ASE - 5909

Abbreviated Environmental Assessment for:

# X-RADIATION FOR INSPECTION OF VEHICLES, CARGO CONTAINERS, FREIGHT, PARCELS OR BAGGAGE THAT MAY INCIDENTALLY CONTAIN FOOD

Prepared for: Petitions Control Branch
Food and Drug Administration
Department of Health and Human Services
Washington, DC 20204

OCT 24 12 37 PM '94

Prepared by: American Science and Engineering, Inc.
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Date: 19 October, 1994

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EA-1

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94F-0455

# ABBREVIATED ENVIRONMENTAL ASSESSMENT
## Radiation Sources as Components of Repeat-Use Articles

**1. Date:** October 19, 1994

**2. *Name* of Applicant/Petitioner:** American Science and Engineering, Inc.

3. Address: Fort Washington
40 Erie Street
Cambridge, MA 02139 - 4286

4. **Description of the proposed action:**

*(a)* ***The proposed regulation and its intended use and effect.***

AS&E proposes to amend 21 CFR, § 179.21 as follows:

1. Add new paragraph 179.2 1 (a) (4) to read:

> (4) X-ray tubes producing X-radiation from operation of the tube source at energy levels of 500 kilovolt peak or lower, where the primary objects of inspection are vehicles, cargo containers, freight, parcels or baggage, which may incidentally contain food, and for which the absorbed dose cannot reasonably be expected to exceed 50 micrograys (5 millirads).

2. Add new paragraph 179.21 (b) (3) to read:

> (3) In the case of a radiation source listed in paragraph (a)(4) of this section the labeling requirements of paragraphs (b)( 1) and (b)(2) of this section shall not apply.

The intent and effect of the proposed amendment is to classify the use of X-radiation produced by X-ray tubes operated at energies up to 500 kilovolts as "safe" for the inspection of vehicles, cargoes, parcels, or baggage, any of which may incidentally contain food, provided that the absorbed dose is 50 micrograys (5 millirads) or less. The intended technical effect of the irradiation is the creation of an X-ray image of the irradiated object, which image will be used to determine whether the object contains contraband or security threats, or for manifest verification.

The petition leading to this Environmental Assessment (EA) is necessary because of an intended use of X-ray tubes operating at energies between 300 and 500 kilovolts, for the inspection of vehicles, cargoes, etc. that may incidentally contain foods. According to the regulations of 21 CFR, § 179.21, tube-produced X-ray irradiation may be safely used

for purposes of food inspection provided that the X-ray tube operates at an energy level of 300 kilovolts peak or lower, that the X-ray tube is appropriately labeled, and that the exposure is limited to a maximum of 1,000 rads (10 grays). 21 CFR, § 179.21 also acknowledges the safety of certain gamma-ray-emitting radioisotopes at energy levels up to 2.2 million electron volts and at 1,000 rads maximum absorbed dose for food inspection. (Gamma-rays and X-rays are 'both electromagnetic radiations, differing only in their means of generation.) Over this spectral region, the amount of radiation dose to the object is a nearly constant fraction of the X-ray energy that passes through it, independent of the actual photon energies. No physical effect would apply to 500 kilovolt spectra that would not also apply to 300 kilovolt and isotopic gamma-ray spectra up to 2.2 MeV.

*(b) Production sites for she* X-my *tubes and the equipment in which they are used.*

X-ray tubes are electronic sources of X-rays that depend on simple electrostatic acceleration of electrons into a metallic target, usually tungsten, to produce X-radiation by the physical process known *as bremsstrahling*. Lower energy X-ray tubes -- i.e., those operating at 300 kilovolts or less -- are manufactured in many locations around the world. AS&E is aware of only three manufacturers of X-ray tubes for operation at energies above 300 kilovolts (although we have not done an intensive search and there may be others): two are located in Germany and one in Switzerland. The tube currently used by AS&E for cargo inspection purposes is manufactured by:

Philips GmbH
Supply Centre Industrial X-ray
Roentgenstrasse 24-26
D-2000 Hamburg 63
Germany

The equipment into which AS&E incorporates the X-ray tubes is manufactured at the company headquarters in Cambridge, Massachusetts, at the address provided at the head of this document.

