

The Euratom Basic Safety Standards Directive

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Abstract: The paper describes the basis for the Euratom Basic Safety Standards Directive and outlines progress to date with its development. The current draft of the Directive is compared and contrasted with the International Basic Safety Standards requirements level document approved by the IAEA Board of Governors on 12th September 2011, and a number of issues discussed. The procedure for finalising the Euratom BSS Directive is described and the progress with establishing the key points for the United Kingdom to take account of during negotiations is outlined.

Key Words: Basic Safety Standards, Euratom, IAEA

1. INTRODUCTION

There has been much research into the biological effects of ionising radiation, including epidemiology and molecular biology, which supports the concepts and principles of radiological protection. For these concepts and principles to have effect they need to be incorporated into regulatory documents. This paper focuses on a regulatory document that covers the whole of the European Union – namely the Euratom Basic Safety Standards Directive (BSSD), but also considers the International Basic Safety Standards (IBSS) requirements level document published by the International Atomic Energy Agency (IAEA).

The European Atomic Energy Community (Euratom) was established by the Euratom Treaty (1957)[ref 1]. Euratom has not merged with the European Union and therefore retains a separate legal identity, while sharing the same institutions. Article 2 of the Euratom Treaty states that "in order to perform its task, the Community shall, as provided for in this Treaty.... establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied". The first BSSD was adopted in 1958, and it was mandatory on all Community Member States, who had to implement the requirements of the Directive via national legislation. This Directive has been updated a number of times and the current Directive was issued in 1996 [ref 2]. The BSSD is now being updated, and the opportunity is being taken to consolidate 5 Directives all relating to radiation safety:

- BSSD 96/29/Euratom
- Public Information 89/618/Euratom
- Outside workers 90/641/Euratom
- Medical exposures 97/43/Euratom
- Control of High Active Sealed Sources (HASS) 2003/122/Euratom

The Group of Experts appointed under Article 31 of the Euratom Treaty worked in close cooperation with European Commission staff to draft a revised BSSD. Working Parties were set up to look at some specific issues (Medical, naturally occurring radioactive material [NORM], Graded Approach), while another Working Party worked in parallel to consider how the new BSSD should be structured, bearing in mind the emerging International Commission on Radiological Protection (ICRP) Recommendations. A Working Party was set up as an actual drafting group once the other WPs had completed their work and the ICRP recommendations had been published [ref 3]. The drafting group produced a revised draft Euratom BSSD, version 24 February 2010 [ref 4] which was accepted by the full Group of Experts, and they issued an Opinion of Article 31 Group of Experts also dated 24 February 2010 [ref 5].

The IAEA is an organization within the United Nations family. The IAEA's International Basic Safety Standards (IBSS) is a requirements level document. The 1996 version [ref 6] of the IBSS was co-sponsored by several international organisations and this made the requirements highly influential around the world. An interim version of an updated IBSS was published in November 2011 [ref 7]. While strictly not mandatory on all IAEA Member States, it is the relevant standard for radiation safety in relation to:

- Nuclear Safety Convention
- Joint Convention on spent fuel and radioactive waste management
- International Labour Office Convention 115

2. BASIS FOR BASIC SAFETY STANDARDS

Both the IBSS and the BSSD draw upon wide-ranging research and development work by scientific and engineering organisations that have published new scientific evidence and operational experience regarding risks from ionising radiation. In particular both the IBSS and the BSSD take account of the Recommendations of the ICRP - in particular those given in Publication 103 [ref 3]. This in turn draws on work compiled by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). UNSCEAR was established by the United Nations (UN) in 1955, and its secretariat collates relevant data submitted by UN Member States, international organisations and non-governmental organisations. UNSCEAR engages specialists to analyse and evaluate those data, and at the end of a 4 - 5 year cycle, substantive reviews of available research are published e.g. reference 8.

ICRP Publication 103 indicates that radiation risks from whole body exposure have not changed significantly since their previous recommendations given in Publication 60 [ref 9] (the basis of the existing BSSD and previous IBSS), and Publication 103 maintains the 3 principles of radiation protection: justification, optimisation, limitation. However, it takes account of new biological and physical information and of trends in the setting of safety standards; it says that focussing on human exposures alone is not sufficient; and it introduces some new terminology and concepts such as planned, emergency and existing exposure situations. The ICRP issued a Statement on Tissue Reactions, dated 21 April 2011 [ref 10], which recommended a reduction in the dose limit (in terms of equivalent dose) for the lens of the eye.

Since both the IBSS and the BSSD draw heavily on ICRP recommendations it is not surprising that there are considerable similarities between these standards. For example both standards take account of new ICRP terminology and concepts such as the three exposure situations. However, scientific considerations are only part of the basis for making decisions on protection and safety. Both the IBSS and the BSSD are replacements for earlier documents. In developing the current standards there was an aim to maintain stability thereby minimising the burden of revising national legislation by keeping as much of the previous requirements and text without modifications to the extent possible subject to the need to bring the standards up to date with current radiological protection thinking. Also both sets of safety standards to some extent include value judgements relating to the management of risks.

