**Principle of responsibility in medical imaging**

Anna SUHOVA (a), Vladislav CHUBUCHNY (b) and Eugenio PICANO (b)

(a) Scuola Superiore Sant’Anna, Università degli Studi, Pisa, Italy  
(b) Istituto di Fisiologia Clinica, Consiglio Nazionale delle Ricerche, Pisa, Italy

**Summary.** - Radiological and medico-nuclear procedures are an essential part of contemporary medicine. They employ ionising energy, differently from other imaging modalities such as echography or magnetic resonance. The use of ionising testing is therefore associated to environmental impact and definite biorisks for the patient and the operator. In many clinical conditions specialty guidelines accept the equivalence of medical information provided by “red” (ionising) and “green” (nonionising) techniques. Medical equivalence is translated into physician freedom of choice. However, common sense, guidelines of Radiological Medical Societies and Euratom directive (incorporated in national laws, such as Italian law 187/26 of May 2000) suggest that a “red” technique should be used only when a “green” alternative is not competitive.  
*Key words:* imaging, law, responsibility.

**Riassunto** (Il principio di responsabilità nell’imaging medico). - Nell’imaging medico coesistono metodiche “verdi” (risonanza magnetica e ultrasonori, innocue per il paziente e l’operatore, prive di impatto ambientale) e “rosse” (radiologia e medicina nucleare, basate su radiazioni ionizzanti e quindi con debito ecologico e biorischi). In molte situazioni cliniche le linee guida delle società specialistiche equiparano metodiche rosse e verdi, lasciando libertà di scelta. Ma se non si percepisce la differenza d’innocuità tra immagine rossa e verde si delinea un bizzarro caso di daltonismo dell’immagine con conseguenze devastanti. L’immagine rossa dovrebbe essere usata solo quando quella verde non è competitiva. Lo suggeriscono le linee guida delle grandi società mediche radiologiche e lo imporrebbero la legge europea (Direttiva Euratom 97/43) e quella italiana (187/26 maggio 2000).  
*Parole chiave:* imaging, legge, responsabilità.

**The physical basis of medical imaging**

Technology is an essential element of our society. Medical imaging began on November 8, 1895, when Professor Wilhelm Conrad Roentgen of the University of Würzburg discovered X-rays. There have been numerous refinements of X-ray techniques over the past 100 years with development of invasive radiology and computed tomography (CT). In addition, entire new modalities have appeared including nuclear medicine, ultrasonography, magnetic resonance imaging [1]. The “4 sisters” of cardiac imaging have very different biological and technological basis. It is important to operate a distinction, which is also relevant for the legal regulations of medical imaging between “ionising” and “non-ionising” techniques. Ionising techniques use high frequency electromagnetic waves, such as X-rays (radiology) and gamma-rays (nuclear medicine). Ionising radiations are only one part of the electromagnetic spectrum (Fig. 1).

There are numerous other radiations (e.g., visible light, infrared waves, radiofrequency electromagnetic waves) that do not posses the ability to ionise atoms of the absorbing matter. According to the general equation \( E = h \cdot v \) radiation energy \( E \) is directly proportional to frequency \( v \). Higher energies can be toxic to the cell through the production of free radicals. Obviously, the use of high energies has also several advantages, including the possibility to go inside the body without obstacles represented by bone and air. However, what is important here is that these energies (employed in nuclear medicine and radiology) have some environmental and biohazards impact: for sake of simplicity, we might call them “red” imaging techniques. As always in medicine, a responsible use of these technologies clearly outweighs the risk. Other technologies employed in cardiac imaging pose no environmental burden or known risk to the patient or to the operator [1]. They include magnetic resonance, which uses low frequency electromagnetic waves and ultrasound. Ultrasonography
employs acoustic (mechanical) waves. Both these forms of physical energy are not capable to produce ionising phenomena (Fig. 1). For sake of clarity, we might call them “green” imaging techniques, with no environmental impact or associated biorisks.

**Medical imaging, risk and environment**

The increased complexity of technology and the pace of scientific progress might cause an increased number of risks. The use of radiological investigations is an accepted part of medical practice, justified in terms of clear clinical benefits to the patient which should far outweigh the small radiation risks. However, even small radiation doses are not entirely without risk. A small fraction of the genetic mutations and malignant diseases occurring in the population can be attributed to natural background radiation. Diagnostic medical exposures, being the major source of man-made radiation exposure of the population, add about one sixth to the population dose from background radiation [1-5].

