

December 28, 2009

NMED 090726

Surendra K. Gupta, Ph.D.
American Radiolabeled Chemicals, Inc.
101 ARC Drive
Saint Louis, MO 63146

SUBJECT: NRC REACTIVE INSPECTION REPORT 030-20567/09-03(DNMS) AMERICAN
RADIOLABELED CHEMICALS, INC.

Dear Dr. Gupta:

On October 27 and 28, 2009, with continued in-office review through December 4, 2009, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a reactive inspection at your St. Louis, Missouri, facility. The purpose of the inspection was to follow up on a NRC Event Notification (EN) Report Number 45358, which described a tritium contamination event that was discovered by the Florida Bureau of Radiation Control at Lockheed Martin Corporation (Lockheed) in Orlando, Florida. The in-office review was to receive and review additional occupational dose information that was unavailable during the on-site inspection.

The source of the tritium originated from American Radiolabeled Chemicals (ARC) as a result of a project to develop a radioisotope-powered battery by a client of ARC at ARC's St. Louis facility in January of 2009. One of the batteries that was constructed at ARC and shipped to Lockheed for prototype testing was found to be leaking and was reported to the NRC by the State of Florida in the above mentioned EN. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that six (6) Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current enforcement policy is included on the NRC website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because they were identified by the NRC. The violations involved: 1) Unauthorized use of licensed material; 2) Failure of the Radiation Safety Officer (RSO) to make a safety evaluation of the use of material; 3) Failure of the Radiation Safety Committee (RSC) to make a safety evaluation of the use of material; 4) Failure of the RSC to review a protocol for the handling of licensed material; 5) Failure of the RSC to meet during the months of June and July of 2009; and 6) Failure to provide adequate training to BetaBatt employees.

S. Gupta

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You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action", is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Furthermore, the NRC is concerned about ARC's safety culture as it pertains to internal communications and competing priorities that appear to hamper ARC's ability to focus on safety. These issues will be addressed in detail in a future inspection report.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website 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.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-20567
License No. 24-21362-01

Enclosures:

1. Notice of Violation
2. Inspection Report 030-20567/09-03
3. Excerpt from NRC Information Notice 96-28

cc: Larry Gadeken, Ph.D., BetaBatt, Inc.
State of Missouri

S. Gupta

-2-

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cc: Larry Gadeken, Ph.D., BetaBatt, Inc.
State of Missouri

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NOTICE OF VIOLATION

American Radiolabeled Chemicals, Inc.
St. Louis, Missouri

Docket No. 030-20567
License No. 24-21362-01

During a Nuclear Regulatory Commission (NRC) inspection conducted on October 27 and 28, 2009, with continued in-office review through December 4, 2009, six violations of the NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Item 9 of the NRC License Number 24-21362-01 on Amendment No. 39 limits the use of licensed material to the manufacture and synthesis of radiolabeled chemicals for distribution.

Contrary to the above, during the week of January 12, 2009, the licensee failed to limit the use of licensed material to the manufacture and synthesis of radiolabeled chemicals for distribution. Specifically, the licensee supervised a research and development project that involved the incorporation of hydrogen-3 labeled beta-carotene into a battery device, which is not an authorized use on the license.

This is a Severity Level IV violation (Supplement VI).

- B. License Condition 22.B. on Amendment No. 39 of NRC License No. 24-21362-01, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated February 8, 2005, including the Radiation Protection Program (RPP), dated October 21, 2004.

Item 3.3.3.8 of the licensee's RPP entitled "Administrative Duties as Radiation Safety Officer (RSO)" requires, in part, that the RSO make safety evaluations of proposed new uses of radioactive material including modifications of facilities, equipment, and procedures.

Contrary to the above, the RSO failed to make a safety evaluation of a proposed new use of radioactive material and related procedures. Specifically, no safety evaluations were conducted for BetaBatt's processing of several hundred curies of hydrogen-3 labeled beta-carotene during the week of January 12, 2009, for incorporation into a battery device.

This is a Severity Level IV violation (Supplement VI).

- C. License Condition 22.B. on Amendment No. 39 of NRC License No. 24-21362-01, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated February 8, 2005, including the RPP, dated October 21, 2004.

