April 18, 2013

Edward G. Wallace, Vice President
Regulatory Affairs
NuScale Power LLC
1100 NE Circle Blvd., Suite 350
Corvallis, OR 97330

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
NO. 99901418/2013-201 AND NOTICE OF VIOLATION

Dear Mr. Wallace:

From March 4, 2013 through March 8, 2013, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Stern Laboratories (Stern) facilities in Hamilton, Canada. The purpose of the NRC inspection was to verify that NuScale Power LLC (NuScale) effectively implemented quality assurance processes and procedures for testing activities performed in support of the NuScale design certification application. The inspection focused on assessing compliance with the provisions of selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance and 10 CFR Part 21, "Reporting of Defects and Noncompliance," programs.

Based on the results of this inspection, the NRC determined that one Severity Level IV violation of NRC requirements occurred. The NRC evaluated the violation in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

This violation is cited in the enclosed Notice of Violation (Notice) and circumstances surrounding them are described in detail in the subject inspection report. The violation is being cited in the Notice because the NRC inspection team identified an example in which NuScale failed to provide objective evidence that Stern complied with the procurement requirements prior to allowing Stern to initiate testing services in accordance with Appendix B to 10 CFR Part 50.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be

made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Project No.: 0769

Enclosures:
1. Notice of Violation
2. Inspection Report No. 99901418/2013-201
and Attachment

made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Project No.: 0769

Enclosures:
1. Notice of Violation
2. Inspection Report No. 99901418/2013-201
and Attachment

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Enclosure

NOTICE OF VIOLATION

NuScale Power LLC
1100 NE Circle Blvd., Suite 350
Corvallis, OR 97330

Project No.: 0769
Report No. 99901418/2013-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection of NuScale Power, LLC, (NuScale) conducted at the Stern Laboratories, Inc. (Stern) facilities in Hamilton, Ontario, Canada, on March 4, 2013, through March 8, 2013, inspectors identified violations of NRC requirements. In accordance with the NRC Enforcement Policy, the violations are described below:

A. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states in part that, "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available."

   NuScale Quality Management Plan, NP-PL-0200-200, Revision 1, dated February 2013, Section 2.7.1, states in part that, "Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis."

   Stern's Quality Procedure QP-02-03, "Qualification and Certification of Quality Audit Personnel," Revision 0, dated November 2012, Section 3.4 states that "the Lead Auditor shall participate in a minimum of five quality assurance audits within three years prior to the date of qualification. One of these shall be to the requirements of 10 CFR Part 50 Appendix B, ASME NQA-1, or other nuclear related quality system standard and have performed within a year prior to qualification."

   Contrary to the above, as of March 8, 2013, NuScale failed to provide objective evidence of quality furnished by the contractor that was evaluated to ensure that only qualified suppliers are used. Specifically:

   1. NuScale failed to provide objective evidence that Stern complied with procurement requirements prior to allowing Stern to initiate the testing services as required by NP-PL-0200-200. The NuScale audit report of Stern did not provide the scope of the review for any of the criteria; did not identify the parameters of the audit; and did not provide any information or conclusion verifying that Criterion XI, "Test Control," and Criterion XII, " Control of Measuring &Test Equipment," of Appendix B to 10 CFR Part 50 were audited adequately.

   2. NuScale, which has the overall responsibility for the quality of CHF testing, failed to provide objective evidence that Stern's lead auditor met the qualification

requirements of Stern's procedure QP-02-03 prior of conducting an internal audit and commercial-grade surveys.

This issue has been identified as Violation 99901418/2013-201-01.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).

In accordance with the provisions of 10 CFR 2.201, "Notice of Violation," NuScale is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality Assurance Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Dated at Rockville, MD, this 18th day of April 2013.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS

Project No.:	0769		
Report No.:	99901418/2013-201		
Applicant:	NuScale Power LLC 1100 NE Circle Blvd., Suite 350 Corvallis, OR 97330		
Applicant Contact:	Mr. Steven Mirsky, P.E. Lead Licensing Engineer		
Background:	NuScale Power, LLC notified the U.S. Nuclear Regulatory Commission in January 2008 of its intent to begin the pre-application review process for its small modular reactor design certification.		
Inspection Dates:	March 4–8, 2013		
Inspectors:	Paul Prescott Aixa Belen-Ojeda James Gilmer	NRO/DCIP/CQAB NRO/DCIP/CQAB NRO/DSRA/SRSB	Team Leader
Approved by:	Kerri A. Kavanagh, Chief Quality Assurance Branch Division of Construction Inspection and Operational Programs Office of New Reactors		

EXECUTIVE SUMMARY

NuScale Power LLC
Project No 0769

The U.S. Nuclear Regulatory Commission (NRC) conducted this inspection to verify that NuScale Power, LLC, (hereafter referred to as NuScale), had implemented an adequate quality assurance (QA) program in support of critical heat flux (CHF) testing activities that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." In addition, the NRC inspection also verified that Stern implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that met the NRC's regulatory requirements. The NRC inspection team conducted the inspection at the at the Stern Laboratories (hereafter referred to as Stern) facilities in Hamilton, Canada, from March 4-8, 2013.

