2 THz



THz image produced by test prototype. Source: VTT Research Centre, Finland.

15.3 Scanning and Screening Times

From an operational point of view the time per scan / image is not the only relevant issue but the throughput and image quality / detection capabilities are important as well.

Better image quality, penetration and material discrimination helps the screener to recognize the objects and speeds up the whole process.

Normal times to the scan / image are following:

- Transmission X-ray: 7-10s / image.
- Back scatter X-ray: 7-10s / scan if dual system scanning both sides simultaneously then 7-10s / image
- Active mmW: 3-8s / 3D-image

15.4 Dealing with Privacy and Safety Issues

Privacy issues together with safety issues are of interest to most people as well as to the authorities. There is no common legislation in the EC to cover all these issues and national legislation varies.

The ALARA-principle is common but because the threat level varies from country to country the interpretation varies when dealing with ionizing technologies.

Privacy issues are normally dealt with by locating the operator who is analyzing the images in a different room. He / she has no contact with the person under inspection and communicates with the assisting security officer using a remote screen and / or phone. This

operator room usually also has restrictions on cameras and mobile phones with CCTV as well for outsiders.

Images / data cannot be stored.

There are also available software versions where faces and / private areas are blurred.

In some countries the operator analyzing the images has to be the same gender as the person screened. In some countries children are not allowed to be screened at all.

Networking equipment (all-to-all) adds an additional layer of privacy since analyst does not know which scanner generated the image.

Automatic threat detection algorithms are under development and in test use. These will stop the discussions about privacy issues because with their introduction there will be no need for the operator to analyze images. The security officer next to the passenger will have a display showing (“gingerbread man”) where to search to locate the object(s) that might present a threat.

15.5 Pros and Cons

Advantages (+)

Non-metallic objects can be found. This increases security.
No need to do whole body hand search because hand search can be targeted.
No need for random hand search.
Little if any physical contact with the passenger.
Public acceptance high; over 80% of passengers choose body scanners instead of a walk through metal detector when given a choice.
Testing methodology and requirements exist.

Disadvantages (-)

Public acceptance; although high acceptance some passenger have doubts about both privacy and safety.
No common legislation: privacy and radiation.

15.6 Future

mmW or back scatter is an open issue but at the moment public acceptance seems to favour mmW. the problem is that the majority do not know the difference between the technologies.

Automatic threat detection algorithms will develop but material discrimination will take time and might need use of other technologies such as THz imaging.

16 HUMAN IRRADIATION AND CHILD PROTECTION

Stephanie Ryan FFR RCSI

Paediatric Radiologist,
Children's University Hospital, Temple Street, Dublin, IRELAND

16.1 Child Protection

In the setting of possible child abuse, irradiation in the form of radiographs and CT, and sometimes radioisotope studies, may be used to diagnose injuries that may need treatment but also injuries that don't need treatment. The aim of the radiographs is to diagnose abuse or establish another diagnosis and also to gather evidence, help avoid further injury, and to help in treatment and / or conviction of perpetrator.

Child Abuse was first described by Tardieu in Paris in 1860. It was not a widely made diagnosed until it was described again by Caffey, a radiologist in Boston 1946.[1] At first there was great reluctance to recognise that parents can injure their own child. This is now more widely accepted. We must however maintain the correct balance between overcalling and under calling physical abuse as errors in either direction may have horrendous consequences.

Investigation of possible child abuse requires a thorough assessment of the history and physical findings, including skin injuries, ophthalmology and dental examination, photography, some coagulation and other laboratory tests as well as a family assessment. This paper deals with the role of imaging in the child with suspected physical abuse and what findings help to distinguish accidental from non-accidental injury (NAI). The possibility of NAI may be raised by the paediatrician who may seek to confirm or exclude this by imaging. In some situations the possibility of abuse may be first raised by the radiologist who may detect features suspicious for NAI in a radiograph done for another reason, such as rib fractures identified in a chest radiograph done for evaluation of respiratory infection in an infant.

Pointers to possible NAI include findings suggestive of injury without a history of injury, or with a history that does not account for the injuries that are detected. An injury that is likely to be accidental in an older child such as femoral or humeral fractures can be very suggestive of non-accidental injury in the pre-ambulatory infant.

Some findings, such as metaphyseal corner fractures, are almost pathognomonic for NAI; other findings are of high, medium or low specificity for NAI.[2-4]

The process of healing of fractures can be seen on radiographs and can be used to estimate the age of the fracture.[5,6] The history given must correspond with the age of the fracture on the radiograph. Healing of the fracture detectable on the radiograph would not be compatible for example with a history of injury on the previous day. The finding of multiple fractures of different ages is more suggestive of NAI than accidental injury. Similarly, brain injuries as seen on CT or MRI scanning can sometimes be dated approximately and compared with the history given.

Several diseases may mimic non-accidental injury and imaging may have a vital role in diagnosing these. Even some variations of normal findings may mimic NAI.

The mainstay of skeletal imaging in NAI is the skeletal survey. This should include several standard projections including oblique views of the ribs and should be interpreted by a radiologist with some expertise in this diagnosis.[7] The reason for the survey should be honestly explained to parents. Consent is necessary to obtain radiographs in this situation. It is very unusual, however, for parents not to consent to these x-ray examinations for their children, as doing so would imply having something to hide. The interests of the child are central. If the parents were to refuse investigations or treatment, the paediatrician or social workers may need to apply to the courts on his behalf for an emergency care order to allow diagnosis and treatment to go ahead.

Radioisotope bone scans have a limited role but may be a useful additional study.[8,9] Most experts advocate the use of follow up skeletal surveys or at least limited skeletal surveys in selected cases.[10,11] Some advocate a tailored combination of scintigraphy and radiography including some follow up studies.[9] In many cases it may be necessary to image siblings especially young siblings to look for occult injury.

When brain injury is suspected both CT and MRI imaging have important roles [12]. The role of neuroimaging in the child with suspected abuse who has no signs of neurological injury is controversial.[13] CT is also used for the evaluation of abdominal injury.

Post-mortem radiography or even CT may be very useful but are outside the scope of this discussion.

A medico-legal procedure is defined in the Medical Exposure Directive 97/43/EURATOM as a procedure performed for insurance or legal purposes without a medical indication. If human irradiation in child protection is a medico-legal exposure, then the EURATOM directive requires that “special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds.” [14]

Justification of an exposure according to the EURATOM directive requires balancing the “net benefit, …… against the individual detriment that the exposure might cause, taking into account …available alternative techniques having the same objective but involving less or no exposure to ionizing radiation.”

In child protection the benefits of the irradiation include the diagnosis of injuries that may need treatment and the identification of alternative diagnoses that may need treatment. The exclusion of abuse is important so that the child can be safely returned to the care of his family. The diagnosis of abuse may lead to treatment and support of the abuser or the establishment of an alternative caring plan for the child or the conviction of the abuser. All of these may directly or indirectly benefit the child.

These benefits need to be balanced against two main risks. The risk associated with the radiation, which for a skeletal survey has been estimated to be approximately 0.15mSv with additional radiation for additional views, follow up surveys and of course for CT brain or CT abdomen. One must remember that children are more radiosensitive than adults and are more likely to live long enough to develop radiation-induced malignancy.

The other main risk is the risk of misdiagnosis, of overcalling or under calling the diagnosis of abuse, or failure to identify an alternative cause of the findings.

16.2 Conclusion

Early detection of child abuse means greater potential for preventing further harm. The possible benefits of the procedure to the child make this a diagnostic rather than medico-legal exposure.

If the grounds for suspicion are adequate, the studies are done meticulously and expertly interpreted, then the benefits to the child will out weigh the risks and the procedure can be considered justified and optimised.

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17 HUMAN IRRADIATION AND AGE DETERMINATION

Keith Horner

Professor of Oral and Maxillofacial Imaging
School of Dentistry, University of Manchester, United Kingdom

17.1 Introduction

A proven identity is the key that unlocks the door to participation in society. An individual may define self identity by name, family, religion, culture or occupation, but the structure of "developed" societies requires documentary proofs of identity to allow access and participation, notably an official registration of birth. Date of birth and chronological age are determinants of how individuals can participate in, or are treated by, the society in which they live.

The fact that evidence of age is fundamental to the realisation of rights and needs in society is recognised in Article 7 of The United Nations Convention on the Rights of the Child, which states that *"The child shall be registered immediately after birth".*[1] Unfortunately, it has been estimated that around 51 million births go unregistered each year in developing countries, mainly in South Asia and sub-Saharan Africa.[2] Even when a birth has been registered, the individual may lose the documentation and have no way of replacing it, particularly in times of upheaval such as war and social unrest. The unfortunate geographical coincidences of incomplete birth registration rates, wars and poverty mean that refugees and asylum seekers may often possess no evidence of age.

Worldwide, there were approximately 15.2 million refugees and 827,000 asylum seekers at the end of 2008, 44% of whom were children.[3] Unaccompanied or separated children formed 4% of asylum claims. Age is a key determinant of how an individual is handled in such circumstances and may be the deciding factor in the success or failure of an asylum application. For children, it also defines access to education and healthcare. Where an individual is accused of a crime, accurate knowledge of chronological age will affect management by a nation's criminal justice system, according to the age of criminal responsibility. In such circumstances, it is probably inevitable that a proportion of refugees may claim to be younger than their real age to help an application claim or to limit or avoid prosecution if accused of a crime.

While the major challenge to societies is ensuring just handling of refugees and asylum seekers, there are others. The increase in trafficking of children, notably by the sex industry, adds a further problem related to age identification. It has been estimated that there were 1.2 million child trafficking victims in 2000.[4] Traffickers may claim that children are older than their true age and the victims are intimidated into corroborating the claims. Even where children are not victims of human trafficking, child "runaways" may claim to be older so as to avoid being taken into social care or returned to their homes.