Item 3.2.4.1 of the licensee's RPP entitled "Evaluations of New Uses of Radioactive Material" requires, in part, that the Radiation Safety Committee (RSC) make safety evaluations of proposed new uses of radioactive material prior to the new use.

Contrary to the above, the RSC failed to make a safety evaluation of a new use of radioactive material prior to the new use. Specifically, the RSC did not conduct a safety evaluation of BetaBatt's proposed use of hydrogen-3 labeled beta-carotene that occurred during the week of January 12, 2009, for incorporation into a battery device, prior to the new use.

This is a Severity Level IV violation (Supplement VI).

- D. License Condition 22.B. on Amendment No. 39 of NRC License No. 24-21362-01, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated February 8, 2005, including the RPP, dated October 21, 2004.

Item 3.2.4.2 of the licensee's RPP entitled "Evaluations of Written Protocols for Syntheses" requires, in part, that the RSC review protocols for the syntheses of radiochemicals and related operations involving the handling of licensed materials.

Contrary to the above, the RSC failed to review a protocol for the syntheses of radiochemicals and related operations involving the handling of licensed materials. Specifically, prior to the week of January 12, 2009, the RSC did not review a protocol for BetaBatt's research and development project that involved the handling of several hundred curies of hydrogen-3 labeled beta-carotene for incorporation into a battery device that occurred during the week of January 12, 2009.

This is a Severity Level IV violation (Supplement VI).

- E. License Condition 22.B. on Amendment No. 39 of NRC License No. 24-21362-01, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated February 8, 2005, including the RPP, dated October 21, 2004.

Item 3.2.5 of the licensee's RPP entitled "Meeting Frequency" requires, in part, that a meeting of the RSC be held at least monthly.

Contrary to the above, during the months of June and July of 2009, the licensee failed to hold monthly meetings of the RSC.

This is a Severity Level IV violation (Supplement VI).

- F. License Condition 22.B. on Amendment No. 39 of NRC License No. 24-21362-01, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated February 8, 2005, including the RPP, dated October 21, 2004.

Item 6.1 of the licensee's RPP entitled "Radiation Safety Training" requires, in part, that all individuals who use radioactive material, before the use of material begins, shall be issued a copy of the RPP, attend training specific to their duties, and that on-the-job training will augment the training session.

Contrary to the above, during the week of January 12, 2009, the licensee failed to provide three individuals who used radioactive material, training that was specific to their duties and responsibilities, a copy of the licensee's RPP, and on-the-job training.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the ARC 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 Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). 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, 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. 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.

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 (ADAMS). ADAMS is accessible from the NRC website 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 copy of your response 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

Notice of Violation

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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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 28th day of December 2009

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-20567

License No.: 24-21362-01

Report No.: 030-20567/09-03(DNMS)

Licensee: American Radiolabeled Chemicals, Inc.

Facility: 101 ARC Drive
St. Louis, Missouri

Inspection Dates: October 27 and 28, 2009
with continued in-office review through
December 4, 2009

Preliminary Exit Meeting: October 28, 2009

Final Exit Teleconference: December 4, 2009

Inspector: Kevin G. Null
Sr. Health Physicist

Approved By: Tamara Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

American Radiolabeled Chemicals, Inc. NRC Inspection Report 030-20567/09-03(DNMS)

An inspector conducted a reactive inspection of American Radiolabeled Chemicals (ARC) (licensee) on October 27 and 28, 2009, to review the circumstances surrounding an event that was reported by the State of Florida on September 17, 2009. The event pertained to a leaking source of tritium (ref. Event Report Notification Number 45358) that was discovered by the State of Florida during a routine inspection of one of their licensees. The source of the tritium was traced back to an activity that was conducted at the licensee's facility in January of 2009 by BetaBatt. BetaBatt is a company located in Houston, Texas, and holds a Radioactive Materials License issued by the State of Texas.

As part of a research project to develop a radioisotope-powered battery using tritium, BetaBatt, through the licensee's owner, contracted with ARC to synthesize a radiolabeled product for incorporation into a battery device. The licensee synthesized tritium labeled beta-carotene, and BetaBatt staff handled several hundred curies of the radiolabeled compound and applied the compound to several silicon diodes that were incorporated into several battery devices. Two of the devices were shipped to Lockheed Martin in Florida for prototype testing. The tritium contamination that the State of Florida discovered originated from one of the two devices.

