

**SECOND SUPPLEMENT TO THE GIBRALTAR
GAZETTE**

No. 3579 of 18 January, 2007

LEGAL NOTICE NO. 5 OF 2007.

HEALTH PROTECTION (IONISING RADIATION) ACT 1995

IONISING RADIATION (AMENDMENT) REGULATIONS 2007

In exercise of the powers conferred upon it by section 2 of the Health Protection (Ionising Radiation) Act 1995, and all other enabling powers, and in order to implement in Gibraltar Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources, the Government has made the following Regulations—

Title.

1. These Regulations may be cited as the Ionising Radiation (Amendment) Regulations 2007.

Amendment of Ionising Radiation Regulations 2004.

2.(1) The Ionising Radiation Regulations 2004 are amended in accordance with the provisions of this regulation.

(2) In regulation 6(1)—

(a) at the end of paragraph (d) for “,” substitute “;”; and

(b) after paragraph (d) insert—

“(e) the keeping, use, accumulation or disposal of a high activity source,”.

(3) After Part VII insert—

**“PART VIII
HIGH ACTIVITY SEALED RADIOACTIVE SOURCES AND
ORPHAN SOURCES**

Interpretation.

56.(1) In this Part–

“authorisation” means an authorisation granted under regulation 6 or regulation 57;

“existing high-activity source” means a high-activity source first placed on the market on or before 1 January 2006;

“the HASS Directive” means Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources;

“high-activity source” has the same meaning as it has in the HASS Directive but excluding any such source once its activity level has fallen below the exemption levels specified in column 2 of Table A to Annex I to the Directive reproduced in Schedule 9;

“orphan source” means a sealed source, the activity level of which, at the time of its discovery is above the exemption level referred to in Article 3(2)(a) of Directive 96/29/Euratom, and which is not under regulatory control (Article 3(2)(a) and Table A to Annex I of Directive 96/29/Euratom are reproduced for information purposes at Schedule 10).

(2) Unless otherwise stated, expressions used that appear in the HASS Directive have the same meaning in these Regulations as they do in the Directive.

Variation of authorisations.

57.(1) Subject to subregulations (2) and (5) where a person holds an authorisation in respect of any high-activity source and either–

- (a) intends to dispose of or accumulate, or keep and use, a high-activity source (other than an existing high-activity source) on or after the date these regulations come into operation; or
- (b) intends to dispose of or accumulate, or keep and use an existing high-activity source on or after 1st January 2008,

that person shall apply to the competent authority to vary his authorisation to enable the competent authority to ensure that the authorisation complies with

the relevant provisions of the HASS Directive and that person shall make that application in accordance with subregulation (3).

(2) The competent authority may notify a person to whom subregulation (1) applies–

- (a) that such person is not required to make an application under subregulation (1); or
- (b) if it is satisfied that in its opinion exceptional circumstances apply to that person, that such person may make an application within a period shorter than that provided for under subregulation (3).

(3) Except where notification is given under subregulation (2)(b), the application under subregulation (1) shall be made–

- (a) at least four months before the date the source is intended to be disposed of or accumulated; or
- (b) in the case of a high-activity source (other than an existing high-activity source) which is intended to be disposed of or accumulated within four months of these Regulations coming into operation, as soon as practicable and in any event at least two weeks before the date of intended disposal or accumulation of the source.

(4) If a person fails to make an application in accordance with subregulation (3) his authorisation shall be revoked by the competent authority in so far as it relates to the high-activity source in question.

(5) In considering an application under regulation 6(1)(e) or an application under subregulation (1) the competent authority must ensure that the application or authorisation complies with Articles 3(2) and (3) of the HASS Directive and that appropriate limitations and conditions are attached to the authorisation and where necessary that such authorisation is made subject to such limitations and conditions as are required for compliance with Articles 5(1) and (2), 6, 7(1) and (2) and 16(1)(b) of the HASS Directive.

Transfer of high activity source.

58. Where an application for the transfer of a high activity source is made under regulation 57 the competent authority shall impose such limitation or conditions to the authorisation as may be required to enable it to be informed of and keep adequate records of such transfers.

Site security.

59.(1) Where the following material is, or will be, kept, used, disposed of or accumulated on any premises—

- (a) high-activity sources; or
- (b) other sealed sources which, in the opinion of the competent authority, are of a similar level of potential hazard to high-activity sources,

the competent authority, in considering if the measures taken, or to be taken, by the applicant or person granted the authorisation ensure the adequate security of any premises, shall where it, considers it appropriate—

- (i) inspect those premises; and
- (ii) consult with the police and such other persons as it, or he, considers appropriate concerning the measures.

