



# FORUM 25

# ICCBBA Global Forum on MPHO September 18 - 20, 2019

**The challenge of ensuring MPHO traceability  
across multiple professional spheres of activity**

Dr Aurora Vassanelli  
Italian National Transplant Center – CNT  
Roma - Italy

I declare  
in the exercise of my functions and for the event in object ,  
not to be in any way involved in personal commercial interests even referred  
to third parties.

The possible relationships which have been held in the last two years with  
people involved in commercial interests haven't been such to allow to the  
above mentioned people to affect my own function in order to get any profit.

*Dr. Aurora Vassanelli*



L 102/48

EN

Official Journal of the European Union

DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF  
the COUNCIL  
of 31 March 2004

on setting standards of quality and safety for the donation, procurement,  
preservation, storage and distribution of human tissues and cells

Article 25

Coding of information

1. Member States shall establish a system for the identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8.

2. The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells.

L 294/32

EN

Official Journal of the European Union

COMMISSION DIRECTIVE 2006/86/EC  
of 24 October 2006

implementing Directive 2004/23/EC of the European Parliament and of the  
Council on setting standards of quality and safety for the donation, procurement,  
preservation, storage and distribution of human tissues and cells

Article 10

European coding system

1. A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells. The code shall incorporate at least the information set out in Annex VII.

9.4.2015

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Official Journal of the European Union

L 93/43

## DIRECTIVES

COMMISSION DIRECTIVE (EU) 2015/565

of 8 April 2015

amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

### *Article 10b*

#### **Requirements related to the application of the Single European Code**

1. Member States shall ensure that the following minimum requirements are complied with by tissue establishments, including importing tissue establishments as defined by Commission Directive (EU) 2015/566 (\*):

- (a) allocate a Single European Code to all tissues and cells requiring application of this code at the latest before their distribution for human application;
- (b) allocate a donation identification sequence after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells from a third country supplier. The donation
- (d) use one of the permitted product coding systems and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human application;

9.4.2015

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# DIRECTIVES

COMMISSION DIRECTIVE (EU) 2015/565

amending Directive

L 93/54

EN

Official Journal of the European Union

9.4.2015

## ANNEX VII

### THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'



The Tissue Establishment plays a key role in the SEC coding and in the code allocation process! (which is allocated at the latest before distribution)

In Italy the national Competent Authority, Transplant National Center **CNT** recognized this **key role of the Tissue Establishment** and launched a three-year project (2014-2016) with the aim of being ready for the correct application of the SEC in April 2017

The project included three steps:

**2014-2015: registration of all the TEs in the European Compendium,**

**2015-2016: definition of all the elements that constitute the SEC and the process of allocation of the SEC**

**2016-2017 : training of all the TEs in the application of the SEC**

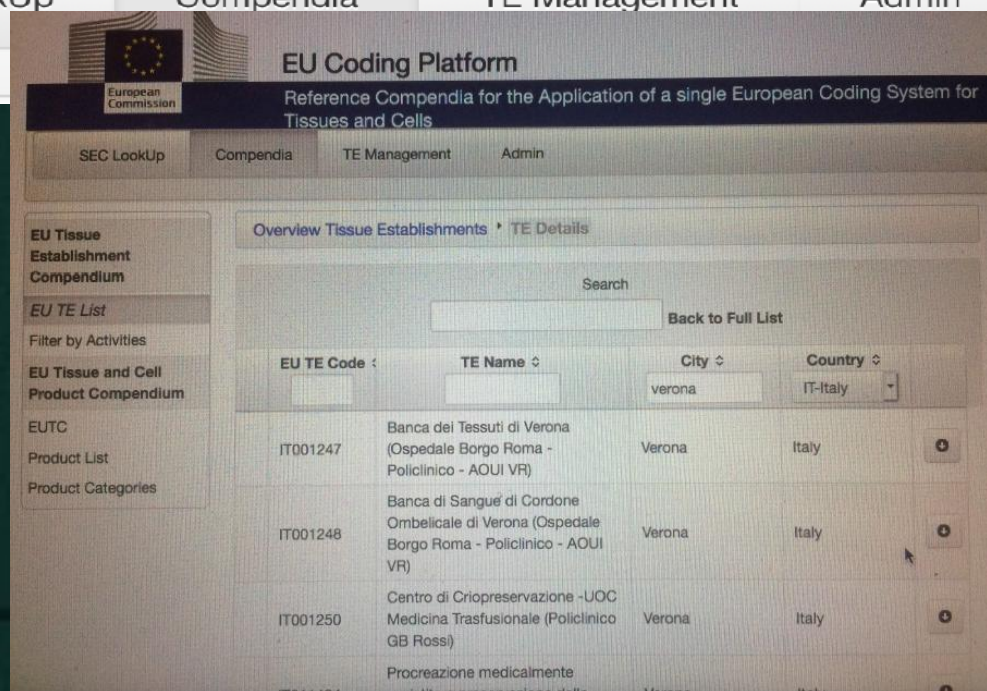
# First step: registration of TE in the European Compendium

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First step: registration of TE in the European Compendium



## EU Coding Platform

Reference Compendia for the Application of a single European Coding System for Tissues and Cells

Overview Tissue Establishments TE Details

Search				
				Back to Full List
EU TE Code	TE Name	City	Country	
		verona	IT-Italy	
IT001247	Banca dei Tessuti di Verona (Ospedale Borgo Roma - Policlinico - AOUI VR)	Verona	Italy	<input type="checkbox"/>
IT001248	Banca di Sangue di Cordone Ombelicale di Verona (Ospedale Borgo Roma - Policlinico - AOUI VR)	Verona	Italy	<input type="checkbox"/>
IT001250	Centro di Criopreservazione -UOC Medicina Trasfusionale (Policlinico GB Rossi)	Verona	Italy	<input type="checkbox"/>
IT011494	Procreazione medicalmente assistita e preservazione della fertilità (AOU Verona)	Verona	Italy	<input type="checkbox"/>
IT001252	Studio Medico Tethys	Verona	Italy	<input type="checkbox"/>

# First step: registration of TE in the European Compendium

## Active Registrations of Laboratory medicine, Dept Clin Immunology & Transfusion medicine

Competent Authorities					Last Update				
SE 061 - Health and Social Care Inspectorate									
Product	Detail	Procurement	Testing	Preservation	Processing	Storage	Distribution	Import	Export
Musculoskeletal, Bone		A		A	A	A	A		
Progenitor Cell, Hematopoietic, Bone Marrow	Autologous	A	A	A	A	A	A		
	Related	A	A	A	A	A	A	A	A
	Unrelated	A	A	A	A	A	A	A	A
Progenitor Cell, Hematopoietic, PBSC	Autologous	A	A	A	A	A	A		
	Related	A	A	A	A	A	A	A	A
	Unrelated	A	A	A	A	A	A	A	A
Progenitor Cell, Hematopoietic, Cord Blood	Autologous								
	Related								
	Unrelated		A			A	A	A	
Mature Cell, T Cell (DLI)		A	A	A	A	A	A	A	A
Mature Cell, Pancreatic Islet Cells		A	A	A	A	A	A	A	A