This technically focused inspection evaluated the implementation of Stern's QA policies and procedures implemented to support the design, fabrication, assembly, and testing for NuScale CHF testing activities as described in NRC Inspection Manual Chapter 2508, "Construction Inspection Program: Design Certification." NuScale notified the NRC in January 2008 of its intent to begin the pre-application review process. Stern provides reliability and safety-related testing services to the nuclear power industry. As part of this effort, Stern is conducting a test program to obtain CHF test data for the NuScale reactor fuel design. NuScale will use the test data for analysis of the core's thermal hydraulic characteristics which will be submitted to the NRC as part of the licensing process.

The NRC inspection team verified the following testing-related activities:

- test plan, procedures and configuration management
- test results and data collection
- translation of design specification into test requirements
- documentation and evaluation of test anomalies
- test personnel qualifications
- commercial-grade dedication packages for U-1 and U-2 uniform fuel simulation test series.

The NRC inspection team observed by the following testing-related activities:

- test bundle assembly demonstration
- different pressures, temperatures and flow combinations for cosine fuel simulation test series

In addition to verifying and observing these activities, the NRC inspection team verified that measuring and test equipment (M&TE) were properly identified, marked, calibrated, and used within calibrated range.

The NRC based its inspection on the following:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"

During this inspection, the NRC inspection team implemented Inspection Procedure (IP) 35034, "Design Certification Testing Inspection," dated January 27, 2012; IP 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008; IP43004, "Inspection of Commercial-Grade Dedication Programs," dated April 25, 2011; and IP 36100, "Inspection of 10 CFR Part 21 Programs for Reporting Defects and Nonconformance," dated February 13, 2012.

With the exception of the one violation described below, the NRC inspection team concluded that NuScale's and Stern's QA policies and procedures comply with the applicable requirements in 10 CFR Part 21 and Appendix B to 10 CFR Part 50, and that Stern's personnel are implementing these policies and procedures effectively in support of NuScale's CHF testing activities. The results of this inspection are summarized below.

10 CFR Part 21

The NRC inspection team concluded that the implementation of Stern's 10 CFR Part 21 program is consistent with the regulatory requirements. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies and procedures in support of NuScale's CHF testing activities. No findings of significance were identified.

Training and Qualification

The NRC inspection team concluded that, with the exception of the example of Violation 99901418/2013-201-01 for NuScale's failure to provide objective evidence that the lead auditor qualification were met, the implementation of Stern's training and qualification program is consistent with the regulatory requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50.

Control of Purchased Equipment, Materials, and Services

The NRC inspection team concluded that, with the exception of the Violation 99901418/2013-201-01 for NuScale's failure to provide objective evidence that Stern complied with procurement requirements prior to initiating testing activities, the implementation of NuScale's control of purchase material, equipment, and services program is consistent with the regulatory requirements of Criterion VII, "Control of Purchased Equipment, Material and Services," of Appendix B to 10 CFR Part 50.

Test Control

The NRC inspection team concluded that the implementation of Stern's test control program is consistent with the regulatory requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies and procedures in support of NuScale's CHF testing activities. No findings of significance were identified.

Control of Measuring and Test Equipment

The NRC inspection team concluded that the implementation of Stern's control of measuring and test equipment program is consistent with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies

and procedures in support of NuScale's CHF testing activities. No findings of significance were identified.

Corrective Actions

The NRC inspection team concluded that the implementation of Stern's corrective action program is consistent with the regulatory requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies and procedures in support of NuScale's CHF testing activities. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed Stern Laboratories' (Stern's) Quality Manual, QAP-01, Issue 3, Revision 0 dated August 2012 and the procedures that govern the evaluation program to determine compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance." Specifically, the NRC inspection team focused on procedure QP-15-02, "Reporting of Defects and Noncompliance in Accordance with U.S. Regulation 10 CFR Part 21," Revision 1, dated February 2013, as well as the associated procedures QP-15-01, "Control of Nonconforming Items," Revision 0, dated February 2013, and QP-16-01, "Corrective Action," Revision 1, dated February 2013.

b. Observations and Findings

The NRC inspection team verified that Stern's procedure QP-15-02 met the requirements of 10 CFR Part 21. The NRC inspection team noted that the procedure outlined the process Stern used for the reporting of defects and noncompliance, as well as the applicability to employees, managers, and the quality assurance (QA) manager with respect to 10 CFR Part 21.

The NRC inspection team noted that QP-15-02 and QP-16-01 have an appropriate procedural nexus between the identification and discovery of a potential deviation and linking to the 10 CFR Part 21 procedure for evaluation.

Stern has not performed a 10 CFR Part 21 evaluation implementing the revised procedure. The NRC inspection team did not identify any potential missed evaluations in the nonconformance and corrective action reports detailed in Section 6.b of this inspection report. The NRC inspection team identified no findings of significance.

c. Conclusions

The NRC inspection team concluded that the implementation of Stern's 10 CFR Part 21 program is consistent with the regulatory requirements. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies and procedures in support of NuScale Power LLC's (NuScale's) critical heat flux (CHF) testing activities. No findings of significance were identified.

