COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.01.2003
COM(2003) 18 final

2003/0005 (CNS)

Proposal for a

COUNCIL DIRECTIVE

on the control of high activity sealed radioactive sources

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. FOREWORD

Radioactive sources are used throughout the world for a wide variety of purposes notably in industry, medicine and research. The risks posed by such sources vary widely, depending on their activity, contained radionuclides, construction, etc.

Risks associated with the planned use of the sources are normally well known. In the European Union, the use of radioactive sources is subject to the requirements set out by the radiation protection legislation adopted pursuant to Chapter III Health and Safety of the Euratom Treaty.

Recently, however, a number of events have drawn the Commission's attention to the problem of sources that for various reasons are not under control. Such "orphan" sources are likely to be recovered by persons, whether workers or members of the public, unaware of the possible risks. This has led to serious radiation injuries and in some cases, although not in the European Union, to death.

Sealed sources may imply particular risks because of their small size, often the size of a pen or smaller, their use in mobile devices, etc. The metallic capsule containing the radioactive substances makes likely their collection by members of the public or by metal scrap handlers. Findings of sources in scrap-yards and in metal production facilities are recurrent events worldwide. Details concerning the nature of radioactive sources of concern, the main risks associated with their use or misuse, a summary of their applications, and a list of the most significant accidents which occurred during the last years are given in the attached Technical Annex.

2. BACKGROUND

The radiation protection authorities worldwide are confronted by the issue of the correct management of radiation sources, especially high activity sealed radioactive sources. Maybe due to their mobility, they have been involved in many of the known radiation incidents and accidents.

Since the first medical applications of radium sources at the beginning of the 20th century, there has been a significant increase in the number and utilisation of radiation sources, especially following the relatively wide availability of artificial radionuclides since the fifties and the sixties.

Within the framework of the Community Plan of Action in the field of radioactive waste[1], the European Commission recently published a study on management and disposal of disused sealed radioactive sources in the European Union[2] .The authors of the study, using their own technique and assumptions, arrived at a rough estimation that approximately 500 000 sealed sources have been supplied during the past 50 years to operators in the EU's current fifteen Member States. Of these, approximately 110 000 sources are currently in use. Most of the remainder have been

[1] Council Resolution of 15 June 1992 on the renewal of the Community Plan of Action in the field of radioactive waste. OJ C158, 25.06.1992

[2] Angus et al. Management and disposal of disused sealed radioactive sources in the European Union – EUR 1886 (2000)

sent to central interim stores, returned to manufacturers or have been disposed of. The sources at greatest risk of being lost from regulatory control are disused sources held in local storage at the users' premises. The study estimates that there are about 30 000 such sources throughout the EU. Further information from the study is summarized in the attached Technical Annex.

Occasionally, the national competent authorities have to deal with cases in which radiation sources are inadequately managed, or radiation sources are found outside of any regulatory control. Both those categories of events could result in serious health consequences for the workers or members of the public involved. The likelihood of such events is increased when the sources are no longer actively used and they are put in storage or simply left unattended for long periods. In fact, there are indications that controls, can become weak between the time when the sources are removed from active use and the time they are returned to producers for possible reuse, or declared as waste and placed under systems of radioactive waste management.

The health and economic consequences of possible accidents involving inadequately controlled radiation sources may be particularly severe. An overview of recent significant events is given in the attached Technical Annex.

3. EXISTING COMMUNITY LEGISLATION

Member States of the European Union, via the Euratom Treaty, conferred on the European Atomic Energy Community the task of establishing uniform safety standards to protect the health of workers and of the general public against dangers arising from ionising radiation. A Directive, first adopted in 1959 and last revised in 1996[3], lays down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The Directive applies to all practices, which involve a risk from ionising radiation, and it imposes the basic principles for radiation protection and other generic requirements, without however giving detailed rules for the wide variety of existing practices.

Although the Basic Safety Standards Directive is of general application, in the past it has already been necessary to complement its requirements with measures aimed at specific purposes. The adoption of such measures was sometimes the response to particular events. For example, the European Parliament Resolution of 6 July 1988 on the findings of the Committee of Inquiry into the Handling and Transport of Nuclear Materials[4] resulted in the adoption of Directive 92/3/Euratom on shipments of radioactive wastes[5].

Another example is the adoption of Regulation 1493/93/Euratom on shipments of radioactive substances between Member States[6] that resulted from the abolition of controls at the intra-Community borders on 31.12.1992.

---

[3] Council Directive laying down basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation. OJ L159, 29.06.1996

[4] European Parliament Resolution of 6 July 1988 on the findings of the Committee of Inquiry into the handling and transport of nuclear materials. OJ C235, 12.09.1988

[5] Council Directive on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community. OJ L35, 12.02.1992

[6] Council Regulation on shipments of radioactive substances between Member States. OJ L148, 19.06.1993

In addition to the regulatory activities, the Commission carried out other actions specific to the management of radioactive sources and to the presence of radioactive materials in scrap metals. Such actions are summarized in the Technical Annex.

4. INTERNATIONAL ACTIONS

At the international level, the European Commission co-sponsored together with the International Atomic Energy Agency (IAEA), the International Criminal Police Organisation (INTERPOL) and the World Custom Organisation (WCO) a symposium on the safety of radiation sources and security of radioactive material that was held in Dijon in 1998 hosted by the French Government[7]. It resulted from the conference that the issue of a strengthened control on radiation sources is particularly topical, due to the intensification of international exchanges, and to the fact that the sources produced in the fifties and the sixties are approaching the end of their life, a phase in which the loss of control is particularly relevant. The IAEA, as a follow-up to the Dijon Symposium established an action plan on Safety of Radiation Sources and Security of Radioactive Materials that was endorsed by the IAEA General Conference in October 1999[8]. Among the initiatives of the action plan particular emphasis is given to the assistance to States in maintaining or establishing their regulatory infrastructures.