TE: a code for each banking activity: example of the banking activities of the TE of Verona :

### Report for EU TE Code IT001247

Name of TE	Banca dei Tessuti di Verona		
National Code	000007		
Competent Authority	IT029-Italian National Transplant Center		
Hospital Name	Ospedale Borgo Roma - Policlinico - AOUI VR		
Country	Italy		
Address	Piazzale Ludovico Antonio Scuro, 1 37134 Verona	Phone	+390458126328
		E-mail	aurora.vassanelli@aovr.veneto.it
		www	
Status			

### Report for EU TE Code IT011494

Name of TE	Procreazione medicalmente assistita e preservazione della fertilità		
National Code	050006		
Competent Authority	IT029-Italian National Transplant Center		
Hospital Name	AOUI Verona		
Country	Italy		
Address	Piazzale Aristide Stefani, 1 37126 Verona Italy	Phone	+39 0458127147
		E-mail	pma@aovr.veneto.it
		www	
Status	Active		
Competent Authority	IT029-Italian National Transplant Center		
Name of Licence Holder			
Type of Authorisation	System site inspection		
	Last Update 18-Jun-2019		

Type of tissues/  
Membrane, Dura  
Membrane, Fasci  
Musculoskeletal,  
Musculoskeletal,  
Musculoskeletal,  
Skin

Type of tissues/cells	Detail	Activities							
		Procurement Donation	Testing	Preservation	Processing	Storage	Distribution	Import	Export
Reproductive, Oocytes	Partner	A		A	A	A	A	A	A
	Non partner	A		A	A	A	A	A	A
	Fertility preservation	A		A	A	A	A	A	A
Reproductive, Sperm	Partner	A		A	A	A	A	A	A
	Non partner	A		A	A	A	A	A	A
	Fertility preservation	A		A	A	A	A	A	A
Reproductive, Embryos/Zygotes	Partner	A		A	A	A	A	A	A
	Non partner	A		A	A	A	A	A	A
	Fertility preservation	A		A	A	A	A	A	A

A - Authorized  
S - Suspended  
R - Revoked  
C - Ceased activity

Tissu  
e  
Bank

ART

Cord blood  
bank

HPC  
bank

### Report for EU TE Code IT001248

Name of TE	Banca di Sangue di Cordone Ombelicale di Verona		
Competent Authority	IT029-Italian National Transplant Center		
Hospital Name	Ospedale Borgo Roma - Policlinico - AOUI VR		
Country	Italy		
Address	Piazzale Ludovico Antonio Scuro, 1 37134 Verona	Phone	+390458124321 - 4738
		E-mail	aurora.vassanelli@aovr.veneto.it
		www	
Status	Active		

### Report for EU TE Code IT001250

Name of TE	Centro di Criopreservazione -UOC Medicina Trasfusionale		
Competent Authority	IT029-Italian National Transplant Center		
Hospital Name	Policlinico GB Rossi		
Country	Italy		
Address	Piazzale Ludovico Antonio Scuro, 1 37134 Verona	Phone	+390458124321 - 4738
		E-mail	aurora.vassanelli@aovr.veneto.it
		www	
Status	Active		
Competent Authority	IT029-Italian National Transplant Center		
Name of Licence Holder			
Type of Authorisation	System site inspection		
	Last Update 29-Mar-2012		

