REPORT N°277

ANALYSIS OF THE CRITERIA USED BY THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION (ICRP) TO JUSTIFY THE SETTING OF NUMERICAL REFERENCE VALUES

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1. INTRODUCTION

Following its Publication 60, ICRP has proposed nine reports specifying quantified values for dose constraints, action levels, etc. Some 25 values have been identified in all these publications. Since a few years, ICRP is preparing new recommendations in order to provide "a more coherent and comprehensible system"\(^1\). The objective of ICRP is to propose to select among the existing quantified values, a few values that could encompass all the other ones. These values are not intended to replace the currently recommended values which remain valid.

In this perspective, IRSN has asked CEPN to make a review of all the values introduced in the ICRP publications in order to obtain a broad view of the rationalities proposed by ICRP in the determination of these values.

The following Publications of ICRP have been reviewed:

- ICRP 60 - 1990 - 1990 Recommendations of ICRP
- ICRP 62 - 1992 - Radiological protection in biomedical research
- ICRP 63 - 1992 - Principles for intervention for protection of the public in a radiological emergency
- ICRP 64 - 1993 - Protection from potential exposure: a conceptual framework
- ICRP 65 - 1993 - Protection against radon-222 at home and at work
- ICRP 68 - 1994 - Dose coefficients for intakes of radionuclides by workers
- ICRP 75 - 1997 - General principles for the radiation protection of workers
- ICRP 77 - 1997 - Radiological protection policy for the disposal of radioactive waste
- ICRP 81 - 2000 - Radiation protection recommendations as applied to the disposal of long-lived solid radioactive waste
- ICRP 82 - 2000 - Protection of the public in situations of prolonged radiation exposure

The different quantitative values found in these publications are presented in this report, grouped by type of value: individual dose limits, "maximum" individual dose, dose constraints, exemption, action and intervention levels. The rationalities proposed by ICRP for setting these values are presented, mainly based on the quotation of ICRP Publications. In some cases, when the rationality is not totally explicit, the authors of this report propose their own interpretation. A table summarizing the values and the rationalities considered by ICRP for their setting is presented in Appendix 1. The extracts from each ICRP publication corresponding to the presentation of the values are presented in Appendix 2.
2. RATIONALITIES BEHIND INDIVIDUAL DOSE LIMITS

The individual dose limits which can be found in ICRP Publications are presented in Table 1. They concern public and worker exposures (including pregnant women and foetal dose).

Table 1. Individual dose limits

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose*</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual dose limit for deliberate practices</td>
<td>1 mSv/y</td>
<td>60 ($190 to 193)</td>
</tr>
<tr>
<td><strong>Occupational exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual dose limit for deliberate practices</td>
<td>20 mSv/y averaged over 5 years (100 mSv in 5 years) 50 mSv in any single year</td>
<td>60 ($149 to 170) 75 ($55 &amp; 56)</td>
</tr>
<tr>
<td>Individual dose limit for intake of radionuclides for deliberate practices</td>
<td>based on 20 mSv/year committed effective dose</td>
<td>60 ($174 &amp; 175) 68 ($41)</td>
</tr>
<tr>
<td>Individual dose limit for pregnant women (for remainder of pregnancy) for deliberate practices</td>
<td>2 mSv equivalent dose to the surface of abdomen 1 mSv equivalent dose to foetus</td>
<td>60 ($176 to 178) 75 ($58 &amp; 124)</td>
</tr>
</tbody>
</table>

* Unless specified.

The criteria used to set up these dose limits include:
- the natural background level of exposure;
- the reference to the associated level of individual risk of death;
- the calculation of quantitative factors to express the individual detriment;
- the lifetime dose, or lifetime risk;
- the necessity to avoid deterministic effect;
- a qualitative judgement on the unacceptable level of consequences.

2.1. Public exposure

The individual dose limit for public exposure as a result of deliberate practices is set at 1 mSv/year in ICRP 60, based on a combination of two approaches ($190 and149):
- the search for the level above which "the consequences for the individual would be widely regarded as unacceptable" (same than for the occupational dose limit, see below), and
- "a judgement based on the variations in the existing level of dose from natural sources."

The assessment of the consequences is based on various quantitative factors including:
- Attributes associated with mortality:
  o the lifetime attributable probability of death;
  o the time lost if the attributable death occurs;
  o the reduction of life expectancy (a combination of the two first attributes);
  o the annual distribution of the attributable probability of death;
  o the increase in the age specific mortality rate, i.e., in the probability of dying in a year at any age, conditional on reaching that age.
- An estimation of morbidity (non fatal cancer and hereditary effects) by using the number of nonfatal conditions weighted for severity and for the period of life lost impaired.

The Annex C of ICRP 60 provides the risk calculations made for judging the significance of the effects of radiation, including the above listed attributes associated with mortality. It would be too long to address here all the values of risk estimated for public exposure. There is clearly no single number used to set the dose limit. Moreover, it is stated in this Annex that these risk data are only one part of the information needed for the selection of the dose limit, and that a number of additional attributes has to be considered.

Concerning the reference to the level of dose from the natural background, the Annex C of ICRP 60 notes in §C74 that "the fact that a man-made practice involving radiation causes doses which are small in comparison with the background doses does not necessarily imply that the practice is justified, but it does imply that the radiation risk situation of the exposed individual is not significantly changed by the new practice." It is also noted in §191 that "excluding the very variable exposure to radon, the annual effective dose from natural sources is about 1 mSv with values at high altitudes above sea level and in some geological areas of at least twice this. "
2.2. Occupational exposure

2.2.1. General practice

In order to set the individual dose limit for occupational exposure, the ICRP 60 states in §149 that "the aim is to establish, for a defined set of practices, a level of dose above which the consequences for the individual would be widely regarded as unacceptable". The criteria used to assess the consequence of any dose are presented above (§2.1). As for public exposure, there is no single value of risk which is used to set the limit. However, it can be noted that ICRP 60 makes a reference to the reduction of life expectancy associated with an annual dose of 50 mSv as well as to the associated level of probability of death: "(...) a regular annual dose of 50 mSv, corresponding to a lifetime effective dose of 2.4 Sv, is probably too high, and would be regarded by many as being clearly so. (...) The reduction of life expectancy at this level (1.1 years) and the fact that there would be a probability exceeding 8% that the radiation hazards in a worker's occupation would be the cause of his death, albeit at late age, would be widely seen as excessive (...) (§161).

