Annex A

Stakeholders represented in, or invited to, meetings of the CHeF FTG "Human tissues"

- T. Chignon (Advisor to CEC/DG Enterprise/G.4)
- K. Gindele (DIN)
- P. Verdonck (Baxter + Chairman of CEN/TC 205)
- R. Geertsma (RIVM, Netherlands)
- J.S. du Pont (Dutch Burns Foundation)
- M. Cox (Medical Device Agency, UK)
- P. Brown (Genzyme BV)
- P. Castle (EDQM - European Pharmacopoeia)
- P. Thompson (CEN Consultant)
- M. Freeman (CEN Consultant)
- R. Voelksen (Swiss Federal Ministry of Health)
- E. Schutte (IsoTis)
- A. Dale (Smith and Nephew)
- J. Lang (Smith and Nephew)
- D. Smith (ASTM F04 Division IV)
- M. Bonnamour (Legal Adviser - Standing Committee of Doctors of EU)
- J. Nevalainen (Governmental Pharmaceutical Agency, Finland)
- Dr. Keith Jones (European Working Group on Xenotransplantation)
- Prof. D. Williams (Dept. of Tissue Engineering, University of Liverpool)
- B. Loty (Etablissement francais des Greffes)
- K. Koschatsky (Tutogen Medical)
- R. Moore (Chairman) (EUCOMED + Secretariat of CEN/TC 316)
- J. Van Loon (NEN + Secretariat of CEN/TC 206 and CEN/TC 285)
- T. Vyze (CEN MC)
- M. Flour
- V. Kessler
- J. Wassenaar
- European Tissue Repair Society
- European Burn Association
- European Tissue Engineering Society
- European Association of Tissue Banks
- European Commission/DG Health and Consumer Protection
- WHO - OECD

ANNEX B

TISSUE ENGINEERING: PRODUCT TYPES, STAKEHOLDERS, CURRENT ACTIVITIES

Products in this table are those which are in research, in development or commercially available. They are considered to be illustrative of tissue engineering as outlined by the definition of scope of interest proposed by CEN CHeF FTG at the meeting of 7 December 2000.

Definition proposed by CEN CHeF FTG:

Tissue Engineering: the development and manufacture of therapeutic products utilising non-viable substances, derivatives and tissues of human origin and/or viable cells of human origin, with or without scaffolds/matrices.

Specifically excluded from this definition are embryos, gametes and reproductive tissues, blood, plasma, solid organs for transplantation, stem cells, tissues stored for the purpose of obtaining genetic information, products falling under the scope of medicinal products regulations.

Product Type	Stakeholders	Current Work/Activity
BONE o Osteoblast seeded scaffold matrix for bone repair (V) o Human DMB matrix for bone remodelling (NV) o HA/TCP/growth factor as a substitute for bone repair (NV) o BMPs in hydroxyapatite 3-D matrix (NV) o Chondrocytes on 3-D ultra-high molecular weight polyethylene (V) o Bone marrow stromal cells on titanium mesh discs (V) o Primary osteoblasts on biodegradable polymer/glass-ceramic composite (V)	Medical Device Industry Pharmaceutical Industry Standards bodies Regulatory bodies Tissue banks Clinicians Reimbursement bodies	ASTM Div IV (specific standards) 41 Normal Biology – 41.01 Bone Cells 41.05 Adult Bone 43 Tissue Engineered Biomaterials – 43.07 Repaired or Regenerated Bone Substitutes 44 Biomolecules – 44.01 In-vitro assay for activity of rh-BMP-2 44.02 Guide for Proteins used in TEMPs 47 Assessment - 47.01 Bone Inductive Materials 47.05 Bone TEMPs
SKIN o Keratinocytes and /or fibroblasts on matrix scaffold (V) o Fibroblasts on polymer membrane (NV) o ECM/growth factors	Medical Device Industry Pharmaceutical Industry Standards bodies	ASTM Div IV (specific standards) 41 Normal Biology 43 Substrates – 43.02 Scaffolds 43.03 Collagen 43.05 Skin 44 Biomolecules - 44.02 Guide for Proteins used