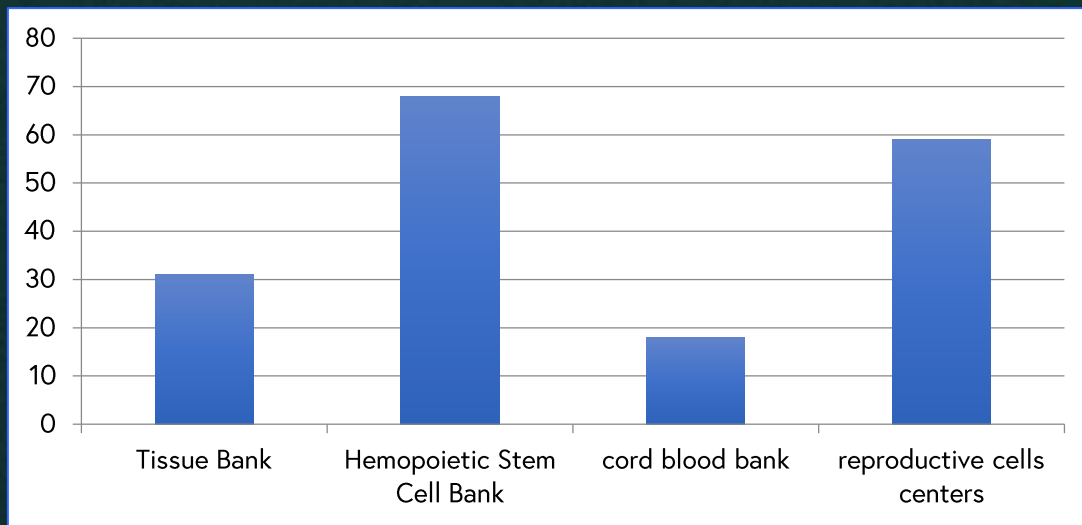
02-Aug-2013

Import	
Export	
	A
	A
	A

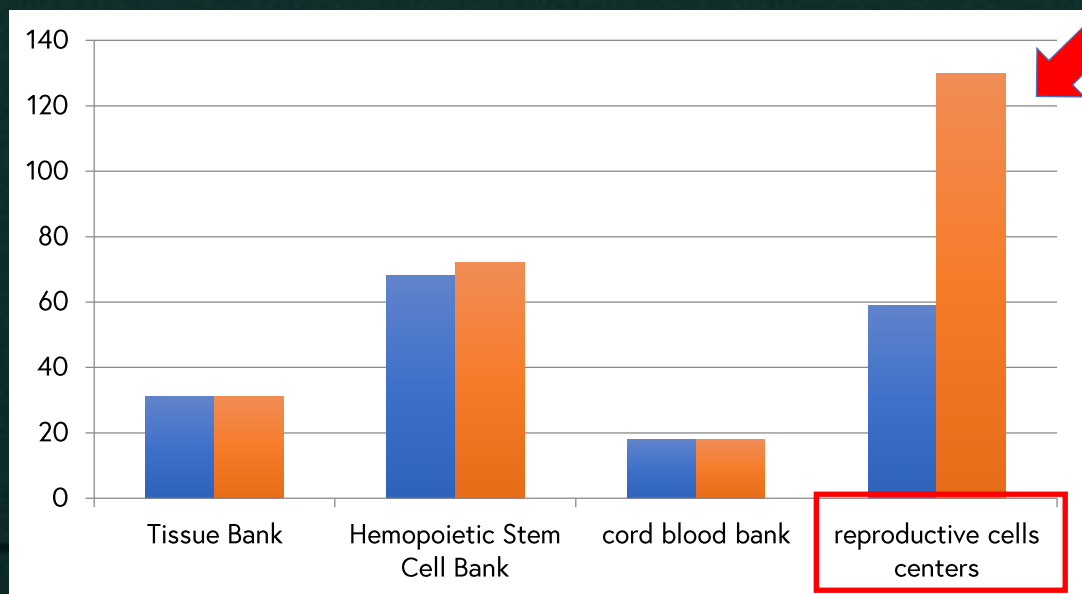
Type of tissues/cells	Detail	Activities							
		Procurement Donation	Testing	Preservation	Processing	Storage	Distribution	Import	Export
Progenitor Cell, Hematopoietic, Bone Marrow	Autologous			A	A	A	A		
	Allogeneic Related			A	A	A	A	A	A
	Allogeneic Unrelated			A	A	A	A	A	A
Progenitor Cell, Hematopoietic, PBSC	Autologous			A	A	A	A		
	Allogeneic Related			A	A	A	A	A	A
	Allogeneic Unrelated			A	A	A	A	A	A
Progenitor Cell, Hematopoietic, Cord Blood	Autologous								
	Allogeneic Related								
	Allogeneic Unrelated			A	A	A	A	A	
Mature Cell, T Cell	Autologous								
	Allogeneic Related			A	A	A	A	A	A
	Allogeneic Unrelated			A	A	A	A	A	A

A - Authorized  
S - Suspended  
R - Revoked  
C - Ceased activity





In 2015 the TEs in Italy were 176



In 2019 the TEs in Italy are 251

## TEs in Europe – data from the European Compendium

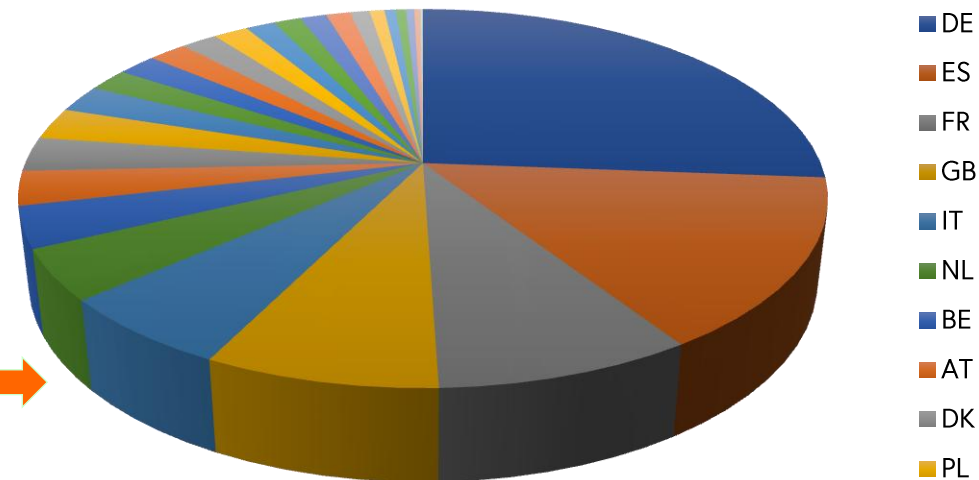
EU 4077

DE	1067
ES	592
FR	354
GB	321
IT	251
NL	176
BE	143
AT	120
DK	119
PL	111
CZ	95
SE	79
GR	77
NO	74
BG	71
FI	67
HU	57
PT	53
SI	52
RO	47
SK	38
IE	29
CY	22
HR	20
LT	16
EE	9
MT	4
LV	2
LU	2
LI	0
IS	0

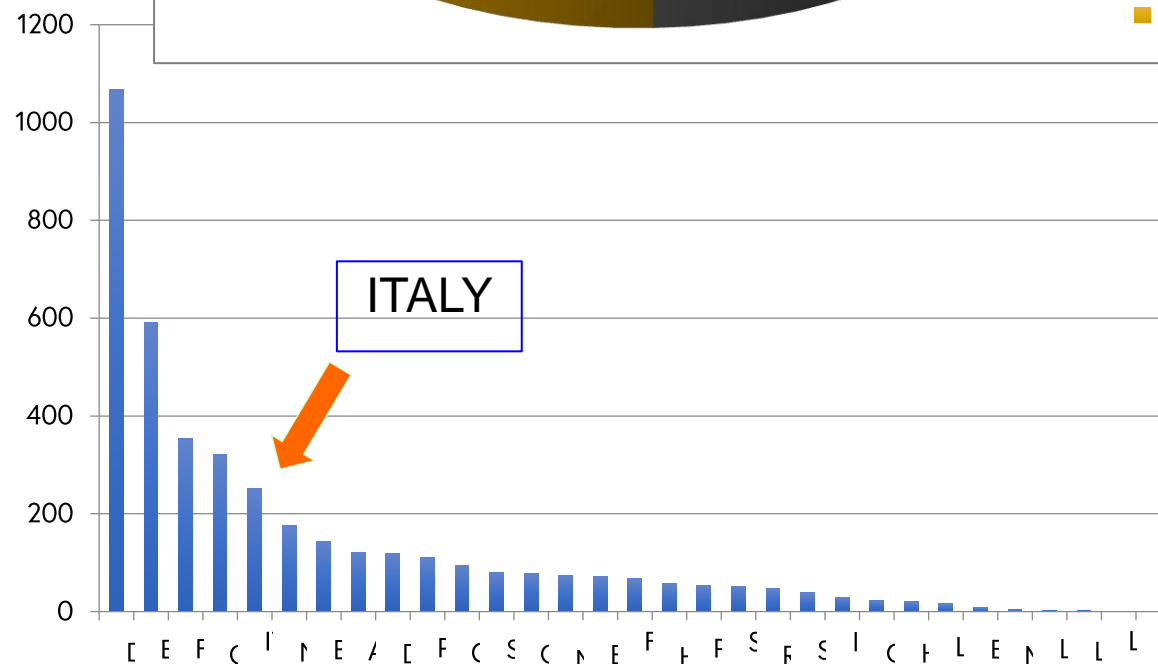
50 % of TE

80 % of TE

31 countries in Europe,  
29 countries have TE registered in the compendium (15-09-2019)



ITALY



Second step: **definition of all the elements that constitute the SEC and the process of allocation of the SEC**

From March 2015 to January 2016 two working groups composed by experts in Hematopoietic stem cell banking and tissue banking worked to identify the best way of applying the SEC to all tissue and cells:

Analysis of the SEC structure

Unique coding of the donor

Choice of the coding system

Product code

Product labeling with SEC

Flow-chart for the allocation of the SEC

Control system for the correct application of the SEC



Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Analysis of the SEC structure

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# ANNEX VII

## THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
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2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'

## Second step: Code of the donor

## Situation to 2015

Tissue establishment		Donor code	Product code
Tissue Bank		Centralized at CNT (from 2009)	local code, assigned by the Bank
Hematopoietic Stem Cell Processing Facility			
	Autologous	Donor name, local code	local code, assigned by the Bank UNI 10529
	Related donor	Donor name, local code	local code, assigned by the Bank , UNI 10529
	Unrelated donor	IBMDR code (from 1989)	local code, assigned by the Bank UNI 10529
Cord Blood Bank			
	Unrelated Cord blood	Local code	local code, assigned by the Cord Blood Bank, UNI 10529
	Related cord blood	Donor name, local code	local code, assigned by the Cord Blood Bank, UNI 10529
Reproductive cells			
	Partner donor	Local code	Local code
	No partner donor	Local code	Local code

## Second step: Code of the donor

Tissue establishment		Donor code	Product code
Tissue Bank		Centralized at CNT (from 2009)	local code, assigned by the Bank
Hematopoietic Stem Cell Processing Facility			
	Autologous	Donor name, local code	local code, assigned by the Bank UNI 10529
	Related donor	Donor name, local code	local code, assigned by the Bank , UNI 10529
	Unrelated donor	IBMDR code (from 1989)	local code, assigned by the Bank UNI 10529

Situation in Italy to 2015 : only for tissue donors and unrelated stem cell donors there was a centralization of the donor code: in particular:

**Tissue donors: centralization of donor code (CUD – Unique Donor Code) by the CNT** at the time of registration of the donor on the national donor database "Donor Manager"

**Unrelated stem cell donors: centralization of donor code by the IBMDR** at the time of registration of the potential stem cell donor on the national donor database "IBMDR"



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THE STRUCTURE OF THE SINGLE EUROPEAN CODE

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21 characters

IT

001247

1234567890123



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THE STRUCTURE OF

DONATION IDENTIFICATION SEQUENCE		
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER
ISO country code	Tissue establishment number	
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters
21 characters		
IT	001247	1234567890123

# SOLUTION 1 : for tissue donors:

Centralization of the Donation Identification Sequence by the CNT as soon as the donor and the tissue bank that will carry out the tissue banking are identified.

Each tissue bank downloads the Donation Identification Sequence (Country code + TE code + CUD) from the CNT site, both in readable code and in barcode



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DONATION IDENTIFICATION SEQUENCE		
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER
ISO country code	Tissue establishment number	
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters
21 characters		
IT	001247	1234567890123

## SOLUTION 2 : for all other donors:


an algorithm was created with which each TE generates its own Donation Identification Sequence entering Country code + TE code + Unique Donation Number (obtained starting from IBMDR code or local code, as shown below ..).

This algorithm has been made available to each TE %





# Algorithm for calculating the SEC

Parte Prima							
Data Donazione (gg/mm/aaaa)	Codice TE*	Cognome Donatore	Nome Donatore	Data Nascita Donatore (gg/mm/aaaa)	Codice UNI/Codice Tracciabilità Interna **	SID (sequenza identificativa della donazione)	

Inserire nelle caselle i dati richiesti relativi al soggetto donatore.  
Verrà generato automaticamente il codice SID (sequenza identificativa della Donazione), da utilizzare per l'assegnazione del SEC.  
\*Il codice da inserire è presente nel foglio "Codifica TE" (colonna C) o consultabile nel Compendio della Comunità europea al seguente link: <https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml>.  
\*\*L'inserimento del Codice UNI/Codice Tracciabilità Interna crea un link con la SID.

Parte Seconda			
Product number ***	Data Scadenza (gg/mm/aaaa)	Sottopartita****	

\*\*\* Nel foglio "Product number" è possibile verificare le caratteristiche del prodotto da inserire (colonna D - Product Characteristic) a cui corrisponde il Product number (colonna B - Product number) che può essere copiato ed incollato nel campo Product number di questo foglio excel. Il Product number è anche consultabile nel Compendio della Comunità europea al seguente link: <https://webgate.ec.europa.eu/eucoding/reports/product/index.xhtml>.  
\*\*\*\* il numero che distingue le aliquote di tessuti e cellule e che identifica in maniera univoca i tessuti e le cellule aventi lo stesso numero unico della donazione e lo stesso codice del prodotto e provenienti dallo stesso istituto dei tessuti.  
\*\*\*\*\* Il SEC generato potrà essere verificato al seguente indirizzo: <https://webgate.ec.europa.eu/eucoding/lookup/compendium/secdipi.xhtml>.

**SOLUTION 2 : for all other donors:**

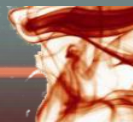
The Donation Identification Sequence is obtained by entering the date of donation + TE code + Donor name and family name (autologous or related allogeneic donor) or IBMDR code + date of birth of the donor.

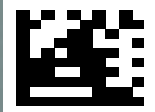
Of course the name of the donor NEVER appears in the SEC but it is the basis for the algorithm to calculate the donor code

SEC import	Product number ***	Data Scadenza (gg/mm/aaaa)	Sottopartita



\*\*\* Nel foglio "Product number" è possibile verificare le caratteristiche del prodotto da inserire (colonna D - Product Characteristic) a cui corrisponde il Product number (colonna B - Product number) che può essere copiato ed incollato nel campo Product number di questo foglio excel. Il Product number è anche consultabile nel Compendio della Comunità europea al seguente link: <https://webgate.ec.europa.eu/eucoding/reports/product/index.xhtml>.  
\*\*\*\* Il SEC generato potrà essere verificato al seguente indirizzo: <https://webgate.ec.europa.eu/eucoding/lookup/compendium/secdipi.xhtml>.