The total effective dose (expressed in milliSievert [mSv]) received by an average person in the United States is 2.8 mSv per year; 2.4 mSv from natural sources and 0.4 mSv from man-made sources [2]. In 1987, the National Council of Radiation Protection and Measurements estimated that nuclear medicine tests accounted for 4% and X-ray testing of 11% of the total radiation exposure of the average person in the United States [2]. Since 1987, the number of nuclear cardiology studies has more than doubled in the country [6] and the number of radiological examinations also increased sharply [7]. In the whole world, an estimated number of 400 million of radiological procedures and 25 million of nuclear medicine procedures were performed in 2002 [7]. Seven million nuclear cardiology studies with unsealed sources of radionuclides are performed each year in the United States, accounting for more than 50% of all nuclear imaging [6].

At the patient level, the effective dose of a single nuclear cardiology stress procedure ranges from 23 mSv from a thallium scan to 10 mSv from a technetium 99m methoxyisobutylisonitrile scan [3, 4] (Table 1, 2).

According to data provided by the International Commission on Radiological Protection, this exposure dose corresponds to an additional risk of cancer that is between 1 in 1000 and 1 in 10 000 [8-11]. A single exposure to 0.01 mSv (a chest radiograph, for instance) corresponds to an average loss of 2 minutes of life expectancy, whereas a single exposure to 10 mSv corresponds to 2 days of lost life expectancy [3, 10, 11] (Table 3; Fig. 2).

The doses from positron emission tomography (PET), cardiac stress scintigraphy and CT examinations are particularly high, show no sign of decreasing and the use of these modalities is still rising [7]. PET and CT now probably contribute almost half of the collective dose from all X-ray examinations with ionising radiations [1]. It is thus particularly important that requests for these methods are thoroughly justified [12].

**Precautionary principle**

Therefore, preventive action becomes very important since in many cases scientific certainty about harmful effects of certain product or service only exists after the damage has been suffered.

The precautionary principle is based on this existence of scientific uncertainty. A part of this uncertainty is inherent to the reality and caused by the
PRINCIPLE OF RESPONSIBILITY IN MEDICAL IMAGING

coincidences determining future. Another part is linked to the scientific methods. Because it is not possible to examine all possible hypotheses, certain degree of uncertainty always exists about scientific results. Law based on the precautionary idea has to convert this scientific uncertainty into social certainty [13].

The precautionary idea was originally accepted as a policy principle in environmental protection law. The precautionary principle became especially popular in this field because of the many scientific uncertainties, such as the difficulties to determine a causal relation between pollution (ionising radiation) and harmful effects and the fact that long-term consequences cannot be subject to experimental research [14]. The precautionary idea means that protective action can be necessary despite scientific uncertainty about harmful effects of a certain application or product in case of potential risks.

In a communication, the European Commission explicitly considers precaution to be a policy principle for the European institutions, not only in environ-

