REGULATIONS CONTROLLING MEDICAL USE OF RADIO-ACTIVE ISOTOPES

In Government Notice No. 1650 of 7 September 1956 the following regulations made by H.E. the Governor General under section 31 of the Atomic Energy Act No. 35 of 1948, as amended, are gazetted under the title 'Regulations in connection with the Use of Radio-active Isotopes for Medical Purposes'.

REGULATIONS

1. In these regulations—

(*a*) 'A-dose' means a dose greater than 50 microcuries or a dose consisting of an isotope with a half-life longer than 30 days;

(*b*) 'B-dose' means a dose equal to or less than 50 microcuries and consisting of an isotope with a half-life of 30 days or less; or such dose consisting of a specific radio-active isotope and having such maximum activity as the Atomic Energy Board may specifically approve;

(*c*) 'qualified hospital physicist' means a person who—

(i) holds a degree of Master of Science in physics, and has obtained 1 year's training in clinical hospital physics at a training institution or hospital approved for this purpose by the Atomic Energy Board; or

(ii) holds an honours degree of Bachelor of Science in physics, and has gained 2 year's training in clinical hospital physics at an institution approved for this purpose by the Atomic Energy Board; or

(iii) holds a degree of Bachelor of Science in physics and has undergone such training or gained such experience as the Atomic Energy Board may deem equivalent to the requirements set out in (i) and (ii) above;

(*d*) 'qualified radiotherapist' means a person who—

(i) holds a degree or diploma in radiotherapy which is recognized by the Atomic Energy Board; or

(ii) holds a recognized degree or diploma in radiology which includes training in both diagnosis and therapy, on condition that the person concerned shall produce documentary evidence that he or she has gained a further full year's experience in the therapeutic application of radio-active isotopes at an institution approved by the Atomic Energy Board; or

(iii) holds qualifications in radiology, when the person concerned can produce evidence to the satisfaction of the Atomic Energy Board that he has undergone training and gained experience which is equivalent to the requirements set out in sub-paragraphs (i) and (ii) above;

(*e*) 'committee' means the committee of control over the use of radio-active isotopes established by the Board in terms of section 14 of the Act;

(*f*) 'Board' means the Atomic Energy Board, as established in terms of section 11 of Act No. 35 of 1948;

(*g*) 'radio-active isotopes' means the radio-active isotopes of any element other than radium and its disintegration products;

(*h*) 'Act' means the Atomic Energy Act, No. 35 of 1948, as amended by Act No. 18 of 1952, as further amended by Act No. 11 of 1956.

2. The Board shall issue to every person recognized by it as a qualified radio-therapist or qualified hospital physicist a certificate to the effect that he has been recognized as such.

3. The Board may grant to hospitals and institutions a general authority to administer A-doses, on condition that the hospital

or institution appoint a local committee of control over the use of radio-active isotopes, such committee to be constituted as follows:

(*a*) Chairman: The head of the department of radiology or the head of the department of radiotherapy, where such departments are organized separately.

(*b*) Member: A qualified radiotherapist.

(*c*) Member: A qualified hospital physicist.

(*d*) Member: A pathologist.

(*e*) Member: A physician.

The first-mentioned 3 members shall constitute the executive of the local committee of control and shall be responsible for the daily decisions in respect of the use and handling of radio-active isotopes at the hospitals or institutions.

4. The appointment of each member of a local committee of control shall be approved by the Board in writing.

5. With the approval of the Board a hospital or institution may nominate a qualified radiotherapist who is in its part-time service as a member of the local committee of control.

6. Before a general authority can be granted to a hospital or institution it shall have at its disposal the services of a full-time qualified hospital physicist.

7. The Board shall have the power, where it may deem it necessary, to require the appointment of an additional qualified hospital physicist before it grants or renews an authority.

8. Before the Board grants an authority in terms of regulation 3, it shall satisfy itself that the hospital or institution has at its disposal the necessary equipment and facilities for the safe and efficient handling, storage, removal or disposal of radio-active isotopes.

9. The Board may, where it deems it necessary, for the safe and efficient use, handling, storage and removal or disposal of radio-active isotopes, by means of written notice of at least 30 days, require the hospital or institution to improve or enlarge its equipment and/or facilities.

10. There shall be placed at the disposal of the qualified hospital physicist a room in which he can handle, store, monitor, assize or dispose of small quantities of radio-active isotopes. This room shall be protected against any interference from external stray irradation while small (tracer) quantities of radio-active isotopes, which have been administered to patients, are monitored.

