

# **A REPORT BY THE CLINICAL ADVISORY COMMITTEE ON DIAGNOSTIC IMAGING ON THE SAFETY AND EFFICACY OF CT SCREENING**

Thanks to all those listed below who provided input to this final draft report.

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## **1. EXECUTIVE SUMMARY**

This is the final Report of The Clinical Advisory Committee of Diagnostic Imaging (CACODI) on the role of diagnostic imaging in preventative medicine, looking specifically at CT screening in the early detection and prevention of certain diseases.

This Committee has not looked at whole body scanning but the scanning of specific areas of the body; lung, heart and colon.

The Clinical Advisory Committee of Diagnostic Imaging was set up in January 2007 to gather information from experts to inform political policy on medical imaging (and CT in particular). This form of health assessment is currently under review by COMARE.

CACODI seeks equal regulation and standards for both government and private sector provision. However, as its remit is specific to private provision, it seeks to establish a framework more focussed on clinical effectiveness and quality rather than on cost-effectiveness.

There is a general worldwide consensus on acceptable levels of radiation and a broad range of bodies that set and regulate the principles for exposure. The recommendations in this document are fully compliant with the national and international agencies that set these standards. A key aspect of this document is to examine the current situation for policing and compliance of these standards in the UK, and the need for an integrated framework that ensures robust scrutiny and adherence to these standards.

Medical imaging has undergone dramatic developments over the last two decades and now finds itself coming to the forefront of preventative medicine in a number of different subspecialties. Throughout the World it is increasingly accepted as useful in the early diagnosis of a number of medical conditions. The spectrum of innovation in imaging and the increasing interest from the public has led to increasing provision in both the state and private sectors.

This report is primarily concerned with the increase in private provision.

In the past year there have been many published studies in peer reviewed medical journals and articles in consumer health publications demonstrating the ongoing debate and interest in medical imaging. The most hotly debated are the value of diagnostic tools for latent illness in screening and preventative health, concerns around safety and effectiveness, and the potential additional costs to the NHS.

### Aims of the Committee

- To facilitate open and transparent debate of the role of CT screening in asymptomatic patients
- To review issues of safety, regulation, compliance and training standards in the private sector and drive the implementation of best practice guidelines.
- To attempt to establish whether claims that private screening results in additional NHS costs are justified.
- To demonstrate using published evidence that some forms of CT screening can be useful in preventative medicine with a demonstrable patient benefit.
- To highlight and review relevant medical literature to assess the risks and benefits of CT techniques.

### CACODI key recommendations are:

- The need for an integrated framework for policing and compliance of national and international protocols for radiation exposure.
- The need for further research and review of the relative merits of the Linear No Threshold and Hormesis Theories as they relate to radiation exposure.
- The Royal College of Radiologists should review its current training and accreditation programme in line with advances in technology and to incorporate training for radiologists in assessing asymptomatic individuals in a "screening" programme.
- An annual audit of outcomes for every private clinic to be reviewed and monitored by an independent body – e.g. the Health Care Commission – and the Royal College of Radiologists to produce an annual UK Report.
- Better and more effective sharing and exchange of information between the NHS and private sector to facilitate more accurate diagnosis and audit of outcomes, and to allow

proper examination of concerns relating to cost effectiveness and potential on-costs to the NHS.

- Clearer and more detailed patient consumer information.

CACODI hope the final report will complement the work of COMARE.

## **2. RADIATION SAFETY CONSIDERATIONS**

### **2.1 Patient Safety at low dosage**

#### Current Situation

The dose of radiation derived from medical imaging is very small compared to total lifetime exposure to radiation from all sources. See Addendum 1 (pie chart of radiation exposure).<sup>1</sup>

The Linear No Threshold theory on radiation risk is widely accepted as the basis for calculating radiation risk yet fails to stand up to close scrutiny.<sup>2</sup> The health risks of low dose exposures (<50 mSv) are very small.<sup>3</sup>

It is known that some people are more sensitive to the effects of radiation than others but with the accepted exception of children currently there is no way of identifying who these are.

Low-dose scanning protocols are used for obtaining images for pre-clinical assessment and as a result there are low resultant effective patient doses.

A typical CT scan of the abdomen or pelvis yields an effective dose of about 10 mSv. If extrapolated to a large population in which every person had 1 scan, the theoretical lifetime risk of radiation induced fatal cancer would be about 1 in 2,000 (0.05%). This can be compared to the normal spontaneous risk of fatal cancer which is about 1 in 4 (25%). Whilst the doses involved are greater than conventional (plain film radiography) any theoretical risks from the doses involved are small and need to be considered alongside potential benefits.<sup>3</sup>

For example, colon screening with CT colonography is considered to be safer than optical colonoscopy.<sup>4</sup> The accepted risk of serious complications in optical colonoscopy is approximately 1 in 1000.<sup>5</sup> This should be compared to the theoretical risks from the radiation exposure of approximately 5mSv which is associated with a risk of 1 in 4,000.