*(c) Environments relating to X-ray tube and equipment production.*

AS&E is not expert with regard to what production byproducts or wastes are generated during X-ray tube manufacture, or of their methods of disposal. Production materials and procedures used for the manufacture of X-ray tubes are the same for tubes operable above and below 300 kilovolts. The latter are much more common, but are not subject to the proposed action. Various heavy metals -- most notably lead and tungsten -- are used in the finished product. The industry is power-intensive.

Cooling water from thermal processing may be drained as wastewater during tube manufacture; there is no reason that it would be contaminated. It is our understanding

[redacted]

that the heavy-metal scrap, being valuable, is recycled. Other solid wastes may be generated, for example during machining operations, and may be disposed of as industrial waste. Solvents used in paints or bonding agents are possibly dispersed into the atmosphere. There is no use of or generation of radioactive materials during the manufacture of X-ray tubes.

Assembly of the X-ray tube into the equipment in which it is used involves no hazardous liquid discharges or gaseous emissions. Incidental manufacturing wastes are recycled as scrap where possibie, or are disposed of as industrial waste. Any toxic or hazardous wastes generated during the manufacturing process are disposed of in compliance with federal and local regulations.

***(d) Type of site where food is irradiated.***

The inspection equipment will typically be permanently sited at ports of entry and other large-scale transportation centers. The prototype installation, for example, is a commercial truck crossing on the border between California and Mexico. Inspection equipment of this type, operating at energies between 300 and 500 kilovolts, is expected to be installed into special facilities, not open to the general public, constructed specifically for the inspection process. They contain the necessary shielding, interlocks, warning signs and indicators, and controls, all as regulated by 21 CFR, § 1020.40 for the control of radiation. According to that regulation, "Radiation emitted from the cabinet x-ray system [i.e., into the local environment] shall not exceed an exposure Of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface."

AS&E is also under contract to build a mobile system for similar purposes, based on the same source technology, which may also result in the incidental irradiation of food. The mobilc system will also comply to the safety regulations and emission limits for cabinet X-ray systems under 21 CFR, § 1020.40.

Only the radiation dose to the environment needs to be restricted; within the spectral region that is the subject of this petition, it makes no difference what photon energy is the source of the dose. Similar equipment, that operates at about 140 kilovolts for similar purposes (which may also result in the incidental irradiation of food), is already widely deployed in both fixed and mobile installations. They must and do comply with the same emission limits. In all cases, radiation shielding in combination with restricted access (by the "cabinet") assures that emitted radiation levels are within the limits set by 21 CFR, § 1020.40.

There are no solid, liquid or gaseous emissions relating to the use and operation of fixed-site installations. Mobile systems carry an on-board diesel generator which emits exhaust gasses into the atmosphere.

*(e) Service life and disposal of the source*

The service life of the X-ray tube is expected to be about one year or 2000 hours of use (based on the manufacturer's warranty). There is no residual radioactivity in an X-ray tube after electrical power has been removed, Parts of the source assembly have value for recycling/reuse purposes. Non-recycleable parts are likely to be disposed as industrial waste.

**5. Identification of chemical substances that are the subject of the proposed action:**

*(a) Source of ionizing radiation.*

The ionizing radiation (X-radiation) is machine-generated by X-ray tubes (i.e., electronic sources of X-rays that depend on simple electrostatic acceleration of electrons into a metallic target, usually tungsten); they produce X-rays by the physical process known as bremsstrahling.