<table>
<thead>
<tr>
<th>Diagnostic procedure</th>
<th>Typical effective dose (mSv)</th>
<th>Equivalent no. of chest X-rays</th>
<th>Approximate equivalent period of natural background radiation (*)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>X-ray examinations:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limbs and joints (except hip)</td>
<td>&lt;0.01</td>
<td>&lt;0.5</td>
<td>&lt;1.5 days</td>
</tr>
<tr>
<td>Chest (single PA film)</td>
<td>0.02</td>
<td>1</td>
<td>3 days</td>
</tr>
<tr>
<td>Skull</td>
<td>0.07</td>
<td>3.5</td>
<td>11 days</td>
</tr>
<tr>
<td>Thoracic spine</td>
<td>0.7</td>
<td>35</td>
<td>4 months</td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>1.3</td>
<td>65</td>
<td>7 months</td>
</tr>
<tr>
<td>Hip</td>
<td>0.3</td>
<td>15</td>
<td>7 weeks</td>
</tr>
<tr>
<td>Pelvis</td>
<td>0.7</td>
<td>35</td>
<td>4 months</td>
</tr>
<tr>
<td>Abdomen</td>
<td>1.0</td>
<td>50</td>
<td>6 months</td>
</tr>
<tr>
<td>IVU</td>
<td>2.5</td>
<td>125</td>
<td>14 months</td>
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<tr>
<td>Barium swallow</td>
<td>1.5</td>
<td>75</td>
<td>8 months</td>
</tr>
<tr>
<td>Barium meal</td>
<td>3</td>
<td>150</td>
<td>16 months</td>
</tr>
<tr>
<td>Barium follow through</td>
<td>3</td>
<td>150</td>
<td>16 months</td>
</tr>
<tr>
<td>Barium enema</td>
<td>7</td>
<td>350</td>
<td>3.2 years</td>
</tr>
<tr>
<td>CT head</td>
<td>2.3</td>
<td>115</td>
<td>1 year</td>
</tr>
<tr>
<td>CT chest</td>
<td>8</td>
<td>400</td>
<td>3.6 years</td>
</tr>
<tr>
<td>CT abdomen or pelvis</td>
<td>10</td>
<td>500</td>
<td>4.5 years</td>
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<tr>
<td><strong>Radionuclide studies:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung ventilation (Xe-133)</td>
<td>0.3</td>
<td>15</td>
<td>7 weeks</td>
</tr>
<tr>
<td>Lung perfusion (Tc-99m)</td>
<td>1</td>
<td>50</td>
<td>6 months</td>
</tr>
<tr>
<td>Kidney (Tc-99m)</td>
<td>1</td>
<td>50</td>
<td>6 months</td>
</tr>
<tr>
<td>Thyroid (Tc-99m)</td>
<td>1</td>
<td>50</td>
<td>6 months</td>
</tr>
<tr>
<td>Bone (Tc-99m)</td>
<td>4</td>
<td>200</td>
<td>1.8 years</td>
</tr>
<tr>
<td>Dynamic cardiac (Tc-99m)</td>
<td>6</td>
<td>300</td>
<td>2.7 years</td>
</tr>
<tr>
<td>PET head (F-18 FDG)</td>
<td>5</td>
<td>250</td>
<td>2.3 years</td>
</tr>
<tr>
<td>Cardiac stress scintigraphy (Tc-99m)</td>
<td>10</td>
<td>500</td>
<td>4.5 years</td>
</tr>
<tr>
<td>Cardiac thallium scintigraphy</td>
<td>23</td>
<td>1150</td>
<td>10 years</td>
</tr>
</tbody>
</table>

(*) UK average background radiation = 2.2 mSv/year: regional averages range from 1.5 to 7.5 mSv/year. IVU: intravenous urography; CT: computed tomography. Adapted from [1].

Table 2. - Classification of the typical effective doses of ionising radiation from common imaging procedures [1]

<table>
<thead>
<tr>
<th>Class</th>
<th>Typical effective Dose (mSv)</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>US, MRI</td>
</tr>
<tr>
<td>I</td>
<td>&lt; 1</td>
<td>CXR, limb XR, pelvis XR</td>
</tr>
<tr>
<td>II (*)</td>
<td>1-5</td>
<td>IVU, lumbar spine XR, NM (e.g. skeletal scintigram), CT head &amp; neck</td>
</tr>
<tr>
<td>III</td>
<td>5-10</td>
<td>CT chest and abdomen, NM (e.g. cardiac)</td>
</tr>
<tr>
<td>IV</td>
<td>&gt; 10</td>
<td>Some NM studies (e.g., cardiac thallium scintigraphy)</td>
</tr>
</tbody>
</table>

(*) The average annual background dose in most parts of Europe falls in Class II. US: ultrasound; MRI: magnetic resonance imaging; CXR: chest X-ray; XR: X-ray; IVU: intravenous urography; NM: nuclear medicine; CT: computed tomography.
mental protection law but also for health and consumer protection [15]. At the European level, the only explicit reference to the principle is made in the context of environmental protection (art. 174 EU-Treaty). The EU-Treaty provides that “a high level of human health protection shall be ensured in the definition and implementation of all community policies and activities” (art. 152 [1]). The Court of Justice and the Court of First Instance of the European Union consider these articles to be sufficient grounds for the application of the precautionary principle [16]. Thus via the codification into law systems the precautionary principle has developed from a policy guideline into a legal rule [17]. Precautionary principle can be interpreted in different ways, more aggressive (“uncertainty requires shifting the burden and standard of proofs”), more conservative (“uncertainty does not justify inaction”) or somewhat intermediate (“uncertainty justifies action”) [18]. However, there is no doubt that the precautionary principle regards technologies of questionable (doubtful) environmental and biohazard impact. In case of ionising testing, this negative impact is beyond doubt - although much debate exists on the amount of the harmful effect [5]. A conservative and restrictive use of these technologies is therefore highly desirable.