Another indication provided in ICRP 60 concerns the total effective dose received in a full working life. The latter should not exceed 1Sv (§162)². As a result of all these consideration, "the Commission recommends a limit on effective dose of 20 mSv per year averaged over 5 years (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year." (§166). The proposal of the 5-years period is recommended to provide flexibility. It can be noted that latter, the ICRP 75 on occupational exposure has stated that where this flexibility is not required, "the regulatory agency may prefer to continue to operate with an annual limit. The dose limit would then be 20 mSv in a year" (§55).

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² It can be noted that ICRP 60 clearly states that "the Commission does not recommend the use of lifetime limits" mainly because the Commission sees difficulties in the practical implementation of such a limit (§165).
2.2.2. Internal exposure

In case of internal exposure, the Commission provides annual limits on intake (ALIs) which are based on a committed effective dose of 20 mSv (ICRP 60, §174, and ICRP 68, §41). These restrictions are provided to ensure that "the lifetime equivalent dose (not committed equivalent dose) in any single organ will not be such as to result in deterministic effects" (ICRP 60, §175).

2.2.3. Pregnant women

In order to protect the foetus for pregnant women, ICRP 60 has recommended to limit the equivalent dose to the surface of abdomen to 2 mSv for the remainder of the pregnancy. There is no clear justification for having chosen this value, except the fact that "the standard of protection for any conceptus (should be) broadly comparable with that provided for members of the general public" (§177). In its Publication 75, the Commission recognises that this advice has "sometimes been interpreted too rigidly" (§124), and recommends that "the working conditions of a pregnant worker, after the declaration of pregnancy, should be such as to make it unlikely that the additional equivalent dose to the conceptus will exceed about 1 mSv during the remainder of the pregnancy." (§124). This dose limit is then clearly related to that of public exposure.
3. RATIONALITIES BEHIND "MAXIMUM" INDIVIDUAL DOSE FOR EMERGENCY SITUATIONS AND IN THE CONTEXT OF BIOMEDICAL RESEARCH

The ICRP proposes, in the case of emergency situations as well as in the context of biomedical research, some values of individual dose which should not be exceeded. These values are not called explicitly individual dose limits, and for the sake of presentation in this document, they are called "maximum" individual dose.

In the case of emergency situations, the ICRP recommends for the emergency team to permit a relaxation of the controls for normal situations and indicates a value of individual dose which should however not be exceed (see Table 2).

In the context of biomedical research, the ICRP recommends levels of individual dose for the volunteers participating to a biomedical research project which can be justified according to the level of societal benefit (see Table 2). These values are determined according to the risk associated with the level of exposure.

Table 2. "Maximum" individual dose

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose*</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Maximum&quot; individual dose for planned emergency work**</td>
<td>500 mSv (5 000 mSv skin)</td>
<td>60 ($225)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>75 ($137)</td>
</tr>
<tr>
<td>Biomedical research</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level of individual exposure for participants, for which justification of exposure must be based on a minor level of benefit of the project for society</td>
<td>&lt; 0.1 mSv</td>
<td>62 ($52 to 56)</td>
</tr>
<tr>
<td>Level of individual exposure for participants, for which justification of exposure must be based on an intermediate level of benefit of project for society</td>
<td>0.1 - 1 mSv</td>
<td>62 ($52 to 56)</td>
</tr>
<tr>
<td>Level of individual exposure for participants, for which justification of exposure must be based on a moderate level of benefit of project for society</td>
<td>1 - 10 mSv</td>
<td>62 ($52 to 56)</td>
</tr>
<tr>
<td>Level of individual exposure for participants, for which justification of exposure must be based on a substantial level of benefit of project for society</td>
<td>&gt; 10 mSv</td>
<td>62 ($52 to 56)</td>
</tr>
</tbody>
</table>

* Unless specified.
** To be noted: values of 1 000 mSv effective dose and 5 000 mSv skin are found in §A2 of Publication 63, recommended to avoid serious deterministic health effects
3.1. Emergency situations

In case of serious accident, the ICRP notes that "some relaxation of the controls for normal situations can be permitted (...) without lowering the long term level of protection." (ICRP 60, §225). However, these relaxation should not permit that the emergency work give effective dose of more than about 0.5 Sv, except for life-saving actions (the equivalent dose to the skin should not be allowed to exceed about 5 Sv).

There is no explanation in ICRP 60 on how these values have been selected. They are also proposed in ICRP 75, but with no more explanation. One reason could be the avoidance of deterministic effects, as it can be found in the Publication 63 related to the principles for interventions. This publication, published between ICRP 60 and ICRP 75 recommends in fact different values to be used to protect workers in case of an accident.

In the Annex A of the Publication 63, it is thus noted that, for Category 1 workers (i.e. doing urgent action at the site of accident), "every efforts should be made to keep doses below those at which serious deterministic health effects occurs; i.e. 1 Sv effective dose or 5 Sv equivalent dose to skin (...) (ICRP 63, §A2)

As the Publication 75 was published after the 63, we have made the assumption in the summary table, that the values to be considered are the latest published, i.e. the value of 0.5 Sv effective dose (5 Sv equivalent dose to the skin).

3.2 Biomedical research

The ICRP Publication 62 dealing with the radiological protection in biomedical research recommends a set of levels of individual dose which can be justified for the volunteers according to the level of societal benefit of the project.