Two important achievements in this context are the Code of Conduct on the safety and security of radioactive sources, endorsed by the IAEA General Conference in September 2000[9], and the technical document on Categorisation of radiation sources[10].

The issue of radioactive contamination of scrap metal and of metal products is presently being addressed by a team of specialists convened by the United Nations Economic Commission for Europe (UNECE) in which experts from the European Commission and from the IAEA participate together with experts from industrial associations and from Member States of UNECE. It is expected that a report prepared by the team of specialists will be available shortly.

5. THE WAY FORWARD

In conclusion, the European Commission is of the opinion that it would be appropriate to adopt specific legislation, based on the Euratom Treaty, supplementing the Basic Safety Standards Directive with a view to strengthen the control by the competent national authorities on those sealed radioactive sources posing the greatest risk and to emphasise the responsibilities of holders of such sources.

A specific regulatory text on the management of sealed sources would improve the protection of man and of the environment by, on one hand strengthening and harmonising the regulatory practices applied in the Member States on the basis of the general requirements of the Basic Safety Standards Directive and, on the other hand,

---

[7] Safety of Radiation Sources and Security of Radioactive Materials. Proceeding Series – IAEA, Vienna, 1999
[8] IAEA GC (43)/RES/10
[9] Code of Conduct on the Safety and Security of Radioactive Sources. IAEA/CODEOC/2001 – Vienna 2001
[10] Categorisation of Radiation Sources - IAEA – TECDOC 1191, Vienna 2000

by strengthening the European Union legal acquis, in the eve of a further enlargement of the Union.

6. PROVISIONS OF THE PROPOSAL

6.1. Preamble

Article 2b of the Euratom Treaty sets out that the Community shall "establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied". Article 31 of the Euratom Treaty lays down the procedure for establishing the standards or for supplementing them as provided for by Article 32.

Therefore, Articles 31 and 32 of the Euratom Treaty provide the legal basis for the proposal.

6.2. Purpose and scope (Article 1)

Council Directive 96/29/Euratom sets out a number of provisions that, properly applied, would prevent the risks connected with the manufacture, use and disposal of high activity sealed sources. However, with respect to potentially highly dangerous sources, additional Community provisions should be in place to further reduce the likelihood of accidents involving such sources.

Many of the provisions required by the proposal are already in place in several Member States pursuant their implementation of the basic safety standards Directive. The proposal extends to the whole European Union the most effective practices applied by some Member States. The form of a Directive, in contrast to a Regulation, allows Member States to modify their regulatory system only for those requirements that are not already in place.

Basically, the Directive would apply to sealed sources giving a dose rate in the order of more than 1 mSv/h at one meter distance. The resulting activity of the source depends on the radionuclides and on the quality of the radiation emitted. Such activity for the radionuclides most utilised in sealed sources is given in Annex 1. The values tabulated are one hundredth of the activity limits applicable for the regulations on the safe transport of radioactive material issued by the International Atomic Energy Agency[11] and above which transport must take place in packages designed and tested to ensure containment of the radioactive substances in accident conditions.

6.3. Definitions (Article 2)

The key definition is that of High Activity Sources. Such definition would include all the radioactive sources that in the last years caused accidents with serious health effects reported in published surveys, all the sources that caused major contamination at plants handling metal scrap, all sources in the IAEA category 1 and a large fraction of those in category 2[12]. The definition has been carefully chosen to strike an optimum balance between the additional technical and administrative burden and the

[11] Regulation for the Safe Transport of Radioactive Materials, Safety Standard Series No. TS-R-1 (ST-1, Revised), IAEA, Vienna 2000

[12] See footnote 10

reduction of the health risks posed by the sources. The Definition of High Activity Sources is not linked to the exemption values in Directive 96/29/Euratom, as these values were defined on the basis of a negligible level of risk, and the requirements of the present Proposal should not put an administrative burden on the holders of small sources that is not commensurate to the possible health detriment.

The definition of Orphan Source is an adaptation of the definition given in the IAEA Code of Conduct on the safety and security of radioactive sources[13].

6.4. Authorisation (Article 3)

The use of radioactive sources for industrial radiography or processing of products or research or the exposure of persons for medical treatment is subject to prior authorisation under Directive 96/29/Euratom (Article 4 (1) (e)).

The proposal requires prior authorisation for any practice involving a high activity source. Before issuing an authorisation, the competent authorities shall ensure that arrangements have been made not only for the safe use of the source, but also for the proper management of the source when it becomes disused. It is in fact proven that the sources most at risk of creating accidents are those that are no longer in active use and whose safe management tends to be neglected. It is therefore necessary to ensure that the control continues until the source has been transferred for its recycling, reuse or disposal under controlled conditions. The authorities must also ensure that financial provisions have been made for the management of the disused sources.

One element that prevents, in some cases, sources from being transferred for disposal is the cost of the disposal that would be normally requested to the last holder of the source. It is therefore necessary that, before the source is used in the practice from which the holder expects to obtain a benefit, financial provisions are made for the end of life of the source. Some examples of financial provisions are provided in paragraph 2(b).

6.5. Transfers (Article 4)

The term transfer used in the proposal refers to the conveyance of responsibility and property from one person to another. It is not to be confounded with the term shipment used in Regulation 1493/93/Euratom where it is defined as follows:

"Shipment means transport operations from the place of origin to the place of destination, including loading and unloading of radioactive substances"

Provisions on shipments of sealed sources are set out by Council Directive 92/3/Euratom[14] and by Council Regulation 1493/93/Euratom[15]. The Commission undertook to review such provisions, in particular to address shipments of sources into and out of the European Union, an issue not covered by the existing provisions. Article 4 of the proposal requires Member States to set up a system of control on

[13] See footnote 9
[14] See footnote 5
[15] See footnote 6

transfers of high activity sealed sources without exceptions, including those within one Member State, and those involving non-Member States.

6.6. Records (Article 5)

The expert advice collected by the Commission recognises that, with a view to ensure safety, it is more efficient to focus the control by the authorities on holders of sources, instead than on the sources themselves. It is therefore proposed the use of a standard record sheet to be kept by holders of sources with information on the holder of the source, checks and tests performed on the source, and its transfers.