Throughout the development of the revised IBSS and the BSSD there has been good cooperation in order to ensure their consistency to the extent possible, given the constraints the different organisations were working to. Harmonisation has been aided by the European Commission playing an active role in the Secretariat of sponsoring organisations of the international standards, and by representatives of European Union Member States providing comments on the various drafts of the IBSS via the different Committees of IAEA, especially the Radiation Safety Standards Committee. Also, IAEA representatives have observer status at meetings of the Article 31 Group of Experts meetings, and provided reports on progress with the international standards.

3. GENERAL COMMENTS ON STANDARDS

The draft BSSD and IBSS are broadly consistent, and there are no essential points that are in contradiction. This is largely because they both use ICRP Publication 103 (and subsequent ICRP advice) as their basis. For example the new more onerous dose limit for the lens of the eye is the same in both documents. However, the IAEA and potential sponsors of the BSS had the aim of keeping as much of the text as possible of the 1996 BSS - Safety Series 115 – [ref 6], and the draft Euratom BSS Directive was prepared with a recast in mind; that is the text from the current 5 Directives (BSS, HASS, Outside workers, Medical, Public information) was used as much as possible. Thus there are differences in wording of the BSSD and IBSS because of the nature of standards the 2 documents replace.

There is considerable harmonisation between the Euratom and international standards; for example numerical values are essentially 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 between the two standards. These result 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 revision of Safety Series 115, and in the spirit of the "recast" of Euratom Directives as well. Hence some 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 across the three exposure situations the principles of radiation protection apply in a very similar way. This has led to the BSSD & IBSS being structured differently. 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 of the exposure situations are reflected. This difference in structure has little impact on the stringency or content of the standards, but it does make the comparison of the two standards more difficult.

A further difference is one of regulatory style. The IBSS tends to be rather more prescriptive than in the BSSD, for example it gives much more detail on requirements applying to different responsible parties, e. g. designers, employers, registrants and licensees. This at least in part is because the BSSD is addressed to European Union Member States who have some flexibility on how they implement the required standards in national legislation, whereas some IAEA Member States may use the IBSS directly in their national legislation.

In order to preserve consistency with the previous standards (and for IAEA also to maintain compatibility with its Safety Fundamentals), the BSSD and IBSS use different definitions in places. For example the concept of "facilities and activities" in IAEA is reflected in the definition of "Undertaking" in BSSD. Also, 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. There are differences in the application of the concepts of exemption and clearance, especially for NORM. With regard to artificial radio-nuclides, while both standards have now introduced the values in IAEA Safety Guide 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 clearance levels for specific materials and pathways of disposal. However, the terminology of the Euratom Standards has been adjusted to reflect 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), although the BSSD gives more detail as to what is required:

Licensing is mandatory for specific types of practice:

- Nuclear fuel cycle, radioactive consumer goods and products, medicinal products, HASS, processing or storage of radioactive waste, practices discharging significant amounts of airborne or liquid effluent to the environment, and where workers are liable to exceed 6 mSv/y in normal operations.

Choice to register or licence a list of 6 practices:

- Administration to persons or animals; use of generators or sources for industrial radiography, processing products, research, medical treatment, and use of accelerators, use of generators or sources for medical exposure, supply and operation of >30kV generators, supplying consumer goods containing radioactive substances, where workers are likely to exceed 1 mSv, and NORM practices where public doses exceed 0.3 mSv/yr

Registration or licensing for unlisted practices

- Member States may choose registration or licensing for practices not listed above.

4. COMPARISON OF THE STANDARDS

Although the BSSD and IBSS are broadly similar, there are a number of notable differences and the key items are discussed below.

Dose limits: while the limits in both documents are similar, they are not the same for either occupational exposure or members of the public. For workers the IBSS has a limit (Schedule III) of 100mSv/5y with no year exceeding 50mSv, whereas the BSSD limit (Article 10) is 20mSv/y but a higher dose may be authorised by the regulatory body in a single year (this is the same as current UK regulations). The Dose Limit for members of the public in the IBSS (Schedule III) allows 5y averaging (i.e. 5mSv/5y) in special circumstances, whereas the BSSD does not provide for averaging (Article 13). This means the IBSS is slightly less stringent than the BSSD.

Categorising Workers: the IBSS does not require different categories of workers. However, the BSSD (Article 62) [and the current Directive] requires the categorisation of workers into Category A & Category B. For example a Category A worker is one who is liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 3/10 of the dose limits for the lens of the eye, skin and extremities. This has been implemented in UK as classified & non-classified radiation workers. Categorisation of workers is believed to be helpful in supporting a graded approach whereby more stringent measures are called for to protect the more highly exposed workers.

Experts: the BSSD (Article 19) includes a requirement regarding a Radiation Protection Expert; the IBSS uses the term Qualified Expert (for example in paragraph 2.46) which is broadly equivalent.

