

**Government Gazette**

Vol. , No. , 3 August 1973

Regulation Gazette, No.1822

No. R. 184, 2002

**PROCLAMATION**

by the President of the Republic of South Africa

**DATE OF THE COMMENCEMENT OF THE PUBLIC HEALTH AMENDMENT ACT, 1971 (ACT 42 OF 1971)**

Under the powers vested in me by section 2 of the Public Health Amendment Act, (Act 42 of 1971), I hereby declare that the provisions of the said Act 42 of 1971 shall come into operation on the date of publication hereof.

Given under my hand and Seal of the Republic of South Africa at Durban this Sixth day of July, One thousand nine hundred and seventy-three.

J.J FOUCHÉ,  
State President.

By Order of the State President-in-Council:

S.W.VAN DER MERWE

**Government Gazette**

Vol. , No. , 3 August 1973

Regulation Gazette, No. 1822

No. R. 1332

**DEPARTMENT OF HEALTH****PUBLIC HEALTH AMENDMENT ACT, 1971 (ACT 42 OF 1971)****REGULATIONS CONCERNING THE CONTROL OF ELECTRONIC PRODUCTS**

The Minister of Health has, in terms of section 1 of the Public Health Amendment Act, 1971(Act 42 of 1971), made the following regulations which shall apply with effect from the date of publication hereof:

**DEFINITIONS**

In these regulation-

1. "absorbed dose (D)" means the quotient of  $E_g$  by  $\Delta m$ , where  $\Delta E_d$  is the energy imparted by ionising radiation to matter in a volume element and  $\Delta m$  is the mass of the matter in that volume element:

$$D = \frac{\Delta E_d}{\Delta m}$$

The rad is the unit of absorbed dose and is equivalent to  $0,01\text{J}(\text{kg})^{-1}$  (11)

2. "added filter" means the filter added to the inherent filtration; (5)
3. "adequate protection" means protection against external radiation in such a way that the dose equivalent received by any person from sources external to the body does not exceed the: maximum permissible doses or dose limits. (as applicable) allowed by these regulations: (42)
4. "adequate, shielding" means, in relation to any building or apparatus housing a listed electronic product, shielding against ionising radiation by the use of lead or other suitable material as appropriate or by distance in such a way that the exposure at any point on the outer surface of such shielding or on the perimeter of any demarcating barrier around such building or product is such, that the maximum permissible doses or dose limits (as applicable) allowed by these-regulations, cannot be exceeded; (41)
5. "aluminium equivalent" means the thickness of aluminium affording the same 'attenuation to a beam of radiation under specified conditions as the material in question; (2)
6. "applicant" means a person applying for a licence or an endorsement of a licence pursuant to regulation II.3 (a): (3)
7. "appointed medical practitioner" means a person registered with the South African Medical and Dental Council as a medical practitioner and designated in terms of regulation III.5 (a) (3): (1)
8. "dose equivalent (DE)" means the product of absorbed dose (D) and the quality factor (OF):

$DE = D \times QF$

The rem is the unit of dose equivalent and is numerically equal to the absorbed dose in rads multiplied by the quality factor. (7)

9. "dose limit" means the maximum dose equivalent that the body or any specific part of the body of a member of the public shall be permitted to receive in a stated period of time; and for the purpose of these regulations the latest dose limit values recommended by the JCRP (details of which are obtainable from the Secretary) shall apply; (8)
10. "enclosed installation" means an installation where the listed electronic product and all objects exposed to ionising radiation produced by such product are permanently within the same enclosure or room described in the premises licence and within which either-
  - i. no person is permitted to remain during radiation exposure; or
  - ii. patients and/or authorised persons may remain during exposure provided that adequate shielding so as to ensure adequate protection is available inside the enclosure; (18)
11. "exposure (X)" is the quotient of  $\Delta Q$  by  $\Delta m$  where  $\Delta Q$  is the sum of the electric charges on all ions of one sign produced in air when all the electrons (negatrons and positrons), liberated by photons in a volume element of air of which the mass is  $\Delta m$ , are completely stopped in air. The unit of exposure is the roentgen (R):

$1\text{R} = 2,58 \times 10^{-4}\text{C}(\text{kg})^{-1}$  (4)

