GENERAL AGREEMENT ON

RESTRICTED

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TARIFFS AND TRADE

Committee on Technical Barriers to Trade

NOTIFICATION

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

- 1. Party to Agreement notifying: <u>UNITED STATES</u>
- 2. Agency responsible: Food and Drug Administration (409)
- 3. Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other:
- 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading):

X-Ray Systems (HS Chapter 9022)

- 5. Title and number of pages of the notified document: Federal Performance Standard for Diagnostic X-Ray Systems and their Major Components (5 pages)
- 6. Description of content: The Food and Drug Administration is proposing amendments to the Federal Performance Standard for Diagnostic X-Ray Systems and their major components (the performance standard). The proposed amendments revise the limits established for maximum radiation emissions for fluoroscopic X-Ray Systems during high-level control and other modes of operation.
- 7. Objective and rationale: Concerns regarding excessively high radiation exposure levels on some fluoroscopy systems.
- 8. Relevant documents: 58 FR 26407, 3 May 1993; 21 CFT Part 1020. Will appear in the Federal Register when adopted.
- 9. Proposed date of adoption and entry into force: The administration proposes that any final rule based on this proposed rule become effective one year after the date of its publication in the Federal Register.
- 10. Final date for comments: 2 August 1993
- 11. Texts available from: National enquiry point [X] or address of other body: