APPENDIX B: **X-ray Partnership Agreement**

PARTNERSHIP AGREEMENT

1. Agreement to Establish Partnership

The Nashville District of the Food and Drug Administration (FDA) and the Tennessee Department of Environment and Conservation (TDEC), agree to establish a partnership for the regulation of the new x-ray assemblies or reassemblies in Tennessee.

This agreement applies to new assemblies and reassemblies of diagnostic/fluoroscopic radiographic tube assemblies, mobile and vertical cassette assemblies, and chiropractic assemblies, where all such assemblies are intended solely for human use.

This agreement does not apply to the regulation of mammography radiographic units, which are currently inspected under the Mammography and Quality Standards Act (MQSA), which is also a cooperative, federal/state/industry program.

2. Partnership Purpose and Goals

a. This agreement covers the period January 1, 1998 through December 31, 2001 and may be extended or terminated as agreed upon by the parties.

b. The anticipated outcomes of the partnership are:

- To promote the inspection of assemblies of x-ray equipment installed within the previous 12 months based on the regulations of the Federal Food, Drug, and Cosmetic Act, As Amended, and the performance standards as outlined in the 21 Code of Federal Regulations 1020.30 - 1020.32.

- To provide protection of the public health by securing compliance with all applicable regulations and standards, and;

- To secure this compliance through adequate and credible inspectional coverage of new and reassemblies of diagnostic radiographic equipment through a combined Federal/State inspection program.

- To improve the efficiency of both the Federal field testing program and that of the state of Tennessee through complementary activities that conserve resources and minimize duplication of effort;

- To improve the proficiency of Federal and State Radiation personnel through joint training and inspection;

- To foster the development and retention of both Federal and State expertise in the inspection and regulation of diagnostic radiographic equipment, and, through training, sharing of information, and other cooperative activities, to help both Federal and State regulators keep pace with new developments and technologies in diagnostic radiography and the regulation of diagnostic radiographic assemblies, and to develop annual inspection work plans and independent projects, and evaluate the effectiveness of this agreement;

- To facilitate timely, accurate regulatory decisions through improved communications between the Nashville District and Tennessee Department of Environment and Conservation through the prompt sharing of policy and other regulatory information.

3. Program Areas and Activities for Partnership

a. Program areas for partnership include:

- Field testing of new and reassemblies of diagnostic radiographic equipment to ensure conformance with the requirements of the Federal Food, Drug, and Cosmetic Act, As Amended, and other applicable regulations and standards;
- Exchange of inspectional and analytical data relating to the installation of diagnostic radiographic equipment and reporting of installations;
- Sharing of policy and other regulatory information between the Nashville District and Tennessee Division of Radiological Health;
- Training and joint inspection activities for diagnostic radiographic equipment which would include but not be limited to annual audits to be conducted by FDA personnel;
- Maintenance and calibration of all testing equipment to be supplied by FDA to the state of Tennessee to further this monitoring program as needed;

b. Cooperating Agency Contacts:

1) FDA

Karen Smallwood, Consumer Safety Officer, Nashville District

2) Tennessee Department of Environment and Conservation

Mike Mobley, Director, Division of Radiological Health

c. Statutory Basis for Partnership Agreement:

FDA
The Federal Food, Drug, and Cosmetic Act;
21 Code of Federal Regulations: Part 1020.30 - 1020.33

4. Responsibilities

a. Joint:

- Each party will provide to the other lists of potential field testing sites within the state.
- The parties will conduct joint emergency meetings when requested by either party.
- Each party will ensure that its inspection personnel that are involved in work under this agreement are adequately trained.
- The combined efforts of FDA and APH will result in the field testing of diagnostic radiographic equipment in Tennessee in a manner consistent with the terms of this agreement.
- For each field test that is covered by this agreement, the surveyor will complete a general information test record, FDA 3071, and specific test records for each procedure followed in the

testing of the system, which shall be attached to the FDA 3071. Instruction for completing the general information test record are contained in HHS Publication FDA 81-8161. Also required is that a copy of the *Report of Assembly of a Diagnostic X-Ray System*, Form FDA 2579, be attached for the system.

- The field test means the completion of one of the following procedures in HHS Publication FDA 81-8161, Routine Compliance Testing for Diagnostic X-Ray Systems. They are listed in descending order of priority.

    1. Abovetable X-Ray Source Radiographic Systems (Including Supplement No. 1, Wall Cassette

    2. Undertable X-Ray source Fluoroscopic and Spot-Film Systems

    3. Stationary C-Arm Fluoroscopic systems

    4. Mobile C-Arm Fluoroscopic systems

    5. Abovetable X-Ray Source Fluoroscopic and Spot-Film Systems

    6. Abovetable X-Ray Source Radiographic System, Supplement No. 2, Chiropractic Systems with a PBL collimator present

    7. Vertically Mounted Cassette Holder (when a dedicated unit)

    8. Head and Neck Radiographic Systems

    - All of the routine field tests performed shall be conducted within twelve (12) months of the installation date of the diagnostic x-ray unit.

