GENERAL AGREEMENT ON

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: **UNITED STATES**

2. Agency responsible: Food and Drug Administration (295)

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):

   Diagnostic X-ray systems and their components (HS 9022)

5. Title: Federal Performance Standard for Diagnostic X-ray Systems and their Major Components

6. Description of content: The Administration is proposing technical amendments to the Federal performance standard for diagnostic X-ray systems and their major components (the performance standard). Amendments would cover applicability, definitions, certification of components, certification by assembler, identification of X-ray components, limits of responsibility, information to be provided to assemblers, beam quality, aluminum equivalent of material between patient and image receptor, assembly and reassembly of diagnostic X-ray system, linearity, field limitation and alignment for mobile and stationary general purpose X-ray systems, field limitation and alignment on stationary general purpose X-ray equipment, field limitation and alignment for spot-film devices, standby radiation from capacitor energy storage equipment, image intensified fluoroscopy (further limitation of the field), entrance exposure rate limits, and change in units throughout the standard.

7. Objective and rationale: Public health and safety

8. Relevant documents: 54 FR 42674, 17 October 1989; 55 FR 5024, 13 February 1990; 21 CFR Part 1020. Will appear in the Federal Register when adopted.

9. Proposed dates of adoption and entry into force: To be determined

10. Final date for comments: 15 March 1990

11. Texts available from: National enquiry point [X] or address of other body:

90-0268