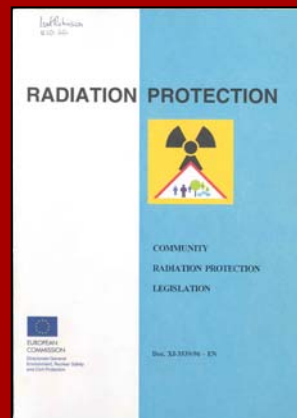


Developing the EC Basic Safety Standards



Gareth Thomas



Basic Safety Standards

Two BSS documents currently being revised:

- **Euratom BSS Directive** – mandatory on EU member states
- **International BSS** – requirements level IAEA document co-sponsored by several international organisations - highly influential but not strictly mandatory



Euratom BSS Directive

- **Revision** of BSS Directive (96/29/Euratom)
- **Consolidation** of existing European RP legislation
 - BSS 96/29/Euratom
 - Public Information 89/618/Euratom
 - Outside workers 90/641/Euratom
 - Control of HASS 2003/122/Euratom
 - Medical exposures 97/43/Euratom
 - (radon – Commission recommendation 90/143/Euratom)
- Article 31 Group of Experts completed their work:
BSS dated 24 February 2010
Opinion of Article 31 Group of Experts
http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm



Euratom BSS Directive

Preamble

Title I Subject Matter and Scope

Title II Definitions

Title III System of Protection

Title IV Responsibilities for Regulatory Control

Title V Requirements for Education, Training and Information

Title VI Justification and Regulatory Control of Planned Exposure Situations

Title VII Protection of Workers, Apprentices and Students

Title VIII Protection of Patients and Other Individuals Submitted to Medical Exposure

Title IX Protection of Members of the Public

Title X Protection of the Environment

Title XI Final provisions

Annexes

Overview of draft Euratom BSS

- Some harmonisation with international Standards (using ICRP103 terminology)
- Integration of natural and artificial sources
 - Impact on NORM and building materials industries
- Better definition of medical/non-medical exposures
- Graded approach to regulatory control
- enhanced role of the competent authorities
- existing exposure situations
 - radon
 - building materials