The inspector identified six violations of the Nuclear Regulatory Commission (NRC) requirements involving: 1) Unauthorized use of licensed material; 2) Failure of the Radiation Safety Officer (RSO) to make a safety evaluation of BetaBatt's use of material at the licensee's facility; 3) Failure of the Radiation Safety Committee (RSC) to make a safety evaluation of BetaBatt's use of material at the licensee's facility; 4) Failure of the RSC to review BetaBatt's protocol for the handling of licensed material; 5) Failure of the RSC to meet during the months of June and July of 2009; and 6) Failure to provide adequate training to BetaBatt employees.

The inspector concluded that the root cause that led to the violations was a misunderstanding of the NRC license and its authorized use. Several factors contributed to the event and the violations that are described in this report. All of the factors can be characterized as a lack of safety culture, including: 1) lack of communication between the owner, RSC, and RSO; 2) an overlying mindset of licensee management that places a priority on production over safety; and 3) competing priorities of the RSO due to the number of positions/titles that he holds.

Report Details

1 Inspection History

A U.S. Nuclear Regulatory Commission (NRC) inspection of the licensee's facility was conducted on March 31 through April 1, 2009, with continued in office review through June 9, 2009. The inspection included an evaluation of the licensee's progress in addressing a Confirmatory Action Letter (CAL) dated February 21, 2008, and a review of corrective actions taken for violations that were identified during an inspection conducted from January 22, 2008, through March 26, 2008.

The inspection conducted from March 31 through April 1, 2009, resulted in one Severity Level IV violation. The NRC also determined that the licensee satisfactorily addressed all of the CAL items, and on July 28, 2009, issued a letter to the licensee closing out the CAL.

The results of the inspection conducted January 22 through 25, and March 11 through 14, 2008, with continued in-office review through March 26, 2008, were described in NRC Inspection Report Number 030-20567/2008-001(DNMS) dated April 23, 2008, and documented five apparent violations. Subsequent to a pre-decisional enforcement conference held in the Region III office on May 20, 2008, to discuss the apparent violations, the NRC issued a Notice of Violation dated July 22, 2008, and Proposed Imposition of Civil Penalty in the amount of \$6500 for a Severity Level III problem for failure to adhere to license conditions and comply with NRC regulations.

2 Follow-up to Event Report Number 45358

2.1 Inspection Scope

On October 27 and 28, 2009, an inspector evaluated the circumstances surrounding a contamination event that occurred in the State of Florida, and its connection to a potential unauthorized use of licensed material at the licensee's facility in the month of January 2009. The inspector interviewed selected licensee staff, reviewed selected records, and interviewed a staff member of a Texas licensee who handled radioactive material at the licensee's facility.

2.2 Observations and Findings

Use of Licensed Material

In late 2008, BetaBatt, a State of Texas licensee, contracted with the owner of American Radiolabeled Chemicals (ARC) to provide them with a tritium labeled product as part of BetaBatt's research project to develop a radioisotope-powered battery. Between January 12 and 17, 2009, three BetaBatt staff members were present at ARC to conduct work with radioisotopes related to the research project.

An authorized user from ARC processed 1400 curies of tritium and labeled it to beta-carotene, in accordance with ARC's NRC license. After the labeling process was completed, a staff member from BetaBatt proceeded with the project, and infiltrated microliter amounts of the labeled product onto silicon chips at the ARC facility. The total amount that was handled by the BetaBatt individual during the week in January was about 500 curies. BetaBatt constructed several radioisotope-powered battery devices at ARC, which is not in accordance with the ARC license. The devices were shipped from ARC to BetaBatt's facility in Texas. From Texas, BetaBatt shipped two of the devices to Lockheed Martin Corporation (Lockheed) in Orlando, Florida for testing purposes. On September 17, 2009, the State of Florida conducted a routine inspection at Lockheed and identified tritium contamination at their facility and reported the event to the NRC Operations Center (ref. Event Notification (EN) Report Number 45358). The source of the contamination was traced back to the batteries that BetaBatt had shipped to Lockheed, and the location where the devices were constructed was traced back to ARC.

