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NOTIFIKAZZJONI TAL-GVERN

GOVERNMENT NOTICE

Nru. 99

No. 99

MINISTERU TAS-SAHHA, L-ANZJANI U KURA FIL-KOMUNITÀ

MINISTRY FOR HEALTH, THE ELDERLY AND COMMUNITY CARE

Standards biex tiġi Assigurata l-Kwalità u Sigurtà tad-Demm Uman u Komponenti Tiegħu

Standards to Ensure Quality and Safety of Huma Blood and Blood Components

NGHARRFU b'din illi l-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità qiegħed hawnhekk jistabbilixxi *standards* sabiex tiġi assigurata l-kwalità u s-sigurtà tad-demm uman u ta' komponenti tad-demm sabiex ikun hemm livell għoli ta' protezzjoni tas-sahha umana.

IT is notified that the Minister for Health, the Elderly and Community Care is hereby establishing standards in order to ensure the quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.

Il-principji għandhom japplikaw għal għbir u ttestjar tad-demm uman u ta' komponenti tad-demm, hu x'inhu l-użu maħsub tagħhom, u għall-ipproċessar, il-ħażna u d-distribuzzjoni meta jkunu intiżi għal trasfużjoni.

The standards shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion.

Fejn id-demm u komponenti tad-demm huma miġbura u ttestjati biss sabiex ikunu użati esklussivament fi trasfużjoni awtologa, u jkunu mmarkati b'mod ċar għal dak il-ghan, il-htigiet li għandhom ikunu sodisfatti għandhom ikunu daww imsemmija f' Artikolu 29(g) tad-Direttiva 2002/98.

Where blood and blood components are collected and tested for the sole purpose and exclusive use in autologous transfusion and are clearly identified as such, the requirements to be complied with in respect thereof shall be in accordance with those referred to in Article 29(g) of Directive 2002/98.

Is-Supretendent tas-Sahha Pubblika, bhala l-awtorità regolatorja, qiegħed ikun magħruf bhala l-awtorità kompetenti responsabbli li tassigura l-implimentazzjoni tal-htigiet tad-Direttiva 2002/98 u li tassigura li l-attivitajiet relatati mal-għbir u ttestjar tad-demm uman u komponenti tad-demm, hu x'inhu l-użu tagħhom, u l-preparazzjoni, il-ħażna u d-distribuzzjoni, meta intiżi għat-trasfużjoni, isiru biss mill-istabbilimenti tad-demm li jkunu ġew magħrufa minnu għal dak il-ghan.

The Superintendent of Public Health, as the regulatory authority, is hereby being designated as the competent authority responsible for ensuring the implementation of the requirements of Directive 2002/98 and to ensure that the activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated by him for that purpose.

Twaqqaf direttorat fl-uffiċċju tas-Segretarju Permanenti

A directorate has been established under the office of the

tas-Sahha. Il-funzjoni ta' dan id-direttorat hija li jamministra l-istabbiliment tad-demmm. Dan ta' l-ahhar ghandu jkun minn naħa tiegħu mmexxi minn persuna responsabbli magħrufa skond kif imsemmi fid-Direttiva msemmija. Id-dmirijiet tal-persuna responsabbli huma daww imsemmi fid-Direttiva.

Fejn ghandu x'jaqsam il-persunal, daww involuti direttament fil-ġbir, ittestjar, ipproċessar, hażna u distribuzzjoni tad-demmm u man u komponenti tad-demmm iridu jkunu kwalifikati sabiex jagħmlu dak ix-xogħol u għandhom ikunu mħarrġa regolarment u dan skond l-Artikolu 10 tad-Direttiva.

Huwa mahsub illi sa Novembru 2005, l-istabbilimenti tad-demmm ikunu stabbiliti u qed iżommu sistema ta' kwalità bbażata fuq il-principji ta' Prattika tajba, jstabbilixxu u jżommu dokumentazzjoni fuq proċeduri operazzjonali, linji gwida, taħriġ u manwali ta' riferenza, u formali ta' rapporti skond Annessi II u IV tad-Direttiva.

