U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection Nos.	03036099/2013-001 and 03036179/2013-001
Docket Nos.	03036099 and 03036179
License Nos.	06-30764-01 and 06-30764-02MD
Licensee:	Eckert & Ziegler BEBIG, Inc. (formerly Biocompatibles, Inc.)
Location:	115 Hurley Drive, Building 3, Oxford, CT 06478
Inspection Dates:	April 4, October 30, and November 1, 2013

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EXECUTIVE SUMMARY

Eckert & Ziegler BEBIG, Inc. (formerly Biocompatibles, Inc.)
NRC Inspection Report Nos. 03036099/2013-001 and 03036179/2013-001

This was a special, announced inspection of a reported incident involving the apparent loss of 10 iodine-125 brachytherapy seeds from a lot containing a total of 60 seeds, distributed by the licensee to Dameron Hospital, a licensee of the Agreement State of California (CA), on February 25, 2013. The customer notified the licensee on February 26, 2013, that the shortfall was discovered during a prostate implant procedure on February 26, 2013. The licensee, in turn, notified the NRC Headquarters Operation Officer (HOO) of the incident on February 26, 2013. The HOO assigned identification number EN 48831 to the event. In the notification, the licensee indicated that each seed had an apparent activity of 0.45 millicuries. "Apparent activity" is a medical term referring to the measured radiation dose rate of the seeds and not the actual amount of radioactive material in the seeds. The inspection consisted of observations of licensee activities and facilities, interviews of personnel, and a review of selected records related to the incident.

No violations of NRC requirements were identified during this inspection.

The inspectors discussed the findings with the licensee during an exit meeting conducted by telephone on November 1, 2013.

REPORT DETAILS

1. Incident on February 26, 2013

The licensee made a shipment of 60 brachytherapy seeds, each with an "apparent activity" of 0.45 millicuries (mCi) of iodine-125, to Dameron Hospital in Stockton, CA on February 25, 2013. On February 26, 2013, the licensee was informed by a representative from Dameron Hospital that they could not account for 10 seeds after performing a prostate implant procedure. The licensee notified the NRC Headquarters Operation Officer (HOO) of the event and the HOO assigned an identification number to the event, i.e., Emergency Notification (EN) 48831.

2. Material Receipt, Use, Transfer, and Control

a. Observations and Findings

The inspection focused on the methodology used by licensee to fill orders for customers for brachytherapy seeds and the Quality Assurance/Quality Control (QA/QC) program that assures that the orders contain the correct number of seeds and the correct activity. The inspectors focused additional attention on the sterile applicator kit (case # 75152) that was shipped to Dameron Hospital and used in a brachytherapy procedure on February 26, 2013.

The inspectors reviewed the licensee's incoming package receipt and opening procedure. All incoming packages containing radioactive material are isolated in a separate area that is labeled with "Caution – Radioactive Material" warning signs. The packages are all monitored within 3 hours of receipt. The exterior surfaces of the packages are smeared for removable contamination. The labels on the packages are compared against the shipping papers to verify that actual contents match and are consistent with what has been ordered. Incoming radioactive seeds are either transferred directly to the production floor or placed in a secured shielded storage location depending on priority of order fulfillment.

When the licensee receives an order from a customer, they order the exact number of radioactive seeds from their suppliers to fill their customer's request. The seeds are shipped in a shielded vial. Barring a mistake at the manufacturer's facility, the shielded vial will contain the number of seeds requested. The first QC check that is performed by the licensee is the verification of the seed "apparent activity" received from the manufacturer. The inspectors observed an individual performing the verification procedures. The licensee's procedures require them to assay either 10 seeds or 10 percent of the order, whichever is greater, and verify that they are the correct apparent activity using a dose calibrator. The individual removed 10 seeds from the shielded vial, assayed them in the dose calibrator and recorded the results. When this task was completed, the seeds were returned to the vial and a survey was performed of the work area and floor to assure that all the seeds had been returned to the vial.

The inspectors reviewed the assay record for the 60 seeds that were prepared for

Dameron Hospital. Ten seeds were assayed. The average "apparent activity" of the seeds was within +/-0.09% of the certified activity documented on the Technical Data Sheet provided by the manufacturer. The average "apparent activity" of 0.45 mCi was consistent with the order placed by Dameron Hospital.

The next step in the production process involves verification that the number of seeds is correct. The shielded vial containing the seeds is transferred to another work station on the processing floor where the seeds are to be loaded into Mick magazines. The technician first verifies that the number of seeds in the vial match the number of seeds that were ordered. Any deviation in the seed count from the number ordered is immediately reported to the supervisor of the shift. The vial is not used, a replacement order is placed with the manufacturer, and the vial with the seeds is returned to the manufacturer.

A Mick magazine holds 15 brachytherapy seeds. Per their procedure, the licensee fills an order with completely filled Mick magazines first. For example, if a customer orders 50 seeds, the technician would completely fill three magazines and place five remaining seeds in the 4th Mick magazine. When a Mick magazine does not contain the full 15 seeds, the technician is required to write the number of seeds on the magazine with a marker.

The Mick magazines that were distributed to Dameron Hospital for the seed implant procedure performed on February 26, 2013, were filled by the licensee on February 19, 2013. A technician filled the magazines in question at load station 30. The technician reviewed the required procedures with the inspectors and confirmed that the first step in the filling process is to count the number of seeds in the shielded vial and assure that the number matches the order. The technician stated that any deviation is reported to the supervisor. The technician showed the inspectors the work station and the trays that are used to count the seeds and load the Mick magazines. The trays have a series of troughs and standard practice is not to place more than 15 seeds in a single trough prior to loading the seeds into the Mick magazines.