### Responsibility in medical imaging diagnostics

In the European Community, a 97/43 Euratom Directive for nuclear medicine (97/43) establishes that indication and execution of diagnostic procedures should follow three basic principles: the justification principle (art. 3), the optimization principle (art. 4), and the responsibility principle (art. 5) [19]. Any responsible prescription of a nuclear test today should follow these principles [12].

Art. 2 of the 97/43 Euratom Directive defines the clinical responsibility as “responsibility regarding individual medical exposures attributed to a practitioner, notably: justification; optimization; clinical evaluation of the outcome; cooperation with other specialists and the staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing radiological information and/or records to other practitioners and/or prescribers, as required; giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate” [19].

The patient, the cardiologist, and the referring physician should be aware of the risks, costs, and environmental impact of this “subjective” choice, even if quantification of these negative effects of low-level radiation remains a challenge [20].

These considerations are also somewhat mirrored in the guidelines developed by the International Commission on Radiological Protection, whose recommendations form the basis of legislation in many countries [11], and of the International Basic Safety Standards issued by the International Atomic Energy Agency [21]. In Italy, a 1995 law (art. 111, DL 230/95)

### Table 3. - Radiation doses and estimated cancer risk from common radiological examinations and isotope scans [3,12]

<table>
<thead>
<tr>
<th>Type of test</th>
<th>Effective radiation dose (mSv)</th>
<th>Equivalent period of natural background Radiation</th>
<th>Lifetime additional risk of cancer per examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest radiograph</td>
<td>0.01</td>
<td>A few days</td>
<td>Negligible risk</td>
</tr>
<tr>
<td>Skull radiograph</td>
<td>0.1</td>
<td>A few weeks</td>
<td>Minimal risk</td>
</tr>
<tr>
<td>Breast (mammography)</td>
<td>1</td>
<td>A few months to a year</td>
<td>(1 in 100000 to 1 in 1000000)</td>
</tr>
<tr>
<td>Cardiac gated study</td>
<td>10</td>
<td>A few years</td>
<td>Very low risk</td>
</tr>
<tr>
<td>Cardiac thallium scan</td>
<td></td>
<td></td>
<td>Low risk</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(1 in 1000 to 1 in 10000)</td>
</tr>
</tbody>
</table>

mSv: milliSievert.

![Fig. 2. - Typical effective doses from diagnostic medical exposures. Adapted from [12].](image-url)
states that a nuclear examination may be performed only when it cannot be replaced by other techniques that do not employ ionising radiation [22].

The Council Directive 97/43 Euratom implies that all new types of radiological practices (including nuclear medicine) shall be justified. It clearly means that if an exposure cannot be justified, it should be prohibited (art. 3). All well-established nuclear medicine practices must be reviewed in the light of new data about their efficacy and consequences. Consequently, dosimetry should become a key element in the competition with other “radiologic” techniques. The winner will be the patient who will benefit from the best indications of examinations with ionising radiations and will escape from unnecessary exposures [23-26].

To the principle of justification it is necessary to add the right of the patient to be informed about potential risks of procedure, in particular, that radionuclide isotopes increase the incidence of cancer in a different fashion and in relation of the isotope used: for instance, for cardiac stress perfusion scintigraphy with a risk of fatal cancer ranging from 1.2 out of 1000 to 2.5 out of 10 000 cases [2, 3].

By way of precaution in the Euratom Directives on radiological protection (97/43) has been adopted the ALARA-principle. This principle describes that the dose of harmful exposure has to be kept as low as reasonably achievable, economic and social factors being taken into account. As a consequence, this principle was implemented in national legislations [13-15].

Because safety does not mean risk free, it would not be reasonable to aim for a “zero-risk” situation. The optimization or ALARA-principle avoids taking protective measures if the benefits are smaller than the economical or social burden. M.C. Boehler [16] mentioned that because of the precautionary principle, law in the field of radioprotection does no longer serve science but promotes ethical responsible conduct in our insecure world. The linear model is no translation of scientific knowledge but an intellectual construction serving as a basis to take measures.

The ALARA-principle has to be applied by individuals and companies on a case-by-case basis. The policy options that, in accordance to the precautionary principle, were taken by government have been transferred by the ALARA-principle to companies and individuals. All imaging departments should have protocols for each common clinical situation. The principle does not impose specific and detailed obligations but can be considered a demand for self-regulation. In referral guidelines for imaging stated that all examinations should be optimised to obtain maximum information with the minimum of radiation [1]. Standardization seems necessary to guarantee a correct application of the precautionary principle. Since the recent Euratom directives have stimulated the promulgation of diagnostic reference levels in case of medical exposure and dose constraints, this demand is explicitly put forward.

