

TROXLER

April 26, 2002

Dr. Donald A. Cool, Director
Mail Stop T-8F5
Division of Industrial and Medical Nuclear Safety
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Dr. Cool:

Thank you and your staff for meeting with Troxler on April 22, 2002 to discuss our request for a license under 10 CFR 32.14 and 10 CFR 30.15(a)(9)(ii) for the manufacture and exempt distribution of the Troxler product known as the CoreReader. This second meeting between Troxler and the NRC Staff on the CoreReader gave us an opportunity to refine the licensing issues related to this request. To maintain the momentum towards finding a final path to licensing the CoreReader, you suggested that Troxler provide written suggestions for addressing the remaining issues. To put those suggestions in perspective, Troxler believes that it will be useful first to review briefly the interactions between the NRC and Troxler.

The CoreReader is a revolutionary device for accurately measuring the density of asphalt in roads. Use of this device would substantially improve the quality and longevity of roads by significantly improving the ability to formulate asphalt mixes and to control the quality of those mixes during the road building process. However, Troxler's experience with licensed gauges shows that despite the CoreReader's advantages, it would not be attractive to end-users unless it could be distributed nationally under a uniform licensing regime without the regulatory requirements that are appropriate for other gauges that contain larger quantities of byproduct material.

The CoreReader uses eight exempt cesium-137 sources arranged in a particular geometric pattern to accurately measure the density of an asphalt sample by measuring the attenuation of ionizing radiation passed through that sample. The sources are used for both internal calibration and standardization and for density measurement. Troxler has applied for a patent for this unique use of such low amounts of byproduct material for these purposes. Troxler believes that this device meets the criteria in 10 CFR 30.15(a)(9)(ii) for exempt distribution of devices that contain up to ten exempt sources.

In anticipation of submitting a license application for the CoreReader, Troxler conducted informal telephone discussions with members of your staff. Troxler was told that some members of the NRC Staff interpreted the exempt licensing under 10 CFR 30.15(a)(9)(ii) for an "ionizing radiation measuring instrument" to be limited to instruments that have the purpose of measuring environmental radiation. Although the NRC's Office of General Counsel ("OGC") has shown flexibility in interpreting this regulation in other contexts to apply to instruments that do not directly measure ionizing radiation but which support such measurements, Troxler was concerned

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that such flexibility in interpretation would not be applied to the CoreReader. Accordingly, Troxler determined not only to request a license for exempt distribution but also, in the alternative, to seek an exemption from the NRC Staff's interpretation in this case.

Troxler met with members of your staff on February 6, 2002. A copy of Troxler's presentation is enclosed. Troxler showed that distribution of the CoreReader under an exempt license would present no undue risk to public health and safety and common defense and security because: (1) the CoreReader contains less than the maximum amount of exempt byproduct material that the NRC has found can be safely licensed for exempt distribution; (2) the CoreReader will be used in a way that minimizes any threat of diversion or theft; and (3) recent NRC studies of exempt distribution showed that the exempt distribution of the CoreReader would not present any safety or security concern. At that meeting, no member of your staff identified any safety or security issue.

Since the NRC staff believes that an instrument distributed under 10 CFR 30.15(a)(9)(ii) must have the purpose of environmental radiation monitoring, even though the rule does not specify such purpose, Troxler suggested that an exemption under 10 CFR 30.11 be granted from this interpretation. Troxler showed that such an exemption would satisfy all of the NRC's exemption criteria and the Commission's four performance objectives. Nevertheless, some NRC Staff members objected to an exemption and suggested that Troxler obtain a general license for the CoreReader. Troxler explained in detail that a general license would likely limit the attractiveness of the CoreReader because it would impose unnecessary regulatory requirements that would not be accepted by potential purchasers of the device and could result in varying requirements by different Agreement States.

Several weeks later, the member of OGC who attended the the February 6 meeting meeting verbally informed Troxler that OGC supported the NRC Staff's interpretation of 10 CFR 30.15(a)(9)(ii). No written explanation of that position has been provided to Troxler.

Troxler then requested a meeting with you to obtain higher level management review of its request. Despite disagreeing with the NRC Staff's limiting interpretation of 10 CFR 30.15(a)(9)(ii), Troxler chose not to challenge that position. Rather, Troxler chose to address what it understood were the NRC Staff's concerns related to the request for an exemption from that interpretation. A copy of Troxler's presentation from the April 22, 2002 meeting is enclosed. It fully addresses all of the NRC Staff's issues. Once again, no one at the meeting identified a safety or security concern related to licensing the CoreReader for exempt distribution under 10 CFR 30.15(a)(9)(ii).

Since there is total agreement between Troxler and the NRC Staff regarding the lack of any safety or security issue associated with the exempt distribution of the CoreReader under 10 CFR 30.15(a)(9)(ii), the remaining issue is how the NRC can apply its regulations to license the CoreReader in a way that implements the Commission's performance goal of reducing

unnecessary regulatory burden. In that regard, you requested Troxler to provide more details on how an exemption from the regulations under 10 CFR 30.11 could be narrowly drafted to apply to this particular device and to propose alternative exemptions from other applicable licensing requirements in 10 CFR Part 30. Troxler's responses to these requests follow.

Regarding the wording of an exemption from the limiting interpretation of 10 CFR 30.15(a)(9)(ii), a narrow exemption would be based on the use of several exempt sources arranged in a particular geometry to achieve accurate measurements. The exemption could be formulated as follows:

Consistent with the Commission's reasons for adopting 10 CFR 30.15(a)(9)(ii), as stated in the supplementary information accompanying the publication of that amendment (46 Fed. Reg. 26471, May 13, 1981), because multiple exempt sources are incorporated in the CoreReader in a particular geometry in order to produce more reliable, less costly measurements of the attenuation of ionizing radiation by an asphalt sample, the CoreReader shall not be precluded from being distributed under 10 CFR 30.15(a)(9)(ii) based on the ultimate purposes of those radiation measurements.

Regarding exemptions from alternative provisions in 10 CFR Part 30, Troxler has reviewed Part 30 and can find no other requirements that could be readily modified by exemption to apply to this situation. Moreover, an exemption from the interpretation of 10 CFR 30.15(a)(9)(ii) would be the most efficient regulatory alternative and, thus, most consistent with the NRC's performance objectives.

Of particular concern to Troxler is the need for a nationally uniform licensing regime. Only the NRC's exempt distribution licensing would provide such uniformity. Any other type of NRC license might not be recognized without change by an Agreement State. Each Agreement State has its own regulations and may allow reciprocity activities within its state. However, there is no reciprocity provision applicable to general licensees. All jurisdictions do not have a comparable general license, and specific provisions of the general license may vary among jurisdictions. Some Agreement States currently require that a device be registered or specifically licensed before it can be used in that State. (NUREG-1556, Vol. 16, Appendix K).