12. "external radiation" means radiation received by the body from radiation sources external to it; (45)
13. "focus-to-skin distance , (FSD)" means the distance from the focal spot of the tube to the skin of the patient being treated; (10)
14. "given dose" means the absorbed dose at the maximum for one radiation field irradiating a phantom; (12)
15. "half value layer (HVL)" means the thickness of an absorber required to attenuate the incident radiation to half the original intensity; (16)
16. "holder" means any individual, corporation, partnership firm, association, trust estate, public or private institution, group or agency who or which is in control of a listed electronic product, and to whom or which a licence was issued in terms of regulation 11.2; (17)
17. "inherent filter." means the filter permanently in the useful beam, and includes the window of the X-ray tube and any permanent tube enclosure; (19)
18. "inspector" means a person referred to in section 133A (1) (g) of the Act; (20)
19. "installation" means a listed electronic product with associated equipment and the space in which it is located; (21)
20. "interlock" means a device for precluding access to an area of radiation hazard by automatically removing the hazard upon entry thereto by a person; (15)
21. "International Committee on Radiological Protection (ICRP)" means the international body of experts in the fields of radiology, radiation protection, physics, biology, genetics, biochemistry and biophysics functioning since 1928 under the auspices of the International Congress of Radiology. The ICRP prepares, reviews and publishes recommendations for the promotion of effective radiation protection;

- (22)
22. "ionising radiation" means radiation emanating from a listed electronic product, capable of producing ions directly or indirectly in its passage through matter;
23. "isodose curves" means curves joining points in a phantom having the same percentage depth dose; (24)
24. "listed electronic product" means an electronic product listed in Annexum F; (13)
25. "maximum permissible dose (MPD)" means the maximum dose equivalent that the body of a radiation worker or specific parts of the body shall be permitted to receive in a stated period of time, and for the purpose of these regulations the latest values of MPD recommended by the ICRP (details of which are obtainable from the Secretary) shall apply; (27)
26. "medical physicist" means a person who is registered as such by the South African Medical and Dental Council and whose certificate of registration as a medical physicist with the Council has been endorsed to the effect that he is competent to practise as a radiation medical physicist; (14)
27. "member of the public" means any person who is not registered as a radiation worker in terms of regulation 111.4 (a); (26)
28. "modification" means an alteration which increases the danger in use as related to the emission of electronic product radiation; and "modify" has a corresponding meaning; (47)
29. "open installation" means an installation where the listed electronic product and all objects exposed to ionising radiation produced by such product are not permanently within the same enclosure or room and are confined to an area designated as the radiation area in a premises licence. (29)
30. "patient" means a human being subjected to diagnostic or therapeutic procedures for reasons;
31. "percentage depth dose" means the ratio of the absorbed dose ( $D_d$ ) at a depth ( $d$ ) to the absorbed dose at the maximum ( $D_m$ ) measured on the central axis of a radiation field irradiating a phantom:

$$\frac{D_d}{D_m} \times 100;$$

Percentage depth dose =

32. "percentage depth dose table" means a table indicating for a specified FSD and a specified radiation quality the percentage depth doses for different field sizes at different depths; (33)
33. "phantom" means a tissue-equivalent medium used to simulate the absorption and scatter characteristics of a patient's body; (9)
34. "premises licence" means a licence referred to in regulation 11.2 (b); (31)
35. "process" means any operation involving the production emission or use of ionising radiation excluding that from radioactive materials; (35)
36. "product, licence" means 'a licence referred to in regulation 11.2 (a); (34)
37. "quality factor (QF)" means the ability of a particular type of ionising radiation to produce damage (details of which are obtainable from the Secretary); (25)
38. "radiation" means ionising radiation; (37)
39. "radiation hazard" means a condition under which persons might receive radiation in excess of the applicable maximum permissible dose or dose limit; (38)
40. "radiation occurrence" means a single event or series of events 'occurring' in the course of the use of a listed electronic product which has resulted in injurious or potentially injurious exposure of any person to ionising radiation as a direct result of the use of that product; (39)
41. "radiation worker" means any person who is potentially exposed to ionising radiation as a result of his occupation and who has been registered in terms of regulation III.4 (a); (39)
42. "register" means the register of radiation workers referred to in regulation II.4 (a); (36)
43. "responsible person" means the person nominated by the holder pursuant to regulation III-3 (e); (46)
44. "Service" means the personnel monitoring service referred to in regulation III.5 (c)(1); (6)
45. "time chart" means a chart indicating for a specified radiation quality the exposure times required with different field sizes to yield specified given dose at a specified FSD; (44)
46. "total filter" means the sum of the inherent and added filters; (43)
47. "useful beam" means any ionising radiation from a listed electronic product that can be employed for the purpose for which such product is used; (28)
48. "X-ray unit" means an electronic product which is designed, manufactured or assembled with the primary purpose of producing X-rays or which utilises X-rays to accomplish its primary purpose and from which such emissions are intended.