Without an accurate method of age determination, there are considerable disadvantages to Society and to the individual. Asylum seekers, illegal immigrants and human trafficking victims fail to receive appropriate care and support. Where an individual is accused of a crime, incorrect age determination leads to unjust management, according to the relevant legal system.

In summary, developed countries face significant challenges in identifying the age of individuals who have no valid proof of identity. Such individuals can be classified into one of the following categories:

- The subject does not know age and has no valid documentation
- The subject may know age but has no valid documentation
- The subject may be attempting to conceal age (for legal/social/asylum reasons).

It is rare that an age assessment is needed for a living adult who is middle-aged or over. Because of the important management decisions that are influenced by age in children, adolescents and young adults, the main challenges in age determination relate to ages around or below 21 years.

17.2 Methods Age of Determination

While the ideal situation would be to identify a diagnostic test that accurately and reproducibly determines chronological age, no such test exists. In reality, age can only be estimated by measuring or observing features that are associated with chronological age. These methods are summarised in Table 1.

Table 1. Methods of age estimation

	Type of assessment	**Features assessed/ measured**
Physical	Clinical	Height and weight Signs of sexual maturity: Boys: *beard growth, axillary hair, pubic hair, laryngeal prominence, penile and testicular development.* Girls: *development of the breasts, pubic hair, axillary hair.*
Psycho-social	Clinical/ social	Responses to interview Observation of behaviour
Skeletal	Radiological	Hand-wrist radiograph Clavicle CT
Dental	Clinical Radiological Histopathological	Dental eruption and tooth wear Dental development Aspartic acid racemization in dentine

17.2.1 Methods not involving the use of X-rays

To facilitate the estimation of age based on physical assessment, various classification methods for sexual maturity have been devised, as reviewed by Schmeling et al.[5] All such estimates suffer from broad normal variation ranges. Furthermore, concurrent diseases may delay sexual maturity or, less commonly, hasten it. Psycho-social examination methods involve a combination of interviews and observation of behaviour by an appropriately trained team (child psychiatrists, psychologists, social workers, educationalists). Behavioural observation includes amongst peers, with adults and with those in authority. While psycho-social assessment provides important indications of maturity, it is influenced by cultural/ethnic background and personal experience of the individual, including the past traumatic experiences likely to have been experienced by a child in this situation. Its role should primarily be seen as a means of determining needs and support for a child.[6]

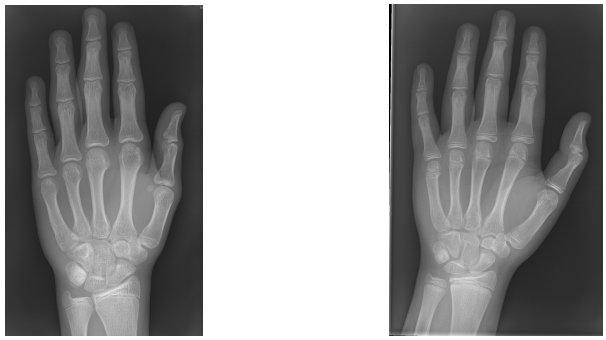
Regular clinical dental examination is appropriate for everyone. Poor socio-economic status is a recognised risk factor for dental disease and is often associated with refugees and others for whom age estimation is required.[7,8] In children, the eruption of teeth follows an age-related sequence and, post-eruption, tooth wear may be found. These clinical dental features may be used to contribute to a "medical" physical assessment for age estimation. Eruption dates of teeth have, however, a normal variation and cannot give an accurate estimate. Similarly, tooth wear varies substantially according to local factors, including diet and habits.

17.2.2 Radiological methods of age estimation

As listed in Table I, both skeletal and dental methods using ionising radiation have been used as means of age estimation. Article 3 of the European Council Directive 97/43 Euratom states that *"special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds"*.[9] This important principle is particularly important in the case of age estimation, where the affected individuals are likely to be children and adolescents, whose risks from X-ray exposure are greater than those of adults. The methods using X-rays that have been most widely used[10,11] for age estimation are evaluation of the hand-wrist radiograph and of dental development on the panoramic radiograph. CT of the clavicle is also recommended by some authorities.[11] This brief review will focus on these three methods, although other anatomical sites continue to be used, for example the cervical vertebrae[12] and ribs[13].

17.2.2.1 Hand-wrist radiograph

The most widely used radiological means of age assessment is the hand-wrist radiograph. During skeletal development, the bones of the hands and the wrist undergo prominent changes that are associated with chronological age (Fig. 1), specifically in the process of epiphyseal ossification and in size and form. This method of age estimation was originally developed to study the developmental skeletal effects of diseases e.g. endocrinopathies. Skeletal development of the hand is typically complete at 17 years in females and 18 years in males.[5] Reference atlases of hand development have been devised, against which an individual image can be judged. Alternative methods, based upon these atlases, have also been developed.[14,15,16]



1a 1b

Figure 1. Hand radiographs of differently aged subjects, demonstrating the different developmental maturity, a): 12 years of age, b): 15 years of age.

While these methods have been widely used in clinical practice, their suitability for non-medical purposes must be approached with caution. The widely used hand atlas of Greulich and Pyle was developed on populations from the United States in the 1930s.[17] The authors

found a standard deviation on age estimates ranging from 0.6 to 1.1 years. An alternative atlas[18], developed using German data originally from the 1970s, has a standard deviation of 0.2 to 1.2 years[19]. It is important to recognise that, assuming a normal distribution of data, +/- one standard deviation indicates only that approximately 68% of individuals will lie within this range. The range for 95% or 99% confidence intervals will obviously be wider. Where bone age estimation is being used as a key determinant of how an individual is handled in a legal context, such inaccuracy must be unacceptable.

Radiographic positioning variation can alter the appearances of hand-wrist radiographs, even for a single subject, and there is inter- and intra-observer error in estimation of age.[10] Furthermore, the applicability of the reference material to a particular subject has to be considered. Likely subjects for age estimation (asylum seekers) most commonly originate from sub-Saharan Africa and the middle-east[20] and appropriate reference data are not available. The low socio-economic status and malnutrition that may coincide with refugee status can delay skeletal maturation[10,21]. Although it has been stated that ethnic variation seems to be small[5], a recent study on a Turkish population found that significant differences existed between chronological age and that assessed by the Grulich and Pyle method, with standard deviations exceeding one year[22].

17.2.2.2 Radiography and CT of the clavicle

The medial epiphysis of the clavicle undergoes fusion over a time period extending from the second to the third decade of life. This process has been documented into four- or five-point classification systems based on the appearances on conventional radiographs or on CT scans. Kreitner et al (1998), in a German population, found that while the different stages of development encompassed broad, overlapping, age bands, complete fusion was not seen below the age of 22 years.[23] According to Schmeling et al (2006)[5], if fusion is complete but an epiphyseal scar is visible, it can be assumed that a woman is at least 20 years old and a man at least 21 years. Furthermore, if no epiphyseal scar is seen, then the subject is at least 26 years of age. A subsequent study, however, has shown that this unequivocal guidance may not be so clear cut.[24]

No studies appear to have been performed in populations from which those requiring age estimation are likely to originate. The evidence seems to show that while total fusion of the medial clavicular epiphysis is not likely to occur below 20 years of age, substantial numbers of those above this age will have unfused epiphyses. Thus, this method of age estimation cannot be seen in any way as definitive. The current evidence suggests might be possible to use it in selected cases where the age assessed by specialists is considered likely to be in the mid-twenties or older and that claimed by the subject is below 20 years. It should be noted that, unlike other radiological age estimation methods, this method uses CT, with a likely higher radiation dose. Justification of this examination consequently requires greater attention to the likely benefits. Therefore it is encouraging that more recent work has been reported using methods not using ionising radiation[25,26], although the limitations related to overlap of maturation stages and lack of relevant reference population data remain.

17.2.2.3 Dental radiographs

Each tooth forms over a period of years, starting at the crowns and finishing at the root tip. Different teeth form at different ages and, at any particular age of childhood or adolescence, characteristic stages of formation of the dentition can be seen on radiographs (Fig. 2). The process of tooth formation encompasses approximately the first 20 years of life, with the final

teeth to develop, the third molars, completing root formation in the early part of the third decade. This process of tooth development has been used by clinicians to estimate a "dental age" for an individual. It is often more useful in determining appropriate times for clinical intervention (e.g. orthodontic treatment) than chronological age. Standard tables of tooth development ages are widely available in dental textbooks, based on large surveys. For any tooth and for any particular developmental stage, there is a range of dates, reflecting the expected normal variation. Dental development on panoramic radiographs is, however, widely used as a method of chronological age estimation and has been applied to children and young people without valid documentation of chronological age, such as asylum seekers. Panoramic radiography carries a low effective dose of radiation[27], of a similar order to that associated with a hand-wrist radiograph.

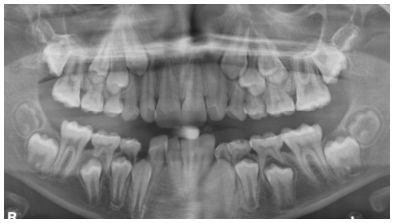


Figure 2. Panoramic radiograph of the jaws of an 11-year old subject, showing a mixed permanent and deciduous dentition. Note the different stages of tooth development. The third molars are only in the early stage of crown development.

One of the most widely used methods is that originally presented by Demirjian et al (1973)[28] and Demirjian and Goldstein (1976)[29]. This classifies a tooth's development into one of eight stages, ranging from A (cusp tips mineralised but not coalesced) through to H (root apices completely closed, with formation of normal periodontal ligament around the apices). Other methods, or modifications of methods, are also used including those of Nolla, 1960[30] and Haavikko, 1970,[31] amongst others. It is important to recognise that, just as with hand-wrist radiographs, dental methods only provide an age estimate with confidence intervals. These confidence intervals tend to be greater for teeth that develop later in childhood. Furthermore, different dental assessment methods can give very different age estimates.[32] A method to reduce the inaccuracies associated with dental age assessment has recently been proposed that uses a meta-analysis method, incorporating all available teeth for analysis, providing a mean dental age.[33] Although this may provide greater accuracy, the authors still reported a maximum chronological/dental age difference of 1.65 years. Furthermore, the number of teeth still forming that can be assessed by this method falls with age.

