



SQL 16-001

January 2, 2016

Mr. Juergen Laucht
Managing Director
NUKEM Isotopes GmbH
Industriestrasse 13
63755 Alzenau, Germany

Dear Mr. Laucht:

**AMEREN JOINT UTILITIES AUDIT OF
NUKEM Isotopes GmbH, ALZENAUE, GERMANY**

On November 30 through December 4, 2015, representatives from Ameren, Arizona Public Service (APS), and Vattenfall (VAT) performed a Joint Utilities Audit of NUKEM Isotopes GmbH in Alzenau, Germany. The audit, which was led by Ameren, determined that NUKEM Isotopes GmbH is implementing an effective quality assurance program in accordance with 10CFR50, Appendix B for the supply of safety related Lithium Hydroxide, Depleted Zinc Oxide, Depleted Zinc Acetate, and Enriched Boric Acid. The audit also resulted in the initiation of one (1) minor Request for Corrective Action (RCA's) to address a deficiency. NUKEM Isotopes GmbH took immediate corrective actions to resolve the concern. As a result the finding was issued closed and no further actions are required.

Attached please find a copy of the audit report, RCA, and checklist for your information. Please note that RCA VA15-006-01 has been closed and no additional response is required. The audit report package will be distributed to APS, VAT, and other NUPIC Members upon request.

On behalf of the team, thank you for the cooperation and courtesy extended to us during the audit. If you need additional information, please contact me at (314) 554-4868 or via email at emayhorn@ameren.com.

Sincerely,

Earl R. Mayhorn
Principal Engineer

cc: L. Kanuckel
M. Hillstrom
H. VU
T. Glaser, NUKEM Isotopes GmbH
M. Kievel, NUKEM Isotopes GmbH
B. Giles, APS
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Enclosure

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AUDIT REPORT VA15-006**

SUPPLIER

NUKEM Isotopes GmbH
Alzenau, Germany

AUDIT DATE

November 30 through December 4, 2015

AUDIT TEAM

Earl Mayhorn, Audit Team Leader, Ameren
Ingvar Krvggh, Audit Team Member, Vattenfall
Bruce Giles, Audit Team Member, Arizona Public Service

PRODUCTS/SERVICES

Safety related Lithium Hydroxide, Depleted Zinc Oxide, and Depleted Zinc Acetate, and Enriched Boric Acid

AUDIT PURPOSE/SCOPE

To verify the adequacy and effectiveness of the NUKEM Isotopes GmbH quality assurance program used to supply Lithium Hydroxide, Depleted Zinc Acetate, Depleted Zinc Oxide, and Enriched Boric Acid. Also, to assess the effectiveness of the corrective actions implemented to resolve the finding issued during the 2012 Ameren Audit.

AUDIT SUMMARY

NUKEM Isotopes GmbH has established and implements an effective quality assurance program that meets the requirements of 10CFR50, Appendix B and 10CFR Part 21 for supplying safety related Lithium Hydroxide, Depleted Zinc Oxide, Depleted Zinc Acetate, and Enriched Boric Acid Products. Also, the corrective actions taken to resolve the finding issued during the 2012 audit were found to be effective. The audit team identified notable strengths which included the following:

- A dedicated and knowledgeable staff
- A Strong Quality Culture
- The use of industry leaders as sub-suppliers
- Excellent oversight of sub-suppliers
- An effective commercial grade dedication process
- Well written quality program including instructions, procedures, and forms

The audit also resulted in the initiation of one (1) Request for Corrective Action (RCA) to address concerns relative to the expiration of commercial grade survey used to approve a supplier of Lithium Hydroxide and the use of a supplier completed self-assessment to approve the supplier. The finding did not have an adverse impact on products supplied to nuclear utilities since the products from both suppliers are independently tested by a NUKEM Isotopes GmbH approved test laboratory. As a result of the administrative nature of the finding and NUKEM Isotopes GmbH's completion of all required corrective action, the RCA VA15-006-01 was issued closed. In addition, NUKEM Isotopes GmbH was also found to be very proactive in addressing observations made by the audit team.