The use of the standard record sheet will facilitate exchange of information and the establishment of registers held by the authorities at national or local level, if they so wish.

The annual return to the competent authorities (paragraph 3) ensures that the holder is still in existence and discharges its obligations as regards the source. Failure to report by a holder should be considered an indication that sources are at risk, and should prompt closer verifications by the authorities.

6.7. Common requirements for holders (Article 6)

Leak tests are essential to ensure that sealed sources maintain their integrity. The integrity of the source ensures that in normal operating conditions and in many accidental conditions, the radioactive materials are firmly contained in the source, and they do not cause contamination of individuals, the working premises or the environment. Risks of contamination can however never be completely ruled out because no source can be designed to resist tampering or processing, for example in a scrap facility.

Paragraph (e) requires holders to return or transfer sources to a supplier or to a recognised installation for the recycling, long-term storage or disposal without undue delay after termination of the use.

Competent authorities have several possibilities to ensure that sources are properly transferred after termination of the use. They include:

- annual fee for holding the source
- time limitation of the authorisation
- deposit of a caution, given back when the source is transferred.

Direct transfer of a source from a user to another user is allowed. However, it must be agreed by the competent authorities, in compliance with paragraph (e), and the transferor must have checked whether the recipient user holds an appropriate authorisation, as specified in paragraph (f).

6.8. Identification and marking (Article 7)

Provisions on identification and marking of sources are needed especially in the event that the control on a source is lost. The information will facilitate the retrieval of the source and ensure that adequate safety measures are taken if it is found. In

addition to these safety needs, identification and marking may be used to trace the holder, or last authorised holder, of the source for prosecution or cost attribution.

6.9. Training and Information (Article 8)

The basic safety standards Directive requires training of persons deliberately dealing with sources. Specific training shall be addressed to the relevant workers using or handling high activity sources or being in the proximity of these sources.

In view of the possibility that sealed sources are found out of control, it is necessary to give appropriate information and training to the persons who normally do not deal with radioactive sources but who work in installations where orphan sources are most likely to appear.

6.10. Orphan sources (Article 9)

The proposal deals mainly with requirements aimed at preventing sources from becoming orphan. However, Article 9 sets out requirements aimed at regaining control on actual orphan sources.

The measures proposed require

- assignment of responsibilities for adequate preparedness in the event of interventions following the detection of an orphan source. Following the Spanish accident of 1998 (see paragraph 4 of the technical annex), the Spanish authorities promoted the establishment of a Protocol for cooperation on the radiological surveillance of metallic materials. The Protocol assigns clear responsibilities for the various actions following the detection of an orphan source, and it has been signed by all the Authorities and Industrial Associations involved. The assignment of responsibilities will depend on the structure of the national administrations involved.

- identification of competent national bodies or points of contact where persons suspecting of being in presence of an orphan source can rapidly obtain advice and assistance.

- establishment of controls where orphan sources are most likely to appear, like large metal scrap yards, major metal recycling installations or significant nodal transit points. Equipment for the detection of radioactivity has been already installed by large industrial operators, aware of the risks posed by orphan sources to the health of their workers and to the quality of their products. Timely detection of orphan sources before processing in the installation will also prevent the sometimes very high costs resulting from the contamination of the installation and of the environment.

- organisation of campaigns for recovering orphan sources, or sources in danger of becoming orphan.

6.11. International cooperation and information exchange (Article 10)

Sources are used throughout the world, and trade in recycled metals is essentially international. The proposal therefore requires Member States to exchange

information and to cooperate with other States with a view to re-establish control on orphan sources.

6.12. Guarantee (Article 11)

In the case of orphan sources, it is not easy to identify who is liable for the costs and damage caused by the source, and often liability has been put on the person who detected an orphan source. Member States have several possibilities for addressing the issue, for instance, the establishment of a fund, to cover the costs and damage resulting from the detection of orphan sources. The fund may be financed by guarantees deposited by persons making benefits from the use of sources

6.13. Inspections (Article 12)

Standard text.

6.14. Competent authorities (Article 13)

It is necessary that the competent authorities empowered the carry out tasks under the Directive have all the information necessary for communicating, pursuant to Article 10, with authorities in other Member States.

The Commission shall publish the necessary information in the Official Journal of the European Communities.

6.15. Report on experience (Article 14)

Three years of practical experience with the implementation of the Directive will allow the Commission, together with the Member States, to make a first assessment of the efficacy of the Directive, and the identification of possible simplifications, additional requirements or clarifications.

6.16. Penalties (Article 15)

Standard text.

6.17. Implementation (Article 16)

Two years are considered a reasonable time for the implementation of the Directive, considering that all Member States have already regulations covering the subject that may need to be completed or modified.

6.18. Entry into force (Article 17)

It is expected that the national provisions implementing the Directive will be applied initially to sources put on the market following the date of implementation. A period of two further years is foreseen for implementing the Directive with respect to the pre-existing sources.

Technical annex

1. DEFINITION OF RADIOACTIVE SEALED SOURCES

A sealed radioactive source is a "source whose structure is such as to prevent, under normal conditions of use, any dispersion of the radioactive substances into the environment"[16].

Sealed radioactive sources are widely used in industry, medicine and research. Until the 1950s, only radionuclides of natural origin, particularly Radium-226, were used to produce sealed sources. Since then, radionuclides produced artificially in nuclear facilities and electrical generators have become widely available. According to the type of radiation, there are four main categories of sealed sources, i.e.

- Gamma sources – mainly used in industry, external beam radiotherapy, brachytherapy and sterilisation;
- Beta sources – mainly used in industry, e.g. in thickness gauges, clinical therapy, education and training;
- Alpha sources – mainly used in smoke detectors, heat sources, in analytical practices, education and training;
- Neutron sources – mainly used in analytical practices, industry, calibration techniques, education and training.