(2) Where subregulation (1) applies, the competent authority shall have regard to any advice it, receives from the police or other persons within such time as it believes is reasonable before—

- (a) determining the authorisation or effecting any variation or cancellation of the authorisation; or
- (b) imposing any limitations and conditions on the authorisation.

(3) Where the competent authority inspects any premises under subregulation (1) it may be accompanied by such other persons as are appropriate to assist it in assessing the measures.

(4) An applicant or person holding authorisation shall permit the competent authority (and any person accompanying them) reasonable access to any premises it, wishes to inspect under subregulation (1).

(5) If an applicant or person holding authorisation fails to comply with subregulation (4), the competent authority may refuse the application or cancel or revoke the authorisation insofar as it relates to the sources referred to in sub regulation (1).

Records and inspections.

60. The competent authority shall–

- (a) keep records of those matters–
 - (i) required by Articles 5(3) and (4) of the HASS Directive; and
 - (ii) notified to it, him or them under Article 6 of that Directive;

and

- (b) establish or maintain a system of inspections to enforce the provisions of Articles 3, 4, 5 and 6, and 7 (subject to Article 16(1)(b)) of the HASS Directive which must be complied with by persons holding authorisations.

Advice and assistance in respect of orphan sources.

61.(1) The competent authority shall ensure that–

- (a) in relation to the public and workers, specialised technical advice and assistance is promptly made available to such persons who are not normally involved in operations subject to radiation protection requirements and who suspect the presence of an orphan source; and
- (b) the primary aim of such advice and assistance is–
 - (i) the safety of the source; and
 - (ii) the protection of the public and workers from radiation.

Directions.

62. Where the Minister gives directions to the competent authority under this regulation for the purpose of implementing provisions of the HASS Directive the following requirements apply—

- (a) any direction shall be published in such manner as the Minister considers appropriate for the purpose of bringing the matters to which it relates to the attention of persons likely to be affected by it;
- (b) copies of a direction shall be made available to the public;
- (c) notice of a direction and of where a copy may be obtained shall be published in the Gazette;
- (d) no direction shall be varied or revoked unless, notwithstanding the variation or revocation, the provisions of the HASS Directive as they have effect for the time being which were implemented by that direction, continue to be implemented, whether by directions or any other instrument or by any enactment.

Recovery and disposal of orphan sources.

63.(1) The competent authority shall be prepared or have made provision, including assignment of responsibilities, to recover any orphan source and shall have drawn up appropriate response plans and measures.

(2) The competent authority shall have the power to recover any expenses reasonably incurred by it (or by a person on its behalf) in the recovery and disposal of an orphan source from the holder of that source or from the occupier or owner of the premises where the source is located.

(3) For the purposes of subregulation (2) “holder” means the person who is or is required to be authorised under these regulations in relation to that orphan source.”.

(4) After Schedule 8 insert the following schedules—

“Schedule 9

This schedule reproduces Annex I of Council Directive 2003/122/EURATOM of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

**ANNEX I
Activity levels**

For radionuclides not listed in the table below, but referred to in Annex I, Table A, of Directive 96/29/Euratom, the relevant activity level is one hundredth of the corresponding A1 value given in the IAEA Regulations for the safe transport of radioactive materials (1).

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 (46)	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.

(1) No TS-R-1 (ST-1, revised) — International Atomic Energy Agency, Vienna 2000.

Schedule 10

This Schedule reproduces Article 3(2)(a) and Table A to Annex 1 of Directive 96/26/Euratom.

Article 3

2. No reporting need be required for practices involving the following:

- (a) radioactive substances where the quantities involved do not exceed in total the exemption values set out in column 2 of Table A to Annex I or, in exceptional circumstances in an individual Member State, different values authorized by the competent authorities that nevertheless satisfy the basic general criteria set out in Annex I.