# Algorithm for calculating the SEC



Parte Prima							
Data Donazione (gg/mm/aaaa)	Codice TE*	Cognome Donatore	Nome Donatore	Data Nascita Donatore (gg/mm/aaaa)	Codice UNI/Codice Tracciabilità Interna **	SID (sequenza identificativa della donazione)	

Inserire nelle caselle i  
Verrà generato autom  
\*Il codice da inserire è  
[https://webgate.ec.eu](https://webgate.ec.europa.eu/)  
\*\*L'inserimento del Co

Codice UNI/Codice Tracciabilità Interna **	SID (sequenza identificativa della donazione)	
	IT000001717107LN211927	

## Parte Seconda

Product number \*\*\*

\*\*\* Nel foglio "Prodotto  
corrisponde il Product  
excel. Il Product numb  
[https://webgate.ec.eu](https://webgate.ec.europa.eu/)  
\*\*\*\* il numero che dis  
aventi lo stesso nume  
\*\*\*\*\* Il SEC genera

## SOLUTION 2 : for all other donors:

To ensure a complete traceability and to facilitate the identification of the product, the **local product code** (UNI code, ISBT code, local code ..) is shown both in the documentation and attached to the product

The local product code is not used in the SEC calculation algorithm

Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Choice of the coding system

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# ANNEX VII

## THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION	
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE	
ISO country code	Tissue establishment number		Product Coding System identifier	Product number
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters
21 characters			8 characters	
IT	001247	1234567890123	A	00S1128

Of the three possible coding system (EUTC – ISBT – Eurocode), identified respectively with the identifier  
E (EUTC)  
A (ISBT)  
B (Eurocode)  
it was decided to use the **A-ISBT product coding system** (agreement CNT – IBBCCA)



Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Choice of the coding system

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# ANNEX VII

## THE STRUCTURE OF THE SINGLE EUROPEAN CODE

Split number and expiry date are entered manually for each product fraction

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'
21 characters			8 characters		11 characters	
IT	001247	1234567890123	A	00S1128	001	20190922

Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Choice of the coding system

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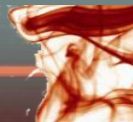
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THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'
21 characters			8 characters		11 characters	
IT	001247	1999123456789	A	00S1128	001	20190922



# Algorithm for calculating the SEC



Parte Prima						
Data Donazione (gg/mm/aaaa)	Codice TE*	Cognome Donatore	Nome Donatore	Data Nascita Donatore (gg/mm/aaaa)	Codice UNI/Codice Tracciabilità Interna **	SID (sequenza identificativa della donazione)

Inserire nelle caselle  
Verrà generato automaticamente  
\*Il codice da inserire è  
<https://webgate.ec.europa.eu/>  
\*\*L'inserimento del codice



## Parte Seconda

Product number ***

Codice UNI/Codice Tracciabilità Interna **	SID (sequenza identificativa della donazione)
	IT00001717107LN211927

\*\*\* Nel foglio "Prodotti" corrisponde il Product number excel. Il Product number è il numero che identifica i prodotti aventi lo stesso numero di lotto  
\*\*\*\* Il SEC genera il codice unico  
<https://webgate.ec.europa.eu/>

SEC***** (Single European Code)
SEC IT00001717107LN211927 A00S062700020171018

\*\*\* Nel foglio "Prodotti" corrisponde il Product number excel. Il Product number è il numero che identifica i prodotti aventi lo stesso numero di lotto  
\*\*\*\* Il SEC genera il codice unico  
<https://webgate.ec.europa.eu/>

the complete SEC is automatically generated in readable code and 2D barcode. The SEC is printed or added to the product label by the TE



Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Flow-chart for the allocation of the SEC

After donation **each cellular product** (stem cells, cord blood, tissues, reproductive cells) is transferred to the appropriate TE and codified with the first part of the SEC.

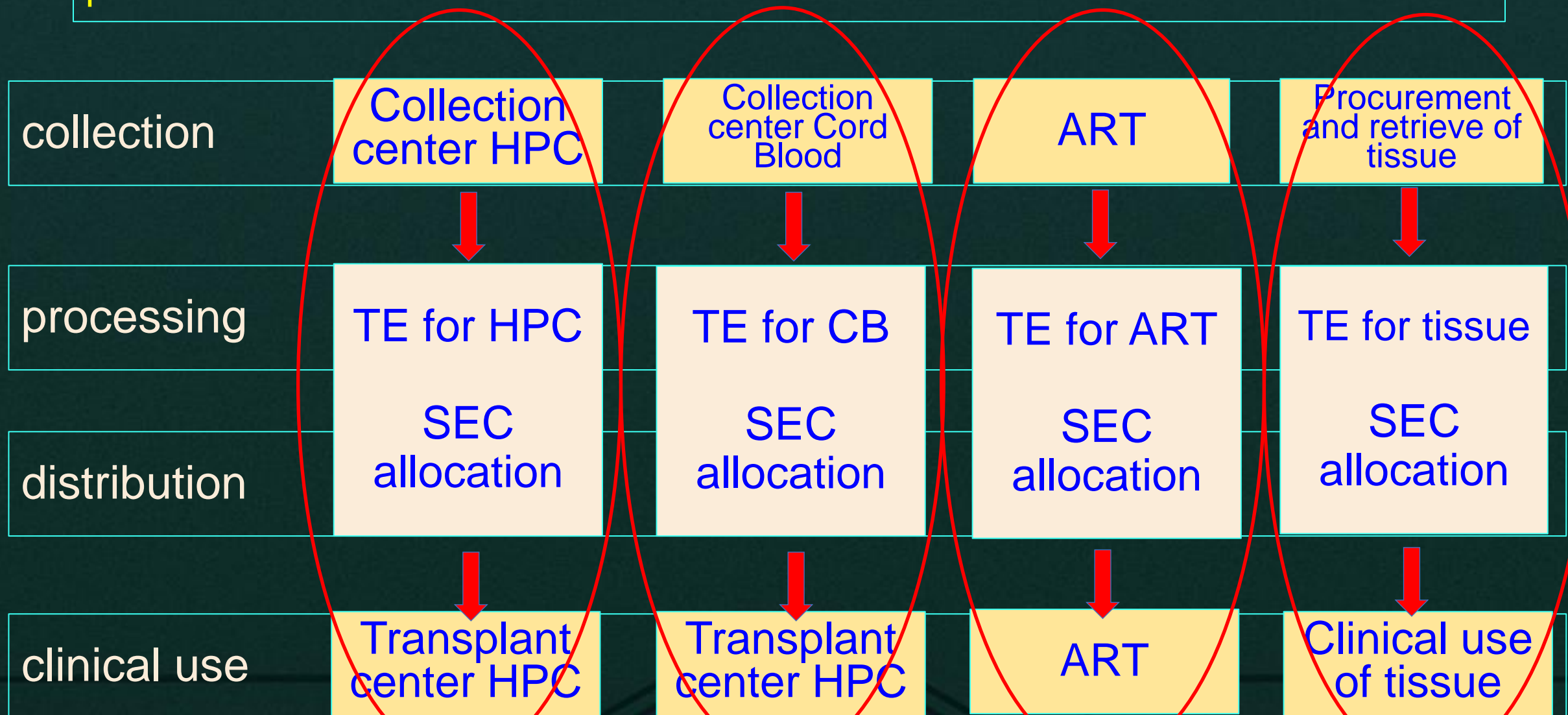
**TE is always the TE which the collection center refers (= TE of collection center)**

After processing (if appropriate) and before release, the **SEC is completed with the product code** (modified after processing, if appropriate), **split number and expiry date**