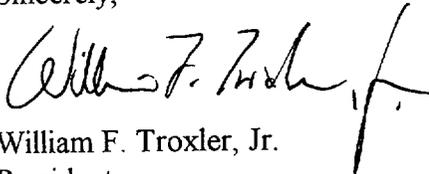
Under these circumstances, Troxler requests the NRC to apply 10 CFR 30.15(a)(9)(ii) to the CoreReader either directly or as modified by an exemption. Such distribution is generally agreed not to present any undue risk to public health and safety or to the common defense and security. Moreover, where the wording of a regulation is capable of more than one interpretation, the Commission's performance objectives imply that the interpretation which maintains safety while reducing unnecessary regulatory burden should be adopted. Even if the regulation has been interpreted differently in the past, the change in the Commission's regulatory philosophy, coupled with the substantive findings of safety and burden reduction, support the adoption of the interpretation which implements the new policy. Finally, in view of Troxler's substantial

Dr. Donald A. Cool
April 26, 2002

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investment in the CoreReader, the societal benefits to be realized by its use in road building, and the extensive interactions between the NRC and Troxler, Troxler respectfully requests a reply by May 13, 2002.

Sincerely,

A handwritten signature in black ink, appearing to read "William F. Troxler, Jr.", with a stylized flourish at the end.

William F. Troxler, Jr.
President

Enclosures (2)

Exempt Licensing Request for Troxler's CoreReader

Presented to NRC Staff

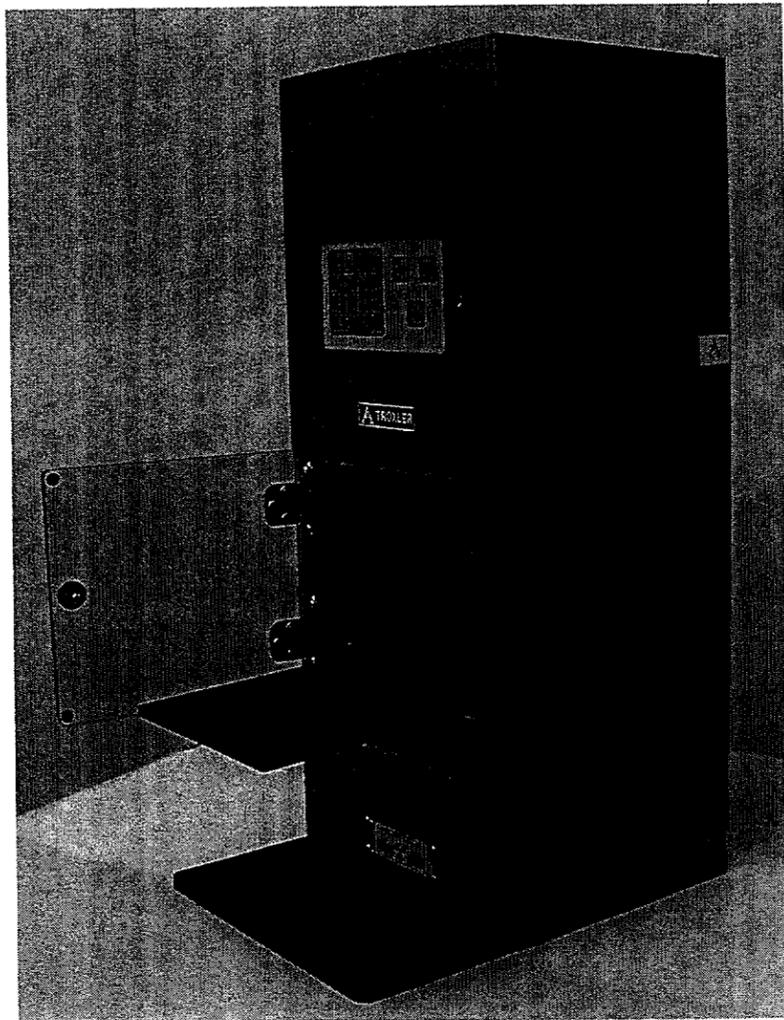
February 6, 2002

Rockville, MD

2/6/02

1

CoreReader



2/6/02

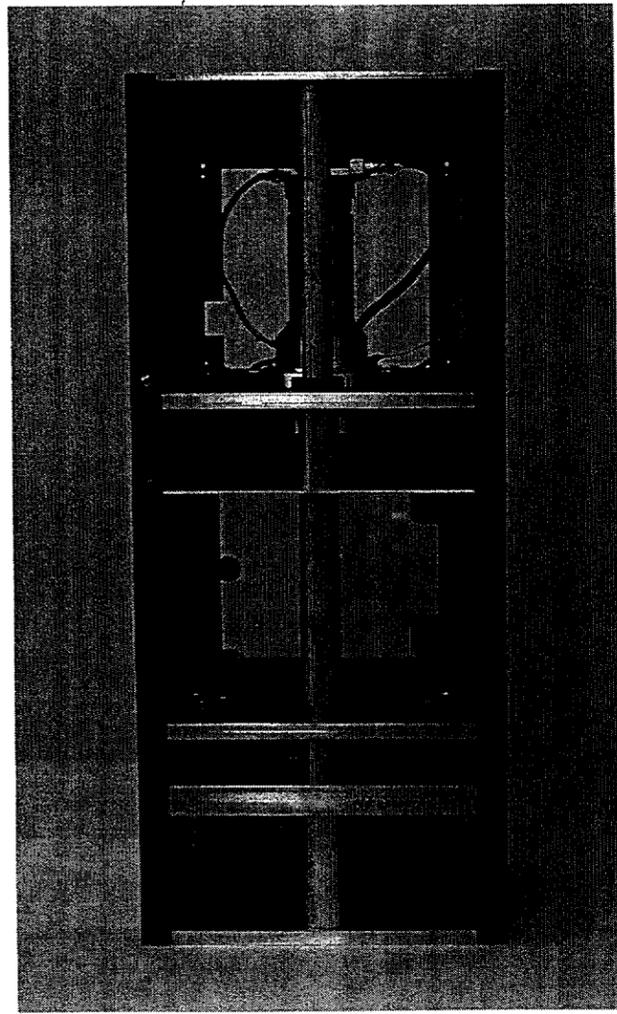
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CoreReader

- The CoreReader is an ionizing radiation measurement instrument with self-contained exempt sources and specialized software for analysis and interpretation of a gamma-ray transmission spectrum to estimate the specific gravity of a compacted asphalt sample
- Bench-top laboratory instrument
 - relatively heavy and bulky

