Aerosol Monitoring & Analysis, Inc.
Environmental, Health & Safety

August 30, 2016

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

Br. 2
03038246

RE: Request of Aerosol Monitoring & Analysis, Inc. for Amendment to NRC Radioactive Material License No. 19-31402-01 to Add Niton XLp 300A Series Lead Paint Analyzer

Dear Administrator:

Aerosol Monitoring & Analysis, Inc. (AMA) has added a new lead paint analyzer to perform lead paint surveys – the Niton XLp 300A Series (Serial #99428). This x-ray fluorescence (XRF) analyzer utilizes 40 mCi of ^{109}Cadmium (Cd) (1,480 Mbq) isotope as an excitation source, which is sealed, and the device is made by Thermo Fisher Scientific. Please amend license accordingly. AMA is now in possession of two (2) Niton XLp 300 Series XRF Analyzers. In addition, AMA will be decommissioning the RMD LPA-1 XRF Analyzer in the upcoming weeks. The unit is no longer in use, and is just being stored in our secure location at our office until it is sent to Thermo Scientific for decommissioning. We would like to remove the RMD LPA-1 XRF Analyzer from our NRC Radioactive Materials License.

Please feel free to contact me by phone at 410-684-3327 or by e-mail at rschoennagel@amaconsulting.com, with any questions. Thank you for your consideration. We appreciate your assistance in this matter.

Respectfully,

Robert Schoennagel, CHMM
Radiation Safety Officer

Gary L. Urban, CHMM
Vice President-Consulting Services

attachments

1331 Ashton Road • P.O. Box 646 • Hanover, MD 21076 • 410-684-3327 • FAX: 410-684-3384

Performance Characteristic Sheet

EFFECTIVE DATE: **September 24, 2004** **EDITION NO.: 1**

MANUFACTURER AND MODEL:

Make: *Niton LLC*
Tested Model: *XLp 300*
Source: ^{109}Cd
Note: This PCS is also applicable to the equivalent model variations indicated below, for the Lead-in-Paint K+L variable reading time mode, in the XLi and XLp series:

XLi 300A, XLi 301A, XLi 302A and XLi 303A.
XLp 300A, XLp 301A, XLp 302A and XLp 303A.
XLi 700A, XLi 701A, XLi 702A and XLi 703A.
XLp 700A, XLp 701A, XLp 702A, and XLp 703A.

Note: The XLi and XLp versions refer to the shape of the handle part of the instrument. The differences in the model numbers reflect other modes available, in addition to Lead-in-Paint modes. The manufacturer states that specifications for these instruments are identical for the source, detector, and detector electronics relative to the Lead-in-Paint mode.

FIELD OPERATION GUIDANCE

OPERATING PARAMETERS:

Lead-in-Paint K+L variable reading time mode.

XRF CALIBRATION CHECK LIMITS:

0.8 to 1.2 mg/cm^2 (inclusive)

The calibration of the XRF instrument should be checked using the paint film nearest 1.0 mg/cm^2 in the NIST Standard Reference Material (SRM) used (e.g., for NIST SRM 2579, use the 1.02 mg/cm^2 film).

If readings are outside the acceptable calibration check range, follow the manufacturer's instructions to bring the instruments into control before XRF testing proceeds.

SUBSTRATE CORRECTION:

For XRF results using Lead-in-Paint K+L variable reading time mode, substrate correction is <u>not</u> needed for:

Brick, Concrete, Drywall, Metal, Plaster, and Wood

INCONCLUSIVE RANGE OR THRESHOLD:

K+L MODE READING DESCRIPTION	SUBSTRATE	THRESHOLD (mg/cm^2)
Results not corrected for substrate bias on any substrate	Brick	1.0
	Concrete	1.0
	Drywall	1.0
	Metal	1.0
	Plaster	1.0
	Wood	1.0

BACKGROUND INFORMATION

EVALUATION DATA SOURCE AND DATE:

This sheet is supplemental information to be used in conjunction with Chapter 7 of the HUD *Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing* ("HUD Guidelines"). Performance parameters shown on this sheet are calculated from the EPA/HUD evaluation using archived building components. Testing was conducted in August 2004 on 133 testing combinations. The instruments that were used to perform the testing had new sources; one instrument's was installed in November 2003 with 40 mCi initial strength, and the other's was installed June 2004 with 40 mCi initial strength.