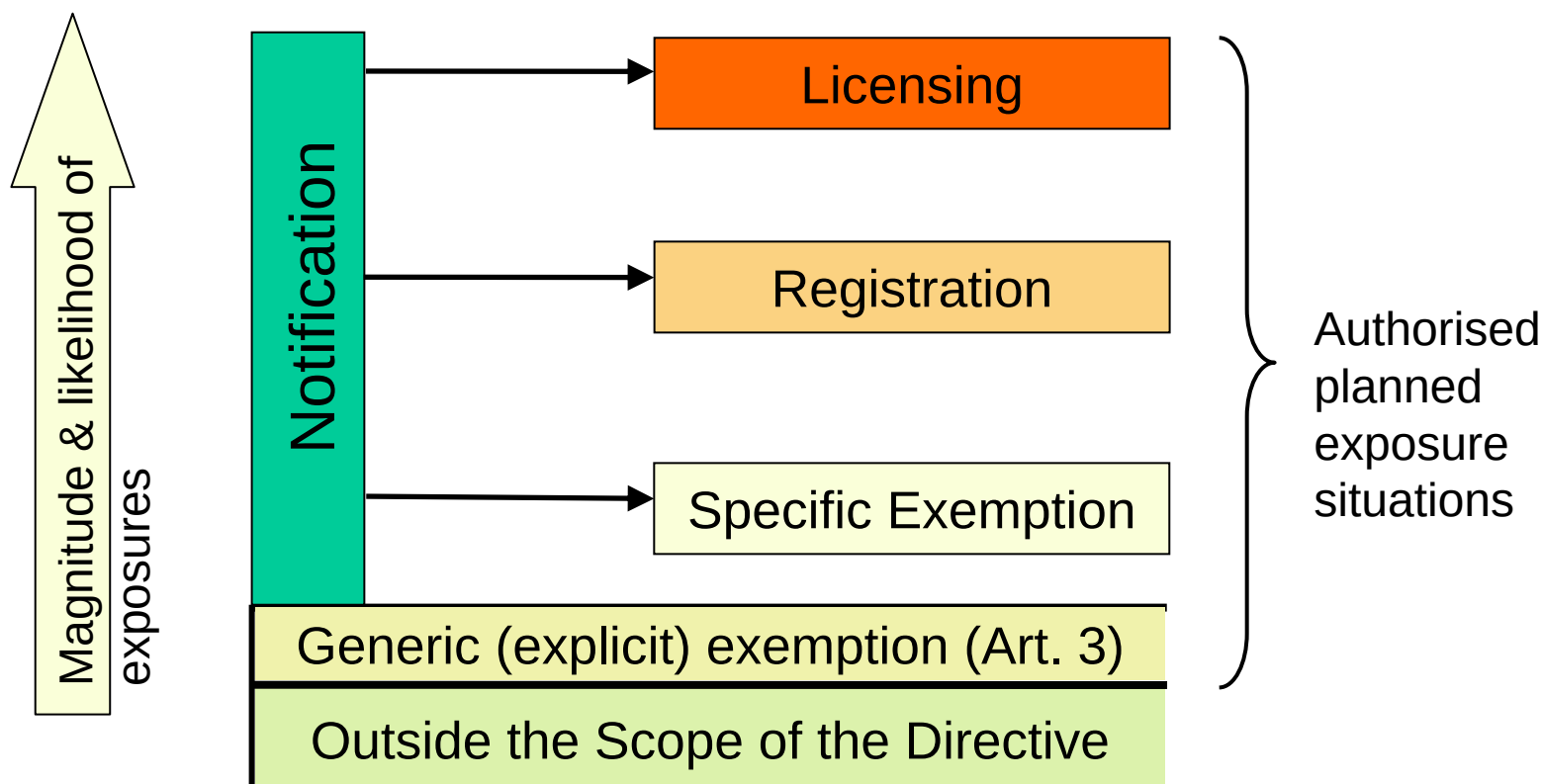
SUMMARY



Areas for comment

- | | | | |
|----|--|----|--|
| A. | Adopting a graded approach | O. | Medical Surveillance |
| B. | Exemption and Clearance Levels | P. | Outside Worker Directive |
| C. | Radon | Q. | Appointed Doctors |
| D. | NORM | R. | Removal of need to Approve
Dosimetry Services |
| E. | Building materials | S. | Removal Supervised Areas |
| F. | Environmental Protection | T. | Risk Assessment (by employers) |
| G. | Protection of Patients and other persons
subjected to medical exposures | U. | Prior Authorisation |
| H. | System of Protection | V. | Monitoring of Workers with Multiple
Employers |
| I. | Personal dosimetry | | |
| J. | Control of Radioactive Materials | | |
| K. | Appointment of Competent Persons
(RPE, MPE, RPO) | | |
| L. | Emergency Preparedness & Response | | |
| M. | Justification | | |
| N. | Education and training | | |

A. Adopting a graded approach



Title VI - Graded approach



Licensing is mandatory for 7 types of practice:

Nuclear fuel cycle, radioactive consumer goods and products, and HASS = current BSS.

Manufacture of medicines, waste disposal, discharging significant amounts of airborne or liquid to the environment, and where workers may exceed 6 mSv = new.

Choice to register or licence another list of 7 practices:

Administration to persons or animals; use of generators or sources for industrial radiography, processing products, research, medical treatment, and use of accelerators = current BSS licensed

Use of generators or sources for medical exposure, supply and operation of >30kV generators, supplying consumer goods containing RAS, where workers are likely to exceed 1 mSv, and NORM practices where public doses exceed 0.3 mSv/yr = new

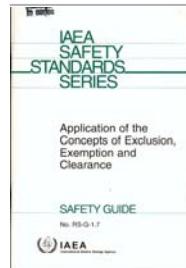
Main Issue:

Licensing requirements where workers may exceed 6 mSv/yr.

B. Exemption and Clearance Levels

Practices < Bq or < Bq/g values in annex 9 exempt

Basis: Bq = current BSS, Bq/g = IAEA RS-G-1.7 (Study launched to evaluate differences with EC RP 122.)



Main Issue:

Some of the activity concentration levels in RS-G-1.7 are significantly below the current generic 0.4Bq/g, for example Cs137 at 0.1Bq/g (common in the nuclear fuel cycle). Could create a major impact on decommissioning activities.

C. Radon

Main Issues:

- Concerns over Action Plan review, audit, goals.
- Measurement requirement for workplaces – risk assessment would be better.
- Radon from water sources and building materials should be irrespective of area status.
- ALARP requirements for workplaces >ref level dependant on <> 6mSV. *Appropriate* measure should apply to all employees.

Max ref level	Situation
200 Bq m⁻³	New buildings
400 Bq m ⁻³ 300 Bq m⁻³	Existing dwellings
400 Bq m ⁻³ 300 Bq m ⁻³	Public buildings (high occupancy)
1000 Bq m ⁻³	Workplaces (~10mSv/y)

D. NORM

Positive list of NORM practices (annex 8) subject to notification - will provide impetus for some sectors to consider NORM doses for the first time.

Where public or worker doses exceed 0.3 mSv or 1 mSv either registration or licensing required.

Main Issue:

Licensing requirements where workers may exceed 6 mSv/yr.

H. Environment

Main Issue:

This is new to BSS – could it be included in a 'Recast' ?