Design and Construction

- Overall
 - Dimensions: 12.2" w x 10.2" d x 29" h
 - Weight: 77 lbs.
 - All metal construction
 - Lead shielding
 - Sources inaccessible and secured against unauthorized removal

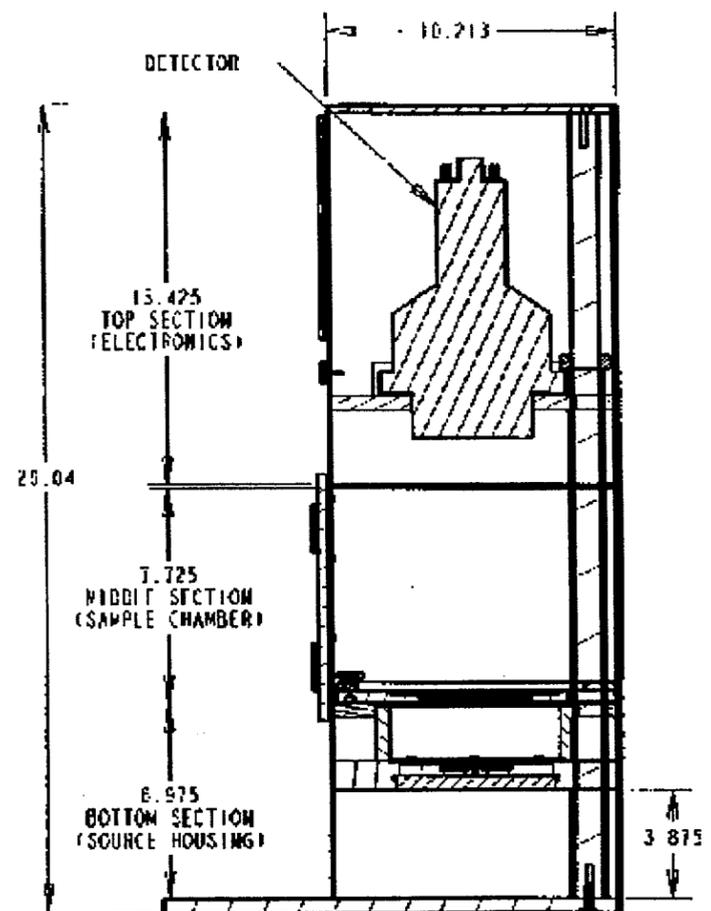


2/6/02

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Design and Construction

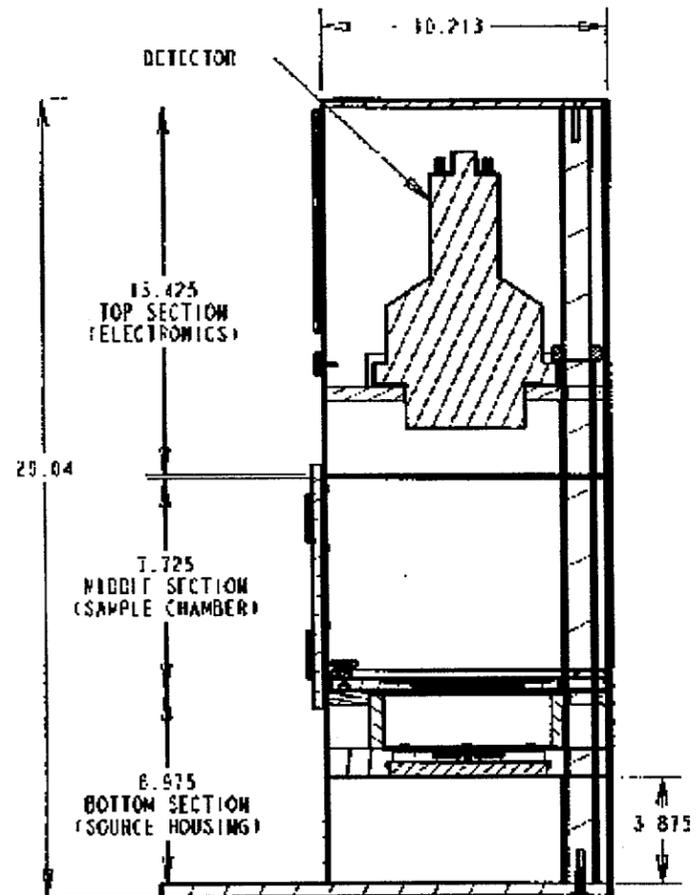
- Top section
 - Detector
 - Electronics
 - Keyboard
 - Display



2/6/02

Design and Construction

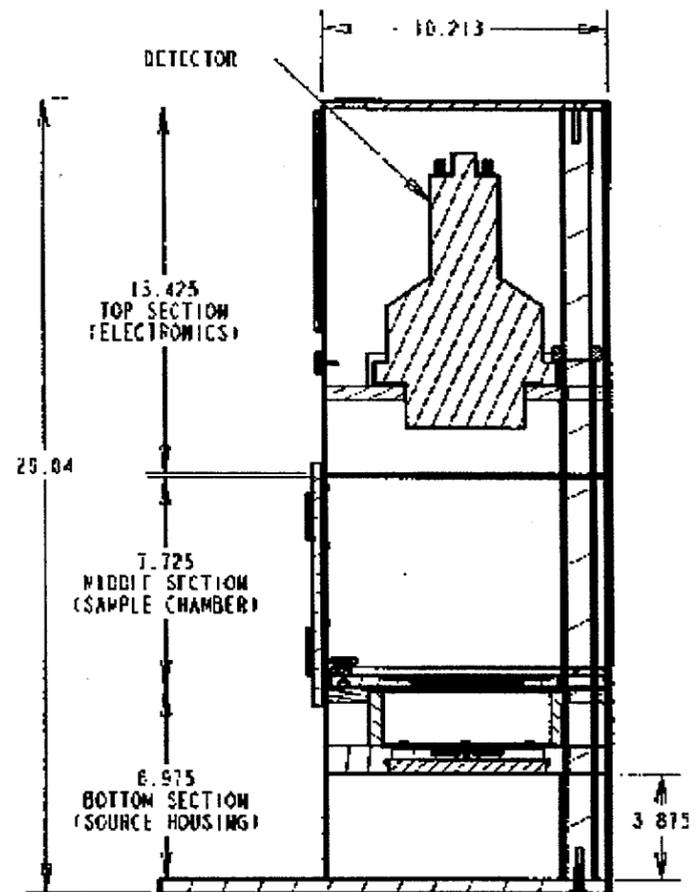
- Middle section
 - Sample chamber
 - Separated from top and bottom sections by solid aluminum plates
 - Access door on front, transparent plastic
 - Tray slides out to insert or remove sample



2/6/02

Design and Construction

- Bottom section
 - Source plate assembly
 - Ring-shaped lead shield atop source plate
 - No user access to the bottom section
 - Al base plate