2. Training and Qualification of Personnel

a. Inspection Scope

The NRC inspection team reviewed Stern's procedures to verify that Stern was implementing training activities in a manner consistent with regulatory requirements and industry standards. The NRC inspection team reviewed the training and qualification process for Stern's test personnel, as well as the training and qualification records of NuScale's personnel responsible for oversight of the ongoing CHF testing to verify conformance with the requirements in Criterion II, "Quality Assurance Program," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic

Licensing of Production and Utilization Facilities." In addition, the NRC inspection team discussed the personnel training and qualification process with Stern's management, interviewed test personnel, and observed them during the performance of testing.

b. Observations and Findings

b.1 Test Personnel Qualifications

The NRC inspection team verified that Stern had a program and procedures in place for the qualification and training of test personnel performing activities that affect quality, and that the program and procedures are consistent with regulatory requirements. The program and procedures also take into account the need for special skills to attain the required quality and the need for verification of quality during the testing. In addition, the program and procedures provide for the indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

To verify effectiveness, the NRC inspection team reviewed all of Stern's personnel training and certification records. The NRC inspection team verified that qualification, training records, and certifications existed for all personnel involved with testing activities and that these records are maintained in accordance with Stern's program requirements and consistent with industry standards. The NRC inspection team reviewed QAP-08, "Qualification and Certification of Personnel," Revision 5, dated August 2012, for the specific requirements for task specific training. The NRC inspection team also observed portions of ongoing CHF testing activities and found the personnel were knowledgeable of testing responsibilities. No issues of significance were identified.

b.2 Auditor Training and Qualification

The NRC inspection team reviewed the training and qualification records of Stern's lead auditor to confirm that all required training has been completed and maintained and that qualifications and certification were in accordance with Stern's procedures. The NRC inspection team reviewed Stern's QA Manual and QP-02-03, "Qualification and Certification of Quality Audit Personnel," Revision 0, dated November 2012.

The NRC inspection team noted that QP-02-03 outlined the relevant lead auditor qualification requirements for education, experience, professional competence, communication skills, training and audit participation. However, upon review of Stern's lead auditor/auditor qualification records, the NRC inspection team identified that the audit participation requirements for a prospective lead auditor were not fulfilled prior to leading an internal audit and conducting commercial-grade surveys. In accordance with QP-02-03, a lead auditor shall have participated in a minimum of five QA audits within 3 years prior to the date of qualification. One of these shall be to the requirements of the American Society of Mechanical Engineers (ASME) NQA-1 Standard, or other nuclear related quality system standard and have been performed within the year prior to qualification. The NRC inspection team identified this issue as an example of Violation 99901418/2013-201-01 for the failure of NuScale to provide objective evidence that the lead auditor qualification requirements for experience were met.

c. Conclusions

The NRC inspection team concluded that, with the exception of the example of Violation 99901418/2013-201-01 for NuScale's failure to provide objective evidence that the

lead auditor qualifications were met, the implementation of Stern's training and qualification program is consistent with the regulatory requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50.

3. Control of Purchased, Material, Equipment and Services

a. Inspection Scope

The NRC inspection team reviewed the implementation of NuScale's and Stern's QA programs for control of purchased material, equipment, and services in support of NuScale's CHF testing. Specifically, the NRC inspection team reviewed the policies and implementing procedures to verify compliance with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed these programs with management and technical staff of NuScale and Stern.

b. Observations and Findings

b.1 Implementation of the Procurement Process

The NRC inspection team reviewed the purchase order document NP-SW-0811-013-R1 from NuScale to Stern created to obtain CHF test data for developing a CHF correlation. The associated statement of work (SOW) stated that the objective of the test data for developing the correlation must be acceptable for analyzing the NuScale reactor core for licensing and that the data are required to cover a range of operating conditions and axial power shapes applicable for analysis of the fuel assembly configuration. The SOW also described the required attributes of the experimental facility, test conditions, test procedures, QA program, program deliverables, and schedule for performing the testing. The purchase order required that engineering and testing services be provided in accordance with Stern's QA program and the Supplier's Project Quality Plan (PQP) SLQP-112, "Quality Plan for Providing Experimental Facilities and Performing Thermal Hydraulic Experiments for NuScale Power, Inc.," Revision 3, dated February 2013. This SOW invoked the applicable requirements of NQA-1-2008 and the 2009 Addenda and imposed 10 CFR Part 21. Additionally, the SOW stated that items identified as safety-related in the technical evaluation or other project documentation requiring commercial-grade dedication were to be dedicated in accordance with Stern's approved PQP.

