

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

)

Docket No. 99901385

C&D Technologies, Inc.

)

EA-15-212

CONFIRMATORY ORDER

I.

C&D Technologies, Inc., (C&D) provides Class 1E batteries for safety-related applications to nuclear power plants located in the United States. The C&D main office is located in Blue Bell, Pennsylvania.

This Confirmatory Order (Order) is the result of an agreement reached between C&D and the U.S. Nuclear Regulatory Commission (NRC) during an alternative dispute resolution (ADR) mediation session conducted on March 10, 2016.

II.

From September 21 to September 25, 2015, the NRC conducted an inspection at the C&D facility in Blue Bell. The purpose of this limited-scope inspection was to assess C&D's

compliance with the provisions of selected portions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” and 10 CFR Part 21, “Reporting of Defects and Noncompliance.”

On January 8, 2016, the NRC issued Inspection Report 99901385/2015-201 to C&D, which documented three apparent violations being considered for escalated enforcement action in accordance with the NRC Enforcement Policy.

The first apparent violation concerned C&D’s failure to implement an adequate 10 CFR Part 21 program to perform a timely and thorough evaluation of a deviation to identify defects, which if left uncorrected, could result in substantial safety hazards. The NRC identified that C&D’s initial evaluation of a deviation in station battery cell separators lacked an adequate technical basis to support closing the evaluation in accordance with 10 CFR 21.21(a)(1). When C&D completed a more thorough evaluation of this deviation, a defect in the battery manufacturing process was identified. This defect was reported to the NRC in accordance with 10 CFR 21.21(d)(1); however, the report was made over 2 1/2 years greater than the 60 day requirement. The second apparent violation concerned multiple additional instances where C&D failed to provide an adequate technical justification to support closing the evaluations of deviations in accordance with 10 CFR 21.21(a)(1). The third apparent violation concerned multiple additional instances where C&D failed to prepare and submit interim reports to the NRC when an evaluation could not be completed within 60 days from the date of discovery in accordance with 10 CFR 21.21(a)(2).

In response to the NRC’s letter dated January 8, 2016, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15307A198), C&D requested the use of the NRC’s ADR process to resolve these issues. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement on resolving any

differences regarding a dispute. This Order is being issued pursuant to the preliminary agreement reached between C&D and the NRC.

III.

During the ADR mediation session, C&D and the NRC reached a preliminary settlement agreement. The elements of the agreement consisted of the following:

1. To ensure that C&D achieves full compliance for all currently identified violations, C&D will take the following actions:

- A. By 30 calendar days from the issuance date of an Order, C&D shall confirm that all outstanding 10 CFR Part 21 evaluations are complete and that all required interim reports are submitted in accordance with the timelines required by 10 CFR Part 21.

- B. By 45 calendar days from the issuance date of an Order, C&D shall review and revise, as necessary, all policies and procedures to provide reasonable assurance that Part 21 evaluations are conducted in accordance with 10 CFR 50, Appendix B quality assurance program requirements.

- a. C&D shall define the Part 21 “discovery date” within their procedures as the date the issue is entered into the Part 21 process, corrective action system, nonconformance process, or reported in the customer complaint database, whichever occurs first.

- b. C&D procedures shall provide reasonable assurance that the evaluation

process of all deviations includes a documented technical evaluation and basis for why the identified deviation would or would not result in a substantial safety hazard, if left uncorrected.

C. By 45 calendar days from the issuance date of an Order, C&D shall contract an independent (not an employee or customer of C&D) third party expert to conduct an assessment of the C&D corrective action program (CAP), and the administrative controls and management controls in place to provide reasonable assurance of an effective Part 21 program, including 10 CFR 50, Appendix B requirements. The initial assessment shall be completed by the end of the calendar year 2016 and assessments will continue annually.

D. C&D shall report the completion of items 1.A, 1.B and 1.C, in writing to the Director, Division of Construction Inspection and Operational Programs (DCIP), Nuclear Regulatory Commission (NRC), Office of New Reactors, no later than 75 calendar days from issuance of the Order.