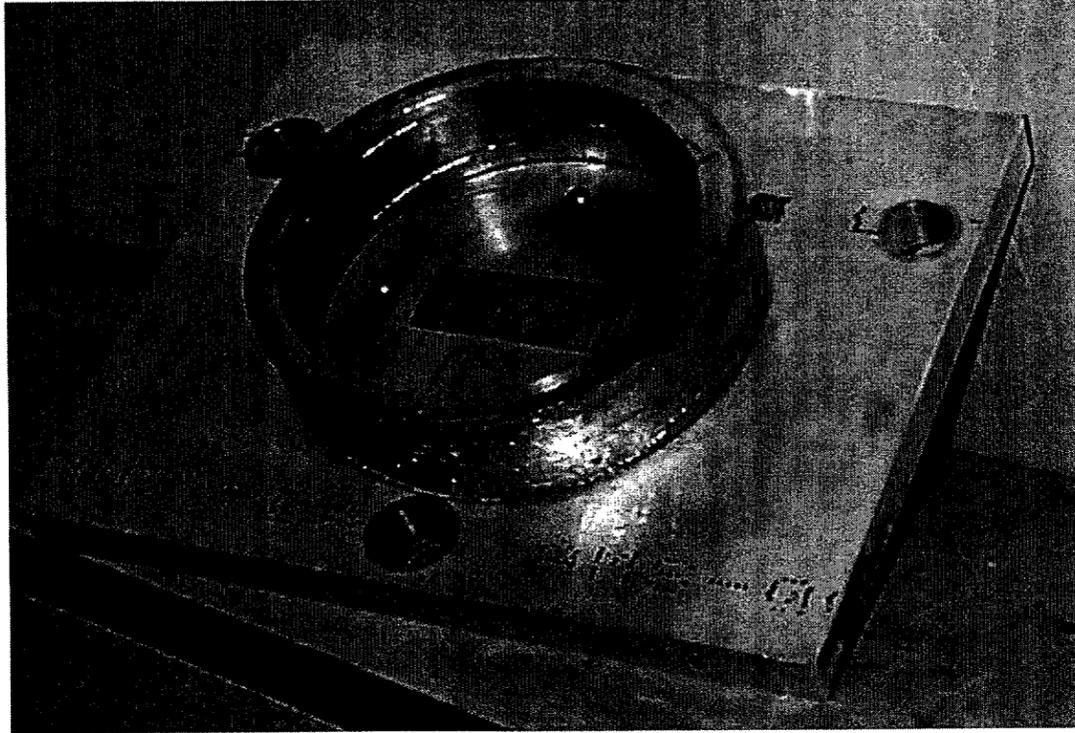
2/6/02

Source Details

- Cs-137, exempt quantity sealed sources, 10 microcuries each
- Sealed in Plexiglass disk, 1" diameter x 0.175" thick
- 8 sources (80 microcuries total)
- Multiple sources (distributed pattern) essential to operation of device

Design and Construction

- Source plate assembly

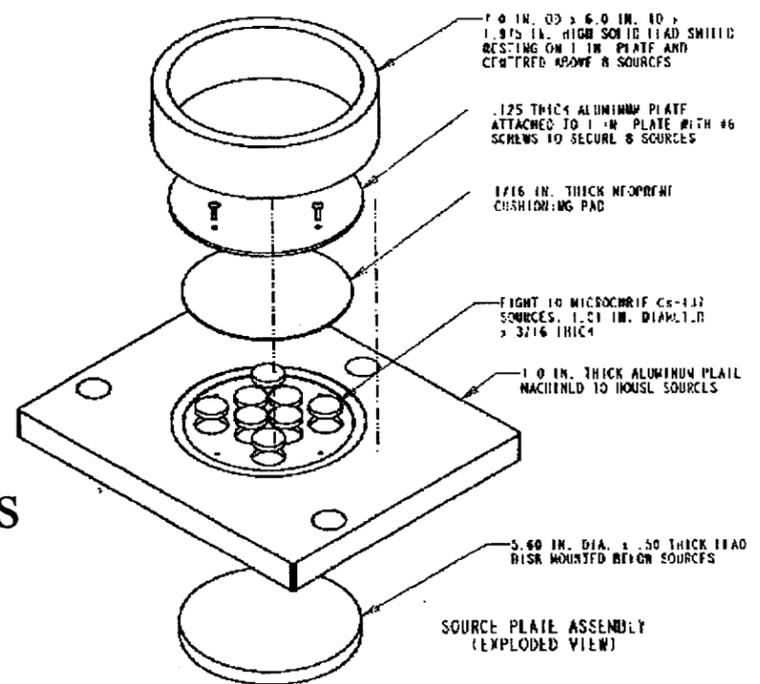


2/6/02

Design and Construction

- Source Plate Assembly

- 0.5” thick x 6” ID lead ring shield
- 0.125” cover plate with neoprene cushion
- 1.0” Al plate with recesses for 8 sources
- 0.5” lead shield

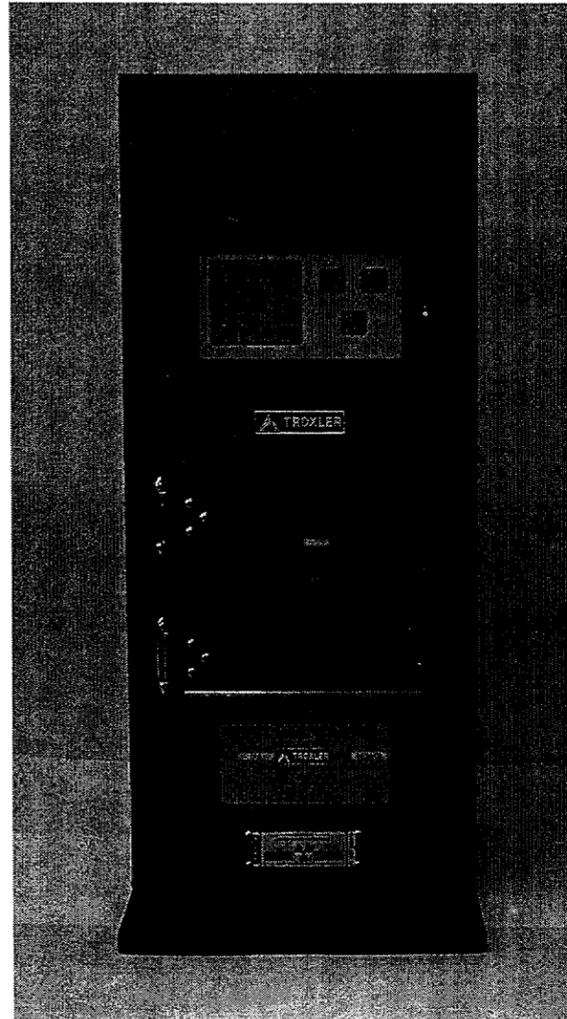


Quality Control

- Manufactured under same quality assurance program as registered portable nuclear gauges for specific licenses
- Leak testing performed on each device prior to distribution to customer