The basic criterion for the definition of the categories is the level of risk, i.e. the total detriment for the exposed individual estimated in terms of fatal cancers, non-fatal cancers and hereditary effects. The risk categories proposed by the Commission are presented in Table 3.
### Table 3. Categories of risk and corresponding levels of benefit - ICRP 62

<table>
<thead>
<tr>
<th>Level of risk</th>
<th>Risk category (total risk-see text)</th>
<th>Corresponding effective dose range (adults) (mSv)</th>
<th>Level of societal benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trivial</td>
<td>Category I (=10⁻⁶ or less)</td>
<td>&lt;0.1</td>
<td>Minor</td>
</tr>
<tr>
<td>Minor to intermediate</td>
<td>Category IIa (= 10⁻⁵)</td>
<td>0.1-1</td>
<td>Intermediate to moderate</td>
</tr>
<tr>
<td></td>
<td>Category IIb (=10⁻⁴)</td>
<td>1-10</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Category III (= 10⁻³ or more)</td>
<td>&gt; 10 *</td>
<td>Substantial</td>
</tr>
</tbody>
</table>

* To be kept below deterministic thresholds except for therapeutic experiments

The qualification of the level of risk, from trivial to moderate, makes allowance for the levels of risks regarded as acceptable or not by the society, as well as with regards to the level of natural background exposure (for the trivial level). The level of the societal benefit of the project which has to be obtained in order to justify the corresponding level of exposure is directly linked to the level of risk.

**Determination of the trivial level of risk**

The Commission considers that: *"The lowest risk category is of the order of one in a million and is in the region in which people are usually content to dismiss the risk as approaching the trivial. The corresponding dose region is less than 100 µSv which is the amount of dose delivered by natural background radiation in a few weeks. It is considerably less than the variations in annual dose from natural background to persons living in different locations. It is therefore concluded that, given the requirement in Section 2 for all investigations to be fully justified, the level of benefit needed as the basis for approval of investigations with risks or doses in Category I will be minor and would include those investigations expected only to increase knowledge."* (ICRP 62, §53).

**Determination of the moderate level of risk**

The Commission considers that: *"At the other extreme the highest risk category includes risks of the order of one in a thousand or greater. This is a moderate risk for a single exposure but is in the region which people tend to regard as verging on the unacceptable for continued or repeated exposure. The corresponding dose region is*
tens of mSv or more which is greater than the current annual dose limit for occupational exposure. It covers the higher part of the range of annual doses from natural background radiation (including radon), a region in which remedial measures to reduce dose are usually recommended. To justify investigations involving doses or risks in Category III, the benefit would have to be substantial and usually directly related to the saving of life or the prevention or mitigation of serious disease." (ICRP 62, §54).

Determination of the minor and intermediate level of risk
The Commission considers that: "Between these two there is a category in which the risks, although neither trivial nor approaching the unacceptable cannot readily be either accepted or used as the basis for refusal. These risks, of the order of one in ten thousand to one in a hundred thousand, cover most of the range of risks about which people express concern but that they are nevertheless willing to accept in a wide range of circumstances for many different types of benefit. In dose terms it includes the annual doses received by essentially all radiation workers in the course of their normal jobs and the annual doses received by members of the public from the totality of sources to which they are exposed, apart from some of the extreme doses from radon. Category II is that within which the balance between benefit and risk is probably the most difficult to make as neither is overwhelming. It may be felt helpful to make some distinction between Category IIb, the upper, intermediate level of risk, covering doses typically received by workers each year, for which a moderate benefit is needed; and Category IIa, a minor level of risk covering dose to the public from controlled sources, for which an intermediate benefit is nonetheless required. As further guidance, to justify risks in Category IIa the benefit will probably be related to increases in knowledge leading to health benefit. For risks in Category IIb the benefit will be more directly aimed at the cure or prevention of disease." (ICRP 62, §55)
4. RATIONALITIES BEHIND DOSE CONSTRAINT

The concept of "dose constraint" is introduced in ICRP 60 as a tool to restrict the doses on individuals when implementing the optimisation process in order to limit the inequity likely to result from the inherent economic and social judgement (§112). The dose constraints are "source-related values of individual dose used to limit the range of options considered in the procedure of optimisation." (§144). This concept is developed in the presentation of the system of protection for the various situations: occupational exposure, medical exposure, public exposure, and potential exposure. ICRP 60 does not propose any value of dose constraint. It is stated that "it will usually be appropriate for dose constraints to be fixed at national or local level." (§145 - occupational exposure).

However, some indications are given on the maximum value that could be given to the dose constraint for public and for the workers. The dose constraint being a single source-related value, it means implicitly that this value should not exceed the dose limit which applies to the sum of exposures from all sources:

- For occupational exposure, ICRP 60 notes at the end of the presentation of the dose limits that "it is implicit in these recommended dose limits that the dose constraint for optimisation should not exceed 20 mSv in a year" (§166). In the presentation of the system, the Commission proposes to determine the dose constraints by using the "level of individual doses likely to be incurred in well-managed operations. This information can then be used to establish a dose constraint for that type of occupation." (§144)

- For public exposure, the same type of rationality (link with the dose limit) is applied to indicate the maximum dose constraint: "it is implicit in this limit that the constraints for the optimisation of protection in the design of new installations should be smaller than 1 mSv in a year". (§192)

After publication of ICRP 60, three publications have introduced a numerical value of dose constraint in the case of public exposure (see Table 4): ICRP 77 on radioactive waste disposal, ICRP 81 on the disposal of long-lived solid radioactive waste, and
ICRP 82 on the protection of public in situations of prolonged radiation exposure. The proposed values are implicitly set as a fraction of the dose limit.
Table 4. Individual dose constraint

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose*</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose constraint for public exposure for prolonged component from long-lived nuclides</td>
<td>0.1 mSv/y</td>
<td>82</td>
</tr>
<tr>
<td>(§33 to 39)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose constraint for public exposure, for radioactive waste disposal</td>
<td>No more than 0.3 mSv/y, and &lt; 1 mSv/y</td>
<td>77</td>
</tr>
<tr>
<td>(§48)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose constraint for public exposure, for long-lived radioactive waste disposal</td>
<td>0.3 mSv/y</td>
<td>81</td>
</tr>
<tr>
<td>(§39, 55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose constraint for public exposure, for prolonged exposure</td>
<td>~ 0.3 mSv/y and &lt; 1 mSv/y</td>
<td>82</td>
</tr>
<tr>
<td>(§33 to 39)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*In these situations, all values can be considered to be expressed as "additional annual dose", using the terminology proposed by ICRP 82.  

