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4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

COUNCIL DIRECTIVE

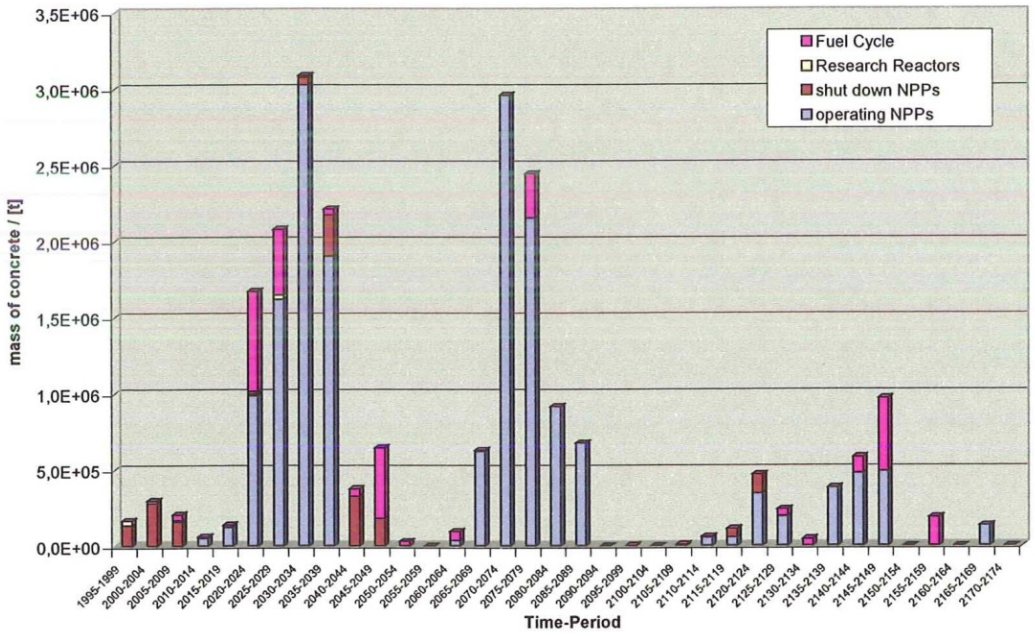
laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

{COM(2012) 242 final}
{SWD(2012) 138 final}

(B) TOTAL EXPECTED MASS OF BUILDING RUBBLE AND STEEL SCRAP

Figure I TOTAL EXPECTED MASS OF BUILDING RUBBLE PER 5a PERIOD FROM ALL PRESENTY EXISTING NUCLEAR FACILITIES IN EUROPE[1]

Figure I

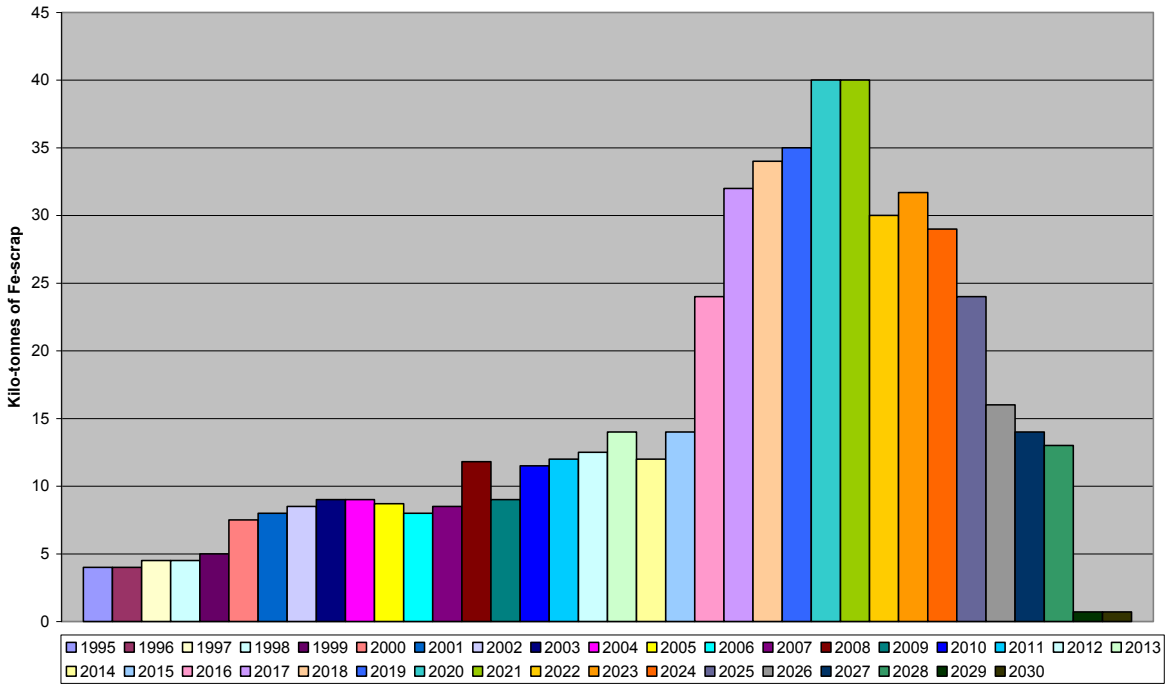


To estimate the total concrete masses arising in Europe and the time of their generation, it is necessary to make generic assumptions. Most of the rubble is produced from the dismantling of nuclear power plants to green field conditions. Because the available data about the concrete masses in power plants is limited, a linear extrapolation of the concrete masses in relation to the power output for smaller and larger units of each type of plant is assumed. The estimation of waste masses in Europe takes into account all types of facilities (nuclear power plants, research reactors and fuel cycle facilities), the number of plants in various countries, the planned operating time, the time for the post-operational period and eventually a safe enclosure and the assumption for the correlation between building masses and electric or thermal power or capacity, respectively. The results of these estimations are presented in figure I. The mass as a function of time shows two distinct peaks in the range between 2020 and 2040 as well as between 2070 and 2090. The first peak is caused by nuclear power plants that will be dismantled soon after their final shut-down, the second peak corresponds to those installations for which a safe enclosure of several decades is foreseen prior to final dismantling. It can be seen that building rubble will also arise in the time after 2100. This corresponds to installations mainly in the UK where a long term safe enclosure with an enclosure period of 130 years is envisaged.

