Form for submitting contributions in Public Consultation

Agência Nacional de Vigilância Sanitária	**FORM FOR SUBMITTING CONTRIBUTIONS IN PUBLIC CONSULTATION**

Introduction and guidance

This form is to be used to submit contributions from the community to assist with the decision to be taken on a Public Consultation drafted by Anvisa.

Please observe the following instructions when completing the Form:

- On completion, this Form can be sent to Anvisa by e-mail, fax or letter, at the addresses shown in the Public Consultation.
- Complete all the boxes on this Form and send your comments during the period in which the Public Consultation is open for the receipt of contributions.
- Contributions received outside the period, or which were not sent on this Form, will not be considered when drafting the final text of the regulation.
- Insufficient or imprecise information provided on this From may prejudice its use by Anvisa.
- Contributions received by Anvisa will be published and will remain available to the community as a whole on Anvisa's website.
- This process will contribute to the transparency and participation of the community and will assist Anvisa in drawing up the final text of the draft regulation.

Many thanks for your participation!

Agência Nacional de Vigilância Sanitária	**FORM FOR SUBMITTING CONTRIBUTIONS IN PUBLIC CONSULTATION**

Public consultation: no. __34__ / year __2011__

I. Identification of the participant

Full name: European Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)		
Address: 80 Bd. A. Reyers		
City: Brussels (Belgium)		**UF: 1030**
Telephone: +32 2 706 89 60	**Fax: +32 2 706 89 69**	**E-mail: denjoy@cocir.org**

1. Please place a cross against the sector that applies to you. *(Mark only one option)*

( ) Consumer (natural person)
( ) Association or entity for the defense and protection of the consumer
( ) Health professional (natural person)
( ) Professional health entity
( ) Businessman or owner of commercial establishment
(X) Association or entity representing the regulated sector
( ) Teaching and research academy or institution
( ) Government body or entity (Federal, State or Municipal)
( ) Other. Specify:

2. How did you hear about this Public Consultation? ***(You can mark more than one answer)***

( ) Federal Official Gazette
( ) Anvisa site
( ) Notice or letter from Anvisa
( ) Other sites
( ) Television
( ) Radio
( ) Newspapers and magazines
(X) Association, entity or institution representing a category or sector of civil society
( ) Friends, colleagues or professionals at work
( ) Other. Specify:

3. In general, what is your opinion about the proposal under discussion? *(Mark only one option)*

( ) Strongly in favor
( ) In favor
( ) Partially in favor
(X) Partially not in favor
( ) Not in favor
( ) Strongly not in favor

II. Contributions to the Public Consultation

Preamble

Clearly define the scope of the consultation, excluding the definitions referring to the proposal for Good Practice in Services and Technical Assistance.

ARTICLE 2º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 2º This Regulation is intended to discuss used, reconditioned, rented **and** leased equipment, subject to health surveillance.	Art. 2º This Regulation is intended to discuss used, reconditioned, rented **or** leased equipment, subject to health surveillance.
Justification: If we use **and** it is implied that the aim of the regulation will be for a situation in which all the events must occur at the same time. Using **or** indicates that we can have any one of the situations covered in the resolution.	

ARTICLE 4º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 4º I - used equipment: equipment that was placed in operation and which it is desired to place in operation again, generally in another location or establishment; and	Art. 4º I - used equipment: equipment that was placed in operation and which it is desired to place in operation again in another location **and legal entity of an economic group different from the ownership of the equipment**; and
Justification: We understand that the word "generally" gives scope for a dual interpretation, making subjective the concept of used equipment. As the health market in Brazil has more and more different economic conglomerations, constant mergers, acquisitions or restructurings it is important that the circulation of equipment within the same group is not impacted, since it is vital to the sector.	

Current published text (if any)	Proposal - COCIR (new wording)
Art 4º II – reconditioned equipment: used equipment that has undergone a restoration process (refurbishment) to return it to the same safety and efficiency conditions of new equipment, including repairs, software/hardware updates, and replacement of defective or worn pieces/parts with original pieces/parts.	Art 4º II – reconditioned equipment: used equipment that has undergone a process to return it to the same safety and efficiency conditions, in conformance with the original design, defined by the manufacturer.
Justification: We suggest simplifying the text to avoid confusion with corrective and preventive maintenance activities. A distinction should be made between Reconditioning and Technical Assistance and Maintenance Services.	

Current published text (if any)	Proposal - COCIR (inclusion)
	Art. 4º III - repaired equipment: equipment that exhibited a defect or failure during its operation, having undergone the actions strictly necessary to return to its normal operational condition.
Justification: We understand it would be necessary to make a better differentiation as regards the concepts of "reconditioning" and "repair". The insertion of a 3rd section containing the definition of repaired equipment, with the aim of avoiding doubts as regards the type of action performed on the equipment. It is further suggested adopting the standard ABNT 5462:1994 for the standardization of the technical terms used by the legislation.	

ARTICLE 5º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 5º, The importation, commercialization, exchange, donation, receiving through donation, and transfer of used equipment subject to health surveillance is prohibited nationwide, with the exception of that described in Paragraph 1 of this article.	Art. 5º, The importation, commercialization, exchange, donation, receiving through donation, and transfer of used equipment subject to health surveillance is prohibited nationwide, with the exception of that described in Paragraph 1 **and 2** of this article.
Justification: Consistent Referencing	

Current published text (if any)	Proposal - COCIR (new wording)
Art. 5º, Paragraph 1 Only the used equipment which is located in the national territory and reconditioned according to the criteria established in this Regulation may be commercialized, donated, received in donation, exchanged or transferred.	Art. 5º, Paragraph 1 Only the used equipment, which are ~~**located in the national territory and**~~ reconditioned according to the criteria established in this Regulation may be commercialized, donated, received in donation, exchanged or transferred.
Justification: Consistent with the principles of the World Trade Organisation (WTO) of which Brazil is a member, any trade restrictions should be avoided. As clear reconditioning criteria has been defined in Article 6, any equipment meeting this criteria, demonstrating its safe and efficient use should be allowed to be placed on the national market.	

Current published text (if any)	Proposal - COCIR (inclusion)
Art. 5º, Paragraph 2 Included in the prohibition described in this article is the importation of equipment subject to health surveillance, which has been reconditioned overseas and whose last place of installation, before reconditioning, was not Brazil.	delete and replace with: Art. 5º, Paragraph 2 **Used equipment imported by companies established in Brazil, authorized by ANVISA, which will be reconditioned in Brazil.**
Justification: Original paragraph 2 is a clear violation of free trade principles and not justifiable with any potential risk or harm equipment from outside Brazil could cause compared to locally installed equipment. Any reconditioned equipment, independent from its place of first installation should be allowed for import, in case it meets the criteria set out by ANVISA in Article 6. It is also a discrimination of foreign companies, since national companies do not have any restriction of selling reconditioned equipment to any other country. Further, it should be left to the economic operator which used equipment available fits best the customers need and is most adequate for reconditioning. Thus, if a Brazilian hospital is in need of a reconditioned equipment the economic operator should be enabled to deliver the most adequate equipment, with the highest quality within a short time. The only criteria for forbidding the placing on the market should be the criteria for safe and effective reconditioning. Additionally, economic operator should be allowed to import used equipment for local reconditioning. Operators should be able to freely sell the reconditioned equipment in Brazil or abroad, as long as they fulfill the local requirements for placing medical equipment on the market and meet the local criteria set out for reconditioned equipment. As additional information, it has to be considered that reconditioning of equipment is a highly complex business: sourcing of used equipment has to be done globally to find the right equipment while the actual reconditioning can only be done in a view specialized reconditioning centers.	

ARTICLE 6º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 6º, III - the reconditioning must be executed only by the equipment manufacturer or a third party, under its responsibility, strictly observing the equipment's original design;	Art. 6º, III - the reconditioning must be executed only by the equipment manufacturer or holder of registration for the equipment or an approved company, under its responsibility, strictly observing the equipment's original design, the actual commercialization being subject to the observance of the provisions in RDC no. 81 of November 5, 2008 concerning the necessity for authorization of the holder of the registration for its use;
Justification: The equipment under health surveillance covered in the resolution in question is technologically highly complex and relates directly to an extremely sensitive topic: public health. The entire process of research and development of the equipment calls for high levels of investment and years of intense work by highly skilled professionals belonging to the manufacturer to ensure products which are safe, reliable and serve the purpose for which they are intended, as an important tool in the diagnosis and treatment of difference diseases; hence it is extremely important that the reconditioning is in fact performed by the manufacturer or a third party formally authorized by him. Without prejudice, it is equally important that the holder of the registration authorizes the commercialization of the equipment after reconditioning so that it can comply with standards for traceability and other pertinent checks, required by the health legislation, for the holders of the registrations.	

Current published text (if any)	Proposal - COCIR (new wording)
Art. 6º IV – the substitution and replacement of pieces/parts of the equipment, during the reconditioning process, must be made only with new and original pieces/parts approved by the manufacturer;	Art. 6º IV - the substitution and replacement of pieces/parts of the equipment, during the reconditioning process, must be made only with original pieces/parts approved by the manufacturer. **The manufacturer needs to guarantee that the piece used is able to ensure that the refurbished equipment is equivalent in terms of safety and effectiveness to new equipment;**
Justification: Section IV initially proposed contradicts the principles of the National Policy on Solid Waste (Federal Law 12.305/2010), since it encourages the disposal of parts and pieces which can still be used. The use of only new parts and pieces promotes the increase in the generation of waste. Under the principles of the National Policy on Solid Waste the management of waste in Brazil must follow the following principles of: non-generation, reduction, reuse and recycling.	

Further considering that much equipment to be reconditioned is no longer being manufactured, new parts and pieces will not be available, thus restricting the process of reconditioning to a very limited pool of equipment.
Section IV of this article contains extremely complex requirements to be complied with which will increase the costs entailed in reconditioning the equipment, since it lays down only the use of new pieces/parts.
Clarification is needed if section IV is not modified, regarding the necessity of disposing of a disassembled piece, even if this is in good working condition and also if the provisions apply to the accessories for the principal product (e.g. source of energy).

Current published text (if any)	**Proposal - COCIR (exclusion)**
Art. 6º V - reuse of pieces/parts that are a result of the disassembly of other equipment is not allowed;	Exclusion

Justification:
It is certainly important to maintain the standard of quality and safety of medical equipment as it has a direct impact on public health. It is necessary to consider, however, that such equipment is subject to continuous technological advances and it is perfectly possible, from the technical point of view, to maintain the quality and safety of the product by implementing suitable procedures, such as reconditioning, dealt with in the Resolution in question. For this reason, it is important to treat the topic uniformly, so that if the equipment can be reconditioned, its components, equally, must be subject to the same criterion. Further, added to this as an important argument, is the fact that this practice tends to bring environmental benefits arising from the generation of less waste in the environment.
To permit an alternative of obtaining original new pieces for the reconditioning process, which may be necessary when there is a lack of original replacement pieces available from the manufacturer or an excessive delay in importing them.
Section IV initially proposed contradicts the principles of the National Policy on Solid Waste (Federal Law 12.305/2010), since it encourages the disposal of parts and pieces which can still be used. The impossibility of reusing reconditioned parts and pieces promotes the increase in the generation of waste. Under the principles of the National Policy on Solid Waste the management of waste in Brazil must follow the following principles of: non-generation, reduction, reuse and recycling.
Further considering that much equipment to be reconditioned is no longer being manufactured, new parts and pieces will not be available, thus restricting the process of reconditioning to a very limited pool of equipment.
Section IV of this article contains extremely complex requirements to be complied with which increase the costs entailed in reconditioning the equipment, since it hinders the reutilization of pieces/parts from other equipment.
Clarification is needed if section IV is not modified, regarding the necessity of disposing of a disassembled piece, even if this is in good working condition and also if the provisions apply to the accessories for the principal product (e.g. source of energy).