Marking and Labeling

- Label locations
 - Nameplate
 - Radiation label

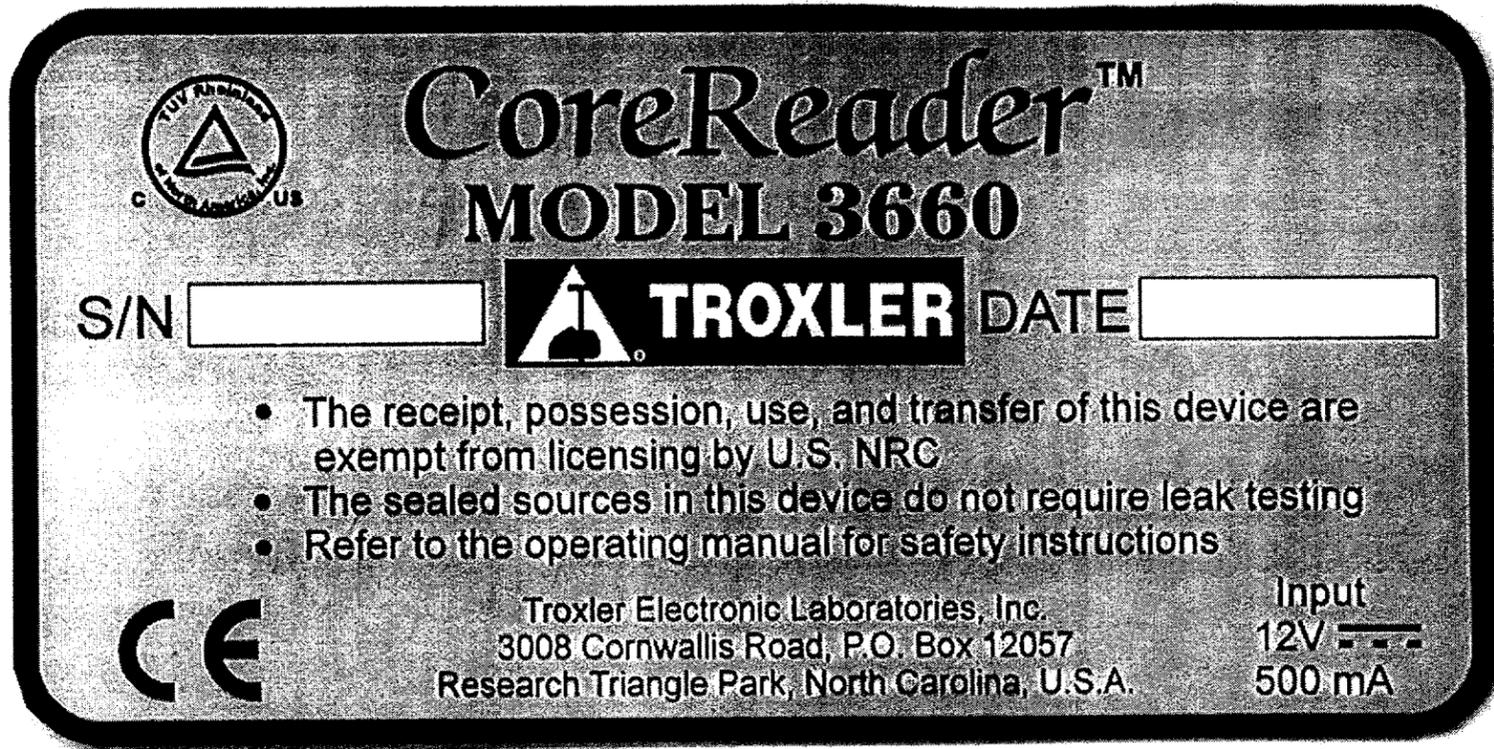


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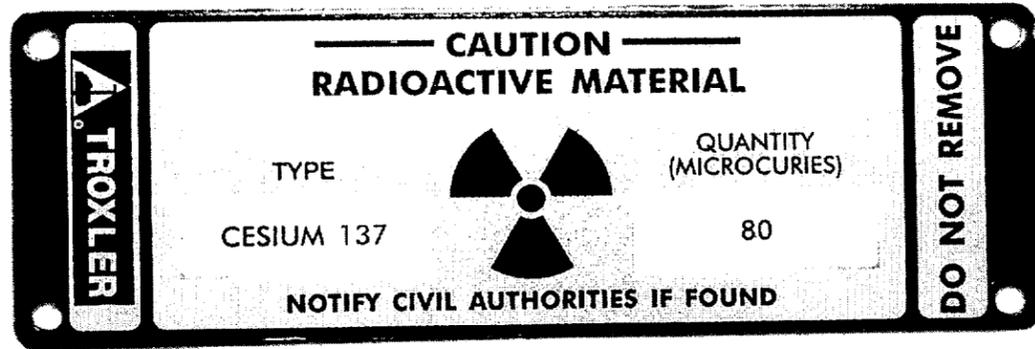
Marking and Labeling

- Nameplate



Marking and Labeling

- Radiation Label



Radiation Levels

- Measured with Bicron Micro Rem survey meter with organic scintillator calibrated to Cs-137

Distance or Location (Maximum dose rate)	Dose Rate Above Bkgd (mrem per hour)
In sample chamber	1.1
5 cm	0.2
30 cm	0.05
100 cm	Not detectable

Radiation Risks

- Normal Operation
 - Dose would not exceed 100 mrem for individual working 2000 hours per year at 30 cm from device
 - Extremity dose would not exceed 10% of annual limit if hands were inside sample chamber for 2000 hours per year.