ICRP 77 is the first publication introducing a numerical value for the public dose constraint to be applied for the control of public exposure from waste disposal in the use of the constrained optimisation of protection. This single source related value is recommended "to allow for exposures to multiple sources" (§48). It is then stated that "the maximum value of the constraint (...) should be less than 1 mSv in a year. A value of no more than about 0.3 mSv in a year would be appropriate" (§48).

Before proposing this value, ICRP 77 notes that "there are a few rare situations in which there are significant exposures to multiple sources within a practice." (§44). The value of 0.3 mSv/y implicitly means that the considered practice (in this case, waste disposal) contributes to one third of the total dose received by the members of the public.

ICRP 81 proposes radiation protection recommendations for the disposal of long lived solid radioactive waste. It makes a reference to ICRP 77 in recommending a dose constraint of 0.3 mSv/y, and notes that this value "corresponds to a risk constraint in the order of 10^{-5} per year" (§55).

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3 A subsidiary quantity used in the context of ICRP 82 is the summation of the annual doses caused by all the persisting sources of prolonged exposure in a given human habitat; this quantity is termed the "existing annual dose". The annual dose that is added to the existing annual dose as a result of a practice is termed the "additional annual dose".
The radiation protection of public for prolonged exposure situations, as presented in ICRP 82, should also be subject to constrained optimisation. The use of the dose constraint is specified: "The optimisation process excludes any protection options that would involve individual annual doses above the selected dose constraint. The Commission uses the term 'constraint' only for this prospective purpose. The dose constraints are used as an integral part of the process of optimising prospectively radiological protection at the source and not as a form of retrospective dose limitation." (§33). It is noted that the determination of the level of the dose constraint should be done on a case-by-case basis, "with due consideration of the maximum annual dose that would be acceptable from a new source at a single location, taking into account exposures from other sources subject to control and equity considerations." (§34).

Making a reference to ICRP 60 and ICRP 77, ICRP 82 notes that "the Commission recommended that the dose constraint should be less than 1 mSv and that a value of no more than about 0.3 mSv would be appropriate. These recommendations are in principle applicable to prolonged exposure." (§35).

Moreover, ICRP 82 recognises that in some situation, the verification of the compliance with the established dose constraint in not feasible. In this case, the Commission considers that "it will obviously be prudent to impose additional restrictions on the prolonged component of the annual individual dose attributable to the source." (§37). In this case the Commission recommends to use a dose constraint of 0.1 mSv in any given year in order to restrict the prolonged component of the individual dose from the source. (§38)
5. RATIONALITIES BEHIND EXEMPTION, ACTION AND INTERVENTION LEVELS

Exemption, action and intervention levels are grouped in this section as these values can be seen as reference levels below or above which some type of action has to be undertaken or not.

5.1. Exemption levels

The grounds for exempting a source or an environmental situations from the regulatory control are given in ICRP Publication 60, but without specifying any value. Two rationalities are proposed:

i. **a value judgement on the level of individual or collective dose**: "the source gives rise to small individual doses and small collective doses in both normal and accident conditions" (§287);

ii. the estimate that the regulatory provisions will produce no significant reductions in individual or collective dose: "no reasonable control procedures can achieve significant reductions in individual and collective doses" (§287).

The first rationality refers implicitly to the determination of a trivial dose level. ICRP 60 notes that "the basis for exemption on the grounds of trivial dose is much sought after, but very difficult to establish. Apart from the difficulty of deciding when an individual or a collective dose is small enough to be disregarded for regulatory purposes, there is a considerable difficulty in defining the source. For example, if the source is defined as a single smoke detector, both the individual and the collective doses from that source may well be trivial, but the individual may be exposed to many other sources. If the source is taken as smoke detectors in general, the individual doses will still be small, but the collective dose may be substantial. The underlying problem is that exemption is necessarily a source-related process, while the triviality of dose is primarily individual-related" (§288).

The second rationality introduced by ICRP 60 refers to the application of the optimisation principle: "the second basis for exemption calls for a study similar to that needed in the optimisation of protection. It provides a logical basis for exemption of
sources that cannot be exempted solely on the grounds of trivial doses, but for which regulation on any reasonable scale will produce little or no improvement" (§290). Three specific values of exemption level are proposed in the ICRP Publications (see Table 5).

**Table 5. Exemption levels**

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption level for practice used in regulatory systems</td>
<td>in the order of 0.01 mSv/year</td>
<td>64 (§86)</td>
</tr>
<tr>
<td>Exemption level for practice under certain conditions</td>
<td>0.01 mSv/year*</td>
<td>82 (§23)</td>
</tr>
<tr>
<td>Exemption level for intervention in case of radioactive substances in commodities</td>
<td>1 mSv/year*</td>
<td>82 (§125 to 126)</td>
</tr>
</tbody>
</table>

* Additional annual dose (see footnote n°3)

The first reference to a specific value used as an exemption level appears in Publication 64 of ICRP on the protection from potential exposure. In the section dedicated to the exemption of potential exposure scenarios, this Publication notes that in the case of normal exposure, most regulatory systems include provisions for granting exemptions from the regulatory system where it is clear that a practice is justified but regulatory provisions are unnecessary. **The grounds for exemption are that the source gives rise to small individual doses (of the order of 10 µSv per year) and the protection is optimised, i.e., regulatory provisions will produce little or no improvement in dose reduction. (If the collective dose is small, e.g., on the order of one man-sievert per year, protection is often assumed to be optimised.)** (§86).