[1] Radiation Protection Publication 113 "Recommended radiological protection criteria for the clearance of buildings and building rubble from the dismantling of nuclear installations"

It should be noted that this estimation does not include any new nuclear installations that might be built in the future, any nuclear installations in countries that might become member states of the European Union in the future, and any accelerators

Figure II PROJECTED AMOUNT OF CLEARABLE STEEL SCRAP FROM DECOMMISSIONING COMMERCIAL POWER REACTORS IN THE EU (under the assumption that no new reactors are built)[2]



[2] Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations, Radiation Protection N° 89, 1998

ANNEX XI:

Table 1: Possible solutions for each identified problem area (the numbers refer to the subsections in section 2 where the issues are explained)

Problem	**Solution 1**	**Solution 2**	**Analysis**
2.2.1 Scientific progress (ICRP 103)	Amend methodology for dose calculation in BSS and revise dose limits for the lens of the eye		As dose calculation methodology and dose limits are explicitly stipulated in the current BSS Directive, there is from a legal point of view only one solution possible.
2.2.2 Insufficient protection of workers			
- Outside workers	Revise the BSS, impose an annual occupational dose limit and incorporate Outside Workers requirements	Revise BSS and impose an annual occupational dose limit	Both solutions provide uniform level of protection for these workers. Solution 1 would facilitate the clarification of the responsibilities of undertakings and employers.
- Workers in NORM industries	Strengthen the requirements on NORM industries in BSS	Establish guidance on NORM industries	Uniform protection of workers can only be achieved with Solution 1.
2.2.3 Health protection of patients and the public due to technical progress			
- patients	Strengthen requirements on justification and optimisation in MED Directive	Strengthen implementation of current requirements through guidance	Solution 1 and solution 2 should both enhance patient protection, but in certain areas it is expected that only binding legislation is effective.
- non-medical imaging exposures	Include specific requirements in the BSS and amend MED correspondingly	Amend MED Directive and issue guidance on non-medical imaging exposures	Solution 1 allows best protection of the public from these exposures.

2.2.4 Public exposure to natural radiation sources –radon and building materials	Legislative measures: 1. Extension of the scope of BSS Directive 2. new Directive(s) on radon and on building materials	Non-legislative measures such as guidance on national action plans for radon, recommendation on building materials	Solution 1.1 provides for best protection from natural radiation and is in line with the simplification objective.
2.2.5 Protection of the environment (non-human species	Legislative measures: 1. Extension of the scope of BSS Directive 2. new Directive on protection of the environment	Non-legislative measures such as guidance on the protection of the environment	Solution 1.1 offers the best coherence with the protection of human health from environmental radioactivity.

ANNEX XII

Working document: Comparison International and Euratom Basic Safety Standards

This document was drafted to give a comprehensive though not exhaustive overview of the differences in approaches and specific requirements in the international standards (draft 3.0) and the revised and recast Euratom Basic Safety Standards (version 24.02.2010, on which the Group of Experts had given an Opinion).

By and large this document is meant to be descriptive, and does not give views on the need for changes in the international standards, except with regard to the overall approach to natural radiation sources.

The Experts have been invited to discuss this document at their meeting on 3 – 4 June 2010 and where appropriate make recommendations either to IAEA or to the Commission. The Commission will forward the recommendations to IAEA and discuss these at the meeting of the BSS-Secretariat (with IAEA and other co-sponsors) Vienna on 25 June 2010.

The Comparison of the draft Standards has been completed to the extent possible with further relevant issues, brought forward by the Experts. This update will continue in order to provide eventually a comprehensive comparison of the different sets of requirements.

1. INTRODUCTION

Throughout the development of the revised international Basic Safety Standards (BSS) and the revised and recast Euratom Basic Safety Standards there has been good cooperation in order to ensure their consistency to the largest possible extent. The Commission has played an active role in the Secretariat of sponsoring organisations of the international standards. Representatives of EU Member States have provided comments to the different Committees of IAEA, especially RASSC. Reports on progress with the international standards have been presented at each meeting of the Group of Experts by IAEA representatives. The Group of Experts has so far never formally given its own views on the international standards. In view of the eventual co-sponsorship of the standards by the Atomic Energy Community it is now the right time to do so, since draft 3.0 has been sent to IAEA Member States for comment and it is envisaged that the final draft will be approved by the Committees by the end of this year. The Experts invite IAEA to consider these comments together with the comments and corrections that have been proposed by the Commission before the deadline for consultation (31.05.2010).

2. GENERAL COMMENTS

To a very large extent the Euratom and international standards are consistent. There are no essential points that are in contradiction. Numerical values are all the same, with the provisional exception of the definition of High Activity Sealed Sources, pending further consideration of the rationale of the two sets of values.

Nevertheless, there are notable differences. These results on the one hand from the constraint to make as little and few changes to the current standards as necessary. This justification of any changes was an essential component of the DPP for the revision of Safety Series 115, and in the spirit of the "recast" of Euratom Directives this applied to the revision of Council Directive 96/29/Euratom as well. Hence many differences which had appeared already in 1996 continue to exist. In addition, while both organisations started from ICRP Publication 103, they have given a slightly different interpretation to the introduction of planned, existing and emergency exposure situations in structuring the requirements. This does not matter too much since the main message of ICRP was that throughout the exposure situations the principles of radiation protection apply very much in the same way. Nevertheless, the allocation of responsibilities and the extent of regulatory control have been addressed in different ways for some situations, especially for exposure to natural radiation sources.

This has also led the Euratom Basic Safety Standards to choose a different structure. While initially both standards were developed along a structure reflecting the three exposure situations, Euratom Standards are now structured along the categories of exposure, occupational, medical and public, within which the differences in management along the exposure situations are reflected. This inversion of the matrix has no implications on content, but makes the comparison of the two standards more difficult.

In order to preserve consistency with the current standards, and for IAEA also with the Safety Fundamentals, the requirements use a different set of definitions. The concept of "facilities and activities" in IAEA is reflected in the definition of "Undertaking" in Euratom BSS. The latter definition incorporates better the concept of legal responsibility for the conduct of activities or the introduction of a radiation source. The term "radiation source" has a very general meaning in the Euratom Standards (including "facilities") and is further differentiated between radiation generators, radioactive sources, natural radiation sources etc.). This allows a more precise formulation of the requirements where the term "source" may be cause of confusion. **IAEA is invited to consider introduction of these definitions and explore whether their use would improve clarity of the text**.

The terminology of the Euratom Standards has been adjusted to the international standards on one important point. The requirements for regulatory control are now structured along the concepts of notification, registration and licensing (as opposed to reporting and prior authorisation in Directive 96/29). The graded approach to regulatory control has been worked out in more detail in the Euratom Standards however, and the differentiation between registration and licensing is more explicit. It should be noted that in principle all requirements in the Euratom BSS apply to Member States or to their competent authorities. It is for national law to transpose the requirements and for the authorities to impose them and ensure their enforcement. The international standards differentiate much more between requirements applying to different responsible parties, e. g. designers, employers, registrants and licensees, often with much more detail than in the Euratom Standards.