### Recommendations

- The current policy to keep ionising dosage as low as possible to obtain an adequate diagnosis should be maintained, and the dose reduced where possible
- Future review and research as to the relative merits of the Linear No threshold and Hormesis Theories should be encouraged so that the true benefits and potential dangers of radiation exposure are better understood.

## **2.2 Equipment standards**

### Current Situation

All users of medical imaging techniques are subject to inspection and control by the appropriate bodies however compliance to regulations and standards relies on effective auditing of private centres which often reflects a local policy for equipment and screening outcomes.

CT scanners from different manufacturers are very similar in the amounts of radiation they produce when used for diagnostic purposes and in terms of the quality of the images.

### Recommendations

- All private providers should ensure that the equipment and software is fit for purpose and is used and maintained in accordance with manufacturers' recommendations.
- Standards should be developed by interested and experienced parties alongside an independent body such as the Healthcare Commission to provide a framework for regulation and protection of the public from inadequately trained operators.

## 2.3 Equipment and Practice Radiation Compliance

In the UK there are a complex and wide range of bodies and organisations that oversee different areas of compliance with radiation.<sup>A1</sup>

### Audit procedures and protocols recommendations

- Random checks should take place across all centres and all radiologists for evidence of the technical quality of the scan and the interpretation/type of reporting.
- An independent Consultant radiologist with training in the relevant area of CT scanning (e.g. colonography, coronary calcium, lung scanning) should audit and review the data. This would identify any significant discrepancies that could be fed back to the reporting radiologists and radiographers. If further intervention is required this can be relayed back to the patient and/or GP. This is a key part of clinical governance.
- When there are significant findings there must be the ability to get outcome data about any subsequent investigations or interventions.

### 2.3.1 Health Care Commission (HCC)

- The Healthcare Commission is the independent inspection body for both the NHS and independent healthcare. Their main role is to check that healthcare services are meeting standards in a range of areas.<sup>6</sup> It is important that similar standards are applied in both the NHS and independent sectors

The Committee has concerns about the effectiveness of the Healthcare Commission to properly monitor and audit radiation use in the private and state sectors. In particular the lack of expertise in many of the inspectors in the field of radiation protection.

### Recommendations

- The Healthcare Commission should seek to appoint a subgroup who have expertise in radiation protection

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<sup>1</sup> See Appendix

OR

- Discussions should take place that a body with more familiarity with radiation protection should be appointed to oversee radiation protection both in the NHS and private screening centres.
- CT screening should be performed to a high ethical standard in accordance with published best practice
- Informed written consent should be obtained for such screening examinations.

### **2.3.2 Royal College of Radiologists**

This is the body responsible for radiologist training, accreditation and advising on relevant professional standards.

#### Recommendations

- The Royal College of Radiologists should advise on and formulate appropriate levels of training and suggest minimum standards of practice for such preventative work, as is currently the case for mammographic screening.
- Other agencies involved in policing the imaging sector should collaborate to devise a revised framework to ensure that all aspects of compliance are followed. This should include a strategic integrated framework to encourage best practice.
- Protocols and procedures should be regularly monitored and audited in accordance with best medical practice.

## **3. CLINICAL EFFECTIVENESS**

### **3.1 Colon**

#### Current Situation

The public are less aware of the importance of cancer of the colon and rectum (lower portions of the large intestine) compared to breast or prostate cancers, but colorectal cancer does have the dubious honour of being the third most common cancer in the United Kingdom and the second leading cause of cancer death.<sup>7</sup> Colon cancer claims the lives of over 16,000 men and women a year.<sup>8</sup> Screening methods can pick up the disease at its earliest, most curable stages.<sup>9</sup>

Colon cancer screening is considered a good target for population-based screening because<sup>10</sup>

- 1) it is a major public health problem
- 2) most cases develop slowly over a number of years as benign adenomas
- 3) provides the opportunity for early detection of asymptomatic conditions

Screening for Colon cancer is well established with level one (randomised controlled trial) evidence of benefit from using faecal occult blood testing (FOBT) with conventional colonoscopy reserved for those testing positive.<sup>10</sup>

The target of FOBT screening is cancer but screening in this way will mean that half the cancers may be missed as only bleeding cancers will be detected. Moreover, 2% of all patients will test positive, 90% of which will not have cancer,<sup>10</sup> causing considerable anxiety to a large number of patients who test positive. The overall reduction in mortality is of the order of 15%.<sup>10,11</sup>

Later this year, a National Screening Programme (NSP) will be introduced to the UK. It will use FOBT for the 60-69 year olds in England and 50-74 year olds in Scotland. It is expected to show a significant (15%) mortality benefit.<sup>10</sup>

The screening programme reinforces the proven evidence-based case for screening. What remains to be proven is the case of one technology over another.