Product Type	Stakeholders	Current Work/Activity
o on PGA scaffold for dermal replacement (NV) o Collagen/GAG dermal matrix template for fibroblast infiltration (NV) o Fibroblasts on modified PGA scaffold for dermal regeneration (V) o Autologous keratinocytes co-applied with fibrin matrix spray o Keratinocytes, fibroblasts and endothelial cells (umbilical) on collagen matrix o Autologous fibroblasts /keratinocytes seeded on porcine collagen (V) o Keratinocytes and fibroblasts on shark collagen matrix (V)	Regulatory bodies Skin/tissue banks Clinical: wound management specialists, diabetologists, long terms care (nursing homes etc?) Patient support groups (diabetics?) Reimbursement bodies EATB ETRS	in TEMPs 45 Cells - 45.01 Living Cells 45.02 Cells and Processing 45.03 Preservation 47 Assessment – 47.05 Skin EUCOMED – Position Paper on Human Tissue Products CPMP – Points to Consider on Somatic Cell Therapy (CPMP/BWP/41450/98)
CARTILAGE o Chondrocytes on PGA mesh framework (V) o Autologous chondrocytes culture systems (V) o Culture of chondrocytes with chondral cores (V) o Chondrocytes on alginate beads (V) o Osteochondral plugs with polyglycolide membrane (V) o Chondrocytes cultured on collagen 3-D scaffold system (V) o Fibrochondrocytes cultured on meniscal shaped bioresorbable PLA scaffolds (V)	Medical Device Industry Pharmaceutical Industry Standards bodies Regulatory bodies Clinical: orthopaedic surgeons, sports medicine Patient support groups Reimbursement bodies ETRS	ASTM Div IV (specific standards) 41 Normal Biology - 41.06 Articular Cartilage 43 Substrates – 43.02 Scaffolds 43.06 Cartilage 45 Cells - 45.01 Living Cells 45.02 Cells and Processing 45.03 Preservation 47 Assessment – 47. 06 Cartilage 47.10 Mensicus TEMPs EUCOMED – Position Paper on Human Tissue Products

Product Type	Stakeholders	Current Work/Activity
BLOOD VESSELS o Endothelial cells on vessel scaffolds for vascular graft (V) o PGLA sponge releasing Endothelial Cell Growth Factor (ECGF) for transplantation site (NV) o Porcine collagen matrix seeded with autologous endothelial cells (V) o Autologous smooth muscle cells seeded in collagen matrix (V)	Medical Device Industry Pharmaceutical Industry Standards bodies Regulatory bodies Clinicians Reimbursement bodies Tissue banks ETRS	ASTM Div IV (specific standards) 42 Tissue Characterisation – 42.02 Mechanical Testing of Cardiovascular TEMPS 43 Tissue Engineered Biomaterials – 43.03 Characterisation of Collagen for Surgical Implants 47 Assessment - 47.02 Cardiovascular Cells
HEART o Human recellularised porcine valve leaflets (V) o Fibroblast repopulation after decellularisation methods on porcine valves (V)		ASTM Div IV (specific standards) 41 Normal Biology - 41.02 Heart Valves 42 Tissue Characterisation – 42.02 Mechanical Testing of Cardiovascular TEMPS
NERVE o Human collagen microtubule for nerve regeneration (NV) o Schwann cells in three dimensional suspension complex of alginate (V)		ASTM Div IV (specific standards) 43 Tissue Engineered Biomaterials – 43.03 Characterisation of Collagen for Surgical Implants
SPINAL CORD o Alginate microencapsulation of primary fibroblasts		ASTM Div IV (specific standards) 43 Tissue Engineered Biomaterials – 43.04 Characterisation of Alginates
DENTAL o Bone morphogenic proteins on collagen sponge (NV) o Mesenchymal stem cells on a tricalcium phosphate matrix scaffold (V)		ASTM Div IV (specific standards) 43 Tissue Engineered Biomaterials – 43.03 Characterisation of Collagen for Surgical Implants