G. Protection of Patients and other persons subjected to medical exposures

Main Issue:

Cost implications if exposure meters are required to be fitted to all new dental intra-oral equipment.

Member states shall ensure the introduction of a course on radiation protection in the basic curriculum of medical and dental schools - Not sure this can be done in this directive as other directives govern contents of undergraduate medical and dental training.

H. System of Protection

Main Issue:

- Appears to be a greater emphasis on optimization of exposure using constraints **rather than ALARP**.
- Propose inclusion of requirements for suppliers to provide appropriate information to users?
- 50 mSv/y eye dose limit possible concern and implications for some interventional radiology type of work and possible increased requirements for classification and dose monitoring.

Other Issues:

Different dose constraint principles: workers = upper bound on doses, public = upper bound in setting discharge limits, medical = upper bound on dose for specific examination.

I. Personal dosimetry

Main Issues:

- Costs and practicality of implementing and operating a single 'live' dose database.
- Possible increased reluctance to designate category A workers - detrimental to radiation protection.
- Significant increased costs and admin burden for employers having to retain dose records for category B workers from 2 yrs to at least 30 yrs. Also likely to result in reduced monitoring of these employees as a consequence.

J. Control of Radioactive Materials

Main Issues:

- There is clear scope here for applying most of it to unsealed sources, and many parts that only applicable to HASS, to all sealed sources.
- Desirable to include a requirement to notify of a leaking sealed source, particularly a HASS?
- It is not clear whether the procedures are aimed at achieving security or safety / generic or detailed.
- There is no de-minimus level for control of sealed sources.

K. Appointment of Competent Person

Main Issues:

- Need a formal recognition system for MPEs.
- Is it possible in H&S law to make the MPE 'responsible' for aspects of H&S?
- BSS needs to enable MSs to recognise RPE 'bodies' and a Medical Physics Services and allow for RPEs and MPEs to provide undertakings with advice rather than **the** RPE or MPE.
- Do we need BSS to require undertaking to consult RPE on application of RP legislation?
- Does requirement to consult an RPE need to exclude practices excluded from notification?
- Need BSS to give flexibility on who is the RPO's employer.

L. Emergency Preparedness & Response

Main Issue:

Inconsistency in dose limits for emergency workers of 20 – 100 mSv and 50 mSv.

M. Justification

Main Issues:

- Non-medical imaging: May require criteria, systems and processes for exceeding public dose limit.
- Non-medical imaging: May require criteria, systems and processes for law enforcement bodies to proceed without informed consent in exceptional circumstances.
- Prevents temporary activation of gem stones.

Other Issues:

- Doesn't seem to consider withdrawal of type approvals which would appear more appropriate.

N. Education and Training (re medical exposure)

Main Issue:

Current legislation does not currently require recognised training.

O. Medical Surveillance

Main Issues:

- Is it possible in H&S law to make the occupational health service 'responsible' for aspects of H&S?
- Should the dose above which special surveillance is required be the dose limit, 20 mSv?
- HSE proposed that the requirement for annual face to face medical reviews could be more flexible and a risk related review period. Nb. May lead to problems in managing reviews and may lead to differing standards

Q. Appointed Doctors

Main Issue:

OHSs must perform medical surveillance of workers - does not specify which workers. Eg. Cat A workers.

Other Issues:

- HSE suggested that it would be appropriate for the BSS to require that Appointed Doctors have appropriate refresher training at a sensible frequency.
- Should OHS be required to have site specific knowledge in some/ all circumstances?
- Should a large site be able specify which appointed doctor should be used re their specific hazards?

S. Removal Supervised Areas

Main Issue:

HSE suggested simplification of no longer having Supervised Areas.

V. Monitoring of Workers with Multiple Employers

Main Issue:

HSE suggested that specific reference to the need to monitor and sum the doses for workers who work with radiation for more than one employer should be included in the BSS.

Next steps



Euratom BSS Directive

- Finalise draft directive (24 February 2010) and associated Article 31 Group of Experts Opinion.
- European Commission legal services preparation of recast procedure.
- Adoption of BSS Directive proposal by Commission (summer 2010)
- Opinion of Economic and Social Committee
- Proposal to Council and European Parliament
- Draft BSS referred to AQG for discussion & negotiation – liable to take 1-2 years
- Council adopts BSS which then becomes mandatory on MS – liable to have 3 or 4 years to transpose into national legislation

International BSS

- Version 3.0 to issued to RASSC members, co-sponsors, Member State for comment through official channels – Deadline 31 May 2010
- initial discussion at RASSC meeting on July 2010 in Vienna
- IAEA hope to get RASSC agreement at December 2010 meeting to send BSS to Commission on Safety Standards for approval before publication