The Council Directive 97/43 Euratom (art. 5) implies that both the referring physician ordering the nuclear medicine test (the prescriber) and the physician performing the test (the practitioner) are responsible for the justification of the test exposing the patient to ionising radiations [19].

The practical aspects for the procedure or part of it may be delegated by the holder of the radiological installation or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognized field of specialization.

Most equipment used in medical establishments has achieved a high degree of sophistication, and its faultless operation is decisive in making good medical diagnosis. In this respect, quality control or, in other words, regular “checks” are absolutely necessary and constitute a major part of the physicist’s professional responsibility. All failures in providing uninterrupted care may not only be a cause of concern for doctors and patients, but may also involve problems of legal responsibility. There is no excuse for any negligence or carelessness, especially when radioisotope or radiation therapy is employed [27].

### Decision-making process

The European Commission is aware of the necessity of a structured decision-making process. In the recent communication [15] stated that the European Commission have to find the correct balance between the freedom and rights of individuals, industry and organizations on the one hand and environment, human, animal and plant health on the other hand. If this balance is found, proportionate, non-discriminatory, transparent and coherent actions can be taken. This communication is a first step to establish guidelines for applying the precautionary principle.

According to the European Commission, a structured decision-making process is provided by the three elements of risk analysis: risk assessment, risk management and risk communication.

Before adequate measures can be taken, a scientific evaluation has to be performed as good as possible. This risk assessment requires reliable scientific data and logical reasoning, leading to a conclusion, which expresses the possibility of occurrence and the severity of a hazard’s impact on environment or human, animal and plant health. It will cast light on the objective evidence, the gaps in knowledge and the scientific uncertainties.

The procedure to evaluate the policy options has to be as transparent as possible. Dab stresses that formalization of the decision-making process and public involvement become more important with increasing uncertainty. The most unacceptable,
Perception of radiation risk by the prescriber.

Prescribing physicians should be aware that their choices place economic and biohazard burdens on the planet and the patient. Art. 3 of the 97/43 Euratom Directive stated that “medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation”.

Professional and legal responsibilities of medical physicists may be expected to grow in direct proportion to the increased scope of physics and engineering methods and techniques to be applied in medicine in future [27].

In every case of medical imaging diagnostics the choice should be made in favour of the most harmless and risk-free method. Accordingly among wide range of imaging modalities, ultrasound has been recommended as the appropriate investigation wherever possible. Because ultrasound avoids ionising radiation and is relatively inexpensive, it is often recommended where more expensive studies (e.g. CT) cannot be justified or resources are limited [1]. The unexpensive, quick, reliable and non-invasive nature of ultrasound makes it an excellent initial investigation for a vast majority of clinical referrals.

Although ultrasound technology is improving steadily, an alternative technique is needed for “acoustically hostile” patients. For these patients, fast magnetic resonance imaging, which incorporates the best aspects of nuclear and ultrasound scanning, can provide an accurate second-line choice [12].

Because MRI does not use ionising radiation, MRI should be preferred where both CT and MRI would provide similar information and when both are available.

**Why good medical practice by law?**

In reality, at least 1 out of 4 ionising exams are inappropriate [29], and many more might be replaced by non-ionising procedures of comparable clinical value [1]. This has created concerns for public health because of radiation doses associated with unnecessary exams [30-32]. There are at least three extra-scientific conditions, which may modulate prescription patterns: economic induction, medical lobbying, and inadequate perception of radiation risk by the prescriber.

Economic induction to prescription may modulate testing. The imaging market consists of 600 million procedures every year. In 2001, over 100 million scans were performed with a medical diagnostic product worldwide, generating UK £ 2.5 billion in revenue for the manufacturers of contrast agents [7]. Economic induction to prescription exists and usually it is more pervasive for more expensive diagnostic services [29]. In addition, in many centres patients have access to such studies without physician referral [33].