Appendix A gives a summary of the sealed sources used in a variety of applications, with their respective range of radioactivity. The sources, the activity of which may result in a dose-rate at one metre distance exceeding 1 mSv/h, are posing important radiological risks. Very few radionuclides are concerned (mainly Cobalt-60, Caesium-137, Iridium-192, Americium-241, Strontium-90, and Radium-226).

In addition to sources in use or disused[17], there is a third category of sources that should be taken into consideration: the so-called "orphan sources" referred to in the IAEA Code of Conduct on the safety and security of radioactive sources. According to the Code[18], orphan sources are those sources:

- that were never subject to regulatory control;
- that were subject to regulatory control but have been abandoned;
- that were subject to regulatory control but have been lost or misplaced;
- that were subject to regulatory control but have been stolen or removed without proper authorisation.

---

[16] Council Directive laying down basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation. OJ L159, 29.06.1996 - Article 1

[17].C. Crumpton. Management of spent radiation sources in the European Union: quantities, storage, recycling and disposal. Ref. EUR 16960 en (1996)

[18] Code of Conduct on the Safety and Security of Radioactive Sources. IAEA/CODEOC/2001 – Vienna 2001

2. INVENTORY OF RADIOACTIVE SEALED SOURCES IN THE EUROPEAN UNION

According to a recent EC-funded study[19] about 500 000 sources were supplied to users in the current Member States (MS) of the European Union (EU) over the past 50 years. Of these 500 000 sources about 110 000 would be still in use. The remaining 390 000 sources that are temporarily or permanently useless for their holders are referred to as being "disused". These latter are stored or disposed of either in central facilities (about 360 000 sources) or at users' premises (about 30 000 sources). However, the fact that sources are disused does not indicate that their radioactivity is negligible nor that the sources have become harmless to man and the environment.

3. EXPOSURE SCENARIOS

In the European Union, disused sources, which are stored at users' premises, are giving the most radiological concern. This is due to the fact that these sources have a significant probability of becoming lost from regulatory control and thereby of becoming "orphan sources". The reasons for this include (by order of importance):

- intentional discarding of sources in order to reduce the liability of the owner with respect to its obligations towards long-term storage and disposal;
- unintentional loss of the source due to the lack of awareness of users.
- poor record keeping by the user (nobody knows the whereabouts of the disused sources);
- disappearance (e.g. bankruptcy) of the user, which would reduce or even suspend any control on the sources;
- theft of the source or the equipment that contains the source (to sell it as scrap).

Orphan sources may cause serious injury including death to workers and members of the public, who are not aware of their existence. This can be the case in steel factories where scrap metal is recycled.

Finally, sealed sources may leak. This might dramatically increase the radiological consequences resulting from their handling both in normal operation and in accidental conditions.

4. RECENT ACCIDENTS

The health and economic consequences of possible accidents involving inadequately controlled radiation sources may be particularly severe. The 1993 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and more recent literature[20] report on several significant accidents, amongst which:

[19] M. Angus et al. Management and disposal of disused sealed radioactive sources in the European Union. EUR 18186 (2000)
[20] IAEA Bulletin Vol 41 No 3.1999

- In Goiania, Brazil, in 1987, a ceasium-137 teletherapy source was removed from its housing and broken up. Fifty-four people were hospitalised following radiation exposure and four died. Contamination of the environment was extensive.

- In China, in 1992, a cobalt-60 source was lost and picked up by a man. Three persons in the family died of overexposure.

- In 1997 in Georgia, after several border frontier guards became ill and showed signs of radiation induced diseases, a group of radioactive sources were found abandoned in a barracks that used to be under the control of the Soviet Union Army. A programme was set up to verify the radiological situation and more than 70 sources were found in many locations throughout the country. Three of the most irradiated guards were treated in France and four others in Germany to benefit from high-specialised treatment techniques.

- In Istanbul, Turkey, in 1998 two cobalt-60 sources in their shipping containers were sold as scrap metal. Ten persons were treated for acute radiation syndrome. Several months following the discovery of the event one of the two sources was still missing.

- In 1999 in Peru, an iridium-192 source intended for non-destructive material testing was left uncontrolled. An unaware worker put the source in its pocket and suffered severe radiation injuries. He was temporarily transferred in France to benefit from highly specialised treatment techniques.

Fortunately, no similar accidents causing deaths occurred in the European Union. However, their possibility cannot be completely ruled out. In May 1998, a caesium-137 source was accidentally melted in a steel factory in Spain. A substantial part of the activity was released to the atmosphere, the rest of the activity was retained in the dust collection systems and as a consequence 270 tons of steel became contaminated. About 400 people were monitored for internal contamination and six of them were found to have detectable levels of caesium contamination. Fortunately, the resulting doses were of no radiological concern. The economic consequences of the accident, including suspension of operation of the practices, decontamination operations and management of the resulting radioactive waste was estimated to the order of 26 million Euro. The origin of the source, whether it came from within the European Union or whether it was imported together with a consignment of metal scrap could not be assessed.

A study[21] reviewing the different management practices for sources in the EU estimated to a maximum of 70 those sources that are lost from regulatory control per year throughout the EU.

5. MAIN REASONS FOR WHICH SOURCES BECOME LOST FROM REGULATORY CONTROL

The reasons for which sources are lost from regulatory control in Member States may be grouped into the hereafter categories. The respective importance of each of these categories is very variable; however the lack of awareness of users, the absence of stringent regulations in the past, and the disappearance of the user are likely to be the three main reasons which could explain why sources are sometimes lost:

[21] See footnote 4

(1) **The lack of awareness** of users of sources about the risks that could occur if some unauthorised persons, workers or members of the public have access to the source. The consequences of this are: diminished control of sealed sources at users' premises, inadequate security during storage and/or disposal of sources.

(2) The **traceability** of sources and disused sealed sources is not assured in every step of their management from their manufacture or importation into a user's country up to their recycling, long-term storage and/or disposal.