The implicit justification of the value of 10 µSv per year is related, as proposed in ICRP 60, to a qualitative judgement on the level of exposures ("small" individual doses). It is also assumed that the exemption level for a practice determines a level below which the protection is supposed to be optimised. It can be noticed that it is the first publication where an implicit value of "trivial collective dose" is proposed (1 man-Sievert/year), as it is noted that below this value, the protection is often assumed to be optimised.

The Publication 82 of ICRP dedicated to the protection of the public in situations of prolonged radiation exposure confirms that the value of 10 µSv per year can be used a
value for exempting practices from the regulatory system: "The Commission therefore considers that: under certain conditions, sources used in justified practices can be exempted from regulatory requirements if the individual additional annual doses attributable to the source are below around 0.01 mSv in a year. (§23).

In presenting the rationality for setting this value, ICRP 82 recall the main principles for setting exemption levels adopted at the international level:

(i) the radiation risks to individuals caused by the exempted practice or source should be sufficiently low as to be of no regulatory concern;
(ii) the collective radiological impact of the exempted practice or source should be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and,
(iii) the exempted practices and sources should be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the previous criteria. (§23)

The Publication 82 notices however that the main criteria used is usually that of the trivial individual dose. This level is said to be "derived on the basis of risk-based considerations and also on the consideration of natural background radiation. (...) The level of annual risk which is held to be of no concern to individuals is taken to be around 10^{-6} to 10^{-7} and a trivial change in the natural background radiation is considered to be in the order of few per cent of its average value of ≅ 2.4 mSv per annum (...). Both considerations lead to an annual dose of the order of few hundredths of a millisievert." (ICRP 82, §23).

ICRP 82 also proposes an exemption level for intervention in commodities. In order to determine the generic value, the Commission makes a reference to the level of individual dose below which intervention is not likely to be justifiable (about 10 mSv/year expressed as "existing dose"). For perspective purposes, ICRP 82 makes a reference to the level of the natural background which can lead to existing annual doses of at least a few millisieverts per annum, stressing that with some exceptions, intervention has rarely, if never, been undertaken to reduce the typically elevated natural background dose of 10 mSv per annum (§76). ICRP 82 states that "it would be illogical to allow the annual dose components attributable to commodities and amenable to intervention even to approach this level." (§125). It concludes that "taking account of
possible annual doses from authorised practices, this leaves an upper bound of the order of a few millisieverts per annum for the annual doses from all commodities to be exempted from intervention. " (§125).

Finally, the Commission considers that:
- A generic intervention exemption level of around 1 mSv is recommended for the individual annual dose expected from a dominant type of commodity amenable to intervention (expressed as an additional annual dose), such as some building materials, which may in some circumstances be a significant cause of prolonged exposure.
- On the basis of this recommendation, concerned national and, as appropriate, relevant international organisations should derive generic, and radionuclide-specific, intervention exemption levels for individual commodities, in particular for specific building materials. (ICRP 82, §126)

Our interpretation of the selection of this value is that an additional prolonged exposure greater than 1 mSv/year could lead to annual doses greater than 10 mSv, this level of exposure being "illogical" for components attributable to commodities amenable to intervention.

5.2. Action levels

Two action levels have been proposed by the ICRP (see Table 6). These levels can be seen as levels above which some kind of action should be undertaken in order to reduce the level of exposure.

Table 6. Action levels

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose*</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Action level&quot; for NORMS to determine if exposure should be considered as occupational</td>
<td>1 - 10 Bq/g (1 - 2 mSv/year)</td>
<td>75 (§159 to 161)</td>
</tr>
<tr>
<td>Action level for intervention in case of Radon-222 at home and at work</td>
<td>3 - 10 mSv/year (200 to 600 Bq/m³ in dwellings 500 to 1500 Bq/m³ in workplace)</td>
<td>65 (§72 &amp; 86)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>75 (§156)</td>
</tr>
</tbody>
</table>
In Publication 75 dedicated to the general principles for the radiation protection of workers, the Commission recommends, for the control of occupational exposure to materials with elevated levels of natural radionuclides, that the "regulatory agencies choose activity concentrations of parent nuclides within the range 1-10 Bq g⁻¹ to determine whether the exposures from these materials should be regarded as occupational" (§161). These values correspond approximately to an effective dose between 1 and 2 mSv per year in case of uranium and thorium ores, as noted in Publication 75:

- The effective doses per unit intake via inhalation for uranium and thorium ores and radium tailings are in the range of 0.03 to 0.09 mSv per Bq of parent nuclide, depending on the radionuclide and the particle size. If one assumes, pessimistically, an average dust loading of 5 mg m⁻³ and continuous occupational exposure of 2000 hours in a year, then concentrations of between 1 and 10 Bq g⁻¹ will lead to an effective dose of about 1-2 mSv in a year. A similar range of activity concentrations is obtained from the consideration of continuous occupational exposure to gamma radiation from bulk quantities of the materials. Experimental data on the exposure of workers to gamma radiation and dusts from the surface mining and milling of sedimentary phosphate ores, containing about 1.5 Bq g⁻¹ of uranium, support this assessment." (§160)

Our interpretation of the selection of an effective dose of 1 - 2 mSv/year to decide that the exposure should be consider as occupational is that it corresponds to the annual dose limit for public exposure. Above this level, it seems coherent to consider that the exposure enters into the field of occupational exposure.