CT colonography (CTC) is generally agreed by experts in the field to be a superior diagnostic test to barium enema with greater accuracy (96% vs 85% for cancer detection) and improved patient experience. Moreover, its performance characteristics are comparable to conventional colonoscopy, when performed in well-equipped centres staffed by suitably trained radiologists.<sup>12</sup>

CTC seeks to identify the advanced adenomatous polyp, a benign precursor of cancer which can be generally removed by minimally invasive endoscopic methods. High rates of compliance with screening are critical to its success and yet there is no hard data to compare compliance rates amongst competing tests. For example, some studies indicate a preference for CT colonography over conventional colonoscopy<sup>12,13</sup> and yet there is no data showing this translates into improved compliance rates.

While there is conflicting evidence in the literature regarding cost effectiveness<sup>14</sup> CT colonography may well prove to be an efficient way of finding lesions, providing useful staging anatomical information to both patient and clinician prior to subsequent therapeutic endoscopy. There is undoubtedly a need for strong collaboration between CT colonography and endoscopy centres to optimise patient management strategies.

The National CT Colonography Trial (ACRIN 2) in the USA is to be published in the coming months and many authorities believe this will pave the way for CTC to be included as a primary screening option, and, in the US, to be reimbursed by the major insurers.

CT Colonography is also being reviewed by the NHS Health Technology Assessment Programme. They report that CT Colonography may have an important role in the NHS for rapid, accurate, acceptable, safe and cost-effective investigation of patients. However, this trial is focussed on patients with symptoms that are potentially attributable to colorectal cancer rather than an asymptomatic population. The final document may not be published for a further 2 years.<sup>15</sup>

There is currently no equivalent guidance for assessing asymptomatic patients in the UK, though NICE have approved CT colonography for use in the NHS for high-risk asymptomatic patients.<sup>12</sup>

Over 70% of radiologists (in both independent and NHS sectors) offering CTC in routine clinical practice favour some form of accreditation (beyond internal audit) to ensure high standards of practice.<sup>16</sup>

### Recommendations

Members of the committee would like to work alongside the Royal College of Radiologists, Society and College of Radiographers and the British Society of Gastrointestinal and Abdominal Radiology to

- Produce guidelines for optimising the quality of CT colonography (patient experience, scan technique, report language and interpretation accuracy) provided by the independent sector
- Making best use of available evidence, debate the relative merits and necessary guidance for screening for colon cancer with CT colonography
- Help define standards for optimising the quality of examinations performed in the independent sector.

## **3.2. Coronary Artery Calcium and Cardiovascular disease**

### Current Situation

Cardiovascular disease remains Britain's most common cause of death and in a significant proportion of patients (40%) the first symptom is sudden death.<sup>17</sup> Despite recent improvements, coronary artery disease remains the leading cause of death in the western world. In the UK in 2004 just over 216,000 deaths occurred due to cardiovascular disease.<sup>18</sup>

Coronary artery calcium scoring (CACS) has been used for cardiovascular risk assessment for over 20 years. The use of CACS for enhanced risk stratification has now been endorsed by both the American College of Cardiology and American Heart Association as well as the SHAPE task force.<sup>19,21,22</sup>

The Royal College of Radiologists publication "Making the best use of clinical radiology service" is due for publication later this year, and will offer some guidance on this procedure.

Though there are currently no trials demonstrating an increased survival in those who are aware of their (high) coronary calcium score, the correlation between the presence of coronary calcium and coronary atheroma is proven.

At present, there is no evidence that finding a high coronary calcium level and starting conventional treatment to lower coronary risk (as used in secondary prevention of heart disease, such as statins, blood pressure lowering, weight loss etc) either does or does not have a positive impact on mortality. Absence of evidence does not constitute evidence of absence of benefit. More importantly, recent research showed that 30-40% of people, when told that their calcium score was high and they were at high risk, would make a significant lifestyle change.<sup>20</sup> This information provided on an individual basis clearly therefore helps to inform individual life choices and may reinforce verbal advice to alter behaviour. It is intuitive that drugs such as statins, which have already been proven to reduce cardiovascular risk in a primary care setting<sup>22</sup> but whose prescription is currently limited by cost to government targets of 15% 10-year cardiovascular risk, are likely to provide proportionately more benefit in those with higher risk. CT Coronary Artery Calcium Scoring can identify risk with significantly greater accuracy than standard clinical parameters.<sup>23</sup>

### Recommendations

- That a trial be undertaken to seek to demonstrate the cost-effectiveness of coronary calcium scoring and subsequent intervention in those with high scores.