No findings of significance were identified in the inspector's review of NuScale's implementation of the procurement process associated with the CHF testing.

b.2 External Audits

The NRC inspection team reviewed the initial external Audit Report CORP-AE-11-13 which NuScale had performed to ensure Stern had the appropriate quality controls in place to conduct the CHF testing. NuScale contracted with Fluor Corporation to perform the audit, which was conducted February 14-16, 2012. The NRC inspection team determined that the audit was deficient in several areas. Although the audit report stated that 11 of 18 criteria were reviewed, the NRC inspection team could only identify 8 criteria. Specifically, the NRC inspection team could not verify that Criterion XI, "Test Control" and Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50 were adequately audited. The NRC inspection team also noted that the audit report did not provide the scope of the review for any of the criteria; did not identify the parameters of the audit; and did not provide any information or

conclusion for the criteria without deficiencies. NuScale failed to provide objective evidence that Stern complied with procurement requirements prior to allowing Stern to initiate the testing services. This has been identified as an example of Violation 99901418/2013-201-01.

b.3 Internal Audits

The NRC inspection team reviewed the last two Stern's internal audits to verify the implementation of Stern's audit program. The NRC inspection team verified that plans identifying the audit scope, focus, and applicable checklist criteria had been prepared and approved before the initiation of the audit activity. In addition, the NRC inspection team verified that a qualified lead auditor and auditor(s) performed the internal audits.

The NRC inspection team reviewed the following last two internal audit reports:

- Audit Report No. IA-14, dated March 10, 2011
- Audit Report No. IA-15, dated November 20, 2012

The NRC inspection team noted that Audit Report No. 1A-14 was a limited scope audit to determine if Stern personnel were following quality procedures as specified in the Stern QA manual. The NRC inspection team also noted that the lead auditor was not qualified (See Section 2.b.1 of the inspection report) and not independent of the areas being reviewed. Stern subsequently hired an independent consultant—Arsenal Consulting of Atlanta, GA—to conduct Audit Report No. IA-15. The audit report encompassed the full scope of Stern's Appendix B to 10 CFR Part 50, activities. The NRC inspection team confirmed that the audit report contained a review of the relevant QA criteria in Appendix B to 10 CFR Part 50 for the activities performed by Stern. The audit noted findings for inadequate dedication of commercial-grade calibration services, lack of an internal audit program, and record keeping requirements that were not being met (fire-rating of storage cabinets). The NRC inspection team confirmed that Stern has addressed the issues.

No findings of significance were identified in the NRC inspection team's review of Stern's implementation of the internal audit process.

c. Conclusions

The NRC inspection team identified one violation with two examples of NuScale's failure to implement the requirements of Criterion VII, "Control of Purchased Equipment, Material, and Services," of Appendix B to 10 CFR Part 50. Violation 99901418/2013-201-01 involved NuScale's failure to provide objective evidence that Stern complied with procurement requirements prior to initiating testing activities.

4. Test Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of NuScale's and Stern's QA program for test control in support of NuScale's CHF testing. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of test control to verify compliance with the regulatory requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the test control program with the management and technical staff of NuScale and Stern.

b. Observations and Findings

b.1 Critical Heat Flux testing

NuScale notified the NRC in January 2008 of its intent to begin the pre-application review process. Stern provides reliability and safety-related testing services to the nuclear power industry. As part of this effort, Stern is conducting a test program to obtain CHF test data for the NuScale reactor fuel design. NuScale will use the test data for analysis of the core's thermal hydraulic characteristics which will be submitted to the NRC as part of the licensing process.

The NRC inspection team reviewed and evaluated test procedures, test analysis and test results associated with CHF testing. The CHF testing was to be executed in accordance with NuScale's specification NP-TSD-0712-001, Revision 1, "Critical Heat Flux Test Development Plan," dated January 2013. The CHF test plan included three test series: uniform fuel simulation U-1 series, uniform fuel simulation U-2 series and cosine fuel simulation C-1 series. In the uniform fuel simulation series, the power was equally distributed through the entire height of the fuel bundle. The only difference between the two uniform series was that the U-2 fuel assembly included a guide tube. In the cosine fuel simulation, the power distribution peaked in the center of the fuel bundle. The series of tests were developed to test different pressures, temperatures and flow combinations which represent the range of expected operating conditions

Stern developed the following three test procedures:

- SLTP-215, "Heat Transfer Experiments for NuScale Power (Test Series U-1)," Revision 1, dated August 2012

- SLTP-216, "Heat Transfer Experiments for NuScale Power (Test Series-2)," Revision 0, dated August 2012

- SLTP-217, "Heat Transfer Experiments for NuScale Power (Test Series C-1)," Revision 2, dated February 2013

The test procedures consisted of an explanation of the quality assurance requirements; description of test assembly, power supply, data acquisition system, a list of the instrumentation, test loop operation, test checkups and the acceptance criteria, steady state critical power test matrix, post-test inspection, and data records. The NRC inspection team verified that the test procedures appropriately incorporated the testing requirements and were reviewed and approved by NuScale.

During the observation of C-1 testing activities, the NRC inspection team noted that the differential pressure gauge DP3 displayed an output outside of acceptable tolerances. The NRC inspection team discussed the observation with NuScale and Stern personnel and reviewed the objective evidence that supported the observation. The DP3 output is a

nonsafety-related measurement that was generally used for the heat balance checkup to determine if the assembly installation was done properly. The DP3 output is generally used as an engineering reference and is not intended to be used in the critical heat flux analysis. The NRC inspection team found NuScale's engineering evaluation was appropriate.