These different contexts and approaches have led to many small differences in formulation. The most notable differences with regard to requirements for occupational, public and medical exposure as well as on the protection of the environment are listed in a comprehensive albeit not exhaustive way in the next chapter. The more fundamental differences with regard to the approaches to natural radiation sources are discussed

separately. Finally, there are important differences in the application of the concepts of exemption and clearance, especially for naturally occurring radionuclides. With regard to artificial radionuclides, while both standards have now introduced the values in IAEA RS-G-1.7, the Euratom Standards give less prominence to the continued use of the old exemption values for "moderate amounts of material", and address more explicitly the role of specific clearance levels for specific materials and pathways of disposal. The Euratom approach allows a better optimisation of the management of materials arising e.g. from dismantling of nuclear facilities. **The Group of Experts hopes that these differences will be resolved through a careful redrafting of the international standards**. The Group of Experts also endorses the comments repeatedly made by the Commission, and now re-introduced with regard to draft 3.0, along the lines of this document.

The System of Protection as laid down respectively in Requirement 1 and Schedule III of the international BSS and Title III of the Euratom BSS are broadly the same, with some differences as a result of the different consideration given to planned and existing exposure situations. It should be noted however that in the Euratom BSS it is in general no longer foreseen that doses be integrated over periods longer than 1 year. The dose limits for the lens-of-the-eye are left open, pending ICRP advice, and dose constraints may apply also to organ doses, as a matter of precaution.

3. COMPARISON OF THE DRAFT STANDARDS

3.1. GENERAL

This chapter compares specific requirements in the international standards (Draft 3.0) with those in the Euratom Basic Safety Standards (draft 24.02.2010) with regard to occupational, public and medical exposures as well as with regard to the protection of the environment.

Draft 3.0, in contrast to the Euratom BSS, contains more detailed requirements, which are often addressed directly to the "responsible parties" (government, regulatory body, licensees and registrants, etc. – defined in Para. 2.40 and 2.41). This approach risks unnecessarily restricting implementation of radiation protection to what is "prescribed" while:

- the level of detail does not seem to correspond to the importance of the issue,
- the requirements and described responsibilities, however detailed, are not exhaustive, and
- the proposed rigid distribution of responsibilities does not allow for national differences and sometimes restricts too much the responsibility of a given party.

3.2. OCCUPATIONAL EXPOSURE

3.2.1. DIFFERENCES

IAEA PARAGRAPHS

3.77: workers exposed to radiation from sources not required by or directly related to their work shall receive "the same level of protection" as if they were members of the public.

Euratom: no such requirements, but for the operational protection of workers specific requirements only apply to those who are "exposed workers": … who are liable to receive doses exceeding one or other of the dose levels equal to the dose limits for members of the public.

There was a similar requirement in Directive 96/29; the new Directive has been drafted so as to ensure the same level of protection without re-introducing it; the term "the same level of protection" is indeed ambiguous in legal terms, in particular for existing and emergency exposure situations where in some situations (e.g. radon in workplace) it may be understood to mean that the dose limit for public exposure would apply. **IAEA is invited to consider whether paragraph 3.77 offers any additional protection and otherwise delete it.**

3.115: no person under the age of 18 years is allowed to work in a controlled area unless under supervision and then only for the purpose of training for employment involving exposure to radiation or for students required to use sources in the course of their studies.

Euratom: In the Euratom BSS this is covered by Article 9: persons under 18 years may not be assigned to any work which would result in their being exposed workers, and Article 12.2: the limit for effective dose for apprentices (and students) aged between 16 and 18 years … shall be 6 mSv per year (as for category B workers).

In both cases the exposure of apprentices and students is restricted, either by their access to controlled areas or by the dose.

Schedule III: An effective dose of 20 mSv per year, averaged over five consecutive years.

Euratom: The dose limit for occupational exposure is now simply 20 mSv per year, without averaging. However, a higher effective dose may be authorised in a single year, subject to a maximum effective dose of 50 mSv, …

EURATOM ARTICLES:

Art. 6.2: categorisation of exposed workers (A or B) with an impact on individual monitoring (Art. 64) and medical surveillance (Art. 69 – 72)

IAEA: the international standards do not introduce different categories of workers but in 3.99 individual monitoring shall be undertaken, where appropriate, adequate and feasible, for any worker who is normally employed in a controlled area or who … may receive significant occupational exposure. No distinction is made between

the health surveillance of different categories of workers or different conditions of work.

Title II: Definitions of Radiation Protection Expert and Radiation Protection Officer

These definitions distinguish between the responsibilities of *experts* (give radiation protection advice) and of *officers* (designated by the undertaking to oversee the implementation of the radiation protection arrangements). The capacity to act as an RPE is recognized by the competent authorities. The RPO shall simply be "technically competent". The arrangements for the recognition of the experts (as well as for the medical physics expert) are laid down in Article 16. The responsibilities of the RPE are spelled out in detail in Article 19.

IAEA: Qualified expert. In the international standards this definition relates to the professional qualifications of an individual. In 2.21 (b) there is formal recognition of these experts by the relevant authority for taking up certain responsibilities (footnote 7)

The involvement of qualified experts is mentioned in several paragraphs throughout the text of the international standards.

3.2.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

WORKERS

3.79: recording of any report received from a worker (see 3.82)
Req. 22: Compliance by workers (3.81, 3.82)
3.86 (a): involve workers in optimization of protection and safety

Euratom: it is not appropriate for a Directive to put requirements on workers.

OPERATIONAL GUIDANCE

3.89: delineation of controlled areas
3.91: delineation of supervised areas
3.92 – 3.94: local rules and personal protective equipment

Euratom: it is not appropriate for a Directive to go into so much practical detail.

CONDITIONS OF SERVICE

Req. 27: no substitute for protection and safety
3.113: conditions of service for pregnant or breastfeeding workers

Euratom: these are basic principles of overall occupational health policy which do not need to be recalled specifically for work with ionizing radiation.

3.2.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

NATIONAL DOSE REGISTER

Article 67.1 (d) requires the results of individual monitoring to be submitted to a centralised network. In 67.2 provisions are made for a future European Radiation Passport for outside workers.

In the international standards there are requirements for the establishment of exposure records and for their transmission to workers and other employers registry (Para. 3.102 – 105), but no central. There is no reference to a radiation passport.