Based on the favorable results of the audit, NUKEM Isotopes GmbH will remain on the AmerenUE Qualified Suppliers List (QSL) for providing safety related Lithium Hydroxide and Depleted Zinc Products including Zinc Acetate and Zinc Oxide, and Enriched Boric Acid. The conclusions of the audit team were based on walk-downs of the NUKEM Isotopes GmbH facility, visits to Fraport Cargo Services, discussions with NUKEM Isotopes GmbH personnel, and reviews of program controls & representative documents/records.

PROGRAM EFFECTIVENESS

NUKEM Isotopes GmbH's quality program was found to be effective except where noted.

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AUDIT REPORT VA15-006

AUDIT DEFICIENCIES AND IMPACT

There was one Request for Corrective Actions (RCA) issued during the audit.

VA15-006-01 was issued to address discrepancies relative to the expiration of a supplier qualified by commercial grade survey and the acceptance of a supplier's self- assessment in lieu of a NUKEM Isotopes GmbH survey of the supplier. . While NUKEM has committed to performing commercial grade surveys of suppliers on a three year frequency, it was noted that the three year survey of a supplier of Lithium Hydroxide expired on October 30, 2015. NUKEM indicated the supplier in question was reluctant to allow NUKEM to perform an on-site survey since the requirement was not specified in the procurement contract. Subsequently, NUKEM has scheduled a survey of the supplier for January 2016. However, it was noted that NUKEM did not have procedure provisions to allow an extension of surveys in the case of scheduling issues. It should be noted that the products supplied by the supplier are independently tested for isotopic and chemical content by an approved NUKEM Isotopes GmbH test laboratory. In the second case, NUKEM Isotopes GmbH accepted a self- assessment from a supplier in lieu of performing an on-site survey of the supplier. However, there were no procedural provisions in place to allow the use of a supplier self-assessment to approve a supplier. Again, it should be noted that the products supplied by the supplier are independently tested for isotopic and chemical content by an approved NUKEM Isotopes GmbH test laboratory. Therefore it was determined that these two concerns did not have an adverse impact on items supplied to customers.

As a result of the identification for this issue, NUKEM Isotopes GmbH took immediate action to revise the applicable procedure to allow a 90 day extension period for surveys and to recognize the use of self-assessments as a method of supplier approval. It should be noted that in both cases, the chemical products supplied by these suppliers are dedicated through independent testing performed by a NUKEM Isotopes GmbH approved test laboratory. RCA VA15-006-01 was issued closed in process due to the administrative nature of the concern and completion of all required corrective action.

ADDITIONAL INFORMATION

The Lithium Hydroxide and Depleted Zinc products included in the scope of this audit were previously supplied by the Isotopes Trading Group within NUKEM GmbH through collaboration with NUKEM, Inc., located in Danbury, CT. US nuclear utilities were required to place purchase order through NUKEM, Inc. NUKEM, Inc. was responsible for transmitting the customer's order to NUKEM GmbH. Upon receipt of an order, NUKEM GmbH would process the order and authorize shipment of products directly to the customer from NUKEM GmbH's approved sub-supplier. As part of a strategic restructuring by NUKEM GmbH and effective November 1, 2011, NUKEM GmbH sold the isotopes trading portion of the business to former employees of NUKEM GmbH. These former employees formed a new company known as NUKEM Isotopes GmbH. NUKEM Isotopes GmbH is a completely new company with no financial affiliation to NUKEM GmbH or NUKEM, Inc. It should be noted that NUKEM Isotopes operates from the same physical location in Alzenau, Germany as the defunct Isotopes Trading Group of NUKEM GmbH.

US utility orders are now required to be placed directly with NUKEM Isotopes GmbH, Alzenau, Germany. Products are still shipped directly to the customer from NUKEM Isotopes GmbH's approved sub-supplier Fraport Cargo Services located at the nearby Frankfurt, Germany International Airport.