Product Type	Stakeholders	Current Work/Activity
KIDNEY o Renal tubular cells on polymer matrix (V)		
EAR o Chondrocytes for cartilage formation on resorbable matrix (V)		
OESOPHAGUS (human) o Transforming Growth Factor (TGF) on collagen based cylindrical scaffold (NV)		ASTM Div IV (specific standards) 43 Tissue Engineered Biomaterials – 43.03 Characterisation of Collagen for Surgical Implants
PANCREAS o Encapsulated islet cells for insulin therapy (V)		ASTM Div IV (specific standards) 41 Normal Biology - 41.04 Islets 47 Assessment - 47.04 – Islets CPMP Points to Consider on Somatic Cell Therapy (CPMP/BWP/41450/98)
MUSCLE o Myocytes & chondrocytes in a PEO/PBT copolymer matrix (V) o		
CORNEA o Epithelial cells cultured on amniotic membrane (V) o		
BLADDER o Urothelial cells cultured on polyglactin mesh framework (V) o		
General (not product-specific)	Medical Device Industry Standards bodies Regulatory bodies	ISO TC 150 Task Force – definition of "Tissue Engineering". Task Force recommendation to delay drafting of performance standards, possible referral of quality systems and biological safety issues to existing ISO TCs

Product Type	Stakeholders	Current Work/Activity
	Clinical staff Patient support groups Reimbursement bodies	rather than set up specific TE committees, and consider ATSM work programme. US WTEC Panel on Tissue Engineering Research – global review of product types, parties involved in tissue engineering, standards activities, undertaken for US regulators and scientists ASTM Div IV** – o 40 Terminology o 41 Normal Biology (various tissue systems) o 42 Characterisation of Tissue *Adaption of General Classification document relevant to Tissue Characterisation (42.00): proposed amendments to sections on Interactions and Product Development/ Preclinical Assessment circulated.* *Tissue Imaging (42.01): draft recommending specific imaging techniques for different tissue types, plus standardisation of imaging analysis.* *Mechanical Characterisation (42.02): working draft reviewed covering identification of relevant mechanical tests for each tissue type.* o 43 Biomaterials/Substrates *Standard on substrates (43.01): being published, including definition of "natural" materials. Suggestions to add chemical and physical properties, energy absorption tests, shear strength and modulus not included in final version.* *Scaffolds (43.02) outline standard document in preparation, covering characterisation tests for bulk and surface, biocompatibility and stability. No progress between Nov 99 and May 00.* *Collagen (43.03) Draft document under revision.* o 44 Biomolecules o 45 Cells o 46 Delivery Systems o 47 Assessment of product/tissue types o 48 Clinical trials

ISO TC 150 WG 11 **N2**

ISO TC 150 WG 11

Delegate Roster

September 2001

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Document	ISO/TC 150	N 475 rev.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

Date: 2000-09-28

Report of the ISO/TC 150 Task Force

on

Tissue Engineering

submitted by A. Brandwood

This report presents current activities in the field of tissue engineering as well as the conclusions and recommendations of the task force

(according to TC 150 resolution 281 / 22 Pforzheim 1999)

(This revised version of document N 475 contains Annex B which by mistake was not attached in N 475)

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Report of the ISO TC 150 Task Force on Tissue Engineering

SCOPE

This task force was established by Resolution 281 of the Pforzheim meeting held in October 1999 to:

1. survey the various standards related activities in different parts of the world related to tissue engineering to attempt to build up a comprehensive overview and
2. make recommendations for actions, if any, by TC 150 in this area. Such recommendations could include (but not be limited to) initiation of new projects or referral of issues to other Technical Committees.