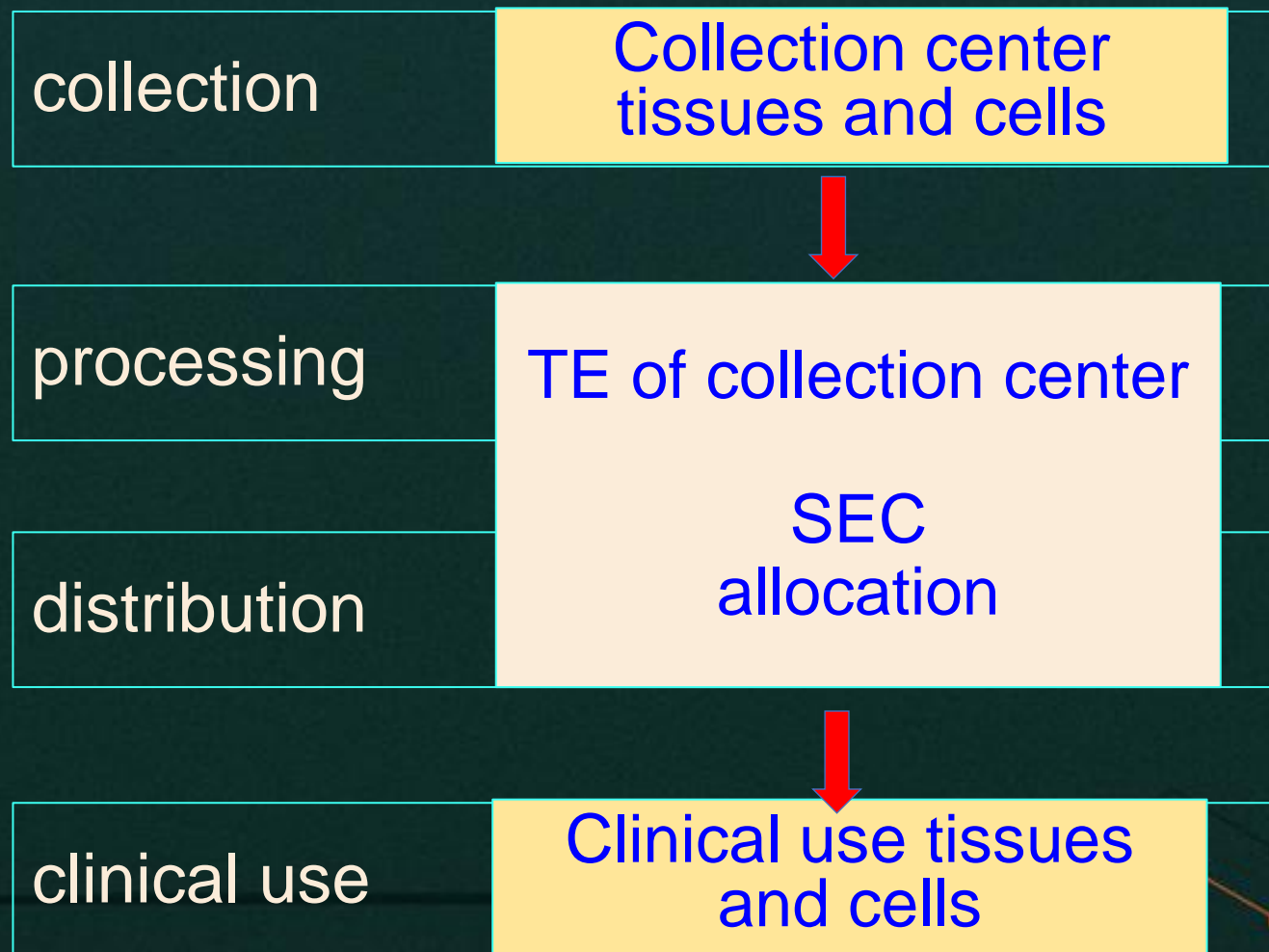
THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'

Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Flow-chart for the allocation of the SEC



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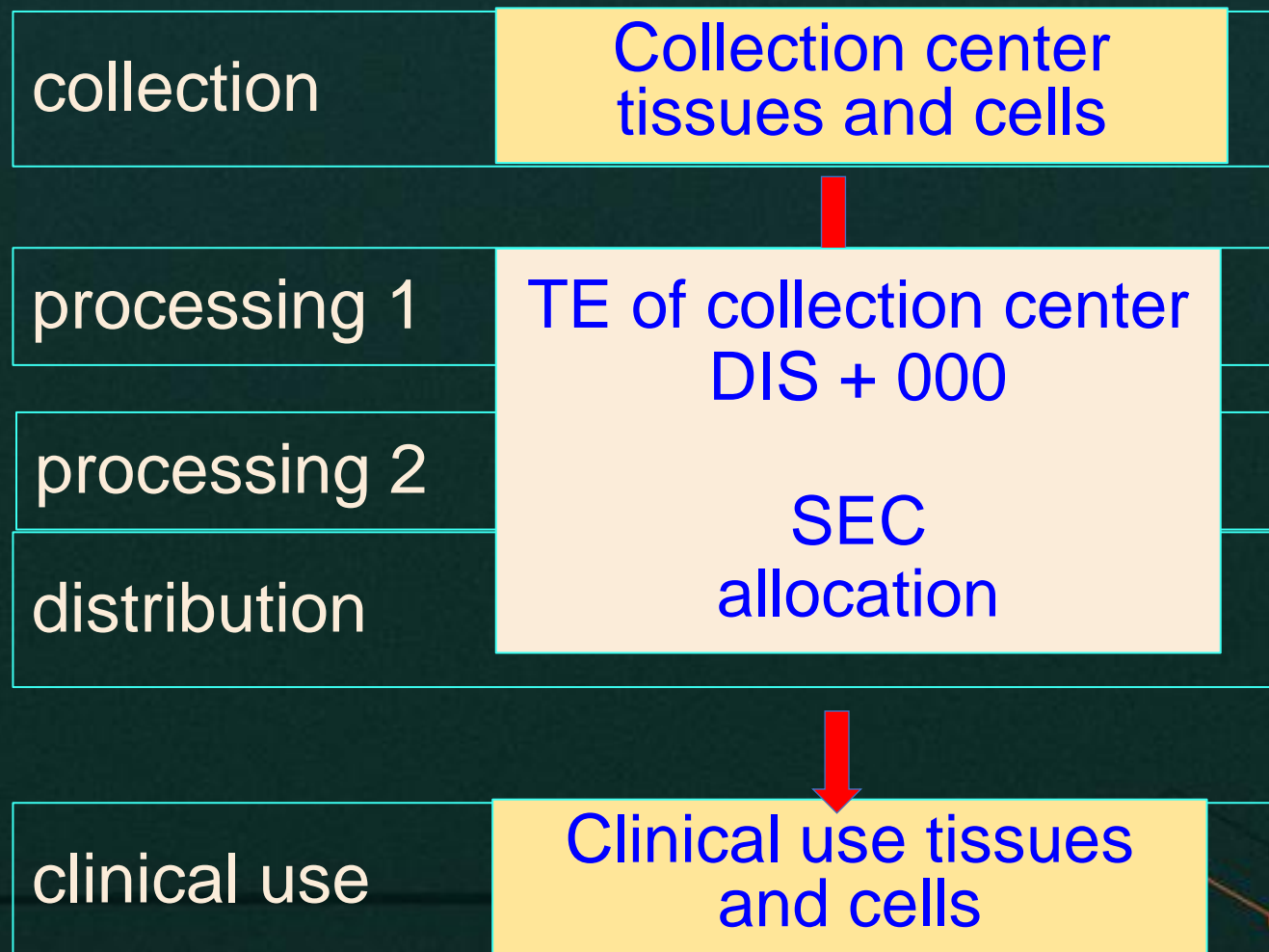
Standard model

In the SEC the TE is the one to which the Collection center refers.