## II LICENCES ISSUED BY THE SECRETARY

### II.1 Applicability

The provisions of this regulation are applicable to any person who uses, modifies or disposes of a listed

electronic product.

## II.2 Licences

- a. No person shall use a listed electronic product unless, such product has been licensed by the Secretary subject to such.. Conditions as he may impose. This licence shall be called a "product licence".
- b. No-person shall use listed electronic product on any-premises unless such premises have been licensed by the. Secretary. subject to such conditions as he may impose. This licence shall be called a "premises licence".
- c. No person shall modify or dispose of a licensed electronic product or modify any licensed premises or the type of or layout of equipment including the electronic product on any such premises, except by approval of the Secretary who shall endorse the relevant licence accordingly.

## II.3 Application,for a licence or an endorsement of a licence

- a. An application for a .licence or an endorsement of a licence in terms of regulation II.2. shall be submitted to the Secretary on.the forms shown in Annexures A and B, respectively, not more than `90 days following the effective date' of these regulations or not less than 90 days prior to the expected date of performing the function contemplated, whichever is later.
- b. The applicant shall furnish the Secretary on Form G 6/10, shown in Annexure D, with any other relevant information regarding radiation dangers that he may be aware of at any time after an application has been filed and that could possibly influence the issue, withdrawal or suspension of such a licence pursuant to regulation III.2(b).

## II.4 Granting of a licence

- a. The. Secretary before granting or endorsing a licence may require an oral representation or an inspection in loco by an inspector or both such oral representation and inspection. The Secretary shall give the applicant written notice to that effect, specifying the place where, and the time when, the applicant shall have an opportunity to make such oral representation and/or the date and time when the applicant shall be personally available for an inspection in loco:
- b. If the Secretary refuses to grant or endorse a licence he shall-give the applicant written notice to that effect, stating-
  1. the reason(s) for his refusal:
  2. the conditions, if any subject to which the licence or endorsement shall be granted:
  3. the latest date on which objections by the applicant may be submitted.
- c. If two or more listed electronic products are in the opinion of the Secretary, situated near enough to-one another to be regarded as one installation, he may, for the purpose of the granting of a premises licence, regard the sites upon which they are situated as one site.
- d. The Secretary may grant a temporary licence authorising the use of a listed electronic product or premises in respect of which an application has been filed, until a licence or endorsement is granted or the applicant is notified pursuant to paragraph (b) of the Secretary's refusal to grant a licence or endorsement.

## III. CONDITIONS SUBJECT TO WHICH LICENCES MAY BE ISSUED

### III.1. Applicability

The provisions of this regulation are applicable to applicants and holders of licences issued in terms of these regulations.

### III.2. Provisions regarding licences

- a. A licence issued in terms of regulation III.2 shall apply only to the holder to whom the licence was issued.
- b. Any licence issued in terms of regulation III may be suspended or withdrawn by the Secretary if
  1. the holder or any of his radiation workers is found guilty of an offence in terms of these regulations;
  2. he considers it in a case of emergency to be in the public interest.
- c. Any licence issued in terms of regulation II.2 shall remain in effect until request for cancellation, or temporary or permanent\* transfer thereof is approved by the Secretary. If a licence has been cancelled

the holder shall return it to the Secretary within 30 days following the date of such cancellation.

- d. In addition to other relevant, provisions a licence granted pursuant to regulation II.2 shall clearly entitle the holder, to use a listed electronic product or licensed premises for a specified purpose only.