11. The qualified hospital physicist shall also be provided with a room to the satisfaction of the Board for the handling of large quantities of radio-active isotopes.

12. All survey instruments and dosimeters shall be calibrated at least once in every 6 months by a person or institution authorized thereto by the Board.

13. The calibrating officer or institution shall issue to the hospital or institution in whose use the instruments are, a certificate whereon the survey instruments and/or dosimeters which have been calibrated by him are shown, as well as the date of the calibration.

14. Patients in whose bodies the equivalent of an A-dose is contained, shall be accommodated in separate wards, exclusively reserved for such patients. The Board shall be empowered in the case of certain treatments which may be prescribed, to grant exemption from this regulation.

15. The wards mentioned in regulation 14 shall, to the satisfaction of the Board, be equipped with facilities for the storage and disposal of radio-active isotopes, the storage of clean and radio-active bedpans, bottles and other equipment, and for the handling of dirty linen and contaminated articles.

16. The wards shall provide sufficient protection to staff members against external irradation.

17. All persons working with radio-active isotopes shall be provided with pocket dosimeters as well as film badges obtainable from the film badge service of the C.S.I.R.

18. All local control committees shall annually, on 30 September, submit to the Board a report containing the following information:

(*a*) Particulars of the radio-active sources in the possession of the institution.

(*b*) Particulars of the equipment and hospital facilities available.

(*c*) Particulars of the medical practices followed in the different therapeutic administrations at the institution.

(*d*) Particulars of the physical practices followed, including the method of standardizing equipment.

(*e*) A list of the members of the local committee of control.

19. A qualified radiotherapist in private practice may be authorised by the Board to administer A-doses at a hospital or institution on condition that it is done under the supervision of the local committee of control appointed at the institution or hospital in terms of regulation 3.

20. (*a*) The Board may grant limited authorities for the administration of A-doses to institutions, firms or qualified radiotherapists in private practice where they are not able to establish a local committee of control as required by regulation 3, on condition, however, that—

(i) the medical administration of the radio-active isotope is done under the direct control of a qualified radiotherapist; and

(ii) a qualified hospital physicist is available on a full-time basis.

(*b*) Where the Board is satisfied that the administration of A-doses can be undertaken with the assistance of a part-time qualified physicist, an authority may be granted on such conditions as the Board may deem fit.

21. Limited authorities for the administration of A-doses shall be subject to such of the conditions laid down in regulations 8, 10, 12, 13, 14, 15, 16, 17 and 18 as the Board may determine.

22. Authorities to administer B-doses may be granted by the Board where it has been satisfied that the applicant has at his disposal the necessary equipment and accommodation facilities for the proper handling, storage and disposal of radio-active isotopes.

23. The Board, shall, as prescribed by section 15 of the Act, appoint a suitably qualified person to carry out inspections of the premises and equipment of applicants for and holders of authorities to hold and use radio-active isotopes, in order to determine whether the equipment and/or accommodation comply with the provisions of these regulations and generally whether they are suitable and efficient for the proper and safe handling of radio-active isotopes.

24. The officer referred to in regulation 23 shall have the right at all reasonable times to enter the premises of applicants for or holders of authorities in order to determine whether the accommodation facilities are suitable, the equipment suitable and efficient, as well as to observe whether the practice employed in the administration of radio-active isotopes complies with the provisions of these regulations and, in general, is safe.

25. Any applicant for an authority or any of his employees who handles radio-active isotopes shall if required by the Board, submit himself for examination by the Board or a person authorised thereto by the Board in order to determine whether the applicant or any of his employees possess the necessary knowledge and/or experience to handle radio-active isotopes.

26. The Board shall cause to be compiled guides regarding the practice to be followed, as well as lists of the minimum requirements of equipment and facilities which it deems necessary for the handling of radio-active isotopes. These guides and lists shall be attached by the Board to each authority or renewal of an authority issued by it.

27. Any authority issued in terms of these regulations may be cancelled by the Board—

(*a*) where the institution or any of its employees contravenes any provision of these regulations; or

(*b*) where, owing to unforeseen circumstances or conditions, the cancellation of the authority is considered by the Board to be in the public interest.

28. All authorities granted in terms of these regulations shall lapse on 30 September of each year, and all holders of authorities must, at least 30 days before the authorities lapse, apply for the renewal thereof.

29. Any person who contravenes these regulations or fails to comply with them, shall be deemed to have contravened or failed to have complied with a condition upon which an authority has been granted to him under section 3 of the Act, and shall be subject to the penalties prescribed by section 33 of the Act.