### 3.3. Lung Cancer

#### Current Situation

Lung cancer is the leading cause of cancer death in both men and women in the United Kingdom, killing more people than cancers of the breast, colon, cervix and prostate combined.<sup>25</sup>

In the year 2005, it was estimated that there would be over 33,500 deaths in the UK alone.<sup>26</sup> Worldwide, more than a million die from it every year. Lung cancer has one of the worst prognoses of all cancers, and one of the lowest survival outcomes of any cancer. In England and Wales only around 25% of patients are alive one year after diagnosis and this falls to 7% at five years.<sup>27</sup>

Major risk factors for lung cancer include tobacco use and certain environmental carcinogen exposures. Around 90% of lung cancer cases in the UK are caused by tobacco smoking.<sup>28</sup> Lung cancer usually does not cause any symptoms until it has reached an advanced stage, when treatment is least likely to be effective. Early Stage I lung cancer discovered through early detection screening, however, has been shown to have a cure rate of 70%, and for some subgroups it is even higher.<sup>29</sup>

There is much interest in screening individuals with heavy smoking histories, who are at increased risk of developing lung cancer, in the hope that this will diagnose the disease at earlier stages when treatment is more likely to be curative.

Lung cancer screening with low dose CT remains controversial in the absence of controlled trials. There have been recent conflicting reports in prestigious medical journals, both getting extensive coverage in the lay press, on the efficacy of lung cancer screening using low dose CT.

There is evidence from large observational studies, such as IELCAP<sup>29</sup>, that such a program can diagnose a majority of lung cancers at early stages when curative treatment is feasible. In routine clinical practice, less than 20% of non-small cell lung cancers would be expected to be stage 1, whereas the IELCAP study

reported that 85% of lung cancers were detected at this early stage. The estimated 10 year survival of patients diagnosed with lung cancer in the IELCAP study was very high at 80%. The authors concluded that deaths from lung cancer could be reduced by 80% if people at a suitable level of risk enrolled in a screening program.

No other intervention from the past 30-40 years has had any impact on lung cancer mortality.

However, the conclusions of the IELCAP study have been questioned as it has been suggested that CT screening may preferentially diagnose indolent lung cancers, which are unlikely to become significant during the patient's natural life. Moreover, it has been suggested that the risks associated with diagnosing and treating indolent screen-detected cancers may not be justified if these cancers are unlikely to shorten the patient's life.

A separate study<sup>30</sup> used a mathematical model based on retrospective data in a non-screened cohort to predict lung cancer deaths, and compared this with three small CT screening studies. 29 The study again demonstrated that the majority of screen-detected lung cancers were early stage but found that there were significantly more cancers than predicted. The study also found that the numbers of advanced lung cancers and the mortality from lung cancer in the screened population was very similar to that predicted. The authors concluded that, although screening led to the detection of indolent cancers at early stages, it failed to diagnose aggressive lung cancers at stages when survival would be improved.

The controversy surrounding CT screening for lung cancer is unlikely to be resolved until large randomized controlled studies have been completed, which compare the disease specific mortality in a screened population with that observed in a control group. Such studies are now in progress but the results will not be available for several years. Until the results of such studies are known, it is reasonable to conclude that CT screening has the capability to detect lung cancers at early stages when curative treatment is feasible but that this approach may not necessarily prevent death from more aggressive tumours.

### Recommendations

- Issues with CT lung screening for cancer include the problem that the vast majority of screen-detected nodules are not cancerous. It is therefore important that suggested protocols

(IELCAP) on further management are followed to avoid unnecessary intervention and associated risks.

- Additionally it is important to understand the risk of treatment. In the USA the risk of dying from surgery is approx 5% while the risk suffering a non-fatal complication is in the region of 20%.<sup>31,32,33,34,</sup>
- Provide patients with balanced information on the perceived value of CT screening, making it clear that, although screening may result in the detection of an early treatable cancer, this approach will not necessarily avoid the development of an aggressive fatal cancer.
- Patients should be informed fully about the potential benefits and risks when considering being screened.
- Provide consultants and GPs with relevant research.