(3) **The long-term storage and/or disposal** route for disused sources is variable from one Member State to another. In Member States where centralised storage facilities are available, storage and disposal services are generally charged to the users of sources. It is important to note that storage and disposal cost may reveal in some countries unexpectedly high, much higher than the purchase price of the radiation source itself. Therefore, users may be tempted to keep them in their own premises for undefined periods, increasing thereby the risks that sources are lost from regulatory control. Member States, which do not have available facilities for storage and disposal of disused sources on their territory, require the users to return disused sources to the supplier based abroad. In this case, the cost of storage and disposal may be included into the purchase price of the source.

(4) The user is no longer able to meet his responsibilities concerning the **management of sealed sources** (lack of management control following change of circumstances, bankruptcy, theft…etc). In this case, if there is no structure (e.g. network of users of sealed sources, state organisation, etc) capable of taking over the responsibility for managing sealed sources and disused sealed sources, accidental exposure is likely to occur.

(5) There was **no satisfactory regulatory system** in force when the sources were being supplied. This is mainly the case for historical sources (Radium-226) that were used in Member States up to the nineteen fifties.

6. REGULATORY FRAMEWORKS IN FORCE IN MEMBER STATES OF THE EUROPEAN UNION

All Member States of the European Union operate regulatory systems, which in particular require users of sealed sources to hold a licence.

In some cases, most regulatory attention is paid to assessing the competence of the prospective user before issuing a licence and thereafter, the amount of attention is limited. This means that the user should have suitably qualified staff and management systems. The management system should be able to ensure that the user knows the location of all sources at any time. In this context, regulatory efforts are placed on inspection of the users to make sure that this is the case.

In other cases, regulatory control is applied throughout the source life cycle, with particular attention being paid to approval of individual source transfers. The regulatory structures also vary considerably. In countries with small sealed sources markets, a single regulator is responsible for all aspects of the use and disposal of sealed sources. In larger states there may be multiple regulators sharing responsibilities on a regional or functional basis.

7. COMMUNITY ACTIONS

The European Commission is well aware of the possibility of accidents occurring with the mismanagement of high activity sealed radioactive sources.

Already in 1996 it organised a meeting with experts from the Member States to analyse the issue with particular attention to the possible presence of radioactivity in scrap metals. At that time, the prevailing attitude was to further industrial agreements on the quality and control of the incoming consignments of scrap metal, and to promote exchanges of information on the origin and movements of possibly contaminated consignments.

Both the national authorities and the operators intensified their controls and, as a consequence, the number of detection of radioactive sources in scrap metals continued to increase. A follow-up meeting on the subject was organised in 1999. In June 1999, the Council[22] concluded that there was a need for the European Union to develop common views to address the problems related to radioactive scrap metals and proper management of spent radioactive sealed sources.

For several years, the Commission services have been actively working in the field of the management of spent or disused sealed radioactive sources with the view to improving the safety of current management schemes in Member States[23] [24], in the Candidate countries as well as in the Russian Federation[25]. A technical workshop reviewing and analysing the management practices for spent sealed radioactive sources in Member States was held in June 1999 in Brussels. Recommendations drawn from this workshop have been taken into account.

This subject has been addressed also in the framework of the Community Plan of Action[26] in the field of radioactive waste.

[22] 2190th Council meeting – Luxembourg 14-15 June 1999
[23] See footnote 2
[24] See footnote 4
[25] J.M. Alardin et al. Management of sealed radioactive sources produced and sold in the Russian Federation. EUR report 18191 (1999)
[26] Council Resolution of 15 June 1992 on the renewal of the Community Plan of Action in the field of radioactive waste. OJ C158, 25.06.1992

APPENDIX A: USE OF RADIATION SOURCES (Table reproduced from "Methods to Identify and Locate Sealed Disused Sources", IAEA TECDOC 804, July 1995

Use of Radiation Sources in Industry

Application	Radionuclide	Half Life	Source Activity in GBq	Comments
Industrial Radiography	^{60}Co	5.3 y	100-5000	Often portable units.
	^{192}Ir	74 d	100-5000	
Moisture Detector	^{241} Am/Be	433 y	0.1-2	Portable units to measure moisture content /density. Normally contains both a neutron and gamma emitter.
	^{137}Cs	30 y	0.4	
Well Logging	^{241}Am/Be	433 y	1-800	Portable units.
	^{137}Cs	30 y	1-100	
Conveyor Gauge	^{137} Cs	30 y	0.1-40	Fixed installations to measure density of coal, silt or ores.
Density Gauge	^{137} Cs	30 y	1-20	Fixed installations to measure density of materials in a constant volume.
	^{241}Am	433 y	1-10	
Level Gauge	^{137}Cs	30 y	0.1 – 20	Fixed installations to measure level of materials in tanks, silos or packages.
	^{60}Co	5.3 y	0.1 – 10	
Thickness Gauge	^{85}Kr	10.8 y	0.1-50	Fixed installations to measure thickness of papers, plastic or similar materials.
	^{90}Sr	28.6 y	0.1-4	
Static Eliminators	^{241}Am	433 y	1-4	Fixed installations and portable units.
	^{210}Po	138 d	1-4	
Lightning preventers	^{241}Am	433 y	0.05-0.5	Fixed installations.

Electron capture detectors	^{63}Ni	100 y	0.2-0.5	Fixed or portable equipment.
	^{3}H	12.3 y	1-7.4	
X-ray fluorescence analyser	^{55}Fe	2.7 y	0.1-5	Often portable units to analyse alloys by simulating fluorescence X-rays.
	^{109}Cd	463 d	1-8	

Uses of Radiation sources in Industry (continued)

Application	Radionuclides	Half life	Source Activity in GBq	Comments
Sterilisation and food preservation	^{60}Co	5.3 y	10^5–$4x10^8$	Fixed installations (individual sources up to $6x10^5$ GBq).
	^{137}Cs	30 y	10^5–$4x10^8$	
Calibration facilities	^{60}Co	5.3 y	10^3 – 10^5	Fixed installations
	^{137}Cs	30 y		
Smoke detectors	^{241}Am	433 y	$2x10^{-5}$ – $3x10^{-3}$	Fixed (easily removed)
Dredgers	^{60}Co	5.3 y	1 – 100	Fixed installations for silt density measurements
	^{137}Cs	30 y	1 – 100	
Blast furnace control	^{60}Co	5.3 y	2	Fixed.