Current published text (if any)	Proposal - COCIR (new wording)
Art. 6. (...) Paragraph 1 - The manufacturer must define the maximum time frame for the reconditioning of its product, observing the service life established in the equipment's original design. Paragraph 2 - The manufacturer must guarantee the supply of pieces and parts for replacement, technical assistance and raw materials, when applicable, until the end of the declared service life of the reconditioned equipment.	Art. 6. (...) Paragraph 1 - The manufacturer or holder of the registration must define the maximum time frame for the reconditioning of its product, when applicable, observing the service life established in the equipment's original design. Paragraph 2 - The manufacturer must guarantee the supply of pieces and parts for replacement, technical assistance and raw materials for the reconditioned equipment, when applicable, until the time provided for in the current legislation after the end of commercialization.
Justification: It is necessary to define the expression "service life". Prediction of the cases in which the service life of the equipment is not applicable or laid down by the manufacturer. It is also necessary to clarify the moment of definition of the maximum period for reconditioning. It is suggested that the concept used by the standard ABNT NBR 5463/1994 be adopted, which defines the terms relating to reliability and maintainability.	

Current published text (if any)	Proposal - COCIR (new wording)
Art 6º Paragraph 4 - The holder of the Anvisa equipment registration is responsible for both the new equipment and the reconditioned equipment placed on the Brazilian market, and for ensuring all the appropriate guarantees.	**Art 6º** Paragraph 4 - The holder of the Anvisa equipment registration is responsible for both the new equipment and the reconditioned equipment placed on the Brazilian market, and for ensuring all the appropriate guarantees, **for all equipment imported by him or under his authorization.**
Justification: To clarify that the responsibility of the holder of the registration is limited to the equipment which they have legally brought into the country. To attribute responsibility for an action or omission, it is important to make it possible to manage the situation. The Resolution now under consideration deals with equipment to be reconditioned after entering the national territory, namely, that it is, generally, outside the scope of RDC no. 81 of November 5, 2008. If the holder of the registration does not have any way of knowing that the equipment is being commercialized, his ability to contribute to the compliance with the Resolution, especially concerning the provisions in Art. 6º, will be prejudiced. It is still necessary to note that other rules such as those on reliability may be impacted if the holder of the registration does not know the fate of the product. For this reason, it is essential that the holder of the registration authorizes the transaction, as already occurs with imported products, so that he can assist with compliance with the standard in question and, in this way, be responsible for the products existing on the market.	

ARTICLE 7º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 7º The manufacturer who wishes to undertake reconditioning of his equipment must include this activity in his Quality System (Good Manufacturing Practices for Medical Products, defined by Anvisa RDC Resolution no. 59, of June 27, 2000, or its updates).	**Art. 7º The manufacturer, holder of the registration or approved third-party company** who wishes to undertake reconditioning of his equipment must include this activity in its Quality System (Good Manufacturing Practices for Medical Products, defined by Anvisa RDC Resolution no. 59, of June 27, 2000, or its updates).
Justification: To clarify that not only the manufacturer, but also the whole company which is duly authorized to perform the activity of reconditioning (manufacturer, or holder of the registration or third party under his responsibility) must include the said activity in its Quality System.	

Current published text (if any)	Proposal - COCIR (inclusion, exclusion or new wording)
Art. 7º Paragraph 2 The manufacturer must maintain a Device History Record for each piece of reconditioned equipment, which may be complementary to the Device History Record of the new equipment, including the date(s) of reconditioning and all other information that guarantees the proper tracking of the equipment and its production process.	Art. 7º Paragraph 2 **The manufacturer, holder of the registration or approved third-party company** responsible for the reconditioning must maintain a Device History Record for each piece of reconditioned equipment, which may be complementary to the Device History Record of the new equipment, including the date(s) of reconditioning and all other information that guarantees the proper tracking of the equipment and its production process.
Justification: The holder of the device history record, in the case of imported products, may be the company responsible for the reconditioning in addition to the manufacturer.	

Current published text (if any)	Proposal - COCIR (new wording)
Art. 7º Paragraph 3 - The inspections and tests intended for the reconditioned equipment must be at least the same ones as those for new equipment.	Art. 7º Paragraph 3 - The inspections and tests intended for the reconditioned equipment, when applicable **must comply with the minimum requirements defined by the manufacturer according to the quality control process of refurbished equipment.**
Justification: The process of reconditioning is different from the process of manufacturing new equipment. The reconditioning process includes phases such as selection and inspection of the used equipment, disinfection and cleaning, together with the entire process of identification using indelible labels, in accordance with the proposal in this Public Consultation. We therefore suggest amending the wording	

to avoid any confusion and misunderstandings during the process of certification of the product reconditioning premises.