As far as Radon-222 is concerned, ICRP 65 (protection against Radon-22 at home and at work) proposes to limit the choice of the action level for public annual effective dose due to radon in dwellings to the range of about 3 - 10 mSv. There is no clear explanation for setting the upper bound of this range: "It seems clear that some remedial measures against radon in dwellings are almost always justified above a continued annual effective dose of 10 mSv." (§72). The lower range is set by considering that lower values could be used for simple remedial action, but would not be justified if
the value would be closed to the natural background exposure: "for simple remedial measures, a somewhat lower figure could be considered, but a reduction by a factor of five or ten would reduce the action level to a value below the dose from natural background sources." (§72).

For occupational exposure, the Commission considers that for occupational exposure, "workers who are not regarded as being occupationally exposed to radiation are usually treated in the same way as members of the public. It is then logical to adopt an action level for intervention in workplaces at the same level of effective dose as the action level for dwellings." (ICRP 65, §86).

The corresponding rounded values of radon concentration is about 200-600 Bq/m$^3$ for radon in dwellings (assuming an annual occupancy of 7000 hours and an equilibrium factor of 0.4), and 500-1500 Bq/m$^3$ for radon in the workplace (assuming an annual occupancy of 2000 hours and an equilibrium factor of 0.4) (ICRP 65, §73 and 86). It can be noticed that the Publication 75 dedicated to the protection of workers adopts the same values than that proposed in ICRP 65, but considers that it could be appropriate to use a different action level in terms of radon concentration in mines where the equilibrium factor could be significantly different from 0.4 (ICRP 75, §156).

### 5.3. Intervention levels for some prolonged exposure situations

Generic reference levels of existing annual dose for intervention in prolonged exposure situations are introduced by the Publication 82 of ICRP (protection of the public in situations of prolonged radiation exposure) (see Table 7). In this Publication, the Commission proposes two values indicating if interventions for some prolonged exposure situations are likely or not likely to be justifiable.

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic reference level for intervention not likely to be justifiable for some prolonged exposure situations</td>
<td>&lt; 10 mSv/year*</td>
<td>82 (§76, 77, 79)</td>
</tr>
<tr>
<td>Generic reference level for intervention almost always justifiable for some prolonged exposure situation</td>
<td>&gt; 100 mSv*</td>
<td>82 (§78, 83)</td>
</tr>
</tbody>
</table>

* Existing annual dose (see footnote n°3)
As noted by the Commission, "the identification of the existing annual doses low enough to make intervention usually not to be expected, and not likely to be justifiable, is not simple, and certainly not straightforward" (ICRP 82, §76). It proposes, for perspective purpose, to use the "natural" existing annual doses experiences in many part of the world. The main considerations are the following (§76):

- "The global average 'natural' dose is ≈ 2.4 mSv per annum (...) and the majority of the world's population incur doses below or at about this level.
- However, many large populations have lived for years in areas of the world experiencing typically elevated doses of up to around ≈ 10 mSv per annum (...), with some populations even incurring doses above ≈ 100 mSv per annum (...).
- With some exception, intervention has rarely, if ever, been undertaken to reduce the typically elevated 'natural' background doses of -10 mSv per annum.
- Moreover, only occasionally, have protective actions been implemented to reduce higher 'natural' background doses, even when these doses were controllable. This might suggest that competent authorities have considered these levels as being unlikely to trigger any intervention in those situations. It should be noted, however, that the reasons why typically elevated levels of existing annual doses due to 'natural' sources have been generally tolerated, not only by the competent authorities but also by those exposed, are probably diverse. (...).
- However, as the expected radiation health effects depend on the dose received and not on the source origin, the Commission also considers that the typically elevated levels of existing annual doses from 'natural' sources, which have not triggered any protective action, may provide an useful insight into decisions related to intervention.

The Commission also reminds that previously in Publications (63 and 65), "the Commission recommended specific reference levels below which any intervention or action is unlikely to be taken in various situations, suggesting levels ranging from a few to a few tens of mSv for a dominant single component of the existing annual dose" (ICRP 82, §77). It notes that "such intervention and action levels have been generally incorporated into international standards and some national regulations." and
concludes that "this suggests - in this case without provisos - that governmental authorities have considered the recommended levels (of around 10 mSv per annum) as being unlikely to trigger intervention, although they refer to exposures due to just a component of the existing annual dose."

From the preceding discussion, the Commission concludes that: "An existing annual dose approaching about 10 mSv may be used as a generic reference level below which intervention is not likely to be justifiable for some prolonged exposure situations." (ICRP 82, §79).

In order to identify a level of existing dose above which intervention will almost always be necessary, the Commission proposes two situations justifying intervention (ICRP 82, §78):

- the existing annual dose approaches the threshold for deterministic effects, or
- the existing annual dose entails a high risk of stochastic effects.

In the same paragraph, the Commission notes that "Prolonged exposure situations resulting in existing annual dose levels below around 100 mSv are not likely to result in serious deterministic effects, provided that the relevant dose thresholds in relevant organs are not exceeded (...). However, at this level of existing annual dose, the risk of stochastic effects would be too high to be considered generally acceptable".

Finally, the Commission concludes that:

- "Situations in which the annual (equivalent) dose thresholds for deterministic effects in relevant organs could be exceeded should require intervention. (In establishing this requirement, uncertainties in the current estimates of deterministic effects from prolonged exposures should prudently be taken into account.)."
- An existing annual dose rising towards 100 mSv will almost always justify intervention and may be used as a generic reference level for establishing protective actions under nearly any conceivable circumstance." (ICRP 82, §83)

5.4. Intervention levels after an accident
In the Publication 63 dedicated to the principles of intervention for protection of the public in a radiological emergency, the Commission proposes a set of values in terms of effective averted dose to be used to justify different type of interventions (Table 8).