In practice, it is older adolescents and young adults for whom age estimation is required to determine whether the individual is above or below the key threshold ages of 18 or 21 years. Typically, at these ages all teeth have completed development except the third molars[34], so particular research interest has centred on this tooth. Unfortunately, as inferred above, this last tooth of the permanent dentition has a wide normal variation in dates of development.[35] Furthermore, the third molars are the most frequent tooth to be developmentally absent from the permanent dentition. Several authors[36,37] have suggested that third molar development is unsuitable for assessment of chronological age because of wide confidence intervals encompassing several years. Nevertheless, research in this area continues to be performed. Even though some studies suggest that identification of third molars which have reached Demirjian Stage H development is highly predictive of an individual being at least 18 years of age, for example Meinl et al in 2007[35], this does not establish that the test is appropriate; very many individuals will be chronologically older than 18 years but be at an earlier dental developmental stage.

Use of third molar development for age estimation is made more uncertain by possible ethnic differences. Although some studies report no differences between ethnic groups in this respect, several studies have demonstrated significant variation.[38-42] In the context of refugee

and asylum, several important ethnic groups have never been studied and no applicable reference data are available. Of course, if such studies were to be performed, the frequent absence of valid birth registration evidence would present a significant obstacle to validation of the radiographic data. The absence of applicable reference data increases doubt over the accuracy of age estimations based on tooth development.

17.3 Radiological Methods of Age Estimation: Can they ever be justified?

It is clear that all methods of radiological age estimation (dental and skeletal) can provide an estimation of age, but that confidence intervals for the estimated age can be substantial and adequate reference data are frequently unavailable. The methods have been described as "qualified guessing".[43] Despite this several countries have used, and continue to use, radiological methods. Regardless of the scientific basis for such practices, an important ethical issue is that of consent from the individuals concerned. Although it appeared that some countries may have carried out procedures under a Court order[43,11], this is not normally the case and informed consent must be obtained.

Obtaining a valid, informed, consent is, however, a considerable challenge. Language and cultural barriers may be substantial and individuals may often be traumatised from past experiences. Furthermore, the validity of consent from an unaccompanied child in such circumstances must be doubted. There may sometimes be unacceptable pressure to agree to age estimation, as illustrated by some national representatives at a Workshop on Age Assessment and Identification held by the Separated Children in Europe Programme in 2003. The representatives were asked about the consequences of an individual refusing to undergo age estimation. One response was "*in [country] it is not possible to refuse*" while another was "*in [country] they will be treated as adults if they refuse*".[43]

The scientific uncertainty and ethical concerns surrounding radiological age estimation practices have led influential professional medical organizations in the UK to provide guidance statements to their members. The Royal College of Paediatrics and Child Health have a policy[44] that: *"there is no single reliable method for making precise estimates. The most appropriate approach is to use an holistic evaluation, incorporating narrative accounts, physical assessment of puberty and growth, and cognitive, behavioural and emotional assessments"*. In 1996, the Royal College of Radiologists advised its members that X-rays should only be used in cases of clinical need and that requests for radiography solely for age determination were unjustified.[45] More recently, the then President of the Royal College of Radiologists has reinforced this guidance, stating that: "*There is very little evidence to prove how effective this [radiological age assessment] is and any that there is tends to be incidental.....We are concerned about both the reliability of x-ray examinations for the assessment of age and the clinical grounds for justification of these x-ray exposures"*.[46] In the United States, a distinguished, multidisciplinary, panel of health professionals wrote to the then Secretary of State for the Department of Homeland Security to express their concerns over the use of skeletally and dentally based age estimation, concluding that: "*we believe that it is irresponsible and unproductive to rely on a fundamentally flawed technique..... We recommend that US authorities not rely on dental and bone age testing practices, particularly not as the sole form of determination, but preferably not at all"*.[47]

The weight of the evidence and professional opinion against radiological methods of age estimation is such that one might question whether there is ever any role for their use. It is, however, possible to countenance situations in which they might have some purpose, for example, where clinical ("holistic" physical and psycho-social) methods of estimating age have failed to give an age estimate that is accepted by the individual concerned (and the

team supporting the individual). Similarly, where there is a substantial and significant difference between the age claimed by the subject and that proposed by the authorities, the confidence intervals around radiological age estimations may be acceptable. Of course, both these situations would still require informed consent of the individual.

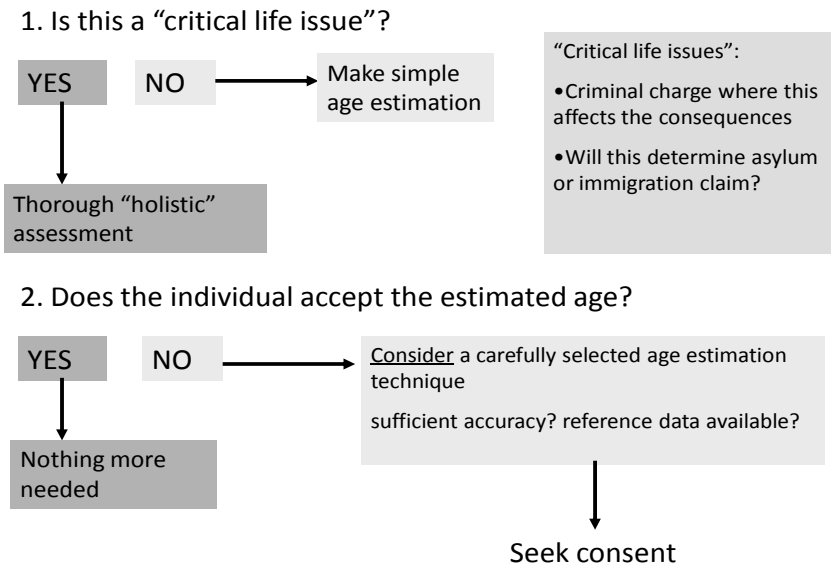
17.4 The Way Forward

It is possible to suggest some basic principles regarding age estimation:

1. Children and young people with no proof of age should be given benefit of the doubt if the exact age is uncertain.[48]
2. When scientific procedures are used in order to determine the age of the child, margins of error should be allowed. Such methods must be safe and respect human dignity.[48]
3. Radiological examinations should only be considered in the context of an holistic assessment of age and maturity by a multidisciplinary team of experts.
4. Justification for radiological examinations for age assessment should be made on an individual basis.
5. Methods involving less, or no, exposure to ionising radiation should be used when these will provide an estimate of age that is adequate and, in any case, should always be performed first.
6. Informed consent is required from the individual being assessed. Refusal to consent should not be assumed to be an indicator of guilt or attempted concealment of true age.
7. Where radiological assessment can be justified, existing radiographs should be used when available, as this may avoid the need for a specific radiological examination for age estimation. In particular, dental radiographs are commonly available from clinical care.

A desirable aim would be the development of a “Care Pathway” for management in these cases that is rational and evidence-based. That presented in Fig. 3 is the suggestion of the author that emphasises the context (“critical life issues”) in which age estimation may be considered. Where there is no “critical” impact associated with the result of the age estimation, then simple (non-radiological) methods should be perfectly acceptable. Radiologically based age estimation methods should be reserved for very specific situations, taking due account of the basic principles listed above.

Figure 3. A possible care pathway for addressing age estimation



Clearly, however, such a Care Pathway should be developed and refined by a multidisciplinary group, including paediatricians, child psychiatrists, psychologists, social workers, educationalists, radiologists, dentists and legal experts. As proposed by the United Nations High Commission for Refugees, the basic guiding principle for any such group must be that of the "best interests of the child" (UNHCR, 1997).

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18 NON-MEDICAL EXPOSURES IN SPORTS MEDICINE AND REFERRAL GUIDELINES

Denis Remedios

Northwick Park Hospital, Harrow, United Kingdom
Chair RCR Guidelines Working Party

18.1 Introduction

The objectives of this presentation were to identify the sources of non-medical exposures in sports and also to propose a strategy for justification using the model of clinical referral criteria. Discussion is largely based around elite athletes and their sports teams.

The International Commission on Radiological Protection reiterates that "the primary aim of radiological protection is to provide an appropriate standard of protection... [and] to make value judgements about the relative importance of different kinds of risk and the balancing of risks and benefits."[1] The concept of risk versus benefit is well understood by sportsmen and sports professionals who will appreciate guidance on what imaging is potentially helpful, both medically and to ensure safe competition. Furthermore the choice of imaging modality may be influenced by many factors including effective radiation dose, cost and availability. Such guidance is already in existence for medical imaging in publications from the Royal College of Radiologists (RCR)[2] and the American College of Radiology (ACR)[3]. The challenge is to identify a role, if any for similar guidelines for non-medical exposures or those in the grey area between medical and non-medical.

18.2 The Use of Imaging in Sport

The Dublin International Symposium for Radiation Protection in 2002[4] [ref Rad Pro 130], reiterated 2 salient points regarding sports medicine (inter alia):

1. Imaging is appropriate in sports medicine when the result will influence management
2. Imaging in sports medicine is for:
    - Acute injuries
    - Chronic overuse injuries
    - Screening

18.2.1 Acute injuries

Imaging for acute sports injuries are, on the whole, medically justified. The choice of imaging modality will be dictated by the type of injury i.e. soft tissue or bony and will be guided by existing referral criteria.[2,3]

18.2.2 Chronic overuse injuries

With chronic overuse injuries, the need for imaging may either be:

- for diagnosis when this is clearly a medical investigation, or
- to enable a decision by the sports team to allow an athlete to compete or how long to stay off competitive sport. This may have financial implications and the over-riding reason to perform such imaging may not be for medical care. Such imaging falls into a grey area which may involve non-medical exposures. The common scenario would be for established bone stress fractures, often in endurance athletes who are referred for computed tomography (CT), additional plain films or bone densitometry (DEXA).