Use of Radiation Sources in Medicine

Application	Radionuclides	Half life	Source Activity in GBq	Comments
Bone densitometry	^{241}Am	433 y	1 – 10	Mobile Units.
	^{153}Gd	242 d	1 – 40	
	^{125}I	60 d	1 – 10	
Manual brachytherapy	^{137}Cs	30 y	0.05 - 0.5	Small portable sources.
	^{226}Ra	1600 y	0.03 - 0.3	
	^{60}Co	5.3 y	0.05 - 0.5	
	^{90}Sr	28.6 y	0.05 - 1.5	
	^{103}Pd	17 d	0.05 - 1.5	
	^{125}I	60 d	0.05 - 1.5	
	^{192}Ir	74 d	0.02 - 1.5	
	^{131}I	8 d	0.05 - 1.5	
	^{198}Au	2.7 d	0.05 - 1.5	
	^{252}Cf	2.6 d	0.05 - 1.5	
Remote afterloading brachytherapy	^{60}Co	5.3 y	10	Mobile units.
	^{137}Cs	30 y	$3x10^{-5}$ - 10^{-2}	
	^{192}Ir	74 d	400	
Teletherapy	^{60}Co	5.3 y	$5x10^{4}$ – 10^{6}	Fixed installations
	^{137}Cs	30 y	$5x10^{5}$	
Blood irradiation	^{137}Cs	30 y	$2x10^{3}$ – 10^{5}	Fixed installations.

Use of Radiation Sources in Research

Application	Radionuclide	Half life	Source Activity in GBq	Comments
Calibration sources	Many		< 0.1	Small portable sources.
Electron capture detector	^{3}H	12.3 y	1 – 50	Can be used in portable units and gas chromatograph detectors.
	^{63}Ni	100 y	0.2 – 0.5	
Irradiators	^{60}Co	5.3 y	$10^{3} – 10^{6}$	Fixed installations.
Calibration facilities	^{137}Cs	30 y	$<10^{5}$	Fixed installations.
	^{60}Co	5.3 y	$<10^{5}$	
	^{252}Cf	2.6 y	$<10^{5}$	
Tritium targets	^{3}H	12.3 y	$10^{3} – 10^{4}$	Fixed installations for neutron production by D.T reaction.

2003/0005 (CNS)

Proposal for a

COUNCIL DIRECTIVE

on the control of high activity sealed radioactive sources

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 (2) and 32 thereof,

Having regard to the proposal from the Commission[27], drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee, from among scientific experts in the Member States, in accordance with Article 31 of the Treaty establishing the European Atomic Energy Community,

Having regard to the opinion of the European Economic and Social Committee[28],

Having regard to the opinion of the European Parliament[29],

Whereas:

(1) Article 30 of the Euratom Treaty requires basic standards to be laid down within the Community for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

(2) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[30], continues the line of directives laying down basic safety standards since 1959.

(3) Directive 96/29/Euratom in Article 4 (1) (e) requires prior authorisation for, amongst other practices, the use of radioactive sources for industrial radiography or processing of products or research or the exposure of persons for medical treatment. It is appropriate to extend this requirement to all practices involving high activity radioactive sources, in order to further reduce the likelihood of accidents involving such sources.

[27] OJ C , , p.
[28] OJ C , , p.
[29] OJ C , , p.
[30] OJ L 159, 29.6.1996,p.1.

(4) The International Atomic Energy Agency (IAEA) issues regulations for the safe transport of radioactive material that include activity limits for the requirements of the regulations, which should provide an appropriate basis for defining high activity sealed radioactive sources within the scope of this Directive[31].

(5) In Directive 96/29/Euratom exemption values have been laid down for the reporting of a practice to the authorities. These values have been defined in that Directive on the basis of a negligible level of risk. As the requirements of this Directive should not put an administrative burden on the holders of small sources that is not commensurate to the possible health detriment, the definition of high activity radioactive sources should not be extended to the exemption levels of Directive 96/29/Euratom.

(6) Shipments of sealed sources between Member States are subject to the procedure established by Council Regulation (Euratom) N° 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States[32].

(7) Although the legal requirements deriving from existing legislation at Community and at national level ensure basic protection, high activity sources still imply considerable potential risks for human health and for the environment and therefore need to be subject to a strict control from the moment they are manufactured to the moment they are conferred to a recognised installation for their long-term storage or disposal.

(8) Prevention of radiological accidents and injuries requires that location of each high activity source is known, recorded and verified from the moment the source is manufactured or imported into the Community to the moment it is transferred to a recognised installation for its long term storage or its disposal or it is exported from the Community. Physical or financial obstacles should not hinder an appropriate reuse, recycling or disposal of such sources when disused under any reasonably foreseeable circumstances.

(9) Movements within the Community of high activity sources make it necessary to harmonise the control of such sources through the application of minimum criteria.

(10) The experience shows that, despite the existence of an appropriate regulatory framework, high activity sources may nevertheless get out of control. Furthermore, the existence of orphan sources resulting from past activities requires that specific initiatives be undertaken.

(11) Accordingly, it is necessary to provide for the identification, marking and record keeping of each high activity source as well as for specific training and information of all those involved in activities related to the use of sources. It is advisable to provide also appropriate training and information to those who may deal accidentally with orphan sources.

(12) It is also necessary to provide for suitable means of dealing with orphan high activity sources, for international cooperation and exchange of information in this area, for inspection and, finally, for making financial provision for the circumstances

[31] IAEA Safety Standards Series No TS R 1 (ST, Revised), Vienna, 2000
[32] OJ L 148, 19.6.1993, p. 1

in which the original holder either cannot be identified or, even if identified, is found to be insolvent.