INTRODUCTION

The task force has mainly conducted its business by correspondence. One *ad hoc* meeting with some of the task force members was held in conjunction with ISO TC 194 in Japan in May 2000. A list of task force members and other contributors is given at the end of this report.

Standardisation of medical products is necessarily considered in the regulatory context. This report includes a review of current regulatory approaches.

1. Definition of Tissue Engineering

At the Japan *ad hoc* meeting , the following definition of Tissue Engineering was agreed and was used as a working definition in preparation of this report.

> **Tissue Engineering** is the manufacture of a medical product in which
>
> - *viable tissue or cells are required to achieve some stage of manufacturing transformation and*
> - *the product is "engineered" by means of a synthetic or biologically derived physical scaffold.*

Note that the above definition *excludes*:

- whole organs or tissues for transplantation;
- non viable biological products such as porcine valves (which are manufactured from harvested tissues but do not require tissue viability for further manufacturing transformation) and
- all blood products.

It was specifically noted that there are a number of products such as bone substitute materials which attempt to achieve tissue regeneration in the patient by means of a physical scaffold, often with added active agents such as growth factors, but which

do not contain viable tissue or require viable tissue for manufacture (although some of these products may have been manufactured from harvested tissue such as bone.) The group believed that these products are essentially analogous to devices such as biological heart valves and did not come under the general definition of tissue medical engineered products. Nonetheless it is worth noting the rapid proliferation of such biological products in the market place with no standards yet in place. Appendix B lists commercially available bone substitute materials identified by the UK Medical Devices Agency survey.

The above definition also excludes products in which cells are manipulated *in vitro* prior to reimplantation but not seeded on any scaffold. Some members of the Task Force believed that such approaches should be included in the definition of tissue engineering.

It should also be noted that other definitions exist such as that of the ASTM expert group (see Appendix A) and that of Vacanti & Langer (*Science*: 260, May 1993):

> *"tissue engineering – applies the principles of biology and engineering to the development of functional substitutes for damaged tissue"*

CURRENT ACTIVITIES

2. ISO standards

There are no current activities in ISO directly addressing tissue engineered products. ISO Technical Committees with a potential interest in this area include:

ISO TC 106 *Dentistry*

ISO TC 150 *Implants for Surgery*

ISO TC 172 *Optics and optical instruments* (includes contact lenses and related devices)

ISO TC 194 *Biological Evaluation of Medical Devices*

ISO TC 210 *Quality management and corresponding general aspects for medical devices*

3. Australia

There are no current Australian standards or regulatory requirements specifically addressing tissue engineered medical products. However the Australian Government has published two codes of Good Manufacturing Practice, the:

- Code of GMP for Blood and Blood Components (December 1995)
- Code of GMP for Human Tissues (September 1995).

Current information concerning these documents is available at the TGA website: http://www.health.gov.au/tga/docs/pdf/gmpcodes.pdf.

Australia is currently developing a broader regulatory approach to tissue based medical products (including tissue engineered products, blood products and transplanted tissues and organs). The regulatory framework being developed is based around the assumption that the level of regulatory intervention should be in proportion to the level of manipulation of the tissue. Australia is currently revising its

medical devices regulations to a framework modelled on the European Medical Devices Directives as modified by the Global Harmonisation Task Force.

4. Canada

A National Consensus Conference was held in Ottawa in October 1995 to address control of tissue and organ transplantation. This conference proposed revision of the General Standard on Safety of Organs and Tissues for Transplantation and development of a risk management and regulatory framework

5. Europe

CEN

CEN TC 316 *Medical devices utilizing tissues* has developed EN 12442: *Animal tissues and their derivatives utilized in the manufacture of medical devices.* The document is in three parts:

Part 1: Analysis and management of risk

Part 2: Controls on sourcing, collection and handling

Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents.

Although the scope of this standard includes only products derived from animal tissue which are non-viable or rendered non-viable, it contains many elements that are also applicable to products derived from viable human or animal tissues.