The NRC inspection team confirmed that the test acceptance criteria were met in establishing the conditions to achieve repeatable test runs. The test log maintained an adequate sequence of events and notes for every day of testing. The test log was reviewed constantly by NuScale's personnel, which were present during the majority of the tests.

b.2 Commercial-Grade Dedication

The NRC inspection team noted that NuScale wrote FL-TRP-0612-001, "Technical Evaluation and Trip Report 1 – Commercial Grade Dedication Process NuScale Task Order NP-SW- 0412-1460 Commercial Grade Dedication of Stern Laboratories Software" on June 11, 2012 to address Stern's gap in compliance with ASME NQA-1 2008/2009a, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade items and Services," and Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facilities Applications." NuScale generated an engineering technical evaluation and commercial-grade dedication plan to support the activities necessary to dedicate Stern's data acquisition system (DAS) as allowed by 10 CFR Part 21 and ASME NQA-1 2008/2009a, Subpart 2.7 and Subpart 2.14.

The NRC inspection team reviewed Stern's procedure QAP-19, "Commercial Grade Dedication of Data Acquisition Systems for Use in Safety Related Applications," Revision 0, dated July 23, 2012, which provided guidelines for performing the commercial-grade dedication of Stern's DAS for use in safety-related applications. The procedure explains briefly how to prepare a commercial-grade dedication package for DAS. Stern developed SLCGD-01, "Commercial Grade Dedication of the DAS for NuScale," Revision 0, dated September 19, 2012, as the overall technical evaluation for all the tests series. However, NuScale directed Stern to create a procedure for each test series so they can have a unique identifier for every test series. Consequently, Stern developed the following procedures:

- SLCGD-01, "Commercial Grade Dedication of the U-1 Series Test Data for NuScale," Revision 1, dated January 25, 2013

- SLCGD-02, "Commercial Grade Dedication of the U-2 Series Test Data for NuScale," Revision 0 dated December 2012

- SLCGD-04, "Commercial Grade Dedication of the C-1 Series Test Data for NuScale," Revision 0, dated January 2013

The NRC inspection team verified that the three procedures describe the technical evaluation, safety significance of the item, critical characteristics, acceptance criteria and checklist referencing the verification documents. The NRC inspection team also verified the personnel signatures and that the checklists and dedication binder were completed, signed, and verified by NuScale.

No findings of significance were identified in the NRC inspection team's review of Stern's implementation of the CGD process.

c. Conclusions

The NRC inspectors concluded that the implementation of Stern's test control program is consistent with the regulatory requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies and procedures in support of NuScale's CHF testing activities. No findings of significance were identified.

5. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed the implementation of NuScale and Stern's QA program for the control of measuring and test equipment (M&TE) in support of NuScale's CHF testing activities. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation to verify compliance with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed control of the M&TE program with the management and technical staff of NuScale and Stern.

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team verified that Stern followed Project Quality Plan SLQP-112, "Quality Plan for Providing Experimental Facilities and Performing Thermal Hydraulic Experiments for NuScale Power, Inc.," Revision 3 dated February 2013. In addition, the NRC inspection team noted that Stern published its QP-12-01 "Control of Measurement and Test Equipment," Revision 0, procedure in February 2013. Stern stated that they had several calibration procedures according to the type of instrument and that the purpose of QP-12-01 is to provide for a system and instructions and to assign responsibilities for identification, calibration and maintenance of M&TE. The NRC inspection team verified a sample of Stern's instruments calibration procedures.

b.2 Implementation of Control of Measuring and Test Equipment

The NRC inspection team noted that Stern performed some of the M&TE calibrations in house, while other M&TE were sent to Canadian recognized laboratories to be calibrated. Also, the NRC inspection team verified that the M&TE sampled had appropriate calibration records and that the M&TE used in testing were calibrated using procedures traceable to known industry standards, and that calibration results were recorded, reviewed, and verified by test personnel. Calibration records indicated the calibration procedure to be used, the as-found and as-left conditions, the accuracy required, the date of calibration, the due date for recalibration, and the applicable international or national traceable reference used in the calibration. In addition, the NRC inspection team verified that the calibration status of M&TE used was identified by stickers.

b.3 Commercial Calibration Laboratory Surveys

The NRC inspection team noted that in November 2012, Stern informed NuScale about an audit finding Stern received related to inadequate dedication of commercial-grade calibration services. The audit finding identified that Stern was accepting laboratory accreditation programs administered by the National Institute of Standards and Technology (NIST) and by the American Association for Laboratory Accreditation (A2LA), as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program in lieu of a supplier commercial-grade survey for the procurement of commercial-grade calibration services for safety-related applications when the alternative method is limited only to United States domestic calibration service suppliers. Consequently, NuScale decided to postpone the start of the C-1 testing activities until Stern performed the surveys and recalibrated all of the safety-related M&TE sent to commercial-grade laboratories.