REVIEW OF ITEMS/AREAS AS REQUESTED (INPUT) BY OTHER LICENSEES

Audit input was provided by AmerenUE (AUE), Arizona Public Service (APS), Dominion (DOM), and Vattenfall (VAT)

REVIEW OF PREVIOUSLY IDENTIFIED INDUSTRY AND AUDIT CONCERNS

The 2012 Joint Utilities Audit of NUKEM GmbH was led by AmerenUE and resulted in the initiation of one (1) Request for Corrective Action.

VA12-009-01 was issued to address a discrepancy relative to the documentation of personnel quality assurance program indoctrination training. There was no documented evidence that personnel

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AUDIT REPORT VA15-006

performing activities affecting quality had undergone indoctrination training on 10CFR50, Appendix B, 10CFR Part 21, and the NUKEM Isotopes GmbH quality program since the new company was formed in November 2011. This finding was found to be administrative with no impact on products previously supplied by NUKEM Isotopes GmbH. Based on discussions with personnel, personnel were cognizant of the requirements of 10CFR50, Appendix B, 10CFR Part 21 and the NUKEM Isotopes GmbH QA program. In addition, these are the same individuals that previously performed the same functions under the NUKEM GmbH Company.

NUKEM Isotopes GmbH provided a written response which was accepted by AUE. The finding was subsequently closed based on verification of corrective action by AUE. Corrective action included properly documenting the quality assurance program indoctrination training for NUKEM Isotopes GmbH personnel. During the current 2015 Audit, there were no similar occurrences identified at NUKEM Isotopes GmbH. The corrective action taken to address VA12-009-01 was found to be effective.

There was no adverse information concerning NUKEM Isotopes GmbH listed in the Industry Issues section of the NUPIC Database. The Nuclear Regulatory Commission has not performed any inspections of NUKEM Isotopes GmbH since the 2012 audit. In addition, NUKEM Isotopes GmbH has not issued any 10CFR Part 21 reports.

UNIQUE ORDER ENTRY REQUIREMENTS/RECOMMENDATIONS TO USERS/APPROVED SHIPPING LOCATION

All customer orders must be placed directly with NUKEM Isotopes GmbH located in Alzenau, Germany. Requests for Quotation, Purchase Order and other correspondence must be sent to:

Mr. Michael Kievel
Director, Global Sales
NUKEM Isotopes GmbH
Industriestrasse 13
63755 Alzenau, Germany
Phone: +49 60 23 91 16 28
Fax: + 49 60 23 91 16 14
e-mail. michael.kievel@nukemisotopes.de

The only approved shipping origin is:

Fraport Cargo Services
Frankfurt, Germany International Airport

Fraport operates a bonded warehouse at the Frankfurt airport and is NUKEM Isotopes GmbH's approved sub-supplier for storage and shipment of products from Germany directly to the customer.

AUDIT DETAILS

A summary of each audit area is provided for below.

Section 1 – Order Entry

NUKEM Isotopes GmbH has established and implements an acceptable program for reviewing customer contract/purchase order requirements and translating them into NUKEM Isotopes GmbH internal documents. Purchase orders issued by nuclear utilities are required to be sent directly to NUKEM Isotopes GmbH, Alzenau, Germany. NUKEM Isotopes GmbH personnel have been trained to recognize orders which impose 10CFR50, Appendix B and 10CFR 21. However, in practice, all orders from nuclear utilities receive the same level of care and processing whether or not the order imposes 10CFR50, Appendix B and 10CFR Part 21. Order review personnel capture standard and special customer requirements on a Document Checklist. A checklist has been developed for Lithium Hydroxide, Depleted Zinc Oxide, and Depleted Zinc Acetate.

Ameren
AUDIT REPORT VA15-006

A Certificate of Compliance and Conformance is typically supplied by NUKEM Isotopes GmbH indicating the NUKEM Isotopes GmbH QA program and customer requirements were met. Figure 1 of the attached audit checklist identifies the customer orders and NUKEM Isotopes GmbH associated documentation reviewed during the audit. No adverse concerns were identified.

This area was found to be satisfactory.