NATURAL RADIATION SOURCES

The approach to natural radiation sources in the Euratom standards is quite different from the international standards (see chapter 4 in this document). With regard to occupational exposure the most striking features of the Euratom standards are the following:

> Article 59.2 (second sentence): Where the effective dose to workers is less than or equal to 6 mSv per year the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process on work instructions.
>
> This requirement is an important element of a graded approach to regulatory control, which is missing in the international standards. **IAEA is invited to consider a similar graded approach for the Regulatory Control of occupational exposure, especially for workers in NORM industries.**
>
> Article 59.3 specifies the assessment and management of the exposure of aircrew to cosmic radiation. In addition, since in the Euratom standards the exposure to aircrew occurs within a planned exposure situation, the requirements for the protection of pregnant aircrew and the child to be born (Article 11.1) are fully applicable.
>
> In the international standards exposure of aircrew is regarded as an existing exposure situation, and the detail of its management is left for Member States to consider. **IAEA is invited to apply similar binding requirements for the protection of aircrew and for the registration of their exposure as in the Euratom Directive; indeed, the operation of airlines calls for international harmonisation.**

3.3. PUBLIC EXPOSURE

3.3.1. DIFFERENCES

IAEA addresses public exposure to consumer products more prominently than in the Euratom standards. See:

3.117: suppliers of consumer products
3.124: responsibilities of suppliers of consumer products
Req. 33: consumer products
3.137: consumer products shall not be made available to members of the public unless exempted or authorised for use by members of the public
3.138: responsibility of the regulatory body
3.139: compliance with the conditions of authorisation (including optimisation of design)
3.140 - 142: labelling and information

Euratom: 1) does not require labelling and information (but this could be part of conditions of use);
2) does not put requirements on the suppliers and designers of the products.

On the other hand the Euratom BSS (Art. 53.2 (b)) require licensing of the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods. The design features and conditions of use will be specified as part of the licence. The introduction of new types of apparatus or products is subject to justification, their use as a consumer product shall explicitly be permitted and a type-approval granted.

Hence the Euratom Standards achieve the same objective but put all responsibility on the licensing authority: the designer or supplier is not responsible for further uses. There is neither an explicit requirement for information of the user or distributor, nor for labelling: it is generally understood that such labelling is contrary to the concept of exempted consumer good, but it can nevertheless be requested by the licensing authority at the time of manufacture or import. Once the consumer good is placed on the market in the EU, no further trade restrictions should apply. However, since national authorities may conclude differently on the justification or type approval, the use of a consumer good may be prohibited or subject to notification; in order to avoid inconsistencies, competent authorities are required to allow for the information provided by other national authorities.

Schedule III (3b): averaging over five years (maximum 5 mSv) has been deleted in the Euratom Directive.

3.3.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

3.123: Impact outside the country

Euratom Treaty provisions under Article 37 allow the Commission to assess such impact; however, in the Joint Convention there is a similar requirement which may be taken up in legislation on waste management.

3.127: Visitors

A Euratom Directive does not require such detail; in addition the phrase "in cooperation with employers" makes this difficult to understand.

3.128: External exposure (details)
3.129: Avoid spread of contamination (implicit in Euratom)
3.130: Details of radioactive waste management (might appear in a specific legislation)
3.135: Access to monitoring data is foreseen in Articles 35 – 36 of the Euratom Treaty.

3.4. MEDICAL EXPOSURE

3.4.1. DIFFERENCES

Roles and responsibilities are distributed differently in the IAEA and the Euratom drafts:

- In draft 3.0 the *government* (Req. 34, Para.3.145-3.147) *and the regulatory body* (Req. 35, Para.3.148, 3.154, 3.163, 3.166, 3.167, etc.) have specific but quite limited responsibilities with respect to medical exposure while in the Euratom BSS the majority of the requirements are addressed to Member States (i.e. government).
- In draft 3.0 a great deal of responsibility is placed on "*registrants and licensees*" (Req. 36, Para.3.149-3.152, 3.160, 3.164, etc.), who shall ensure that "no person receives medical exposure" unless a series of conditions are fulfilled. In the Euratom BSS the requirements directly addressed to "undertakings" are limited to issues like QA and provision of information to patients and there are almost no prohibitive requirements (with the exception of examinations which "can not be justified").

Definitions:

medical exposure: Draft 3.0 mentions asymptomatic individuals in paragraph 3.149: ("whether asymptomatic or not …"). In the Euratom BSS these are grouped with, but are different from, patients. Draft 3.0 also does not refer to the intended benefit to the health or the wellbeing of the exposed person, as in the Euratom BSS. **IAEA is invited to give explicit consideration to asymptomatic individuals and to exposures benefiting to the well-being of the exposed person, in particular to sharpen the definition of non-medical imaging exposures.**

In the Euratom Directive (Article 5 (b)) medical exposures shall be "as low as reasonably achievable, commensurate with the medical purpose". "ALARA" is here to be distinguished from other contexts where economic and social considerations need to be taken into account. **The Experts believe that the mere reference to "commensurate with ..." is not sufficient.**

optimization *of protection and safety* for medical exposure: Draft 3.0 states that it is "management of the radiation dose to the patient commensurate with the medical purpose" without any reference to ALARA as is the case in the Euratom BSS.

radiological medical practitioner*:* Draft 3.0 defines the responsibilities of the *radiological medical practitioner* more rigidly, especially for justification of

medical exposure for individual patients (Para. 3.155). This is done in a more indirect and flexible way in the Euratom BSS by Art. 82.2 requiring that the exposure is undertaken under the clinical responsibility (including justification) of a radiological practitioner but allowing Member States to define the level of involvement of the practitioner and the referrer in justification process (Art. 82.1).

medical physicist: The role of the *medical physicist* is more specifically and with more detail defined in Draft 3.0 (Para. 3.152, 3.165, 3.166, 3.168, 3.169, etc.). The IAEA definition of medical physicist (MP) differs from the Euratom definition of medical physics expert (MPE) mainly in that the MP is defined by IAEA as "health professional" (i.e. recognized to practice a profession related to health).

medical radiation technologist*:* Draft 3.0 defines "*medical radiation technologist*", who is included in the list of "other parties who have responsibilities for protection and safety" (Para. 2.41) and is assigned to a number of tasks and responsibilities – Para. 3.161-3.163, 3.168, 3.173, etc. The Euratom BSS have no such definition.

There are the following differences with regard to ***justification***:

- Para. 3.149 (a) effectively prohibits *self-presentation*, which is not explicitly done in Euratom BSS. The same article requires information on the clinical context to be provided.
- Para. 3.149 (b) puts responsibility for justification on the radiological practitioner, in consultation with the referring medical practitioner. The Euratom BSS do not put so much emphasis on the role of the radiological practitioner.
- Para. 3.153 – only *alternative techniques* that do not involve medical exposure shall be taken into account, against the Euratom BSS requirement of taking into account also techniques involving less exposure (Art. 80.1).
- Para. 3.154 – *generic justification* shall be carried out by the health authority in conjunction with the appropriate professional bodies – missing in Euratom BSS.
- Para. 3.155 – there is a requirement that the practitioner shall take into account the *appropriateness* (missing in Euratom BSS) and the *urgency* of the request (required only for pregnant and breastfeeding women in the Euratom BSS – Art. 87.1).
- Para. 3.159 – exposure of *volunteers for biomedical* research is not justified if it doesn't comply with the Helsinki Declaration and the respective guidelines by the CIOMS and the recommendations of ICRP. No such references in Euratom BSS.

In Article 81 on Justification in the Euratom Directive, the requirements are to a large extent written in the passive "shall" style.