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose*</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of effective averted dose almost always justifying intervention for foodstuff after an accident</td>
<td>10 mSv/year (1 - 10 Bq/kg - β/γ, 10 - 100 Bq/kg - α)</td>
<td>63 (§89 &amp; 90)</td>
</tr>
<tr>
<td>Level of averted effective dose justifying sheltering after an accident</td>
<td>50 mSv</td>
<td>63 (§62)</td>
</tr>
<tr>
<td>Dose rate from deposited activity at which relocation is optimised after an accident for continuing and prolonged exposure</td>
<td>10 mSv/month</td>
<td>63 (§102, C9, C10)</td>
</tr>
<tr>
<td>Level of effective averted dose almost always justifying evacuation after an accident</td>
<td>500 mSv in a day or for the duration of evacuation (5 000 mSv skin)</td>
<td>63 (§67)</td>
</tr>
<tr>
<td>Level of effective averted dose almost always justifying distribution of stable iodine after an accident</td>
<td>500 mSv (thyroid)</td>
<td>63 (§77)</td>
</tr>
<tr>
<td>Level of effective averted dose almost always justifying relocation after an accident</td>
<td>1 000 mSv</td>
<td>63 (§102)</td>
</tr>
</tbody>
</table>

* Unless specified

The Publication 63 recommends to perform justification and optimisation analysis in order to select the appropriate value for each type of countermeasure, based on considerations of the costs and benefits associated with these countermeasures. It proposes also some global values usually "estimated on a generic basis" (the parameters used for the determination of these values are not explicit). For relocation, a "short" reference is made to the level of doses which could lead to deterministic effect and would be unacceptable. Two examples of generic optimisation are proposed in Annex B and C of Publication 63 for food stuffs and relocation.

**Foodstuff**

The Commission considers that: "For any single foodstuff, an intervention level that is almost always justified is an averted effective dose of 10 mSv in a year. In situations where alternative food supplies are not readily available, or where population groups..."
might suffer serious disruption, intervention may be justified only at levels of projected dose much higher than 10 mSv per year." (ICRP63, §89)

Sheltering
The Commission considers that: "It has been estimated on a generic basis that sheltering will almost always be justified provided that an averted effective dose of 50 mSv can be achieved during the time considered feasible for sheltering. Optimised levels will be lower but not by more than a factor of 10 when consideration is given to specific accident conditions and sub-groups of the population." (ICRP63, §62)

Relocation
The Commission considers that: "From generic considerations, an average averted effective dose of about 1 Sv may serve as an almost always justified level for relocation. Depending on the circumstances, relocation may be justified at lower levels of averted dose, but after a very severe accident the justified level of averted dose for relocation may be even higher than this reference level. An example of generic optimisation for relocation is developed in Annex C; the dose rate from deposited activity at which relocation is optimised is about 10 mSv per month for continuing and prolonged exposure." (ICRP63, §102)

The example of generic optimisation in case of relocation, presented in annex C of ICRP 63, concludes that the dose rate at which relocation is optimised is about 10 mSv per month, this value being coherent with different cost of relocation and different monetary values of the averted man-sievert (§C8). In the same annex, the Commission makes a reference to the action level used for radon exposure in homes and notes that: "The Action Level, at about 400 Bq m⁻³, corresponds to an annual Effective Dose of about 10 mSv, or about 1 mSv per month. This figure is the one at which simple remedial measures are suggested and which fall far short of removing people from their homes. A relocation criterion derived above 10 mSv per month would not seem unreasonable for situations where relocation is the only available countermeasure. Similarly, were the relocation criterion to be 10 times higher, at 100mSv per month or about 1 Sv y⁻¹, there would almost certainly be deterministic effects in the non-relocated population. (C9). The conclusion therefore has to be that
relocation is going to be justified for continuing doses of the order of 10 mSv per month. (C10)

Evacuation
The Commission considers that: "It has been estimated on a generic basis that evacuation is almost always justified if the projected average individual dose to the whole body is likely to exceed 0.5 Sv within a day or the averted average individual effective dose for the duration of the evacuation is 0.5 Sv or 5 Sv skin dose. It is expected that, for most foreseeable accident situations, an optimised level of averted effective dose for evacuation will be lower but not by more than a factor of 10." (ICRP 63, §67)

Distribution of stable iodine
The Commission considers that: "It has been estimated, on a generic basis, that iodine prophylaxis will almost always be justified provided that an average individual thyroid dose of 0.5 Sv can be averted. However, consideration of specific accident conditions may indicate that the generically optimised level will be lower but not by more than a factor of 10." (ICRP 63, §77)

5.5. Level of exposure to consider potential exposure scenarios for long live radioactive waste disposal

In the Publication 81 dedicated to the radiation protection recommendations as applied to the disposal of long-lived solid radioactive waste, the ICRP proposes some criteria in order to determine if a scenario of human intrusion into a waste disposal should be or not further analysed to reduce the probability and/or the consequences of this scenario (Table 9).

Table 9. Level of exposure to consider potential exposure scenarios for long live radioactive waste disposal

<table>
<thead>
<tr>
<th>Type of value</th>
<th>Effective dose</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>No necessity to consider how to reduce the probability and/or consequences of human intrusion scenarios</td>
<td>&lt; 10 mSv/year</td>
<td>81 (§64)</td>
</tr>
<tr>
<td>Necessity to consider how to reduce the probability and/or consequences of human intrusion scenarios leading to this level of dose</td>
<td>&gt;100 mSv</td>
<td>81 (§64)</td>
</tr>
</tbody>
</table>

For this purpose, the Commission considers that if a scenario of human intrusion is such that it could lead to doses to those living around the site sufficiently high to justify an intervention, then measures should be taken to reduce the probability and/or the consequences of the human intrusion (§64). In this respect, the Commission makes a reference to the levels of existing annual doses recommended by ICRP 82 for the justification of the intervention in case of prolonged exposure situation (10 mSv and 100 mSv): "The Commission considers that in circumstances where human intrusion could lead to doses to those living around the site sufficiently high that intervention on current criteria would almost always be justified, reasonable efforts should be made to reduce the probability of human intrusion or to limit its consequences. In this respect, the Commission has previously advised that an existing annual dose of around 10 mSv may be used as a generic reference level below which intervention is not likely to be justifiable. Conversely, an existing annual dose of around 100 mSv per year may be used as a generic reference level above which intervention should be considered almost always justifiable. Similar considerations apply in situations where the thresholds for deterministic effects in relevant organs are exceeded." (ICRP 81, §64)
6. CONCLUSION