OPERATING PARAMETERS:

Performance parameters shown in this sheet are applicable only when properly operating the instrument using the manufacturer's instructions and procedures described in Chapter 7 of the HUD Guidelines.

SUBSTRATE CORRECTION VALUE COMPUTATION:

Substrate correction is not needed for brick, concrete, drywall, metal, plaster or wood when using Lead-in-Paint K+L variable reading time mode, the normal operating mode for these instruments. If substrate correction is desired, refer to Chapter 7 of the HUD Guidelines for guidance on correcting XRF results for substrate bias.

EVALUATING THE QUALITY OF XRF TESTING:

Randomly select ten testing combinations for retesting from each house or from two randomly selected units in multifamily housing. Use the K+L variable time mode readings.

Conduct XRF retesting at the ten testing combinations selected for retesting.

Determine if the XRF testing in the units or house passed or failed the test by applying the steps below.

Compute the Retest Tolerance Limit by the following steps:

Determine XRF results for the original and retest XRF readings. Do not correct the original or retest results for substrate bias. In single-family housing a result is defined as the average of three readings. In multifamily housing, a result is a single reading. Therefore, there will be ten original and ten retest XRF results for each house or for the two selected units.

Calculate the average of the original XRF result and retest XRF result for each testing combination.

Square the average for each testing combination.

Add the ten squared averages together. Call this quantity C.

Multiply the number C by 0.0072. Call this quantity D.

Add the number 0.032 to D. Call this quantity E.

Take the square root of E. Call this quantity F.

Multiply F by 1.645. The result is the Retest Tolerance Limit.

Compute the average of all ten original XRF results.

Compute the average of all ten re-test XRF results.

Find the absolute difference of the two averages.

If the difference is less than the Retest Tolerance Limit, the inspection has passed the retest. If the difference of the overall averages equals or exceeds the Retest Tolerance Limit, this procedure should be repeated with ten new testing combinations. If the difference of the overall averages is equal to or greater than the Retest Tolerance Limit a second time, then the inspection should be considered deficient.

Use of this procedure is estimated to produce a spurious result approximately 1% of the time. That is, results of this procedure will call for further examination when no examination is warranted in approximately 1 out of 100 dwelling units tested.

TESTING TIMES:

For the Lead-in-Paint K+L variable reading time mode, the instrument continues to read until it is moved away from the testing surface, terminated by the user, or the instrument software indicates the reading is complete. The following table provides testing time information for this testing mode. The times have been adjusted for source decay, normalized to the initial source strengths as noted above. Source strength and type of substrate will affect actual testing times. At the time of testing, the instruments had source strengths of 26.6 and 36.6 mCi.

Testing Times Using K+L Reading Mode (Seconds)						
	All Data			Median for laboratory-measured lead levels (mg/cm^2)		
Substrate	25^{th} Percentile	Median	75^{th} Percentile	Pb < 0.25	0.25 ≤ Pb<1.0	1.0 ≤ Pb
Wood Drywall	4	11	19	11	15	11
Metal	4	12	18	9	12	14
Brick Concrete Plaster	8	16	22	15	18	16

CLASSIFICATION RESULTS:

XRF results are classified as positive if they are greater than or equal to the threshold, and negative if they are less than the threshold.

DOCUMENTATION:

A document titled *Methodology for XRF Performance Characteristic Sheets* provides an explanation of the statistical methodology used to construct the data in the sheets, and provides empirical results from using the recommended inconclusive ranges or thresholds for specific XRF instruments. For a copy of this document call the National Lead Information Center Clearinghouse at 1-800-424-LEAD.