### III.3: Provisions regarding applicant and licence holder

- a. An act or omission of any person which constitutes an offence under these regulations shall be deemed to be the act or omission of the holder unless he proves-
1. that he did not permit or connive at such act or omission; and
  2. that he took all reasonable measures to prevent an act or omission of the nature in question; and
  3. that an act or omission, whether legal or illegal, of the nature in question did not under any conditions or in any circumstances fall within the course of the work or the scope of the authority of the person concerned.
- b. The holder shall be liable for the entire scope of radiation protection with regard to a listed electronic product or premises for which he holds a licence. Such liability shall relate to any aspect that could reasonably be included under radiation protection, and, in addition to other relevant responsibilities which the Secretary may specify in the licence, shall include-
1. effective protection organisation and continual conscientious regard for optimum methods of working with particular reference to routine operations;
  2. technical investigations to ensure reliability and overall technical excellence of equipment, buildings and interlocks;
  3. the display of appropriate warning signs or notices which are easily intelligible to all persons, at the entrances to or at appropriate places in, all areas where persons may enter and may be exposed to ionising radiation;
  4. ensuring that radiation workers and members of the public are subjected to minimal risks from radiation exposure, and that the maximum permissible doses and dose limits are not exceeded.
- c. The applicant shall satisfy the Secretary as to his knowledge and or experience regarding the-
1. basic principles of radiation protection in general; as well as
  2. specific aspects of radiation protection as applicable to the installations under his control.
- d. An applicant who-
1. is unable to comply with the provisions of paragraph (c); or
  2. finds it more appropriate
- may nominate in the application for a licence a medical Physicist or any other person or persons to be approved by the Secretary who comply with the provisions of paragraph (c) to execute on behalf of the holder the holder's obligations, under the applicable licence and who shall be referred to as the "responsible person".
- e. The responsible person shall receive designation as such, in writing, from the holder, which shall provide that-
1. it will remain in effect until any request for withdrawal or replacement thereof is approved by the Secretary;
  2. the responsible person is exclusively responsible to the holder of the licence for the fulfilment of his obligations under the designation.
- f. Any applicant for or holder of a licence or nominated or designated responsible person shall; if required by the Secretary, submit himself for examination by a person or committee authorised thereto by the Secretary to order to determine whether such person complies with the provisions of paragraph (c).
- g. The holder shall permit an inspector to inspect licensed electronic products and premises and to inspect and take copies of applicable registers, books, records, papers and documents which may assist in determining whether the holder is complying with these regulations.
- h. If so required by the inspector the holder or his responsible person shall accompany such inspector on the inspection.

### III.4 Provisions regarding radiation workers

- a. Every holder shall keep a register (hereinafter referred to as his "register") in which all persons who as a result of their occupation are potentially exposed to radiation from a listed electronic product for which he holds the licence and who, in accordance with the latest applicable recommendations of the ICRP: are regarded by the holder as radiation workers or trainee radiation workers shall be registered as such. The register shall comprise--
1. the reports furnished by the Service in accordance with regulation III.5 (c) (d); and
  2. a record of registration for every registered person consisting of-
    - i. Form G 6/8 shown in Annexure C; and -
    - ii. the results of the medical examinations, prescribed in regulation III.5 (b), entered on Form

G 6/9 shown in Annexure C.