Para. 3.146 of draft 3.0 stipulates the government shall ensure that ***diagnostic reference levels*** *(DRLs*) are established against the weaker Euratom BSS requirements that Member States "promote the establishment" of DRLs.

3.4.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

Para. 3.152 (c) requiring that registrants and licensees shall ensure that ***sufficient medical and paramedical personnel*** are available as specified by the health authority does not have correspondence in Euratom BSS.

Para. 3.147 specifies that ***dose constraints*** are established as a result of consultation between the health authority, relevant professional bodies and regulatory body, which is not specified in Euratom BSS. Dose constraints are required only for research *volunteers* undergoing diagnostic investigations (in Euratom BSS this applies to all medical exposures but restricted to cases where there is no direct health benefit to the exposed person).

Para. 3.160 contains ***design considerations*** for the medical radiological equipment and software, which shall comply with the IEC and the ISO standards or to national standards "adopted by the regulatory body". This is out of the scope of the Euratom BSS, since design and pre-marketing phases of medical equipment are regulated under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[3].

Para. 3.165 – requirements for ***calibration***, missing in the Euratom BSS.

Para. 3.166 – detailed requirements for ***clinical dosimetry*** in relation to a "typical patient".

Para. 3.168-170 contains detailed (but not exhaustive and not specific to the type of the procedure) requirements on ***quality assurance***, which are absent from the Euratom BSS:

- Reference to "principles established by the WHO, PAHO and relevant professional bodies".
- QA shall include verification of physical and clinical factors used in patient diagnosis or treatment, records of procedures and results, periodic checks of dosimetry and monitoring equipment, QA audits.

Quite a few paragraphs require ***records and documentation*** for instance on personnel with radiation protection responsibilities (3.148 (c)), on advice by a medical physicist (3.152 (e)), on delegations of responsibility (3.152 (f) and 3.181 (a)), on training records (3.181 (b)), on calibrations and periodic checks of relevant clinical parameters (3.182), on data allowing dose assessment (3.183).

Para. 3.177-179 on ***unintended and accidental medical exposures***:

- 3.177 defines the main causes of unintended and accidental exposures (design flaws and operational failures of equipment and software and human errors) and puts the responsibility for reducing the likelihood of these exposures with the registrants and licensees. This can be too restrictive since design and software flaws are hard to predict and deal with by the licensees alone.
- 3.178 defines a (exhaustive) list of types of unintended and accidental exposures which should be investigated.

[3] The Directive's main purpose is to ensure that medical devices placed on the European market do not compromise the safety and health of patients, users and other individuals. The medical devices must meet the essential requirements for their design and construction, including those for justification of the intended use of the equipment on the basis of risk/benefit weighting and for incorporation of technical features for radiation protection of patients, users and other individuals. This is ensured, inter alia, through a system of harmonized standards issued by the European standardization organizations (CENELEC in this case), pre-market conformity assessment procedures and appropriate supervision by the competent authorities.

3.4.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

unintended and accidental medical exposures: the requirement in Euratom BSS Art. 88 (b) that the QA programme for radiotherapeutic practices shall include a study of risk of accidental or unintended exposures is missing in draft 3.0 (see Para. 3.177-179 above).

While the international standards highlight quality assurance and introduce the concept of "radiological reviews" (Para. 3.180), this does not match the more powerful Euratom concept of "***clinical audit***" (Article 83.4).

Draft 3.0 does not contain a requirement for ***estimating population doses*** from medical exposure procedures, as in Euratom BSS (Art. 89).

3.5. PROTECTION OF THE ENVIRONMENT

Both standards address the protection of the environment but in different ways. In principle, the protection of the environment has a prominent place in draft 3.0. It is part of the objectives of the international standards and is specifically addressed in one of the Fundamental Safety Principles referred to in the first chapter of draft 3.0 (Para.1.7 and 1.26). Whenever draft 3.0 speaks about radiation risks, the risks to ecosystems are included in this term (footnote 6 and Glossary), for instance when setting up legal frameworks and regulatory control (Para.2.13 and 2.14), and making arrangements for the protection of the environment (Para.2.25). However, further on in the draft 3.0 there are only general requirements with regard to the protection of the environment for discharge authorisation (Para.3.122 and 3.131), emergency (Para.3.42, 4.2 and 4.5) and monitoring programmes (Para.2.23), and it is difficult to detect if these requirements are issued to protect the environment itself or it they are set to protect the environment as being a resource to humans (food production, recreation, industrial use). In the first case both Standards have the same set of requirements but the Euratom BSS is more to the point consolidating all requirements for the protection of non-human species in one Title. In the second case the Euratom approach is indeed more elaborate as it includes a separate Title with clear and well-balanced requirements for the radiation protection of non-human species while leaving sufficient flexibility for Member States to adopt these requirements to national situations.

4. DIFFERENT APPROACHES WITH REGARD TO NATURAL RADIATION SOURCES

Both set of standards have a comprehensive approach towards natural radiation sources. The Euratom BSS are more explicit when it comes to actual requirements, mainly for building materials where the international standards basically have only one specific requirement, but also for NORM industries, aircrew and radon. The main difference exists however on a philosophical level – whether to classify the different exposure situations as planned or existing according to ICRP terminology.

4.1. NORM

Although the Euratom BSS are clearer about which specific requirements concern NORM, these industries are essentially regulated in the same way in both standards and the same exemption, clearance or threshold values apply, for the benefit of international harmonisation. The Euratom BSS have explicitly incorporated NORM industries in the framework for practices in a planned exposure situation (Title VI), while the international standards regard them as existing exposure situations while applying the requirements in Section 3, Planned Exposure Situations (Para.3.4). Another difference is that the Euratom BSS use the assessment of doses to workers as a tool for identifying the appropriate level of regulatory control and measures to be taken for the protection of workers (above 6 mSv/y then licensing and full range of requirements in Title VII, between 1-6 mSv/y then registration or licensing and merely requiring undertakings to regularly review exposures) (Art.53), whereas draft 3.0 leaves it to the Member State to decide on which requirements in Section 3 Occupational Exposure (Para.3.68-3.115) should apply. The Euratom BSS also consider doses to members of the public when requiring authorisation for NORM industries (public exposure ≥0.3 mSv/y) (Art.53.3.(f)), while draft 3.0 gives no indication of such a criterion. The Euratom Directive is much more clear about which industries may be of concern by introducing a list of industrial sectors (Annex 8).

4.2. RADON

For radon in dwellings or buildings with public access the approaches are the same in both standards and they both use 300 Bq/m3 as the upper boundary on the reference level for existing buildings. Terminology differs slightly where the Euratom BSS talk about buildings with public access (Art.100) when draft 3.0 uses the term "other buildings with a high occupancy factor of the public" (Para.5.19). Draft 3.0 includes kindergartens, schools and hospitals in that term (footnote 35). The Euratom BSS are more specific about the content of a national action plan for radon (Annex 13) and specify also which types of exposure to radon this plan should include - radon exposures in dwellings, buildings with public access and in workplaces, from all sources of radon: soil, building materials or water (Art.38.1). The IAEA approach is to demand an action plan, if appropriate, for public exposure to indoor radon (Requirement 50). Concerning reference levels there are two further differences: Draft 3.0 does not include a requirement for setting reference levels for new buildings and it does not contain any requirements for setting reference levels for the "other buildings with high occupancy factors of the public".