ARTICLE 8º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 8º Reconditioned equipment must have an indelible label attached, complementary to the labeling and tags required for new equipment, including: I – corporate name(s) and address(es) of the company or companies that executed and is(are) responsible for the reconditioning; II – date of the last reconditioning; III – number of times the equipment has been reconditioned; IV – indication that the equipment in question is reconditioned; and V – service life after reconditioning.	Art. 8º Reconditioned equipment must have an indelible label attached to indicate that this is reconditioned equipment and, each time it is reconditioned, a certificate of reconditioning must be provided to the user/customer, containing all the information listed below: I – corporate name(s) and address(es) of the company or companies that executed and is(are) responsible for the reconditioning; II – date of the last reconditioning; and III – indication that the equipment in question is reconditioned.
Justification: It is necessary to define the expression "service life". Prediction of the cases in which the service life of the equipment is not applicable or laid down by the manufacturer. It is also necessary to clarify the moment of definition of the maximum period for reconditioning. It is suggested that the concept used by the standard ABNT NBR 5463/1994 be adopted, which defines the terms relating to reliability and maintainability.	

ARTICLE 9º

Current published text (if any)	Proposal - COCIR (inclusion, exclusion or new wording)
Art. 9º Equipment subject to health surveillance, which is categorized as rented or leased must have preventive and corrective maintenance work ensured, in accordance with the determinations of its manufacturer, respecting the criteria for substitution and replacement of pieces/parts, calibrations and time frames for actions.	Art. 9º Equipment subject to health surveillance, which is categorized as rented or leased **must have the right of access to** implementation of preventive and corrective maintenance work ensured, in accordance with the determinations of its manufacturer, respecting the criteria for substitution and replacement of pieces/parts, calibrations and time frames for actions.
Justification: Not to generate expectations in the marketplace that all the corrective maintenance will be free of charge. This must be looked at in the contract.	

ARTICLE 11º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 11. The only companies that may offer rental or lease services of equipment under health surveillance are those which are authorized and possess an accountable, formally designated, college-graduated technician, who is duly registered with his/her professional council, to perform the activities of management and maintenance of equipment for medical, odontological, laboratory or physiotherapy purposes.	Art. 11. The only companies that may offer rental or lease services of equipment under health surveillance are those which are authorized and possess an accountable, formally designated, college-graduated technician, who is duly registered with his/her professional council, to perform the activities of management of the maintenance system of equipment for medical, odontological, laboratory or physiotherapy purposes.
Justification: • To better clarify the concept of legalized companies. To bring about reconciliation with Chapter III, art. 6, item III where it is mentioned that a third party under the responsibility of the manufacturer may carry out reconditioning. • To permit the technical person responsible to manage the service but not be the only one to carry out the maintenance, namely that a team trained and managed by the RT can also do it.	

ARTICLE 15º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 15. The user or health service establishment that desires to resell, transfer, and exchange or donate its used equipment must reach an agreement with the new owner as to who will be responsible for contacting the holder of the product's Anvisa registration to make arrangements for its reconditioning.	Art. 15. The user or health service establishment that desires to resell, transfer, and exchange or donate its used equipment must reach an agreement with the new owner as to who will be responsible for contacting the manufacturer or holder of the product's Anvisa registration to make arrangements for its reconditioning, if the refurbishment process is available.
Justification: To clarify that the reconditioning is a process provided by the manufacturer, registration holder or duly approved company. It must not be compulsory for all companies to offer the reconditioning process.	

Current published text (if any)	Proposal - COCIR (new wording)
Art. 15 Paragraph 3 The equipment owner must provide records of the interventions and maintenance work carried out on the equipment to the manufacturer or its representative, in	Art. 15 Paragraph 3 The equipment owner must provide records of the interventions and maintenance work carried out on the equipment to the manufacturer, **holder of the registration or approved**

order to evaluate the possibility of reconditioning.	**company,** in order to evaluate the possibility of reconditioning.
Justification: Considering that in the case of imported equipment, the holder of the registration is the person responsible for providing the reconditioning, the latter must also have access to the records of interventions and maintenance carried out on the equipment when necessary.	