- b. Every holder shall within 90 days following the date of issue of the applicable licence, furnish the Secretary with a copy of Form G 6/8 (Annexure Q) in respect of each radiation worker whose name appears in his register.
- c. Every holder shall immediately notify the Secretary of any change in his register due to the termination, for whatever reason and period, of the registration of a radiation worker or due to the registration or re-registration of a radiation worker. Such notification shall be on Form G 6/8 shown in Annexure C.
- d. A radiation worker shall, on the termination of his registration with a holder, be furnished with a record of service on Form G 6/8 shown in Annexure C.
- e. Prior to re-registration as a radiation worker a person shall furnish the record referred to in paragraph (d) and any other details, regarding radiation work done by him to the holder-
  1. for his consideration and assurance that there are no objections arising from previous radiation work to further registration of such a person as radiation worker, and
  2. for entry in his register.
- f. The record of registration of every radiation worker kept in the register pursuant to paragraph (a) shall-
  1. be preserved for a period of 10 years from the date of the last entry and made available for inspection in accordance with regulation IM (g);
  2. if required by the Secretary, be forwarded to him within 30 days following the date of suspension withdrawal or cancellation of a licence pursuant to regulation III.2 (b) and (c).
- g. Every holder shall ensure that-
  1. only persons registered as radiation workers pursuant to paragraph (a) are with his approval potentially exposed to radiation from listed electronic products for which he holds the licence, if the conditions are such that the resulting doses might exceed  $\frac{3}{10}$  of the annual maximum permissible doses;
  2. any person potentially exposed to radiation from a listed electronic product the licence for which is held by another holder shall notwithstanding the provisions of subparagraph (1) be registered by him as a radiation worker;
  3. no radiation worker exposes himself or is exposed to ionising radiation from a listed electronic product for which he holds the licence without adequate protection; and
  4. in cases of emergency, no person receives a dose from a listed electronic product for which he holds the licence in excess of the maximum permissible dose currently recommended by the International Commission on Radiological Protection for emergency exposure, details of which are obtainable from the Secretary.
- h. Every holder shall-
  1. immediately report to the Secretary on Form G 6/10 shown in Annexure D all suspected radiation occurrences reported or otherwise known to him;
  2. jointly with his responsible person if applicable, and appointed doctor examine the circumstances of the exposure and the possible effects on a person concerned and decide on the action to be taken.
- i. Every holder shall satisfy himself that any person who registers as radiation worker pursuant to paragraph (a)
  1. is not known to be medically unfit at the time of registration and while so registered;
  2. is at the time of registration not known to be pregnant and that if such a radiation worker while so registered notifies the holder pursuant to regulation IV.2 (e) (1) that she has become pregnant, or if her pregnancy becomes evident her registration is terminated;
  3. has adequate knowledge and experience to operate and is fully conversant with health and safety measures and operating instructions applicable to the listed electronic products under his control.
- j. A radiation worker who does not comply with the provisions of paragraph (i) (3) shall be regarded as a trainee radiation worker and shall operate a listed electronic product or be exposed to radiation whilst working with such product, only under supervision of a radiation worker who complies with the provisions of paragraph (i) (3),
- k. The registration of a person as radiation worker shall be terminated by the holder if-
  1. the radiation worker does not, comply with, the requirements of regulation IV.2;
  2. he deems it necessary in the interests of radiation safety measures; or
  3. the Secretary deems it necessary in the interests of radiation safety measures.
- l. If the Secretary disapproves of the continued registration of a person as radiation worker he shall notify the holder and such person, in writing, stating-
  1. the reason(s) therefore;
  2. the condition(s); if any, subject to which registration need not be terminated;
  3. the date of termination, if applicable;
  4. the latest date on which representations by the holder or the radiation worker may be submitted.

### III.5 Provisions regarding medical control and monitoring of radiation workers

- a. The appointed medical practitioner-
  1. A medical practitioner shall be nominated as the appointed medical practitioner in the application for a licence.
  2. If the holder of the licence is a medical practitioner, he may nominate himself .
  3. If the nomination is approved by the Secretary the appointed medical practitioner shall be named in the licence and receive designation as such in writing, from the holder.
  4. Such designation shall provide that-
    1. it will remain in effect until the nomination of a successor is approved by the Secretary;
    2. the appointed medical practitioner shall be responsible only to the holder for the radiation medical control of radiation workers and for advice to the holder regarding the necessity for suspension of a person's registration as radiation worker for radiation medical reasons;
    3. the appointed medical practitioner shall enter under his signature the information required in the register;
    4. the appointed medical practitioner be conversant with the general harmful effects of ionising radiation and versed in all aspects of diagnosing such effects.
  5. More than one medical practitioner may be nominated and designated as appointed medical practitioner.
- b. Medical examinations and tests of radiation workers.-
  1. No person shall be registered or re-registered as radiation worker unless within a period of 30 days immediately preceding his registration or re-registration he has been examined by the appointed medical practitioner and certified medically fit for registration by signed entry in the register.
  2. The holder shall arrange for every person registered as & -radiation worker to be examined by the appointed medical practitioner-
    - i. at intervals of not more than 14 months during the course of his registration as such;
    - ii. when a radiation occurrence- is suspected or has been established;
    - iii. if the appointed medical practitioner deems it necessary, after notification in terms of regulation IV.2 (e);
    - iv. at such other times as the holder or the Secretary may deem necessary.