This XRF Performance Characteristic Sheet was developed by the Midwest Research Institute (MRI) and QuanTech, Inc., under a contract between MRI and the XRF manufacturer. HUD has determined that the information provided here is acceptable when used as guidance in conjunction with Chapter 7, Lead-Based Paint Inspection, of HUD's *Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing.*

ThermoFisher
SCIENTIFIC

The world leader
in serving science

SEALED SOURCE LEAK TEST CERTIFICATE

Certificate # : **3836**

LEAK TEST LABORATORY INFORMATION			
COMPANY NAME	THERMO SCIENTIFIC PORTABLE ANALYTICAL INSTRUMENTS		
LICENSE NUMBER	MASSACHUSETTS 55-0238	CONTACT NAME/RSO	JAMES BLUTE
ADDRESS	2 RADCLIFF ROAD	CONTACT NUMBER	978-670-7460
	TEWKSBURY MA 01876	FAX NUMBER	978-513-3504

A copy of certificate should be maintained for a minimum of 3 years and for inspection by the regulatory agency.

SAMPLE KIT INFORMATION

Sample ID # : N-3513

Sample date : 8/16/2016

SEALED SOURCE INFORMATION

Manufacturer : Eckert & Ziegler

Source model : XFB-3

Source serial number : TR3773

Radioisotope : Cd-109

Assay Date : 8/15/2016

Activity (mCi) : 40

DEVICE/ANALYZER INFORMATION

Device make : Thermo Scientific Portable XRF Analyzers

Device model : XLp

Serial number : 99428

LEAK TEST RESULT:

Analysis of the above sample kit on date **8/16/2016** yield the following result:

☑ The analysis of the radioactive material of this leak test sample indicated the activity present is less than 0.005 uCi (or 185 Bq). The source may be used as authorized.

☐ Statistical analysis of the radioactive count data of this leak test sample indicated the activity present is greater than 0.005 uCi (or 185 Bq). This source should be considered leaking. Consult your device operations procedure; place this source in storage or quarantine area and make the required notification to your regulatory agency.

DEVICE/SOURCE LEAK TEST IS DUE ON OR BEFORE 2/16/2017

Leak test performed by: Ralph Badger

Certified by: James Blute, RSO

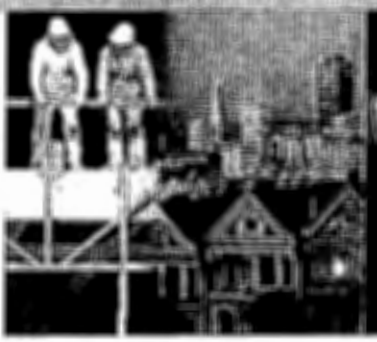
Date: 8/16/2016

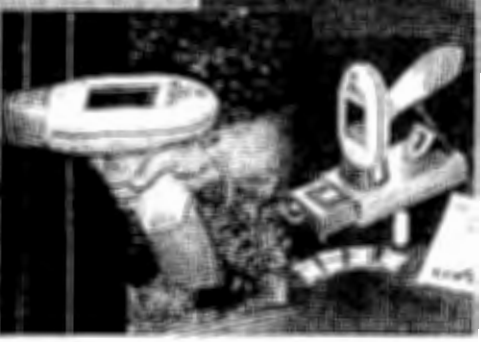
Product Specifications

Thermo Scientific Niton XLp 300

The ideal tool for lead analysis

Thermo Scientific Niton XLp 300 Series analyzers set the industry standard for lead analysis in applications ranging from paint, to soils and sediments, to dust wipes and air filters, to screening for the presence of lead in toys, fabrics, ceramic goods, and other child-accessible products.