#### **4.TRAINING**

##### Current Situation

There is no regulatory audit system of training in the NHS or private sector.

At present there is no mandatory requirement for radiologists or radiographers to attend any specialist training when undertaking these and similar advanced techniques.

For virtual colonoscopy on asymptomatic patients, the low prevalence of abnormality and the form that abnormality will take – i.e. polyps - are much more difficult to detect thus requiring greater expertise and additional specialist training. A similar situation exists with mammographic breast screening where specialist training and regular monitoring are common-place and mandatory.

##### Recommendations

- All radiographic and medical personnel should have appropriate training and attend recognised courses under the aegis of the Royal College of Radiologists and the College and Society of Radiographers to ensure minimum standards are met and maintained.
- These courses should have modules that address asymptomatic screening, and new advances in technology.
- They should be subject to regular internal audit and feed back. This audit should include an external element.
- Members of CACODI are offering to work in collaboration with relevant agencies to review and revise current training programmes.

## **5. OUTCOMES AND POTENTIAL ON COSTS TO THE NHS**

### Current Situation

The Committee notes that auditing of outcomes across a vast range of medical procedures and tests are not currently mandatory.

However, the Committee believes there is a need to track patient outcome and it is important that organisations work together to produce standard audit protocols.

### **5.1: False negatives and positives**

#### Current Situation

Current published data suggests

- Approximately 10% of patients have clinically significant findings. There are currently standardised reporting protocols that minimise false positive results and the need for further work up of incidental findings.<sup>35,36,39</sup>
- Using appropriate protocols the incidence of false positive/negative results from colon and lung cancer screening are extremely low<sup>29,35,36,38,39</sup>
- New technology is coming on-stream which may allow for computer assisted diagnosis, thereby reducing the risk of human error
- The incidence of false positives in coronary artery screening is virtually non-existent and false negatives extremely rare.<sup>37</sup>

#### Recommendations

- Private clinics should undertake an annual audit of outcome data to ensure that their clinic's results are comparable to published data and that performance is satisfactory. The incidence of positive findings should be reviewed against published standards where these exist.
- Private clinics should submit this data to be reviewed by the Health Care Commission and The Royal College of Radiologists and outcomes collated into an annual UK report.

## 5.2 Potential on-cost to the NHS

### Current Situation

There is currently no follow-up procedure for tracking and monitoring a patient who returns to the NHS for follow up tests or surgery after having had private CT screening or any other private medical intervention.

In many cases, patients requiring further medical intervention will be covered by private health insurance.

Any extra costs to the NHS or insurers should be offset by savings encountered from cheaper treatment options made possible by early diagnosis.

Most private clinics send reports to GP unless expressly requested by the patient.

In asymptomatic patients the need for follow up tests is small (8-10%).<sup>35,36,38</sup> The need for repeat tests is minimised by using standard reporting models and recognition that most incidental findings are of no clinical significance.<sup>38</sup>

5-8% of patients will be found to have colon polyps requiring removal or closer observation.<sup>35</sup>

Approx 11% of patients will be found to have lung nodules of which 50% will require a scan earlier than the usual 12 month follow up.<sup>29</sup>

Patients with a very high coronary artery calcium scores (>400) should be considered for exercise testing and aggressive secondary preventative measures.

### Recommendations

- Where repeat scans are indicated as a follow up to a previously abnormal scan (providing such an interval test strategy is supported by clinical evidence or accepted best practice), clinics should offer these at reduced cost. Any repeat scan should only be undertaken with the agreement of a radiologist or other suitably qualified clinician, and in line with any published and accepted guidelines.
- All patients should be followed up by the clinic and have the opportunity to discuss their findings with a radiologist or other

trained clinician who can make appropriate referrals when indicated and with the patient's agreement.

- Patients however should retain the right be able to return to the NHS following a Private consultation as is the case now.
- There should be greater exchange of information between the private sector and the NHS. Access to a patients' earlier medical records will allow any private clinic to make a better and more accurate diagnosis; and follow-up patient data from the NHS would allow a proper assessment of any on-costs to the NHS and more robust audit of clinical and cost-effectiveness.

## **6. THE WORRIED WELL**

### Current Situation

The 'Worried Well' experience the same incidence of disease as the remainder of the population. Reassurance may convert the 'worried well' into the 'Unworried Well'.

Additionally, not all those attending will be the worried well; many will be those who have genuine symptomatology, or concerns about their health based on legitimate facts, such as a positive family history, and who wish to understand their current health status. This was something that was encouraged in the 2002 Wanless report.<sup>40</sup>

### Recommendations

- Clearly written, high quality literature should be available to all consumers to ensure that the implications and limitations of any test performed are fully understood.