The technician informed the inspectors that after the Mick magazines are loaded, the filled magazines are placed behind a shield and an extensive survey is performed of the work area. Surveys are performed of the tray, the tabletop, the floor, and the open shield vial to assure that there are no misplaced seeds. The inspectors asked the technician if the technician had ever detected a misplaced seed. The technician indicated that the surveys that were performed had never identified more than one seed after completing a magazine loading. When asked about the paperwork with the technician's initials verifying the sixty seeds were counted and loaded on February 19, 2013, the technician confirmed the veracity of the record.

The inspectors also interviewed the QC manager. The QC manager indicated that the technician had been loading magazines for approximately one year. The QC manager added that the technician was very conscientious and had never filled an order improperly. The QC manager confirmed that the technician had, once or twice, detected a misplaced seed by performing a survey of the work area. The QC manager described one of the required duties as performing a visual inspection of all the Mick magazines

prior to shipment. The QC manager indicated that Mick magazines are aligned when loaded into the shipping pouch. It would be noticeable if the magazines were short a seed since the plungers would not be in alignment with each other. If the plungers were misaligned, the QC manager indicated that she would have the work area surveyed and, if no seeds were found, have the seeds in the magazines recounted. If the Mick magazine was intended to have less than 15 seeds, it would have the number of seeds written on the magazine. The QC manager did inform the inspectors that, in the past, the QC manager had identified a magazine that was missing a seed, but never more than one seed and never on an order assembled by the technician interviewed by the inspectors.

The inspectors also interviewed another technician who had several duties. The technician indicated that the duties did not include the assaying of seeds or the filling of Mick magazines. The technician stated that surveys were performed of all the work stations at the end of the day shift to identify if there were any misplaced seeds. The technician informed the inspectors that surveys included the work benches, floors around the work benches, and any waste receptacles. Survey records for load station 30 indicated that the radiation fields were measured at background, 0.02 milliRem per hour, on February 19-21, 2013, and the survey meter used was in current calibration.

A representative of the licensee confirmed for the inspectors that the procedure in question was performed on February 26, 2013, and the customer could only account for 50 seeds at the end of the medical procedure. A total of 49 seeds were implanted into a patient and one seed jammed in the applicator.

The inspectors interviewed a sales representative, via telephone on April 4, 2013. The sales representative was present at Dameron Hospital on February 26, 2013, the day that the procedure was performed. The sales representative stated that standard practice was to be present in the Operating Room (OR) at the start of the procedure but the hospital was having issues with the ultrasound probe and the sales representative was informed that the start of surgery was delayed. The sales representative made some phone calls during the delay and, upon reentering the OR, found that the procedure was underway. The sales representative could not recall what the Mick magazines looked like in the shipping pouch. The sales representative also recalled that one magazine jammed with the last seed. The sales representative added that it wasn't until late into the procedure that the medical staff stated that 10 brachytherapy seeds were missing.

The inspectors interviewed the sales representative by telephone again on October 30, 2013. The sales representative reaffirmed that he was not in the OR at Dameron Hospital when the brachytherapy procedure in question began. He added that when he entered the OR he was surprised that the physician was approximately half way through the procedure and had almost finished implanting the seeds from the second of four Mick magazines. He further stated that he never had a good look at the shipping pouch and the magazines because they were in a sterile area when he entered the OR. Per hospital procedure, he was not permitted in that part of the room. The sales representative indicated that he could not confirm or deny that the plungers of the Mick magazines were at different heights since he was not present when the shipping

pouch was opened. Therefore, he could not confirm or deny that each Mick cartridge contained 15 seeds as indicated by the licensee's shipping records. The sales representative

again stated that it was very late in the procedure while the physician was working with the last magazine before the physician identified that 10 seeds were missing.

b. Conclusions

No violations were identified

3. Transportation

a. Observations and Findings

The inspectors reviewed the shipping paper that accompanied the shipment of brachytherapy seeds to Dameron Hospital. The shipping paper met all the Department of Transportation regulatory requirements. The inspectors also looked to see if other shipments were made to other customers looking for a similar request to determine if two orders were unknowingly switched, but there was no evidence to substantiate this hypothesis.

b. Conclusions

No violations were identified.

4. Exit Meeting

On November 1, 2013, the inspectors discussed the results of the inspection with Bill Dowd, Chief Operating Officer and other members of his staff. No violations were identified during the inspection.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Lisa August, Quality Control
Carmen Perez, Technician
Irena Kuczynski, Technician
Anthony Visselli, Sales Representative**
Matthew Bouffard, Physicist
Timothy Delaney, Supervisor of Production Area
Wayne Richardson, Radiation Safety Officer*
James Matons, President (Biocompatibles, Inc.)
Bill Dowd, Chief Operating Officer (Eckert & Ziegler BEBIG, Inc.)*
Len Glatkowski, Interim Quality Director*

*Telephone exit meeting 11/01/2013.
**Telephone interview 4/4/2013 & 10/30/2013

INSPECTION PROCEDURES USED

87103

ITEMS OPEN, CLOSED, AND DISCUSSED

Apparent loss of 10 iodine-125 brachytherapy seeds out of 60 seeds distributed to a customer in California (EN 48831) and NMED 130138.

LIST OF DOCUMENTS REVIEWED

NRC EN 48831 (March 20, 2013)

LIST OF ACRONYMS AND ABBREVIATIONS USED

CA – California
CT – Connecticut
EN – Emergency Notification
HOO – Headquarters Operation Officer
Inc. - Incorporated
mCi – millicurie(s)
Nos. - Numbers
NRC – Nuclear Regulatory Commission
OR – Operating Room
QA/QC – Quality Assurance/Quality Control
R&D – Research and Development
U.S. – United States