Georgia Department of Natural Resources
4244 International Parkway, Suite 114, Atlanta, Georgia 30354
Lonice C. Barrett, Commissioner
Environmental Protection Division
Harold F. Reheis, Director
(404) 362-2675

March 11, 1997

Mr. Walter J. Ramsey
Radiation Safety Officer
Scan Technologies, Inc.
2915 Courtyards Drive, Suite B
Norcross, GA 30071

Dear Mr. Ramsey:

We have received and completed the initial review of your Application for Sealed Source and Device Evaluation and Registration for the COALSCAN Model 2600 Series of analyzers. Additional information is required before we can continue the review. The text that follows itemizes any questions we have had to date.

1) Section 1.6, Radioactive Source Model Designation, lists Cs-137 Isotope Products Laboratories Model A3015 as a source to be used in the Model 2600. Isotope Products Laboratories Model A3015 is not listed in the Sealed Source & Device (SS&D) Registry. Please provide the information listed on the SS&D Registry sheet.

2) Section 3.2, Details of Construction, provides the parts list for the Model 2600. Please provide the accompanying engineering drawing(s) for the source housing and shielding/containment aspects of the device.

3) Section 3.4, Testing of Prototypes, mentions that the Model 2600 will utilize the same source containment and shutter mechanism as the Model 9000 Device, registration number GA-0176-D-103-S. Registration number GA-0176-D-103-S lists the Model 9200/9500 devices. Please indicate to which device -- the Model 9000 or Model 9200/9500 -- the Model 2600 is similar. Also, please describe the methods and conditions under which testing was performed, including a justification that the Model 2600 can withstand the given temperature range from -18°C to 46°C.

4) Both the text of the application and the picture in Section 2.2 do not provide a clear indication of the location of the shutter lever and shutter position indications. Please provide this information. Also indicate if the shutter position is indicated on the remote operator's control console.

5) Section 3.1, Conditions of Use, provides information about the expected life of the source capsules. In addition, please provide an expected working life of the Model 2600 device itself.

Georgia Department of Natural Resources
4244 International Parkway, Suite 114, Atlanta, Georgia 30354
Lonice C. Barrett, Commissioner
Environmental Protection Division
Harold F. Reheis, Director
(404) 362-2675

6) Is the copy of the label provided in Section 3.3 actual size?

7) Section 3.6, Radiation Profiles, does not mention the date the radiation survey was performed. Please provide the date the measurements were performed. Also, please indicate, for both the BEAM ON and BEAM OFF conditions, along which axis the highest readings were observed.

8) The radiation profile for most devices utilizing sources containing radioactive material will have higher dose rates for the BEAM ON condition than for the BEAM OFF condition. Please provide an explanation for why the dose rates did not drop going from BEAM ON to BEAM OFF.

9) Section 6.4 of the Field Service Radiation Safety Procedures pertains to the testing of the ON/OFF Mechanism. As part of this test, step 6 mentions that the measurement should drop from a high number during the ON mode to almost zero during the OFF mode. Please explain how the Field Service Representative will verify proper operation of the ON/OFF Mechanism if the measured dose rate is the same for the ON and OFF positions.

10) Are there any references to the radioactive source and/or shutter mechanisms listed in the standard Operator's Manual? Will persons who will not be performing their own shutter mechanism checks be provided with the test procedures?

Upon receipt of the above information, we will be able to resume the Device Evaluation amendment for the COALSCAN Model 2600 series of analyzers. Any information previously submitted that meets the conditions listed in Rule 391-3-17-.01(5)(c) will be classified and maintained as confidential. If you have any questions, please feel free to give our office a call at (404) 362-2675.

Sincerely,

Eric T. Jameson
Radiological Health Specialist