In response to the EN, the State of Texas conducted an inspection at BetaBatt's facility on September 18, 2009, and identified considerable tritium contamination in the room where BetaBatt stored their batteries. BetaBatt is required by their Texas license to conduct periodic bioassay for tritium. Bioassay of BetaBatt staff was conducted subsequent to the identification of tritium contamination and the results were positive, and staff were being evaluated for intake of tritium and internal dose.

BetaBatt also conducted similar activities at ARC in 2004, 2006 and 2008. The purpose of the activities that were conducted in these earlier years was similar in nature to the activity conducted in 2009 in that the overall project pertained to the development of a radioisotope-powered battery. However, the protocols and procedures differed from year to year as the company worked to make improvements in the product. For example, there were different volumes and quantities of radiolabeled product used, and there were changes in the number of silicon diodes that were infiltrated with radiolabeled product. Prior to each visit at ARC, BetaBatt staff modified their protocols to account for these changes.

The inspector informed licensee representatives that the license limited their use of material to the manufacture, synthesis, and distribution of radiolabeled compounds, which does not include research and development or incorporation of licensed material into devices, e.g., radioisotope-powered batteries. The inspector reviewed the circumstances surrounding the event in an effort to determine what led ARC staff to believe that they were in compliance with their license. Based on interviews conducted of the owner of the company, the Radiation Safety Officer (RSO), and an authorized user, each indicated that they believed that authorization to manufacture and synthesize radiolabeled compounds indirectly included research.

In order to assess the extent and potential for additional unauthorized activities, the inspector reviewed selected records related to the use of material at ARC, and interviewed the owner, RSO and an authorized user. The inspector determined that two other companies had contracted with ARC to synthesize radiolabeled compounds which may have involved activities outside the scope of their license.

ARC staff indicated that in order for clients to certify that ARC procedures follow Good Laboratory Practices (GLP), they often observe radiolabeling procedures at ARC. In late 2007, a company contracted with ARC to manufacture a specific, complex radiolabeled chemical. Staff member(s) from the company observed the labeling process at ARC's facility, and the labeled material remained in storage at ARC. ARC staff periodically counted samples in a liquid scintillation counter to evaluate the purity of the radiochemical, with the goal to include the compound in their product catalogue, in accordance with their license. In the summer of 2009, another company contracted with ARC to synthesize radiolabeled compounds with carbon-14 and hydrogen-3 for a polymerization project. The company ordered radiolabeled products from ARC on a frequent basis and company staff members observed ARC's labeling process. ARC performed the synthesis of the radionuclides in accordance with their license, and shipped the labeled product to the company. The product was used by the company at their facility for the project.

Item 9 of the license limits the use of licensed material to the manufacture and synthesis of radiolabeled compounds for distribution to persons authorized to receive the material under a specific license. Incorporating radiolabeled tritium into a device during the week of January 12 through 17, 2009, and conducting research and the development of a radioisotope-powered battery is an unauthorized use of licensed material, and was a violation of Item 9 of the license.

Duties of the Radiation Safety Officer

The inspector interviewed licensee personnel regarding the details of BetaBatt's use of material at ARC. According to the RSO, he became aware that BetaBatt was planning to work under ARC's license approximately one week before their arrival. In addition, he was not informed of the details of the planned work, procedures, or quantity of material that BetaBatt planned to handle until the work had begun. As a result, it appears that the RSO had an insufficient amount of time to thoroughly evaluate the safety implications of the proposed work.

Item 3.3.3.8 of the licensee's RPP dated October 21, 2004, entitled "Administrative Duties of the RSO" states, in part, that the RSO make safety evaluations of proposed new uses of radioactive material. The failure of the RSO to make a safety evaluation of BetaBatt's use of material at the ARC facility was a violation of License Condition 22.B., which requires that the licensee conduct its program in accordance with RPP dated October 21, 2004.

Based on the interviews that the inspector conducted, the RSO's failure to conduct a safety evaluation resulted from a lack of communication between the owner and the RSO, and a failure to recognize that the activity was not authorized on the license.