Non-medical imaging is used to aid selection for competition and to support decisions on training and nutrition as opposed to medical imaging which is primarily to establish diagnosis. The grey area is in repeat examinations performed at a more frequent interval than would normally be done for a non-athlete. Non-medical imaging is clearly justified to prevent further or higher grade injury as a result of return to competition too early. This preventative role of imaging is important but requires guidance to ensure unnecessary repeat exposures too frequently.

18.2.3 Screening

Screening athletes for injury is particularly needed in fighting sports and to a lesser extent in contact sports. The inclusion of women's boxing as an Olympic sport has highlighted this need. The three common reasons for screening are:

- Contractual
- Regulatory
- Precautionary

18.2.4 Contractual

Pre-signing medical examinations for elite footballers often require imaging of the knees and ankles. Fortunately this type of screening is usually for soft tissue injury and involves magnetic resonance imaging (MRI), avoiding ionising radiation. There are still concerns regarding anxiety and morbidity from incidental findings but in most cases non-medical radiological exposures are avoided.

18.2.5 Regulatory

Sports bodies such as for professional boxing and other fighting sports require brain imaging, often CT on an annual or regular basis. No unified approach has been taken globally or even within the same country:

- some professional bodies do not requiring imaging[5] ,
- some require CT once at initial licensing to exclude congenital problems[6] ,
- some require annual CT for licensing[7] ,
- some allow a choice of CT or MRI enabling the less costly option[8], and
- others e.g. UK insist on annual MRI identifying the value of the investigation and avoidance of ionising radiation[9].

The alternative to surveillance is protective regulations such as mandatory head guards worn in amateur boxing, the last amateur sport in the Olympic Games.[10]

18.2.6 Precautionary

In boxing, a knock out or technical knock out is associated with a heightened risk of brain injury. Over 650 boxers are known to have died from the sport, usually through brain haemorrhage or chronic traumatic encephalopathy (dementia pugilistica or "punch drunkenness") [ref Robles, Hernandez. 2006. Injury Extra; 37:375] Imaging, often with CT is frequently performed. This is a grey area which is medically justified when there is clinical concern but is all too often performed too frequently for lesser injury.

The need for guidance for non-medical exposures in sports:

- The global practice of most sports is particularly persuasive to professional regulatory bodies, to use similar guidance to govern safety and surveillance. This is especially pertinent for brain imaging in the fighting sports.
- Guidance must be evidence-based where possible and also take into account radiation dose before cost. The evidence base is slim but where available should inform regulation eg protection against congenital brain lesions such as arachnoid cysts.

18.3 Referral Criteria

Referral guidelines for diagnostic and interventional radiology have been in existence for 20 years and have been published in the United Kingdom (the Royal College of Radiologists' Making the best use of clinical radiology services[2]), United States (American College of Radiology's Appropriateness criteria[3]), Europe[12], Australia[13] and New Zealand[14], Hong Kong[15], Canada [16] and other countries. Early versions were intended to guide referring medical practitioners to select the most helpful investigation for a particular clinical problem and were based on expert opinion. The methodology for guideline development has evolved to avoid bias, allow for regional variations and is increasingly based on published and validated evidence. The intention is to provide guidance towards the correct choice of investigation by clinician and radiologist for an individual patient rather than to be prescriptive. Referral criteria have also been used to produce referral pathways and protocols with algorithms designed and agreed by relevant stakeholders (clinician, radiologist and health organisation) for use within a defined community or health organisation. The value of referral guidelines in justification is to avoid unnecessary ionising exposures when an investigation without ionising radiation is of greater or equal diagnostic efficacy.

18.3.1 Development of Referral Criteria

Guideline development has evolved and matured to incorporate a more evidence-based approach. For the published 6th edition of referral guidelines[2] and the 7th edition in preparation, the methodology used by the RCR includes:

- Centralised literature searches with inclusion and exclusion filters including an electronic "hand search" of 7 journals with high impact factors,
- Expert panels from special interest groups which are system-based, age-based (paediatrics) or modality-based (especially for nuclear medicine),
- Delphi consensus to agree recommendations, comments and grading of evidence. These Delphi groups comprise approximately 10 experts and may have a mix of specialty and modality base. Consensus is reached with 75% participation and 75% agreement at 5, 6 or 7 on a 7-point Likert scale. Expert bias is avoided by anonymising data and geographical bias avoided by use of Delphi experts from different centres.

- Wide consultation with colleges and organisations.
- Consideration of additional evidence through consultation
- Ordering of recommended investigations is based on:
  1. Evidence-based diagnostic impact. Selection of the best test is ensured for the clinical indication.
  2. Radiation effective dose. Low or no dose investigations are promoted.
  3. Cost effectiveness.
- Particular consideration has been made for guidance in the paediatric population recognising the different spectrum of diseases and the increased sensitivity to radiation in this age group.

The 6th edition of the RCR Referral Guidelines[2] published in 2007 contains 315 guidelines, 43 of which are new. The evidence base has been strengthened with fewer than a quarter reliant on expert opinion alone.

The American College of Radiology's Appropriateness Criteria[3] were first published in1993 and the current version was released in October 2008. These imaging referral criteria are intended to offer guidance for common clinical problems, to radiologists and referring physicians and also to hospitals and payers. Guideline development is based on attributes from the Agency for Healthcare Research and Quality:

- Validity
- Reliability/reproducibility
- Clinical Applicability
- Clinical Flexibility
- Clarity
- Multidisciplinary Process
- Scheduled review
- Documentation.

It is recognised that data from scientific studies is frequently insufficient and consensus for the ACR Appropriateness Criteria was reached using a Delphi technique with a maximum of 3 rounds, scoring 1 to 9 for appropriateness of an examination. Consensus is reached with 80% agreement. Guidance for initial imaging is offered with caveats that the availability of equipment and personnel will influence choice and that the final decision will be reached by referring physician and radiologist together. The aim is for quality and cost-effectiveness.

Development of referral criteria on both sides of the Atlantic have converged on a reasonably similar methodology summarised in the table below.

Table 1. Similarities between the Royal College of Radiologists' referral guidelines and the American College of Radiology's Appropriateness Criteria

Features	ACR	RCR
Evidence-based	+	+
Based on common clinical problems	159 (800 var.)	315 (647 var.)
Cycle of review	1 yr selective	4 yrs
Expert Panels	18	16
Consensus Technique	Delphi	Delphi
Level of agreement for consensus	80%	75%
Involvement of other organisations	15 through consensus	100 through consultation
Dose information	Rel. radiation level (= ED)	Effective dose (ED)
Publication	web	Paper and restricted web

18.3.2 At whom are guidelines aimed?

Globally, referral criteria are aimed at referring medical practitioners (prescribers) to select the best choice of investigation for their patient. In the UK the RCR guidelines are specifically targeted at General Practitioners and doctors-in-training. Additionally since 2006 imaging referrals have been accepted from appropriately trained, experienced healthcare professionals who are not medically qualified. Referral guidelines are also helpful to radiological practitioners for the ICRP level 2 justification[16] of investigations for a given diagnostic problem, especially to avoid ionising exposures where a suitable and effective non-ionising alternative exists. Whereas the ICRP level 3 justification on an individual basis can only be made with dialogue between referrers and radiological practitioners, guidance incorporating an up-to date knowledge base informs this process of both efficacy and radiation dose. Such guidance must include choice where appropriate, to enable the best test within constraints of resources.

Healthcare organisations and national departments/ministries of health will find referral criteria helpful to plan and resource departments of radiology. However, guidelines should not be used to limit helpful investigations and procedures. Patients may be reassured that a procedure recommended by their doctor using recognised guidelines is appropriate but should not feel that referral criteria are a substitute for advice from their doctor.

Radiographers who act as the justifying practitioner as well as operator will also find referral criteria useful. In the UK, RCR referral guidelines have been adopted by the Department of Health for distribution throughout the National Health Service. Private hospitals also use these guidelines for effective and efficient imaging. Promotion of good medical practice and clinical/radiation risk reduction are elements of clinical governance for any hospital and imaging centre.

In sports medicine guidelines relevant to acute or overuse injury and for screening will be helpful to sports physicians, team managers, regulatory bodies and organisers of national and international meetings as well as to the athlete and provider of imaging.

18.3.3 What is the evidence that referral guidelines work?

There is evidence that justification is lacking for many radiological procedures and that the number of such procedures may be reduced by use of referral guidelines.

After the publication of the first edition of the RCR referral guidelines in 1989, the RCR showed a reduction in referrals for plain radiographs by 13%, from 88.4 to 77.2 referrals per thousand patients.[17] The following year a randomised controlled study by General Practitioners (GPs) in the UK showed significantly fewer referrals for lumbar spine radiography and a higher proportion of requests conforming to guidelines in the group of GPs to whom guidelines were distributed.[18] This early success by simple distribution of guidelines unfortunately was not sustained in a longer study over 4 years.[19] Additional strategies were clearly required. Feedback of audit data regarding unjustified referrals for lumbar spine and knee radiographs was ineffective at reducing referral rates but an educational reminder in reports for such incompletely justified investigations was helpful in producing a 20% reduction.[20] This effect was sustained.[21]

In North America application of ACR guidelines have been shown to reduce the number of radiological examinations performed by non-radiologists.[22] A study of computed tomography (CT) for trauma showed that there was potential for a 44% reduction in number of these high dose investigations if ACR guidelines were used to guide justification.[23]

Improvement of compliance with guidelines for skull radiographs in children was shown when all specialties involved were included and agreed the guidelines. Subsequent reduction was shown in both the number of unnecessary radiographs and the total number.[24]

Presentation of a guideline is important and a psychological study showed that the more precisely behaviours are specified (what, who, when, where, and how**)** the more they are likely to be carried out.[25]

The challenge for the future is to present the right guideline(s) at the right time possibly as part of a clinical decision support system. Such systems are under development in North America and in the UK. The concept in the UK, that a referral for imaging is a request for a radiological opinion concords with such guidance. Other challenges are:

- difficulty with universal applicability and acceptance.
- agreed approach between referring and radiology practitioner supported by healthcare organisation and sports governing body
- decision for imaging should be supported by agreed referral criteria. A suggestion for such guidelines is given in table 2.
- avoidance of repeat investigations. Use of centralised e-health records, patient-held imaging record or a Smart Card.[26]

Table 2. Suggestion for sports guidelines

problem	investigation	dose	recommendation	comment
Suspected chronic overuse injury	MRI	0	Indicated	Best choice for bone or soft tissue
	XR	+	Indicated	For bone injury
	CT/NM	++	Indicated only in specific circumstances	When MRI is not possible.
Brain screening in fighting sports	MRI	0	Indicated	For arachnoid cyst. Follow up for chronic traumatic encephalopathy.
	CT	++	Indicated only in specific circumstances	When MRI is not possible.
Pre-signing screening	MRI	0	Specialised investigation	Decision and scan areas influenced by sport and level.
	XR	+	Indicated only in specific circumstances	Previous fracture properly united?