The SEC represents the characteristics of the product **AT THE TIME OF DISTRIBUTION** to Clinical unit



Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Flow-chart for the allocation of the SEC

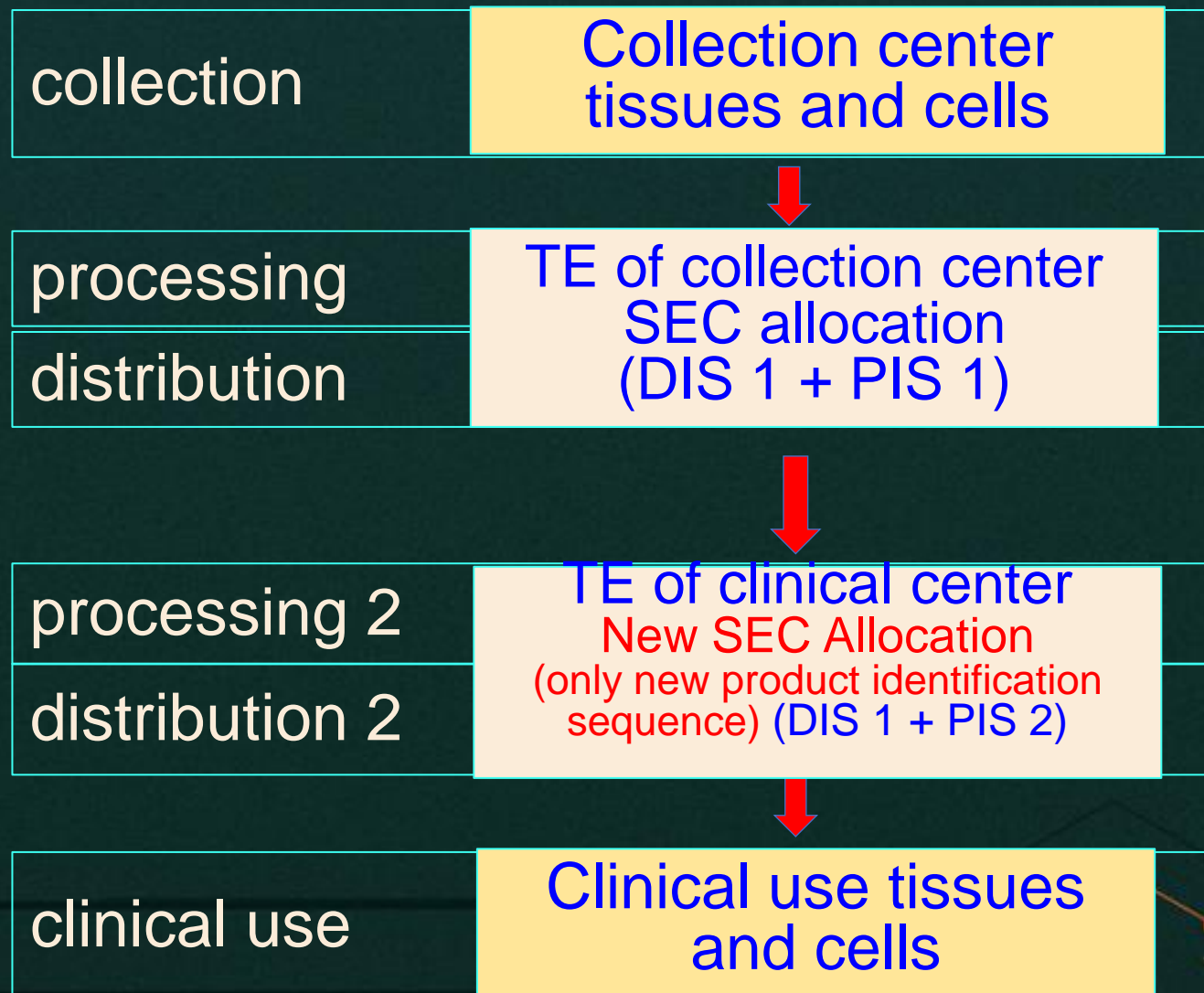


## Exception 1

If the processing involves an **activity performed by another TE or third party** (eg irradiation of tissue), in this phase the SEC **only contains the donor identification sequence**, without product identification sequence, which is attributed by the first TE after this part of processing, only at the time of final distribution to the clinical unit

The SEC represents the characteristics of the product **AT THE TIME OF DISTRIBUTION** to Clinical unit