The NRC inspection team reviewed QP-07-04, "Commercial-Grade Dedication," Revision 0, dated December 11, 2012, which provided guidance for the commercial grade dedication of calibration services. Also, the NRC inspection team reviewed Stern's surveys (conducted in November 2012) of the following commercial calibration laboratories:

- Pylon Electronics of Missisauga, Ontario: This facility performs of calibration activities for electrical temperature indicators, direct current (DC) resistance and alternating current (AC) measurement devices. It is accredited by the Standards Council of Canada.

- Pylon Electronics of Ottowa, Ontario: This facility performs calibration activities for micrometers, calipers, indicator dials, and AC, DC, voltage, and electrical temperature indicators. It is accredited by the Standards Council of Canada.

- Cal Matrix Methodology of Burlington, Ontario: This facility performs calibration activities for pressure measurement devices. It is accredited by the Standards Council of Canada.

The NRC inspection team noted that the survey report discussed the programmatic areas of the calibration laboratories identified as critical characteristics that needed to be verified to ensure adequate controls were in place to credit for acceptance. The NRC inspection team noted no technical deficiencies in the surveys or with the recalibration of the safety-related M&TE. However, the NRC inspection team did note that Stern did not meet its lead auditor/auditor qualifications before performing the commercial-grade surveys. Section 2.b.2 discusses this issue in detail.

c. Conclusions

The NRC inspectors concluded that the implementation of Stern's control of measuring and test equipment program is consistent with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that Stern is adequately implementing its policies and procedures in support of NuScale's CHF testing activities. No findings of significance were identified.

6. Corrective Actions and Nonconformances

a. Inspection Scope

The NRC inspection team reviewed Stern's QA manual, QP-16-01, "Corrective Action," Revision 1, dated February 2013, and QP-15-01, "Control of Nonconforming Items," Revision 0, dated February 2013, which govern the implementation of Stern's corrective action and nonconformance programs respectfully, to ensure there was adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed the corrective action reports (CARs) and nonconformances associated with the CHF testing services that Stern provided to NuScale to assess the implementation of the corrective action and nonconformance program.

b. Observations and Findings

The NRC inspection team reviewed the two major CARs issued as a result of the CHF testing for NuScale. NuScale periodically halted the CHF testing until issues could be resolved and corrective actions confirmed in a subsequent limited scope audit of Stern's corrective actions. CAR No. 64 documented that during the final review of the inspection reports for the uniform and cosine fuel simulators, it was identified that several of the calibrated instruments used were not properly dedicated in accordance with quality requirements. CAR No. 65 documented that the instrumentation used for the CHF testing was calibrated partly in-house against reference standards and partly by procurement of outside services. The reference standards used for the in-house calibrations were calibrated by procurement of outside calibrations services.

The suppliers that provided the calibration services were certified to ISO 17025:2005 by A2LA, National Voluntary Laboratory Accreditation Program or the National Research Council of Canada/Standards Council of Canada which is the Canadian equivalent of NIST. However, an appropriate commercial-grade dedication process was not in place or described in Stern's QA program. Stern believed that the calibration of the instrumentation being traceable to a national standard was sufficient to provide reasonable assurance of the measurements and it was not aware of the requirement for commercial-grade dedication of the calibration services. Stern sent all of the affected instruments used for the CHF testing for re-calibration in accordance with the commercial-grade dedication program. The calibrations and calibration tolerances were evaluated to determine acceptability. As detailed in Section 5.b.3 of this inspection report, the NRC inspection team reviewed Stern's surveys of the commercial calibration laboratories. Also, as detailed in Section 5, of this inspection report, the NRC inspection team reviewed a sample of calibration records associated with measuring and test equipment used in the conduct of NuScale's CHF testing activities.

In addition, the NRC inspection team reviewed the corrective actions from the mPower Audit Report SA 12-005, of Stern conducted November 5-7, 2012. Based on the results of this audit, mPower issued a stop work order to Stern on November 15, 2012. NuScale had just completed the second phase of CHF testing and determined that testing would be halted until the potential issues associated with commercial-grade dedication of calibration services was resolved. NuScale subsequently conducted a follow-up audit from January 28-31, 2013. Based on the results of this audit, NuScale determined that Stern had adequately addressed the commercial-grade dedication of calibration services issue and testing was allowed to proceed.

The NRC inspection team reviewed the following CARs that resulted from mPower Audit Report SA 12-005:

- CAR 50, “Change Made to Purchase Order without Obtaining Documented Approval.”
- CAR 51, “Several Elements Related to Design Missing From Stern QA Program.”
- CAR 52, “Fabrication Drawing for Heaters Referenced a Fabrication Procedure not Yet Issued.”
- CAR 53, “Stern Procurement Procedure does not Identify Requirement to Meet Appendix B.”
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- CAR 54, “Stern did not have Any Properly Trained and Qualified Lead Auditors that Meet NQA-1.”
- CAR 55, “QAP-20 (Corrective Action) does not have Provision for Classifying and Defining a Significant Condition Adverse to Quality.”
- CAR 56, “QAP-03 (Part 21 Evaluation Procedure) did not Provide Specifics on how an Evaluation would be performed.”
- CAR 58, “Stern has not performed an Internal Audit in accordance with Appendix B.”
- CAR 59, “Unclear how Inspections were conducted for Testing without a Requisite Procedure.”
- CAR 60, “CGD not performed for Testing.”
- CAR 62, “Records not maintained in accordance with NQA-1 Requirements.”
- CAR 63, “Calibration of M&TE not calibrated in accordance with NQA-1 Requirements.”