The results of such examinations shall be recorded in the register.

3. In the case of a person registered as a radiation worker by more than one holder the medical examinations referred to in subparagraphs (1) and (2) may be done by only one of the appointed medical practitioners of the holders involved from whom the other holders shall then obtain copies of the results of such examinations for inclusion in their registers pursuant to' regulation III.4 (a) (2) (ii).
- c. **Monitoring of radiation workers.-** Every holder shall ensure that-
    1. his radiation workers be monitored by a Personnel Monitoring Service previously approved by the Secretary and hereinafter referred to as the "Service" Information regarding the Service may be obtained from the Secretary;
    2. in addition to any other monitoring equipment every radiation worker always, during working hours, wears a film badge or equivalent monitoring device supplied by the Service;
    3. film badge films are replaced by the Service-
      - i. at regular intervals not exceeding 32 days; and
      - ii. whenever a radiation occurrence is suspected or has been established;
    4. the radiation dose represented by the results of the examination of each film badge is furnished by the Service to him for inclusion in his register and the accumulated dose of a radiation worker, for completion of item (10d) of Form G 6/8 shown in Annexure C, is received on request from the Service;
    5. pocket dosimeters, having full scale deflections of not more than 250 milliroentgens are available and worn by radiation workers whose working conditions are such that-
      - i. they are liable to be exposed to whole body irradiation in excess of 20 millirems during any one day; or
      - ii. the Secretary deems it necessary.
    6. radiation workers are provided with such other appropriate monitoring equipment as the Secretary may require;
    7. pocket dosimeters and other monitoring equipment are read at suitable intervals not exceeding five days during use and the readings entered in the register
    8. pocket dosimeters and 'any other monitor in equipment prescribed by the Secretary are calibrated and tested by a medical physicist, or a person or institution approved by the Secretary-
      - i. before being brought into use;- and
      - ii. after repairs;

and that such calibrations are checked at regular intervals not exceeding 14 months while in use and the instrument- recalibrated if a check shows evidence a variation in output of more than approximately 10 per cent;

9. a record of the date and result of every calibration and check done in terms of sub and certified by the person or institution therefore is kept for a period of five years

### III.6 Provisions regarding patients

Every holder of a licence for a listed electronic product used for medical purposes shall ensure that-

- a. exposure of human beings to a useful beam is permitted only for strictly necessary medical purposes and after ascertaining that there has been no previous radiological examination which would make further examination unnecessary;
- b. the exposure of and the exposed area on the patient are limited to the lowest value compatible with successful diagnosis or therapy;
- c. in all diagnostic and therapeutic irradiations every effort is made to keep the gonad skin and integral dose at the lowest possible values consistent with clinical requirements;
- d. appropriate special precautions are taken in the irradiation of persons under the age of 18 years women of reproductive age and pregnant women on whom only essential examinations shall be done;
- e. his radiation workers using such product are, in addition to having the technical knowledge required in terms of regulation III.4 (i) (3) fully, conversant with currently accepted principles and techniques to minimise radiation hazards to patients and that such workers in fact take advantage of such techniques and any improvements thereof, literature references of which are obtainable from the Secretary;
- f. a record is kept of every patient exposed to radiation from : an electronic product for which be it the holder of the licence. Such record shall be preserved for a period of five years from the-date of the last entry and include the information shown in Annexure E:
- g. every electronic product licensed for diagnostic examinations bears a technique chart, where appropriate, indicating the technique factors (tube potential, tube current and exposure time or the product of tube current and re time) applicable to each of the examinations= falls within the scope of its licence;
- h. every electronic product licensed for therapeutic application is-
  1. calibrated by a medical physicist or a person or institution approved by the Secretary before being brought into use and after repairs that such calibrations are checked at 'regular intervals not exceeding three months in the course ' of use and the product recalibrated if a' check shows evidence of a variation in output of more than approximately 5 per cent;
  2. provided with an appropriate set(s) of isodose curves or percentage depth dose table(s), indicating the percentage depth dose for the different field sizes to be used;
- i. the medical physicist or other person referred to in paragraph (h) (1), on completion of every check and calibration respectively furnishes him with a dated signature on the existing time chart or an appropriate time chart duly signed and dated each time chart with signatures and dates as required, shall be retained by the holder for a period of 12 months from the date of the last signature as record of such checks and calibration;
- j. radiation dosimeters used in the performance of calibrations pursuant to paragraph (h) (1) are calibrated and tested in accordance with procedures prescribed for monitoring equipment in regulation III.5 (c) (8) and (9)