Section 2– Design Control

NUKEM Isotopes GmbH supplies primary chemicals including Lithium Hydroxide, Depleted Zinc Oxide, Depleted Zinc Acetate, and Enriched Boric Acid. Design is not included in NUKEM Isotopes GmbH's scope of supply. This area was found to be not applicable.

Section 3 – Commercial Grade Dedication

NUKEM Isotopes GmbH has established and implements an effective commercial grade dedication program for the acceptance of commercially procured products and services. The process requires a technical evaluation to identify the critical characteristics of the chemicals being supplied by NUKEM Isotopes GmbH. The process does not require the identification of a safety function but all technical characteristics of the chemicals are identified as critical and are verified prior to acceptance. The process identifies the EPRI NP 5652 four (4) acceptance methods. NUKEM Isotopes employs Method 1- Test/Inspections and Method 2- Commercial Grade Surveys for the verification of the acceptability of the identified critical characteristics. The commercial suppliers of each chemical are surveyed by NUKEM Isotopes GmbH to verify the supplier's lot/batch control, product traceability, and material handling/storage/shipping. The test laboratory contracted to perform isotopic and chemical analysis is surveyed to verify the laboratory controls the critical characteristics of testing service. The chemical products are dedicated based on acceptable test results demonstrating the critical characteristics of the products are acceptable. NUKEM Isotopes GmbH's approved supplier for storing and shipping products is surveyed to verify the supplier controls the identified critical characteristics for those services.

This area was found to be satisfactory.

Section 4- Software Quality Assurance

NUKEM Isotopes GmbH supplies primary chemicals including Lithium Hydroxide, Depleted Zinc Oxide, Depleted Zinc Acetate, and Enriched Boric Acid. Safety related computer software is not utilized by NUKEM Isotopes GmbH to supply these products. This area was found to be not applicable.

Section 5 – Procurement

NUKEM Isotopes GmbH has established an acceptable program for the procurement of items and services. While NUKEM Isotopes does not employ the use of safety related 10CFR50, Appendix B suppliers, reputable suppliers which are industry experts are utilized. Commercial dedication is the basis of acceptance of items and services from these suppliers. NUKEM Isotopes is required to perform commercial grade surveys at the suppliers' facilities on a three year cycle to verify the suppliers' control of the identified critical characteristics. In addition, written purchase orders are issued which include the appropriate technical and quality requirements. Concerns were identified with the approval of two suppliers. **RCA VA15-006-01** was issued to address a discrepancy relative to the expiration of a supplier qualified by commercial grade survey. While NUKEM has committed to performing commercial grade surveys of suppliers on a three year frequency, it was noted that the three year survey of a supplier of Lithium Hydroxide expired on October 30, 2015. NUKEM indicated the supplier in question was reluctant to allow NUKEM to perform an on-site survey since the requirement was not specified in the procurement contract. **RCA VA15-006-01** addressed NUKEM Isotopes GmbH acceptance of a self- assessment from a supplier in lieu of performing an on-site survey of the supplier. There were no procedural provisions in place to allow the use of a supplier self-assessment to approve a supplier. Again, it should be noted that the products supplied by the supplier are independently tested for isotopic and chemical content by an

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AUDIT REPORT VA15-006

approved NUKEM Isotopes GmbH test laboratory. Therefore it was determined that these two concerns did not have an adverse impact on items supplied to customers. Subsequently, NUKEM revised the procurement contract to invoke a survey requirement and has scheduled a survey of the supplier for January 2016.

This area was found to be unsatisfactory.

Section 6 – Fabrication/Assembly Activities, Material Control and Handling, Storage & Shipping

NUKEM Isotopes GmbH has developed that the necessary procedure controls for the identification, handling, storage, and shipment of products that they sell as nuclear safety related. It should be noted that material handling, storage, and shipping services are subcontracted to a supplier which NUKEM Isotopes has surveyed and approved. Fraport Cargo Services, Frankfurt, Germany is used to receive products from NUKEM Isotopes' suppliers; handle and storage the material until an order is received; and ship the product after confirmation from NUKEM Isotopes the product is acceptable and after NUKEM Isotopes has processed and accepted a customer order.