Government regulations, increased public awareness, and legal action have all driven requirements for the identification of lead hazards in the environment. With documented effects, such as diminished learning abilities in children, kidney and central nervous system damage, as well as reduced fertility and miscarriages, researchers concluded almost a decade ago that there is no safe level of lead exposure.[1]

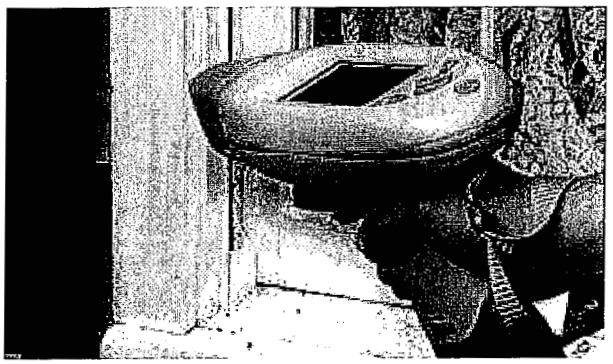
Public health officials, environmental professionals, and community activists face an overwhelming challenge: pinpoint lead's location in the environment, identify the sources of contamination, and confirm that clearance criteria have been achieved after abatement. The traditional approach built on field-based sample collection, combined with laboratory analysis, largely has been replaced by the use of handheld equipment – effectively bringing the lab into the field. Thermo Scientific Niton x-ray fluorescence (XRF) analyzers quickly identify and quantify lead in virtually all sample types: paint, consumer goods, soil, sediment, dust, air, and more.

Supported by a Performance Characteristic Sheet (PCS) documenting no inconclusive readings, no need for substrate correction, and no false positives/false negative readings, the Niton® XLp 300 Series can determine in seconds whether lead is positive (defined by the US EPA as greater than or equal to 1.0 mg/cm²) or negative. If you are in a jurisdiction with more stringent standards, you can easily change the action level to ensure compliance with local regulations. Actual lead values are also displayed, permitting you to more accurately quantify the hazards associated with particular samples. And our patented depth index goes one step further, telling you whether lead is present on the surface, or whether it is deeply buried within the paint matrix.

The analysis of lead dust poses another challenge. Widely acknowledged as the primary source of childhood lead poisoning[2], lead dust is hazardous even in very small amounts. Standard practice involves collecting the dust on an ASTM-compliant towelette wiped over a defined area. This step is followed by analysis of the "wipe" for determination of the lead load, which yields a lead-dust concentration in µg/ft². The Niton XLp 300 Series XRF analyzer offers the ability to perform this analysis on site using the optional Dust Wipe Analysis mode.

Thermo Scientific Niton XLp 300 Series analyzers provide many distinct advantages:

- **The only lead paint analyzer with the ideal PCS**
- **Soil mode to evaluate outdoor risks**
- **Dust mode to pre-screen abatement or renovation work**
- **Consumer Products mode for complete EBL evaluation**



Unparalled performance for residential lead inspection.

Product Specifications

Industrial lead paint measurement for site assessment and worker protection.

In the outdoor environment, lead presents additional challenges. Whether the result of damaged exterior paint, residual contamination from leaded gasoline, a former pesticide application, or by-products from an industrial process, the sheer volume of samples required to accurately determine the extent of contamination and surgically delineate its boundaries demand the speed and accuracy of a Thermo Scientific Niton analyzer. The EPA recognizes this technology's advantage and has based its Method 6200 soil testing procedures on handheld XRF. "The result is a clearer delineation of how soil contamination differs from one part of the property to another."[3] When combined with optional Bluetooth™ communications and a portable GPS device, latitude, longitude, and elevation are stored along with the analysis data from each test, permitting real-time contamination mapping.

Further, the Niton XLp 300 Series has the added capability of measuring lead in consumer products with its "Consumer Goods" mode. This mode allows you to screen for lead in accordance with the Consumer Product Safety Improvement Act (CPSIA) of 2008 by adding the extended capability to measure lead in plastics, fabric, and other products. Lead in plastics and similar substrates is reported in parts per million (ppm), while lead in paint is measured in micrograms per square centimeter (µg/cm²). The instrument is the only analyzer with a PCS that does not contain an inconclusive range while still featuring the detection limits necessary to comply with the CPSIA.