ARTICLE 16º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 16, Single paragraph. At the end of its service life, imported equipment must be returned to its country of origin, and the importer is responsible for returning the equipment to its manufacturer.	Single paragraph. Used equipment which cannot be utilized any more must be returned to its supplier, manufacturer or importer for the appropriate disposal actions, **in accordance with the National Policy on Solid Waste (Law no. 12305 of August 2010 and DL 7404).**

Justification:

The principal aims of the Basel Convention, Brazil's accession to which is contained in Decree no. 875 of June 19, 1993, are:

- To minimize cross-border carriage of hazardous waste and other types of waste in accordance with its correct ecological management;
- To process and dispose of hazardous waste and other types of waste as close as possible to its source of generation in a manner which is environmentally friendly;
- To minimize the generation of hazardous waste and other types of waste (in terms of both quantity and potential risk).

Also defined in the same convention are conditions for the transborder carriage of waste which will only be permitted, among other factors, if the State of exportation has the technical capacity and the installations necessary, capability or premises suitable for the purpose, in order to eliminate the waste in question in a manner which is environmentally correct and efficient.

Also, in accordance with the National Policy on Solid Waste (Federal Law 12.305/2010), importers and manufacturers of electronic equipment are processors on an equal basis, and both are responsible for the environmentally friendly fate of the electrical and electronic waste. Also, said Policy does not mention that the importer of electrical and electronic equipment must reexport this equipment once it is no longer being used. Further, under the terms of the Policy, the management of waste in Brazil must follow the following principles:

- non-generation;
- reduction;
- reuse;
- recycling; and,
- processing of solid waste, as well as the final environmentally friendly fate of waste.

In this way, it is important that the wording be revised to ensure that:
(i) it is in accordance with the applicable (international) standards; and
(ii) the responsibility of the importer for reexportation / return to the manufacturer is not in conflict with the other applicable legislation, such as the

Federal Law dealing with the National Policy on Solid Waste, as well as being appropriate to the principle of free will of the parties so that they can contractually establish the responsible person by these means.

ARTICLE 19º

Current published text (if any)	Proposal - COCIR (new wording)
Art. 19. This Resolution becomes effective on the date of its publication.	Art. 19 This Resolution becomes effective 18 (eighteen) months after its publication.
Justification: Considering that the rules contained in the Resolution will require major adjustment to its terms and that there are complex associated processes, it is important to provide a period of *vacatio* to ensure the efficacy of the standard in a way appropriate to the interests of all the parties.	

Appendix I
Instructions for Public Consultation

1- Participation in the public consultation procedure requires the interested parties to be identified and use of the proper form.

2- The form for submitting contributions will be available on the Anvisa website at www.anvisa.gov.br and can be collected from the head office of the Agency in Brasilia or be obtained by fax on request of the interested party in the sector responsible for public consultation, as indicated in the respective invitation.

3- Contributions delivered personally to the head office of the Agency in Brasilia or sent by e-mail, fax or letter will be accepted, in accordance with the guidelines in the invitation for the public consultation.

4- All contributions received will be examined by Anvisa and will remain available to the public on the Agency's website www.anvisa.gov.br.

5- Contributions sent outside the prescribed period, contributions without identification or contributions not made on the corresponding form will not be considered.

6- On termination of the consultation period and following deliberation by the Board of Directors a report containing the analysis of the contributions and justification of the institutional position will be made available.

7- The result of the analysis of the contributions may contain answers consolidated in blocks.

8 - The Contribution Analysis Report will remain available on the Anvisa website at www.anvisa.gov.br and can be collected from the head office of the Agency in Brasilia or be obtained by fax on request of the interested party in the sector responsible for public consultation, as indicated in the respective invitation.

9 – Following deliberation by the Board of Directors the consolidated version of the draft of the legislative measure submitted to public consultation will also be available.

10- The doubts relating to the public consultation must be clarified to the public by the sector responsible for the consultation, as indicated in the respective invitation.