On Wednesday, December 2, 2015, the audit team visited Fraport Cargo Services to meet the key individuals and observe product handling, storage, and shipping. Personnel from NUKEM Isotopes GmbH also participated in the visit. Fraport personnel were found to be knowledgeable and conscientious.

Section 7 - Special Processes

NUKEM Isotopes GmbH supplies primary chemicals including Lithium Hydroxide, Depleted Zinc Oxide, d Depleted Zinc Acetate, and Enriched Boric Acid. Special processes are not included in NUKEM Isotopes GmbH's scope of supply. This area was found to be not applicable.

Section 8 – Tests/Inspections/Calibration

NUKEM Isotopes GmbH has developed and implements the appropriate controls for the inspection and testing of products sold to nuclear utilities. Actual product testing which includes isotopic and chemical analysis is performed by an approved subtier supplier. SGS Fresenius is recognized as an industry leader in chemical testing throughout Germany and the world. Testing is performed using industry standards (DIN) to verify compliance to NUKEM Isotopes GmbH specifications. Testing is performed by qualified individuals using test and analytical equipment whose calibration and chemical standards are traceable to national standards. The 2012 audit team visited the laboratory and found it to be modern, clean, well-organized, and equipped with the appropriate test equipment for performing isotopic and chemical analysis of Lithium Hydroxide and Depleted Zinc products. The control of samples received for testing was found to be well maintained and test results are reported in accordance with NUKEM Isotopes GmbH requirements. SGS Fresenius is accredited to ISO/IEC 17025 for laboratory testing by DAR.

This area was found to be satisfactory.

Section 9 - Document Control

NUKEM Isotopes GmbH has established and implements a program to control the identification, preparation, review, approval, and distribution of quality documents. Documents controlled under NUKEM Isotopes' document control program include the Quality Assurance Manual, procedures, product specifications, forms, work instructions, and etc. All controlled documents reviewed during the audit were found to have been reviewed and approved for adequacy. Documents were found to include the appropriate acceptance criteria and were distributed to the appropriate work locations. In addition, all documents revised during the audit were found to be current and the correct revisions.

This area was found to be satisfactory.

Section 10 Organization/Program

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AUDIT REPORT VA15-006

NUKEM Isotopes GmbH has established an acceptable organization and quality program. The NUKEM Isotopes GmbH quality assurance program is based on ISO 9001:2000 and 10CFR50, Appendix B. The program requires the NUKEM Isotopes GmbH's Principal Officers to appoint a Quality Assurance Manager. The Quality Assurance Manager reports directly to the Managing Director. The Quality Assurance Manager is designated as the person responsible for maintenance of the NUKEM Isotopes quality program and was found to have the organizational freedom to identify/ resolve problems and remain sufficiently independent of production pressures. The QA program requires an annual management review to determine the suitability and effectiveness of the program and to introduce changes or improvements. Records of these reviews for the past two years were reviewed and found to be acceptable and in accordance with NUKEM Isotopes GmbH program requirements.

This area was found to be satisfactory.

Section 11 Nonconforming Items

NUKEM Isotopes GmbH has developed a program for the identification, control, evaluation, and disposition of items which are found to be nonconforming or do not meet established specifications or requirements.

In addition, NUKEM Isotopes GmbH has developed the appropriate procedures for the identification and evaluation of deviation to determine a defect or substantial exist. The procedure requires deviations to be evaluated within 60 days to determine if a defect exists. If the evaluation cannot be completed within 60 days, an interim report must be issued to the NRC describing the deviation along with an estimated evaluation completion date. The Managing Director is required to be notified within five (5) working days after the completion of an evaluation that determines a defect exists. The Managing Director is required to issue an initial report to the NRC within two (2) days of receiving this information. The Managing Director is responsible for issuing a written report to the NRC within 30 days of being notified that a defect was identified. If NUKEM Isotopes determines at any time during the evaluation they do not have the capability to perform the evaluation, NUKEM Isotopes GmbH must notify the customer within five (5) working days of making this determination.