18.4 Conclusions

- **Guidelines help referring & radiology practitioners, health organisations & sports teams**
- **Justification using guidelines can reduce 20% exams with potential for 44% reduction**
- **Scope for considerable dose reduction by using MRI instead of CT**

In their quest to go ***faster, higher and stronger***, sports teams should be ***slower*** to image, use ***lower*** dose exams but become ***stronger*** in evidence-based practice through use of referral guidelines.

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19 BORDER SECURITY

Michaela Strohschneider

Aviation Security Policy Officer
European Commission, Directorate General for Mobility and Transport

Geraldine O'Reilly

Department of Medical Physics & Bioengineering, St.James's Hospital, Dublin, Ireland

19.1 Introduction

The protection of EU citizens' is a significant challenge and the European Commission has taken important steps to address this in recent years, especially in the field of aviation security. Following the events of 11 September 2001, there was a renewed and heightened focus on security world wide and the Commission was given a mandate in the field of aviation security. The approach within the Commission has been to attempt to harmonise what is done within Member States and to establish agreed standards.

The initial steps involved the development of high-level baseline standards for aviation security that are harmonised as much as possible across the European Union. This approach offers advantages to both the airline industry and passengers. The benefit to industry, whether it is airports, airlines or equipment manufacturers, is that common standards are created which apply equally to all parties. Issues such as the minimum detection rate, the alarm rate and other measurable parameters can be set in standards with which manufacturers must then comply. For passengers, a high level of security is ensured throughout the European Union, whilst also allowing for common application of rules and, equally importantly, the creation of a 'one-stop security' zone within the EU.

19.2 Hand Baggage

For the last three years the discussion on aviation security issues has focussed on the threat of liquid explosives in hand baggage. New measures and restrictions were introduced in 2006 following events in the UK which subsequently became the subject of judicial proceedings and resulted in imprisonment of those involved. Three persons were convicted of plotting to blow up seven transatlantic aircraft using home-made liquid explosives. In September 2009, these individuals were sentenced to 40 year jail sentences.

There was a great deal of negotiation following the first set of measures in 2006 which saw restrictions placed on the quantity of liquids that could be carried on board by passengers as part of their hand baggage. The ban on significant volumes of liquids was accompanied by increased efforts to detect liquid explosives both in hand baggage and secreted on the body. The measures taken have been unpopular with passengers and also with those responsible for implementing them at airports.

The Commission is committed to find technology-based solutions that can identify prohibited substances whether they are in a bag or hidden on the body. The Commission would like to see airports acquire and install equipment for screening for liquid explosives as swiftly as possible.

For the detection of liquids in hand baggage the discussion is well advanced and technological solutions exist. The current situation is that there is almost complete prohibition of liquids being brought on board aircrafts. The intention is to replace this ban by an obligation to screen liquids. The details of these new measures are being presently negotiated between the Commission Member States and the European Parliament in order to have a new system apply as of 29 April 2010.

19.3 Screening of Persons

Technological solutions exist for the screening of individuals but a number of issues of concern arise. One possible method of screening persons at airports is by use of machines known as 'body scanners'. There are ethical issues surrounding the screening of humans including a concern relating to invasion of privacy. There are also concerns about data protection and lesser concerns in relation to radiation dose for those methods that use ionising radiation. As concerns liquid explosives carried on a person's body or in his clothes, detection depends on the appropriate screening technology to be introduced in the list of optional screening methods provided by EU legislation. So far this has not happened due to concerns related to health, privacy and possibly data protection.

When considering and eventually proposing new screening technology the Commission takes input from three key players:

- the airports (who have to procure the equipment),
- the Member States (who have to make the political decision) and
- equipment manufacturers (for defining the actual threats that equipment must detect).

19.4 Review of Legislation & Security Measures

The Commission is in the final stages of overhauling its whole package of aviation security legislation, which was adopted in the aftermath of 9/11. The principle of better rulemaking has been followed in this work, but the development of security rules is an on-going task as risks change and technologies develop.

In March 2008, The European Council adopted a Regulation[1] aimed at protecting persons and goods travelling by air within the European Union. One of the means for ensuring this is to screen persons before they enter security restricted areas at airports and board an aircraft. The Commission is required by this Regulation to adopt general measures on aviation security, which must include the 'methods of screening allowed'.

Aviation security legislation is developed using a layered structure. When body scanners were first proposed as a method of screening passengers, it had been thought that the allowed screening methods and technologies could be listed in the first layer of legislation. This could include approved body scanning technologies – using both ionising and non ionising radiation. The next layer of legislation could then incorporate all of the relevant provisions relating to the use of those technologies. This would allow issues such as privacy, remote viewing of images, data protection and other considerations to be addressed.

In order to decide whether or not 'body scanners' could be allowed as a method of screening persons at airports and if so, under what conditions, the Commission carried out a consultation on the impact of the use of body scanners in the field of aviation security on human rights, privacy, personal dignity, health and data protection. The consultation was carried out in the light of a Resolution adopted by the European Parliament (EP) in October 2008 on the impact of aviation security measures and body scanners on human rights, privacy, personal dignity and data protection.[2]

The EP Resolution asked the Commission to:

- carry out an impact assessment relating to fundamental rights;
- consult the European Data Protection Supervisor (EDPS), the Article 29 Working Party and the Fundamental Rights Agency (FRA);
- carry out a scientific and medical assessment of the possible health impact of such technologies;
- carry out an economic, commercial and cost-benefit impact assessment.

The consultation process in 2008 revealed that there was considerable unease within the European Union which prevented further development of the legislation. The consequence of this is that the only technology approved for use at the moment is that which relies on metal detection.

It is envisaged that, in the future, a team of airport inspectors, employed by the European Commission, would review security arrangements in airports. This would allow rapid feedback on how measures were implemented. This could inform further reviews of legislation and standards.

Legislation has been devised to deal with liquids which might pose the threat of liquid explosives. There is a list of prohibited items. The challenge in the efforts was how to differentiate between harmless liquid and liquid that might be explosive. In 2006, legislation was drafted which resulted in liquids being prohibited other than in small volumes. Some exemptions were made.

It is important to note however that while body scanning technology is not dealt with in current EU legislation (with the exception of metal detectors), it is not prohibited. The consequence of this is that there is not a legislative framework within which current body scanners can be regulated. This means that the original objective of the Commission to harmonise practice across the EU can not be achieved by purely legislative means.

19.5 Conclusions and the Way Forward

In the context of imaging technology, fundamental rights and health issues are being discussed with appropriate authorities and other entities responsible.

The international dimension to security screening remains an important issue in the overall approach. An on-going dialogue with other countries exists to ensure that similar, if not identical, standards and timelines are developed. There is close contact and co-operation with international partners in the US, Canada and Australia to consider a single security initiative. Such an approach would allow a single screening in one country to provide the basis for travel across international borders as part of a single journey.

The Commission also remains in close contact with manufacturers in order to ensure that there a high level of awareness in relation to the latest technology. These meetings are part of a series of meetings with all of the relevant stake holders including manufacturers, security officials and airport authorities.

The Commission is of the opinion that the optimal way to develop technology-driven policy is to have the maximum degree of transparency and dialogue with all of the key players.

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20 HUMAN IRRADIATION AND CRIME PREVENTION

Mrs. Arja Pullianen

Finnish Civil Aviation Authority
P.O.Box 186, FI-01531 Vantaa, Finland

Aviation has been a popular target for terrorists and other perpetrators for a long time. The first recorded act of unlawful interference against civil aviation occurred in 1931 in Peru. A small aircraft was hijacked by armed revolutionaries in order to distribute anti-government pamphlets from the air.

Since then, the means and methods of unlawful interference have changed as well as the motives. Civil aviation can be subject to illegal activities in many ways, but most of them require that some kind of weapon or explosive is introduced in the airside of an airport or into an aircraft.

To prevent this, all persons having access to security restricted areas or aircraft are subject to screening. Security screening methods in Europe are harmonized by Community legislation, which currently allows only the use of walk-through metal detectors (WTMD) and hand search. However, practice has shown that even the combination of these methods is not effective enough to respond to the growing threat posed by new prohibited articles. Liquid explosives are a new challenge and many explosives can easily be shaped so that it is quite difficult to identify them even by hand on a human body.

At present, the persons are first screened by WTMD and after that subjected to random hand search. Many people do not want to be touched by a stranger at all. They feel that their privacy and sometimes even decency are offended. In addition, some passengers' traditional or religious clothing prevents a thorough hand search.

New technology offers opportunities, one of which is body scanning. New methods and equipment have to be tested, and when Helsinki-Vantaa Airport expressed their interest for testing, the Finnish Civil Aviation Authority supported the proposal. The European Commission granted the permission to start the test in November 2007.