Is-sistema mħaddma mill-istabbilimenti tad-demmm għandha tkun f'pożizzjoni li tidentifika kull donazzjoni ta' demmm u kull unità waħdanija ta' demmm u komponenti tad-demmm sabiex tagħti lok li jiġi individwalizzat id-donatur kif ukoll it-trasfużjoni u min ikun irċieva d-demmm. Is-sistema għandha mingħajr ebda żball tidentifika kull donazzjoni unika u t-tip ta' komponent tad-demmm. Is-sistema għandha tkun stabbilita skond il-htigiet imsemmi f'Artikolu 29(a). Dan japplika wkoll għal demmm impurtat minn pajjiżi terzi.

Is-sistema użata għall-ittikkettjar tad-demmm u komponenti tad-demmm, u komponenti tad-demmm miġbura, ittestjati, ipproċessati, mahżuna, u rilaxxati, u jew imqassma f'Malta għandhom ikunu konformi mas-sistema ta' identifikazzjoni msemmija aktar 'il fuq u l-htigiet ta' ttikkettjar imnizzlin f'annex III tad-Direttiva.

Fl-interess tas-Sahha Pubblika stabbilimenti tad-demmm magħrufa għandhom:

- skond l-Artikolu 15(1) tad-Direttiva jirraportaw lill-awtorità kompetenti kull każ avvers u gravi (inċidenti u żbalji) relatat mal-ġbir, ittestjar, ipproċessar, hażna u distribuzzjoni tad-demmm u komponenti tad-demmm li jista' jaffettwa l-kwalità u s-sigurtà tal-prodott, kif ukoll kull reazzjoni avversa u serja li tkun ġiet osservata waqt jew wara t-trafuzzjoni li tkun tista' tiġi attribwita għall-kwalità u sigurtà tad-demmm jew komponenti tad-demmm. In-notifika ta' kull każ u reazzjoni avversa u serja għandha tkun skond il-mod preskritt fl-Artikolu 29(i),

- ikollhom stabbilita proċedura eżatta, effiċjenti u ta' verifika

Permanent Secretary for Health. The function of this directorate is to administer the blood establishment. The latter shall be in turn be managed by a designated responsible person in terms of the aforementioned Directive. The duties of the responsible person are those mentioned in the Directive.

As far as personnel are concerned those directly involved in collection, testing, processing, storage, and distribution of human blood and blood components need to be qualified to perform those tasks and be provided with timely relevant and regularly updated training and this in terms of Article 10 of the Directive.

It is envisaged that by November, 2005 blood establishments have established and maintain a quality system based on the principles of good practice, keep and maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms in line with Annexes II and IV of the Directive.

The system operated by blood establishments needs to be capable of identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a). This applies also to blood imported from third countries.

The system used for the labelling of blood and blood components blood and blood components collected, tested, processed, stored, released, and/or distributed in Malta needs to comply with the identification system referred to above and the labelling requirements listed in annex III of the Directive.

In the interest of public health designated blood establishments must:

- In accordance with Article 15(1) of the Directive report any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority. The notification of any serious adverse event and reaction has to be in accordance with the format prescribed under Article 29(i),

- have in place a procedure accurately efficiently and

ghall-irtirar mid-distribuzzjoni ta' demm u komponenti tad-demmm assoċjati man-notifika msemmija hawn fuq.

Huwa mistenni illi sa Novembru 2005, id-donaturi prospettivi kollha tad-demmm u komponenti tad-demmm ikunu pprovduti bl-informazzjoni msemmija fl-Artikolu 29(b) tad-Direttiva u li wara li jkun hemm qbil dwar ir-rieda li jibdedw jaghtu d-demmm u komponenti tad-demmm, id-donaturi fil-Komunità jaghtu lill-istabbiliment tad-demmm l-informazzjoni msemmija fl-Artikolu 29(c).

Huwa imperattiv illi l-istabbilimenti tad-demmm jassiguraw illi hemm stabbiliti proċeduri ta' evalwazzjoni ghad-donaturi kollha tad-demmm u komponenti tad-demmm u li l-kriterji ghad-donazzjoni msemmija fl-Artikolu 29(d) jintlahqu u li r-rizultati ta' l-evalwazzjoni tad-donatur u l-proċeduri ta' ttestjar huma dokumentati u li kull rizultat anormali rilevanti jgħarrfuhom lid-donatur.