2. To ensure that C&D senior management, first-line supervision and employees are committed to, and accountable for, complying with NRC requirements, and maintaining a robust safety culture, C&D will take the following actions:

A. By 30 calendar days from the issuance date of an Order, C&D shall issue a letter from President and Chief Executive Officer (CEO)¹ to employees in all C&D

¹ In lieu of a letter to all employees, the NRC would consider it to be acceptable if C&D produced a video message from the CEO and other senior managers that would have wide-spread distribution and be shown at required all-hands meeting(s).

locations, working with nuclear-related activities, outlining C&D's management's expectations, including a commitment that all nuclear-related activities are performed and documented in a complete and accurate manner in accordance with approved procedures. C&D shall notify the DCIP Director no later than 30 calendar days after issuance of the letter and shall provide a copy of the letter to the DCIP Director. The letter shall address the following:

- (1) where the NRC inspection report can be found that describe the 2015 apparent violations;
- (2) include a brief overview of the apparent violations;
- (3) C&D senior management, mid-level managers and first-line supervisors expect all employees to follow approved policies and procedures; and
- (4) C&D management has an expectation that all employees are to report procedure concerns to their supervisors (or to another appropriate level of management), and that supervisors are responsible for encouraging this reporting by staff and ensuring procedure issues are resolved appropriately and in a timely manner.

B. By 90 calendar days from the issuance date of an Order, Senior Management's commitment and expectations will be further reinforced through the use of conspicuously posted company-wide posters and/or other appropriate forms of communication. Communications will specifically discuss 10 CFR Part 21 requirements, and best practices identified by C&D's evaluation of issues and violations (including root causes), corrective actions to prevent recurrence, and promote a strong safety culture.

- C. Management expectations shall be further reinforced at the local level with an overt commitment from mid-level management and first line supervisors regarding procedure adherence. Opportunities to communicate this commitment may include organizational all-hands meetings during which site managers and/or supervisors can convey the lessons learned from NRC inspections and any applicable industry assessments (e.g., Nuclear Procurement Issues Committee (NUPIC)), and explain how to handle similar situations if and when they should arise in their organization or group.
3. To ensure that C&D policies, procedures and work practices provide the necessary guidance to promote compliance with NRC requirements, C&D shall take the following actions:
- A. By 180 calendar days of the issuance date of an Order, C&D shall enter the existing issue of procedure compliance into its corrective action program (CAP), and this issue shall be considered a significant condition adverse to quality. As a result, C&D shall conduct a formal root cause analysis of known procedure violations to determine the extent of condition of C&D work practices and identify corrective actions to improve procedure guidance. In addition, the extent of condition shall address the last five years of C&D's nuclear related customer complaints, corrective actions, or nonconformances that meet the Part 21 definition of a deviation. C&D shall ensure that the extent of condition review is complete and that all 10 CFR Part 21 deviations are identified and entered into C&D's Part 21 (A-14) procedure to ensure that they are adequately evaluated for reportable defects. By

30 calendar days of corrective action completion, C&D shall provide the results of its root cause and extent of condition report to the DCIP Director.

B. By 60 calendar days of the issuance date of an Order, C&Ds corrective action program shall be revised to have the ability to trend 10 CFR Part 21 related issues, such as failure to follow 10 CFR Part 21 procedure requirements or failure to enter a deviation into the 10 CFR Part 21 process.

4. To ensure that all C&D employees understand their roles and responsibilities regarding compliance with NRC requirements, C&D will provide training and other forms of continuous reinforcement to its employees:

By 90 calendar days from the issuance date of an Order, C&D will complete the development of a training program as described below. The initial training shall be submitted to the NRC for review and comment before being implemented. The NRC will review the draft training provided by C&D within 10 business days. The initial training shall then be conducted and documented for all current employees and supervisors no later than 30 calendar days from the completion of the NRC review. C&D shall report to the DCIP Director by telephone within 7 calendar days of completion of the initial training.

A. Training (initial and annual) shall cover the basic regulatory requirements of 10 CFR; the legal authority granted to the NRC to inspect for compliance; the enforcement actions that can be taken against the company, the customer and company employees for noncompliance; 10 CFR 50, Appendix B and 10 CFR Part 21 requirements; and the associated C&D procedures. This shall be documented and

provided to all employees involved in nuclear-related work activities, including management.

- B. Develop, implement and document initial training and annual refresher training for item 4.A.
- C. For employees involved in nuclear-related activities (including supervisors) hired after the date of initial training completion, the initial training shall be provided and documented within 45 calendar days of hire.
- D. For 3 years following the effective date of the Order, C&D shall assess the effectiveness of training and procedure compliance by reviewing and trending information obtained from C&D's CAP.