Helsinki-Vantaa Airport is the main airport of Finland with 13 million passengers annually and 20 thousand employees. The equipment selected for the test was Rapiscan Secure 1000, which is based on backscatter technology.

As the equipment uses radiation, permission from the authority supervising radiation issues in Finland was also needed. The Radiation Agency inspected the equipment and the process. The result of their inspection was that the screener operating the equipment is not subjected to radiation and the amount of radiation received by the screened person is minimal. Effective dose for the screened person is 0.044 μSv (microsievert). In proportion to the annual radiation exposure, the radiation received from one scan is minimal. For example, a flight from Helsinki to Frankfurt results in a dose of approx. 10 μSv.

The aim of the test was to collect information on the passengers' willingness to use scanning, to find out how effective the method was in finding prohibited articles and to determine if any savings could be achieved in time and money used for the screening process.

The test was based on voluntary participation. Passengers were selected for interview from the airport screening point queue at random, so that the tester or the passenger could not have any influence on the selection process. The selected passengers were interviewed and it was explained to them how the equipment works, what kind of a picture would be taken, who was going to look at it and what was the amount of radiation received.

On the recommendation of the Radiation Agency, all selected passengers who were under the age of 18 and women who were pregnant or suspecting to be pregnant, were advised in the interview not to participate in the test.

To protect the privacy of the passenger, the screening officer looking at the image had no possibility to identify or recognize who the screened passenger was. The actual scanning equipment and the officer looking at the image on display were located in different rooms. Access to the image room was restricted only to specially trained screening officers on duty.

The image viewer only has a few seconds to look at the picture before it is destroyed. In the event that he/she sees an item that cannot be identified in the image, he points the location of the item to another officer who is with the passenger by using the computer screen. The other officer assisting the passenger can then ask him/her for example to empty the pockets to see what the item is. The pictures are not saved, and they cannot be returned back onto the screen.

During the test period of 18 months, more than 13 thousand passengers were asked to participate in the test. 84 % of them accepted to be scanned. The willingness to participate was nearly equal for men and women.

The actual screening process took around 40 seconds per person. Real-time passenger flow could not be calculated because all selected persons were interviewed, which prevented the continuous flow. During screening the screeners could identify metallic items, like cigarette lighters and coins, and non-metallic items like plastic combs, but no prohibited items were found.

The main advantage for the passengers was the possibility to avoid hand search. Interviews proved that the passengers found this method to be much more convenient than a hand search. As an anonymous person was watching the image with no possibility to recognize the subject, the passengers felt that scanning was not compromising their privacy. Screening conducted with a machine was considered much more acceptable than a personal hand search.

The screeners using the equipment concluded that it was very easy and quick to identify items on the screen. Moreover, passengers had to be subjected only to one screening method, which means that savings could be achieved in staff costs.

A significant benefit is that the system detects all kinds of materials. Effectiveness of detection is much better than with any method covered by the legislation today.

Session 6 - Review, Consensus, Conclusions & Recommendations

21 SYMPOSIUM REPORT

Geraldine O'Reilly

Department of Medical Physics and Bioengineering, St.James's Hospital, Dublin, Ireland

21.1 Scene Setting

21.1.1 Introduction

Presentations in the first session outlined previous work and the background to the Symposium. The definitions contained within the Medical Exposure Directive, the rationale behind these definitions and the approach taken was reviewed. The list of exposures types that might be considered to fall into the category of medico-legal exposures was presented as:

- *Insurance*
- *Civil Litigation*
- Suspicion of Child Abuse
- Weapons or Drugs Search
- Sports medicine (Predictive/Preventative)
- Age Assessment
- Vehicle inspection
- Immigration
- Emigration
- Search of Prisoners
- Pre-employment

The list illustrates the diverse range of exposure types and practices that might fall into the category of medico-legal exposures. It was noted during the first session that as all of the exposure type's fall within the scope of medical exposures and many will be carried out within a medical facility, it is possible that practices might effectively escape from regulatory control. It was stated that medical exposures tend, to a large extent, to be left to the professionals and regulators tend not to intervene. Without a proper regulatory framework, radiation protection issues may be ignored and existing medical frameworks may not be well suited to what are essentially non-medical purposes.

The categories of exposure contained within existing legislation, (96/29/Euratom) were reviewed. There are 3 categories of exposure: public, occupational and medical. Although the European Basic Safety Standards (BSS) is currently under revision, it is envisaged that the categories of exposures will remain unchanged and that there will be no additional categories. Currently, all medico-legal exposures are grouped together, as a sub-set of medical exposures, and this is almost certainly not the most appropriate way to deal with them as significant differences exist between different exposure types. It was noted that one possible solution might have been to consider grouping all of the exposures under public exposures. However, a review of the likely doses for some practices (e.g. drugs search) immediately reveals that public dose limits would be breached. Yet, to continue to group these practices within medical exposures would, in some instances, lead to high doses without a direct benefit to the individual exposed. This suggests that optimisation strategies

including the use of specific dose constraints will be required as part of the approach. It is very clear that the central issue in the approach to dealing with medico-legal exposures will be justification.

21.1.2 Review of Previous Work

Previous work had looked into how Member States had implemented the Medical Exposure Directive in relation to medico-legal exposures. This had been reported on in the 2002 Symposium and a short review of this work was presented. From this work, it was clear that medico-legal exposures were carried out in many Member States. It was also evident that there was a lack of clear knowledge and understanding within Member States of the practices that existed. The survey carried out prior to 2002 had identified the need for new data and information. It was also clear that for any approach to be successful, it would require the participation of a broad range of professionals. This might be achieved by the creation of international networks comprising the expertise needed for the various applications. A clear need for guidance documents was identified but there was also a recognition that these should be developed following consultation and collaboration with all relevant stake holders. Previous work had also identified the importance of developing referral or appropriateness criteria for each individual practice.

21.2 Update from International Organisations

A number of international organisations have considered the issue of medico-legal exposures. There were presentations from the IAEA, the ICRP and also from the European Commission outlining existing legislation and guidance as well as indicating more recent initiatives and likely future developments. The material presented at the symposium and detailed in these proceedings represented the situation as it was in October 2009.

21.2.1 ICRP

The ICRP in their 2007 document ICRP 103 have stated that ‘certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances. These include radiological examination for occupational, health insurance, or legal purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations’. The ICRP go on to state that ‘this almost always means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified’. At the moment the ICRP have not expanded on what might be considered to be exceptional circumstances, leaving the situation somewhat vague. The ICRP have stated that justification of practices is a matter for national authorities and that this will include consideration of matters other than radiation protection. There are no current plans within the ICRP to produce a guidance document on this issue, instead they maintain a watching brief.

21.2.2 IAEA

The IAEA have developed a new approach to medico-legal exposures which will be incorporated in to the new International Basic Safety Standards which is currently being revised. One of the objectives of the IAEA revision is to ensure a consistent and

comprehensive approach by all member states to radiation protection. The IAEA refer to ‘medico-legal exposures’ as ‘non-medical human imaging’. They define two categories of exposures, the first of which:

- takes place in a medical radiation facility,
- uses medical radiological equipment,
- is performed by radiology personnel and
- produces images reported by a radiologist or other doctor

for the purposes of:

- obtaining legal evidence
- insurance
- employment
- immigration
- age determination
- assessing physiological suitability or status
- detection of drugs within a person.

For procedures in this category, the imaged person is afforded the same protection as if they were a patient undergoing a medical exposure, with the exception that specific dose constraints replace diagnostic reference levels (DRLs) and these dose constraints may in fact be lower than the DRLs.

The second category is non-medical human imaging that:

- takes place in a non-medical facility (often in a public place),
- uses specialized inspection imaging equipment,
- is performed by non-radiology personnel and
- produces images viewed by a non-medical person

for the purposes of:

- detection of concealed weapons on:
    - airline passengers
    - persons crossing a national border
    - visitors to prisons, court houses, public buildings, etc.
    - prisoners within a prison;
- theft detection
- screening cargo containers and vehicles.

For procedures in this category, the imaged person is afforded protection as a member of the public, again with purpose-specific dose constraints. Furthermore, the individual to be exposed should be offered an alternative technique that does not use ionising radiation, where such an option is available. In this category, the public dose limits apply.

The draft IAEA requirements are based on the ICRP principles of radiation protection. Government is assigned responsibility for the essential justification process and all justified activities are subject to regulatory control, including requirements for optimisation with dose constraints and dose limits, where appropriate.

21.2.3 European Commission

The European Commission presented the provisions relating to medico-legal exposures from the draft of the revised European BSS. The term "medico-legal procedures" has been replaced by that of "non-medical imaging exposure" (NMIE). This was defined as "any exposure of humans for imaging purposes where the primary motivation for making the exposure is not related to the health of the individual being exposed". The intention in the draft BSS was to consider that these exposures would normally be considered to be public

exposures but in exceptional circumstances, where the expected advantages for the population as a whole are sufficient to compensate for the disadvantages, the public dose limit could be exceeded. In such cases the practice should be subject to dose constraints and the criteria for individual implementation of the exposure are particularly relevant.

The draft BSS maintains a strong requirement for justification and optimisation of such exposures and a requirement for authorisation of relevant practices. It envisages that the requirements for implementation would be established by the regulatory body in cooperation with relevant agencies and professional bodies. Dose constraints shall be set for the justified NMIE practices. The constraints shall be defined in such a way as to ensure compliance with the dose limit for the sum of doses to the same individual from all regulated sources.

The draft Directive includes a requirement for informed consent of the exposed individuals, allowing for exceptional circumstances where the law enforcement bodies may proceed without consent in accordance with national legislation. The draft also requires that alternative techniques, not involving ionizing radiation, be available where the exposure is routinely carried for security purposes.