Accidental and unintended medical exposures The BSSD (Article 88) requires that **all reasonable** steps to minimize the probability and the magnitude of accidental or unintended exposures of patients from all medical radiological procedures are taken, economic and social factors being taken into account. Whereas the IBSS (Requirement 41) requires that "Registrants and licensees shall ensure that **all practicable** measures are taken to minimize the likelihood of unintended or accidental medical exposures". The latter would seem to be a much more onerous requirement.

Optimisation of medical exposure IBSS (Requirement 38) requires that "Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure". Whereas the BSSD (Article 81) requires doses to be kept ALARA **consistent with the medical purpose**.

Responsibility for medical exposure The IBSS states that the radiological medical practitioner is responsible for justification & optimisation. The BSSD more flexible - medical exposures are undertaken under the clinical responsibility of a radiological practitioner but Member States may define level of involvement of practitioner and referrer.

Diagnostic reference level (DRL) The IBSS requires government to establish DRLs; whereas the BSSD only requires governments to promote establishment and use of DRLs

Aircrew and space crew: the BSSD treats such exposure as a planned exposure situation; IAEA regard such exposure as an existing exposure situation.

Industries dealing with NORM: the BSSD treats occupational exposure as a planned exposure situation; IAEA regard as an existing exposure situation - but apply requirements for planned exposure situations.

Building materials: the BSSD gives much more specific requirements on building materials than the IBSS.

5. THE UK INPUT TO THE STANDARDS

The UK provided a significant input, along with other Member States, to the revision of the IBSS through the IAEA's four Safety Standards Committees and also the Commission on Safety Standards, as well as inputs via Technical Meetings and through Consultants Meetings.

European Union Member States, including the UK, are currently discussing a draft BSSD in the AQG. In order to support this work the UK formed a BSS Cross Government (and Agencies) Group, and this group agreed to forming three stakeholder working groups covering:

1. Medical exposures;
2. Occupational radiation exposures;
3. Public & environment

The key tasks of these working groups was to identify issues with draft BSS, having consulted relevant stakeholders, and also to develop narrative summaries, and assess the potential impact for UK. These working groups identified various potential issues including:

A Occupational Exposures

- Licensing where workers $>6\text{mSv/y}$ [article 53.2]
- New Dose Limit for lens of the eye [article 10, 12, & 13]
- Extension of scope of Outside Workers to include work in supervised areas [article 4]
- Removal of direct references to individual radiological monitoring documents

B Medical Exposures

- Fitting exposure meters to dental intra-oral equipment [article 85.5]
- Will recognition of Radiation Protection Expert impact on existing Medical Physics Expert arrangements? [article 19, 20]

C Public & Environment Exposures

- Elimination of ionising radiation exposure from licensed practices [article 91.1]
- Classifying building materials as radioactive material where they give 1mSv/y [article 101.6]

6 NEXT STEPS FOR IBSS & BSSD

The IBSS requirements level document was approved by the IAEA Board of Governors on 12th September 2011 and an interim version was published in November 2011. The IAEA had invited representatives of UN and other intergovernmental organizations to participate in developing a revised IBSS through the establishment of a BSS Secretariat. This secretariat was made up of representatives of the potential sponsoring organizations, namely: the European Commission (EC), the Food and Agriculture Organization of the United Nations, the International Labour Organization, the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development, the Pan American Health Organization, the United Nations Environment Programme (who provide the secretariat for UNSCEAR) and the World Health Organization. These organisations have either already indicated that they will sponsor the IBSS or are still considering whether they will. The IAEA expect to receive confirmation of sponsorship from all of these organisations by the end of 2012 - although endorsement of the standards by the Euratom Community could perhaps take a little longer. It is of note that the Article 31 Group of Experts has given an Opinion [ref 11] that supports sponsorship of the IBSS, without prejudice to the development of the BSSD. A final version of the IBSS is expected to be published in 2013.

On 29 September 2011, the European Commission adopted a slightly revised version of the BSSD drafted by the Article 31 Group of Experts [ref 12]. The proposed Directive is currently under discussion in the Council's Working Party on Atomic Questions - often called the Atomic Question Group (AQG), and on completion of these discussions the Directive is expected to be adopted by the European Council. It will then become mandatory on all European Union Member States, albeit with some time to translate the requirements into national legislation.

Discussion and amendment of the draft BSSD in AQG of Council is on-going and is liable to last about 2 years. Eventual transposition into national legislation is liable to allow perhaps two years for most of the Directive but several years to implement some Titles of Directive; so it may well be some time before all of the necessary new radiation protection legislation comes into force.

7 CONCLUSIONS

The previous Basic Safety Standards documents (of both the BSSD and IBSS) offered generally satisfactory levels of protection for workers and for members of the public in relation to the dangers arising from ionising radiation. However, new scientific evidence and operational experience regarding risks from ionising radiation pointed to the benefits of revising the BSSD and IBSS. The two documents are structured differently and use some differing terminology. Nevertheless these standards are broadly consistent, and represent a greater degree of harmonisation of regulatory requirements between EU countries and international standards. Forthcoming changes to the UK's radiation safety legislation are expected to be evolutionary rather than revolutionary.

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