In addition to the elements described above, C&D has taken or committed to take the following corrective actions.

1. Complete implementation of an improved process that customers use to report information (i.e., the iSight system) to C&D for battery issues. This process shall assure prompt entry and classification of issues to determine if the issue is a deviation, if applicable.
2. Complete implementation of a new 10 CFR Part 21 process that includes biweekly meetings that are attended by executive management, and logs of actions and schedules for reporting to the NRC.

3. Complete implementation of new qualification report documentation to reconstitute the design basis of the K and L battery product lines by linking the specification requirements to specific test results required by the Institute of Electrical and Electronics Engineers (IEEE) specifications.
4. Complete implementation of new internal reporting requirements. Quality assurance issues shall be reported to the CEO.
5. Hold monthly corrective action meetings with plant managers and the executive team to ensure timely correction of identified issues.
6. Complete implementation of more robust Safety Committee meetings conducted with particular attention paid to due dates. In addition, the process for initial reporting of customer identified issues has been established so that the Quality Systems manager conducts the first review of the issue as soon as correspondence begins with a nuclear customer.
7. Complete institution of a third party 10 CFR Part 21 and Appendix B audit program, using experienced and qualified personnel reporting directly to the CEO and General Counsel. The audits shall be executed annually. Inputs to the audits will include all customer communications, customer complaint information, and 10 CFR Part 21 and Safety Committee records. The initial audit shall occur by the end of March 2016 for the 10 CFR Part 21 program and by September 2016 of Appendix B to 10 CFR Part 50.

Based on the actions described above, and the commitments described in Section V below, the NRC agrees to the following conditions:

1. The NRC will consider this Order as an escalated enforcement action for the purposes of determining future enforcement action per the NRC Enforcement Policy,
2. The NRC will refrain from issuing a proposed imposition of a civil penalty and a Notice of Violation for the above referenced apparent violations.

On April 12, 2016, C&D consented to issuing this Order with the commitments, as described in Section V below. C&D further agreed that this Order is to be effective 30 calendar days after its issuance, the agreement memorialized in this Order settles the matter between the parties, and that C&D has waived its right to a hearing.

IV.

I find that C&D's actions completed or committed to take, as described in Section III above, combined with the commitments as set forth in Section V are acceptable and necessary, and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that C&D's commitments be confirmed by this Order. Based on the above and C&D's consent, this Order is effective 30 calendar days after its issuance.

V.

Accordingly, pursuant to Sections 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 21, and 50, IT IS HEREBY ORDERED THAT:

A. Compliance with 10 CFR Part 21

1. By 45 calendar days from the issuance date of this Order, C&D shall confirm that all outstanding 10 CFR Part 21 evaluations are complete and that all required interim reports are submitted in accordance with the timelines required by 10 CFR Part 21.
2. By 45 calendar days from the issuance date of this Order, C&D shall review and revise, as necessary, all policies and procedures to provide reasonable assurance that Part 21 evaluations are conducted in accordance with 10 CFR 50, Appendix B quality assurance program requirements.
 - a. C&D shall define the Part 21 "discovery date" within their procedures as "the date the issue is entered into the Part 21 process, corrective action system, nonconformance process, or reported in the customer complaint database, whichever occurs first."
 - b. C&D procedures shall provide reasonable assurance that the evaluation process used for all deviations includes a documented technical evaluation and basis for why the identified deviation would or would not result in a substantial safety hazard, if left uncorrected.

3. By 45 calendar days from the issuance date of this Order, C&D shall contract an independent third party expert (not an employee or customer of C&D) to conduct an assessment of the C&D corrective action program, and the administrative controls and management controls in place to provide reasonable assurance of an effective Part 21 program, including 10 CFR 50, Appendix B requirements. The initial assessment shall be completed by the end of the calendar year 2016 and assessments will continue annually thereafter.
4. C&D shall report the completion of items A.1, A.2, and A.3, in writing to the DCIP Director no later than 75 calendar days from issuance of this Order.