Prototype Testing

- Procedure
 - Based on Type A package test
 - Vibration of 1/8” total displacement at 15 Hz for 24 hours
 - Drop test on all six surfaces from 36”
 - Drop test on four bottom corners and four top corners from 1 foot followed by 40” drop on top rear corner

Prototype Testing

- Results
 - Minor distortion of outer sheet metal
 - No damage to source plate assembly
 - No movement or damage to lead shielding
 - No change in radiation profile before and after test

Prototype Testing

- Radiation levels before and after

Gauge Surface	Before Test 10/12/01 (mrem/hr)*	After Vibration Test 10/26/01 (mrem/hr)*	After Drop Test 11/7/01 (mrem/hr)*
Front	0.25	0.2	0.2
Back	0.16	0.16	0.15
Right side	0.17	0.15	0.15
Left side	0.16	0.14	0.15
Top	0.04	0.04	0.05
Bottom	0.14	0.15	0.15

Radiation Risks

- Accident
 - No significant increase in surface radiation fields after prototype testing
 - Inhalation or ingestion of total activity in device highly unlikely
 - would not exceed annual limit on intake for Cs-137

Purposes of Radioactive Material

- Internal calibration and standardization of the detector
- Measurement of sample properties

Purpose of Radioactive Material

- Internal calibration and standardization
 - Internal Cs-137 sources counted with empty sample chamber to calibrate and standardize the gamma scintillation detector and associated multichannel analyzer electronics
 - Calibration check is prerequisite to system operation

Purpose of Radioactive Material

- Measurement of sample properties
 - Asphalt sample placed on the sample tray between gamma-ray sources and detector
 - Cylindrical: 100 - 150 mm dia, 25 - 175 mm thick
 - Instrument measures the ionizing radiation transmitted through the sample
 - CoreReader software analyzes spectrum and converts to estimate of bulk specific gravity
 - Average measurement time about 4.5 minutes

Licensing Requirements

- Exempt license under 10 CFR 30.15(a)(9)
 - Ionizing radiation measuring instrument
 - Containing sources for purposes of internal calibration or standardization
 - Limits on sources
 - Each source no greater than one exempt quantity
 - No more than 10 exempt quantities

Applicability of 30.15(a)(9)

30.15 (a)(9)	CoreReader
<i>"Ionizing radiation measuring instruments"</i>	NaI detector based gamma ray spectrometer
<i>"Containing, for purposes of internal calibration or standardization, one or more sources of byproduct material"</i>	The sources are used for internal calibration and standardization of the NaI detector and spectrometer system
<i>"Provided that each source contains no more than one exempt quantity set forth in 30.71, Schedule B, and..."</i>	Each source is no more than the exempt quantity for Cs-137 (10 microcuries)
<i>Each instrument contains no more than 10 exempt quantities</i>	Contains 8 exempt quantities

History of 30.15(a)(9)

- Established in 1970
 - “sources, when installed in instruments, constitute a smaller risk than as separate quantities”
- Multiple sources added in 1981
- Interpreted in 1995 to apply to Dosimeter Calibrators and TLD Readers
 - Not ionizing radiation measuring instruments
 - Directly support measurements of radiation
 - No longer licensed under 10 CFR 31.5

Bundling of Exempt Sources

- Generic Letter 99-01
 - Addressed concerns over bundling of more than 10 exempt sources in gauging devices
 - Bundling of 10 or fewer exempt sources affirmed as not presenting new safety issues
 - Devices with no more than 10 exempt sources not found to violate NRC requirements
 - NRC determined distribution of sources for bundling in devices not allowed
 - Exemption in 30.15(a)(9) unaffected

Recent Licensing Guidance

- NUREG-SR1556, Vol. 8
 - Program-Specific Guidance About Exempt Distribution Licenses (1998)
- Exempt Bases
 - No unreasonable risk to public health or safety or common defense and security
 - Limited amount of byproduct material
 - Safety-features built into devices

Safety of Exempt Products

- NRC reviewed safety of exempt licensing:
 - Systematic Radiological Assessment of Exemptions for Sources and Byproduct Materials, NUREG-1717
 - Risk Analysis and Evaluation of Regulatory Options for Nuclear byproduct Material Systems, NUREG/CR-6642
- Results supported guidance in NUREG-1556
- Results used to support achievement of performance goals in NRC strategic plan

Safety Bases of Exempt Licensing

- Products with 10 exempt sources considered
 - System type # 30 - very small sealed sources
 - 10,000 devices with Cs-137 sources assumed
- Accident risks found very small due to low source strengths
- Disposal dose less than use dose
- Several factors limiting dose identified
 - Inaccessibility of materials in multiple containers
 - Specialty equipment used by qualified technicians
 - Low accident dose to public

Potential Licensing Issues

- Applicability of 10 CFR 30.15(a)(9)
 - Ionizing radiation measurement instrument
 - Dual purpose uses of sources
- Theft of device
- Disposal of device
- Coordination with Agreement States
- Consistency with NRC performance goals
- Bundling of exempt sources

Potential Licensing Issues

- Ionizing radiation measurement instrument
 - Rule does not specify purpose of radiation measurement
 - Safety of a device depends on type, form, and quantity of radioactive material, and the design, construction, and operation of the device, not the purpose of measurement

Potential Licensing Issues

- Dual use of source
 - 30.15(a)(9) requires only that the sources be used for internal calibration and standardization
 - 30.15(a)(9) does not prohibit the sources from being used for other purposes consistent with the safety bases for the rule
 - licensing the CoreReader under this rule is consistent with its intent because the additional purpose does not substantially increase the risk associated with using this instrument and furthers the goal of not distributing loose sources

Potential Licensing Issues

- Theft of device
 - Most thefts involve portable nuclear gauges stolen from parked vehicles, especially pickup trucks
 - CoreReader is a laboratory instrument and would seldom be transported
 - If stolen, radiation risk to public negligible because of the low source activity and dose rates

Potential Licensing Issues

- Disposal of device
 - Rule authorizes disposal in ordinary waste
 - Low activity presents negligible public exposure risk
 - Troxler will, however, accept gauges returned for disposal at no charge

Potential Licensing Issues

- Coordination with Agreement States

When Appropriate	CoreReader
<i>Where granting a license application would be a substantial change in precedent</i>	No change in precedent would be established.
<i>If a large number of devices could become eligible to be distributed as exempt</i>	Relatively limited distribution of devices to asphalt labs
<i>If the licensing basis for devices already licensed might be changed.</i>	Licensing of other devices not affected.
<i>If the risks associated with exempt distribution might be greater than those already considered in the Materials Risk Study</i>	Risks no greater than those considered in the Materials Risks Study (NUREG/CR-6642)

Potential Licensing Issues

- Bundling of Exempt Sources
 - CoreReader is not a case of bundling because multiple exempt quantities are not used in lieu of a single source to avoid licensing
 - Multiple sources are essential to achieving measurement accuracy by averaging over a larger sample volume
 - A point source would irradiate a smaller volume which leads to larger measurement errors due lack of sample homogeneity

Potential Licensing Issues

- NRC performance goals

Goals	How Met
<i>Maintain safety, protection of the environment, and the common defense and security</i>	NRC has already found this quantity of source material is safe for exempt distribution
<i>Increase public confidence</i>	No relaxation of any safety rules. No compensatory safety measures necessary.
<i>Make the NRC activities more effective, efficient, and realistic</i>	Consistent with Materials Risks Study. Risks no greater than for distribution of multiple individual exempt quantities.
<i>Reduce unnecessary regulatory burden on stakeholders and associated costs</i>	The burden of general licensing would go beyond what is necessary and sufficient to provide reasonable assurance that public health and safety, the environment, and the common defense and security will be protected and would increase costs

