

Health and Safety Executive OC 483/9

Field Operations Division

To

Factory Inspectors

Senior/Employment Medical Advisers

FCG Specialist Inspectors (Elec)

THE ELECTRO-MEDICAL EQUIPMENT (EEC REQUIREMENTS) REGULATIONS 1988

Introduction

1 This OC introduces the above Regulations which came into force on 11 October 1988. The Regulations implement European Council Directive No 84/539/EEC relating to electro-medical equipment which is intended by its nature for use in human or veterinary medicine. It is a defence in legal proceedings or in an appeal against a notice if the supplier can prove conformity with the Directive although this may not extend to maintenance of the equipment.

Background

2 The Regulations were proposed by DHSS, in consultation with HSE and others, and made by the Secretary of State for Health. They are enforced by local authority trading standards officers but they provide a defence against proceedings under HSW Act.

3 The effect of the Regulations is to extend the application of the Trade Descriptions Act 1968 to electro-medical equipment listed in Annex II to the Directive itself (essentially a fairly comprehensive list of diagnostic and therapeutic equipment used in hospitals). This means that where any person supplies electro-medical equipment which is marked with a reversed epsilon sign as depicted in Annex III of the Directive or to which a declaration of conformity as found in Annex IV has been applied, an offence is committed if the equipment does not comply with the technical requirements contained in Annex I of the Directive. (Essentially the CENELEC harmonization document HD 395-1 based on IEC standard No 601-1).

4 In order to comply with the Directive it is necessary to ensure that the sale, free movement and use of the equipment covered is not refused, prohibited or

restricted on grounds of safety. To this end, reg.5(1) provides that it shall be a defence in any proceedings against a person for an offence under any of the relevant statutory provisions (as defined by HSW Act s.53) which imposes requirements on grounds of safety relating to the manufacture of electro-medical equipment for use at work, to show that equipment conforms with the requirements of the Directive.

5 Regulation 5(2) covers the eventuality of such equipment becoming the subject of an appeal against a notice before an industrial tribunal. It should be noted that these defence provisions mirror the Directive itself in that they are confined to "...grounds of safety relating to the manufacture of electro-medical equipment".

6 This last point is stressed because it has been observed that IEC Standard No 601-1 is unsatisfactory with regard to the degree of protection it extends to those engaged in, or affected by equipment maintenance. Regulation 5 should not prevent enforcement under HSW Act against those with duties relating to such activities.

Action

7 SGPA 4 would like to be advised, through the usual divisional channels, of any problems arising from the existence of either the Directive or the Regulations.

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ASI headings

Electrical equipment: Electro-Medical Equipment (EEC Requirements) Regulations 1988: hospitals: veterinary.