B. Communications

1. By 45 calendar days from the issuance date of this Order, C&D shall issue a letter and/or a video message from the President and CEO to employees in all C&D locations working with nuclear-related activities, outlining C&D's management's expectations, including a commitment that all nuclear-related activities are performed and documented in a complete and accurate manner in accordance with approved procedures. C&D shall notify the DCIP Director no later than 30 calendar days after issuance of the letter and shall provide a copy of the letter to the DCIP Director. The letter shall address the following:
 - a. how to obtain the NRC inspection report that describes the 2015 apparent violations;
 - b. a brief overview of the apparent violations;

- c. a statement that C&D senior management, mid-level managers, and first-line supervisors expect all employees to follow approved policies and procedures; and
 - d. a statement that C&D management has an expectation that all employees are to report procedure concerns to their supervisors, or to another appropriate level of management, and that supervisors are responsible for encouraging this reporting by staff, and ensuring procedure issues are resolved appropriately and in a timely manner.
2. By 90 calendar days from the issuance date of this Order, C&D senior management's commitment and expectations will be further reinforced through the use of conspicuously posted company-wide posters and/or other appropriate forms of communication. Communications will specifically discuss 10 CFR Part 21 requirements, and best practices identified by C&D's evaluation of issues and violations (including root causes), corrective actions to prevent recurrence, and promote a strong safety culture.

C. Work Processes

1. C&D shall ensure that the existing issue of procedure compliance has been entered into its CAP, and this issue shall be considered a significant condition adverse to quality. As a result, within 180 days of the issuance date of this Order, C&D shall conduct a formal root cause analysis of known procedure violations to determine the extent of condition of C&D work practices and identify corrective actions to improve procedure guidance. In addition, the extent of condition shall address the last five years of C&D's nuclear-related customer complaints, corrective actions, or nonconformances that meet the Part 21 definition of a "deviation." C&D shall ensure that the extent of condition review is

complete and that all 10 CFR Part 21 deviations are identified and entered into C&D's 10 CFR Part 21 program to ensure that they are adequately evaluated for reportable defects. By 30 calendar days of corrective action completion, C&D shall provide the results of its root cause and extent of condition report to the DCIP Director.

2. By 60 calendar days of the issuance date of this Order, C&Ds CAP shall be revised to have the ability to trend 10 CFR Part 21 related issues, such as failure to follow 10 CFR Part 21 procedure requirements or failure to enter a deviation into the 10 CFR Part 21 process.

D. Training

1. By 90 calendar days from the issuance date of this Order, C&D will develop a training program as described below. The training program, including the initial training, shall be submitted to the NRC for review and comment before being implemented. Within 10 business days of submission, the NRC will perform an initial review and provide comments to C&D. Within 30 days of receiving NRC comments, C&D shall adequately address these comments in writing, at which time the NRC will provide a final review of the program. The NRC will inform C&D of its approval of the training program in writing and by telephone within 10 days of re-submittal by C&D. The initial training shall then be conducted and documented for all current employees and supervisors no later than 30 calendar days from the NRC final approval date. C&D shall report to the DCIP Director in writing and by telephone within 7 calendar days of completion of the initial training.
 - a. Training (initial and annual) shall cover the basic requirements (e.g., what they are

and how they apply) of 10 CFR 50, Appendix B and 10 CFR Part 21; the legal authority granted to the NRC to inspect for compliance; the enforcement actions that can be taken against the company, the customer and company employees for noncompliance; and the associated C&D procedures. This training shall be provided to all employees involved in nuclear-related work activities, including management.

- b. Develop, implement and document initial training and annual refresher training for item D.1.a.
- c. For employees involved in nuclear-related activities, including supervisors, who are hired after the date of initial training completion, the initial training shall be provided and documented within 45 calendar days of hire.
- d. For three years following the effective date of this Order, C&D shall assess the effectiveness of training and procedure compliance by reviewing and trending information obtained from C&D's CAP.

The terms of this Order apply to the successors and assigns of C&D.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by C&D of good cause.

VI.

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Order, other than C&D, may request a hearing within 30 days of the issuance date of this Order. Where good cause is shown, consideration will be given to extending the time to request a

hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007), as amended by 77 FR 46562; August 3, 2012 (codified in pertinent part at 10 CFR Part 2, Subpart C). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene through the EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time (ET) on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice

that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., ET, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of

deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, participants are requested not to include copyrighted materials in their submission, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue a separate Order designating the time and place of any hearings, as appropriate. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days after issuance of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

Dated at Rockville, Maryland, this 20th day of April 2016.

For the Nuclear Regulatory Commission.

/RA/

Patricia K. Holahan, Director
Office of Enforcement