(13) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented; those penalties must be effective, proportionate and dissuasive

HAS ADOPTED THIS DIRECTIVE:

Article 1
Purpose and scope

1. The purpose of this Directive is to prevent exposure to ionising radiation arising from inadequate control of high activity sealed radioactive sources and to harmonise controls in place in the Member States by setting out specific requirements ensuring that each such source is kept under control.

2. The Directive applies to high activity sources as defined in Article 2.

3. The obligations resulting from this Directive supplement those set out in Directive 96/29/Euratom.

Article 2
Definitions

For the purpose of this Directive, the following definitions shall apply:

(a) *High activity source* or *source* means a sealed source containing a radionuclide whose activity at the time of fabrication or of the first placing on the market is equal to or exceeds the relevant activity level specified in Annex I;

(b) *Authorisation* means a permission granted in a document by competent authorities, on application, to carry out a practice involving a high activity source;

(c) *Competent authority* means any authority designated by a Member State to carry out tasks under this directive;

(d) *Disused source* means a source which is no longer used, nor intended to be used, for the practice for which an authorisation was granted;

(e) *Holder* means any natural or legal person who is in possession of a source;

(f) *Manufacturer* means any natural or legal person who manufactures a source;

(g) *Orphan source* means a source which is not under regulatory control, either because it has never been under regulatory control, or because it has been abandoned, lost, misplaced, stolen or transferred without proper authorisation;

(h) *Recognised installation* means a facility located in the territory of a Member State authorised by the competent authorities of that Member State in accordance with national law for the long-term storage or disposal of high activity sources;

(i) *Reused source* means a source which is used by another user for the same or another practice;

(j) *Sealed source* has the meaning given to it by Directive 96/29/Euratom;

(k) *Supplier* means any natural or legal person who supplies or makes available a high activity source;

(l) *User* means any natural or legal person who uses a high activity source;

(m) *Transfer* of a high activity source means a transfer of a high activity source from one holder to another one.

Article 3
Authorisation

1. Member States shall require prior authorisation for any practice involving a high activity source.

2. Member States shall ensure that, before issuing an authorisation:

(a) arrangements have been made for the safe management of high activity sources, including when they become disused sources;

(b) financial provision has been made for the safe management of high activity sources when they become disused sources.

The financial provision referred to in point (b) of paragraph 2 may consist *inter alia* in:

(i) an institutionalised bank deposit under the control of the Member State;

(ii) an auditable provision made within an organisation's fiscal account;

(iii) an insurance provision used only when normal commercial processes fail.

3. Member States shall ensure that the authorisation covers:

(a) responsibilities;

(b) minimum staff competencies;

(c) minimum equipment performance criteria;

(d) requirements for emergency procedures and communication links;

(e) work procedures to be followed;

(f) maintenance of equipment and high activity sources;

(g) adequate management of disused high activity sources, including agreements regarding the possible transfer of disused sources to a supplier or a recognised installation.

Article 4
Transfers

Member States shall set up a system for the adequate control of individual transfers of high activity sources.

Article 5
Records

1. The competent authority shall maintain appropriate records of holders of authorisations, with a clear indication of the type(s) of such sources that they are authorised to hold. The competent authority shall also maintain appropriate records of the transfer and disposal of high activity sources on termination of authorisation.

2. The holder shall keep records of all high activity sources in his possession, their location and their transfer. The records shall be drawn up in compliance with the standard record sheet set out in Annex II as regards both the information contained and the format.

3. The holder shall notify forthwith the competent authority a copy of the records referred to in paragraph 2

   (a) at the time of opening of such records;

   (b) at intervals of 12 months thereafter;

   (c) at the closing of such records, when he no longer holds any sources and

   (d) whenever so requested by the competent authority.

   The holder's records shall be available for inspection by the competent authority.

4. The Commission may update the standard record sheet for the records set out in Annex II.

Article 6
Requirements for holders

Each holder of high activity sources shall:

(a) ensure that leak tests are undertaken regularly to check the integrity of each high activity source;

(b) regularly verify that each high activity source is present at its place of use or of storage;

(c) ensure that each fixed and mobile high activity source is subject to adequate measures to prevent unauthorised access to or loss, theft, fire and unlawful use of the source;

(d) promptly notify to the competent authority loss, theft, unlawful use of a high activity source and any event, including fire, that may have damaged the source;

(e) return or transfer each disused high activity source to a supplier or to a recognised installation unless otherwise agreed by the competent authority, without undue delay after termination of the use.

(f) ascertain before any transfer of a high radioactive source that the recipient holds an appropriate authorisation.

Article 7
Identification and marking

1. The manufacturer shall identify each high activity source by a unique number. Where practicable, the number shall be marked on the source.

The manufacturer shall mark and label the container, and where practicable, also the high activity sources, with an appropriate sign to warn people of the radiation hazard.

2. Member States shall ensure that each high activity source is accompanied by written information that the source is identified and marked in compliance with paragraph 1. The information shall include photographs of source, source container, transport packaging, device and equipment as appropriate.

Article 8
Training and information

1. When arranging training in the field of radiation protection in compliance with Article 22 of Directive 96/29/Euratom, the holder shall ensure that this training includes specific requirements on the safe management of high activity sources.

The training shall give particular emphasis to the necessary safety requirements and it shall contain specific information on possible consequences of loss of adequate control on high activity sources.

The training shall be addressed to the relevant workers using or handling high activity sources or being in the proximity of these sources.

The training shall be repeated at regular intervals.

2. Member States shall encourage that the management and the workers of installations where orphan high activity sources are most likely to be found or processed like large metal scrap yards and major metal scrap recycling plants, and the management and the workers of significant nodal transit points like custom posts, are

(a) informed of the possibility that they may be confronted with a high activity source;

(b) advised on the visual detection of high activity sources and of their containers;

(c) informed on basic facts about radioactivity and its effects;

(d) informed on the actions to be taken in the event of the detection or suspected detection of a high activity source.