This review of the rationalities used by ICRP to recommend the various reference levels shows the complexity of the determination of numerical values. The main rationalities which can be found are the following:

- The individual dose limits and the maximum individual doses (emergency situation and biomedical research context) are determined by using a set of criteria including:
  
  o A qualitative judgement on the "unacceptable" level of consequences (occupational and public dose limit, "maximum" individual doses in biomedical research context). This assessment of the consequences includes attributes associated with the mortality and estimation of the morbidity.
  
  o The necessity to avoid deterministic effects (occupational and public dose limit, dose limits for internal exposures, "maximum" individual dose in case of emergency situations).
  
  o The level of exposure from natural background (public dose limit).
  
  o A reference to the public dose limit for pregnant women in the case of occupational exposures.

- The dose constraints for public exposure are set using a fraction of the public dose limit to allow for the exposure to multiple sources.

- The exemption level for practices is based on two rationalities:
  
  o A value judgement on the level of individual or collective dose, i.e. the implicit determination of a trivial dose level. It can be noticed that the Commission recognises the difficulty related to the determination of exemption level as it considers that exemption is a source-related process, while the triviality of dose is primarily individual-related. The trivial individual dose is assumed to be based on considerations of the level of risk being of no concern to individuals (values of $10^{-6}$ to $10^{-7}$ are proposed) and to a reference to trivial variations (a few percent) of the natural background radiation.
o The estimate that the regulatory provisions will produce no significant reductions in individual or collective dose, which means implicitly that the protection is optimised.

- The exemption level for intervention in case of radioactive substances in commodities makes allowance for the level of natural background radiation.

- The "action level" to determine if an exposure at work to materials with elevated levels of natural radionuclides should be regarded as occupational seems to be based on the value of the dose limit for the public. But it is not clearly specified in the Publication of the Commission.

- The range of action levels for intervention in case of Radon-222 at home or at work for the lower bound makes allowance for the natural background of radiation. There is no clear explanation of the selection of the upper bound of the range.

- The determination of the generic reference level below which intervention is not likely to be justified for some prolonged exposure situations is based on a discussion on the natural existing annual doses for which no actions have been undertaken, and consequently which seem to be accepted by the national authorities. The generic reference level above which intervention is almost always justified for some prolonged exposure situations is set in order to avoid deterministic effects, and based on a consideration that above this level the risk of stochastic effects would be too high to be considered generally acceptable.

- ICRP recommends to perform justification and optimisation analysis in order to set specific values of effective averted dose to be used to justify different types of interventions after an accident. The proposed values are "estimated on a generic basis". In case of relocation, an example of generic optimisation is provided to confirm that the selection of the value seems coherent with an optimisation process. It is also mentioned that at a factor ten above this value, some deterministic effects may occur in the non-relocated population.
- Finally, the Commission proposes some criteria to decide if a scenario of human intrusion in a waste disposal should lead to consider or not a reduction of the probability and/or consequences of this scenario. It is proposed to use the generic level justifying or not interventions in case of prolonged exposure situations.
Table 10. Reference values found in ICRP's Publications

<table>
<thead>
<tr>
<th>Situation 1</th>
<th>Situation 2</th>
<th>Situation 3</th>
<th>Situation 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal operation of a practice</td>
<td>Prolonged exposure</td>
<td>Biomedical research</td>
<td>Single events</td>
</tr>
<tr>
<td>ICRP</td>
<td>ICRP</td>
<td>ICRP</td>
<td>ICRP</td>
</tr>
<tr>
<td><strong>more than a few 10s of mSv</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 100 mSv/y – generic reference level for intervention almost always justifiable - existing annual dose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 mSv in a single year</td>
<td>limit for workers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 mSv/y - limit for workers for intakes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 mSv/y average over 5 years - limit for workers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1 - 10 mSv</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 mSv - surface abdomen pregnant women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 2 mSv/y - &quot;action level&quot; for NORMS at work</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 mSv/y - limit for public - foetal dose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 mSv/y - exemption level for intervention for commodities – additional annual dose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>0.01 - 1 mSv</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.3 mSv/y - constraint for public - additional annual dose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1 mSv/y and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1 mSv/y -</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- **1000 mSv** - averted dose - relocation
- **500 mSv** (Thyroid) - averted dose - distribution of stable iodine
- **500 mSv** (5000 mSv skin) – "maximum" individual dose for planned emergency work
- **500 mSv** in a day or for the duration of evacuation (5000 mSv skin) - averted dose - evacuation
- **> 10 mSv/month** dose rate at which relocation is optimised
- **> 10 mSv/y** - substantial societal benefit
- **< 10 mSv/y** - generic reference level for intervention not likely to be justifiable – existing annual dose
- **3 - 10 mSv/y** - Action Level for intervention for Rn 222
- **1 - 10 mSv** - moderate social benefit
- **10 mSv/y** - averted dose - intervention for foodstuff
- **0.1 - 1 mSv** - intermediate social benefit
- **0.01 - 1 mSv** - additional annual dose
<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Description</th>
<th>Additional Annual Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.01 mSv</td>
<td>Exemption level</td>
<td>64, 82</td>
</tr>
<tr>
<td>0.01 mSv/y</td>
<td>- constraint for public for the prolonged component of the dose</td>
<td>82</td>
</tr>
<tr>
<td>&lt; 0.1 mSv</td>
<td>- minor societal benefit</td>
<td>62</td>
</tr>
</tbody>
</table>