Huwa importanti wkoll illi l-eżami tad-donatur, inkluż l-intervista, isiru qabel kull donazzjoni ta' demm u komponenti tad-demmm. Professjonist tas-saħħa kwalifikat huwa meqjus responsabbli, partikolarment sabiex jaghti u jiġbor minghand id-donaturi l-informazzjoni li hija meħtieġa sabiex tiġi eżaminata l-eligibilità għall-ghoti tad-demmm, u għandu, fuq dik il-bażi, jeżamina l-eligibilità ghad-donazzjoni u għandu a bażi ta' dak jeżamina l-eligibilità tad-donaturi.

Huwa mistenni illi l-istabbilimenti tad-demmm jassiguraw illi kull donazzjoni ta' demm u komponenti ta' demm ikunu ttestjati skond il-htigiet imsemmija fl-Anness IV tad-Direttiva u li l-ħażna, trasport u kundizzjonijiet tad-distribuzzjoni tad-demmm u komponenti tad-demmm ikunu skond il-htigiet imsemmija fl-Artikolu 29(e).

Id-Direttiva tirreferi wkoll għall-Banek tad-demmm fl-isptarijiet li għandhom jikkonformaw mal-htigiet speċifikament applikabbli għalihom. Huwa mistenni illi dawn il-banek tad-demmm jiġu konformi mar-rekwiziti sa Novembru 2005.

Huwa imperattiv illi jiġi assigurat illi r-rekwiziti tal-kwalità u s-sigurtà tad-demmm u komponenti tad-demmm jilhqqu l-livell għoli skond ir-rekwiziti msemmija fl-Artikolu 29(f).

Fl-aħħarnett sabiex jiġi assigurat illi r-responsabbiltajiet u l-obbligi mill-partijiet kollha konċernati u msemmija fid-Direttiva jintlahqu, se jiġu stabbiliti b'liġi penalitajiet effettivi, proporzjonali u disswassivi. Dan se jimxi id f'id ma' monitoraġġ perjodiku u ispezzjonijiet ta' stabbilimenti u banek tad-demmm mill-awtorità kompetenti.

verifiably to withdraw from distribution blood and blood components associated with the notification referred to above.

It is expected that by that November 2005 all prospective donors of blood or blood components are provided with information referred to in Article 29(b) of the Directive and that upon agreement of a willingness to commence the donation of blood and blood components, all donors in the Community provide the information referred to in Article 29(c) to the blood establishment.

It is imperative that blood establishments ensure that there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation referred to in Article 29(d) are met and that the results of the donor evaluation and testing procedures are documented and any relevant abnormal findings reported to the donor.

Furthermore it is important that examination of the donor, including an interview, be carried out before any donation of blood and blood components. A qualified health professional is deemed responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.

It is expected that Blood establishments ensure that each donation of blood and blood components is tested in conformity with requirements listed in Annex IV of the Directive and that the storage, transport and distribution conditions of blood and blood components comply with the requirements referred to in Article 29(e).

The Directive also refers to Hospital Blood Banks which have to abide by the requirements specified as applicable to them therein. It is expected these blood banks are brought in line with the requirements by November, 2005.

It is imperative to ensure that quality and safety requirements for blood and blood components meet the high standards in compliance with the requirements referred to in article 29(f).

Finally to ensure adherence to the responsibility and obligations by all the parties concerned and referred to in the Directive, effective, proportionate and dissuasive penalties shall be prescribed in the law. This shall be in consonance with the periodical monitoring and inspection of establishments and blood banks by the competent authority.

ATT TA' L-1993 DWAR KUNSILLI LOKALI

LOCAL COUNCILS' ACT, 1993

Avviż

Notice

Skond id-dispożizzjonijiet tar-regolament 17 (1) (i) tat-Tielet Skeda ta' l-Att ta' l-1993 dwar Kunsilli Lokali, il-Kummissjoni Elettorali tgharrarf illi hija m'ghandhiex ritratt tal-persuni li isimhom jidher hawn taht. Ghalkemm isimhom huwa nkluż fir-Registru Elettorali ghall-Kunsilli Lokali pubblikat f'Ottubru, 2004, ma jkunx jista' jinhargilhom Dokument ghall-Votazzjoni.

In accordance with the provisions of regulation 17 (1) (i) of the Third Schedule of the Local Councils' Act, 1993, the Electoral Commission notifies that it is not in possession of a photograph for the persons whose names are listed hereunder. Although their names are included in the Local Councils' Electoral Register published in October, 2004, it would not be possible to issue a Voting Document to these persons.