*(b) The apparatus and its operation; shielding.*

The X-ray tube used in the apparatus is rated for operation at up to 450 kV at 10 mA of beam current. It provides a 43" cone of radiation through a 5 mm thick beryllium window. Outside the 43" cone, the tube housing is shielded with internal lead to limit the radiation to a maximum of 1 R/hr at 1 meter from the focal spot.

Within the imaging apparatus, the X-ray tube is further installed inside a shielded source assembly shown in the attached Figure 1. The tube occupies the shaded volume in the figure; end caps, not shown in the figure, further enclose the tube, allowing only egress for the high-voltage cables and oil-cooling lines. The source assembly shielding varies from 1/4" to 2" of lead, depending on location within the housing, and further reduces the X-ray leakage to well below 0.5 mR/hr at the surface of the assembly at all but four places: the primary beam apertures, described below; in line with the two high-voltage cable egress apertures; and near a small side aperture within which a reference detector is installed. Leakage radiation levels from the two cables and the reference detector aperture do not exceed 10 mR/hr at 1 meter; typically they are less than 2 mR/hr at 1 meter. They are easily brought below the 0.5 mR/hr limit by a little external shielding, or by placing the cabinet walls at least 5 meters from the focal spot.

The source assembly further restricts the 43" cone of radiation from the X-ray tube to a rapidly scanning pencil beam, which sweeps across a 43" arc at a rate of 30 sweeps per second. The pencil beam is defined by apertures, typically 4 mm by 6 mm, located at the ends of lead-lined pipes that extend radially outward from the focal spot to a distance of 36". Objects under inspection are located, typically, at 3 to 6 meters from the focus, and are pulled through the plane of the scanning beam at a speed of 3/4"/sec to 6"/sec,

depending on the scan mode, so that their exposure time totals only a fraction of a second. Entrance exposures measured at a distance of 3.5 meters range from 100 microR to a little under 800 microR, depending on the scan speed selected. Worst-case scatter to the environment was measured to be at a rate of 0.3 mR/hour. Realistic correction for maximum duty cycle would reduce that value by another factor of 2 to 3.

Figure 2 shows the scan geometry of the system. The source assembly is located below ground level. The primary scanning beam is intercepted by an Lshaped transmission detector located opposite the source. The detector itself, together with steel support structures and a backing of 1/4" of lead (neither is shown), attenuates the primary beam to less than 0.5 mR/hr. (Sidescatter and backscatter detectors are also shown, which are used for *some* applications.) The system itself is housed in the cabinet shown in the photographs of Figure 3. The cabinet has open 'ports" (as defined in 21 CFR, § 1020.40) on each end, for the passage of the vehicles to be inspected. The X-radiation is almost entirely contained and absorbed within the cabinet of the equipment. Absorption is either in shielding specifically provided for that purpose, in the irradiated object, or in the walls, floor and roof of the cabinet. X-ray emissions outside the cabinet are limited to less than 0.5 mR/hr, as required.

Other configurations are also possible within the context of the proposed modifications to 21 CFR, § 176.21. All of them would rely on the same approach to the design of the source assembly, and would adhere to the same cabinet emission limits.

**6. Introduction of substances** into the environment:

***(a) Substances expected to be emitted during use.***

Only electromagnetic radiation (X-rays), having a continuous spectrum ranging in energy from a minimum of about 30 keV to a maximum of 500 keV, are emitted from the source during operation of the equipment. Warning sounds and warning lights are also energized during operation of the source; these are intended for operational safety, and in most cases are required to comply with federal or state regulations.

***(b) Controls to minimize occupational and environmental introductions of the substances.***

The X-ray source and power supply are interlocked so that X-ray generation is possible only when the chopper wheel is rotating, the transport system is in motion (except during warmup and calibration sequences), an object to be inspected is in place (except during warmup and calibration sequences), the data aquisiton subsystem is ready to receive data, and the operator has requested a scan. Radiation is shielded and contained within the cabinet, as described in Part 5 above. Audible and visible warnings are activated to notify personnel when a scan is in process. Emergency stop buttons enable the system to be shut down from a number of locations throughout the installation. A CCTV camera

system and an intercom system enable operators to monitor activities in and around the cabinet, and to communicate with each other.