With regard to radon in workplaces; the basic requirements are the same as well as the upper boundary for the reference level (1000 Bq/m^3). In reality there are no major differences between the standards on this point.

4.3. COSMIC RADIATION

While exposure to aircrew is addressed in both standards, the Euratom BSS offer detailed requirements such as clarifying what kind of measures to take with regard to occupational doses depending on the dose to the aircrew (Art.59.3). Draft 3.0 includes a more general requirement on the possible assessment of doses to aircrew and subsequent requirements for occupational exposure (Para.5.30). With regard to space crew the Euratom BSS treat this as a specially authorised exposure where specific requirements apply (Art.77.3) whereas draft 3.0 requires that a framework for radiation protection applicable to humans in space-based activities is established, when appropriate (Para.5.31). Another difference is that the Euratom Directive regards both types of

exposure as planned exposure situations while draft 3.0 regards them as existing exposure situations.

4.4. BUILDING MATERIALS

With regard to exposure to building materials both standards address this as an existing exposure situation. The Euratom BSS are however much more specific in terms of requirements. While draft 3.0 merely requires that reference levels are set (Para.5.22) that would generally not exceed around 1 mSv/y, the Euratom BSS allocate a whole section of the Directive to new requirements for building materials (Art.101), based on earlier guidelines (RP 112). The aim is to address exposure from building materials in a clear and comprehensive way and enable harmonisation between Member States and smoother trans-boundary movement of these types of material. Another difference is that the Euratom Directive defines the term building materials, deliberately not using the wider term construction material, while the draft 3.0 mentions construction materials without defining the term.

4.5. EXEMPTION AND CLEARANCE

With the introduction of the IAEA RS-G-1.7 values as exemption and clearance levels in the Euratom BSS, the two standards have the same set of values for exemption and clearance. For natural radiation sources the draft 3.0 Schedule I (Para.I-4) gives Member States a large degree of flexibility by stating that exemption should be made on a case by case basis and refers to levels commensurate with natural background levels. On the other hand paragraph 3.4(a) indicates that 1 and 10 Bq/g should be used to detect when an activity should be regulated as a planned exposure situation. This is confusing. For clearance however, draft 3.0 gives the levels 1 and 10 Bq/g. The Euratom BSS also use those values with the difference that they should be used as both exemption and clearance for natural radiation sources. The Euratom approach is more coherent, in particular as it not only sets general criteria for artificial radionuclides but introduces exemption and clearance criteria for natural radionuclides as well (in the order of 0.3 mSv/y or less for members of the public and 1 mSv/y for workers). Furthermore, the Euratom BSS include a comprehensive and cautious use of the clearance criterion for NORM residues, in particular for recycling in building materials and in case of ground water contamination. IAEA is further invited to include relevant isotopes of Uranium and Thorium, Table I-2, for application to clearance of materials arising from the dismantling of nuclear installations such as uranium enrichment or fuel fabrication plants (on the basis of the 10 mSv exemption criterion).

Recommendation: It should be made clear in the international standards what values to use as exemption levels for natural radionuclides. It would also be beneficial to introduce a dose criterion for clearance of natural radionuclides, indicating that if drinking water supplies might be affected this would call for special attention. Basically the whole Schedule I would need to be rewritten. At least the paragraphs in draft 3.0 Schedule I that cause confusion should be deleted, pending on more thorough revision:

- Schedule I Para.I-4
  This paragraph is still very confusing. The restriction to "other than incorporated into consumer products…" is redundant with footnote 42. The intention is probably to provide for exemption of bulk amounts. There is no need for such exemption since the scope of "planned exposure situations" is already defined in

Para.3.4. A case by case assessment in relation to doses to individuals (workers?) of about 1 mSv per year would only apply for the application for instance of requirements for occupational exposure (after assessment of doses when the concentration exceeds the levels defined in Para.3.4, so on a retrospective basis, not for prospective exemption).

- Schedule I Para.I-5 (b)
  It is redundant to include the levels defined in Para.3.4 as clearance levels, since this is the entry point for a planned exposure. In addition, despite footnote 45 this may still easily be misunderstood as applying to building materials or to situations where the residues of NORM industries would contaminate groundwater. There is no clearance criterion (in dose) for natural radionuclides. The criterion in Para.I-4 is more useful in the context of clearance (case-by-case assessment on the basis of a dose criterion which should not exceed 1 mSv per year). However this would require a full restructuring of the requirements or of Schedule I.

5. FURTHER ISSUES IDENTIFIED BY THE ARTICLE 31 EXPERTS

5.1. NON-MEDICAL HUMAN IMAGING EXPOSURE

5.1.1. DIFFERENCES

IAEA PARAGRAPHS

3.61. The government shall ensure that the measures described in para. 3.16 for the justification of practices are applied to any imaging procedure that exposes humans to radiation not intended for diagnostic or therapeutic purposes. The justification process shall consider, inter alia,
(a) Appropriateness of the radiation equipment for the proposed use.
(b) The use of alternative techniques that do not utilize ionizing radiation[4].
(c) The benefits and detriments of implementing the procedure
(d) The benefits and detriments of not implementing the procedure.
(e) Evaluation of various radiation technologies available, including the effectiveness and limitations of the procedures.
(f) Availability of sufficient resources to safely conduct the imaging procedure during the intended period of use.
(g) The impact of any legal or ethical issues which may be raised by the use of the technology

Euratom: Items (a) and (c) to (g) are not considered.
Item (b), referring to alternative techniques, differs from EURATOM item (f) of Annex 16 in as far as IAEA requires the use of alternative techniques that do not utilize ionizing radiation to be considered as part of the justification whereas EURATOM

[4] Such techniques may include manual examination, electrical and magnetic source imaging, ultrasound and sonar, magnetic resonance imaging, microwave imaging, terahertz imaging, infrared imaging and visible imaging

requires that alternative techniques which do not involve exposure to ionising radiation are available where the exposure is routinely carried out for security purposes. This item (b) is believed to be redundant (it applies to justification also in other contexts). The Euratom requirement is in addition to justification.

5.1.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

IAEA PARAGRAPHS

3.18. Human imaging using radiation performed for occupational, legal or health insurance purposes, and undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the justification of such imaging is to be considered, the requirements of paras 3.60 to 3.64 shall apply.

Euratom: no such statement.
However, the list of practices in Annex 16 and the list of the exceptional circumstances mentioned by IAEA (note 19 of para 3.64) are the same.