This area was found to be satisfactory.

Section 12 Internal Audits

NUKEM Isotopes GmbH has established an internal audit program which requires periodic audits to be conducted to evaluate the effectiveness and implementation of the NUKEM Isotopes quality assurance program. Written procedures govern the planning, conduct, and reporting of internal audits. The NUKEM QA Program is required to be audited every 12 months and when significant changes have been made in the program, or when deficiencies are suspected. Audits are required to be scheduled, planned, performed and reported in accordance with written procedures. Internal audits for the past couple of years were reviewed and found to be effective and in accordance with NUKEM Isotopes GmbH program requirements.

This area was found to be satisfactory.

Section 13 Corrective Action

NUKEM Isotopes GmbH has established and implements an adequate program for the identification, documentation, and corrective action for conditions adverse to quality. A quality management system task list is used as a tool to track corrective action items. The list includes the responsible person for implementing the action, the target and actual completion dates and confirmation of completion. The status of the actions is reviewed by the section quality representative and the quality management officer at quarterly meetings. The responsible organization is responsible for implementing the corrective and preventive action described. An Internal Audit Plan list is used as a tool to track status and corrective

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AUDIT REPORT VA15-006**

action items to internal audit findings and recommendations.

This area was found to be satisfactory.

Section 14 Training/Certification

NUKEM Isotopes GmbH has established and implements the appropriate measures for the indoctrination, training, and qualification of personnel performing activities affecting quality. Personnel performing activities affecting quality include those involved with contract review; procurement; review of test results; coordination of handling, storage, and shipping; and internal and external oversight functions. Personnel performing audit activities were found to be appropriately certified for their assigned duties in accordance with NUKEM Isotopes GmbH.

This area was found to be satisfactory.

Section 15 Field Services

NUKEM Isotopes GmbH supplies primary chemicals including Lithium Hydroxide, Depleted Zinc Oxide, and Depleted Zinc Acetate. Field services are not included in NUKEM Isotopes GmbH's scope of supply. This area was found to be not applicable.

Section 16 Records

NUKEM Isotopes GmbH has established the appropriate measures for the identification, generation, control, storage and maintenance of quality records. Record storage locations and minimum retention times are specified in the appropriate departmental procedures. All records reviewed during the audit were found to be legible, readily identifiable and retrievable. Also records were stored in a manner to prevent damage and deterioration.

This area was found to be satisfactory.

PERSONNEL CONTACTED DURING THE AUDIT

<u>COMPANY/NAME/TITLE</u>	<u>ATTENDED THE PRE-AUDIT MEETING</u>	<u>CONTACTED DURING AUDIT</u>	<u>ATTENDED THE POST-AUDIT MEETING</u>
<u>NUKEM Isotopes GmbH</u>			
Mr. Juergen Laucht, Managing Director & Export Officer	X	X	X
Mr. Tilo Glaeser, QA Manager / Director-Business Dev.	X	X	X
Mr. Michael Kievel, Director- Global Sales	X	X	X
Ms. Carmen Leiherer, Manager, Shipping/Export Control	X	X	X
Mr. Sebastian Heininger, Manager, Shipping	X	X	X
Ms. Astrid Betz, Executive Assistant		X	
Ms. Britta Winkel, Manager Accounting		X	
Mr. Christian Schuch, Chemist	X	X	

Fraport Cargo Services

Mr. Klaus Doring, Commissioner for Occupational Safety	X	X	X
Mr. Steffen Kuhn, Quality Manager	X	X	X
Mr. Rolf Opperman, Dangerous Goods & Aviation Security Process Manager	X	X	X

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AUDIT REPORT VA15-006

The results of the audit were discussed during the post audit conference on December 4, 2015.

Ed K. Griffin #7580 1/2/16
Audit Team Leader Date

Ed K. Griffin for Mark Hillcat #7580 1/2/16
Supervisor, Audits Date