## **7. ADVERTISING**

### Current situation

- The Advertising Standards Association (ASA) sets and controls regulations for promoting and publicising laser eye surgery.
- On the Internet, there are no control mechanisms.

### Recommendations

- Advertisements must include warnings on possible risks

- The Royal College of Radiologists should set out controls and guidelines that include the Internet, to be communicated to the ASA.
- All text or promotional materials promoting CT screening, including the Internet, should comply with these guidelines.

## **8. Committee on Medical Aspects of radiation and the Environment (COMARE)**

### Current Situation

COMARE is an independent expert advisory committee with members chosen for their medical and scientific expertise and recruited from Universities, Research and Medical Institutes.

The Committee offers independent advice to all Government Departments and Devolved Authorities, not just the Health Departments, and is responsible for assessing and advising them on the health effects of natural and man-made radiation. Its terms of reference are "to assess and advise Government and the devolved authorities on the health effects of natural and man-made radiation and to assess the adequacy of the available data and the need for further research". It is also asked to assess the adequacy of the available data and advise on the need for further research.

In 2006, the Department of Health asked COMARE to address issues of radiation doses arising from new medical procedures starting with unregulated screening. The secretariat set up a Medical Practices Subcommittee to address these issues and which had its first meeting on 6 March 2006. A final draft report is expected to be presented to COMARE at a meeting in June 2007.

### Recommendations

- CACODI members to be invited to submit recommendations to COMARE and to be consulted on how best to address issues of radiation doses arising from screening in the private sector.



## APPENDIX 1

### SYNOPSIS OF RELEVANT LEGISLATION

#### Prepared for the Clinical Advisory Committee of Diagnostic Imaging

## 1 INTRODUCTION

These notes set out current legislation relevant to the use of ionising radiations in medical x-ray imaging. Each reference is listed with a brief description of important points. More detail is given to the descriptions of the Ionising Radiations Regulations 1999 (IRR99) in section 2.2; and the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) in section 2.3 - otherwise known as the IR(ME) Regulations. At the end are references to various relevant guidance documents.

## 2 LEGISLATION

### **2.1 Health and Safety at Work etc. Act 1974.**

Umbrella legislation under which all safety aspects of work are organised, including radiation safety. Employers have a duty to ensure that a framework of policies and working procedures exist to safeguard the health, safety and welfare of all employees whilst at work. Every member of staff has an obligation to ensure their own safety as well as the safety of others who may be directly or indirectly affected by their actions.

### **2.2 The Ionising Radiations Regulations 1999 (SI 1999. No 3232).**

IRR99 governs the use of ionising radiation in any establishment from a dentist surgery to a nuclear power station. Resulting from the EC Revised Basic Safety Standards Directive (96/29/EURATOM), the regulations update previous regulations (Ionising Radiation Regulations 1985) and describe the duties and responsibilities of the employer and employees, and interpret provisions of the Health and Safety at Work etc. Act for work with ionising radiation. There are 41 regulations and 9 schedules. The following describes the relevance of a few of the regulations:

- Regulation 7 – *Prior risk assessment*: -  
Prior to any work activity involving ionising radiation, the employer is required to carry out a risk assessment to identify the nature and magnitude of the hazard to staff, patients and the public, and to

take appropriate steps to prevent or reduce any significant risks so identified.

- Regulation 8 - *Restriction of exposure*: -  
Introduces the concept of keeping doses to staff, patients and the general public **As Low As Reasonably Practicable** (the **ALARP** principle). The employer must provide systems of work to restrict, so far as is reasonably practicable, the exposure of persons to ionising radiation. The word "Practicable" implies the use of economic factors being taken into account against the risk when deciding on the level of protection to be attained.
- Regulation 11 - *Dose limitation*: -  
The employer must keep doses to staff and other persons (but not patients) below the individual annual dose limits. These limits, defined in Schedule 4 of IRR99, are specified for whole body dose (Effective Dose) as well as the absorbed dose to the eyes, extremities and skin, and to the female abdomen:

	Classified Workers (mSv)	Workers <18 years old (mSv)	Public (mSv)
Whole Body per year	20	6	1
Extremities, skin per year	500	150	50
Lens of Eye per year	150	50	15
Female Abdomen per 3 months	13	13	NA
Foetus during pregnancy	NA	NA	1

- Regulation 13 - *Radiation protection adviser*: -  
Describes the requirements for appointing a RPA for work involving ionising radiation. The employer must consult with the RPA on the series of issues listed in Schedule 5. The RPA should have gained suitable experience and qualifications to fulfil this role. The employer must appoint the RPA in writing.
- Regulation 14 - *Information, instruction and training*: -  
Specifies the requirements for the training of staff involved in work with ionising radiation. The employer has a duty to provide training and to keep training records. Female staff have a duty to inform the employer if they may be pregnant.
- Regulation 32 – *Equipment used for medical exposures*: -  
The employer is required to ensure that any equipment used for medical exposure is so designed, installed and maintained such that it restricts the exposure to any person as low as reasonably practicable compatible with the intended use.