With the exception of CAR 54, the NRC inspection team’s review of the corrective actions for the CARs generated as a result of the mPower audit and identified no issues. The proposed corrective actions were not adequate to meet the ASME NQA-1 requirements, which Stern had committed to meet for this testing. Section 2 of this inspection report provides additional details of the lead auditor/auditor training issue.

The NRC inspection team reviewed the following nonconformances reports:

- 131-1, “Fuel Simulator Tubing”
- 131-2, “Flow Channel Pressure Tap Holes”
- 131-3, “Fuel Simulator Tubing”
- 131-4, “Spacer Grids”
- 131-5, “Drawings Number Assignments”
- 131-6, “Thimble Tube Machining”

- 131-7, “Fuel Simulator OD”
- 131-8, “C-1 Bundle Assembly”

The NRC inspection team’s review did not identify any findings of significance related to Stern’s identification and corrective actions associated with the nonconformances.

c. Conclusions

The NRC inspection team concluded that Stern’s program requirements for corrective action and nonconformance are consistent with the requirements of Criterion XVI and Criterion XV of Appendix B to 10 CFR Part 50, respectfully. The NRC inspection team also concluded that Stern’s QA manual and associated corrective action and nonconformance procedures were adequate and effectively implemented. The NRC inspection team identified no findings of significance.

Entrance and Exit Meetings

On March 4, 2013, the NRC inspection team presented the inspection scope during an entrance meeting with NuScale and Stern personnel. On March 8, 2013, the NRC inspection team presented the inspection results during an exit meeting with NuScale and Stern personnel.

1. PERSONS CONTACTED

Name	Company	Entrance Meeting	Exit Meeting	Interviewed
Kathryn Dunbar	NuScale	X	X	X
Adam Rasmussen	NuScale	X	X	X
Robert Houser	NuScale	X	X	X
Jose Reyes*	NuScale		X	
Don Prigel*	NuScale		X	
Ed Wallace*	NuScale		X	
Don Ramey*	NuScale		X	
Steven Mirsky*	NuScale		X	
Alex Giurgiuman*	NuScale		X	
Gordon Hadaller	Stern	X	X	
Richard VanLochem	Stern	X	X	X
Angela Ward	Stern	X	X	X
Rick Fortman	Stern	X	X	X
Bob Hayes	Stern	X	X	X
Paul Prescott	NRC	X	X	
Aixa Belen-Ojeda	NRC	X	X	
James Gilmer	NRC	X	X	
Paul Wong	CNSC	X	X	
Dan Constantinescu	CNSC	X	X	

* participated in the exit meeting by conference call

2. INSPECTION PROCEDURES USED

Inspection Procedure 35034, "Design Certification Testing Inspection," dated January 27, 2010

Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008

Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs," dated April 25, 2011

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 Programs for Reporting Defects and Nonconformance," dated February 13, 2012

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901418/2013-201-01	Opened	NOV	Criterion VII

4. DOCUMENTS REVIEWED

Procurement Control and Audit Documents

NP-SW-0811-013-R1 NuScale purchase order document to Stern, Revision 1, dated January 2013

NuScale Audit Report CORP-AE-11-13 of Stern, dated February 14–16, 2012

Stern Internal Audit Report No. IA-14, dated March 10, 2011

Stern Internal Audit Report No. IA-15, dated November 20, 2012

NuScale Power, NP-PL-0200-200, Revision 1, "Quality Management Plan", February 2013

Stern Laboratories, Inc., Quality Assurance Procedure QAP-01, Issue 3, Revision 0, "Quality Manual", August 2012

Stern Laboratories, Inc., Quality Assurance Procedure QAP-04, Revision 7, "Evaluation of Subcontractors and Suppliers," September 2012

Stern Laboratories, Inc., Quality Assurance Procedure QAP-09, Revision 6, "Preparation of Quality Plans," September 2012

Stern Laboratories, Inc. Quality Assurance Procedure QAP-10, Revision 5, "Internal Audits", September 2012.

Stern Laboratories, Inc., Quality Assurance Procedure QAP-20, Revision 0, "Quality System to Meet Requirements of Standards 10 CFR 50, Appendix B, 10 CFR Part 21, and/or NQA-1," August 2012.

Training and Qualifications

Stern Laboratories, Inc., Quality Assurance Procedure QAP-08, Revision 5, “Qualification and Certification of Personnel”, August 2012

QP-02-03, Qualification and Certification of Quality Audit Personnel,” Revision 0, dated November 2012.