Other implementations of the technology will have similar safety controls and procedures.

***(c) Statement of compliance.***

Cabinet X-ray systems are regulated under Title 21 CFR, Subchapter J -- Radiological Health. The emission limit for cabinet X-ray systems is stated in 21 CFR, § 1020.40 (c) (1) (i), and reads: "Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface."

The cargo inspection system described in Part 5 above complies with all applicable standards under 21 CFR, Subchapter J, including the emission Limit cited above. A certification statement, in the form of a label permanently attached to the equipment in accordance with the requirements, reads, "Complies with FDA radiation performance standards, 21 CFR Subchapter J."

***(d) Effect that approval of the proposed action will have on compliance with current emission requirements.***

Approvai of proposed action will have no effect upon compliance with current emission requirements. It will simply enable X-ray inspections that are currently being done in compliance with the emission standards to be applied to containers, vehicles, etc. that may incidentally contain food.

***(e) Method to ensure that facilities are in compliance with all applicable emission requirements.***

In the case of equipment manufactured by AS&E, the company also installs the equipment for fixed-site installations. For mobile systems, the equipment is delivered as a complete system. In either case, assuring that the equipment is in compliance with all applicable emission limits is part of the test and quality-control procedure. This applies to federal emission standards as cited above, as well as to any local requirements that may apply. AS&E certifies compliance with federal standards.

Facilities for the operation of cargo inspection equipment of the type proposed are generally not required to be licensed (the sources are electronic, and do not fall under NRC regulations). In the event that local licensing is required, AS&E supports the end-user by providing radiation data, measurement procedures, and other system-specific information that may be necessary for licensing. Operation and maintenance training is provided by AS&E as part of the sales price of a system.

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**7. Fate of emitted substances in the environment:**

Documentation for this item is ordinarily not required for this type of food additive.

8. Environmental effects of released substances:

Documentation for this item is ordinarily not required for this type of food additive.

**9. Use of resources and energy:**

Documentation for this item is ordinarily not required for this type of food additive.

10. **Mitigation measures:**

Documentation for this item is ordinarily not required for this type of food additive.

**11. Alternatives to the proposed action:**

Documentation for this item is ordinarily not required for this type of food additive.

**12. Lii of preparers:**

This assessment was prepared by Dr. Roderick Swift, Senior Staff Scientist at AS&E. Dr. Swift has a Ph.D. in Physics from Yale University. He has been employed at AS&E since 1965, where he has worked on the development of various types of X-ray imaging systems since 1970. Dr. Swift is a co-inventor of the "Flying Spot" X-ray imaging technology used by AS&E for aquisiton of both transmission and backscatter images. He is Chairman of AS&E's Radiation Safety Committee.

In preparation for the subject petition and for this environmental assessment, Dr. Swift consulted Dr. Patricia A. Hansen and Dr. Vincent Zenger, both of the Center for Food Safety and Applied Nutrition, Food and Drug Administration. This document was prepared in accordance with the format and guidance contained in a four-page FDA document provided by Dr. Hansen, entitled ABBREVIATED ENVIRONMENTAL ASSESSMENT FOR RADIATION SOURCES AS COMPONENTS OF FOOD-CONTACT SURFACES OF PERMANENT OR SEMI-PERMANENT EQUIPMENT.

**13. Certification:**

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of American Science and Engineering, Inc.

Date: 10/20/94

Signature: James C. Nemiah

James C. Nemiah

Title: Vice President and General Counsel

14. References:

None provided.

15. Appendices:

Documentation for this item is ordinarily not required.