21.2.4 US Activities

Information was presented on the regulatory system in the US and how the various agencies work together in the control of artificial sources of radiation. Of particular relevance was the Guidance document developed by ISCORS on security screening of humans. The document is advisory rather than mandatory. It includes advice on the process and factors to be considered in making a justification decision. It also provides advice on appropriate systems of radiation protection for justified practices. The document notes that the justification process will have to consider many factors in addition to those relating to radiation protection.

A review of relevant ANSI standards was also presented. Of particular relevance is ANSI N43.17 which deals with radiation safety of security screening systems and sets out the dose limits that apply. These are given both as an annual (250μSv) and per scan (0.1 μSv) value for effective dose.

21.3 Ethical & Legal Issues

There is clearly a need for balance between individual & societal rights, the particular issue being the extent that one can justifiably resort to such exposures in circumstances which are not determined by or necessitated on medical grounds. There were two presentations relating to ethical and legal issues arising from exposures that might be considered to be medico-legal or non-medical imaging, to use the new term. It was clear from the material presented that ethical and legal principles can be used to inform the approach to all human imaging exposures but they are especially relevant when the motivation for the exposure is not directly related to the health and well being of the individual exposed.

The issue of balancing individual and public interests has both concrete and theoretical aspects. Those who have to make the decision, based on certain relevant evidence and relying on a value judgement, are faced with the concrete demands of the situation. Public interest may outweigh individual concerns in certain circumstances. A philosophical analysis can provide a conceptual tool that can aid with the decision-making. A guiding principle is that no human person should be subjected to any practice or activity that would violate his/her dignity. However, a practice that is truly good serves both the individual and society.

Common good should not be confused with the majority view or welfare. Continuous review of such practices is required to assess the impact on individuals and society.

Using the wider philosophical context to the topic can provide a framework within which some relatively specific guidelines can be developed. The hope is that with these guidelines, those who do have to make the judgement as to the use of non-medical exposures in the various situations will be enabled to make an ethical judgment where the dignity and autonomy of the exposed individual is respected.

The issue of “informed consent” (or lack of it) in non-medical situations is important and makes these situations distinct from medical ones. Consent can be both ‘actual’ and ‘implied’ (i.e. assumed). Confidentiality and consent are usually integral to medical exposures but this can not be assumed to be the norm in exposures that arise from medico-legal issues. It may even be the case that in certain circumstances, other considerations over ride this individual right. The requirement for consent demonstrates a respect for the dignity and rights of the individual and is only true where it is voluntarily and freely given. The real issue therefore is whether those situations or activities can be ethically justified or not in the first place.

21.4 Update on Practical Experience of Implementation

In the process of developing draft requirements, it had become apparent that there was a still a lack of information about how the use of radiation for non-medical imaging was being regulated in Member States. To address this deficit, there were a number of presentations from Member States and the IAEA, which outlined either the approach that had been taken in various countries in relation to medico legal exposures or described particular activities/practices that had to be considered and regulated. These presentations illustrated the many challenges that face regulatory authorities in this new and diverse area.

It was evident from the material presented that imaging for purposes other than medical diagnosis or treatment is being performed in many different applications in many countries and states. It was clear that there was often poor regulatory coordination and an absence of a formal justification process. Existing practices were sometimes characterised by poor optimization of radiation protection for the exposed person. There was also a lack of guidance available for those tasked with justification, regulation and implementation.

An issue of concern that emerged from these presentations was that a significant number of radiation protection regulatory bodies were unaware of the extent of practices involving non-medical imaging exposures in their jurisdictions, indicating that better coordination and cooperation between authorities is needed.

The objective of a consistent and harmonised approach between countries will require increased emphasis on justification, purpose-specific optimization utilizing dose constraints, and public dose limitation where applicable. To facilitate implementation specific and comprehensive guidance documents are required.

21.5 Review of Practices

21.5.1 Security Screening

Since 9/11, there have been enhanced security requirements world wide. This has led to renewed interest in security scanning and the introduction of x-ray scanning techniques at ports and airports. The scanning devices utilise low dose technology with a typical dose per

scan of <0.1μSv for the back scatter technique and of the order of 6μSv for transmission devices. Non-ionising techniques have also been used and this technology is likely to become more important in the future. With doses of this level, even frequent travellers could possibly fall within the public dose limit.

Given that these devices are now being used in areas where there is little previous experience of such technology, it raises the questions as to whether radiation protection issues are adequately addressed. Scanning devices have also been used in other areas such as in prisons, at public events and in public places but perhaps without a suitable supporting educational and professional framework. The ethical issues that arise include consent, invasion of privacy and the appropriateness of including children in the scanned population. There are technological and operational methods available to deal with some of the privacy issues and this may address some of the concerns raised. Justification of these practices must take input from a wide social base.

At the time of the Symposium (October 2009), the scanners had been used on a 'trial' basis within Europe as aviation security legislation did not permit routine use of body scanners. In order for this application to be supported within a legal framework, it was noted that an amendment and/or revision of this legislation would be required. Such a revision was considered as part of a consultation exercise held by the European Commission (DG TREN, Aviation Security Section) in 2008. During that process, many of the ethical issues outlined above were raised by various interest groups. The outcome of the consultation was never published but since that time the focus within the Commission in relation to aviation security had moved to measures relating to hand baggage and a revision of the security legislation on body scanning has been, for the time being, deferred to a future date.

The issues that remain relate to the harmonisation of practice in Member States and the establishment of agreed standards. The screening methods chosen will require acceptance from Member States, airport authorities and members of the public. Existing medical techniques and technology have been adapted and are being applied for non-medical reasons outside of medical institutions; nevertheless, their application should be carried out within an appropriate framework of radiation protection.

It is important to note that since the Symposium, there have been further developments in the area of aviation security in the EC which have addressed previous restrictions on the use of scanners in this area.

21.5.2 Detection of Concealed Objects

21.5.2.1 Vehicle Scanning

Vehicle scanning techniques are used both for detection of attempted clandestine entry via deep concealment in vehicles and to detect trafficking of illegal goods hidden in container vehicles. The latter application is most probably an industrial exposure and therefore covered by the Basic Safety Standards. However, the use for detection of clandestine entry is less clear. Some would consider this to be covered by the MED under the category of medico-legal exposures and others would feel that the MED does not apply and only the BSS is relevant here. This remains as an issue to be resolved.

When the objective in scanning the vehicle is to detect contraband, some facilities in a number of Member States have in place controls for dealing with stowaways. These controls are aimed at alerting persons hidden within the vehicle to the fact that an exposure is about

to take place. The dose to individuals who fail to leave the vehicle prior to scanning would be low, less than 10μSv. There are plans to develop techniques involving drive-through scanning. The dose to the driver in these situations would be less than 0.01 μSv per scan.

21.5.2.2 Drugs Detection

Both plain radiography and CT are used in the surveillance of those suspected of drug trafficking. When a suspect is believed to have swallowed drugs, scanning the individual offers an alternative to enforced detention. Selection of individuals relies heavily on prior information, profiling, observation and conversation. So while it is obvious that the selection process is sophisticated, it would appear to rely to a great extent on the skill of the investigating team and the individuals involved. This would indicate the need for agreed selection or referral criteria for scanning. It is clear that using standard scanning techniques, the public dose limits are likely to be breached. This means that the exposures can not be considered to be public exposures and an alternative framework is required.

21.5.3 Suspected Child Abuse

Imaging is an important tool in diagnosing Non Accidental Injury (NAI) in children. Plain radiographs and CT, and sometimes radioisotope studies, may be used to diagnose injuries that may need treatment but also injuries that don't need treatment. The aim of the radiographs is to diagnose abuse or establish another diagnosis and also to gather evidence, help avoid further injury, and to help in treatment and/or conviction of perpetrator. It may also be a necessary step in providing alternative care for the child.

Early detection of child abuse means greater potential for preventing further harm. If the grounds for suspicion are adequate, the studies are done meticulously and expertly interpreted, then the benefits to the child will out-weigh the risks and the procedure can be considered justified and optimised.

In many of these imaging studies, the dose to the child will exceed the public dose limit. However, it is argued that this is a medical rather than a non-medical imaging exposure as the primary focus is the health and welfare of the child and siblings, if relevant. If this is the case then dose limits should not apply.

21.5.4 Sports Medicine

Imaging is used in both elite and recreational athletes. Imaging in sports medicine can be for acute or chronic overuse injuries or for screening purposes. Imaging for acute sports injuries are, on the whole, medically justified, providing that the intention is to diagnose and treat. With chronic overuse injuries, the need for imaging may either be for diagnosis or prognosis. While the former is clearly a medical exposure, the latter may have financial implications and the motivation to perform such imaging may not be for medical care. Such imaging falls into a grey area which may involve non-medical exposures.

Imaging is also used to aid selection for competition, to support decisions on training and nutrition and as a preventative tool. The preventive use of imaging is important but requires guidance to avoid misuse.

Imaging is also used for screening purposes in certain contact sports as a precautionary tool to rule out certain conditions which if present would lead to heightened risk for the individual involved.

A further screening application, without a specific clinical indication, is when x-rays are used to assess an individuals potential before a transfer or appointment, as part of professional or contractual obligations or, with young persons, to assess their potential growth. Each of these examples should be treated as a separate type of practice requiring explicit justification. As part of the justification process it is useful to consider the motivation for the practice. In some cases the benefit would be primarily to the requestor of the examination but there is also a view that the imaging provides a general benefit to the individual as it allows them to participate and compete. In these cases, consent is usually readily given and in fact athletes and sports persons tend to accept imaging and sometimes even demand it.

Imaging in elite athletes and sports persons tends to be used more frequently and exams can often be repeated. The effective doses will depend on the type of examination to be conducted but it is likely that in many cases, doses will exceed the public dose limit, so it is clear that these exposures can not be dealt with as public exposures. There is a clear need for evidence based guidance. It is also important that adequate information about the risk of repeated imaging is given so that consent is informed.