Il-Kummissjoni Elettorali tistieden dawn il-persuni biex jiġu l-Uffiċċju Elettorali halli jittehdilhom ritratt.

The Electoral Commission invites these persons to call at the Electoral Office in order to have their photograph taken.

Giannotta Giuseppe – 19190A – 3, Misrah Indipendenza, Valletta
 Zammit Anthony – 242851M – 58, Triq l-Isptar, Valletta
 Jobe Maria Rosaria – 969847M – 69, Fl 2, Triq il-Merkanti, Valletta
 Crisafulli Alfio – 21155A – 28, Triq Sciortino, Żejtun
 Fardell Ravi – 31686M – 57, Triq id-Dahla ta' San Tumas, Żejtun
 Spencer Nicole Louise – 18025A – Villa Jaxtar, Triq il-Kunċizzjoni, Żurrieq
 Muir Richie Laurie – 18633A – 50, Villa Wojtyla, Triq il-Papa Alessandru VII, Balzan
 Jansen Gisela Susanne – 27682A – 25, Randa Crt, Triq Giuseppe Cali, Ta' Xbiex
 Condorelli Paolo Matteo – 223299M – Blk 6, Fl 7, Triq Pietru D'Armenia, Pembroke
 Martinelli Ferdinando – 17829A – 102, Triq Spinola, Paceville, San Ġiljan
 Bonali Laura – 21036A – Verdala Crt/Fl 6, Il-Qasam ta' San Gorg, San Ġiljan
 Grossi Giuseppina – 19371A – 2, Taormina Crt/Fl 10, Triq il-Kbira, San Ġiljan
 Jansen Luigi Franciscus Ignazio – 18199A – Oakdridge/Fl 3, Triq is-Sur Fons, San Ġiljan
 Dietz Petra Michaela – 17937A – Monte Rosa/Fl 2, Sqaq is-Sigra, San Ġiljan
 Herold Susanne Jutta – 21307A – 1, Shamrock, Triq il-Palm, San Ġiljan
 Jokisch Anja – 28404A – Fl 14, Triq il-Migħba, Mellieha
 Covil Peter – 21759A – 110, Fl 2, Triq il-Kappillan Magri, Mellieha
 Lord John Andrew – 27316A – Marray Crt, Blk B, Fl 2, Triq il-Magħsar (Burmarrad), San Pawl il-Bahar
 Romain James George – 27680A – Qawar Sun Crt, Fl 12, Triq il-Port Ruman, San Pawl il-Bahar
 Attard Geoffrey Ryan Christopher Corey – 441501L – 131, Fl 3, Triq Salvatore Borg, San Pawl il-Bahar
 Mifsud Christopher James – 21760A – Twilight Apt/Fl 3, Triq il-Mulett, San Pawl il-Bahar
 Cremona James – 388558M – Sueliz/Fl 4, Tal-Fjuri, Limiti ta', San Pawl il-Bahar
 Cremona Angela Kay – 18434A – Sueliz/Fl 4, Tal-Fjuri, Limiti ta', San Pawl il-Bahar
 Keith Alexandria – 17637A – 620, Qawra Palace, Triq il-Qawra, San Pawl il-Bahar
 Dingli Raphael – 53956M – The Tower, Il-Wardija, Limiti ta', San Pawl il-Bahar
 Piskozub-Puzio Elzbieta – 27576A – Blue Marvel, Fl 3, Plajjet Bognor, San Pawl il-Bahar
 Wisdom Craig Lee – 9385A – Pink Rose/Fl 2, Triq il-Hgejjeġ, San Pawl il-Bahar
 Kunzel Otto Jaroslav – 27942A – 20, The White House, Triq id-Duluri, San Pawl il-Bahar
 White Michael John – 19319A – Sydney Crt/Fl 3, Triq Raymond Caruana, Ghajnsielem

C. L. De GABRIELE
Kummissjonarju Elettorali Prinċipali

C. L. De GABRIELE
Chief Electoral Commissioner

Uffiċċju tal-Kummissjoni Elettorali,
 Evans Building,
 Misrah Sant'Jiermu,
 Il-Belt Valletta.

Office of the Electoral Commission,
 Evans Building,
 St Elmo Square,
 Valletta.

Il-31 ta' Jannar, 2005

31st January, 2005