### III.7 Provisions regarding the exposure of human beings to a useful beam for non-medical purposes

- a. Unless permission is granted in the-product licence the,exposure of human beings to a useful beam for non medical purposes shall not be allowed, except in the case of essential examinations undertaken for the purpose of law enforcement-
  1. by the Department of Police;
  2. by a person empowered to carry out a search pursuant to the provisions of section 123 of the Precious Stones Act, 1964 (Act 73 of 1964); in which cases the following provisions shall apply:
    - i. Only an electronic product licensed b the Secretary for medical diagnostic examinations shall be used
    - ii. The signed approval of the holder shall be obtained for undertaking the process.
    - iii. The Process shall be carried out in accordance with the provisions of the regulations regarding
- b. When an electronic product is licensed for the exposure of human beings to the useful beam for routine non-medical purposes such exposure shall be subject to the following provisions:
  1. For members of the public the process shall be carried out in accordance with all the relevant provisions of the regulations regarding patients



2. For a special group(s) of workers the process shall be carried out in accordance with all the relevant provisions of the regulations regarding radiation workers.

#### **IV. CONDITIONS FOR REGISTRATION AS RADIATION WORKERS**

##### **IV.1 Applicability**

The provisions of this regulation are applicable to persons being registered as radiation workers and to radiation workers.

##### **IV.2, Registration requirements**

Every person referred to in subregulation 1 shall-

- a. in addition to the record referred to in regulation III:4 (d) furnish the holder with any other relevant information including-
  1. that of pregnancy she may be aware of; and
  2. any other radiation work that he may be involved in at the date of registration or at any time thereafter.
- b. in the course of his registration practise effective radiation protection in accordance with currently recognised national and international radiation protection guidelines, details of which are the holder;
- c. at anytime during his registration as such submit himself for examination by a person or committee authorised thereto by the Secretary in order to determine whether he complies with the provisions of regulation 111.4 (i) (3);
- d. notify the holder immediately he suspects that a radiation occurrence has taken-place;
- e. notify the holder immediately she suspects that-
  1. she is pregnant;
  2. her health has been or might be adversely affected by occupational factors;
- f. co-operate with the holder in the application of the regulations and comply, with requirements which apply to him,

#### **ANNEXURE E**

##### **DEPARTMENT OF HEALTH**

##### **INFORMATION TO BE INCLUDED IN THE RECORD REQUIRED IN TERMS OF REGULATION III.6 (f)**

**(This information may be included in the patient's medical record) Identification:**

1. Surname
2. Names
3. Date of birth. (If not available, estimated age)
4. Sex

Radiation procedure:

5. Date or period
6. Diagnostic or therapeutic
7. Briefly state the clinical indications for undertaking the radiation examination or treatment.
8. For diagnostic examination:
  - a. The type of diagnostic procedure followed, e.g.. Radiography, Fluoroscopy or Photofluorography.
  - b. Number of exposures (if applicable).
  - c. Briefly state the diagnostic information obtained from the examination.
9. For radiotherapy:
  - a. Type of radiation.
  - b. Quality of radiation.
  - c. Radiation output of product.
  - d. For every radiotherapy treatment a radiation treatment plan of a description of such a plan including the following informations
    - i. Number of radiation fields.
    - ii. Field sizes.

- iii. Maximum tumour dose (if applicable)
- iv. Minimum tumour dose (if applicable).
- v. Maximum tissue dose.

## **ANNEXURE F**

### **DEPARTMENT OF HEALTH**

#### **LISTED ELECTRONIC PRODUCTS**

1. Diagnostic X-ray units.
2. Therapeutic X-ray units.
3. X-ray volts used for industrial, research, educational or any other purposes.
4. Electron accelerators.
5. Heavy particle accelerators.
6. Neutron generators.