In addition, EN 1441(Risk Analysis) will have application in the area of tissue engineered products.

The CEN Healthcare Forum (CheF) considered the current status of various activities and initiatives on tissue engineering at a meeting in Brussels in May 2000. The earlier meeting had identified the need to consider other existing standards programmes (ie ASTM, proposals by ISO) and the possibility of horizontal standards on risk assessment and terminology for tissue engineering. The consensus was that it would be appropriate to commence some standardisation activity even though regulatory frameworks are not yet developed. The recent CheF meeting invited representatives of CEN TC 285 *Non active implants*, CEN TC 206 *Biological Evaluation of Medical Devices* and CEN TC 316 *Tissue Products*. (CEN TC 316 has previously only considered animal tissues.) The Healthcare forum will be meeting in October 2000 to review product types, current issues, potential stakeholders, with a view to developing proposals for further consideration.

European Regulation

There is currently no pan-European approach to regulation of tissue engineered medical products. The European Medical Device Directive (Article 1) specifically does *NOT* apply to:

> *"(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin.*
>
> *(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue."*

The level of variation in national approaches to regulation in Europe can be illustrated by consideration of the national regulation of tissue engineered skin grafts which in the different member states of the European Community may be variously controlled as a cellular product, medicinal product, modified device product, tissue, organ transplantation, unregulated, medicinal product if used in a clinical trial, or uncontrolled.

Netherlands

The Netherlands is proposing national regulations covering donor selection, ethics, quality system requirements for tissue banks and other organisations that work with tissues and possibly also risk management for tissue products. It is expected that these will be available in mid 2001.

6. Japan

The Japanese Ministry of Health and Welfare is preparing notices about the principles of regulation of tissue engineered products. These will apply only to commercially available products. These notices will:

- Outline the principles of regulation and
- Provide detailed guidance on sourcing, GMP, clinical investigation.

Currently there is no regulatory division of the Ministry of Health and Welfare responsible for these products. There are no national technical standardisation activities at this stage.

7. USA

American Society for Testing and Materials (ASTM)

The ASTM has established a Tissue Engineered Medical Products group (TEMPS) which is developing documents under the headings of Terminology, Normal Biology, Tissue Characterization, Tissue Engineered Biomaterials, Biomolecules, Cells, Delivery Systems, Assessment, Clinical Trials, Microbiological Safety.

The activities of ASTM are broader that the definition for tissue engineered products defined in this report and, as yet, performance standards have not been dealt with but they will as appropriate in the future. They are concentrating on the components of the products: cells, biomaterials and biomolecules and their interactions with each other and the host, and describing critical elements of normal biology and electing the minimal set that will permit regeneration.

A progress report generated from the May 23-25, 2000 Toronto meeting of the ASTM TEMPS group is attached as Appendix A. The next ASTM meeting is in Orlando Florida, November 14-16, 2000.

Current information on this activity can be obtained at http://lindacuster.com/temps.

FDA regulatory approach

FDA now handlesTissue engineered products via the tissue reference group (combined effort of CBER/CDRH). Products can be regulated in the CBER or CDRH. Premarket approval as devices (PMA) is required when the tissue engineered product falls under the primary jurisdiction of the CDRH.

The US FDA announced its regulatory guideline for tissue banks in February, 1997. The guideline was subsequently refined by the US General Audit Office . These guidelines appear to encompass tissue engineered products.

The US approach fits within the existing regulatory framework. It encompasses:

- Donor Selection Guidelines
- Premarket assessment as Biologics for highly manipulated tissues
- Registration of Tissue Facilities
- Consent
- Labelling and advertising claims (eg Cord Blood Banks)

The scope of the US FDA approach will include:

- human cellular and tissue-based products;
- musculoskeletal tissue;
- ocular tissue;
- cellular therapies;
- hematopoeitic stem cells;
- reproductive tissue;
- combination tissue/device or tissue/drug;
- human heart valves and
- dura mater.