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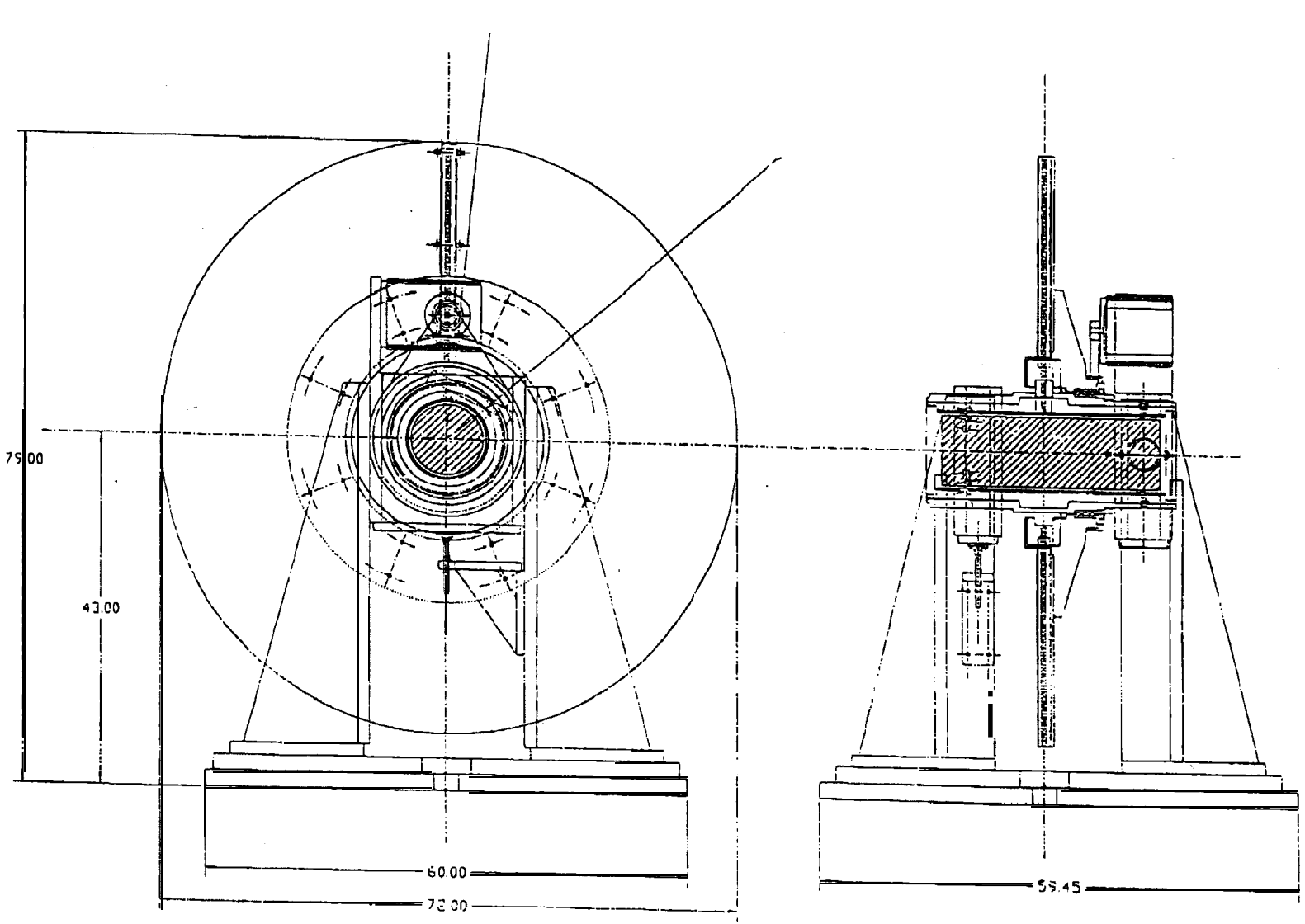


FIG 2: X-RAY SOURCE OUTLINE
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Figure 1: 450 kV Flying-Spot X-Ray Source Outline for Cargo Inspection