Table A

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
H-3	10 ⁹	10 ⁶
Be-7	10 ⁷	10 ³
C-14	10 ⁷	10 ⁴
O-15	10 ⁹	10 ²
F-18	10 ⁶	10
Na-22	10 ⁶	10
Na-24	10 ⁵	10
Si-31	10 ⁶	10 ³
P-32	10 ⁵	10 ³
P-33	10 ⁸	10 ⁵
S-35	10 ⁸	10 ⁵
Cl-36	10 ⁶	10 ⁴
Cl-38	10 ⁵	10
Ar-37	10 ⁸	10 ⁶
Ar-41	10 ⁹	10 ²
K-40	10 ⁶	10 ²
K-42	10 ⁶	10 ²
K-43	10 ⁶	10
Ca-45	10 ⁷	10 ⁴
Ca-47	10 ⁶	10

Sc-46	10 ₆	10
Sc-47	10 ₆	10 ₂
Sc-48	10 ₅	10
V-48	10 ₅	10
Cr-51	10 ₇	10 ₃
Mn-51	10 ₅	10
Mn-52	10 ₅	10
Mn-52m	10 ₅	10
Mn-53	10 ₉	10 ₄
Mn-54	10 ₆	10
Mn-56	10 ₅	10
Fe-52	10 ₆	10
Fe-55	10 ₆	10 ₄
Fe-59	10 ₆	10
Co-55	10 ₆	10
Co-56	10 ₅	10
Co-57	10 ₆	10 ₂
Co-58	10 ₆	10
Co-58m	10 ₇	10 ₄
Co-60	10 ₅	10
Co-60m	10 ₆	10 ₃
Co-61	10 ₆	10 ₂
Co-62m	10 ₅	10
Ni-59	10 ₈	10 ₄
Ni-63	10 ₈	10 ₅
Ni-65	10 ₆	10
Cu-64	10 ₆	10 ₂
Zn-65	10 ₆	10
Zn-69	10 ₆	10 ₄
Zn-69m	10 ₆	10 ₂
Ga-72	10 ₅	10
Ge-71	10 ₈	10 ₄
As-73	10 ₇	10 ₃
As-74	10 ₆	10
As-76	10 ₅	10 ₂
As-77	10 ₆	10 ₃
Se-75	10 ₆	10 ₂
Br-82	10 ₆	10
Kr-74	10 ₉	10 ₂
Kr-76	10 ₉	10 ₂

Kr-77	10 ₉	10 ₂
Kr-79	10 ₅	10 ₃
Kr-81	10 ₇	10 ₄
Kr-83m	10 ₁₂	10 ₅
Kr-85	10 ₄	10 ₅
Kr-85m	10 ₁₀	10 ₃
Kr-87	10 ₉	10 ₂
Kr-88	10 ₉	10 ₂
Rb-86	10 ₅	10 ₂
Sr-85	10 ₆	10 ₂
Sr-85m	10 ₇	10 ₂
Sr-87m	10 ₆	10 ₂
Sr-89	10 ₆	10 ₃
Sr-90 +	10 ₄	10 ₂
Sr-91	10 ₅	10
Sr-92	10 ₆	10
Y-90	10 ₅	10 ₃
Y-91	10 ₆	10 ₃
Y-91m	10 ₆	10 ₂
Y-92	10 ₅	10 ₂
Y-93	10 ₅	10 ₂
Zr-93 +	10 ₇	10 ₃
Zr-95	10 ₆	10
Zr-97 +	10 ₅	10
Nb-93m	10 ₇	10 ₄
Nb-94	10 ₆	10
Nb-95	10 ₆	10
Nb-97	10 ₆	10
Nb-98	10 ₅	10
Mo-90	10 ₆	10
Mo-93	10 ₈	10 ₃
Mo-99	10 ₆	10 ₂
Mo-101	10 ₆	10
Tc-96	10 ₆	10
Tc-96m	10 ₇	10 ₃
Tc-97	10 ₈	10 ₃
Tc-97m	10 ₇	10 ₃
Tc-99	10 ₇	10 ₄
Tc-99m	10 ₇	10 ₂
Ru-97	10 ₇	10 ₂