Exemption from 30.15(a)(9)

- Section 30.11 authorizes the Commission to grant exemptions from requirements of Parts 30 through 36 and 39
- Exemption requested from:
 - Ionizing radiation measuring instrument requirement
 - Containing for purposes of standardization and calibration requirement

Basis for Granting Exemption

- Will not endanger life or property or the common defense and security
 - NRC has repeatedly determined that exempt quantities pose a negligible risk to health or safety
 - Normal or accident conditions will not cause overexposures to workers and unlikely to do so for members of public

Basis for Granting Exemption

- Is otherwise in the public interest
 - CoreReader is designed for quality control measurements of highway construction materials (not a frivolous use)
 - Alternate methods are less accurate and reproducible and more subject to human error
 - The ultimate benefits of higher quality pavements are reduced road maintenance and increased safety

Basis for Granting Exemption

- Exemption is not intended for a large class of licenses; limited to a unique situation
 - An exemption would not affect a whole class of licenses, but would only apply to the CoreReader (a unique product)
 - Would not likely lead to a large number of similar exemption requests, because similar products do not exist

Basis for Granting Exemption

- Why it is needed
 - To avoid unnecessary and burdensome requirements of general or specific licensing which increase costs and may discourage use of the CoreReader
 - The NRC has already determined that the amount of source material in the CoreReader represents a negligible risk and may be safely distributed as exempt either in the form of individual sources or incorporated in devices

Basis for Granting Exemption

- Proposed compensatory safety measures
 - None are necessary as the NRC has repeatedly determined that the amount of source material in the CoreReader represents a negligible risk and may be safely distributed as exempt either in the form of individual sources or incorporated in devices

Basis for Granting Exemption

- Alternative methods and why not feasible
 - CoreReader complies with all safety related requirements of 30.15(a)(9)
 - Alternatives would be specific or general licensing which are inappropriate and unnecessarily burdensome for the form and quantity of source material, the purpose of use, and the limited potential for exposure to workers or members of the public

Exempt Licensing Request for Troxler's CoreReader

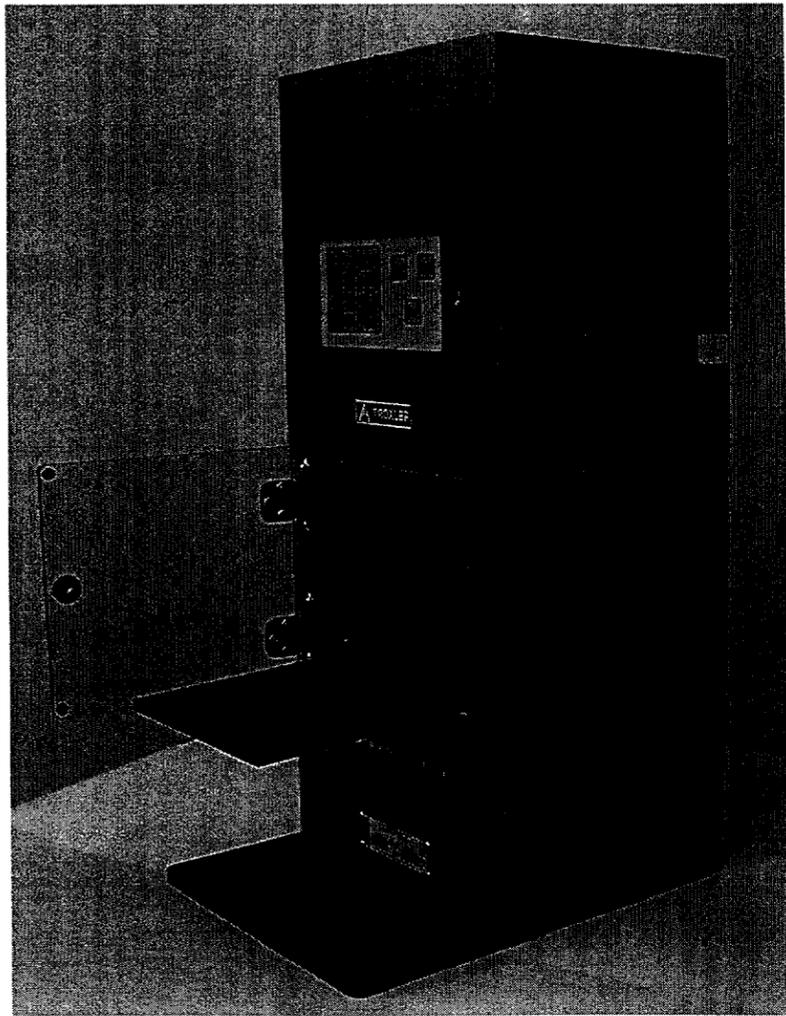
Presented to Dr. Donald A. Cool and NRC Staff

April 22, 2002

Rockville, MD

CoreReader

The CoreReader is a bench-top ionizing radiation measurement instrument employing proprietary software to interpret the gamma-ray transmission spectrum from an array of exempt-quantity sources to estimate the specific gravity of a compacted asphalt sample



4/22/02

Troxler's Licensing Request

- Issue a license to Troxler under 32.14 to manufacture and distribute the CoreReader as an exempt device under 30.15(a)(9)

Device Design and Construction

- Dimensions: 12.2" w x 10.2" d x 29" h
- Weight: 77 lbs.
- All metal construction
- Lead shielding
- Sources inaccessible and secured against unauthorized removal
- Design, construction, labeling, quality assurance, radiation levels and prototype testing presented in detail to NRC staff at previous meeting
- No safety-related concerns expressed by NRC staff

Source Details

- Cs-137, exempt quantity sealed sources, 10 microcuries each
- Sealed in Plexiglass disk, 1" diameter x 0.175" thick
- 8 sources (80 microcuries total)
- Multi-source geometry essential to operation of device

Device Radiation Levels

Distance or Location	Max. Dose Rate (mrem per hour above bkgd)
In sample chamber	1.1
5 cm	0.2
30 cm	0.05
100 cm	Not detectable

- Measured with Bicron Micro Rem survey meter with organic scintillator calibrated to Cs-137

Radiation Risks

- Routine operation (extreme case)
 - Whole body dose would not exceed 100 mrem per year (based on 2000 hours per year at 30 cm)
 - Extremity dose would not exceed 10% of annual limit (based on hands being inside sample chamber for 2000 hours per year)
- Accident (worst case)
 - Inhalation or ingestion of total activity in device (not credible) would not exceed annual limit on intake for Cs-137

