The following notification is being circulated in accordance with Article 10.4.

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| 1. | Party and Agency: United States  
Food and Drug Administration |
| 2. | Provision of the Agreement:  
Proposed Technical Regulation (Article 2.5.2) |
| 3. | Product(s) covered, CCCN Heading (National Tariff Heading where applicable):  
Diagnostic X-ray systems and their major components |
| 4. | Title of project: N/A |
| 5. | Description:  
To amend the performance standard for diagnostic X-ray systems and their major components by revising and adding requirements concerning computed tomography (ct) X-ray systems |
| 6. | Objective and rationale:  
Human safety and to amend the standard to address the radiation safety problems unique to ct systems |
| 7. | Relevant document(s):  
45 Federal Register 72204 80-10-31 21 crf part 1020 |
| 8. | Where published, when adopted:  
Federal Register |
| 9. | Final date for submission of comments:  
80-12-30 |
| 10. | Proposed date of adoption and entry into force:  
1 year after the date of its publication as final rule in the federal register |