- Regulation 34 - *Duties of employees* :-  
Employees must exercise "reasonable care" and not deliberately expose themselves or other people more than is reasonably necessary. Employees must make full and proper use of any protective equipment supplied. They must notify the employer of any defects in this protective equipment.

### **2.3 Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000, No 1059).**

Known as the IR(ME) Regulations, these control the exposure of human patients and volunteers to ionising radiation for the purposes of diagnosis, treatment or research, as required by the European Medical Exposures Directive 97/43/EURATOM. Defines the roles and duties of the "Employer", "Practitioner", "Operator", and "Referrer" for a medical exposure, and the training required if not part of a professional qualification. A Schedule gives particulars of the syllabus to be covered by training courses. Every exposure to be in accordance with accepted practice and at a dose As Low As Reasonably Practicable consistent with the clinical objectives. Specific regulations are listed here:

- Regulation 4 – *Duties of the employer*:-  
The employer must ensure that there are written procedures for all medical exposures and that they are complied with by all staff involved. Written protocols should also be in place for each type of standard radiological practice and for each piece of equipment. The employer is also required to establish referral criteria for medical exposures, and to make these available to referrers. The employer must set up local diagnostic reference levels (DRLs) which should not be exceeded for diagnostic examination types carried out on standard sized patients. Finally the employer must ensure that all staff involved in medical exposures are adequately trained, undergo continuous development training, and that records are kept of such training.
- Regulation 5 – *Duties of the Practitioner, Operator and Referrer*:-  
The Practitioner is responsible for justifying that the benefit of a medical exposure to the patient outweighs the risks. The Operator is responsible for the practical aspects of the medical exposure as well as for specific justification processes given under Reg. 6. The Referrer is responsible for providing the Practitioner with appropriate clinical information on the patient such that the Practitioner may make an informed decision on justifying the medical exposure.
- Regulation 6 – *Justification of Individual Medical Exposures*:-  
Lays down the requirement for the justification of all medical exposures such that the perceived benefit sufficiently outweighs the risks from the ionising radiation. Specifies extra requirements for

medical exposure during pregnancy, to children, and for medico-legal or health screening purposes.

- Regulation 7 – *Optimisation*: -  
All doses arising from diagnostic medical exposures must be as low as reasonably practicable consistent with the clinical objective. This should be done by the selection of equipment and exposure parameters, paying attention to quality assurance, assessment of patient dose, and comparison to the local DRLs. The clinical evaluation of the outcome of all medical exposures must be recorded.
- Regulation 9 – *Expert advice*: -  
Employers must ensure that the advice of a suitably qualified “medical physics expert” is available for every medical exposure. The MPE should be involved in aspects of optimisation and patient dosimetry, quality assurance, and radiation protection.
- Regulation 10 - *Equipment*: -  
The employer must keep an up-to-date inventory of equipment capable of producing ionising radiation.
- Regulation 11 – *Training*: -  
No person can carry out the duties of Practitioner or Operator unless adequately trained. This may be vocational training, or specific practical and theoretical training for the tasks to be carried out. Other persons not so trained may only carry out radiological procedures under supervision. The employer must keep records of training.

### 3 GUIDANCE

#### 3.1 Work with Ionising Radiation - Approved Code of Practice and Guidance. HSE, 2000.

"Approved" means by the HSE, this Code of Practice describes the means of complying with the Ionising Radiations Regulation 1999 and should be adhered to unless a proposed system can be demonstrated to be a suitable alternative. The document also includes non-compulsory guidance. This document may be cited in a Court of Law.

#### 3.2 Medical and Dental Guidance Notes (IPEM 2002).

Readable practical guide to IRR 1999. It has no legal status but is the most likely document to be cited by inspectors carrying out an audit. It is recommended that all establishments using ionising radiation for medical purposes have immediate access to a copy of these Guidance Notes. This revision of an earlier document

published by NRPB also includes guidance on compliance with IR(ME)R2000.