Not included are: vascularized organs, bone marrow, xenografts, transfusable blood products or secreted or extracted products; e.g., human milk, collagen, urokinase.

DISCUSSION

It is clear that the science of tissue engineering is developing very rapidly and the Task Force did not attempt to describe or quantify the current range of activities. There will be increasing overlap and blurring of distinctions between the different types of biological products (transplants, blood products, non viable biological prostheses, biological drugs, which will present increasing challenges for standards writing.

Nonetheless, although new developments in biotechnology may challenge standards writers and regulators, the underlying issues are not new, although there may be greater emphasis on matters of biological safety and biocompatibility than with more conventional medical devices. It should also be remembered that conventional safety and performance issues such as adequate physical properties remain.

The mechanisms and tools of standardisation and regulation also will remain essentially the same, i.e. specifications for performance, manufacturing quality systems and risk assessment.

The current standardisation effort is not well developed and is fragmented, with a number of initiatives in both standardisation and regulation occurring, mainly at the national level. Most well developed are quality systems/GMP standards, with the broader quality systems standards (ISO 13485, ISO 13488) remaining applicable to manufacture of tissue engineered medical products, and a number of national codes of practice developed by governments, professional organisations or other societies that specifically address the operations and activities of tissue banks.

Currently the only substantial effort to develop performance standards for tissue engineered products is that of the ASTM, as summarised in Appendix A. The Task

Force was in agreement that any future performance standardisation activity for tissue engineered products in TC 150 or other ISO Technical committees should be developed in the context of this ASTM work.

The Task Force identified the following prerequisites for effective standardisation in this area.

- Establishment of agreed definitions and lexicon including adequate definitions of the different categories of biological products, of which tissue engineered devices are just one subset
- Establishment of benchmarks for "normal" biological tissue against which to measure technical performance parameters which may be incorporated into standards.

The consensus of the task force was that the pace of technological change in this field was such that it is currently premature to attempt to develop specific performance standards for tissue engineered medical products.

However there is clearly a need for further development of a *generic* approach for quality systems, biological issues (immunological, toxicological, genetic, etc), risk assessments, and microbiological issues for common principles to minimise the risk of infection (eg donor factors, sourcing controls, etc) There are currently a number of established national and regional activities which provide a basis for initiation of international standerdisation in this area. Such activity would most appropriately be developed by ISO TC 210, although it may be necessary to involve other groups such as ISO TC 194, where there may be access to a greater range of required technical expertise in biological safety aspects. It is recognised that a different range of other experts (eg tissue bankers, clinicians, experts) would be required to establish protocols for tissue engineering practices that use material of human origin for therapeutic purposes.

RECOMMENDATIONS

1. That, although it would be within the scope of ISO TC 150 to prepare performance standards for tissue engineered medical products, such an activity is premature given the current state of technical development.
2. That future development of performance standards by ISO TC 150 should consider the current work programme being carried out by ASTM Division IV.
3. That there is a need for and the potential to develop international standardisation in quality systems, biological safety, risk assessments and microbiological safety (donor selection and prevention of pathogen transmission) for tissue engineered products. Some of these activities would be most appropriately developed by other technical committees, in particular ISO TC 210, which has expertise in quality systems and ISO TC 194 which has expertise in biological safety.
4. That this report be forwarded to the ISO Central Secretariat, CEN Secretariat, CEN Healthcare Forum and the Secretariats of ISO TC 194 *Biological Evaluation of Medical Devices* and ISO TC 210 *Quality management and corresponding general aspects for medical devices* for consideration of the recommendations.
5. That this report be forwarded to the secretariats of ISO TC 106 *Dentistry*, ISO TC 172 *Optics and optical instruments*, CEN TC 316 *Medical devices utilizing tissues*, CEN TC 285 *Non-active surgical implants* and CEN TC 206 *Biocompatibility of medical and dental materials and devices* for information.