Duties of the Radiation Safety Committee

The inspector interviewed licensee staff, including members of the RSC, and reviewed records of RSC minutes in order to evaluate the Committee's involvement in the proposed use of licensed material by BetaBatt under ARC's license. Based on the results of these interviews and a review of RSC records, there was no indication

that the RSC reviewed BetaBatt's protocol, or that the RSC conducted a safety evaluation of BetaBatt's protocol and procedures prior to the material being handled by BetaBatt staff members.

Items 3.4.2.1, entitled "Evaluations of New Uses of Radioactive Materials," and 3.2.4.2 entitled "Evaluations of Written Protocols for Syntheses," require that the RSC make safety evaluations of proposed new uses of radioactive material prior to the new use, and that the RSC review protocols for the synthesis of radiochemicals and related operations involving the handling of licensed material. The failure of the RSC to make a safety evaluation of the use of material by BetaBatt, and to review BetaBatt's protocol for incorporating the labeled tritium into the radioisotope-powered batteries were violations of License Condition 22.B, which requires that the licensee conduct its program in accordance with RPP, dated October 21, 2004.

Failure of the RSC to evaluate BetaBatt's proposed activities under ARC'S license appears to have resulted from a lack of communication between the owner of the company, RSO, and members of the Committee; a misunderstanding of the limitations in item 9 of the license with regard to authorized use; and a lack of understanding and knowledge of the duties and responsibilities of the RSC as described in the license.

The inspector reviewed minutes from the licensee's RSC meetings that were held since the inspection that was conducted in January through March 2008. The Committee is responsible for administering the RPP and is chaired by the president of the company, Dr. Surendra Gupta. Other members included the RSO and two Class 1 level radioactive material users.

License Condition 22.B. requires that the licensee conduct its program in accordance with RPP dated October 21, 2004. Item 3.2.5 entitled "Meeting Frequency" requires that the RSC meet at least monthly. Based on the review of RSC meeting minutes and interviews of the RSO and RSC chairman, the inspector determined that the RSC failed to meet in June and July 2009, which was a violation of license condition number 22.B. Further discussions with licensee representatives indicated that the licensee missed these two months due to competing priorities, and a lack of availability of RSC members during the summer of 2009.

Training

The inspector conducted interviews of ARC and BetaBatt staff to evaluate the training that ARC provided to BetaBatt employees prior to authorizing them to conduct work using radioactive material under ARC's license. The RSO stated that training was provided to BetaBatt Staff in accordance with Standard Operating Procedure (SOP) No. 21, entitled "Training and Dose Estimates for Non-ARC Personnel."

SOP-21 provides examples of groups of workers for whom this training applies. SOP-21 states that "training is required for individuals who perform work functions such as the installation or repair of air supply or exhaust systems, HVAC systems, plumbing, and carpentry within restricted areas." In addition, SOP-21 emphasizes that trainee's in this group "DO NOT TOUCH OR HANDLE RADIOACTIVE MATERIALS."

The use of SOP-21 to train BetaBatt staff was inappropriate for the level and extent of work that BetaBatt staff performed at ARC. Further discussions with the RSO and BetaBatt staff indicated that the RSO conducted a supplemental training session that included about a 1 hour discussion of ARC's procedures, as well as good radiation protection practices to follow in the laboratory.

Based on the type of work conducted by BetaBatt staff and their direct contact with licensed material and the quantities of material handled these individuals should have been trained as Class 2 worker. In accordance with ARC's definition of a Class 2 worker, as described in Item 3.2.4.5 of the licensee's RPP dated October 21, 2004, a Class 2 worker is one who may use radioactive materials within their area of responsibility only under supervision of a Class 1 individual. Class 2 workers are required to have formal training, be issued the RPP, and to be provided on-the-job training by the RSO, or a Class 1 worker. During January 12 through 17, 2009, BetaBatt staff's use of radioactive material at the ARC facility was conducted under the supervision of a Class 1 individual.

Interviews of BetaBatt staff with regard to their experience with radioactive material, along with a review of their resumes, indicated that their experience was limited to sealed sources. This provided further evidence that BetaBatt staff did not receive an appropriate level of training by the licensee to prepare them to safely handle several hundred curies of unsealed tritium.

Item 6. of the licensee's RPP dated October 21, 2004, entitled, "Radiation Safety Training" requires, in part, that all individuals who use radioactive material shall attend a training session specific to their duties and responsibilities, be issued a copy of ARC's RPP, and that the training session would be augmented with on-the-job-training.

