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ISO/TC 194/WG 15 Strategic approach to biological assessment

BRIEF MINUTES AND PROGRESS ACHIEVED AT THE MEETING IN HAYAMA-MACHI; JAPAN; ON 23 AND 26 MAY 2000

The meeting was attended by .....38.... delegates from .....9.... countries.

The meeting was chaired by ....B. Page.....

Conclusions of WG15:

1:
WG15 decided to disbandon TF1 *Immunotoxicology* as it has completed its work.

2:
WG15 noticed the report of TF2 *Format for Guidance* and recommends to ISO/TC 194 that the short version of "Guidelines for preparation of standards for the biological evaluation of medical devices" be distributed to ISO/TC 194 for consideration as NWIP for a Technical Specification and for collecting comments.

3:
WG15 recommends to distribute the long version of "Guidelines for preparation of standards for the biological evaluation of medical devices" for consideration if this is helpful as an Annex to this potential TS and for collecting comments on the content.

4:
WG15 noticed the document on a general guidance to ISO 10993 on the definition, content and documentation of a biological evaluation. WG15 recommends to distribute this document within WG15 for further consideration and collecting comments with the view to then forwarding it to WG1 for consideration as an informative Annex to ISO 10993 Part 1.

5:
WG 15 noticed the report of TF3 *Topological and physicochemical characteristics of materials* and recommends that this subject should be further discussed within WG15 taking into consideration if this subject fits under the scope of ISO/TC 194 and if it does, what the scope of a potential NWIP should be.

6:
WG 15 decided to disbandon TF4 *Quality assurance in testing* since part of its work has been covered by TF2 and since there has not been reported any progress.

7:
WG15 noticed the positive results on the questionnaire on the experience with the ISO 10993 series of standards. The results show a very high level of recognition of the usefulness of the standards. The comments focussed on the one hand on technical details which will be forwarded to the relevant WG's for consideration. On the other hand comments address the different levels of acceptance of the ISO 10993 series of standards by regulatory bodies worldwide. This can only be dealt with on a political level and therefore WG15 recommends that a platform be established for harmonizing global regulatory requirements concerning biological safety evaluation and that ISO/TC 194 should participate in this process.

8:
WG15 acknowledged the work of the Global Harmonization Task Force and recommends ISO/TC 194 to propose to the Global Harmonization Task Force to take biological safety evaluation on board in liaison with ISO/TC 194.

9:
WG15 noticed the value of scientific lectures given to the participants of ISO/TC 194 even if the content of such lectures has a controversial nature. To avoid misunderstanding WG15 however recommends that the status of the lecture regarding the level of consensus on the content is always clearly stated in advance.

10:
WG15 recommends to forward the following subjects to ISO/CS for further consideration of addition to the ISO workprogram:
- de-activation of prions for multi-patient use of medical devices
- EN 12442 Animal tissues and their derivatives utilized in the manufacture of medical devices
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

11:
WG 15 noticed the fact that B. Krug has changed jobs and therefore will not be able to continue her task as one of the co-convenors of WG15. WG15 thanked B. Krug for her excellent job and fruitful contributions to the work of WG15. WG15 recommends to ask CEN/TC 206 to nominate a new European co-convenor for WG15.