3.19. Human imaging using radiation for theft detection purposes shall be deemed to be not justified.

Euratom: no such statement

3.66. Registrants and licensees shall ensure that all persons that are about to be exposed to radiation for inspection procedures, are informed about the possibility of choosing an alternative technique that does not use ionizing radiation, where vailable.

Euratom: guarantee that people are informed is not required

5.1.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

Art. 49.3: Practices involving the deliberate exposure of humans for non-medical purposes

(e) Informed consent of the individual to be exposed is sought, allowing for cases when the law enforcement bodies may proceed without consent according to national legislation.

IAEA: informed consent is not sought

(d) Relevant requirements of Title VIII, including those for equipment, optimisation, responsibilities and special protection during pregnancy, are

met for procedures implemented by medical staff using medical radiological equipment.

IAEA: special protection during pregnancy is not mentioned

5.2. GENERAL REQUIREMENTS

5.2.1. SCHEDULE III: TABLE III-I. CONVERSION COEFFICIENTS FOR RADON AND THORON PROGENY

Comment: These coefficients are really obsolete: those for radon are taken from ICRP 65 (1993) and were criticised in the 2009 ICRP Radon statement (2009), those for thoron are taken from ICRP 50 (1987) and they were repeatedly declared scientifically incorrect in international literature. ICRP has announced the publication of new dose coefficients.

Euratom: no mention to dose conversion coefficients for radon and thoron. Reference in general is made in article 14 (b)

> "For internal exposure from a radionuclide or from a mixture of radionuclides…ingestion and inhalation dose coefficients in the international basic safety standards published by IAEA shall be used to estimate the effective doses".

In this way Euratom will also adopt these dose conversion coefficients

IAEA is invited to delete Table III–I pending receipt of new dose coefficients from ICRP

SCHEDULE III: DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

For occupational exposure of workers over the age of 18 years, the dose limits are:

…

(b) An equivalent dose to the lens of the eye of 150 mSv in a year;

Euratom: The Experts asked to the Commission to establish a lower value, even if ICRP would not do it, in view of abundant scientific evidence of a higher risk than estimated in the past.

5.2.2. SCHEDULE IV: CRITERIA FOR USE IN EMERGENCY PREPAREDNESS AND RESPONSE

TABLE IV-1: GENERIC CRITERIA FOR ACUTE DOSES AT WHICH PROTECTIVE AND OTHER ACTIONS ARE EXPECTED TO BE UNDERTAKEN UNDER ANY CIRCUMSTANCES TO AVOID OR MINIMIZE SEVERE DETERMINISTIC HEALTH EFFECTS

Euratom: no generic criteria to prevent severe deterministic effects is made

5.2.3. SCOPE

Art.3: Exclusion ("This Directive shall not apply to …") of radionuclides not usually contained in the human body…

IAEA: Para. 1.31: These Standards shall apply to all situations that are amendable to control (footnote 3 gives some examples of the opposite).

5.3. OTHER EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

Metal scrap and orphan sources:

Art. 28.2: Member States shall make arrangements for the establishment of systems aimed at detecting orphan sources in places such as **large metal scrap yards and major metal scrap recycling installations** ...

and

Art. 29: Metal contamination

IAEA: possible melting of a source in metal foundry is not mentioned.

Miscellaneous:

Art. 97 and 98, annex 12A and B: information of the public

IAEA: information of the public is not mentioned

Art. 48: Prohibition of the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and the import or export of such goods.

IAEA: such practices are not prohibited but only "deemed to be unjustified".

Art. 82.3: The practitioner shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent.

IAEA only information of the patient is required, informed consent is not required.

Natural radiation sources (see also section 4):

Art. 50: Member States shall ensure the identification of NORM industries which cannot be disregarded from the radiation protection point of view, taking the list of industrial sectors in Annex 8 into account

IAEA: No establishment of a list of NORM industries is required

Reading and comparing par. 3.4 and 5.1 (b) it is not clear how agricultural fertilizers and soil amendments should be considered.

A contradiction seems to be present between para 5.22 and 5.23. Drinking water cannot have a reference level of 1 mSv/y, because WHO recommended a reference level of 0.1 mSv/y, moreover a reference level of 1 mSv/y from each of the cited sources is not acceptable.

It is also not clear how building materials should be managed.

ANNEX XIII

CONSULTATION WITH FOREATOM[5]

The last draft version of the Euratom Basic Safety Standards Directive (Council Directive 96/29) was released on 24 February 2010. This draft has taken into account the ICRP recommendations in Publication 103 by structuring the requirements along the concepts of planned, existing and emergency exposure situations.

ENISS (The European Nuclear Installations Safety Standards) has in accordance with its working procedures set up special expert groups on radiation protection and on exemption and clearance in relation to decommissioning, with the mission to follow the revision of the Euratom BSS. As the revision process has advanced in parallel to the revision of the IAEA BSS the same expert groups have worked on the IAEA draft. ENISS welcome the fact that the fundamental requirements in the two documents are very close, while the draft Euratom BSS is much more concise, easier to read and thus should prove easier to be transposed into national regulations. You will find enclosed the industry detailed comments on the draft BSS.

The members of the ENISS Radiation Protection Expert Group have welcomed the opportunities that have been given during the revision process of the Euratom BSS to meet and discuss with you items of special concern. We would therefore very much appreciate a new opportunity to meet you again to discuss in detail the new draft of the BSS.

At present, the Council Directive 96/29 is the basis of all regulations regarding radiation protection in EU Member States and it has been proven effective and sufficient since it came into force. From our experience we thus do not see the necessity of significant changes. This view largely goes in line with ICRP 103, proclaiming in essence "continuity and stability". Therefore some proposed changes in the draft BSS raise our concern and we are not convinced that the envisaged changes in the radiation protection system will enhance worker or public safety and health or offer a better protection of environment.

Optimisation and the use of dose constraints

Optimisation is one of the major guiding principles according to the ICRP system of radiation protection. The radiation protection expert group of ENISS would therefore like to emphasise its importance for radiation protection in general and in particular for the continuing trends of decreasing radiation doses in nearly all industries using ionizing radiation. The concept of dose constraints already introduced by the ICRP long time ago can be viewed as one of the tools that could be used in the optimisation process.

According to the ALARA principle, licensees have for decades optimised radiation protection, starting at the design of the new facility up to the day to day optimisation of protection, including the wide use of experience feedback. Thus it seems appropriate to consider the setting of dose constraints for occupational exposures as a tool used by licensee and employer, under their responsibility, in the optimization process. In this

[5] FORATOM ENISS comments dated 19 November 2010

context, the licensee may use the term constraint for designing the maximum target dose for an operator doing a particular task or the target collective dose for a team doing a particular maintenance task. It could also mean the target dose for workers and subcontractors during a year, based on the planned activities. The definition of the dose constraint is therefore not essential for setting an efficient radiation protection management system resulting in decreasing dose trends. Consequently having too strict definitions or a dependency of some regulatory supervision might act contradictory and lead to a change of a system that has worked very well. Accordingly, ENISS proposes that the general frame of optimisation should be addressed more clearly in the BSS, along with the establishment of dose constraints.