Applicability of 30.15(a)(9)

30.15 (a)(9)	CoreReader
“Ionizing radiation measuring instruments...”	<ul style="list-style-type: none"> • NaI detector, gamma ray spectrometer. • Nothing in rule or statement of consideration limits purpose of instrument.
“containing, for purposes of internal calibration or standardization, one or more sources of byproduct material...”	<ul style="list-style-type: none"> • Sources used for internal calibration and standardization. • Other purposes not specifically precluded in rule. • Purpose doesn’t affect safety.
“provided that each source contains no more than one exempt quantity set forth in 30.71, Schedule B, and...”	<ul style="list-style-type: none"> • Each source contains no more than the exempt quantity for Cs-137 (10 microcuries)
“each instrument contains no more than 10 exempt quantities.”	<ul style="list-style-type: none"> • Contains 8 exempt quantities

NRC Concerns:

(as we understand them)

- 30.15(a)(9) not applicable because inferred intent limits purpose to measuring environmental radiation
- Granting an exemption for CoreReader would set a broadly applicable precedent
- Material control
- Bundling exempt sources

Safety Not a Concern

- No indication from previous meeting or conversations with NRC that safety of CoreReader is a concern (the question has been asked)
- GL 99-01 concluded multiple exempt sources in a device not a safety concern
- Lack of safety concern corroborated more recently by NRC research
 - Systematic Radiological Assessment of Exemptions for Sources and Byproduct Materials, NUREG-1717
 - Risk Analysis and Evaluation of Regulatory Options for Nuclear byproduct Material Systems, NUREG/CR-6642

Material Control

- Theft and diversion
- Disposal
- Accountability

Material Control

- Theft and diversion
 - Most thefts involve portable nuclear gauges stolen from open vehicles (e.g., pickup trucks)
 - Theft unlikely because:
 - CoreReader bulky and heavy
 - Used indoors in fixed locations, out of public view, and under better security
 - relatively few units expected to be in use
 - Diversion unattractive because of low activity (e.g., a moisture-density gauge contains 100,000 times more exempt quantity units)
 - low activity + low dose rate = low risk to public

Material Control

- Disposal of device
 - Rule authorizes disposal in ordinary waste
 - Low activity presents negligible public exposure risk in event of disposal
 - Troxler has an industry-leading source recovery and disposal program to prevent orphan sources
 - Troxler will encourage and accept return of devices for disposal as licensed material via device labeling, literature, and website

Material Control

- Accountability
 - Troxler will maintain permanent records of all device transfers including:
 - Name and address of transferee
 - Model and serial of device
 - Date of transfer

Bundling Exempt Sources

- Generic Letter 99-01 addressed concerns over bundling more than 10 exempt sources in devices
- Bundling of 10 or fewer exempt sources affirmed as not presenting new safety issues
- Devices with no more than 10 exempt sources not found to violate NRC requirements
- NRC determined distribution of sources for bundling in devices not allowed
- Exemption in 30.15(a)(9) unaffected

Bundling Exempt Sources

- CoreReader does not represent bundling because multiple exempt quantities are not used in lieu of a single larger source
- Possibility of exempt distribution not identified until after device designed
- Multi-source geometry essential to achieving accuracy goal by averaging over larger sample volume to reduce error from sample inhomogeneities

Proposed Path Forward

- Exemption from 30.15(a)(9)
 - Section 30.11 authorizes the Commission to grant exemptions from requirements of Parts 30 through 36 and 39
 - Exemption requested from NRC interpretation that creates limiting purpose on ionizing radiation measuring instruments covered by 30.15(a)(9)
 - Exemption based on geometric necessity implements Commission performance goals while suitably limiting scope of applicability

Proposed Path Forward

- Broadly applicable precedent not a concern because...
 - Exemptions are discretionary (NRC has refused to grant “copycat” exemptions)
 - Possibility of many similar requests speculative and, therefore, premature
 - Possibility of setting a precedent not a factor legally recognized in 30.11 in granting exemptions, otherwise all but most unusual, singular requests for relief would be denied, contrary to NRC practice.
 - If other requests materialize, NRC can deal with them at that time or initiate rulemaking

Basis for Granting Exemption

- Will not endanger life or property or the common defense and security
 - NRC has repeatedly determined that exempt quantities pose a negligible risk to health or safety
 - Normal or accident conditions will not cause overexposures to workers or members of public
 - Troxler will maintain records of transfers
 - Troxler will take devices back when no longer needed
 - Laboratory instrument has low risk of theft
 - Low activity unattractive for diversion

Basis for Granting Exemption

- Is otherwise in the public interest
 - CoreReader is designed for quality control measurements of highway construction materials
 - Alternate measurement methods are less accurate and reproducible and more subject to human error
 - The ultimate benefits are higher quality pavements, reduced road maintenance (lower overall cost), and increased safety
 - Actual benefits outweigh minimal theoretical risk

Basis for Granting Exemption

- Exemption is not intended for a large class of licenses; limited to a unique situation
 - An exemption would not affect a whole class of licenses, but would only apply to the CoreReader (a unique product)
 - Would not likely lead to a large number of similar exemption requests, because similar products do not exist (patent applied for)
 - An exemption can be narrowly tailored to the use of multiple sources for geometry reasons (similar to multiple sources for energy reasons)

Basis for Granting Exemption

- Why it is needed
 - To avoid unnecessary and burdensome regulatory requirements which increase costs and may discourage use of the CoreReader
 - The NRC has already determined that the amount of source material in the CoreReader represents a negligible risk and may be safely distributed as exempt either in the form of individual sources or incorporated in devices

Basis for Granting Exemption

- Proposed compensatory safety measures
 - None are necessary as the NRC has repeatedly determined that the amount of source material in the CoreReader represents a negligible risk and may be safely distributed as exempt either in the form of individual sources or incorporated in devices

Basis for Granting Exemption

- Alternative methods and why not feasible
 - CoreReader complies with all safety-related requirements of 30.15(a)(9)
 - Specific or general licensing are inappropriate and unnecessarily burdensome for the form and quantity of source material, purpose of use, and limited risk
 - No reciprocity for general licenses
 - Varying requirements for licensing, fees, registration, etc. in 32 Agreement States creates unnecessary and costly administrative burden
 - Requirement to provide extensive information prior to purchase decision adds a burden

Basis for Granting Exemption

- Alternative methods and why not feasible (cont.)
 - Agreement States may require a GL device to be put on a specific license if the user has one, which adds a complicating second set of labeling, license verification, and reporting requirements for Troxler
 - General licensee must appoint responsible person who has many responsibilities that are administratively burdensome and require knowledge and tracking of many different events that trigger actions to be taken