    - The testing of a combination radiographic and fluoroscopic diagnostic x-ray unit counts as two (2) field tests if both systems are tested in accordance with the proper procedures. This includes above table radiographic and abovetable fluoroscopic systems with one tube.

    - The testing of an above table radiographic system including a wall cassette using Supplement No. 1 to Test Procedure ARA will count as only one (1) field test.

    - The combined number of routine field tests performed on Vertically Mounted Cassette Radiographic Systems and Chiropractic Systems with PBL collimator present shall be limited to no more than ten percent (10%) of the total number of contracted field tests.

    - A minimum of fifty percent (50%) of the tests performed on each of the stationary general purpose radiographic and mobile general radiographic units shall include the Peak Kilovoltage (kVp) Determination. This test shall be conducted in accordance with the procedures for Peak Kilovoltage Determination contained in HHS Publication FDA 81-8161.

b. FDA:

- FDA will maintain records of all new and reassemblies of x-ray equipment for a period of 3 years in the district office.

- An annual audit will be conducted by the FDA on each state surveyor who conducts field testing as a result of this agreement. This audit will consist of field testing of one above-table

radiographic/under-table fluoroscopic combination unit, and one above-table radiographic unit for each surveyor who conducts at a minimum of 10 field tests per year as a result of this agreement.

- The radiation measuring instruments and applicable testing equipment will be furnished by FDA for use in this agreement. Reports shall be furnished on forms developed by FDA and available through the Regional Radiological Health Representative (RRHR) or district X-ray auditor. The RRHR or District X-ray auditor will provide instruction on the use of these forms.

- FDA will provide training for FDA and Tennessee survey personnel in the performance of a diagnostic X-ray field test.

- FDA will provide to APH copies of all correspondence in regard to field testing of all equipment located within the state of Tennessee.

c. TDEC :

- Tennessee survey personnel will annually conduct at a minimum of twenty-five (25) field tests as outlined under Section 4 of this agreement.

5. Planned Resources

- All radiation measuring equipment and applicable testing equipment required for use in the performance of the services required hereunder will be furnished by the FDA. Delivery will be made in a timely manner to the state, such that the required services can be performed within the effective dates of the agreement.

- The state is authorized the retention and use of the equipment listed below. The accountability of the equipment is hereby transferred with this agreement as listed below:

Item	Quantity	Estimated Value
Field Test Kits (w/kVp meters)	3	$8,000.00(ea.)

- The state shall comply with the provision of The FDA Staff Manual Guide, 2620.4, which is incorporated by reference. This guide is available upon request.

- Training funding will be based on availability on an annual basis.

6. Government Furnished Materials

The following forms will be furnished to the state as needed:

Form No.	Title
FDA 2732	Field Test Record Continuation
FDA 2783	Mobile Radiographic Systems Field Test Record
FDA 2784	Abovetable X-Ray Source Radiographic Systems Field Test Record
FDA 2785	Dental Radiographic Systems Field Test Record
FDA 2786	Undertable X-ray Source Fluoroscopic and Spot-Film System Field Test Record
FDA 3068	Peak Kilovoltage Determination Field Test Record
FDA 3069	Abovetable X-ray Source Fluoroscopic and Spot-Film Systems Field Test Record

FDA 3071	General Information Field Test Record
FDA 3260	C-Arm Fluoroscopic and Spot-Film Systems Field Test Record
FDA 3261	Vertically Mounted Cassette Holder Radiographic Systems Field Test Record
FDA 3297	Head and Neck Radiographic Systems Field Test Record

PUBLICATIONS; HHS Publication FDA-81-8161, Routine Compliance Testing for Diagnostic X-Ray Systems.

7. Assessment Mechanisms

Signing of this agreement formalizes the partnership between Nashville District FDA and TDEC for the regulation of the diagnostic radiographic x-ray installation/assembly industry. It becomes effective on the date of the last signature.

Annual evaluations will be performed with the reports due on the last working day of October. The project coordinators will jointly prepare options for follow-up agency actions, as appropriate, for approval by the signatories to this agreement.

8. Signatures of Responsible Parties (and Date signed)

For FDA

Raymond K. Hedblad
Director
Nashville District

Date _____

For Tennessee *Department of Environment and Conservation*

Mike Mobley
Director
Tennessee Division of Radiological Health

Date _____