Ru-103	10 ₆	10 ₂
Ru-105	10 ₆	10
Ru-106 +	10 ₅	10 ₂
Rh-103m	10 ₈	10 ₄
Rh-105	10 ₇	10 ₂
Pd-103	10 ₈	10 ₃
Pd-109	10 ₆	10 ₃
Ag-105	10 ₆	10 ₂
Ag-108m +	10 ₆	10
Ag-110m	10 ₆	10
Ag-111	10 ₆	10 ₃
Cd-109	10 ₆	10 ₄
Cd-115	10 ₆	10 ₂
Cd-115m	10 ₆	10 ₃
In-111	10 ₆	10 ₂
In-113m	10 ₆	10 ₂
In-114m	10 ₆	10 ₂
In-115m	10 ₆	10 ₂
Sn-113	10 ₇	10 ₃
Sn-125	10 ₅	10 ₂
Sb-122	10 ₄	10 ₂
Sb-124	10 ₆	10
Sb-125	10 ₆	10 ₂
Te-123m	10 ₇	10 ₂
Te-125m	10 ₇	10 ₃
Te-127	10 ₆	10 ₃
Te-127m	10 ₇	10 ₃
Te-129	10 ₆	10 ₂
Te-129m	10 ₆	10 ₃
Te-131	10 ₅	10 ₂
Te-131m	10 ₆	10
Te-132	10 ₇	10 ₂
Te-133	10 ₅	10
Te-133m	10 ₅	10
Te-134	10 ₆	10
I-123	10 ₇	10 ₂
I-125	10 ₆	10 ₃
I-126	10 ₆	10 ₂
I-129	10 ₅	10 ₂
I-130	10 ₆	10

I-131	10 ₆	10 ₂
I-132	10 ₅	10
I-133	10 ₆	10
I-134	10 ₅	10
I-135	10 ₆	10
Xe-131m	10 ₄	10 ₄
Xe-133	10 ₄	10 ₃
Xe-135	10 ₁₀	10 ₃
Cs-129	10 ₅	10 ₂
Cs-131	10 ₆	10 ₃
Cs-132	10 ₅	10
Cs-134m	10 ₅	10 ₃
Cs-134	10 ₄	10
Cs-135	10 ₇	10 ₄
Cs-136	10 ₅	10
Cs-137 +	10 ₄	10
Cs-138	10 ₄	10
Ba-131	10 ₆	10 ₂
Ba-140 +	10 ₅	10
La-140	10 ₅	10
Ce-139	10 ₆	10 ₂
Ce-141	10 ₇	10 ₂
Ce-143	10 ₆	10 ₂
Ce-144 +	10 ₅	10 ₂
Pr-142	10 ₅	10 ₂
Pr-143	10 ₆	10 ₄
Nd-147	10 ₆	10 ₂
Nd-149	10 ₆	10 ₂
Pm-147	10 ₇	10 ₄
Pm-149	10 ₆	10 ₃
Sm-151	10 ₈	10 ₄
Sm-153	10 ₆	10 ₂
Eu-152	10 ₆	10
Eu-152m	10 ₆	10 ₂
Eu-154	10 ₆	10
Eu-155	10 ₇	10 ₂
Gd-153	10 ₇	10 ₂
Gd-159	10 ₆	10 ₃
Tb-160	10 ₆	10
Dy-165	10 ₆	10 ₃

Dy-166	10 ₆	10 ₃
Ho-166	10 ₅	10 ₃
Er-169	10 ₇	10 ₄
Er-171	10 ₆	10 ₂
Tm-170	10 ₆	10 ₃
Tm-171	10 ₈	10 ₄
Yb-175	10 ₇	10 ₃
Lu-177	10 ₇	10 ₃
Hf-181	10 ₆	10
Ta-182	10 ₄	10
W-181	10 ₇	10 ₃
W-185	10 ₇	10 ₄
W-187	10 ₆	10 ₂
Re-186	10 ₆	10 ₃
Re-188	10 ₅	10 ₂
Os-185	10 ₆	10
Os-191	10 ₇	10 ₂
Os-191m	10 ₇	10 ₃
Os-193	10 ₆	10 ₂
Ir-190	10 ₆	10
Ir-192	10 ₄	10
Ir-194	10 ₅	10 ₂
Pt-191	10 ₆	10 ₂
Pt-193m	10 ₇	10 ₃
Pt-197	10 ₆	10 ₃
Pt-197m	10 ₆	10 ₂
Au-198	10 ₆	10 ₂
Au-199	10 ₆	10 ₂
Hg-197	10 ₇	10 ₂
Hg-197m	10 ₆	10 ₂
Hg-203	10 ₅	10 ₂
Tl-200	10 ₆	10
Tl-201	10 ₆	10 ₂
Tl-202	10 ₆	10 ₂
Tl-204	10 ₄	10 ₄
Pb-203	10 ₆	10 ₂
Pb-210+	10 ₄	10
Pb-212+	10 ₅	10
Bi-206	10 ₅	10
Bi-207	10 ₆	10