### **3.3 Making the best use of a Department of Clinical Radiology - Guidelines for Doctors. Second Edition (RCR, 1993).**

Provides guidance on indications for carrying out examinations involving ionising radiation and the available alternatives. Endorsed by the NRPB, it is designed as a small pocket book to be carried by all doctors who may request an examination involving ionising radiation.

### **3.4 Patient Dose Reduction in Diagnostic Radiology - Report of the RCR / NRPB Joint Working Party. (Documents of NRPB Volume 1, No. 3, 1990).**

Assessing the possible health effects to patients as a result of medical exposure, the working party identified the great potential for dose reduction due to un-optimised x-ray examinations in the UK (up to half the collective dose to the population from medical x-rays could be unnecessary). It reviewed a range of methods for reducing doses, both in the justification and optimisation of medical exposures. It recommended the adoption of a quality assurance programme in diagnostic radiology departments.

### **3.5 Implementation of a Patient Dose Reduction Programme. (RCR, 1994).**

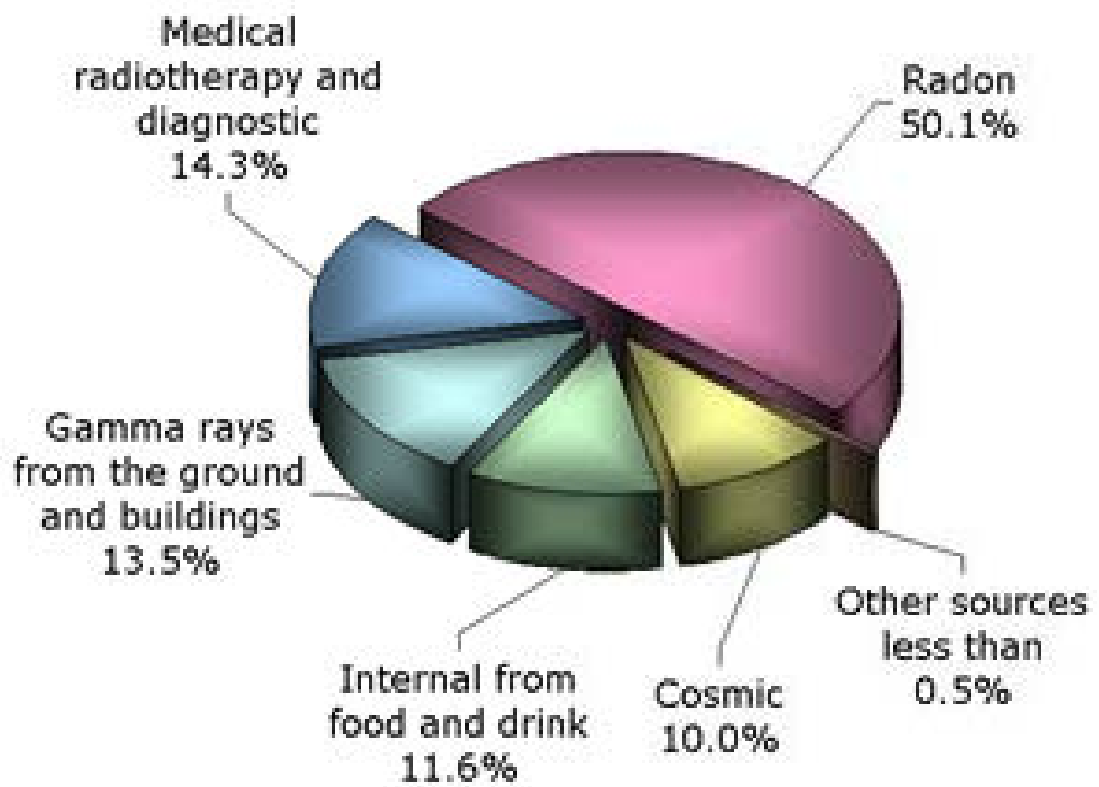
Introduces the concepts of organisational structure, quality assurance and technical aspects involved in the implementation of a dose reduction programme. Briefly discusses the requirements for policies on vetting requests for special examinations, employment screening, and the use of other imaging modalities. Lays down the structure for a programme of monitoring, assessing and further reducing patient doses.

## **4 SUMMARY**

Legislation exists in the UK to control the medical use of ionising radiation. Control is managerial in nature, combining appropriate restriction of access to areas and equipment, with quality assurance programmes, and audit review of faults / problems. The major driver for this legislation has been Directives by the European Commission and UK Government identifying specific issues under the Health and Safety Act, May 2007

## APPENDIX 2

[www.npl.co.uk/publications/ionising\\_radiation](http://www.npl.co.uk/publications/ionising_radiation)



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