Based on interviews of ARC and BetaBatt staff, ARC failed to provide BetaBatt staff training that was specific to their duties and responsibilities in the use of material from January 12 through 17, a copy of ARC's RPP, and on-the-job training in this case as a Class 2 worker. This was a violation of License Condition 22.B., which requires that the licensee conduct its program in accordance with RPP dated October 21, 2004.

As noted in previous discussions in this report dealing with the cause of other violations, the inspector determined that the failure to provide training to BetaBatt staff in accordance with ARC's license appears to be due to a lack of sufficient time for the RSO to thoroughly prepare for BetaBatt's proposed use of material, resulting from poor communication between the owner and the RSO.

2.3 Conclusion

The NRC inspector identified six violations that included the following:

- 1) Unauthorized use of material;
- 2) Failure of the RSC to review BetaBatt's protocol involving the handling of licensed material;
- 3) Failure of the RSC to make a safety evaluation of BetaBatt's proposed use of licensed material;
- 4) Failure of the licensee to determine prior occupational dose received by BetaBatt staff during the calendar year 2009;
- 5) Failure of the RSC to meet during the months of June and July 2009; and
- 6) Failure of the licensee to adequately train BetaBatt staff.

3 Root Cause and Contributing Factors

3.1 Inspection Scope

The inspector assessed the root cause and contributing factors for the event through interviews of selected licensee and BetaBatt staff, and reviews of selected records.

3.2 Observations and Findings

The inspector determined that there is an overall focus on production activities over safety. This appears to have led to a lack of communication between the owner and RSO without regard to activities that specifically pertain to the licensee's RPP. As a result, the RSO was not afforded the time or opportunity to fulfill his duties and responsibilities.

The inspector determined that in addition to being responsible for day to day activities related to licensee's RPP, the RSO also holds the following additional titles and responsibilities which appear to have impacted on his ability to effectively oversee the RPP: 1) Director of Regulatory Affairs; 2) Drug Enforcement Agency Compliance Coordinator; 3) Industrial Safety Officer; 4) Liaison Officer with other regulatory agencies; and 5) Supervisor for new building, building permits, and occupancy permits.

The inspector also noted that licensee staff does not have a clear understanding of the requirements in their license. Interviews of the owner, RSO, and an authorized user indicate that they felt that the authorized use in their license to manufacture and synthesize radiolabeled compounds inherently included research and development, and that the activities conducted in January 2009 were therefore in compliance with their license.

Further interviews of licensee staff also revealed a number of misconceptions with regard to the authority that is granted in ARC's NRC license. The owner and RSO believed that the license authorized ARC, through the RSC, to modify their RPP and Standard Operating Procedures (SOP's) without requesting an amendment. The inspector reviewed the license and informed the owner and RSO that both the RPP and SOP's are tied to the license in license condition 22.B. Therefore, changes to these documents require an amendment.

3.3. Conclusion

The root cause that led to the violations was a misunderstanding of the NRC license and its licensed, authorized use. Several factors contributed to the event and the violations that are described in this report. All of the factors can be characterized as a lack of safety culture, including: 1) lack of communication between the owner, RSC, and RSO; 2) an overlying mindset of licensee management that places a priority on production over safety; and 3) competing priorities of the RSO due to the number of positions and associated responsibilities that he holds.

4 Exit Meeting

The inspector discussed the preliminary conclusions described in this report with licensee management during a meeting conducted at the licensee's facility on October 28, 2009. The inspector discussed the final conclusions described in this report with the RSO during a final exit teleconference conducted on December 4, 2009. The licensee did not identify any information reviewed during this inspection and selected for inclusion in this inspection report as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

American Radiolabeled Chemicals, Inc.

- # Surendra Gupta, Ph.D., Owner/RSC Chair
- #* Regis Greenwood, CHP, Radiation Safety Officer
Janardhanam Selvasekaran, Ph.D., Vice President and Authorized User

BetaBatt, Inc.

Larry Gadeken, Ph.D.

- # participated in preliminary exit meeting
- * contacted by telephone for final exit meeting

Distribution: Larry Gadeken, Ph.D., BetaBatt, Inc.