



9 March 2015

(15-1313)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>BRAZIL</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> ANVISA – Brazilian Health Surveillance Agency <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> National Institute of Metrology, Quality and Technology – INMETRO Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">http://www.inmetro.gov.br/barreirastecnicas</a>  The comments to this Draft Regulation shall be sent to <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=19051">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=19051</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medical devices emitting ionizing radiation in health services
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Technical Resolution N° 06, 4 February 2015, Regarding Good Practices for Operation, Safety and Quality of Diagnostic Imaging Health Services that Use Equipments that Emit Ionizing Radiation (6 pages, in Portuguese)
<b>6. Description of content:</b> Draft Technical Resolution n° 06, 4 February 2015, regarding good practices for operation, safety and quality of diagnostic imaging health services that use equipments that emit ionizing radiation.  This draft Technical Resolution has the goal of establishing requirements of good practices of operation of diagnostic imaging services that use equipments emitting ionizing radiation in health, contemplating the management of risks inherent to the technologies used.  The Technical Resolution applies to all the diagnostic imaging services that use those products in Brazil, even though it is public, private, philanthropic, civil or military, including those which practice teaching and research actions.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety
<b>8. Relevant documents:</b> Brazilian Official Journal (Diário Oficial da União), 9 February 2015; Section 1, p. 27, Draft Resolution (Consulta Pública) n° 06, 4 February 2015, issued by Brazilian Health Surveillance Agency – Anvisa. When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.

9.	<b>Proposed date of adoption:</b> To be determined after the end of the consultation period <b>Proposed date of entry into force:</b> To be determined after the end of the consultation period
10.	<b>Final date for comments:</b> 18 May 2015
11.	<b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  Agency responsible Brazilian Health Surveillance Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF/Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: <a href="http://portal.anvisa.gov.br">http://portal.anvisa.gov.br</a>  <a href="http://portal.anvisa.gov.br/wps/wcm/connect/9aba6e00473e6ca7af14efdbbe781ae8/Consulta+P%C3%ABblica+n%C2%B0+06+GGTES.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/9aba6e00473e6ca7af14efdbbe781ae8/Consulta+P%C3%ABblica+n%C2%B0+06+GGTES.pdf?MOD=AJPERES</a>