It is clear that many of the exposures are not true medical exposures in the sense that we would normally understand these. One possible solution to this issue is to broaden the definition of medical exposure in the context of radiology. If instead of simply referring to an exposure incurred to benefit the health of the exposed individual, this is expanded to cover the ‘health and well being’, then the definition takes on a more general and expanded meaning. This may be sufficient to deal with many of the exposures encountered in sports imaging within the framework of medical exposures. It may also provide a mechanism for dealing with exposures required for other purposes such as insurance or emigration where the individual will derive some benefit albeit it of a nature that is not related primarily to their health.

21.5.5 Age Assessment

The request for an age determination usually originates in some legal circumstance where there is no valid proof of date of birth. This may be for adoption, for refugees seeking asylum, for illegal immigrants or when the police need to decide whether to apply the adult penal law. The common factor is that the subjects of examination are young persons. Two types of examination are carried out, dental and skeletal, in both cases using x-rays. The skeletal examination is normally of a selected part of the body such as the hand and wrist, iliac crest or clavicle.

The main rationale and hence benefit is to the authorities to provide a sound basis for a decision. There may or may not be a direct benefit to the person being examined in accurate age estimation.

Material presented at the Symposium indicated that radiological methods of age estimation have significant limitations in accuracy and suggested that such techniques would only be useful where there is a large difference between the age claimed by the individual and the true chronological age. For many methods, accuracy falls with chronological age, becoming less accurate in adolescents than in children, and even less accurate in adults than in adolescents. This factor is in addition to the uncertainties inherent in the technique itself and any inter-and intra-observer variability. The techniques available may not be sufficiently

accurate for use in confirming or otherwise whether an individual is above 18 years (or other threshold of majority).

Given the fact that radiological methods of age estimation have significant limitations in accuracy, the use of such techniques not only requires justification in general but individual justification should be applied. As racial, gender and possibly socio-economic differences exist in dental and skeletal development, the correct reference data should be available and the validity of the method established for the individual case.

The effective doses from such examinations will usually be small, of the order of 0.1 mSv but the usefulness of the technique is brought into question as it may lack the precision to satisfactorily answer the question asked. So while it can be of value as part of a holistic approach, a care and decision pathway is needed for the practice to be justified.

21.6 Problems/Issues Identified

The presentations at the symposium provided much valuable information and led to some very interesting and useful discussions. It was clear from the material presented on the various categories of exposures that public dose limits would be an obstacle for some practices. It was also clear that for those practices that were already established, the justification process was not as effective as it might. However the necessity for some of the existing practices was not disputed.

Following the construct within the Medical Exposure Directive, all individual exposures are supposed to be justified both by the prescriber and the practitioner. Where exposures are carried out in a medical facility, some level of justification would be carried out by the radiologist accepting the referral, however radiologists are not trained to handle public health and security issues and so justification must be dealt with prior to the individual being referred to the medical facility.

A further issue that arises for those exposures carried out in a medical facility is the fact that in the case of medical exposures, consent and confidentiality are integral to the process and practices take place within strong governance arrangements. In non-medical imaging exposures, there are consent and confidentiality issues and the governance is disseminated.

Addressing the deficits noted above was seen as essential to ensuring that those exposures that are carried out in a medical facility are appropriately justified and are carried out within an appropriate legal framework.

The ICRP approach whereby it is assumed that for medical exposures there are three levels of justification may offer a way forward and consideration should be given to incorporating this into the revised approach to non-medical imaging exposures. This would mean, for instance, that the use of CT scanning for drugs detection would have to be first justified as a practice. This justification would have to follow a structured approach which took account of all relevant considerations, views and interests. Then, for justified practices, individual justification would have to take place for each exposure. The considerations that would form part of the individual justification would be very different to those pertaining to a medical exposure although there might be some elements that would overlap albeit with different weightings.

For those practices that are deemed to be justified, generic justification must be socially acceptable and justification should be broadened to include benefits other than health benefits.

21.7 Review, Consensus and Conclusions from the Symposium

The final session in the symposium allowed for discussion of the main conclusions that had emerged over the course of the two days. It was generally agreed that the central issue in non-medical imaging exposures is justification. It was clear from the material presented during the meeting that public dose limits are likely to be exceeded in exposures for drugs search, sports medicine and NAI. Because of the altered risk/benefit ratio that will apply in the case of non-medical imaging exposures, dose constraints will be required and these may be significantly less than standard dose reference levels (DRLs) for similar type examinations that fall in to the category of medical exposures. One approach that had been suggested at the start of the symposium was to consider all non-medical imaging exposures as public exposures but to allow dose limits to be breached in certain circumstances. However, it was clear from the discussions at the end of the symposium that dose constraints which exceed dose limits was not an acceptable concept or approach for many of those participating.

So it is not possible to deal with all non-medical imaging exposures as public exposures. It's worth noting that the starting point for the deliberations of those attending the symposium was outlined by the Commission in one of the first presentations. This presentation made clear that the revised and recast BSS would still retain the concepts of planned exposures falling into three categories of exposure – public, occupational and medical. This constraint means that non-medical imaging exposures have to be dealt with within this framework and the various practices have to fall under one of these three categories. Without the freedom to consider defining a fourth category of exposure, the resultant approach will of necessity still have some serious deficits both in terms of concept and design.

One possible way to deal with some aspects of this problem is to broaden the definition of medical exposure to include the concept of benefit to the health, welfare and general well being of the exposed individual. By doing this, some non-medical imaging exposures would then clearly be included within the category of medical exposures. Those exposures that do not offer benefit to the individual being exposed would still remain outside that category.

Another proposed solution to deal with some types of non-medical imaging exposures was to create new approved screening programmes with defined criteria of admission that allow the problems involved be addressed. This could be used to deal with the problems that arise in the areas of sports medicine and non accidental injuries of children. This approach would require little change to the legislation but would require significant administrative and professional initiatives. It would not offer a solution, however, for some of the other non-medical imaging exposures for which the dose limit is an issue (e.g. detection of drugs).

All of the discussions over the course of the symposium highlighted the fact that input from a broad range of professionals is required in order to arrive at a satisfactory and workable system of dealing with the wide range of non-medical imaging exposures that currently take place. This may be something that would benefit from an international network as although harmonisation of practices is unlikely, a harmonised approach and sharing of information might be appropriate and beneficial.

Without the construction of an appropriate and robust legal framework, practices may escape from regulatory control and indeed it is likely that the extent of current practices is unknown at both a national and international level. There is a clear need to improve knowledge and tighten the regulatory framework to ensure that radiation protection issues are adequately addressed.

21.8 Future Work

Implementation of the provisions of the MED in relation to medico-legal exposures across the EU has clearly been challenging for Member States. There is a clear need for a guidance document to support the implementation of existing and future legislation in this area. The document should focus on the justification of such practices and how this can be achieved while ensuring inclusion of relevant stakeholders. There is a need for guidance on a structured approach to justification and how it might be applied in this area. It should also provide clarity on the categorisation of practices and identify the key issues in relation to these. The material in the proceedings and the discussions that took place during the symposium, as documented in this report, should provide a sound basis for development of such guidance.

One of the constraints in relation to the revision of the European BSS in the area of non-medical imaging exposures was the fact that exposures had to fall into one of the three existing categories – public, medical or occupational. This posed significant problems in terms of constructing a legislative approach that was both internally consistent and achieved the necessary objectives. It would be useful to look at the difficulties and problems that the introduction of a fourth category of exposures (non-medical imaging) might have brought. The conclusions of such a review would either support the approach that has been adopted or offer opportunities for an alternative approach in the future.

As part of the approach to non-medical imaging exposures in the revised BSS, the definition of medical exposure has been broadened to include general well being as well as health. While it is understood that this definition is only relevant in the context of the recast BSS, it would be worth reviewing whether or not this revised definition has implications in other areas of medicine or in other legal documents.

The material presented on dosimetry and existing practices in Session 5 identified significant gaps within the published literature on doses to exposed individuals. It was also identified that there was a need for the development of both referral or selection criteria and standard protocols. This was particularly evident in the areas of NAI and sports medicine. These are areas which would benefit from further work. In parallel with addressing the current knowledge and practice deficits, it would be interesting to study the essential features of screening programmes to see if they could accommodate some of the practices such as NAI and some aspects of sports medicine.

Finally, there was a general assumption that some of the exposure types discussed during the symposium were low dose and hence could easily be categorised as public exposures. While this is likely to be the case for most individuals exposed, some further work is required to confirm the inherent assumptions and identify any areas where significant exceptions will arise.

21.9 Final Conclusions

The experts who were invited to present at the Symposium have knowledge of the origins of the problems involved and the history of the Commission's efforts to deal with them over the last two to three decades. Speakers were also invited with expert knowledge of the scientific, medical, legal and ethical issues involved and how they are viewed in the frame of contemporary social thinking. Most speakers took account of attempts made by governments and the international organizations to devise effective paths though the intricate issues involved. Overall the presentations combined to create a rich mix which explored many possible options and a variety of solutions.

These proceedings reflect this rich mixture, and where possible the consensus position emerging is noted in the final section of this meeting report. Most of the speakers presented their manuscripts after the Dublin seminar and hence did so knowing the flavour of the discussion that took place and the consensus for action that emerged. We have not edited differences in the manuscripts which reflect the richness of the workshop. The manuscripts reflect the expert authors' views rather than the Commission's and we feel it is better leave the expert opinions to speak for themselves. However, for the benefit of those who did not have the opportunity to be present, we also note the substantial areas of consensus, which were evident during the final session, and hope they help the Commission identify the paths for future action that are open to it.

The Symposium provided much valuable information on the area of medico-legal/non-medical imaging exposures and helped identify the way forward in terms of revisions to the European BSS. It is clear that there is a need to retain the level of protection and justification that applies to medical exposures. However in doing this it is also necessary to ensure that the over-arching framework is such that all practices are regulated and appropriate levels of control are in place. Justification must be applied for every practice and individual exposure. It will also be necessary to develop referral or selection criteria and to ensure that procedures are established for each practice.