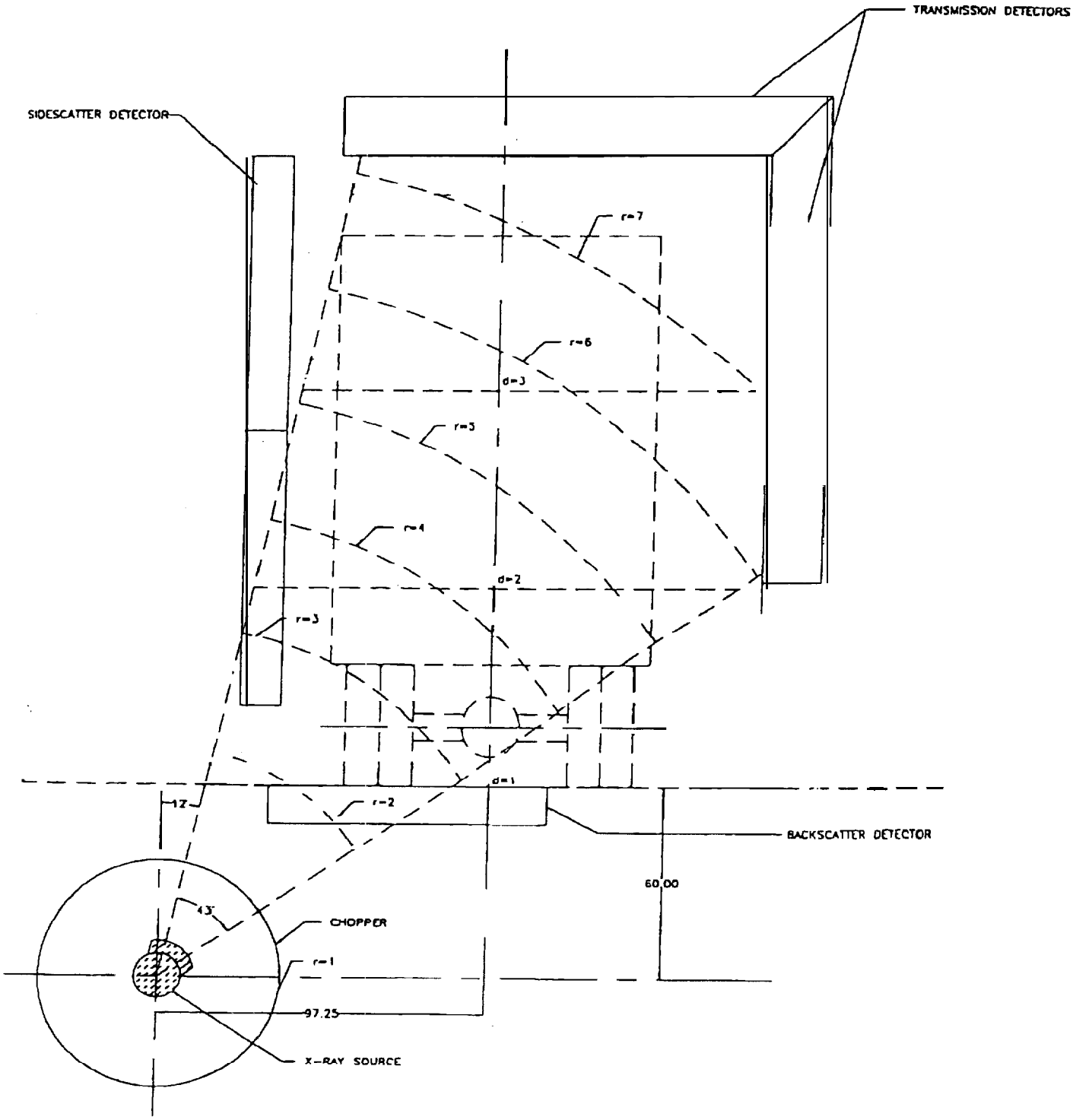


Figure 2: Scan Geometry for Truck Inspection System



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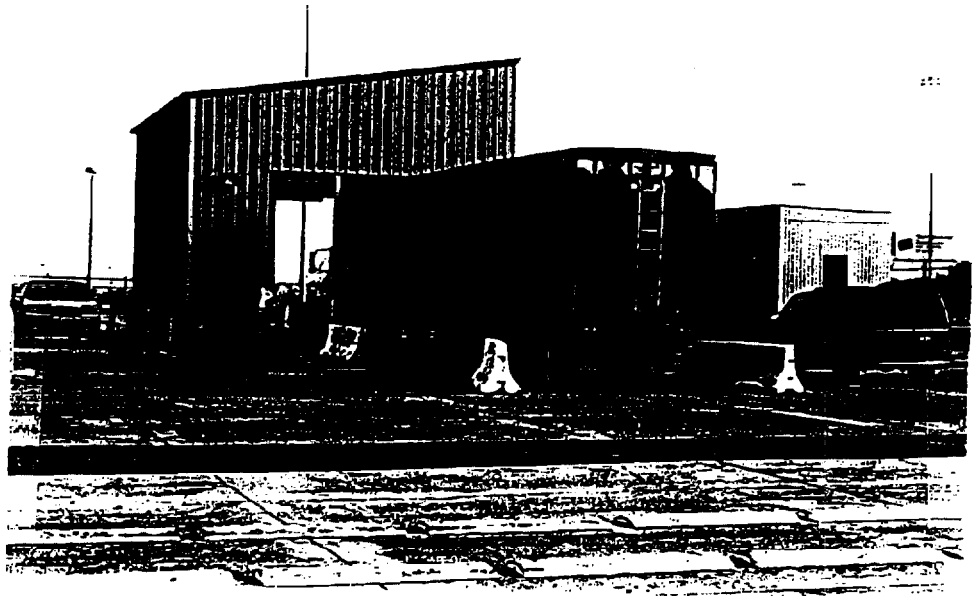