10 CFR Part 21, Corrective Action, Nonconformance Programs

Stern Laboratories, Inc., Quality Assurance Procedure QAP-03, Revision 5, “Procedures for compliance with NRC Regulations for Reporting of Defects and Nonconformance,” July 2012

Stern Laboratories, Inc., QP-15-02, Revision 1, “Reporting Defects and Noncompliance in accordance with U.S. Regulation 10 CFR Part 21,” February 2013

QP-15-01, Control of Nonconforming Items,” Revision 0, dated February 2013

QP-16-01, Corrective Action,” Revision 1, dated February 2013

Test Control Documents

NuScale Power, NP-EP-1102, Revision 0, “Test Control,” June 2010

NuScale Power, NP-TSD-0712-001, Revision 1, “Critical Heat Flux Test Development Plan,” January 2013

Stern Laboratories, Inc., SLFP-147, Revision 0, “Fabrication Procedure, NuScale Test Assembly (Test Series C-1),” July 2012

Stern Laboratories, Inc., SLFP-150, Revision 0, “NuScale Post Test Assembly Inspection,” October 2012

Stern Laboratories, Inc., SLTP-215, Revision 1, “Heat Transfer Experiments for NuScale Power (Test Series U-1),” August 2012

Stern Laboratories, Inc., SLTP-216, Revision 0, “Heat Transfer Experiments for NuScale Power (Test Series U-2),” August 2012

Stern Laboratories, Inc., SLTP-217, Revision 2, “Heat Transfer Experiments for NuScale Power (Test Series C-1)”, February 2013.

Stern Laboratories, Inc., Quality Assurance Procedure QAP-02, Revision 13, “Qualification Testing,” September 2012
Stern Laboratories, Inc., Quality Assurance Procedure QAP-06, Revision 7, “Control and Verification of Data Acquisition Software,” September 2012

Stern Laboratories, Inc., Quality Assurance Procedure QAP-07, Revision 8, “Purchasing, Shipping, and Receiving,” October 2012

Stern Laboratories, Inc. Quality Assurance Procedure QAP-15, Revision 1, “Operation of Data Acquisition System and Associated Instrumentation,” December 2006

Stern Laboratories, Inc., Quality Assurance Procedure QAP-16, Revision 2, “Preparation of Stern Laboratories Reports,” October 2012

Stern Laboratories, Inc., Quality Assurance Procedure QAP-17, Revision 1, “Preparation and Maintenance of Project Files,” October 2012

Stern Laboratories, Inc., Quality Assurance Procedure QAP-21, Revision 0, “Preparation of Inspection and Test Plans,” September 2012

Stern Laboratories, Inc., Project Quality Plan (PQP) SLQP-112, “Quality Plan for Providing Experimental Facilities and Performing Thermal Hydraulic Experiments for NuScale Power, Inc.,” Revision 3, dated February 2013

NuScale Power, NP-TRR-0912-3313, “Test Readiness Review, U-1 Series,” February 13, 2013

NuScale Power, NP-TRR-0213-3310, “Test Readiness Review, C-1,” February 13, 2013

NuScale Power, NP-TRR-0213-3310, “Test Readiness Review, C-1,” February 13, 2013

NuScale Power, NP-TRR-1012-3311, “Post-Test Assessment Review, U-1 Series,” October 16, 2013

NuScale Power, NP-TRR-0213-3310, “Post-Test Assessment Review, U-2,” February 13, 2013.

NuScale Power, NP-TRR-0213-3310, “Post-Test Assessment Review, C-1,” February 13, 2013

Stern Laboratories, Inc., SLTM-111, Revision 1, “Verification of the NuScale Uniform Test Series Instrumentation,” February 2013

Stern Laboratories, Inc., SLTM-106, “Flow Channel Pressure Sense Line Corrections Used by Data Acquisition System,” November 2012

Inspection Report IR-689-54, Revision 1, “Final Inspection of Cosine Fuel Simulator for NuScale Series # 689-C-01 to 689-C-30,” November 21, 2012

QP-12-01 “Control of Measurement and Test Equipment,” Revision 0, dated February 2013

Commercial-Grade Dedication Documents

Stern Laboratories, Inc., Quality Assurance Procedure QAP-19, Revision 0, “Commercial Grade Dedication of Data Acquisition System for Use in Safety Related Applications,” July 2012

FL-TRP-0612-001 “Technical Evaluation and Trip Report 1 – Commercial Grade Dedication Process,” NuScale Task Order NP-SW- 0412-1460, “Commercial Grade Dedication of Stern Laboratories Software,” June 11, 2012

SLCGD-01 “Commercial Grade Dedication of the DAS for NuScale,” Revision 0, dated September 19, 2012

SLCGD-01, “Commercial Grade Dedication of the U-1 Series Test Data for NuScale,” Revision 1, dated January 25, 2013

SLCGD-02, “Commercial Grade Dedication of the U-2 Series Test Data for NuScale,” Revision 0, dated December 2012

SLCGD-04, “Commercial Grade Dedication of the C-1 Series Test Data for NuScale,” Revision 0, dated January 2013

QP-07-04, “Commercial Grade Dedication,” Revision 0, dated December 11, 2012