

July 5, 2002

Mr. William F. Troxler, President
Troxler Electronic Laboratories, Inc.
3008 Cornwallis Road
P.O. Box 12057
Research Triangle Park, NC 27709

Dear Mr. Troxler:

This is a response to your letter dated April 26, 2002, requesting information on the registration and licensing of your CoreReader densitometer as an exempt product. Based on the information you have provided, we understand that the CoreReader is designed to use multiple exempt sources to measure the porosity of asphalt samples for road construction. The proposed design and use of your device may be exempted from the provisions of 10 CFR 30.15(a)(9) which specify the use of exempt sources for ionizing radiation measuring instruments; however, in order to make a determination whether such an exemption can be granted, we need additional information.

If you should decide to continue, please provide a complete, formal application for the registration of the device. In addition, to support your request for an exemption, please provide additional information regarding the environmental effects and the risks to public health and safety, including subversion of the sources, that the exempt distribution of the CoreReader might present.

In the Enclosure to this letter, we have delineated the specific issues that your application should address which will enable us to make a decision on your request. If you have any further questions, you may contact Thomas Essig, of my staff, at (301) 415-7231, or through e-mail, at the@nrc.gov.

Sincerely,

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As stated

July 5, 2002

Mr. William F. Troxler, President
Troxler Electronic Laboratories, Inc.
3008 Cornwallis Road
P.O. Box 12057
Research Triangle Park, NC 27709

Dear Mr. Troxler:

This is a response to your letter dated April 26, 2002, requesting information on the registration and licensing of your CoreReader densitometer as an exempt product. Based on the information you have provided, we understand that the CoreReader is designed to use multiple exempt sources to measure the porosity of asphalt samples for road construction. The proposed design and use of your device may be exempted from the provisions of 10 CFR 30.15(a)(9) which specify the use of exempt sources for ionizing radiation measuring instruments; however, in order to make a determination whether such an exemption can be granted, we need additional information.

If you should decide to continue, please provide a complete, formal application for the registration of the device. In addition, to support your request for an exemption, please provide additional information regarding the environmental effects and the risks to public health and safety, including subversion of the sources, that the exempt distribution of the CoreReader might present.

In the Enclosure to this letter, we have delineated the specific issues that your application should address which will enable us to make a decision on your request. If you have any further questions, you may contact Thomas Essig, of my staff, at (301) 415-7231, or through e-mail, at the@nrc.gov.

Sincerely,
/RA/
Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As stated

Distribution:
IMNS r/f
JJankovich

ADAMS Ascension Number: ML021840743
g:\jankovich\ Exempt reply - OGC version.wpd

OFC	MSIB*	E	OGC*	E	MSIB*		MSIB*		IMNS	
NAME	JJankovich/jj		MSchwartz/NLO		CCox		TEssig		DCool	
DATE	06/ 26 /02		07/ 3 /02		7/05/02		7/05/02		07/5/02	

OFFICIAL RECORD COPY

In your application for registration of the CoreReader as an exempt product, please address the issues listed below. The NRC reports we reference, are accessible at the NRC web site: www.nrc.gov.

1. Device Registration

Please follow the guidance provided in NRC report entitled "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Registration," NUREG-1556, Vol. 3. Section 10 of this volume lists the specific technical issues that must be addressed in the application.

2. Environmental Assessment

Please follow the guidance provided in NRC draft report entitled "Environmental Review Guidance For Licensing Actions Associated with NMSS Programs," NUREG-1748. Section 3 of this report lists the specific technical issues that must be addressed in the environmental assessment. The NRC staff will prepare the environmental assessment; however, the staff will need the information listed in Section 3 of the report regarding the CoreReader device. Specifically, please address:

Purpose and need for the exemption:

Provide the benefits provided by the exemption, if granted, and a description of the detriment that would be experienced without the approval. Specifically, please discuss the issues that you included in your letter, dated April 26, 2002, that there "is a need for a nationally uniform licensing regime" regarding your design, and that "[a]ll jurisdictions do not have comparable general license...Some Agreement States currently require that the device be registered or specifically licensed..." Please provide examples such as the unique technical features of the device with respect to other porosity measurement techniques that are currently available, and the road building improvements nationwide that could be achieved with the device.

Alternatives to the exemption:

Describe identifiable environmental impacts of distributing the CoreReader as an exempt product vs distributing as a generally licensed device.

Affected environment:

Describe the affected environment where the CoreReader will be used. Address the issue on a nationwide basis. Consider the working life of the devices. Consider the total number of devices that will be in use for extended periods of time.

Environmental impacts:

Describe whether there are significant impacts (radiological and non-radiological) for an exempt distribution of this product. Impacts can be direct, indirect, cumulative, long-term, and short-term. Although impacts may exist, they may not be significant, and impact can be beneficial as well as adverse. An impact that is not significant does not equate to "no impact." Accident analysis is to be discussed below in risk assessment.

Disposal:

Describe the recommended practice of disposal, estimate the number of units to be disposed on a yearly basis, estimate the impact of disposed units. Please also address whether Troxler will accept the units for disposal of the sources.

3. Risk Assessment

Please follow the guidance provided in NRC report entitled "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," NUREG-1717. Section 2.10 of this report lists the specific technical issues that must be addressed in the risk assessment. The NRC staff will prepare the risk assessment; however, the staff will need the information listed in Section 2.10 of the report regarding the CoreReader device. Specifically, please address:

Quantifiable measures:

Provide estimated values for the number of units, the number persons, and the length of time associated with distribution and transportation, routine use, repair, disposal, accidents and misuse.

Estimated potential radiation doses

Provide estimates for (a) the annual effective dose equivalent for the individuals who are involved in the activities listed above, and (b) collective effective dose equivalent which is a sum of the individual doses for all the persons involved in these activities.

Security

Recently, there has been heightened concern for the availability of radioactive sealed sources and the possibility that all licensed material will have to be tracked. Please provide information why the increased availability, presumed to exist with making the CoreReader an exempt device, does not represent an unacceptable increase in the risk of the sources becoming subverted.