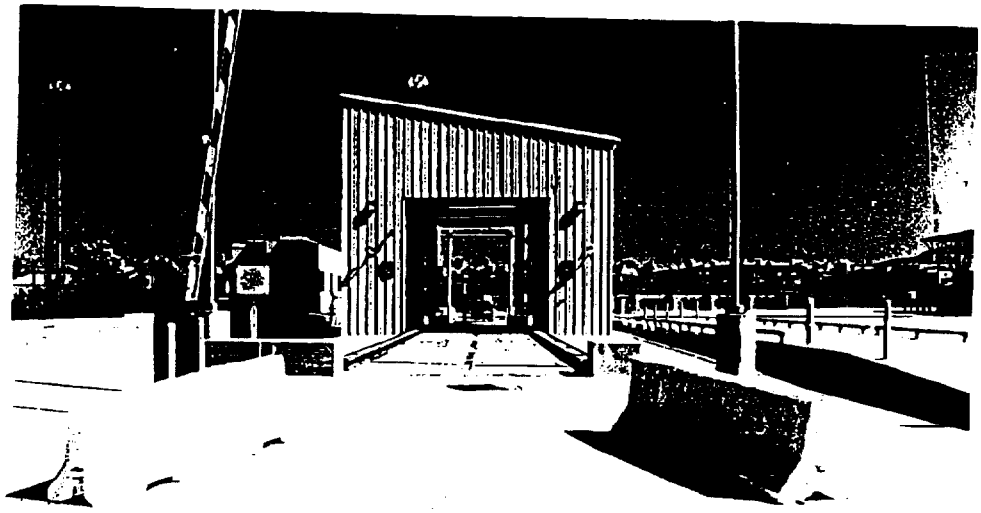

Figure 3: Two Views of the X-Ray Truck Inspection Facility Installed at Otay Mesa, California.



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