All of our analyzers include fully customizable data fields for rapid entry of sample location/condition and site conditions, simplifying reporting and maximizing inspector productivity.

[1]Lanphear BP, Dietrich K, Auinger P, Cox C. "Cognitive deficits associated with blood lead concentrations <10 microg/dL in US children and adolescents." Public Health Report 2000 Nov-Dec; 115(6) 521–529.

[2]Lanphear BP, Matte TD, Rogers J, Clickner RP, Dietz B, Bornschein RL, Succop P, Mahaffey KR, Dixon S, Galke W, Rabinowitz M, Farfel M, Rohde C, Schwartz J, Ashley P, Jacobs DE. "The Contribution of Lead-Contaminated House Dust and Residential Soil to Children's Blood Lead Levels. A pooled analysis of 12 epidemiologic studies." Environ Research. 1998 Oct 79(1):51–68.

[3]Lead-Safe Yards, Developing and Implementing a Monitoring, Assessment, and Outreach Program for Your Community, United States Environmental Protection Agency, January 2001, page 68.

Thermo Scientific Niton XLp 300 Series analyzers are just one of our handheld Niton analyzer solutions, which include XRF analysis tools for metal alloy identification, lead-based paint testing, RCRA metals in soil, toy and consumer goods screening, RoHS and WEEE compliance screening, and many other analysis needs.

Niton XLp 300 Series Specifications

Weight	**3.0 lbs (1.4 kg)**
Dimensions	**9.75 x 10.5 x 3.75 inches (248 x 273 x 95 mm)**
Batteries	**(2) Rechargeable Quick Swap lithium-ion battery packs** **6-14 hour use each**
Excitation Source	**40 mCi ^{109}Cd (1,480 Mbq) sealed radioisotope**
X-ray Detector	**High-performance, electronically cooled, solid-state detector optimized for Pb L-shell and K-shell x-ray detection**
System Electronics	**Hitachi SH-4 CPU** **ASICS high-speed DSP** **4096 channel MCA**
Display	**Backlit VGA touch-screen LCD**
Testing Modes	**Lead-based Paint Mode (standard)** **K & L Paint Mode (standard)** **Bulk Sample Mode (optional)** **Thin Sample Mode, including Dust Wipe Mode, 37mm Filter Mode (optional)** **Thin Sample Mode (user defined) (optional)** **Consumer Goods Mode (optional)**
Data Storage	**Internal ~6000 readings + spectra**
Data Entry	**Three methods for user data entry:** **Virtual touch-screen keyboard** **User-programmable pull-down lists** **Integrated barcode reader**
Data Transfer	**RS-232 serial cable or optional Bluetooth™ wireless connection** **NDT© PC software utility easily exports data for use in common PC applications and provides data encryption QA/QC documentation**
Standard Accessories	**Portable test stand or inverted stand** **Check/verification standards** **Shielded belt holster** **Locking shielded waterproof carrying case** **110/220 VAC charger/adapter** **Spare lithium-ion battery pack with holster** **RS-232 PC data transfer cable** **NIST-traceable Lead Paint Standards**
Optional Accessories	**Bluetooth wireless communication** **Wireless printers and portable GPS**
Security	**Password-protected user security**
Licensing/Registration	**Varies by region. Contact your local distributor**

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NC 3-201 03/2009

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NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
Aerosol Monitoring & Analysis, Inc. ATTN: Joseph A. Coco, CIH, Senior Vice President 1331 Ashton Road, Suite A Hanover, MD 21076	September 6, 2016
	License Number(s) 19-31402-01
	Mail Control Number(s) 591852
	Licensing and/or Technical Reviewer or Branch Commercial, Industrial, R&D, & Academic Branch (Branch 2)

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 08/30/2016

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

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