



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Mr. Ibrahim Shafii

Secretariat of the Basel, Rotterdam and
Stockholm Conventions
United Nations Environment
Programme
11-13 chemin des Anemones,
Chatelaine/Geneva
Switzerland

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Dear Mr Shafii,

On behalf of the DITTA ENVI TF, I would like to thank the Basel Secretariat for the efforts spent organizing the SIWG meeting in Konstanz on 19 and 20 January, which was pleasant and productive. We believe the progress achieved during this meeting has brought the Technical Guidance closer to finalization before the 30 March deadline.

We understand that the proposal advanced by Riccardo Corridori, representing COCIR and DITTA, on 20 January, to reintroduce a specific wording for medical devices was widely supported by Parties, Industry and NGOs. Therefore, we would like to present here below the wording submitted before the September 2014 OEWG, amending it slightly to match the conclusions of the SIWG meeting.

We suggest to introduce the following text before the actual point 26.b) or as a new 26 (c) point. The part in square brackets needs to be updated according to the decisions which will be taken in May by the COP on criteria VI, on which no consensus was reached in the SIWG.

26. *Used equipment should normally not be considered waste:*

(a) Where the criteria in paragraph 24 (a) to (d) above are met and it is not destined for any of the operations listed in Annex IV of the Convention (recovery or disposal operations) and is directly reused for the purpose for which it was originally intended or presented for sale, or exported for the purpose of being put back to direct reuse or sold to end consumers for such reuse; or

(b) Where used medical devices¹ and their components are sent by and to the manufacturer or a third party acting on behalf of the manufacturer, for any of the following purposes:

- root cause analysis, failure analysis, diagnostic testing,***
- refurbishment, or***

¹ As per definition in GHTF in SG1(PD)/N71R04



- **repair**
under a valid agreement²; [and

hazardous³ wastes resulting from the operations in 26(b) are shipped for environmentally sound management [to Annex VII Countries] [or to non-Annex VII countries as long as systems are in place to achieve the equivalent level of environmental protection].

(c) [When an exporter of used equipment and their components exports such equipment for testing, repair and refurbishment and all of the following conditions are met:

(i) Equipment and their components are exported only to Parties that have notified the Secretariat of the Basel Convention via Article 13(2) that they do not

Opt-in criteria – Grace periods

DITTA would also like to re-iterate the importance for introducing “grace periods” in criteria 1. Companies need sufficient time between the publication of the guideline and the “deadline” for the opt-in of parties. Additional time will then be needed in case of a negative declaration (or no declaration) by Parties, to relocate facilities into other countries that will accept shipments of used devices. We believe that at least two years should be given to companies between the publication of the Guidance and the entry into force of any ban on shipments.

Definitions

DITTA would also like to express some concerns on the proposed definitions for “refurbishment” under discussion in the Legal Clarity WG contained in the Glossary:

[Process for transforming reusable equipment or components into a refurbished good through refurbishing or reconditioning the equipment. With respect to used equipment, refurbishment may include such activities as cleaning, data sanitization and minor repair.]
[Creating refurbished or reconditioned equipment, including such activities as cleaning, data sanitization and (software) upgrading.][Modification of fully functional equipment to increase its performance and/or functionality or to meet applicable technical standards or regulatory requirements, including through such activities as cleaning, data sanitization and upgrading.]

As there is no harmonized definition for refurbishment at global level and as there are different definitions developed by different industrial sectors, we believe that trying to introduce a definition in this TG is going to create confusion. It is preferable not to have a definition for refurbishment in the TG because such an exercise is destined to fall short for some specific sectors, not to mention

² ‘valid agreement’: a long term contract between the manufacturer and the third party shipping or performing the refurbishment, repair or root cause analysis identifying responsibilities and procedures for the correct handling of used EEE.

³ As per definition under Basel Convention



the difficulties in enforcing such a definition by custom authorities. The criteria are tight enough to make sure the term is not misused.

Best regards

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