Radiation protection officers and experts

In the current draft, the role of the "qualified expert" in the Council Directive 96/29/Euratom has been split between two functions: the radiation protection expert and the radiation protection officer. ENISS does not see any reason behind such a change. In addition, almost all the responsibilities are given to the radiation protection expert. A better balance must be achieved between the tasks requiring an expertise and the practical implementation of protection carried out by the radiation protection officer.

In addition the current version of the BSS gives most of the responsibility for the occupational exposure to the undertaking. This is a shift from current practice in many Member States where the responsibility for the protection of workers lies mainly with the employer. We suggest, whenever possible, to leave the flexibility and let national regulations assign the responsibilities between undertaking and the employer.

Exemption and clearance

The ENISS special expert group on exemption and clearance has through a questionnaire collected data of current practices of clearance in the different EU Member States using nuclear energy and Switzerland. The responses showed that the strategies in the respective countries were to large extent based on the current recommendations of the European Commission. In the Draft EURATOM Basic Safety Standards Directive the clearance levels endorsed for the sake of international harmonization are coming from the IAEA recommendations (RS-G-1.7) and not from the respective EU guidance documents that have been issued on general clearance levels for any type of material [RP 122 part 1]. The EC guidance on clearance levels – the general clearance levels (see above) as well as clearance levels for metals [RP 89], for buildings and building rubble [RP 113] – has received a lot of positive attention internationally and it is commonly assumed that they are scientifically even better founded than the IAEA guidance levels. Concomitantly, several European Member States, with large decommissioning projects ahead, have recently issued new regulations on clearance based on the current EC guidance. The EU members of ENISS therefore proposes that the BSS Directive should contain the general clearance levels from EU recommendation RP 122/1 instead of IAEA exemption levels from RS-G-1.7 and directly incorporate the levels from EU recommendations RP 89 and 113, in order to harmonise the clearance levels in the EU Member States (see appendix to the ENISS comments on the draft BSS).

Protection of the environment

In the draft Euratom BSS requirements for the protection of the environment have been laid down. However, neither the underlying principles for the suggested actions nor any definitions on the environment are stated. In addition, there are large numbers of open scientific and technical questions still to be solved in this field which makes the suggested detailed requirements doubtful. ENISS would be opposed to enlarge the regulatory and surveillance efforts and waste human and monetary resources without being sure of improving radiation protection of the environment.

ANNEX XIV

Comparison of options 2 to 6

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Economic					
Functioning of the internal market	(+) competitiveness of NORM industries due to harmonised regulation	(+) competitiveness of NORM industries due to harmonised regulation	(+) 1. competitiveness of NORM industries due to harmonised regulation 2. harmonised labelling and control of building materials	(+) competitiveness of NORM industries due to harmonised regulation	(+) 1. competitiveness of NORM industries due to harmonised regulation 2. harmonised labelling and control of building materials
Administrative burden on businesses	(+) reduction of dismantling costs by better application of the concept of clearance	(+) reduction of dismantling costs by better application of the concept of clearance	(+) reduction of dismantling costs by better application of the concept of clearance (-) cost for monitoring and labelling of building materials	(+) reduction of dismantling costs by better application of the concept of clearance (-) monitoring and assessment of environmental impact	(+) reduction of dismantling costs by better application of the concept of clearance (-) 1. cost for monitoring and labelling of building materials 2. monitoring and assessment of environmental impact
Regulatory authorities	(-) transposition into national law	(+) overall coherent set of legislation	(-) New requirements, extended scope	(-) New requirements, extended scope	(+) overall coherent set of legislation (--) New requirements, extended scope

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Environment					
Protection of the environment	(+) regulating residues and effluents from NORM	(+) regulating residues and effluents from NORM	(+) regulating residues and effluents from NORM	(++) 1. regulating residues and effluents from NORM	(++) 1. regulating residues and effluents from NORM

	industries	industries	industries	industries 2. better demonstration and understanding of protection of non-human species	industries 2. better demonstration and understanding of protection of non-human species

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Social and Health					
Health and safety at work	(+) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye	(++) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye 3. Better Protection of Outside Worker through clearer assignment of responsibilities to the undertaking and the employer	(+) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye	(+) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye	(++) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye 3. Better Protection of Outside Worker through clearer assignment of responsibilities to the undertaking and the employer
Mobility of workers and experts	(+) Harmonisation of dose limits eases mobility of outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers 2. Radiation passport for outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers 2. Radiation passport for outside workers
Protection of patients	(+) Better justification of medical examinations and corresponding reduction in number of exposures	(+) Better justification of medical examinations and corresponding reduction in number of exposures			(+) Better justification of medical examinations and corresponding reduction in number of exposures
Protection of the public	(+) Regulation of non-medical	(+) Regulation of non-medical	(++) 1. Regulation of non-	(+) Regulation of non-medical	(++) 1. Regulation of non-

	imaging exposures	imaging exposures Guidance on radon and protection of non-human species	medical imaging exposures 2. Reduction of lung cancer incidence through binding requirements on radon in dwellings	imaging exposures	medical imaging exposures 2. Reduction of lung cancer incidence through binding requirements on radon in dwellings

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Coherence and clarity of legislation	(+) 1. Clearer requirements 2. Graded approach to regulatory control	(++) 1. Clearer requirements 2. Graded approach to regulatory control 3. Simplification and integration of five Euratom Directives	(+) 1. Clearer requirements 2. Graded approach to regulatory control 3. Commission recommendation indoor radon incorporated in Directive	(+) 1. Clearer requirements 2. Graded approach to regulatory control 3. Coherent approach to protection of man and the environment for authorisation of effluent discharges	(++) 1. Clearer requirements 2. Graded approach to regulatory control 3. Simplification and integration of five Euratom Directives 4. Comprehensive framework for all exposure situations 5. Commission recommendation indoor radon incorporated in Directive 6. Coherent approach to protection of man and the environment for authorisation of effluent discharges
International coherence	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(++) 1. Exemption and clearance levels, 2. Overall approach and definitions

	3. Requirements for authorisation of practices	3. Requirements for authorisation of practices 4. Harmonisation of categorisation of sealed sources	3. Requirements for authorisation of practices 4. Protection against indoor radon exposure in the same way as international standards	3. Requirements for authorisation of practices 4. Protection of the environment covered in the same way as in the international standards	3. Requirements for authorisation of practices 4. Harmonisation of categorisation of sealed sources 5.Full range of exposure situations and categories of exposure, including environmental exposures, covered in the same way as in the international standards
Overall impact	+	++	++	+	+++