Article 9
Orphan high activity sources

1. Member States shall ensure that the competent authorities are prepared, or have established provisions, including assignment of responsibilities, to recover orphan high activity sources and to deal with radiological emergencies and have established appropriate response plans and measures.

2. Member States shall ensure that specialised technical advice and assistance is promptly available to the persons, not normally involved in operations subject to radiation protection requirements, that suspect the presence of an orphan high activity source. The primary aim of advice and assistance shall be the radiation protection of workers and members of the public and the safety of the source.

3. Member States shall ensure the establishment of controls aimed at detecting orphan high activity sources. Such controls shall be performed in places where orphan sources may be encountered, like large metal scrap yards and major metal scrap recycling installations or at significant nodal transit points, like customs posts.

4. Member States shall ensure the organisation of campaigns for recovering orphan high activity sources, which are left behind from past activities.

   The campaigns may include financial participation of Member States in the costs of recovering, managing and disposing of the sources and surveys of historical records of authorities, like customs, and of holders, such as research institutes, material testing institutes or hospitals.

Article 10
International co-operation and information exchange

Each Member State shall exchange information and co-operate with other Member States or third countries and with relevant International Organisations as regards losses, removal, theft and discovery of high activity sources and as regards related investigations.

Article 11
Guarantee

Member States shall ensure the establishment of a system of guarantee for damage to human health caused by high activity sources as well as for the costs of interventions relating to them, in particular those intervention costs which may result from implementation of the

requirements set out in Article 9, so as to apprehend such situations as may arise from the impossibility of identifying a holder or where the holder is found to be insolvent.

Article 12
Inspections

Member States shall establish a system of inspection to enforce the provisions introduced in compliance with this Directive.

Article 13
Competent authority

1. Member States shall designate the competent authority to carry out tasks under this Directive.

2. Member States shall forward to the Commission by […….] at the latest, the name and the address of the competent authority and all necessary information for rapidly communicating with such authorities.

3. In the event that within a Member State several authorities are competent, Member States shall designate one point of contact to act as an interface with correspondents in other Member States.

4. Member States shall forward to the Commission any changes to data referred to in paragraphs 2 and 3.

5. The Commission shall communicate the information referred to in paragraphs 2, 3 and 4 to all competent authorities in the Community and shall publish it in the *Official Journal of the European Communities.*

Article 14
Report on experience

Five years after the date referred to in Article 17 (1), the Member States shall report to the Commission on the experience gained in the implementation of this Directive.

On that basis, the Commission shall present a report to the European Parliament, the Council and the European Economic and Social Committee.

Article 15
Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by the date specified in Article 16 (1) at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 16
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [……..] at the latest. They shall forthwith inform the Commission thereof.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main laws, regulations or administrative provisions, which they adopt in the field covered by this Directive.

Article 17
Transitory provision

As regards high activity sources put on the market before the date set out in Article 16, Articles 3, 4, 5 and 6 shall apply at the latest 24 months from that date.

Article 18
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities.*

Article 19

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

Activity levels

For radionuclides not listed in the table below, the relevant activity level is one hundredth of the corresponding A1 value given in the IAEA Regulations for the safe transport of radioactive materials, no TS-R-1 (ST-1, Revised) – International Atomic Energy Agency, Vienna 2000.

Element (Atomic number)	***Radionuclide***	***Activity level (Bq)***
Iron (26)	Fe-55	4×10^{11}
Cobalt (27)	Co-60	4×10^{9}
Selenium (34)	Se-75	3×10^{10}
Krypton (36)	Kr-85	1×10^{11}
Strontium (38)	Sr-90 (a)	3×10^{9}
Palladium (40)	Pd-103 (a)	4×10^{11}
Iodine (53)	I-125	2×10^{11}
Caesium (55)	Cs-137 (a)	2×10^{10}
Promethium (61)	Pm-147	4×10^{11}
Gadolinium (64)	Gd-153	1×10^{11}
Thulium (69)	Tm-170	3×10^{10}
Iridium (77)	Ir-192	1×10^{10}
Thallium (81)	Tl-204	1×10^{11}
Radium (88)	Ra-226(b)	2×10^{9}
Plutonium (94)	Pu-238 (a)	1×10^{11}
Americium (95)	Am-241(b)	1×10^{11}
Californium (98)	Cf-252	5×10^{8}

(a) the activity level includes contributions from daughter nuclides with half-lives less than 10 days;

(b) Includes neutron sources with beryllium

ANNEX II

STANDARD RECORD SHEET FOR HIGH ACTIVITY SOURCES (HAS) *(optional in italics)*

(1) HAS IDENTIFICATION NUMBER:	**(2) IDENTIFICATION OF AUTHORISED HOLDER** Name: Address: Country: Manufacturer: ☐ Supplier: ☐ User: ☐	**(3) LOCATION OF HAS** (USE OR STORAGE) Name: Address: Fixed use: ☐ Storage (mobile): ☐
(4) REGISTRATION Date of start of registration: Date of transfer of Registration to historic file:	**(5) AUTHORIZATION** *Number:* *Date of issue:* *Date of expiry:*	**(6) OPERATIONAL CONTROL OF HAS** Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐
(7) HAS CHARACTERISTIC Radionuclide: Activity at the date of manufacturing: Date of manufacturing: Manufacturer / Supplier[33]: Name: Address:	**(8) RECEIPT OF HAS** Date of receipt: Receipt from Name: Address: Country: Manufacturer: ☐ Supplier: ☐ Another user: ☐	Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐
Country: Physical and chemical characteristics: *Source type identification:* *Capsule identification:* *ISO classification:* *ANSI classification:* *Special form certificate:*	**(9) TRANSFER OF HAS** Date of transfer Transfer to: Name: Address: Country: Manufacturer: ☐ Supplier: ☐ Another user: ☐ Recognized installation: ☐	Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐ Date: Leak test: ☐ Location: ☐

[33] In case the manufacturer of the sources is established outside the Community, the name and address of the importer-supplier may be provided instead.