Medical imaging superspecialists are expensively - and lifelong - trained to do one single thing. For instance, an imaging specialist has to undergo 6 years of medical school and 3 years of internship and additional 4 to 5 years of imaging fellowship. For academic qualification, an additional 3 year PhD program is helpful. Basically, the uneventful training is started at the age of 19 and ends sometimes between 35 and 40 years. At that time, the situation in the imaging market can be totally different from what it was at the beginning, and emerging techniques may be at risk of becoming obsolete and non-competitive in some fields, due to the birth and growth of alternative modalities [12]. Nevertheless, trained specialists exist and must be kept alive. This makes a timely reallocation of human and economic resources a sensitive and not bloodless issue. According to an eminent cardio-pathologist, Giorgio Baroldi, “the specialist falls in love with the only technique, better if sophisticated, that he is able to master and must defend it if he wants to justify his survival, production, success and audience - and he becomes dangerous” [34]. Unfortunately we, the imaging experts, are all super-specialists. Last - and probably not least - many clinicians and researchers working with patients with cardiovascular disease may not yet be familiar with the radiation doses that are received with the different examinations [33]. In addition, for the very same examination such as for instance computed tomography of the heart, radiation doses may differ widely [33]. To further complicate matters, radiation dose estimates can be expressed in various ways and it is not always clear in elite publications - not to speak of clinical practice - which parameters are used [33].

Even more confusing, some guidelines - such as those released by the UK Radiological Society and endorsed by European Union - clearly state that, generally speaking, a non-ionising exam should always be preferred to a ionising exam - when information is comparable [1]. Other guidelines issued by specialist societies, such as cardiological societies, overtly state that the information provided by nuclear cardiology and echocardiography (in evaluating cardiac function, myocardial viability, inducible ischemia and prognosis) is comparable and therefore ... “the choice of which test to perform depends on issues of local expertise, available facilities and considerations of
cost-effectiveness” [35]. No mention is made of environmental impact, biohazard and responsibility. Accuracy of “green” and “red” techniques is also considered largely comparable in other disease, such as cancer detection. Yet, guidelines suggest that they can be used without difference or preference: for instance, American Cancer Society Guidelines for cancer detection recommend for colorectal cancer screening flexible sigmoidoscopy or double-contrast barium enema or colonoscopy [36]. But colonoscopy and sigmoidoscopy are “green”, and double-contrast barium enema is “deep red”! The consequence is a daltonic Pontius Pilate - like hand washing with serious potential impact on public health.

To make things even more confusing, the “best available evidence” of radiological risk estimation is provided by the International Commission of Radiological Protection [3, 4]. Such estimation is referred to in the legislation of many countries, including Italy [22, 26] and European Union [19]. Guidelines of the radiological society refer to this estimation of risk [1]. And yet, such estimation is overtly challenged by other societies and distinguished scientists working in the field [37]: “the international consensus in that there are no major health risks associated with diagnostic utilization of radio pharmaceuticals. Moreover, the metrics that have been used to estimate the hypothetical risk have no relation to modern medicine or accepted biological principles”. Maybe Michael Crichton - a writer and a Harvard-laureate physician - was right in stating that “medical writing is a highly skilled, calculated attempt to confuse the reader” [38]. It is interesting to notice the International Agency for Research on Cancer found in 2000 “sufficient evidence for carcinogenicity in humans” of X-radiation and γ-radiation. The primary exposure to these sources are “past use of atomic weapons and medical uses of radiations”. On the basis of this evidence, the National Institute of Environmental Health Sciences nominated X-radiation and γ-radiation to the National Toxicity Program together with other 16 different substances. The committee is scheduled to put the 17 substances into 3 categories: known human carcinogen; reasonably anticipated to be a carcinogen; insufficient evidence. The 11th Report on carcinogens is due for release in the winter of 2004. The listing as a carcinogen “ is meant to alert congress, regulating agencies and others, including the public, to see if current limits, labelling, etc. are sufficient to safeguard the public” [39].

Conclusions

Physicians and patients should always evaluate the cost-benefit and the risk-benefit ratios of their actions, not only the benefit. For instance, the radiation risk of mammography is very low. In a population of 1 million, one would expect 800 occult, naturally occurring cancers and only 1-3 cancers induced by mammography [40]. However, not always in clinical practice the benefit clearly outweighs risk. A useful investigation is one in which the result - positive or negative - will alter management or add confidence to the clinician’s diagnosis. A significant number of radiological and medicinuclear investigations do not fulfil these aims and may add unnecessarily to patient irradiation due to repeating investigations which have already been done, doing the wrong or inappropriate investigation.

The European law accepts high level of individual and environmental protection and adopts tight legal regulation criteria trying to restrict access to ionising testing to strictly needed indications. In everyday practice, the application of the law is tempered by diffuse ignorance of European legislation and therefore lack of its implementation into medical recommendations and guidelines. Tighter interaction between legal and medical regulatory bodies is necessary to enhance the level of social protection from “friendly fire” of radiological and nuclear medical testing.

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