PARTICIPANTS

The following individuals contributed to this report.

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Akitada Nakamura ..... Japan.
Toshie Tsuchiya ..... Japan.
Robert Geertsma ..... Netherlands.
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Appendix A

F04 Division IV on Tissue Engineered Medical Products

Structure and Work Program

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Informational WEB Sites:

http://www.astm.org/COMMIT/F04.htm
http://www.fda.gov/cdrh/tisseng/temps.htm
http://lindacuster.com/temps

SCOPE: The development of standards and promotion of related materials for tissue engineered medical products focusing on components of combination medical products intended to repair, replace or regenerate human tissue. These comprise the biological components such as the cells, tissue, cellular products, and /or biomolecules and biomaterials used in combination, including biologic, biomimetic, and/or synthetic materials. This division will work with other committees within ASTM and other organizations having mutual interests.

DIVISION STRUCTURE, SUBCOMMITTEE SCOPES and DRAFT STANDARDS

F04.40 on Terminology

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Scope: To develop standard definitions of the terminology for use with standards for tissue engineered medical products.

Task Groups:

F04.40.01 - Terminology - David Smith (dssmith@tissueinformatics.com)
F04.40.02 - Generic Classification - Grace Picciolo - (picciolograce@mail-me.com)

Draft Documents and Status:

Subcommittee/ Task Group	Designation	Title	Status
F04.40.01 Smith	z7781z	*Draft Terminology Related to Tissue Engineered Medical Products*	Expect ballot for 8/00.
F04.40.02 Picciolo	New draft	*Draft General Classification of TEMPS*	Expect draft for discussion for 11/00 meeting

F04.41 on Normal Biology

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Scope: To develop standards that identify the normal biological functional characteristics that would be required of a tissue-engineered medical product.

F04.41 Task Groups:

F04.41.01 - Bone/Orthopedic
F04.41.02 – Heart Valves – Robert Nerem (robert.nerem@ibb.gatech.edu)
F04.41.03 - Liver – Linda Custer (custer@alum.mit.edu)
F04.41.04 - Islets - John O'Neil (oneilj@joslab.harvard.edu
F04.41.05 – Adult Bone – Barbara Boyan (boyanb@uthscsa.edu)
F04.41.06 - Cartilage

Draft Documents and Status:

Subcommittee/ Task Group	Designation	Title	Status
F04.41.01	Pre-draft	*Draft Guide for the Classification of Bone Cells*	Under development
F04.41.02 Nerem	Pre-draft	*Draft Guide for the Biology of Heart Valves*	Under development
F04.41.03 Custer	Pre-draft	*Draft Guide for Classification of Liver Cells*	Under development
F04.41.04 O'Neill	Pre-draft	*Draft Guide for Classification of Islets*	Under development

F04.41.05 Boyan	Pre-draft	*Draft Guide for Classification of Adult Bone*	Under development
F04.41.06 Frondoza	Pre-draft	*Draft Guide for Classification of Articular Cartilage*	Under development

F04.42 on Tissue Characterization

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F04.42 on Tissue Characterization (Continued)

Scope: To develop standards for the structural and mechanical characterization of tissue engineered medical products.

Task Groups:

F04.42.01 - Tissue Imaging and Analysis -Sujal Shah (sshah@tissueinformatics.com)
F04.42.02 - Mechanical Characterization - Michael Sacks (msacks@engrng.pitt.edu)

Draft Documents and Status:

Subcommittee/ Task Group	Designation	Title	Status
F04.42.01 Shah	Pre-draft	*Draft Classification for Imaging Approaches*	Expect draft for discussion at 11/00 meeting
F04.42.02 Sacks	Pre-draft	*Draft Guide for Analysis of Mechanical Testing for Cardiovascular TEMPS*	Under development

F04.43 on Tissue Engineered Biomaterials

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