Bi-210	10 ₆	10 ₃
Bi-212+	10 ₅	10
Po-203	10 ₆	10
Po-205	10 ₆	10
Po-207	10 ₆	10
Po-210	10 ₄	10
At-211	10 ₇	10 ₃
Rn-220+	10 ₇	10 ₄
Rn-222+	10 ₈	10
Ra-223+	10 ₅	10 ₂
Ra-224+	10 ₅	10
Ra-225	10 ₅	10 ₂
Ra-226+	10 ₄	10
Ra-227	10 ₆	10 ₂
Ra-228+	10 ₅	10
Ac-228	10 ₆	10
Th-226+	10 ₇	10 ₃
Th-227	10 ₄	10
Th-228+	10 ₄	1
Th-229+	10 ₃	1
Th-230	10 ₄	1
Th-231	10 ₇	10 ₃
Th-232sec	10 ₃	1
Th-234+	10 ₅	10 ₃
Pa-230	10 ₆	10
Pa-231	10 ₃	1
Pa-233	10 ₇	10 ₂
U-230+	10 ₅	10
U-231	10 ₇	10 ₂
U-232+	10 ₃	1
U-233	10 ₄	10
U-234	10 ₄	10
U-235+	10 ₄	10
U-236	10 ₄	10
U-237	10 ₆	10 ₂
U-238+	10 ₄	10
U-238sec	10 ₃	1
U-239	10 ₆	10 ₂
U-240	10 ₇	10 ₃
U-240+	10 ₆	10

Np-237+	10 ₃	1
Np-239	10 ₇	10 ₂
Np-240	10 ₆	10
Pu-234	10 ₇	10 ₂
Pu-235	10 ₇	10 ₂
Pu-236	10 ₄	10
Pu-237	10 ₇	10 ₃
Pu-238	10 ₄	1
Pu-239	10 ₄	1
Pu-240	10 ₃	1
Pu-241	10 ₅	10 ₂
Pu-242	10 ₄	1
Pu-243	10 ₇	10 ₃
Pu-244	10 ₄	1
Am-241	10 ₄	1
Am-242	10 ₆	10 ₃
Am-242m+	10 ₄	1
Am-243+	10 ₃	1
Cm-242	10 ₅	10 ₂
Cm-243	10 ₄	1
Cm-244	10 ₄	10
Cm-245	10 ₃	1
Cm-246	10 ₃	1
Cm-247	10 ₄	1
Cm-248	10 ₃	1
Bk-249	10 ₆	10 ₃
Cf-246	10 ₆	10 ₃
Cf-248	10 ₄	10
Cf-249	10 ₃	1
Cf-250	10 ₄	10
Cf-251	10 ₃	1
Cf-252	10 ₄	10
Cf-253	10 ₅	10 ₂
Cf-254	10 ₃	1
Es-253	10 ₅	10 ₂
Es-254	10 ₄	10
Es-254m	10 ₆	10 ₂
Fm-254	10 ₇	10 ₄
Fm-255	10 ₆	10 ₃

”

Dated this 18th day of January, 2007.

J NETTO,

Minister for the Environment.

EXPLANATORY MEMORANDUM

These Regulations make provision in connection with the implementation of Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources (the HASS Directive) and make relevant amendments to the Ionising Radiation Regulations 2004 (“the Ionising Regulations”).

High-activity sources as defined in Article 2 of the HASS Directive are radioactive material and as such are regulated under the Ionising Regulations. High-activity sources for the purposes of these Regulations do not include such sources once their activity level has fallen below the exemption levels specified in column 2 of Table A to Annex I to Council Directive 96/29/EURATOM

High-activity sources first placed on the market on or before 31st December 2005 are referred to in these Regulations as existing high-activity sources.

Regulation 57 provides for applications for variation of authorisations concerning high-activity sources. The competent authority will consider if any variation of the registration is required to comply with the HASS Directive. Failure to make an application as required means that the registration is revoked so far as it relates to the high-activity source in question.

Regulation 59 imposes requirements in relation to premises where high-activity sources and other sources will be kept, used, disposed of or accumulated.

Regulation 60 provides for the competent authority to keep various records and to establish or maintain a system of inspections to enforce the provisions of the HASS Directive.

Regulation 61 provides for specialised technical advice and assistance to be made available in connection with the presence of orphan sources.

Regulation 62 makes provision for the Minister to give directions to the competent authority for the purposes of implementing the HASS directive.

Regulation 63 provides for the competent authority to comply with Article 9(1) of the HASS Directive in relation to the recovery of orphan sources. It also provides that the costs and expenses of recovery and disposal of orphan sources may be recovered from the holder of the source or from the occupier or owner of the premises where the source is located.

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