

تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواء كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 62) "فريق عمل مواصفات الأجهزة الكهربائية في التطبيقات الطبية" بتبني المواصفة الدولية رقم (IEC 61331-3:2014) " أجهزة الحماية ضد الأشعة السينية الطبية التشخيصية - الجزء 3: ملابس الحماية وأجهزة الحماية للأعضاء التناسلية " ، والتي أصدرتها " المنظمة الدولية الكهروتقنية " وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم () والذي عقد بتاريخ (..../..../20 م).

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs).SFDA medical devices sector through the work program of technical committee (SFDA/MDS/TC 62) "Electrical Equipment in Medical Practice Standards" has adopted Identically Standard No. (IEC 61331-3:2014) "Protective devices against diagnostic medical X-radiation - Part 3: Protective clothing and protective devices for gonads", issued by "International electrotechnical Commission" in its original language. This standard is adopted identically in its original language and has been approved as national standard by SFDA board of directors in its meeting No () Held on (// AH) , agreed with (// G).

Scope

IEC 61331-3:2014 applies to protective devices such as protective clothing and eyewear for the protection of persons against X radiation up to 150 kV, during radiological examinations and interventional procedures. This standard deals with general requirements on the accompanying documents, on design and on materials used and with sizing, particular design features, minimum attenuation properties of materials, marking and standardized forms of statements of compliance with this standard. It covers protective clothing mainly for the protection of the operator, such as:

- protective aprons;
- thyroid collars;
- protective gloves;
- protective mittens; and
- protective eyewear. It also covers protective devices for the protection of the patient, such as:
 - protective gonad aprons;
 - scrotum shields;
 - ovary shields;
 - shadow shields; and
 - protective aprons for dental use. The latter group of protective devices is intended to be used during radiological examinations to minimize the effects of irradiation on the reproductive organs particularly with regard to genetic damage. This second edition cancels and replaces the first edition of IEC 61331-3, published in 1998. It constitutes a technical revision. This second edition has been adapted to apply to the present technology. It includes a requirement to use a better method for the determination of attenuation properties over a broader and more clinically relevant range of radiation qualities appropriate to the use of the devices. It also covers three additional protective devices, thyroid collars, protective eyewear and protective aprons for dental use

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