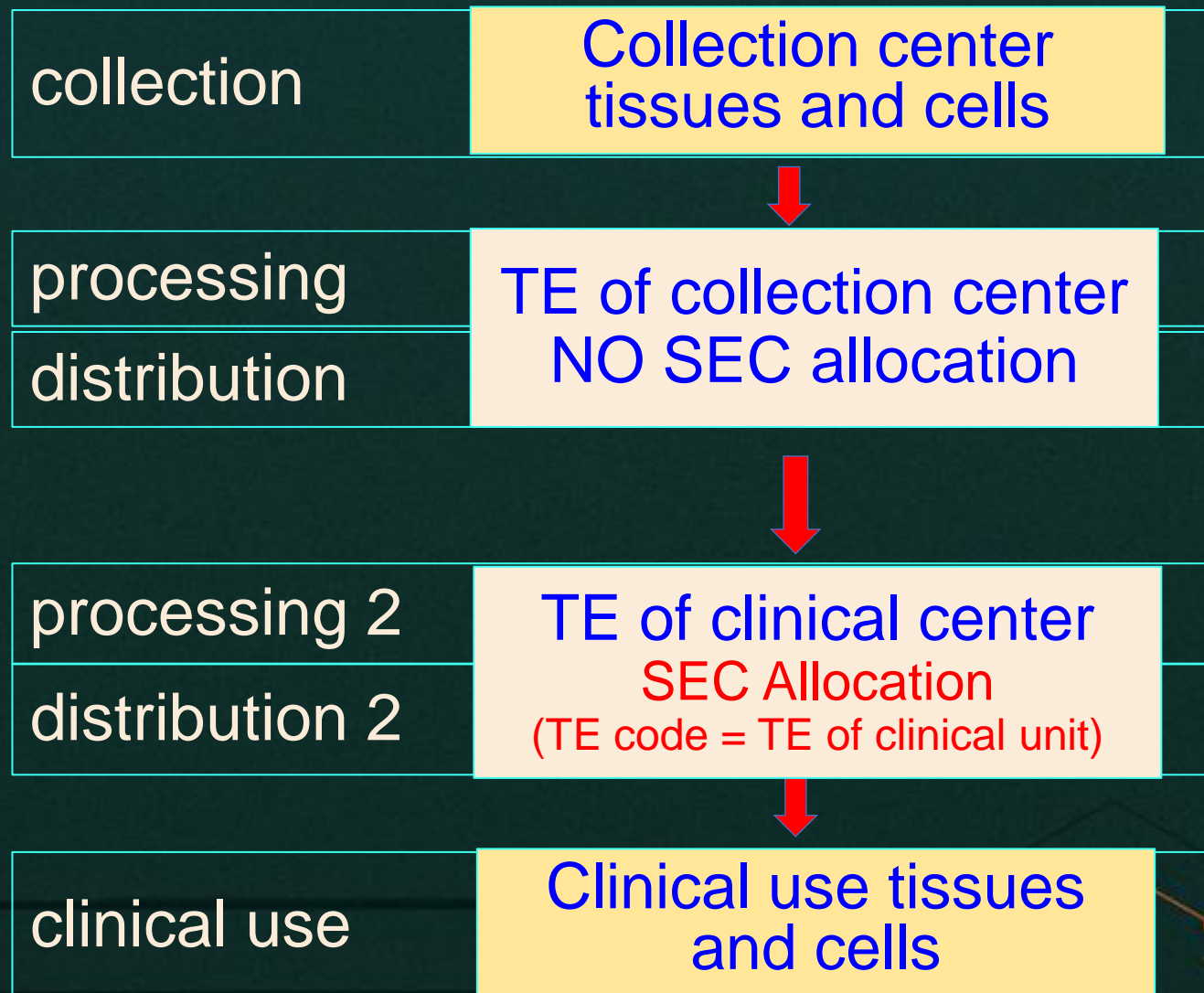
Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Flow-chart for the allocation of the SEC



Exception 2

If before clinical use the product is processed, the **TE to which the Clinical Unit refers** assigns a **new SEC** modifying only the characteristics of the product, but **not the Unique donation sequence**, nor therefore the initial TE code (which remains unchanged)

Second step: definition of all the elements that constitute the SEC and the process of allocation of the SEC :Flow-chart for the allocation of the SEC



Exception 3

If the product is distribute without SEC, the **TE to which the Clinical Unit refers, that receives it assigns it, indicating its own code**



## Third step: **Training of all the TEs in the application of the SEC :** Dissemination of the procedures and training

### *Attribuzione e Applicazione del SEC alle Cellule Staminali Emopoietiche*

**Il recepimento della DE 565 nella legislazione italiana:  
applicazione del compendio  
europeo dei TE e codifica delle cellule staminali  
emopoietiche**

Letizia Lombardini  
CNT – Centro Nazionale Trapianti

Roma, 20 febbraio 2016  
Aula Rossi, Istituto Superiore di Sanità

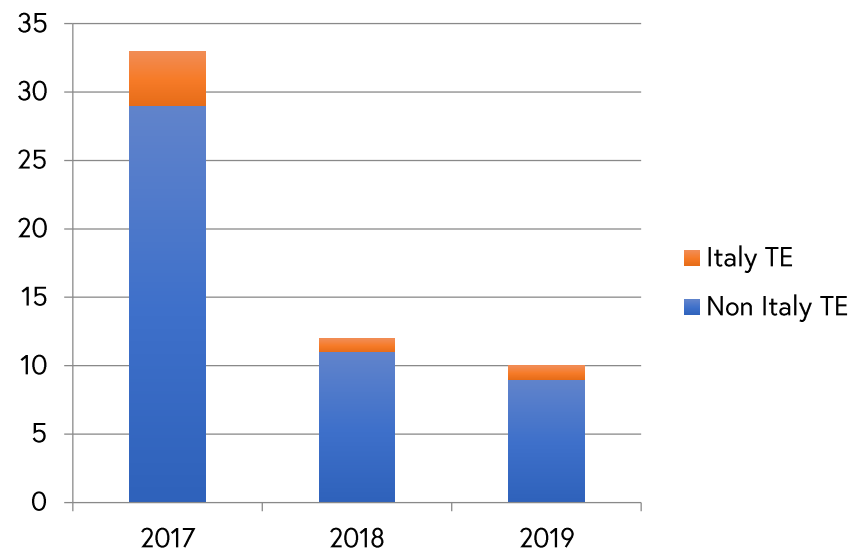
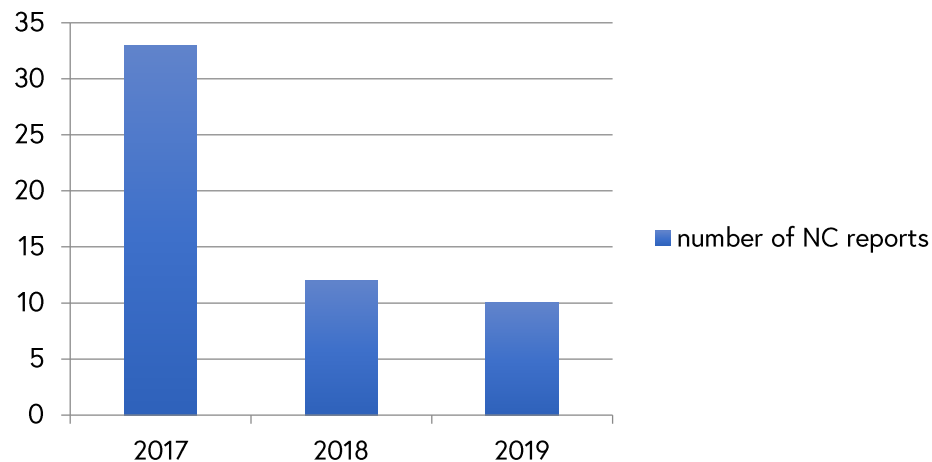


## Fourth step: Monitoring the correct application of SEC

The TE that receives tissues and cells verifies the **presence of SEC on the product and on the documentation**

If the SEC has not been applied by mistake, or it is uncorrect, the receiving **TE reports the non-compliance to the CNT**

number of NC reports



Next step will be the complete centralization of the SEC  
with online acquisition by all TEs

Thank you for your attention